

|                                                                                                                                         |                      |                                                          |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------------------------------------------|
| <p><b>PRELIMINARY<br/>AMENDMENT</b></p> <p>Address to:<br/>Commissioner for Patents<br/>P.O. Box 1450<br/>Alexandria, VA 22313-1450</p> | Attorney Docket      | 9261.17142-PCT-US-CON                                    |
|                                                                                                                                         | Confirmation No.     | Not yet assigned                                         |
|                                                                                                                                         | First Named Inventor | Aboul-Hosn                                               |
|                                                                                                                                         | Application Number   | Unassigned (Continuation of<br>11/375,926)               |
|                                                                                                                                         | Filing Date          | herewith                                                 |
|                                                                                                                                         | Group Art Unit       | 3761                                                     |
|                                                                                                                                         | Examiner Name        | Not yet assigned                                         |
|                                                                                                                                         | Title                | Guidable Intravascular Blood Pump<br>and Related Methods |

Sir:

Prior to examination, please amend the current application as follows:

**REMARKS**

**Formal Matters**

Claim 1 is pending after entry of the amendments set forth herein.

Applicants respectfully request consideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

**Conclusion**

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-2653, order number 9261.17142-PCT-US-CON.

Respectfully submitted,  
LAW OFFICE OF ALAN W. CANNON

Date: May 3, 2010

By: /Alan W. Cannon/  
Alan W. Cannon  
Registration No. 34,977

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## Electronic Patent Application Fee Transmittal

**Application Number:**

**Filing Date:**

**Title of Invention:**

Guidable Intravascular Blood Pump and Related Methods

**First Named Inventor/Applicant Name:**

Walid N. Aboul-Hosn

**Filer:**

Alan W. Cannon

**Attorney Docket Number:**

9261-17142-PCT-US-CON

Filed as Large Entity

### Utility under 35 USC 111(a) Filing Fees

| Description                | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
|----------------------------|----------|----------|--------|----------------------|
| <b>Basic Filing:</b>       |          |          |        |                      |
| Utility application filing | 1011     | 1        | 330    | 330                  |
| Utility Search Fee         | 1111     | 1        | 540    | 540                  |
| Utility Examination Fee    | 1311     | 1        | 220    | 220                  |

**Pages:**

**Claims:**

**Miscellaneous-Filing:**

**Petition:**

**Patent-Appeals-and-Interference:**

| Description                       | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
|-----------------------------------|----------|----------|--------|----------------------|
| Post-Allowance-and-Post-Issuance: |          |          |        |                      |
| Extension-of-Time:                |          |          |        |                      |
| Miscellaneous:                    |          |          |        |                      |
| Total in USD (\$)                 |          |          |        | 1090                 |



## Electronic Acknowledgement Receipt

|                                             |                                                       |
|---------------------------------------------|-------------------------------------------------------|
| <b>EFS ID:</b>                              | 7540822                                               |
| <b>Application Number:</b>                  | 12772810                                              |
| <b>International Application Number:</b>    |                                                       |
| <b>Confirmation Number:</b>                 | 4661                                                  |
| <b>Title of Invention:</b>                  | Guidable Intravascular Blood Pump and Related Methods |
| <b>First Named Inventor/Applicant Name:</b> | Walid N. Aboul-Hosn                                   |
| <b>Customer Number:</b>                     | 89729                                                 |
| <b>Filer:</b>                               | Alan W. Cannon/Maria J. Cannon                        |
| <b>Filer Authorized By:</b>                 | Alan W. Cannon                                        |
| <b>Attorney Docket Number:</b>              | 9261-17142-PCT-US-CON                                 |
| <b>Receipt Date:</b>                        | 03-MAY-2010                                           |
| <b>Filing Date:</b>                         |                                                       |
| <b>Time Stamp:</b>                          | 18:13:19                                              |
| <b>Application Type:</b>                    | Utility under 35 USC 111(a)                           |

### Payment information:

|                                          |                |
|------------------------------------------|----------------|
| Submitted with Payment                   | yes            |
| Payment Type                             | Credit Card    |
| Payment was successfully received in RAM | \$ 1090        |
| RAM confirmation Number                  | 10272          |
| Deposit Account                          | 502653         |
| Authorized User                          | CANNON,ALAN W. |

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

## File Listing:

| Document Number                                 | Document Description                                | File Name                                       | File Size(Bytes)/ Message Digest                     | Multi Part /.zip | Pages (if appl.) |
|-------------------------------------------------|-----------------------------------------------------|-------------------------------------------------|------------------------------------------------------|------------------|------------------|
| 1                                               |                                                     | Application_9261_17142_PCT_US_CON.pdf           | 19354706<br>91b84f014fd1303d21850c5869fea149d2ee8252 | yes              | 39               |
|                                                 | Multipart Description/PDF files in .zip description |                                                 |                                                      |                  |                  |
|                                                 | Document Description                                |                                                 | Start                                                | End              |                  |
|                                                 | Specification                                       |                                                 | 1                                                    | 37               |                  |
|                                                 | Claims                                              |                                                 | 38                                                   | 38               |                  |
|                                                 | Abstract                                            |                                                 | 39                                                   | 39               |                  |
| Warnings:                                       |                                                     |                                                 |                                                      |                  |                  |
| Information:                                    |                                                     |                                                 |                                                      |                  |                  |
| 2                                               | Drawings-only black and white line drawings         | Drawings_9261_17142_PCT_US_CON.pdf              | 4507827<br>8aa48750090c0da5cb0825e78fa3563fa0a80b9f  | no               | 18               |
| Warnings:                                       |                                                     |                                                 |                                                      |                  |                  |
| Information:                                    |                                                     |                                                 |                                                      |                  |                  |
| 3                                               | Oath or Declaration filed                           | Declaration_9261_17142_PCT_US_CON.pdf           | 3698053<br>39e47109b49b9d8a8c2c2b91908fb908e2fcb4e5  | no               | 8                |
| Warnings:                                       |                                                     |                                                 |                                                      |                  |                  |
| Information:                                    |                                                     |                                                 |                                                      |                  |                  |
| 4                                               | Application Data Sheet                              | ADS_9261_17142_PCT_US_CON.pdf                   | 256754<br>1c4b22681781801e42c5326da3df2a1d6b819fc5   | no               | 2                |
| Warnings:                                       |                                                     |                                                 |                                                      |                  |                  |
| Information:                                    |                                                     |                                                 |                                                      |                  |                  |
| This is not an USPTO supplied ADS fillable form |                                                     |                                                 |                                                      |                  |                  |
| 5                                               |                                                     | Amendment_Preliminary_9261_17142_PCT_US_CON.pdf | 292336<br>5460fc7b9adc48d5de1e98fc0386cd2e2b6708ed   | yes              | 3                |
| Page 6 of 638                                   | Multipart Description/PDF files in .zip description |                                                 |                                                      |                  |                  |
|                                                 | Document Description                                |                                                 | Start                                                | End              |                  |
|                                                 | Preliminary Amendment                               |                                                 | 1                                                    | 2                |                  |
|                                                 | Applicant Arguments/Remarks Made in an Amendment    |                                                 | 3                                                    | 3                |                  |
| ABIOMED Ex. 1036                                |                                                     |                                                 |                                                      |                  |                  |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                         |              |                                          |    |   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|------------------------------------------|----|---|
| <b>Warnings:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                         |              |                                          |    |   |
| <b>Information:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                         |              |                                          |    |   |
| 6                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Fee Worksheet (PTO-875) | fee-info.pdf | 33166                                    | no | 2 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                         |              | 39f8c7ea9d9db6271335357b844d3985f082a387 |    |   |
| <b>Warnings:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                         |              |                                          |    |   |
| <b>Information:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                         |              |                                          |    |   |
| <b>Total Files Size (in bytes):</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                         |              | 28142842                                 |    |   |
| <p><b>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</b></p> <p><b><u>New Applications Under 35 U.S.C. 111</u></b><br/> <b>If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</b></p> <p><b><u>National Stage of an International Application under 35 U.S.C. 371</u></b><br/> <b>If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</b></p> <p><b><u>New International Application Filed with the USPTO as a Receiving Office</u></b><br/> <b>If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</b></p> |                         |              |                                          |    |   |

FIG. 1

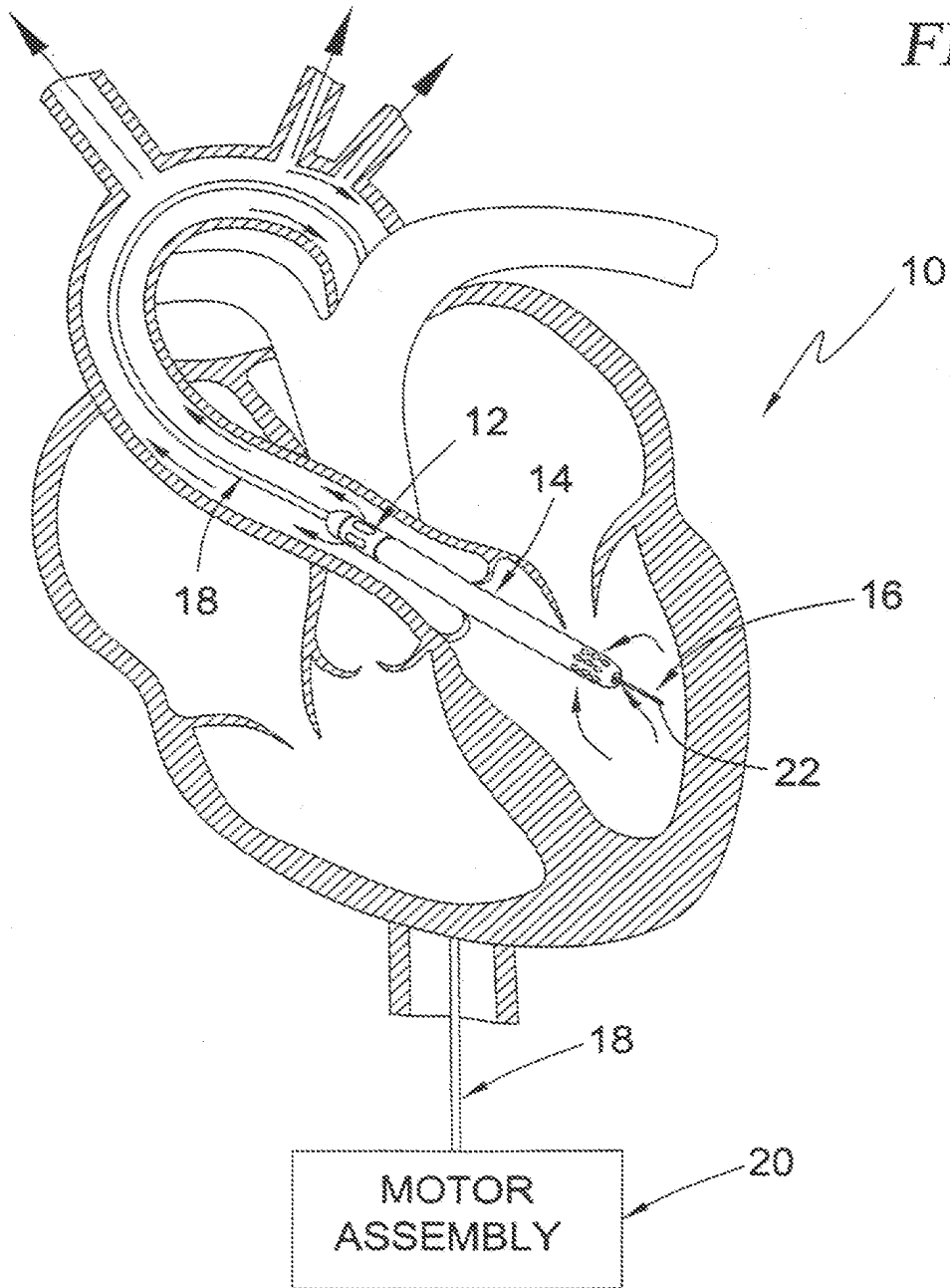


FIG. 2

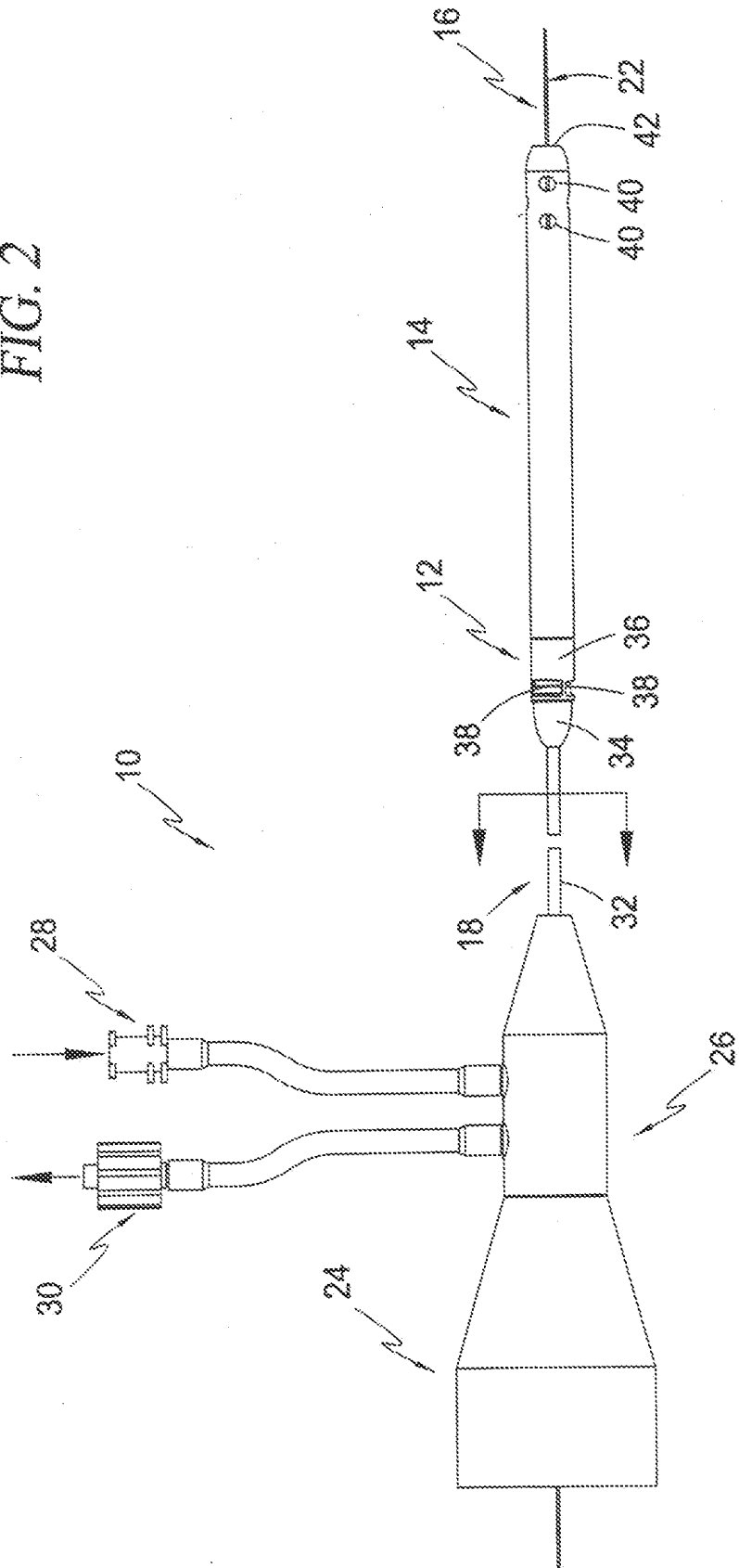
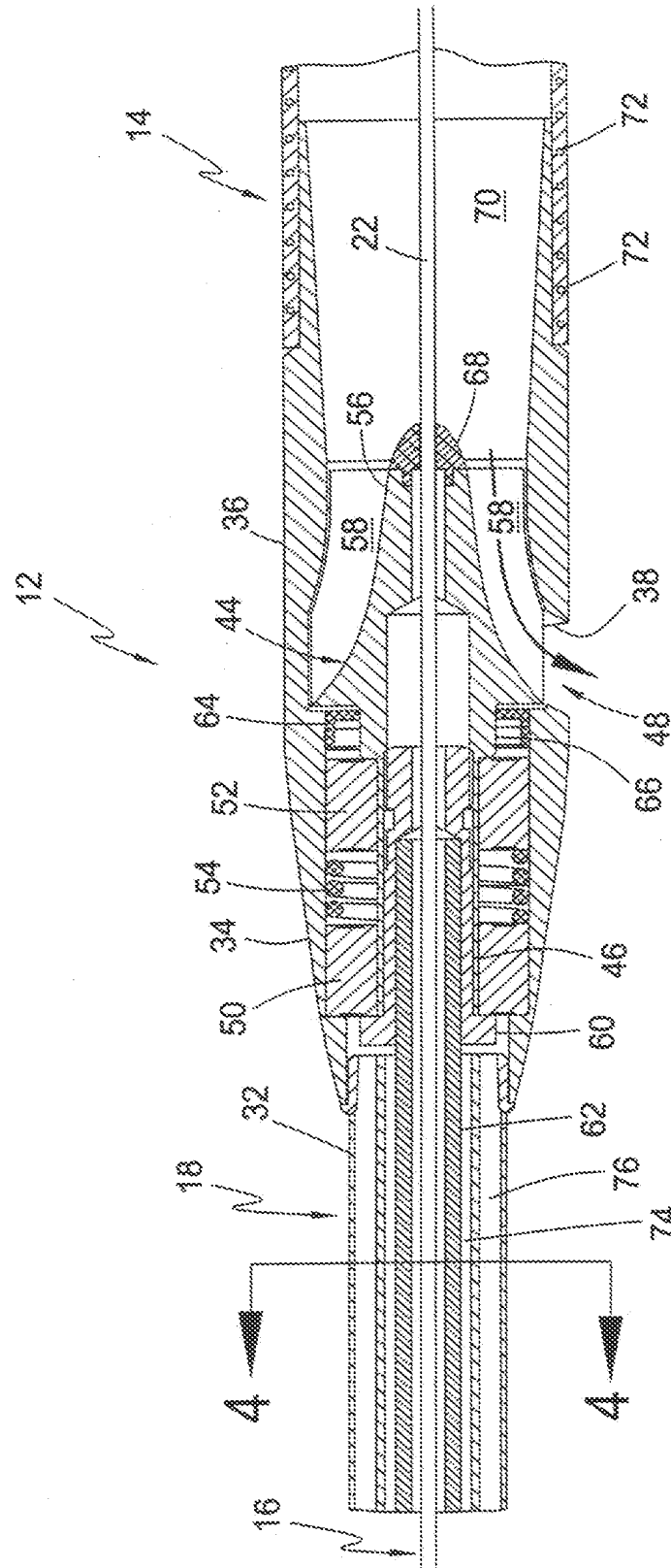


FIG. 3



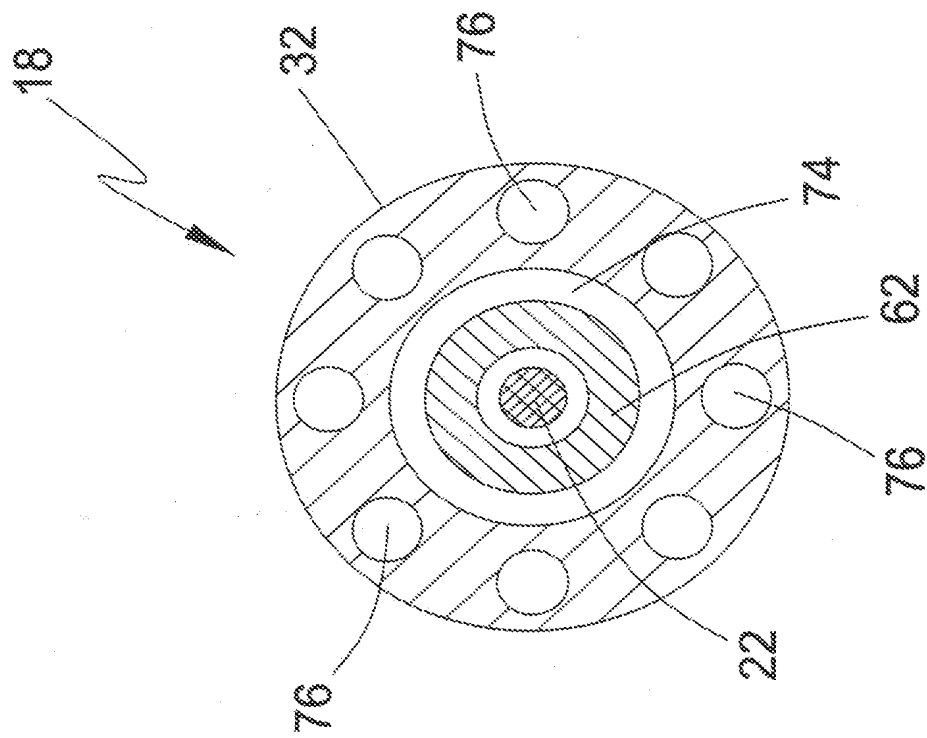
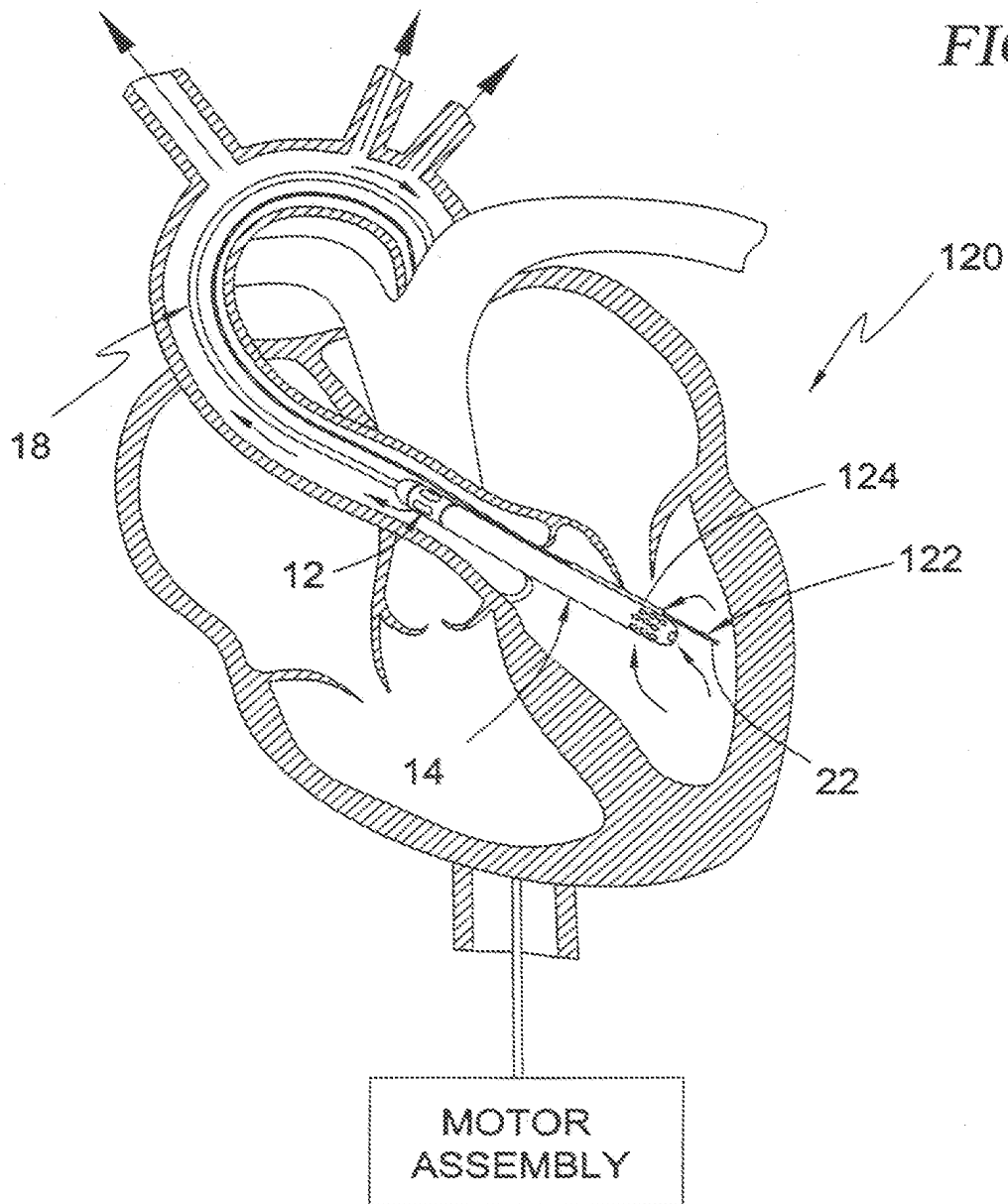


FIG. 4





FIG. 6





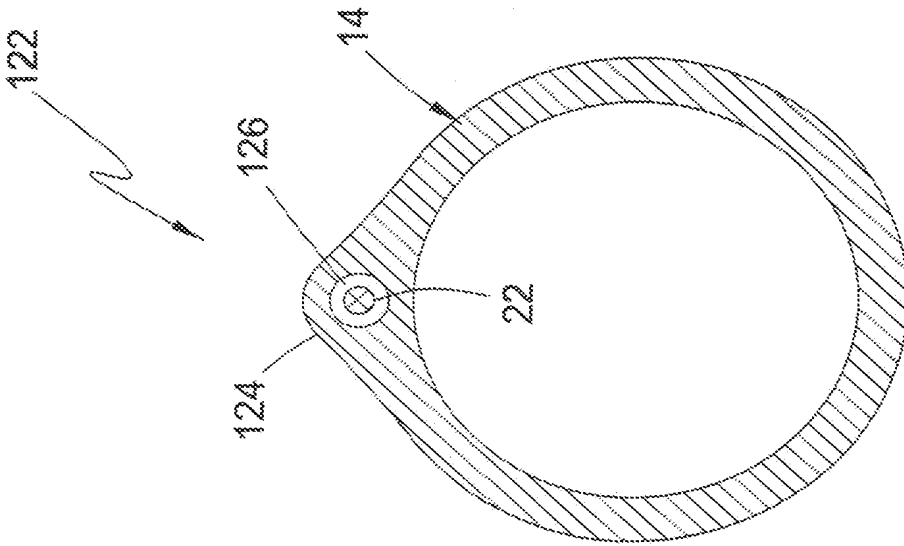


FIG 8

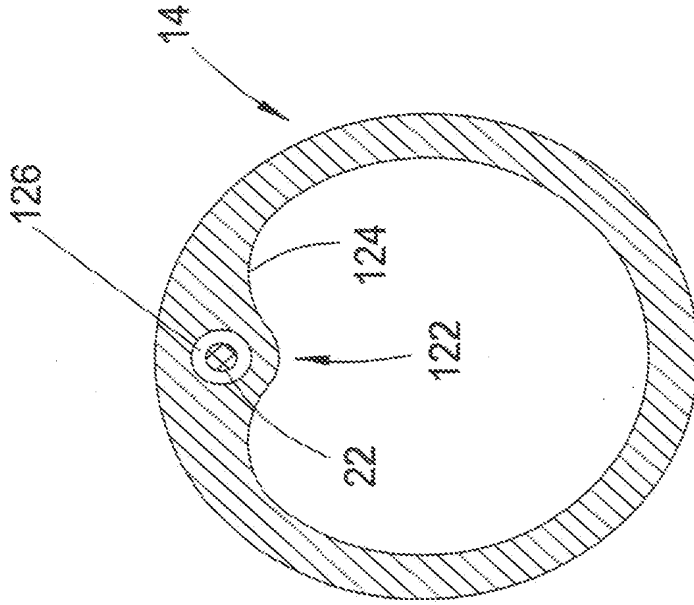


FIG 9

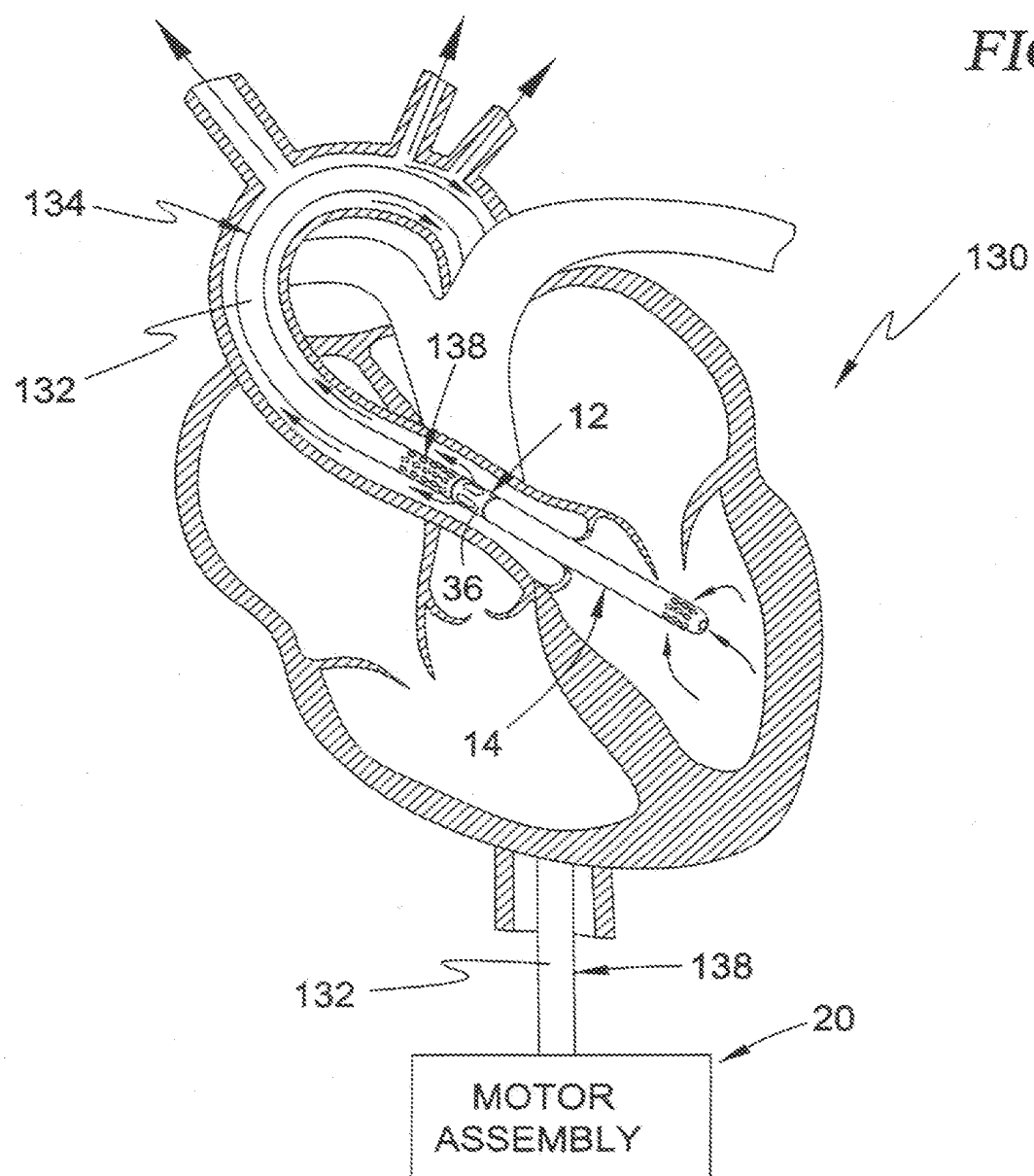






FIG 13

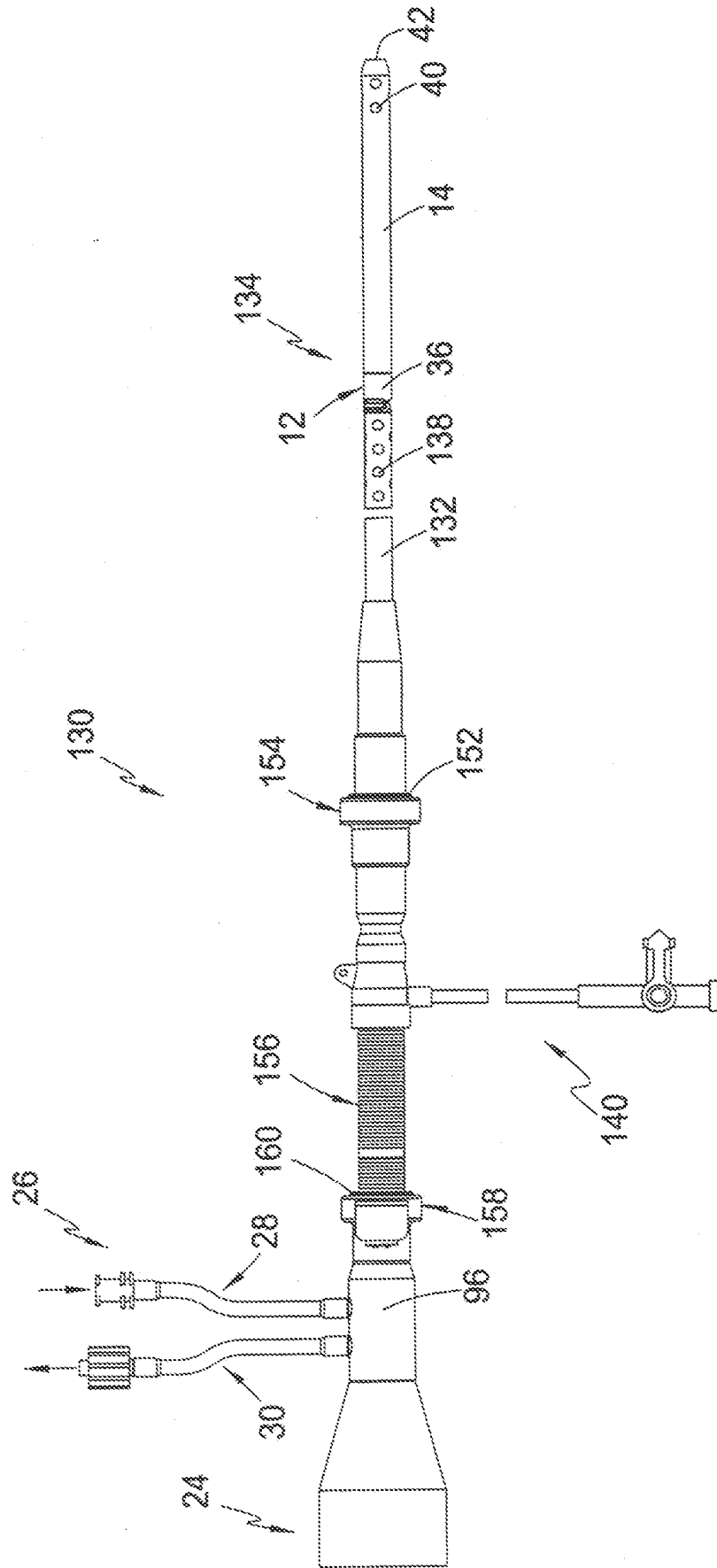
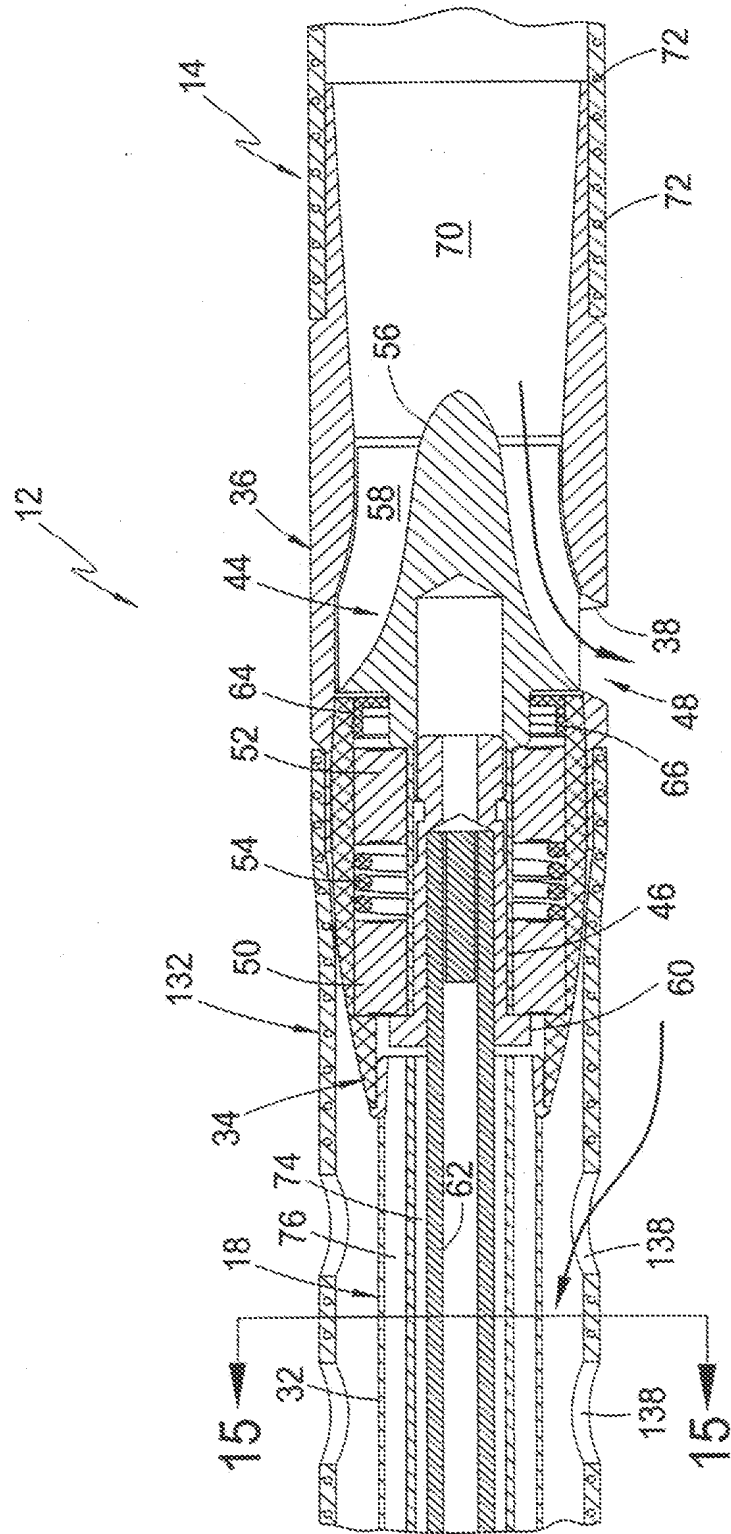


FIG. 14





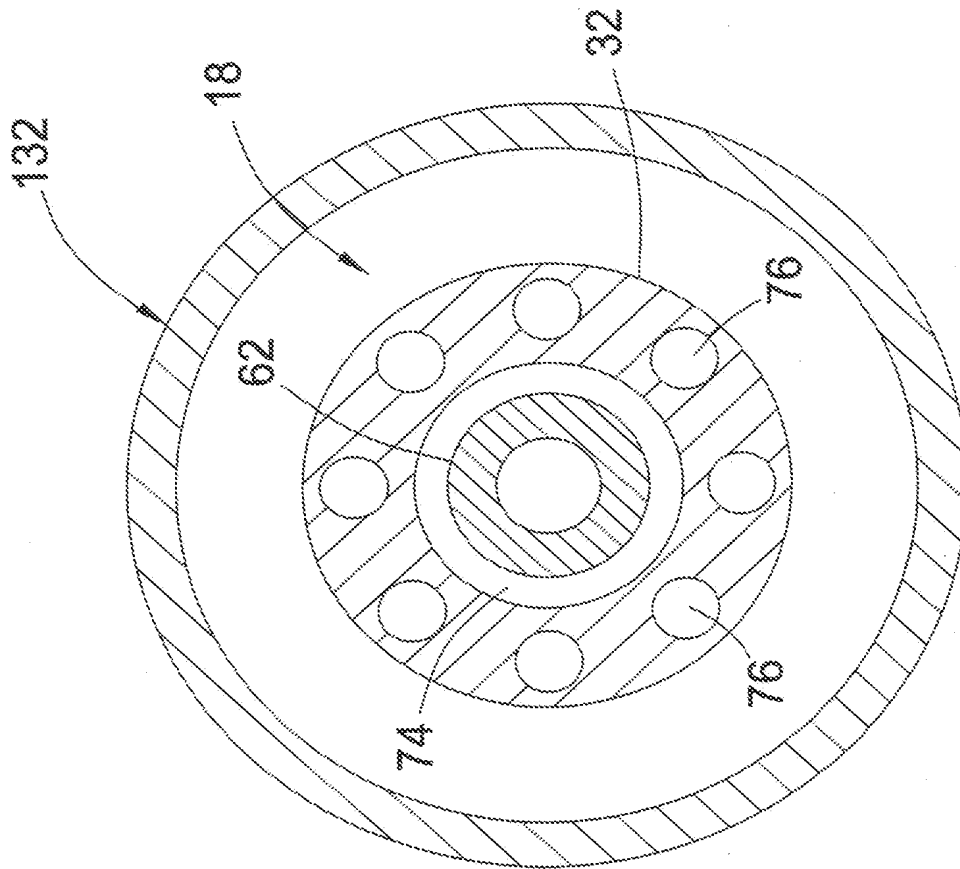
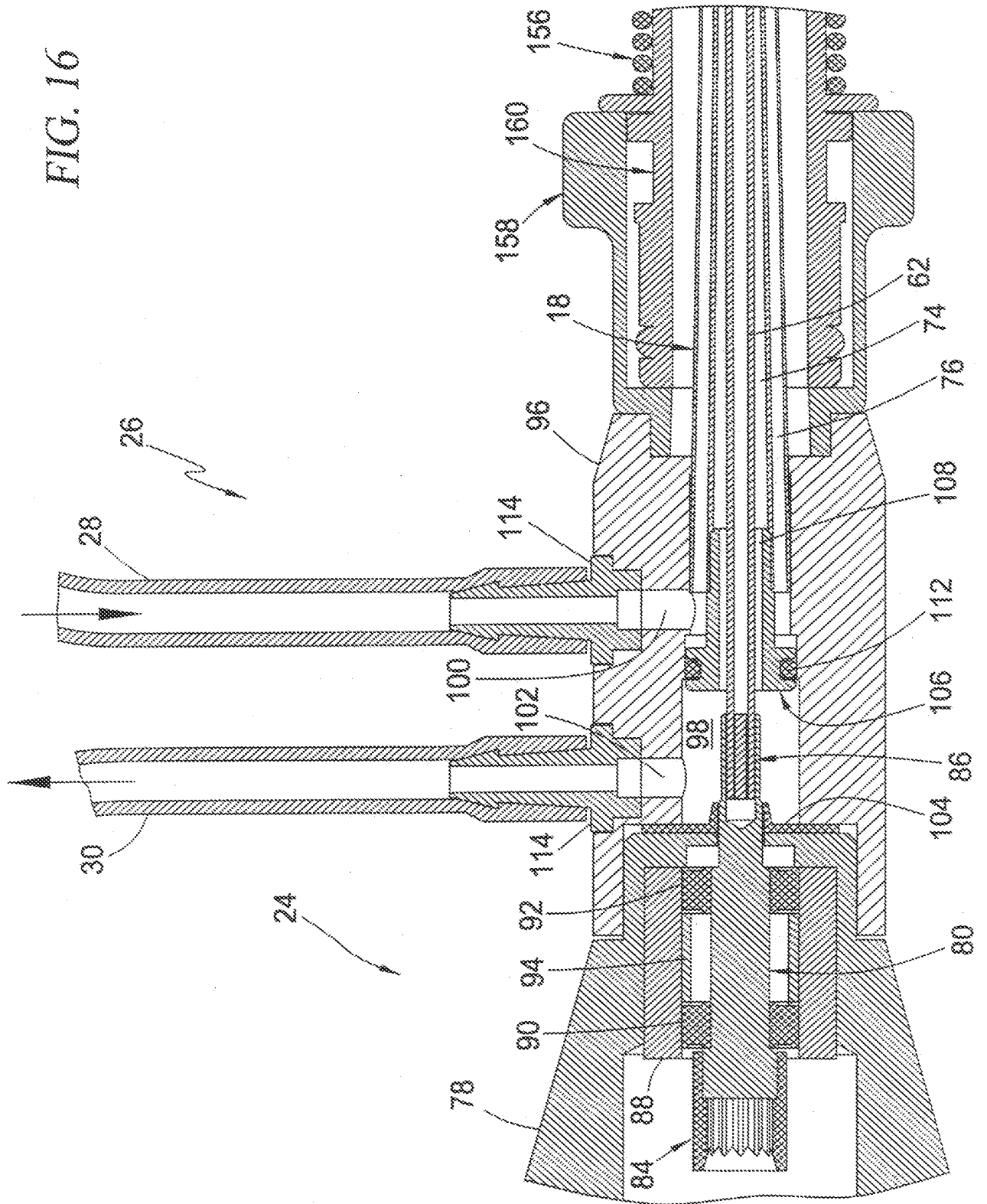


FIG. 15

FIG. 16



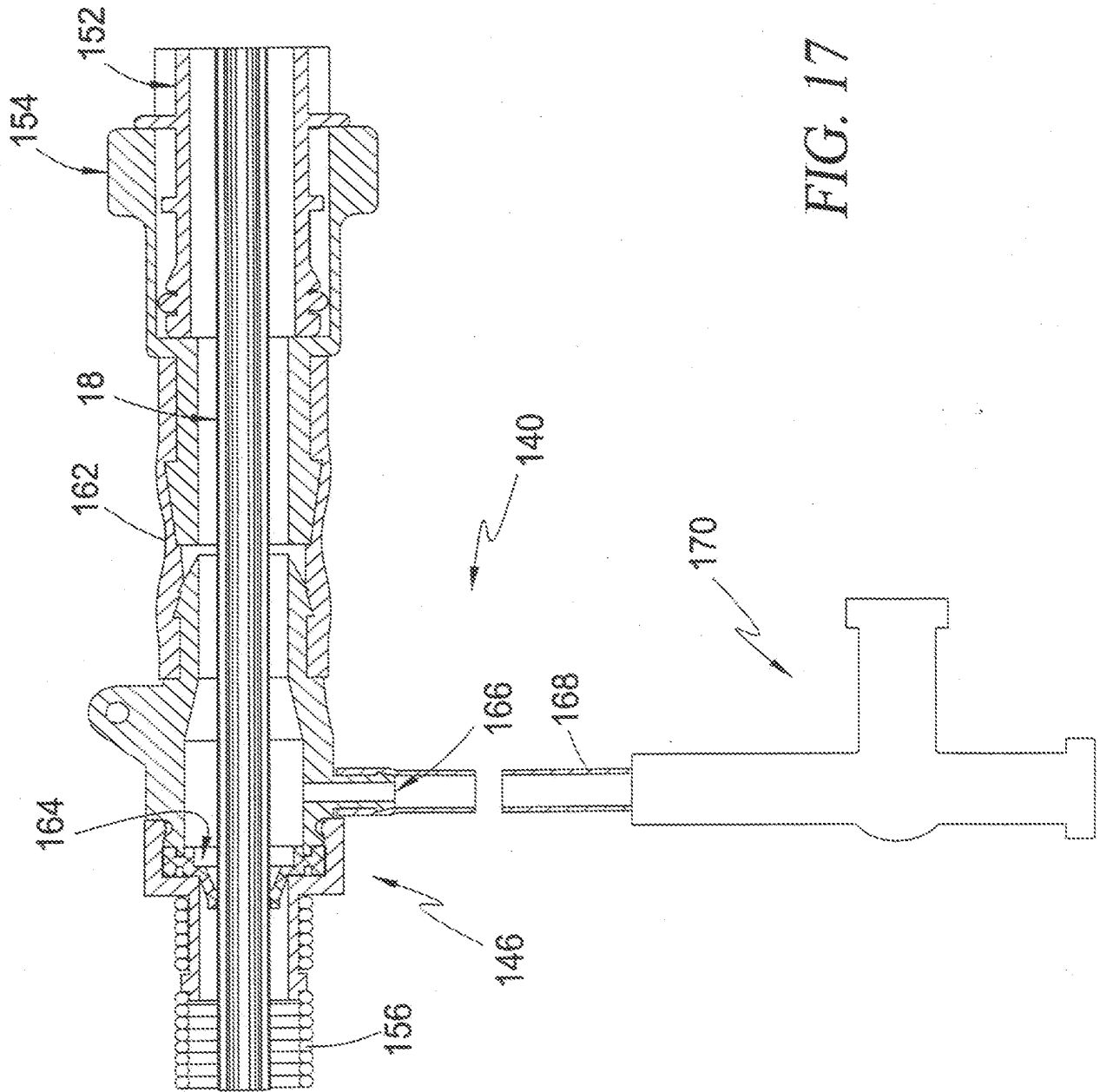
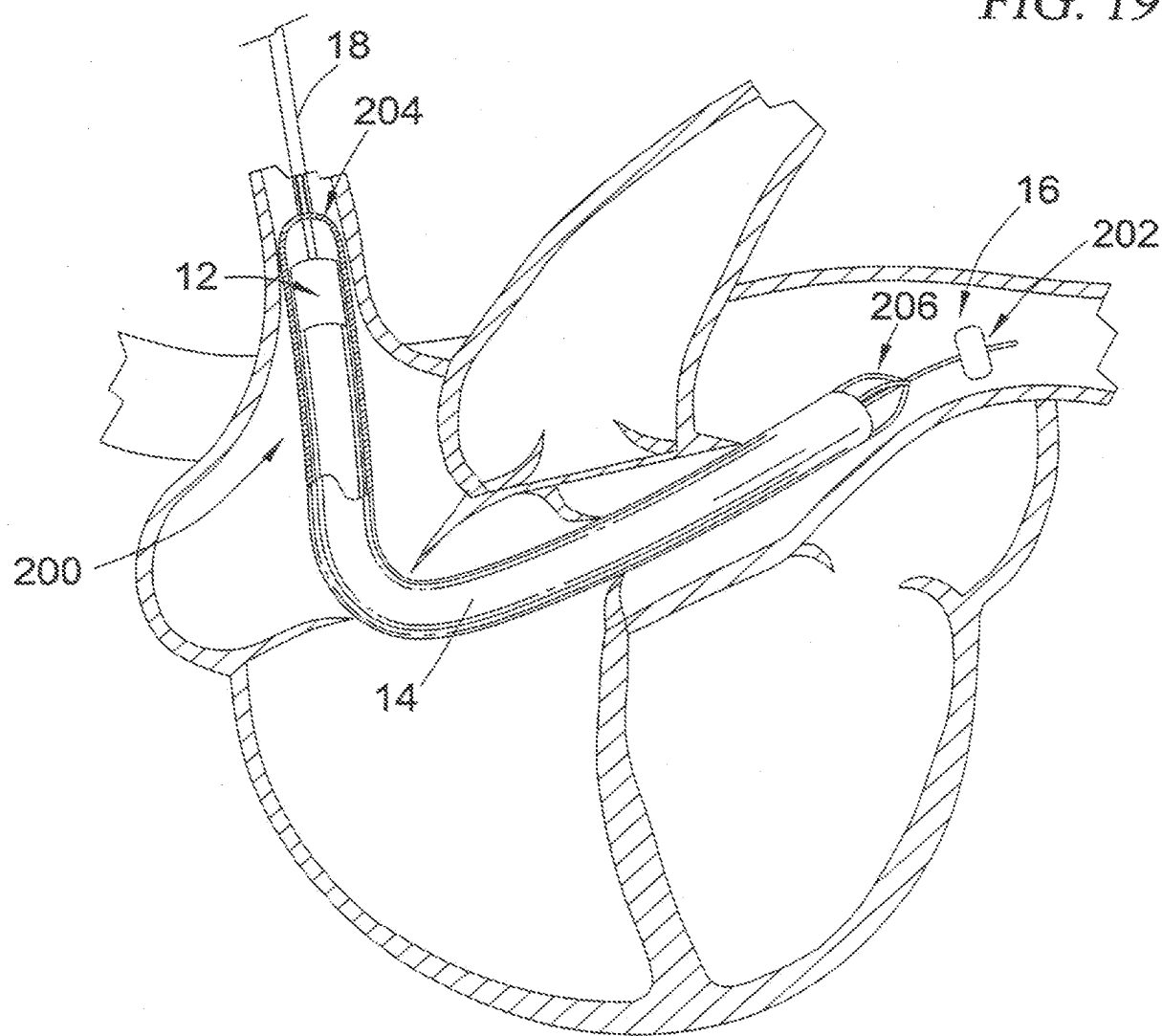




FIG. 19



COMBINED DECLARATION AND POWER OF ATTORNEY  
(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL,  
CONTINUATION OR CIP)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type: (check one applicable item below)

- ☐ original  
☐ design  
☐ supplemental

NOTE: If the declaration is for an international Application being filed as a divisional, continuation or continuation-in-part application do not check next item; check appropriate one of last three items.

- ☒ national stage of PCT

NOTE: If one of the following 3 items apply then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR CIP.

- ☐ divisional  
☐ continuation  
☐ continuation-in-part (CIP)



INVENTORSHIP IDENTIFICATION

WARNING: If the inventors are each not the inventors of all the claims an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.

My residence, post office address and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS

SPECIFICATION IDENTIFICATION

the specification of which: (complete (a), (b) or (c))

- (a) ☐ is attached hereto.  
(b) ☒ was nationally filed on 1 March 2002 as ☒ Serial No. 10/070,178  
or ☐ Express Mail No., as Serial No. not yet known \_\_\_\_\_  
and was amended on \_\_\_\_\_ (if applicable).

NOTE: Amendments filed after the original papers are deposited with the PTO which contain new matter are not accorded a filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 CFR 1.67.

- (c) ☒ was described and claimed in PCT International Application No. PCT/US00/24515  
filed on 1 Sept 2000 and as amended under PCT Article 19 on \_\_\_\_\_ (if any).

# ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37, Code of Federal Regulations, § 1.56

(also check the following item, if desired)

☐ In compliance with this duty there is attached an information disclosure statement in accordance with 37 CFR 1.98.

## PRIORITY CLAIM (35 U.S.C. § 119)

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(complete (d) or (e))

(d) ☒ no such applications have been filed.

(e) ☐ such applications have been filed as follows.

NOTE: Where item (c) is entered above and the international application which designated the U.S. itself claimed priority check item (e), enter the details below and make the priority claim.

### A. PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. § 119

| COUNTRY (OR INDICATE IF PCT) | APPLICATION NUMBER | DATE OF FILING (day, month, year) | PRIORITY CLAIMED UNDER 37 USC 119                        |
|------------------------------|--------------------|-----------------------------------|----------------------------------------------------------|
|                              |                    |                                   | <input type="checkbox"/> YES NO <input type="checkbox"/> |
|                              |                    |                                   | <input type="checkbox"/> YES NO <input type="checkbox"/> |
|                              |                    |                                   | <input type="checkbox"/> YES NO <input type="checkbox"/> |
|                              |                    |                                   | <input type="checkbox"/> YES NO <input type="checkbox"/> |
|                              |                    |                                   | <input type="checkbox"/> YES NO <input type="checkbox"/> |

ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS  
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

PCT/US00/24515 filed 1 September 2000

NOTE: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CIP APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. § 120.

POWER OF ATTORNEY

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (List name and registration number)

Daniel D. Ryan (29,243)  
John M. Manion (38,957)  
Daniel R. Johnson (46,204)  
Laura A. Dable (46,436)

Joseph A. Kromholz (34,204)  
Patricia Jones (46,318)  
Arnold J. Ericson (16,879)  
Patricia A. Limbach (50,295)

(check the following item, if applicable)

☐ Attached as part of this declaration and power of attorney is the authorization of the above-named attorney(s) to accept and follow instructions from my representative(s).

SEND CORRESPONDENCE TO

Daniel D. Ryan  
RYAN KROMHOLZ & MANION, S.C.  
Post Office Box 26618  
Milwaukee, Wisconsin 53226-0618

DIRECT TELEPHONE CALLS TO:

Daniel D. Ryan  
PHONE CALLS  
(262) 783 - 1300

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



## SIGNATURE(S)

NOTE: Carefully indicate the family (or last) name as it should appear on the filing receipt and all other documents

Full name of sole or first inventor

WALID \_\_\_\_\_ N \_\_\_\_\_ ABOUL-HOSN \_\_\_\_\_  
 (GIVEN NAME) (MIDDLE INITIAL OR NAME) FAMILY (OR LAST NAME)  
 Inventor's signature *x* *Walid* \_\_\_\_\_  
 Date *x* *7-3-2002* \_\_\_\_\_ Country of Citizenship *US* \_\_\_\_\_  
 Residence (City, State/Country) *FAIR OAKS, CALIFORNIA* \_\_\_\_\_  
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*FAIR OAKS, CALIFORNIA 94628 US* \_\_\_\_\_

Full name of second joint inventor, if any

WILLIAM \_\_\_\_\_ R \_\_\_\_\_ KANZ \_\_\_\_\_  
 (GIVEN NAME) (MIDDLE INITIAL OR NAME) FAMILY (OR LAST NAME)  
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 Date *x* *7-3-2002* \_\_\_\_\_ Country of Citizenship *US* \_\_\_\_\_  
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Full name of third joint inventor, if any

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 Date *x* \_\_\_\_\_ Country of Citizenship *US* \_\_\_\_\_  
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 Post Office Address *1146 ORO LORNA DRIVE* \_\_\_\_\_  
*PLACERVILLE, CALIFORNIA 95667 US* \_\_\_\_\_

Full name of fourth joint inventor, if any

\_\_\_\_\_  
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 Inventor's signature \_\_\_\_\_  
 Date \_\_\_\_\_ Country of Citizenship \_\_\_\_\_  
 Residence (City, State/Country) \_\_\_\_\_  
 Post Office Address \_\_\_\_\_

Full name of fifth joint inventor, if any

\_\_\_\_\_  
 (GIVEN NAME) (MIDDLE INITIAL OR NAME) FAMILY (OR LAST NAME)  
 Inventor's signature \_\_\_\_\_  
 Date \_\_\_\_\_ Country of Citizenship \_\_\_\_\_  
 Residence (City, State/Country) \_\_\_\_\_  
 Post Office Address \_\_\_\_\_

## SIGNATURE(S)

NOTE: Carefully indicate the family (or last) name as it should appear on the filing receipt and all other documents.

Full name of sole or first inventor

WALID  
(GIVEN NAME) N  
(MIDDLE INITIAL OR NAME) ABOUL-HOSN  
(FAMILY (OR LAST NAME))  
Inventor's signature X  
Date X Country of Citizenship US  
Residence (City, State/Country) FAIR OAKS, CALIFORNIA  
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Full name of second joint inventor, if any

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(MIDDLE INITIAL OR NAME) KANZ  
(FAMILY (OR LAST NAME))  
Inventor's signature X  
Date X Country of Citizenship US  
Residence (City, State/Country) SACRAMENTO, CALIFORNIA  
Post Office Address 4695 FRANCIS COURT  
SACRAMENTO, CALIFORNIA 95822 US

Full name of third joint inventor, if any

BRUCE  
(GIVEN NAME) A.  
(MIDDLE INITIAL OR NAME) BAKER  
(FAMILY (OR LAST NAME))  
Inventor's signature [Signature]  
Date X 25 June 2007 Country of Citizenship US  
Residence (City, State/Country) PLACERVILLE, CALIFORNIA  
Post Office Address 1146 ORO LORNA DRIVE  
PLACERVILLE, CALIFORNIA 95667 US

Full name of fourth joint inventor, if any

(GIVEN NAME)   
(MIDDLE INITIAL OR NAME)   
(FAMILY (OR LAST NAME))  
Inventor's signature   
Date   
Country of Citizenship   
Residence (City, State/Country)   
Post Office Address

Full name of fifth joint inventor, if any

(GIVEN NAME)   
(MIDDLE INITIAL OR NAME)   
(FAMILY (OR LAST NAME))  
Inventor's signature   
Date   
Country of Citizenship   
Residence (City, State/Country)   
Post Office Address

CHECK PROPER BOX(ES) FOR ANY OF THE FOLLOWING AD. PAGE(S) WHICH  
FORM A PART OF THIS DECLARATION

☐ Signature for sixth and subsequent joint inventors. Number of pages added \_\_\_\_\_

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☐ Signature by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor. Number of pages added \_\_\_\_\_

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☐ Signature for inventor who refuses to sign or cannot be reached by person authorized under 37 CFR 1.47. Number of pages added \_\_\_\_\_

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☒ Added pages to combined declaration and power of attorney for divisional, continuation, or continuation-in-part (CIP) application.

☒ Number of pages added 2

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☐ Authorization of attorney(s) to accept and follow instructions from representative

\*\*\*

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**ADDED PAGE TO COMBINED DECLARATION AND POWER OF ATTORNEY  
FOR US PRIORITY CLAIM**

**CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S) UNDER 35 U.S.C. 120**

I hereby claim the benefit under Title 35, United States Code, S 120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, S 112, I acknowledge the duty to disclose information that is material to the examination of this application, namely, information where there is substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent, which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application.

**PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS  
DESIGNATING THE U.S. FOR BENEFIT UNDER 35 USC 120:**

Status  
(CHECK ONE)

| U.S. APPLICATIONS | U.S. FILING DATE | Patented | Pending | Abandoned |
|-------------------|------------------|----------|---------|-----------|
| 1. 60 / 152,249   | 3 SEPTEMBER 1999 |          |         | X         |
| 2. 0 /            |                  |          |         |           |
| 3. 0 /            |                  |          |         |           |

**PCT APPLICATIONS DESIGNATING THE U.S.**

| PCT APPLICATION NO. | PCT FILING DATE  | U.S. SERIAL NOS. ASSIGNED (if any) |
|---------------------|------------------|------------------------------------|
| 4. PCT/US00/24515   | 1 SEPTEMBER 2000 |                                    |
| 5.                  |                  |                                    |
| 6.                  |                  |                                    |

DETAILS OF FOREIGN APPLICATION FROM WHICH PRIORITY APPLICATION  
CLAIMED UNDER 35 USC 119

| Above Appln. No. | Country | Application No. | Date of filing<br>(day, month, year) | Date of issue<br>(day, month, year) |
|------------------|---------|-----------------|--------------------------------------|-------------------------------------|
| 1.               |         |                 |                                      |                                     |
| 2.               |         |                 |                                      |                                     |
| 3.               |         |                 |                                      |                                     |
| 4.               |         |                 |                                      |                                     |
| 5.               |         |                 |                                      |                                     |
| 6.               |         |                 |                                      |                                     |

**APPLICATION INFORMATION**

|                                |                                                          |
|--------------------------------|----------------------------------------------------------|
| Application Type::             | Utility                                                  |
| Title::                        | Guidable Intravascular Blood Pump and<br>Related Methods |
| Attorney Docket Number::       | 9261-17142-PCT-US-CON                                    |
| Request for Non-Publication?:: |                                                          |
| Total Drawing Sheets::         | 18                                                       |
| Small Entity?::                | Large                                                    |

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**CONTINUITY INFORMATION**

|                         |                 |
|-------------------------|-----------------|
| This application is a:: | Continuation of |
| > Application One::     | 11/375,926      |
| Filing Date::           | March 15, 2006  |

|                     |               |
|---------------------|---------------|
| Which is a::        | Divisional of |
| > Application Two:: | 10/070,178    |
| Filing Date::       | July 19, 2002 |
| U.S. Patent No.     | 7,022,100     |

|                       |                    |
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| Which Claims::        | The Benefit of     |
| > Application Three:: | PCT/US00/24515     |
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| Which Claims::       | The Benefit of Provisional |
| > Application Four:: | 60/152,249                 |
| Filing Date::        | September 03, 1999         |

## AMENDMENTS TO THE SPECIFICATION

Please amend the paragraph beginning on page 1, line 3 of the specification as follows:

This application is a continuation of Application Serial No. 11/375,926, pending, which is  
~~application~~ is a divisional of ~~co-pending~~ U.S. patent application Ser. No. 10/070,178, filed Jul. 19,  
2002, now U.S. Patent No. 7,022,100, which claims the benefit of PCT/US00/24515 filed Sep. 1,  
2000, which claims the benefit of provisional U.S. patent application Ser. No. 60/152,249 filed Sep.  
3, 1999. We hereby claim priority to the aforementioned application and also incorporate each of the  
afore-listed patents and applications, in its entirety, by reference thereto.



Patent

**GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS**  
**Related Applications**

This application is a divisional of co-pending U.S. Patent Application Serial No. 10/070,178, filed July 19, 2002, which claims the benefit of PCT/US00/24515 filed September 1, 2000, which claims the benefit of provisional U.S. Patent Application Serial No. 60/152,249 filed September 3, 1999.

**Field of the Invention**

The present invention relates generally to blood pumps and, more particularly, to an improved intravascular blood pump having a guide mechanism which provides the ability to selectively guide the intravascular pump to a desired location within a patient's circulatory system.

**Description of Related Art**

Over the years, various types of blood pumps have been developed for the purpose of augmenting or replacing the blood pumping action of damaged or diseased hearts. Blood pumps are commonly used in three situations: (1) for acute support during cardio-pulmonary operations; (2) for short-term support while awaiting recovery of the heart from surgery; or (3) as a bridge to keep a patient alive while awaiting heart transplantation. The pumps may be designed to provide

right and/or left ventricular assist, although left ventricle assist is the most common application in that it is far more common for the left ventricle to become diseased or damaged than it is for the right ventricle.

5           Blood pumps must provide leak-free operation and must avoid contamination of the fluid by the pump components and the external environment. Such pumps must also pump the fluid at a suitable rate without applying excessive Reynolds shear stress to the fluid. It is well  
10 known to those skilled in the art that lysis or cell destruction may result from application of shear stress to cell membranes. Red blood cells are particularly susceptible to shear stress damage as their cell membranes do not include a reinforcing cytoskeleton to  
15 maintain cell shape. Lysis of white blood cells and platelets also occurs upon application of high shear stress. Lysis of red blood cells can result in release of cell contents which trigger subsequent platelet  
20 aggregation. Sublytic shear stress leads to cellular alterations and direct activation and aggregation of platelets and white blood cells.

          Intravascular blood pumps comprise miniaturized blood pumps capable of being percutaneously or surgically introduced into the vascular system of a  
25 patient, typically to provide left and/or right heart support. One type of intravascular pump is an axial flow blood pump comprising a cable-mounted rotor surrounded by a protective shroud. The pump, along with the rotor and shroud, are mounted at the end of an elongated flexible  
30 catheter. The catheter is inserted into the aorta from a remote entry point, such as an incision below the groin that provides access into a femoral artery. The catheter then passes through the descending aorta until it reaches the ascending aorta, near the heart. The catheter device  
35 encloses a rotating drive cable which is coupled to the

impeller blade at one end, and which emerges from the exposed end of the catheter, near the patient's groin, at the other end. When the exposed end of the drive cable is mechanically rotated, using a device located outside the patient's body, it conveys the rotational force through the length of the catheter, causing the impeller to spin at high speed near the heart. This type of blood pump finds particular application in providing ventricular assist during surgery or providing temporary bridging support to help a patient survive a crisis.

While generally effective in providing ventricular assisting functions, prior art intravascular blood pumps nonetheless suffer various drawbacks. A significant drawback is that prior art intravascular blood pumps are difficult to guide into the appropriate position within the circulatory system of a patient. This is due largely to the fact that the elongated catheter is incapable of providing the degree of control necessary to easily negotiate the pump through the tortuous pathways leading up to and into the heart. When attempting to place the blood pump in a trans-valvular configuration (with the inlet in the left ventricle and the pump outlet in the ascending aorta), the natural tendency of the catheter to stay straight may cause the pump to be inadvertently placed in the carotid ostia, which can be dangerous if the pump is operated to withdraw blood from the brain.

To overcome these difficulties, certain guide mechanisms may be employed to assist the physician placing the pump in the appropriate position within the circulatory system. One type of supplemental guide mechanism is a guide catheter. Guide catheters are designed with certain guidability characteristics such that physicians can selectively position them within the vasculature or heart with relative ease. A central lumen

is provided within the guide catheter such that the intravascular pump may be introduced therein and guided while it is advanced towards the predetermined circulatory site. While generally effective at providing  
5 a guiding feature for such intravascular blood pumps, employing such supplemental guide mechanisms is nonetheless disadvantageous in that they consume valuable space within the vessels. A guide catheter, for example, would necessarily be larger in diameter than the diameter  
10 of the pump and protective shroud in order to provide adequate passage of those components. As will be appreciated, this restricts the amount of space available for blood to flow within the particular vessel, and increases the size of the required puncture wound for  
15 accessing the vessel.

The present invention is directed at eliminating and/or reducing the effects of the foregoing drawbacks of prior art intravascular blood pumps.

#### **Summary of the Invention**

20 The present invention overcomes the drawbacks of the prior art by providing an improved intravascular blood pump equipped with integrated features for selectively guiding the intravascular blood pump to a predetermined location in the patient's circulatory  
25 system, i.e. heart and/or vasculature. In so doing, the intravascular blood pump of the present invention eliminates the need for supplemental guiding mechanisms, such as a separate, large diameter guide catheter as used in the prior art.

30 In a first broad aspect of the present invention, an intravascular blood pump system is provided comprising an intravascular blood pump having a cannula coupled thereto and an "over-the-wire" type guide mechanism for selectively positioning the intravascular  
35 blood pump and cannula at a predetermined location within

the circulatory system of a patient. To accomplish this, a central lumen is formed through at least a portion of the intravascular blood pump system such that a guide element, such as a guide wire, may be progressed  
5 therethrough and advanced to the predetermined location in the circulatory system of the patient. After the guide element is advanced to this desired location, the intravascular blood pump and cannula may thereafter be advanced along the guide element to the desired location.

10 In a second broad aspect of the present invention, an intravascular blood pump system is provided comprising an intravascular blood pump having a cannula coupled thereto and a "side-rigger" or "rapid exchange"  
15 type guide mechanism for selectively positioning the intravascular blood pump and cannula at a predetermined location within the circulatory system of a patient. To accomplish this, a side lumen is formed along a length of at least one of the intravascular blood pump and the  
20 cannula. A guide element, such as a guide wire, may be advanced to the predetermined location in the circulatory system of the patient. After the guide element is advanced to this desired location, the intravascular blood pump and cannula may thereafter be advanced along the guide element to the desired location.

25 In a third broad aspect of the present invention, an intravascular blood pump system is provided comprising an intravascular blood pump having a cannula coupled thereto and a "guide catheter" type guide  
30 mechanism for selectively positioning the intravascular blood pump and cannula at a predetermined location within the circulatory system of a patient. The pump system of this broad aspect includes a conduit assembly and a separate pump assembly. The conduit assembly includes a  
35 guide catheter, a rotor shroud, and a cannula, with the cannula and guide catheter disposed on either side of the

rotor shroud. The pump assembly includes a rotor, a drive member coupled to the rotor, and a pump disposed between the rotor and the drive member. The guide catheter is dimensioned to receive and guide the pump assembly to the point where the rotor docks within the rotor shroud so as to form an operational blood pump. This configuration allows the conduit assembly to be precisely and efficiently guided into a desired position within the body through the use of conventional guiding techniques well known in interventional cardiology. The pump assembly may thereafter be introduced into and guided within the conduit until the pump assembly is docked within the rotor shroud. This dual construction arrangement provides improved placement of the pump assembly by using the conduit as a guiding mechanism.

The foregoing broad aspects of the present invention may be manifested according to the following recitations:

According to a first broad recitation of the present invention, an intravascular blood pump system is provided comprising an intravascular blood pump having a cannula coupled thereto, and a guide mechanism adapted to guide the intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient.

In a further embodiment, the intravascular blood pump includes a rotor, a shroud for receiving the rotor, and a drive cable coupled to the rotor for driving the rotor within the shroud.

In a further embodiment, the cannula is coupled to the shroud of the intravascular blood pump.

In a further embodiment, the guide mechanism comprises a guide catheter coupled to the shroud.

In a further embodiment, the guide catheter may be used to guide the shroud and cannula to the

predetermined location within the circulatory system of the patient, after which point the rotor and drive cable of the intravascular blood pump may be docked within the shroud for pump operation.

5 In a further embodiment, the drive cable sheath is provided having a central lumen for receiving the drive cable, and wherein a purge fluid delivery system is coupled to the drive cable sheath to deliver purge fluid to the rotor.

10 In a further embodiment, the drive cable sheath includes at least one side lumen for delivering the purge fluid towards the rotor.

In a further embodiment, a portion of the purge fluid is delivered through the at least one side lumen and past the rotor, and a portion of purge fluid is rerouted back from the rotor through the central lumen of the drive cable.

15 In a further embodiment, a perfusion assembly is provided communicatively coupled to the guide catheter for selectively rerouting blood from within the guide catheter to a point downstream from the introduction site of the guide catheter into the vasculature of the patient.

20 In a further embodiment, the perfusion assembly includes a first conduit communicatively coupled to the guide catheter, a second conduit dimensioned to be introduced into the vasculature of the patient, and a selectively operable valve disposed in between the first conduit and the second conduit.

25 In a further embodiment, a blood pressure detection mechanism is provided to detect the pressure of the blood proximate at least one of the intravascular blood pump and cannula.

30 In a further embodiment, the blood pressure detection mechanism comprises at least one of fluid

filled column disposed within at least a portion of the cannula, a piezoelectric element coupled to at least one of the intravascular blood pump and cannula, and a strain gauge coupled to at least one of the intravascular blood  
5 pump and cannula.

In a further embodiment, the blood pressure detection mechanism involves calculating blood pressure based on the relationship between the torque and motor current of a motor used to drive the rotor.

10 In a further embodiment, the guide mechanism comprises a guide element disposed at least partially within the cannula.

In a further embodiment, the guide element comprises a guide wire for passage through a side lumen  
15 formed in the cannula.

In a further embodiment, the guide element comprises a selectively deformable element disposed at least partially within the cannula.

In a further embodiment, the intravascular  
20 blood pump and cannula may be selectively advanced to the predetermined location within the vasculature of the patient by first passing the guide wire to the predetermined location and thereafter sliding the intravascular blood pump and cannula along the guide wire  
25 to the predetermined location.

In a further embodiment, the guide element comprises a guide wire for passage through a lumen extending through the drive cable and rotor.

In a further embodiment, the intravascular  
30 blood -pump and cannula may be selectively advanced to the predetermined location within the vasculature of the patient by first passing the guide wire to the predetermined location and thereafter sliding the intravascular blood pump and cannula along the guide wire  
35 to the predetermine location.



In a further embodiment, the guide mechanism further includes guide element for passage through the guide catheter to facilitate placement of the shroud and the cannula at the predetermined location within the vasculature of the patient.

In a further embodiment, the guide mechanism further includes a guide element for passage through a side lumen formed along at least a portion of the guide catheter.

In a further embodiment, the guide element comprises at least one of a guide wire and a balloon catheter.

#### **Brief Description of the Drawings**

Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

FIG. 1 is a partial sectional view of a human heart illustrating an intravascular blood pump system having an "over-the-wire" type guide mechanism according to a first broad aspect of the present invention positioned, by way of example, in a trans-valvular configuration to provide left-heart assist;

FIG. 2 is side view of the guidable intravascular blood pump system of the type shown in FIG. 1 including a motor coupler and purge fluid delivery system according to an exemplary embodiment of the present invention;

FIG. 3 is a cross-sectional view illustrating an exemplary construction of the blood pump, drive cable assembly, and cannula of the intravascular blood pump system according to the first broad aspect of the present invention;

FIG. 4 is a cross-sectional view taken along

lines 4-4 of FIG. 3 illustrating an exemplary construction of the drive cable assembly and guide mechanism according to the first broad aspect of the present invention;

5               FIG. 5 is a cross-sectional view illustrating an exemplary construction of the motor coupler and purge fluid delivery system according to the first broad aspect of the present invention;

10              FIG. 6 is a partial sectional view of a human heart illustrating an intravascular blood pump system having a "rapid exchange" or "side-rigger" type guide mechanism according to a second broad aspect of the present invention positioned, by way of example, in a trans-valvular configuration to provide left-heart  
15              assist;

              FIG. 7 is side view of the guidable intravascular blood pump system of the type shown in FIG. 6 including a motor coupler and purge fluid delivery system according to an exemplary embodiment of the  
20              present invention;

              FIG. 8 is a cross-sectional view taken along lines 8-8 of FIG. 7 illustrating the "side-rigger" or "rapid exchange" type guide mechanism according to the second broad aspect of the present invention;

25              FIG. 9 is a cross-sectional view of the type shown in FIG. 8 illustrating an alternate configuration of the guide mechanism according to the second broad aspect of the present invention;

30              FIG. 10 is a partial sectional view of a human heart illustrating an intravascular blood pump system having a "guide catheter" type guide mechanism according to a third broad aspect of the present invention positioned, by way of example, in a trans-valvular configuration to provide left-heart assist;

35              FIG. 11 is a schematic view of a human being

illustrating the intravascular blood pump system of the type shown in FIG. 10 inserted through the femoral artery and including an optional perfusion assembly for perfusing the vasculature downstream from the incision  
5 site where guide catheter enters the femoral artery;

FIG. 12 is a side view of the intravascular blood pump system shown in FIGS. 10-11 illustrating the separable nature of a pump assembly and a conduit assembly which collectively form the intravascular blood  
10 pump system according to the third broad aspect of the present invention;

FIG. 13 is a side view illustrating the intravascular blood pump system shown in FIG. 12 with the pump assembly docked into the conduit assembly according  
15 to the third broad aspect of the present invention;

FIG. 14 is a cross-sectional view illustrating an exemplary construction of the blood pump, drive cable assembly, cannula, and guide catheter of the intravascular blood pump system shown in FIG. 13;  
20

FIG. 15 is a cross-sectional view taken along lines 15-15 of FIG. 14 illustrating an exemplary construction of the drive cable assembly and guide catheter according to the third broad aspect of the present invention;

FIG. 16 is a cross-sectional view illustrating an exemplary construction of the motor coupler, purge fluid delivery system, and a proximal portion of the guide catheter biasing assembly according to the third broad aspect of the present invention;  
25

FIG. 17 is a cross-sectional view illustrating an exemplary construction of the perfusion assembly and a distal portion of the guide catheter biasing assembly according to the third broad aspect of the present invention;  
30

FIG. 18 is a cross-sectional view of an  
35

intravascular blood pump system of the type shown in FIGS. 12-13 having an alternate configuration for docking the rotor within the shroud according to the principles of the present invention; and

5           FIG. 19 is a partial sectional view of a human heart illustrating an alternate intravascular blood pump system having an "over-the-wire" type guide mechanism according to the first broad aspect of the present invention positioned, by way of example, in a trans-  
10           valvular configuration to provide right-heart assist.

**Detailed Description of the Invention**

          Illustrative embodiments of the invention are described below. In the interest of clarity, not all features of an actual implementation may be described in  
15           this specification. It will of course be appreciated that in the development of any such actual embodiment, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related  
20           constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would nevertheless be a routine undertaking for those of ordinary skill in the art having the benefit of this  
25           disclosure.

          The present invention involves an intravascular pump system for use in a number of broad ranging applications involving the augmentation of blood flow within the circulatory system of a patient. As will  
30           be described below, the intravascular blood pump system of the present invention overcomes the drawbacks of the prior art by providing a guide mechanism as part of the intravascular blood pump. This advantageously allows the intravascular blood pump to be selectively guided to a  
35           predetermined location within the circulatory system of a

patient without the need for bulky supplemental guide mechanisms, such as a separate guide catheter.

The intravascular pump assembly of the present invention is particularly suited for trans-valvular use, such as for left and/or right ventricular assist procedures. By way of example only, such ventricular assist procedures may be employed in cardiac operations including, but not limited to, coronary bypass graft (CABG), cardio-pulmonary bypass (CPB), open chest and closed chest (minimally invasive) surgery, bridge-to-transplant and/or failure-to-wean-from-bypass situations. It is to be readily understood, however, that the intravascular blood pump assembly and methods of the present invention are not to be limited to such applications. Moreover, while illustrated and described largely with reference to left-heart assist applications, it is to be readily understood that the principles of the present invention apply equally with regard to right-heart assist application, which are contemplated as within the scope of the present invention. These and other variations and additional features will be described throughout.

Referring to FIG. 1, shown is a guidable intra-vascular blood pump system 10 according to a first broad aspect of the present invention shown, by way of example only, in a left-heart assist configuration within a human heart. The system 10 includes an intravascular blood pump 12, a cannula 14, and an "over-the-wire" type guide mechanism 16. A drive cable assembly 18 and a motor assembly 20 are provided to drive the intravascular blood pump 12. The "over-the-wire" guide mechanism 16 comprises a suitable guide element dimensioned to pass slideably through a central lumen extending through the drive cable 18, blood pump 12, and cannula 14. Suitable guide elements may include any number of conventional guiding

devices, including but limited to those employed in cardiology. By way of example only, the guide element is shown as a guide wire 22. According to the present invention, the "over-the-wire" guide mechanism 16  
5 provides the ability to selectively guide the blood pump 12 and cannula 14 to a predetermined position in the circulatory system of a patient, such as the trans-valvular position shown.

To accomplish this, the guide wire 22 is first  
10 introduced into the vascular system of a patient through any suitable access point, such as through the use of the well known Seldinger technique. The guide wire 22 can then be advanced within the patient to a desired location within the circulatory system of the patient. This may be  
15 done using the control features of the guide wire 22 itself, or may be facilitated through the use of any number of supplemental guidance mechanisms or techniques to ensure the proper and efficient placement of the guide wire 22. Such supplemental guidance techniques may  
20 include, but are not necessarily limited to, guide catheters and/or techniques involving ultra-sound or flouroscopy. Once the guide wire 22 is positioned at the desired location (such as in left ventricle as shown), the blood pump 12 and cannula 14 may thereafter be  
25 advanced along the guide wire 22 and positioned in the trans-valvular configuration shown. Under the operation of the motor assembly 20, the blood pump 12 may be used for left-heart assist by selectively withdrawing blood from the left ventricle (through the interior of the  
30 cannula 14) for delivery outward through outflow apertures formed in the blood pump 12. This outflow from the blood pump 12 flows along the exterior of the drive cable assembly 18 in a substantially axial fashion for arterial coupler 24 and, as will be described in greater  
35 detail below, a purge fluid distribution throughout the

body.

Referring to FIGS. 2-5, an exemplary embodiment of the intravascular blood pump system 10 of FIG. 1 will now be described. As shown in FIG. 2, the intravascular blood pump system 10 includes a motor delivery system 26 for providing a two-way fluid flow within the drive cable assembly 18 during pump operation. The purge fluid delivery system 26 includes a fluid inlet conduit 28 for introducing pressurized purge fluid from a fluid source (not shown) for delivery into the blood pump 12, and a fluid outlet conduit 30 to withdraw a return flow of purge fluid from the blood pump 12. The motor coupler 24 establishes a mechanical connection between a motor (not shown) and a drive cable (not shown) for providing motive force to the blood pump 12 for pump operation. The drive cable assembly 18 includes a drive cable sheath 32 which, in addition to serving a purge fluid delivery function, also serves as a protective housing for the drive cable (not shown). Although shown in broken form for clarity, it will be appreciated that the drive cable assembly 18 (and all components thereof) may be provided in any suitable length sufficient for intravascular applications. That is to say, the length of the drive cable assembly 18 must be enough to reach between the motor coupler 24 and purge fluid delivery system 26, located outside the patient, and the desired location within the patient's circulatory system where the blood pump 12 is to be positioned.

The intravascular blood pump 12 is shown (by way of example only) as an axial flow intravascular blood pump. The blood pump 12 includes pump body 34, a rotor shroud 36 having flow ports 38, and an internally disposed rotor (not shown) having a shaft rotatably disposed within the pump body 34 and an impeller rotatably disposed within the rotor shroud 36. The

cannula 14 is fixedly attached to the rotor shroud 36 and may extend any suitable length therefrom depending upon the particular intravascular application. The cannula 14 preferably includes a plurality of ports or fenestrations 5 40 about its distal region, as well as an end port 42, which allow for the ingress or egress of blood into or from the cannula 14 depending upon the operation of the blood pump 12. That is to say, if the pump 12 is configured for left-heart assist as shown in FIG. 1, then 10 the ports 40, 42 will allow the ingress of blood into the cannula 14 from the left ventricle. If, on the other hand, the blood pump 12 is configured for right-heart assist (i.e. with the pump 12 in the right atrium and the distal end of the cannula 14 located within the pulmonary 15 artery), then the ports 40, 42 will allow the egress of blood from the cannula 14 into the pulmonary artery. (Details on right-heart assist applications will be discussed in greater detail below.) The pump 12 and cannula 14 may be dimensioned to any suitable diameter 20 for intravascular applications. For example, the range of sizes may include, but is not necessarily limited to, 9 French to 30 French, although the range is more preferably from 14 French to 24 French, and most preferably from 18 French to 20 French.

25 The "over-the-wire" type guide mechanism 16 includes the guide wire 22 and, as will be explained in greater detail below, a central lumen extending through the cannula 14, blood pump 12, drive cable assembly 18, purge fluid delivery system 26, and motor coupler 24. As 30 noted above, the central lumen is dimensioned to slideably receive the guide wire 22 such that the blood pump 12 and cannula 14 may be slideably advanced along the guide wire 22 to a desired location within the circulatory system of a patient after the guide wire 22 35 has been so positioned using conventional guidance



techniques. It is to be readily understood that, while shown as a conventional guide wire 22, the guide element forming part of the guide mechanism 16 of the present invention may include any number of well known guidance mechanisms depending upon the application, including but not limited to balloon catheters, imaging wires, and guide catheters dimensioned to be slideably received through the central lumen. For example, although not appropriate for retrograde progression (such as the left-heart application shown in FIG. 1), a balloon catheter may be a suitable guidance mechanism for a right-heart assist application. In such a case, the balloon may be inflated and used as a "sail" to direct the catheter to a desired location (such as the pulmonary artery), after which point the blood pump 12 and cannula 14 can be advanced over the catheter to a trans-valvular configuration with the blood pump 12 in the right atrium and the ports 38, 40 of the cannula 14 in the pulmonary artery.

FIGS. 3 and 4 further detail the construction of the blood pump 12, cannula 14, drive cable assembly 18, and "over-the-wire" guide mechanism 16. The blood pump 12 includes a rotor 44 having a shaft 46 and an impeller 48. The shaft 46 is rotatably disposed within the pump body 34 via a bearing pack comprising, by way of example, ball bearing assemblies 50, 52 and spring 54. Ball bearings assemblies 50, 52 are well known in the art, each comprising an inner race which rotates along with the rotor shaft 46, an outer race which remains in a static and fixed position against the inner surface of the pump body 34, and a plurality of ball bearings disposed between the inner and outer races. The spring 54 biases each bearing assembly 50, 52 axially away from one another to reduce axial play during pump operation. The shaft 46 is generally hollow and dimensioned to receive a

cable adapter 60 therein for the purpose of coupling the rotor 44 to a drive cable 62 forming part of the drive cable assembly 18. The drive cable 62 may be secured to the cable adapter 60 in any number of suitable fashions, including but not limited to the use of adhesives, crimping, and laser welding. These same techniques may be used to secure the cable adapter 60 within the shaft 46 of the rotor 44. A radial seal 64 is provided in between the wall of the pump body 34 and a distal stepped region 66 on the rotor shaft 46, the function of which will be described below.

The impeller 48 includes a hub 56 and a plurality of blades 58 extending therefrom. The hub 56 is generally conical and, according to the first broad aspect of the present invention, is hollow throughout to form part of the central lumen of the guide mechanism 16. In this regard, the hub 56 is preferably provided with a gasket or seal member 68 at its distal tip. The seal member 68 may be made of any suitable sealing material (including but not limited to silicone) such that the pump 12 and cannula 14 may be easily progressed along the guide wire 22 for delivery to a desired circulatory site. The seal member 68 should also be robust enough to prevent the ingress of blood into the interior of the rotor hub 56 during pump operation, whether the guide wire 22 remains in place or is fully withdrawn. The blades 58 are dimensioned to reside in close tolerance with the interior surface of the shroud 36. In operation, the blades 58 impart both an axial and radial vector on the blood which causes it to flow outward through the flow ports 38 formed in the shroud 36. As used herein, the term "axial flow" is deemed to include flow characteristics like that shown in FIG. 3, which include both an axial and slight radial component. It is to be readily appreciated that, although shown as an axial flow

type, blood pump 12 may comprise any number of suitable types of intravascular blood pumps, including but not limited to so-called "mixed flow" intravascular blood pumps without departing from the scope of the present invention.

The cannula 14 is coupled at its proximal end to the rotor shroud 36. This may be accomplished in any number of fashions, including but not limited to the use of adhesives. This may also be facilitated by dimensioning the shroud 36 to include a narrow inlet region 70 capable of being received flushly within the proximal end of the cannula 14. The inlet region 70 of the shroud 36 should preferably have a tapered interior surface for establishing a smooth flow transition between the cannula 14 and the region containing the impeller blades 58. Although shown as a single integral element, it is to be understood that the pump body 34 and shroud 36 may comprise two separate (and sometimes separable) components, the significance of which will become apparent below. The pump body 34 and shroud 36 may be constructed from any number of suitable materials, including but not limited to stainless steel or other medical grade compositions or alloys. The cannula 14 may also be constructed from any number of suitable materials, including but not limited to medical grade plastics. As shown, the cannula 14 may also be fortified with spiral-wound reinforcement wire 72 within the walls of the cannula 14.

The drive cable assembly 18 includes the drive cable 62 and the drive cable sheath 32. The drive cable 62 is coupled to the rotor 44 via the cable adapter 60. The drive cable sheath 32 includes a central lumen 74 and a plurality of side lumens 76. The central lumen 74 serves as a protective covering for the drive cable 62. The central lumen 74, along with the side lumens 76, also

forms part of the purge fluid delivery system 26 shown above in FIG. 2, which will be described in greater detail below. The side lumens 76 are provided in fluid communication with the fluid inlet conduit 28, while the  
5 central lumen 74 is provided in fluid communication with the fluid outlet conduit 30. The side lumens 76 are thus configured to deliver purge, fluid into the pump 12, while the central lumen 74 is configured to transport purge fluid away from the pump 12 along the length of the  
10 drive cable 62.

The pressurized purge fluid within the side lumens 76 may take one of two flow paths upon entry into the pump 12. One flow path passes through the interior of the pump 12 and onward past the radial seal 64 to prevent  
15 the ingress of blood into the pump body 34 during pump operation. More specifically, the purge fluid flows distally around the cable adapter 60, through the ball bearing assemblies 50, 52, and onward past the radial seal 64. This egress of purge fluid past the radial seal  
20 64 can be controlled to effectively thwart the ingress of blood past the radial seal 64, which might otherwise cause clotting and/or pump damage. The other flow path is directed back out the central lumen 74 for delivery to the fluid outlet conduit 30. In so doing, this flow path  
25 bathes the components of the pump 12 and/or drive cable 62 and thereby reduces frictional heating within the pump 12 and/or the central lumen 74 of the sheath 32 during pump operation.

The "over-the-wire" guide mechanism 16  
30 includes a central lumen through which the guide wire 22 may extend for the purpose of slideably advancing the blood pump 12 and cannula 14 into a desired position within the circulatory system of a patient. In the embodiment shown, this central lumen is established by  
35 forming and co-aligning the individual central lumens

within each of the drive cable 62, the cable adapter 60, the shaft 46 and hub 56 of the rotor 44, and the cannula 14. In this regard, the drive cable 62 is preferably of wound-wire construction having a central lumen formed therein. The central lumens within the cable adapter 60, rotor 44, and gasket 68 may be formed via machining or molding processes. These central lumens should preferably be sized such that they permit the slideable passage of the pump 12 and cannula 14 therealong, but do not interfere with or constrain the guide wire 22 to cause inadvertent rotation of the guide wire 22 during pump operation. As noted above, it is also contemplated to remove the guide wire 22 after the pump 12 and cannula 14 are properly positioned in the patient. In this case, the gasket or seal 68 on the hub 56 should be robust enough to reseal after the guide wire 22 is withdrawn and prevent the ingress of blood into the interior of the rotor 44.

Referring to FIG. 5, the motor coupler 24 includes a housing 78, a drive shaft adapter 80, and a bearing assembly 82. The drive shaft adapter 80 includes a drive shaft coupler 84 dimensioned to receive a drive shaft of a motor (not shown), and a drive cable coupler 86 dimensioned to receive the drive cable 62. Any of a variety of attachment techniques may be employed to securely fasten the drive cable 62 to the drive cable coupler 86, including but not limited to adhesives, crimping, and laser welding. The drive shaft adapter 80 is rotatably disposed within the housing 78 by the bearing assembly 82. The bearing assembly 82 includes a sleeve 88 (which may alternatively be formed as an integral part of the housing 78) for retaining a pair of ball bearing assemblies 90, 92 and a spring 94 of the type described above. That is, each bearing assembly 90, 92 generally comprises an inner race which rotates along

with the drive shaft adapter 80, an outer race which remains in a static and fixed position against the inner surface of the retaining sleeve 88, and a plurality of ball bearings disposed between the inner and outer races.

- 5 The spring 94 is provided to bias each bearing assembly 90, 92 axially away from one another to reduce axial play during operation.

The purge fluid delivery system 26 includes a housing 96 having a central lumen 98, an inflow port 100, and an outflow port 102. The housing 96 is also dimensioned to matingly receive a portion of the motor coupler 24. In this regard, a seal element 104 is provided sandwiched in between the housing 96 and housing 78 and including an aperture which extends about the drive shaft adapter 80 as it exits the housing 78 to prevent the ingress of purge fluid into the motor coupler 24. A fluid guide structure 106 is also provided within the central lumen 98 for the purpose of separating the inflow and outflow ports 100, 102. The fluid guide structure 106 includes a central lumen 108 through which the drive cable 62 extends, and an elevated portion 110 that retains an O-ring 112 against the inner surface of the central lumen 98 of the housing 96. The drive cable sheath 32 is secured to the housing 96 such that the inflow port 100 is communicatively coupled to the side lumens 76, and the outflow port 102 is communicatively coupled to the central lumen 74. In this fashion, pressurized purge fluid may be introduced through the inflow port 100 via inflow conduit 28, and removed through the outflow port 102 via outflow conduit 30. By way of example, the inflow conduit 28 and outflow conduit 30 may be coupled to their respective ports 100, 102 via barbed connectors 114. Similarly, the inflow and outflow conduits 28, 30 may be equipped with any number of suitable connectors (such as those illustrated by way of

example in FIG. 2) for establishing fluid communication with a source of pressurized fluid (not shown). The pressurized fluid source (not shown) may include, but is not necessarily limited to, the use of a syringe, an  
5     indeflator, a fluid delivery pump, or an accumulator arrangement to provide the requisite delivery of pressurized fluid. The purge fluid delivery system 26 thus provides a two-way transmission of purge fluid within the drive cable sheath 32 for the purposes of  
10    cooling the blood pump 12 and preventing the ingress of blood past the radial seal 64 and into blood pump 12.

Referring to FIG. 6, shown is a guidable intra-vascular blood pump system 120 according to a second broad aspect of the present invention. As will be  
15    described hereinafter, the intravascular blood pump system 120 differs from the intravascular blood pump system 10 described above only as to the type of guide mechanism employed. In the interest of clarity and consistency, then, like reference numerals will be used  
20    to denote like elements and distinctions pointed out where necessary. Moreover, due to the commonality of principles employed in both intravascular blood pump systems 10, 120, a discussion to the level of detail set forth above is not deemed necessary with regard to the  
25    intravascular blood pump system 120. Instead, those aspects in common with the intravascular blood pump 10 are hereby incorporated into the discussion of the intravascular blood pump system 120.

In its most general form, the intravascular  
30    blood pump system 120 of this second broad aspect of the present invention comprises the blood pump 12 and cannula 14 arrangement, wherein the cannula 14 is equipped with a "side-rigger" or "rapid exchange" guide mechanism 122. In an important aspect of the present invention, the "rapid  
35    exchange" or "side-rigger" guide mechanism 122 includes a

guide carriage 124 formed along at least a portion of the cannula 14, and a suitable guide element (such as guide wire 22) dimensioned to pass slidably through a lumen (not shown) extending through the guide carriage 124. The  
5 "rapid exchange" guide mechanism 122 thereby provides the ability to selectively guide the blood pump 12 and cannula 14 to a predetermined position in the circulatory system of a patient in the manner described above. Namely, the guide wire 22 may be first introduced into  
10 the vascular system of a patient through any suitable access point and guided to a desired location within the circulatory system of the patient, i.e. the left ventricle as shown. The blood pump 12 and cannula 14 may thereafter be advanced along the guide wire 22 and  
15 positioned in the trans-valvular configuration shown for providing left-heart assist.

FIGS. 7-9 further illustrate the "side-rigger" or "rapid-exchange" guide mechanism 122 of this second broad aspect of the present invention. In a preferred  
20 embodiment, the "side-rigger" guide mechanism 122 includes a lumen 126 formed within the guide carriage 124. The guide carriage 124 is preferably formed as an integral extension of the wall of the cannula 14. FIGS. 7 and 8 comport with the embodiment shown in FIG. 6, namely  
25 illustrating the guide carriage 124 formed along the exterior surface of the cannula 14. FIG. 9 illustrates an alternate embodiment wherein the guide carriage 124 may be formed along the interior surface of the cannula 14. In either case, the guide wire 22 is advanced to a  
30 desired location in the vasculature of the patient, after which point the blood pump 12 and cannula 14 can be slidably advanced therealong for delivery to the desired location according to the present invention. The guide wire 22 may thereafter be withdrawn from the patient. If  
35 the guide carriage 124 is formed along the exterior



surface of the cannula 14 (as shown in FIGS. 7-8), then the cannula 14 should preferably be positioned so that the guide carriage 124 does not extend in a trans-valvular fashion. For example, with reference to FIG. 6, the guide carriage 124 should be positioned wholly within the left ventricle such that the pulsatile blood flow during beating heart procedures will not inadvertently pass through the side lumen 126 and pass through the aortic valve.

10           The intravascular blood pump system 120 is constructed in virtually the same manner as the intravascular blood pump system 10 shown and described above, with the exception of the location of the respective guide mechanisms 16, 122. More specifically, 15 because the guide mechanism 122 is disposed along the side of the cannula 14, there is no need to form a central lumen extending through the blood pump 12, drive cable assembly 18, purge fluid delivery system 26, and motor coupler 24 as detailed above with regard to the 20 intravascular blood pump system 10. As such, these components need not be specially machined or molded to include such central lumens as was required with the intravascular blood pump system 10 set forth above.

Referring to FIG. 10, shown is a guidable 25 intravascular blood pump system 130 according to a third broad aspect of the present invention. Again, due to the commonality between many of the same components and features of the intravascular blood pump systems described above and the intravascular blood pump system 130, like reference numerals will be used to denote like 30 elements and distinctions pointed out where necessary. As will be explained in greater detail below, the intravascular blood pump system 130 employs yet another unique and useful guide mechanism according to the 35 present invention. However, because many of the same

components are employed, a discussion to the level of detail set forth above is not deemed necessary with regard to the intravascular blood pump system 130. Instead, those aspects in common with the intravascular  
5 blood pumps described above are hereby incorporated into the discussion of the intravascular blood pump system 130.

In its most general form, the intravascular blood pump system 130 of this third broad aspect of the  
10 present invention comprises the blood pump 12 and cannula 14 arrangement, wherein a "guide catheter" 132 is provided as the guide mechanism for positioning the pump 12 and cannula 14 at a desired location within the circulatory system of the patient. More specifically,  
15 with brief reference to FIG. 12, the intravascular blood pump system 130 is formed in two separate assemblies according to the present invention: a conduit assembly 134 and pump assembly 136. In its most basic form, the conduit assembly 134 comprises the guide catheter 132 and  
20 cannula 14 coupled to the. Rotor shroud 35. The pump assembly 136 is constructed such that the pump body 34 and rotor 44 can be disengaged from the rotor shroud 36 and removed entirely from the conduit assembly 134. Referring again to FIG. 10, this dual construction forms  
25 a significant feature of the present invention because it provides the ability to form the blood pump 12 at a desired location in a patient using two separate and distinct steps. The first step involves positioning the conduit assembly 134 (with the pump assembly 136 removed)  
30 within a patient such that the shroud 36 and cannula 14 are each disposed in a desired location, such as a trans-valvular configuration for cardiac assist procedures. In an important aspect, the task of positioning the conduit assembly 134 within the patient may be advantageously  
35 facilitated through the use of any number of well known

guidance mechanisms, including but not limited to guide wires, balloon catheters, imaging wires, guide catheters, and/or techniques involving ultra-sound or flouroscopy. The second step in providing the intravascular blood pump system 130 of the present invention involves advancing the pump assembly 136 through the conduit assembly 134 such that the rotor 44 docks within the shroud 36 to form the pump 12 at the desired location.

By way of clarification, the term "cannula" is used to denote cannula 14 because it serves a primary purpose of transporting fluid into the blood pump 12, whereas the term "catheter" is used to denote the catheter 132 because it serves a primary purpose of guiding or directing devices or components (i.e. the pump assembly 136) to a desired location within the body. It is to be readily understood, however, that these terms are only used for convenience and in a general fashion such that the cannula 14 may serve certain guiding functions and the catheter 132 may serve certain fluid transportation functions without departing from the scope of the present invention. For example, the cannula 14 may be equipped with dedicated lumens to receive various guide mechanisms (such as guide wires, balloon catheters, selectively deformable elements such as Nitinol, etc). In similar fashion, the guide catheter 132 may be used to transport fluid to and/or from the patient, such as by providing apertures 138 along predetermined regions of the catheter 132.

FIG. 11 demonstrates a significant feature of the present invention involving the use of the guide catheter 132 to transport fluid to and/or from the patient. An optional perfusion assembly 140 is provided as part of the intravascular blood pump system 130 of the present invention. The perfusion assembly 140 includes a conduit 142 in fluid communication with the apertures

138, which in this case are formed near the distal region of the guide catheter 132 a short distance downstream from the blood pump 12. In use, blood will pass along the exterior of the guide catheter 132 for distribution throughout the body, as well as within the interior of the guide catheter 132 after passing into the apertures 138. The perfusion assembly 140 may then be employed to selectively reroute blood from within the guide catheter 132 to a point within the patient's vasculature downstream from the point where the guide catheter 132 enters the body. A hemostasis valve assembly 146 of the perfusion assembly 140 permits the drive cable assembly 18 to pass through to the purge fluid delivery system 26 while preventing blood flow other than into the perfusion assembly 140. A seal assembly 150 of the purge fluid delivery system 26 permits the drive cable 62 to pass through to the motor 20 while preventing the flow of purge fluid other than into and from the purge fluid delivery system 26. The perfusion assembly 140 includes a control mechanism 148 for selectively controlling the distribution of perfusion blood flow from the perfusion assembly 140 into the patient. This control mechanism 148 may be automatic based on certain feedback criteria or manually operated.

FIGS. 12-17 illustrate an exemplary construction of the intravascular blood pump system 130 according to the third broad aspect of the present invention. As shown in FIG. 12, the conduit assembly 134 may be selectively disengaged so as to remove the pump assembly 136 therefrom. According to the present invention, the conduit assembly 134 may be introduced (without the pump assembly 136) into the circulatory system of a patient and selectively guided such that the rotor shroud 36 and cannula 14 are positioned at a desired location. The pump assembly 136 can thereafter be

selectively introduced into the conduit assembly 134. A challenge in such a "back-loading" arrangement is ensuring that the pump assembly 136 docks appropriately within the rotor shroud 36 and is maintained in proper engagement during operation of the resulting pump 12.

5 An exemplary docking arrangement will now be described with reference to FIG. 14. In a preferred embodiment, the rotor 44 may be properly and accurately docked within the shroud 36 by forming angled mating surfaces on corresponding portions of the shroud 36 and  
10 pump body 34. More specifically, an angled mating surface may be formed on the interior surface of the rotor shroud 36 along that portion extending proximally from the flow aperture 38. A corresponding angled mating surface may be  
15 provided along the exterior surface of the pump body 34 along a distal portion thereof. The mating surfaces shown in FIG. 14 may preferably be formed in the range from about 2 degrees to 10 degrees, and more preferably formed in the range from about 3 degrees to 6 degrees. Mating  
20 angles within these ranges are adequate to guide the distal end of the pump body 34 to a point generally flush with the proximal edge of the flow aperture 38 as shown in FIG. 14. In this fashion, the pump assembly 136 and the rotor shroud 36 combine to form the blood pump 12.  
25 More importantly, this docking is carried out such that the rotor 44 and rotor blades 58 are maintained in proper position for efficient and safe pump operation.

An exemplary biasing scheme for maintaining the pump assembly 136 in this docked relationship will  
30 now be described with reference to FIGS. 12-13 and 16-17. The conduit assembly 134 is preferably equipped with a male quick-connect coupling 152 capable of engaging with a female quick-connect coupling 154 forming part of the perfusion assembly 140 of the present invention. A bias  
35 spring 156 is provided in between the perfusion assembly

140 and the housing 96 of the purge fluid delivery system 26. The bias spring 156 is preferably dimensioned so as to be in tension when the male quick-connect 152 is engaged within the female quick-connect 154 as part of the docking process of the present invention. As such, the bias spring 156 serves to maintain the pump assembly 136 in the docked position within the rotor shroud 36. The bias spring 156 may be coupled to the housing 96 of the purge fluid delivery system 26 in any number of suitable fashions. One such coupling arrangement may comprise a female quick-connect coupling 158 attached to the housing 96 and a male quick-connect coupling 160 attached to the bias spring 156.

An exemplary embodiment of the perfusion assembly 140 is shown with reference to FIGS. 12-13 and 17. The perfusion assembly 140 shown includes the hemostasis valve 146 coupled to the female quick-connect coupling 154. A length of tubing 162 extends between the opposing barb connectors of the hemostasis valve 146 and the female quick-connect coupling 154. A continuous lumen is formed extending through the interior of the male quick-connect coupling 152, the female-quick-connect coupling 154, the tubing 162, and the hemostasis valve 146. The drive cable assembly 18 extends through this continuous lumen and exits through a Touhey-Borst hemostasis seal 164 which prevents the migration of blood out of the proximal end of the perfusion assembly 140. A side-port 166 is disposed in fluid communication with the central lumen of the perfusion assembly 140. In one embodiment, this side-port 166 may be equipped with a conduit 168 having a stop-cock 170 to selectively control the distribution of blood through a perfusion conduit (i.e. conduit 142 of FIG. 11) coupled to the stop-cock 170. It will be appreciated that this type of manual control system for selectively perfusing the patient may

be replaced with control circuitry for automatically controlling the rate of perfusion. Such automatic perfusion may be based on control algorithms based on contemporaneous feedback or pre-programmed thresholds.

5           The foregoing discussion details a host of inventive aspects forming part of the present invention. It will be appreciated by those skilled in the art that changes could be made to the embodiments described above without departing from the broad inventive concepts thereof. The following evidences, by way of example only, various additional aspects forming part of the present invention.

FIG. 18 illustrates an alternate configuration of the intravascular blood pump system 130 of the third broad aspect of the present invention having an alternate bearing assembly, purge fluid delivery, and docking scheme. The bearing assembly includes a seal spring 182 and a bearing assembly 180. The bearing assembly 180 includes an inner race 184, an outer race 186, and a plurality of balls 188 which enable the inner race 184 to rotate along with the rotor shaft 46 while the outer race 186 remains in a static and fixed position relative to an inner surface of the pump body 34. An O-ring 190 is disposed within a groove formed in the rotor shaft 46 so as to maintain the bearing assembly 180 against the seal spring 182. The O-ring 190 is further secured within the groove in the rotor shaft 46 via a contoured lip portion extending from the distal end of the cable adapter 60. The proximal end of the cable adapter 60 flushly engages the drive cable 62.

The purge fluid delivery system of the embodiment shown in FIG. 18 provides for a one way delivery of purge fluid to the blood pump 12. That is, pressurized fluid (namely, fluid pressurized to some level elevated above the blood pressure in the

surrounding vessel) is injected in between the drive cable 62 and the interior of the protective sheath 32 during operation. This serves to reduce any frictional heating that exists between the drive cable 62 and sheath 32. The pressurized fluid also flows through the interior of the pump 12 such that, if the seal at 192 is broken, the pressurized fluid will flow past the open seal 192 and onward through the blood flow ports 38 formed in the shroud 36. This serves to keep blood from entering the pump 12 in an effort to avoid clotting and/or damaging the pump 12.

The pump assembly 136 may be docked within the conduit assembly 134 in any number of different fashions without departing from the scope of the present invention. That is to say, the docking scheme shown in FIG. 18 is set forth by way of example only and is not to be deemed limiting or restrictive as to numerous ways to temporarily engage or "dock" the pump assembly 136 within the conduit assembly 134. The only requirement is that the pump assembly 136 and conduit assembly 134 dock such that the rotor 44 is disposed within the shroud 36 to provide the desired axial flow through the cannula 14 and out the shroud 36. The exemplary docking scheme involves forming an annular engagement groove 194 along the interior of the shroud 36, and forming a complementary annular ridge 196 along the exterior surface of the pump body 34. During insertion, the pump assembly 136 will be advanced into the conduit assembly 134 until the annular ridge 196 on the pump body 34 engages within the groove 194 formed in the shroud 36. This docking scheme is generally advantageous in that the engagement action between the annular ridge 196 and groove 194 will provide tactile feedback to the physician during the process of inserting the pump assembly 136 into the conduit assembly 134 such that the physician will be able to determine



when the docking has been completed.

As will be appreciated by those skilled in the art, the location of the annular ridge 196 and engagement groove 194 may be varied such that they are disposed closer or farther away from the flow apertures 38. It may be advantageous to form these docking structures close to the flow apertures 38 in an effort to thwart the ingress of blood into the junction extending between the interior of the shroud 36 and the exterior surface of the pump body 34. It is also contemplated to employ selectively inflatable structures, such as balloons, in an effort to temporarily engage or dock the pump assembly 136 within the conduit assembly 134. In this regard, one or more lumens may be formed within the pump body 34 extending from the interior of the pump body 34 in fluid communication with a balloon disposed along the exterior surface of the pump body 34. The pressurized fluid flowing within the interior of the pump body 34 may then be used to inflate the balloon, which will then engage within an annular groove in the shroud 36, such as at 194. Of course, the engagement structures may also be reversed without departing from the scope of the present invention. For example, the shroud 36 may be equipped with a fluid delivery lumen therein for inflating a balloon disposed on the interior surface of the shroud 36, which may in turn be disposed within an annular engagement groove formed along the exterior surface of the pump body 34.

While this invention has been shown in use largely in during left-heart applications it is to be readily appreciated that this does not limit the applications of this invention for use in left heart support only. Rather, the guidable intravascular blood pump of the present invention can be utilized in right-heart support applications and a wide variety of other

applications apparent to those skilled in the art. For example, with reference to FIG. 19, shown is an intravascular blood pump 200 (of the type shown and described above with reference to FIGS. 2-5) configured  
5 for use in a right-heart support application. In this embodiment, the intravascular blood pump system 200 is equipped, by way of example, with an "over-the-wire" guide mechanism 16 comprising a balloon catheter 202. It is to be readily appreciated that, although shown and  
10 described below in terms of an embodiment of the type shown in FIGS. 2-5, the intravascular blood pump systems 120, 130 disclosed herein may also be configured for use in right-heart applications. Such right-heart configurations, and others apparent to those skilled in  
15 the art based on the broad principles enumerated in this application, are contemplated as being within the scope of the present invention.

The intravascular blood pump system 200 is shown positioned within the heart, such as may be  
20 advantageous to provide right heart support during beating heart surgery. To position the guidable intravascular blood pump system 200 in the right heart according to the present invention, a suitable guide element (such as balloon catheter 202) is first advanced  
25 to a desired location within the heart via the "sail" action of an inflated balloon. After the balloon catheter 202 is located in the desired position (such as in the pulmonary artery as shown), the intravascular blood pump system 200 according to the present invention may be  
30 advanced over the balloon catheter 202 and guided into a desired arrangement. For right heart support, this would involve advanced into the pump 12 and cannula 14 overt the balloon catheter 202 until the fluid inlet 204 is disposed within the vena cava (or right atrium) and the  
35 fluid outlet 206 is positioned within the pulmonary

artery. The pump 12 may then be selectively (i.e. automatically or on-demand) controlled to transport blood from the vena cava (or right atrium) in a trans-valvular fashion through the tricuspid valve, the right ventricle, and the pulmonary valve for deposit within the pulmonary artery. Providing right-heart support during beating heart surgery advantageously overcomes conditions where cardiac output may become compromised during beating heart surgery, such as when the heart is lifted to gain access to posterior vessels, thereby avoiding the need for cardiopulmonary bypass.

It is also contemplated as part of the present invention that the guidable intravascular blood pump systems can be introduced into the patient's vasculature to achieve the intravascular access into the right or left heart through any number of access points, including but not limited to the internal jugular vein, the brachiocephalic vein, carotid artery, axillary artery, femoral vein, femoral artery, and subclavian artery. The intravascular blood pump systems of the present invention may also be introduced via direct introduction, such as into the aorta, the atria, and the ventricles. As is well known in the art, such intravascular access may be achieved percutaneously through the use of the Seldinger technique or directly through the use of minimally invasive access techniques.

Those skilled in the art will also appreciate that, although shown and described above in terms of "axial flow," the present invention is not limited to the axial flow type intravascular blood pumps. Rather, the intravascular blood pumps 12 may comprise any number of suitable types of intravascular blood pumps, including but not limited to so-called "mixed flow" intravascular blood pumps, without departing from the scope of the present invention.

With regard to the embodiments shown in FIGS. 10-17, it is furthermore contemplated that the guide catheter 132 may be separable from the conduit assembly 134 after the pump assembly 136 is docked within the shroud 36 to form the pump 12 at the desired location within the circulatory system of the patient. This may be accomplished by providing the guide catheter 132 in a detachable fashion via any number of suitable arrangements. By removing the guide catheter 132 after the pump 12 assembled, wound management of the access point into the patient's vasculature may be improved. This is due, in part, to the substantial reduction in size of the device extending into the patient (i.e. the drive cable assembly 18 as opposed to the larger diameter guide catheter 132).

It is also contemplated to incorporate various pressure sensing and/or guidability features into at least one of the cannula, 14 and pump 12. Such features may include, but are not necessarily limited to, those shown and described in commonly-owned and co-pending U.S. Patent Application No. 09/280,988 (filed March 30, 1999) entitled "Steerable Cannula," and U.S. Patent Application No. 09/280,970 (filed March 30, 1999) entitled "Pressure Sensing Cannula," the disclosures of which are hereby expressly incorporated by reference as if set forth herein in their entirety. These pressure sensing features may include, but are not necessarily limited to, the use of fluid-filled lumens, piezo-electric pressure sensing elements, strain gauges, and analysis of the torque/current relationship (based on the dynamic pressure differential between the inlet and outlet of the pump). The guidability features may include, but are not necessarily limited to, the use of side lumens and deformable materials (i.e. Nitinol).

Various pump and cannula arrangements have

been described and shown above for providing right and/or left heart support wherein blood is deliberately re-routed through and past the right and/or left ventricle in an effort to reduce the volume of blood to be pumped by the particular ventricle. While "unloading" the ventricles in this fashion is preferred in certain instances, it is to be readily understood that the pump and cannula arrangements described herein may also be employed to "preload" the ventricles. Ventricular preloading may be accomplished by positioning the outflow cannula from the pump into a given ventricle such that the pump may be employed to fill or preload the ventricle with blood. This may be particularly useful with the right ventricle. On occasion, the right ventricle is not supplied with sufficient levels of blood from the right atrium such that, upon contraction, the right ventricle delivers an insufficient quantity of blood to the pulmonary artery. This may result when the right ventricle and/or right atrium are in a stressed or distorted condition during surgery. Preloading overcomes this problem by actively supplying blood into the right ventricle, thereby facilitating the delivery of blood into the pulmonary artery. The same technique can be used to preload the left ventricle and thus facilitate the delivery of blood from the left ventricle into the aorta.

**What is claimed is:**

1. An improved intravascular blood pump system, comprising:
  - an intravascular blood pump having a cannula
  - 5 coupled thereto; and
  - a guide mechanism adapted to guide said intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient.

**Abstract**

An improved intravascular blood pump and related methods involving the broad inventive concept of equipping the intravascular blood pump with guiding  
5 features such that the intravascular blood pump can be selectively positioned at a predetermined location within the circulatory system of a patient.

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Substitute for Form PTO-875

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12/772,810

APPLICATION AS FILED – PART I

(Column 1)(Column 2)

SMALL ENTITY

OR

OTHER THAN SMALL ENTITY

| FOR                                                                       | NUMBER FILED                                                                                                                                                                                                         | NUMBER EXTRA | RATE (\$) | FEE (\$) | RATE (\$) | FEE (\$) |  |  |
|---------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|-----------|----------|-----------|----------|--|--|
| BASIC FEE<br>(37 CFR 1.16(a), (b), or (c))                                | N/A                                                                                                                                                                                                                  | N/A          | N/A       |          | N/A       | 330      |  |  |
| SEARCH FEE<br>(37 CFR 1.16(k), (l), or (m))                               | N/A                                                                                                                                                                                                                  | N/A          | N/A       |          | N/A       | 540      |  |  |
| EXAMINATION FEE<br>(37 CFR 1.16(o), (p), or (q))                          | N/A                                                                                                                                                                                                                  | N/A          | N/A       |          | N/A       | 220      |  |  |
| TOTAL CLAIMS<br>(37 CFR 1.16(i))                                          | 1                                                                                                                                                                                                                    |              | x\$26     |          | x\$52     |          |  |  |
| INDEPENDENT CLAIMS<br>(37 CFR 1.16(h))                                    | 1                                                                                                                                                                                                                    |              | x\$110    |          | x\$220    |          |  |  |
| APPLICATION SIZE FEE<br>(37 CFR 1.16(s))                                  | If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$260 (\$130 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR |              |           |          |           |          |  |  |
| MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))                         |                                                                                                                                                                                                                      |              | 195       |          | 390       |          |  |  |
| * If the difference in column 1 is less than zero, enter "0" in column 2. |                                                                                                                                                                                                                      |              | TOTAL     |          | TOTAL     | 1090     |  |  |

APPLICATION AS AMENDED – PART II

(Column 1)(Column 2)(Column 3)

SMALL ENTITY

OR

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| AMENDMENT A                                                     | CLAIMS REMAINING AFTER AMENDMENT | HIGHEST NUMBER PREVIOUSLY PAID FOR | PRESENT EXTRA | RATE (\$)       | ADDITIONAL FEE (\$) | RATE (\$)       | ADDITIONAL FEE (\$) |
|-----------------------------------------------------------------|----------------------------------|------------------------------------|---------------|-----------------|---------------------|-----------------|---------------------|
| Total<br>(37 CFR 1.16(i))                                       | *                                | Minus **                           | =             | X =             |                     | X =             |                     |
| Independent<br>(37 CFR 1.16(h))                                 | *                                | Minus ***                          | =             | X =             |                     | X =             |                     |
| Application Size Fee (37 CFR 1.16(s))                           |                                  |                                    |               |                 |                     |                 |                     |
| FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j)) |                                  |                                    |               | N/A             |                     | N/A             |                     |
|                                                                 |                                  |                                    |               | TOTAL ADD'T FEE |                     | TOTAL ADD'T FEE |                     |

(Column 1)(Column 2)(Column 3)

SMALL ENTITY

OR

OTHER THAN SMALL ENTITY

| AMENDMENT B                                                     | CLAIMS REMAINING AFTER AMENDMENT | HIGHEST NUMBER PREVIOUSLY PAID FOR | PRESENT EXTRA | RATE (\$)       | ADDITIONAL FEE (\$) | RATE (\$)       | ADDITIONAL FEE (\$) |
|-----------------------------------------------------------------|----------------------------------|------------------------------------|---------------|-----------------|---------------------|-----------------|---------------------|
| Total<br>(37 CFR 1.16(i))                                       | *                                | Minus **                           | =             | X =             |                     | X =             |                     |
| Independent<br>(37 CFR 1.16(h))                                 | *                                | Minus ***                          | =             | X =             |                     | X =             |                     |
| Application Size Fee (37 CFR 1.16(s))                           |                                  |                                    |               |                 |                     |                 |                     |
| FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j)) |                                  |                                    |               | N/A             |                     | N/A             |                     |
|                                                                 |                                  |                                    |               | TOTAL ADD'T FEE |                     | TOTAL ADD'T FEE |                     |

\* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

\*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

\*\*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.





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| APPLICATION<br>NUMBER | FILING or<br>371(c) DATE | GRP ART<br>UNIT | FIL FEE REC'D | ATTY. DOCKET NO       | TOT CLAIMS | IND CLAIMS |
|-----------------------|--------------------------|-----------------|---------------|-----------------------|------------|------------|
| 12/772,810            | 05/03/2010               | 3766            | 1090          | 9261-17142-PCT-US-CON | 1          | 1          |

**CONFIRMATION NO. 4661**

36154  
LAW OFFICE OF ALAN W. CANNON  
942 MESA OAK COURT  
SUNNYVALE, CA 94086

## FILING RECEIPT



\*OC000000041573756\*

Date Mailed: 05/13/2010

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

### Applicant(s)

Walid N. Aboul-Hosn, Fair Oaks, CA;  
William R. Kanz, Sacramento, CA;  
Bruce A. Baker, Placerville, CA;

### Power of Attorney:

Arnold Ericson--16879                      Laura Dable--46436  
Daniel Ryan III--29243                      Patricia Limbach--50295  
Joseph Kromholz--34204  
John Manion--38957  
Daniel Johnson--46204

### Domestic Priority data as claimed by applicant

This application is a CON of 11/375,926 03/15/2006  
which is a DIV of 10/070,178 07/19/2002 PAT 7,022,100  
which is a 371 of PCT/US00/24515 09/01/2000  
which claims benefit of 60/152,249 09/03/1999

### Foreign Applications

**If Required, Foreign Filing License Granted:** 05/11/2010

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/772,810**

**Projected Publication Date:** 08/19/2010

**Non-Publication Request:** No

**Early Publication Request:** No

**Title**

Guidable Intravascular Blood Pump and Related Methods

**Preliminary Class**

600

**PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES**

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** ( Not for submission under 37 CFR 1.99)

|                        |                       |
|------------------------|-----------------------|
| Application Number     | 12772810              |
| Filing Date            | 2010-05-03            |
| First Named Inventor   | Walid N. Aboul-Hosn   |
| Art Unit               | 3766                  |
| Examiner Name          | Unassigned            |
| Attorney Docket Number | 9261-17142-PCT-US-CON |

## **U.S. PATENTS**

| Examiner Initial* | Cite No | Patent Number | Kind Code <sup>1</sup> | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear |
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| Attorney Docket Number | 9261-17142-PCT-US-CON |

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| Attorney Docket Number | 9261-17142-PCT-US-CON |

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| Examiner Name          | Unassigned            |
| Attorney Docket Number | 9261-17142-PCT-US-CON |

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| Examiner Name          | Unassigned            |
| Attorney Docket Number | 9261-17142-PCT-US-CON |

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**U.S.PATENT APPLICATION PUBLICATIONS**

| Examiner Initial* | Cite No | Publication Number | Kind Code <sup>1</sup> | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear |
|-------------------|---------|--------------------|------------------------|------------------|-------------------------------------------------|--------------------------------------------------------------------------|
|                   | 1       | 20030023201        |                        | 2003-01-30       | Aboul-Hosn, et al.                              |                                                                          |
|                   | 2       | 20030205233        |                        | 2003-11-06       | Aboul-Hosn, et al.                              |                                                                          |

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|                        |                       |
|------------------------|-----------------------|
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| First Named Inventor   | Walid N. Aboul-Hosn   |
| Art Unit               | 3766                  |
| Examiner Name          | Unassigned            |
| Attorney Docket Number | 9261-17142-PCT-US-CON |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initial* | Cite No | Foreign Document Number <sup>3</sup> | Country Code <sup>2</sup> | Kind Code <sup>4</sup> | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear | T <sup>5</sup>           |
|-------------------|---------|--------------------------------------|---------------------------|------------------------|------------------|-------------------------------------------------|--------------------------------------------------------------------------|--------------------------|
|                   | 1       | DE 196 22 335 A1                     |                           |                        | 1997-12-11       | Gleich Anmelder                                 |                                                                          | <input type="checkbox"/> |
|                   | 2       | DE 0 916 359 B1                      |                           |                        | 1999-05-19       | Siess, Thorsten                                 |                                                                          | <input type="checkbox"/> |
|                   | 3       | CA 2 256 427                         |                           |                        | 1998-10-08       | Siess, Thorsten                                 |                                                                          | <input type="checkbox"/> |
|                   | 4       | WO 89/05164                          |                           |                        | 1989-06-15       | Walpler, Richard, K.                            |                                                                          | <input type="checkbox"/> |
|                   | 5       | WO 99/02204                          |                           |                        | 1999-01-21       | Aboul-Hosn                                      |                                                                          | <input type="checkbox"/> |
|                   | 6       | WO 00/12148                          |                           |                        | 2000-03-09       | Aboul-Hosn                                      |                                                                          | <input type="checkbox"/> |
|                   | 7       | WO 00/18448                          |                           |                        | 2000-04-06       | Aboul-Hosn                                      |                                                                          | <input type="checkbox"/> |
|                   | 8       | WO 00/19097                          |                           |                        | 2000-04-06       | Aboul-Hosn                                      |                                                                          | <input type="checkbox"/> |
|                   | 9       | WO 00/37139                          |                           |                        | 2000-06-26       | Aboul-Hosn                                      |                                                                          | <input type="checkbox"/> |

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| Attorney Docket Number | 9261-17142-PCT-US-CON |

|    |             |  |  |            |            |  |                          |
|----|-------------|--|--|------------|------------|--|--------------------------|
| 10 | WO 00/69489 |  |  | 2000-11-23 | Aboul-Hosn |  | <input type="checkbox"/> |
| 11 | WO 01/78807 |  |  | 2001-10-25 | Aboul-Hosn |  | <input type="checkbox"/> |

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|--------------------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
|                    | 1       | Online encyclopedia article "Pyrolytic Carbon" accessed 02/19/2009. <a href="http://en.wikipedia.org/wiki/Pyrolytic_carbon">http://en.wikipedia.org/wiki/Pyrolytic_carbon</a>                                                                                   | <input type="checkbox"/> |
|                    | 2       | Online encyclopedia article "Ventricular assist device, List of implantable VAD devices" accessed 01/12/2010. <a href="http://en.wikipedia.org/wiki/Ventricular_assist_device">http://en.wikipedia.org/wiki/Ventricular_assist_device</a>                       | <input type="checkbox"/> |

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<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

|                        |                       |
|------------------------|-----------------------|
| Application Number     | 12772810              |
| Filing Date            | 2010-05-03            |
| First Named Inventor   | Walid N. Aboul-Hosn   |
| Art Unit               | 3766                  |
| Examiner Name          | Unassigned            |
| Attorney Docket Number | 9261-17142-PCT-US-CON |

**CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

**OR**

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

|            |                  |                     |            |
|------------|------------------|---------------------|------------|
| Signature  | /Alan W. Cannon/ | Date (YYYY-MM-DD)   | 2010-06-17 |
| Name/Print | Alan W. Cannon   | Registration Number | 34,977     |

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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|---------------------------------------------|-------------------------------------------------------|
| <b>EFS ID:</b>                              | 7839564                                               |
| <b>Application Number:</b>                  | 12772810                                              |
| <b>International Application Number:</b>    |                                                       |
| <b>Confirmation Number:</b>                 | 4661                                                  |
| <b>Title of Invention:</b>                  | Guidable Intravascular Blood Pump and Related Methods |
| <b>First Named Inventor/Applicant Name:</b> | Walid N. Aboul-Hosn                                   |
| <b>Customer Number:</b>                     | 36154                                                 |
| <b>Filer:</b>                               | Alan W. Cannon/Maria J. Cannon                        |
| <b>Filer Authorized By:</b>                 | Alan W. Cannon                                        |
| <b>Attorney Docket Number:</b>              | 9261-17142-PCT-US-CON                                 |
| <b>Receipt Date:</b>                        | 17-JUN-2010                                           |
| <b>Filing Date:</b>                         | 03-MAY-2010                                           |
| <b>Time Stamp:</b>                          | 17:49:12                                              |
| <b>Application Type:</b>                    | Utility under 35 USC 111(a)                           |

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| Submitted with Payment | no |
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| Document Number | Document Description                                    | File Name                                          | File Size(Bytes)/<br>Message Digest                     | Multi Part /.zip | Pages (if appl.) |
|-----------------|---------------------------------------------------------|----------------------------------------------------|---------------------------------------------------------|------------------|------------------|
| 1               | Information Disclosure Statement (IDS)<br>Filed (SB/08) | IDS_filed_06_17_2010_9261_1<br>7142_PCT_US_CON.pdf | 1745495<br>95042a093422681a1201f2c1a9d1997978b<br>a0fb9 | no               | 10               |

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**National Stage of an International Application under 35 U.S.C. 371**

**If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.**

**New International Application Filed with the USPTO as a Receiving Office**

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| APPLICATION NUMBER | FILING OR 371(C) DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO./TITLE |
|--------------------|-----------------------|-----------------------|------------------------|
| 12/772,810         | 05/03/2010            | Walid N. Aboul-Hosn   | 9261-17142-PCT-US-CON  |

**CONFIRMATION NO. 4661**

## PUBLICATION NOTICE



\*OC000000043117725\*

36154  
LAW OFFICE OF ALAN W. CANNON  
942 MESA OAK COURT  
SUNNYVALE, CA 94086

**Title:**Guidable Intravascular Blood Pump and Related Methods

**Publication No.**US-2010-0210895-A1

**Publication Date:**08/19/2010

## NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at [www.uspto.gov](http://www.uspto.gov). The direct link to access the publication is currently <http://www.uspto.gov/patft/>.

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|                                                                                                                                         |                      |                                                          |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------------------------------------------|
| <p><b>PRELIMINARY<br/>AMENDMENT</b></p> <p>Address to:<br/>Commissioner for Patents<br/>P.O. Box 1450<br/>Alexandria, VA 22313-1450</p> | Attorney Docket      | 9261.17142-PCT-US-CON                                    |
|                                                                                                                                         | Confirmation No.     | 4661                                                     |
|                                                                                                                                         | First Named Inventor | Aboul-Hosn                                               |
|                                                                                                                                         | Application Number   | 12/772,810                                               |
|                                                                                                                                         | Filing Date          | 05/03/2010                                               |
|                                                                                                                                         | Group Art Unit       | 3766                                                     |
|                                                                                                                                         | Examiner Name        | Not yet assigned                                         |
|                                                                                                                                         | Title                | Guidable Intravascular Blood Pump<br>and Related Methods |

Sir:

Prior to examination, please amend the current application as follows:

## AMENDMENTS TO THE CLAIMS

1. (Canceled)
2. (New) An intravascular blood pump system, comprising:
  - an intravascular blood pump having a cannula coupled thereto, said intravascular blood pump including a rotor, a shroud for receiving said rotor, and a drive cable coupled to said rotor for driving said rotor within said shroud; and
  - a guide mechanism adapted to guide said intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient;
  - wherein said guide mechanism is configured to accept a guide wire for passage through a side lumen formed in a distal portion of said intravascular blood pump system.
3. (New) The intravascular blood pump system of Claim 2, and further, wherein said intravascular blood pump and cannula may be selectively advanced to said predetermined location within the vasculature of the patient by first passing said guide wire to said predetermined location and thereafter sliding said distal portion of said intravascular blood pump system along said guide wire to said predetermined location.
4. (New) The intravascular blood pump system of Claim 2, wherein the cannula is fixedly attached to the rotor shroud.
5. (New) The intravascular blood pump system of Claim 2, wherein a drive cable sheath is provided having a central lumen for receiving said drive cable, and wherein a purge fluid delivery system is coupled to said drive cable sheath to deliver purge fluid to said rotor.
6. (New) The intravascular blood pump system of Claim 5, wherein said drive cable sheath includes at least one side lumen for delivering said purge fluid towards said rotor.

7. (New) The intravascular blood pump system of Claim 6 and further, wherein a portion of said purge fluid is delivered through said at least one side lumen and past said rotor, and a portion of purge fluid is rerouted back from said rotor through said central lumen of said drive cable sheath.

8. (New) The intravascular blood pump system of Claim 6 wherein said at least one side lumen for delivering said purge fluid comprises a plurality of side lumens disposed circumferentially about the periphery of said drive cable sheath.

9. (New) The intravascular blood pump system of Claim 2, wherein the side lumen has a proximal end disposed distally of said blood pump.

10. (New) The intravascular blood pump system of Claim 2, wherein the side lumen is formed along the interior surface of the cannula.

11. (New) The intravascular blood pump system of Claim 2, further comprising a motor coupler disposed at the proximal end of the system, the motor coupler comprising a housing adapted to couple with a motor.

12. (New) The intravascular blood pump system of Claim 11, wherein the motor coupler is adapted to mechanically couple to a motor.

13. (New) The intravascular blood pump system of Claim 11, further comprising a motor having a shaft, the motor coupler configured to receive the shaft.

14. (New) The intravascular blood pump system of Claim 11, wherein the motor coupler comprises a first rotatable component at least partially disposed within the housing, and further comprising a motor comprising a second rotatable component, at least one of the first and second rotatable components configured to be received within the other of the first and second rotatable components to transmit torque to the drive cable.

15. (New) An intravascular blood pump system, comprising:

an intravascular blood pump including a rotor, a shroud within which said rotor is rotatably disposed, and a drive cable coupled to said rotor for driving said rotor within said shroud; and

a guide mechanism adapted to guide a distal portion of said intravascular blood pump system to a predetermined location within the circulatory system of a patient;

wherein said guide mechanism is configured to accept a guide wire for passage through a side lumen formed in said distal portion of said intravascular blood pump system.

16. (New) The intravascular blood pump system of Claim 15, wherein a drive cable sheath is provided having a central lumen for receiving said drive cable, and wherein a purge fluid delivery system is coupled to said drive cable sheath to deliver purge fluid to said rotor.

17. (New) The intravascular blood pump system of Claim 15, further comprising a driven member disposed adjacent to the proximal end of the drive cable.

18. (New) The intravascular blood pump system of Claim 17, further comprising a motor and a drive member coupled with the motor, one of the driven and the drive members being configured to be received within the other of the driven and the drive members to provide a rotatable coupling.

19. (New) The intravascular blood pump system of Claim 18, wherein the drive member is configured to be received within the driven member.

20. (New) An intravascular blood pump system, comprising:

an intravascular blood pump including a rotor and a housing within which said rotor is rotatably disposed, and a drive cable coupled to said rotor for driving said rotor within said housing;

a side lumen disposed in a distal portion of said intravascular blood pump system; and

wherein the side lumen is adapted to track over a guidewire to guide said distal portion of said intravascular blood pump system to a predetermined location within the circulatory system of a patient.

21. (New) The intravascular blood pump system of Claim 20, wherein said housing includes a shroud for receiving the rotor and a cannula coupled with the shroud and extending distally thereof to an intake port.

22. (New) The intravascular blood pump system of Claim 20, further comprising:

a purge fluid system comprising a purge fluid housing and a drive cable sheath extending distally therefrom, the drive cable sheath having a central lumen for receiving said drive cable, the purge fluid delivery system configured to deliver purge fluid to said rotor through said purge fluid housing and said drive cable sheath;

a motor coupler comprising a housing and a torque transfer element disposed to rotate in the housing of the motor coupler; and

a seal element disposed between the purge fluid housing and the motor coupler housing.

**REMARKS**

**Formal Matters**

Claims 2-22 are pending after entry of the amendments set forth herein.

Claim 1 has been canceled without prejudice to the possibility of filing one or more continuing applications directed to the subject matter recited therein.

Applicants respectfully request consideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

**Conclusion**

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-2653, order number 9261.17142-PCT-US-CON.

Respectfully submitted,  
LAW OFFICE OF ALAN W. CANNON

Date: June 16, 2011

By: /Alan W. Cannon/  
Alan W. Cannon  
Registration No. 34,977

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942 Mesa Oak Court  
Sunnyvale, CA 94086  
Telephone: (408) 736-3554  
Facsimile: (408) 736-3564

## Electronic Patent Application Fee Transmittal

|                                                |                                                       |                 |               |                             |
|------------------------------------------------|-------------------------------------------------------|-----------------|---------------|-----------------------------|
| <b>Application Number:</b>                     | 12772810                                              |                 |               |                             |
| <b>Filing Date:</b>                            | 03-May-2010                                           |                 |               |                             |
| <b>Title of Invention:</b>                     | Guidable Intravascular Blood Pump and Related Methods |                 |               |                             |
| <b>First Named Inventor/Applicant Name:</b>    | Walid N. Aboul-Hosn                                   |                 |               |                             |
| <b>Filer:</b>                                  | Alan W. Cannon/Maria J. Cannon                        |                 |               |                             |
| <b>Attorney Docket Number:</b>                 | THOR-17142CON                                         |                 |               |                             |
| Filed as Large Entity                          |                                                       |                 |               |                             |
| <b>Utility under 35 USC 111(a) Filing Fees</b> |                                                       |                 |               |                             |
| <b>Description</b>                             | <b>Fee Code</b>                                       | <b>Quantity</b> | <b>Amount</b> | <b>Sub-Total in USD(\$)</b> |
| <b>Basic Filing:</b>                           |                                                       |                 |               |                             |
| <b>Pages:</b>                                  |                                                       |                 |               |                             |
| <b>Claims:</b>                                 |                                                       |                 |               |                             |
| Claims in excess of 20                         | 1202                                                  | 1               | 52            | 52                          |
| <b>Miscellaneous-Filing:</b>                   |                                                       |                 |               |                             |
| <b>Petition:</b>                               |                                                       |                 |               |                             |
| <b>Patent-Appeals-and-Interference:</b>        |                                                       |                 |               |                             |
| <b>Post-Allowance-and-Post-Issuance:</b>       |                                                       |                 |               |                             |
| <b>Extension of Time:</b>                      |                                                       |                 |               |                             |

| Description       | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
|-------------------|----------|----------|--------|----------------------|
| Miscellaneous:    |          |          |        |                      |
| Total in USD (\$) |          |          |        | 52                   |



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| <b>EFS ID:</b>                              | 10323874                                              |
| <b>Application Number:</b>                  | 12772810                                              |
| <b>International Application Number:</b>    |                                                       |
| <b>Confirmation Number:</b>                 | 4661                                                  |
| <b>Title of Invention:</b>                  | Guidable Intravascular Blood Pump and Related Methods |
| <b>First Named Inventor/Applicant Name:</b> | Walid N. Aboul-Hosn                                   |
| <b>Customer Number:</b>                     | 36154                                                 |
| <b>Filer:</b>                               | Alan W. Cannon/Maria J. Cannon                        |
| <b>Filer Authorized By:</b>                 | Alan W. Cannon                                        |
| <b>Attorney Docket Number:</b>              | THOR-17142CON                                         |
| <b>Receipt Date:</b>                        | 16-JUN-2011                                           |
| <b>Filing Date:</b>                         | 03-MAY-2010                                           |
| <b>Time Stamp:</b>                          | 17:33:41                                              |
| <b>Application Type:</b>                    | Utility under 35 USC 111(a)                           |

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| Submitted with Payment                   | yes            |
| Payment Type                             | Credit Card    |
| Payment was successfully received in RAM | \$52           |
| RAM confirmation Number                  | 4486           |
| Deposit Account                          | 502653         |
| Authorized User                          | CANNON,ALAN W. |

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## File Listing:

| Document Number | Document Description | File Name                                                      | File Size(Bytes)/ Message Digest                  | Multi Part /.zip | Pages (if appl.) |
|-----------------|----------------------|----------------------------------------------------------------|---------------------------------------------------|------------------|------------------|
| 1               |                      | Amendment_Second_Preliminary_filed_6_16_2011_THOR_17142CON.pdf | 28184<br>cc8ba27fc78d8bba3684bc46dd99e754f6ffdcbf | yes              | 6                |

### Multipart Description/PDF files in .zip description

| Document Description                             | Start | End |
|--------------------------------------------------|-------|-----|
| Preliminary Amendment                            | 1     | 1   |
| Claims                                           | 2     | 5   |
| Applicant Arguments/Remarks Made in an Amendment | 6     | 6   |

### Warnings:

### Information:

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| 2 | Fee Worksheet (SB06) | fee-info.pdf | 30163<br>d04bd17d99a27a0ec6b6b76f5aeb70d97bb3849 | no | 2 |
|---|----------------------|--------------|--------------------------------------------------|----|---|

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| <b>EFS ID:</b>                              | 10323874                                              |
| <b>Application Number:</b>                  | 12772810                                              |
| <b>International Application Number:</b>    |                                                       |
| <b>Confirmation Number:</b>                 | 4661                                                  |
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| <b>Customer Number:</b>                     | 36154                                                 |
| <b>Filer:</b>                               | Alan W. Cannon/Maria J. Cannon                        |
| <b>Filer Authorized By:</b>                 | Alan W. Cannon                                        |
| <b>Attorney Docket Number:</b>              | THOR-17142CON                                         |
| <b>Receipt Date:</b>                        | 16-JUN-2011                                           |
| <b>Filing Date:</b>                         | 03-MAY-2010                                           |
| <b>Time Stamp:</b>                          | 17:33:41                                              |
| <b>Application Type:</b>                    | Utility under 35 USC 111(a)                           |

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| Submitted with Payment                   | yes            |
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| Authorized User                          | CANNON,ALAN W. |

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Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

## File Listing:

| Document Number | Document Description | File Name                                                      | File Size(Bytes)/ Message Digest                  | Multi Part /.zip | Pages (if appl.) |
|-----------------|----------------------|----------------------------------------------------------------|---------------------------------------------------|------------------|------------------|
| 1               |                      | Amendment_Second_Preliminary_filed_6_16_2011_THOR_17142CON.pdf | 28184<br>cc8ba27fc78d8bba3684bc46dd99e754f6ffdcbf | yes              | 6                |

### Multipart Description/PDF files in .zip description

| Document Description                             | Start | End |
|--------------------------------------------------|-------|-----|
| Preliminary Amendment                            | 1     | 1   |
| Claims                                           | 2     | 5   |
| Applicant Arguments/Remarks Made in an Amendment | 6     | 6   |

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### Information:

|   |                      |              |                                                  |    |   |
|---|----------------------|--------------|--------------------------------------------------|----|---|
| 2 | Fee Worksheet (SB06) | fee-info.pdf | 30163<br>d04bd17d99a27a0ec6b6b76f5aeb70d97bb3849 | no | 2 |
|---|----------------------|--------------|--------------------------------------------------|----|---|

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If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

#### New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| <b>PATENT APPLICATION FEE DETERMINATION RECORD</b><br>Substitute for Form PTO-875                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                               |                                  |            |                                    | Application or Docket Number<br><b>12/772,810</b> |                                          | Filing Date<br><b>05/03/2010</b> |                         | <input type="checkbox"/> To be Mailed |                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|------------|------------------------------------|---------------------------------------------------|------------------------------------------|----------------------------------|-------------------------|---------------------------------------|---------------------|
| <b>APPLICATION AS FILED – PART I</b>                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                               |                                  |            |                                    |                                                   |                                          |                                  |                         |                                       |                     |
| (Column 1)                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                               |                                  | (Column 2) |                                    |                                                   | SMALL ENTITY <input type="checkbox"/> OR |                                  | OTHER THAN SMALL ENTITY |                                       |                     |
| FOR                                                                                                                                                                                                                                                                                                                                                                                                                                  | NUMBER FILED                                                                                                                                                                                                                  | NUMBER EXTRA                     | RATE (\$)  | FEE (\$)                           |                                                   | RATE (\$)                                | FEE (\$)                         |                         |                                       |                     |
| <input type="checkbox"/> BASIC FEE<br>(37 CFR 1.16(a), (b), or (c))                                                                                                                                                                                                                                                                                                                                                                  | N/A                                                                                                                                                                                                                           | N/A                              | N/A        |                                    |                                                   | N/A                                      |                                  |                         |                                       |                     |
| <input type="checkbox"/> SEARCH FEE<br>(37 CFR 1.16(k), (l), or (m))                                                                                                                                                                                                                                                                                                                                                                 | N/A                                                                                                                                                                                                                           | N/A                              | N/A        |                                    |                                                   | N/A                                      |                                  |                         |                                       |                     |
| <input type="checkbox"/> EXAMINATION FEE<br>(37 CFR 1.16(o), (p), or (q))                                                                                                                                                                                                                                                                                                                                                            | N/A                                                                                                                                                                                                                           | N/A                              | N/A        |                                    |                                                   | N/A                                      |                                  |                         |                                       |                     |
| TOTAL CLAIMS<br>(37 CFR 1.16(j))                                                                                                                                                                                                                                                                                                                                                                                                     | minus 20 =                                                                                                                                                                                                                    | *                                | X \$       | =                                  |                                                   | X \$                                     | =                                |                         |                                       |                     |
| INDEPENDENT CLAIMS<br>(37 CFR 1.16(h))                                                                                                                                                                                                                                                                                                                                                                                               | minus 3 =                                                                                                                                                                                                                     | *                                | X \$       | =                                  |                                                   | X \$                                     | =                                |                         |                                       |                     |
| <input type="checkbox"/> APPLICATION SIZE FEE<br>(37 CFR 1.16(s))                                                                                                                                                                                                                                                                                                                                                                    | If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s). |                                  |            |                                    |                                                   |                                          |                                  |                         |                                       |                     |
| <input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                               |                                  |            |                                    |                                                   |                                          |                                  |                         |                                       |                     |
|                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                               |                                  | TOTAL      |                                    |                                                   | TOTAL                                    |                                  |                         |                                       |                     |
| <b>APPLICATION AS AMENDED – PART II</b>                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                               |                                  |            |                                    |                                                   |                                          |                                  |                         |                                       |                     |
| (Column 1)                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                               |                                  | (Column 2) |                                    |                                                   | SMALL ENTITY OR                          |                                  | OTHER THAN SMALL ENTITY |                                       |                     |
| <b>AMENDMENT</b>                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>06/16/2011</b>                                                                                                                                                                                                             | CLAIMS REMAINING AFTER AMENDMENT |            | HIGHEST NUMBER PREVIOUSLY PAID FOR | PRESENT EXTRA                                     | RATE (\$)                                | ADDITIONAL FEE (\$)              |                         | RATE (\$)                             | ADDITIONAL FEE (\$) |
|                                                                                                                                                                                                                                                                                                                                                                                                                                      | Total (37 CFR 1.16(i))                                                                                                                                                                                                        | * 21                             | Minus      | ** 20                              | = 1                                               | X \$                                     | =                                |                         | X \$52=                               | 52                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                      | Independent (37 CFR 1.16(h))                                                                                                                                                                                                  | * 3                              | Minus      | ***3                               | = 0                                               | X \$                                     | =                                |                         | X \$220=                              | 0                   |
|                                                                                                                                                                                                                                                                                                                                                                                                                                      | <input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))                                                                                                                                                                |                                  |            |                                    |                                                   |                                          |                                  |                         |                                       |                     |
|                                                                                                                                                                                                                                                                                                                                                                                                                                      | <input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))                                                                                                                                      |                                  |            |                                    |                                                   |                                          |                                  |                         |                                       |                     |
|                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                               |                                  |            |                                    |                                                   | TOTAL ADD'L FEE                          |                                  |                         | TOTAL ADD'L FEE                       | <b>52</b>           |
| <b>AMENDMENT</b>                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                               | CLAIMS REMAINING AFTER AMENDMENT |            | HIGHEST NUMBER PREVIOUSLY PAID FOR | PRESENT EXTRA                                     | RATE (\$)                                | ADDITIONAL FEE (\$)              |                         | RATE (\$)                             | ADDITIONAL FEE (\$) |
|                                                                                                                                                                                                                                                                                                                                                                                                                                      | Total (37 CFR 1.16(i))                                                                                                                                                                                                        | *                                | Minus      | **                                 | =                                                 | X \$                                     | =                                |                         | X \$                                  | =                   |
|                                                                                                                                                                                                                                                                                                                                                                                                                                      | Independent (37 CFR 1.16(h))                                                                                                                                                                                                  | *                                | Minus      | ***                                | =                                                 | X \$                                     | =                                |                         | X \$                                  | =                   |
|                                                                                                                                                                                                                                                                                                                                                                                                                                      | <input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))                                                                                                                                                                |                                  |            |                                    |                                                   |                                          |                                  |                         |                                       |                     |
|                                                                                                                                                                                                                                                                                                                                                                                                                                      | <input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))                                                                                                                                      |                                  |            |                                    |                                                   |                                          |                                  |                         |                                       |                     |
|                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                               |                                  |            |                                    |                                                   | TOTAL ADD'L FEE                          |                                  |                         | TOTAL ADD'L FEE                       |                     |
| <p>* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.</p> <p>** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".</p> <p>*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".</p> <p>The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.</p> |                                                                                                                                                                                                                               |                                  |            |                                    |                                                   |                                          |                                  |                         |                                       |                     |

Legal Instrument Examiner:  
/TINA BELL/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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|                                                                                                                                                   |                        |                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|---------------------------------------------|
| <b>POWER OF ATTORNEY<br/>OR<br/>REVOCATION OF POWER OF ATTORNEY<br/>WITH A NEW POWER OF ATTORNEY<br/>AND<br/>CHANGE OF CORRESPONDENCE ADDRESS</b> | Application Number     | 12/772,810                                  |
|                                                                                                                                                   | Filing Date            | May 3, 2010                                 |
|                                                                                                                                                   | First Named Inventor   | Walid N. Aboul-Hosn                         |
|                                                                                                                                                   | Title                  | Guidable Intravascular Blood Pump and Relat |
|                                                                                                                                                   | Art Unit               | 3761                                        |
|                                                                                                                                                   | Examiner Name          | Marcetich, Adam M.                          |
|                                                                                                                                                   | Attorney Docket Number | THOR-17142CON                               |

I hereby revoke all previous powers of attorney given in the above-identified application.

☐ A Power of Attorney is submitted herewith.

OR

☒ I hereby appoint Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith:

99185

OR

☐ I hereby appoint Practitioner(s) named below as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith:

| Practitioner(s) Name | Registration Number |
|----------------------|---------------------|
|                      |                     |
|                      |                     |
|                      |                     |
|                      |                     |
|                      |                     |

Please recognize or change the correspondence address for the above-identified application to:

☐ The address associated with the above-mentioned Customer Number.

OR

☒ The address associated with Customer Number:

99185

OR

☐ Firm or Individual Name

Address

City

State

Zip

Country

Telephone

Email

I am the:

☐ Applicant/Inventor.

OR

☒ Assignee of record of the entire interest. See 37 CFR 3.71.

Statement under 37 CFR 3.73(b) (Form PTO/SB/96) submitted herewith or filed on \_\_\_\_\_

SIGNATURE of Applicant or Assignee of Record

Signature

Date

7 December 2011

Name

Mary R. Zimmerman

Telephone

408.635.0625

Title and Company

Assistant Secretary, Maquet Cardiovascular LLC

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below\*.

☒ \*Total of 2 forms are submitted.

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

**STATEMENT UNDER 37 CFR 3.73(b)**

Applicant/Patent Owner: MAQUET Cardiovascular LLC

Application No./Patent No.: 12/772,810

Filed/Issue Date: May 3, 2010

Titled: Guidable Intravascular Blood Pump and Related Methods

MAQUET Cardiovascular LLC

, a Delaware limited liability company

(Name of Assignee)

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest in;
2. ☐ an assignee of less than the entire right, title, and interest in  
(The extent (by percentage) of its ownership interest is \_\_\_\_\_ %); or
3. ☐ the assignee of an undivided interest in the entirety of (a complete assignment from one of the joint inventors was made)  
the patent application/patent identified above, by virtue of either:

A. ☐ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy therefore is attached.

OR

B. ☒ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: Inventors To: A-Med Systems, Inc.

The document was recorded in the United States Patent and Trademark Office at  
Reel 013243, Frame 0387, or for which a copy thereof is attached.

2. From: A-Med Systems, Inc. To: Guidant Corporation

The document was recorded in the United States Patent and Trademark Office at  
Reel 016274, Frame 0961, or for which a copy thereof is attached.

3. From: Guidant Corporation To: Maquet Cardiovascular LLC

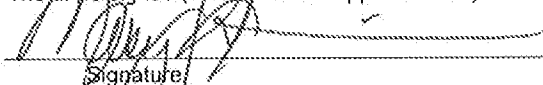
The document was recorded in the United States Patent and Trademark Office at  
Reel 020986, Frame 0839, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☐ As required by 37 CFR 3.73(b)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

  
Signature

7 December 2011

Date

Mary R. Zimmerman

Assistant Secretary

Printed or Typed Name

Title

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

## Electronic Acknowledgement Receipt

|                                             |                                                       |
|---------------------------------------------|-------------------------------------------------------|
| <b>EFS ID:</b>                              | 11560614                                              |
| <b>Application Number:</b>                  | 12772810                                              |
| <b>International Application Number:</b>    |                                                       |
| <b>Confirmation Number:</b>                 | 4661                                                  |
| <b>Title of Invention:</b>                  | Guidable Intravascular Blood Pump and Related Methods |
| <b>First Named Inventor/Applicant Name:</b> | Walid N. Aboul-Hosn                                   |
| <b>Customer Number:</b>                     | 36154                                                 |
| <b>Filer:</b>                               | Kirk D. Swenson/Mary Zimmerman                        |
| <b>Filer Authorized By:</b>                 | Kirk D. Swenson                                       |
| <b>Attorney Docket Number:</b>              | THOR-17142CON                                         |
| <b>Receipt Date:</b>                        | 07-DEC-2011                                           |
| <b>Filing Date:</b>                         | 03-MAY-2010                                           |
| <b>Time Stamp:</b>                          | 12:54:00                                              |
| <b>Application Type:</b>                    | Utility under 35 USC 111(a)                           |

### Payment information:

|                        |    |
|------------------------|----|
| Submitted with Payment | no |
|------------------------|----|

### File Listing:

| Document Number | Document Description | File Name             | File Size(Bytes)/<br>Message Digest                 | Multi Part /.zip | Pages (if appl.) |
|-----------------|----------------------|-----------------------|-----------------------------------------------------|------------------|------------------|
| 1               |                      | POA_373b_20111207.pdf | 1016942<br>cd7331fc9fb1b509ec4e2d7f211195649481817b | yes              | 2                |



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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Document Description                                | Start   | End |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Power of Attorney                                   | 1       | 1   |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Assignee showing of ownership per 37 CFR 3.73(b).   | 2       | 2   |
| Warnings:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                     |         |     |
| Information:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                     |         |     |
| Total Files Size (in bytes):                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                     | 1016942 |     |
| <p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><b><u>New Applications Under 35 U.S.C. 111</u></b><br/>If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><b><u>National Stage of an International Application under 35 U.S.C. 371</u></b><br/>If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><b><u>New International Application Filed with the USPTO as a Receiving Office</u></b><br/>If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p> |                                                     |         |     |



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United States Patent and Trademark Office  
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| APPLICATION NUMBER | FILING OR 371(C) DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO./TITLE |
|--------------------|-----------------------|-----------------------|------------------------|
| 12/772,810         | 05/03/2010            | Walid N. Aboul-Hosn   | THOR-17142CON          |

**CONFIRMATION NO. 4661**

**POA ACCEPTANCE LETTER**

99185  
MAQUET Cardiovascular LLC  
170 Baytech Drive  
San Jose, CA 95134



Date Mailed: 12/15/2011

**NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY**

This is in response to the Power of Attorney filed 12/07/2011.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/ddinh/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101



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| APPLICATION NUMBER | FILING OR 371(C) DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO./TITLE |
|--------------------|-----------------------|-----------------------|------------------------|
| 12/772,810         | 05/03/2010            | Walid N. Aboul-Hosn   | THOR-17142CON          |

**CONFIRMATION NO. 4661**

## POWER OF ATTORNEY NOTICE

36154  
LAW OFFICE OF ALAN W. CANNON  
1999 South Bascom Ave., Suite 700  
Campbell, CA 95008



Date Mailed: 12/15/2011

## NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 12/07/2011.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

/ddinh/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

PLUS Search Results for S/N 12772810, Searched Fri Feb 03 10:34:05 EST 2012

The Patent Linguistics Utility System (PLUS) is a USPTO automated search system for U.S. Patents from 1971 to the present PLUS is a query-by-example search system which produces a list of patents that are most closely related linguistically to the application searched. This search was prepared by the staff of the Scientific and Technical Information Center, SIRA.

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| 6059759 99     |            |
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| 6248091 99     |            |
| 6471683 99     |            |
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| 7022100 99     |            |
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| 5269758 78     |            |
| 5293868 78     |            |



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|                                                                      |             |                      |                               |                  |
|----------------------------------------------------------------------|-------------|----------------------|-------------------------------|------------------|
| APPLICATION NO.                                                      | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |
| 12/772,810                                                           | 05/03/2010  | Walid N. Aboul-Hosn  | 06-01506US04                  | 4661             |
| 99185                                                                | 7590        | 02/17/2012           |                               |                  |
| MAQUET Cardiovascular LLC<br>170 Baytech Drive<br>San Jose, CA 95134 |             |                      | EXAMINER<br>MARCETICH, ADAM M |                  |
|                                                                      |             |                      | ART UNIT                      | PAPER NUMBER     |
|                                                                      |             |                      | 3761                          |                  |
|                                                                      |             |                      | NOTIFICATION DATE             | DELIVERY MODE    |
|                                                                      |             |                      | 02/17/2012                    | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

legal@maquet.com

|                              |                                      |                                          |  |
|------------------------------|--------------------------------------|------------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>12/772,810 | <b>Applicant(s)</b><br>ABOUL-HOSN ET AL. |  |
|                              | <b>Examiner</b><br>ADAM MARCETICH    | <b>Art Unit</b><br>3761                  |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) 2-22 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 2-22 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 03 May 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/17/2010</u> .                                              | 6) <input type="checkbox"/> Other: ____.                          |

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## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 2-4, 15, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Summers; David P. et al. (US 5112349) in view of Bagaoisan; Celso J. et al. (US 6849068).

4. Regarding claim 2, Summers discloses an intravascular blood pump system (col.

1, lines 8-12, col. 3, lines 4-8, Fig. 1, pump 14), comprising:

a pump including a rotor (col. 3, lines 49-68, Fig. 3, rotor 42);

a shroud for receiving said rotor (col. 3, lines 49-68, Fig. 3, housing 36); and

a drive cable coupled to said rotor for driving said rotor within said shroud (col. 3, lines 64-68, Fig. 3, drive shaft 30).

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Summers discloses the invention substantially as claimed, but lacks a cannula and guide mechanism as claimed. Bagaoisan discloses an aspiration catheter (col. 2, lines 34-43, col. 4, lines 51-63, cols. 7-8, lines 66-11, Fig. 5, catheter 30 ); comprising:

a port for aspirating blood (cols. 7-8, lines 66-11, Fig. 5, distal end 38);

a cannula coupled to the catheter (cols. 7-8, lines 66-11, Fig. 5, guidewire lumen 40);

a guide mechanism adapted to guide said intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient (col. 8, lines 16-28, Fig. 7A, guidewire 26);

wherein said guide mechanism is configured to accept a guide wire for passage through a side lumen formed in a distal portion of the catheter (col. 8, lines 16-28, Fig. 7A, guidewire lumen advanced over guidewire 26).

Bagaoisan guides a device within vasculature accurately with a guidewire. In other words, a guidewire is easier to manipulate within vessels than sending an unguided catheter alone. Therefore it would have been obvious to add a guiding device such as the guidewire lumen 40 of Bagaoisan to the pump of Summers in order to guide a catheter to its destination within vasculature.

Examiner notes that Bagaoisan claims priority to application 08/813,808 filed on 06 March 1997, which discloses a guide mechanism configured to accept a guide wire for passage through a side lumen.

5. Regarding claim 3, Summers discloses the invention substantially as claimed, including an intravascular blood pump. However, Summers lacks a guide wire as



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claimed. Bagaoisan discloses an intravascular catheter, wherein said intravascular device and cannula may be selectively advanced to said predetermined location within the vasculature of the patient by first passing said guide wire to said predetermined location and thereafter sliding said distal portion of said intravascular blood pump system along said guide wire to said predetermined location (col. 7, lines 51-65, especially lines 60-65, long guidewire 26 used to facilitate insertion of catheter 10 ).

Here also, Bagaoisan provides access to vessels deep within the body using a guidewire that is thinner and therefore easier to manipulate. One would be motivated to modify Summers with the guidewire and cannula of Bagaoisan to access vessels from a distant incision since Summers calls for accessing the heart from the femoral artery (col. 3, lines 8-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Summers as discussed with the guidewire and cannula of Bagaoisan in order to access the heart from a remote incision such as at the femoral artery.

6. Regarding claim 4, Summers discloses the invention as substantially claimed, including a rotor shroud (col. 3, lines 57-58, Fig. 3, housing 36). However, Summers lacks a cannula. Bagaosian discloses a cannula is fixedly attached to an intravascular device (col. 8, lines 7-8, Figs. 7A, 7B, guidewire lumen 40 attached to shaft 38). Bagaosian forms a guiding device as an integral part of a catheter guided into vasculature, which will remain secure until the catheter reaches its destination. Therefore, it would have been obvious to modify the invention of Summers as discussed with the attached cannula of Bagaoisan in order to guide a catheter in place.

7. Regarding claim 15, Summers discloses an intravascular blood pump system (col. 1, lines 8-12, col. 3, lines 4-8, Fig. 1, pump 14 ), comprising:

an intravascular blood pump including a rotor, a shroud within which said rotor is rotatably disposed (col. 3, lines 49-68, Fig. 3, rotor 42 disposed in housing 36); and

a drive cable coupled to said rotor for driving said rotor within said shroud (col. 3, lines 64-68, Fig. 3, drive shaft 30).

Summers discloses the invention substantially as claimed, but lacks the claimed guide mechanism. Bagaoisan discloses a guide mechanism adapted to guide a distal portion of an intravascular device to a predetermined location within the circulatory system of a patient (col. 8, lines 16-28, Fig. 7A, guidewire lumen 40 and guidewire 26);

wherein said guide mechanism is configured to accept a guide wire for passage through a side lumen formed in said distal portion of said intravascular blood pump system (col. 8, lines 16-28, Fig. 7A, guidewire lumen 40 advanced over guidewire 26).

Bagaoisan places a larger pump in the body by first introducing a guidewire, and then advancing a catheter over the guidewire. One would have been motivated to add a guiding device to the system of Summers since Summers calls for manipulating a pump catheter from an incision in a femoral artery to the heart (col. 3, lines 4-10). Therefore, it would have been obvious to modify the invention of Summers as discussed with the guiding system of Bagaoisan.

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8. Regarding claim 20, Summers discloses an intravascular blood pump system (col. 1, lines 8-12, col. 3, lines 4-8, Fig. 1, pump 14 ), comprising:

an intravascular blood pump including a rotor and a housing within which said rotor is rotatably disposed (col. 3, lines 49-68, Fig. 3, rotor 42 and housing 36); and  
a drive cable coupled to said rotor for driving said rotor within said housing (col. 3, lines 64-68, Fig. 3, drive shaft 30).

Summers discloses the invention as substantially claimed but lacks a side lumen as claimed. Examiner cites Bagaoisan as teaching a side lumen for tracking over a guidewire to guide the distal portion of a catheter. Regarding rationale and motivation to modify Summers in view of Bagaoisan, see discussion of claims 2 and 15 above.

9. Regarding claim 21, Summers discloses a housing including a shroud for receiving the rotor (col. 3, lines 55-62, Fig. 3, housing 36 surrounding rotor 42).

Summers discloses the invention as substantially claimed, but lacks a cannula as claimed. Bagaoisan discloses a cannula coupled with an intravascular catheter (col. 8, lines 16-28, Fig. 7a, guidewire lumen 40);

extending distally thereof to an intake port (Fig. 5, guidewire lumen 40 extending towards tip 44). One would be motivated to modify Summers with the guiding cannula of Bagaoisan since it guides the distal tip of a catheter towards its destination in vasculature. That is, since the catheter tip is maneuvered into the heart, it is important to guide the distal end towards the heart. Therefore it would have been obvious to modify the invention of Summers with the distally extending cannula of Bagaoisan in

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order to guide the distal end of a catheter into the heart.

10. Claims 5-7, 9-14, 16-19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Summers; David P. et al. (US 5112349) in view of Bagaoisan; Celso J. et al. (US 6849068), further in view of Moise; John C. et al. (US 4895557).

11. Regarding claim 5, Summers and Bagaoisan disclose the invention substantially as claimed, but lack a drive cable sheath and purge fluid delivery system as claimed. Moise discloses an extracorporeal drive mechanism (col. 1, lines 5-11, col. 2, lines 39-43, Fig. 1a, system 10), comprising:

an intravascular blood pump having a rotor (col. 2, lines 39-43, Fig. 1a, pump 12). Moise incorporates an intravascular blood pump by reference to Wampler US 4625712 (col. 2, lines 50-52). Wampler discloses an intravascular blood pump (col. 2, lines 57-68, Figs. 1a, 1b, pump 10) which also has a rotor (col. 3, lines 30-39, Fig. 4, rotor 44).

Moise also discloses a drive cable (cols. 2-3, lines 62-6, Fig. 1a, drive cable); and a drive cable sheath provided having a central lumen for receiving said drive cable (col. 2, lines 53-62, Fig. 1a, cable sheath 20); and

wherein a purge fluid delivery system is coupled to said drive cable sheath to deliver purge fluid to said rotor (col. 2, lines 53-62, purge fluid pumped through outer lumen 19 towards pump 12; cols. 2-3, lines 62-6, Fig. 1a, purge fluid supply 33 for pump 12).

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Moise prevents abraded debris from entering the bloodstream by flushing it with purge fluid (col. 2, lines 13-17). One would be motivated to modify Summers and Bagaoisan with the cable sheath and purge fluid system of Moise since Summers also places a blood pump with rotating components into vasculature. In other words, flushing a cable sheath with purge fluid prevents debris from entering the bloodstream. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Summers and Bagaoisan as discussed with the cable sheath and purge fluid of Moise in order to remove potentially harmful particles from entering the bloodstream.

12. Regarding claims 6, 7, 9, 10 and 16, Summers and Bagaoisan disclose the invention substantially as claimed, but lack a drive cable sheath as claimed. Moise discloses a drive cable sheath,

wherein a portion of said purge fluid is delivered through at least one side lumen and past said rotor (col. 2, lines 53-62, Fig. 1a, cable sheath 20 having outer lumen 10 delivering fluid towards pump 12, indicated by purge fluid supply 33); and

a portion of purge fluid is rerouted back from said rotor through said central lumen of said drive cable sheath (col. 2, lines 53-62, Fig. 1a, fluid drawn from inner lumen 30 to disposal container 31);

wherein the side lumen has a proximal end disposed distally of said blood pump (Wampler col. 3, lines 7-13, 21-29, Fig. 2, flexible shaft 24 extending through catheter 26, and terminating distal of housing 30);

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wherein the side lumen is formed along the interior surface of the cannula (col. 2, lines 53-62, Fig. 1a, outer lumen 19 depicted as on interior surface of cable sheath 20);

Moise selects a portion of an existing lumen to deliver fluid that rinses away debris. In other words, the cable sheath 20 of Moise is already inserted into vasculature, so providing a side lumen allows the fluid to travel along an existing path. Therefore it would have been obvious to modify the cable of Summers with a side lumen as taught by Moise in order to deliver purge fluid with a conduit placed in the body while performing a simultaneous procedure.

13. Regarding claims 11-14 17, 18, 19 and 22, Summers and Bagaoisan disclose the invention substantially as claimed, but lack a motor coupler as claimed. Moise discloses:

a motor coupler disposed at the proximal end of the system (col. 2, lines 53-62, Fig. 1a, cable drive unit 22);

the motor coupler comprising a housing adapted to couple with a motor (col. 3, lines 62-68, Fig. 3, drive unit 22 including rotor 74 with non-circular drive hole 78 receiving spline 80);

wherein the motor coupler is adapted to mechanically couple to a motor (col. 3, lines 62-68, Fig. 3, non-circular drive hole 78 receiving spline 80 to transmit torque); further comprising a motor having a shaft, the motor coupler configured to receive the shaft (col. 3, lines 62-68, rotor 74 mounted to shaft 76);

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wherein the motor coupler comprises a first rotatable component at least partially disposed within the housing (col. 3, lines 62-68, Fig. 3, non-circular drive hole 78 on rotor 74);

further comprising a motor comprising a second rotatable component or torque transfer mechanism (col. 3, lines 62-68, Fig. 3, non-circular drive hole 78);

at least one of the first and second rotatable components configured to be received within the other of the first and second rotatable components to transmit torque to the drive cable (col. 3, lines 62-68, Fig. 3, drive hole 78 receiving spline 80); and

a driven member disposed adjacent to the proximal end of the drive cable (Fig. 3, spline 80);

wherein the drive member is configured to be received within the driven member (col. 3, lines 62-68, Fig. 3, spline 80 within non-circular drive hole 78); and

a seal element disposed between a purge fluid housing and a motor coupler housing (col. 4, lines 9-19, Fig. 4, O-ring 110 between adaptor 100 and collar 104).

To clarify, Examiner interprets the rotor 74 as analogous to the claimed first rotatable component, and interprets spline 80 as the second rotatable component. By selecting two components that fit mechanically, Moise allows part of the system to be used only once. This prevents contamination between patients, since each only one pump unit and cable sheath contact the patient, and the unit is later disposed. One would be motivated to modify Summers and Bagaoisan with the motor coupler and rotatable components of Moise since Summers calls for a pump mechanism using the Moineau principle (col. 3, lines 58-62), which creates sealed cavities for pushing blood

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(cols. 5-6, lines 66-7). These cavities will fill with blood during pumping, and would be difficult to clean or sterilize for another patient. Also, Moise directs fluid to flow in two directions through a cable sheath with O-ring 110. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Summers and Bagaoisan as discussed with the motor coupler and rotating components of Moise in order to retain a motor while using a different pump for each patient.

14. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Summers; David P. et al. (US 5112349) in view of Bagaoisan; Celso J. et al. (US 6849068) in view of Moise; John C. et al. (US 4895557), further in view of Saab; Mark A. (US 6440158).

15. Regarding claim 8, Summers, Bagaoisan and Moise disclose the invention as substantially claimed, but lack a plurality of side lumens. Instead, Moise calls for a single lumen 19 within cable sheath 20. Saab discloses a heat transfer catheter (col. 7, lines 15-26, col. 8, lines 19-27, Fig. 1, catheter apparatus 10), comprising:

an intravascular catheter having an outer sheath (col. 9, lines 8-16, Fig. 2, sleeve 20);

a plurality of side lumens disposed circumferentially about the periphery of a sheath for delivering fluid (col. 16, lines 1-10, Fig. 8, lumens 426, 427, 428, 430 as inlet lumens for heat transfer fluid).



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Saab provides multiple delivery paths for cooling fluids at different temperatures (col. 16, lines 20-24, heat transfer fluids at different temperatures for inlet lumens 427, 428). That is, Saab allows closer control of cooling with a pair of fluids at different temperatures. One would have been motivated to modify the invention of Summers, Bagaoisan and Moise with the plurality of side lumens as taught by Saab since to control the temperature of purge fluid within the heart, since the overall temperature of purge fluid can be controlled by changing the ratio of fluids having two different temperatures.

### ***Double Patenting***

16. Aboul-Hosn '675 et al. (US 7731675) claims an intravascular blood pump system (claim 1), including a rotor, shroud and drive cable (claim 1). While Aboul-Hosn '675 also claims a guide mechanism, it is claimed to accept a guide wire through a central instead of a side lumen (claim 3). Therefore no double patenting rejection is applied.

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

18. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

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double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

19. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claims 2-7, 15, 16 and 20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,4-6,9,12 and 15 of Aboul-Hosn '100 et al. (US 7022100). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

21. Regarding instant claim 2, Aboul-Hosn '100 claims an intravascular blood pump system (claim 1), comprising:

an intravascular blood pump having a cannula coupled thereto (claim 1);

said intravascular blood pump including a rotor, a shroud for receiving said rotor (claim 1); and

a drive cable coupled to said rotor for driving said rotor within said shroud (claim 1); and

a guide mechanism adapted to guide said intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient (claim 1);

wherein said guide mechanism is configured to accept a guide wire (claim 4, guide element for passage through guide catheter; claim 5, guide element comprising guide wire);

for passage through a side lumen formed in a distal portion of said intravascular blood pump system (claim 6, guide mechanism including guide element for passage through side lumen in guide catheter).

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22. Regarding instant claim 3, Aboul-Hosn '100 claims all the limitations in claim 12.

23. Regarding instant claim 4, Aboul-Hosn '100 claims a cannula fixedly attached to the rotor shroud (claim 1, cannula coupled to shroud).

24. Regarding instant claims 5 and 16, Aboul-Hosn '100 claims all the limitations in claim 9.

25. Regarding instant claim 6, Aboul-Hosn '100 claims all the limitations in claim 6.

26. Regarding instant claim 7, Aboul-Hosn '100 claims all the limitations in claim 15.

27. Regarding instant claim 15, Aboul-Hosn '100 claims an intravascular blood pump system (claim 1), comprising:

an intravascular blood pump including a rotor (claim 1);

a shroud within which said rotor is rotatably disposed (claim 1, rotor within shroud); and

a drive cable coupled to said rotor for driving said rotor within said shroud (claim 1); and

a guide mechanism adapted to guide a distal portion of said intravascular blood pump system to a predetermined location within the circulatory system of a patient (claim 1, guide mechanism guiding pump and therefore also guiding a distal portion of the pump);

wherein said guide mechanism is configured to accept a guide wire (claims 4, 5);

for passage through a side lumen formed in said distal portion of said intravascular blood pump system (claim 6).

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Regarding the limitation of guiding a distal portion of the pump, Aboul-Hosn '100 claims a guide mechanism for guiding the pump and cannula. Therefore Examiner interprets claim 1 of Aboul-Hosn '100 as guiding the pump in its entirety, including a distal portion.

28. Regarding instant claim 20, Aboul-Hosn '100 claims an intravascular blood pump system (claim 1), comprising:

- an intravascular blood pump including a rotor (claim 1); and
- a housing within which said rotor is rotatably disposed (claim 1, rotor in shroud);
- a drive cable coupled to said rotor for driving said rotor within said housing (claim 1, drive cable coupled to said rotor for driving said rotor within said shroud);
- a side lumen disposed in a distal portion of said intravascular blood pump system (claim 6, guide mechanism further including a guide element for passage through a side lumen formed along at least a portion of said guide catheter); and
- wherein the side lumen is adapted to track over a guidewire to guide said distal portion of said intravascular blood pump system to a predetermined location within the circulatory system of a patient (claims 4, 5).

Regarding the side lumen disposed in a distal portion of the pump, Aboul-Hosn '100 calls for guiding the pump and cannula within the circulatory system. A cannula entering the circulatory system extends into vessels as during minimally invasive surgery. It would have been obvious to locate a side lumen on a distal portion of the pump in order to guide it accurately into vasculature.

***Conclusion***

29. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

◆ Savage; Steven D. et al. US 5827267

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

ADAM MARCETICH  
Tel (571)272-2590  
Fax 571-273-2590  
Email [Adam.Marcetich@uspto.gov](mailto:Adam.Marcetich@uspto.gov)

31. The Examiner can be reached 8:00am to 4:00pm Monday-Friday.

32. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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33. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/  
Examiner, Art Unit 3761

|                                   |                                       |  |                                                                 |             |
|-----------------------------------|---------------------------------------|--|-----------------------------------------------------------------|-------------|
| <b>Notice of References Cited</b> | Application/Control No.<br>12/772,810 |  | Applicant(s)/Patent Under<br>Reexamination<br>ABOUL-HOSN ET AL. |             |
|                                   | Examiner<br>ADAM MARCETICH            |  | Art Unit<br>3761                                                | Page 1 of 1 |

#### U.S. PATENT DOCUMENTS

| * |   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Name              | Classification |
|---|---|--------------------------------------------------|-----------------|-------------------|----------------|
| * | A | US-5,827,267 A                                   | 10-1998         | Savage et al.     | 606/16         |
| * | B | US-6,440,158 B1                                  | 08-2002         | Saab, Mark A.     | 607/105        |
| * | C | US-6,849,068 B1                                  | 02-2005         | Bagaoisan et al.  | 604/523        |
| * | D | US-7,731,675 B2                                  | 06-2010         | Aboul-Hosn et al. | 604/6.11       |
|   | E | US-                                              |                 |                   |                |
|   | F | US-                                              |                 |                   |                |
|   | G | US-                                              |                 |                   |                |
|   | H | US-                                              |                 |                   |                |
|   | I | US-                                              |                 |                   |                |
|   | J | US-                                              |                 |                   |                |
|   | K | US-                                              |                 |                   |                |
|   | L | US-                                              |                 |                   |                |
|   | M | US-                                              |                 |                   |                |

#### FOREIGN PATENT DOCUMENTS

| * |   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Country | Name | Classification |
|---|---|--------------------------------------------------|-----------------|---------|------|----------------|
|   | N |                                                  |                 |         |      |                |
|   | O |                                                  |                 |         |      |                |
|   | P |                                                  |                 |         |      |                |
|   | Q |                                                  |                 |         |      |                |
|   | R |                                                  |                 |         |      |                |
|   | S |                                                  |                 |         |      |                |
|   | T |                                                  |                 |         |      |                |

#### NON-PATENT DOCUMENTS

| * |   | Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) |
|---|---|-------------------------------------------------------------------------------------------|
|   | U |                                                                                           |
|   | V |                                                                                           |
|   | W |                                                                                           |
|   | X |                                                                                           |

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** ( Not for submission under 37 CFR 1.99)

|                        |                       |
|------------------------|-----------------------|
| Application Number     | 12772810              |
| Filing Date            | 2010-05-03            |
| First Named Inventor   | Walid N. Aboul-Hosn   |
| Art Unit               | 3766                  |
| Examiner Name          | Unassigned            |
| Attorney Docket Number | 9261-17142-PCT-US-CON |

## **U.S. PATENTS**

| Examiner Initial* | Cite No | Patent Number | Kind Code <sup>1</sup> | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear |
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|                   | 3       | 3904901       |                        | 1975-09-09 | Renard, et al.                                  |                                                                          |
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|                   | 7       | 4591355       |                        | 1986-05-27 | Hilse, Gernot R. K.                             |                                                                          |
|                   | 8       | 4625712       |                        | 1986-12-02 | Wampler                                         |                                                                          |

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.M./



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| 10 | 4704121 | 1987-11-03 | Moise            |
| 11 | 4728319 | 1988-03-01 | Masch, Helmut    |
| 12 | 4817586 | 1989-04-04 | Wampler          |
| 13 | 4895557 | 1990-01-23 | Moise, et al.    |
| 14 | 4908012 | 1990-03-13 | Moise, et al.    |
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| 16 | 4917102 | 1990-04-17 | Miller, et al.   |
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| 18 | 4955856 | 1990-09-11 | Phillips         |
| 19 | 4964839 | 1990-10-23 | Gloor, Peter     |

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| Attorney Docket Number | 9261-17142-PCT-US-CON |

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| 20 | 5041131 | 1991-08-20 | Nagase, Toshio      |
| 21 | 5112349 | 1992-05-12 | Summers, et al.     |
| 22 | 5163910 | 1992-11-17 | Schwartz, et al.    |
| 23 | 5300112 | 1994-04-05 | Barr, Iwrin R.      |
| 24 | 5678306 | 1997-10-21 | Bozeman, et al.     |
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| 30 | 5810088 | 1998-09-22 | Lamirand, et al.    |

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| 43 | 6176822 | 2001-01-23 | Nix, et al.        |
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| Examiner Name          | Unassigned            |
| Attorney Docket Number | 9261-17142-PCT-US-CON |

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**U.S.PATENT APPLICATION PUBLICATIONS**

| Examiner Initial* | Cite No | Publication Number | Kind Code <sup>1</sup> | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear |
|-------------------|---------|--------------------|------------------------|------------------|-------------------------------------------------|--------------------------------------------------------------------------|
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|                   | 2       | 20030205233        |                        | 2003-11-06       | Aboul-Hosn, et al.                              |                                                                          |

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| Art Unit               | 3766                  |
| Examiner Name          | Unassigned            |
| Attorney Docket Number | 9261-17142-PCT-US-CON |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initial* | Cite No | Foreign Document Number <sup>3</sup> | Country Code <sup>2</sup> | Kind Code <sup>4</sup> | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear | T <sup>5</sup>           |
|-------------------|---------|--------------------------------------|---------------------------|------------------------|------------------|-------------------------------------------------|--------------------------------------------------------------------------|--------------------------|
|                   | 1       | DE 196 22 335 A1                     |                           |                        | 1997-12-11       | Gleich Anmelder                                 |                                                                          | <input type="checkbox"/> |
|                   | 2       | DE 0 916 359 B1                      |                           |                        | 1999-05-19       | Siess, Thorsten                                 |                                                                          | <input type="checkbox"/> |
|                   | 3       | CA 2 256 427                         |                           |                        | 1998-10-08       | Siess, Thorsten                                 |                                                                          | <input type="checkbox"/> |
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|                   | 5       | WO 99/02204                          |                           |                        | 1999-01-21       | Aboul-Hosn                                      |                                                                          | <input type="checkbox"/> |
|                   | 6       | WO 00/12148                          |                           |                        | 2000-03-09       | Aboul-Hosn                                      |                                                                          | <input type="checkbox"/> |
|                   | 7       | WO 00/18448                          |                           |                        | 2000-04-06       | Aboul-Hosn                                      |                                                                          | <input type="checkbox"/> |
|                   | 8       | WO 00/19097                          |                           |                        | 2000-04-06       | Aboul-Hosn                                      |                                                                          | <input type="checkbox"/> |
|                   | 9       | WO 00/37139                          |                           |                        | 2000-06-26       | Aboul-Hosn                                      |                                                                          | <input type="checkbox"/> |

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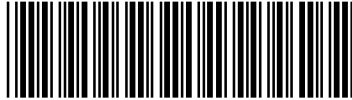
**EXAMINER SIGNATURE**

|                    |                  |                 |            |
|--------------------|------------------|-----------------|------------|
| Examiner Signature | /Adam Marcetich/ | Date Considered | 02/03/2012 |
|--------------------|------------------|-----------------|------------|

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|                                                                                                                        |                                                |                                                                         |
|------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|-------------------------------------------------------------------------|
| <b><i>Index of Claims</i></b><br><br> | <b>Application/Control No.</b><br><br>12772810 | <b>Applicant(s)/Patent Under Reexamination</b><br><br>ABOUL-HOSN ET AL. |
|                                                                                                                        | <b>Examiner</b><br><br>ADAM MARCETICH          | <b>Art Unit</b><br><br>3761                                             |

|   |                 |   |                   |   |                     |   |                 |
|---|-----------------|---|-------------------|---|---------------------|---|-----------------|
| ✓ | <b>Rejected</b> | - | <b>Cancelled</b>  | N | <b>Non-Elected</b>  | A | <b>Appeal</b>   |
| = | <b>Allowed</b>  | ÷ | <b>Restricted</b> | I | <b>Interference</b> | O | <b>Objected</b> |

| <input type="checkbox"/> <b>Claims renumbered in the same order as presented by applicant</b> |          |            | <input type="checkbox"/> <b>CPA</b> |  |  | <input type="checkbox"/> <b>T.D.</b> |  |  | <input type="checkbox"/> <b>R.1.47</b> |  |  |
|-----------------------------------------------------------------------------------------------|----------|------------|-------------------------------------|--|--|--------------------------------------|--|--|----------------------------------------|--|--|
| CLAIM                                                                                         |          | DATE       |                                     |  |  |                                      |  |  |                                        |  |  |
| Final                                                                                         | Original | 02/06/2012 |                                     |  |  |                                      |  |  |                                        |  |  |
|                                                                                               | 1        | -          |                                     |  |  |                                      |  |  |                                        |  |  |
|                                                                                               | 2        | ✓          |                                     |  |  |                                      |  |  |                                        |  |  |
|                                                                                               | 3        | ✓          |                                     |  |  |                                      |  |  |                                        |  |  |
|                                                                                               | 4        | ✓          |                                     |  |  |                                      |  |  |                                        |  |  |
|                                                                                               | 5        | ✓          |                                     |  |  |                                      |  |  |                                        |  |  |
|                                                                                               | 6        | ✓          |                                     |  |  |                                      |  |  |                                        |  |  |
|                                                                                               | 7        | ✓          |                                     |  |  |                                      |  |  |                                        |  |  |
|                                                                                               | 8        | ✓          |                                     |  |  |                                      |  |  |                                        |  |  |
|                                                                                               | 9        | ✓          |                                     |  |  |                                      |  |  |                                        |  |  |
|                                                                                               | 10       | ✓          |                                     |  |  |                                      |  |  |                                        |  |  |
|                                                                                               | 11       | ✓          |                                     |  |  |                                      |  |  |                                        |  |  |
|                                                                                               | 12       | ✓          |                                     |  |  |                                      |  |  |                                        |  |  |
|                                                                                               | 13       | ✓          |                                     |  |  |                                      |  |  |                                        |  |  |
|                                                                                               | 14       | ✓          |                                     |  |  |                                      |  |  |                                        |  |  |
|                                                                                               | 15       | ✓          |                                     |  |  |                                      |  |  |                                        |  |  |
|                                                                                               | 16       | ✓          |                                     |  |  |                                      |  |  |                                        |  |  |
|                                                                                               | 17       | ✓          |                                     |  |  |                                      |  |  |                                        |  |  |
|                                                                                               | 18       | ✓          |                                     |  |  |                                      |  |  |                                        |  |  |
|                                                                                               | 19       | ✓          |                                     |  |  |                                      |  |  |                                        |  |  |
|                                                                                               | 20       | ✓          |                                     |  |  |                                      |  |  |                                        |  |  |
|                                                                                               | 21       | ✓          |                                     |  |  |                                      |  |  |                                        |  |  |
|                                                                                               | 22       | ✓          |                                     |  |  |                                      |  |  |                                        |  |  |



## EAST Search History

## EAST Search History (Prior Art)

| Ref # | Hits | Search Query                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | DBs                                                           | Default Operator | Plurals | Time Stamp          |
|-------|------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|------------------|---------|---------------------|
| L1    | 1883 | (604/43,156,158,540).CCLS.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | US-PGPUB;<br>USPAT                                            | OR               | OFF     | 2012/02/06<br>07:11 |
| L2    | 201  | (623/3.1).CCLS.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | US-PGPUB;<br>USPAT                                            | OR               | OFF     | 2012/02/06<br>07:11 |
| L3    | 524  | (604/6.11).CCLS.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | US-PGPUB;<br>USPAT                                            | OR               | OFF     | 2012/02/06<br>07:11 |
| L4    | 1161 | (L1 L2 L3) and @ay< "2000"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2012/02/06<br>07:11 |
| L5    | 425  | l4 and ( multiple multiplicity<br>multiplication dual duality<br>double doubled doubling<br>duplicate duplicating duplicated<br>triple triplicate third triplicate<br>several plurality second<br>secondary third pair paired<br>pairing collection combination<br>group grouping grouped<br>number array arrayed matrix<br>row column) with (border<br>bordered bordering boundary<br>bounded bounding boundaries<br>perimeter periphery peripherally<br>peripheral rim side lateral<br>laterally skirt\$4 subordinate<br>edge edged edging edger<br>flange flanged flanging ) same<br>( ingress\$3 bypass\$3 detour\$3<br>hole channel channeled<br>channeler channeling<br>channelable conductor<br>conducted conductor<br>conducting conductable coursed<br>coursing duct ducted ducting<br>ductable flow lumen luminal<br>passage passaging pipe piped<br>piping pipeable pipable pipeline<br>tube tubing conduit ) | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2012/02/06<br>07:14 |
| L6    | 27   | l5 and (cable wire rod) with<br>( revolve revolved revolving<br>spin spun spinning trundle turn<br>turned turning turnable rotor<br>rotate rotated rotater rotating<br>rotation rotateably rotatably<br>twist twisted twister twisting<br>torque )                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2012/02/06<br>07:15 |

|    |       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                               |    |    |                     |
|----|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|----|----|---------------------|
| L7 | 41081 | (catheter cannula ) and<br>( multiple multiplicity<br>multiplication dual duality<br>double doubled doubling<br>duplicate duplicating duplicated<br>triple triplicate third triplicate<br>several plurality second<br>secondary third pair paired<br>pairing collection combination<br>group grouping grouped<br>number array arrayed matrix<br>row column) with (border<br>bordered bordering boundary<br>bounded bounding boundaries<br>perimeter periphery peripherally<br>peripheral rim side lateral<br>laterally skirt\$4 subordinate<br>edge edged edging edger<br>flange flanged flanging ) same<br>( ingress\$3 bypass\$3 detour\$3<br>hole channel channeled<br>channeler channeling<br>channelable conductor<br>conducted conductor<br>conducting conductable coursed<br>coursing duct ducted ducting<br>ductable flow lumen lumenal<br>passage passing pipe piped<br>piping pipeable pipable pipeline<br>tube tubing conduit ) | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2012/02/06<br>07:20 |
| L8 | 7588  | 17 and (cable wire rod) with<br>( revolve revolved revolving<br>spin spun spinning trundle turn<br>turned turning turnable rotor<br>rotate rotated rotater rotating<br>rotation rotateably rotatably<br>twist twisted twister twisting<br>torque )                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2012/02/06<br>07:21 |
| L9 | 27854 | (catheter cannula ) and<br>( multiple multiplicity<br>multiplication dual duality<br>double doubled doubling<br>duplicate duplicating duplicated<br>triple triplicate third triplicate<br>several plurality second<br>secondary third pair paired<br>pairing collection combination<br>group grouping grouped<br>number array arrayed matrix<br>row column) with (border<br>bordered bordering boundary<br>bounded bounding boundaries<br>perimeter periphery peripherally<br>peripheral rim side lateral<br>laterally skirt\$4 subordinate<br>edge edged edging edger<br>flange flanged flanging ) with<br>( ingress\$3 bypass\$3 detour\$3                                                                                                                                                                                                                                                                                               | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2012/02/06<br>07:21 |

|     |      |                                                                                                                                                                                                                                                                                               |                                                               |    |     |                     |
|-----|------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|----|-----|---------------------|
|     |      | hole channel channeled<br>channeler channeling<br>channelable conductor<br>conducted conductor<br>conducting conductable coursed<br>coursing duct ducted ducting<br>ductable flow lumen luminal<br>passage passaging pipe piped<br>piping pipeable pipable pipeline<br>tube tubing conduit )  |                                                               |    |     |                     |
| L10 | 5136 | I9 and (cable wire rod) with<br>( revolve revolved revolving<br>spin spun spinning trundle turn<br>turned turning turnable rotor<br>rotate rotated rotater rotating<br>rotation rotateably rotatably<br>twist twisted twister twisting<br>torque )                                            | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/06<br>07:21 |
| L11 | 1108 | I10 and @ay<"2000"                                                                                                                                                                                                                                                                            | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/06<br>07:22 |
| L12 | 791  | I11 and blood                                                                                                                                                                                                                                                                                 | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/06<br>07:22 |
| L13 | 725  | I12 and (vascular cardiovascular<br>vessels hart cardiac )                                                                                                                                                                                                                                    | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/06<br>07:22 |
| L14 | 610  | I13 and (intake outtake outake<br>suction suctioner suctioned<br>suctioning suctionable suck<br>sucker sucked sucking vacuum<br>vacuummer vacuumed<br>vacuuming vacuumable<br>(negative positive) adj pressure<br>pump pumped pumper<br>pumping pumpable aspirat\$3<br>aspir\$3 withdraw\$3 ) | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/06<br>07:23 |
| L15 | 577  | I13 and (intake outtake outake<br>suction suctioner suctioned<br>suctioning suctionable suck<br>sucker sucked sucking vacuum<br>vacuummer vacuumed<br>vacuuming vacuumable aspirat<br>\$3 aspir\$3 withdraw\$3 )                                                                              | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/06<br>07:24 |
| L16 | 351  | (604/173,258).CCLS.                                                                                                                                                                                                                                                                           | US-PGPUB;<br>USPAT                                            | OR | OFF | 2012/02/06<br>07:33 |

|     |     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                               |    |     |                     |
|-----|-----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|----|-----|---------------------|
| L17 | 72  | I16 and @ay< "2000"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/06<br>07:33 |
| L24 | 112 | ("6083260"   "6086570"  <br>"6123725"   "6234960"  <br>"6395026"   "5776190"  <br>"5957672"   "3904901"  <br>"4895557"   "5746709"  <br>"6113536"   "5911685"  <br>"6123659"   "6176848"  <br>"4909781"   "4964839"  <br>"5746758"   "6217541"  <br>"4955856"   "5692882"  <br>"6228063"   "6295877"  <br>"6245007"   "4413989"  <br>"4728319"   "5888241"  <br>"5041131"   "6093001"  <br>"5888241"   "4391547"  <br>"4919647"   "6336939"  <br>"6346120"   "4704121"  <br>"6613008"   "5851174"  <br>"5947892"   "7022100"  <br>"4392836"   "4817586"  <br>"5741234"   "6210133"  <br>"6287319"   "6709418"  <br>"6176822"   "4696667"  <br>"3602009"   "20030205233"  <br>"4625712"   "6210397"  <br>"6532964"   "4917102"  <br>"5678306"   "4591355"  <br>"4908012"   "5300112"  <br>"20030023201"   "6152704"  <br>"5112349"   "5810088").PN.<br>and @ay< "2000" | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/06<br>07:44 |
| L25 | 1   | ("5741234").PN.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | US-PGPUB;<br>USPAT                                            | OR | OFF | 2012/02/06<br>07:58 |
| L26 | 72  | ("2899960"   "3783454"  <br>"4516578"   "4642101"  <br>"5122122"   "5176697"  <br>"5234455"   "5250058"  <br>"5358488"   "5456714").PN. OR<br>("5741234").URPN.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | US-PGPUB;<br>USPAT; USOCR                                     | OR | ON  | 2012/02/06<br>07:58 |
| L27 | 15  | I26 and @ay< "2000"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/06<br>07:58 |

|     |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                               |    |    |                     |
|-----|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|----|----|---------------------|
| L28 | 34 | ("20030023201"  <br>"20030205233"   "3904901"  <br>"4625712"   "4704121"  <br>"4817586"   "4895557"  <br>"4955856"   "5692882"  <br>"5741234"   "5746709"  <br>"6083260"   "6086570"  <br>"6113536"   "6123725"  <br>"6152704"   "6210133"  <br>"6210397"   "6228063"  <br>"6234960"   "6287319"  <br>"6295877"   "6395026"  <br>"6532964"   "6613008"  <br>"6709418").PN. OR ("7022100").<br>URPN.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | US-PGPUB;<br>USPAT; USOCR                                     | OR | ON | 2012/02/06<br>08:00 |
| L29 | 22 | l28 and @ay< "2000"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2012/02/06<br>08:00 |
| L30 | 77 | ("3568659"   "3592184"  <br>"3802551"   "3804553"  <br>"4019830"   "4173796"  <br>"4591355"   "4625712"  <br>"4690002"   "4697574"  <br>"4704121"   "4753221"  <br>"4763032"   "4779614"  <br>"4785795"   "4817586"  <br>"4846152"   "4895557"  <br>"4906229"   "4908012"  <br>"4944722"   "4957504"  <br>"4964864"   "4969865"  <br>"4984972"   "4989609"  <br>"4993418"   "4994078"  <br>"5011469"   "5040944"  <br>"5061256"   "5092879"  <br>"5098256"   "5112349"  <br>"5133870"   "5139391"  <br>"5147388"   "5163910"  <br>"5176619"   "5211546"  <br>"5275580"   "5290227"  <br>"5299938"   "5354288"  <br>"5370509"   "5376114"  <br>"5399074"   "5527159"  <br>"5588812"   "5603337"  <br>"5613935"   "5616137"  <br>"5643226"   "5685865"  <br>"5692882"   "5695471"  <br>"5707218"   "5738626"  <br>"5755784"   "5776190"  <br>"5817586"   "5824070"  <br>"5840070"   "5851174"  <br>"6132364").PN. OR ("6245007").<br>URPN. | US-PGPUB;<br>USPAT; USOCR                                     | OR | ON | 2012/02/06<br>08:06 |

|     |      |                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                               |    |    |                     |
|-----|------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|----|----|---------------------|
| L31 | 65   | I30 and @ay<"2000"                                                                                                                                                                                                                                                                                                                                                                                                                 | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2012/02/06<br>08:06 |
| L32 | 4081 | (catheter cannula ) and<br>( multiple multiplicity plurality<br>plural) with ( perimeter<br>periphery peripherally<br>peripheral side ) with( hole<br>channel duct ducted ducting<br>ductable lumen lumenal<br>passage passaging pi conduit )                                                                                                                                                                                      | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2012/02/06<br>08:11 |
| L33 | 960  | I32 and @ay<"2000"                                                                                                                                                                                                                                                                                                                                                                                                                 | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2012/02/06<br>08:11 |
| L34 | 592  | I33 and (vascular cardiovascular<br>vessels hart cardiac )                                                                                                                                                                                                                                                                                                                                                                         | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2012/02/06<br>08:11 |
| L35 | 45   | ("4739768"   "4747405"  <br>"5041108"   "5059200"  <br>"5085659"   "5095915"  <br>"5207988"   "5304171"  <br>"5312356"   "5370617"  <br>"5437659"   "5472406"  <br>"5599492"   "5649923"  <br>"5662590"   "5746709"  <br>"5944687"   "5964751"  <br>"6022309"   "6024738"  <br>"6033371"   "6056743"  <br>"6066130"   "6102905"  <br>"6106546"   "6139543"  <br>"6156029"   "6200307"  <br>"6210400").PN. OR ("6547779").<br>URPN. | US-PGPUB;<br>USPAT; USOCR                                     | OR | ON | 2012/02/06<br>08:34 |
| L36 | 34   | ("3769984"   "4522212"  <br>"4777955"   "5251643"  <br>"5330522"   "5409652"  <br>"5458629"   "5499981"  <br>"5591142"   "5632274"  <br>"5676694").PN. OR ("6181971").<br>URPN.                                                                                                                                                                                                                                                    | US-PGPUB;<br>USPAT; USOCR                                     | OR | ON | 2012/02/06<br>08:41 |
| L37 | 23   | ("4676242"   "4819630"  <br>"4832024"   "4848339"  <br>"4959063"   "4971034"  <br>"4988163"   "5034010"  <br>"5129896"   "5152277").PN. OR<br>("5827267").URPN.                                                                                                                                                                                                                                                                    | US-PGPUB;<br>USPAT; USOCR                                     | OR | ON | 2012/02/06<br>08:49 |

|     |     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                           |    |    |                     |
|-----|-----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----|----|---------------------|
| L38 | 75  | (<br>"2308484"   "3162190"  <br>"3425419"   "3698791"  <br>"3794091"   "3809072"  <br>"4038519"   "4201199"  <br>"4299226"   "4299237"  <br>"4422447"   "4470407"  <br>"4540404"   "4576772"  <br>"4581017"   "4646722"  <br>"4672962"   "4681092"  <br>"4681564"   "4748979"  <br>"4754752"   "4819620"  <br>"4820349"   "4869263"  <br>"4878485"   "4899741"  <br>"4907395"   "4941475"  <br>"4957112"   "4994003"  <br>"4994066"   "5019075"  <br>"5041089"   "5049132"  <br>"5092841"   "5106360"  <br>"5108370"   "5147355"  <br>"5147385"   "5151100"  <br>"5191883"   "5196024"  <br>"5211631"   "5248312"  <br>"5250070"   "5257977"  <br>"5474533"   "RE32983").PN. OR<br>("6440158").URPN. | US-PGPUB;<br>USPAT; USOCR | OR | ON | 2012/02/06<br>09:03 |
| L39 | 188 | (<br>"20010007951"  <br>"20010016764"  <br>"20010041923"  <br>"20020007203"  <br>"20020016621"  <br>"20020068964"  <br>"20020077680"  <br>"20020091429"  <br>"20020111616"  <br>"20020151946"  <br>"20020177804"  <br>"20020183692"  <br>"20020193738"  <br>"20020193853"  <br>"20020193854"  <br>"20030078641"  <br>"20030114835"  <br>"20030144714"  <br>"20030187489"  <br>"20030195465"  <br>"20030195466"  <br>"20030195597"  <br>"20030216799"  <br>"20040044388"  <br>"20040087934"  <br>"20040102825"  <br>"20040102826"  <br>"20040102827"  <br>"20040106969"  <br>"20040116987"  <br>"20040116988"  <br>"20040127851"  <br>"20050038079"                                                   | US-PGPUB;<br>USPAT; USOCR | OR | ON | 2012/02/06<br>09:06 |

|               |                   |
|---------------|-------------------|
| "20050043579" | "5207640"         |
| "5230862"     | "5271743"         |
| "5450516"     | "5470659"         |
| "5725949"     | "5735809"         |
| "5755690"     | "5837003"         |
| "5876667"     | "5879329"         |
| "5989238"     | "6004289"         |
| "6019783"     | "6042559"         |
| "6096068"     | "6110168"         |
| "6126684"     | "6146411"         |
| "6149670"     | "6149673"         |
| "6149676"     | "6149677"         |
| "6165207"     | "6224624"         |
| "6231594"     | "6231595"         |
| "6235048"     | "6238428"         |
| "6245095"     | "6251129"         |
| "6251130"     | "6254626"         |
| "6264679"     | "6287326"         |
| "6290717"     | "6299599"         |
| "6306161"     | "6312452"         |
| "6325818"     | "6338727"         |
| "6364899"     | "6368304"         |
| "6379378"     | "6383210"         |
| "6393320"     | "6405080"         |
| "6409747"     | "6416533"         |
| "6419643"     | "6428563"         |
| "6432124"     | "6436130"         |
| "6436131"     | "6440158"         |
| "6447474"     | "6450987"         |
| "6450990"     | "6451045"         |
| "6454792"     | "6454793"         |
| "6458150"     | "6460544"         |
| "6464716"     | "6468296"         |
| "6471717"     | "6475231"         |
| "6478811"     | "6478812"         |
| "6482226"     | "6491039"         |
| "6491716"     | "6494903"         |
| "6497721"     | "6516224"         |
| "6520933"     | "6527798"         |
| "6529775"     | "6530946").PN. OR |
| ("6533804"    | "6540771"         |
| "6544282"     | "6551349"         |
| "6554797"     | "6558412"         |
| "6572538"     | "6572638"         |
| "6572640"     | "6576001"         |
| "6576002"     | "6581403"         |
| "6582398"     | "6582455"         |
| "6582457"     | "6585692"         |
| "6585752"     | "6589271"         |
| "6595967"     | "6599312"         |
| "6602243"     | "6602276"         |
| "6607517"     | "6610083"         |
| "6620130"     | "6620131"         |
| "6620188"     | "6620189"         |
| "6623516"     | "6635076"         |
| "6641602"     | "6641603"         |
| "6645234"     | "6648906"         |
| "6648908"     | "6652565"         |
| "6656209"     | "6660028"         |



|     |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                               |    |     |                     |
|-----|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|----|-----|---------------------|
|     |    | "6673098"   "6676688"  <br>"6676689"   "6676690"  <br>"6679906"   "6679907"  <br>"6682551"   "6685732"  <br>"6685733"   "6692488"  <br>"6692519"   "6695873"  <br>"6695874"   "6699268"  <br>"6702783"   "6702839"  <br>"6702840"   "6702841"  <br>"6702842"   "6706060"  <br>"6709448"   "6716188"  <br>"6716236"   "6719723"  <br>"6719724"   "6719779"  <br>"6726653"   "6726708"  <br>"6726710"   "6733517"  <br>"6740109"   "6749585"  <br>"6749625"   "6752786"  <br>"6755850"   "6755851"  <br>"RE35330").PN. OR<br>("7892270").URPN. |                                                               |    |     |                     |
| L40 | 52 | I39 and @ay<"2000"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/06<br>09:06 |
| L41 | 1  | ("5,957,963").PN.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | US-PGPUB;<br>USPAT                                            | OR | OFF | 2012/02/06<br>09:12 |
| L42 | 1  | ("6,051,019").PN.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | US-PGPUB;<br>USPAT                                            | OR | OFF | 2012/02/06<br>09:12 |
| L45 | 1  | ("7731675").PN.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | US-PGPUB;<br>USPAT                                            | OR | OFF | 2012/02/06<br>10:03 |
| L46 | 1  | ("7022100").PN.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | US-PGPUB;<br>USPAT                                            | OR | OFF | 2012/02/06<br>10:04 |
| L47 | 11 | (US-7731675-\$ or US-7022100-\$ or US-6287319-\$ or US-6245007-\$ or US-4728319-\$ or US-4895557-\$ or US-5112349-\$ or US-6849068-\$ or US-6440158-\$ or US-5827267-\$).did. or (WO-8905668-\$).did.                                                                                                                                                                                                                                                                                                                                        | USPAT;<br>DERWENT                                             | OR | ON  | 2012/02/06<br>10:05 |
| L48 | 4  | I47 not ("20030023201"  <br>"20030205233"   "3585983"  <br>"3602009"   "3904901"  <br>"4391547"   "4392836"  <br>"4413989"   "4591355"  <br>"4628712"   "4696667"  <br>"4704121"   "4728319"  <br>"4746758"   "4817586"  <br>"4895557"   "4908012"  <br>"4909781"   "4917102"  <br>"4919647"   "4955856"  <br>"4964839"   "5041131"  <br>"5112349"   "5163910"  <br>"5300112"   "5678306"  <br>"5692882"   "5741234"  <br>"5746709"   "5776190"                                                                                              | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/06<br>10:05 |

|    |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                |    |    |                     |
|----|----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----|----|---------------------|
|    |    | "5810088"   "5851174"  <br>"5888241"   "5911685"  <br>"5947892"   "5957672"  <br>"6083260"   "6086570"  <br>"6093001"   "6113536"  <br>"6123659"   "6123725"  <br>"6152704"   "6176822"  <br>"6176848"   "6210133"  <br>"6210397"   "6217541"  <br>"6228063"   "6234960"  <br>"6245007"   "6287319"  <br>"6295877"   "6336939"  <br>"6346120"   "6395026"  <br>"6532964"   "6613008"  <br>"6709418"   "7022100").PN.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                |    |    |                     |
| S1 | 71 | (US-20030171642-\$ or US-<br>20040241019-\$ or US-<br>20040191116-\$ or US-<br>20060069299-\$ or US-<br>20040044266-\$ or US-<br>20030069465-\$ or US-<br>20020026944-\$ or US-<br>20050279370-\$ or US-<br>20020128587-\$ or US-<br>20030208097-\$ or US-<br>20050154250-\$ or US-<br>20010041934-\$ or US-<br>20020045795-\$).did. or (US-<br>5678306-\$ or US-6015272-\$ or<br>US-4817586-\$ or US-4625712-\$<br>or US-5376114-\$ or US-<br>5707218-\$ or US-6245007-\$ or<br>US-6716189-\$ or US-7022100-\$<br>or US-5957672-\$ or US-<br>4846152-\$ or US-5776190-\$ or<br>US-6176848-\$ or US-5921913-\$<br>or US-4969865-\$ or US-<br>7011620-\$ or US-6537315-\$ or<br>US-6123659-\$ or US-4957504-\$<br>or US-4661094-\$ or US-<br>5851174-\$ or US-5040944-\$ or<br>US-4944722-\$ or US-5947892-\$<br>or US-6926662-\$ or US-<br>5112349-\$).did. or (US-<br>5527159-\$ or US-6974436-\$ or<br>US-6532964-\$ or US-7090659-\$<br>or US-5755784-\$ or US-<br>6176822-\$ or US-5911685-\$ or<br>US-4964864-\$ or US-5964694-\$<br>or US-4413989-\$ or US-<br>4591355-\$ or US-4696667-\$ or<br>US-4728319-\$ or US-4909781-\$<br>or US-5324263-\$ or US-<br>5888241-\$ or US-5746709-\$ or<br>US-6582388-\$ or US-7027875-\$<br>or US-6135729-\$ or US-<br>6794789-\$ or US-6093001-\$ or<br>US-4704121-\$ or US-4908012-\$ | US-PGPUB;<br>USPAT;<br>DERWENT | OR | ON | 2012/02/03<br>09:46 |

|    |     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                               |    |     |                     |
|----|-----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|----|-----|---------------------|
|    |     | or US-5300112-\$ or US-6336939-\$ or US-6346120-\$).<br>did. or (US-4919647-\$ or US-5041131-\$ or US-6217541-\$).<br>did. or (EP-363661-\$ or US-5851174-\$).did.                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                               |    |     |                     |
| S2 | 203 | ABOUL-HOSN-WALID\$.in. or KANZ-WILLIAM\$.in. or BAKER-BRUCE\$.in.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/03<br>10:01 |
| S3 | 22  | S2 and blood and pump and ( intravascular rotor cable shroud motor purge ).clm.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/03<br>10:07 |
| S4 | 23  | S2 and ( blood and pump and intravascular rotor cable shroud motor purge ).clm.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/03<br>10:30 |
| S5 | 102 | ("5591129" "6059759"<br>"6059759" "6248091"<br>"6471683" "7011620"<br>"7022100" "7731675"<br>"7736296" "20060161095"<br>"20080086027" "20100210895"<br>"6247892" "5984893"<br>"5911685" "5921913"<br>"5964694" "4373023"<br>"4625712" "4846152"<br>"4976270" "5527159"<br>"5531679" "5678306"<br>"5692882" "6024692"<br>"6176848" "6241652"<br>"4465072" "4755167"<br>"4779614" "4817586"<br>"4850954" "4895557"<br>"4906229" "4908012"<br>"4934339" "4944722"<br>"4964864" "4969865"<br>"5010875" "5013303"<br>"5061256" "5178603"<br>"5205153" "5211849"<br>"5257978" "5269758"<br>"5293868" "5300112" ).pn. | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/03<br>10:52 |
| S6 | 1   | ("7731675").PN.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | US-PGPUB;<br>USPAT                                            | OR | OFF | 2012/02/03<br>11:14 |

|     |     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                               |    |    |                     |
|-----|-----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|----|----|---------------------|
| S7  | 269 | ( "6083260"   "6086570"  <br>"6123725"   "6234960"  <br>"6395026"   "5776190"  <br>"5957672"   "3904901"  <br>"4895557"   "5746709"  <br>"6113536"   "5911685"  <br>"6123659"   "6176848"  <br>"4909781"   "4964839"  <br>"5746758"   "6217541"  <br>"4955856"   "5692882"  <br>"6228063"   "6295877"  <br>"6245007"   "4413989"  <br>"4728319"   "5888241"  <br>"5041131"   "6093001"  <br>"5888241"   "4391547"  <br>"4919647"   "6336939"  <br>"6346120"   "4704121"  <br>"6613008"   "5851174"  <br>"5947892"   "7022100"  <br>"4392836"   "4817586"  <br>"5741234"   "6210133"  <br>"6287319"   "6709418"  <br>"6176822"   "4696667"  <br>"3602009"   "20030205233"  <br>"4625712"   "6210397"  <br>"6532964"   "4917102"  <br>"5678306"   "4591355"  <br>"4908012"   "5300112"  <br>"20030023201"   "6152704"  <br>"5112349"   "5810088").PN. or<br>("6083260"   "6086570"  <br>"6123725"   "6234960"  <br>"6395026"   "5746709"  <br>"6113536"   "3904901"  <br>"4895557"   "5692882"  <br>"4955856"   "6228063"  <br>"6295877"   "6613008"  <br>"5741234"   "6210133"  <br>"6287319"   "6709418"  <br>"4817586"   "20030205233"  <br>"6210397"   "6532964"  <br>"4625712"   "20030023201"  <br>"6152704").PN. "5746709"<br>"5692882" | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2012/02/03<br>11:26 |
| S10 | 102 | ( "5591129" "6059759"<br>"6059759" "6248091"<br>"6471683" "7011620"<br>"7022100" "7731675"<br>"7736296" "20060161095"<br>"20080086027" "20100210895"<br>"6247892" "5984893"<br>"5911685" "5921913"<br>"5964694" "4373023"<br>"4625712" "4846152"<br>"4976270" "5527159"<br>"5531679" "5678306"<br>"5692882" "6024692"<br>"6176848" "6241652"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2012/02/03<br>14:41 |

|     |     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                               |    |    |                     |
|-----|-----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|----|----|---------------------|
|     |     | "4465072" "4755167"<br>"4779614" "4817586"<br>"4850954" "4895557"<br>"4906229" "4908012"<br>"4934339" "4944722"<br>"4964864" "4969865"<br>"5010875" "5013303"<br>"5061256" "5178603"<br>"5205153" "5211849"<br>"5257978" "5269758"<br>"5293868" "5300112" ).pn.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                               |    |    |                     |
| S11 | 269 | ( "6083260"   "6086570"  <br>"6123725"   "6234960"  <br>"6395026"   "5776190"  <br>"5957672"   "3904901"  <br>"4895557"   "5746709"  <br>"6113536"   "5911685"  <br>"6123659"   "6176848"  <br>"4909781"   "4964839"  <br>"5746758"   "6217541"  <br>"4955856"   "5692882"  <br>"6228063"   "6295877"  <br>"6245007"   "4413989"  <br>"4728319"   "5888241"  <br>"5041131"   "6093001"  <br>"5888241"   "4391547"  <br>"4919647"   "6336939"  <br>"6346120"   "4704121"  <br>"6613008"   "5851174"  <br>"5947892"   "7022100"  <br>"4392836"   "4817586"  <br>"5741234"   "6210133"  <br>"6287319"   "6709418"  <br>"6176822"   "4696667"  <br>"3602009"   "20030205233"  <br>"4625712"   "6210397"  <br>"6532964"   "4917102"  <br>"5678306"   "4591355"  <br>"4908012"   "5300112"  <br>"20030023201"   "6152704"  <br>"5112349"   "5810088").PN. or<br>( "6083260"   "6086570"  <br>"6123725"   "6234960"  <br>"6395026"   "5746709"  <br>"6113536"   "3904901"  <br>"4895557"   "5692882"  <br>"4955856"   "6228063"  <br>"6295877"   "6613008"  <br>"5741234"   "6210133"  <br>"6287319"   "6709418"  <br>"4817586"   "20030205233"  <br>"6210397"   "6532964"  <br>"4625712"   "20030023201"  <br>"6152704").PN. "5746709"<br>"5692882" | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2012/02/03<br>14:41 |

|     |       |                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                               |    |    |                     |
|-----|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|----|----|---------------------|
| S12 | 264   | (S11 S10) and pump\$3                                                                                                                                                                                                                                                                                                                                                                                                                                   | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2012/02/03<br>14:41 |
| S13 | 146   | S12 and @ay< "2000"                                                                                                                                                                                                                                                                                                                                                                                                                                     | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2012/02/03<br>14:42 |
| S14 | 40    | S13 and (border bordered<br>bordering boundary bounded<br>bounding boundaries perimeter<br>periphery peripherally<br>peripheral rim sect wing side<br>oblique obliquely sidelong<br>sideward sideways sidewise skirt<br>\$4 edge edged edging edger<br>flange flanged flanging seam<br>seamed seaming crease<br>creased creasing lip lipped<br>lipping ) with (guidewire wire<br>cable guide eyelet islet hook<br>thread\$3 hole opening notch\$3)      | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2012/02/03<br>14:46 |
| S15 | 14    | ("1902418"   "4690672"  <br>"4790813"   "4898574"  <br>"4913698"   "5135482"  <br>"5318518").PN. OR ("6471683").<br>URPN.                                                                                                                                                                                                                                                                                                                               | US-PGPUB;<br>USPAT; USOCR                                     | OR | ON | 2012/02/03<br>14:59 |
| S16 | 52    | ("6083260"   "6086570"  <br>"6123725"   "6234960"  <br>"6395026"   "5746709"  <br>"6113536"   "3904901"  <br>"4895557"   "5692882"  <br>"4955856"   "6228063"  <br>"6295877"   "6613008"  <br>"5741234"   "6210133"  <br>"6287319"   "6709418"  <br>"4817586"   "20030205233"  <br>"6210397"   "6532964"  <br>"4625712"   "20030023201"  <br>"6152704").PN.                                                                                             | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2012/02/03<br>15:01 |
| S17 | 45747 | catheter and (border bordered<br>bordering boundary bounded<br>bounding boundaries perimeter<br>periphery peripherally<br>peripheral rim sect wing side<br>oblique obliquely sidelong<br>sideward sideways sidewise skirt<br>\$4 edge edged edging edger<br>flange flanged flanging seam<br>seamed seaming crease<br>creased creasing lip lipped<br>lipping ) with (guidewire wire<br>cable guide eyelet islet hook<br>thread\$3 hole opening notch\$3) | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2012/02/03<br>15:05 |

|     |       |                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                               |    |     |                     |
|-----|-------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|----|-----|---------------------|
| S18 | 31112 | S17 and blood                                                                                                                                                                                                                                                                                                                                                                                                                                      | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/03<br>15:06 |
| S19 | 7402  | S18 and @ay< "2000"                                                                                                                                                                                                                                                                                                                                                                                                                                | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/03<br>15:06 |
| S20 | 1883  | (604/43,156,158,540).CCLS.                                                                                                                                                                                                                                                                                                                                                                                                                         | US-PGPUB;<br>USPAT                                            | OR | OFF | 2012/02/03<br>15:18 |
| S21 | 201   | (623/3.1).CCLS.                                                                                                                                                                                                                                                                                                                                                                                                                                    | US-PGPUB;<br>USPAT                                            | OR | OFF | 2012/02/03<br>15:18 |
| S22 | 911   | S20 and @ay< "2000"                                                                                                                                                                                                                                                                                                                                                                                                                                | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/03<br>15:18 |
| S23 | 72    | S21 and @ay< "2000"                                                                                                                                                                                                                                                                                                                                                                                                                                | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/03<br>15:18 |
| S24 | 1858  | 600/16                                                                                                                                                                                                                                                                                                                                                                                                                                             | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/03<br>15:27 |
| S25 | 618   | S24 and @ay< "2000"                                                                                                                                                                                                                                                                                                                                                                                                                                | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/03<br>15:27 |
| S26 | 485   | S22 and (border bordered<br>bordering boundary bounded<br>bounding boundaries perimeter<br>periphery peripherally<br>peripheral rim sect wing side<br>oblique obliquely sidelong<br>sideward sideways sidewise skirt<br>\$4 edge edged edging edger<br>flange flanged flanging seam<br>seamed seaming crease<br>creased creasing lip lipped<br>lipping ) with (guidewire wire<br>cable guide eyelet islet hook<br>thread\$3 hole opening notch\$3) | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/03<br>15:31 |
| S27 | 307   | S26 and (vascular vessel<br>cardiovascular arter\$3 ven\$3<br>vein)                                                                                                                                                                                                                                                                                                                                                                                | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/03<br>15:32 |

|     |     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                               |    |     |                     |
|-----|-----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|----|-----|---------------------|
| S28 | 524 | (604/6.11).CCLS.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | US-PGPUB;<br>USPAT                                            | OR | OFF | 2012/02/03<br>15:42 |
| S29 | 179 | S28 and @ay<"2000"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/03<br>15:42 |
| S30 | 287 | intravascular near3 pump\$3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/03<br>15:46 |
| S31 | 106 | S30 and @ay<"2000"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/03<br>15:46 |
| S32 | 71  | ("2635547"   "3608088"  <br>"3647324"   "3685059"  <br>"3957389"   "3995617"  <br>"4037984"   "4135253"  <br>"4173796"   "4382199"  <br>"4507048"   "4589822"  <br>"4625712"   "4662355"  <br>"4688998"   "4704121"  <br>"4753221"   "4763032"  <br>"4779614"   "4817586"  <br>"4846152"   "4895493"  <br>"4898518"   "4906229"  <br>"4908012"   "4927407"  <br>"4944722"   "4955856"  <br>"4957504"   "4964864"  <br>"4969865"   "4984972"  <br>"4994078"   "4995857"  <br>"5049134"   "5055005"  <br>"5092879"   "5112292"  <br>"5112349"   "5118264"  <br>"5145333"   "5147388"  <br>"5346458"   "5507629"  <br>"Re28742").PN. OR<br>("5888241").URPN. | US-PGPUB;<br>USPAT; USOCR                                     | OR | ON  | 2012/02/03<br>15:50 |
| S33 | 49  | S32 and @ay<"2000"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | US-PGPUB;<br>USPAT; FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/02/03<br>15:51 |
| S34 | 53  | ("3479960"   "4817586"  <br>"4944722"   "4957504"  <br>"4969865").PN. OR ("5112349").<br>URPN.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | US-PGPUB;<br>USPAT; USOCR                                     | OR | ON  | 2012/02/03<br>15:52 |



|     |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                           |    |    |                     |
|-----|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----|----|---------------------|
| S35 | 64 | ( "20030023201"  <br>"20030205233"   "3585983"  <br>"3602009"   "3904901"  <br>"4391547"   "4392836"  <br>"4413989"   "4591355"  <br>"4625712"   "4696667"  <br>"4704121"   "4728319"  <br>"4817586"   "4895557"  <br>"4908012"   "4909781"  <br>"4917102"   "4919647"  <br>"4955856"   "4964839"  <br>"5041131"   "5112349"  <br>"5163910"   "5300112"  <br>"5678306"   "5692882"  <br>"5741234"   "5746709"  <br>"5746758"   "5776190"  <br>"5810088"   "5851174"  <br>"5888241"   "5911685"  <br>"5947892"   "5957672"  <br>"6083260"   "6086570"  <br>"6093001"   "6113536"  <br>"6123659"   "6123725"  <br>"6152704"   "6176822"  <br>"6176848"   "6210133"  <br>"6210397"   "6217541"  <br>"6228063"   "6234960"  <br>"6245007"   "6287319"  <br>"6295877"   "6336939"  <br>"6346120"   "6395026"  <br>"6532964"   "6613008"  <br>"6709418"   "7022100").PN. OR<br>("7731675").URPN. | US-PGPUB;<br>USPAT; USOCR | OR | ON | 2012/02/03<br>15:54 |
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**EAST Search History (Interference)**

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**2/ 6/ 2012 10:07:13 AM****C:\ Documents and Settings\ amarcetich\ My Documents\ EAST\ Workspaces\ 12772810.wsp**



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## BIB DATA SHEET

CONFIRMATION NO. 4661

| SERIAL NUMBER                                                                                                                                                                                                                                                | FILING or 371(c)<br>DATE                                                                                          | CLASS                                        | GROUP ART UNIT                                               | ATTORNEY DOCKET<br>NO.          |                     |                           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|----------------------------------------------|--------------------------------------------------------------|---------------------------------|---------------------|---------------------------|
| 12/772,810                                                                                                                                                                                                                                                   | 05/03/2010                                                                                                        | 604                                          | 3761                                                         | 06-01506US04                    |                     |                           |
| <b>RULE</b>                                                                                                                                                                                                                                                  |                                                                                                                   |                                              |                                                              |                                 |                     |                           |
| <b>APPLICANTS</b><br>Walid N. Aboul-Hosn, Fair Oaks, CA;<br>William R. Kanz, Sacramento, CA;<br>Bruce A. Baker, Placerville, CA;                                                                                                                             |                                                                                                                   |                                              |                                                              |                                 |                     |                           |
| <b>** CONTINUING DATA *****</b><br>This application is a CON of 11/375,926 03/15/2006 PAT 7,731,675<br>which is a DIV of 10/070,178 07/19/2002 PAT 7,022,100<br>which is a 371 of PCT/US00/24515 09/01/2000<br>which claims benefit of 60/152,249 09/03/1999 |                                                                                                                   |                                              |                                                              |                                 |                     |                           |
| <b>** FOREIGN APPLICATIONS *****</b>                                                                                                                                                                                                                         |                                                                                                                   |                                              |                                                              |                                 |                     |                           |
| <b>** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **</b><br>05/11/2010                                                                                                                                                                                       |                                                                                                                   |                                              |                                                              |                                 |                     |                           |
| Foreign Priority claimed                                                                                                                                                                                                                                     | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No                                               | <input type="checkbox"/> Met after Allowance | <b>STATE OR COUNTRY</b>                                      | <b>SHEETS DRAWINGS</b>          | <b>TOTAL CLAIMS</b> | <b>INDEPENDENT CLAIMS</b> |
| 35 USC 119(a-d) conditions met                                                                                                                                                                                                                               | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No                                               |                                              | CA                                                           | 18                              | 1                   | 1                         |
| Verified and                                                                                                                                                                                                                                                 | /ADAM M<br>MARCETICH/                                                                                             | Initials                                     |                                                              |                                 |                     |                           |
| Acknowledged                                                                                                                                                                                                                                                 | Examiner's Signature                                                                                              |                                              |                                                              |                                 |                     |                           |
| <b>ADDRESS</b><br>MAQUET Cardiovascular LLC<br>170 Baytech Drive<br>San Jose, CA 95134<br>UNITED STATES                                                                                                                                                      |                                                                                                                   |                                              |                                                              |                                 |                     |                           |
| <b>TITLE</b><br>Guidable Intravascular Blood Pump and Related Methods                                                                                                                                                                                        |                                                                                                                   |                                              |                                                              |                                 |                     |                           |
| <b>FILING FEE RECEIVED</b><br>1142                                                                                                                                                                                                                           | FEES: Authority has been given in Paper<br>No. _____ to charge/credit DEPOSIT ACCOUNT<br>No. _____ for following: |                                              | <input type="checkbox"/> All Fees                            |                                 |                     |                           |
|                                                                                                                                                                                                                                                              |                                                                                                                   |                                              | <input type="checkbox"/> 1.16 Fees (Filing)                  |                                 |                     |                           |
|                                                                                                                                                                                                                                                              |                                                                                                                   |                                              | <input type="checkbox"/> 1.17 Fees (Processing Ext. of time) |                                 |                     |                           |
|                                                                                                                                                                                                                                                              |                                                                                                                   |                                              | <input type="checkbox"/> 1.18 Fees (Issue)                   |                                 |                     |                           |
|                                                                                                                                                                                                                                                              |                                                                                                                   |                                              | <input type="checkbox"/> Other _____                         |                                 |                     |                           |
|                                                                                                                                                                                                                                                              |                                                                                                                   |                                              |                                                              | <input type="checkbox"/> Credit |                     |                           |

|                                                                                                              |                                                |                                                                         |
|--------------------------------------------------------------------------------------------------------------|------------------------------------------------|-------------------------------------------------------------------------|
| <b>Search Notes</b><br><br> | <b>Application/Control No.</b><br><br>12772810 | <b>Applicant(s)/Patent Under Reexamination</b><br><br>ABOUL-HOSN ET AL. |
|                                                                                                              | <b>Examiner</b><br><br>ADAM MARCETICH          | <b>Art Unit</b><br><br>3761                                             |

| SEARCHED |                |          |          |
|----------|----------------|----------|----------|
| Class    | Subclass       | Date     | Examiner |
| 604      | 43,156,158,540 | 2/3/2012 | AMM      |
| 623      | 3.1            | 2/3/2012 | AMM      |
| 600      | 16             | 2/3/2012 | AMM      |

| SEARCH NOTES                                                                              |          |          |
|-------------------------------------------------------------------------------------------|----------|----------|
| Search Notes                                                                              | Date     | Examiner |
| Inventor search: PALM and EAST (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT, IBM_TDB) | 2/3/2012 | AMM      |
| Review PLUS search results returned Friday, 3 February 2012                               | 2/3/2012 | AMM      |
| Review cited art for related cases 11/375926, 10/070178                                   | 2/3/2012 | AMM      |
| Review ISR for PCT/US00/24515 performed 19 March 2001, Angie Sykes USPTO                  | 2/3/2012 | AMM      |

| INTERFERENCE SEARCH |          |      |          |
|---------------------|----------|------|----------|
| Class               | Subclass | Date | Examiner |
|                     |          |      |          |

|                                            |  |
|--------------------------------------------|--|
| /ADAM MARCETICH/<br>Examiner.Art Unit 3761 |  |
|--------------------------------------------|--|

**Inventor Name Search Result**

Your Search was:

Last Name = ABOUL-HOSN

First Name = WALID

| Application#             | Patent#       | PG Pub#     | Status | Date Filed | Title                                                                                                           | Examiner Name    | Inventor Name        |
|--------------------------|---------------|-------------|--------|------------|-----------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| <a href="#">08933566</a> | 6083260       |             | 150    | 09/19/1997 | REVERSE FLOW<br>TRANSPORT<br>PUMP AND<br>ORGAN<br>STABILIZATION<br>APPARATUS<br>INCLUDING<br>RELATED<br>METHODS | SNOW,BRUCE       | ABOUL-HOSN,<br>WALID |
| <a href="#">09327500</a> | Not<br>Issued |             | 161    | 06/08/1999 | REVERSE FLOW<br>TRANSPORT AND<br>PUMP AND<br>ORGAN<br>STABILIZATION<br>APPARATUS                                | SNOW,BRUCE       | ABOUL-HOSN,<br>WALID |
| <a href="#">10132880</a> | 6814713       | 20030023201 | 150    | 04/25/2002 | SYSTEMS AND<br>METHODS FOR<br>PERFORMING<br>MINIMALLY<br>INVASIVE<br>CARDIAC<br>MEDICAL<br>PROCEDURES           | THANH,LOAN       | ABOUL-HOSN,<br>WALID |
| <a href="#">10918295</a> | Not<br>Issued | 20050020968 | 161    | 08/13/2004 | Systems and<br>methods for<br>performing<br>minimally invasive<br>cardiac medical<br>procedures                 | ANDERSON,MICHAEL | ABOUL-HOSN,<br>WALID |
| <a href="#">60168795</a> | Not<br>Issued |             | 159    | 12/02/1999 | SURGICAL<br>DRAPE AND<br>PANEL<br>ASSEMBLY                                                                      | ,                | ABOUL-HOSN,<br>WALID |
| <a href="#">60218001</a> | Not<br>Issued |             | 159    | 07/12/2000 | Minimally invasive<br>bypass apparatus<br>and methods of use                                                    | ,                | ABOUL-HOSN,<br>WALID |

|                          |                         |  |     |            |                                                                                  |                 |                         |
|--------------------------|-------------------------|--|-----|------------|----------------------------------------------------------------------------------|-----------------|-------------------------|
| <a href="#">60286623</a> | Not Issued              |  | 159 | 04/25/2001 | Systems and methods for performing minimally invasive cardiac medical procedures | ,               | ABOUL-HOSN, WALID       |
| <a href="#">60388136</a> | Not Issued              |  | 159 | 06/11/2002 | Small diameter blood pump and related methods                                    | ,               | ABOUL-HOSN, WALID       |
| <a href="#">60388137</a> | Not Issued              |  | 159 | 06/11/2002 | Combined blood pump and oxygenator system and related methods                    | ,               | ABOUL-HOSN, WALID       |
| <a href="#">60388138</a> | Not Issued              |  | 159 | 06/11/2002 | Intracardiac blood pump and related methods                                      | ,               | ABOUL-HOSN, WALID       |
| <a href="#">60115786</a> | Not Issued              |  | 159 | 01/13/1999 | INTEGRATED CANNULA AND PUMP ASSEMBLY                                             | ,               | ABOUL-HOSN, WALID JAJIB |
| <a href="#">09462656</a> | <a href="#">6976996</a> |  | 250 | 01/14/2000 | TRANSPORT PUMP AND ORGAN STABILIZATION APPARATUS INCLUDING RELATED METHODS       | SNOW,BRUCE      | ABOUL-HOSN, WALID N     |
| <a href="#">09720016</a> | <a href="#">6709418</a> |  | 150 | 04/16/2001 | APPARATUS AND METHODS FOR ENTERING CAVITIES OF THE BODY                          | NGUYEN,CAMTU    | ABOUL-HOSN, WALID N     |
| <a href="#">09763911</a> | <a href="#">6969379</a> |  | 250 | 02/27/2001 | INTRAVASCULAR CANNULATION APPARATUS AND METHODS OF USE                           | MAIORINO,ROZ    | ABOUL-HOSN, WALID N     |
| <a href="#">09786703</a> | <a href="#">6641558</a> |  | 150 | 06/28/2001 | METHOD AND APPARATUS FOR PREVENTING AIR EMBOLISMS                                | NGUYEN,CAMTU    | ABOUL-HOSN, WALID N     |
| <a href="#">10070178</a> | <a href="#">7022100</a> |  | 150 | 07/19/2002 | GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS                            | BIANCO,PATRICIA | ABOUL-HOSN, WALID N     |

|                 |               |             |     |            |                                                                                                                  |                  |                         |
|-----------------|---------------|-------------|-----|------------|------------------------------------------------------------------------------------------------------------------|------------------|-------------------------|
| <u>10182314</u> | Not<br>Issued | 20050165269 | 161 | 11/15/2002 | Cannulation system<br>and related methods                                                                        | NGUYEN,CAMTU     | ABOUL-HOSN,<br>WALID N  |
| <u>09724348</u> | 6558319       |             | 250 | 11/27/2000 | HEART<br>STABILIZER<br>APPARATUS                                                                                 | PRIDDY,MICHAEL   | ABOUL-HOSN,<br>WALID N. |
| <u>09868973</u> | 6926662       |             | 150 | 08/20/2001 | LEFT AND RIGHT<br>SIDE HEART<br>SUPPORT                                                                          | JASTRZAB,JEFFREY | ABOUL-HOSN,<br>WALID N. |
| <u>09889442</u> | 6974436       |             | 250 | 12/09/2002 | INTEGRATED<br>PUMP AND<br>CANNULA<br>SYSTEM AND<br>RELATED<br>METHODS                                            | BIANCO,PATRICIA  | ABOUL-HOSN,<br>WALID N. |
| <u>10677468</u> | 8029491       | 20040073167 | 150 | 10/02/2003 | METHOD AND<br>APPARATUS FOR<br>PREVENTING AIR<br>EMBOLISMS                                                       | NGUYEN,CAMTU     | ABOUL-HOSN,<br>WALID N. |
| <u>10764664</u> | 7090659       | 20040158206 | 250 | 01/26/2004 | APPARATUS AND<br>METHODS FOR<br>ENTERING<br>CAVITIES OF THE<br>BODY                                              | NGUYEN,CAMTU     | ABOUL-HOSN,<br>WALID N. |
| <u>11018872</u> | 7785246       | 20050154250 | 150 | 12/21/2004 | LEFT AND RIGHT<br>SIDE HEART<br>SUPPORT                                                                          | STOKLOSA,JOSEPH  | ABOUL-HOSN,<br>WALID N. |
| <u>11214374</u> | Not<br>Issued | 20050279370 | 164 | 08/29/2005 | METHODS AND<br>SYSTEMS FOR<br>PROVIDING<br>RIGHT AND/OR<br>LEFT HEART<br>SUPPORT<br>DURING<br>CARDIAC<br>SURGERY | MATTHEWS,WILLIAM | ABOUL-HOSN,<br>WALID N. |
| <u>11280547</u> | Not<br>Issued | 20060069299 | 161 | 11/16/2005 | Integrated pump<br>and cannula systems<br>and related methods                                                    | MARCETICH,ADAM   | ABOUL-HOSN,<br>WALID N. |
| <u>11312087</u> | Not<br>Issued | 20060100565 | 161 | 12/20/2005 | Transport pump and<br>organ stabilization<br>apparatus including<br>related methods                              | SNOW,BRUCE       | ABOUL-HOSN,<br>WALID N. |
| <u>11375926</u> | 7731675       | 20060161095 | 150 | 03/15/2006 | GUIDABLE<br>INTRAVASCULAR<br>BLOOD PUMP<br>AND RELATED<br>METHODS                                                | MARCETICH,ADAM   | ABOUL-HOSN,<br>WALID N. |

|                          |                         |             |     |            |                                                                               |                 |                      |
|--------------------------|-------------------------|-------------|-----|------------|-------------------------------------------------------------------------------|-----------------|----------------------|
| <a href="#">12772810</a> | Not Issued              | 20100210895 | 30  | 05/03/2010 | Guidable Intravascular Blood Pump and Related Methods                         | MARCETICH,ADAM  | ABOUL-HOSN, WALID N. |
| <a href="#">12846366</a> | Not Issued              | 20110021865 | 30  | 07/29/2010 | Left and Right Side Heart Support                                             | STOKLOSA,JOSEPH | ABOUL-HOSN, WALID N. |
| <a href="#">13252062</a> | Not Issued              | 20120022316 | 20  | 10/03/2011 | Method and Apparatus for Preventing Air Embolisms                             | ,               | ABOUL-HOSN, WALID N. |
| <a href="#">08680929</a> | <a href="#">5741234</a> |             | 250 | 07/16/1996 | ANATOMICAL CAVITY ACCESS SEALING CONDUIT                                      | YEH,LUKE        | ABOUL-HOSN, WALID N. |
| <a href="#">08891456</a> | <a href="#">6123725</a> |             | 150 | 07/11/1997 | YINGLE PORT CARDIAC SUPPORT APPARATUS                                         | NGUYEN,TRAM     | ABOUL-HOSN, WALID N. |
| <a href="#">09163102</a> | Not Issued              |             | 164 | 09/29/1998 | HEMOSTASIS VALVE WITH SELF-SEALING FLAP                                       | MENDEZ,MANUEL   | ABOUL-HOSN, WALID N. |
| <a href="#">09163103</a> | <a href="#">6086570</a> |             | 150 | 09/29/1998 | HEMOSTASIS VALVE WITH MEMBRANES HAVING OFFSET APERTURES.                      | RODRIGUEZ,CRIS  | ABOUL-HOSN, WALID N. |
| <a href="#">09164395</a> | <a href="#">6113536</a> |             | 150 | 09/30/1998 | DEVICE AND METHOD OF ATTACHING A BLOOD PUMP AND TUBES TO A SURGICAL RETRACTOR | HIRSCH,PAUL     | ABOUL-HOSN, WALID N. |
| <a href="#">09164397</a> | <a href="#">6234960</a> |             | 250 | 09/30/1998 | HEART STABILIZER APPARATUS                                                    | PRIDDY,MICHAEL  | ABOUL-HOSN, WALID N. |
| <a href="#">09280967</a> | Not Issued              |             | 161 | 03/30/1999 | INTEGRATED CANNULA ILLUMINATION SYSTEM                                        | RAM,JOCELYN     | ABOUL-HOSN, WALID N. |
| <a href="#">09280970</a> | <a href="#">6295877</a> |             | 250 | 03/30/1999 | PRESSURE SENSING CANNULA                                                      | OEN,WILLIAM     | ABOUL-HOSN, WALID N. |
| <a href="#">09280987</a> | <a href="#">6287319</a> |             | 250 | 03/30/1999 | CANNULA WITH BALLOON TIP                                                      | BUI,VY          | ABOUL-HOSN, WALID N. |
| <a href="#">60098118</a> | Not Issued              |             | 159 | 08/27/1998 | INTRAVASCULAR CANNULATION APPARATUS AND                                       | ,               | ABOUL-HOSN, WALID N. |

|                          |                         |             |     |            |                                                                                          |                   |                         |
|--------------------------|-------------------------|-------------|-----|------------|------------------------------------------------------------------------------------------|-------------------|-------------------------|
|                          |                         |             |     |            | METHODS OF USE                                                                           |                   |                         |
| <a href="#">60102561</a> | Not Issued              |             | 159 | 09/30/1998 | EMBOLISM PREVENTION CANNULA                                                              | ,                 | ABOUL-HOSN, WALID N.    |
| <a href="#">60113727</a> | Not Issued              |             | 159 | 12/23/1998 | CANNULA ASSEMBLY HAVING BENT DISTAL TIP AND METHODS OF USE                               | ,                 | ABOUL-HOSN, WALID N.    |
| <a href="#">60113771</a> | Not Issued              |             | 159 | 12/23/1998 | DEVICE AND METHODS FOR SUPPORTING THE LEFT AND RIGHT SIDE OF THE HEART DURING SURGERY    | ,                 | ABOUL-HOSN, WALID N.    |
| <a href="#">10521044</a> | Not Issued              | 20060155158 | 161 | 12/07/2005 | Percutaneously introduced blood pump and related methods                                 | FLORY,CHRISTOPHER | ABOUL-HOSN, WALID NAGIB |
| <a href="#">60178479</a> | Not Issued              |             | 159 | 01/27/2000 | Cannulation system and related methods                                                   | ,                 | ABOUL-HOSN, WALID NAGIB |
| <a href="#">60200812</a> | Not Issued              |             | 159 | 04/28/2000 | Cannulation system and related methods                                                   | ,                 | ABOUL-HOSN, WALID NAGIB |
| <a href="#">60262742</a> | Not Issued              |             | 159 | 01/19/2001 | Method and apparatus for maintaining flow through a vessel or duct                       | ,                 | ABOUL-HOSN, WALID NAGIB |
| <a href="#">60431174</a> | Not Issued              |             | 159 | 12/04/2002 | Intracardiac rotary blood pump and related methods                                       | ,                 | ABOUL-HOSN, WALID NAGIB |
| <a href="#">09481730</a> | <a href="#">6935344</a> |             | 250 | 01/11/2000 | METHODS AND SYSTEMS FOR PROVIDING RIGHT AND/OR LEFT HEART SUPPORT DURING CARDIAC SURGERY | MATTHEWS,WILLIAM  | ABOUL-HOSN, WALID NAGIB |
| <a href="#">60152249</a> | Not Issued              |             | 159 | 09/03/1999 | INTRAVASCULAR BLOOD PUMP                                                                 | ,                 | ABOUL-HOSN, WALID NAGIB |

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# **PALM INTRANET**

## Inventor Name Search Result

Your Search was:

Last Name = ABOUL-HOSN

First Name = WALID

| Application#             | Patent#                 | PG Pub#                     | Status | Date Filed | Title                                                                                         | Examiner Name    | Inventor Name           |
|--------------------------|-------------------------|-----------------------------|--------|------------|-----------------------------------------------------------------------------------------------|------------------|-------------------------|
| <a href="#">60211713</a> | Not Issued              |                             | 159    | 06/13/2000 | Integrated system for cardiopulmonary bypass and related methods                              |                  | ABOUL-HOSN, WALID NAGIB |
| <a href="#">09440462</a> | Not Issued              |                             | 161    | 11/15/1999 | PULMONARY AND CIRCULATORY BLOOD FLOW SUPPORT DEVICES AND METHODS FOR HEART SURGERY PROCEDURES | BLANCO,JAVIER    | ABOUL-HOSN, WALID NAGIB |
| <a href="#">09470697</a> | Not Issued              |                             | 161    | 12/23/1999 | APPARATUS AND METHODS FOR ENTERING CAVITIES OF THE BODY                                       | BIANCO,PATRICIA  | ABOUL-HOSN, WALID NAGIB |
| <a href="#">09641012</a> | Not Issued              |                             | 161    | 08/16/2000 | Supplemental port for catheter perfusion of surgical site                                     | BIANCO,PATRICIA  | ABOUL-HOSN, WALID NAGIB |
| <a href="#">09669104</a> | <a href="#">6858001</a> |                             | 150    | 09/25/2000 | SINGLE PORT CADIAC SUPPORT APPARATUS                                                          | MACHUGA,JOSEPH   | ABOUL-HOSN, WALID NAGIB |
| <a href="#">09729740</a> | Not Issued              |                             | 164    | 12/04/2000 | SURGICAL DRAPE AND PANEL ASSEMBLY                                                             | HAMILTON,LALITA  | ABOUL-HOSN, WALID NAGIB |
| <a href="#">09877488</a> | <a href="#">6613008</a> | <a href="#">20020044889</a> | 250    | 06/08/2001 | INTEGRATED SYSTEM FOR CARDIOPULMONARY BYPASS AND RELATED METHODS                              | FRISTOE JR,JOHN  | ABOUL-HOSN, WALID NAGIB |
| <a href="#">10021549</a> | Not Issued              | <a href="#">20020045795</a> | 161    | 12/12/2001 | Pulmonary and circulatory blood flow support devices and methods for heart surgery procedures | MATTHEWS,WILLIAM | ABOUL-HOSN, WALID NAGIB |
| <a href="#">10079053</a> | Not Issued              | <a href="#">20020128587</a> | 161    | 02/19/2002 | Pulmonary and circulatory blood flow support devices and methods for heart surgery procedures | MATTHEWS,WILLIAM | ABOUL-HOSN, WALID NAGIB |
| <a href="#">10445639</a> | Not Issued              | <a href="#">20030205233</a> | 164    | 05/27/2003 | SURGICAL DRAPE AND PANEL ASSEMBLY                                                             | BROWN,MICHAEL    | ABOUL-HOSN, WALID NAGIB |
| <a href="#">10644599</a> | Not Issued              | <a href="#">20040210300</a> | 161    | 08/19/2003 | Apparatus and method for maintaining flow                                                     | BUI,VY           | ABOUL-HOSN, WALID NAGIB |

|                 |                |             |     |            |                                                                                               |                        |                         |
|-----------------|----------------|-------------|-----|------------|-----------------------------------------------------------------------------------------------|------------------------|-------------------------|
|                 |                |             |     |            | through a vessel or duct                                                                      |                        |                         |
| <u>10840195</u> | Not Issued     | 20050143801 | 161 | 05/05/2004 | Systems and methods for overcoming or preventing vascular flow restrictions                   | SZPIRA,JULIE           | ABOUL-HOSN, WALID NAJIB |
| <u>10991255</u> | Not Issued     | 20050119599 | 161 | 11/17/2004 | Supplemental port for catheter perfusion of surgical site and methods of use                  | WIEST,PHILIP           | ABOUL-HOSN, WALID NAJIB |
| <u>11057273</u> | <u>7182727</u> | 20050148811 | 250 | 02/11/2005 | SINGLE PORT CARDIAC SUPPORT APPARATUS                                                         | JOHNSON,SHEVON         | ABOUL-HOSN, WALID NAJIB |
| <u>11058621</u> | Not Issued     | 20050145254 | 164 | 02/15/2005 | SURGICAL DRAPE AND PANEL ASSEMBLY                                                             | BROWN,MICHAEL          | ABOUL-HOSN, WALID NAJIB |
| <u>11136126</u> | <u>7381179</u> | 20050234288 | 150 | 05/24/2005 | PULMONARY AND CIRCULATORY BLOOD FLOW SUPPORT DEVICES AND METHODS FOR HEART SURGERY PROCEDURES | BLANCO,JAVIER          | ABOUL-HOSN, WALID NAJIB |
| <u>11142721</u> | Not Issued     | 20050228212 | 161 | 06/01/2005 | Pulmonary and circulatory blood flow support devices and methods for heart surgery procedures | MATTHEWS,WILLIAM       | ABOUL-HOSN, WALID NAJIB |
| <u>11273162</u> | Not Issued     | 20060063965 | 161 | 11/14/2005 | Apparatus and methods for entering cavities of the body                                       | WIEST,PHILIP           | ABOUL-HOSN, WALID NAJIB |
| <u>11711439</u> | Not Issued     | 20070156010 | 161 | 02/26/2007 | Single port cardiac support apparatus related applications                                    | NARAYANASWAMY,SHUBATRA | ABOUL-HOSN, WALID NAJIB |
| <u>60327742</u> | Not Issued     |             | 159 | 10/06/2001 | Systems and methods for overcoming vascular flow restrictions                                 |                        | ABOUL-HOSN, WALID NAJIB |
| <u>60351125</u> | Not Issued     |             | 159 | 01/22/2002 | Cannulation system and related methods                                                        |                        | ABOUL-HOSN, WALID NAJIB |
| <u>08956654</u> | <u>6228063</u> |             | 150 | 10/23/1997 | AN ANATOMICAL CAVITY ACCESS SEALING CONDUIT                                                   | WILLIAMS,CATHERINE     | ABOUL-HOSN, WALID NAJIB |
| <u>09079836</u> | <u>6395026</u> |             | 150 | 05/15/1998 | APPARATUS AND METHODS FOR BEATING HEART BYPASS SURGERY                                        | MILANO,MICHAEL         | ABOUL-HOSN, WALID NAJIB |
| <u>09099713</u> | Not Issued     |             | 161 | 06/19/1998 | APPARATUS AND METHODS FOR ENTERING CAVITIES OF THE BODY                                       | BIANCO,PATRICIA        | ABOUL-HOSN, WALID NAJIB |
| <u>09164396</u> | <u>6152704</u> |             | 150 | 09/30/1998 | BLOOD PUMP WITH TURBINE DRIVE                                                                 | FREAY,CHARLES          | ABOUL-HOSN, WALID NAJIB |
| <u>09164407</u> | Not Issued     |             | 161 | 09/30/1998 | BLOOD PUMP SYSTEM WITH MAGNETIC CABLE DRIVE                                                   | FREAY,CHARLES          | ABOUL-HOSN, WALID NAJIB |

|                          |                         |             |     |            |                                                                                                                 |                 |                               |
|--------------------------|-------------------------|-------------|-----|------------|-----------------------------------------------------------------------------------------------------------------|-----------------|-------------------------------|
| <a href="#">09166135</a> | <a href="#">6210133</a> |             | 150 | 09/30/1998 | BLOOD PUMP WITH<br>STERILE MOTOR<br>HOUSING                                                                     | FREAY,CHARLES   | ABOUL-HOSN,<br>WALID NAJIB    |
| <a href="#">09229806</a> | <a href="#">6210397</a> |             | 150 | 01/13/1999 | SEALING CANNULA<br>DEVICE                                                                                       | SIRMONS,KEVIN   | ABOUL-HOSN,<br>WALID NAJIB    |
| <a href="#">09231320</a> | <a href="#">6532964</a> | 20020026944 | 150 | 01/13/1999 | PULMONARY AND<br>CIRCULATORY<br>BLOOD FLOW<br>SUPPORT DEVICES<br>AND METHODS FOR<br>HEART SURGERY<br>PROCEDURES | CAMPEN,KELLY    | ABOUL-HOSN,<br>WALID NAJIB    |
| <a href="#">09280988</a> | Not<br>Issued           |             | 161 | 03/30/1999 | STEERABLE<br>CANNULA                                                                                            | NGUYEN,ANH TUAN | ABOUL-HOSN,<br>WALID NAJIB    |
| <a href="#">09313268</a> | Not<br>Issued           |             | 161 | 05/18/1999 | SUPPLEMENTAL<br>PORT FOR<br>CATHETER<br>PERFUSION OF<br>SURGICAL SITE                                           | BIANCO,PATRICIA | ABOUL-HOSN,<br>WALID NAJIB    |
| <a href="#">11410417</a> | <a href="#">7458376</a> | 20060191541 | 150 | 04/25/2006 | SURGICAL DRAPE<br>AND PANEL<br>ASSEMBLY                                                                         | BROWN,MICHAEL   | ABOUL-HOSN,<br>WALID<br>NALIB |

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## Inventor Name Search Result

Your Search was:

Last Name = BAKER

First Name = BRUCE

| Application#    | Patent#        | PG Pub#     | Status | Date Filed | Title                                                                           | Examiner Name  | Inventor Name |
|-----------------|----------------|-------------|--------|------------|---------------------------------------------------------------------------------|----------------|---------------|
| <u>06451064</u> | <u>4477080</u> |             | 150    | 12/20/1982 | BOARD GAME DEVICE HAVING PLURAL TIERS                                           | NOT,DEFINED    | BAKER, BRUCE  |
| <u>08470243</u> | Not Issued     |             | 161    | 06/06/1995 | GOLF PUTTER                                                                     | MARLO,GEORGE   | BAKER, BRUCE  |
| <u>10182314</u> | Not Issued     | 20050165269 | 161    | 11/15/2002 | Cannulation system and related methods                                          | NGUYEN,CAMTU   | BAKER, BRUCE  |
| <u>10821766</u> | Not Issued     | 20050241110 | 163    | 04/09/2004 | Ergonomic handles, especially for garden tools                                  | WILLIAMS,MARK  | BAKER, BRUCE  |
| <u>11008013</u> | Not Issued     | 20050223499 | 161    | 12/09/2004 | Ergonomic hand tools, construction thereof, and packaging therefor              | WILLIAMS,MARK  | BAKER, BRUCE  |
| <u>11664212</u> | <u>8066127</u> | 20080311651 | 150    | 08/05/2008 | INSTRUMENTALITY FOR SEQUESTERING LIQUIDS BASED ON DENSITY: METHOD AND APPARATUS | MENON,KRISHNAN | BAKER, BRUCE  |
| <u>12343899</u> | <u>7836557</u> | 20090183343 | 150    | 12/24/2008 | ERGONOMIC GARDEN TROWEL                                                         | WILLIAMS,MARK  | BAKER, BRUCE  |
| <u>12426656</u> | <u>8006474</u> | 20100263347 | 150    | 04/20/2009 | POND CLEANING IMPLEMENT                                                         | PEZZUTO,ROBERT | BAKER, BRUCE  |
| <u>12951566</u> | <u>8006351</u> | 20110061883 | 150    | 11/22/2010 | SHORT-HANDLED, ERGONOMIC GARDEN TOOLS                                           | WILLIAMS,MARK  | BAKER, BRUCE  |
| <u>13221069</u> | Not Issued     | 20110308225 | 41     | 08/30/2011 | ERGONOMIC GARDEN TOOLS                                                          | WILLIAMS,MARK  | BAKER, BRUCE  |
| <u>29275709</u> | <u>D569697</u> |             | 150    | 01/04/2007 | HANDLE FOR GARDEN IMPLEMENTS                                                    | LANE,SHERYL    | BAKER, BRUCE  |
| <u>29277924</u> | <u>D570653</u> |             | 150    | 03/14/2007 | SHOVEL                                                                          | LANE,SHERYL    | BAKER, BRUCE  |
| <u>29277926</u> | <u>D570654</u> |             | 150    | 03/14/2007 | SPADE                                                                           | LANE,SHERYL    | BAKER, BRUCE  |

|                          |                         |  |     |            |                                                                                             |             |              |
|--------------------------|-------------------------|--|-----|------------|---------------------------------------------------------------------------------------------|-------------|--------------|
| <a href="#">29277927</a> | <a href="#">D579288</a> |  | 150 | 03/14/2007 | TRANSPLANTER                                                                                | LANE,SHERYL | BAKER, BRUCE |
| <a href="#">29277930</a> | <a href="#">D569698</a> |  | 150 | 03/14/2007 | WEEDER                                                                                      | LANE,SHERYL | BAKER, BRUCE |
| <a href="#">29277931</a> | <a href="#">D588424</a> |  | 150 | 03/14/2007 | BULB AUGER                                                                                  | LANE,SHERYL | BAKER, BRUCE |
| <a href="#">29283514</a> | <a href="#">D563742</a> |  | 150 | 08/16/2007 | CULTIVATOR                                                                                  | LANE,SHERYL | BAKER, BRUCE |
| <a href="#">29283517</a> | <a href="#">D564314</a> |  | 150 | 08/16/2007 | TRANSPLANTER                                                                                | LANE,SHERYL | BAKER, BRUCE |
| <a href="#">29283521</a> | <a href="#">D564315</a> |  | 150 | 08/16/2007 | TROWEL                                                                                      | LANE,SHERYL | BAKER, BRUCE |
| <a href="#">29283523</a> | <a href="#">D564313</a> |  | 150 | 08/16/2007 | WEEDER                                                                                      | LANE,SHERYL | BAKER, BRUCE |
| <a href="#">29283526</a> | <a href="#">D569202</a> |  | 150 | 08/16/2007 | HANDLE FOR A GARDEN TOOL                                                                    | LANE,SHERYL | BAKER, BRUCE |
| <a href="#">29403575</a> | Not Issued              |  | 30  | 10/07/2011 | GARDEN FORK                                                                                 | LANE,SHERYL | BAKER, BRUCE |
| <a href="#">29405208</a> | Not Issued              |  | 30  | 10/31/2011 | SHOVEL BLADE                                                                                | LANE,SHERYL | BAKER, BRUCE |
| <a href="#">29405216</a> | Not Issued              |  | 30  | 10/31/2011 | GARDEN SCOOP                                                                                | LANE,SHERYL | BAKER, BRUCE |
| <a href="#">60152249</a> | Not Issued              |  | 159 | 09/03/1999 | INTRAVASCULAR BLOOD PUMP                                                                    | ,           | BAKER, BRUCE |
| <a href="#">60178479</a> | Not Issued              |  | 159 | 01/27/2000 | Cannulation system and related methods                                                      | ,           | BAKER, BRUCE |
| <a href="#">60200812</a> | Not Issued              |  | 159 | 04/28/2000 | Cannulation system and related methods                                                      | ,           | BAKER, BRUCE |
| <a href="#">60286623</a> | Not Issued              |  | 159 | 04/25/2001 | Systems and methods for performing minimally invasive cardiac medical procedures            | ,           | BAKER, BRUCE |
| <a href="#">60351125</a> | Not Issued              |  | 159 | 01/22/2002 | Cannulation system and related methods                                                      | ,           | BAKER, BRUCE |
| <a href="#">60719472</a> | Not Issued              |  | 159 | 09/21/2005 | Current measuring device                                                                    | ,           | BAKER, BRUCE |
| <a href="#">60809670</a> | Not Issued              |  | 159 | 05/31/2006 | 14" Abrasive compound miter chop saw                                                        | ,           | BAKER, BRUCE |
| <a href="#">60875360</a> | Not Issued              |  | 159 | 12/18/2006 | Developing an appropriate icon set for a mandarin Chinese augmentative communication system | ,           | BAKER, BRUCE |
| <a href="#">61066859</a> | Not Issued              |  | 159 | 02/25/2008 | Mite-R-Saw aka: 14 abrasive compound miter saw                                              | ,           | BAKER, BRUCE |

|                 |                |             |     |            |                                                                                                                                   |                  |                 |
|-----------------|----------------|-------------|-----|------------|-----------------------------------------------------------------------------------------------------------------------------------|------------------|-----------------|
| <u>61244898</u> | Not Issued     |             | 159 | 09/23/2009 | VISUAL SIMULATED FIRE TRAINER FOR FIRE TRAINING                                                                                   |                  | BAKER, BRUCE    |
| <u>61344905</u> | Not Issued     |             | 159 | 11/12/2010 | Sequenced multi-meaning tactile symbols useable to produce synthetic plural word messages including words, phrases, and sentences |                  | BAKER, BRUCE    |
| <u>61536260</u> | Not Issued     |             | 20  | 09/19/2011 | PLANT WATERING APPARATUS                                                                                                          |                  | BAKER, BRUCE    |
| <u>10070178</u> | <u>7022100</u> |             | 150 | 07/19/2002 | GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS                                                                             | BIANCO,PATRICIA  | BAKER, BRUCE A. |
| <u>10132880</u> | <u>6814713</u> | 20030023201 | 150 | 04/25/2002 | SYSTEMS AND METHODS FOR PERFORMING MINIMALLY INVASIVE CARDIAC MEDICAL PROCEDURES                                                  | THANH,LOAN       | BAKER, BRUCE A. |
| <u>10918295</u> | Not Issued     | 20050020968 | 161 | 08/13/2004 | Systems and methods for performing minimally invasive cardiac medical procedures                                                  | ANDERSON,MICHAEL | BAKER, BRUCE A. |
| <u>11375926</u> | <u>7731675</u> | 20060161095 | 150 | 03/15/2006 | GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS                                                                             | MARCETICH,ADAM   | BAKER, BRUCE A. |
| <u>11825542</u> | Not Issued     | 20070269887 | 93  | 07/06/2007 | STEM AND PROGENITOR CELL COMPOSITIONS RECOVERED FROM BONE MARROW OR CORD BLOOD; SYSTEM AND METHOD FOR PREPARATION THEREOF         | MENON,KRISHNAN   | BAKER, BRUCE A. |
| <u>12772810</u> | Not Issued     | 20100210895 | 30  | 05/03/2010 | Guidable Intravascular Blood Pump and Related Methods                                                                             | MARCETICH,ADAM   | BAKER, BRUCE A. |
| <u>08987465</u> | <u>5876344</u> |             | 150 | 12/09/1997 | MODULAR IMAGING/TREATMENT CATHETER ASSEMBLY AND METHOD                                                                            | JAWORSKI,FRANCIS | BAKER, BRUCE A. |
| <u>09234967</u> | <u>6080109</u> |             | 150 | 01/21/1999 | MODULAR IMAGING /TREATMENT CATHETER ASSEMBLY                                                                                      | JAWORSKI,FRANCIS | BAKER, BRUCE A. |

|                          |                         |  |     |            |                                                                              |                  |                 |
|--------------------------|-------------------------|--|-----|------------|------------------------------------------------------------------------------|------------------|-----------------|
| <a href="#">09332700</a> | <a href="#">6453644</a> |  | 250 | 06/14/1999 | METHOD AND MEANS FOR PRODUCING, CONVEYING, STORING AND UTILIZING AIR PILLOWS | GERRITY,STEPHEN  | BAKER, BRUCE A. |
| <a href="#">29371793</a> | Not Issued              |  | 30  | 09/23/2011 | Profiled abrasive segment                                                    | PALASIK,PATRICIA | BAKER, BRUCE C. |
| <a href="#">29374774</a> | Not Issued              |  | 30  | 10/04/2011 | Segmented profiled wheel                                                     | PALASIK,PATRICIA | BAKER, BRUCE C. |
| <a href="#">29374775</a> | Not Issued              |  | 30  | 10/04/2011 | Segmented profiled wheel                                                     | PALASIK,PATRICIA | BAKER, BRUCE C. |
| <a href="#">29374776</a> | Not Issued              |  | 30  | 10/04/2011 | Segmented profiled wheel                                                     | PALASIK,PATRICIA | BAKER, BRUCE C. |
| <a href="#">29374777</a> | Not Issued              |  | 30  | 10/04/2011 | Segmented profiled wheel                                                     | PALASIK,PATRICIA | BAKER, BRUCE C. |

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**Inventor Name Search Result**

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| Application#             | Patent#                 | PG Pub# | Status | Date Filed | Title                                                                                       | Examiner Name | Inventor Name   |
|--------------------------|-------------------------|---------|--------|------------|---------------------------------------------------------------------------------------------|---------------|-----------------|
| <a href="#">07115171</a> | <a href="#">4926452</a> |         | 150    | 10/30/1987 | AUTOMATED LAMINOGRAPHY SYSTEM FOR INSPECTION OF ELECTRONICS                                 | NOT,DEFINED   | BAKER, BRUCE D. |
| <a href="#">07463523</a> | <a href="#">5081656</a> |         | 150    | 01/11/1990 | AUTOMATED LAMINOGRAPHY SYSTEM FOR INSPECTION OF ELECTRONICS                                 | WONG,DON      | BAKER, BRUCE D. |
| <a href="#">07479092</a> | <a href="#">5097492</a> |         | 150    | 02/12/1990 | AUTOMATED LAMINOGRAPHY SYSTEM FOR INSPECTION OF ELECTRONICS                                 | WONG,DON      | BAKER, BRUCE D. |
| <a href="#">07575342</a> | <a href="#">5259012</a> |         | 150    | 08/30/1990 | LAMINOGRAPHY SYSTEM AND METHOD WITH ELECTROMAGNETICALLY DIRECTED MULTIPATH RADIATION SOURCE | CHU,KIM KWOK  | BAKER, BRUCE D. |
| <a href="#">07575550</a> | <a href="#">5199054</a> |         | 150    | 08/30/1990 | METHOD AND APPARATUS FOR HIGH RESOLUTION INSPECTION OF ELECTRONIC ITEMS                     | WONG,DON      | BAKER, BRUCE D. |
| <a href="#">07740631</a> | <a href="#">5291535</a> |         | 150    | 08/05/1991 | METHOD AND APPARATUS FOR DETECTING EXCESS/INSUFFICIENT SOLDER DEFECTS                       | WONG,DON      | BAKER, BRUCE D. |
| <a href="#">08143081</a> | Not Issued              |         | 161    | 10/26/1993 | MULTIPATH LAMINOGRAPHY SYSTEM                                                               | CHU,KIM KWOK  | BAKER, BRUCE D. |
| <a href="#">08192413</a> | <a href="#">5621811</a> |         | 150    | 02/04/1994 | LEARNING METHOD AND APPARATUS FOR DETECTING AND CONTROLLING SOLDER DEFECTS                  | COUSO,YON     | BAKER, BRUCE D. |
| <a href="#">08433230</a> | <a href="#">5561696</a> |         | 150    | 05/02/1995 | METHOD AND APPARATUS FOR INSPECTING ELECTRICAL CONNECTIONS                                  | WONG,DON      | BAKER, BRUCE D. |

|                          |                         |             |     |            |                                                                                                 |                      |                 |
|--------------------------|-------------------------|-------------|-----|------------|-------------------------------------------------------------------------------------------------|----------------------|-----------------|
| <a href="#">09666276</a> | <a href="#">6497465</a> |             | 250 | 09/21/2000 | ANTI-TILT MECHANISM FOR A DRAWER ASSEMBLY                                                       | HANSEN,JAMES         | BAKER, BRUCE E. |
| <a href="#">10306373</a> | <a href="#">6819567</a> | 20040100775 | 150 | 11/27/2002 | APPARATUS AND SYSTEM FOR FUNCTIONAL EXPANSION OF A BLADE                                        | DUONG,HUNG           | BAKER, BRUCE E. |
| <a href="#">10723111</a> | <a href="#">6994572</a> | 20050112923 | 250 | 11/26/2003 | APPARATUS, SYSTEM, AND METHOD FOR COMPONENT DEACTIVATED INTERLOCK                               | TSUKERMAN,LARISA     | BAKER, BRUCE E. |
| <a href="#">11368778</a> | <a href="#">7416481</a> | 20070207723 | 150 | 03/06/2006 | BLOWER EXHAUST BACKFLOW DAMPER                                                                  | OREILLY,PATRICK      | BAKER, BRUCE E. |
| <a href="#">12169378</a> | Not Issued              | 20080280552 | 161 | 07/08/2008 | BLOWER EXHAUST BACKFLOW DAMPER METHODS                                                          | MILLER,SAMANTHA      | BAKER, BRUCE E. |
| <a href="#">06070008</a> | Not Issued              |             | 161 | 08/27/1979 | METHOD OF FORMING A HEAT SINK FOR, AND IN COMBINATION WITH, A HEAT PUMP                         | ,                    | BAKER, BRUCE E. |
| <a href="#">07191896</a> | <a href="#">4879426</a> |             | 150 | 05/09/1988 | PALLADIUM-CATALYZED ARYLATION OF CYCLOALKENES                                                   | NOT,DEFINED          | BAKER, BRUCE E. |
| <a href="#">08685085</a> | <a href="#">5789508</a> |             | 150 | 07/23/1996 | POLYMERIZATION PROCESS                                                                          | SAROFIM,NABIL        | BAKER, BRUCE E. |
| <a href="#">08686499</a> | <a href="#">5716290</a> |             | 250 | 08/22/1996 | BALANCED PUTTER WITH TOP SPIN FACILITY                                                          | GRIEB,WILLIAM        | BAKER, BRUCE E. |
| <a href="#">08700258</a> | <a href="#">5688884</a> |             | 150 | 08/20/1996 | POLYMERIZATION PROCESS                                                                          | SAROFIM,NABIL        | BAKER, BRUCE E. |
| <a href="#">08951072</a> | <a href="#">5931743</a> |             | 250 | 10/15/1997 | PUTTER HAVING CLUB HEAD WITH A GOLF BALL ENGAGEMENT INSERT AND A SHAFT REARWARDLY OF THE INSERT | GRIEB,WILLIAM        | BAKER, BRUCE E. |
| <a href="#">09056123</a> | <a href="#">6007434</a> |             | 250 | 04/06/1998 | GOLF CLUB                                                                                       | PASSANITI,SEBASTIANO | BAKER, BRUCE E. |
| <a href="#">09656649</a> | <a href="#">6378966</a> |             | 250 | 09/07/2000 | Device for use with a computer drawer assembly                                                  | HANSEN,JAMES         | BAKER, BRUCE E. |
| <a href="#">60003085</a> | Not Issued              |             | 159 | 08/31/1995 | POLYMERIZATION PROCESS                                                                          | ,                    | BAKER, BRUCE E. |
| <a href="#">60003097</a> | Not Issued              |             | 159 | 08/31/1995 | POLYMERIZATION PROCESS                                                                          | ,                    | BAKER, BRUCE E. |

|                          |                         |             |     |            |                                                                                                                |                    |                     |
|--------------------------|-------------------------|-------------|-----|------------|----------------------------------------------------------------------------------------------------------------|--------------------|---------------------|
| <a href="#">09640820</a> | <a href="#">6336828</a> |             | 150 | 08/17/2000 | Power bus bar docking mechanism                                                                                | PATEL,TULSIDAS     | BAKER, BRUCE EDWIN  |
| <a href="#">11627151</a> | <a href="#">7660108</a> | 20080180918 | 150 | 01/25/2007 | APPARATUS FOR POSITIONING ELECTRONIC COMPONENT MODULES WITHIN AN EQUIPMENT CHASSIS                             | DESAI,NIDHI        | BAKER, BRUCE EDWIN  |
| <a href="#">12119292</a> | <a href="#">7782606</a> | 20090279248 | 150 | 05/12/2008 | HARD DISK DRIVE CARRIER LATCH APPARATUS                                                                        | DESAI,NIDHI        | BAKER, BRUCE EDWIN  |
| <a href="#">29171711</a> | <a href="#">D493152</a> |             | 150 | 11/27/2002 | SERVER BLADE CHASSIS MIDPLANE PRINTED CIRCUIT BOARD WITH COVER                                                 | SIKDER,SELINA      | BAKER, BRUCE EDWIN  |
| <a href="#">06604655</a> | <a href="#">4610975</a> |             | 150 | 04/19/1984 | CATALYSTS AND NETHODS OF THEIR MANUFACTURE                                                                     | SHINE,WILLIAM      | BAKER, BRUCE G.     |
| <a href="#">06831553</a> | <a href="#">4666880</a> |             | 250 | 02/20/1986 | CATALYSTS                                                                                                      | SHINE,WILLIAM      | BAKER, BRUCE G.     |
| <a href="#">06909903</a> | Not Issued              |             | 161 | 09/22/1986 | CLEANING SYSTEM                                                                                                | MOORE,CHRISTOPHER  | BAKER, BRUCE G.     |
| <a href="#">07016353</a> | <a href="#">4767792</a> |             | 150 | 02/19/1987 | A PROCESS FOR CATALYTICALLY CONVERTING A CARBON MONOXIDE- AND HYDROGEN-CONTAINING FEED STREAM INTO HYDROCARBON | MARS,HOWARD        | BAKER, BRUCE G.     |
| <a href="#">07208094</a> | <a href="#">4827075</a> |             | 150 | 06/17/1988 | CATALYSTS                                                                                                      | NOT,DEFINED        | BAKER, BRUCE G.     |
| <a href="#">08529207</a> | <a href="#">5829419</a> |             | 250 | 09/15/1995 | IONIZATION COMBUSTION ENERGIZER                                                                                | MCMAHON,MARGUERITE | BAKER, BRUCE G.     |
| <a href="#">09043362</a> | <a href="#">6474315</a> |             | 250 | 12/16/1999 | ELECTRON STIMULATION VIA PHOTON EMITTING RADIATION                                                             | MCMAHON,MARGUERITE | BAKER, BRUCE G.     |
| <a href="#">61210692</a> | Not Issued              |             | 159 | 03/23/2009 | Mite-R-saw aka: 14 agrasive compound miter saw                                                                 | ,                  | BAKER, BRUCE JUNIUS |
| <a href="#">07404335</a> | <a href="#">4971228</a> |             | 150 | 09/07/1989 | GRAIN STREAM DAMPER DEVICE                                                                                     | HUSON,GREGORY      | BAKER, BRUCE L.     |
| <a href="#">07521321</a> | Not Issued              |             | 161 | 05/09/1990 | AIR DEFLECTOR FOR MOTORCYCLES                                                                                  | HOGGE,GARY         | BAKER, BRUCE L.     |

|                          |                         |             |     |            |                                                                                                                                  |                  |                  |
|--------------------------|-------------------------|-------------|-----|------------|----------------------------------------------------------------------------------------------------------------------------------|------------------|------------------|
| <a href="#">07797453</a> | Not Issued              |             | 161 | 11/22/1991 | GRAIN STREAM DAMPER APPARATUS FOR MOVABLE EQUIPMENT                                                                              | BOMBERG,KENNETH  | BAKER, BRUCE L.  |
| <a href="#">12105158</a> | <a href="#">7938193</a> | 20090260841 | 150 | 04/17/2008 | NOVEL VEHICLE MOUNTED EDGING DEVICE                                                                                              | TROUTMAN,MATTHEW | BAKER, BRUCE LEE |
| <a href="#">07430713</a> | <a href="#">5121777</a> |             | 150 | 11/01/1989 | VAPOR RECOVERY NOZZLES AND SUB-ASSEMBLIES THEREFOR                                                                               | JACYNA,J         | BAKER, BRUCE P.  |
| <a href="#">07883680</a> | <a href="#">5421382</a> |             | 250 | 05/15/1992 | VAPOR RECOVERY NOZZLES AND SUB-ASSEMBLIES THEREFOR                                                                               | JACYNA,J         | BAKER, BRUCE P.  |
| <a href="#">08453012</a> | <a href="#">5655576</a> |             | 250 | 05/30/1995 | VAPOR RECOVERY NOZZLES AND SUB-ASSEMBLIES THEREFOR                                                                               | JACYNA,J         | BAKER, BRUCE P.  |
| <a href="#">09621801</a> | Not Issued              |             | 161 | 07/21/2000 | Interactive library of text strings in an edit system                                                                            | STORK,KYLE       | BAKER, BRUCE R.  |
| <a href="#">09652035</a> | <a href="#">7194404</a> |             | 150 | 08/31/2000 | LINGUISTIC RETRIEVAL SYSTEM AND METHOD                                                                                           | SPOONER,LAMONT   | BAKER, BRUCE R.  |
| <a href="#">09652036</a> | <a href="#">7177797</a> |             | 150 | 08/31/2000 | LINGUISTIC RETRIEVAL SYSTEM AND METHOD                                                                                           | SPOONER,LAMONT   | BAKER, BRUCE R.  |
| <a href="#">09714442</a> | <a href="#">7318019</a> |             | 150 | 11/17/2000 | WORD OUTPUT DEVICE AND MATRIX KEYBOARD FOR USE THEREIN                                                                           | SPOONER,LAMONT   | BAKER, BRUCE R.  |
| <a href="#">09797179</a> | <a href="#">7076738</a> | 20020163544 | 150 | 03/02/2001 | COMPUTER DEVICE, METHOD AND ARTICLE OF MANUFACTURE FOR UTILIZING SEQUENCED SYMBOLS TO ENABLE PROGRAMMED APPLICATION AND COMMANDS | HAILU,TADESSE    | BAKER, BRUCE R.  |
| <a href="#">10426692</a> | <a href="#">7506256</a> | 20030210280 | 150 | 05/01/2003 | DEVICE AND METHOD FOR PREVIEWING THEMES AND CATEGORIES OF SEQUENCED SYMBOLS                                                      | HAILU,TADESSE    | BAKER, BRUCE R.  |
| <a href="#">10456716</a> | <a href="#">6822426</a> | 20040245970 | 150 | 06/06/2003 | REGULATOR WITH FEEDBACK VOLTAGE AND CURRENT SIGNAL SUMMING INTO CONTROLLER                                                       | RILEY,SHAWN      | BAKER, BRUCE R.  |

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| Application#             | Patent#                 | PG Pub#     | Status | Date Filed | Title                                                                                                                             | Examiner Name          | Inventor Name   |
|--------------------------|-------------------------|-------------|--------|------------|-----------------------------------------------------------------------------------------------------------------------------------|------------------------|-----------------|
| <a href="#">10989152</a> | Not Issued              | 20050108702 | 61     | 11/15/2004 | On-demand software module deployment                                                                                              | BUI,HANH               | BAKER, BRUCE R. |
| <a href="#">11342770</a> | <a href="#">7765485</a> | 20070192339 | 150    | 01/30/2006 | EXTENSIBLE USER INTERFACE FRAMEWORK FOR A COMPONENTIZED APPLICATION ENVIRONMENT                                                   | PHANTANA ANGKOOL,DAVID | BAKER, BRUCE R. |
| <a href="#">11365584</a> | Not Issued              | 20060148520 | 161    | 03/02/2006 | Computer device, method and article of manufacture for utilizing sequenced symbols to enable programmed applications and commands | HAILU,TADESSE          | BAKER, BRUCE R. |
| <a href="#">12000707</a> | Not Issued              | 20080183460 | 41     | 12/17/2007 | PICTORIAL KEYBOARD WITH POLYSEMOUS KEYS FOR CHINESE CHARACTER OUTPUT                                                              | STORK,KYLE             | BAKER, BRUCE R. |
| <a href="#">12076046</a> | Not Issued              | 20080233546 | 30     | 03/13/2008 | Visual scene displays, uses thereof, and corresponding apparatuses                                                                | UTAMA,ROBERT           | BAKER, BRUCE R. |
| <a href="#">12238135</a> | Not Issued              | 20100077380 | 41     | 09/25/2008 | FRAMEWORK FOR AUTOMATICALLY MERGING CUSTOMIZATIONS TO STRUCTURED CODE THAT HAS BEEN REFACTORED                                    | KENDALL,CHUCK          | BAKER, BRUCE R. |
| <a href="#">12320918</a> | Not Issued              | 20090150828 | 90     | 02/09/2009 | DEVICE AND METHOD FOR PREVIEWING THEMES AND CATEGORIES OF SEQUENCED SYMBOLS                                                       | HAILU,TADESSE          | BAKER, BRUCE R. |
| <a href="#">13293208</a> | Not Issued              | 0           | 20     | 11/10/2011 | SEQUENCED MULTI-MEANING TACTILE SYMBOLS USEABLE TO PRODUCE SYNTHETIC PLURAL WORD                                                  | ,                      | BAKER, BRUCE R. |

|                 |                |  |     |            |                                                                                |                |                 |
|-----------------|----------------|--|-----|------------|--------------------------------------------------------------------------------|----------------|-----------------|
|                 |                |  |     |            | MESSAGES INCLUDING WORDS, PHRASES AND SENTENCES                                |                |                 |
| <u>60907076</u> | Not Issued     |  | 159 | 03/19/2007 | Visual screen displays, uses thereof, and corresponding apparatuses            |                | BAKER, BRUCE R. |
| <u>06340287</u> | Not Issued     |  | 166 | 01/18/1982 | SYSTEM FOR METHOD FOR PRODUCING SYNTHETIC PLURAL WORD MESSAGES                 | KEMENY,EMANUEL | BAKER, BRUCE R. |
| <u>06659878</u> | Not Issued     |  | 166 | 10/15/1984 | SYSTEM FOR METHOD FOR PRODUCING SYNTHETIC PLURAL WORD MESSAGES                 | KEMENY,EMANUEL | BAKER, BRUCE R. |
| <u>06815196</u> | <u>4661916</u> |  | 150 | 12/27/1985 | SYSTEM FOR METHOD FOR PRODUCING SYNTHETIC PLURAL WORD MESSAGES                 | KEMENY,EMANUEL | BAKER, BRUCE R. |
| <u>07003464</u> | Not Issued     |  | 166 | 01/15/1987 | SYSTEM FOR METHOD FOR PRODUCING SYNTHETIC PLURAL WORD MESSAGES                 | KEMENY,EMANUEL | BAKER, BRUCE R. |
| <u>07325044</u> | Not Issued     |  | 166 | 03/16/1989 | SYSTEM FOR METHOD FOR PRODUCING SYNTHETIC PLURAL WORD MESSAGES                 | KEMENY,EMANUEL | BAKER, BRUCE R. |
| <u>07374869</u> | Not Issued     |  | 166 | 07/03/1989 | SYSTEM FOR METHOD FOR PRODUCING SYNTHETIC PLURAL WORD MESSAGES                 | KEMENY,EMANUEL | BAKER, BRUCE R. |
| <u>07536022</u> | <u>5097425</u> |  | 150 | 06/11/1990 | PREDICTIVE SCANNING INPUT SYSTEM FOR RAPID SELECTION OF VISUAL INDICATORS      | KEMENY,EMANUEL | BAKER, BRUCE R. |
| <u>07564835</u> | Not Issued     |  | 166 | 08/09/1990 | NATURAL LANGUAGE PROCESSING SYSTEM                                             | HAYES,GAIL     | BAKER, BRUCE R. |
| <u>07573276</u> | Not Issued     |  | 166 | 08/27/1990 | SYSTEM FOR METHOD FOR PRODUCING SYNTHETIC PLURAL WORD MESSAGES                 | KEMENY,EMANUEL | BAKER, BRUCE R. |
| <u>07633535</u> | <u>5210689</u> |  | 150 | 12/28/1990 | SYSTEM AND METHOD FOR AUTOMATICALLY SELECTING AMONG A PLURALITY OF INPUT MODES | HUNTLEY,DAVID  | BAKER, BRUCE R. |
| <u>07652255</u> | <u>5309546</u> |  | 250 | 02/06/1991 | SYSTEM FOR METHOD FOR PRODUCING SYNTHETIC PLURAL WORD MESSAGES                 | TUNG,KEE       | BAKER, BRUCE R. |

|                 |                |             |     |            |                                                                                                                                                           |                 |                      |
|-----------------|----------------|-------------|-----|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|----------------------|
| <u>07796926</u> | <u>5317671</u> |             | 250 | 11/22/1991 | SYSTEM FOR METHOD FOR PRODUCING SYNTHETIC PLURAL WORD MESSAGES                                                                                            | TUNG,KEE        | BAKER, BRUCE R.      |
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| <u>11781067</u> | <u>8036214</u> | 20080025294 | 150 | 07/20/2007 | VOICE OVER DATA TELECOMMUNICATIONS NETWORK ARCHITECTURE                                                                                                   | HARPER,KEVIN    | BAKER, BRUCE W.      |
| <u>11781098</u> | <u>8089958</u> | 20080025295 | 150 | 07/20/2007 | VOICE OVER DATA TELECOMMUNICATIONS NETWORK ARCHITECTURE                                                                                                   | HARPER,KEVIN    | BAKER, BRUCE W.      |
| <u>11781118</u> | <u>8085761</u> | 20080013531 | 150 | 07/20/2007 | VOICE OVER DATA TELECOMMUNICATIONS NETWORK                                                                                                                | HARPER,KEVIN    | BAKER, BRUCE W.      |



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|-----------------|----------------|-------------|-----|------------|------------------------------------------------------------------|---------------|-----------------------|
|                 |                |             |     |            | ARCHITECTURE                                                     |               |                       |
| <u>13341170</u> | Not<br>Issued  |             | 19  | 12/30/2011 | VOICE OVER DATA<br>TELECOMMUNICATIONS<br>NETWORK<br>ARCHITECTURE | ,             | BAKER,<br>BRUCE W.    |
| <u>09197203</u> | <u>6614781</u> |             | 150 | 11/20/1998 | VOICE OVER DATA<br>TELECOMMUNICATIONS<br>NETWORK<br>ARCHITECTURE | YAO,KWANG     | BAKER,<br>BRUCE W.    |
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| <u>06614455</u> | Not<br>Issued  |             | 161 | 05/25/1984 | PAPER CLAMP                                                      | SAKRAN,VICTOR | BAKERMAN,<br>BRUCE M. |

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|--------------------------|-------------------------|-------------|--------|------------|------------------------------------------------------------------------------------------|------------------|---------------|
| <a href="#">09481730</a> | <a href="#">6935344</a> |             | 250    | 01/11/2000 | METHODS AND SYSTEMS FOR PROVIDING RIGHT AND/OR LEFT HEART SUPPORT DURING CARDIAC SURGERY | MATTHEWS,WILLIAM | KANZ, WILLIAM |
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| <u>10070178</u> | <u>7022100</u> |             | 150 | 07/19/2002 | GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS                            | BIANCO,PATRICIA  | KANZ, WILLIAM R  |
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| <u>09889442</u> | <u>6974436</u> |             | 250 | 12/09/2002 | INTEGRATED PUMP AND CANNULA SYSTEM AND RELATED METHODS                           | BIANCO,PATRICIA  | KANZ, WILLIAM R. |
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| <a href="#">10021549</a> | Not Issued              | 20020045795 | 161 | 12/12/2001 | Pulmonary and circulatory blood flow support devices and methods for heart surgery procedures | MATTHEWS,WILLIAM | KANZ, WILLIAM RUSSELL |
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| <a href="#">10991255</a> | Not Issued              | 20050119599 | 161 | 11/17/2004 | Supplemental port for catheter perfusion of surgical site and methods of use                  | WIEST,PHILIP     | KANZ, WILLIAM RUSSELL |
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| <u>11870308</u> | <u>8029447</u> | 20080269572 | 150 | 10/10/2007 | MULTIPURPOSE<br>HOST SYSTEM FOR<br>INVASIVE<br>CARDIOVASCULAR<br>DIAGNOSTIC<br>MEASUREMENT<br>ACQUISITION<br>INCLUDING AN<br>ENHANCED<br>DYNAMICALLY<br>CONFIGURED<br>GRAPHICAL<br>DISPLAY | NATNITHITHADHA,NAVIN | KANZ,<br>WILLIAM<br>RUSSELL |
| <u>13222920</u> | Not<br>Issued  | 20110319773 | 20  | 08/31/2011 | Multipurpose Host<br>System for Invasive<br>Cardiovascular<br>Diagnostic<br>Measurement<br>Acquisition Including<br>an Enhanced<br>Dynamically<br>Configured Graphical<br>Display          | ,                    | KANZ,<br>WILLIAM<br>RUSSELL |
| <u>60828961</u> | Not<br>Issued  |             | 159 | 10/10/2006 | MULTIPURPOSE<br>HOST SYSTEM FOR<br>INVASIVE<br>CARDIOVASCULAR<br>DIAGNOSTIC<br>MEASUREMENT<br>ACQUISITION<br>INCLUDING AN<br>ENHANCED<br>DYNAMICALLY<br>CONFIGURED<br>GRAPHICAL<br>DISPLAY | ,                    | KANZ,<br>WILLIAM<br>RUSSELL |
| <u>09079836</u> | <u>6395026</u> |             | 150 | 05/15/1998 | APPARATUS AND<br>METHODS FOR<br>BEATING HEART<br>BYPASS SURGERY                                                                                                                            | MILANO,MICHAEL       | KANZ,<br>WILLIAM<br>RUSSELL |
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| <u>09164395</u> | <u>6113536</u> |             | 150 | 09/30/1998 | DEVICE AND<br>METHOD OF<br>ATTACHING A<br>BLOOD PUMP AND<br>TUBES TO A<br>SURGICAL<br>RETRACTOR                                                                                            | HIRSCH,PAUL          | KANZ,<br>WILLIAM<br>RUSSELL |

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| 09164397 | 6234960 |  | 250 | 09/30/1998 | HEART<br>STABILIZER<br>APPARATUS | PRIDDY,MICHAEL | KANZ,<br>WILLIAM<br>RUSSELL |
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|--------------------------|-------------------------|-------------|--------|------------|-----------------------------------------------------------------------------------------------|-----------------|-----------------------|
| <a href="#">09164407</a> | Not Issued              |             | 161    | 09/30/1998 | BLOOD PUMP SYSTEM WITH MAGNETIC CABLE DRIVE                                                   | FREAY,CHARLES   | KANZ, WILLIAM RUSSELL |
| <a href="#">09166135</a> | <a href="#">6210133</a> |             | 150    | 09/30/1998 | BLOOD PUMP WITH STERILE MOTOR HOUSING                                                         | FREAY,CHARLES   | KANZ, WILLIAM RUSSELL |
| <a href="#">09229806</a> | <a href="#">6210397</a> |             | 150    | 01/13/1999 | SEALING CANNULA DEVICE                                                                        | SIRMONS,KEVIN   | KANZ, WILLIAM RUSSELL |
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| <a href="#">60115786</a> | Not Issued              |             | 159    | 01/13/1999 | INTEGRATED CANNULA AND PUMP ASSEMBLY                                                          |                 | KANZ, WILLIAM RUSSELL |

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| <p style="text-align: center;"><b>AMENDMENT UNDER<br/>37 C.F.R. §1.111</b></p> <p style="text-align: center;">Address to:<br/>Commissioner for Patents<br/>P.O. Box 1450<br/>Alexandria, VA 22313-1450</p> | Attorney Docket      | 06-01506US04                                          |
|                                                                                                                                                                                                            | Confirmation No.     | 4661                                                  |
|                                                                                                                                                                                                            | First Named Inventor | Aboul-Hosn, Walid N.                                  |
|                                                                                                                                                                                                            | Application Number   | 12/772,810                                            |
|                                                                                                                                                                                                            | Filing Date          | 05/03/2010                                            |
|                                                                                                                                                                                                            | Group Art Unit       | 3766                                                  |
|                                                                                                                                                                                                            | Examiner Name        | MARCETICH, ADAM M                                     |
|                                                                                                                                                                                                            | Title                | Guidable Intravascular Blood Pump and Related Methods |

Sir:

This amendment is responsive to the Office Action dated February 17, 2012 for which a three-month period for response was given making this response due on or before May 17, 2012. A Petition for a two-month extension of time is being filed concurrently herewith to extend the response date to July 17, 2012. In view of the amendments to the claims and the remarks put forth below, reconsideration and allowance are respectfully requested.

The **Claims** begin on page 2.

**Remarks** being on page 5.

## AMENDMENTS TO THE CLAIMS

Claims 1 – 14 (Cancelled)

15. (Currently Amended) An intravascular blood pump system, comprising:  
an intravascular blood pump ~~including~~ comprising a rotor, a shroud within which said rotor is rotatably disposed, and an elongate and flexible drive member ~~eable~~-coupled to said rotor for driving said rotor within said shroud; ~~and~~  
a cannula extending from the shroud and comprising an outer cannula surface, the outer cannula surface having a substantially circular cross-section along a portion of its length;  
and  
a guide mechanism adapted to guide a distal portion of said intravascular blood pump system to a predetermined location within the circulatory system of a patient;  
wherein said guide mechanism is positioned along a length of the cannula and interior to a region delimited by the outer cannula surface, wherein the guide mechanism is configured to ~~accept~~ allow for a guide wire to slideably advance therealong for passage through a side lumen formed in said distal portion of said intravascular blood pump system.

16 – 22 (Cancelled)

23. (New) The intravascular blood pump system of claim 15, wherein the rotor comprises a rotor hub and a blade extending radially from the rotor hub.
24. (New) The intravascular blood pump system of claim 15, wherein the guide mechanism further comprises a lumen having a diameter larger than a diameter of the guide wire.
25. (New) The intravascular blood pump system of claim 15, wherein the guide mechanism is configured such that the guide wire is in slidable contact with the guide mechanism over a length that is shorter than the length of the cannula.
26. (New) The intravascular blood pump system of claim 15, further comprising a guide

catheter, wherein the cannula and intravascular blood pump are too large to pass through the guide catheter.

27. (New) The intravascular blood pump system of claim 15, further comprising:  
a sheath surrounding a length of the drive; and  
a blood pressure detection mechanism comprising a fluid column configured to detect the pressure of the blood proximate the intravascular blood pump.
28. (New) The intravascular blood pump system of claim 27, further comprising:  
a sheath surrounding a length of the drive;  
wherein the fluid column is disposed between the sheath and the drive member.
29. (New) An intravascular blood pump system comprising:  
an intravascular blood pump coupled to a catheter on a proximal end and a cannula on a distal end, the catheter including one or more apertures adjacent a distal end of the catheter;  
a guide mechanism adapted to guide said intravascular blood pump, cannula, and catheter to a predetermined location within the circulatory system of a patient; and  
a blood pressure detection mechanism comprising a fluid column configured to detect the pressure of the blood proximate the intravascular blood pump.
30. (New) The intravascular blood pump system of claim 29, wherein the guide mechanism comprises a guide wire, the blood pump system configured such that it is guidable in the circulatory system over the guide wire passing through a lumen in the cannula but not extending through the catheter.
31. (New) The intravascular blood pump system of claim 29, wherein the cannula is reinforced with a spiral wire.
32. (New) The intravascular blood pump system of claim 31, wherein the spiral wire is embedded in a wall of the cannula.
33. (New) The intravascular blood pump system of claim 29, further comprising a guide

catheter configured to be guidable through the vasculature into the heart, the cannula and intravascular blood pump too large to pass through the guide catheter.

34. (New) The intravascular blood pump system of claim 29, further comprising a rotor.
35. (New) The intravascular blood pump system of claim 34, wherein the rotor comprises a rotor hub and a blade extending radially from the rotor hub.
36. (New) The intravascular blood pump system of claim 29, wherein the cannula comprises an outer cannula surface having a substantially circular cross-section along a portion of its length.
37. (New) The intravascular blood pump system of claim 29, further comprising a plurality of egress flow ports disposed in the shroud, and a plurality of ingress flow ports disposed in the cannula and distal to the egress flow ports.
38. (New) The intravascular blood pump system of claim 37, wherein the ingress flow ports comprise an end port located at the cannula distal end and a plurality of ports located about the cannula and proximal to the end port.
39. (New) The intravascular blood pump system of claim 34, wherein the egress ports are configured to direct blood passing through the cannula and towards the rotor in a direction that is both proximal and radially outward with respect to the rotor hub.
40. (New) The intravascular blood pump system of claim 29, wherein the guide mechanism comprises a central lumen.
41. (New) The intravascular blood pump system of claim 29, wherein the central lumen extends through the cannula and blood pump.

## **REMARKS**

### **Formal Matters**

Claims 15 and 23 - 41 are pending after entry of the amendments set forth herein.

Claims 2-14 and 16 – 22 have been canceled without prejudice to the possibility of filing one or more continuing applications directed to the subject matter recited therein.

Claims 2 – 22 were examined. Claims 2 – 22 were rejected.

Claim 15 has been amended and claims 23 – 41 are new.

Support for new claims 23, 34 and 35 can be found throughout the specification and drawings, including for example paragraph [0065].

Support for new claim 24 can be found throughout the specification and drawings, including for example Figures 4, 8, and 9.

Support for new claim 25 can be found throughout the specification and drawings, including for example Figures 6 and 7.

Support for new claims 26 and 33 can be found throughout the specification and drawings, including for example paragraphs [0060], [0063] and [0077].

Support for new claims 27, 28 and 29 can be found throughout the specification and drawings, including for example paragraphs [0024], [0025] and [0026].

Support for new claim 30 can be found throughout the specification and drawings, including for example paragraph [0072] through [0075] and Figures 6 through 9.

Support for new claims 31 and 32 can be found throughout the specification and drawings, including for example paragraph [0066].

Support for new claims 34 and 35 can be found throughout the specification and drawings, including for example paragraphs [0062], [0064] through [0067], [0064], [0069], [0077], [0080], [0082] and [0085].

Support for new claim 36 can be found throughout the specification and drawings, including for example paragraph [0074] and Figure 9.

Support for new claims 37 - 39 can be found throughout the specification and drawings, including for example paragraph [0062] and Figures 3, 10 and 15.

Support for new claims 40 and 41 can be found throughout the specification and drawings, including for example paragraph[0010] , [0059], [0063], [0065] and Figures 1 through 6.

No new matter has been added.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

## **The Office Action**

### **I. Claims Rejected Under 35 U.S.C. Section 103(a) (Summers et al. in view of Bagaoisan et al.)**

In the office action dated February 17, 2012 (herein the Office Action), claims 2-4, 15, 20 and 21 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Summers et al. (US Patent 5,112,349) in view of Bagaoisan et al (US Patent 6,849,068).

Claims 2 - 4, 20 and 21 have been cancelled without prejudice or disclaimer.

With respect to claim 15, the Examiner asserts that Summers et al. and Bagaoisan et al. teach all of the elements of the claimed invention and that it would have been obvious to combine Summers et al. and Bagaoisan et al. to achieve the claimed invention.

Applicants respectfully disagree with the Examiner's interpretation of the cited references, however in light of the amendments made to claim 15, this rejection does not anticipate or render obvious the currently claimed invention.

Claim 15 as amended recites among other things, "a cannula extending from the shroud and comprising an outer cannula surface, the outer cannula surface having a substantially circular cross-section along a portion of its length", "a guide mechanism adapted to guide a distal portion of said intravascular blood pump system to a predetermined location within the circulatory system of a patient," and "wherein said guide mechanism is positioned along a length of the cannula and interior to a region delimited by the outer cannula surface." Applicants respectfully submit that neither Summers et al., nor Bagaoisan et al., individually or in any proper combination disclose, teach or suggest the amended claim.

New claims 23 through 28 depend from independent claim 15, and are allowable for at least the same reasons as their base claim.

Withdrawal of the rejection is respectfully requested.



**II. Claims Rejected Under 35 U.S.C. Section 103(a) (Summers et al., in view of Bagaoisan et al.), further in view of Moise;**

In the Official Action, claims 6, 7, 9-14, 16-19 and 22 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Summers et al. (US Patent 5,112,349) in view of Bagaoisan et al (US Patent 6,849,068), in further view of Moise (US Pat. 4,895,557).

In light of the cancellation of claims 6, 7, 9-14, 16-19 and 22, the Examiner's rejection is now moot.

**III. Claims Rejected Under 35 U.S.C. Section 103(a) (Summers et al., in view of Bagaoisan et al.), further in view of Moise;**

In the Official Action, claim 8 has been rejected under 35 U.S.C. being unpatentable over Summers et al. (US Patent 5,112,349) in view of Bagaoisan et al (US Patent 6,849,068), in view of Moise (US Pat. 4,895,557), in further in view of Saab (US Pat. 6,440,158).

In light of the cancellation of claim 8, the Examiner's rejection is now moot.

**IV. Claims Rejected On the Ground of Non-statutory Obviousness-Type Double Patenting (U.S. Patent 7,022,100)**

In the Official Action at #20, claim 2 – 7, 15, 16 and 20 have been rejected on the ground of non-statutory obviousness type double patenting as being unpatentable over claims 1, 4 – 6, 9, 12, and 15 of U.S. Patent 7,022,100 to Aboul-Hosn (herein Aboul-Hosn '100).

Applicants respectfully request that any Double Patenting rejection be held in abeyance until allowable subject matter is indicated.

**V. New Claims 23 - 41**

New claims 23 - 41 have been submitted above, of which claim 29 is independent. The Examiner is respectfully requested to indicate the allowance of independent claims 15 and 29, as well as their dependent claims 23 – 28 and 30 – 41 in the next Official Action.

**Conclusion**

Applicants have made a good faith effort to place the claims in condition for allowance. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-5722, order number 06-01506US04.

Respectfully submitted,

Date: July 17, 2012

/Kirk D. Swenson/  
Kirk D. Swenson  
(Reg. No. 52,265)

Maquet Cardiovascular LLC  
1300 MacArthur Boulevard  
Mahwah, NJ 07470  
Telephone: 201-995-8816

## Electronic Patent Application Fee Transmittal

|                                                |                                                       |                 |               |                             |
|------------------------------------------------|-------------------------------------------------------|-----------------|---------------|-----------------------------|
| <b>Application Number:</b>                     | 12772810                                              |                 |               |                             |
| <b>Filing Date:</b>                            | 03-May-2010                                           |                 |               |                             |
| <b>Title of Invention:</b>                     | Guidable Intravascular Blood Pump and Related Methods |                 |               |                             |
| <b>First Named Inventor/Applicant Name:</b>    | Walid N. Aboul-Hosn                                   |                 |               |                             |
| <b>Filer:</b>                                  | Kirk D. Swenson                                       |                 |               |                             |
| <b>Attorney Docket Number:</b>                 | 06-01506US04                                          |                 |               |                             |
| Filed as Large Entity                          |                                                       |                 |               |                             |
| <b>Utility under 35 USC 111(a) Filing Fees</b> |                                                       |                 |               |                             |
| <b>Description</b>                             | <b>Fee Code</b>                                       | <b>Quantity</b> | <b>Amount</b> | <b>Sub-Total in USD(\$)</b> |
| <b>Basic Filing:</b>                           |                                                       |                 |               |                             |
| <b>Pages:</b>                                  |                                                       |                 |               |                             |
| <b>Claims:</b>                                 |                                                       |                 |               |                             |
| <b>Miscellaneous-Filing:</b>                   |                                                       |                 |               |                             |
| <b>Petition:</b>                               |                                                       |                 |               |                             |
| <b>Patent-Appeals-and-Interference:</b>        |                                                       |                 |               |                             |
| <b>Post-Allowance-and-Post-Issuance:</b>       |                                                       |                 |               |                             |
| <b>Extension-of-Time:</b>                      |                                                       |                 |               |                             |
| Extension- 2 months with \$0 paid              | 1252                                                  | 1               | 560           | 560                         |

| Description       | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
|-------------------|----------|----------|--------|----------------------|
| Miscellaneous:    |          |          |        |                      |
| Total in USD (\$) |          |          |        | 560                  |

## Electronic Acknowledgement Receipt

|                                             |                                                       |
|---------------------------------------------|-------------------------------------------------------|
| <b>EFS ID:</b>                              | 13276866                                              |
| <b>Application Number:</b>                  | 12772810                                              |
| <b>International Application Number:</b>    |                                                       |
| <b>Confirmation Number:</b>                 | 4661                                                  |
| <b>Title of Invention:</b>                  | Guidable Intravascular Blood Pump and Related Methods |
| <b>First Named Inventor/Applicant Name:</b> | Walid N. Aboul-Hosn                                   |
| <b>Customer Number:</b>                     | 99185                                                 |
| <b>Filer:</b>                               | Kirk D. Swenson                                       |
| <b>Filer Authorized By:</b>                 |                                                       |
| <b>Attorney Docket Number:</b>              | 06-01506US04                                          |
| <b>Receipt Date:</b>                        | 17-JUL-2012                                           |
| <b>Filing Date:</b>                         | 03-MAY-2010                                           |
| <b>Time Stamp:</b>                          | 23:51:12                                              |
| <b>Application Type:</b>                    | Utility under 35 USC 111(a)                           |

### Payment information:

|                                          |             |
|------------------------------------------|-------------|
| Submitted with Payment                   | yes         |
| Payment Type                             | Credit Card |
| Payment was successfully received in RAM | \$560       |
| RAM confirmation Number                  | 7149        |
| Deposit Account                          |             |
| Authorized User                          |             |

### File Listing:

| Document Number | Document Description | File Name | File Size(Bytes)/<br>Message Digest | Multi<br>Part / .zip | Pages<br>(if appl.) |
|-----------------|----------------------|-----------|-------------------------------------|----------------------|---------------------|
| Page 201 of 698 |                      |           |                                     |                      |                     |

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| <b>Warnings:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                          |                           |                                                        |    |   |
| <b>Information:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                          |                           |                                                        |    |   |
| 2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Fee Worksheet (SB06)                                     | fee-info.pdf              | 30623<br>aff837d352dd0771588596dd9dob1e8b12c<br>50970  | no | 2 |
| <b>Warnings:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                          |                           |                                                        |    |   |
| <b>Information:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                          |                           |                                                        |    |   |
| <b>Total Files Size (in bytes):</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                          |                           | 139622                                                 |    |   |
| <p><b>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</b></p> <p><b><u>New Applications Under 35 U.S.C. 111</u></b><br/> <b>If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</b></p> <p><b><u>National Stage of an International Application under 35 U.S.C. 371</u></b><br/> <b>If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</b></p> <p><b><u>New International Application Filed with the USPTO as a Receiving Office</u></b><br/> <b>If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</b></p> |                                                          |                           |                                                        |    |   |

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| <b>PATENT APPLICATION FEE DETERMINATION RECORD</b><br>Substitute for Form PTO-875                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                               |                                  |            |                                    | Application or Docket Number<br><b>12/772,810</b> |                 | Filing Date<br><b>05/03/2010</b> |                                         | <input type="checkbox"/> To be Mailed |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|------------|------------------------------------|---------------------------------------------------|-----------------|----------------------------------|-----------------------------------------|---------------------------------------|---------------------|
| <b>APPLICATION AS FILED – PART I</b>                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                               |                                  |            |                                    |                                                   |                 |                                  |                                         |                                       |                     |
| (Column 1)                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                               |                                  | (Column 2) |                                    | SMALL ENTITY <input type="checkbox"/> OR          |                 |                                  | OTHER THAN SMALL ENTITY                 |                                       |                     |
| FOR                                                                                                                                                                                                                                                                                                                                                                                                               | NUMBER FILED                                                                                                                                                                                                                  | NUMBER EXTRA                     | RATE (\$)  | FEE (\$)                           | OR                                                | RATE (\$)       | FEE (\$)                         |                                         |                                       |                     |
| <input type="checkbox"/> BASIC FEE<br>(37 CFR 1.16(a), (b), or (c))                                                                                                                                                                                                                                                                                                                                               | N/A                                                                                                                                                                                                                           | N/A                              | N/A        |                                    |                                                   | N/A             |                                  |                                         |                                       |                     |
| <input type="checkbox"/> SEARCH FEE<br>(37 CFR 1.16(k), (l), or (m))                                                                                                                                                                                                                                                                                                                                              | N/A                                                                                                                                                                                                                           | N/A                              | N/A        |                                    |                                                   | N/A             |                                  |                                         |                                       |                     |
| <input type="checkbox"/> EXAMINATION FEE<br>(37 CFR 1.16(o), (p), or (q))                                                                                                                                                                                                                                                                                                                                         | N/A                                                                                                                                                                                                                           | N/A                              | N/A        |                                    |                                                   | N/A             |                                  |                                         |                                       |                     |
| TOTAL CLAIMS<br>(37 CFR 1.16(j))                                                                                                                                                                                                                                                                                                                                                                                  | minus 20 =                                                                                                                                                                                                                    | *                                | X \$       | =                                  |                                                   | X \$            | =                                |                                         |                                       |                     |
| INDEPENDENT CLAIMS<br>(37 CFR 1.16(h))                                                                                                                                                                                                                                                                                                                                                                            | minus 3 =                                                                                                                                                                                                                     | *                                | X \$       | =                                  |                                                   | X \$            | =                                |                                         |                                       |                     |
| <input type="checkbox"/> APPLICATION SIZE FEE<br>(37 CFR 1.16(s))                                                                                                                                                                                                                                                                                                                                                 | If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s). |                                  |            |                                    |                                                   |                 |                                  |                                         |                                       |                     |
| <input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                               |                                  |            |                                    |                                                   |                 |                                  |                                         |                                       |                     |
|                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                               |                                  | TOTAL      |                                    |                                                   | TOTAL           |                                  |                                         |                                       |                     |
| * If the difference in column 1 is less than zero, enter "0" in column 2.                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                               |                                  |            |                                    |                                                   |                 |                                  |                                         |                                       |                     |
| <b>APPLICATION AS AMENDED – PART II</b>                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                               |                                  |            |                                    |                                                   |                 |                                  |                                         |                                       |                     |
| (Column 1)                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                               |                                  | (Column 2) |                                    | (Column 3)                                        |                 |                                  | SMALL ENTITY OR OTHER THAN SMALL ENTITY |                                       |                     |
| <b>AMENDMENT</b>                                                                                                                                                                                                                                                                                                                                                                                                  | <b>07/17/2012</b>                                                                                                                                                                                                             | CLAIMS REMAINING AFTER AMENDMENT |            | HIGHEST NUMBER PREVIOUSLY PAID FOR | PRESENT EXTRA                                     | RATE (\$)       | ADDITIONAL FEE (\$)              | OR                                      | RATE (\$)                             | ADDITIONAL FEE (\$) |
|                                                                                                                                                                                                                                                                                                                                                                                                                   | Total (37 CFR 1.16(i))                                                                                                                                                                                                        | * 20                             | Minus      | ** 20                              | = 0                                               | X \$            | =                                |                                         | X \$60=                               | 0                   |
|                                                                                                                                                                                                                                                                                                                                                                                                                   | Independent (37 CFR 1.16(h))                                                                                                                                                                                                  | * 2                              | Minus      | ***3                               | = 0                                               | X \$            | =                                |                                         | X \$250=                              | 0                   |
|                                                                                                                                                                                                                                                                                                                                                                                                                   | <input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))                                                                                                                                                                |                                  |            |                                    |                                                   |                 |                                  |                                         |                                       |                     |
|                                                                                                                                                                                                                                                                                                                                                                                                                   | <input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))                                                                                                                                      |                                  |            |                                    |                                                   |                 |                                  |                                         |                                       |                     |
|                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                               |                                  |            |                                    |                                                   | TOTAL ADD'L FEE |                                  |                                         | TOTAL ADD'L FEE                       | <b>0</b>            |
| <b>AMENDMENT</b>                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                               | CLAIMS REMAINING AFTER AMENDMENT |            | HIGHEST NUMBER PREVIOUSLY PAID FOR | PRESENT EXTRA                                     | RATE (\$)       | ADDITIONAL FEE (\$)              | OR                                      | RATE (\$)                             | ADDITIONAL FEE (\$) |
|                                                                                                                                                                                                                                                                                                                                                                                                                   | Total (37 CFR 1.16(i))                                                                                                                                                                                                        | *                                | Minus      | **                                 | =                                                 | X \$            | =                                |                                         | X \$                                  | =                   |
|                                                                                                                                                                                                                                                                                                                                                                                                                   | Independent (37 CFR 1.16(h))                                                                                                                                                                                                  | *                                | Minus      | ***                                | =                                                 | X \$            | =                                |                                         | X \$                                  | =                   |
|                                                                                                                                                                                                                                                                                                                                                                                                                   | <input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))                                                                                                                                                                |                                  |            |                                    |                                                   |                 |                                  |                                         |                                       |                     |
|                                                                                                                                                                                                                                                                                                                                                                                                                   | <input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))                                                                                                                                      |                                  |            |                                    |                                                   |                 |                                  |                                         |                                       |                     |
|                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                               |                                  |            |                                    |                                                   | TOTAL ADD'L FEE |                                  |                                         | TOTAL ADD'L FEE                       |                     |
| * If the entry in column 1 is less than the entry in column 2, write "0" in column 3.<br>** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".<br>*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".<br>The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1. |                                                                                                                                                                                                                               |                                  |            |                                    |                                                   |                 |                                  |                                         |                                       |                     |

Legal Instrument Examiner:  
/ANGELA s. WHITE/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 12/772,810      | 05/03/2010  | Walid N. Aboul-Hosn  | 06-01506US04        | 4661             |

99185 7590 08/28/2012  
MAQUET Cardiovascular LLC  
170 Baytech Drive  
San Jose, CA 95134

|          |
|----------|
| EXAMINER |
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MARCETICH, ADAM M

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3761

|                   |               |
|-------------------|---------------|
| NOTIFICATION DATE | DELIVERY MODE |
|-------------------|---------------|

08/28/2012

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

legal@maquet.com



|                                                    |                                      |                                          |  |
|----------------------------------------------------|--------------------------------------|------------------------------------------|--|
| <b><i>Examiner-Initiated Interview Summary</i></b> | <b>Application No.</b><br>12/772,810 | <b>Applicant(s)</b><br>ABOUL-HOSN ET AL. |  |
|                                                    | <b>Examiner</b><br>ADAM MARCETICH    | <b>Art Unit</b><br>3761                  |  |

All participants (applicant, applicant's representative, PTO personnel):

(1) Kirk Swenson, Applicant's Representative.                      (3) Adam Marcetich.

(2) Abraham Ronai, Applicant's Representative.                      (4) \_\_\_\_.

Date of Interview: 17 August 2012.

Type:    ☒ Telephonic    ☐ Video Conference  
           ☐ Personal [copy given to: ☐ applicant    ☐ applicant's representative]

Exhibit shown or demonstration conducted:    ☐ Yes    ☐ No.  
           If Yes, brief description: \_\_\_\_\_.

Issues Discussed    ☐ 101    ☐ 112    ☐ 102    ☐ 103    ☒ Others  
 (For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: 26-29 and 33.

Identification of prior art discussed: \_\_\_\_\_.

**Substance of Interview**  
 (For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

See Continuation Sheet.

**Applicant recordation instructions:** It is not necessary for applicant to provide a separate record of the substance of interview.

**Examiner recordation instructions:** Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

|                                             |  |
|---------------------------------------------|--|
| /Adam Marcetich/<br>Examiner, Art Unit 3761 |  |
|---------------------------------------------|--|

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:

Examiner requested clarification for claims 26 and 33, which call for “guide catheter, wherein the cannula and intravascular blood pump are too large to pass through the guide catheter”

Examiner notes that the specification describes a guide catheter (¶ [0077], Fig. 12, guide catheter 132). This embodiment calls for a guide catheter 132 which is joined to a cannula 14. Pump body 34 is sized to fit within the guide catheter as shown in Fig. 13. This description does not appear to correspond to claims 26 and 33, which require that “the cannula and intravascular blood pump are too large to pass through the guide catheter.”

Examiner inquired as to which figures in the drawing sheets illustrate the guide catheter described in claims 26 and 33. Applicants noted that the guide catheter is not depicted in any figures, and asserted that a description can be found in ¶ [0059]. Applicants explained that a guide catheter is the first structure which positions the guide wire. However, Examiner finds no description of a guide catheter which positions the guide wire.

Examiner requested clarification for claims 27-29, which call for “a blood pressure detection mechanism comprising a fluid column” and a “fluid column is disposed between the sheath and the drive member.” The specification references another application for pressure sensing (¶ [0094]). Application 09/280,970, published as Aboul-Hosn; Walid N. et al. (US 6295877), describes pressures measured in Venturi tubes, but does not describe pressure measured in a fluid column. Applicants noted that support for the fluid column is found in ¶ [0025].

Examiner thanks Applicants for clarifying the nature of the invention.

|                              |                                      |                                          |  |
|------------------------------|--------------------------------------|------------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>12/772,810 | <b>Applicant(s)</b><br>ABOUL-HOSN ET AL. |  |
|                              | <b>Examiner</b><br>ADAM MARCETICH    | <b>Art Unit</b><br>3761                  |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2012.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) 15 and 23-41 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 15 and 23-41 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 03 May 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                     |                                                                    |
|-------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>20120809</u> .                           |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application  |
| Paper No(s)/Mail Date ____.                                                         | 6) <input type="checkbox"/> Other: ____.                           |

## DETAILED ACTION

### *Priority*

1. The present application 12/772,810 is a continuation of 11/375,926 filed 15 March 2006;  
  
which is a division of 10/070,178 filed 19 July 2002;  
  
which is a national stage entry of PCT/US00/24515 filed 01 September 2000;  
  
which claims priority from provisional 60/152249 filed 03 September 1999.
2. Claim 15 has been amended to call for a guide mechanism described in the specification (¶ [0074], Fig. 9, guide carriage 124 formed along the interior surface of the cannula 14). This limitation does not appear in any correspondence filed with the original priority application 60/152249. It first appears in PCT/US00/24515.
3. Claim 29 calls for a blood pressure detection mechanism comprising a fluid column. This limitation also appears initially in PCT/US00/24515.
4. Therefore claims 15 and 23-41 are granted a priority date of 01 September 2000.

### ***Claim Rejections - 35 USC § 112 First Paragraph***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
6. Claims 26 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

7. Claims 26 and 33 call for “a guide catheter configured to be guidable through the vasculature into the heart, the cannula and intravascular blood pump too large to pass through the guide catheter.” The specification describes a guide catheter (¶ [0077], Fig. 12, guide catheter 132). However, this catheter does not match the description of claims 26 and 33, since pump body 34 is sized to fit within the guide catheter as shown in Fig. 13.

During a telephone interview Friday, 17 August 2012, Examiner inquired as to which figures in the drawing sheets illustrate the guide catheter described in claims 26 and 33. Applicants noted that the guide catheter is not depicted in any figures, and asserted that a description can be found in ¶ [0059]. Applicants explained that a guide catheter is the first structure which positions the guide wire. However, Examiner finds no description of a guide catheter which positions the guide wire. Therefore, the descriptions in the specification raise doubt as to possession of the claimed invention at the time of filing.

***Claim Rejections - 35 USC § 112 Second Paragraph***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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9. Claims 37 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 37 recites the limitation ". . .a plurality of egress flow ports disposed in the shroud. . ." in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 37 depends on claim 29, which only recites a catheter and cannula. Figs. 12 and 13 of the drawings depicts apertures 138 in guide catheter 132, therefore Examiner interprets the "shroud" of claim 37 as the claimed "catheter" of claim 29.

11. Claim 39 recites the limitation "wherein the egress ports are configured to direct blood. . ." in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 39 depends on claims 34 and 29, which lack "egress ports." Instead, only claim 37 recites "egress ports."

### ***Claim Objections***

12. Claims 27 and 28 objected to because of the following informalities: each claim calls for ". . .a sheath surrounding a length of the drive. . ." However, claim 15 provides antecedent basis for a "drive member." Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claims 15 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Summers; David P. et al. (US 5112349) in view of Gordon; Lucas S. (US 5938645).

16. Regarding claim 15, Summers discloses an intravascular blood pump system (col. 1, lines 8-12, col. 3, lines 4-8, Fig. 1, pump 14), comprising:

an intravascular blood pump comprising a rotor and a shroud within which said rotor is rotatably disposed (col. 3, lines 49-68, Fig. 3, rotor 42 disposed in housing 36); and

an elongate and flexible drive member coupled to said rotor for driving said rotor within said shroud (col. 3, lines 64-68, Fig. 3, flexible drive shaft 30);

a cannula extending from the shroud and comprising an outer cannula surface (col. 3, lines 49-55, Fig. 3, intake end 32 forming outer surface);

the outer cannula surface having a substantially circular cross-section along a portion of its length (col. 3, lines 49-55, Fig. 3, intake end 32 having cone-like profile and therefore a circular cross-section along at least a portion of its length).

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17. Summers teaches the device substantially as claimed by Applicant with the exception of a guide mechanism. Gordon discloses a system for removing thrombi (col. 4, lines 53-61, col. 8, lines 13-22, Fig. 1, catheter 12), comprising:

a cannula (col. 8, lines 23-32, Fig. 5a, catheter 18);

a guide mechanism adapted to guide a distal portion of said catheter to a predetermined location within the circulatory system of a patient (col. 9, lines 1-4, Fig. 5c, internal guidewire lumen 46);

wherein said guide mechanism is positioned along a length of the cannula and interior to a region delimited by the outer cannula surface (Fig. 5a, guidewire lumen 46 positioned along length of catheter 18);

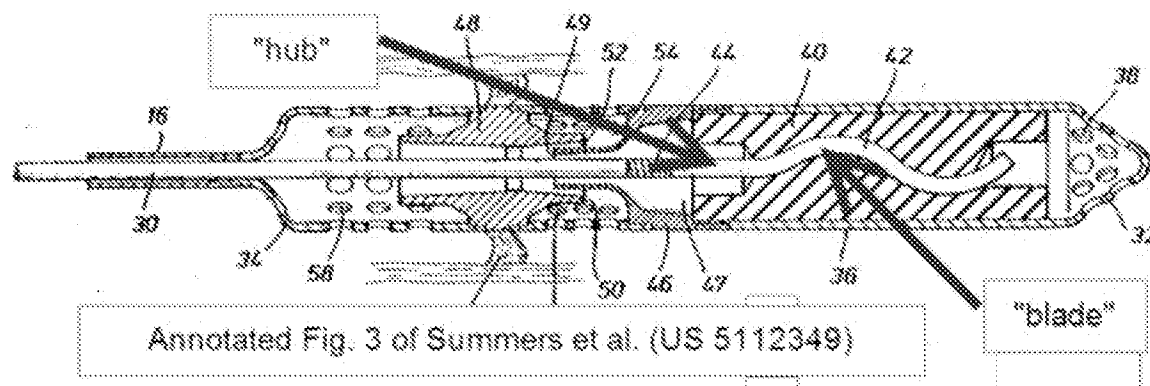
wherein the guide mechanism is configured to allow for a guide wire to slideably advance therealong (col. 2, lines 57-63, catheter following guidewire around bends and restrictions).

Gordon guides a larger cannula through tight bends by positioning means for capturing a guidewire on the side of the cannula (col. 5, lines 5-22, especially lines 20-22). One would be motivated to modify Summers with the guide mechanism as taught by Gordon to maneuver a catheter through winding vessels since Summers calls for manipulating a pump catheter from an incision in a femoral artery to the heart (col. 3, lines 4-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Summers as discussed with the guide mechanism of Gordon in order to deliver a cannula through vessels.



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18. Regarding claim 23, Summers discloses the rotor comprises a rotor hub and a blade extending radially from the rotor hub (Fig. 3, pump having hub and blade).



19. Regarding claims 24 and 25, Summers teaches the device substantially as claimed by Applicant with the exception of a guide mechanism. Gordon discloses:

the guide mechanism further comprises a lumen having a diameter larger than a diameter of the guide wire (Fig. 5a, guidewire 14 having smaller diameter than guidewire lumen 46);

the guide mechanism is configured such that the guide wire is in slideable contact with the guide mechanism over a length that is shorter than the length of the cannula (Fig. 5a, guidewire lumen 46 extending over only distal tip of catheter 18).

Gordon provides the structures required to guide a larger catheter through the vascular system. Regarding rationale and motivation to modify Summers in view of Gordon, see discussion of claim 15 above.

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20. Regarding claim 26, Summers discloses the invention substantially as claimed including a cannula and intravascular blood pump (Fig. 3, intake end 32 and rotor 42). However, Summers lacks a guide catheter. Gordon discloses a guide catheter (col. 11, lines 35-49, Fig. 13, fixed guide wire tip 120);

wherein the main catheter is too large to pass through the guide catheter (Fig. 13, fixed guide wire tip 120 smaller than catheter 18).

Gordon forms a guide mechanism that does not occupy space within the lumen of a main catheter, while allowing the main catheter to navigate through tortuous vessels (col. 11, lines 42-49). Therefore it would have been obvious to modify the invention of Summers with the guide catheter of Gordon in order to navigate a catheter while preserving high flow rates in the blood pump.

21. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Summers; David P. et al. (US 5112349) in view of Gordon; Lucas S. (US 5938645), further in view of Watkins; David H. et al. (US 3995617).

22. Regarding claims 27 and 28, Summers discloses a sheath surrounding a length of the drive member (col. 3, lines 33-48, Fig. 3, portion of catheter 16 surrounding flexible drive shaft 30). Summers and Gordon teach the device substantially as claimed by Applicant with the exception of a blood pressure detection mechanism. Watkins discloses an apparatus for augmenting heart function (col. 1, lines 3-10, col. 3, lines 6-18, Figs. 1, 2, shaft portion 50 and flexible tube 51); comprising:

a sheath (Figs. 1-5, shaft / catheter 50);

a blood pressure detection mechanism comprising a fluid column configured to detect the pressure of the blood proximate the intravascular blood pump (col. 4, lines 28-43, Fig. 5, interior channel member 56; lines 44-58, corresponding channel member 57);

wherein the fluid column is disposed inside the sheath (Fig. 5, interior channel members 56, 57 within catheter 50).

This rejection modifies the intravascular pump of Summers and Gordon as discussed with the pressure-measuring columns of Watkins. The pressure measurements of Watkins measure whether the heart is responding to treatment (cols. 4-5, lines 58-5). One would be motivated to modify Summers and Gordon with the blood pressure detection mechanism as taught by Watkins to since Summers calls for augmenting heart function during healing (col. 6, lines 46-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Summers and Gordon as discussed with the blood pressure detection mechanism of Watkins in order to evaluate a healing response of the heart.

23. Claims 29-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Summers; David P. et al. (US 5112349) in view of Gordon; Lucas S. (US 5938645) in view of Siess; Thorsten et al. (US 6007478).

24. Regarding claim 29, Summers discloses an intravascular blood pump system (col. 1, lines 8-12, col. 3, lines 4-8, Fig. 1, pump 14), comprising:

an intravascular blood pump (col. 3, lines 49-68, Fig. 3, rotor 42);

coupled to a catheter on a proximal end (col. 3, lines 49-68, Fig. 3, housing 36);  
and

a cannula on a distal end (col. 3, lines 49-55, Fig. 3, intake end 32 forming outer surface);

the catheter including one or more apertures adjacent a distal end of the catheter (Fig. 3, housing 36 having at least central aperture for blood to enter).

25. Summers teaches the device substantially as claimed by Applicant with the exception of a guide mechanism and blood pressure detection mechanism. Gordon discloses a system for removing thrombi (col. 4, lines 53-61, col. 8, lines 13-22, Fig. 1, catheter 12), comprising:

a cannula (col. 8, lines 23-32, Fig. 5a, catheter 18);

a guide mechanism adapted to guide said intravascular blood pump, cannula, and catheter to a predetermined location within the circulatory system of a patient (col. 9, lines 1-4, Fig. 5c, internal guidewire lumen 46). Regarding rationale and motivation to modify Summers in view of Gordon, see discussion of claim 15 above.

26. Summers and Gordon teach the device substantially as claimed by Applicant with the exception of a blood pressure detection mechanism. Siess discloses a cannula for use as an intravascular blood pump (col. 4, lines 29-37); comprising:

a pump (col. 4, lines 38-45, Fig. 1, pump 14);

a catheter (col. 4, lines 56-65, Fig. 2, stiff material 28);

a cannula (col. 4, lines 56-65, Fig. 2, flexible material 30);

a blood pressure detection mechanism comprising a fluid column configured to detect the pressure of the blood proximate the intravascular blood pump (col. 3, lines 41-46, pressure sensor; col. 6, lines 53-65, Fig. 10, sensor 52 located within lumen and therefore within fluid column).

Siess monitors patient conditions and pump performance (col. 6, lines 62-65). One would be motivated to modify Summers and Gordon with the blood pressure detection mechanism of Siess since Summers calls for treating a patient while their heart is repairing itself (col. 6, lines 46-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Summers and Gordon as discussed with the blood pressure detection mechanism as taught by Siess in order to monitor a patient during recovery.

27. Regarding claim 30, Summers teaches the device substantially as claimed by Applicant with the exception of a guide mechanism. Gordon discloses a guide mechanism comprising a guide wire (col. 8, lines 13-22, Figs. 1, 5a, guidewire 14);

the system configured such that it is guidable in the circulatory system over the guide wire passing through a lumen in the cannula but not extending through the catheter (col. 9, lines 1-4, Fig. 5c, guidewire lumen 46 not extending through hemostasis valve 22).

Gordon guides an intravascular device through the body while navigating through tight bends (col. 5, lines 5-22). One would have been motivated to modify the invention

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of Summers with the guide mechanism of Gordon since Summers manipulates an intravascular device through vessels in the body.

28. Regarding claims 31 and 32, Summers and Gordon teach the device substantially as claimed by Applicant with the exception of a spiral wire. Siess discloses a cannula (col. 4, lines 56-65, Fig. 2, flexible material 30);

wherein the cannula is reinforced with a spiral wire embedded in a wall of the cannula (col. 5, lines 28-38, Figs. 2, 3, spiral spring 29 of NiTi).

Siess adjusts the stiffness of a cannula to guide it through vasculature (col. 3, lines 47-56). One would have been motivated to modify the invention of Summers and Gordon as discussed with the spiral wire of Siess to maneuver the cannula more easily through vasculature.

29. Regarding claim 33, Summers teaches the device substantially as claimed by Applicant with the exception of a guide catheter. Gordon discloses a guide catheter configured to be guidable through the vasculature into the heart (col. 11, lines 35-49, Fig. 13, fixed guide wire tip 120);

the cannula and intravascular blood pump too large to pass through the guide catheter (Fig. 13, fixed guide wire tip 120 smaller than catheter 18).

Regarding rationale and motivation to modify Summers in view of Gordon, see discussion of claim 26 above.

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30. Regarding claims 34-36, Summers discloses an intravascular blood pump system further comprising:

a rotor (col. 3, lines 57-58, Fig. 3, rotor 42);

wherein the rotor comprises a rotor hub and a blade extending radially from the rotor hub (col. 3, lines 64-68, Fig. 3, rotor 42 depicted as extending radially from proximal end of flexible joint 44; col. 5, lines 58-66, rotor having single helix shape);

wherein the cannula comprises an outer cannula surface having a substantially circular cross-section along a portion of its length (col. 3, lines 49-554, Fig. 3, intake end 32 having cone-like profile).

31. Regarding claims 37-39, Summers discloses an intravascular blood pump system further comprising:

a plurality of egress flow ports disposed in the catheter (col. 4, lines 50-52, Fig. 3, outlet ports 58); and

a plurality of ingress flow ports disposed in the cannula and distal to the egress flow ports (col. 3, lines 49-57, Fig. 3, intake end 32 having intake ports 38);

wherein the ingress flow ports comprise an end port located at the cannula distal end (Fig. 3, at least one intake port 38 at distal end); and

a plurality of ports located about the cannula and proximal to the end port (Fig. 3, plurality of intake ports 38);

wherein the egress ports are configured to direct blood passing through the cannula and towards the rotor in a direction that is both proximal and radially outward

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with respect to the rotor hub (col. 4, lines 47-52, blood exiting through outlet ports 58 into aorta 24).

32. Claims 29, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Summers; David P. et al. (US 5112349) in view of Masch; Helmut (US 4728319) in view of Siess; Thorsten et al. (US 6007478). Claim 29 is rejected over Summers, Masch and Siess in addition to the rejection citing Summers, Gordon and Siess.

33. Regarding claim 29, Summers teaches the device substantially as claimed by Applicant with the exception of a guide mechanism. Masch discloses an intravascular device (col. 1, lines 45-49, col. 2, lines 26-40, Fig. 1, catheter assembly 10); comprising:

a catheter including one or more apertures adjacent a distal end of the catheter (col. 2, lines 26-40, col. 4, lines 60-63, Fig. 1, catheter 11 comprising sleeve 62);

a guide mechanism adapted to guide said catheter to a predetermined location within the circulatory system of a patient (col. 2, lines 41-51, Fig. 1, guide wire 14).

Masch delivers a catheter through vessels in the body with a steerable guide mechanism (cols. 2-3, lines 63-2, Fig. 1, rotating guide wire 14). One would be motivated to modify Summers with the guide mechanism of Masch to position the pump accurately. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Summers as discussed with the guide mechanism of Masch in order to navigate through vessels in the body.

Summers and Masch teach the device substantially as claimed by Applicant with the exception of a blood pressure detection mechanism. Siess discloses a blood



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pressure detection mechanism as discussed for claim 29 rejected over Summers, Gordon and Siess.

34. Regarding claims 40 and 41, Summers teaches the device substantially as claimed by Applicant with the exception of a guide mechanism comprising a central lumen. Masch discloses a guide mechanism comprising a central lumen (col. 2, lines 41-51, guide wire 14 within first tube / sheath 15);

wherein the central lumen extends through the cannula (col. 3, lines 38-47, Fig. 1, first tube 15 extending through bore 25).

This rejection modifies the intravascular blood pump of Summers with the central guide wire of Masch. One would have been able to modify the pump of Summers with the central guide wire of Masch, since Masch also discloses a helical component towards the distal end of the catheter (col. 8, lines 8-23, Figs. 6, 7, screw threads 79, 80 having guide wire 14 passing through). One would have been motivated to modify the invention of Summers with the guidewire of Masch since this would allow a surgeon to steer the catheter by rotating the guidewire before advancing the blood pump. Therefore it would have been obvious to modify the invention of Summers with the guidewire of Masch in order to deliver an intravascular blood pump through vessels in the body.

### ***Response to Arguments***

35. Applicant's arguments filed 17 July 2012 with regard to the rejection of claims 2-22, as amended, under 35 USC § 103 over Summers, Bagaoisan, Moise and Saab are persuasive. After consideration of the amended claims, the claims are rejected on new grounds over Summers, Gordon, Watkins, Siess and Masch (see above).

36. Applicant's amendments filed 17 July 2012 have overcome the double patenting rejections over Aboul-Hosn '100 et al. (US 7022100).

37. Applicant contends that Summers and Bagaoisan fail to teach all limitations of amended claim 15. The amendments filed 17 July 2012 call for a guide mechanism interior to a region delimited by the outer cannula surface. Examiner cites Gordon as teaching this limitation in the new grounds of rejection.

### ***Conclusion***

38. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Willard; Lloyd et al. US 6066100
- Jarvik; Robert et al. US 5965089
- Auth; David C. et al. US 5827229
- Ruggio; Joseph M. US 5476450
- Mahurkar; Sakharam D. US 5221256

39. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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40. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

41. Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Adam Marcetich

Tel 571-272-2590

Fax 571-273-2590

Email [Adam.Marcetich@uspto.gov](mailto:Adam.Marcetich@uspto.gov)

The Examiner can be reached 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/  
Examiner, Art Unit 3761

/Leslie R. Deak/  
Primary Examiner, Art Unit 3761  
22 August 2012

|                                   |                                       |  |                                                                 |             |
|-----------------------------------|---------------------------------------|--|-----------------------------------------------------------------|-------------|
| <b>Notice of References Cited</b> | Application/Control No.<br>12/772,810 |  | Applicant(s)/Patent Under<br>Reexamination<br>ABOUL-HOSN ET AL. |             |
|                                   | Examiner<br>ADAM MARCETICH            |  | Art Unit<br>3761                                                | Page 1 of 1 |

#### U.S. PATENT DOCUMENTS

| * |   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Name                  | Classification |
|---|---|--------------------------------------------------|-----------------|-----------------------|----------------|
| * | A | US-3,995,617 A                                   | 12-1976         | Watkins et al.        | 600/16         |
| * | B | US-5,221,256 A                                   | 06-1993         | Mahurkar, Sakharam D. | 604/43         |
| * | C | US-5,476,450 A                                   | 12-1995         | Ruggio, Joseph M.     | 604/28         |
| * | D | US-5,827,229 A                                   | 10-1998         | Auth et al.           | 604/171        |
| * | E | US-5,938,645 A                                   | 08-1999         | Gordon, Lucas S.      | 604/264        |
| * | F | US-5,965,089 A                                   | 10-1999         | Jarvik et al.         | 422/44         |
| * | G | US-6,007,478 A                                   | 12-1999         | Siess et al.          | 600/16         |
| * | H | US-6,066,100 A                                   | 05-2000         | Willard et al.        | 600/452        |
|   | I | US-                                              |                 |                       |                |
|   | J | US-                                              |                 |                       |                |
|   | K | US-                                              |                 |                       |                |
|   | L | US-                                              |                 |                       |                |
|   | M | US-                                              |                 |                       |                |

#### FOREIGN PATENT DOCUMENTS

| * |   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Country | Name | Classification |
|---|---|--------------------------------------------------|-----------------|---------|------|----------------|
|   | N |                                                  |                 |         |      |                |
|   | O |                                                  |                 |         |      |                |
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#### NON-PATENT DOCUMENTS

| * |   | Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) |
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|   | U |                                                                                           |
|   | V |                                                                                           |
|   | W |                                                                                           |
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\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

EAST Search History

EAST Search History (Prior Art)

| Ref # | Hits | Search Query                                                                                                                                                                                                                                                                                                                                                 | DBs                                                              | Default Operator | Plurals | Time Stamp          |
|-------|------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|------------------|---------|---------------------|
| S112  | 205  | S111 and (guidewire guide adj wire)                                                                                                                                                                                                                                                                                                                          | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2012/08/18<br>12:59 |
| S111  | 970  | (604/43,156,158,540).ccls. and @ad<"20000901"                                                                                                                                                                                                                                                                                                                | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2012/08/18<br>12:59 |
| S110  | 43   | ("4688998"   "5385581").PN. OR ("5964694").URPN.                                                                                                                                                                                                                                                                                                             | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR               | OFF     | 2012/08/18<br>12:57 |
| S109  | 7    | S108 and (guidewire guide adj wire)                                                                                                                                                                                                                                                                                                                          | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2012/08/18<br>11:44 |
| S108  | 139  | (623/3.1,3.13,3.14,3.15).ccls. and @ad<"20000901"                                                                                                                                                                                                                                                                                                            | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2012/08/18<br>11:44 |
| S107  | 31   | S105 and pressure near3 (detect\$3 measur\$3 measurement sens\$3 transduc\$3) and @ad<"20000901"                                                                                                                                                                                                                                                             | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR               | ON      | 2012/08/18<br>09:28 |
| S105  | 145  | ("3384089"   "3568659"   "3592184").PN. OR ("3995617").URPN.                                                                                                                                                                                                                                                                                                 | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR               | OFF     | 2012/08/18<br>09:27 |
| S104  | 8    | S103 and pressure near3 (detect\$3 measur\$3 measurement sens\$3 transduc\$3) and @ad<"20000901"                                                                                                                                                                                                                                                             | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR               | ON      | 2012/08/17<br>17:05 |
| S103  | 53   | ("3568659"   "3995617"   "4382199"   "4512726"   "4688998"   "4704121"   "4779614"   "4817586"   "4846152"   "4895557"   "4906229"   "4908012"   "4919647"   "4944722"   "5061256"   "5092879"   "5112292"   "5376114"   "5385454"   "5385581"   "5393207"   "5507629"   "5527159"   "5695471"   "5911685"   "5921913"   "5964694").PN. OR ("6176822").URPN. | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR               | OFF     | 2012/08/17<br>17:04 |
| S102  | 26   | S101 and pressure near3 (detect\$3 measur\$3 measurement sens\$3 transduc\$3)                                                                                                                                                                                                                                                                                | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR               | ON      | 2012/08/17<br>16:59 |

|      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                  |    |     |                     |
|------|------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|----|-----|---------------------|
| S101 | 71   | S100 and pump                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR | ON  | 2012/08/17<br>16:59 |
| S100 | 79   | S99 and @ad< "20000901"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/08/17<br>16:59 |
| S99  | 206  | (623/3.1).OCLS.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | US-PGPUB;<br>USPAT                                               | OR | OFF | 2012/08/17<br>16:59 |
| S98  | 59   | S97 and pump                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR | ON  | 2012/08/17<br>16:52 |
| S97  | 109  | S96 not S93                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR | ON  | 2012/08/17<br>16:40 |
| S96  | 109  | S95 and pressure near3 (detect\$3<br>measur\$3 measurement sens\$3<br>transduc\$3)                                                                                                                                                                                                                                                                                                                                                                                                                                                             | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR | ON  | 2012/08/17<br>16:40 |
| S95  | 947  | S94 and @ad< "20000901"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/08/17<br>16:40 |
| S94  | 1953 | (604/43,156,158,540).OCLS.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | US-PGPUB;<br>USPAT                                               | OR | OFF | 2012/08/17<br>16:40 |
| S93  | 24   | S92 and pressure near3 (detect\$3<br>measur\$3 measurement sens\$3<br>transduc\$3)                                                                                                                                                                                                                                                                                                                                                                                                                                                             | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR | ON  | 2012/08/17<br>16:31 |
| S92  | 111  | S91 and @ad< "20000901"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/08/17<br>16:31 |
| S91  | 299  | intravascular near3 pump\$3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/08/17<br>16:31 |
| S90  | 11   | S89 and pressure near3 (detect\$3<br>measur\$3 measurement sens\$3<br>transduc\$3)                                                                                                                                                                                                                                                                                                                                                                                                                                                             | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR | ON  | 2012/08/17<br>16:28 |
| S89  | 47   | (US-20060161095-\$ or US-20060155158-\$<br>or US-20050165269-\$ or US-20030023201-\$).<br>did. or (US-7731675-\$ or US-7022100-\$<br>or US-6976996-\$ or US-6210133-\$<br>or US-6083260-\$ or US-6287319-\$<br>or US-4909781-\$ or US-6245007-\$<br>or US-4728319-\$ or US-4591355-\$<br>or US-4895557-\$ or US-4817586-\$<br>or US-4979936-\$ or US-5112349-\$<br>or US-6849068-\$ or US-6248091-\$<br>or US-5888241-\$ or US-6217541-\$<br>or US-6228063-\$ or US-6547779-\$<br>or US-6454997-\$ or US-6440158-\$<br>or US-6181971-\$ or US- | US-PGPUB;<br>USPAT;<br>DERWENT                                   | OR | OFF | 2012/08/17<br>16:27 |

|     |     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                  |    |     |                     |
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|     |     | 7130700-\$ or US-6036654-\$ or US-5827267-\$).did. or (US-5713860-\$ or US-7892270-\$ or US-6231595-\$ or US-6235048-\$ or US-6238428-\$ or US-6251130-\$ or US-6159195-\$ or US-5921971-\$ or US-5833644-\$ or US-5827229-\$ or US-5569215-\$ or US-5476450-\$ or US-5221256-\$ or US-6066100-\$ or US-5938645-\$).did. or (WO-8905668-\$ or US-5741234-\$).did.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                  |    |     |                     |
| S88 | 0   | (09/280,988 ).app.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/08/09<br>16:38 |
| S87 | 1   | (09/280,988 09/280,970).app.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/08/09<br>16:37 |
| S86 | 77  | S85 not (S79 S82)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/08/09<br>14:25 |
| S85 | 90  | S84 and (guidewire guide adj wire)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/08/09<br>14:25 |
| S84 | 171 | S83 and @ad< "20000901"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/08/09<br>14:24 |
| S83 | 356 | ("2173527"   "2936761"   "3359974"  <br>"3394705"   "3437088"   "3593713"  <br>"3670729"   "3726281"   "3769981"  <br>"3915168"   "3995623"   "4004588"  <br>"4016879"   "4033331"   "4052989"  <br>"4057065"   "4072146"   "4100246"  <br>"4168703"   "4180068"   "4180076"  <br>"4217895"   "4257416"   "4270535"  <br>"4367740"   "4403985"   "4406656"  <br>"4445509"   "4484585"   "4540402"  <br>"4552554"   "4573966"   "4577637"  <br>"4601701"   "4619643"   "4631052"  <br>"4646736"   "4661110"   "4692139"  <br>"4692141"   "4701159"   "4728319"  <br>"4729763"   "4749376"   "4753640"  <br>"4756303"   "4762120"   "4769005"  <br>"4784636"   "4787892"   "4790812"  <br>"4790813"   "4795439"   "4798193"  <br>"4813429"   "4824435"   "4834102"  <br>"4894051"   "4894057"   "4898591"  <br>"4922924"   "4928693"   "4932413"  <br>"4934340"   "4955863"   "4957484" | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR | OFF | 2012/08/09<br>14:24 |



|     |     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                  |    |     |                     |
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|     |     | "4968307"   "4976689"   "4995865"  <br>"4998919"   "5004455"   "5007897"  <br>"5009636"   "5011488"   "5015232"  <br>"5019057"   "5029580"   "5053023"  <br>"5057073"   "5084013"   "5090960"  <br>"5163905"   "5176693"   "5181920"  <br>"5203338"   "5219335"   "5234403"  <br>"5273526"   "5318576"   "5346469"  <br>"5370609"   "5370653"   "5395332"  <br>"5419774"   "5451233"   "5476450"  <br>"5527292"   "Re31873").PN. OR<br>("5221256"   "5476450"   "5827229"  <br>"6066100").URPN.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                  |    |     |                     |
| S82 | 99  | S80 and @ad< "20000901"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/08/09<br>14:02 |
| S81 | 1   | 10/070178.app.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2012/08/09<br>13:40 |
| S80 | 123 | ("3144868"   "4468216"   "4511354"  <br>"4573966"   "4589412"   "4610662"  <br>"4662871"   "4692139"   "4696668"  <br>"4713060"   "4748982"   "4754755"  <br>"4782834"   "4784636"   "4790812"  <br>"4790813"   "4850957"   "4867156"  <br>"4950238"   "4964409"   "4994067"  <br>"5002528"   "5026384"   "5053023"  <br>"5059178"   "5078688"   "5087265"  <br>"5135484"   "5135531"   "5163905"  <br>"5163906"   "5167239"   "5167623"  <br>"5184627"   "5192291"   "5195955"  <br>"5221256"   "5221270"   "5250060"  <br>"5267958"   "5273527"   "5279546"  <br>"5286253"   "5318576"   "5322508"  <br>"5328480"   "5336205"   "5342306"  <br>"5349950"   "5358472"   "5370609"  <br>"5376071"   "5376084"   "5395311"  <br>"5405321"   "5405322"   "5405341"  <br>"5415636"   "5419774"   "5423742"  <br>"5431673"   "5439000"   "5449343"  <br>"5451206"   "5451209"   "5460610"  <br>"5462529"   "5476450"   "5478309"  <br>"5492763"   "5496346"   "5500180"  <br>"5569182"   "5569204"   "5569215"  <br>"5578018"   "5634897"   "5662671"  <br>"5695507"   "5695519"   "5700252"  <br>"5713849"   "5743883"   "5766211"  <br>"5769868"   "5772642"   "5792118"  <br>"5807311"   "5814064"   "5827229"  <br>"5830196"   "5833644"   "5849016"  <br>"5921971"   "6019350"   "6066100"  <br>"6095990"   "6129708"   "6152909"  <br>"6159195").PN. OR ("6849068").URPN. | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR | OFF | 2012/08/09<br>13:31 |
| S79 | 38  | (US-20060161095-\$ or US-20060155158-\$<br>or US-20050165269-\$ or US-<br>20030023201-\$).did. or (US-7731675-\$<br>or US-7022100-\$ or US-6976996-\$ or US-                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | US-PGPUB;<br>USPAT;<br>DERWENT                                   | OR | OFF | 2012/08/09<br>12:34 |

|     |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                  |    |    |                     |
|-----|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|----|----|---------------------|
|     |   | 6210133-\$ or US-6083260-\$ or US-6287319-\$ or US-4909781-\$ or US-6245007-\$ or US-4728319-\$ or US-4591355-\$ or US-4895557-\$ or US-4817586-\$ or US-4979936-\$ or US-5112349-\$ or US-6849068-\$ or US-6248091-\$ or US-5888241-\$ or US-6217541-\$ or US-6228063-\$ or US-6547779-\$ or US-6454997-\$ or US-6440158-\$ or US-6181971-\$ or US-7130700-\$ or US-6036654-\$ or US-5827267-\$).did. or (US-5713860-\$ or US-7892270-\$ or US-6231595-\$ or US-6235048-\$ or US-6238428-\$ or US-6251130-\$).did. or (WO-8905668-\$ or US-5741234-\$).did. |                                                                  |    |    |                     |
| S78 | 1 | 12/772,810.app.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2012/08/09<br>10:11 |

EAST Search History (Interference)

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8/ 18/ 2012 2:21:47 PM  
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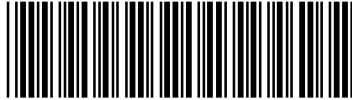
|                                                                                                              |                                                |                                                                         |
|--------------------------------------------------------------------------------------------------------------|------------------------------------------------|-------------------------------------------------------------------------|
| <b>Search Notes</b><br><br> | <b>Application/Control No.</b><br><br>12772810 | <b>Applicant(s)/Patent Under Reexamination</b><br><br>ABOUL-HOSN ET AL. |
|                                                                                                              | <b>Examiner</b><br><br>ADAM MARCETICH          | <b>Art Unit</b><br><br>3761                                             |

| SEARCHED |                |           |          |
|----------|----------------|-----------|----------|
| Class    | Subclass       | Date      | Examiner |
| 604      | 43,156,158,540 | 2/3/2012  | AMM      |
| 623      | 3.1            | 2/3/2012  | AMM      |
| 600      | 16             | 2/3/2012  | AMM      |
|          | search update  | 8/17/2012 | AMM      |

| SEARCH NOTES                                                                              |           |           |
|-------------------------------------------------------------------------------------------|-----------|-----------|
| Search Notes                                                                              | Date      | Examiner  |
| Inventor search: PALM and EAST (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT, IBM_TDB) | 2/3/2012  | AMM       |
| Review PLUS search results returned Friday, 3 February 2012                               | 2/3/2012  | AMM       |
| Review cited art for related cases 11/375926, 10/070178                                   | 2/3/2012  | AMM       |
| Review ISR for PCT/US00/24515 performed 19 March 2001, Angie Sykes USPTO                  | 2/3/2012  | AMM       |
| search update                                                                             | 8/17/2012 | 8/18/2012 |

| INTERFERENCE SEARCH |          |      |          |
|---------------------|----------|------|----------|
| Class               | Subclass | Date | Examiner |
|                     |          |      |          |

|                                            |  |
|--------------------------------------------|--|
| /ADAM MARCETICH/<br>Examiner.Art Unit 3761 |  |
|--------------------------------------------|--|

|                                                                                                                        |                                                |                                                                         |
|------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|-------------------------------------------------------------------------|
| <b><i>Index of Claims</i></b><br><br> | <b>Application/Control No.</b><br><br>12772810 | <b>Applicant(s)/Patent Under Reexamination</b><br><br>ABOUL-HOSN ET AL. |
|                                                                                                                        | <b>Examiner</b><br><br>ADAM MARCETICH          | <b>Art Unit</b><br><br>3761                                             |

|   |                 |   |                   |   |                     |   |                 |
|---|-----------------|---|-------------------|---|---------------------|---|-----------------|
| ✓ | <b>Rejected</b> | - | <b>Cancelled</b>  | N | <b>Non-Elected</b>  | A | <b>Appeal</b>   |
| = | <b>Allowed</b>  | ÷ | <b>Restricted</b> | I | <b>Interference</b> | O | <b>Objected</b> |

| <input type="checkbox"/> Claims renumbered in the same order as presented by applicant |          |            |            | <input type="checkbox"/> CPA |  |  |  | <input type="checkbox"/> T.D. |  |  |  | <input type="checkbox"/> R.1.47 |  |  |  |
|----------------------------------------------------------------------------------------|----------|------------|------------|------------------------------|--|--|--|-------------------------------|--|--|--|---------------------------------|--|--|--|
| CLAIM                                                                                  |          | DATE       |            |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
| Final                                                                                  | Original | 02/06/2012 | 08/20/2012 |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 1        | -          | -          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 2        | ✓          | -          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 3        | ✓          | -          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 4        | ✓          | -          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 5        | ✓          | -          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 6        | ✓          | -          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 7        | ✓          | -          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 8        | ✓          | -          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 9        | ✓          | -          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 10       | ✓          | -          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 11       | ✓          | -          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 12       | ✓          | -          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 13       | ✓          | -          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 14       | ✓          | -          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 15       | ✓          | ✓          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 16       | ✓          | -          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 17       | ✓          | -          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 18       | ✓          | -          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 19       | ✓          | -          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 20       | ✓          | -          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 21       | ✓          | -          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 22       | ✓          | -          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 23       |            | ✓          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 24       |            | ✓          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 25       |            | ✓          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 26       |            | ✓          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 27       |            | ✓          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 28       |            | ✓          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 29       |            | ✓          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 30       |            | ✓          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 31       |            | ✓          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 32       |            | ✓          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 33       |            | ✓          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 34       |            | ✓          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 35       |            | ✓          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |
|                                                                                        | 36       |            | ✓          |                              |  |  |  |                               |  |  |  |                                 |  |  |  |

|                                                                                                                                       |                                            |                                                                     |
|---------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|---------------------------------------------------------------------|
| <p align="center"><b><i>Index of Claims</i></b></p>  | <b>Application/Control No.</b><br>12772810 | <b>Applicant(s)/Patent Under Reexamination</b><br>ABOUL-HOSN ET AL. |
|                                                                                                                                       | <b>Examiner</b><br>ADAM MARCETICH          | <b>Art Unit</b><br>3761                                             |

|   |                 |   |                   |   |                     |   |                 |
|---|-----------------|---|-------------------|---|---------------------|---|-----------------|
| ✓ | <b>Rejected</b> | - | <b>Cancelled</b>  | N | <b>Non-Elected</b>  | A | <b>Appeal</b>   |
| = | <b>Allowed</b>  | ÷ | <b>Restricted</b> | I | <b>Interference</b> | O | <b>Objected</b> |

| <input type="checkbox"/> Claims renumbered in the same order as presented by applicant |          |            |            | <input type="checkbox"/> CPA |  | <input type="checkbox"/> T.D. |  | <input type="checkbox"/> R.1.47 |  |
|----------------------------------------------------------------------------------------|----------|------------|------------|------------------------------|--|-------------------------------|--|---------------------------------|--|
| CLAIM                                                                                  |          | DATE       |            |                              |  |                               |  |                                 |  |
| Final                                                                                  | Original | 02/06/2012 | 08/20/2012 |                              |  |                               |  |                                 |  |
|                                                                                        | 37       |            | ✓          |                              |  |                               |  |                                 |  |
|                                                                                        | 38       |            | ✓          |                              |  |                               |  |                                 |  |
|                                                                                        | 39       |            | ✓          |                              |  |                               |  |                                 |  |
|                                                                                        | 40       |            | ✓          |                              |  |                               |  |                                 |  |
|                                                                                        | 41       |            | ✓          |                              |  |                               |  |                                 |  |

## REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL (Submitted Only via EFS-Web)

|                      |                     |             |            |                               |                    |          |      |
|----------------------|---------------------|-------------|------------|-------------------------------|--------------------|----------|------|
| Application Number   | 12/772,810          | Filing Date | 2010-05-03 | Docket Number (if applicable) | 06-01506US04       | Art Unit | 3761 |
| First Named Inventor | Walid N. ABOUL-HOSN |             |            | Examiner Name                 | Marcetich, Adam M. |          |      |

**This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.**

Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

### SUBMISSION REQUIRED UNDER 37 CFR 1.114

**Note:** If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on \_\_\_\_\_

☐ Other \_\_\_\_\_

☒ Enclosed

☒ Amendment/Reply

☐ Information Disclosure Statement (IDS)

☐ Affidavit(s)/ Declaration(s)

☒ Other \_\_\_\_\_  
Petition for Extension of Time

### MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months \_\_\_\_\_  
(Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other \_\_\_\_\_

### FEES

**The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**

☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to  
Deposit Account No 040170

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

| Signature of Registered U.S. Patent Practitioner |                   |                     |            |
|--------------------------------------------------|-------------------|---------------------|------------|
| Signature                                        | /Kirk D. Swenson/ | Date (YYYY-MM-DD)   | 2013-02-28 |
| Name                                             | Kirk D. Swenson   | Registration Number | 52265      |

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

## Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

|                                                                     |                                       |                                                 |
|---------------------------------------------------------------------|---------------------------------------|-------------------------------------------------|
| <b>PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)</b>         |                                       | Docket Number (Optional)<br><b>06-01506US04</b> |
| Application Number<br><b>12/772,810</b>                             | Filed<br><b>2010-05-03</b>            |                                                 |
| For<br><b>Guidable Intravascular Blood Pump and Related Methods</b> |                                       |                                                 |
| Art Unit<br><b>3761</b>                                             | Examiner<br><b>Marcetich, Adam M.</b> |                                                 |

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

|                                                                      | <u>Fee</u> | <u>Small Entity Fee</u> |                   |
|----------------------------------------------------------------------|------------|-------------------------|-------------------|
| <input type="checkbox"/> One month (37 CFR 1.17(a)(1))               | \$150      | \$75                    | \$ _____          |
| <input type="checkbox"/> Two months (37 CFR 1.17(a)(2))              | \$570      | \$285                   | \$ _____          |
| <input checked="" type="checkbox"/> Three months (37 CFR 1.17(a)(3)) | \$1,290    | \$645                   | \$ <b>1290.00</b> |
| <input type="checkbox"/> Four months (37 CFR 1.17(a)(4))             | \$2,010    | \$1,005                 | \$ _____          |
| <input type="checkbox"/> Five months (37 CFR 1.17(a)(5))             | \$2,730    | \$1,365                 | \$ _____          |

☐ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to  
Deposit Account Number 040170.

☒ Payment made via EFS-Web.

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. 37 CFR 3.73(b) statement is enclosed (Form PTO/SB/96).
- ☒ attorney or agent of record. Registration number 52265.
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number \_\_\_\_\_.

/Kirk D. Swenson/2013-02-28

Signature

Date

Kirk D. Swenson201.995.8816

Typed or printed name

Telephone Number

**NOTE:** This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below\*.☐ \* Total of \_\_\_\_\_ forms are submitted.

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

## Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

## Electronic Patent Application Fee Transmittal

|                                                |                                                       |                 |               |                             |
|------------------------------------------------|-------------------------------------------------------|-----------------|---------------|-----------------------------|
| <b>Application Number:</b>                     | 12772810                                              |                 |               |                             |
| <b>Filing Date:</b>                            | 03-May-2010                                           |                 |               |                             |
| <b>Title of Invention:</b>                     | Guidable Intravascular Blood Pump and Related Methods |                 |               |                             |
| <b>First Named Inventor/Applicant Name:</b>    | Walid N. Aboul-Hosn                                   |                 |               |                             |
| <b>Filer:</b>                                  | Kirk D. Swenson/Mary Zimmerman                        |                 |               |                             |
| <b>Attorney Docket Number:</b>                 | 06-01506US04                                          |                 |               |                             |
| Filed as Large Entity                          |                                                       |                 |               |                             |
| <b>Utility under 35 USC 111(a) Filing Fees</b> |                                                       |                 |               |                             |
| <b>Description</b>                             | <b>Fee Code</b>                                       | <b>Quantity</b> | <b>Amount</b> | <b>Sub-Total in USD(\$)</b> |
| <b>Basic Filing:</b>                           |                                                       |                 |               |                             |
| <b>Pages:</b>                                  |                                                       |                 |               |                             |
| <b>Claims:</b>                                 |                                                       |                 |               |                             |
| Claims in Excess of 20                         | 1202                                                  | 4               | 62            | 248                         |
| <b>Miscellaneous-Filing:</b>                   |                                                       |                 |               |                             |
| <b>Petition:</b>                               |                                                       |                 |               |                             |
| <b>Patent-Appeals-and-Interference:</b>        |                                                       |                 |               |                             |
| <b>Post-Allowance-and-Post-Issuance:</b>       |                                                       |                 |               |                             |
| <b>Extension of Time:</b>                      |                                                       |                 |               |                             |

| Description                        | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
|------------------------------------|----------|----------|--------|----------------------|
| Extension - 3 months with \$0 paid | 1253     | 1        | 1290   | 1290                 |
| <b>Miscellaneous:</b>              |          |          |        |                      |
| Request for continued examination  | 1801     | 1        | 930    | 930                  |
| <b>Total in USD (\$)</b>           |          |          |        | <b>2468</b>          |

## Electronic Acknowledgement Receipt

|                                             |                                                       |
|---------------------------------------------|-------------------------------------------------------|
| <b>EFS ID:</b>                              | 15087765                                              |
| <b>Application Number:</b>                  | 12772810                                              |
| <b>International Application Number:</b>    |                                                       |
| <b>Confirmation Number:</b>                 | 4661                                                  |
| <b>Title of Invention:</b>                  | Guidable Intravascular Blood Pump and Related Methods |
| <b>First Named Inventor/Applicant Name:</b> | Walid N. Aboul-Hosn                                   |
| <b>Customer Number:</b>                     | 99185                                                 |
| <b>Filer:</b>                               | Kirk D. Swenson/Mary Zimmerman                        |
| <b>Filer Authorized By:</b>                 | Kirk D. Swenson                                       |
| <b>Attorney Docket Number:</b>              | 06-01506US04                                          |
| <b>Receipt Date:</b>                        | 28-FEB-2013                                           |
| <b>Filing Date:</b>                         | 03-MAY-2010                                           |
| <b>Time Stamp:</b>                          | 19:51:37                                              |
| <b>Application Type:</b>                    | Utility under 35 USC 111(a)                           |

### Payment information:

|                                          |                 |
|------------------------------------------|-----------------|
| Submitted with Payment                   | yes             |
| Payment Type                             | Deposit Account |
| Payment was successfully received in RAM | \$ 2468         |
| RAM confirmation Number                  | 10004           |
| Deposit Account                          | 040170          |
| Authorized User                          |                 |

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

| File Listing:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                         |                                          |                                                    |                  |                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|------------------------------------------|----------------------------------------------------|------------------|------------------|
| Document Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Document Description                    | File Name                                | File Size(Bytes)/<br>Message Digest                | Multi Part /.zip | Pages (if appl.) |
| 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Amendment After Final                   | Response_to_final_rejection_02282013.pdf | 71893<br>906c308d41e57d314f980472684c3c51ad29466e  | no               | 15               |
| <b>Warnings:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                         |                                          |                                                    |                  |                  |
| <b>Information:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                         |                                          |                                                    |                  |                  |
| 2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Request for Continued Examination (RCE) | sb0030e_fill_RCE_Transmittal.pdf         | 798022<br>6b53df86ba4a899482738a71a6c1521e6ca11d21 | no               | 3                |
| <b>Warnings:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                         |                                          |                                                    |                  |                  |
| <b>Information:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                         |                                          |                                                    |                  |                  |
| 3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Extension of Time                       | sb0022_extension_of_time_02282013.pdf    | 82968<br>128d40c4637f72edeb493bb1a190d0a691a270fc  | no               | 2                |
| <b>Warnings:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                         |                                          |                                                    |                  |                  |
| <b>Information:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                         |                                          |                                                    |                  |                  |
| 4                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Fee Worksheet (SB06)                    | fee-info.pdf                             | 34513<br>5e37ab04c172510daf2e9f5ba6d262195ab993d8  | no               | 2                |
| <b>Warnings:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                         |                                          |                                                    |                  |                  |
| <b>Information:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                         |                                          |                                                    |                  |                  |
| <b>Total Files Size (in bytes):</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                         |                                          | 987396                                             |                  |                  |
| <p><b>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</b></p> <p><b><u>New Applications Under 35 U.S.C. 111</u></b><br/> <b>If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</b></p> <p><b><u>National Stage of an International Application under 35 U.S.C. 371</u></b><br/> <b>If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</b></p> <p><b><u>New International Application Filed with the USPTO as a Receiving Office</u></b><br/> <b>If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</b></p> |                                         |                                          |                                                    |                  |                  |

|                                                                                                                                                                   |                      |                                                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|-------------------------------------------------------|
| <b>AMENDMENT AND RCE<br/>UNDER 37 C.F.R. §1.114</b><br><br>Address to:<br>Mail Stop RCE<br>Commissioner for Patents<br>P.O. Box 1450<br>Alexandria, VA 22313-1450 | Attorney Docket      | 06-01506US04                                          |
|                                                                                                                                                                   | Confirmation No.     | 4661                                                  |
|                                                                                                                                                                   | First Named Inventor | Aboul-Hosn, Walid N.                                  |
|                                                                                                                                                                   | Application Number   | 12/772,810                                            |
|                                                                                                                                                                   | Filing Date          | 05/03/2010                                            |
|                                                                                                                                                                   | Group Art Unit       | 3766                                                  |
|                                                                                                                                                                   | Examiner Name        | MARCETICH, ADAM M                                     |
|                                                                                                                                                                   | Title                | Guidable Intravascular Blood Pump and Related Methods |

Sir:

This amendment is responsive to the Final Office Action dated August 28, 2012 for which a three-month period for response was given making this response due on or before November 28, 2012. A three-month extension of time is being filed concurrently making this response due on or before February 28, 2013. In view of the amendments to the claims and the remarks put forth below, reconsideration and allowance are respectfully requested.

The **Claims** begin on page 2.

**Remarks** being on page 8.

## AMENDMENTS TO THE CLAIMS

Claims 1 – 14 (Cancelled)

15. (Currently Amended) An intravascular blood pump system, comprising:

an intravascular blood pump comprising:

a rotor having a rotor hub tapering in the distal direction, at least one blade extending radially outward from the rotor hub, the hub has a distal end extending distally beyond the most distal portion of the blade, and

a shroud within which ~~said the~~ rotor is rotatably disposed, ~~and an elongate and flexible drive member coupled to said rotor for driving said rotor within said shroud;~~

a cannula extending from the shroud and comprising an outer cannula surface, the outer cannula surface having a substantially circular cross-section along a portion of its length; and

a guide mechanism configured as a lumen having a proximal end and a distal end, the guide mechanism adapted to guide a distal portion of said intravascular blood pump system to a predetermined location within the circulatory system of a patient;

wherein an axis coaxial with and extending through a portion of said guide mechanism positioned along a length of the cannula and extends through a region delimited by the outer cannula surface, and wherein the guide mechanism is configured to allow for a guide wire to slideably advance therealong.

16 – 22 (Cancelled)



23. (Currently Amended) The intravascular blood pump system of claim 15, wherein the rotor comprises ~~a rotor hub and a~~ second blade extending radially from the rotor hub.

24. (Currently Amended). The intravascular blood pump system of claim 15, wherein the rotor hub is generally conical~~guide mechanism further comprises a lumen having a diameter larger than a diameter of the guide wire.~~

25. (Currently Amended) The intravascular blood pump system of claim 15, wherein the guide mechanism is configured such that the guide wire passes through the region delimited by the outer cannula surface at a location proximal to where the guide wire establishes ~~is in~~ slidable contact with the guide mechanism ~~over a length that is shorter than the length of the cannula.~~

26. (Currently Amended) The intravascular blood pump system of claim 15, further comprising a guide catheter, wherein the guide catheter is configured to facilitate the placement of the guide wire into the heart~~annula and intravascular blood pump are too large to pass through the guide catheter.~~

27. (Currently Amended) The intravascular blood pump system of claim 15, further comprising:

an elongate catheter extending proximally with respect to the intravascular blood pump~~sheath surrounding a length of the drive; and~~

a blood pressure detection mechanism comprising a fluid column disposed within the catheter and configured to detect the pressure of the blood proximate the intravascular blood pump.

28. (Cancelled)

29. (Previously Presented) An intravascular blood pump system comprising:

an intravascular blood pump comprising a rotor having a rotor hub

tapering in the distal direction, at least one blade extending radially outward from the rotor hub, the intravascular blood pump and coupled to a catheter on a proximal end and a cannula on a distal end, the catheter including one or more apertures adjacent a distal end of the catheter;

a first set and a second set of apertures establishing fluid communication between an interior of the cannula and an exterior region of the cannula, wherein the first set of apertures is located in proximity to the rotor and the second set of apertures is spaced apart from and located distal to the first set of apertures towards a distal region of the cannula;

a guide mechanism configured as an elongate lumen and adapted to guide said intravascular blood pump, cannula, and catheter to a predetermined location within the circulatory system of a patient; and

a blood pressure detection mechanism comprising a fluid column configured to detect the pressure of the blood proximate the intravascular blood pump;

wherein the guide mechanism has a lumen sized substantially smaller than an outer diameter of the cannula and intravascular blood pump.

30. (Currently Amended) The intravascular blood pump system of claim 29, wherein the guide mechanism comprises a guide wire, the blood pump system configured such that it is guidable in the circulatory system over the guide wire passing through ~~a~~ the elongate lumen in the cannula but not extending through the catheter.

31. (Previously Presented) The intravascular blood pump system of claim 29, wherein the cannula is reinforced with a spiral wire.

32. (Cancelled)

33. (Previously Presented) The intravascular blood pump system of claim 29, further comprising a guide wire and a guide catheter, wherein the guide catheter is configured facilitate the placement of the guide wire to be guidable through the vasculature into the heart, ~~the cannula and intravascular blood pump too large to pass~~

~~through the guide catheter.~~

34. (Cancelled)

35. (Currently Amended) The intravascular blood pump system of claim ~~29~~2934, wherein the rotor comprises ~~a rotor hub and a~~ second blade extending radially from the rotor hub.

36. (Previously Presented) The intravascular blood pump system of claim 29, wherein the cannula comprises an outer cannula surface having a substantially circular cross-section along a portion of its length, the distal region of the outer cannula surface is distally tapered about its circumference.

37. (Currently Amended) The intravascular blood pump system of claim 29, further comprising a plurality of egress flow ports disposed in the shroud, and a plurality of ingress flow ports disposed ~~in the cannula and~~ at a location spaced apart from and distal to the egress flow ports.

38. (Previously Presented) The intravascular blood pump system of claim 37, wherein the ingress flow ports comprise an end port located at the cannula distal end and a plurality of ports located about the cannula and proximal to the end port.

39. (Currently Amended) The intravascular blood pump system of claim ~~29~~2934, wherein the first set of apertures are egress ports and the second set of apertures are ingress ports, and wherein the egress ports are configured to direct blood passing through the interior of the cannula and towards the rotor in a direction that is both proximal and radially outward with respect to the rotor hub.

40. (Currently Amended) The intravascular blood pump system of claim 29, wherein the elongate lumen of the guide mechanism comprises is a central lumen longitudinally offset with respect to the cannula.

41. (Currently Amended) The intravascular blood pump system of claim 40, wherein the central lumen extends through the cannula and blood pump.

42. (New) The intravascular blood pump system of claim 40, wherein the lumen of the central lumen is proximal to the cannula.

43. (New) The intravascular blood pump system of claim 15, wherein the cannula is bent at a location between distal and proximal ends thereof.

44. (New) The intravascular blood pump system of claim 29, wherein the cannula is bent at a location between distal and proximal ends thereof.

45. (New) An intravascular blood pump system configured to be advanced to a predetermined location in a patient's circulatory system, the intravascular blood pump system comprising:

- an intravascular blood pump, the intravascular blood pump comprising a rotor having a generally conical rotor hub tapering in the distal direction, at least two blades extending radially from the rotor hub, the generally conical rotor hub having a distal tip extending distally beyond the blades;

- a cannula extending distally from the intravascular blood pump;

- a plurality of ingress ports located towards the proximal region of the cannula and a plurality of egress ports located in proximity to the blood pump such that movement of fluid proximally through an interior region of the cannula is steered towards the egress ports;

- a guide wire having a cross-section substantial smaller than the cannula;

- and

- an elongate lumen having a luminal interior sized (i) smaller than an inside diameter of the cannula lumen and (ii) sufficiently large enough to accommodate the guide wire when the guide wire is advanced therealong.

46. (New) The intravascular blood pump system of claim 45, wherein the blood pump system is configured to allow for the guide wire to extend through the elongate lumen and exit pass through the cannula at a location proximal to the elongate lumen which further provides for the guide wire to pass through an outer cannula surface of the cannula.

47. (New) The intravascular blood pump system of claim 45, wherein the lumen is longitudinally offset with respect to the cannula.

48 (New). The intravascular blood pump system of claim 47, wherein the lumen is proximal with respect to the cannula.

## **REMARKS**

### **Formal Matters**

Claims 15 and 23 - 41 were examined.

Claims 1-14 and 16 – 22 were previously cancelled.

Claims 28, 32, and 34 are currently cancelled.

Claims 15, 23 – 27, 29 - 30, 33, 35 – 37 and 39 – 41 are currently amended.

Claims 43 – 48 are new.

Claims 15, 23-27, 29-33, and 35 – 48 remain pending after entry of the new claims and amendments.

Support for the amendments and new claims can be found throughout the specification and drawings. More specifically, support can be found as follows:

Support for amended claim 36 can be found in figures 1, 2, 6, 10, 12 and 13.

Support for amended claim 40 and new claims 42, 47 and 48 can be found in Figure 3.

Support for new claims 43 and 44 can be found for example in Figure 19.

Support for new claim 45 can be found for example can be found throughout the specification and drawings, including for example Figures 4, 8, and 9.

No new matter has been added.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

### **The Office Action**

#### **I. Claims Rejected Under 35 U.S.C. Section 112 First Paragraph**

Claims 26 and 33.

In the office action dated August 28, 2012 (herein the Office Action), claims 26 and 33 have been rejected under 35 U.S.C. 112 First Paragraph as failing to comply with the written description requirement.

With respect to claims 26 and 33, the Examiner points out that the claims call for "a guide catheter configured to be guidable through the vasculature into the heart,

the cannula and intravascular blood pump too large to pass through the guide catheter."

The Examiner asserts that the statement conflicts with a description of a guide catheter in the specification, more particularly paragraph [0077] referencing element 132 of Fig. 12. Applicants note that this topic was specifically discussed during the interview with the Examiner on August 17<sup>th</sup>, 2012.

Applicants respectfully traverse the rejection, as the Examiner has erred in the interpretation of "guide catheter" as used in full the context of the specification.

In Applicant's prior response of July 17, 2012, applicants pointed out that the guide catheter as claimed in claims 26 and 33 can be found in paragraphs [0060], [0063], and [0077] (see page 5 under "Formal Matters").

In the current rejection under section 112, first paragraph, the Examiner has apparently ignored the full support provided by Applicants as to where "guide catheter" is taught in the application, and instead solely relies on the disclosure based in paragraph [0077] which admittedly discloses two different guide catheters, of which the latter guide catheter disclosed supports claims 26 and 33 as previously presented.

More specifically, the first "guide catheter" mentioned in paragraph [0077] relates to a guide catheter 132 which is a portion of the conduit assembly 134 depicted in Figures 12. Towards the end of paragraph [0077], the specification teaches an additional guide catheter (not shown in the related figures) useful for positioning the conduit assembly 134 (and its integrated guide catheter 132) within the patient. This second "guide catheter" is disclosed within paragraph [0077] is among a list other devices which are taught to be useful for positioning the conduit assembly 134, the full list including "guide wires, balloon catheters, imaging wires, *guide catheters*, and/or techniques involving ultra-sound or fluoroscopy." (emphasis added)

Applicants contend that one skilled in the art would recognize that the claim limitations in claims 26 and 33 relating to the sizing of the guide catheter would not be in conflict with the specification and drawings, and would be able to appreciate the meaning of the guide catheter as claimed.

To expedite prosecution, Applicants have amended claims 26 and 33 to clarify that the guide catheter of claims 26 and 33 relates to a guide catheter for facilitating the positioning of the guide wire into the patient. This amendment should provide a sufficient distinction between the two types of guide catheter embodiments disclosed.

Guide Catheter to Position the Guide Wire:

In the Office Action, the Examiner asserts that the description in the specification, including paragraph [0059], raises doubt as to the possession of the claim invention at the time of filing with respect to a teaching that a guide catheter is used to position the guide wire. Applicants respectfully traverse.

Paragraph [0059] discloses a guide wire 22. Paragraph [0060] teaches how the guide wire 22 may be placed into the patient.

...“This [placement of the guide wire 22] may be done using the control features of the guide wire 22 itself, or may be facilitated through the use of any number of supplemental guidance mechanisms or techniques to ensure the proper and efficient placement of the guide wire 22. Such supplemental guidance techniques may include, but are not necessarily limited to, **guide catheters** and/or techniques involving ultrasound or flouroscopy. “

In light of the above amendments and remarks, the rejection under section 112, first paragraph, should be withdrawn.

**II. Claims Rejected Under 35 U.S.C. §112 Second Paragraph**

In the Office Action claims 37 and 39 have rejected under 35 U.S.C. 112 Second Paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

More specifically, the Examiner has indicated that the egress flow ports of Claims 37 and 39 lack antecedent basis with respect to the claims in which they depend from.

In light of the cancellation of claim 34, and the amendments made to claims 29, 37, and 39, the Examiner’s rejection should now be moot.

Withdrawal of the rejection is respectfully requested.

**III. Claims Objected to For Lack of Antecedent Basis**

In the Office Action, claims 27 and 28 have been objected to for lack of antecedent basis relating to the “drive.” In light of the cancellation of claim 28 and the amendment to claim 15, which no longer recites a “drive,” the Examiner’s objection is now moot.



Withdrawal of the objection is respectfully requested.

**IV. Claims Rejected Under 35 U.S.C. §103(a) (Summers in view of Gordon)**

In the Office Action, claims 15 and 23 – 26 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Summers et al. (US Patent 5,112,349) in view of Gordon (US Patent 5,938,645).

With respect to claim 15, the Examiner asserts that Summers and Gordon teach all of the elements of the claimed invention and that it would have been obvious to combine Summers and Gordon to achieve the claimed invention.

Applicants respectfully traverse and disagree with the Examiner's interpretation of the cited references, and submit that the references fail to teach or suggest each element of the claimed invention.

By way of the present amendment, independent claim 15 now recites (i) "a rotor hub tapering in the distal direction", (ii) "at least one blade extending radially outward from the rotor hub", and (iii) "the hub has a distal end extending distally beyond the most distal portion of the blade." The recitation of "at least one blade" was previously presented in dependent claim 23, of which the Examiner interpreted to exist in Summers at Figure 3 as having a blade.

Applicants submit that the Examiner's interpretation of Summers et al. is erroneous, and that the structure of Figure 3 of Summers is directed to a moineau-type pump. This type of pump is described in Summers to have a rotor 42 is fabricated of stainless steel material and formed in a helical shape. Applicants submit that the Summers rotor appears to have a shape resembling a cork-screw of a consistent cross-sectional shape. Notably, this cork-screw rotor does not extend radially from a rotor hub and therefore cannot be construed as a blade of the claimed invention.

Additionally, Summers at Col. 6, lines 51 -52, explains that the embodiments disclosed therein do not teach the existence of a blade, and actually teaches away from pumps having blades.

"The pump of the present disclosure does not utilize propellers or turbine blades to pump blood." (emphasis added)

Applicants respectfully submit that neither Summers, nor Gordon, individually

or in any proper combination disclose, teach or suggest the amended claim.

In view of the foregoing, Applicants respectfully submit that the cited combination of references do not render independent claim 15 obvious. Claims 23 - 26 depend from claim 15 and are patentable based on their dependencies in addition to their own claim limitations. In view of the foregoing, withdrawal of the rejection is respectfully requested.

**V. Claims Rejected Under 35 U.S.C. §103(a) (Summers in view of Gordon, further in view of Watkins);**

In the Office Action, claims 27 and 28 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Summers (US Patent 5,112,349) in view of Gordon (US Patent 5,112,349), in further view of Watkins (US Pat. 3,995,617).

Claim 28 has been cancelled without prejudice or disclaimer for later submission in this or a subsequent application.

The Office Action alleges that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Summers and Gordon with the blood pressure detection mechanism as taught by Watkins. Applicants respectfully traverse and submit that the disclosure of Watkins fails to cure the aforementioned deficiencies of Summers and Gordon.

In addition to the grounds previously articulated by Applicants with respect to claim 15, Applicants respectfully submit that the disclosure of Watkins fails to cure the aforementioned deficiencies of Summers and Gordon. In particular, Watkins also fails to teach a blade extending from a rotor. Additionally, with respect to the pressure detection mechanism of claim 28, Watkins fails to detect the pressure of blood proximate the blood pump. While Watkins references a pump, Watkins fails to specifically disclose the specific claimed pump structure as well as where the pump would be located. Absent the identification of pump structure and its location, it is not possible for Watkins, alone or in an proper combination, to teach the relative location (e.g., distal or proximal) of any pressure detection mechanism with respect to a pump as currently claimed.

In light of the above arguments, remarks, cancellation of claim 28 and the

amendments made to claims 15 and 27, the Examiner's rejection is now moot. In view of the foregoing, withdrawal of the rejection is respectfully requested.

**VI. Claims Rejected Under 35 U.S.C. §103(a) (Summers in view of Gordon in view of Siess);**

In the Official Action, claims 29 – 39 has been rejected under 35 U.S.C. being unpatentable over Summers (US Patent 5,112,349) in view of Gordon (US Patent 5,938,645) and Siess (US Pat. 6,007,478).

Claims 32 and 34 have been cancelled without prejudice or disclaimer for later submission in this or a subsequent application.

With respect to claim 29, the Examiner asserts that Summers, Gordon and Siess teach all of the elements of the claimed invention and that it would have been obvious to combine Summers, Gordon and Siess to achieve the claimed invention.

Applicants respectfully traverse and disagree with the Examiner's interpretation of the cited references, and submit that the references fail to teach or suggest each element of the claimed invention.

By way of the present amendment, independent claim 29 now recites "an intravascular blood pump comprising a rotor having a rotor hub tapering in the distal direction, at least one blade extending radially outward from the rotor hub." The recitation of "at least one blade" was previously presented in dependent claim 34, of which the Examiner interpreted in the Office Action to exist in Summers at Figure 3 as having a blade.

As previously articulated with respect to Claim 15, applicants submit that the Examiner's interpretation of Summers et al. is erroneous, and that the structure of Figure 3 of Summers is directed to a moineau-type pump and does not disclose or teach a blade. Siess and Gordon fail to cure this deficiency.

Applicants respectfully submit that none of Summers, Siess and Gordon, individually or in any proper combination disclose, teach or suggest the amended claim 29.

In view of the foregoing, Applicants respectfully submit that the cited combination of references do not render independent claim 29 obvious. Claims 30 –

31 and 35 - 39 depend from claim 29 and are patentable based on their dependencies in addition to their own claim limitations.

In view of the foregoing, withdrawal of the rejection is respectfully requested.

**VII. Claims Rejected Under 35 U.S.C. §103(a) (Summers in view of Masch and Gordon, and Summers, Gordon and Siess);**

In the Official Action, claims 29, 40 and 41 have been rejected under 35 U.S.C. as being unpatentable over Summers (US Patent 5,112,349) in view of Masch (US Patent 4,728,319) in view of Siess (6,007,478). Claim 29 is additionally rejected under 35 U.S.C. as being unpatentable over Summers, Masch and Siess in addition to Summers, Gordon and Siess.

With respect to claim 29, the Examiner asserts that Summers, Masch and Siess teach all of the elements of the claimed invention and that it would have been obvious to combine Summers and Gordon and Siess to achieve the claimed invention.

Applicants respectfully traverse and disagree with the Examiner's interpretation of the cited references, and submit that the references fail to teach or suggest each element of the claimed invention.

As mentioned previously, independent claim 29 now recites "an intravascular blood pump comprising a rotor having a rotor hub tapering in the distal direction, at least one blade extending radially outward from the rotor hub." As previously articulated with respect to Claim 15 at section IV and claim 29 at section VI, applicants submit that the Examiner's interpretation of Summers is erroneous, and that the structure of a "blade" is not found in Summers, nor is the structure of a "blade" taught or suggested in Siess, Masch, or Gordon.

In view of the foregoing, Applicants respectfully submit that the cited combination of references do not render independent claim 29 or its dependent claims 40 and 41 as obvious. Claims 30 – 31 and 35 - 39 depend from claim 29 and are patentable based on their dependencies in addition to their own claim limitations.

In view of the foregoing, withdrawal of the rejection is respectfully requested.

**VIII. New Claims 42 -48**

New claims 42 - 48 have been submitted above, of which claim 43 depends

from claim 15, claim 44 depends from 29 and claims 46 – 48 depend from new independent claim 45. The Examiner is respectfully requested to indicate the allowance of independent claims 15, 29 and 45 as well as their dependent claims in the next Official Action.

**Conclusion**

Applicants have made a good faith effort to place the claims in condition for allowance. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 04-0170, order number 06-01506US04.

Respectfully submitted,

Date: February 28, 2013

/Kirk D. Swenson/  
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| <b>PATENT APPLICATION FEE DETERMINATION RECORD</b><br>Substitute for Form PTO-875                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                               |                                  |                                    |               | Application or Docket Number<br><b>12/772,810</b> |                                          | Filing Date<br><b>05/03/2010</b> |                            | <input type="checkbox"/> To be Mailed |     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|------------------------------------|---------------|---------------------------------------------------|------------------------------------------|----------------------------------|----------------------------|---------------------------------------|-----|
| <b>APPLICATION AS FILED – PART I</b>                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                               |                                  |                                    |               |                                                   |                                          |                                  |                            |                                       |     |
| (Column 1)                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                               |                                  | (Column 2)                         |               |                                                   | SMALL ENTITY <input type="checkbox"/> OR |                                  | OTHER THAN<br>SMALL ENTITY |                                       |     |
| FOR                                                                                                                                                                                                                                                                                                                                                                                                                                  | NUMBER FILED                                                                                                                                                                                                                  | NUMBER EXTRA                     | RATE (\$)                          | FEE (\$)      | OR                                                | RATE (\$)                                | FEE (\$)                         |                            |                                       |     |
| <input type="checkbox"/> BASIC FEE<br>(37 CFR 1.16(a), (b), or (c))                                                                                                                                                                                                                                                                                                                                                                  | N/A                                                                                                                                                                                                                           | N/A                              | N/A                                |               |                                                   | N/A                                      |                                  |                            |                                       |     |
| <input type="checkbox"/> SEARCH FEE<br>(37 CFR 1.16(k), (l), or (m))                                                                                                                                                                                                                                                                                                                                                                 | N/A                                                                                                                                                                                                                           | N/A                              | N/A                                |               |                                                   | N/A                                      |                                  |                            |                                       |     |
| <input type="checkbox"/> EXAMINATION FEE<br>(37 CFR 1.16(o), (p), or (q))                                                                                                                                                                                                                                                                                                                                                            | N/A                                                                                                                                                                                                                           | N/A                              | N/A                                |               |                                                   | N/A                                      |                                  |                            |                                       |     |
| TOTAL CLAIMS<br>(37 CFR 1.16(j))                                                                                                                                                                                                                                                                                                                                                                                                     | minus 20 =                                                                                                                                                                                                                    | *                                | X \$                               | =             |                                                   | X \$                                     | =                                |                            |                                       |     |
| INDEPENDENT CLAIMS<br>(37 CFR 1.16(h))                                                                                                                                                                                                                                                                                                                                                                                               | minus 3 =                                                                                                                                                                                                                     | *                                | X \$                               | =             |                                                   | X \$                                     | =                                |                            |                                       |     |
| <input type="checkbox"/> APPLICATION SIZE FEE<br>(37 CFR 1.16(s))                                                                                                                                                                                                                                                                                                                                                                    | If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s). |                                  |                                    |               |                                                   |                                          |                                  |                            |                                       |     |
| <input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                               |                                  |                                    |               |                                                   |                                          |                                  |                            |                                       |     |
|                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                               |                                  | TOTAL                              |               |                                                   | TOTAL                                    |                                  |                            |                                       |     |
| <b>APPLICATION AS AMENDED – PART II</b>                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                               |                                  |                                    |               |                                                   |                                          |                                  |                            |                                       |     |
| (Column 1)                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                               |                                  | (Column 2)                         |               |                                                   | SMALL ENTITY OR                          |                                  | OTHER THAN<br>SMALL ENTITY |                                       |     |
| <b>AMENDMENT</b>                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>02/28/2013</b>                                                                                                                                                                                                             | CLAIMS REMAINING AFTER AMENDMENT | HIGHEST NUMBER PREVIOUSLY PAID FOR | PRESENT EXTRA | RATE (\$)                                         | ADDITIONAL FEE (\$)                      | OR                               | RATE (\$)                  | ADDITIONAL FEE (\$)                   |     |
|                                                                                                                                                                                                                                                                                                                                                                                                                                      | Total (37 CFR 1.16(i))                                                                                                                                                                                                        | * 24                             | Minus                              | ** 20         | = 4                                               | X \$                                     | =                                | OR                         | X \$62=                               | 248 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                      | Independent (37 CFR 1.16(h))                                                                                                                                                                                                  | * 3                              | Minus                              | ***3          | = 0                                               | X \$                                     | =                                | OR                         | X \$250=                              | 0   |
|                                                                                                                                                                                                                                                                                                                                                                                                                                      | <input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))                                                                                                                                                                |                                  |                                    |               |                                                   |                                          |                                  |                            |                                       |     |
|                                                                                                                                                                                                                                                                                                                                                                                                                                      | <input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))                                                                                                                                      |                                  |                                    |               |                                                   |                                          |                                  |                            |                                       |     |
|                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                               |                                  |                                    |               | TOTAL ADD'L FEE                                   |                                          |                                  | OR                         | TOTAL ADD'L FEE                       | 248 |
| <b>AMENDMENT</b>                                                                                                                                                                                                                                                                                                                                                                                                                     | Total (37 CFR 1.16(i))                                                                                                                                                                                                        | *                                | Minus                              | **            | =                                                 | X \$                                     | =                                | OR                         | X \$                                  | =   |
|                                                                                                                                                                                                                                                                                                                                                                                                                                      | Independent (37 CFR 1.16(h))                                                                                                                                                                                                  | *                                | Minus                              | ***           | =                                                 | X \$                                     | =                                | OR                         | X \$                                  | =   |
|                                                                                                                                                                                                                                                                                                                                                                                                                                      | <input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))                                                                                                                                                                |                                  |                                    |               |                                                   |                                          |                                  |                            |                                       |     |
|                                                                                                                                                                                                                                                                                                                                                                                                                                      | <input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))                                                                                                                                      |                                  |                                    |               |                                                   |                                          |                                  |                            |                                       |     |
|                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                               |                                  |                                    |               | TOTAL ADD'L FEE                                   |                                          |                                  | OR                         | TOTAL ADD'L FEE                       |     |
|                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                               |                                  |                                    |               |                                                   |                                          |                                  |                            |                                       |     |
| <p>* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.</p> <p>** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".</p> <p>*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".</p> <p>The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.</p> |                                                                                                                                                                                                                               |                                  |                                    |               |                                                   |                                          |                                  |                            |                                       |     |

Legal Instrument Examiner:  
/KIMBERLY WHITE/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 12/772,810      | 05/03/2010  | Walid N. Aboul-Hosn  | 06-01506US04        | 4661             |

99185 7590 05/08/2013  
MAQUET Cardiovascular LLC  
170 Baytech Drive  
San Jose, CA 95134

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| EXAMINER |
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MARCETICH, ADAM M

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

3761

|                   |               |
|-------------------|---------------|
| NOTIFICATION DATE | DELIVERY MODE |
|-------------------|---------------|

05/08/2013

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

legal@maquet.com

|                              |                                      |                                          |  |
|------------------------------|--------------------------------------|------------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>12/772,810 | <b>Applicant(s)</b><br>ABOUL-HOSN ET AL. |  |
|                              | <b>Examiner</b><br>ADAM MARCETICH    | <b>Art Unit</b><br>3761                  |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2013.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) 15,23-27,29-31,33 and 35-48 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 15,23-27,29-31,33 and 35-48 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 03 May 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                     |                                                                   |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.                                                         | 6) <input type="checkbox"/> Other: ____.                          |



## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 February 2013 has been entered.

### ***Priority***

The present application 12/772,810 is a continuation of 11/375,926 filed 15 March 2006;

which is a division of 10/070,178 filed 19 July 2002;

which is a national stage entry of PCT/US00/24515 filed 01 September 2000;

which claims priority from provisional 60/152249 filed 03 September 1999.

Claim 15 has been amended to describe the "side-rigger" or "rapid-exchange" guide mechanism described in the specification (¶ [0074], Fig. 9, guide carriage 124 formed along the interior surface of the cannula 14). This limitation does not appear in any correspondence filed with the original priority application 60/152249. It first appears in PCT/US00/24515.

Claim 29 calls for a blood pressure detection mechanism comprising a fluid column. This limitation also appears initially in PCT/US00/24515.

New claim 45 calls for a guide wire and an elongate lumen having a luminal interior sized smaller than an inside diameter of the cannula lumen. Provisional 60/152249 describes a that “. . . lumens may be provided within such structures as the pump body 30, the cable drive sheath 46, the catheter section 20 of the conduit assembly 14, etc., in order to receive wires. . .” (p. 12). However, this is a broad description which is not enabling for the elongate lumen having a luminal interior sized smaller than an inside diameter of the cannula lumen. Enabling support for this limitation first appears in PCT/US00/24515.

Therefore claims 15 and 23-48 are granted a priority date of 01 September 2000.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 43 and 44 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. New claims 43 and 44 call for a cannula that is bent between the distal and proximal ends. Fig. 19 gives enabling support for a bent cannula.

The specification describes that the intravascular blood pump system may be advanced over a balloon catheter and guided into a desired arrangement (§ [0090]). Parent claims 15 and 29 each call for a guide mechanism according to Figs. 7-9, which delivers a catheter via a guidewire (§ [0074]).

Delivering the pump intravascularly requires delivering the bent catheter through blood vessels that arrive at the heart through the aorta or vena cava. It does not appear possible to deliver a bent catheter through the vascular system, since the bent catheter of Fig. 19 would resist passage vessel that having a straight shape or curvature different from the bent catheter.

The specification is silent whether the cannula is made of rigid or flexible materials, and only discloses medical grade plastics optionally reinforced with spiral-wound wire 72 (§ [0066]). It is unclear whether the cannula can bend into a straight shape for passage through vessels, or whether it retains its bent shape as a rigid cannula.

***Claim Rejections - 35 USC § 112 Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37, 40-42, 45, 47 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 recites the limitation ". . . a plurality of egress flow ports disposed in the shroud. . ." in line 2. There is insufficient antecedent basis for the "shroud" in the claim. Claim 37 depends on claim 29, which only recites a catheter and cannula, and does not recite a "shroud." Figs. 12 and 13 of the drawings depicts apertures 138 in guide

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catheter 132, therefore Examiner interprets the “shroud” of claim 37 as the claimed “catheter” of claim 29.

Claim 40 calls for “. . . a central lumen longitudinally offset with respect to the cannula.” This description is ambiguous, since a lumen cannot be simultaneously central and offset.

Claims 41 and 42 depend on claim 40, and therefore contain the limitation of a longitudinally offset central lumen.

Claim 45 calls for “. . . an inside diameter of the **cannula lumen**. . .” There is insufficient antecedent basis for the “cannula lumen” in this claim. The claim describes that the cannula extends distally from the intravascular blood pump and has a plurality of ingress and egress ports, but does not explicitly establish a “cannula lumen.”

Claims 47 and 48 describe “. . . the lumen. . .” However, it is unclear whether “the lumen” refers to the “elongate lumen” or “catheter lumen” of parent claim 45.

### ***Claim Objections***

Claim 46 is objected to for minor informalities. The language “. . . and **exit pass through** the cannula. . .” should be changed for proper grammar.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 15, 23-25, 29, 30, 35-42 and 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nix; Christoph et al. (US 6176822) in view of Gordon; Lucas S. (US 5938645).**

Regarding claim 15, Nix discloses an intravascular blood pump system (col. 1, lines 29-34), comprising:

an intravascular blood pump (col. 3, lines 11-19, Fig. 1, pump 10), comprising:

a rotor having a rotor hub tapering in the distal direction (col. 3, lines 37-47, Fig. 1, impeller wheel 34 having hub 35);

at least one blade extending radially outward from the rotor hub (col. 3, lines 37-47, Fig. 1, blades 36);

the hub has a distal end extending distally beyond the most distal portion of the blade (Fig. 1, impeller wheel 34 having distal end extending distally beyond blades 36);  
and

a shroud within which the rotor is rotatably disposed (col. 3, lines 37-47, Fig. 1, pump housing 32);

a cannula extending from the shroud and comprising an outer cannula surface (cols. 3-4, lines 61-11, Fig. 1, hose 13);

the outer cannula surface having a substantially circular cross-section along a portion of its length (Fig. 1, hose 13 connected to pump housing 32 which holds rotating impeller wheel 34, necessitating a substantially circular cross-section).

Nix teaches the invention substantially as claimed by Applicant with the exception of a guide mechanism. Gordon discloses an intravascular system for removing thrombi (col. 4, lines 53-61, col. 8, lines 13-22, Fig. 1, catheter 12), comprising:

a cannula (col. 8, lines 23-32, Fig. 5a, catheter 18);

a guide mechanism configured as a lumen having a proximal end and a distal end (col. 8, lines 54-67, Figs. 5a, 5c, catheter lumen 46 having proximal and distal ends);

the guide mechanism adapted to guide a distal portion of said intravascular system to a predetermined location within the circulatory system of a patient end (col. 8, lines 54-67, Figs. 5a, 5c, catheter lumen 46 for accepting guidewire 14);

wherein an axis coaxial with and extending through a portion of said guide mechanism extends through a region delimited by the outer cannula surface (Fig. 5c, axis extending through guidewire 46 within region delimited by catheter 18); and

wherein the guide mechanism is configured to allow for a guide wire to slideably advance therealong (col. 8, lines 54-67, Figs. 5a, 5b, catheter lumen 46 for accepting guidewire 14).

Gordon guides a larger cannula through tight bends by positioning means for capturing a guidewire on the side of the cannula (col. 5, lines 5-22, especially lines 20-22). One would be motivated to modify Nix with the guide mechanism as taught by Gordon to maneuver a catheter through winding vessels since Nix calls for introducing the pump into the heart intravascularly (col. 2, lines 45-54). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Nix as discussed with the guide mechanism of Gordon in order to deliver a cannula through vessels.

Regarding claims 23 and 24, Nix discloses:

the rotor comprises a second blade extending radially from the rotor hub (col. 3, lines 37-47, Fig. 1, impeller wheel 34 having plural blades 36);

the rotor hub is generally conical (Fig. 1, impeller wheel 34 generally conical);

Regarding claim 25, Nix teaches the invention substantially as claimed by Applicant with the exception of a guide mechanism. Gordon discloses a guide mechanism configured such that the guide wire passes through the region delimited by the outer cannula surface at a location proximal to where the guide wire establishes slidable contact with the guide mechanism (Fig. 5a, proximal entrance to guidewire lumen 46 is located proximally to guidewire 46). Gordon improves the ability for a surgeon to guide an intravascular device through vessels towards the heart as discussed for claim 15 above.

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Regarding claim 29, Nix discloses an intravascular blood pump system (col. 1, lines 29-34), comprising:

an intravascular blood pump (col. 3, lines 11-19, Fig. 1, pump 10), comprising  
a rotor having a rotor hub tapering in the distal direction (col. 3, lines 37-47, Fig. 1, impeller wheel 34 having hub 35);

at least one blade extending radially outward from the rotor hub (col. 3, lines 37-47, Fig. 1, blades 36);

the intravascular blood pump coupled to a catheter on a proximal end (col. 3, lines 37-47, Fig. 1, pump housing 32); and

a cannula on a distal end (cols. 3-4, lines 61-11, Fig. 1, hose 13);

a first set and a second set of apertures establishing fluid communication between an interior of the cannula and an exterior region of the cannula (col. 3, lines 37-47, col. 4, lines 27-39, Fig. 3, radial opening 51 surrounded by webs 38 and perforations on distal end of hose 13);

wherein the first set of apertures is located in proximity to the rotor (Fig. 3, opening 51 proximal of impeller wheel 34); and

the second set of apertures is spaced apart from and located distal to the first set of apertures towards a distal region of the cannula (Fig. 3, perforations in hose 13 located distally of opening 51);

a blood pressure detection mechanism comprising a fluid column (col. 5, lines 44-56, Fig. 3, sensors 60, 61 and column of fluid passing through pump);



configured to detect the pressure of the blood proximate the intravascular blood pump (col. 5, lines 57-64, sensors 60, 61 detecting pressure).

Regarding the limitation of a blood pressure detection mechanism comprising a fluid column, the immediate invention relies on Aboul-Hosn; Walid N. et al. (US 6295877). Aboul-Hosn discloses examples of fluid columns used to detect blood pressure. One embodiment arranges a fluid column around a cannula (col. 5, lines 29-48, Fig. 7), and another embodiment arranges the fluid column outside, in a separate tube (cols. 5-6, lines 49-17, Fig. 8). Examiner interprets the “fluid column” of claim 29 consistently with this description, as calling for fluid stored within a tube. Similarly to Aboul-Hosn, blood will form a column in the hose and housing of Nix, and be in contact with pressure sensors 60, 61.

Nix teaches the invention substantially as claimed by Applicant with the exception of a guide mechanism. Gordon discloses an intravascular system (col. 4, lines 53-61, col. 8, lines 13-22, Fig. 1, catheter 12), comprising:

a guide mechanism configured as an elongate lumen (col. 8, lines 54-67, Figs. 5a, 5c, catheter lumen 46 having proximal and distal ends); and

adapted to guide said intravascular device to a predetermined location within the circulatory system of a patient (col. 8, lines 54-67, Figs. 5a, 5c, catheter lumen 46 for accepting guidewire 14); and

wherein the guide mechanism has a lumen sized substantially smaller than an outer diameter of the device (Fig. 5c, guidewire lumen 46 substantially smaller than outer diameter of catheter 18).

Gordon improves the maneuverability of an intravascular device as discussed for claim 15 above.

Regarding claim 30, Nix teaches the device substantially as claimed by Applicant with the exception of a guide mechanism. Gordon discloses a guide mechanism comprising a guide wire (col. 8, lines 13-22, Figs. 1, 5a, guidewire 14);

the system configured such that it is guidable in the circulatory system over the guide wire passing through the elongate lumen in the cannula but not extending through the catheter (col. 9, lines 1-4, Fig. 5c, guidewire lumen 46 not extending through hemostasis valve 22).

Gordon guides an intravascular device through the body while navigating through tight bends (col. 5, lines 5-22). One would have been motivated to modify the invention of Nix with the guide mechanism of Gordon since Nix manipulates an intravascular device through vessels in the body.

Regarding claims 35-39, Nix discloses:

the rotor comprises a second blade extending radially from the rotor hub (col. 3, lines 37-47, Fig. 1, plurality of blades 36);

the cannula comprises an outer cannula surface having a substantially circular cross-section along a portion of its length (Fig. 1, hose 13 connected to pump housing 32 which holds rotating impeller wheel 34, necessitating a substantially circular cross-section);

the distal region of the outer cannula surface is distally tapered about its circumference (Fig. 3, distal region of left cardiac pump 10b tapered distally);

a plurality of egress flow ports disposed in the shroud (Fig. 3, radial opening 51 surrounded by webs 38); and

a plurality of ingress flow ports disposed at a location spaced apart from and distal to the egress flow ports (Fig. 3, perforations at distal end of hose 13);

wherein the ingress flow ports comprise an end port located at the cannula distal end (Fig. 3, open distal end); and

a plurality of ports located about the cannula and proximal to the end port (Fig. 3, plurality of perforations proximal to open distal end);

wherein the first set of apertures are egress ports and the second set of apertures are ingress ports (cols. 3-4, lines 61-11, 27-39, Fig. 3, left cardiac pump 10 takes in through hose 13); and

wherein the egress ports are configured to direct blood passing through the interior of the cannula and towards the rotor in a direction that is both proximal and radially outward with respect to the rotor hub (Fig. 3, blood will travel both proximal and radially outward from radial opening 51).

Regarding claims 40-42, Nix teaches the invention substantially as claimed by Applicant with the exception of a guide mechanism. Gordon discloses:

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the elongate lumen of the guide mechanism is a central lumen longitudinally offset with respect to the cannula (Figs. 5a, 5c, guidewire lumen 46 offset from central lumen of catheter 18);

the central lumen extends through the intravascular device (Fig. 5a, guidewire lumen 46 extending through catheter 18);

the lumen of the central lumen is proximal to the cannula (Fig. 5a, guidewire lumen 46 having portion proximal to catheter 18).

Regarding rationale and motivation to modify Nix in view of Gordon, see discussion of claim 15 above.

Regarding claim 45, Nix discloses an intravascular blood pump system configured to be advanced to a predetermined location in a patient's circulatory system (col. 1, lines 29-34);

the intravascular blood pump system comprising:

an intravascular blood pump (col. 3, lines 11-19, Fig. 1, pump 10),

the intravascular blood pump comprising a rotor having a generally conical rotor hub tapering in the distal direction (col. 3, lines 37-47, Fig. 1, impeller wheel 34 having hub 35 tapering in distal direction);

at least two blades extending radially from the rotor hub (col. 3, lines 37-47, Fig. 1, blades 36);

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the generally conical rotor hub having a distal tip extending distally beyond the blades (Fig. 1, impeller wheel 34 having distal end extending distally beyond blades 36); and

a cannula extending distally from the intravascular blood pump (cols. 3-4, lines 61-11, Fig. 1, hose 13);

a plurality of ingress ports located towards the proximal region of the cannula (Fig. 3, ingress ports at distal end of left cardiac pump 10a); and

a plurality of egress ports located in proximity to the blood pump (col. 4, lines 27-39, Fig. 3, radial opening 51 and webs 38);

such that movement of fluid proximally through an interior region of the cannula is steered towards the egress ports (cols. 3-4, lines 61-11, pump 10a takes in through hose 13).

Nix teaches the invention substantially as claimed by Applicant with the exception of a guide wire and an elongate lumen. Gordon discloses an intravascular system (col. 4, lines 53-61, col. 8, lines 13-22, Fig. 1, catheter 12), comprising:

a guide wire having a cross-section substantial smaller than the cannula (col. 8, lines 54-63, Fig. 5a, guidewire 14 having small cross-section); and

an elongate lumen having a luminal interior (col. 8, lines 64-67, Fig. 5a, guidewire lumen 46);

sized (i) smaller than an inside diameter of the cannula lumen (Fig. 5a, guidewire lumen 46 having lumen smaller than lumen of catheter 18); and

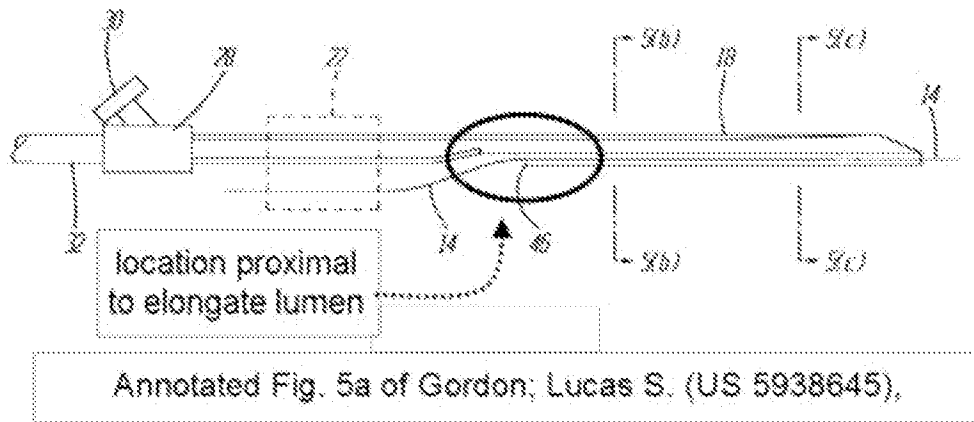
(ii) sufficiently large enough to accommodate the guide wire when the guide wire is advanced therealong (Fig. 5a, passing guidewire 14 through guidewire lumen 46).

Gordon enhances the maneuverability of an intravascular device as discussed for claim 15 above.

Regarding claims 46-48, Nix teaches the invention substantially as claimed by Applicant with the exception of a guide wire and an elongate lumen. Gordon discloses:

the intravascular system is configured to allow for the guide wire to extend through the elongate lumen (Fig. 5a, passing guidewire 14 through guidewire lumen 46); and

exit pass through the cannula at a location proximal to the elongate lumen (Fig. 5a, guidewire 14 passing through guidewire lumen 46 at proximal location);



which further provides for the guide wire to pass through an outer cannula surface of the cannula (Fig. 5a, guidewire 14 passing through outer surface of cannula 18 at proximal and distal points);

wherein the lumen is longitudinally offset with respect to the cannula (Fig. 5c, guidewire lumen 46 longitudinally offset);

wherein the lumen is proximal with respect to the cannula (Fig. 5a, guidewire lumen 46 having proximal portion along catheter 18).

Regarding rationale and motivation to modify Nix in view of Gordon, see discussion of claim 1 above.

**Claims 26 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nix; Christoph et al. (US 6176822) in view of Gordon; Lucas S. (US 5938645), further in view of Teirstein; Paul S. et al. (US 5234407).**

Regarding claims 26 and 33, Nix and Gordon teach the invention substantially as claimed by Applicant with the exception of a guide catheter for placing the guide wire into the heart. Teirstein discloses a cardiovascular exchange catheter (col. 3, lines 31-38), comprising:

a guidewire (cols. 10-11, lines 62-6, Fig. 13a, guide wire 32); and

a guide catheter (cols. 10-11, lines 62-6, Fig. 13a, guide catheter 10);

wherein the guide catheter is configured to facilitate the placement of the guide wire into the heart (col. 11, lines 6-15, guide catheter removed and optionally replaced with substitute guide catheter 10a).

Teirstein allows components of an intravascular system to be guided through vasculature without removing a guidewire during surgery (cols. 7-8, lines 59-2). Guide catheter 10 of Teirstein also provides an entrance to vasculature through the skin. One

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would be motivated to modify Nix and Gordon with the guide catheter of Teirstein to deliver a guidewire through a patient's skin. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Nix and Gordon as discussed with the guide catheter of Teirstein in order to deliver an intravascular component through the skin.

**Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nix; Christoph et al. (US 6176822) in view of Gordon; Lucas S. (US 5938645), further in view of Watkins; David H. et al. (US 3995617).**

Regarding claim 27, Nix discloses a blood pump system comprising a blood pressure detection mechanism (col. 5, lines 44-56, Fig. 3, sensors 60, 61). Nix and Gordon teach the invention substantially as claimed by Applicant with the exception of an elongate catheter and pressure detection mechanism.

Watkins discloses an apparatus for augmenting heart function (col. 1, lines 3-10, col. 3, lines 6-18, Figs. 1, 2, shaft portion 50 and flexible tube 51); comprising:

an intravascular device (Figs. 1-5, shaft / catheter 50);

an elongate catheter extending proximally with respect to the intravascular device (col. 4, lines 28-43, Fig. 5, interior channel member 56; lines 44-58, corresponding channel member 57); and

a blood pressure detection mechanism comprising a fluid column disposed within the catheter (Fig. 5, fluid occupying each of channels 56, 57); and



configured to detect the pressure of the blood proximate the intravascular blood pump (col. 4, lines 31-35, 47-51, gauges connected to openings 56a, 57a).

This rejection modifies the intravascular pump of Nix and Gordon as discussed with the pressure-measuring columns of Watkins. The pressure measurements of Watkins measure whether the heart is responding to treatment (cols. 4-5, lines 58-5). One would be motivated to modify Nix and Gordon with the blood pressure detection mechanism as taught by Watkins to since Nix calls for augmenting heart function during healing (col. 1, lines 3-6), and differential pressure sensors (cols. 1-2, lines 64-5). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Nix and Gordon as discussed with the blood pressure detection mechanism of Watkins in order to evaluate a healing response of the heart.

**Claims 31, 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nix; Christoph et al. (US 6176822) in view of Gordon; Lucas S. (US 5938645), further in view of Siess; Thorsten et al. (US 6007478).**

Regarding claim 31, Nix and Gordon teach the device substantially as claimed by Applicant with the exception of a spiral wire. Siess discloses a cannula (col. 4, lines 56-65, Fig. 2, flexible material 30);

wherein the cannula is reinforced with a spiral wire (col. 5, lines 28-38, Figs. 2, 3, spiral spring 29 of NiTi).

Siess adjusts the stiffness of a cannula to guide it through vasculature (col. 3, lines 47-56). One would have been motivated to modify the invention of Nix and Gordon as discussed with the spiral wire of Siess to maneuver the cannula more easily through vasculature.

Regarding claims 43 and 44, Nix and Gordon teach the invention substantially as claimed by Applicant with the exception of a bent cannula. Siess discloses a cannula for use as an intravascular blood pump (col. 4, lines 29-37); comprising:

a pump (col. 4, lines 38-45, Fig. 1, pump 14);

a catheter (col. 4, lines 56-65, Fig. 2, stiff material 28);

a cannula (col. 4, lines 56-65, Fig. 2, flexible material 30);

wherein the cannula is bent at a location between distal and proximal ends thereof (col. 5, lines 3-11, Fig. 2, flexible material allowing body portion 22 to bend).

Siess improves the maneuverability of an intravascular device (col. 7, lines 43-49). One would be motivated to modify Nix and Gordon with the bent cannula of Siess to improve maneuverability when delivering the pump through vasculature towards the heart. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Nix and Gordon as discussed with the bent cannula of Siess in order to improve maneuverability.

***Response to Arguments***

Objections to claims 27 and 28 for minor informalities and rejections of claims 26, 33 and 39 under 35 USC § 112 applied in the previous office action are withdrawn in view of the amendments filed 28 February 2013.

Applicant's arguments filed 28 February 2013 regarding the rejection of claims 15 and 23-41 as amended, under 35 USC § 103 over Summers, Gordon, Watkins, Siess and Masch, are persuasive. After consideration of the amended claims, the claims are rejected on new grounds under 35 USC § 103 over Nix, Gordon, Watkins, Teirstein and Siess (see above).

Applicant's arguments with respect to Summers and Masch have been considered but are moot because the arguments do not apply to any of the references being used in the current rejection.

Applicant contends that the amendment should provide a sufficient distinction between the two types of guide catheter embodiments disclosed (remarks p. 9). Examiner has withdrawn the 112.1 rejections of claims 26 and 33.

Applicant asserts that the Summers rotor appears to have a shape resembling a cork-screw of a consistent cross-sectional shape (remarks p. 11). Examiner instead cites Nix in the new grounds of rejection as teaching a rotor having a hub and blades.

Applicant submits that Watkins fails to detect the pressure of blood proximate the blood pump (remarks p. 12). Examiner instead cites Watkins as teaching the elongate catheter of claim 27. One would have been able to modify the invention of Nix and

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Gordon with the elongate catheter (channel members 56, 57 of Watkins), in order to measure a pressure differential across the intravascular pump of Nix.

Applicant contends that the combinations of Summers, Siess and Gordon or Summers, Masch and Siess fail to teach the limitations of amended claim 29 (remarks p. 13-14). Examiner instead cites Nix and Gordon in the new grounds of rejection as teaching all limitations of claim 29.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Tel 571-272-2590  
Fax 571-273-2590  
Email [Adam.Marcetich@uspto.gov](mailto:Adam.Marcetich@uspto.gov)

The Examiner can be reached 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/  
Examiner, Art Unit 3761

|                                   |                                       |                                                                 |             |
|-----------------------------------|---------------------------------------|-----------------------------------------------------------------|-------------|
| <b>Notice of References Cited</b> | Application/Control No.<br>12/772,810 | Applicant(s)/Patent Under<br>Reexamination<br>ABOUL-HOSN ET AL. |             |
|                                   | Examiner<br>ADAM MARCETICH            | Art Unit<br>3761                                                | Page 1 of 1 |

**U.S. PATENT DOCUMENTS**

| * |   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Name             | Classification |
|---|---|--------------------------------------------------|-----------------|------------------|----------------|
| * | A | US-5,234,407 A                                   | 08-1993         | Teirstein et al. | 604/528        |
|   | B | US-                                              |                 |                  |                |
|   | C | US-                                              |                 |                  |                |
|   | D | US-                                              |                 |                  |                |
|   | E | US-                                              |                 |                  |                |
|   | F | US-                                              |                 |                  |                |
|   | G | US-                                              |                 |                  |                |
|   | H | US-                                              |                 |                  |                |
|   | I | US-                                              |                 |                  |                |
|   | J | US-                                              |                 |                  |                |
|   | K | US-                                              |                 |                  |                |
|   | L | US-                                              |                 |                  |                |
|   | M | US-                                              |                 |                  |                |

**FOREIGN PATENT DOCUMENTS**

| * |   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Country | Name | Classification |
|---|---|--------------------------------------------------|-----------------|---------|------|----------------|
|   | N |                                                  |                 |         |      |                |
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**NON-PATENT DOCUMENTS**

| * |   | Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) |
|---|---|-------------------------------------------------------------------------------------------|
|   | U |                                                                                           |
|   | V |                                                                                           |
|   | W |                                                                                           |
|   | X |                                                                                           |

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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|--------------------------------------------------------------------------------------------------------------|------------------------------------------------|-------------------------------------------------------------------------|
| <b>Search Notes</b><br><br> | <b>Application/Control No.</b><br><br>12772810 | <b>Applicant(s)/Patent Under Reexamination</b><br><br>ABOUL-HOSN ET AL. |
|                                                                                                              | <b>Examiner</b><br><br>ADAM MARCETICH          | <b>Art Unit</b><br><br>3761                                             |

| CPC- SEARCHED |      |          |
|---------------|------|----------|
| Symbol        | Date | Examiner |
|               |      |          |

| CPC COMBINATION SETS - SEARCHED |      |          |
|---------------------------------|------|----------|
| Symbol                          | Date | Examiner |
|                                 |      |          |

| US CLASSIFICATION SEARCHED |                |            |          |
|----------------------------|----------------|------------|----------|
| Class                      | Subclass       | Date       | Examiner |
| 604                        | 43,156,158,540 | 2/3/2012   | AMM      |
| 623                        | 3.1            | 2/3/2012   | AMM      |
| 600                        | 16             | 2/3/2012   | AMM      |
|                            | search update  | 8/17/2012  | AMM      |
|                            | search update  | 05/02/2013 | AMM      |

| SEARCH NOTES                                                                              |            |           |
|-------------------------------------------------------------------------------------------|------------|-----------|
| Search Notes                                                                              | Date       | Examiner  |
| Inventor search: PALM and EAST (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT, IBM_TDB) | 2/3/2012   | AMM       |
| Review PLUS search results returned Friday, 3 February 2012                               | 2/3/2012   | AMM       |
| Review cited art for related cases 11/375926, 10/070178                                   | 2/3/2012   | AMM       |
| Review ISR for PCT/US00/24515 performed 19 March 2001, Angie Sykes USPTO                  | 2/3/2012   | AMM       |
| search update                                                                             | 8/17/2012  | 8/18/2012 |
| search update                                                                             | 05/02/2013 | AMM       |

| INTERFERENCE SEARCH     |                         |      |          |
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| US Class/<br>CPC Symbol | US Subclass / CPC Group | Date | Examiner |
|                         |                         |      |          |

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| /Adam Marcetich/<br>Examiner, Art Unit 3761 |  |
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EAST Search History

EAST Search History (Prior Art)

| Ref # | Hits | Search Query                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | DBs                                                              | Default Operator | Plurals | Time Stamp          |
|-------|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|------------------|---------|---------------------|
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| L8    | 2    | (US-6176822-\$ or US-5234407-\$).did.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | USPAT                                                            | OR               | OFF     | 2013/05/02<br>16:43 |
| L7    | 7    | 6 and @ad<"20000901"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2013/05/02<br>14:26 |
| L6    | 28   | ("4508535"   "5435308"   "5755687"   "5797948"   "5814004").PN. OR ("6295877").URPN.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR               | OFF     | 2013/05/02<br>14:25 |
| L5    | 1    | "6295877".pn.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR               | OFF     | 2013/05/02<br>14:22 |
| S138  | 260  | S137 and (wire guidewire) with (plac\$3 placement placment locat\$3 deliver\$3 send sending sent establish\$3 fix thread\$3)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2013/05/02<br>11:06 |
| S137  | 834  | (604/164.01,164.08,164.09,164.1,164.11,164.12,164.13).ccls. and @ad<"20000901"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2013/05/02<br>11:05 |
| S136  | 85   | S135 and (rotor blade impeller impeler turbine wheel propeller propeler fin fins petal\$1) and blood                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2013/05/02<br>09:08 |
| S135  | 139  | (623/3.1,3.13,3.14,3.15).ccls. and @ad<"20000901"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | US-PGPUB;<br>USPAT;                                              | OR               | ON      | 2013/05/02<br>09:07 |

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|      |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB                        |    |     |                     |
| S134 | 13 | S133 and @ad<"20000901" not (S130 S132)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2013/05/02<br>09:06 |
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| S132 | 11 | S131 and @ad<"20000901" not S130                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2013/05/02<br>09:05 |
| S131 | 57 | ("4382199"   "4688998"   "4817586"   "5376114"  <br>"5385581"   "5443503"   "5507629"   "5695471").PN. OR<br>("5921913"   "5964694").URPN.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR | OFF | 2013/05/02<br>09:05 |
| S130 | 30 | S129 and @ad<"20000901"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2013/05/02<br>08:52 |
| S129 | 57 | ("3568659"   "3995617"   "4382199"   "4512726"  <br>"4688998"   "4704121"   "4779614"   "4817586"   "4846152"<br>  "4895557"   "4906229"   "4908012"   "4919647"  <br>"4944722"   "5061256"   "5092879"   "5112292"   "5376114"<br>  "5385454"   "5385581"   "5393207"   "5507629"  <br>"5527159"   "5695471"   "5911685"   "5921913"  <br>"5964694").PN. OR ("6176822").URPN.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR | OFF | 2013/05/02<br>08:51 |
| S116 | 73 | ("5776190"   "5810088"   "5957672"   "6083260"  <br>"6086570"   "6123725"   "6217541"   "6234960"   "6336939"<br>  "6395026"   "3904901"   "4895557"   "5300112"  <br>"5746709"   "5911685"   "6113536"   "6123659"   "6176848"<br>  "7731675"   "5965089"   "6007478"   "4955856"  <br>"5041131"   "5692882"   "6093001"   "6228063"   "6245007"<br>  "6295877"   "5476450"   "4392836"   "4591355"  <br>"4628712"   "4696667"   "4746758"   "4909781"   "4964839"<br>  "5888241"   "3585983"   "3602009"   "4704121"  <br>"4919647"   "5851174"   "5947892"   "6613008"   "7022100"<br>  "5827267"   "5221256"   "5827229"   "4817586"  <br>"5163910"   "5741234"   "6176822"   "6210133"   "6287319"<br>  "6709418"   "6849068"   "3995617"   "20030205233"  <br>"4391547"   "4917102"   "5678306"   "6210397"   "6532964"<br>  "6440158"   "5938645"   "6066100"   "20030023201"  <br>"4413989"   "4728319"   "4908012"   "5112349"   "6152704"<br>  "6346120").PN. | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR | OFF | 2013/05/01<br>16:57 |

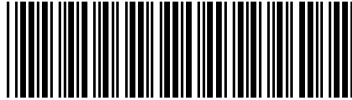
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| <b><i>Index of Claims</i></b><br><br> | <b>Application/Control No.</b><br><br>12772810 | <b>Applicant(s)/Patent Under Reexamination</b><br><br>ABOUL-HOSN ET AL. |
|                                                                                                                        | <b>Examiner</b><br><br>ADAM MARCETICH          | <b>Art Unit</b><br><br>3761                                             |

|   |                 |   |                   |   |                     |   |                 |
|---|-----------------|---|-------------------|---|---------------------|---|-----------------|
| ✓ | <b>Rejected</b> | - | <b>Cancelled</b>  | N | <b>Non-Elected</b>  | A | <b>Appeal</b>   |
| = | <b>Allowed</b>  | ÷ | <b>Restricted</b> | I | <b>Interference</b> | O | <b>Objected</b> |

| <input type="checkbox"/> Claims renumbered in the same order as presented by applicant |          |            |            |            | <input type="checkbox"/> CPA |  |  |  |  | <input type="checkbox"/> T.D. |  |  |  |  | <input type="checkbox"/> R.1.47 |  |  |  |  |
|----------------------------------------------------------------------------------------|----------|------------|------------|------------|------------------------------|--|--|--|--|-------------------------------|--|--|--|--|---------------------------------|--|--|--|--|
| CLAIM                                                                                  |          | DATE       |            |            |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
| Final                                                                                  | Original | 02/06/2012 | 08/20/2012 | 05/02/2013 |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 1        | -          | -          | -          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 2        | ✓          | -          | -          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 3        | ✓          | -          | -          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 4        | ✓          | -          | -          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 5        | ✓          | -          | -          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 6        | ✓          | -          | -          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 7        | ✓          | -          | -          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 8        | ✓          | -          | -          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 9        | ✓          | -          | -          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 10       | ✓          | -          | -          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 11       | ✓          | -          | -          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 12       | ✓          | -          | -          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 13       | ✓          | -          | -          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 14       | ✓          | -          | -          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 15       | ✓          | ✓          | ✓          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 16       | ✓          | -          | -          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 17       | ✓          | -          | -          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 18       | ✓          | -          | -          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 19       | ✓          | -          | -          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 20       | ✓          | -          | -          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 21       | ✓          | -          | -          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 22       | ✓          | -          | -          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 23       |            | ✓          | ✓          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 24       |            | ✓          | ✓          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 25       |            | ✓          | ✓          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 26       |            | ✓          | ✓          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 27       |            | ✓          | ✓          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 28       |            | ✓          | -          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 29       |            | ✓          | ✓          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 30       |            | ✓          | ✓          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 31       |            | ✓          | ✓          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 32       |            | ✓          | -          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 33       |            | ✓          | ✓          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 34       |            | ✓          | -          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 35       |            | ✓          | ✓          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 36       |            | ✓          | ✓          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |

|                                                                                                                        |                                                |                                                                         |
|------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|-------------------------------------------------------------------------|
| <b><i>Index of Claims</i></b><br><br> | <b>Application/Control No.</b><br><br>12772810 | <b>Applicant(s)/Patent Under Reexamination</b><br><br>ABOUL-HOSN ET AL. |
|                                                                                                                        | <b>Examiner</b><br><br>ADAM MARCETICH          | <b>Art Unit</b><br><br>3761                                             |

|   |                 |   |                   |   |                     |   |                 |
|---|-----------------|---|-------------------|---|---------------------|---|-----------------|
| ✓ | <b>Rejected</b> | - | <b>Cancelled</b>  | N | <b>Non-Elected</b>  | A | <b>Appeal</b>   |
| = | <b>Allowed</b>  | ÷ | <b>Restricted</b> | I | <b>Interference</b> | O | <b>Objected</b> |

| <input type="checkbox"/> Claims renumbered in the same order as presented by applicant |          |            |            |            | <input type="checkbox"/> CPA |  |  |  |  | <input type="checkbox"/> T.D. |  |  |  |  | <input type="checkbox"/> R.1.47 |  |  |  |  |
|----------------------------------------------------------------------------------------|----------|------------|------------|------------|------------------------------|--|--|--|--|-------------------------------|--|--|--|--|---------------------------------|--|--|--|--|
| CLAIM                                                                                  |          | DATE       |            |            |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
| Final                                                                                  | Original | 02/06/2012 | 08/20/2012 | 05/02/2013 |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 37       |            | ✓          | ✓          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 38       |            | ✓          | ✓          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 39       |            | ✓          | ✓          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 40       |            | ✓          | ✓          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 41       |            | ✓          | ✓          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 42       |            |            | ✓          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 43       |            |            | ✓          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 44       |            |            | ✓          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 45       |            |            | ✓          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 46       |            |            | ✓          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 47       |            |            | ✓          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |
|                                                                                        | 48       |            |            | ✓          |                              |  |  |  |  |                               |  |  |  |  |                                 |  |  |  |  |

|                                                                                                                                                                                                                                     |                      |                                                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|-------------------------------------------------------|
| <p style="text-align: center;"><b>AMENDMENT<br/>UNDER 37 C.F.R. §1.111</b></p> <p style="text-align: center;">Address to:<br/>Mail Stop: Amendment<br/>Commissioner for Patents<br/>P.O. Box 1450<br/>Alexandria, VA 22313-1450</p> | Attorney Docket      | 06-01506US04                                          |
|                                                                                                                                                                                                                                     | Confirmation No.     | 4661                                                  |
|                                                                                                                                                                                                                                     | First Named Inventor | Walid N. ABOUL-HOSN                                   |
|                                                                                                                                                                                                                                     | Application Number   | 12/772,810                                            |
|                                                                                                                                                                                                                                     | Filing Date          | May 3, 2010                                           |
|                                                                                                                                                                                                                                     | Group Art Unit       | 3761                                                  |
|                                                                                                                                                                                                                                     | Examiner Name        | Marcetich, Adam M.                                    |
|                                                                                                                                                                                                                                     | Title                | Guidable Intravascular Blood Pump and Related Methods |

Sir:

This amendment is responsive to the Non-Final Office Action dated May 8, 2013 for which a three-month period for response was given making this response due on or before August 8, 2013. A three-month extension of time is being filed concurrently making this response due on or before November 8, 2013. In view of the amendments to the claims and the remarks put forth below, reconsideration and allowance are respectfully requested.

The **Claims** begin on page 2.

**Remarks** being on page 8.

## AMENDMENTS TO THE CLAIMS

Claims 1 – 14 (Cancelled)

15. (Currently Amended) An intravascular blood pump system, comprising:

an intravascular blood pump comprising:

a rotor having a rotor hub tapering in the distal direction, at least one blade extending radially outward from the rotor hub, the hub has a distal end extending distally beyond the most distal portion of the blade and

a shroud within which the rotor is rotatably disposed;

a cannula extending from the shroud and comprising an outer cannula surface, the outer cannula surface having a substantially circular cross-section along a portion of its length;

a first lumen in fluid communication with the intravascular blood pump and operatively arranged to deliver purge fluid to the intravascular blood pump; and

a guide mechanism configured as a second lumen having a proximal end and a distal end, the guide mechanism adapted to guide a distal portion of said intravascular blood pump system to a predetermined location within the circulatory system of a patient;

wherein an axis coaxial with and extending through a portion of said guide mechanism extends through a region delimited by the outer cannula surface, and wherein the guide mechanism is configured to allow for a guide wire to slideably advance therealong.

16 – 22 (Cancelled)

23. (Previously Presented) The intravascular blood pump system of claim 15, wherein the rotor comprises a second blade extending radially from the rotor hub.

24. (Previously Presented) The intravascular blood pump system of claim 15, wherein the rotor hub is generally conical.

25. (Previously Presented) The intravascular blood pump system of claim 15, wherein the guide mechanism is configured such that the guide wire passes through the region delimited by the outer cannula surface at a location proximal to where the guide wire establishes slidable contact with the guide mechanism.

26. (Previously Presented) The intravascular blood pump system of claim 15, further comprising a guide catheter, wherein the guide catheter is configured to facilitate the placement of the guide wire into the heart.

27. (Previously Presented) The intravascular blood pump system of claim 15, further comprising:

an elongate catheter extending proximally with respect to the intravascular blood pump; and

a blood pressure detection mechanism comprising a fluid column disposed within the catheter and configured to detect the pressure of the blood proximate the intravascular blood pump.

28. (Cancelled)

29. (Currently Amended) An intravascular blood pump system comprising:  
an intravascular blood pump comprising a rotor having a rotor hub tapering in the distal direction, at least one blade extending radially outward from the rotor hub, the intravascular blood pump coupled to a catheter on a proximal end and a cannula on a distal end;

a first set and a second set of apertures establishing fluid communication between an interior of the cannula and an exterior region of the cannula, wherein the first set of apertures is located in proximity to the rotor and the second set of apertures

is spaced apart from and located distal to the first set of apertures towards a distal region of the cannula;

a guide mechanism configured as an elongate lumen and adapted to guide said intravascular blood pump, cannula, and catheter to a predetermined location within the circulatory system of a patient; and

a blood pressure detection mechanism comprising a fluid column configured to detect the pressure of the blood proximate the intravascular blood pump;

wherein the guide mechanism has a lumen sized substantially smaller than an ~~outer~~-inner diameter of the cannula and intravascular blood pump and a guide wire arranged to be advanced along the lumen, the lumen is arranged coaxially with at least one of a distal end or a proximal end of the cannula, and the cannula and the lumen are arranged in series longitudinally.

30. (Previously Presented) The intravascular blood pump system of claim 29, wherein the guide mechanism comprises a guide wire, the blood pump system configured such that it is guidable in the circulatory system over the guide wire passing through the elongate lumen in the cannula but not extending through the catheter.

31 (Previously Presented) The intravascular blood pump system of claim 29, wherein the cannula is reinforced with a spiral wire.

32. (Cancelled)

33. (Previously Presented) The intravascular blood pump system of claim 29, further comprising a guide wire and a guide catheter, wherein the guide catheter is configured facilitate the placement of the guide wire through the vasculature into the heart.

34. (Cancelled)

35. (Previously Presented) The intravascular blood pump system of claim 29, wherein the rotor comprises a second blade extending radially from the rotor hub.

36. (Previously Presented) The intravascular blood pump system of claim 29, wherein the cannula comprises an outer cannula surface having a substantially circular cross-section along a portion of its length, the distal region of the outer cannula surface is distally tapered about its circumference.

37. (Currently Amended) The intravascular blood pump system of claim 29, further comprising a plurality of egress flow ports disposed in ~~the~~ a shroud of the intravascular blood pump, and a plurality of ingress flow ports disposed at a location spaced apart from and distal to the egress flow ports.

38. (Previously Presented) The intravascular blood pump system of claim 37, wherein the ingress flow ports comprise an end port located at the cannula distal end and a plurality of ports located about the cannula and proximal to the end port.

39. (Previously Presented) The intravascular blood pump system of claim 29, wherein the first set of apertures are egress ports and the second set of apertures are ingress ports, and wherein the egress ports are configured to direct blood passing through the interior of the cannula and towards the rotor in a direction that is both proximal and radially outward with respect to the rotor hub.

40. (Cancelled)

41. (Currently Amended) The intravascular blood pump system of claim ~~40~~29, wherein the central lumen extends through the cannula and blood pump.

42. (Currently Amended) The intravascular blood pump system of claim ~~40~~29, wherein the lumen of the central lumen is proximal to the cannula.

43. (Currently Amended) The intravascular blood pump system of claim 15, wherein the cannula is operatively arranged to bend ~~bent~~ at a location between distal and proximal ends thereof.



44. (Currently Amended) The intravascular blood pump system of claim 29, wherein the cannula is operatively arranged to bend ~~bent~~ at a location between distal and proximal ends thereof.

45. (Currently Amended) An intravascular blood pump system configured to be advanced to a predetermined location in a patient's circulatory system, the intravascular blood pump system comprising:

an intravascular blood pump, the intravascular blood pump comprising a rotor having a generally conical rotor hub tapering in the distal direction, at least two blades extending radially from the rotor hub, the generally conical rotor hub having a distal tip extending distally beyond the blades;

a cannula extending distally from the intravascular blood pump;

a plurality of ingress ports located towards the proximal region of the cannula and a plurality of egress ports located in proximity to the blood pump such that movement of fluid proximally through an interior region of the cannula is steered towards the egress ports;

a guide wire having a cross-section substantially smaller than the cannula;

and

an elongate lumen having a luminal interior sized (i) smaller than an inside diameter of the cannula ~~lumen~~ and (ii) sufficiently large enough to accommodate the guide wire when the guide wire is advanced therealong, wherein the lumen is arranged coaxially with respect to at least one of a distal end or a proximal end of the cannula, and the lumen and the cannula are arranged in series longitudinally.

46. (Currently Amended) The intravascular blood pump system of claim 45, wherein the blood pump system is configured to allow for the guide wire to extend through the elongate lumen and exit ~~pass through~~ the cannula at a location proximal to the elongate lumen which further provides for the guide wire to pass through an outer cannula surface of the cannula.

47. (Cancelled)

48. (Currently Amended) The intravascular blood pump system of claim ~~45~~7, wherein the lumen is proximal with respect to the cannula.

49. (New) The intravascular blood pump system of claim 15, further comprising a first conduit and a second conduit terminating in a fitting that is configured to be located outside a patient when the intravascular blood pump and cannula are located inside the patient, at least one of the first conduit and second conduit in fluid communication with the first lumen.

## **REMARKS**

### **Formal Matters**

Claims 15, 23-27, 29-31, 33, and 35 – 48 were examined.

Claims 1-14, 16 – 22, 28, 32 and 34 were previously cancelled.

Claims 40 and 47 are currently cancelled.

Claims 15, 29, 37, 41-46, and 48 are currently amended.

Claim 49 is newly added.

Claims 15, 23-27, 29-31, 33, 35-39, 41-46, 48-49 are pending after entry of the new claim and amendments.

Support for the amendments and new claim can be found throughout the specification and drawings. More specifically, support can be found as follows:

Support for amended claim 15 can be found at least in paragraphs [0067]-[0068].

Support for amended claim 29 can be found in Figures 1-3 and now cancelled claim 40.

Support for amended claim 37 can be found in paragraph [0062].

Support for amended claims 43-44 can be found in Figures 1 and 19.

Support for amended claim 45 can be found in Figures 1-3.

Support for new claim 49 can be found for example in paragraph [0061].

No new matter has been added.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

### **The Office Action**

#### **I. Claims Rejected Under 35 U.S.C. Section 101**

##### **Claims 43 and 44**

Claims 43 and 44 have been rejected under 35 U.S.C. 101, since the Examiner alleges that the disclosed invention as claimed is inoperative and therefore lacks utility. Claims 43 and 44 have each been amended to specify that the cannula is operatively arranged to bend between the distal and proximal ends. For example, Figure 1 shows a

cannula 14 in a straight configuration, while Figure 19 shows the cannula 14 in a bent configuration that enables positioning into and/or within a heart. Necessarily the cannula 14 is operatively arranged to bend since it takes both the straight configuration of Figure 1 and the bent configuration of Figure 19. Applicant respectfully submits that no new matter has been added and that the subject matter of claims 43 and 44 is fully supported by the current application as originally disclosed.

## **II. Claims Rejected Under 35 U.S.C. §112 Second Paragraph**

The Examiner has rejected claims 37, 40-42, 47 and 48 under 35 U.S.C. 112 Second Paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claim 37 has been amended to correct the antecedent basis issue with respect to the shroud.

Claim 40 has been cancelled, rendering the rejection with respect to that claim moot.

Claim 45 has been amended to address the antecedent basis issue regarding the cannula lumen.

Claim 47 has been cancelled. The dependency of claim 48 has been changed, addressing the issue regarding that claim.

Withdrawal of the rejection is respectfully requested.

## **III. Claim Objections**

The Examiner has objected to claim 46 for a minor grammatical error. Claim 46 has been amended accordingly. Withdrawal of the objection is respectfully requested.

## **IV. Claims Rejected Under 35 U.S.C. §103(a) (Nix in view of Gordon)**

In the Office Action, claims 15, 23-25, 29, 30, 35-42, and 45-48 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,112,349 to Nix et al. (“Nix”) in view of U.S. Patent No. 5,938,645 to Gordon (“Gordon”).

Amended claim 15 recites, in pertinent part: “*a first lumen in fluid*

*communication with the intravascular blood pump and operatively arranged to deliver purge fluid to the intravascular blood pump”.*

Paragraphs [0067]-[0068] disclose aspects according to the embodiment recited by claim 15. A lumen, e.g., of a purge fluid delivery system, can be utilized, for example as described in these paragraphs, in order to purge the blood pump, which can advantageously affect operation of the pump, e.g., by reducing frictional heating within the pump. Gordon does not disclose a pump and Nix is completely silent regarding a lumen in fluid communication with a blood pump that is operatively arranged to deliver purge fluid to the blood pump.

Amended claim 29 recites, in pertinent part, “*wherein the guide mechanism has a lumen sized substantially smaller than an inner diameter of the cannula and intravascular blood pump and a guide wire arranged to be advanced along the lumen, the lumen is arranged coaxially with at least one of a distal end or a proximal end of the cannula, and the cannula and the lumen are arranged in series longitudinally*”.

Amended claim 45 similarly recites, “*an elongate lumen having a luminal interior sized (i) smaller than an inside diameter of the cannula and (ii) sufficiently large enough to accommodate the guide wire when the guide wire is advanced therealong, wherein the lumen is arranged coaxially with respect to at least one of a distal end or a proximal end of the cannula, and the lumen and the cannula are arranged in series longitudinally*”.

It is noted at the outset that some of the above-quoted limitations were based on the language of claims 40 and 47, which are now cancelled as redundant. However, in order to assist in clarifying the intended meaning of the claims and avoid the possibility of further misinterpretation, the language that now appears in claims 29 and 45 recites that the cannula and the lumen are “longitudinally arranged in series” as noted above. That is, from the Examiner’s comments with respect to claims 40 and 47, it appears that the Examiner has misinterpreted the term “offset longitudinally”, as previously presented in claims 40 and 47, to mean “offset radially” or “eccentric”. As shown throughout the drawings, the meaning of “offset longitudinally” was instead that the cannula and the lumen are arranged longitudinally such that one is after the other in the longitudinal direction, or alternatively stated, that in the longitudinal or axial direction, the cannula and the lumen are spaced apart, arranged sequentially or in series, etc. For

example, Figures 1-3 depicts one embodiment in which a lumen (74) terminates at a shroud (36), with a cannula (14) extending from the shroud (36) such that the cannula (14) and the lumen (74) are arranged in series longitudinally. This language is now used.

As admitted by the Examiner, Nix is completely silent regarding the inclusion of a guide wire, a guide mechanism, or an elongate lumen. Accordingly, Gordon is relied upon solely for the teaching of these elements. However, Gordon does not teach a guide mechanism having a lumen that has a diameter smaller than that of a cannula and is arranged in series longitudinally with the cannula, and where the lumen is coaxial with at least one of the distal or proximal ends of the cannula. Instead, Gordon teaches embodiments of a catheter (18) through which a guide wire (14) is run. In some embodiments, e.g., Figures 5b and 5c of Gordon, the catheter (18) includes a separate lumen (see element 46) through which the guide wire (14) is run. However, this lumen (46) of Gordon is not coaxial with either the distal or proximal ends of the catheter. Additionally, the lumen (46) is formed as part of the catheter (18), not arranged with the catheter in series longitudinally. Gordon therefore fails to teach the very limitations of claims 15, 29, and 45 for which that reference was cited.

Accordingly, the combination of Nix and Gordon fail to teach each and every limitation of the current claims. In view of the foregoing, Applicants respectfully submit that the cited combination of references do not render independent claims 15, 29, or 45 obvious. The remaining claims depend from one of claims 15, 29, and 45, and are thus patentable at least based on their respective dependencies. In view of the foregoing, withdrawal of the rejection is respectfully requested.

**V. Claims Rejected Under 35 U.S.C. §103(a) (Nix in view of Gordon, further in view of Teirstein)**

The Examiner has rejected claims 26 and 33 under 35 U.S.C. 103(a) as being unpatentable over Nix in view of Gordon, and further in view of U.S. Patent No. 5,234,407 to Teirstein et al. (“Teirstein”).

Teirstein is cited only with respect to the particular limitations of claims 26 and 33, and clearly fails to disclose the base limitations of claim 15, from which claim 26 depends, or claim 29, from which claim 33 depends. Since Nix and Gordon also fail to

disclose each and every limitation of independent claims 15 and 29, as discussed above, no combination also including Teirstein could possibly have enabled one of ordinary skill in the art to arrive at the claimed invention.

In view of the foregoing, Applicants respectfully submit that the cited combination of references do not render claims 26 and 33 as obvious, at least due to their dependency from claims 15 and 29. In view of the foregoing, withdrawal of the rejection is respectfully requested.

**VI. Claims Rejected Under 35 U.S.C. §103(a) (Nix in view of Gordon, and further in view of Watkins)**

The Examiner has rejected claim 27 under 35 U.S.C. § 103 as being unpatentable over Nix in view of Gordon and further in view of U.S. Patent No. 3,995,617 to Watkins et al. (“Watkins”).

Watkins is cited only with respect to the particular limitations of claim 27, and clearly fails to disclose the base limitations of claim 15, from which claim 27 depends. Since Nix and Gordon also fail to disclose each and every limitation of claim 15, as discussed above, no combination also including Watkins could possibly have enabled one of ordinary skill in the art to arrive at the claimed invention.

In view of the foregoing, Applicants respectfully submit that the cited combination of references do not render claim 27 as obvious, at least due to its dependency from claim 29. In view of the foregoing, withdrawal of the rejection is respectfully requested.

**VII. Claims Rejected Under 35 U.S.C. §103(a) (Nix in view of Gordon and further in view of Siess)**

The Examiner has rejected claims 31, 33, and 44 under 35 U.S.C. § 103 as being unpatentable over Nix in view of Gordon and further in view of U.S. Patent No. 6,007,478 to Siess et al. (“Siess”).

Watkins is cited only with respect to the particular limitations of claims 31, 33, and 44, and clearly fails to disclose the base limitations of claim 29, from which these claims depend. Since Nix and Gordon also fail to disclose each and every limitation of

claim 29, as discussed above, no combination also including Siess could possibly have enabled one of ordinary skill in the art to arrive at the claimed invention.

In view of the foregoing, Applicants respectfully submit that the cited combination of references do not render claims 31, 33, or 44 as obvious, at least due to their dependency from claim 29. In view of the foregoing, withdrawal of the rejection is respectfully requested.

### **VIII. New Claim**

New claim 49 has been submitted above, which claim depends from claim 15. Support for new claim 49 is found at least in paragraph [0061] of the application as originally filed. In addition to being patentable due to the dependency from claim 15 (discussed above), the cited references fail to teach the limitations of new claim 49. Accordingly, applicants respectfully submit that claim 49 is in condition for allowance, which action is courteously requested.

### **Conclusion**

Applicants have made a good faith effort to place the claims in condition for allowance. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 04-0170, order number 06-01506US04.

Respectfully submitted,

Date: November 8, 2013

/Kurt R. Denniston/  
Kurt R. Denniston  
Reg. No. 59,605

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Mahwah, NJ 07470  
Telephone: 201-995-8983



## Electronic Patent Application Fee Transmittal

|                                                    |                                                       |                 |                        |                             |
|----------------------------------------------------|-------------------------------------------------------|-----------------|------------------------|-----------------------------|
| <b>Application Number:</b>                         | 12772810                                              |                 |                        |                             |
| <b>Filing Date:</b>                                | 03-May-2010                                           |                 |                        |                             |
| <b>Title of Invention:</b>                         | Guidable Intravascular Blood Pump and Related Methods |                 |                        |                             |
| <b>First Named Inventor/Applicant Name:</b>        | Walid N. Aboul-Hosn                                   |                 |                        |                             |
| <b>Filer:</b>                                      | Kurt Raymond Denniston/Mary Zimmerman                 |                 |                        |                             |
| <b>Attorney Docket Number:</b>                     | 06-01506US04                                          |                 |                        |                             |
| Filed as Large Entity                              |                                                       |                 |                        |                             |
| <b>Utility under 35 USC 111(a) Filing Fees</b>     |                                                       |                 |                        |                             |
| <b>Description</b>                                 | <b>Fee Code</b>                                       | <b>Quantity</b> | <b>Amount</b>          | <b>Sub-Total in USD(\$)</b> |
| <b>Basic Filing:</b>                               |                                                       |                 |                        |                             |
| <b>Pages:</b>                                      |                                                       |                 |                        |                             |
| <b>Claims:</b>                                     |                                                       |                 |                        |                             |
| <b>Miscellaneous-Filing:</b>                       |                                                       |                 |                        |                             |
| <b>Petition:</b>                                   |                                                       |                 |                        |                             |
| <b>Patent-Appeals-and-Interference:</b>            |                                                       |                 |                        |                             |
| <b>Post-Allowance-and-Post-Issuance:</b>           |                                                       |                 |                        |                             |
| <b>Extension-of-Time:</b>                          |                                                       |                 |                        |                             |
| Page 3 of 638<br>Extension- 3 months with \$0 paid | 1253                                                  | 1               | 400<br>ABOMED Ex. 1036 | 400                         |

| Description       | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
|-------------------|----------|----------|--------|----------------------|
| Miscellaneous:    |          |          |        |                      |
| Total in USD (\$) |          |          |        | 1400                 |

## Electronic Acknowledgement Receipt

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| <b>EFS ID:</b>                              | 17358205                                              |
| <b>Application Number:</b>                  | 12772810                                              |
| <b>International Application Number:</b>    |                                                       |
| <b>Confirmation Number:</b>                 | 4661                                                  |
| <b>Title of Invention:</b>                  | Guidable Intravascular Blood Pump and Related Methods |
| <b>First Named Inventor/Applicant Name:</b> | Walid N. Aboul-Hosn                                   |
| <b>Customer Number:</b>                     | 99185                                                 |
| <b>Filer:</b>                               | Kurt Raymond Denniston/Mary Zimmerman                 |
| <b>Filer Authorized By:</b>                 | Kurt Raymond Denniston                                |
| <b>Attorney Docket Number:</b>              | 06-01506US04                                          |
| <b>Receipt Date:</b>                        | 08-NOV-2013                                           |
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The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

| File Listing:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                       |                       |                                                   |                  |                  |
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| Document Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Document Description                                  | File Name             | File Size(Bytes)/<br>Message Digest               | Multi Part /.zip | Pages (if appl.) |
| 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Amendment/Req. Reconsideration-After Non-Final Reject | Response_11082013.pdf | 65491<br>95f5021ef7f2154f90e01801708d1a5a3142ee66 | no               | 13               |
| Warnings:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                       |                       |                                                   |                  |                  |
| Information:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                       |                       |                                                   |                  |                  |
| 2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Fee Worksheet (SB06)                                  | fee-info.pdf          | 30616<br>4e20c55dc5bf88139062436b99a2cb70db1d5f51 | no               | 2                |
| Warnings:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                       |                       |                                                   |                  |                  |
| Information:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                       |                       |                                                   |                  |                  |
| Total Files Size (in bytes):                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                       |                       | 96107                                             |                  |                  |
| <p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><b><u>New Applications Under 35 U.S.C. 111</u></b><br/>           If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><b><u>National Stage of an International Application under 35 U.S.C. 371</u></b><br/>           If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><b><u>New International Application Filed with the USPTO as a Receiving Office</u></b><br/>           If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p> |                                                       |                       |                                                   |                  |                  |



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| APPLICATION NO.                                                      | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |
|----------------------------------------------------------------------|-------------|----------------------|-------------------------------|------------------|
| 12/772,810                                                           | 05/03/2010  | Walid N. Aboul-Hosn  | 06-01506US04                  | 4661             |
| 99185                                                                | 7590        | 11/25/2013           |                               |                  |
| MAQUET Cardiovascular LLC<br>120 Baytech Drive<br>San Jose, CA 95134 |             |                      | EXAMINER<br>MARCETICH, ADAM M |                  |
|                                                                      |             |                      | ART UNIT                      | PAPER NUMBER     |
|                                                                      |             |                      | 3761                          |                  |
|                                                                      |             |                      | NOTIFICATION DATE             | DELIVERY MODE    |
|                                                                      |             |                      | 11/25/2013                    | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

legal@maquet.com

|                              |                                      |                                          |  |
|------------------------------|--------------------------------------|------------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>12/772,810 | <b>Applicant(s)</b><br>ABOUL-HOSN ET AL. |  |
|                              | <b>Examiner</b><br>ADAM MARCETICH    | <b>Art Unit</b><br>3761                  |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2013.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) 15.23-27,29-31,33,35-39,41-46,48 and 49 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 15.23-27,29-31,33,35-39,41-46,48 and 49 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 03 May 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.                                                |

## DETAILED ACTION

### ***Notice of Pre-AIA or AIA Status***

The present application is being examined under the pre-AIA first to invent provisions.

### ***Claim Rejections - 35 USC § 112 first paragraph***

The following is a quotation of 35 U.S.C. 112(a):

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), first paragraph:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30 and 46 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 30 calls for "... the guide wire passing through the elongate lumen in the cannula but not extending through the catheter." Parent claim 29 has been amended to describe a guide mechanism having a lumen arranged coaxially with the cannula. This describes the embodiment of Figs. 1-5 (¶ [0069], "over-the-wire" guide mechanism 16). The claimed embodiment has a guide lumen that extends through the catheter. Another

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embodiment describes a guide mechanism that does not extend through the catheter (¶ [0073], Figs. 6-9, "side-rigger" guide mechanism 122). However, no single embodiment or combination of embodiments discloses a coaxial guide lumen that passes through an elongate lumen in the cannula and does not extend through the catheter.

Claim 46 calls for "...which further provides for the guide wire to pass through an outer cannula surface of the cannula." This describes the embodiment of Figs. 6-9. However, parent claim 45 has been amended to describe the "over-the-wire" guide mechanism 16 of Figs. 1-5. Similarly to claim 30 discussed above, no single embodiment or combination of embodiments describes a coaxial guide wire lumen which passes through an outer surface of the cannula.

***Claim Rejections - 35 USC § 112 second paragraph***

The following is a quotation of 35 U.S.C. 112(b):

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 49 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.



New claim 49 calls for "...a first conduit and a second conduit **terminating in a fitting** that is configured to be located outside a patient..." This language is unclear whether the first, second or both conduits terminate in a fitting. Examiner has interpreted the claim to require only one of the first or second conduits terminating in a fitting.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 15, 23-25 and 49 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Bedingham; William et al. (US 6245007) in view of Nix; Christoph et al. (US 6176822) in view of Gordon; Lucas S. (US 5938645).**

Regarding claim 15, Bedingham discloses an intravascular blood pump system (col. 1, lines 58-64, blood pump), comprising:

an intravascular blood pump (col. 4, lines 27-39, Fig. 1, blood pump 20),  
comprising:

a rotor having a rotor hub (col. 6, lines 15-24; col. 8, lines 1-17, Figs. 7, 9, 9a,  
impeller 56 / 56a);

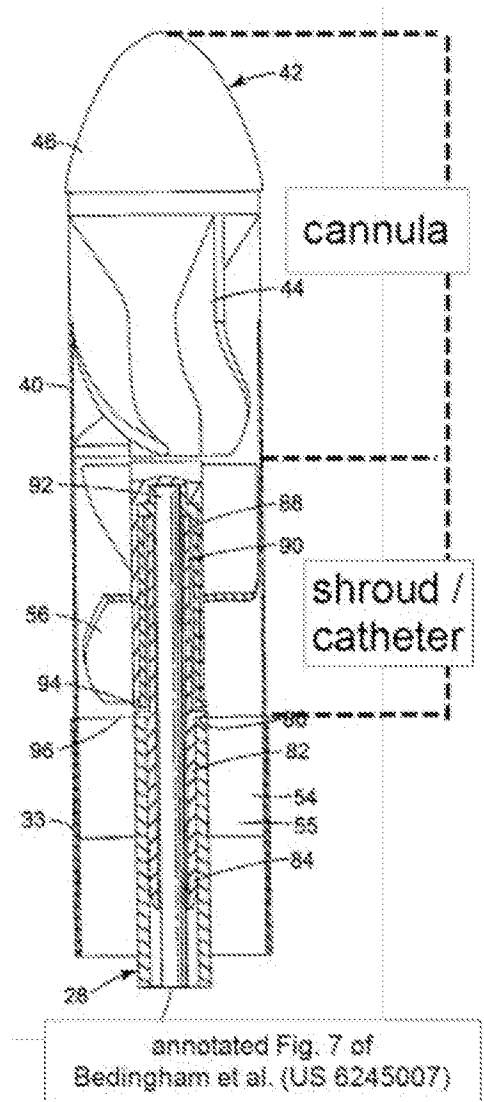
at least one blade extending radially outward from the  
rotor hub (Figs. 7, 9, 9a, impeller 56 / 56a having plurality of  
blades);

a shroud within which the rotor is rotatably disposed  
(col. 4, lines 40-52, annotated Fig. 7, proximal portion of  
inner sleeve 38 and inner sleeve wall 40);

a cannula extending from the shroud and comprising  
an outer cannula surface (col. 4, lines 40-52, annotated Fig.  
7, distal portion of inner sleeve 38 and tip 46);

the outer cannula surface having a substantially  
circular cross-section along a portion of its length (col. 5,  
lines 58-63, generally cylindrical inner sleeve);

a first lumen in fluid communication with the  
intravascular blood pump and operatively arranged to  
deliver purge fluid to the intravascular blood pump (col. 7,  
lines 51-62, Figs. 3, 7, 8, liquid is introduced into the lumen



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of the inner sheath 28, then exits the inner sheath 28 through the channels 100 and into the slots 98; cols. 6-7, lines 65-14, Figs. 5, 6, internal passageways 74, 75 for conducting fluids towards pump mechanism 24); and

a guide mechanism adapted to guide a distal portion of said intravascular blood pump system to a predetermined location within the circulatory system of a patient (col. 9, lines 35-43, guide wire advancing the pump into position, by passing through the pump housing between the distal tip and the distal end of the cable sheath);

wherein the guide mechanism is configured to allow for a guide wire to slideably advance therealong (col. 9, lines 35-43, guide wire passing through the pump housing and therefore allowing a guide wire to slide).

Bedingham teaches the invention substantially as claimed by Applicant with the exception of a tapered rotor hub extending distally beyond a blade. Nix discloses an intravascular blood pump (col. 3, lines 11-19, Fig. 1, pump 10), comprising:

a rotor having a rotor hub tapering in the distal direction (col. 3, lines 37-47, Fig. 1, impeller wheel 34 having hub 35);

at least one blade extending radially outward from the rotor hub (col. 3, lines 37-47, Fig. 1, blades 36); and

the hub has a distal end extending distally beyond the most distal portion of the blade (Fig. 1, impeller wheel 34 having distal end extending distally beyond blades 36).

Nix selects a contoured shape that will minimize damage to blood as it flows past the rotor and other flow-directing components. A skilled artisan would have been able to modify Bedingham with the teachings of Nix by tapering impeller 56 on its distal edge.

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One would be motivated to modify Bedingham with the tapered rotor of Nix to reduce blood turbulence since Bedingham calls for minimizing damage to blood cells (col. 8, lines 1-17, especially lines 9-17). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Bedingham with the tapered rotor of Nix in order to minimize hemolysis.

Bedingham and Nix teach the invention substantially as claimed by Applicant with the exception of a guide mechanism configured as a second lumen that extends through the outer cannula surface. Gordon discloses an intravascular system (col. 4, lines 53-61, col. 8, lines 13-22, Fig. 1, catheter 12), comprising:

- a cannula (col. 8, lines 23-32, Fig. 5a, catheter 18);

- a guide mechanism configured as a second lumen having a proximal end and a distal end (col. 8, lines 54-67, Figs. 5a, 5c, catheter lumen 46 having proximal and distal ends);

- the guide mechanism adapted to guide a distal portion of said intravascular system to a predetermined location within the circulatory system of a patient end (col. 8, lines 54-67, Figs. 5a, 5c, catheter lumen 46 for accepting guidewire 14);

- wherein an axis coaxial with and extending through a portion of said guide mechanism extends through a region delimited by the outer cannula surface (Fig. 5c, axis extending through guidewire 46 within region delimited by catheter 18); and

- wherein the guide mechanism is configured to allow for a guide wire to slideably advance therealong (col. 8, lines 54-67, Figs. 5a, 5b, catheter lumen 46 for accepting guidewire 14).

Gordon guides a larger cannula through tight bends by positioning means for capturing a guidewire on the side of the cannula (col. 5, lines 5-22, especially lines 20-22). One would be motivated to modify Bedingham and Nix with the guide mechanism as taught by Gordon to maneuver a catheter through winding vessels since Bedingham calls for delivering the blood pump into the heart (col. 1, lines 58-65). Additionally, the guide mechanism of Gordon would avoid passing a guidewire in proximity to the blades on impeller 56 of Bedingham. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Bedingham and Nix with the guide mechanism of Gordon in order to deliver a cannula through vessels towards the heart.

Regarding claim 23, Bedingham discloses that the rotor comprises a second blade extending radially from the rotor hub (Figs. 3, 7, 9, 9a, at least three blades depicted on impeller 56 / 56a).

Regarding claim 24, Bedingham teaches the invention substantially as claimed by Applicant with the exception of a conical rotor hub. Nix discloses a rotor hub that is generally conical (Fig. 1, impeller wheel 34 generally conical).

Nix streamlines a rotor hub to promote smooth blood flow, thereby avoiding blood damage. One would be motivated to modify Bedingham with the conical rotor hub of Nix to reduce turbulence as called for by Bedingham (col. 8, lines 1-17). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made

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to modify Bedingham with the conical rotor hub of Nix in order to reduce blood turbulence.

Regarding claim 25, Bedingham and Nix teach the invention substantially as claimed by Applicant with the exception of a guide mechanism. Gordon discloses a guide mechanism configured such that the guide wire passes through the region delimited by the outer cannula surface at a location proximal to where the guide wire establishes slidable contact with the guide mechanism (Fig. 5a, proximal entrance to guidewire lumen 46 is located proximally to guidewire 46). Gordon improves the ability for a surgeon to guide an intravascular device through vessels towards the heart as discussed for claim 15 above.

Regarding claim 49, Bedingham, discloses a first conduit (col. 7, lines 9-14, Fig. 5, tube 72); and

a second conduit (col. 7, lines 9-14, Fig. 6, tube 73);

terminating in a fitting that is configured to be located outside a patient when the intravascular blood pump and cannula are located inside the patient (cols. 6-7, lines 65-8, Fig. 5, fluid connectors 70, 71);

at least one of the first conduit and second conduit in fluid communication with the first lumen (col. 7, lines 9-14, Figs. 5, 6, internal passageways 74 and 75 connect with tubes 72 and 73 respectively).

**Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bedingham, Nix and Gordon, further in view of Teirstein; Paul S. et al. (US 5234407).**

Regarding claim 26, Bedingham, Nix and Gordon teach the invention substantially as claimed by Applicant with the exception of a guide catheter for placing the guide wire into the heart. Teirstein discloses a cardiovascular exchange catheter (col. 3, lines 31-38), comprising:

a guidewire (cols. 10-11, lines 62-6, Fig. 13a, guide wire 32); and

a guide catheter (cols. 10-11, lines 62-6, Fig. 13a, guide catheter 10);

wherein the guide catheter is configured to facilitate the placement of the guide wire into the heart (col. 11, lines 6-15, guide catheter removed and optionally replaced with substitute guide catheter 10a).

Teirstein allows components of an intravascular system to be guided through vasculature without removing a guidewire during surgery (cols. 7-8, lines 59-2). Guide catheter 10 of Teirstein also provides an entrance to vasculature through the skin. One would be motivated to modify Bedingham, Nix and Gordon with the guide catheter of Teirstein to deliver a guidewire through a patient's skin. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Bedingham, Nix and Gordon as discussed with the guide catheter of Teirstein in order to deliver an intravascular component through the skin.

**Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nix; Bedingham, Nix and Gordon, further in view of Watkins; David H. et al. (US 3995617).**

Regarding claim 27, Bedingham, Nix and Gordon teach the invention substantially as claimed by Applicant with the exception of an elongate catheter and pressure detection mechanism.

Watkins discloses an apparatus for augmenting heart function (col. 1, lines 3-10, col. 3, lines 6-18, Figs. 1, 2, shaft portion 50 and flexible tube 51); comprising:

an intravascular device (Figs. 1-5, shaft / catheter 50);

an elongate catheter extending proximally with respect to the intravascular device (col. 4, lines 28-43, Fig. 5, interior channel member 56; lines 44-58, corresponding channel member 57); and

a blood pressure detection mechanism comprising a fluid column disposed within the catheter (Fig. 5, fluid occupying each of channels 56, 57); and

configured to detect the pressure of the blood proximate the intravascular blood pump (col. 4, lines 31-35, 47-51, gauges connected to openings 56a, 57a).

This rejection modifies the intravascular pump of Bedingham, Nix and Gordon as discussed with the pressure-measuring columns of Watkins. The pressure measurements of Watkins measure whether the heart is responding to treatment (cols. 4-5, lines 58-5). One would be motivated to modify Bedingham, Nix and Gordon with the blood pressure detection mechanism as taught by Watkins to since Bedingham calls for measuring blood flow (col. 9, lines 26-30). Pressure is provide another valuable



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measurement that indicates how the pump is functioning within a blood vessel.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Bedingham, Nix and Gordon as discussed with the blood pressure detection mechanism of Watkins in order to measure a parameter that indicates whether the pump is operating correctly.

**Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bedingham, Nix and Gordon, further in view of Siess; Thorsten et al. (US 6007478).**

Regarding claim 43, Bedingham, Nix and Gordon teach the invention substantially as claimed by Applicant with the exception of a cannula arranged to bend. Siess discloses a cannula for use as an intravascular blood pump (col. 4, lines 29-37); comprising:

a pump (col. 4, lines 38-45, Fig. 1, pump 14);

a catheter (col. 4, lines 56-65, Fig. 2, stiff material 28);

a cannula (col. 4, lines 56-65, Fig. 2, flexible material 30);

wherein the cannula is operatively arranged to bend at a location between distal and proximal ends thereof (col. 5, lines 3-11, Fig. 2, flexible material allowing body portion 22 to bend).

Siess improves the maneuverability of an intravascular device (col. 7, lines 43-49). One would be motivated to modify Bedingham, Nix and Gordon with the bendable cannula of Siess to improve maneuverability when delivering the pump through

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vasculature towards the heart. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Bedingham, Nix and Gordon as discussed with the bendable cannula of Siess in order to improve maneuverability.

Claims 29, 35-39, 41, 42, 45 and 48 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Bedingham; William et al. (US 6245007) in view of Nix; Christoph et al. (US 6176822) in view of Masch; Helmut (US 4728319).

Regarding claim 29, Bedingham discloses an intravascular blood pump system (col. 1, lines 58-64, blood pump), comprising:

an intravascular blood pump (col. 4, lines 27-39, Fig. 1, blood pump 20),  
comprising:

a rotor having a rotor hub (col. 6, lines 15-24; col. 8, lines 1-17, Figs. 7, 9, 9a, impeller 56 / 56a);

at least one blade extending radially outward from the rotor hub (Figs. 7, 9, 9a, impeller 56 / 56a having plurality of blades);

the intravascular blood pump coupled to a catheter on a proximal end (col. 4, lines 40-52, annotated Fig. 7, proximal portion of inner sleeve 38 and inner sleeve wall 40); and

a cannula on a distal end (col. 4, lines 40-52, annotated Fig. 7, distal portion of inner sleeve 38 and distal member 42);

a first set (col. 4, lines 27-39, Fig. 1, first or proximal port 34); and

a second set of apertures (col. 4, lines 40-52, Fig. 1, opening near vane portion 44);

establishing fluid communication between an interior of the cannula and an exterior region of the cannula (col. 5, lines 40-50, in an alternative design, the more proximally-located port would be the "outlet," by feeding the pump into the heart from the other direction);

wherein the first set of apertures is located in proximity to the rotor (Fig. 3, impeller 56 in proximity to proximal port 34); and

the second set of apertures is spaced apart from and located distal to the first set of apertures towards a distal region of the cannula (Fig. 3, openings near vane portion 44 spaced from proximal port 34 and towards distal region of inner sleeve 38);

a guide mechanism adapted to guide said intravascular blood pump, cannula, and catheter to a predetermined location within the circulatory system of a patient (col. 9, lines 35-43, guide wire advancing the pump into position); and

a guide wire (col. 9, lines 35-43, guide wire).

Regarding the limitation of a first set of apertures being located in proximity to the rotor, the term "in proximity" is interpreted as a relative term. since impeller 56 is located within the same pump assembly 24 as proximal port 34, impeller 56 can be said to be "in proximity" to proximal port 34. See MPEP 2173.05(b).

Bedingham teaches the invention substantially as claimed by Applicant with the exception of a rotor hub tapering in the distal direction and blood pressure detection mechanism. Nix discloses an intravascular blood pump (col. 1, lines 29-34), comprising:

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a rotor hub tapering in the distal direction (col. 3, lines 37-47, Fig. 1, impeller wheel 34 having hub 35);

a blood pressure detection mechanism comprising a fluid column (col. 5, lines 44-56, Fig. 3, sensors 60, 61 and column of fluid passing through pump); and

configured to detect the pressure of the blood proximate the intravascular blood pump (col. 5, lines 57-64, sensors 60, 61 detecting pressure).

Nix selects a tapered rotor shape which reduces blood turbulence as discussed for claim 15 above. The blood pressure detection mechanism of Nix provides feedback regarding the position of the pump during operation (cols. 5-6, lines 65-8, pressures changing when pump becomes obstructed). One would have been motivated to modify Bedingham with the blood pressure detection mechanism of Nix in order to maneuver the blood pump without damaging organs, and verify that it is operating correctly. Therefore it would have been obvious to modify Bedingham with the blood pressure detection mechanism of Nix in order to guide an intravascular blood pump without damaging tissues.

Bedingham and Nix teach the invention substantially as claimed by Applicant with the exception of a guide mechanism configured as an elongate lumen. Masch discloses a catheter for clearing blocked blood vessels (col. 1, lines 45-49; col. 2, lines 26-40, Fig. 1, catheter assembly 10), comprising:

a guide mechanism configured as an elongate lumen (col. 2, lines 41-51, Fig. 2, first tube 15 having lumen); and

adapted to guide said catheter to a predetermined location within the circulatory system of a patient (col. 2, lines 26-40, flexible guide wire 14 is rotatably and reciprocally mounted in catheter 11 to guide the catheter through the aorta); and

wherein the guide mechanism has a lumen sized substantially smaller than an outer-inner diameter of the intravascular device (Fig. 2, lumen of first tube 15 is the smallest of all other concentrically arranged lumens); and

a guide wire arranged to be advanced along the lumen (col. 2, lines 26-40, flexible guide wire 14);

the lumen is arranged coaxially with at least one of a distal end or a proximal end of the intravascular device (Fig. 2, first tube 15 arranged concentrically within catheter 11).

Regarding the limitation of the cannula and the lumen being arranged in series longitudinally, this rejection modifies Bedingham and Nix with the teachings of Masch by adding a lumen that passes through drive cable 30, impeller 56 and tip 46 of Bedingham.

Masch allows a surgeon to steer a catheter by rotating the guidewire (cols. 2-3, lines 63-2). One would have been motivated to modify Bedingham and Nix with the concentric guide mechanism of Masch in order to maneuver a catheter more accurately and avoid passing a guide wire in contact with blades on impeller 56 of Bedingham. Therefore, it would have been obvious to modify Bedingham and Nix with the concentric guide mechanism of Masch in order to steer a catheter more accurately within blood vessels.

Regarding claim 35, Bedingham discloses that the rotor comprises a second blade extending radially from the rotor hub (Figs. 3, 7, 9, 9a, at least three blades depicted on impeller 56 / 56a).

Regarding claim 36, Bedingham discloses a cannula comprising an outer cannula surface having a substantially circular cross-section along a portion of its length (col. 5, lines 58-63, generally cylindrical inner and outer sleeves);

the distal region of the outer cannula surface is distally tapered about its circumference (col. 4, lines 40-52, Fig. 7, tapering distal member 42).

Regarding claim 37, Bedingham discloses a plurality of egress flow ports disposed in a shroud of the intravascular blood pump (col. 4, lines 27-39, Figs. 1, 2, first port 34); and

a plurality of ingress flow ports disposed at a location spaced apart from and distal to the egress flow ports (col. 4, lines 40-52, Figs. 1, 2, ports at vane portion 44);

Regarding claim 38, Bedingham discloses that the ingress flow port comprises an end port located at the cannula distal end (Figs. 1, 2, vane portion 44 located at distal end).

Bedingham teaches the invention substantially as claimed by Applicant with the exception of plurality of ports located about the cannula. Nix discloses a plurality of ports located about the cannula and proximal to the end port (Fig. 3, plurality of perforations in hose 13). Nix provides further openings to diffuse blood flow. One would

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have been motivated to modify Bedingham with the plural ports of Nix in order to diffuse blood flow and reduce turbulence. Therefore it would have been obvious to modify Bedingham with the plural ports of Nix in order to diffuse blood entering the pump.

Regarding claim 39, Bedingham discloses that the first set of apertures are egress ports and the second set of apertures are ingress ports (col. 5, lines 40-50, in an alternative design, the more proximally-located port would be the "outlet" port; col. 8, lines 1-17, Fig. 9a, reverse acting impeller 56a); and

wherein the egress ports are configured to direct blood passing through the interior of the cannula and towards the rotor in a direction that is both proximal and radially outward with respect to the rotor hub (Figs. 1-3, blood will flow towards impeller 56 and radially outward through ports 34).

Regarding claims 41 and 42, Bedingham and Nix teach the invention substantially as claimed by Applicant with the exception of a central lumen. Masch discloses a central lumen extending through the entire intravascular device (col. 3, lines 38-47, Fig. 2, annular passage 28);

wherein the lumen of the central lumen is proximal to the intravascular device (col. 2, lines 41-51, Fig. 1, first tube 15 passing through entire catheter assembly 10).

Masch provides a guide mechanism that can steer an intravascular device through blood vessels (cols. 2-3, lines 63-2, guide wire can be reciprocated and twisted within tube 15). A skilled artisan would have been able to modify Bedingham and Nix with the teachings of Masch by forming a lumen inside cable 30, impeller 56 and tip 46 of Bedingham. One would have been motivated to modify Bedingham and Nix with the

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central lumen of Masch in order to steer the blood pump of Bedingham, since Bedingham calls for guiding the pump through blood vessels towards the heart (col. 9, lines 35-43). Therefore, it would have been obvious to modify Bedingham and Nix with the central lumen of Masch in order to steer a catheter more accurately.

Regarding claim 45, Bedingham discloses an intravascular blood pump system (col. 1, lines 58-64, blood pump);

configured to be advanced to a predetermined location in a patient's circulatory system (col. 9, lines 35-43);

the intravascular blood pump system comprising:

an intravascular blood pump (col. 4, lines 27-39, Fig. 1, blood pump 20);

the intravascular blood pump comprising a rotor having a rotor hub (col. 6, lines 15-24; col. 8, lines 1-17, Figs. 7, 9, 9a, impeller 56 / 56a);

at least two blades extending radially from the rotor hub (Figs. 7, 9, 9a, impeller 56 / 56a having plurality of blades);

a cannula extending distally from the intravascular blood pump (col. 4, lines 40-52, annotated Fig. 7, distal portion of inner sleeve 38 and tip 46);

a plurality of ingress ports located towards the proximal region of the cannula (col. 4, lines 40-52, Figs. 1, 2, ports at vane portion 44); and

a plurality of egress ports located in proximity to the blood pump (col. 4, lines 27-39, Figs. 1, 2, first port 34);



such that movement of fluid proximally through an interior region of the cannula is steered towards the egress ports (col. 5, lines 40-50, alternative design having proximally-located outlet port);

a guide wire having a cross-section substantially smaller than the cannula (col. 9, lines 35-43, removable guidewire which passes through pump housing).

Bedingham teaches the invention substantially as claimed by Applicant with the exception of a conical rotor hub extending beyond blades. Nix discloses an intravascular blood pump (col. 3, lines 11-19, Fig. 1, pump 10),

comprising a rotor having a generally conical rotor hub tapering in the distal direction (col. 3, lines 37-47, Fig. 1, impeller wheel 34 having hub 35);

at least two blades extending radially from the rotor hub (col. 3, lines 37-47, Fig. 1, blades 36);

the generally conical rotor hub having a distal tip extending distally beyond the blades (Fig. 1, impeller wheel 34 having distal end extending distally beyond blades 36).

Nix minimizes damage to blood by selecting a contoured shape for a rotor hub. Regarding rationale and motivation to modify Bedingham in view of Nix, see discussion of claim 15 above.

Bedingham and Nix teach the invention substantially as claimed by Applicant with the exception of an elongate lumen arranged coaxially. Masch discloses a catheter (col. 2, lines 26-40, Fig. 1, catheter assembly 10), comprising:

an elongate lumen (col. 3, lines 38-47, Figs. 1, 2, first tube 15 having passage 28);

having a luminal interior sized (i) smaller than an inside diameter of a cannula (col. 3, lines 38-47; col. 4, lines 29-34, Fig. 2, passage 28 smaller than guide sleeve 62); and

(ii) sufficiently large enough to accommodate the guide wire when the guide wire is advanced therealong (cols. 2-3, lines 63-2, guide wire reciprocating and twisting within tube 15);

wherein the lumen is arranged coaxially with respect to at least one of a distal end or a proximal end of the cannula (Fig. 2, passage 28 arranged coaxially within guide sleeve 62); and

the lumen and the cannula are arranged in series longitudinally (Fig. 1, passage 28 extending over full length of first tube 15; guide sleeve 62 extending over only distal portion of catheter assembly 10).

Masch provides a steerable guide mechanism that will allow a blood pump to be steered within blood vessels. Regarding rationale and motivation to modify Bedingham and Nix in view of Masch, see discussion of claim 29 above.

Regarding claim 48, Bedingham and Nix teach the invention substantially as claimed by Applicant with the exception of an elongate lumen. Masch discloses an elongate lumen, wherein the lumen is proximal with respect to a cannula (Fig. 2, annular passage 28 of first tube 15 extending proximal with respect to guide sleeve 62).

Regarding rationale and motivation to modify Bedingham and Nix in view of Masch, see discussion of claim 29 above.

Claims 30 and 46 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Bedingham, Nix and Masch, further in view of Gordon.

Claims 30 and 46 are also rejected over 35 USC 112 first paragraph as discussed above.

Regarding claim 30, Bedingham, Nix and Masch teach the invention substantially as claimed by Applicant with the exception of a guide wire passing through an elongate lumen in the cannula but not through a catheter. Gordon discloses a guide mechanism comprising a guide wire (col. 8, lines 13-22, Figs. 1, 5a, guidewire 14);

the system configured such that it is guidable in the circulatory system over the guide wire passing through the elongate lumen in the cannula but not extending through the catheter (col. 9, lines 1-4, Fig. 5c, guidewire lumen 46 not extending through hemostasis valve 22).

Gordon guides an intravascular device through the body while navigating through tight bends (col. 5, lines 5-22). One would have been motivated to modify the invention of Bedingham, Nix and Masch with the guide mechanism of Gordon in order to maneuver the pump through vessels in the body.

Regarding claim 46, Bedingham, Nix and Masch teaches the invention substantially as claimed by Applicant with the exception of a guide wire that passes through an outer cannula surface. Gordon discloses an intravascular device having a guide mechanism and guide wire (col. 4, lines 53-61; col. 8, lines 13-22, Figs. 1, 5a, guidewire 14);

wherein the intravascular device is configured to allow for the guide wire to extend through an elongate lumen and exit a cannula at a location proximal to the elongate lumen (cols. 8-9, lines 64-4, Figs. 5b, 5c, guidewire lumen 46);

which further provides for the guide wire to pass through an outer cannula surface of the cannula (Fig. 5a, guidewire 14 passing through distal end of catheter 18).

Regarding rationale and motivation to modify Bedingham, Nix and Masch in view of Gordon, see discussion of claim 30 above.

**Claims 31 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bedingham, Nix and Masch, further in view of Siess; Thorsten et al. (US 6007478).**

Regarding claim 31, Bedingham, Nix and Masch teach the invention substantially as claimed by Applicant with the exception of a spiral wire. Siess discloses a cannula (col. 4, lines 56-65, Fig. 2, flexible material 30);

wherein the cannula is reinforced with a spiral wire (col. 5, lines 28-38, Figs. 2, 3, spiral spring 29 of NiTi).

Siess adjusts the stiffness of a cannula to guide it through vasculature (col. 3, lines 47-56). One would have been motivated to modify Bedingham, Nix and Masch with the spiral wire of Siess to maneuver the cannula more easily through vasculature.

Regarding claim 44, Bedingham, Nix and Masch teach the invention substantially as claimed by Applicant with the exception of a cannula arranged to bend. Siess discloses a cannula that is operatively arranged to bend at a location between distal and

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proximal ends thereof (col. 5, lines 3-11, Fig. 2, flexible material of body portion 22).

Regarding rationale and motivation to modify Bedingham, Nix and Masch in view of Siess, see discussion of claim 43 above.

**Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bedingham, Nix and Masch, further in view of Teirstein; Paul S. et al. (US 5234407).**

Regarding claim 33, Bedingham, Nix and Masch teach the invention substantially as claimed by Applicant with the exception of a guide catheter for placing the guide wire into the heart. Teirstein discloses a cardiovascular exchange catheter (col. 3, lines 31-38), comprising a guide catheter that is configured to facilitate the placement of the guide wire into the heart (col. 11, lines 6-15, guide catheter and substitute guide catheter 10a). Regarding rationale and motivation to modify Bedingham, Nix and Masch in view of Teirstein, see discussion of claim 26 above.

### ***Response to Arguments***

Rejections of claims 43 and 44 under 35 U.S.C. 101 and rejections of claims 37, 40-42, 45, 47 and 48 under 35 U.S.C. 112, second paragraph applied in the previous office action are withdrawn in view of the amendments filed 08 November 2013.

Applicant's arguments filed 08 November 2013 regarding the rejection of claims 15, 23-27, 29-31, 33 and 35-48 as amended, under 35 USC § 103 over Nix, Gordon, Watkins, Teirstein and Siess, are persuasive. After consideration of the amended

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claims, the claims are rejected on new grounds under 35 USC § 103 over Bedingham, Nix, Gordon, Masch, Teirstein, Watkins and Siess (see above).

Applicant contends that Gordon does not disclose a pump and Nix is completely silent regarding a lumen in fluid communication with a blood pump that is operatively arranged to deliver purge fluid to the blood pump (remarks p. 10). Examiner instead cites Bedingham in the new grounds of rejection as teaching a purge fluid lumen (cols. 6-7, lines 65-14; col. 7, lines 51-62). Bedingham can deliver purge fluid through either passageways 74, 75 or through the lumen of inner sheath 28.

Applicant asserts that it appears that the Examiner has misinterpreted the term "offset longitudinally", as previously presented in claims 40 and 47, to mean "offset radially" or "eccentric" (remarks p. 10). Examiner acknowledges that amended claims 29 and 45 describe a cannula and lumen arranged in series longitudinally, which reflects the arrangement shown in Fig. 3 of Applicant's drawing sheets. Masch is cited in the new grounds of rejection as teaching a guide wire lumen and cannula arranged in series longitudinally.

Applicant submits that lumen (46) of Gordon is not coaxial with either the distal or proximal ends of the catheter (remarks p. 11). Examiner instead cites Masch as teaching a coaxial lumen in the new grounds of rejection.

Applicant contends that Teirstein, Watkins and Siess fail to remedy the deficiencies of Nix and Gordon (remarks p. 11-13). Examiner instead cites Teirstein, Watkins and Siess for limitations in dependent claims. The combination of Bedingham

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Nix and Masch is cited for claim 15, and the combination of Bedingham Nix and Gordon is cited for claims 29 and 45.

Applicant asserts that the cited references fail to teach the limitations of new claim 49 (remarks p. 13). Examiner cites Bedingham as teaching the first and second conduits and fitting of claim 49.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Isaacson; Milton S. et al. US 5211546

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Tel 571-272-2590  
Fax 571-273-2590  
Email [Adam.Marcetich@uspto.gov](mailto:Adam.Marcetich@uspto.gov)

The Examiner can be reached 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/  
Primary Examiner, Art Unit 3761



|                                   |                                       |                                                                 |             |
|-----------------------------------|---------------------------------------|-----------------------------------------------------------------|-------------|
| <b>Notice of References Cited</b> | Application/Control No.<br>12/772,810 | Applicant(s)/Patent Under<br>Reexamination<br>ABOUL-HOSN ET AL. |             |
|                                   | Examiner<br>ADAM MARCETICH            | Art Unit<br>3761                                                | Page 1 of 1 |

**U.S. PATENT DOCUMENTS**

| * |   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Name             | Classification |
|---|---|--------------------------------------------------|-----------------|------------------|----------------|
| * | A | US-5,211,546 A                                   | 05-1993         | Isaacson et al.  | 417/356        |
| * | B | US-6,245,007 B1                                  | 06-2001         | Bedingham et al. | 600/16         |
|   | C | US-                                              |                 |                  |                |
|   | D | US-                                              |                 |                  |                |
|   | E | US-                                              |                 |                  |                |
|   | F | US-                                              |                 |                  |                |
|   | G | US-                                              |                 |                  |                |
|   | H | US-                                              |                 |                  |                |
|   | I | US-                                              |                 |                  |                |
|   | J | US-                                              |                 |                  |                |
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|   | M | US-                                              |                 |                  |                |

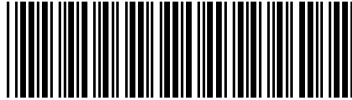
**FOREIGN PATENT DOCUMENTS**

| * |   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Country | Name | Classification |
|---|---|--------------------------------------------------|-----------------|---------|------|----------------|
|   | N |                                                  |                 |         |      |                |
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**NON-PATENT DOCUMENTS**

| * |   | Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) |
|---|---|-------------------------------------------------------------------------------------------|
|   | U |                                                                                           |
|   | V |                                                                                           |
|   | W |                                                                                           |
|   | X |                                                                                           |

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

|                                                                                                                        |                                                |                                                                         |
|------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|-------------------------------------------------------------------------|
| <b><i>Index of Claims</i></b><br><br> | <b>Application/Control No.</b><br><br>12772810 | <b>Applicant(s)/Patent Under Reexamination</b><br><br>ABOUL-HOSN ET AL. |
|                                                                                                                        | <b>Examiner</b><br><br>ADAM MARCETICH          | <b>Art Unit</b><br><br>3761                                             |

|   |                 |   |                   |   |                     |   |                 |
|---|-----------------|---|-------------------|---|---------------------|---|-----------------|
| ✓ | <b>Rejected</b> | - | <b>Cancelled</b>  | N | <b>Non-Elected</b>  | A | <b>Appeal</b>   |
| = | <b>Allowed</b>  | ÷ | <b>Restricted</b> | I | <b>Interference</b> | O | <b>Objected</b> |

| <input type="checkbox"/> Claims renumbered in the same order as presented by applicant |          |            |            |            |            | <input type="checkbox"/> CPA |  | <input type="checkbox"/> T.D. |  | <input type="checkbox"/> R.1.47 |  |
|----------------------------------------------------------------------------------------|----------|------------|------------|------------|------------|------------------------------|--|-------------------------------|--|---------------------------------|--|
| CLAIM                                                                                  |          | DATE       |            |            |            |                              |  |                               |  |                                 |  |
| Final                                                                                  | Original | 02/06/2012 | 08/20/2012 | 05/02/2013 | 11/19/2013 |                              |  |                               |  |                                 |  |
|                                                                                        | 1        | -          | -          | -          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 2        | ✓          | -          | -          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 3        | ✓          | -          | -          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 4        | ✓          | -          | -          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 5        | ✓          | -          | -          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 6        | ✓          | -          | -          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 7        | ✓          | -          | -          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 8        | ✓          | -          | -          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 9        | ✓          | -          | -          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 10       | ✓          | -          | -          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 11       | ✓          | -          | -          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 12       | ✓          | -          | -          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 13       | ✓          | -          | -          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 14       | ✓          | -          | -          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 15       | ✓          | ✓          | ✓          | ✓          |                              |  |                               |  |                                 |  |
|                                                                                        | 16       | ✓          | -          | -          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 17       | ✓          | -          | -          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 18       | ✓          | -          | -          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 19       | ✓          | -          | -          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 20       | ✓          | -          | -          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 21       | ✓          | -          | -          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 22       | ✓          | -          | -          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 23       |            | ✓          | ✓          | ✓          |                              |  |                               |  |                                 |  |
|                                                                                        | 24       |            | ✓          | ✓          | ✓          |                              |  |                               |  |                                 |  |
|                                                                                        | 25       |            | ✓          | ✓          | ✓          |                              |  |                               |  |                                 |  |
|                                                                                        | 26       |            | ✓          | ✓          | ✓          |                              |  |                               |  |                                 |  |
|                                                                                        | 27       |            | ✓          | ✓          | ✓          |                              |  |                               |  |                                 |  |
|                                                                                        | 28       |            | ✓          | -          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 29       |            | ✓          | ✓          | ✓          |                              |  |                               |  |                                 |  |
|                                                                                        | 30       |            | ✓          | ✓          | ✓          |                              |  |                               |  |                                 |  |
|                                                                                        | 31       |            | ✓          | ✓          | ✓          |                              |  |                               |  |                                 |  |
|                                                                                        | 32       |            | ✓          | -          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 33       |            | ✓          | ✓          | ✓          |                              |  |                               |  |                                 |  |
|                                                                                        | 34       |            | ✓          | -          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 35       |            | ✓          | ✓          | ✓          |                              |  |                               |  |                                 |  |
|                                                                                        | 36       |            | ✓          | ✓          | ✓          |                              |  |                               |  |                                 |  |

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|------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|-------------------------------------------------------------------------|
| <b><i>Index of Claims</i></b><br><br> | <b>Application/Control No.</b><br><br>12772810 | <b>Applicant(s)/Patent Under Reexamination</b><br><br>ABOUL-HOSN ET AL. |
|                                                                                                                        | <b>Examiner</b><br><br>ADAM MARCETICH          | <b>Art Unit</b><br><br>3761                                             |

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| ✓ | <b>Rejected</b> | - | <b>Cancelled</b>  | N | <b>Non-Elected</b>  | A | <b>Appeal</b>   |
| = | <b>Allowed</b>  | ÷ | <b>Restricted</b> | I | <b>Interference</b> | O | <b>Objected</b> |

| <input type="checkbox"/> Claims renumbered in the same order as presented by applicant |          |            |            |            |            | <input type="checkbox"/> CPA |  | <input type="checkbox"/> T.D. |  | <input type="checkbox"/> R.1.47 |  |
|----------------------------------------------------------------------------------------|----------|------------|------------|------------|------------|------------------------------|--|-------------------------------|--|---------------------------------|--|
| CLAIM                                                                                  |          | DATE       |            |            |            |                              |  |                               |  |                                 |  |
| Final                                                                                  | Original | 02/06/2012 | 08/20/2012 | 05/02/2013 | 11/19/2013 |                              |  |                               |  |                                 |  |
|                                                                                        | 37       |            | ✓          | ✓          | ✓          |                              |  |                               |  |                                 |  |
|                                                                                        | 38       |            | ✓          | ✓          | ✓          |                              |  |                               |  |                                 |  |
|                                                                                        | 39       |            | ✓          | ✓          | ✓          |                              |  |                               |  |                                 |  |
|                                                                                        | 40       |            | ✓          | ✓          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 41       |            | ✓          | ✓          | ✓          |                              |  |                               |  |                                 |  |
|                                                                                        | 42       |            |            | ✓          | ✓          |                              |  |                               |  |                                 |  |
|                                                                                        | 43       |            |            | ✓          | ✓          |                              |  |                               |  |                                 |  |
|                                                                                        | 44       |            |            | ✓          | ✓          |                              |  |                               |  |                                 |  |
|                                                                                        | 45       |            |            | ✓          | ✓          |                              |  |                               |  |                                 |  |
|                                                                                        | 46       |            |            | ✓          | ✓          |                              |  |                               |  |                                 |  |
|                                                                                        | 47       |            |            | ✓          | -          |                              |  |                               |  |                                 |  |
|                                                                                        | 48       |            |            | ✓          | ✓          |                              |  |                               |  |                                 |  |
|                                                                                        | 49       |            |            |            | ✓          |                              |  |                               |  |                                 |  |

EAST Search History

EAST Search History (Prior Art)

| Ref # | Hits | Search Query                                                                                                                                     | DBs                                                              | Default Operator | Plurals | Time Stamp          |
|-------|------|--------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|------------------|---------|---------------------|
| S169  | 73   | S167 and (round\$3 taper\$3 gradual\$2 contour\$3 soft\$2 soften\$3 sofen\$3) with (blade\$1 vane\$1 vein\$1 propeller\$1 fin\$1)                | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2013/11/18<br>14:17 |
| S168  | 68   | S167 and (round\$3 taper\$3 gradual\$2 contour\$3) with (blade\$1 vane\$1 vein\$1 propeller\$1 fin\$1)                                           | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2013/11/18<br>14:16 |
| S167  | 543  | S155 and pump\$3 with blood                                                                                                                      | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2013/11/18<br>14:15 |
| S166  | 14   | Bedingham.in. and @ad<"20000901"                                                                                                                 | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2013/11/18<br>13:19 |
| S164  | 10   | Bedingham-William\$.in. and @ad<"20000901"                                                                                                       | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2013/11/18<br>13:18 |
| S163  | 43   | S162 and @ad<"20000901"                                                                                                                          | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2013/11/18<br>11:23 |
| S162  | 85   | ("3568659"   "3904901"   "4102610"   "4445509"   "4591355"   "4625712"   "4631052"   "4688998"   "4729763"   "4753221").PN. OR ("4895557").URPN. | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR               | OFF     | 2013/11/18<br>11:23 |
| S161  | 1    | "4895557".pn.                                                                                                                                    | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR               | OFF     | 2013/11/18<br>11:22 |
| S160  | 123  | S159 not S157                                                                                                                                    | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2013/11/18<br>11:17 |
| S159  | 262  | S158 and @ad<"20000901"                                                                                                                          | US-PGPUB;<br>USPAT;<br>FPRS;                                     | OR               | ON      | 2013/11/18<br>11:17 |

|      |     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                  |    |     |                     |
|------|-----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|----|-----|---------------------|
|      |     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | EPO; JPO;<br>DERWENT;<br>IBM_TDB                                 |    |     |                     |
| S158 | 604 | ("2635547"   "3291381"   "3487784"   "3505987"  <br>"3568659"   "3592184"   "3608088"   "3647324"   "3667069"<br>  "3685059"   "3734648"   "3802551"   "3804553"  <br>"3904901"   "3935876"   "3957389"   "3995617"   "4019830"<br>  "4037984"   "4051840"   "4068521"   "4102610"  <br>"4135253"   "4166310"   "4173796"   "4173981"   "4185617"<br>  "4275988"   "4280495"   "4382199"   "4407271"  <br>"4445509"   "4507048"   "4512726"   "4589822"   "4591355"<br>  "4625712"   "4631052"   "4657529"   "4662355"  <br>"4688998"   "4690002"   "4697574"   "4704121"   "4729763"<br>  "4747826"   "4753221"   "4763032"   "4769001"  <br>"4779614"   "4785795"   "4795314"   "4817586"   "4817886"<br>  "4846152"   "4861330"   "4865581"   "4895493"  <br>"4895557"   "4898518"   "4906229"   "4908012"   "4919647"<br>  "4922910"   "4927407"   "4944722"   "4955856"  <br>"4957504"   "4964864"   "4968293"   "4969865"   "4976682"<br>  "4984972"   "4989609"   "4993418"   "4994078"  <br>"4995857"   "5011469"   "5017103"   "5030197"   "5040944"<br>  "5049134"   "5055005"   "5059167"   "5061256"  <br>"5069661"   "5092836"   "5092844"   "5092879"   "5098256"<br>  "5098370"   "5100374"   "5108360"   "5112292"  <br>"5112349"   "5118264"   "5133870"   "5139391"   "5145333"<br>  "5147281"   "5147388"   "5163910"   "5171212"  <br>"5176619"   "5178603"   "5211546"   "5242384"   "5267569"<br>  "5275580"   "5276611"   "5282849"   "5285792"  <br>"5290227"   "5290236"   "5299938"   "5324177"   "5334136"<br>  "5344443"   "5352180"   "5354288"   "5368554"  <br>"5370509"   "5376114"   "5385454"   "5385581").PN. OR<br>("5391142"   "5393207"   "5399074"   "5405251"  <br>"5437601"   "5441535"   "5442503"   "5443503"   "5456715"<br>  "5458459"   "5470208"   "5472614"   "5507629"  <br>"5527159"   "5531789"   "5588812"   "5603337"   "5611667"<br>  "5613935"   "5616137"   "5643226"   "5662711"  <br>"5685700"   "5685865"   "5692882"   "5695471"   "5707218"<br>  "5711753"   "5713865"   "5738626"   "5749855"  <br>"5755784"   "5776190"   "5810758"   "5817586"   "5824070"<br>  "5827220"   "5830370"   "5840070"   "5851174"  <br>"5882339"   "5888241"   "5900142"   "5911685"   "5921913"<br>  "5947892"   "5951262"   "5951263"   "5957672"  <br>"5964694"   "5965089"   "6007312"   "6018208"   "6042347"<br>  "6080133"   "6083187"   "6132364"   "RE28742"  <br>"Re28742").PN. OR ("4817586"   "4846152"   "4895557"  <br>"4964864"   "4969865"   "5851174"   "5921913"   "5964694"<br>  "5965089"   "6135729"   "6139487"   "6176822"  <br>"6176848"   "6217541"   "6245007"   "6346120"   "6387125"<br>  "6716189").URPN. | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR | OFF | 2013/11/18<br>11:14 |
| S157 | 455 | S156 and (rotor rotat\$3 spin\$1 spun spinning turn\$3 blade\$1<br>fin\$1 finned propeller\$1 )                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2013/11/18<br>10:37 |
| S156 | 518 | S155 and pump\$3 same (heart\$2 cardiac cardio)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2013/11/18<br>10:36 |
| S155 | 589 | (A61M1/10 A61M1/12 A61M1/101 A61M2001/10<br>A61M2001/12 A61M2001/122 A61M2001/125 ).cpc. and<br>@ad<"20000901"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | US-PGPUB;<br>USPAT;<br>FPRS;                                     | OR | ON  | 2013/11/18<br>10:35 |

|      |      |                                                                                                                                                       |                                                                  |    |     |                     |
|------|------|-------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|----|-----|---------------------|
|      |      |                                                                                                                                                       | EPO; JPO;<br>DERWENT;<br>IBM_TDB                                 |    |     |                     |
| S154 | 0    | (A61M/1/10 A61M/1/12 A61M/1/101 A61M/2001/10 A61M/2001/12 A61M/2001/122 A61M/2001/125 ).cpc. and @ad<"20000901"                                       | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2013/11/18<br>10:35 |
| S153 | 8669 | (intravascular vascular) same pump\$3 and (heart cardiac )                                                                                            | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR | OFF | 2013/11/18<br>10:18 |
| S150 | 2068 | intravascular same pump\$3 and heart                                                                                                                  | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR | OFF | 2013/11/18<br>08:38 |
| S149 | 49   | S147 and pump\$3 with heart not S148                                                                                                                  | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2013/11/15<br>16:28 |
| S148 | 66   | S147 and (fluid\$2 liquid\$1 solution\$1 cool\$3 ) with (cool\$3 purg\$3 lubricat\$3 lubricant\$1)                                                    | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2013/11/15<br>16:21 |
| S147 | 526  | (S145 S146 ) and (fluid\$2 liquid\$1 solution\$1 cool\$3 ) with (lumen\$1 path\$1 pathway tube\$1 tubing\$1 channel\$3 space\$1 hole\$1 aperture\$1 ) | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2013/11/15<br>16:20 |
| S146 | 919  | (604/164.01,164.08,164.09,164.1,164.11,164.12,164.13).ccls. and @ad<"20000901"                                                                        | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2013/11/15<br>16:20 |
| S145 | 147  | (623/3.1,3.13,3.14,3.15).ccls. and @ad<"20000901"                                                                                                     | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2013/11/15<br>16:20 |
| S144 | 1    | 12/772,810.app.                                                                                                                                       | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR | OFF | 2013/11/13<br>14:18 |

EAST Search History (Interference)

< This search history is empty >

11/ 19/ 2013 10:02:36 AM  
H:\ EAST searches\ workspaces\ 12772810 rce.wsp

|                                                                                                              |                                                |                                                                         |
|--------------------------------------------------------------------------------------------------------------|------------------------------------------------|-------------------------------------------------------------------------|
| <b>Search Notes</b><br><br> | <b>Application/Control No.</b><br><br>12772810 | <b>Applicant(s)/Patent Under Reexamination</b><br><br>ABOUL-HOSN ET AL. |
|                                                                                                              | <b>Examiner</b><br><br>ADAM MARCETICH          | <b>Art Unit</b><br><br>3761                                             |

| CPC- SEARCHED                                                                       |            |          |
|-------------------------------------------------------------------------------------|------------|----------|
| Symbol                                                                              | Date       | Examiner |
| A61M1/10; A61M1/12; A61M1/101; A61M2001/10; A61M2001/12; A61M2001/122; A61M2001/125 | 11/19/2013 | AMM      |

| CPC COMBINATION SETS - SEARCHED |      |          |
|---------------------------------|------|----------|
| Symbol                          | Date | Examiner |
|                                 |      |          |

| US CLASSIFICATION SEARCHED |                |            |          |
|----------------------------|----------------|------------|----------|
| Class                      | Subclass       | Date       | Examiner |
| 604                        | 43,156,158,540 | 2/3/2012   | AMM      |
| 623                        | 3.1            | 2/3/2012   | AMM      |
| 600                        | 16             | 2/3/2012   | AMM      |
|                            | search update  | 8/17/2012  | AMM      |
|                            | search update  | 05/02/2013 | AMM      |
|                            | search update  | 11/19/2013 | AMM      |

| SEARCH NOTES                                                                              |            |          |
|-------------------------------------------------------------------------------------------|------------|----------|
| Search Notes                                                                              | Date       | Examiner |
| Inventor search: PALM and EAST (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT, IBM_TDB) | 2/3/2012   | AMM      |
| Review PLUS search results returned Friday, 3 February 2012                               | 2/3/2012   | AMM      |
| Review cited art for related cases 11/375926, 10/070178                                   | 2/3/2012   | AMM      |
| Review ISR for PCT/US00/24515 performed 19 March 2001, Angie Sykes USPTO                  | 2/3/2012   | AMM      |
| search update                                                                             | 8/17/2012  | AMM      |
| search update                                                                             | 05/02/2013 | AMM      |
| search update                                                                             | 11/19/2013 | AMM      |

| INTERFERENCE SEARCH |
|---------------------|
|---------------------|

|  |                                                     |
|--|-----------------------------------------------------|
|  | /Adam Marcetich/<br>Primary Examiner, Art Unit 3761 |
|--|-----------------------------------------------------|

| US Class/<br>CPC Symbol | US Subclass / CPC Group | Date | Examiner |
|-------------------------|-------------------------|------|----------|
|                         |                         |      |          |

|  |                                                     |
|--|-----------------------------------------------------|
|  | /Adam Marcetich/<br>Primary Examiner, Art Unit 3761 |
|--|-----------------------------------------------------|





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| APPLICATION NO.                                                      | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |
|----------------------------------------------------------------------|-------------|----------------------|-------------------------------|------------------|
| 12/772,810                                                           | 05/03/2010  | Walid N. Aboul-Hosn  | 06-01506US04                  | 4661             |
| 99185                                                                | 7590        | 03/06/2014           |                               |                  |
| MAQUET Cardiovascular LLC<br>120 Baytech Drive<br>San Jose, CA 95134 |             |                      | EXAMINER<br>MARCETICH, ADAM M |                  |
|                                                                      |             |                      | ART UNIT                      | PAPER NUMBER     |
|                                                                      |             |                      | 3761                          |                  |
|                                                                      |             |                      | NOTIFICATION DATE             | DELIVERY MODE    |
|                                                                      |             |                      | 03/06/2014                    | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

legal@maquet.com

|                                                     |                                      |                                          |  |
|-----------------------------------------------------|--------------------------------------|------------------------------------------|--|
| <b><i>Applicant-Initiated Interview Summary</i></b> | <b>Application No.</b><br>12/772,810 | <b>Applicant(s)</b><br>ABOUL-HOSN ET AL. |  |
|                                                     | <b>Examiner</b><br>ADAM MARCETICH    | <b>Art Unit</b><br>3761                  |  |

All participants (applicant, applicant's representative, PTO personnel):

(1) Kurt Denniston, Applicant's Representative. (3) \_\_\_\_.

(2) Adam Marcetich, Examiner. (4) \_\_\_\_.

Date of Interview: 28 February 2014.

Type:    ☒ Telephonic    ☐ Video Conference  
              ☐ Personal [copy given to: ☐ applicant    ☐ applicant's representative]

Exhibit shown or demonstration conducted:    ☐ Yes    ☒ No.  
     If Yes, brief description: \_\_\_\_.

Issues Discussed    ☐101    ☐112    ☐102    ☒103    ☐Others  
 (For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: 15,30 and 46.

Identification of prior art discussed: Bedingham; William et al. (US 6245007), Nix; Christoph et al. (US 6176822), Gordon; Lucas S. (US 5938645).

**Substance of Interview**  
 (For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Applicant clarified the nature of the invention, noting that the rotors require a space to rotate within the shroud while pumping blood. Applicant noted that Gordon is a catheter, not a blood pump, and therefore does not require an open lumen for a rotor. if Bedingham were modified with guidewire lumen 46 of Gordon, it would occupy space within the shroud and obstruct impeller 56 of Bedingham.

Examiner acknowledged that this combination would destroy the teachings of Bedingham. Examiner suggested filing a response under the AFCP 2.0 program. Guidelines are available online regarding submission requirements: [http://www.uspto.gov/patents/init\\_events/afcp.jsp](http://www.uspto.gov/patents/init_events/afcp.jsp)

Examiner noted that claims 30 and 46 are rejected under 35 USC 112 first paragraph. It appears that multiple embodiments have been combined in each of these claims.

**Applicant recordation instructions:** The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

**Examiner recordation instructions:** Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

|                                                     |  |
|-----------------------------------------------------|--|
| /ADAM MARCETICH/<br>Primary Examiner, Art Unit 3761 |  |
|-----------------------------------------------------|--|

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

#### Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

|                                                                                                                                                                                                                                                 |                      |                                                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|-------------------------------------------------------|
| <b>RESPONSE AFTER FINAL<br/>REJECTION -<br/>AMENDMENT UNDER<br/>37 C.F.R. §1.116(b) – After<br/>Final Consideration Pilot 2.0</b><br><br>Address to:<br>Mail Stop: AF<br>Commissioner for Patents<br>P.O. Box 1450<br>Alexandria, VA 22313-1450 | Attorney Docket      | 06-01506US04                                          |
|                                                                                                                                                                                                                                                 | Confirmation No.     | 4661                                                  |
|                                                                                                                                                                                                                                                 | First Named Inventor | Walid N. ABOUL-HOSN                                   |
|                                                                                                                                                                                                                                                 | Application Number   | 12/772,810                                            |
|                                                                                                                                                                                                                                                 | Filing Date          | May 3, 2010                                           |
|                                                                                                                                                                                                                                                 | Group Art Unit       | 3761                                                  |
|                                                                                                                                                                                                                                                 | Examiner Name        | Marcetich, Adam M.                                    |
|                                                                                                                                                                                                                                                 | Title                | Guidable Intravascular Blood Pump and Related Methods |

Sir:

This amendment is responsive to the Final Office Action dated November 25, 2014 according to the provisions of the After Final Consideration Pilot 2.0 program. An extension of time is being filed concurrently making this response timely filed. In view of the amendments to the claims and the remarks put forth below, reconsideration and allowance are respectfully requested.

The **Claims** begin on page 2.

**Remarks** being on page 8.

## AMENDMENTS TO THE CLAIMS

Claims 1 – 14 (Cancelled)

15. (Previously Presented) An intravascular blood pump system, comprising:

an intravascular blood pump comprising:

a rotor having a rotor hub tapering in the distal direction, at least one blade extending radially outward from the rotor hub, the hub has a distal end extending distally beyond the most distal portion of the blade and

a shroud within which the rotor is rotatably disposed;

a cannula extending from the shroud and comprising an outer cannula surface, the outer cannula surface having a substantially circular cross-section along a portion of its length;

a first lumen in fluid communication with the intravascular blood pump and operatively arranged to deliver purge fluid to the intravascular blood pump; and

a guide mechanism configured as a second lumen having a proximal end and a distal end, the guide mechanism adapted to guide a distal portion of said intravascular blood pump system to a predetermined location within the circulatory system of a patient;

wherein an axis coaxial with and extending through a portion of said guide mechanism extends through a region delimited by the outer cannula surface, and wherein the guide mechanism is configured to allow for a guide wire to slideably advance therealong.

16 – 22 (Cancelled)

23. (Previously Presented) The intravascular blood pump system of claim

15, wherein the rotor comprises a second blade extending radially from the rotor hub.

24. (Previously Presented) The intravascular blood pump system of claim 15, wherein the rotor hub is generally conical.

25. (Previously Presented) The intravascular blood pump system of claim 15, wherein the guide mechanism is configured such that the guide wire passes through the region delimited by the outer cannula surface at a location proximal to where the guide wire establishes slidable contact with the guide mechanism.

26. (Previously Presented) The intravascular blood pump system of claim 15, further comprising a guide catheter, wherein the guide catheter is configured to facilitate the placement of the guide wire into the heart.

27. (Previously Presented) The intravascular blood pump system of claim 15, further comprising:

an elongate catheter extending proximally with respect to the intravascular blood pump; and

a blood pressure detection mechanism comprising a fluid column disposed within the catheter and configured to detect the pressure of the blood proximate the intravascular blood pump.

28. (Cancelled)

29. (Currently Amended) An intravascular blood pump system comprising:  
an intravascular blood pump comprising a rotor having a rotor hub tapering in the distal direction, at least one blade extending radially outward from the rotor hub, the intravascular blood pump coupled to a catheter on a proximal end and a cannula on a distal end;

a first set and a second set of apertures establishing fluid communication between an interior of the cannula and an exterior region of the cannula, wherein the first set of apertures is located in proximity to the rotor and the second set of apertures

is spaced apart from and located distal to the first set of apertures towards a distal region of the cannula;

a guide mechanism configured as an elongate lumen and adapted to guide said intravascular blood pump, cannula, and catheter to a predetermined location within the circulatory system of a patient; and

a blood pressure detection mechanism comprising a fluid column configured to detect the pressure of the blood proximate the intravascular blood pump;

wherein the ~~guide mechanism has a~~ elongate lumen is sized substantially smaller than an inner diameter of the cannula and intravascular blood pump; and

a guide wire arranged to be advanced along the lumen, wherein the lumen is arranged coaxially with at least one of a distal end or a proximal end of the cannula, and the cannula and the lumen are arranged in series longitudinally.

30. (Cancelled)

31. (Previously Presented) The intravascular blood pump system of claim 29, wherein the cannula is reinforced with a spiral wire.

32. (Cancelled)

33. (Previously Presented) The intravascular blood pump system of claim 29, further comprising a guide wire and a guide catheter, wherein the guide catheter is configured facilitate the placement of the guide wire through the vasculature into the heart.

34. (Cancelled)

35. (Previously Presented) The intravascular blood pump system of claim 29, wherein the rotor comprises a second blade extending radially from the rotor hub.

36. (Previously Presented) The intravascular blood pump system of claim 29, wherein the cannula comprises an outer cannula surface having a substantially

circular cross-section along a portion of its length, the distal region of the outer cannula surface is distally tapered about its circumference.

37. (Previously Presented) The intravascular blood pump system of claim 29, further comprising a plurality of egress flow ports disposed in a shroud of the intravascular blood pump, and a plurality of ingress flow ports disposed at a location spaced apart from and distal to the egress flow ports.

38. (Previously Presented) The intravascular blood pump system of claim 37, wherein the ingress flow ports comprise an end port located at the cannula distal end and a plurality of ports located about the cannula and proximal to the end port.

39. (Previously Presented) The intravascular blood pump system of claim 29, wherein the first set of apertures are egress ports and the second set of apertures are ingress ports, and wherein the egress ports are configured to direct blood passing through the interior of the cannula and towards the rotor in a direction that is both proximal and radially outward with respect to the rotor hub.

40. (Cancelled)

41. (Previously Presented) The intravascular blood pump system of claim 29, wherein the central lumen extends through the cannula and blood pump.

42. (Previously Presented) The intravascular blood pump system of claim 29, wherein the lumen of the central lumen is proximal to the cannula.

43. (Previously Presented) The intravascular blood pump system of claim 15, wherein the cannula is operatively arranged to bend at a location between distal and proximal ends thereof.

44. (Previously Presented) The intravascular blood pump system of claim 29, wherein the cannula is operatively arranged to bend at a location between distal and



proximal ends thereof.

45. (Previously Presented) An intravascular blood pump system configured to be advanced to a predetermined location in a patient's circulatory system, the intravascular blood pump system comprising:

an intravascular blood pump, the intravascular blood pump comprising a rotor having a generally conical rotor hub tapering in the distal direction, at least two blades extending radially from the rotor hub, the generally conical rotor hub having a distal tip extending distally beyond the blades;

a cannula extending distally from the intravascular blood pump;

a plurality of ingress ports located towards the proximal region of the cannula and a plurality of egress ports located in proximity to the blood pump such that movement of fluid proximally through an interior region of the cannula is steered towards the egress ports;

a guide wire having a cross-section substantially smaller than the cannula;

and

an elongate lumen having a luminal interior sized (i) smaller than an inside diameter of the cannula and (ii) sufficiently large enough to accommodate the guide wire when the guide wire is advanced therealong, wherein the lumen is arranged coaxially with respect to at least one of a distal end or a proximal end of the cannula, and the lumen and the cannula are arranged in series longitudinally.

46. (Cancelled)

47. (Cancelled)

48. (Previously Presented) The intravascular blood pump system of claim 45, wherein the lumen is proximal with respect to the cannula.

49. (Currently Amended) The intravascular blood pump system of claim 15, further comprising a first conduit and a second conduit, at least one of the first conduit

or the second conduit terminating in a fitting that is configured to be located outside a patient when the intravascular blood pump and cannula are located inside the patient, at least one of the first conduit and second conduit in fluid communication with the first lumen.

50. (New) The intravascular blood pump system of claim 15, wherein a distal end of the cannula is open in order to enable the guide wire to pass axially through the distal end of the cannula.

51. (New) The intravascular blood pump system of claim 29, wherein the distal end of the cannula is open to enable the guide wire to pass axially through the distal end of the cannula.

52. (New) The intravascular blood pump system of claim 45, wherein the distal end of the cannula is open to enable the guide wire to pass axially through the distal end of the cannula.

## **REMARKS**

### **Formal Matters**

Claims 15, 23-27, 29-31, 33, 35-39, 41-46, 48-49 were examined.

Claims 1-14, 16 – 22, 28, 32, 34, 40 and 47 were previously canceled.

Claims 30 and 46 are currently canceled.

Claims 29 and 49 are currently amended.

Claims 50-52 are newly added.

Claims 15, 23-27, 29, 31, 33, 35-39, 41-45, and 48-52 are pending after entry of and amendments.

Support for the amendments can be found throughout the specification and drawings. More specifically, support can be found as follows:

Support for amended claim 29 can be found for example in Figure 3.

Support for amended claim 49 can be found for example in paragraph [0061] and Figure 2.

Support for new claims 50-52 can be appreciated in view of Figure 1.

No new matter has been added.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

### **The Office Action**

#### **I. Teleconference of February 28, 2014**

A teleconference was held between the Examiner and the undersigned attorney of record, Kurt Denniston, on Friday, February 28, at 2:00pm. The obviousness combinations of Bedingham and Nix with the secondary references, *i.e.*, Gordon and Masch were discussed. More specifically, it was discussed that while Bedingham and Nix are directed generally to blood pumps, Gordon and Masch are not. Arguments against the combination were discussed, notably with respect to Gordon as detailed in the Examiner's Interview Summary dated March 6, 2014, wherein the Examiner indicated that the arguments would be persuasive if presented in a reply in the After Final 2.0 program.

## **II. Claims Rejected Under 35 U.S.C. § 112 First Paragraph**

The Examiner has rejected claims 30 and 46 for allegedly failing to comply with the enablement requirement. Applicant has cancelled Claims 30 and 46, rendering the objections thereto moot.

## **III. Claims Rejected Under 35 U.S.C. § 112 Second Paragraph**

The Examiner has rejected claim 49 as allegedly failing to particularly point out and distinctly claim the subject matter which the inventor regards as the invention. Applicant believes the amendments made to claim 49 clarify the intended meaning of this claim and overcome the Examiner's rejection. As no prior art rejection has been made with respect to claim 49, claim 49 is understood by the Applicants to be allowable in light of the amendment to overcome the rejection under 35 U.S.C. § 112 second paragraph.

## **IV. Claims Rejected Under 35 U.S.C. § 103(a)**

In the Office Action, claims 15, 23-25, 29, 30, 35-42, and 45-48 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,245,007 to Bedingham et al. ("Bedingham") in view of U.S. Patent No. 6,176,822 to Nix et al. ("Nix") and U.S. Patent No. 5,938,645 to Gordon ("Gordon").

Claim 15 recites, in pertinent part, "*a guide mechanism configured as a second lumen having a proximal end and a distal end, the guide mechanism adapted to guide a distal portion of said intravascular blood pump system to a predetermined location within the circulatory system of a patient...wherein the guide mechanism is configured to allow for a guide wire to slideably advance therealong.*"

Instead of a guide wire mechanism configured as a lumen, Bedingham only suggests inserting a guide wire into the existing structure of the pump housing, as taught at column 9, lines 35-42, so that the guide wire "passes between the vanes of the outlet flow straightener, impeller and inlet flow straightener". The use of a lumen is not taught in Bedingham. Nix is also silent with respect to a guide mechanism configured as a lumen that allows for a guide wire to slideably advance therealong. Accordingly,

the Examiner relies upon Gordon to teach a guide wire mechanism configured as a lumen and that allows for a guide wire to slideably advance therealong. Unlike Nix and Bedingham, however, Gordon is not directed to an intravascular blood pump. Instead, Gordon is directed to a percutaneous aspiration catheter (for in-vivo insertion) which may fluidically connect to a vacuum pump that remains at all times ex-vivo. The catheter of Gordon is essentially an open tubular structure that requires only an open space to provide vacuum suction therethrough, and does not house any type of impeller structure for that portion which is inserted in-vivo.

Bedingham effectively teaches away from the combination with Gordon, as Bedingham indicates no need for a specially constructed lumen, such as the catheter lumen 46 of Gordon. More specifically, Bedingham already teaches a solution for enabling its blood pump to be positioned with a guide wire, namely, by threading the guide wire in through the existing vane structure of the outlet straightener, past the blood pump in the space between blades of the impeller, and out through the existing vane structure of the inlet straightener of the pump. The guide wire of Bedingham would therefore enter and exit the pump housing through the pump housing's sidewalls. The Examiner has provided no reasoning as to why one would forsake the teaching of Bedingham, which actually teaches a solution for positioning a blood pump on a guide wire, and instead implement a structure utilized by the catheter of Gordon. Simply, one of ordinary skill in the art would not look to Gordon for solutions for delivering a blood pump to a location within a patient, particularly when that problem was already solved by Bedingham.

Additionally, even assuming *arguendo* that one were to look to Gordon, the Examiner has not provided any guidance as to how one would implement the proposed modifications to the device of Bedingham. Importantly, again unlike Bedingham and Nix (and other blood pump systems), the catheter 18 of Gordon does not need to accommodate for in-vivo insertion of a blood pump, *e.g.*, having a rotor and blades, in, along, adjacent to, or otherwise disposed with the catheter 18. That is, as noted above, Gordon essentially only requires an open lumen to provide a vacuum pressure, and does not need to accommodate a blood pump. Accordingly, additional modifications would be necessary to teach one of ordinary skill in the art how to arrange the catheter lumen 46 of Gordon so that it would enable a guide wire to pass along, in, through, about, or

otherwise with the blood pump of Bedingham. The Examiner has failed to provide such teaching with any sort of rational underpinning. For the reasons given above, the combination of Bedingham and Gordon is not proper and cannot be supported.

Assuming further, arguendo, that the combination of Bedingham and Nix with Gordon were proper and permissible, which it is not for the reasons discussed above, modifying the Bedingham device as proposed by the Examiner would render the resulting modified device inoperable. More specifically, as discussed above, Bedingham relates to a blood pump, which has blades extending radially outwardly from a rotor. Necessarily, the rotor and blades rotate to pump blood. Bedingham does not include simply an open lumen akin to the Gordon catheter. As a result, Bedingham teaches guiding the blood pump into a location by threading a guide wire in through one of a plurality of outlets of the blood pump, through the space between the blades, and out through one of the plurality of inlet of the blood pump. Modifying the Bedingham device with the structure of the lumen 46 of Gordon would thus result in the lumen 46 and its sidewall being located in the open space between the blades of the blood pump of Bedingham. If such a lumen were so arranged, the blades of the motor would hit the wall of the lumen and be unable to rotate, thereby preventing the blood pump from operating.

Accordingly, one of ordinary skill in the art both could not and would not combine Bedingham, Nix, and Gordon. In view of the foregoing, Applicants respectfully submit that the cited combination of references do not render independent claim 15 obvious. Applicants respectfully submit that claim 15, and all claims depending therefrom are thus in condition for allowance, which action is courteously requested.

**V. Claims Rejected Under 35 U.S.C. § 103(a) (Bedingham, Nix, and Gordon in view of Teirstein)**

The Examiner has rejected claim 26 under 35 U.S.C. 103(a) as being unpatentable over Bedingham, Nix, and Gordon, in view of U.S. Patent No. 5,234,407 to Teirstein et al. (“Teirstein”).

Teirstein is cited only with respect to the particular limitations of claim 26, and clearly fails to disclose the base limitations of claim 15, from which claim 26 depends.

Since the combination of Bedingham, Nix, and Gordon fails for all of the reasons discussed above, no combination also including Teirstein could possibly have enabled one of ordinary skill in the art to arrive at the claimed invention.

In view of the foregoing, Applicants respectfully submit that the cited combination of references do not render claim 26 as obvious, at least due to their dependency from claim 15. In view of the foregoing, withdrawal of the rejection is respectfully requested.

**VI. Claims Rejected Under 35 U.S.C. §103(a) (Bedingham, Nix, and Gordon, in view of Watkins)**

The Examiner has rejected claim 27 under 35 U.S.C. § 103 as being unpatentable over Bedingham, Nix, and Gordon in view of U.S. Patent No. 3,995,617 to Watkins et al. (“Watkins”).

Watkins is cited only with respect to the particular limitations of claim 27, and clearly fails to disclose the base limitations of claim 15, from which claim 27 depends. Since the combination of Bedingham, Nix, and Gordon fails for all the reasons discussed above, no combination also including Watkins could possibly have enabled one of ordinary skill in the art to arrive at the claimed invention.

In view of the foregoing, Applicants respectfully submit that the cited combination of references do not render claim 27 as obvious, at least due to its dependency from claim 29. In view of the foregoing, withdrawal of the rejection is respectfully requested.

**VII. Claims Rejected Under 35 U.S.C. §103(a) (Bedingham, Nix, and Gordon, in view of Siess)**

The Examiner has rejected claim 43 under 35 U.S.C. § 103 as being unpatentable over Bedingham, Nix, and Gordon, in view of U.S. Patent No. 6,007,478 to Siess et al. (“Siess”).

Siess is cited only with respect to the particular limitations of claim 43, and clearly fails to disclose the base limitations of claim 29, from which this claims depends. Since the combination of Bedingham, Nix, and Gordon fails for all the

reasons discussed above, no combination also including Siess could possibly have enabled one of ordinary skill in the art to arrive at the claimed invention.

In view of the foregoing, Applicants respectfully submit that the cited combination of references do not render claims 31, 33, or 44 as obvious, at least due to their dependency from claim 29. In view of the foregoing, withdrawal of the rejection is respectfully requested.

**VIII. Claims Rejected Under 35 U.S.C. §103(a) (Bedingham and Nix in view of Masch)**

The Examiner has rejected claims 29, 35-39, 41, 42, 45, and 48 under 35 U.S.C. § 103 as being unpatentable over Bedingham and Nix in view of U.S. Patent No. 4,728,319 to Masch (“Masch”).

Claim 29 recites, in pertinent part, “*the intravascular blood pump coupled to a catheter on a proximal end and a cannula on a distal end...a guide mechanism configured as an elongate lumen and adapted to guide said intravascular blood pump, cannula, and catheter to a predetermined location within the circulatory system of a patient...and wherein the lumen is arranged coaxially with at least one of a distal end or a proximal end of the cannula, and the cannula and the lumen are arranged in series longitudinally*”. Claim 45 similarly recites, in pertinent part, “*a cannula extending distally from the intravascular blood pump...an elongate lumen having a luminal interior sized...sufficiently large enough to accommodate the guide wire when the guide wire is advanced therealong, wherein the lumen is arranged coaxially with respect to at least one of a distal end or a proximal end of the cannula, and the lumen and the cannula are arranged in series longitudinally*”.

As noted above, instead of a guide wire mechanism configured as a lumen, Bedingham only teaches inserting a guide wire in through one of a plurality of blood outlets, past the blades of an impeller, and out through one of a plurality of blood inlets. The blood inlets and outlets are located on a sidewall, and are aligned with “vanes” to guide blood passing therebetween. Nix is silent regarding a guide wire mechanism configured as a lumen and/or an elongate lumen that allows for a guide wire to slideably advance therealong. Accordingly, the Examiner relies upon Masch for this teaching. Unlike Nix and Bedingham, however, Masch is not directed to a blood pump.



Instead, Masch is directed to an intravascular catheter configured to clear blocked blood vessels with a rotary cutting means.

Bedingham effectively teaches away from the Examiner's proposed combination, as Bedingham indicates no need for the tube 15 of Masch. More specifically, Bedingham already teaches a solution for enabling its blood pump to be positioned with a guide wire, namely, by threading the guide wire in through one of the plurality of outlets in the pump's sidewall, past the blood pump's impeller in the space between the impeller's blades, and out through one of the plurality of inlets of the pump's sidewall. The Examiner has provided no reasoning with some rational underpinning as to why one would forsake the teaching of Bedingham, which actually teaches a solution for positioning a blood pump on a guide wire, and instead implement a structure utilized by the catheter of Masch. Simply, one of ordinary skill in the art would not look to Masch for solutions for delivering a blood pump to a location within a patient, particularly when that problem was already solved by Bedingham.

Even assuming *arguendo* that Masch was considered for combination with Bedingham, the Examiner has not provided any guidance as to how one would implement the proposed modifications to the device of Bedingham. Importantly, and unlike Bedingham and Nix (and other blood pump systems), the catheter 11 of Masch does not need to accommodate a blood pump, *e.g.*, having a rotor and blades, in, along, adjacent to, or otherwise disposed with the catheter 11. It is only by coincidence and convenience that the tube 15 of Masch is concentric with respect to the catheter 11 of Masch; namely, due to the hollow nature of the cutting means 17, as that is where there was free and unutilized space. Likewise, the guide wire in Bedingham is threaded through the location that is most convenient due to there being free space, which happens to be in the space between the longitudinal arrangement of outlet vanes which are adjacent blades of the blood pump's impeller, which are subsequently adjacent the inlet vanes. Arranging the tube 15 of Masch in this space would result in it not being concentric to any structure in Bedingham that could conceivably be interpreted as a cannula, and thus would fail to meet the limitations of the claims. Bedingham only teaches arranging a guide wire in through one of a plurality of radially located outlets, axially past a blood pump in the space between its blades, and then out through one of a plurality of radially located inlets. There is no teaching how a lumen for a guide wire

would or could be arranged in series longitudinally with a cannula extending distally from the blood pump of Bedingham, or coaxially with an end of such a cannula.

Accordingly, one of ordinary skill in the art both could not and would not combine Bedingham, Nix, and Masch. In view of the foregoing, Applicants respectfully submit that the cited combination of references do not render independent claims 29 and 45 obvious. Applicants respectfully submit that claims 29 and 45, and all claims depending therefrom, are thus in condition for allowance, which action is courteously requested.

**IX. Claims Rejected Under 35 U.S.C. §103(a) (Bedingham, Nix, and Masch in view of Siess)**

The Examiner has rejected claims 31 and 44 under 35 U.S.C. § 103 as being unpatentable over Bedingham, Nix and Masch in view of Siess.

Siess is cited only with respect to the particular limitations of claims 31 and 44, and clearly fails to disclose the base limitations of claim 29, from which this claims depends. Since the combination of Bedingham, Nix, and Masch fails for all the reasons discussed above, as no reasonable combination also including Siess could possibly have enabled one of ordinary skill in the art to arrive at the claimed invention.

In view of the foregoing, Applicants respectfully submit that the cited combination of references do not render claims 31 or 44 as obvious, at least due to their dependency from claim 29. In view of the foregoing, withdrawal of the rejection is respectfully requested.

**X. Claims Rejected Under 35 U.S.C. § 103(a) (Bedingham, Nix, and Masch in view of Teirstein)**

The Examiner has rejected claim 33 under 35 U.S.C. 103(a) as being unpatentable over Bedingham, Nix, and Masch, in view of Teirstein.

Teirstein is cited only with respect to the particular limitations of claim 33, and clearly fails to disclose the base limitations of claim 29, from which claim 33 depends. Since the combination of Bedingham, Nix, and Masch fails for all the reasons discussed above, no combination also including Teirstein could possibly have enabled one of

ordinary skill in the art to arrive at the claimed invention.

In view of the foregoing, Applicants respectfully submit that the cited combination of references do not render claim 33 as obvious, at least due to its dependency from claim 29. In view of the foregoing, withdrawal of the rejection is respectfully requested.

#### **XI. New Claims**

Claims 50-52 are newly added, and depend from claims 15, 29, and 45, respectively. These claims are presented to further distinguish over the cited art. Namely, these claims recite that a distal end of the cannula is open to enable a guide wire to pass axially therethrough. Contrarily, the system of the primary cited reference, Bedingham, is arranged so that a guide wire can only pass through the blood pump via radially positioned outlet and inlet ports (*i.e.*, see reference numerals 34 and 44 in Figure 1). Further, the Bedingham system is capped off without an opening at its distal end (*i.e.*, by a tip portion 46).

**Conclusion**

Applicants have made a good faith effort to place the claims in condition for allowance. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 04-0170, order number 06-01506US04.

Respectfully submitted,

Date: March 27, 2014

/Kurt R. Denniston/  
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## Electronic Patent Application Fee Transmittal

|                                                     |                                                       |                 |                        |                             |
|-----------------------------------------------------|-------------------------------------------------------|-----------------|------------------------|-----------------------------|
| <b>Application Number:</b>                          | 12772810                                              |                 |                        |                             |
| <b>Filing Date:</b>                                 | 03-May-2010                                           |                 |                        |                             |
| <b>Title of Invention:</b>                          | Guidable Intravascular Blood Pump and Related Methods |                 |                        |                             |
| <b>First Named Inventor/Applicant Name:</b>         | Walid N. Aboul-Hosn                                   |                 |                        |                             |
| <b>Filer:</b>                                       | Kurt Raymond Denniston/Mary Zimmerman                 |                 |                        |                             |
| <b>Attorney Docket Number:</b>                      | 06-01506US04                                          |                 |                        |                             |
| Filed as Large Entity                               |                                                       |                 |                        |                             |
| <b>Utility under 35 USC 111(a) Filing Fees</b>      |                                                       |                 |                        |                             |
| <b>Description</b>                                  | <b>Fee Code</b>                                       | <b>Quantity</b> | <b>Amount</b>          | <b>Sub-Total in USD(\$)</b> |
| <b>Basic Filing:</b>                                |                                                       |                 |                        |                             |
| <b>Pages:</b>                                       |                                                       |                 |                        |                             |
| <b>Claims:</b>                                      |                                                       |                 |                        |                             |
| <b>Miscellaneous-Filing:</b>                        |                                                       |                 |                        |                             |
| <b>Petition:</b>                                    |                                                       |                 |                        |                             |
| <b>Patent-Appeals-and-Interference:</b>             |                                                       |                 |                        |                             |
| <b>Post-Allowance-and-Post-Issuance:</b>            |                                                       |                 |                        |                             |
| <b>Extension-of-Time:</b>                           |                                                       |                 |                        |                             |
| Page 36 of 698<br>Extension- 2 months with \$0 paid | 1252                                                  | 1               | 690<br>ABOMED Ex. 1036 | 690                         |

| Description       | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
|-------------------|----------|----------|--------|----------------------|
| Miscellaneous:    |          |          |        |                      |
| Total in USD (\$) |          |          |        | 600                  |

## Electronic Acknowledgement Receipt

|                                             |                                                       |
|---------------------------------------------|-------------------------------------------------------|
| <b>EFS ID:</b>                              | 18618052                                              |
| <b>Application Number:</b>                  | 12772810                                              |
| <b>International Application Number:</b>    |                                                       |
| <b>Confirmation Number:</b>                 | 4661                                                  |
| <b>Title of Invention:</b>                  | Guidable Intravascular Blood Pump and Related Methods |
| <b>First Named Inventor/Applicant Name:</b> | Walid N. Aboul-Hosn                                   |
| <b>Customer Number:</b>                     | 99185                                                 |
| <b>Filer:</b>                               | Kurt Raymond Denniston/Mary Zimmerman                 |
| <b>Filer Authorized By:</b>                 | Kurt Raymond Denniston                                |
| <b>Attorney Docket Number:</b>              | 06-01506US04                                          |
| <b>Receipt Date:</b>                        | 28-MAR-2014                                           |
| <b>Filing Date:</b>                         | 03-MAY-2010                                           |
| <b>Time Stamp:</b>                          | 17:58:18                                              |
| <b>Application Type:</b>                    | Utility under 35 USC 111(a)                           |

### Payment information:

|                                          |                 |
|------------------------------------------|-----------------|
| Submitted with Payment                   | yes             |
| Payment Type                             | Deposit Account |
| Payment was successfully received in RAM | \$600           |
| RAM confirmation Number                  | 4572            |
| Deposit Account                          | 040170          |
| Authorized User                          |                 |

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Page 363 of 638

ADDITIONAL EX-1036

| File Listing:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                             |                       |                                                    |                  |                  |
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| Document Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Document Description        | File Name             | File Size(Bytes)/<br>Message Digest                | Multi Part /.zip | Pages (if appl.) |
| 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Response After Final Action | Response_03282014.pdf | 167735<br>0cc1df0d82ec7f2f16f51cae092426d23d218181 | no               | 17               |
| Warnings:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                             |                       |                                                    |                  |                  |
| Information:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                             |                       |                                                    |                  |                  |
| 2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Fee Worksheet (SB06)        | fee-info.pdf          | 30665<br>6e4e4b8e403fb11e72a1ba391b4c1642fb1b284f  | no               | 2                |
| Warnings:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                             |                       |                                                    |                  |                  |
| Information:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                             |                       |                                                    |                  |                  |
| Total Files Size (in bytes):                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                             |                       | 198400                                             |                  |                  |
| <p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><b><u>New Applications Under 35 U.S.C. 111</u></b><br/>           If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><b><u>National Stage of an International Application under 35 U.S.C. 371</u></b><br/>           If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><b><u>New International Application Filed with the USPTO as a Receiving Office</u></b><br/>           If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p> |                             |                       |                                                    |                  |                  |



| <b>CERTIFICATION AND REQUEST FOR CONSIDERATION UNDER THE<br/>AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                               |                                          |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|------------------------------------------|
| <b>Practitioner Docket No.:</b><br><b>06-01506US04</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Application No.:</b><br><b>12772810</b>                                    | <b>Filing Date:</b><br><b>2010-05-03</b> |
| <b>First Named Inventor:</b><br><b>Walid N. ABOUL-HOSN</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>Title:</b><br><b>Guidable Intravascular Blood Pump and Related Methods</b> |                                          |
| <p>APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0 (AFCP 2.0) OF THE ACCOMPANYING RESPONSE UNDER 37 CFR 1.116.</p> <ol style="list-style-type: none"> <li>1. The above-identified application is (i) an original utility, plant, or design nonprovisional application filed under 35 U.S.C. 111(a) [a continuing application (<i>e.g.</i>, a continuation or divisional application) is filed under 35 U.S.C. 111(a) and is eligible under (i)], or (ii) an international application that has entered the national stage in compliance with 35 U.S.C. 371(c).</li> <li>2. The above-identified application contains an outstanding final rejection.</li> <li>3. Submitted herewith is a response under 37 CFR 1.116 to the outstanding final rejection. The response includes an amendment to at least one independent claim, and the amendment does not broaden the scope of the independent claim in any aspect.</li> <li>4. This certification and request for consideration under AFCP 2.0 is the only AFCP 2.0 certification and request filed in response to the outstanding final rejection.</li> <li>5. Applicant is willing and available to participate in any interview requested by the examiner concerning the present response.</li> <li>6. This certification and request is being filed electronically using the Office's electronic filing system (EFS-Web).</li> <li>7. Any fees that would be necessary consistent with current practice concerning responses after final rejection under 37 CFR 1.116, <i>e.g.</i>, extension of time fees, are being concurrently filed herewith. [There is no additional fee required to request consideration under AFCP 2.0.]</li> <li>8. By filing this certification and request, applicant acknowledges the following:               <ul style="list-style-type: none"> <li>• Reissue applications and reexamination proceedings are not eligible to participate in AFCP 2.0.</li> <li>• The examiner will verify that the AFCP 2.0 submission is compliant, <i>i.e.</i>, that the requirements of the program have been met (see items 1 to 7 above). For compliant submissions:                   <ul style="list-style-type: none"> <li>○ The examiner will review the response under 37 CFR 1.116 to determine if additional search and/or consideration (i) is necessitated by the amendment and (ii) could be completed within the time allotted under AFCP 2.0. If additional search and/or consideration is required but cannot be completed within the allotted time, the examiner will process the submission consistent with current practice concerning responses after final rejection under 37 CFR 1.116, <i>e.g.</i>, by mailing an advisory action.</li> <li>○ If the examiner determines that the amendment does not necessitate additional search and/or consideration, or if the examiner determines that additional search and/or consideration is required and could be completed within the allotted time, then the examiner will consider whether the amendment places the application in condition for allowance (after completing the additional search and/or consideration, if required). If the examiner determines that the amendment does not place the application in condition for allowance, then the examiner will contact the applicant and request an interview.                       <ul style="list-style-type: none"> <li>▪ The interview will be conducted by the examiner, and if the examiner does not have negotiation authority, a primary examiner and/or supervisory patent examiner will also participate.</li> <li>▪ If the applicant declines the interview, or if the interview cannot be scheduled within ten (10) calendar days from the date that the examiner first contacts the applicant, then the examiner will proceed consistent with current practice concerning responses after final rejection under 37 CFR 1.116.</li> </ul> </li> </ul> </li> </ul> </li> </ol> |                                                                               |                                          |
| <b>Signature</b><br><b>/Kurt D. Denniston/</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Date</b><br><b>2014-03-28</b>                                              |                                          |
| <b>Name</b><br><b>(Print/Typed) Kurt D. Denniston</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <b>Practitioner</b><br><b>Registration No. 59,605</b>                         |                                          |
| <p><b>Note:</b> This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                               |                                          |
| <input type="checkbox"/> * Total of _____ forms are submitted.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                               |                                          |

## Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

## Electronic Acknowledgement Receipt

|                                             |                                                       |
|---------------------------------------------|-------------------------------------------------------|
| <b>EFS ID:</b>                              | 18618409                                              |
| <b>Application Number:</b>                  | 12772810                                              |
| <b>International Application Number:</b>    |                                                       |
| <b>Confirmation Number:</b>                 | 4661                                                  |
| <b>Title of Invention:</b>                  | Guidable Intravascular Blood Pump and Related Methods |
| <b>First Named Inventor/Applicant Name:</b> | Walid N. Aboul-Hosn                                   |
| <b>Customer Number:</b>                     | 99185                                                 |
| <b>Filer:</b>                               | Kurt Raymond Denniston/Mary Zimmerman                 |
| <b>Filer Authorized By:</b>                 | Kurt Raymond Denniston                                |
| <b>Attorney Docket Number:</b>              | 06-01506US04                                          |
| <b>Receipt Date:</b>                        | 28-MAR-2014                                           |
| <b>Filing Date:</b>                         | 03-MAY-2010                                           |
| <b>Time Stamp:</b>                          | 18:23:38                                              |
| <b>Application Type:</b>                    | Utility under 35 USC 111(a)                           |

### Payment information:

|                        |    |
|------------------------|----|
| Submitted with Payment | no |
|------------------------|----|

### File Listing:

| Document Number | Document Description                      | File Name  | File Size(Bytes)/<br>Message Digest                 | Multi Part /.zip | Pages (if appl.) |
|-----------------|-------------------------------------------|------------|-----------------------------------------------------|------------------|------------------|
| 1               | After Final Consideration Program Request | sb0434.pdf | 1251735<br>8b1e09c95244fc40b03801758d986fe6625e1712 | no               | 2                |

### Warnings:

### Information:

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

**New Applications Under 35 U.S.C. 111**

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

**National Stage of an International Application under 35 U.S.C. 371**

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

**New International Application Filed with the USPTO as a Receiving Office**

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

## NOTICE OF ALLOWANCE AND FEE(S) DUE

99185 7590 04/07/2014  
MAQUET Cardiovascular LLC  
120 Baytech Drive  
San Jose, CA 95134

EXAMINER

MARCETICH, ADAM M

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 04/07/2014

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

12/772,810

05/03/2010

Walid N. Aboul-Hosn

06-01506US04

4661

TITLE OF INVENTION: Guidable Intravascular Blood Pump and Related Methods

| APPLN. TYPE    | ENTITY STATUS | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE   |
|----------------|---------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | UNDISCOUNTED  | \$960         | \$0                 | \$0                  | \$960            | 07/07/2014 |

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.**

**THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.**

### HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

# **PART B - FEE(S) TRANSMITTAL**

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
or Fax (571)-273-2885**

**INSTRUCTIONS:** This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

99185 7590 04/07/2014  
**MAQUET Cardiovascular LLC**  
120 Baytech Drive  
San Jose, CA 95134

## **Certificate of Mailing or Transmission**

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

|                    |
|--------------------|
| (Depositor's name) |
| (Signature)        |
| (Date)             |

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 12/772,810      | 05/03/2010  | Walid N. Aboul-Hosn  | 06-01506US04        | 4661             |

TITLE OF INVENTION: Guidable Intravascular Blood Pump and Related Methods

| APPLN. TYPE    | ENTITY STATUS | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE   |
|----------------|---------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | UNDISCOUNTED  | \$960         | \$0                 | \$0                  | \$960            | 07/07/2014 |

| EXAMINER          | ART UNIT | CLASS-SUBCLASS |
|-------------------|----------|----------------|
| MARCETICH, ADAM M | 3761     | 604-006110     |

|                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).</b><br><input type="checkbox"/> Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.<br><input type="checkbox"/> "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. <b>Use of a Customer Number is required.</b> | <b>2. For printing on the patent front page, list</b><br>(1) The names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____<br>(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____<br>3 _____ |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## **3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)**

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

|                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>4a. The following fee(s) are submitted:</b><br><input type="checkbox"/> Issue Fee<br><input type="checkbox"/> Publication Fee (No small entity discount permitted)<br><input type="checkbox"/> Advance Order - # of Copies _____ | <b>4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)</b><br><input type="checkbox"/> A check is enclosed.<br><input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.<br><input type="checkbox"/> The Director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form). |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## **5. Change in Entity Status (from status indicated above)**

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
- ☐ Applicant asserting small entity status. See 37 CFR 1.27
- ☐ Applicant changing to regular undiscounted fee status.

**NOTE:** Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

**NOTE:** If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

**NOTE:** Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

**NOTE:** This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature \_\_\_\_\_ Date \_\_\_\_\_

Typed or printed name \_\_\_\_\_ Registration No. \_\_\_\_\_



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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 12/772,810      | 05/03/2010  | Walid N. Aboul-Hosn  | 06-01506US04        | 4661             |

99185 7590 04/07/2014  
MAQUET Cardiovascular LLC  
120 Baytech Drive  
San Jose, CA 95134

|          |
|----------|
| EXAMINER |
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MARCETICH, ADAM M

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3761

DATE MAILED: 04/07/2014

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

## OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

### Privacy Act Statement

**The Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.



|                               |                                      |                                          |                                                  |
|-------------------------------|--------------------------------------|------------------------------------------|--------------------------------------------------|
| <b>Notice of Allowability</b> | <b>Application No.</b><br>12/772,810 | <b>Applicant(s)</b><br>ABOUL-HOSN ET AL. |                                                  |
|                               | <b>Examiner</b><br>ADAM MARCETICH    | <b>Art Unit</b><br>3761                  | <b>AIA (First Inventor to File) Status</b><br>No |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 28 March 2014.  
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on \_\_\_\_.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 15,23-27,29,31,33,35-39,41-45 and 48-52. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see [http://www.uspto.gov/patents/init\\_events/pph/index.jsp](http://www.uspto.gov/patents/init_events/pph/index.jsp) or send an inquiry to [PPHfeedback@uspto.gov](mailto:PPHfeedback@uspto.gov).
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

**Certified copies:**

- a) ☐ All    b) ☐ Some    \*c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_.

Applicant has **THREE MONTHS FROM THE "MAILING DATE"** of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.  
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |                                                                                                            |                                                                                      |
|------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 5. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                  |
| 2. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date ____     | 6. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 7. <input type="checkbox"/> Other ____.                                              |
| 4. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date ____.                      |                                                                                      |

/ADAM MARCETICH/  
Primary Examiner, Art Unit 3761

**EXAMINER'S COMMENT / REASONS FOR ALLOWANCE**

***Notice of Pre-AIA or AIA Status***

The present application is being examined under the pre-AIA first to invent provisions.

***Examiner's Comment***

Rejection of claims 30 and 46 under 35 U.S.C. 112 (pre-AIA), first paragraph and rejection of claim 49 under 35 U.S.C. 112 (pre-AIA), second paragraph are withdrawn in view of the amendments filed 29 March 2014.

***Allowable Claims***

Claims 15, 23-27, 29, 31, 33, 35-39, 41-45 and 48-52 are allowed.

***Reasons for Allowance***

Regarding claim 15, Applicant's arguments filed 28 March 2014 regarding Bedingham; William et al. (US 6245007), Nix; Christoph et al. (US 6176822) and Gordon; Lucas S. (US 5938645) have been considered and are persuasive. Examiner advances additional reasons for allowance.

Modifying Bedingham and Nix with Gordon would not provide an operable device since Bedingham requires free space for impeller 56 to rotate. Impeller 56 would be impinged upon by guidewire lumen 46 of Gordon when modified in the proposed manner. Applicant's Fig. 7 shows carriage 124 as longitudinally offset from rotor shroud 36, which allows rotors 44 to spin without interference. In comparison, Bedingham does not provide any location along the length of outer sleeve 32 or inner sleeve 38 to add

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guidewire lumen 46 of Gordon. Adding guidewire lumen 46 of Gordon along any point on inner sleeve 38 of Bedingham would interfere with the rotation of impeller 56.

A combination of Nix in view of Bedingham and Gordon would likewise be inoperable, since Nix does not provide any space to add a first lumen for delivering purge fluid. Nix calls for an electrically powered pump (col. 3, lines 11-19, Fig. 1, electric motor 21 and electric lines 23), and therefore cannot accommodate an additional purge fluid lumen.

Not cited in a previous action, Teirstein; Paul S. (US 5336184) discloses a guide mechanism configured as a second lumen (col. 5, lines 63-66; col. 6, lines 8-22, Fig. 7, guidewire channel 36),

the guide mechanism adapted to guide a distal portion of a catheter (col. 5, lines 35-49, balloon catheter can be advanced partly into the artery);

wherein said guide mechanism extends through a cannula surface (Figs. 6, 7, guidewire channel 36 extends through a portion of catheter body 26); and

wherein the guide mechanism accepts a guide wire (Figs. 6, 7, guidewire 14).

However, Teirstein requires a "Y" shape 22 (col. 4, lines 6-12, Figs. 1, 6), which would interfere with the operation of a strictly linear blood pump as disclosed by Gordon. That is, Teirstein does not provide a guide mechanism suitable for an intravascular blood pump.

Regarding claims 29 and 49, Applicant's arguments filed 28 March 2014 regarding Bedingham, Nix and Masch; Helmut (US 4728319) have been considered and are persuasive. Examiner agrees that a skilled artisan would not have been motivated to modify Bedingham with the concentric lumen of Masch. Bedingham calls for a close-ended distal member 42 and tip portion 46 (Fig. 7). Masch provides no teaching for how to modify drive cable 30, impeller 56, vane portion and distal member 42 in order to pass a guidewire. Motivation is lacking to modify Bedingham with the concentric guide mechanism of Masch since Bedingham already solves the problem of guiding the catheter by passing a guidewire through the pump housing (col. 9, lines 35-43).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Tel 571-272-2590  
Fax 571-273-2590  
Email [Adam.Marcetich@uspto.gov](mailto:Adam.Marcetich@uspto.gov)

The Examiner can be reached 8:00am to 4:00pm Monday through Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/  
Primary Examiner, Art Unit 3761

|                                   |                                       |                                                                 |             |
|-----------------------------------|---------------------------------------|-----------------------------------------------------------------|-------------|
| <b>Notice of References Cited</b> | Application/Control No.<br>12/772,810 | Applicant(s)/Patent Under<br>Reexamination<br>ABOUL-HOSN ET AL. |             |
|                                   | Examiner<br>ADAM MARCETICH            | Art Unit<br>3761                                                | Page 1 of 1 |

**U.S. PATENT DOCUMENTS**

| * |   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Name               | Classification |
|---|---|--------------------------------------------------|-----------------|--------------------|----------------|
| * | A | US-5,336,184 A                                   | 08-1994         | Teirstein, Paul S. | 604/103.04     |
|   | B | US-                                              |                 |                    |                |
|   | C | US-                                              |                 |                    |                |
|   | D | US-                                              |                 |                    |                |
|   | E | US-                                              |                 |                    |                |
|   | F | US-                                              |                 |                    |                |
|   | G | US-                                              |                 |                    |                |
|   | H | US-                                              |                 |                    |                |
|   | I | US-                                              |                 |                    |                |
|   | J | US-                                              |                 |                    |                |
|   | K | US-                                              |                 |                    |                |
|   | L | US-                                              |                 |                    |                |
|   | M | US-                                              |                 |                    |                |

**FOREIGN PATENT DOCUMENTS**

| * |   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Country | Name | Classification |
|---|---|--------------------------------------------------|-----------------|---------|------|----------------|
|   | N |                                                  |                 |         |      |                |
|   | O |                                                  |                 |         |      |                |
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|   | R |                                                  |                 |         |      |                |
|   | S |                                                  |                 |         |      |                |
|   | T |                                                  |                 |         |      |                |

**NON-PATENT DOCUMENTS**

| * |   | Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) |
|---|---|-------------------------------------------------------------------------------------------|
|   | U |                                                                                           |
|   | V |                                                                                           |
|   | W |                                                                                           |
|   | X |                                                                                           |

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

|                                                                                                                 |                                            |                                                                     |  |
|-----------------------------------------------------------------------------------------------------------------|--------------------------------------------|---------------------------------------------------------------------|--|
| <b>Issue Classification</b><br> | <b>Application/Control No.</b><br>12772810 | <b>Applicant(s)/Patent Under Reexamination</b><br>ABOUL-HOSN ET AL. |  |
|                                                                                                                 | <b>Examiner</b><br>ADAM MARCETICH          | <b>Art Unit</b><br>3761                                             |  |

| CPC    |  |      |   |      |      |          |
|--------|--|------|---|------|------|----------|
| Symbol |  |      |   |      | Type | Version  |
| A61M   |  | 1    | / | 12   | F    | 20130101 |
| A61M   |  | 1    | / | 10   | I    | 20130101 |
| A61M   |  | 1    | / | 101  | I    | 20130101 |
| A61M   |  | 25   | / | 0015 | I    | 20130101 |
| A61M   |  | 25   | / | 0052 | I    | 20130101 |
| A61M   |  | 25   | / | 0169 | I    | 20130101 |
| A61M   |  | 25   | / | 0172 | I    | 20130101 |
| A61M   |  | 2039 | / | 0235 | A    | 20130101 |
| Y10S   |  | 415  | / | 90   | A    | 20130101 |
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|----------------------------------------------------|------------|------------------------------|-------------------|
| NONE                                               |            | <b>Total Claims Allowed:</b> |                   |
|                                                    |            | 24                           |                   |
| (Assistant Examiner)                               | (Date)     |                              |                   |
| /ADAM MARCETICH/<br>Primary Examiner.Art Unit 3761 | 04/01/2014 | O.G. Print Claim(s)          | O.G. Print Figure |
| (Primary Examiner)                                 | (Date)     | 1                            | 6                 |





|                                                                                                                 |                                            |                                                                     |
|-----------------------------------------------------------------------------------------------------------------|--------------------------------------------|---------------------------------------------------------------------|
| <b>Issue Classification</b><br> | <b>Application/Control No.</b><br>12772810 | <b>Applicant(s)/Patent Under Reexamination</b><br>ABOUL-HOSN ET AL. |
|                                                                                                                 | <b>Examiner</b><br>ADAM MARCETICH          | <b>Art Unit</b><br>3761                                             |

| <input type="checkbox"/> Claims renumbered in the same order as presented by applicant |          |       |          |       |          |       |          |       |          |       |          |       |          |       |          |
|----------------------------------------------------------------------------------------|----------|-------|----------|-------|----------|-------|----------|-------|----------|-------|----------|-------|----------|-------|----------|
| <input type="checkbox"/> CPA                                                           |          |       |          |       |          |       |          |       |          |       |          |       |          |       |          |
| <input type="checkbox"/> T.D.                                                          |          |       |          |       |          |       |          |       |          |       |          |       |          |       |          |
| <input type="checkbox"/> R.1.47                                                        |          |       |          |       |          |       |          |       |          |       |          |       |          |       |          |
| Final                                                                                  | Original | Final | Original | Final | Original | Final | Original | Final | Original | Final | Original | Final | Original | Final | Original |
|                                                                                        | 1        |       | 17       | 12    | 33       | 8     | 49       |       |          |       |          |       |          |       |          |
|                                                                                        | 2        |       | 18       |       | 34       | 9     | 50       |       |          |       |          |       |          |       |          |
|                                                                                        | 3        |       | 19       | 13    | 35       | 21    | 51       |       |          |       |          |       |          |       |          |
|                                                                                        | 4        |       | 20       | 14    | 36       | 24    | 52       |       |          |       |          |       |          |       |          |
|                                                                                        | 5        |       | 21       | 15    | 37       |       |          |       |          |       |          |       |          |       |          |
|                                                                                        | 6        |       | 22       | 16    | 38       |       |          |       |          |       |          |       |          |       |          |
|                                                                                        | 7        | 2     | 23       | 17    | 39       |       |          |       |          |       |          |       |          |       |          |
|                                                                                        | 8        | 3     | 24       |       | 40       |       |          |       |          |       |          |       |          |       |          |
|                                                                                        | 9        | 4     | 25       | 18    | 41       |       |          |       |          |       |          |       |          |       |          |
|                                                                                        | 10       | 5     | 26       | 19    | 42       |       |          |       |          |       |          |       |          |       |          |
|                                                                                        | 11       | 6     | 27       | 7     | 43       |       |          |       |          |       |          |       |          |       |          |
|                                                                                        | 12       |       | 28       | 20    | 44       |       |          |       |          |       |          |       |          |       |          |
|                                                                                        | 13       | 10    | 29       | 22    | 45       |       |          |       |          |       |          |       |          |       |          |
|                                                                                        | 14       |       | 30       |       | 46       |       |          |       |          |       |          |       |          |       |          |
| 1                                                                                      | 15       | 11    | 31       |       | 47       |       |          |       |          |       |          |       |          |       |          |
|                                                                                        | 16       |       | 32       | 23    | 48       |       |          |       |          |       |          |       |          |       |          |

|                                                    |            |                              |                   |
|----------------------------------------------------|------------|------------------------------|-------------------|
| NONE                                               |            | <b>Total Claims Allowed:</b> |                   |
| (Assistant Examiner)                               | (Date)     | 24                           |                   |
| /ADAM MARCETICH/<br>Primary Examiner.Art Unit 3761 | 04/01/2014 | O.G. Print Claim(s)          | O.G. Print Figure |
| (Primary Examiner)                                 | (Date)     | 1                            | 6                 |

## AMENDMENTS TO THE CLAIMS

Claims 1 – 14 (Cancelled)

15. (Previously Presented) An intravascular blood pump system,  
comprising:

an intravascular blood pump comprising:

a rotor having a rotor hub tapering in the distal direction, at least one blade extending radially outward from the rotor hub, the hub has a distal end extending distally beyond the most distal portion of the blade and

a shroud within which the rotor is rotatably disposed;

a cannula extending from the shroud and comprising an outer cannula surface, the outer cannula surface having a substantially circular cross-section along a portion of its length;

a first lumen in fluid communication with the intravascular blood pump and operatively arranged to deliver purge fluid to the intravascular blood pump; and

a guide mechanism configured as a second lumen having a proximal end and a distal end, the guide mechanism adapted to guide a distal portion of said intravascular blood pump system to a predetermined location within the circulatory system of a patient;

wherein an axis coaxial with and extending through a portion of said guide mechanism extends through a region delimited by the outer cannula surface, and wherein the guide mechanism is configured to allow for a guide wire to slideably advance therealong.

16 – 22 (Cancelled)

23. (Previously Presented) The intravascular blood pump system of claim



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## BIB DATA SHEET

CONFIRMATION NO. 4661

| SERIAL NUMBER                                                                                                                                                                                                                                                                 | FILING or 371(c)<br>DATE                                                                                          | CLASS                             | GROUP ART UNIT                                                                                                                                                                                                                                                            | ATTORNEY DOCKET<br>NO.                      |                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|-----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|-------------------------------------------------|
| 12/772,810                                                                                                                                                                                                                                                                    | 05/03/2010                                                                                                        | 604                               | 3761                                                                                                                                                                                                                                                                      | 06-01506US04                                |                                                 |
| <b>APPLICANTS</b><br><b>INVENTORS</b><br>Walid N. Aboul-Hosn, Fair Oaks, CA;<br>William R. Kanz, Sacramento, CA;<br>Bruce A. Baker, Placerville, CA;                                                                                                                          |                                                                                                                   |                                   |                                                                                                                                                                                                                                                                           |                                             |                                                 |
| <b>** CONTINUING DATA *****</b><br>This application is a CON of 11/375,926 03/15/2006 PAT 7731675<br>which is a DIV of 10/070,178 07/19/2002 PAT 7022100<br>which is a 371 of PCT/US00/24515 09/01/2000<br>which claims benefit of 60/152,249 09/03/1999                      |                                                                                                                   |                                   |                                                                                                                                                                                                                                                                           |                                             |                                                 |
| <b>** FOREIGN APPLICATIONS *****</b>                                                                                                                                                                                                                                          |                                                                                                                   |                                   |                                                                                                                                                                                                                                                                           |                                             |                                                 |
| <b>** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **</b><br>05/11/2010                                                                                                                                                                                                        |                                                                                                                   |                                   |                                                                                                                                                                                                                                                                           |                                             |                                                 |
| Foreign Priority claimed <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No<br>35 USC 119(a-d) conditions met <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No<br>Verified and /ADAM M<br>MARCETICH/<br>Acknowledged Examiner's Signature | <input type="checkbox"/> Met after Allowance<br>Initials                                                          | <b>STATE OR<br/>COUNTRY</b><br>CA | <b>SHEETS<br/>DRAWINGS</b><br>18                                                                                                                                                                                                                                          | <b>TOTAL<br/>CLAIMS</b><br><del>24</del> 24 | <b>INDEPENDENT<br/>CLAIMS</b><br><del>3</del> 3 |
| <b>ADDRESS</b><br>MAQUET Cardiovascular LLC<br>120 Baytech Drive<br>San Jose, CA 95134<br>UNITED STATES                                                                                                                                                                       |                                                                                                                   |                                   | total claims: 24<br>independent: 3<br>updated 01 Apr 2014<br>/AMM/                                                                                                                                                                                                        |                                             |                                                 |
| <b>TITLE</b><br>Guidable Intravascular Blood Pump and Related Methods                                                                                                                                                                                                         |                                                                                                                   |                                   |                                                                                                                                                                                                                                                                           |                                             |                                                 |
| <b>FILING FEE<br/>RECEIVED</b><br>1390                                                                                                                                                                                                                                        | FEES: Authority has been given in Paper<br>No. _____ to charge/credit DEPOSIT ACCOUNT<br>No. _____ for following: |                                   | <input type="checkbox"/> All Fees<br><input type="checkbox"/> 1.16 Fees (Filing)<br><input type="checkbox"/> 1.17 Fees (Processing Ext. of time)<br><input type="checkbox"/> 1.18 Fees (Issue)<br><input type="checkbox"/> Other _____<br><input type="checkbox"/> Credit |                                             |                                                 |

EAST Search History

EAST Search History (Prior Art)

| Ref # | Hits | Search Query                                                                                                                                                                                                     | DBs                                                              | Default Operator | Plurals | Time Stamp          |
|-------|------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|------------------|---------|---------------------|
| L1    | 4    | "5211546".pn.                                                                                                                                                                                                    | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2014/04/01<br>10:15 |
| S204  | 8    | S203 not (S188 S195 S197 S199)                                                                                                                                                                                   | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2014/04/01<br>08:52 |
| S203  | 201  | (S202) and (wire guidewire track\$3 lumen outrigger\$1 hole channel channeling path pathway) with (central\$2 concentric concentrically centered centre centred inner interior inside core nested nesting main ) | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2014/04/01<br>08:51 |
| S202  | 1258 | S201 and pump\$3                                                                                                                                                                                                 | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2014/04/01<br>08:51 |
| S201  | 1589 | (A61M1/101 A61M1/125 A61M1/1034 A61M1/102 Y10S415/90 ).cpc. and @ad<"20000901"                                                                                                                                   | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2014/04/01<br>08:51 |
| S200  | 162  | S199 and pump\$3                                                                                                                                                                                                 | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2014/04/01<br>08:47 |
| S199  | 307  | S198 not (S188 S195 S197)                                                                                                                                                                                        | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2014/04/01<br>08:46 |
| S198  | 572  | (S184 S185) and (wire guidewire track\$3 lumen outrigger\$1 hole channel channeling path pathway) with (inner interior inside core nested nesting main )                                                         | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR               | ON      | 2014/04/01<br>08:46 |
| S197  | 170  | S196 not (S188 S195)                                                                                                                                                                                             | US-PGPUB;<br>USPAT;                                              | OR               | ON      | 2014/04/01<br>08:28 |

|      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                  |    |     |                     |
|------|------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|----|-----|---------------------|
|      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB                        |    |     |                     |
| S196 | 268  | (S184 S185) and (wire guidewire track\$3 lumen outrigger\$1 hole channel channeling path pathway) with (central\$2 concentric concentrically centered centre centred )                                                                                                                                                                                                                                                                                                                                                               | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2014/04/01<br>08:28 |
| S195 | 239  | S194 not S188                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2014/04/01<br>08:09 |
| S194 | 300  | S193 and (wire guidewire track\$3 lumen outrigger\$1 hole channel channeling path pathway) with (side\$1 peripheral\$2 edge\$1 perimeter border )                                                                                                                                                                                                                                                                                                                                                                                    | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2014/04/01<br>08:09 |
| S193 | 1619 | (A61M2025/0183 ).cpc. and @ad<"20000901"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2014/04/01<br>08:09 |
| S192 | 33   | S191 and @ad<"20000901"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2014/04/01<br>07:17 |
| S191 | 93   | ("4771777"   "4819751"   "4909781"   "4944745"   "5061273"   "5135535"   "5147377"   "5154725"   "5156594"   "5171222"   "5180367"   "5205822"   "5232445").PN. OR ("5336184").URPN.                                                                                                                                                                                                                                                                                                                                                 | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR | OFF | 2014/04/01<br>07:16 |
| S190 | 45   | S189 and @ad<"20000901"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON  | 2014/04/01<br>07:13 |
| S189 | 171  | ("4306562"   "4748982"   "4820349"   "4932413"   "4944740"   "4947864"   "4976689"   "4988356"   "5234407"   "5255690"   "5263932"   "5267958"   "5318527"   "5334147"   "5336184"   "5342297"   "5364376"   "5387226"   "5395335"   "5425709"   "5454785"   "5468225"   "5549551"   "5554118"   "5571086"   "5571094"   "5630427"   "5634901"   "5645533"   "5658262"   "5667521"   "5690120"   "5690613"   "5728067"   "5779673"   "5833644"   "5849016"   "5873880"   "5947925"   "5980486"   "6022336").PN. OR ("6159195").URPN. | US-PGPUB;<br>USPAT;<br>USOCR                                     | OR | OFF | 2014/04/01<br>07:13 |
| S188 | 169  | S186 and (wire guidewire track\$3 lumen                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | US-PGPUB;                                                        | OR | ON  | 2014/04/01          |

|      |      |                                                                                                                                                                                                                                            |                                                                  |    |    |                     |
|------|------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|----|----|---------------------|
|      |      | outrigger\$1 hole channel channeling path<br>pathway) with (side\$1 peripheral\$2<br>edge\$1 perimeter border )                                                                                                                            | USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB              |    |    | 07:08               |
| S187 | 156  | S186 and (wire guidewire track\$3 lumen<br>outrigger\$1) with (side\$1 peripheral\$2<br>edge\$1 perimeter border )                                                                                                                         | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2014/04/01<br>07:08 |
| S186 | 411  | S185 and (wire guidewire track\$3 lumen<br>outrigger\$1) with (plac\$3 placement<br>placment locat\$3 deliver\$3 send sending<br>sent establish\$3 fix thread\$3 steer\$3<br>steer?Ble guid\$3 guid?ble)                                   | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2014/04/01<br>06:17 |
| S185 | 1204 | (A61M25/0015 A61M25/0052<br>A61M25/0169 A61M25/0172<br>A61M2025/0079 A61M2039/0235 ).cpc.<br>and @ad<"20000901"                                                                                                                            | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2014/04/01<br>06:17 |
| S184 | 2514 | (A61M/1/10 A61M/1/12 A61M/1/101<br>A61M/2001/10 A61M/2001/12<br>A61M/2001/122 A61M/2001/125 ).cpc.<br>and @ad<"20000901"                                                                                                                   | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2014/04/01<br>06:13 |
| S183 | 222  | S182 not S177                                                                                                                                                                                                                              | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2014/03/31<br>17:03 |
| S182 | 309  | S170 and (wire guidewire track\$3 lumen<br>outrigger\$1 channel tube hole path<br>pathway) with (plac\$3 placement<br>placment locat\$3 deliver\$3 send sending<br>sent establish\$3 fix thread\$3 steer\$3<br>steer?Ble guid\$3 guid?ble) | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2014/03/31<br>17:03 |
| S181 | 127  | S170 and (wire guidewire track\$3 lumen<br>outrigger\$1) with (plac\$3 placement<br>placment locat\$3 deliver\$3 send sending<br>sent establish\$3 fix thread\$3 steer\$3<br>steer?Ble guid\$3 guid?ble)                                   | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2014/03/31<br>17:02 |
| S177 | 87   | S174 and (wire guidewire track\$3 lumen<br>outrigger\$1) with (plac\$3 placement<br>placment locat\$3 deliver\$3 send sending<br>sent establish\$3 fix thread\$3 steer\$3<br>steer?Ble guid\$3 guid?ble)                                   | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2014/03/31<br>16:51 |
| S174 | 524  | S172 and (rotor rotors rotat\$3 spin\$1<br>spun spinning turn\$3 blade\$1 fin\$1 finned<br>propeller\$1 )                                                                                                                                  | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2014/03/31<br>16:49 |
| S172 | 847  | S170 and pump\$3 same (heart\$2 cardiac                                                                                                                                                                                                    | US-PGPUB;                                                        | OR | ON | 2014/03/31          |

|      |      |                                                                                                                   |                                                                  |    |    |                     |
|------|------|-------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|----|----|---------------------|
|      |      | cardio cardiovascular myocardium<br>myocardial vascular endoscope<br>endoscopic)                                  | USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB              |    |    | 16:49               |
| S170 | 2514 | (A61M1/10 A61M1/12 A61M1/101<br>A61M2001/10 A61M2001/12<br>A61M2001/122 A61M2001/125 ).cpc. and<br>@ad<"20000901" | US-PGPUB;<br>USPAT;<br>FPRS;<br>EPO; JPO;<br>DERWENT;<br>IBM_TDB | OR | ON | 2014/03/31<br>16:48 |

EAST Search History (I nterference)

| Ref # | Hits | Search Query                                                                                                                                                                                                      | DBs                   | Default Operator | Plurals | Time Stamp          |
|-------|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|------------------|---------|---------------------|
| L2    | 6    | (A61M1/10 A61M1/12 A61M1/101<br>A61M2001/10 A61M2001/12 A61M2001/122<br>A61M2001/125 A61M2001/1034 A61M25/0015<br>A61M25/0052 A61M25/0169 A61M25/0172<br>A61M2025/0079 A61M2039/0235 ).cpc. and<br>@ad<"20000901" | US-<br>PGPUB;<br>UPAD | OR               | OFF     | 2014/04/01<br>10:26 |

4/ 1/ 2014 10:56:47 AM  
H:\ EAST searches\ workspaces\ 12772810 rce.wsp

|                                                                                                              |                                                |                                                                         |
|--------------------------------------------------------------------------------------------------------------|------------------------------------------------|-------------------------------------------------------------------------|
| <b>Search Notes</b><br><br> | <b>Application/Control No.</b><br><br>12772810 | <b>Applicant(s)/Patent Under Reexamination</b><br><br>ABOUL-HOSN ET AL. |
|                                                                                                              | <b>Examiner</b><br><br>ADAM MARCETICH          | <b>Art Unit</b><br><br>3761                                             |

| CPC- SEARCHED                                                                                      |            |          |
|----------------------------------------------------------------------------------------------------|------------|----------|
| Symbol                                                                                             | Date       | Examiner |
| A61M1/10; A61M1/12; A61M1/101; A61M2001/10; A61M2001/12; A61M2001/122; A61M2001/125                | 11/19/2013 | AMM      |
| A61M1/10; A61M1/12; A61M1/101; A61M2001/10; A61M2001/12; A61M2001/122; A61M2001/125; A61M2001/1034 | 04/01/2014 | AMM      |
| A61M25/0015; A61M25/0052; A61M25/0169; A61M25/0172; A61M2025/0079; A61M2039/0235                   | 04/01/2014 | AMM      |

| CPC COMBINATION SETS - SEARCHED |      |          |
|---------------------------------|------|----------|
| Symbol                          | Date | Examiner |
|                                 |      |          |

| US CLASSIFICATION SEARCHED |                |            |          |
|----------------------------|----------------|------------|----------|
| Class                      | Subclass       | Date       | Examiner |
| 604                        | 43,156,158,540 | 2/3/2012   | AMM      |
| 623                        | 3.1            | 2/3/2012   | AMM      |
| 600                        | 16             | 2/3/2012   | AMM      |
|                            | search update  | 8/17/2012  | AMM      |
|                            | search update  | 05/02/2013 | AMM      |
|                            | search update  | 11/19/2013 | AMM      |
|                            | search update  | 04/01/2014 | AMM      |

| SEARCH NOTES                                                                              |            |          |
|-------------------------------------------------------------------------------------------|------------|----------|
| Search Notes                                                                              | Date       | Examiner |
| Inventor search: PALM and EAST (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT, IBM_TDB) | 2/3/2012   | AMM      |
| Review PLUS search results returned Friday, 3 February 2012                               | 2/3/2012   | AMM      |
| Review cited art for related cases 11/375926, 10/070178                                   | 2/3/2012   | AMM      |
| Review ISR for PCT/US00/24515 performed 19 March 2001, Angie Sykes USPTO                  | 2/3/2012   | AMM      |
| search update                                                                             | 8/17/2012  | AMM      |
| search update                                                                             | 05/02/2013 | AMM      |

|  |                                                    |
|--|----------------------------------------------------|
|  | /ADAM MARCETICH/<br>Primary Examiner.Art Unit 3761 |
|--|----------------------------------------------------|



## SEARCH NOTES

| Search Notes  | Date       | Examiner |
|---------------|------------|----------|
| search update | 11/19/2013 | AMM      |
| search update | 04/01/2014 | AMM      |

## INTERFERENCE SEARCH

| US Class/<br>CPC Symbol | US Subclass / CPC Group                                                                                  | Date       | Examiner |
|-------------------------|----------------------------------------------------------------------------------------------------------|------------|----------|
|                         | A61M1/10; A61M1/12; A61M1/101; A61M2001/10;<br>A61M2001/12; A61M2001/122; A61M2001/125;<br>A61M2001/1034 | 04/01/2014 | AMM      |
|                         | A61M25/0015; A61M25/0052; A61M25/0169;<br>A61M25/0172; A61M2025/0079; A61M2039/0235                      | 04/01/2014 | AMM      |

/ADAM MARCETICH/  
Primary Examiner.Art Unit 3761

## REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL (Submitted Only via EFS-Web)

|                      |                     |             |            |                               |                   |          |      |
|----------------------|---------------------|-------------|------------|-------------------------------|-------------------|----------|------|
| Application Number   | 12/772,810          | Filing Date | 2010-05-03 | Docket Number (if applicable) | 06-01506US04      | Art Unit | 3761 |
| First Named Inventor | Walid N. ABOUL-HOSN |             |            | Examiner Name                 | Adam M. Marcetich |          |      |

**This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.**

Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

### SUBMISSION REQUIRED UNDER 37 CFR 1.114

**Note:** If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on \_\_\_\_\_

☐ Other \_\_\_\_\_

☒ Enclosed

☐ Amendment/Reply

☒ Information Disclosure Statement (IDS)

☐ Affidavit(s)/ Declaration(s)

☐ Other \_\_\_\_\_

### MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months \_\_\_\_\_  
(Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other \_\_\_\_\_

### FEES

**The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**

☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to  
Deposit Account No 400170

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

| Signature of Registered U.S. Patent Practitioner |                     |                     |            |
|--------------------------------------------------|---------------------|---------------------|------------|
| Signature                                        | /Kurt R. Denniston/ | Date (YYYY-MM-DD)   | 2014-07-07 |
| Name                                             | Kurt R. Denniston   | Registration Number | 59605      |

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

## Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re the Application of:

Aboul-Hosn et al.

Serial No.: 12/772,810

Filing Date: 05-03-2010

For:

Guidable Intravascular Blood  
Pump and Related Methods

Confirmation No.: 4661

Group Art Unit: 3761

Examiner: MARCETICH,  
ADAM M

**INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

Sir:

Pursuant to 37 CFR § 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached Information Disclosure Statement (IDS) form (i.e., form PTO-1449, form PTO/SB/08, or modified variations thereof) . Unless otherwise indicated herein, one copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

The filing of this Information Disclosure Statement and the enclosed IDS form(s), shall not be construed as an admission that the information cited is prior art, or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b).

Applicants have listed the publication date on the attached IDS form(s) based on information presently available to the undersigned. However, the listed publication date should not be construed as an admission that the information was actually published on the date indicated. Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This submission is not a representation that a search has been made. The paragraphs marked below are applicable. It is believed that no fees other than those indicated below are due, but authorization is hereby given to charge any additional fees due, or to credit any overpayment, to deposit account **04-0170**, reference number **06-01506US04**.

1. ☒ This Information Disclosure Statement is being filed before the mailing of a first office action after filing of a request for continued examination. No certification or fee is required.

2. ☐ The reference(s) was/were cited in a counterpart foreign application. An English language version of the foreign search report is attached for the Examiner's information.
3. ☐ A concise explanation of the relevance of the non-English language reference(s) appears in the Appendix attached hereto.
4. ☐ The Examiner's attention is directed to co-pending U.S. Patent Application No. \_\_\_\_\_ filed, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination of the present application.
5. ☐ This application is one of a series of related applications, identified in the attached Appendix, which are directed to related technical subject matter. The identification of those U.S. Patent Applications is not to be construed as a waiver of secrecy as to those applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during the examination.
6. ☐ The reference(s) was/were cited by or submitted to the Office in parent application No. \_\_\_\_\_ filed \_\_\_\_\_ which is relied upon for an earlier filing date under 35 U.S.C. §120. Thus, copies of these references are not attached. 37 CFR §1.98(d).
7. ☒ Documents Not in English
  - a. ☒ A machine translation of document(s) C2, C3, C4, C5, and C6 are included, as translated by the European Patent Office's "Patent Translate" website feature. Applicant does not attest to the accuracy of the machine translation.
8. ☒ Since this application was filed after June 30, 2003, in accordance with 37 CFR § 1.98(a)(2)(ii), Applicant has not submitted copies of copies of U.S. patent and patent application references.
9. ☐ This application claims the benefit of priority to U.S. serial number \_\_\_\_\_, filed on \_\_\_\_\_. Pursuant to § 1.98(d), a copy of item(s) \_\_\_\_\_ is not provided for in this IDS since the document(s) and information were already provided to the USPTO, in an IDS of the priority application in a manner that complies with § 1.98(a) through (c).

10. ☒ Item(s) C1 claims priority to item C4. An English translation of C1 is not provided in this IDS as it is believed to be cumulative to the translation provided for C4.
11. ☐ Copies of item(s) are not attached, and relate to applications on file with the USPTO, including for instance file wrappers, office actions, notices of allowance, amendments, pending claims, application parts, etc. Applicants trust that the Examiner has ready access to the relate documents listed on the attached IDS form.
12. ☐ Other

It is respectfully requested that the Examiner indicate consideration of the cited references by returning a copy of the attached IDS form (i.e., PTO/SB/08, PTO-1449 or equivalents thereof) with initials or other appropriate marks. In the unlikely event that the transmittal letter is separated from this document and the U.S. Patent Office determines that an extension and/or other relief is required, Applicant(s) petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Account No. 40-0170, reference number 06-01506US04. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

DATE: July 7, 2014

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| <b>Sheet 1 of 1</b>                                                                                                                     |                          |                     |

| FOREIGN PATENT DOCUMENTS |                          |                                      |                           |                        |                  |                                                 |                                                                          |                |
|--------------------------|--------------------------|--------------------------------------|---------------------------|------------------------|------------------|-------------------------------------------------|--------------------------------------------------------------------------|----------------|
| Examiner Initial*        | Cite No. (C1, C2, ...Cn) | Foreign Document Number <sup>3</sup> | Country Code <sup>2</sup> | Kind Code <sup>4</sup> | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear | T <sup>5</sup> |
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| <b>Examiner Signature</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |  | <b>Date Considered</b> |  |
| <b>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</b>                                                                                                                                                                                                                                                                                                                                  |  |                        |  |
| <sup>1</sup> See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached. |  |                        |  |



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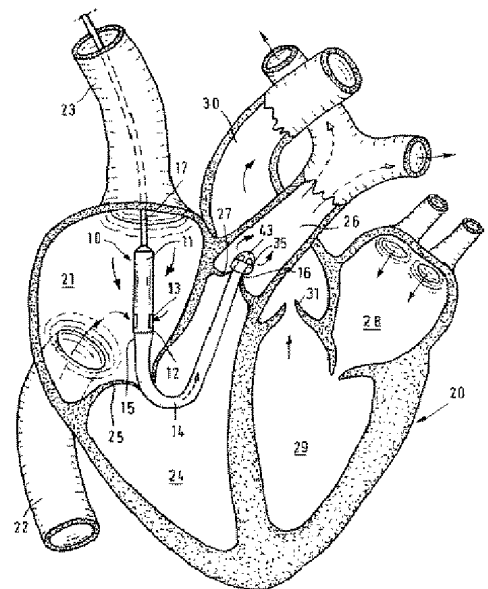
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最終頁に続く

(54) 【発明の名称】 心臓内血液ポンプ

## (57) 【要約】

心臓内血液ポンプ(10)は駆動部(11)およびポンプ部(12)を含んで成る。可撓性ポンプホース(14)はポンプ部(12)に連結される。ポンプホース(14)を右心房(21)から肺動脈(26)へ設置するために、ポンプホース(14)の末梢端はバルーン(35)を含んで成り、これは血液流内で案内エレメントとして作動し、また生来の血液流によって一緒に運ばれるものである。このことが心臓内に血液ポンプを位置づけるのを容易にする。



【特許請求の範囲】

【請求項1】 ポンプホース（14）が、その末梢端に隣接して、血液流によって一緒に運ばれることができた案内エレメントとして作動可能であるバルーン（35）を含んで構成されることを特徴とする、カテーテル（17）に連結される半径方向取り入れおよび軸方向送り出しポンプ部（11）と、ポンプ出口に連結されるポンプホース（14）であって、ポンプ出口に隣接する基部端（15）およびホース出口を形成する末梢端（16）を有するものを含んで成る心臓内血液ポンプ。

【請求項2】 ポンプホースが100°を超えて、好ましくは約150°予め屈曲されることを特徴とする請求項1記載の血液ポンプ。

【請求項3】 ポンプホース（14）が基部端（15）から末梢端（16）へ減少する曲げ剛性を示すことを特徴とする請求項1または2記載の血液ポンプ。

【請求項4】 ポンプホース（14）が、その内側またはその外側でポンプホースの末梢端（16）を超えて突出するカテーテル（46, 48）と、その末梢端を超えるバルーン（35a）とを含んで成ることを特徴とする請求項1-3のいずれかに記載の血液ポンプ。

【請求項5】 環状バルーンとして構成されたバルーン（35）がポンプホース（14）を取り囲むことを特徴とする請求項1-3のいずれかに記載の血液ポンプ。

【請求項6】 環状バルーンが丸くしたホース先端（40）を形成することを特徴とする請求項5記載の血液ポンプ。

【請求項7】 ポンプホース（14b）が圧潰可能ホースであることを特徴とする請求項1-6のいずれかに記載の血液ポンプ。

【請求項8】 ポンプホース（14a）が弾力性支持構造体（45）を含むことを特徴とする請求項1-7のいずれかに記載の血液ポンプ。

【請求項9】 ポンプホース（14b）がカテーテル（48）を含んで成ること、およびカテーテル（48）内に挿入可能である案内ワイヤー（51）を設けることを特徴とする請求項1-8のいずれかに記載の血液ポンプ。

【請求項１０】 カテーテル（４８）が、案内ワイヤー（５１）用の管腔（５０）と、圧力管腔（４９）とを含んで成ることを特徴とする請求項１－９のいずれかに記載の血液ポンプ。

【請求項１１】 カテーテル（４８）が、圧力測定管腔として使用出来る管腔（５０）を含んで成ることを特徴とする請求項１－１０のいずれかに記載の血液ポンプ。

【請求項１２】 膨張状態におけるバルーンの直径が３０mmを超えないことを特徴とする請求項１－１１のいずれかに記載の血液ポンプ。

【請求項１３】 ポンプホース（１４）の末梢端（１６）において、牽引エレメント（４３）が固定され、それに対しポンプ処理された流れが指向されることを特徴とする、カテーテル（１７）に連結される半径方向取り入れおよび軸方向送り出しポンプ部（１１）と、ポンプ出口に連結される可撓性ポンプホース（１４）であって、ポンプ出口に隣接する基部端（１５）およびホース出口を形成する末梢端（１６）を有するものを含んで成る心臓内血液ポンプ。

【発明の詳細な説明】

【0001】

本発明は心臓内血液ポンプに関し、特に隣接する容器を介して心臓内に完全に挿入して心臓の自然なポンプ機能をサポートするか、あるいはそれを継続的なポンプ作用によって置き換えることの出来る血液ポンプに関する。

【0002】

心臓機能をサポートするためのポンプ装置はW094/09835(Jarvik)中に記載されている。前記ポンプ装置は、互いに独立して作動するポンプ部と、そのポンプ装置に強固に連結された駆動部とを含んで構成される。その1基のポンプのポンプ部は根尖切除手術開口部を経由して、それが左心室から大動脈内に届くように左心室内に挿入される。他方のポンプ部は別の好ましくは根尖切除手術開口部を介して右心室に挿入されるので、それは右心房から肺動脈内に届く。それぞれのポンプはホース型出口カニューレであって、各心臓弁を介して案内可能であるものによって、そのポンプ出口において伸展されている。

【0003】

心臓内血液ポンプであって、大動脈から大動脈弁を経由して左心室に挿入されるものはW097/37696(Rau et al)により知られている。ここでは、そのポンプ入口は大動脈弁を通過するホースによって伸展されている。

【0004】

W097/37697(Rau et al)により、脈管内血液ポンプが知られており、これは血管を介して移動可能である。この血液ポンプもまた、その出口端において取り入れホースによって伸展されている。前記取り入れホースは膨張可能バルーンであって、単離装置および取り入れホースの外側に沿って横方向に血液が流れるのを阻止するために機能するものを含んで構成される。

【0005】

最後に、米国特許第4 753 221号(Kensey et al.)は心臓内に配置すべきポンプを有するポンプカテーテルを記載している。前記ポンプはインペラーおよび前記インペラーを取り囲むポンプケーシングを含んで構成される。ポンプケーシングが潰れた状態になると、それを心臓内に配置することが可能であり、そして引き

続きそのポンプケーシングに連結されたバルーンを膨張させることにより展開することが出来る。

【0006】

更に、圧力用および容積流量測定用の小管腔が知られており、これらは診断目的のために機能し、そして末梢カテーテル端部において膨張可能なバルーンを含んで構成される。前記バルーンはカテーテル先端を肺動脈内に位置決めするために使用される。

【0007】

血管を介して心臓内に挿入される心臓内血液ポンプはその心臓中に正確に配置することが困難である。特に、血液ポンプが上部大静脈を経由して挿入され、右心房から肺動脈へ血液をポンプ送りする際には、血液ポンプの正確な配置は困難である。それは取り入れ開口部が右心房内に位置決めされ、また出口開口部が肺動脈内に位置決めされることを保証するために、そのポンプは略180°の湾曲を遂行せねばならないからである。更に、おびたしい繊維および腱が右心室内に存在し、これは三尖弁を保持し、膨隆に十分に抗して弁の小葉を保護し、そして心臓の固有の安定性を保証するものである。大静脈を介して挿入された血液ポンプはこの種の繊維および腱の間で案内されねばならない。

【0008】

本発明の目的は、心臓内に比較的容易に位置づけることが出来る心臓内血液ポンプを提供することである。

【0009】

本発明によれば、この目的は請求項1記載の手段によって解決される。

【0010】

本発明による血液ポンプのポンプ出口には可撓性ホースが取り付けられており、このホースの末梢端は血液流中で案内エレメントとして作用するバルーンを含んで構成される。本発明は、もともと血液が大静脈から右心房へ、そして右心室を経由して肺動脈内へと心臓中を流れるという事実を利用している。そのホースの末梢端にバルーンを含んで成る血液ポンプはこの通路に沿って挿入され、血液流内を浮遊するバルーンは、右心房から肺動脈内への道を自動的に見出す。この

ホースの出口はその後肺動脈内で安定するのに対し、ポンプ部は右心房内に配置される。このポンプホースは略180°の湾曲を遂行する。この方法によって、ホース出口が心室隔壁または必要とされる（X線または超音波）診断用補助器具に接触して押圧することなく、ポンプホースと共に血液ポンプを正確に心臓内に位置づけることが可能となる。

【0011】

本発明の意義の範囲内で術語「心臓内」は心臓チャンバ（心室）、心房および隣接の血管基部を包含するものとする。

【0012】

ポンプホースは心臓内を想定した、その最終位置に従って予め湾曲されるべきことが好ましい。これは少なくとも約150°の湾曲を要する。ポンプホースは大静脈を経由して挿入するために伸張可能であらねばならないが、それは緩んだ状態でU字状またはV字状を想定すべきである。特に好ましいのは、ポンプホースが曲げ剛性を示すことであり、これは基部端から末梢端へと減少するものである。この様式において、その末梢端は経路発見者として容易に移動されるので、バルーンは固有の血液の流れにより良く従うことが出来る。

【0013】

このバルーンは必ずしもポンプホースに直接取り付けねばならぬことはない。それはまた、カテーテルに固定してもよく、このカテーテルはポンプホースの部分を形成し、また後者の内側または外側に延在するものである。如何なる場合にも、管腔をバルーンにまで延長せねばならず、それを介してバルーンは膨張可能である。第二の管腔を付加的に設けてもよく、その中に案内ワイヤーが挿入され、これは脈管系を経由するポンプホースの前進を容易とする。案内ワイヤーの除去後、前記第二管腔は圧力測定管腔として利用してもよい。

【0014】

好ましい実施態様によれば、バルーンは環状バルーンとして構成され、ポンプホースを取り囲んでいる。この種の構成の利点は、バルーンが存在の故で末梢ホース端は増大した外径を有し、従ってそれは肺動脈弁により保持される。これによって、バルーンはホース端部を肺動脈弁に留めることを補助し、一方ホース出

口は肺動脈弁内に位置決めされる。これがホース出口の肺動脈からの抜け落ちを阻止する。もう一つの利点は、環状バルーンはポンプホースの丸くした尖っていない端部を形成するので、そのポンプホースが血管または心臓壁あるいは心臓のその他の部分を損傷する可能性が無いことである。最後に、ホース端部が心臓内で弁縁または腱に引っ掛かることを阻止する。

**【0015】**

ポンプ部がポンプホースを動かすので、そのポンプホースは自動的に開放された儘になる。このようにして、圧潰可能なホース、たとえばその壁が本質的に安定ではないシート材料から調製されるものをポンプホースとして使用することが出来る。このホースを経由して、カテーテルを末梢端に配置されたバルーンに伸展させればよい。

**【0016】**

可撓性ポンプホースを備えた心臓内血液ポンプを使用すると、血液がホース出口を出て行くことがホースの後退を生ずるという危険があり、それはホースの後退変位をもたらす可能性がある。このような訳で、ホースは肺動脈弁から滑り出す可能性がある。従って、本発明の別の目的は、心臓内血液ポンプであって、液圧反力に起因するホースの変位が阻止されるものを提供することである。

**【0017】**

本発明によれば、この目的は請求項13記載の特徴によって達成される。ホースの末梢端には、牽引エレメントが固定され、これに対しポンプ送りされた流れが指向される。前記牽引エレメントはリーフレットまたはバルーンとして構成することができる。ホース端部を出て行く血液流は牽引エレメントを押圧し、これがホースの後退力に反対して作用する前方に向かう力を生成する。この方法で、牽引エレメントはポンプホースの安定した位置決めのために機能する。以下、本発明の実施態様を詳細に添付図面を参照して説明する。

**【0018】**

図1に照らして、血液ポンプ10は心臓内血液ポンプ、すなわち患者の血管系を経由して心臓内へ挿入可能な血液ポンプである。この種の血液ポンプの外径が8mmを超える個所はない。ポンプ10は駆動部11およびこの駆動部に固定され

たポンプ部を含んで構成される。このポンプは、たとえばW097/37696中に記載されたものに相当するので、その内部構造はここで詳細に説明する必要は無い。駆動部 1 1 およびポンプ部 1 2 間の通過領域において、取り入れ開口部 1 3 は、それを経由して血液が外側から半径方向へ取り込まれるように配置されている。ポンプ部 1 2 はインペラー（図示せず）であって、血液を軸方向に移動させるものを含んで構成される。ポンプ部 1 2 の出口に、ポンプホース 1 4 が連結される。前記ポンプホースはポンプ出口に連結された基部端 1 5 とホース出口を形成する末梢端 1 6 とを含んで構成される。

#### 【0019】

ポンプ 1 0 の基部端はカテーテル 1 7 に連結され、これはまた、駆動部 1 1 のための電気供給ラインを含んでいる。更に、このカテーテル 1 7 は圧搾空気源に連結可能な管腔を含んで成る。

#### 【0020】

ポンプホース 1 4 およびカテーテル 1 7 は可撓性設計から成っている。ポンプ 1 0 の硬質部分の長さは、血管系の屈曲部を経由してポンプの移動を許容するために 3 5 mm を超えることはない。ポンプホース 1 4 の長さはポンプの硬質部分長さの少なくとも 2 倍である。このポンプホースは長さ約 1 2 cm であり、そして外径約 8 mm を有している。その壁厚は 0. 0 5 mm 乃至 0. 2 mm である。ホース屈曲部の屈曲半径は 4 0 mm 乃至 6 0 mm である。

#### 【0021】

図 1 は心臓 2 0 の横断面を示している。下部大静脈 2 2 および上部大静脈 2 3 は右心房 2 1 内で終端する。右心房 2 1 および右心室 2 4 間には三尖弁が確認される。右心室 2 4 および肺動脈 2 6 間には肺動脈弁 2 7 が位置している。血液は肺動脈 2 6 から肺へ流れ、そしてそこから左心房 2 8 および左心室 2 9 に戻る。左心室 2 9 および大動脈 3 0 間には大動脈弁 3 1 が位置する。

#### 【0022】

ポンプ 1 0 は右心室ポンプとして、それが右心房 2 1 から肺動脈 2 6 内へ届くように位置づけられる。この目的のために、示された実施態様において、それは上部大静脈 2 3 を経由して配置される。それはまた、下部大静脈 2 2 を経由して



配置することも可能である。ポンプ10挿入の間、そのポンプのポンプホース14は前方に横たわっている。すなわち、それはポンプを取り囲む血液の流れの方向において理解されるように、ポンプ10の下流に位置づけられている。

#### 【0023】

ポンプホース14の末梢端16において、バルーン35が配置されており、ここでは図2および図3中に示すように、環状バルーンとして構成されている。バルーン35はガス（たとえば、空気、ヘリウム、CO<sub>2</sub>）または液体をもって充填され、ポンプホース14より大きな外径を有している。従って、バルーン35は固有の血液流により一緒に運ばれる案内エレメントとして作用する。その結果、バルーン35は生来の血液路を介して先ず右心室24内に、次いで肺動脈26内に押し流される。

#### 【0024】

バルーン35はポンプホース14の圧力管腔36内で生成される圧力によって膨張される。圧力管腔36は開口部37を経由して環状バルーン35の内側に連結される。ポンプホース14内で、血液は圧力管腔36の横断面よりも可成り大きい血液管腔38を経由して流れる。圧力管腔36は基部カテーテル17の対応する圧力管腔に連結されているので、その圧力を対外的に制御することが可能である。

#### 【0025】

ポンプホース14は図2中に弛められた状態で示されている。ポンプホースはU字状またはV字状に予め屈曲され、すなわちそれはその形状を記憶することが出来るので、心臓内で如何なる本質的な拘束を受けることは無く、それはまた図1中に示すように、心臓に対し如何なる本質的な制限を加えることもない。図2において、点を打って黒くした領域はポンプホース14の剛性を示している。基部端15において、前記剛性は非常に大きく、そして末梢端16に向かって連続的に減少する。これは、バルーン35が配置されている末梢端16が自由に移動可能であり、そしてバルーンによって案内し得ることを意味している。

#### 【0026】

図3から理解し得るように、バルーン35の末梢端はポンプホース14の端部

39を越えて突出するので、バルーン35は丸くしたホース端部40を形成し、これが障害物に引っ掛かる危険をもたらさない。バルーン35の基部端において、環状逃げ溝41が形成され、図1に示すように、その中に肺動脈弁27の尖端が貫入出来るので、その肺動脈弁はホース端部が退出することを妨げる。

#### 【0027】

図2および3中に示すように、牽引エレメント43はドーム型リーフレットの形状において、ホース出口42を横切っている。前記牽引エレメント43は薄く、かつ可撓性の隔膜であって、ウェブ44によってバルーン35に固定されるものを含んで構成される。ホース出口42を流れ出て行く血液は牽引エレメント43に抗して流れる結果、ポンプホース14に対し牽引力を及ぼし、これは後退作用を妨げる。このことが液圧減少に起因する肺動脈弁27からのポンプホース末梢端16の変位およびあり得る滑り出しを阻止する。

#### 【0028】

ポンプホース14は好ましくはポリウレタンから調製され、これは特に適切であることが判明している。

#### 【0029】

図4に示される実施態様において、ポンプホース14aはポンプ10に連結され、これはカートンまたは金属スパイラル形状の弾力性支持構造体45を含んで構成される。前記支持構造体45はポンプホースを開放状態とし、そして所望の曲げ剛性を生じるが、これはホースの長さに亘り一様でなくても良い。カテーテル46はポンプホース45を経由して延在し、これはその末梢端にバルーン35aを備えている。前記バルーンはポンプホース14aのための案内エレメントとして作動する。カテーテル46は圧力管腔を有している。その外径はポンプホース14aの直径よりも可成り小さいので、ポンプホース内で血液流にとって適切な横断面が得られる。カテーテル46はカテーテル17に連結される。

#### 【0030】

牽引エレメント43aとしてのボールはホース出口42の後方に配置され、カテーテル46に固定される。牽引エレメント43aを押しつけながら進む血液流は、末梢ホース端16がポンプ10に向かって後退するのを阻止する。ポンプホ

ース14aは保持取付具47によって牽引エレメント43aに固定される。

#### 【0031】

図5および6に示された実施態様において、ポンプホース14aは、固有の安定性を有さない薄いシート材料から調製された圧潰可能なポンプホースである。その末梢端にバルーン35aを含んで成るカテーテル48はポンプホース14bを介して延在する。前記カテーテル48はカテーテル17に連結される。ポンプホース14bの末梢端16はカテーテル48に連結され、またポンプホース14bは出口開口部49を含んで構成され、これを経由して血液は流出する。ポンプが図5に示すように挿入されると、そのポンプは操作されていないので、ポンプホース14bは圧潰される。バルーン35aの助けによって、軟質かつ可撓性のカテーテル48が心臓内に配置される結果、ポンプホースを位置づける。ポンプがその後作業に入ると、ポンプホース14bは拡張される。

#### 【0032】

位置づけ工程を容易にするために、図6に示すカテーテル36、36、48はバルーン35aに導く圧力管腔49の他に、もう一つの管腔50であって、案内ワイヤー51を収容し案内ワイヤーの除去後は外部圧力を測定するようにしたものを含んでいてもよい。同様にカテーテル17およびポンプ10を経由して延在する前記案内ワイヤー51は、手術する外科医によりポンプホースの設定に関し制御可能に影響を及ぼすことができる。それに引き続いて、案内ワイヤー51は除去される。

#### 【0033】

図6によれば、開口部52をカテーテル48に設けてもよく、これは管腔50に連結され、そして案内ワイヤー51によってブロックされる。案内ワイヤー51が管腔50から除去されると、血液は開口部52を介して管腔50に入る。管腔50は血圧測定器と接続出来るので、肺動脈内の血圧は測定可能であり、その結果、必要ならば、ポンプ工程の間に影響を与えることが出来る。

#### 【0034】

もし、案内ワイヤーなしでポンプホースの配置が行われる場合は、圧力は管腔50内の位置52で測定可能な圧力プロファイルの助けによって測定することが

出来る。この圧力プロフィールに基づく結果、末梢のポンプホース尖端の精確な位置を決定することが出来る。

【0035】

バルーンの直径は、それが肺動脈26を介する流れを本質的に妨げ、あるいはそれどころか肺動脈を孤立化させる程に大きいものではない。原則として、その直径は30mmを超えるものではない。更に、膨張性バルーンとは反対に、このバルーンは高い弾力性を示すべきである。シリコーン、ラテックスおよび好ましくはポリウレタンが、それらの弾力特性の故に適切なバルーン材料である。

【0036】

カテーテルホース用の案内エレメントとして血液流中で浮遊する間バルーンは高圧において顕著に膨張してもよく、その後ポンプ送りされた流れが指向される牽引エレメントとして作動させるために圧力を減少させることによって寸法を減少させてもよい。

【図面の簡単な説明】

【図1】

その中に配置された血液ポンプと共に心臓の横断面を示す図である。

【図2】

図1の血液ポンプの表示を示す図である。

【図3】

図2の細目線IIIの断面を示す図である。

【図4】

血液ポンプの第二実施態様を示す図である。

【図5】

第三実施態様を示す図である。

【図6】

図5に示した実施態様のカテーテルの表示を拡大スケールで示す図である。

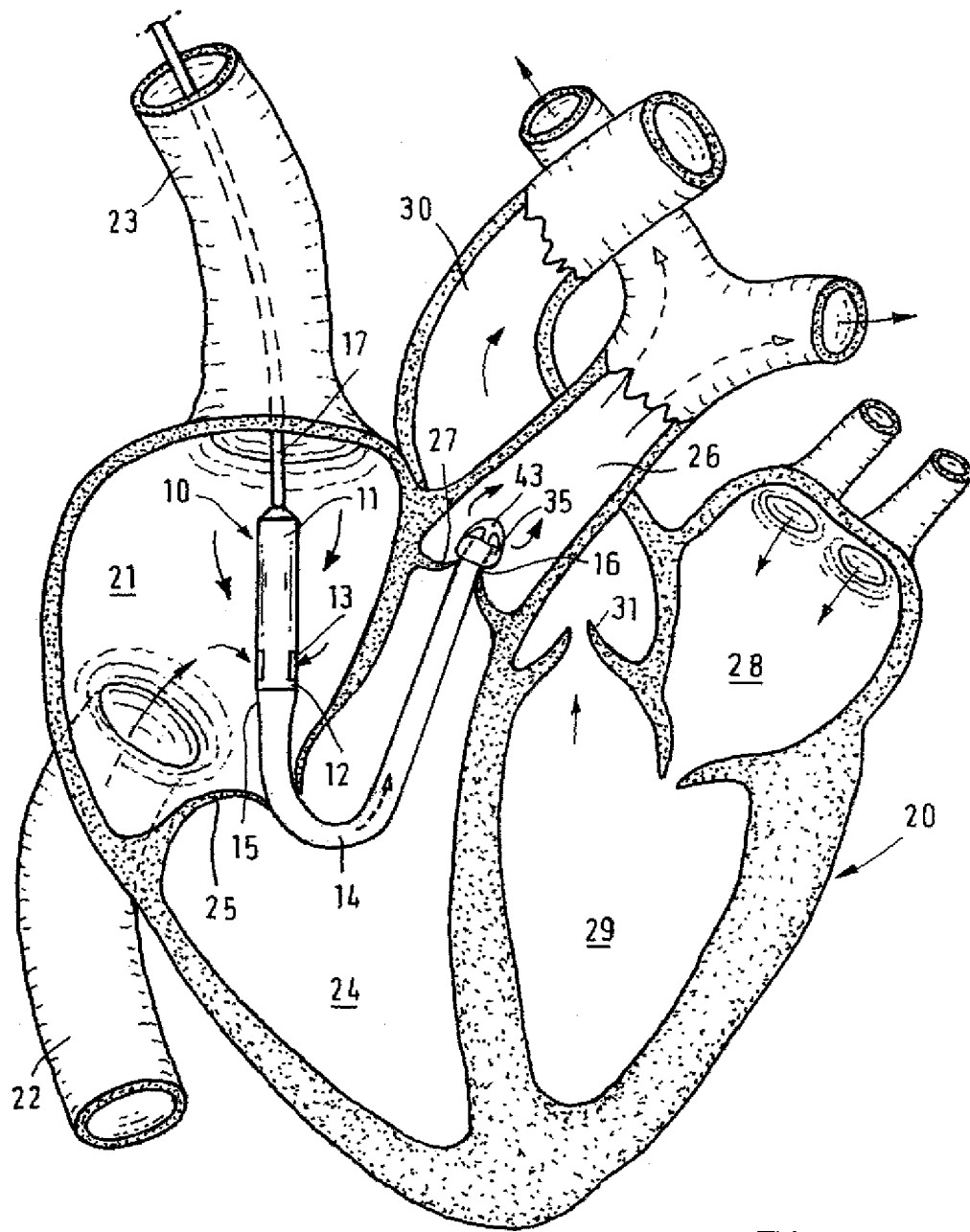
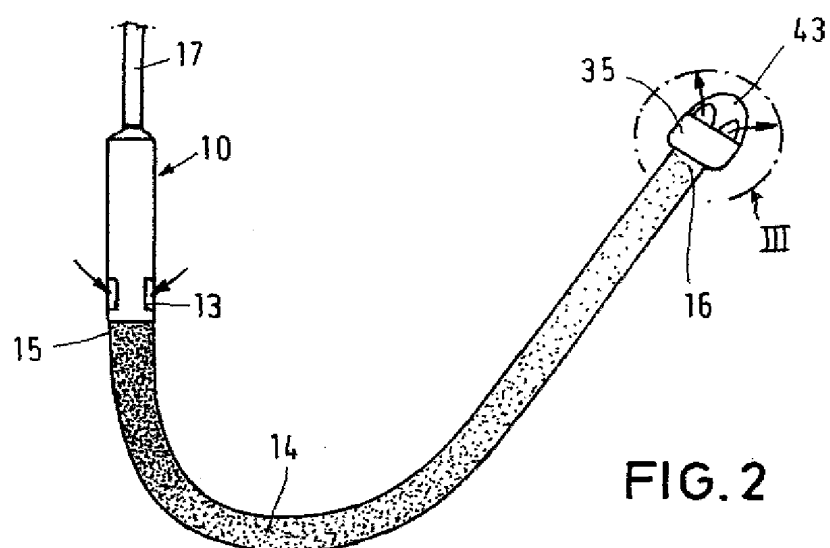
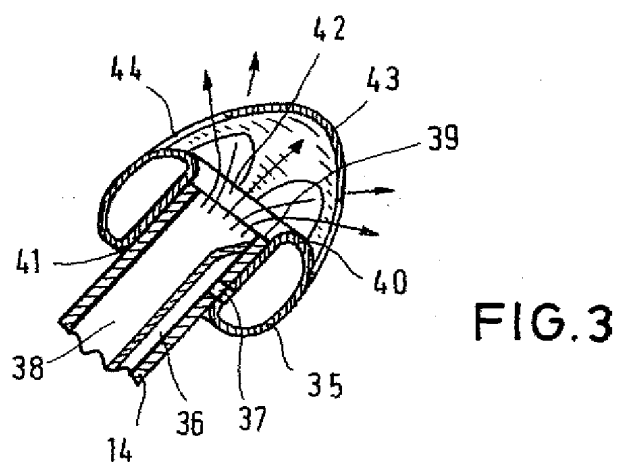


FIG. 1

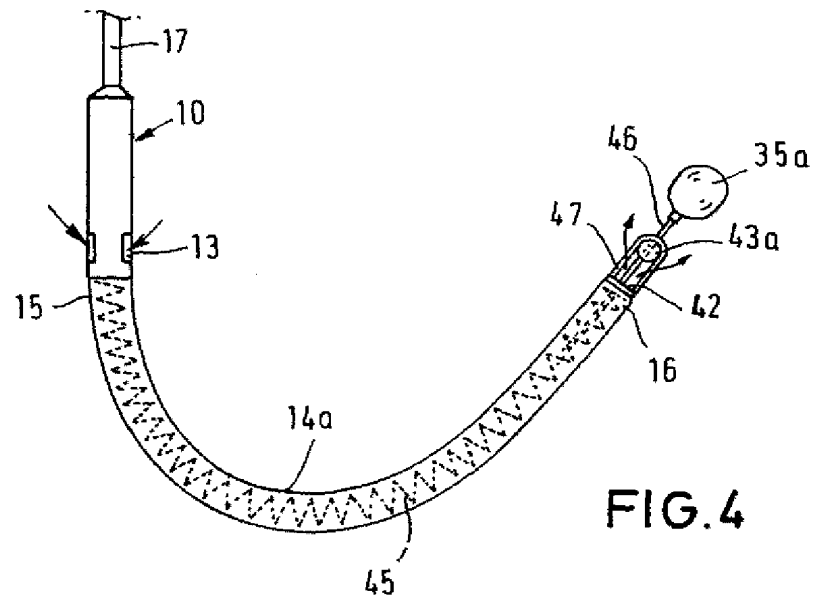
【図 2】



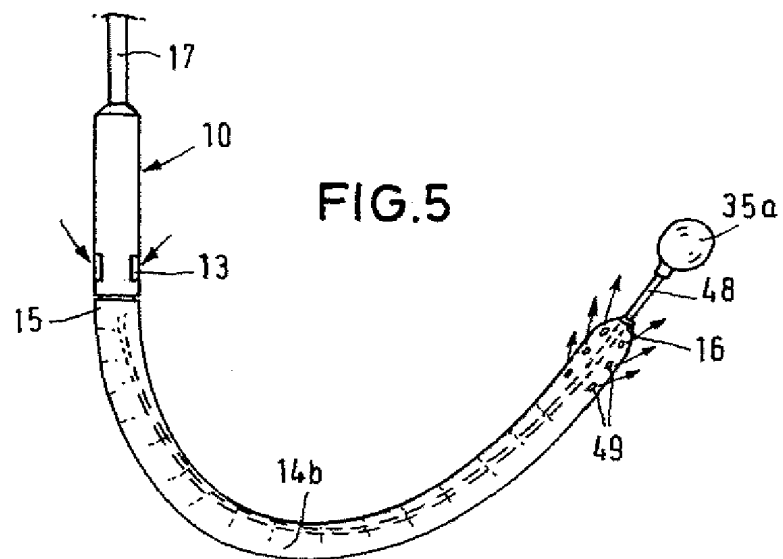
【図 3】



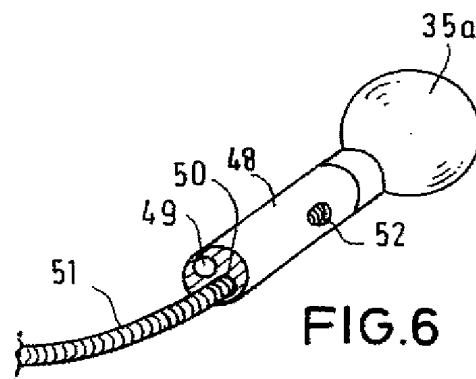
【図 4】



【図 5】



【図 6】



## INTERNATIONAL SEARCH REPORT

International Application No.  
PCT/EP 99/02790

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61M1/10 A61M25/01

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages                                                                                                                                                                            | Relevant to claim No. |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
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| X          | DE 196 22 335 A (VÖLKER)<br>11 December 1997 (1997-12-11)<br>column 1, line 42 - column 2, line 33<br>column 3, line 2 - column 4, line 19<br>figures 1-3<br>---<br>-/-                                                                                       | 1, 5, 9               |

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents:

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"Z" document member of the same patent family

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page 1 of 2



# INTERNATIONAL SEARCH REPORT

International Application No.

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP 99/02790

| Patent document<br>cited in search report |   | Publication<br>date | Patent family<br>member(s)                                                                                                                                                                                | Publication<br>date                                                                                                                                                                |
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Fターム(参考) 4C077 AA04 BB10 DD08 FF04 KK25



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DEUTSCHLAND**



**DEUTSCHES  
PATENT- UND  
MARKENAMT**

⑫ **Patentschrift**  
⑩ **DE 198 21 307 C 1**

⑤① Int. Cl.<sup>6</sup>:  
**A 61 M 1/12**  
A 61 M 25/01

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②② Anmeldetag: 13. 5. 98  
④③ Offenlegungstag: –  
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Innerhalb von 3 Monaten nach Veröffentlichung der Erteilung kann Einspruch erhoben werden

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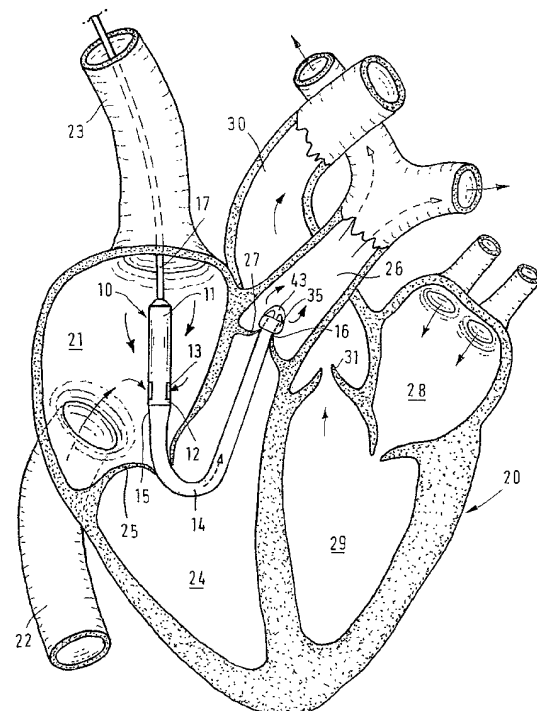
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⑤⑥ Für die Beurteilung der Patentfähigkeit in Betracht  
gezogene Druckschriften:

US 47 53 221  
WO 97 37 697  
WO 97 37 696  
WO 94 09 835

⑤④ **Intrakardiale Blutpumpe**

⑤⑦ Die intrakardiale Blutpumpe (10) weist einen Antriebs-  
teil (11) und einen Pumpenteil (12) auf. An den Pumpen-  
teil (12) ist ein flexibler Pumpenschlauch (14) angeschlos-  
sen. Um den Pumpenschlauch (14) von dem rechten Atri-  
um (21) zur Pulmonalarterie (26) zu verlegen, ist am dista-  
len Ende des Pumpenschlauchs (14) ein Ballon (35) vorge-  
sehen, der als Führungselement im Blutstrom wirkt und  
von der natürlichen Blutströmung mitgenommen wird.  
Dadurch wird die Platzierung der Blutpumpe im Herzen  
vereinfacht.



**DE 198 21 307 C 1**

Die Erfindung geht aus von einer intrakardiale Blutpumpe, gemäß dem Oberbegriff des Anspruchs 1 und eignet sich insbesondere für eine Blutpumpe, die vollständig in das Herz über angrenzende Gefäße eingeführt werden kann, um die natürliche Pumpfunktion des Herzens zu unterstützen oder durch kontinuierlichen Pumpbetrieb zu ersetzen.

Eine Pumpvorrichtung zur Herzunterstützung ist beschrieben in WO 94/09835 (Jarvik). Diese Pumpvorrichtung weist voneinander unabhängige Pumpen auf, die jeweils aus einem Pumpenteil und einem starr damit verbundenen Antriebsteil bestehen. Der Pumpenteil der einen Pumpe wird durch eine apekale Operationsöffnung hindurch derart in den linken Ventrikel eingeführt, daß er aus dem linken Ventrikel heraus in die Aorta fördert. Der andere Pumpenteil wird durch eine weitere, vorzugsweise apekale, Operationsöffnung hindurch in den rechten Ventrikel so eingeführt, daß er aus dem rechten Atrium in die Pulmonalarterie hineinfördert. Die Pumpen sind jeweils an ihrem Pumpenauslaß mit einer schlauchförmigen Auslaßkanüle verlängert, die durch die jeweilige Herzklappe hindurchgeführt werden kann.

Eine intrakardiale Blutpumpe, die von der Aorta durch die Aortenklappe hindurch in den linken Ventrikel eingeführt wird, ist bekannt aus WO 97/37696 (Rau et al.). Hierbei ist der Pumpeneinlaß durch einen Schlauch verlängert, welcher durch die Aortenklappe hindurchgeht.

Aus WO 97/37697 (Rau et al.) ist eine intravasale Blutpumpe bekannt, die durch ein Blutgefäß hindurchgeschoben werden kann. Auch diese Blutpumpe ist an ihrem Einlaßende durch einen Ansaugschlauch verlängert. Dieser Ansaugschlauch trägt einen aufblasbaren Ballon, welcher als Sperrvorrichtung dient, um einen seitlich an dem Ansaugschlauch vorbeiführenden Blutfluß zu verhindern.

Schließlich ist aus US-Patent 4 753 221 (Kensey et al.) ein Pumpenkatheter bekannt, der eine im Herzen zu platzierende Pumpe aufweist. Diese Pumpe besteht aus einem Flügelrad und einem das Flügelrad umgebenden Pumpengehäuse. Das Pumpengehäuse kann im kollabierten Zustand im Herzen platziert und anschließend durch Aufblasen eines mit dem Pumpengehäuse verbundenen Ballons aufgefaltet werden.

Ferner sind zu diagnostischen Zwecken kleinumige Katheter zur Druck- und Volumenstromerfassung bekannt, die am distalen Katheterende einen aufblasbaren Ballon aufweisen. Dieser Ballon wird zur Platzierung der Katheterspitze in der Pulmonalarterie verwendet.

Bei intrakardialen Blutpumpen, die durch ein Blutgefäß hindurch in das Herz eingeführt werden, besteht die Schwierigkeit der korrekten Platzierung der Blutpumpe im Herzen. Insbesondere wenn die Blutpumpe durch die obere Hohlvene hindurch eingeführt wird, um Blut von dem rechten Atrium in die Pulmonalarterie zu pumpen, ist die korrekte Platzierung der Blutpumpe schwierig, weil die Pumpe eine Umlenkung um nahezu 180° durchführen muß, damit die Ansaugöffnung im rechten Atrium und die Auslaßöffnung in der Pulmonalarterie liegt. Hinzu kommt, daß in dem rechten Ventrikel zahlreiche Fäden und Sehnen vorhanden sind, die die Tricuspidalklappe festhalten und die Segel der Klappe gegen Durchschlagen sichern und die Formstabilität des Herzens gewährleisten. Zwischen solchen Sehnen und Fäden hindurch muß eine Blutpumpe, die durch eine Hohlvene hindurch eingeführt wird, geführt werden.

Der Erfindung liegt die Aufgabe zugrunde, eine intrakardiale Blutpumpe zu schaffen, die relativ leicht im Herzen platziert werden kann.

Die Lösung dieser Aufgabe erfolgt mit dem Gegenstand

des Patentanspruchs 1 oder des Patentanspruchs 13.

Bei der im Anspruch 1 beanspruchten Blutpumpe ist an den Pumpenauslaß ein flexibler Schlauch angesetzt, dessen distales Ende einen als Führungselement im Blutstrom wirkenden Ballon aufweist. Hierbei wird der Umstand ausgenutzt, daß der natürliche Blutstrom im Herzen von der Hohlvene aus in das rechte Atrium durch den rechten Ventrikel hindurch in die Pulmonalarterie führt. Die Blutpumpe, die am distalen Ende des Schlauchs mit einem Ballon versehen ist, wird entlang eben dieses Weges eingeführt, wobei der in dem Blutstrom treibende Ballon automatisch seinen Weg von dem rechten Atrium in die Pulmonalarterie findet. Der Schlauchauslaß wird anschließend in der Pulmonalarterie stabilisiert, während der Pumpenteil sich im rechten Atrium befindet. Der Pumpenschlauch erfährt dabei eine Biegung von annähernd 180°. Auf diese Weise gelingt es, die Blutpumpe einschließlich des Pumpenschlauchs korrekt im Herzen zu platzieren, ohne daß ein abtastendes Anstoßen des Schlauchauslasses an den Herzkammerwänden erfolgen müßte, oder diagnostische Hilfsmittel (Röntgen oder Ultraschall) benötigt werden.

Intrakardial im Sinne der vorliegenden Erfindung umfaßt die Herzkammern (Ventrikel), die Vorhöfe und die angrenzenden Gefäßstümpfe.

Es ist zweckmäßig, wenn der Pumpenschlauch entsprechend seiner endgültigen Lage, die er im Herzen einnimmt, vorgebogen ist. Dies erfordert eine Biegung um mindestens etwa 150°. Zwar muß der Pumpenschlauch, um durch die Hohlvene hindurch eingeführt zu werden, gestreckt werden können, jedoch sollte er im entspannten Zustand eine U-Form oder V-Form annehmen. Besonders vorteilhaft ist es, wenn der Pumpenschlauch eine Biegesteifigkeit hat, die vom proximalen Ende zum distalen Ende hin abnimmt. Auf diese Weise kann das distale Ende als Wegfinder leicht bewegt werden, so daß der Ballon der natürlichen Blutströmung besser folgen kann.

Der Ballon muß nicht notwendigerweise direkt an dem Pumpenschlauch angebracht sein. Er kann auch an einem Katheter befestigt sein, der Bestandteil des Pumpenschlauchs ist und innen oder außen durch diesen hindurch verläuft. In jedem Fall muß zu dem Ballon ein Lumen verlaufen, durch das der Ballon aufgeblasen werden kann. Es kann zusätzlich ein zweites Lumen vorgesehen sein, in das ein Führungsdraht eingeführt wird, mit welchem das Verschieben des Pumpenschlauchs durch das Gefäßsystem erleichtert wird. Nach Entfernen des Führungsdrahtes kann dieses zweite Lumen als Druckmeßlumen verwendet werden.

Gemäß einer bevorzugten Ausführungsform ist vorgesehen, daß der Ballon als Ringballon den Pumpenschlauch umgibt. Dies hat den Vorteil, daß das distale Schlauchende durch den Ballon einen vergrößerten Außendurchmesser aufweist, und dadurch von der Pulmonalklappe festgehalten wird. Auf diese Weise trägt der Ballon zur Verankerung des Schlauchendes an der Pulmonalklappe bei, während sich der Schlauchauslaß in der Pulmonalarterie befindet. Dadurch wird verhindert, daß der Schlauchauslaß aus der Pulmonalarterie herausgleitet. Ein weiterer Vorteil besteht darin, daß der Ringballon ein abgerundetes stumpfes Ende des Pumpenschlauchs bildet, so daß mit dem Pumpenschlauch keine Verletzung der Gefäß- und Herzwände oder anderer Herzteile hervorgerufen werden können. Schließlich wird auch verhindert, daß das Schlauchende sich am Klappenrand oder an Sehnen im Herzen verhakt.

Da der Pumpenteil Blut in den Pumpenschlauch hineinpumpt, wird der Pumpenschlauch selbsttätig offengehalten. Als Pumpenschlauch kann daher ein kollabierbarer Schlauch benutzt werden, beispielsweise ein Folien-

schlauch, dessen Wand nicht formstabil ist. Durch diesen Schlauch hindurch kann ein Katheter zu dem am distalen Ende angeordneten Ballon verlaufen.

Bei einer intrakardialen Blutpumpe mit einem flexiblen Pumpenschlauch besteht die Gefahr, daß das aus dem Schlauchauslaß ausströmende Blut am Schlauch einen Rückstoß verursacht, welcher eine retrograde Verschiebung des Schlauchs zur Folge haben kann. Auf diese Weise kann es geschehen, daß der Schlauch aus der Pulmonalklappe herausgleitet. Der Erfindung löst daher die weitere Aufgabe, eine intrakardiale Blutpumpe zu schaffen, bei der Verschiebungen des Schlauchs infolge von hydraulischen Reaktionskräften vermieden werden.

Bei der Lösung der der Erfindung zu Grunde liegenden Aufgabe mit dem Gegenstand des Patentanspruchs 13 ist am distalen Ende des Schlauchs ein Zugelement befestigt, welches von dem Pumpenstrom angeströmt wird. Bei diesem Zugelement kann es sich um ein Segel handeln oder um einen Ballon. Der aus dem Schlauchende austretende Blutstrom stößt gegen das Zugelement, wodurch eine der Rückzugskraft des Schlauchs entgegenwirkende, nach vorne gerichtete Kraft entsteht. Auf diese Weise dient das Zugelement der Stabilisierung der Positionierung des Pumpenschlauchs.

Im folgenden werden unter Bezugnahme auf die Zeichnungen Ausführungsbeispiele der Erfindung näher erläutert. Es zeigen:

**Fig. 1** eine Querschnittsdarstellung des Herzens mit darin angeordneter Blutpumpe,

**Fig. 2** eine Darstellung der Blutpumpe von **Fig. 1**,

**Fig. 3** einen Schnitt durch die Einzelheit III von **Fig. 2**,

**Fig. 4** ein zweites Ausführungsbeispiel der Blutpumpe,

**Fig. 5** ein drittes Ausführungsbeispiel und

**Fig. 6** in vergrößertem Maßstab eine Darstellung des Katheters aus dem Ausführungsbeispiel von **Fig. 5**.

Gemäß **Fig. 1** ist die Blutpumpe **10** eine intravasale Blutpumpe, also eine Blutpumpe, die durch das Blutgefäßsystem eines Patienten geschoben werden kann, um bis in das Herz hinein vorzudringen. Der Außendurchmesser einer solchen Blutpumpe ist an keiner Stelle größer als 8 mm. Die Pumpe **10** weist einen Antriebsteil **11** und einen damit starr verbundenen Pumpenteil **12** auf. Die Pumpe entspricht beispielsweise derjenigen von WO 97/37696, so daß ihr interner Aufbau hier nicht näher erläutert wird. Im Übergangsbereich zwischen Antriebsteil **11** und Pumpenteil **12** befinden sich Ansaugöffnungen **13**, durch die Blut radial von außen her angesaugt wird. Der Pumpenteil **12** enthält ein (nicht dargestelltes) Flügelrad, das das Blut in axialer Richtung antreibt. An den Auslaß des Pumpenteils **12** ist ein Pumpenschlauch **14** angeschlossen. Dieser weist ein mit dem Pumpenauslaß verbundenes proximales Ende **15** und ein den Schlauchauslaß bildendes distales Ende **16** auf.

Das proximale Ende der Pumpe **10** ist mit einem Katheter **17** verbunden, welcher auch die elektrischen Versorgungsleitungen für den Antriebsteil **11** enthält. Ferner weist der Katheter **17** ein Lumen auf, das an eine Druckluftquelle angeschlossen werden kann.

Der Pumpenschlauch **14** und der Katheter **17** sind flexibel. Die rigide Länge der Pumpe **10** beträgt nicht mehr als 35 mm, damit die Pumpe durch Krümmungen des Blutgefäßsystems hindurchgeht. Die Länge des Pumpenschlauchs **14** ist mindestens doppelt so groß wie die rigide Länge der Pumpe. Der Pumpenschlauch hat eine Länge von etwa 12 cm und einen Außendurchmesser von etwa 8 mm. Seine Wandstärke beträgt 0,05 mm bis 0,2 mm. Der Krümmungsradius der Schlauchbiegung beträgt 40 mm bis 60 mm.

In **Fig. 1** ist ein Querschnitt durch das Herz **20** dargestellt. In das rechte Atrium **21** münden die untere Hohlvene **22** und

die obere Hohlvene **23**. Zwischen dem rechten Atrium **21** und dem rechten Ventrikel **24** befindet sich die Tricuspidalklappe **25**. Zwischen dem rechten Ventrikel **24** und der Pulmonalarterie **26** befindet sich die Pulmonalklappe **27**. Von der Pulmonalarterie **26** fließt das Blut zur Lunge und von dort zurück in das linke Atrium **28** und zum linken Ventrikel **29**. Zwischen dem linken Ventrikel **29** und der Aorta **30** befindet sich die Aortenklappe **31**.

Die Pumpe **10** wird als Rechtsherzpumpe so verlegt, daß sie von dem rechten Atrium **21** in die Pulmonalarterie **26** hinein fördert. Hierzu ist sie bei dem dargestellten Ausführungsbeispiel durch die obere Hohlvene **23** hindurch verlegt. Es wäre auch möglich, die Verlegung durch die untere Hohlvene **22** hindurch vorzunehmen. Während des Einführens der Pumpe **10** liegt der Pumpenschlauch **14** der Pumpe voran, d. h. er liegt in Strömungsrichtung des die Pumpe umgebenden Blutes stromab von der Pumpe **10**.

Am distalen Ende **16** des Pumpenschlauchs **14** befindet sich ein Ballon **35**, der hier gemäß **Fig. 2** und **Fig. 3** als Ringballon ausgebildet ist. Der mit Gas (z. B. Luft, Helium, CO<sub>2</sub>) oder einer Flüssigkeit aufgeblähte Ballon **35** hat einen größeren Außendurchmesser als der Pumpenschlauch **14**. Folglich bildet der Ballon **35** ein Führungselement, an dem der natürliche Blutstrom angreift, um dieses Führungselement mitzuziehen. Dadurch wird der Ballon **35** auf dem natürlichen Blutweg zunächst in den rechten Ventrikel **24** und danach in die Pulmonalarterie **26** gespült.

Der Ballon **35** wird dadurch aufgebläht, daß in einem Drucklumen **36** des Pumpenschlauchs **14** ein Druck erzeugt wird. Das Drucklumen **36** steht über Öffnungen **37** mit dem Inneren des ringförmigen Ballons **35** in Verbindung. Im Pumpenschlauch **14** fließt das Blut durch das Blutlumen **38**, dessen Querschnitt wesentlich größer ist als derjenige des Drucklumens **36**. Das Drucklumen **36** ist an ein entsprechendes Drucklumen des proximalen Katheters **17** angeschlossen, so daß sein Druck extrakorporal gesteuert werden kann.

Der Pumpenschlauch **14** ist in **Fig. 2** im entspannten Zustand dargestellt. Der Pumpenschlauch ist U-förmig oder V-förmig vorgebogen, d. h. er hat ein Formgedächtnis, so daß er im Herzen gemäß **Fig. 1** keinem wesentlichen Zwang ausgesetzt ist und auch seinerseits keinen wesentlichen Zwang auf das Herz ausübt. In **Fig. 2** gibt die Schwärzung des gepunkteten Bereichs die Steifigkeit des Pumpenschlauchs **14** an. Am proximalen Ende **15** ist diese Steifigkeit sehr groß und sie nimmt dann stetig zum distalen Ende **16** hin ab. Dies bedeutet, daß das distale Ende **16**, an dem sich der Ballon **35** befindet, durch den Ballon frei bewegt und geführt werden kann.

Wie aus **Fig. 3** hervorgeht, steht der Ballon **35** am distalen Ende über das Ende **39** des Pumpenschlauchs **14** hinaus vor, so daß der Ballon **35** ein abgerundetes Schlauchende **40** bildet, welches nicht die Gefahr des Verhakens an Hindernissen bietet. An dem proximalen Ende des Ballons **35** bildet dieser eine ringförmige Hinterschneidung **41**, in die gemäß **Fig. 1** die Spitzen der Pulmonalklappe **27** eindringen können, so daß die Pulmonalklappe ein Zurückweichen des Schlauchendes verhindert.

Wie in den **Fig. 2** und **3** dargestellt ist, spannt sich über dem Schlauchauslaß **42** ein Zugelement **43** in Form eines kuppelförmigen Segels. Dieses Zugelement **43** besteht aus einer dünnen flexiblen Haut, die mit Stegen **44** an dem Ballon **35** befestigt ist. Das aus dem Schlauchauslaß **42** ausströmende Blut strömt gegen das Zugelement **43** und übt somit auf den Pumpenschlauch **14** einen Zug aus, der der Rückstoßwirkung entgegengesetzt ist. Dadurch wird verhindert, daß das distale Ende **16** des Pumpenschlauchs sich infolge des hydraulischen Rückstoßes verschiebt und evtl. aus der

Pulmonalklappe 27 herausgleitet.

Der Pumpenschlauch 14 besteht vorzugsweise aus Polyurethan, das sich als besonders geeignet erwiesen hat.

Bei dem Ausführungsbeispiel von Fig. 4 ist an die Pumpe 10 ein Pumpenschlauch 14a angeschlossen, der eine elastische Stützstruktur 45 in Form einer aus Carbon oder Metall bestehenden Schraubenwendel enthält. Diese Stützstruktur 45 hält den Pumpenschlauch offen und bewirkt die gewünschte Biegesteifigkeit, die auch über die Schlauchlänge variieren kann. Durch den Pumpenschlauch 45 hindurch verläuft ein Katheter 46, der am distalen Ende mit einem Ballon 35a versehen ist. Dieser Ballon bildet das Führungselement für den Pumpenschlauch 14a. Der Katheter 46 enthält ein Drucklumen. Sein Außendurchmesser ist wesentlich kleiner als der Durchmesser des Pumpenschlauchs 14a, so daß im Pumpenschlauch genügend Querschnitt für den Blutfluß zur Verfügung steht. Der Katheter 46 ist mit dem Katheter 17 verbunden.

Als Zugelement 43a ist eine Kugel im Abstand hinter dem Schlauchauslaß 42 angeordnet und am Katheter 46 befestigt. Die gegen das Zugelement 43a drückende Blutströmung verhindert ein Zurückweichen des distalen Schlauchendes 16 zur Pumpe 10. Der Pumpenschlauch 14a ist mit einer Haltevorrichtung 47 an dem Zugelement 43a verankert.

Bei dem Ausführungsbeispiel der Fig. 5 und 6 ist der Pumpenschlauch 14b ein kollabierbarer Pumpenschlauch, der aus dünnem Folienmaterial besteht, das keine eigene Formstabilität aufweist. Durch den Pumpenschlauch 14b verläuft ein Katheter 48, der an seinem distalen Ende einen Ballon 35a trägt. Dieser Katheter 48 ist mit dem Katheter 17 verbunden. Das distale Ende 16 des Pumpenschlauchs 14b ist mit dem Katheter 48 verbunden und der Pumpenschlauch 14b weist Austrittsöffnungen 49 für den Blutaustritt auf. Beim Einführen der Pumpe nach Fig. 5 ist die Pumpe nicht in Betrieb, so daß der Pumpenschlauch 14b kollabiert ist. Mittels des Ballons 35a wird der weiche und flexible Katheter 48 im Herzen verlegt, wobei er den Pumpenschlauch 14b positioniert. Wird anschließend die Pumpe in Betrieb gesetzt, so wird der Pumpenschlauch 14b aufgeweitet.

Zur Erleichterung der Platzierung kann der Katheter 48 gemäß Fig. 6 außer dem zum Ballon 35a führenden Drucklumen 49 ein weiteres Lumen 50 enthalten, das zur Aufnahme eines Führungsdrahtes 51 und nach Entfernen des Führungsdrahtes zur externen Druckmessung bestimmt ist. Dieser Führungsdraht 51, der auch durch den Katheter 17 und die Pumpe 10 hindurchgeht, ermöglicht es dem Operateur, die Verlegung des Pumpenschlauchs steuernd zu beeinflussen. Danach wird der Führungsdraht 51 herausgezogen.

Gemäß Fig. 6 kann an dem Katheter 48 eine Öffnung 52 vorgesehen sein, die mit dem Lumen 50 verbunden ist und die durch den Führungsdraht 51 versperrt wird. Nachdem der Führungsdraht 51 aus dem Lumen 50 herausgezogen ist, dringt durch die Öffnung 52 Blut in das Lumen 50 ein. Das Lumen 50 kann mit einem Blutdruckmesser verbunden werden, um somit den Blutdruck in der Pulmonalarterie während des Pumpens zu messen und ggf. beeinflussen zu können.

Erfolgt die Platzierung des Pumpenschlauches ohne Führungsdraht, so kann mit Hilfe der meßbaren Druckverläufe im weiteren Lumen 50 der Druck an der Stelle 52 gemessen werden. Aus den Druckverläufen kann so die genaue Position der distalen Pumpenschlauchspitze ermittelt werden.

Der Durchmesser des Ballons darf nicht so groß sein, daß er den Durchfluß durch die Pulmonalarterie 26 wesentlich behindert oder die Pulmonalarterie sogar absperrt. In der Regel darf der Durchmesser nicht größer sein als 30 mm. Ferner sollte der Ballon eine hohe Elastizität haben, im Un-

terschied zu einem Dilatationsballon. Als Ballonmaterial eignen sich wegen der Elastizitätseigenschaften Silikon, Latex, und vorzugsweise Polyurethan.

Der Ballon kann, während er als Führungselement für den Katheterschlauch im Blutstrom floatet, mit hohem Druck stark aufgebläht sein und anschließend durch Verringerung des Druckes verkleinert werden, um als Zugelement zu wirken, das von der Pumpenströmung angeströmt wird.

#### Patentansprüche

1. Intrakardiale Blutpumpe, mit einem radial ansaugenden und axial fördernden Pumpenteil (11), der mit einem Katheter (17) verbunden ist, und einem mit dem Pumpenauslaß verbundenen flexiblen Pumpenschlauch (14), welcher ein an den Pumpenauslaß angrenzendes proximales Ende (15) und ein den Schlauchauslaß bildendes distales Ende (16) aufweist, dadurch gekennzeichnet,

daß der Pumpenschlauch (14) nahe seinem distalen Ende einen von dem Blutstrom mitnehmbaren, als Führungselement wirkenden Ballon (35) aufweist.

2. Blutpumpe nach Anspruch 1, dadurch gekennzeichnet, daß der Pumpenschlauch um mehr als 100°, vorzugsweise um etwa 150°, vorgebogen ist.

3. Blutpumpe nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß der Pumpenschlauch (14) eine Biegesteifigkeit hat, die vom proximalen Ende (15) zum distalen Ende (16) hin abnimmt.

4. Blutpumpe nach einem der Ansprüche 1–3, dadurch gekennzeichnet, daß der Pumpenschlauch (14) innen oder außen einen zweiten Katheter (46; 48) aufweist, der das distale Ende (16) des Pumpenschlauchs überragt und jenseits des distalen Endes den Ballon (35a) trägt.

5. Blutpumpe nach einem der Ansprüche 1–3, dadurch gekennzeichnet, daß der Ballon (35) als Ringballon den Pumpenschlauch (14) umgibt.

6. Blutpumpe nach Anspruch 5, dadurch gekennzeichnet, daß der Ringballon eine abgerundete Schlauchspitze (40) bildet.

7. Blutpumpe nach einem der Ansprüche 1–6, dadurch gekennzeichnet, daß der Pumpenschlauch (14b) ein kollabierbarer Schlauch ist.

8. Blutpumpe nach einem der Ansprüche 1–6, dadurch gekennzeichnet, daß der Pumpenschlauch (14a) eine elastische Stützstruktur (45) enthält.

9. Blutpumpe nach einem der Ansprüche 1–8, wobei der Pumpenschlauch (14b) einen zweiten Katheter (48) aufweist, gemäß dem Anspruch 4, dadurch gekennzeichnet, daß ein in den Katheter (48) einführbarer Führungsdraht (51) vorgesehen ist.

10. Blutpumpe nach einem Anspruch 9, dadurch gekennzeichnet, daß der zweite Katheter (48) ein Lumen (50) für den Führungsdraht (51) und ein Drucklumen (49) aufweist.

11. Blutpumpe nach Anspruch 9 oder 10, dadurch gekennzeichnet, daß der Katheter (48) ein als Druckmeßlumen benutzbares Lumen (50) aufweist.

12. Blutpumpe nach einem der Ansprüche 1–11, dadurch gekennzeichnet, daß der Durchmesser des Ballons (35) im aufgeblähten Zustand nicht größer ist als 30 mm.

13. Intrakardiale Blutpumpe, mit einem radial ansaugenden und axial fördernden Pumpenteil (11), der mit einem Katheter (17) verbunden ist, und einem mit dem Pumpenauslaß verbundenen flexiblen Pumpenschlauch (14), welcher ein an den Pumpenauslaß angrenzendes

proximales Ende (**15**) und ein den Schlauchauslaß bildendes distales Ende (**16**) aufweist, dadurch gekennzeichnet, daß an dem distalen Ende (**16**) des Pumpenschlauchs (**14**) ein von dem Pumpenstrom angeströmtes Zugelement (**43**) befestigt ist.

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Hierzu 3 Seite(n) Zeichnungen

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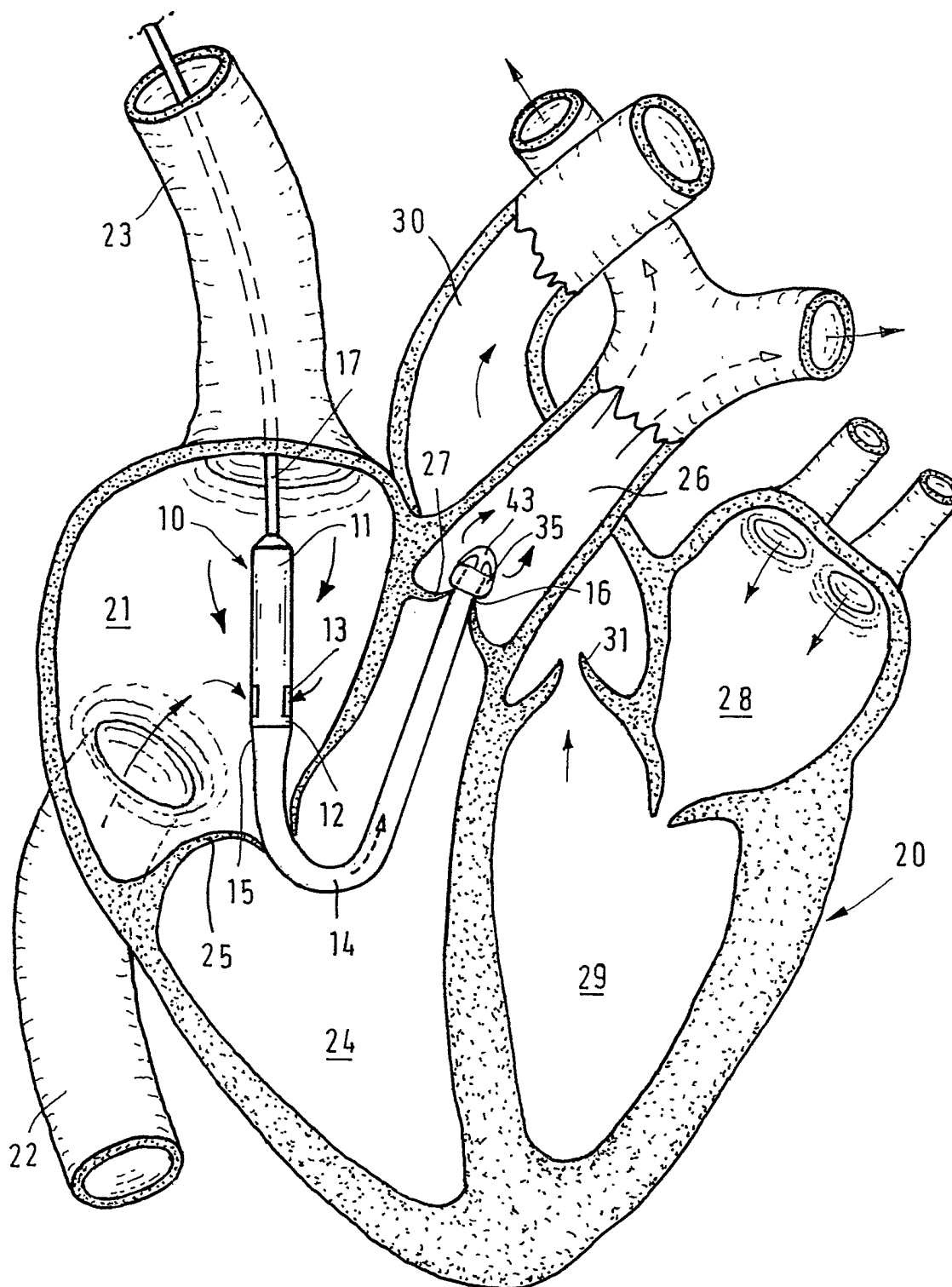
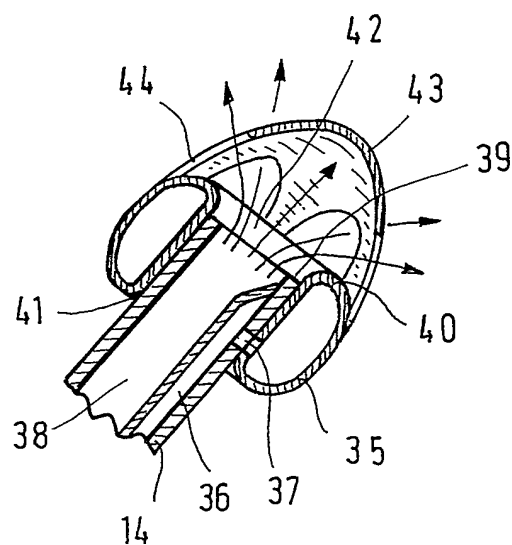
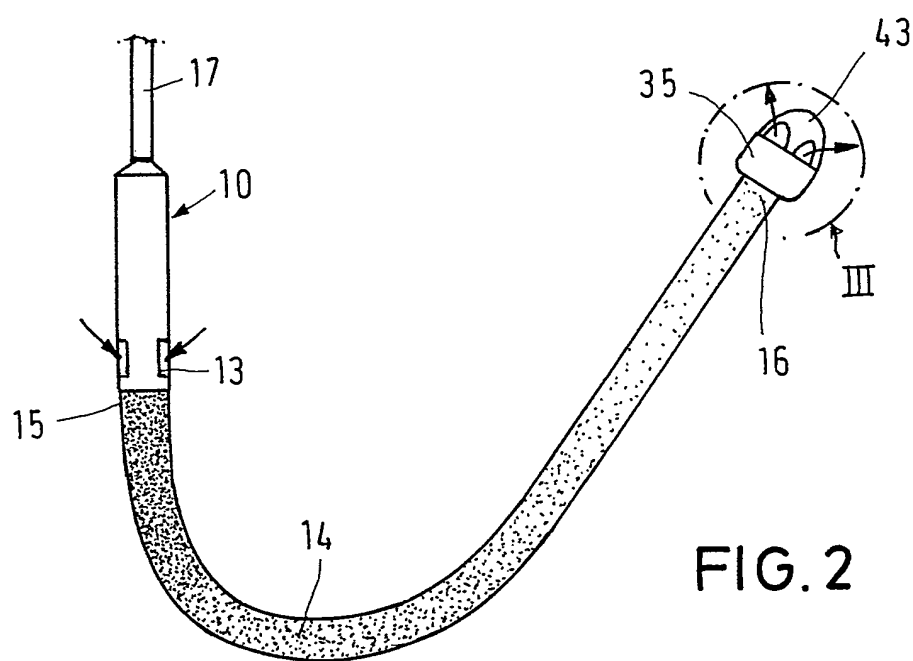
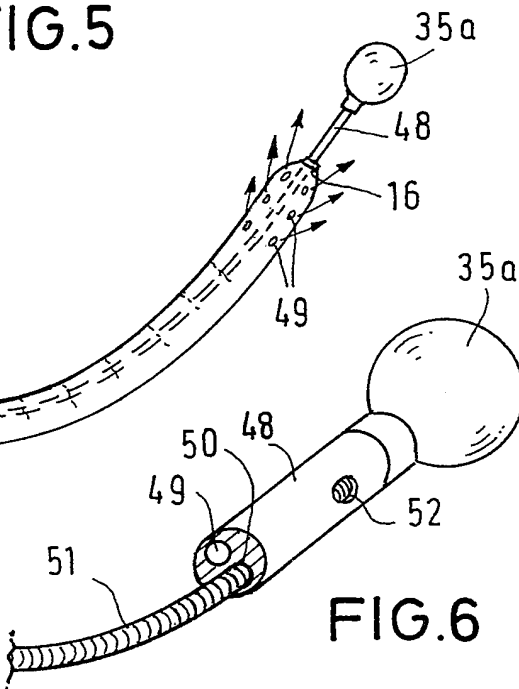
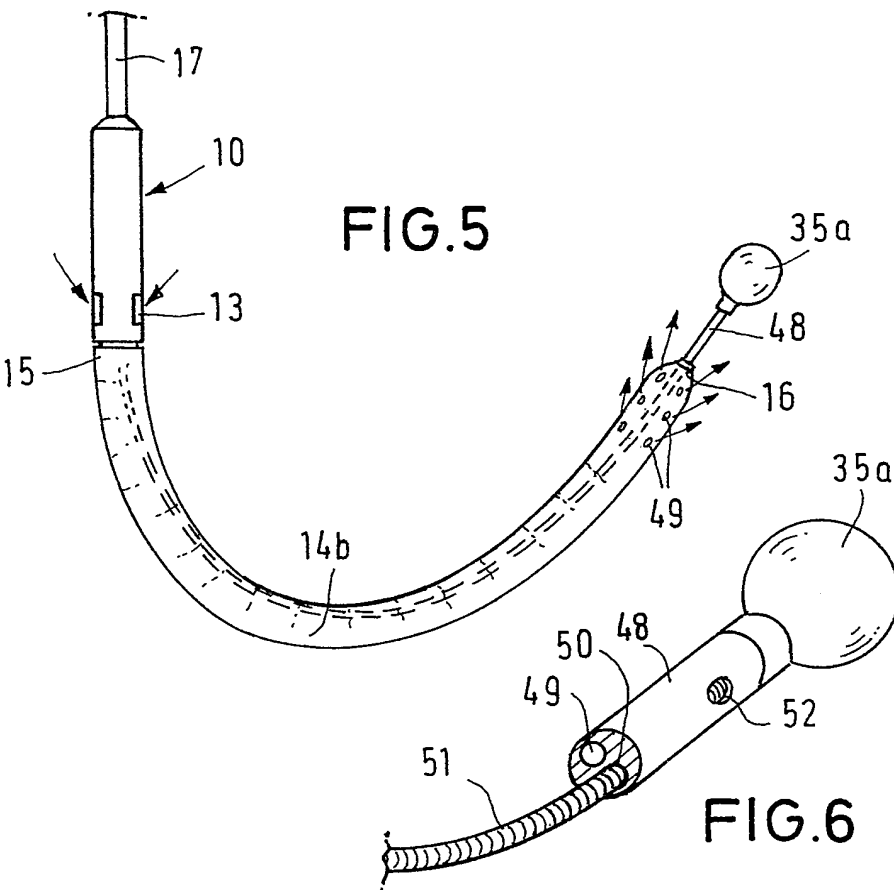
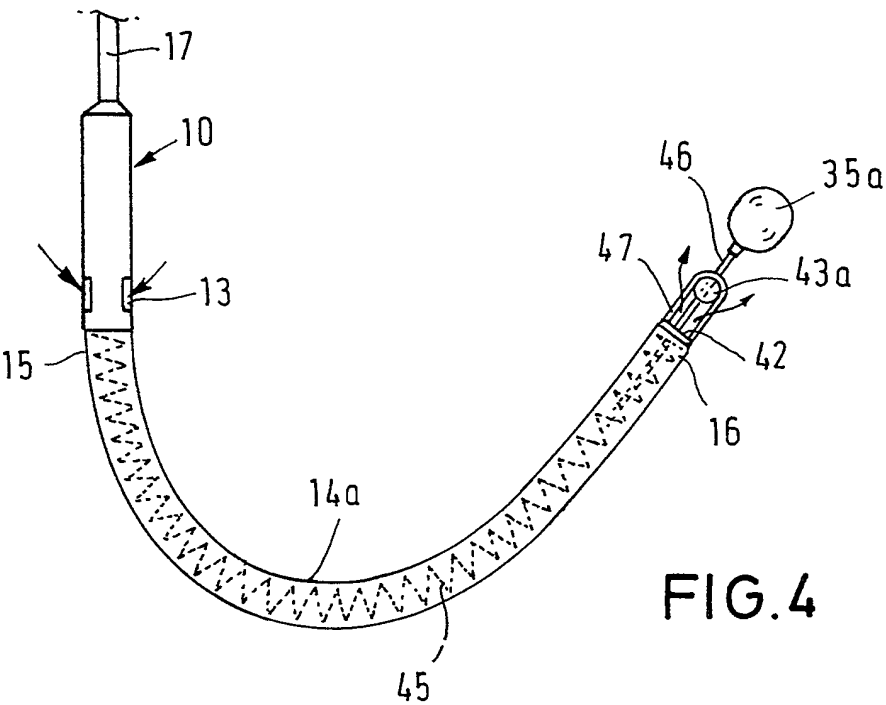


FIG. 1





## Notice

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## CLAIMS DE19821307

1.

Intracardiac blood pump comprising a radially aspirated and axially delivering pump portion (11) connected to a catheter (17) is connected, and connected to the pump outlet flexible pump hose (14) having an adjacent to the pump outlet proximal end (15) and a the hose outlet forming distal end (16)

---

Intrakardiale Blutpumpe, mit einem radial ansaugenden und axial fördernden Pumpenteil (11), der mit einem Katheter (17) verbunden ist, und einem mit dem Pumpenauslass verbundenen flexiblen Pumpenschlauch (14), welcher ein an den Pumpenauslass angrenzendes proximales Ende (15) und ein den Schlauchauslass bildendes distales Ende (16) aufweist,

characterized in

---

dadurch gekennzeichnet,

that the pump hose (14) near its distal end be carried along one of the blood flow and acting as guide element balloon (35).

---

dass der Pumpenschlauch (14) nahe seinem distalen Ende einen von dem Blutstrom mitnehmbaren, als Führungselement wirkenden Ballon (35) aufweist.

2.

The blood pump according to claim 1, characterized in that the pump hose by more than 100 °, preferably by approximately 150 °, pre-bent.

---

Blutpumpe nach Anspruch 1, dadurch gekennzeichnet, dass der Pumpenschlauch um mehr als 100 DEG , vorzugsweise um etwa 150 DEG , vorgebogen ist.

3.

The blood pump according to claim 1 or 2, characterized in that the pump hose (14) has a bending stiffness from the proximal end (15) to the distal end (16) decreases towards.

---

Blutpumpe nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass der Pumpenschlauch (14) eine Biegesteifigkeit hat, die vom proximalen Ende (15) zum distalen Ende (16) hin abnimmt.

4.

The blood pump of one of claims 1-3, characterized in that the pump hose (14) inside or outside a second catheter (46, 48) which projects beyond the distal end (16) of the pump hose and outside the distal end of the balloon (35a ) bears.

---

Blutpumpe nach einem der Ansprüche 1-3, dadurch gekennzeichnet, dass der Pumpenschlauch (14) innen oder aussen einen zweiten Katheter (46; 48) aufweist, der das distale Ende (16) des Pumpenschlauchs überragt und jenseits des distalen Endes den Ballon (35a) trägt.

5.

The blood pump of one of claims 1-3, characterized in that the balloon (35) as an annular balloon surrounds the pump hose (14).

---

Blutpumpe nach einem der Ansprüche 1-3, dadurch gekennzeichnet, dass der Ballon (35) als Ringballon den Pumpenschlauch (14) umgibt.

6.

The blood pump according to claim 5, characterized in that the annular balloon forms a rounded hose tip (40).

---

Blutpumpe nach Anspruch 5, dadurch gekennzeichnet, dass der Ringballon eine abgerundete Schlauchspitze (40) bildet.

7.

The blood pump of one of claims 1-6, characterized in that the pump hose (14b) is a collapsible hose.

---

Blutpumpe nach einem der Ansprüche 1-6, dadurch gekennzeichnet, dass der Pumpenschlauch (14b) ein kollabierbarer Schlauch ist.

8.

The blood pump of one of claims 1-6, characterized in that the pump hose (14a) contains an elastic supporting structure (45).

---

Blutpumpe nach einem der Ansprüche 1-6, dadurch gekennzeichnet, dass der Pumpenschlauch (14a) eine elastische Stützstruktur (45) enthält.

9.

The blood pump according to any one of claims 1-8, wherein the pump hose (14b) comprises a second catheter (48) according to claim 4, characterized in that the catheter (48) insertable guide wire (51) is provided.

---

Blutpumpe nach einem der Ansprüche 1-8, wobei der Pumpenschlauch (14b) einen zweiten Katheter (48) aufweist, gemäss dem Anspruch 4, dadurch gekennzeichnet, dass ein in den Katheter (48) einführbarer Führungsdraht (51) vorgesehen ist.

10.

Blood pump according to claim 9, characterized in that the second catheter (48) having a lumen (50) for the guide wire (51) and a pressure lumen (49).

---

Blutpumpe nach einem Anspruch 9, dadurch gekennzeichnet, dass der zweite Katheter (48) ein Lumen (50) für den Führungsdraht (51) und ein Drucklumen (49) aufweist.

11.

The blood pump according to claim 9 or 10, characterized in that the catheter (48) usable as a pressure measurement lumen lumen (50).

---

Blutpumpe nach Anspruch 9 oder 10, dadurch gekennzeichnet, dass der Katheter (48) ein als Druckmesslumen benutzbares Lumen (50) aufweist.

12.

The blood pump according to any one of claims 1-11, characterized in that the diameter of the balloon (35) in the inflated state is not greater than 30 mm.

---

Blutpumpe nach einem der Ansprüche 1-11, dadurch gekennzeichnet, dass der Durchmesser des Ballons (35) im aufgeblähten Zustand nicht grösser ist als 30 mm.

13.

Intracardiac blood pump comprising a radially aspirated and axially delivering pump portion (11) connected to a catheter (17) is connected, and connected to the pump outlet flexible pump hose (14) having an adjacent to the pump outlet proximal end (15) and a the hose outlet forming distal end (16), characterized in that at the distal end (16) of the pump hose (14) is flowed through by the pump current traction element (43) is attached.

---

Intrakardiale Blutpumpe, mit einem radial ansaugenden und axial fördernden Pumpenteil (11), der mit einem Katheter (17) verbunden ist, und einem mit dem Pumpenauslass verbundenen flexiblen Pumpenschlauch (14), welcher ein an den Pumpenauslass angrenzendes proximales Ende (15) und ein den Schlauchauslass bildendes distales Ende (16) aufweist, dadurch gekennzeichnet, dass an dem distalen Ende (16) des Pumpenschlauchs (14) ein von dem Pumpenstrom angeströmtes Zuelement (43) befestigt ist.



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## DESCRIPTION DE 19821307

The invention proceeds from a intracardiac blood pump according to the preamble of claim 1 and is particularly suited for a blood pump which can be completely inserted into the heart through adjacent blood vessels, to support or replace the continuous pump operation, the natural pumping action of the heart.

---

Die Erfindung geht aus von einer intrakardiale Blutpumpe, gemäss dem Oberbegriff des Anspruchs 1 und eignet sich insbesondere für eine Blutpumpe, die vollständig in das Herz über angrenzende Gefässe eingeführt werden kann, um die natürliche Pumpfunktion des Herzens zu unterstützen oder durch kontinuierlichen Pumpbetrieb zu ersetzen.

A pump device for supporting the heart is described in WO 94/09835 (Jarvik).

---

Eine Pumpvorrichtung zur Herzunterstützung ist beschrieben in WO 94/09835 (Jarvik).

This pumping device includes spaced independent pumps, each of which consists of a pump part and a drive member rigidly connected thereto.

---

Diese Pumpvorrichtung weist voneinander unabhängige Pumpen auf, die jeweils aus einem Pumpenteil und einem starr damit verbundenen Antriebsteil bestehen.

The pump portion of a pump through such inserted through a surgical opening apical into the left ventricle, that it promotes out from the left ventricle into the aorta.

---

Der Pumpenteil der einen Pumpe wird durch eine apekale Operationsöffnung hindurch derart in den linken Ventrikel eingeführt, dass er aus dem linken Ventrikel heraus in die Aorta fördert.

---

The other pump part is passed as introduced by another, preferably apical, surgical opening into the right ventricle, that he promotes in from the right atrium into the pulmonary artery.

---

Der andere Pumpenteil wird durch eine weitere, vorzugsweise apekale, Operationsöffnung hindurch in den rechten Ventrikel so eingeführt, dass er aus dem rechten Atrium in die Pulmonalarterie hineinfördert.

---

The pumps are each extended at its pump outlet with a tubular outflow cannula, which can pass through the respective valve.

---

Die Pumpen sind jeweils an ihrem Pumpenauslass mit einer schlauchförmigen Auslasskanüle verlängert, die durch die jeweilige Herzklappe hindurchgeführt werden kann.

---

An intracardiac blood pump which is inserted from the aorta through the aortic valve and into the left ventricle, is known from WO 97/37696 (Rau et al.).

---

Eine intrakardiale Blutpumpe, die von der Aorta durch die Aortenklappe hindurch in den linken Ventrikel eingeführt wird, ist bekannt aus WO 97/37696 (Rau et al.).

---

Here, the pump inlet is extended by a tube which passes through the aortic valve.

---

Hierbei ist der Pumpeneinlass durch einen Schlauch verlängert, welcher durch die Aortenklappe hindurchgeht.

---

WO 97/37697 (Rau et al.) An intravascular blood pump is known, which can be pushed through a blood vessel.

---

Aus WO 97/37697 (Rau et al.) ist eine intravasale Blutpumpe bekannt, die durch ein Blutgefäss hindurchgeschoben werden kann.

These blood pump is extended at its inlet end by a suction hose.

---

Auch diese Blutpumpe ist an ihrem Einlassende durch einen Ansaugschlauch verlängert.

This suction tube carries an inflatable balloon, which is used as a blocking device to prevent the side leading to the suction tube by blood flow.

---

Dieser Ansaugschlauch trägt einen aufblasbaren Ballon, welcher als Sperrvorrichtung dient, um einen seitlich an dem Ansaugschlauch vorbeiführenden Blutfluss zu verhindern.

Finally, from U.S. Patent 4,753,221 (Kensey et al.) A catheter pump is known which has a pump to be placed in the heart.

---

Schliesslich ist aus US-Patent 4 753 221 (Kensey et al.) ein Pumpenkatheter bekannt, der eine im Herzen zu platzierende Pumpe aufweist.

This pump consists of an impeller and a pump housing surrounding the impeller.

---

Diese Pumpe besteht aus einem Flügelrad und einem das Flügelrad umgebenden Pumpengehäuse.

The pump casing can be placed in the collapsed state in the heart, and then unfolded by inflation of a balloon attached to the pump housing.

---

Das Pumpengehäuse kann im kollabierten Zustand im Herzen platziert und anschliessend durch Aufblasen eines mit dem Pumpengehäuse verbundenen Ballons aufgefaltet werden.

Furthermore, small-lumen catheter for pressure and flow rate measurement are known for diagnostic purposes that have an inflatable balloon at the distal end of the catheter.

---

Ferner sind zu diagnostischen Zwecken kleinlumige Katheter zur Druck- und Volumenstromerfassung bekannt, die am distalen Katheterende einen aufblasbaren Ballon aufweisen.

---

This balloon is used for placement of the catheter tip in the pulmonary artery.

---

Dieser Ballon wird zur Plazierung der Katheterspitze in der Pulmonalarterie verwendet.

---

Wherein the intracardiac blood pumps, which are inserted through a blood vessel and into the heart, there is the problem of the correct positioning of the blood pump in the heart.

---

Bei intrakardialen Blutpumpen, die durch ein Blutgefäß hindurch in das Herz eingeführt werden, besteht die Schwierigkeit der korrekten Plazierung der Blutpumpe im Herzen.

---

In particular, when the blood pump is inserted through the superior vena cava through in order to pump blood from the right atrium into the pulmonary artery, the correct placement of the blood pump is difficult because the pump has to perform a deflection of almost 180 °, so that the suction opening in the right atrium and the outlet port is in the pulmonary artery.

---

Insbesondere wenn die Blutpumpe durch die obere Hohlvene hindurch eingeführt wird, um Blut von dem rechten Atrium in die Pulmonalarterie zu pumpen, ist die korrekte Plazierung der Blutpumpe schwierig, weil die Pumpe eine Umlenkung um nahezu 180 DEG durchführen muss, damit die Ansaugöffnung im rechten Atrium und die Auslassöffnung in der Pulmonalarterie liegt.

---

In addition, in the right ventricle numerous threads and tendons are present, hold the tricuspid valve and secure the sails of the flap against strike-through and ensure the dimensional stability of the heart.

---

Hinzu kommt, dass in dem rechten Ventrikel zahlreiche Fäden und Sehnen vorhanden sind, die die Tricuspidalklappe festhalten und die Segel der Klappe gegen Durchschlagen sichern und die Formstabilität des Herzens gewährleisten.

---

Among such tendons and yarns must be guided through a blood pump is inserted through a vena cava through.

---

Zwischen solchen Sehnen und Fäden hindurch muss eine Blutpumpe, die durch eine Hohlvene hindurch eingeführt wird, geführt werden.

---

The invention has for its object to provide an intracardiac blood pump that can relatively easily be placed in the heart.

---

Der Erfindung liegt die Aufgabe zugrunde, eine intrakardiale Blutpumpe zu schaffen, die relativ leicht im Herzen plaziert werden kann.

---

The solution of this task is carried out with the subject matter of claim 1 or claim 13

---

Die Lösung dieser Aufgabe erfolgt mit dem Gegenstand des Patentanspruchs 1 oder des Patentanspruchs 13.

---

Claimed in claim 1 wherein the blood pump, a flexible hose is attached to the pump outlet, the distal end having a guide element which acts as a balloon in the bloodstream.

---

Bei der im Anspruch 1 beanspruchten Blutpumpe ist an den Pumpenauslass ein flexibler Schlauch angesetzt, dessen distales Ende einen als Führungselement im Blutstrom wirkenden Ballon aufweist.

---

Here, the fact is exploited that the natural blood flow in the heart from the vena cava into the right atrium through the right ventricle and into the pulmonary artery.

---

Hierbei wird der Umstand ausgenutzt, dass der natürliche Blutstrom im Herzen von der Hohlvene aus in das rechte Atrium durch den rechten Ventrikel hindurch in die Pulmonalarterie führt.

---

The blood pump that is provided at the distal end of the tube with a balloon, is inserted along this same path, wherein the driving in the bloodstream of the balloon will automatically find its way from the right atrium into the pulmonary artery.

---

Die Blutpumpe, die am distalen Ende des Schlauchs mit einem Ballon versehen ist, wird entlang eben dieses Weges eingeführt, wobei der in dem Blutstrom treibende Ballon automatisch seinen Weg von dem rechten Atrium in die Pulmonalarterie findet.

The hose outlet is then stabilized in the pulmonary artery, while the pump part is located in the right atrium.

---

Der Schlauchauslass wird anschliessend in der Pulmonalarterie stabilisiert, während der Pumpenteil sich im rechten Atrium befindet.

The pump hose experiences a deflection of approximately 180 °.

---

Der Pumpenschlauch erfährt dabei eine Biegung von annähernd 180 DEG .

In this way it is possible, the blood pump, including the pump hose to be correctly placed in the heart, without a scanning toast of Schlauchauslasses would have to occur at the ventricular walls, or diagnostic services (X-ray or ultrasound) are required.

---

Auf diese Weise gelingt es, die Blutpumpe einschliesslich des Pumpenschlauchs korrekt im Herzen zu plazieren, ohne dass ein abtastendes Anstossen des Schlauchauslasses an den Herzkammerwänden erfolgen müsste, oder diagnostische Hilfsmittel (Röntgen oder Ultraschall) benötigt werden.

Intracardially in accordance with the present invention, the chambers of the heart (ventricle), the atria and the adjacent vessel stumps.

---

Intrakardial im Sinne der vorliegenden Erfindung umfasst die Herzkammern (Ventrikel), die Vorhöfe und die angrenzenden Gefässstümpfe.

It is expedient if the pump hose is according to its final position which it occupies in the heart, pre-bent.

---

Es ist zweckmässig, wenn der Pumpenschlauch entsprechend seiner endgültigen Lage, die er im Herzen einnimmt, vorgebogen ist.

---

This requires a deflection of at least about 150 DEG.

---

Dies erfordert eine Biegung um mindestens etwa 150 DEG .

---

Although the pump tube has to be inserted through the vena cava, through, can be stretched, but it should take on a U-shape or V-shape in the relaxed state.

---

Zwar muss der Pumpenschlauch, um durch die Hohlvene hindurch eingeführt zu werden, gestreckt werden können, jedoch sollte er im entspannten Zustand eine U-Form oder V-Form annehmen.

---

There, if the pump hose has a flexural rigidity that decreases from the proximal end toward the distal end is particularly advantageous.

---

Besonders vorteilhaft ist es, wenn der Pumpenschlauch eine Biegesteifigkeit hat, die vom proximalen Ende zum distalen Ende hin abnimmt.

---

In this way, the distal end can be moved easily as pathfinder, so that the balloon of the natural blood flow can better follow.

---

Auf diese Weise kann das distale Ende als Wegfinder leicht bewegt werden, so dass der Ballon der natürlichen Blutströmung besser folgen kann.

---

The balloon must not necessarily be attached directly to the pump hose.

---

Der Ballon muss nicht notwendigerweise direkt an dem Pumpenschlauch angebracht sein.

---

It can also be attached to a catheter that is an integral part of the pump hose and runs inside or outside therethrough.

---

Er kann auch an einem Katheter befestigt sein, der Bestandteil des Pumpenschlauchs ist und innen oder aussen durch diesen hindurch verläuft.

---

In each case, the balloon has a lumen extending through the balloon can be inflated.

---

In jedem Fall muss zu dem Ballon ein Lumen verlaufen, durch das der Ballon aufgeblasen werden kann.

---

There may also be provided a second lumen into which a guide wire is inserted, with which the advance of the pump hose easier through the vasculature.

---

Es kann zusätzlich ein zweites Lumen vorgesehen sein, in das ein Führungsdraht eingeführt wird, mit welchem das Vorschieben des Pumpenschlauches durch das Gefässsystem erleichtert wird.

---

After removal of the guide wire of this second lumen can be used as pressure measuring lumen.

---

Nach Entfernen des Führungsdrahtes kann dieses zweite Lumen als Druckmesslumen verwendet werden.

---

According to a preferred embodiment it is provided that the balloon as annular balloon surrounds the pump hose.

---

Gemäss einer bevorzugten Ausführungsform ist vorgesehen, dass der Ballon als Ringballon den Pumpenschlauch umgibt.

---

This has the advantage that the distal end of the tube has an enlarged outer diameter by the balloon and is thereby held by the pulmonary valve.

---

Dies hat den Vorteil, dass das distale Schlauchende durch den Ballon einen vergrößerten



Aussendurchmesser aufweist, und dadurch von der Pulmonalklappe festgehalten wird.

In this way, the balloon contributes to the anchoring of the hose end to the pulmonary valve, while the hose outlet is located in the pulmonary artery.

---

Auf diese Weise trägt der Ballon zur Verankerung des Schlauchendes an der Pulmonalklappe bei, während sich der Schlauchauslass in der Pulmonalarterie befindet.

This prevents the hose outlet from sliding out of the pulmonary artery.

---

Dadurch wird verhindert, dass der Schlauchauslass aus der Pulmonalarterie herausgleitet.

A further advantage is that the annular balloon has a rounded blunt end of the pump hose forms, so that no injury of the vascular and cardiac walls or other parts of the heart can be induced to the pump hose.

---

Ein weiterer Vorteil besteht darin, dass der Ringballon ein abgerundetes stumpfes Ende des Pumpenschlauches bildet, so dass mit dem Pumpenschlauch keine Verletzung der Gefäss- und Herzwände oder anderer Herzteile hervorgerufen werden können.

Finally, also prevent the hose end is hooked to the flap edge or tendons in the heart.

---

Schliesslich wird auch verhindert, dass das Schlauchende sich am Klappenrand oder an Sehnen im Herzen verhakt.

Since the pump part blood into pumped into the pump hose, the pump tube is held open by itself.

---

Da der Pumpenteil Blut in den Pumpenschlauch hineinpumpt, wird der Pumpenschlauch selbsttätig offengehalten.

Can be used as the pump tube, therefore, a collapsible tube to be used, for example, a film tube, the wall of which is not dimensionally stable.

---

Als Pumpenschlauch kann daher ein kollabierbarer Schlauch benutzt werden, beispielsweise ein Folienschlauch, dessen Wand nicht formstabil ist.

Through this tube through which a catheter can extend to the distal-end balloon.

---

Durch diesen Schlauch hindurch kann ein Katheter zu dem am distalen Ende angeordneten Ballon verlaufen.

With an intracardiac blood pump comprising a flexible tube pump there is a risk that the blood flowing out of the hose outlet in the hose causes a recoil, which can result in a retrograde movement of the tube.

---

Bei einer intrakardialen Blutpumpe mit einem flexiblen Pumpenschlauch besteht die Gefahr, dass das aus dem Schlauchauslass ausströmende Blut am Schlauch einen Rückstoss verursacht, welcher eine retrograde Verschiebung des Schlauchs zur Folge haben kann.

In this way, it can happen that the tube of the pulmonary valve from slipping out.

---

Auf diese Weise kann es geschehen, dass der Schlauch aus der Pulmonalklappe herausgleitet.

The invention therefore solves the further object to provide an intracardiac blood pump can be avoided in the displacements of the tube as a result of hydraulic reaction forces.

---

Der Erfindung löst daher die weitere Aufgabe, eine intrakardiale Blutpumpe zu schaffen, bei der Verschiebungen des Schlauchs infolge von hydraulischen Reaktionskräften vermieden werden.

In the solution of the invention underlying task with the subject matter of claim 13 to the distal end of the tube a traction element is fixed, which is flowing from the pump current.

---

Bei der Lösung der der Erfindung zu Grunde liegenden Aufgabe mit dem Gegenstand des Patentanspruchs 13 ist am distalen Ende des Schlauchs ein Zügelement befestigt, welches von dem Pumpenstrom angeströmt wird.

In this tension member, there may be a sail or a balloon.

---

Bei diesem Zugelement kann es sich um ein Segel handeln oder um einen Ballon.

The exiting from the hose end abuts against the tension member blood flow, thereby the pull-back force of the opposing tube, forward force is produced.

---

Der aus dem Schlauchende austretende Blutstrom stösst gegen das Zugelement, wodurch eine der Rückzugskraft des Schlauch entgegenwirkende, nach vorne gerichtete Kraft entsteht.

In this way the tension member to stabilize the positioning of the pump hose is used.

---

Auf diese Weise dient das Zugelement der Stabilisierung der Positionierung des Pumpenschlauchs.

In the following the invention will be explained in more detail with reference to drawings of exemplary embodiments.

---

Im folgenden werden unter Bezugnahme auf die Zeichnungen Ausführungsbeispiele der Erfindung näher erläutert.

In the drawings:

---

Es zeigen:

Figure 1 is a cross-sectional view of the heart with a blood pump disposed therein,

---

Fig. 1 eine Querschnittsdarstellung des Herzens mit darin angeordneter Blutpumpe,

Figure 2 is a representation of the blood pump of Figure 1,

---

Fig. 2 eine Darstellung der Blutpumpe von Fig. 1,

Figure 3 is a section through the detail III of Figure 2,

---

Fig. 3 einen Schnitt durch die Einzelheit III von Fig. 2,

4 shows a second embodiment of the blood pump,

---

Fig. 4 ein zweites Ausführungsbeispiel der Blutpumpe,

5 shows a third embodiment and

---

Fig. 5 ein drittes Ausführungsbeispiel und

Figure 6 in enlarged scale, a view of the catheter of the embodiment of Figure 5

---

Fig. 6 in vergrössertem Massstab eine Darstellung des Katheters aus dem Ausführungsbeispiel von Fig. 5.

According to Figure 1, the blood pump 10 is an intravascular blood pump, which is a blood pump that can be pushed through the vascular system of a patient in order to penetrate up into the heart.

---

Gemäss Fig. 1 ist die Blutpumpe 10 eine intravasale Blutpumpe, also eine Blutpumpe, die durch das Blutgefässsystem eines Patienten geschoben werden kann, um bis in das Herz hinein vorzudringen.

The outer diameter of such a blood pump is higher than 8 mm at any point.

---

Der Aussendurchmesser einer solchen Blutpumpe ist an keiner Stelle grösser als 8 mm.

The pump 10 has a driving part 11 and a pump portion rigidly connected 12.

---

Die Pumpe 10 weist einen Antriebsteil 11 und einen damit starr verbundenen Pumpenteil 12 auf.

---

The pump for example, corresponds to that of WO 97/37696 so that their internal structure is not discussed here.

---

Die Pumpe entspricht beispielsweise derjenigen von WO 97/37696, so dass ihr interner Aufbau hier nicht näher erläutert wird.

---

In the transition region between the drive part 11 and part 12 suction pumps are 13, is sucked through the blood radially from the outside.

---

Im Übergangsbereich zwischen Antriebsteil 11 und Pumpenteil 12 befinden sich Ansaugöffnungen 13, durch die Blut radial von aussen her angesaugt wird.

---

The pump portion 12 includes a (not shown) impeller which drives the blood in the axial direction.

---

Der Pumpenteil 12 enthält ein (nicht dargestelltes) Flügelrad, das das Blut in axialer Richtung antreibt.

---

At the outlet of the pump part 12, a pump tube 14 is connected.

---

An den Auslass des Pumpenteils 12 ist ein Pumpenschlauch 14 angeschlossen.

---

This has one end connected to the pump outlet proximal end 15 and a distal end 16 of the hose outlet forming properties.

---

Dieser weist ein mit dem Pumpenauslass verbundenes proximales Ende 15 und ein den Schlauchauslass bildendes distales Ende 16 auf.

---

The proximal end of pump 10 is connected to a catheter 17 which includes the electrical supply lines for the drive member 11.

---

Das proximale Ende der Pumpe 10 ist mit einem Katheter 17 verbunden, welcher auch die elektrischen Versorgungsleitungen für den Antriebsteil 11 enthält.

---

Furthermore, the catheter 17 has a lumen in which can be connected to a compressed air source.

---

Ferner weist der Katheter 17 ein Lumen auf, das an eine Druckluftquelle angeschlossen werden kann.

---

The pump tube 14 and catheter 17 are flexible.

---

Der Pumpenschlauch 14 und der Katheter 17 sind flexibel.

---

The rigid length of the pump 10 is not more than 35 mm in order for the pump to pass through bends of the blood vessel system.

---

Die rigide Länge der Pumpe 10 beträgt nicht mehr als 35 mm, damit die Pumpe durch Krümmungen des Blutgefäßsystems hindurchgeht.

---

The length of the pump tube 14 is at least twice as large as the rigid length of the pump.

---

Die Länge des Pumpenschlauchs 14 ist mindestens doppelt so gross wie die rigide Länge der Pumpe.

---

Of the pump hose has a length of about 12 cm and an outer diameter of about 8 mm.

---

Der Pumpenschlauch hat eine Länge von etwa 12 cm und einen Aussendurchmesser von etwa 8 mm.

---

Its thickness is 0.05 mm to 0.2 mm.

---

Seine Wandstärke beträgt 0,05 mm bis 0,2 mm.

---

The radius of curvature of the hose bend is 40 mm to 60 mm.

---

Der Krümmungsradius der Schlauchbiegung beträgt 40 mm bis 60 mm.

1 shows a cross section through the heart 20.

---

In Fig. 1 ist ein Querschnitt durch das Herz 20 dargestellt.

Into the right atrium 21, the inferior vena cava and the superior vena cava 22 open 23

---

In das rechte Atrium 21 münden die untere Hohlvene 22 und die obere Hohlvene 23.

The tricuspid valve is located between the right atrium 25, 21 and the right ventricle 24

---

Zwischen dem rechten Atrium 21 und dem rechten Ventrikel 24 befindet sich die Tricuspidalklappe 25.

The pulmonary valve is located between the right ventricle 27, 24 and 26 of the pulmonary artery

---

Zwischen dem rechten Ventrikel 24 und der Pulmonalarterie 26 befindet sich die Pulmonalklappe 27.

26, the blood from the pulmonary artery to the lungs and from there flows back into the left atrium 28 and left ventricle 29

---

Von der Pulmonalarterie 26 fließt das Blut zur Lunge und von dort zurück in das linke Atrium 28 und zum linken Ventrikel 29.

The aortic valve is located between the left ventricle 31, 29 and aorta 30

---

Zwischen dem linken Ventrikel 29 und der Aorta 30 befindet sich die Aortenklappe 31.

The pump 10 is as right heart pump routed so that it supports from the right atrium into the pulmonary artery 26 into 21.

---

Die Pumpe 10 wird als Rechtsherzpumpe so verlegt, dass sie von dem rechten Atrium 21 in die Pulmonalarterie 26 hinein fördert.

---

For this purpose, it is routed through the superior vena cava 23 in the illustrated embodiment.

---

Hierzu ist sie bei dem dargestellten Ausführungsbeispiel durch die obere Hohlvene 23 hindurch verlegt.

---

It would also be possible to make the transfer through the inferior vena cava 22.

---

Es wäre auch möglich, die Verlegung durch die untere Hohlvene 22 hindurch vorzunehmen.

---

During insertion of the pump 10 of the pump tube 14 is located above the pump, that is, it lies in the flow direction of the blood surrounding the pump downstream from the pump 10

---

Während des Einführens der Pumpe 10 liegt der Pumpenschlauch 14 der Pumpe voran, d. h. er liegt in Strömungsrichtung des die Pumpe umgebenden Blutes stromab von der Pumpe 10.

---

At the distal end 16 of the pump tube 14 is a balloon 35 which is formed here in accordance with Figure 2 and Figure 3 as an annular balloon.

---

Am distalen Ende 16 des Pumpenschlauchs 14 befindet sich ein Ballon 35, der hier gemäss Fig. 2 und Fig. 3 als Ringballon ausgebildet ist.

---

The gas (eg

---

Der mit Gas (z.

---



, Air, helium, CO2) or a fluid inflated balloon 35 has a larger outer diameter than the pump hose 14

---

B. Luft, Helium, CO2) oder einer Flüssigkeit aufgeblähte Ballon 35 hat einen grösseren Aussendurchmesser als der Pumpenschlauch 14.

Thus, the balloon 35 defines a guiding element on which the natural blood flow acts to entrain this guide element.

---

Folglich bildet der Ballon 35 ein Führungselement, an dem der natürliche Blutstrom angreift, um dieses Führungselement mitzuziehen.

Thus, the balloon 35 is flushed on the first natural bloodstream into the right ventricle 24, and then into the pulmonary artery 26.

---

Dadurch wird der Ballon 35 auf dem natürlichen Blutweg zunächst in den rechten Ventrikel 24 und danach in die Pulmonalarterie 26 gespült.

The balloon 35 is inflated characterized in that in a pressure lumen 36 of the pump hose 14, a pressure is generated.

---

Der Ballon 35 wird dadurch aufgebläht, dass in einem Drucklumen 36 des Pumpenschlauchs 14 ein Druck erzeugt wird.

The pressure lumen 36 communicates through openings 37 with the interior of the annular balloon 35.

---

Das Drucklumen 36 steht über Öffnungen 37 mit dem Inneren des ringförmigen Ballons 35 in Verbindung.

In the pump tube 14, the blood flows through the blood lumens 38, whose cross section is substantially larger than that of the pressure lumen 36

---

Im Pumpenschlauch 14 fliesst das Blut durch das Blutlumen 38, dessen Querschnitt wesentlich grösser ist als derjenige des Drucklumens 36.

The pressure lumen 36 is connected to a corresponding pressure lumen of the proximal catheter 17 so that its pressure can be controlled extracorporeally.

---

Das Drucklumen 36 ist an ein entsprechendes Drucklumen des proximalen Katheters 17 angeschlossen, so dass sein Druck extrakorporal gesteuert werden kann.

The pump tube 14 is shown in Figure 2 in a relaxed state.

---

Der Pumpenschlauch 14 ist in Fig. 2 im entspannten Zustand dargestellt.

The pump tube is U-shaped or V-shaped pre-bent, ie, it has a shape memory, so it is not exposed to significant constraint in the heart according to Figure 1 and also in turn exerts no significant constraint on the heart.

---

Der Pumpenschlauch ist U-förmig oder V-förmig vorgebogen, d. h. er hat ein Formgedächtnis, so dass er im Herzen gemäss Fig. 1 keinem wesentlichen Zwang ausgesetzt ist und auch seinerseits keinen wesentlichen Zwang auf das Herz ausübt.

In Figure 2, the density of the dotted area indicates the rigidity of the pump tube 14.

---

In Fig. 2 gibt die Schwärzung des gepunkteten Bereichs die Steifigkeit des Pumpenschlauchs 14 an.

At the proximal end 15 of this rigidity is very big and it shall then steadily toward the distal end 16 from.

---

Am proximalen Ende 15 ist diese Steifigkeit sehr gross und sie nimmt dann stetig zum distalen Ende 16 hin ab.

This means that the distal end 16 to which the balloon is 35 to move freely through the balloon,

and can be carried out.

---

Dies bedeutet, dass das distale Ende 16, an dem sich der Ballon 35 befindet, durch den Ballon frei bewegt und geführt werden kann.

---

As is apparent from Figure 3, the balloon 35 is at the distal end of the end 39 of the pump tube 14 also before, so that the balloon 35 has a rounded end of the tube 40 forms, which does not provide the risk of snagging on obstacles.

---

Wie aus Fig. 3 hervorgeht, steht der Ballon 35 am distalen Ende über das Ende 39 des Pumpenschlauchs 14 hinaus vor, so dass der Ballon 35 ein abgerundetes Schlauchende 40 bildet, welches nicht die Gefahr des Verhakens an Hindernissen bietet.

---

At the proximal end of the balloon 35 that forms an annular undercut 41 in accordance with Figure 1, the tips of the pulmonary valve 27 can penetrate, such that the pulmonary valve prevents retraction of the hose end.

---

An dem proximalen Ende des Ballons 35 bildet dieser eine ringförmige Hinterschneidung 41, in die gemäss Fig. 1 die Spitzen der Pulmonalklappe 27 eindringen können, so dass die Pulmonalklappe ein Zurückweichen des Schlauchendes verhindert.

---

As shown in Figures 2 and 3, the hose outlet 42 spans a traction element 43 in the form of a dome-shaped sail.

---

Wie in den Fig. 2 und 3 dargestellt ist, spannt sich über dem Schlauchauslass 42 ein Zugelement 43 in Form eines kuppelförmigen Segels.

---

This tension member 43 consists of a thin flexible skin, which is fastened by webs 44 to the balloon 35.

---

Dieses Zugelement 43 besteht aus einer dünnen flexiblen Haut, die mit Stegen 44 an dem Ballon 35 befestigt ist.

---

The effluent from the hose outlet 42 blood flows against the tension member 43, thereby exerting on the pump hose 14 from a train, which is opposite to the recoil effect.

---

Das aus dem Schlauchauslass 42 ausströmende Blut strömt gegen das Zugelement 43 und übt somit auf den Pumpenschlauch 14 einen Zug aus, der der Rückstosswirkung entgegengesetzt ist.

---

This prevents the distal end 16 of the pump hose is displaced as a result of the hydraulic recoil and possibly sliding out of the pulmonary valve 27.

---

Dadurch wird verhindert, dass das distale Ende 16 des Pumpenschlauchs sich infolge des hydraulischen Rückstosses verschiebt und evtl. aus der Pulmonalklappe 27 herausgleitet.

---

The pump tube 14 is preferably made of polyurethane, which has proven to be particularly suitable.

---

Der Pumpenschlauch 14 besteht vorzugsweise aus Polyurethan, das sich als besonders geeignet erwiesen hat.

---

In the embodiment of Figure 4, a pump tube 14a is connected to the pump 10, 45 includes a resilient support structure in the form of an existing carbon or metal helical coil.

---

Bei dem Ausführungsbeispiel von Fig. 4 ist an die Pumpe 10 ein Pumpenschlauch 14a angeschlossen, der eine elastische Stützstruktur 45 in Form einer aus Carbon oder Metall bestehenden Schraubenwendel enthält.

---

This supporting structure 45 holding the pump tubing open and effect the desired bending stiffness can also vary over the length of hose.

---

Diese Stützstruktur 45 hält den Pumpenschlauch offen und bewirkt die gewünschte Biegesteifigkeit, die auch über die Schlauchlänge variieren kann.

---

Through the pump hose 45 extends through a catheter 46, which is provided at the distal end with a balloon 35a.

---

Durch den Pumpenschlauch 45 hindurch verläuft ein Katheter 46, der am distalen Ende mit einem Ballon 35a versehen ist.

---

This balloon is the guiding element for the pump tube 14a.

---

Dieser Ballon bildet das Führungselement für den Pumpenschlauch 14a.

---

The catheter 46 includes a pressure lumen.

---

Der Katheter 46 enthält ein Drucklumen.

---

Its outside diameter is considerably smaller than the diameter of the pump tube 14, so that the pump hose cross-section is sufficient for the flow of blood are available.

---

Sein Aussendurchmesser ist wesentlich kleiner als der Durchmesser des Pumpenschlauchs 14a, so dass im Pumpenschlauch genügend Querschnitt für den Blutfluss zur Verfügung steht.

---

The catheter 46 is connected to the catheter 17.

---

Der Katheter 46 ist mit dem Katheter 17 verbunden.

---

A tension member 43a, a ball is disposed at a distance behind the hose outlet 42 and affixed to the catheter 46.

---

Als Zugelement 43a ist eine Kugel im Abstand hinter dem Schlauchauslass 42 angeordnet und am Katheter 46 befestigt.

---

The pressing against the traction element 43a blood flow prevents retraction of the distal end of the tubing 16 to the pump 10

---

Die gegen das Zugelement 43a drückende Blutströmung verhindert ein Zurückweichen des distalen Schlauchendes 16 zur Pumpe 10.

The pump tube 14a is anchored to a retaining device 47 to the tension member 43a.

---

Der Pumpenschlauch 14a ist mit einer Haltevorrichtung 47 an dem Zugelement 43a verankert.

In the embodiment of Figures 5 and 6 of the pump hose is a collapsible pump tubing 14b, which is made of thin sheet material which has no own dimensional stability.

---

Bei dem Ausführungsbeispiel der Fig. 5 und 6 ist der Pumpenschlauch 14b ein kollabierbarer Pumpenschlauch, der aus dünnem Folienmaterial besteht, das keine eigene Formstabilität aufweist.

Through the pump hose 14b extends a catheter 48, which carries at its distal end a balloon 35a.

---

Durch den Pumpenschlauch 14b verläuft ein Katheter 48, der an seinem distalen Ende einen Ballon 35a trägt.

This catheter 48 is connected to the catheter 17.

---

Dieser Katheter 48 ist mit dem Katheter 17 verbunden.

The distal end 16 of the pump hose 14b is connected to the catheter 48 and the pump tube 14b has exit openings 49 for the exit of blood.

---

Das distale Ende 16 des Pumpenschlauchs 14b ist mit dem Katheter 48 verbunden und der Pumpenschlauch 14b weist Austrittsöffnungen 49 für den Bluttaustritt auf.

Upon insertion of the pump according to Figure 5, the pump is not in operation, so that the pump hose 14b is collapsed.

---

Beim Einführen der Pumpe nach Fig. 5 ist die Pumpe nicht in Betrieb, so dass der

Pumpenschlauch 14b kollabiert ist.

By means of the balloon 35a is the soft and flexible catheter 48 installed in the heart, where he positioned the pump tube 14b.

---

Mittels des Ballons 35a wird der weiche und flexible Katheter 48 im Herzen verlegt, wobei er den Pumpenschlauch 14b positioniert.

If then the pump is put into operation, the pump tube 14b is expanded.

---

Wird anschliessend die Pumpe in Betrieb gesetzt, so wird der Pumpenschlauch 14b aufgeweitet.

To facilitate the placement of the catheter a further lumen 48 may as shown in FIG 6 in addition to the pressure lumen leading to the balloon 35a, 49 50, which method is intended for receiving a guide wire 51, and after removal of the guide wire to the external pressure measurement.

---

Zur Erleichterung der Plazierung kann der Katheter 48 gemäss Fig. 6 ausser dem zum Ballon 35a führenden Drucklumen 49 ein weiteres Lumen 50 enthalten, das zur Aufnahme eines Führungsdrahtes 51 und nach Entfernen des Führungsdrahtes zur externen Druckmessung bestimmt ist.

This guide wire 51, which also passes through the catheter 17 and the pump 10, allowing the operator to influence the laying of the pump hose controlling.

---

Dieser Führungsdraht 51, der auch durch den Katheter 17 und die Pumpe 10 hindurchgeht, ermöglicht es dem Operateur, die Verlegung des Pumpenschlauchs steuernd zu beeinflussen.

Thereafter, the guide wire 51 is drawn out.

---

Danach wird der Führungsdraht 51 herausgezogen.

According to Figure 6 may be provided on the catheter 48 has an opening 52 which is connected to the lumen 50 and is blocked by the guide wire 51.

---

Gemäss Fig. 6 kann an dem Katheter 48 eine Öffnung 52 vorgesehen sein, die mit dem Lumen 50 verbunden ist und die durch den Führungsdraht 51 versperrt wird.

---

After the guidewire 51 is pulled out of the lumen 50, passes through the opening 52 into the lumen of the blood 50.

---

Nachdem der Führungsdraht 51 aus dem Lumen 50 herausgezogen ist, dringt durch die Öffnung 52 Blut in das Lumen 50 ein.

---

The lumen 50 can be connected to a blood pressure monitor, so as to measure the blood pressure in the pulmonary artery during pumping and, if necessary, to be able to influence.

---

Das Lumen 50 kann mit einem Blutdruckmesser verbunden werden, um somit den Blutdruck in der Pulmonalarterie während des Pumpens zu messen und ggf. beeinflussen zu können.

---

If the placement of the pump tube without a guide wire, it can be measured with the aid of the pressure variations in the measurable other lumen 50 of the pressure at the point 52.

---

Erfolgt die Platzierung des Pumpenschlauches ohne Führungsdraht, so kann mit Hilfe der messbaren Druckverläufe im weiteren Lumen 50 der Druck an der Stelle 52 gemessen werden.

---

Can so the exact position of the distal tip of the pump hose are determined from the pressure gradients.

---

Aus den Druckverläufen kann so die genaue Position der distalen Pumpenschlauchspitze ermittelt werden.

---

The diameter of the balloon should not be so great that it significantly impedes the flow through the pulmonary artery, the pulmonary artery 26 or even shut off.



---

Der Durchmesser des Ballons darf nicht so gross sein, dass er den Durchfluss durch die Pulmonalarterie 26 wesentlich behindert oder die Pulmonalarterie sogar absperrt.

In general, the diameter must not be larger than 30 mm.

---

In der Regel darf der Durchmesser nicht grösser sein als 30 mm.

Further, the balloon should have a high elasticity, in contrast to a dilatation balloon.

---

Ferner sollte der Ballon eine hohe Elastizität haben, im Unterschied zu einem Dilatationsballon.

As balloon material are due to the elastic properties of silicone, latex, and preferably polyurethane.

---

Als Ballonmaterial eignen sich wegen der Elastizitätseigenschaften Silikon, Latex, und vorzugsweise Polyurethan.

The balloon may, while it floats as a guide element for the catheter tube in the blood stream, to be strong inflated with high pressure and are then reduced by reducing the pressure to act as a pulling element, which is flown by the pump flow.

---

Der Ballon kann, während er als Führungselement für den Katheterschlauch im Blutstrom floatet, mit hohem Druck stark aufgebläht sein und anschliessend durch Verringerung des Druckes verkleinert werden, um als Zuelement zu wirken, das von der Pumpenströmung angeströmt wird.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
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| (51) Internationale Patentklassifikation <sup>6</sup> :<br><b>A61M 1/10, 25/01</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>A1</b> | (11) Internationale Veröffentlichungsnummer: <b>WO 99/58170</b><br>(43) Internationales<br>Veröffentlichungsdatum: 18. November 1999 (18.11.99)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <p>(21) Internationales Aktenzeichen: PCT/EP99/02790</p> <p>(22) Internationales Anmeldedatum: 24. April 1999 (24.04.99)</p> <p>(30) Prioritätsdaten:<br/>198 21 307.7 13. Mai 1998 (13.05.98) DE</p> <p>(71) Anmelder (für alle Bestimmungsstaaten ausser US): IMPELLA CARDIOTECHNIK AKTIENGESELLSCHAFT [DE/DE]; Pauwelsstrasse 19, D-52074 Aachen (DE).</p> <p>(72) Erfinder; und<br/>(75) Erfinder/Anmelder (nur für US): SAMMLER, Rolf [DE/DE]; Peiekskamp 13, D-59348 Lüdinghausen (DE). SIESS, Thorsten [DE/DE]; Kirchenstrasse 8, D-52146 Würselen (DE). NIX, Christoph [DE/DE]; Schmithoferstrasse 245, D-52076 Aachen (DE). EISEN, Max [DE/DE]; Kellenstrasse 14, D-52074 Aachen (DE). HUTZENLAUB, Jens, Peter [DE/DE]; Habsburger Allee 31, D-52064 Aachen (DE). MEYNS, Bart [BE/BE]; University of Leuven, UZ Gasthuisberg, Herestraße 49, B-3000 Leuven (BE).</p> <p>(74) Anwälte: SELTING, Günther usw.; Deichmannhaus am Dom, Bahnhofsvorplatz 1, D-50667 Köln (DE).</p> |           | <p>(81) Bestimmungsstaaten: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO Patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), eurasisches Patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), europäisches Patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI Patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p><b>Veröffentlicht</b><br/><i>Mit internationalem Recherchenbericht.<br/>Vor Ablauf der für Änderungen der Ansprüche zugelassenen Frist; Veröffentlichung wird wiederholt falls Änderungen eintreffen.</i></p> |

(54) Title: INTRACARDIAC BLOOD PUMP

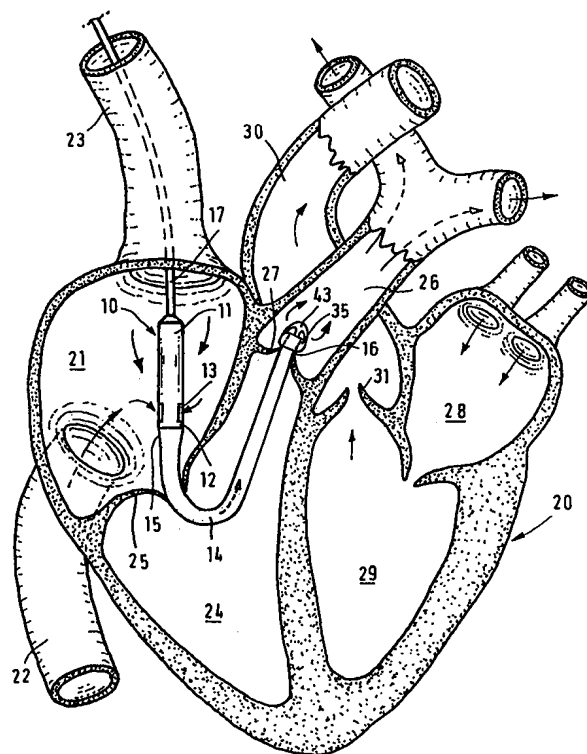
(54) Bezeichnung: INTRAKARDIALE BLUTPUMPE

## (57) Abstract

The intracardiac pump (10) comprises a drive section (11) and a pump section (12). Flexible tubing (14) is connected to the pump section (12). A balloon (35) is provided on the distal end of the tubing (14) in order to displace said tubing (14) from the right atrium (21) to the pulmonary artery (26). The balloon acts as a guiding element in the bloodstream and is driven by natural blood flow, thus facilitating placement of the blood pump in the heart.

## (57) Zusammenfassung

Die intrakardiale Blutpumpe (10) weist einen Antriebsteil (11) und einen Pumpenteil (12) auf. An den Pumpenteil (12) ist ein flexibler Pumpenschlauch (14) angeschlossen. Um den Pumpenschlauch (14) von dem rechten Atrium (21) zur Pulmonalarterie (26) zu verlegen, ist am distalen Ende des Pumpenschlauchs (14) ein Ballon (35) vorgesehen, der als Führungselement im Blutstrom wirkt und von der natürlichen Blutströmung mitgenommen wird. Dadurch wird die Platzierung der Blutpumpe im Herzen vereinfacht.



### **LEDIGLICH ZUR INFORMATION**

Codes zur Identifizierung von PCT-Vertragsstaaten auf den Kopfbögen der Schriften, die internationale Anmeldungen gemäss dem PCT veröffentlichen.

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| EE | Estland                      |    |                                   |    |                                                 |    |                                |

### Intrakardiale Blutpumpe

Die Erfindung betrifft eine intrakardiale Blutpumpe, und insbesondere eine Blutpumpe, die vollständig in das Herz über angrenzende Gefäße eingeführt werden kann, um die natürliche Pumpfunktion des Herzens zu unterstützen oder durch kontinuierlichen Pumpbetrieb zu ersetzen.

Eine Pumpvorrichtung zur Herzunterstützung ist beschrieben in WO94/09835 (Jarvik). Diese Pumpvorrichtung weist voneinander unabhängige Pumpen auf, die jeweils aus einem Pumpenteil und einem starr damit verbundenen Antriebsteil bestehen. Der Pumpenteil der einen Pumpe wird durch eine apekale Operationsöffnung hindurch derart in den linken Ventrikel eingeführt, daß er aus dem linken Ventrikel heraus in die Aorta fördert. Der andere Pumpenteil wird durch eine weitere, vorzugsweise apekale, Operationsöffnung hindurch in den rechten Ventrikel so eingeführt, daß er aus dem rechten Atrium in die Pulmonalarterie hineinfördert. Die Pumpen sind jeweils an ihrem

Pumpenauslaß mit einer schlauchförmigen Auslaßkanüle verlängert, die durch die jeweilige Herzklappe hindurchgeführt werden kann.

Eine intrakardiale Blutpumpe, die von der Aorta durch die Aortenklappe hindurch in den linken Ventrikel eingeführt wird, ist bekannt aus WO97/37696 (Rau et al.). Hierbei ist der Pumpeneinlaß durch einen Schlauch verlängert, welcher durch die Aortenklappe hindurchgeht.

Aus WO97/37697 (Rau et al.) ist eine intravasale Blutpumpe bekannt, die durch ein Blutgefäß hindurchgeschoben werden kann. Auch diese Blutpumpe ist an ihrem Einlassende durch einen Ansaugschlauch verlängert. Dieser Ansaugschlauch trägt einen aufblasbaren Ballon, welcher als Sperrvorrichtung dient, um einen seitlich an dem Ansaugschlauch vorbeiführenden Blutfluß zu verhindern.

Schließlich ist aus US-Patent 4 753 221 (Kensey et al.) ein Pumpenkatheter bekannt, der eine im Herzen zu platzierende Pumpe aufweist. Diese Pumpe besteht aus einem Flügelrad und einem das Flügelrad umgebenden Pumpengehäuse. Das Pumpengehäuse kann im kollabierten Zustand im Herzen plaziert und anschließend durch Aufblasen eines mit dem Pumpengehäuse verbundenen Ballons aufgefaltet werden.

Ferner sind zu diagnostischen Zwecken kleinlumige Katheter zur Druck- und Volumenstromerfassung bekannt, die am distalen Katheterende einen aufblasbaren Ballon aufweisen. Dieser Ballon wird zur Platzierung der Katheterspitze in der Pulmonalarterie verwendet.

Bei intrakardialen Blutpumpen, die durch ein Blutgefäß hindurch in das Herz eingeführt werden, besteht die Schwierigkeit der korrekten Platzierung der Blutpumpe im Herzen. Insbesondere wenn

die Blutpumpe durch die obere Hohlvene hindurch eingeführt wird, um Blut von dem rechten Atrium in die Pulmonalarterie zu pumpen, ist die korrekte Platzierung der Blutpumpe schwierig, weil die Pumpe eine Umlenkung um nahezu 180° durchführen muß, damit die Ansaugöffnung im rechten Atrium und die Auslaßöffnung in der Pulmonalarterie liegt. Hinzu kommt, daß in dem rechten Ventrikel zahlreiche Fäden und Sehnen vorhanden sind, die die Tricuspidalklappe festhalten und die Segel der Klappe gegen Durchschlagen sichern und die Formstabilität des Herzens gewährleisten. Zwischen solchen Sehnen und Fäden hindurch muß eine Blutpumpe, die durch eine Hohlvene hindurch eingeführt wird, geführt werden.

Der Erfindung liegt die Aufgabe zugrunde, eine intrakardiale Blutpumpe zu schaffen, die relativ leicht im Herzen plaziert werden kann.

Die Lösung dieser Aufgabe erfolgt erfindungsgemäß mit den im Patentanspruch 1 angegebenen Merkmalen.

Bei der erfindungsgemäßen Blutpumpe ist an den Pumpenauslaß ein flexibler Schlauch angesetzt, dessen distales Ende einen als Führungselement im Blutstrom wirkenden Ballon aufweist. Die Erfindung nutzt den Umstand aus, daß der natürliche Blutstrom im Herzen von der Hohlvene aus in das rechte Atrium durch den rechten Ventrikel hindurch in die Pulmonalarterie führt. Die Blutpumpe, die am distalen Ende des Schlauchs mit einem Ballon versehen ist, wird entlang eben dieses Weges eingeführt, wobei der in dem Blutstrom treibende Ballon automatisch seinen Weg von dem rechten Atrium in die Pulmonalarterie findet. Der Schlauchauslaß wird anschließend in der Pulmonalarterie stabilisiert, während der Pumpenteil sich im rechten Atrium befindet. Der Pumpenschlauch erfährt dabei eine Biegung von

annähernd 180°. Auf diese Weise gelingt es, die Blutpumpe einschließlich des Pumpenschlauchs korrekt im Herzen zu plazieren, ohne daß ein abtastendes Anstoßen des Schlauchauslasses an den Herzkammerwänden erfolgen müßte, oder diagnostische Hilfsmittel (Röntgen oder Ultraschall) benötigt werden.

Intrakardial im Sinne der vorliegenden Erfindung umfaßt die Herzkammern (Ventrikel), die Vorhöfe und die angrenzenden Gefäßstümpfe.

Es ist zweckmäßig, wenn der Pumpenschlauch entsprechend seiner endgültigen Lage, die er im Herzen einnimmt, vorgebogen ist. Dies erfordert eine Biegung um mindestens etwa 150°. Zwar muß der Pumpenschlauch, um durch die Hohlvene hindurch eingeführt zu werden, gestreckt werden können, jedoch sollte er im entspannten Zustand eine U-Form oder V-Form annehmen. Besonders vorteilhaft ist es, wenn der Pumpenschlauch eine Biegesteifigkeit hat, die vom proximalen Ende zum distalen Ende hin abnimmt. Auf diese Weise kann das distale Ende als Wegfinder leicht bewegt werden, so daß der Ballon der natürlichen Blutströmung besser folgen kann.

Der Ballon muß nicht notwendigerweise direkt an dem Pumpenschlauch angebracht sein. Er kann auch an einem Katheter befestigt sein, der Bestandteil des Pumpenschlauchs ist und innen oder außen durch diesen hindurch verläuft. In jedem Fall muß zu dem Ballon ein Lumen verlaufen, durch das der Ballon aufgeblasen werden kann. Es kann zusätzlich ein zweites Lumen vorgesehen sein, in das ein Führungsdraht eingeführt wird, mit welchem das Verschieben des Pumpenschlauches durch das Gefäßsystem erleichtert wird. Nach Entfernen des Führungsdrahtes kann dieses zweite Lumen als Druckmeßlumen verwendet werden.

Gemäß einer bevorzugten Ausführungsform ist vorgesehen, daß der Ballon als Ringballon den Pumpenschlauch umgibt. Dies hat den Vorteil, daß das distale Schlauchende durch den Ballon einen vergrößerten Außendurchmesser aufweist, und dadurch von der Pulmonalklappe festgehalten wird. Auf diese Weise trägt der Ballon zur Verankerung des Schlauchendes an der Pulmonalklappe bei, während sich der Schlauchauslaß in der Pulmonalarterie befindet. Dadurch wird verhindert, daß der Schlauchauslaß aus der Pulmonalarterie herausgleitet. Ein weiterer Vorteil besteht darin, daß der Ringballon ein abgerundetes stumpfes Ende des Pumpenschlauches bildet, so daß mit dem Pumpenschlauch keine Verletzung der Gefäß- und Herzwände oder anderer Herzteile hervorgerufen werden können. Schließlich wird auch verhindert, daß das Schlauchende sich am Klappenrand oder an Sehnen im Herzen verhakt.

Da der Pumpenteil Blut in den Pumpenschlauch hineinpumpt, wird der Pumpenschlauch selbsttätig offengehalten. Als Pumpenschlauch kann daher ein kollabierbarer Schlauch benutzt werden, beispielsweise ein Folienschlauch, dessen Wand nicht formstabil ist. Durch diesen Schlauch hindurch kann ein Katheter zu dem am distalen Ende angeordneten Ballon verlaufen.

Bei einer intrakardialen Blutpumpe mit einem flexiblen Pumpenschlauch besteht die Gefahr, daß das aus dem Schlauchauslaß ausströmende Blut am Schlauch einen Rückstoß verursacht, welcher eine retrograde Verschiebung des Schlauchs zur Folge haben kann. Auf diese Weise kann es geschehen, daß der Schlauch aus der Pulmonalklappe herausgleitet. Der Erfindung liegt daher die weitere Aufgabe zugrunde, eine intrakardiale Blutpumpe zu schaffen, bei der Verschiebungen des Schlauchs infolge von hydraulischen Reaktionskräften vermieden werden.



Die Lösung dieser Aufgabe erfolgt erfindungsgemäß mit den Merkmalen des Patentanspruchs 13. Hiernach ist am distalen Ende des Schlauchs ein Zugelement befestigt, welches von dem Pumpenstrom angeströmt wird. Bei diesem Zugelement kann es sich um ein Segel handeln oder um einen Ballon. Der aus dem Schlauchende austretende Blutstrom stößt gegen das Zugelement, wodurch eine der Rückzugskraft des Schlauch entgegenwirkende, nach vorne gerichtete Kraft entsteht. Auf diese Weise dient das Zugelement der Stabilisierung der Positionierung des Pumpenschlauchs.

Im folgenden werden unter Bezugnahme auf die Zeichnungen Ausführungsbeispiele der Erfindung näher erläutert.

Es zeigen:

- Fig. 1 eine Querschnittsdarstellung des Herzens mit darin angeordneter Blutpumpe,
- Fig. 2 eine Darstellung der Blutpumpe von Fig. 1,
- Fig. 3 einen Schnitt durch die Einzelheit III von Fig. 2,
- Fig. 4 ein zweites Ausführungsbeispiel der Blutpumpe,
- Fig. 5 ein drittes Ausführungsbeispiel und
- Fig. 6 in vergrößertem Maßstab eine Darstellung des Katheters aus dem Ausführungsbeispiel von Fig. 5.

Gemäß Fig. 1 ist die Blutpumpe 10 eine intravasale Blutpumpe, also eine Blutpumpe, die durch das Blutgefäßsystem eines Patienten geschoben werden kann, um bis in das Herz hinein

vorzudringen. Der Außendurchmesser einer solchen Blutpumpe ist an keiner Stelle größer als 8 mm. Die Pumpe 10 weist einen Antriebsteil 11 und einen damit starr verbundenen Pumpenteil 12 auf. Die Pumpe entspricht beispielsweise derjenigen von WO97/37696, so daß ihr interner Aufbau hier nicht näher erläutert wird. Im Übergangsbereich zwischen Antriebsteil 11 und Pumpenteil 12 befinden sich Ansaugöffnungen 13, durch die Blut radial von außen her angesaugt wird. Der Pumpenteil 12 enthält ein (nicht dargestelltes) Flügelrad, das das Blut in axialer Richtung antreibt. An den Auslaß des Pumpenteils 12 ist ein Pumpenschlauch 14 angeschlossen. Dieser weist ein mit dem Pumpenauslaß verbundenes proximales Ende 15 und ein den Schlauchauslaß bildendes distales Ende 16 auf.

Das proximale Ende der Pumpe 10 ist mit einem Katheter 17 verbunden, welcher auch die elektrischen Versorgungsleitungen für den Antriebsteil 11 enthält. Ferner weist der Katheter 17 ein Lumen auf, das an eine Druckluftquelle angeschlossen werden kann.

Der Pumpenschlauch 14 und der Katheter 17 sind flexibel. Die rigide Länge der Pumpe 10 beträgt nicht mehr als 35 mm, damit die Pumpe durch Krümmungen des Blutgefäßsystems hindurchgeht. Die Länge des Pumpenschlauchs 14 ist mindestens doppelt so groß wie die rigide Länge der Pumpe. Der Pumpenschlauch hat eine Länge von etwa 12 cm und einen Außendurchmesser von etwa 8 mm. Seine Wandstärke beträgt 0,05 mm bis 0,2 mm. Der Krümmungsradius der Schlauchbiegung beträgt 40 mm bis 60 mm.

In Fig. 1 ist ein Querschnitt durch das Herz 20 dargestellt. In das rechte Atrium 21 münden die untere Hohlvene 22 und die obere Hohlvene 23. Zwischen dem rechten Atrium 21 und dem rechten Ventrikel 24 befindet sich die Tricuspidalklappe 25. Zwischen dem rechten Ventrikel 24 und der Pulmonalarterie 26 befindet

sich die Pulmonalklappe 27. Von der Pulmonalarterie 26 fließt das Blut zur Lunge und von dort zurück in das linke Atrium 28 und zum linken Ventrikel 29. Zwischen dem linken Ventrikel 29 und der Aorta 30 befindet sich die Aortenklappe 31.

Die Pumpe 10 wird als Rechtsherzpumpe so verlegt, daß sie von dem rechten Atrium 21 in die Pulmonalarterie 26 hinein fördert. Hierzu ist sie bei dem dargestellten Ausführungsbeispiel durch die obere Hohlvene 23 hindurch verlegt. Es wäre auch möglich, die Verlegung durch die untere Hohlvene 22 hindurch vorzunehmen. Während des Einführens der Pumpe 10 liegt der Pumpenschlauch 14 der Pumpe voran, d.h. er liegt in Strömungsrichtung des die Pumpe umgebenden Blutes stromab von der Pumpe 10.

Am distalen Ende 16 des Pumpenschlauchs 14 befindet sich ein Ballon 35, der hier gemäß Fig. 2 und Fig. 3 als Ringballon ausgebildet ist. Der mit Gas (z.B. Luft, Helium, CO<sub>2</sub>) oder einer Flüssigkeit aufgeblähte Ballon 35 hat einen größeren Außendurchmesser als der Pumpenschlauch 14. Folglich bildet der Ballon 35 ein Führungselement, an dem der natürliche Blutstrom angreift, um dieses Führungselement mitzuziehen. Dadurch wird der Ballon 35 auf dem natürlichen Blutweg zunächst in den rechten Ventrikel 24 und danach in die Pulmonalarterie 26 gespült.

Der Ballon 35 wird dadurch aufgebläht, daß in einem Drucklumen 36 des Pumpenschlauchs 14 ein Druck erzeugt wird. Das Drucklumen 36 steht über Öffnungen 37 mit dem Inneren des ringförmigen Ballons 35 in Verbindung. Im Pumpenschlauch 14 fließt das Blut durch das Blutlumen 38, dessen Querschnitt wesentlich größer ist als derjenige des Drucklumens 36. Das Drucklumen 36 ist an ein entsprechendes Drucklumen des proximalen Katheters 17 angeschlossen, so daß sein Druck extrakorporal gesteuert werden kann.

Der Pumpenschlauch 14 ist in Fig. 2 im entspannten Zustand dargestellt. Der Pumpenschlauch ist U-förmig oder V-förmig vorgebogen, d.h. er hat ein Formgedächtnis, so daß er im Herzen gemäß Fig. 1 keinem wesentlichen Zwang ausgesetzt ist und auch seinerseits keinen wesentlichen Zwang auf das Herz ausübt. In Fig. 2 gibt die Schwärzung des gepunkteten Bereichs die Steifigkeit des Pumpenschlauchs 14 an. Am proximalen Ende 15 ist diese Steifigkeit sehr groß und sie nimmt dann stetig zum distalen Ende 16 hin ab. Dies bedeutet, daß das distale Ende 16, an dem sich der Ballon 35 befindet, durch den Ballon frei bewegt und geführt werden kann.

Wie aus Fig. 3 hervorgeht, steht der Ballon 35 am distalen Ende über das Ende 39 des Pumpenschlauchs 14 hinaus vor, so daß der Ballon 35 ein abgerundetes Schlauchende 40 bildet, welches nicht die Gefahr des Verhakens an Hindernissen bietet. An dem proximalen Ende des Ballons 35 bildet dieser eine ringförmige Hinterschneidung 41, in die gemäß Fig. 1 die Spitzen der Pulmonalklappe 27 eindringen können, so daß die Pulmonalklappe ein Zurückweichen des Schlauchendes verhindert.

Wie in den Fign. 2 und 3 dargestellt ist, spannt sich über dem Schlauchauslaß 42 ein Zugelement 43 in Form eines kuppelförmigen Segels. Dieses Zugelement 43 besteht aus einer dünnen flexiblen Haut, die mit Stegen 44 an dem Ballon 35 befestigt ist. Das aus dem Schlauchauslaß 42 ausströmende Blut strömt gegen das Zugelement 43 und übt somit auf den Pumpenschlauch 14 einen Zug aus, der der Rückstoßwirkung entgegengesetzt ist. Dadurch wird verhindert, daß das distale Ende 16 des Pumpenschlauchs sich infolge des hydraulischen Rückstoßes verschiebt und evtl. aus der Pulmonalklappe 27 herausgleitet.

Der Pumpenschlauch 14 besteht vorzugsweise aus Polyurethan, das sich als besonders geeignet erwiesen hat.

Bei dem Ausführungsbeispiel von Fig. 4 ist an die Pumpe 10 ein Pumpenschlauch 14a angeschlossen, der eine elastische Stützstruktur 45 in Form einer aus Carbon oder Metall bestehenden Schraubenwendel enthält. Diese Stützstruktur 45 hält den Pumpenschlauch offen und bewirkt die gewünschte Biegesteifigkeit, die auch über die Schlauchlänge variieren kann. Durch den Pumpenschlauch 45 hindurch verläuft ein Katheter 46, der am distalen Ende mit einem Ballon 35a versehen ist. Dieser Ballon bildet das Führungselement für den Pumpenschlauch 14a. Der Katheter 46 enthält ein Drucklumen. Sein Außendurchmesser ist wesentlich kleiner als der Durchmesser des Pumpenschlauchs 14a, so daß im Pumpenschlauch genügend Querschnitt für den Blutfluß zur Verfügung steht. Der Katheter 46 ist mit dem Katheter 17 verbunden.

Als Zugelement 43a ist eine Kugel im Abstand hinter dem Schlauchauslaß 42 angeordnet und am Katheter 46 befestigt. Die gegen das Zugelement 43a drückende Blutströmung verhindert ein Zurückweichen des distalen Schlauchendes 16 zur Pumpe 10. Der Pumpenschlauch 14a ist mit einer Haltevorrichtung 47 an dem Zugelement 43a verankert.

Bei dem Ausführungsbeispiel der Fign. 5 und 6 ist der Pumpenschlauch 14b ein kollabierbarer Pumpenschlauch, der aus dünnem Folienmaterial besteht, das keine eigene Formstabilität aufweist. Durch den Pumpenschlauch 14b verläuft ein Katheter 48, der an seinem distalen Ende einen Ballon 35a trägt. Dieser Katheter 48 ist mit dem Katheter 17 verbunden. Das distale Ende 16 des Pumpenschlauchs 14b ist mit dem Katheter 48 verbunden und der Pumpenschlauch 14b weist Austrittsöffnungen 49 für den Blutaustritt auf. Beim Einführen der Pumpe nach Fig. 5 ist die

Pumpe nicht in Betrieb, so daß der Pumpenschlauch 14b kollabiert ist. Mittels des Ballons 35a wird der weiche und flexible Katheter 48 im Herzen verlegt, wobei er den Pumpenschlauch 14b positioniert. Wird anschließend die Pumpe in Betrieb gesetzt, so wird der Pumpenschlauch 14b aufgeweitet.

Zur Erleichterung der Plazierung kann der Katheter 36,36,48 gemäß Fig. 6 außer dem zum Ballon 35a führenden Drucklumen 49 ein weiteres Lumen 50 enthalten, das zur Aufnahme eines Führungsdrahtes 51 und nach Entfernen des Führungsdrahtes zur externen Druckmessung bestimmt ist. Dieser Führungsdraht 51, der auch durch den Katheter 17 und die Pumpe 10 hindurchgeht, ermöglicht es dem Operateur, die Verlegung des Pumpenschlauchs steuernd zu beeinflussen. Danach wird der Führungsdraht 51 herausgezogen.

Gemäß Fig. 6 kann an dem Katheter 48 eine Öffnung 52 vorgesehen sein, die mit dem Lumen 50 verbunden ist und die durch den Führungsdraht 51 versperrt wird. Nachdem der Führungsdraht 51 aus dem Lumen 50 herausgezogen ist, dringt durch die Öffnung 52 Blut in das Lumen 50 ein. Das Lumen 50 kann mit einem Blutdruckmesser verbunden werden, um somit den Blutdruck in der Pulmonalarterie während des Pumpens zu messen und ggf. beeinflussen zu können.

Erfolgt die Plazierung des Pumpenschlauches ohne Führungsdraht, so kann mit Hilfe der meßbaren Druckverläufe im weiteren Lumen 50 der Druck an der Stelle 52 gemessen werden. Aus den Druckverläufen kann so die genaue Position der distalen Pumpenschlauchspitze ermittelt werden.

Der Durchmesser des Ballons darf nicht so groß sein, daß er den Durchfluß durch die Pulmonalarterie 26 wesentlich behindert oder die Pulmonalarterie sogar absperrt. In der Regel darf der

Durchmesser nicht größer sein als 30 mm. Ferner sollte der Ballon eine hohe Elastizität haben, im Unterschied zu einem Dilatationsballon. Als Ballonmaterial eignen sich wegen der Elastizitätseigenschaften Silikon, Latex, und vorzugsweise Polyurethan.

Der Ballon kann, während er als Führungselement für den Katheterschlauch im Blutstrom floatet, mit hohem Druck stark aufgebläht sein und anschließend durch Verringerung des Druckes verkleinert werden, um als Zugelement zu wirken, das von der Pumpenströmung angeströmt wird.

**PATENTANSPRÜCHE**

1. Intrakardiale Blutpumpe, mit einem radial ansaugenden und axial fördernden Pumpenteil (11), der mit einem Katheter (17) verbunden ist, und einem mit dem Pumpenauslaß verbundenen flexiblen Pumpenschlauch (14), welcher ein an den Pumpenauslaß angrenzendes proximales Ende (15) und ein den Schlauchauslaß bildendes distales Ende (16) aufweist,  
  
d a d u r c h   g e k e n n z e i c h n e t ,  
  
daß der Pumpenschlauch (14) nahe seinem distalen Ende einen von dem Blutstrom mitnehmbaren, als Führungselement wirkenden Ballon (35) aufweist.
2. Blutpumpe nach Anspruch 1, dadurch gekennzeichnet, daß der Pumpenschlauch um mehr als 100°, vorzugsweise um etwa 150°, vorgebogen ist.
3. Blutpumpe nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß der Pumpenschlauch (14) eine Biegesteifigkeit hat, die vom proximalen Ende (15) zum distalen Ende (16) hin abnimmt.
4. Blutpumpe nach einem der Ansprüche 1-3, dadurch gekennzeichnet, daß der Pumpenschlauch (14) innen oder außen einen Katheter (46;48) aufweist, der das distale Ende (16) des Pumpenschlauchs überragt und jenseits des distalen Endes den Ballon (35a) trägt.
5. Blutpumpe nach einem der Ansprüche 1-3, dadurch gekennzeichnet, daß der Ballon (35) als Ringballon den Pumpenschlauch (14) umgibt.



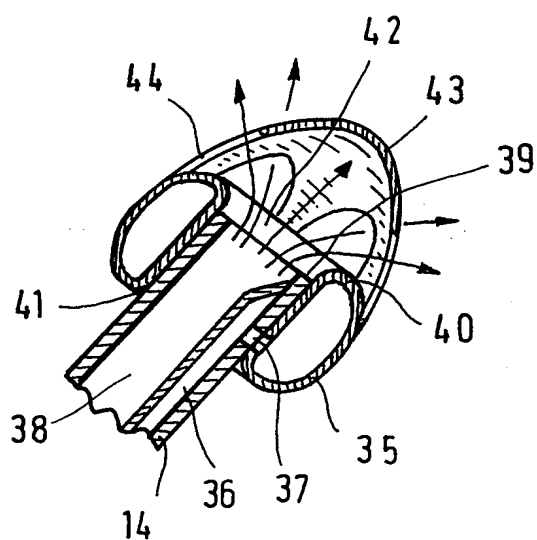
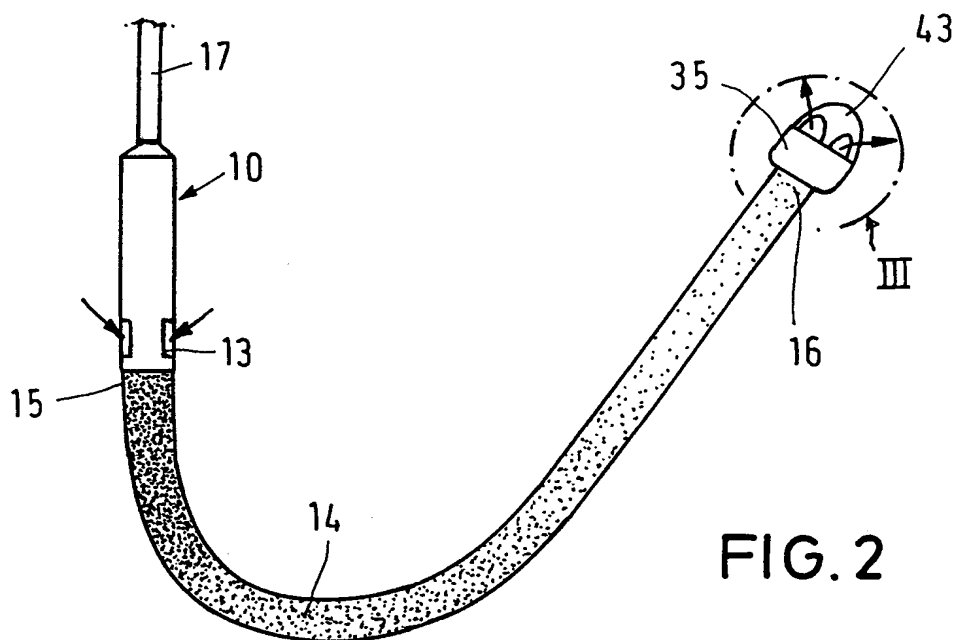
6. Blutpumpe nach Anspruch 5, dadurch gekennzeichnet, daß der Ringballon eine abgerundete Schlauchspitze (40) bildet.
7. Blutpumpe nach einem der Ansprüche 1-6, dadurch gekennzeichnet, daß der Pumpenschlauch (14b) ein kollabierbarer Schlauch ist.
8. Blutpumpe nach einem der Ansprüche 1-7, dadurch gekennzeichnet, daß der Pumpenschlauch (14a) eine elastische Stützstruktur (45) enthält.
9. Blutpumpe nach einem der Ansprüche 1-8, dadurch gekennzeichnet, daß der Pumpenschlauch (14b) einen Katheter (48) aufweist, daß ein in den Katheter (48) einführbarer Führungsdraht (51) vorgesehen ist.
10. Blutpumpe nach einem der Ansprüche 1-9, dadurch gekennzeichnet, daß der Katheter (48) ein Lumen (50) für den Führungsdraht (51) und ein Drucklumen (49) aufweist.
11. Blutpumpe nach einem der Ansprüche 1-10, dadurch gekennzeichnet, daß der Katheter (48) ein als Druckmeßlumen benutzbares Lumen (50) aufweist.
12. Blutpumpe nach einem der Ansprüche 1-11, dadurch gekennzeichnet, daß der Durchmesser des Ballons im aufgeblähten Zustand nicht größer ist als 30 mm.
13. Intrakardiale Blutpumpe, mit einem radial ansaugenden und axial fördernden Pumpenteil (11), der mit einem Katheter (17) verbunden ist, und einem mit dem Pumpenauslaß verbundenen flexiblen Pumpenschlauch (14), welcher ein an den Pumpenauslaß angrenzendes proximales Ende (15) und ein

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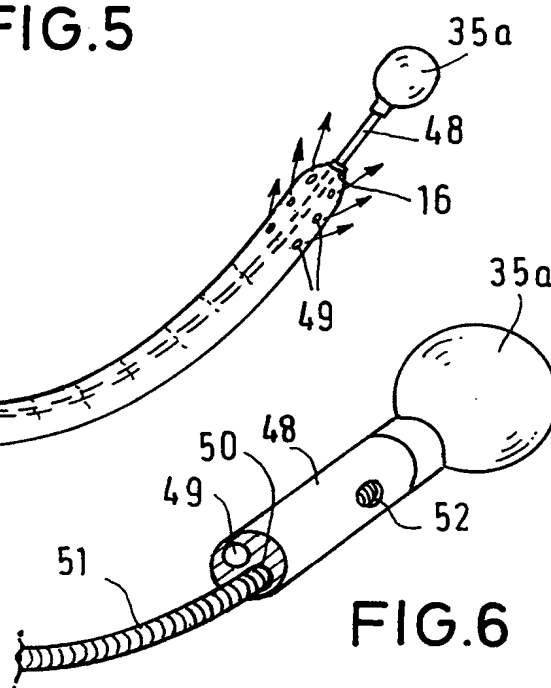
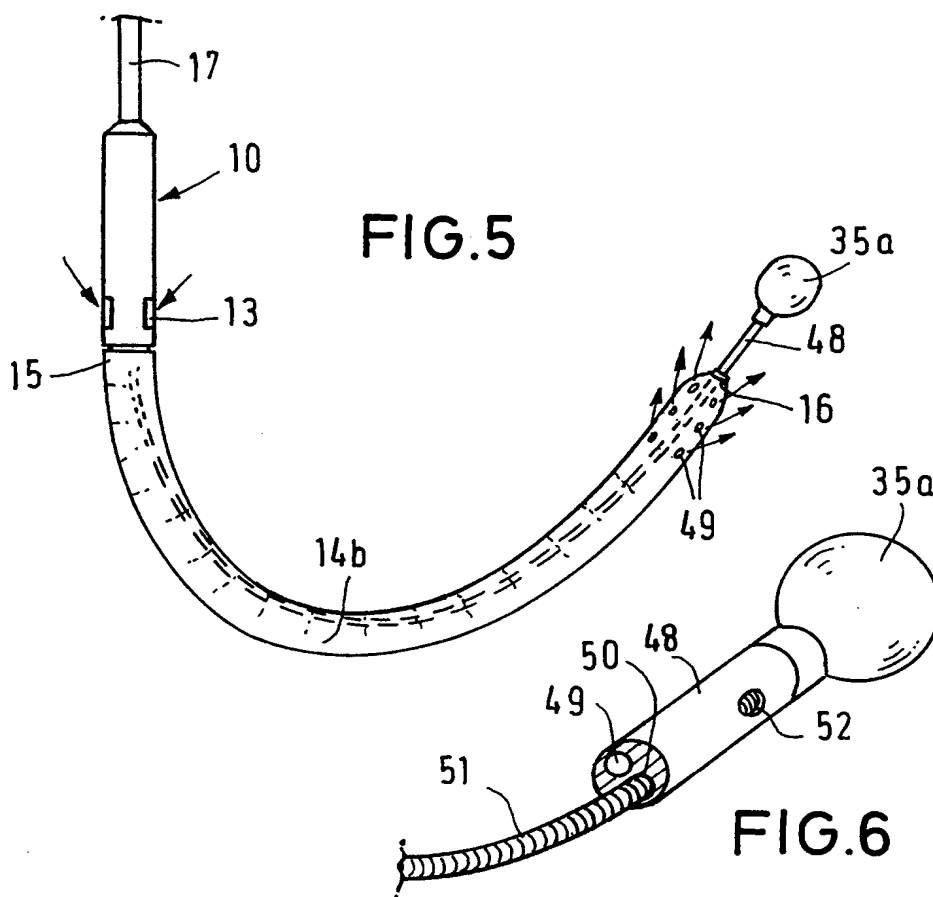
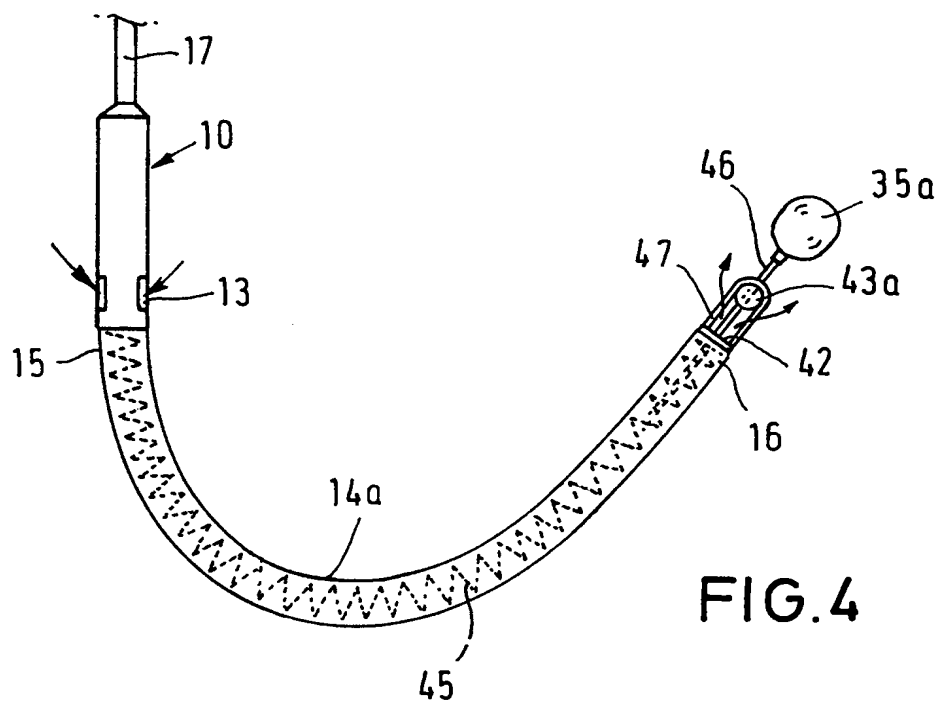
den Schlauchauslaß bildendes distales Ende (16) aufweist, dadurch gekennzeichnet, daß an dem distalen Ende (16) des Pumpenschlauchs (14) ein von dem Pumpenstrom angeströmtes Zuelement (43) befestigt ist.



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# INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 99/02790

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61M1/10 A61M25/01

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages                                                                                                                                                                         | Relevant to claim No. |
|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| X          | NAKATANI T ET AL: "IN VITRO AND IN VIVO ASSESSMENT OF AN INTRAVENOUS AXIAL FLOW PUMP FOR RIGHT HEART ASSIST" ASAIO JOURNAL, vol. 40, no. 3, 1 July 1994 (1994-07-01), pages 723-727, XP000498263 ISSN: 1058-2916 page 723, column 2, paragraph 2; figure 2 | 1,2,4,8               |
| A          | ---                                                                                                                                                                                                                                                        | 13                    |
| X          | DE 196 22 335 A (VÖLKER) 11 December 1997 (1997-12-11) column 1, line 42 - column 2, line 33 column 3, line 2 - column 4, line 19 figures 1-3<br>---<br>-/--                                                                                               | 1,5,9                 |

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### ° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

30 August 1999

Date of mailing of the international search report

07/09/1999

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# INTERNATIONAL SEARCH REPORT

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document, with indication, where appropriate, of the relevant passages                                                                             | Relevant to claim No. |
|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Y        | <p>WO 94 09835 A (JARVIK)<br/> 11 May 1994 (1994-05-11)<br/> cited in the application<br/> page 14, line 34 - page 16, line 9<br/> figures 8,10</p> <p>---</p> | 1,5                   |
| Y        | <p>US 3 995 623 A (BLAKE ET AL.)<br/> 7 December 1976 (1976-12-07)<br/> column 1, line 51 - column 2, line 19<br/> figures 1,3</p> <p>---</p>                  | 1,5                   |
| A        | <p>DE 298 04 046 U (SCHMITZ-RODE)<br/> 30 April 1998 (1998-04-30)<br/> page 3, line 11 - line 18</p> <p>-----</p>                                              | 7,8                   |

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International application No.

PCT EP99/02790

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See supplemental sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.  
☐ No protest accompanied the payment of additional search fees.



## ADDITIONAL MATTER PCT/ISA/210

The International Searching Authority found that this international application contains multiple inventions, as follows:

## 1. Claims Nos. 1-12

Intracardiac blood pump comprising a balloon that is arranged on the flexible pump tube and can be driven along by the bloodstream in addition to acting as a guiding element.

## 2. Claim No. 13:

Intercardiac blood pump comprising a traction element that is arranged on the flexible pump tube and whereby the flow of the pump flows against said traction element.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP 99/02790

| Patent document<br>cited in search report | Publication<br>date | Patent family<br>member(s)                                                                                                                                                                                | Publication<br>date                                                                                                                                                                |
|-------------------------------------------|---------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| DE 19622335 A                             | 11-12-1997          | CA 2257356 A<br>WO 9746270 A<br>EP 0902690 A                                                                                                                                                              | 11-12-1997<br>11-12-1997<br>24-03-1999                                                                                                                                             |
| WO 9409835 A                              | 11-05-1994          | US 5376114 A<br>AU 683994 B<br>AU 1770395 A<br>AU 678697 B<br>AU 1770495 A<br>AU 678411 B<br>AU 5363594 A<br>CA 2147616 A<br>EP 0746344 A<br>JP 8504621 T<br>US 5776190 A<br>US 5755784 A<br>US 5888241 A | 27-12-1994<br>27-11-1997<br>29-06-1995<br>05-06-1997<br>29-06-1995<br>29-05-1997<br>24-05-1994<br>11-05-1994<br>11-12-1996<br>21-05-1996<br>07-07-1998<br>26-05-1998<br>30-03-1994 |
| US 3995623 A                              | 07-12-1976          | NONE                                                                                                                                                                                                      |                                                                                                                                                                                    |
| DE 29804046 U                             | 30-04-1998          | NONE                                                                                                                                                                                                      |                                                                                                                                                                                    |

# INTERNATIONALER RECHERCHENBERICHT

Internationale Aktenzeichen

PCT/EP 99/02790

**A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES**  
IPK 6 A61M1/10 A61M25/01

Nach der Internationalen Patentklassifikation (IPK) oder nach der nationalen Klassifikation und der IPK

## B. RESEARCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)  
IPK 6 A61M

Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)

## C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

| Kategorie* | Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile                                                                                                                                                                          | Betr. Anspruch Nr. |
|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| X          | NAKATANI T ET AL: "IN VITRO AND IN VIVO ASSESSMENT OF AN INTRAVENOUS AXIAL FLOW PUMP FOR RIGHT HEART ASSIST"<br>ASAIO JOURNAL,<br>Bd. 40, Nr. 3, 1. Juli 1994 (1994-07-01),<br>Seiten 723-727, XP000498263<br>ISSN: 1058-2916<br>Seite 723, Spalte 2, Absatz 2; Abbildung 2 | 1,2,4,8            |
| A          | ---                                                                                                                                                                                                                                                                         | 13                 |
| X          | DE 196 22 335 A (VÖLKER)<br>11. Dezember 1997 (1997-12-11)<br>Spalte 1, Zeile 42 - Spalte 2, Zeile 33<br>Spalte 3, Zeile 2 - Spalte 4, Zeile 19<br>Abbildungen 1-3<br>---<br>-/-                                                                                            | 1,5,9              |

☒ Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen

☒ Siehe Anhang Patentfamilie

\* Besondere Kategorien von angegebenen Veröffentlichungen :

"A" Veröffentlichung, die den allgemeinen Stand der Technik definiert, aber nicht als besonders bedeutsam anzusehen ist

"E" älteres Dokument, das jedoch erst am oder nach dem internationalen Anmeldedatum veröffentlicht worden ist

"L" Veröffentlichung, die geeignet ist, einen Prioritätsanspruch zweifelhaft erscheinen zu lassen, oder durch die das Veröffentlichungsdatum einer anderen im Recherchenbericht genannten Veröffentlichung belegt werden soll oder die aus einem anderen besonderen Grund angegeben ist (wie ausgeführt)

"O" Veröffentlichung, die sich auf eine mündliche Offenbarung, eine Benutzung, eine Ausstellung oder andere Maßnahmen bezieht

"P" Veröffentlichung, die vor dem internationalen Anmeldedatum, aber nach dem beanspruchten Prioritätsdatum veröffentlicht worden ist

"T" Spätere Veröffentlichung, die nach dem internationalen Anmeldedatum oder dem Prioritätsdatum veröffentlicht worden ist und mit der Anmeldung nicht kollidiert, sondern nur zum Verständnis des der Erfindung zugrundeliegenden Prinzips oder der ihr zugrundeliegenden Theorie angegeben ist

"X" Veröffentlichung von besonderer Bedeutung; die beanspruchte Erfindung kann allein aufgrund dieser Veröffentlichung nicht als neu oder auf erfinderischer Tätigkeit beruhend betrachtet werden

"Y" Veröffentlichung von besonderer Bedeutung; die beanspruchte Erfindung kann nicht als auf erfinderischer Tätigkeit beruhend betrachtet werden, wenn die Veröffentlichung mit einer oder mehreren anderen Veröffentlichungen dieser Kategorie in Verbindung gebracht wird und diese Verbindung für einen Fachmann naheliegend ist

"&" Veröffentlichung, die Mitglied derselben Patentfamilie ist

Datum des Abschlusses der internationalen Recherche

30. August 1999

Absenddatum des internationalen Recherchenberichts

07/09/1999

Name und Postanschrift der Internationalen Recherchenbehörde  
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Bevollmächtigter Bediensteter

Schönleben, J

# INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen

PCT/EP 99/02790

## C.(Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

| Kategorie | Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile                                                    | Betr. Anspruch Nr. |
|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Y         | WO 94 09835 A (JARVIK)<br>11. Mai 1994 (1994-05-11)<br>in der Anmeldung erwähnt<br>Seite 14, Zeile 34 - Seite 16, Zeile 9<br>Abbildungen 8,10<br>---- | 1,5                |
| Y         | US 3 995 623 A (BLAKE ET AL.)<br>7. Dezember 1976 (1976-12-07)<br>Spalte 1, Zeile 51 - Spalte 2, Zeile 19<br>Abbildungen 1,3<br>----                  | 1,5                |
| A         | DE 298 04 046 U (SCHMITZ-RODE)<br>30. April 1998 (1998-04-30)<br>Seite 3, Zeile 11 - Zeile 18<br>-----                                                | 7,8                |

# INTERNATIONALER RECHERCHENBERICHT

internationales Aktenzeichen

PCT/EP 99/ 02790

Feld I Bemerkungen zu den Ansprüchen, die sich als nicht recherchierbar erwiesen haben (Fortsetzung von Punkt 2 auf Blatt 1)

Gemäß Artikel 17(2)a) wurde aus folgenden Gründen für bestimmte Ansprüche kein Recherchenbericht erstellt:

1. ☐ Ansprüche Nr.  
weil sie sich auf Gegenstände beziehen, zu deren Recherche die Behörde nicht verpflichtet ist, nämlich
  
2. ☐ Ansprüche Nr.  
weil sie sich auf Teile der internationalen Anmeldung beziehen, die den vorgeschriebenen Anforderungen so wenig entsprechen, daß eine sinnvolle internationale Recherche nicht durchgeführt werden kann, nämlich
  
3. ☐ Ansprüche Nr.  
weil es sich dabei um abhängige Ansprüche handelt, die nicht entsprechend Satz 2 und 3 der Regel 6.4 a) abgefaßt sind.

Feld II Bemerkungen bei mangelnder Einheitlichkeit der Erfindung (Fortsetzung von Punkt 3 auf Blatt 1)

Die internationale Recherchenbehörde hat festgestellt, daß diese internationale Anmeldung mehrere Erfindungen enthält:

SIEHE ANHANG

1. ☐ Da der Anmelder alle erforderlichen zusätzlichen Recherchegebühren rechtzeitig entrichtet hat, erstreckt sich dieser internationale Recherchenbericht auf alle recherchierbaren Ansprüche.
  
2. ☒ Da für alle recherchierbaren Ansprüche die Recherche ohne einen Arbeitsaufwand durchgeführt werden konnte, der eine zusätzliche Recherchegebühr gerechtfertigt hätte, hat die Behörde nicht zur Zahlung einer solchen Gebühr aufgefordert.
  
3. ☐ Da der Anmelder nur einige der erforderlichen zusätzlichen Recherchegebühren rechtzeitig entrichtet hat, erstreckt sich dieser internationale Recherchenbericht nur auf die Ansprüche, für die Gebühren entrichtet worden sind, nämlich auf die Ansprüche Nr.
  
4. ☐ Der Anmelder hat die erforderlichen zusätzlichen Recherchegebühren nicht rechtzeitig entrichtet. Der internationale Recherchenbericht beschränkt sich daher auf die in den Ansprüchen zuerst erwähnte Erfindung; diese ist in folgenden Ansprüchen erfaßt:

**Bemerkungen hinsichtlich eines Widerspruchs**

- ☐ Die zusätzlichen Gebühren wurden vom Anmelder unter Widerspruch gezahlt.
- ☐ Die Zahlung zusätzlicher Recherchegebühren erfolgte ohne Widerspruch.

## WEITERE ANGABEN

PCT/ISA/ 210

Die Internationale Recherchenbehörde hat festgestellt, dass diese internationale Anmeldung mehrere (Gruppen von) Erfindungen enthält, nämlich:

## 1. Ansprüche: 1-12

Intrakardiale Blutpumpe mit einem am Pumpenschlauch angeordneten, von Blutstrom mitnehmbaren und als Führungselement wirkenden Ballon

## 2. Anspruch : 13

Intrakardiale Blutpumpe mit einem am Pumpenschlauch angeordneten, vom Pumpenstrom angeströmten Zugelement

# INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

Internationales Aktenzeichen

PCT/EP 99/02790

| Im Recherchenbericht<br>angeführtes Patentdokument | Datum der<br>Veröffentlichung | Mitglied(er) der<br>Patentfamilie | Datum der<br>Veröffentlichung |
|----------------------------------------------------|-------------------------------|-----------------------------------|-------------------------------|
| DE 19622335 A                                      | 11-12-1997                    | CA 2257356 A                      | 11-12-1997                    |
|                                                    |                               | WO 9746270 A                      | 11-12-1997                    |
|                                                    |                               | EP 0902690 A                      | 24-03-1999                    |
| WO 9409835 A                                       | 11-05-1994                    | US 5376114 A                      | 27-12-1994                    |
|                                                    |                               | AU 683994 B                       | 27-11-1997                    |
|                                                    |                               | AU 1770395 A                      | 29-06-1995                    |
|                                                    |                               | AU 678697 B                       | 05-06-1997                    |
|                                                    |                               | AU 1770495 A                      | 29-06-1995                    |
|                                                    |                               | AU 678411 B                       | 29-05-1997                    |
|                                                    |                               | AU 5363594 A                      | 24-05-1994                    |
|                                                    |                               | CA 2147616 A                      | 11-05-1994                    |
|                                                    |                               | EP 0746344 A                      | 11-12-1996                    |
|                                                    |                               | JP 8504621 T                      | 21-05-1996                    |
|                                                    |                               | US 5776190 A                      | 07-07-1998                    |
|                                                    |                               | US 5755784 A                      | 26-05-1998                    |
|                                                    |                               | US 5888241 A                      | 30-03-1994                    |
| US 3995623 A                                       | 07-12-1976                    | KEINE                             |                               |
| DE 29804046 U                                      | 30-04-1998                    | KEINE                             |                               |

## Notice

This translation is machine-generated. It cannot be guaranteed that it is intelligible, accurate, complete, reliable or fit for specific purposes. Critical decisions, such as commercially relevant or financial decisions, should not be based on machine-translation output.

## CLAIMS WO9958170

### CLAIMS 1

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#### PATENTANSPRÜCHE 1.

Intracardiac blood pump comprising a radially aspirated and axially delivering pump portion (11) connected to a catheter (17) is connected, and connected to the pump outlet flexible pump hose (14) having an adjacent to the pump outlet proximal end (15) and a the hose outlet forming distal end (16), characterized in that the pump tube (14) near its distal end be carried along one of the blood flow and acting as guide element balloon (35).

---

Intrakardiale Blutpumpe, mit einem radial ansaugenden und axial fördernden Pumpenteil (11), der mit einem Katheter (17) verbunden ist, und einem mit dem Pumpenauslass verbundenen flexiblen Pumpenschlauch (14), welcher ein an den Pumpenauslass angrenzendes proximales Ende (15) und ein den Schlauchauslass bildendes distales Ende (16) aufweist, dadurch gekennzeichnet, dass der Pumpenschlauch (14) nahe seinem distalen Ende einen von dem Blutstrom mitnehmbaren, als Führungselement wirkenden Ballon (35) aufweist.

2.

The blood pump according to claim 1, characterized in that the

---



Blutpumpe nach Anspruch 1, dadurch gekennzeichnet, dass der

Pump hose is more than 100, preferably to about 150, pre-bent.

---

Pumpenschlauch um mehr als 100 , vorzugsweise um etwa 150 , vorgebogen ist.

3.

The blood pump according to claim 1 or 2, characterized in that the pump hose (14) has a bending stiffness from the proximal end (15) to the distal end (16) decreases towards.

---

Blutpumpe nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass der Pumpenschlauch (14) eine Biegesteifigkeit hat, die vom proximalen Ende (15) zum distalen Ende (16) hin abnimmt.

4.

The blood pump of one of claims 1-3, characterized in that the pump hose (14) inside or outside of a catheter (46, 48), the distal

---

Blutpumpe nach einem der Ansprüche 1-3, dadurch gekennzeichnet, dass der Pumpenschlauch (14) innen oder aussen einen Katheter (46 ; 48) aufweist, der das distale

End (16) of the pump hose extends beyond both sides of the distal end of the balloon (35a) bears.

---

Ende (16) des Pumpenschlauchs überragt und jenseits des distalen Endes den Ballon (35a) trägt.

5.

The blood pump of one of claims 1-3, characterized in that the balloon (35) as an annular balloon to the

---

Blutpumpe nach einem der Ansprüche 1-3, dadurch gekennzeichnet, dass der Ballon (35) als Ringballon den

Pump tube (14) surrounding it.

---

Pumpenschlauch (14) umgibt.

6

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6.

The blood pump according to claim 5, characterized in that the

---

Blutpumpe nach Anspruch 5, dadurch gekennzeichnet, dass der

Ring balloon a rounded tube tip (40).

---

Ringballon eine abgerundete Schlauchspitze (40) bildet.

7.

The blood pump of one of claims 1-6, characterized in that the pump hose (14b) is a collapsible hose.

---

Blutpumpe nach einem der Ansprüche 1-6, dadurch gekennzeichnet, dass der Pumpenschlauch (14b) ein kollabierbarer Schlauch ist.

8.

The blood pump of one of claims 1-7, characterized in that the pump hose (14a) contains an

elastic supporting structure (45).

---

Blutpumpe nach einem der Ansprüche 1-7, dadurch gekennzeichnet, dass der Pumpenschlauch (14a) eine elastische Stützstruktur (45) enthält.

9.

Blood pump according to any one of claims 1-8, in that the pump hose (14b) comprises a

---

Blutpumpe nach einem der Ansprüche 1-8, dadurch gekennzeichnet, dass der Pumpenschlauch (14b) einen

The catheter (48), in that in the catheter (48) insertable guide wire (51) is provided.

---

Katheter (48) aufweist, dass ein in den Katheter (48) einführbarer Führungsdraht (51) vorgesehen ist.

10.

The blood pump of one of claims 1-9, characterized in that the catheter (48) having a lumen (50) for the guide wire (51) and a pressure lumen (49).

---

Blutpumpe nach einem der Ansprüche 1-9, dadurch gekennzeichnet, dass der Katheter (48) ein Lumen (50) für den Führungsdraht (51) und ein Drucklumen (49) aufweist.

11.

The blood pump of one of claims 1-10, characterized in that the catheter (48) as

---

Blutpumpe nach einem der Ansprüche 1-10, dadurch gekennzeichnet, dass der Katheter (48) ein als

Comprises pressure measurement lumen usable lumen (50).

---

Druckmesslumen benutzbares Lumen (50) aufweist.

12.

The blood pump according to any one of claims 1-11, characterized in that the diameter of the balloon in the inflated state is not greater than 30 mm.

---

Blutpumpe nach einem der Ansprüche 1-11, dadurch gekennzeichnet, dass der Durchmesser des Ballons im aufgeblähten Zustand nicht grösser ist als 30 mm.

13.

Intracardiac blood pump comprising a radially aspirated and axially delivering pump portion (11) connected to a catheter (17) is connected, and connected to the pump outlet flexible pump hose (14) having an adjacent to the pump outlet proximal end (15) and a the hose outlet forming distal end (16), characterized in that at the distal end (16) of the pump hose (14) is flowed through by the pump current traction element (43) is attached.

---

Intrakardiale Blutpumpe, mit einem radial ansaugenden und axial fördernden Pumpenteil (11), der mit einem Katheter (17) verbunden ist, und einem mit dem Pumpenauslass verbundenen flexiblen Pumpenschlauch (14), welcher ein an den Pumpenauslass angrenzendes proximales Ende (15) und ein den Schlauchauslass bildendes distales Ende (16) aufweist, dadurch gekennzeichnet, dass an dem distalen Ende (16) des Pumpenschlauchs (14) ein von dem Pumpenstrom angeströmtes Zugelement (43) befestigt ist.

## Notice

This translation is machine-generated. It cannot be guaranteed that it is intelligible, accurate, complete, reliable or fit for specific purposes. Critical decisions, such as commercially relevant or financial decisions, should not be based on machine-translation output.

## DESCRIPTION WO9958170

Intracardiac blood pump The invention relates to an intracardiac blood pump, and more particularly to a blood pump which can be completely inserted into the heart through adjacent blood vessels, to support or replace the continuous pumping the natural pumping action of the heart.

---

Intrakardiale Blutpumpe Die Erfindung betrifft eine intrakardiale Blutpumpe, und insbesondere eine Blutpumpe, die vollständig in das Herz über angrenzende Gefäße eingeführt werden kann, um die natürliche Pumpfunktion des Herzens zu unterstützen oder durch kontinuierlichen Pumpbetrieb zu ersetzen.

A pumping apparatus for cardiac support is described in W094/09835 (Jarvik).

---

Eine Pumpvorrichtung zur Herzunterstützung ist beschrieben in W094/09835 (Jarvik).

This pumping device includes spaced independent pumps, each of which consists of a pump part and a drive member rigidly connected thereto.

---

Diese Pumpvorrichtung weist voneinander unabhängige Pumpen auf, die jeweils aus einem Pumpenteil und einem starr damit verbundenen Antriebsteil bestehen.

The pump portion of a pump through such inserted through a surgical opening apical into the left ventricle, that it promotes out from the left ventricle into the aorta.

---

Der Pumpenteil der einen Pumpe wird durch eine apekale Operationsöffnung hindurch derart in den linken Ventrikel eingeführt, dass er aus dem linken Ventrikel heraus in die Aorta fördert.

The other pump part is passed as introduced by another, preferably apecal, surgical opening into the right ventricle, that he promotes in from the right atrium into the pulmonary artery.

---

Der andere Pumpenteil wird durch eine weitere, vorzugsweise apekale, Operationsöffnung hindurch in den rechten Ventrikel so eingeführt, dass er aus dem rechten Atrium in die Pulmonalarterie hineinfördert.

The pumps are each extended at its pump outlet with a tubular outflow cannula, which can pass through the respective valve.

---

Die Pumpen sind jeweils an ihrem Pumpenauslass mit einer schlauchförmigen Auslasskanüle verlängert, die durch die jeweilige Herzklappe hindurchgeführt werden kann.

An intracardiac blood pump which is inserted from the aorta through the aortic valve and into the left ventricle, is known from W097/37696 (Rau et al.).

---

Eine intrakardiale Blutpumpe, die von der Aorta durch die Aortenklappe hindurch in den linken Ventrikel eingeführt wird, ist bekannt aus W097/37696 (Rau et al.).

Here, the pump inlet is extended by a tube which passes through the aortic valve.

---

Hierbei ist der Pumpeneinlass durch einen Schlauch verlängert, welcher durch die Aortenklappe hindurchgeht.

From W097/37697 (Rau et al.) An intravascular blood pump is known, which can be inserted through a blood vessel.

---

Aus W097/37697 (Rau et al.) ist eine intravasale Blutpumpe bekannt, die durch ein Blutgefäss hindurchgeschoben werden kann.

These blood pump is extended at its inlet end by a suction hose.

---

Auch diese Blutpumpe ist an ihrem Einlassende durch einen Ansaugschlauch verlängert.

This suction tube carries an inflatable balloon, which is used as a blocking device to prevent the side leading to the suction tube by blood flow.

---

Dieser Ansaugschlauch trägt einen aufblasbaren Ballon, welcher als Sperrvorrichtung dient, um einen seitlich an dem Ansaugschlauch vorbeiführenden Blutfluss zu verhindern.

Finally, from U.S. Patent 4,753,221 (Kensey et al.) A catheter pump is known which has a pump to be placed in the heart.

---

Schliesslich ist aus US-Patent 4 753 221 (Kensey et al.) ein Pumpenkatheter bekannt, der eine im Herzen zu plazierende Pumpe aufweist.

This pump consists of an impeller and a pump housing surrounding the impeller.

---

Diese Pumpe besteht aus einem Flügelrad und einem das Flügelrad umgebenden Pumpengehäuse.

The pump casing can be placed in the collapsed state in the heart, and then unfolded by inflation of a balloon attached to the pump housing.

---

Das Pumpengehäuse kann im kollabierten Zustand im Herzen plaziert und anschliessend durch Aufblasen eines mit dem Pumpengehäuse verbundenen Ballons aufgefaltet werden.

Furthermore, small-lumen catheter for pressure and flow rate measurement are known for diagnostic purposes that have an inflatable balloon at the distal end of the catheter.

---

Ferner sind zu diagnostischen Zwecken kleinlumige Katheter zur Druck-und Volumenstromerfassung bekannt, die am distalen Katheterende einen aufblasbaren Ballon aufweisen.

This balloon is used for placement of the catheter tip in the pulmonary artery.

---

Dieser Ballon wird zur Plazierung der Katheterspitze in der Pulmonalarterie verwendet.

Wherein the intracardiac blood pumps, which are inserted through a blood vessel and into the heart, there is the problem of the correct positioning of the blood pump in the heart.

---

Bei intrakardialen Blutpumpen, die durch ein Blutgefäß hindurch in das Herz eingeführt werden, besteht die Schwierigkeit der korrekten Plazierung der Blutpumpe im Herzen.

In particular, when the blood pump is inserted through the superior vena cava through in order to pump blood from the right atrium into the pulmonary artery, the correct placement of the blood pump is difficult because the pump has to perform a deflection of almost 180, so that the suction opening in the right atrium and the outlet opening in the pulmonary artery lies.

---

Insbesondere wenn die Blutpumpe durch die obere Hohlvene hindurch eingeführt wird, um Blut von dem rechten Atrium in die Pulmonalarterie zu pumpen, ist die korrekte Plazierung der Blutpumpe schwierig, weil die Pumpe eine Umlenkung um nahezu 180 durchführen muss, damit die Ansaugöffnung im rechten Atrium und die Auslassöffnung in der Pulmonalarterie liegt.

In addition, in the right ventricle numerous threads and tendons are present, hold the tricuspid valve and secure the sails of the flap against strike-through and ensure the dimensional stability of the heart.

---

Hinzu kommt, dass in dem rechten Ventrikel zahlreiche Fäden und Sehnen vorhanden sind, die die Tricuspidalklappe festhalten und die Segel der Klappe gegen Durchschlagen sichern und die Formstabilität des Herzens gewährleisten.

Among such tendons and yarns must be guided through a blood pump is inserted through a vena cava through.

---

Zwischen solchen Sehnen und Fäden hindurch muss eine Blutpumpe, die durch eine Hohlvene hindurch eingeführt wird, geführt werden.

The invention has for its object to provide an intracardiac blood pump that can relatively easily be placed in the heart.

---

Der Erfindung liegt die Aufgabe zugrunde, eine intrakardiale Blutpumpe zu schaffen, die relativ



leicht im Herzen plaziert werden kann.

The solution of this task is carried out according to the invention with the features specified in claim 1.

---

Die Lösung dieser Aufgabe erfolgt erfindungsgemäss mit den im Patentanspruch 1 angegebenen Merkmalen.

In the inventive blood pump, a flexible hose is attached to the pump outlet, the distal end having a guide element which acts as a balloon in the bloodstream.

---

Bei der erfindungsgemässen Blutpumpe ist an den Pumpenauslass ein flexibler Schlauch angesetzt, dessen distales Ende einen als Führungselement im Blutstrom wirkenden Ballon aufweist.

The invention utilizes the fact that the natural blood flow in the vena cava of the heart passes into the right atrium through the right ventricle into the pulmonary artery.

---

Die Erfindung nutzt den Umstand aus, dass der natürliche Blutstrom im Herzen von der Hohlvene aus in das rechte Atrium durch den rechten Ventrikel hindurch in die Pulmonalarterie führt.

The blood pump that is provided at the distal end of the tube with a balloon, is inserted along this same path, wherein the driving in the bloodstream of the balloon will automatically find its way from the right atrium into the pulmonary artery.

---

Die Blutpumpe, die am distalen Ende des Schlauchs mit einem Ballon versehen ist, wird entlang eben dieses Weges eingeführt, wobei der in dem Blutstrom treibende Ballon automatisch seinen Weg von dem rechten Atrium in die Pulmonalarterie findet.

The hose outlet is then stabilized in the pulmonary artery, while the pump part is located in the right atrium.

---

Der Schlauchauslass wird anschliessend in der Pulmonalarterie stabilisiert, während der Pumpenteil sich im rechten Atrium befindet.

The pump hose experiences a deflection of approximately 180th

---

Der Pumpenschlauch erfährt dabei eine Biegung von annähernd 180 .

In this way it is possible, including placing the blood pump of the pump hose at the heart correctly, without a scanning abutment of Schlauchauslasses should be made to the ventricular walls, or diagnostic tools (X-ray or ultrasound) are required.

---

Auf diese Weise gelingt es, die Blutpumpe ein- schliesslich des Pumpenschlauchs korrekt im Herzen zu plazieren, ohne dass ein abtastendes Anstossen des Schlauchauslasses an den Herzkammerwänden erfolgen müsste, oder diagnostische Hilfsmittel (Röntgen oder Ultraschall) benötigt werden.

Intracardially in accordance with the present invention, the chambers of the heart (ventricle), the atria and the adjacent vessel stumps.

---

Intrakardial im Sinne der vorliegenden Erfindung umfasst die Herzkammern (Ventrikel), die Vorhöfe und die angrenzenden Gefässstümpfe.

It is expedient if the pump hose is according to its final position which it occupies in the heart, prebent.

---

Es ist zweckmässig, wenn der Pumpenschlauch entsprechend seiner endgültigen Lage, die er im Herzen einnimmt, vorgebogen ist.

This requires a deflection of at least approximately 150 bar.

---

Dies erfordert eine Biegung um mindestens etwa 150 .

Although the pump tube has to be inserted through the vena cava, through, can be stretched, but it should take on a U-shape or V-shape in the relaxed state.

---

Zwar muss der Pumpenschlauch, um durch die Hohlvene hindurch eingeführt zu werden, gestreckt werden können, jedoch sollte er im entspannten Zustand eine U-Form oder V-Form annehmen.

There, if the pump hose has a flexural rigidity that decreases from the proximal end toward the distal end is particularly advantageous.

---

Besonders vorteilhaft ist es, wenn der Pumpenschlauch eine Biegesteifigkeit hat, die vom proximalen Ende zum distalen Ende hin abnimmt.

In this way, the distal end can be moved easily as pathfinder, so that the balloon of the natural blood flow can better follow.

---

Auf diese Weise kann das distale Ende als Wegfinder leicht bewegt werden, so dass der Ballon der natürlichen Blutströmung besser folgen kann.

The balloon must not necessarily be attached directly to the pump hose.

---

Der Ballon muss nicht notwendigerweise direkt an dem Pumpenschlauch angebracht sein.

It can also be attached to a catheter that is an integral part of the pump hose and runs inside or outside therethrough.

---

Er kann auch an einem Katheter befestigt sein, der Bestandteil des Pumpenschlauchs ist und innen oder aussen durch diesen hindurch verläuft.

In each case, the balloon has a lumen extending through the balloon can be inflated.

---

In jedem Fall muss zu dem Ballon ein Lumen verlaufen, durch das der Ballon aufgeblasen werden kann.

There may also be provided a second lumen into which a guide wire is inserted, with which the advance of the pump hose easier through the vasculature.

---

Es kann zusätzlich ein zweites Lumen vorgesehen sein, in das ein Führungsdraht eingeführt wird, mit welchem das Verschieben des Pumpenschlauches durch das Gefäßsystem erleichtert wird.

After removal of the guide wire of this second lumen can be used as pressure measuring lumen.

---

Nach Entfernen des Führungsdrahtes kann dieses zweite Lumen als Druckmesslumen verwendet werden.

According to a preferred embodiment it is provided that the balloon as annular balloon surrounds the pump hose.

---

Gemäss einer bevorzugten Ausführungsform ist vorgesehen, dass der Ballon als Ringballon den Pumpenschlauch umgibt.

This has the advantage that the distal end of the tube has an enlarged outer diameter by the balloon and is thereby held by the pulmonary valve.

---

Dies hat den Vorteil, dass das distale Schlauchende durch den Ballon einen vergrößerten Aussendurchmesser aufweist, und dadurch von der Pulmonalklappe festgehalten wird.

In this way, the balloon contributes to the anchoring of the hose end to the pulmonary valve, while the hose outlet is located in the pulmonary artery.

---

Auf diese Weise trägt der Ballon zur Verankerung des Schlauchendes an der Pulmonalklappe bei, während sich der Schlauchauslass in der Pulmonalarterie befindet.

This prevents the hose outlet from sliding out of the pulmonary artery.

---

Dadurch wird verhindert, dass der Schlauchauslass aus der Pulmonalarterie herausgleitet.

A further advantage is that the annular balloon has a rounded blunt end of the pump hose forms, so that no injury of the vascular and cardiac walls or other parts of the heart can be induced to the pump hose.

---

Ein weiterer Vorteil besteht darin, dass der Ringballon ein abgerundetes stumpfes Ende des Pumpenschlauches bildet, so dass mit dem Pumpenschlauch keine Verletzung der Gefäss- und Herzwände oder anderer Herzteile hervorgerufen werden können.

Finally, also prevent the hose end is hooked to the flap edge or tendons in the heart.

---

Schliesslich wird auch verhindert, dass das Schlauchende sich am Klappenrand oder an Sehnen im Herzen verhakt.

---

Since the pump part blood into pumped into the pump hose, the pump tube is held open by itself.

---

Da der Pumpenteil Blut in den Pumpenschlauch hineinpumpt, wird der Pumpenschlauch selbsttätig offengehalten.

---

Can be used as the pump tube, therefore, a collapsible tube to be used, for example, a film tube, the wall of which is not dimensionally stable.

---

Als Pumpenschlauch kann daher ein kollabierbarer Schlauch benutzt werden, beispielsweise ein Folienschlauch, dessen Wand nicht formstabil ist.

---

Through this tube through which a catheter can extend to the distal-end balloon.

---

Durch diesen Schlauch hindurch kann ein Katheter zu dem am distalen Ende angeordneten Ballon verlaufen.

---

With an intracardiac blood pump comprising a flexible tube pump there is a risk that the blood flowing out of the hose outlet in the hose causes a recoil, which can result in a retrograde movement of the tube.

---

Bei einer intrakardialen Blutpumpe mit einem flexiblen Pumpenschlauch besteht die Gefahr, dass das aus dem Schlauchauslass ausströmende Blut am Schlauch einen Rückstoss verursacht, welcher eine retrograde Verschiebung des Schlauchs zur Folge haben kann.

---

In this way, it can happen that the tube of the pulmonary valve from slipping out.

---

Auf diese Weise kann es geschehen, dass der Schlauch aus der Pulmonalklappe herausgleitet.

---

The invention has the further object-based, therefore, to provide an intracardiac blood pump can

be avoided in the displacements of the tube as a result of hydraulic reaction forces.

---

Der Erfindung liegt daher die weitere Aufgabe zugrunde, eine intrakardiale Blutpumpe zu schaffen, bei der Verschiebungen des Schlauchs infolge von hydraulischen Reaktionskräften vermieden werden.

The solution of this task is carried out according to the invention with the features of claim 13,

---

Die Lösung dieser Aufgabe erfolgt erfindungsgemäss mit den Merkmalen des Patentanspruchs 13.

Thereafter attached to the distal end of the hose a traction element, which is flown by the pump current.

---

Hiernach ist am distalen Ende des Schlauchs ein Zugelement befestigt, welches von dem Pumpenstrom angeströmt wird.

In this tension member, there may be a sail or a balloon.

---

Bei diesem Zugelement kann es sich um ein Segel handeln oder um einen Ballon.

The exiting from the hose end abuts against the tension member blood flow, thereby the pull-back force of the opposing tube, forward force is produced.

---

Der aus dem Schlauchende austretende Blutstrom stösst gegen das Zugelement, wodurch eine der Rückzugskraft des Schlauch entgegenwirkende, nach vorne gerichtete Kraft entsteht.

In this way the tension member to stabilize the positioning of the pump hose is used.

---

Auf diese Weise dient das Zugelement der Stabilisierung der Positionierung des Pumpenschlauchs.

In the following the invention will be explained in more detail with reference to drawings of exemplary embodiments.

---

Im folgenden werden unter Bezugnahme auf die Zeichnungen Ausführungsbeispiele der Erfindung näher erläutert.

In the drawings: Figure 1 is a cross-sectional view of the heart with disposed therein a blood pump, Figure 2 is a representation of the blood pump of Figure 1, Figure 3 a section through the detail III of Figure 2, Figure 4 shows a second embodiment of the blood pump, 5 shows a third embodiment, and Figure 6 in enlarged scale, a representation of the

---

Es zeigen : Fig. 1 eine Querschnittsdarstellung des Herzens mit darin angeordneter Blutpumpe, Fig. 2 eine Darstellung der Blutpumpe von Fig. 1, Fig. 3 einen Schnitt durch die Einzelheit III von Fig. 2, Fig. 4 ein zweites Ausführungsbeispiel der Blutpumpe, Fig. 5 ein drittes Ausführungsbeispiel und Fig. 6 in vergrössertem Massstab eine Darstellung des

The catheter of the embodiment of Figure 5

---

Katheters aus dem Ausführungsbeispiel von Fig. 5.

According to Figure 1, the blood pump 10 an intravascular blood pump, which is a blood pump that can be pushed through the vascular system of a patient in order to penetrate up into the heart.

---

Gemäss Fig. 1 ist die Blutpumpe 10 eine intravasale Blutpumpe, also eine Blutpumpe, die durch das Blutgefässsystem eines Patienten geschoben werden kann, um bis in das Herz hinein vorzudringen.

The outer diameter of such a blood pump is higher than 8 mmm at any point.

---

Der Aussendurchmesser einer solchen Blutpumpe ist an keiner Stelle grösser als 8 mmm.

The pump 10 has a driving part 11 and a pump portion rigidly connected 12.

---

Die Pumpe 10 weist einen Antriebsteil 11 und einen damit starr verbundenen Pumpenteil 12 auf.

The pump for example, corresponds to that of W097/37696, so that their internal structure is not

discussed here.

---

Die Pumpe entspricht beispielsweise derjenigen von W097/37696, so dass ihr interner Aufbau hier nicht näher erläutert wird.

---

In the transition region between the drive part 11 and part 12 suction pumps are 13, is sucked through the blood radially from the outside.

---

Im Übergangsbereich zwischen Antriebsteil 11 und Pumpenteil 12 befinden sich Ansaugöffnungen 13, durch die Blut radial von aussen her angesaugt wird.

---

The pump portion 12 includes a (not shown) impeller which drives the blood in the axial direction.

---

Der Pumpenteil 12 enthält ein (nicht dargestelltes) Flügelrad, das das Blut in axialer Richtung antreibt.

---

At the outlet of the pump part 12, a pump tube 14 is connected.

---

An den Auslass des Pumpenteils 12 ist ein Pumpenschlauch 14 angeschlossen.

---

This has one end connected to the pump outlet proximal end 15 and a distal end 16 of the hose outlet forming properties.

---

Dieser weist ein mit dem Pumpenauslass verbundenes proximales Ende 15 und ein den Schlauchauslass bildendes distales Ende 16 auf.

---

The proximal end of pump 10 is connected to a catheter 17 which includes the electrical supply lines for the drive member 11.

---

Das proximale Ende der Pumpe 10 ist mit einem Katheter 17 verbunden, welcher auch die elektrischen Versorgungsleitungen für den Antriebsteil 11 enthält.

---

Furthermore, the catheter 17 has a lumen in which can be connected to a compressed air source.

---

Ferner weist der Katheter 17 ein Lumen auf, das an eine Druckluftquelle angeschlossen werden



kann.

The pump tube 14 and catheter 17 are flexible.

---

Der Pumpenschlauch 14 und der Katheter 17 sind flexibel.

The rigid length of the pump 10 is not more than 35 mm, so that the pump passes through curves of the blood vascular system.

---

Die rigide Länge der Pumpe 10 beträgt nicht mehr als 35 mm, damit die Pumpe durch Krümmungen des Blutgefäßsystems hindurchgeht.

The length of the pump tube 14 is at least twice as large as the length of the rigid pump.

---

Die Länge des Pumpenschlauchs 14 ist mindestens doppelt so gross wie die rigide Länge der Pumpe.

Of the pump hose has a length of about 12 cm and an outer diameter of about 8 mm.

---

Der Pumpenschlauch hat eine Länge von etwa 12 cm und einen Aussendurchmesser von etwa 8 mm.

Its thickness is 0.05 mm to 0.2 mm.

---

Seine Wandstärke beträgt 0,05 mm bis 0,2 mm.

The radius of curvature of the hose bend is 40 mm to 60 mm.

---

Der Krümmungsradius der Schlauchbiegung beträgt 40 mm bis 60 mm.

1 shows a cross section through the heart 20.

---

In Fig. 1 ist ein Querschnitt durch das Herz 20 dargestellt.

Into the right atrium 21, the inferior vena cava and the superior vena cava 22 open 23

---

In das rechte Atrium 21 münden die untere Hohlvene 22 und die obere Hohlvene 23.

The tricuspid valve is located between the right atrium 25, 21 and the right ventricle 24

---

Zwischen dem rechten Atrium 21 und dem rechten Ventrikel 24 befindet sich die Tricuspidalklappe 25.

The pulmonary valve is located between the right ventricle 27, 24 and 26 of the pulmonary artery

---

Zwischen dem rechten Ventrikel 24 und der Pulmonalarterie 26 befindet sich die Pulmonalklappe 27.

26, the blood from the pulmonary artery to the lungs and from there flows back into the left atrium 28 and left ventricle 29

---

Von der Pulmonalarterie 26 fließt das Blut zur Lunge und von dort zurück in das linke Atrium 28 und zum linken Ventrikel 29.

The aortic valve is located between the left ventricle 31, 29 and aorta 30

---

Zwischen dem linken Ventrikel 29 und der Aorta 30 befindet sich die Aortenklappe 31.

The pump 10 is as right heart pump routed so that it supports from the right atrium into the pulmonary artery 26 into 21.

---

Die Pumpe 10 wird als Rechtsherzpumpe so verlegt, dass sie von dem rechten Atrium 21 in die Pulmonalarterie 26 hinein fördert.

For this purpose, it is routed through the superior vena cava 23 in the illustrated embodiment.

---

Hierzu ist sie bei dem dargestellten Ausführungsbeispiel durch die obere Hohlvene 23 hindurch verlegt.

It would also be possible to make the transfer through the inferior vena cava 22.

---

Es wäre auch möglich, die Verlegung durch die untere Hohlvene 22 hindurch vorzunehmen.

---

During insertion of the pump 10 of the pump tube 14 is located above the pump, that is, it lies in the flow direction of the blood surrounding the pump downstream from the pump 10

---

Während des Einführens der Pumpe 10 liegt der Pumpenschlauch 14 der Pumpe voran, d. h. er liegt in Strömungsrichtung des die Pumpe umgebenden Blutes stromab von der Pumpe 10.

---

At the distal end 16 of the pump tube 14 is a balloon 35 which is formed here in accordance with Figure 2 and Figure 3 as an annular balloon.

---

Am distalen Ende 16 des Pumpenschlauchs 14 befindet sich ein Ballon 35, der hier gemäss Fig. 2 und Fig. 3 als Ringballon ausgebildet ist.

---

The gas (eg

---

Der mit Gas (z.

---

As air, helium, CO<sub>2</sub>) or liquid inflated balloon 35 has a larger outer diameter than the pump tube 14

---

B. Luft, Helium, CO<sub>2</sub>) oder einer Flüssigkeit aufgeblähte Ballon 35 hat einen grösseren Aussendurchmesser als der Pumpenschlauch 14.

---

Thus, the balloon 35 defines a guiding element on which the natural blood flow acts to entrain this guide element.

---

Folglich bildet der Ballon 35 ein Führungselement, an dem der natürliche Blutstrom angreift, um dieses Führungselement mitzuziehen.

---

Thus, the balloon 35 is flushed on the first natural bloodstream into the right ventricle 24, and then

into the pulmonary artery 26.

---

Dadurch wird der Ballon 35 auf dem natürlichen Blutweg zunächst in den rechten Ventrikel 24 und danach in die Pulmonalarterie 26 gespült.

---

The balloon 35 is inflated characterized in that in a pressure lumen 36 of the pump hose 14, a pressure is generated.

---

Der Ballon 35 wird dadurch aufgebläht, dass in einem Drucklumen 36 des Pumpenschlauchs 14 ein Druck erzeugt wird.

---

The pressure lumen 36 communicates through openings 37 with the interior of the annular balloon 35.

---

Das Drucklumen 36 steht über Öffnungen 37 mit dem Inneren des ringförmigen Ballons 35 in Verbindung.

---

In the pump tube 14, the blood flows through the blood lumens 38, whose cross section is substantially larger than that of the pressure lumen 36

---

Im Pumpenschlauch 14 fließt das Blut durch das Blutlumen 38, dessen Querschnitt wesentlich grösser ist als derjenige des Drucklumens 36.

---

The pressure lumen 36 is connected to a corresponding pressure lumen of the proximal catheter 17 so that its pressure can be controlled extracorporeally.

---

Das Drucklumen 36 ist an ein entsprechendes Drucklumen des proximalen Katheters 17 angeschlossen, so dass sein Druck extrakorporal gesteuert werden kann.

---

The pump tube 14 is shown in Figure 2 in a relaxed state.

---

Der Pumpenschlauch 14 ist in Fig. 2 im entspannten Zustand dargestellt.

The pump tube is U-shaped or V-shaped pre-bent, ie, it has a shape memory, so it is not exposed to significant constraint in the heart according to Figure 1 and also in turn exerts no significant constraint on the heart.

---

Der Pumpenschlauch ist U-förmig oder V-förmig vorgebogen, d. h. er hat ein Formgedächtnis, so dass er im Herzen gemäss Fig. 1 keinem wesentlichen Zwang ausgesetzt ist und auch seinerseits keinen wesentlichen Zwang auf das Herz ausübt.

---

In Figure 2, the density of the dotted area indicates the rigidity of the pump tube 14.

---

In Fig. 2 gibt die Schwärzung des gepunkteten Bereichs die Steifigkeit des Pumpenschlauchs 14 an.

---

At the proximal end 15 of this rigidity is very big and it shall then steadily toward the distal end 16 from.

---

Am proximalen Ende 15 ist diese Steifigkeit sehr gross und sie nimmt dann stetig zum distalen Ende 16 hin ab.

---

This means that the distal end 16 to which the balloon is 35 to move freely through the balloon, and can be carried out.

---

Dies bedeutet, dass das distale Ende 16, an dem sich der Ballon 35 befindet, durch den Ballon frei bewegt und geführt werden kann.

---

As is apparent from Figure 3, the balloon 35 is at the distal end of the end 39 of the pump tube 14 also before, so that the balloon 35 has a rounded end of the tube 40 forms, which does not provide the risk of snagging on obstacles.

---

Wie aus Fig. 3 hervorgeht, steht der Ballon 35 am distalen Ende über das Ende 39 des Pumpenschlauchs 14 hinaus vor, so dass der Ballon 35 ein abgerundetes Schlauchende 40 bildet, welches nicht die Gefahr des Verhakens an Hindernissen bietet.

---

At the proximal end of the balloon 35 that forms an annular undercut 41 in accordance with Figure

1, the tips of the pulmonary valve 27 can penetrate, such that the pulmonary valve prevents retraction of the hose end.

---

An dem proximalen Ende des Ballons 35 bildet dieser eine ringförmige Hinterschneidung 41, in die gemäss Fig. 1 die Spitzen der Pulmonalklappe 27 eindringen können, so dass die Pulmonalklappe ein Zurückweichen des Schlauchendes verhindert.

As shown in Figs. 2 and 3 is shown, spans the hose outlet 42, a traction element 43 in the form of a dome-shaped sail.

---

Wie in den Fig. 2 und 3 dargestellt ist, spannt sich über dem Schlauchauslass 42 ein Zugelement 43 in Form eines kuppelförmigen Segels.

This tension member 43 consists of a thin flexible skin, which is fastened by webs 44 to the balloon 35.

---

Dieses Zugelement 43 besteht aus einer dünnen flexiblen Haut, die mit Stegen 44 an dem Ballon 35 befestigt ist.

The effluent from the hose outlet 42 blood flows against the tension member 43, thereby exerting on the pump hose 14 from a train, which is opposite to the recoil effect.

---

Das aus dem Schlauchauslass 42 ausströmende Blut strömt gegen das Zugelement 43 und übt somit auf den Pumpenschlauch 14 einen Zug aus, der der Rückstosswirkung entgegengesetzt ist.

This prevents the distal end 16 of the pump hose is displaced as a result of the hydraulic recoil and possibly sliding out of the pulmonary valve 27.

---

Dadurch wird verhindert, dass das distale Ende 16 des Pumpenschlauchs sich infolge des hydraulischen Rückstosses verschiebt und evtl. aus der Pulmonalklappe 27 herausgleitet.

The pump tube 14 is preferably made of polyurethane, which has proven to be particularly suitable.

---

Der Pumpenschlauch 14 besteht vorzugsweise aus Polyurethan, das sich als besonders geeignet erwiesen hat.

In the embodiment of Figure 4, a pump tube 14a is connected to the pump 10, 45 includes a resilient support structure in the form of an existing carbon or metal helical coil.

---

Bei dem Ausführungsbeispiel von Fig. 4 ist an die Pumpe 10 ein Pumpenschlauch 14a angeschlossen, der eine elastische Stützstruktur 45 in Form einer aus Carbon oder Metall bestehenden Schraubenwendel enthält.

This supporting structure 45 holding the pump tubing open and effect the desired bending stiffness can also vary over the length of hose.

---

Diese Stützstruktur 45 hält den Pumpenschlauch offen und bewirkt die gewünschte Biegesteifigkeit, die auch über die Schlauchlänge variieren kann.

Through the pump hose 45 extends through a catheter 46, which is provided at the distal end with a balloon 35a.

---

Durch den Pumpenschlauch 45 hindurch verläuft ein Katheter 46, der am distalen Ende mit einem Ballon 35a versehen ist.

This balloon is the guiding element for the pump tube 14a.

---

Dieser Ballon bildet das Führungselement für den Pumpenschlauch 14a.

The catheter 46 includes a pressure lumen.

---

Der Katheter 46 enthält ein Drucklumen.

Its outer diameter is substantially smaller than the diameter of the pump tube 14a so that the pump hose cross-section is sufficient for the flow of blood are available.

---

Sein Aussendurchmesser ist wesentlich kleiner als der Durchmesser des Pumpenschlauchs 14a, so dass im Pumpenschlauch genügend Querschnitt für den Blutfluss zur Verfügung steht.

The catheter 46 is connected to the catheter 17.

---

Der Katheter 46 ist mit dem Katheter 17 verbunden.

A tension member 43a, a ball is disposed at a distance behind the hose outlet 42 and affixed to the catheter 46.

---

Als Zugelement 43a ist eine Kugel im Abstand hinter dem Schlauchauslass 42 angeordnet und am Katheter 46 befestigt.

The pressing against the traction element 43a blood flow prevents retraction of the distal end of the tubing 16 to the pump 10

---

Die gegen das Zugelement 43a drückende Blutströmung verhindert ein Zurückweichen des distalen Schlauchendes 16 zur Pumpe 10.

The pump tube 14a is anchored to a retaining device 47 to the tension member 43a.

---

Der Pumpenschlauch 14a ist mit einer Haltevorrichtung 47 an dem Zugelement 43a verankert.

In the embodiment of FIGS. 5 and 6, the pump tubing 14b, a collapsible pump hose, which is made of thin sheet material, which does not have its own dimensional stability.

---

Bei dem Ausführungsbeispiel der Fign. 5 und 6 ist der Pumpenschlauch 14b ein kollabierbarer Pumpenschlauch, der aus dünnem Folienmaterial besteht, das keine eigene Formstabilität aufweist.

Through the pump hose 14b extends a catheter 48, which carries at its distal end a balloon 35a.

---

Durch den Pumpenschlauch 14b verläuft ein Katheter 48, der an seinem distalen Ende einen Ballon 35a trägt.

This catheter 48 is connected to the catheter 17.



---

Dieser Katheter 48 ist mit dem Katheter 17 verbunden.

The distal end 16 of the pump hose 14b is connected to the catheter 48 and the pump tube 14b has exit openings 49 for the exit of blood.

---

Das distale Ende 16 des Pumpenschlauchs 14b ist mit dem Katheter 48 verbunden und der Pumpenschlauch 14b weist Austrittsöffnungen 49 für den Bluttaustritt auf.

Upon insertion of the pump according to Figure 5, the pump is not in operation, so that the pump hose 14b is collapsed.

---

Beim Einführen der Pumpe nach Fig. 5 ist die Pumpe nicht in Betrieb, so dass der Pumpenschlauch 14b kollabiert ist.

By means of the balloon 35a is the soft and flexible catheter 48 installed in the heart, where he positioned the pump tube 14b.

---

Mittels des Ballons 35a wird der weiche und flexible Katheter 48 im Herzen verlegt, wobei er den Pumpenschlauch 14b positioniert.

If then the pump is put into operation, the pump tube 14b is expanded.

---

Wird anschliessend die Pumpe in Betrieb gesetzt, so wird der Pumpenschlauch 14b aufgeweitet.

To facilitate the placement of the catheter, another lumen may 36,36,48 of Figure 6 except the leading to the balloon lumen 49 50 35 a pressure, which method is intended for receiving a guide wire 51, and after removal of the guide wire to the external pressure measurement.

---

Zur Erleichterung der Platzierung kann der Katheter 36,36,48 gemäss Fig. 6 ausser dem zum Ballon 35a führenden Drucklumen 49 ein weiteres Lumen 50 enthalten, das zur Aufnahme eines Führungsdrahtes 51 und nach Entfernen des Führungsdrahtes zur externen Druckmessung bestimmt ist.

This guide wire 51, which also passes through the catheter 17 and the pump 10, allowing the

operator to influence the laying of the pump hose controlling.

---

Dieser Führungsdraht 51, der auch durch den Katheter 17 und die Pumpe 10 hindurchgeht, ermöglicht es dem Operateur, die Verlegung des Pumpenschlauchs steuernd zu beeinflussen.

---

Thereafter, the guide wire 51 is drawn out.

---

Danach wird der Führungsdraht 51 herausgezogen.

---

According to Figure 6 may be provided on the catheter 48 has an opening 52 which is connected to the lumen 50 and is blocked by the guide wire 51.

---

Gemäss Fig. 6 kann an dem Katheter 48 eine Öffnung 52 vorgesehen sein, die mit dem Lumen 50 verbunden ist und die durch den Führungsdraht 51 versperrt wird.

---

After the guidewire 51 is pulled out of the lumen 50, passes through the opening 52 into the lumen of the blood 50.

---

Nachdem der Führungsdraht 51 aus dem Lumen 50 herausgezogen ist, dringt durch die Öffnung 52 Blut in das Lumen 50 ein.

---

The lumen 50 can be connected to a blood pressure monitor, so as to measure the blood pressure in the pulmonary artery during pumping and, if necessary, to be able to influence.

---

Das Lumen 50 kann mit einem Blutdruckmesser verbunden werden, um somit den Blutdruck in der Pulmonalarterie während des Pumpens zu messen und ggf. beeinflussen zu können.

---

If the placement of the pump tube without a guide wire, it can be measured with the aid of the pressure variations in the measurable other lumen 50 of the pressure at the point 52.

---

Erfolgt die Plazierung des Pumpenschlauches ohne Führungsdraht, so kann mit Hilfe der messbaren Druckverläufe im weiteren Lumen 50 der Druck an der Stelle 52 gemessen werden.

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Can so the exact position of the distal tip of the pump hose are determined from the pressure gradients.

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Aus den Druckverläufen kann so die genaue Position der distalen Pumpenschlauchspitze ermittelt werden.

The diameter of the balloon should not be so great that it significantly impedes the flow through the pulmonary artery, the pulmonary artery 26 or even shut off.

---

Der Durchmesser des Ballons darf nicht so gross sein, dass er den Durchfluss durch die Pulmonalarterie 26 wesentlich behindert oder die Pulmonalarterie sogar absperrt.

In general, the diameter must not be larger than 30 mm.

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In der Regel darf der Durchmesser nicht grösser sein als 30 mm.

Further, the balloon should have a high elasticity, in contrast to a dilatation balloon.

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Ferner sollte der Ballon eine hohe Elastizität haben, im Unterschied zu einem Dilatationsballon.

As balloon material are due to the elastic properties of silicone, latex, and preferably polyurethane.

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Als Ballonmaterial eignen sich wegen der Elastizitätseigenschaften Silikon, Latex, und vorzugsweise Polyurethan.

The balloon may, while it floats as a guide element for the catheter tube in the blood stream, to be strong inflated with high pressure and are then reduced by reducing the pressure to act as a pulling element, which is flown by the pump flow.

---

Der Ballon kann, während er als Führungselement für den Katheterschlauch im Blutstrom floatet, mit hohem Druck stark aufgebläht sein und anschliessend durch Verringerung des Druckes verkleinert werden, um als Zügelement zu wirken, das von der Pumpenströmung angeströmt wird.



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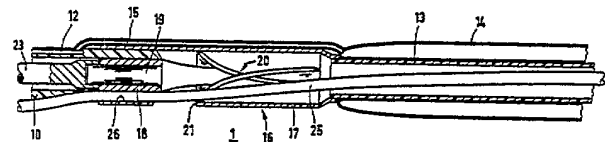
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54 Ballonkatheter

57 Der Ballonkatheter weist einen Katheterschlauch (10) und einen auf einem Ballonträger (13) sitzenden hydraulisch aufweitbaren Ballon (14) auf. Zwischen dem Katheterschlauch (10) und dem Ballonträger (13) ist eine Pumpe (16) von kleinem Durchmesser angeordnet, die Blut durch seitliche Einlässe (21) einsaugt und es durch den rohrförmigen Ballonträger (13) pumpt. Die Pumpe (16) wird über eine flexible Welle (23), die durch den Katheterschlauch (10) verläuft, oder mittels direkt integriertem Mikromotor angetrieben.



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Die Erfindung betrifft einen Ballonkatheter, der in ein Blutgefäß eingeführt werden kann, um beispielsweise Gefäßverengungen aufzuweiten oder einen Teil der Wand des Blutgefäßes vorübergehend vom Kontakt mit dem Blutstrom abzusperren.

Bekannt sind Ballonkatheter mit einem Katheterschlauch, der am distalen Ende einen rohrförmigen Ballonträger aufweist, auf welchem ein ringförmiger Ballon sitzt. Der Ballon steht über ein durch den Katheterschlauch hindurchgehendes Lumen mit einer extrakorporalen Druckquelle in Verbindung. Durch Einleiten einer Flüssigkeit unter Druck wird der Ballon aufgeweitet. Dabei erfolgt normalerweise ein Totalverschuß des Blutgefäßes, mit der Folge einer Mangelversorgung (Ischämie) der nachfolgenden Organregionen. Um diese zu vermeiden, werden Perfusionskatheter (Durchblutungskatheter) benutzt. Zu diesen gehören Autoperfusionskatheter, die einen durch den Ballonträger hindurchgehenden Durchlaß aufweisen, so daß eine Blutströmung durch das Innere des ringförmigen Ballons erfolgt, sowie aktive Perfusionssysteme, bei denen mit Hilfe einer externen Hochdruckpumpe, die an das distale Katheterende angeschlossen wird, eine kontinuierliche Perfusion durch das Katheterlumen erfolgt. Im Gegensatz zu Autoperfusionskathetern wird bei aktiven Perfusionssystemen ein bestimmter Druck aktiv aufgebaut, der unabhängig von dem aktuellen Blutdruck des Patienten ist. Hierzu muß dem Patienten jedoch arteria-

lisieretes Blut entnommen werden, das extrakorporal in das Lumen des Katheterschlauchs gepumpt wird. Zudem sind sehr hohe Pumpendrucke (bis ca. 12 bar) aufgrund der großen Druckverluste im kleinumigen Katheterschlauch erforderlich, um ca. 40 bis 60 ml/min. zu fördern.

Der Erfindung liegt die Aufgabe zugrunde, einen Ballonkatheter zu schaffen, der ein vereinfachtes aktives Perfusionssystem bildet.

Die Lösung dieser Aufgabe erfolgt erfindungsgemäß mit den im Patentanspruch 1 angegebenen Merkmalen.

Bei dem erfindungsgemäßen Ballonkatheter ist eine Pumpe im Zuge des Katheters angeordnet, und zwar proximal von dem Ballonträger. Die Pumpe saugt seitlich über entsprechende Öffnungen Blut aus dem Blutgefäß an und pumpt es axial durch den Ballonträger hindurch. Da die Pumpe unmittelbar vor dem Ballonträger angeordnet ist, ist nur ein relativ geringer Pumpendruck erforderlich. Die Pumpe ist so klein, daß sie direkt im Bereich des Eingriffs, also in der Nähe des Ballons, im Katheter plaziert werden kann, so daß die Länge des zu durchspülenden Lumens kurz ist, wodurch der Druckverlust relativ gering gehalten wird. Die Pumpe hat einen so kleinen Durchmesser, daß sie im Zuge des Katheters in das Blutgefäß eingeführt werden kann, ohne dieses zu versperren. Von einer Behandlung mit Ballonkathetern sind in der Regel kleinere Blutgefäße betroffen. Der maximale Außendurchmesser der Pumpe sollte etwa 1,4 mm nicht übersteigen. Eine derartig kleine Pumpe kann in den Katheter integriert werden, so daß sie unmittelbar vor dem Ballonträger, der durch die Behandlungsstelle des Blutgefäßes hindurchgeht, liegt. Dabei saugt die Pumpe in Strömungsrichtung des Gefäßes aus dem Bereich höheren Drucks Blut über mindestens einen seitlichen Einlaß an und fördert dieses in den Niederdruckbereich jenseits der aufgeblasenen Ballons.

Wegen der erforderlichen Kleinheit der Pumpe muß diese mit relativ hohen Drehzahlen betrieben werden,

um die erforderliche Förderleistung von beispielsweise 60 cm<sup>3</sup>/min. zu erreichen. Die Pumpendrehzahl liegt vorzugsweise im Bereich von 80 000 bis 150 000 U/min.

Der Ballonkatheter wird vorzugsweise für das Dehnen von Gefäßverengungen, speziell im Herzkranzgefäßbereich, in den Halsschlagadern u. dgl., eingesetzt. Es ist aber auch möglich, den Ballonkatheter dazu zu benutzen, einen Drahtkorb (Stent) zur Weitstellung von Gefäßverengungen zu plazieren oder einen Ballonkatheter mit mehreren hintereinander angeordneten Ballons zu verwenden, um zwischen den Ballons das Annähen von Bypässen zu ermöglichen.

Die Erfindung schafft einen aktiven Perfusionskatheter mit integrierter Pumpe. Dieser entspricht in seiner Handhabung weitgehend den passiven Autoperfusionskathetern, ist in seiner Leistung aber den aktiven Perfusionssystemen vergleichbar. Ein weiterer Vorteil besteht darin, daß der Ballonträger mit einem sehr geringen Außendurchmesser von etwa 1 mm realisiert werden kann. Hierdurch ist in fast allen Fällen, selbst bei starken Stenosen, gewährleistet, daß eine Platzierung des Ballonbereichs in der Stenose erfolgen kann.

Vorzugsweise ist die Pumpe von einer flexiblen Welle angetrieben, die mit einem am proximalen Ende des Katheterschlauchs vorgesehenen Motor verbunden ist. Solche Pumpen, die nur aus einem Pumpengehäuse und dem darin rotierend angeordneten Flügelrad bestehen, können mit einem sehr geringen Außendurchmesser von etwa 1,5 mm gefertigt werden. Generell ist es im Rahmen der Erfindung aber auch möglich, einen Pumpenmotor in den Katheter, in direkter Nähe zur Pumpe, zu integrieren, wobei der Motor dann das Pumpenrad unmittelbar antreibt.

Um einen Ballonkatheter in einem Blutgefäß zu plazieren, wird in der Regel ein Führungsdraht eingebracht, über den der Katheter anschließend geschoben wird. Eine derartige Verlegung mit einem Führungsdraht ist auch bei dem erfindungsgemäßen Ballonkatheter möglich. Hierbei muß der Führungsdraht allerdings durch die Pumpe hindurchgeführt werden. Das Flügelrad der Pumpe oder die Pumpe selbst ist demnach so ausgebildet, daß es den Durchgang eines Führungsdrahtes, der einen Durchmesser von etwa 0,3 mm hat, ermöglicht. Zu berücksichtigen ist, daß die Pumpe erst in Betrieb genommen wird, nachdem der Führungsdraht hinreichend weit aus dem unmittelbaren Pumpenbereich herausgezogen wurde. Während der Verlegung des Katheters ist es hinnehmbar, wenn der Führungsdraht das Pumpenrad blockiert.

Im folgenden werden unter Bezugnahme auf die Zeichnungen Ausführungsbeispiele der Erfindung näher erläutert.

Es zeigen:

Fig. 1 einen Längsschnitt durch den distalen Endbereich des Ballonkatheters bei einem ersten Ausführungsbeispiel,

Fig. 2 den Ballonkatheter nach Fig. 1 mit eingeschobenem Führungsdraht, wobei die Pumpe eine Monorail-Führung bildet, und

Fig. 3 ein Ausführungsbeispiel, bei dem der Führungsdraht koaxial durch die Pumpe hindurchgeht.

Der Ballonkatheter 1 nach Fig. 1 weist einen langgestreckten Katheterschlauch 10 auf, dessen Länge etwa 1 m beträgt und dessen Durchmesser ca. 1,3 mm beträgt. Der flexible Katheterschlauch 10 weist ein zentrisches Schlauchlumen 11 mit einem Durchmesser von ca. 0,8 mm auf. Ferner verläuft durch die Wand des Katheterschlauchs 10 ein weiteres Lumen 12 zur Zuleitung

von Druckfluid zu dem Ballon 14.

An der Katheterspitze befindet sich der rohrförmige Ballonträger 13 mit einem Innendurchmesser von ca. 0,8 mm und einem Außendurchmesser von ca. 1,0 mm. Dieser Ballonträger 13 ist von mindestens einem Ballon 14 umgeben. Der Ballon 14 steht über eine Leitung 15 mit dem Lumen 12 des Katheterschlauchs 10 in Verbindung. Das vordere Ende des Ballonträgers 12 ist verjüngt ausgebildet und weist eine axiale und mehrere seitliche Blutaustrittsöffnungen auf.

Zwischen dem Katheterschlauch 10 und dem Ballonträger 13 befindet sich die Pumpe 16. Diese weist ein rohrförmiges Pumpengehäuse 17 mit einem Außendurchmesser von ca. 1,5 mm auf. Das proximale Ende 17a des Pumpengehäuses ist an dem Ende des Katheterschlauchs 10 befestigt und das distale Ende 17b ist mit dem Ballonträger 13 verbunden. Das Pumpengehäuse 17 besteht aus Metall und es enthält ein Lager 18, in dem die Welle 19 des Pumpenrades 20 gelagert ist. Das Ende des Katheterschlauchs 10 ist zwischen dem Lager 18 und dem Pumpengehäuse 17 eingepaßt. Unmittelbar im Anschluß an das Ende des Katheterschlauchs 10 sind an dem Gehäuse 17 seitliche Einlässe 21 vorgesehen, durch die Blut radial in das Pumpengehäuse 17 eintreten kann. In dem Bereich, in dem sich das Pumpenrad 20 befindet, ist das Gehäuse 17 umfangsmäßig geschlossen. Das Pumpenrad 20 weist mehrere Flügel 22 auf, die schraubenförmig um die Achse herum angeordnet sind und sich über einen Winkelbereich von mindestens 150° erstrecken. Die axiale Länge des Pumpenrades 20 beträgt ca. das Doppelte des maximalen Durchmessers dieses Pumpenrades. Das Pumpenrad 20 endet unmittelbar vor dem Ballonträger 13.

Die Welle 19 des Pumpenrades 20 ist mit einer flexiblen Welle 23 verbunden, die im Innern des Lumens 11 des Katheterschlauchs 10 verläuft und am proximalen Ende mit einem externen Elektromotor verbunden ist, der die Welle mit einer Drehzahl in der Größenordnung von 100 000 U/min. antreibt.

Während der Ballonbereich des Katheters beispielsweise in den Bereich einer Stenose eingeführt und der Ballon 14 unter Druck gesetzt und dadurch aufgeweitet wurde, fördert die Pumpe 16 Blut von den Einlässen 21 durch den Ballonträger 13 hindurch. Das distale Ende des Ballonträgers 13 ist offen oder mit Öffnungen versehen, so daß das Blut dort aus dem Ballonträger 13 in das Blutgefäß hinein austreten kann.

Das Ausführungsbeispiel von Fig. 2 unterscheidet sich von demjenigen der Fig. 1 nur dadurch, daß zusätzlich ein Führungsdraht 25 vorgesehen ist, der zunächst in dem Blutgefäß plaziert wird und über den dann der Katheter geschoben wird. Dieser flexible Führungsdraht 25 verläuft generell außerhalb des Katheterschlauchs 10. Am distalen Ende des Katheterschlauchs, vorzugsweise auf den letzten 10 cm des Katheterschlauchs 10 und in einem Teil des Pumpengehäuses 17, befindet sich ein längslaufender Kanal 26, der einen Führungsbereich (Monorail) bildet, durch den der Führungsdraht 25 in das Pumpengehäuse 17 geleitet wird. Der Durchmesser des Führungsdrahtes beträgt ca. 0,3 mm, so daß der Führungsdraht durch das Pumpenrad 20 zwischen dessen Flügeln hindurch verlaufen kann. Während der Führungsdraht 25 sich im Pumpengehäuse befindet, erfolgt keine Rotation des Pumpenrades. Nach dem Plazieren des Katheters wird der Führungsdraht für die Behandlung mindestens an dem Pumpengehäuse herausgezogen. Dabei ist der Kanal 26 so plaziert und das Flügelrad 20 so gestaltet, daß der Füh-

rungsdraht 25 jederzeit nach erfolgter Behandlung erneut über das stehende Flügelrad 20 in Richtung des Ballons durch den Ballonträger 13 hindurch geschoben werden kann, um das System erneut mit Hilfe des Führungsdrahtes 25 in einer veränderten Position zu plazieren, ohne den Ballonkatheter 1 hierfür völlig zurückziehen zu müssen.

Bei dem Ausführungsbeispiel von Fig. 3 verläuft der Führungsdraht 25 koaxial durch die flexible Welle 23, die Welle 19 und das Flügelrad 20 hindurch. Diese Teile haben entsprechende Axialkanäle, um über den Führungsdraht geschoben werden zu können (Over-the-Wire-Technique). Während des Betriebes der Pumpe kann der Führungsdraht zurückgezogen werden, um den Durchfluß durch den Ballonträger 13 zu verbessern. Nach dem Zurückziehen des Führungsdrahtes ist ein erneutes Vorschieben möglich, wenn die Plazierung des Katheters verändert werden soll. Für die Funktion der Pumpe ist dies allerdings nicht erforderlich.

Befinden sich auf dem Ballonträger mehrere Ballons, so kann für jeden der Ballons eine hydraulische Zuleitung 15 über die Pumpe 16 hinweg vorgesehen werden. Dennoch darf der Katheter in seinem dicksten Bereich, also im Bereich der Pumpe 16, speziell für den Einsatz im Koronabereich (Karotinen), nicht wesentlich über 1,5 mm Durchmesser hinausgehen, da sonst eine Plazierung des Katheters über einen standardmäßigen Einführkatheter mit 2 mm Innendurchmesser nicht mehr möglich wäre. Ferner ist es erforderlich, daß die Länge des Pumpengehäuses 17 ca. 6 mm nicht übersteigt.

Die zuvor beschriebenen Ausführungsbeispiele beziehen sich auf einen Ballonkatheter, der eine nach dem Niederdruckprinzip arbeitenden Pumpe 16 enthält, die in der Nähe des Ballonträgers, also am Ende des Katheterschlauchs, angeordnet ist. Hierbei braucht die Pumpe nur einen relativ geringen Druck zu erzeugen. Im Rahmen der Erfindung ist es aber auch möglich, eine intravasale Pumpe im Zuge des Katheterschlauchs anzuordnen, die einen größeren Abstand von dem Ballonträger hat. Eine solche Pumpe muß einen höheren Pumpendruck liefern, weil im Zuge des Katheterschlauchs ein Druckabfall stattfindet.

#### Patentansprüche

1. Ballonkatheter (1) mit einem Katheterschlauch (10) und einem mit dem Katheterschlauch verbundenen rohrförmigen Ballonträger (13), der mindestens einen aufweitbaren Ballon (14) trägt, dadurch gekennzeichnet, daß im Bereich des Katheterschlauchs (10) oder zwischen diesem und dem Ballonträger (13) eine intravasale Pumpe (16) angeordnet ist, die durch mindestens einen seitlichen Einlaß (21) Blut ansaugt und axial in den Ballonträger (13) fördert.
2. Ballonkatheter nach Anspruch 1, dadurch gekennzeichnet, daß die Pumpe (16) von einer flexiblen Welle (23) angetrieben ist, die mit einem am proximalen Ende des Katheterschlauchs (10) vorgesehenen Motor verbunden ist.
3. Ballonkatheter nach Anspruch 1, dadurch gekennzeichnet, daß die Pumpe (16) von einem im Verlauf des Katheterschlauchs angeordneten Motor angetrieben ist.
4. Ballonkatheter nach einem der Ansprüche 1—3, dadurch gekennzeichnet, daß die Pumpe (16) ein Pumpenrad (20) mindestens einen Flügel (22) aufweist, dessen Länge mindestens so groß ist wie der

maximale Durchmesser des Pumpenrades (20).

5. Ballonkatheter nach einem der Ansprüche 1—4, dadurch gekennzeichnet, daß die Pumpe (16) einen längslaufenden Führungskanal (26) für einen längs des Katheterschlauchs (10) verlaufenden Führungs- draht (25) aufweist. 5

6. Ballonkatheter nach Anspruch 5, dadurch gekennzeichnet, daß der Führungsdraht (25) weitgehend außerhalb des Katheterschlauchs (10) verläuft und der Führungskanal (26) in das Innere der Pumpe (16) hineinführt. 10

7. Ballonkatheter nach Anspruch 5 oder 6, dadurch gekennzeichnet, daß sich der Führungskanal (26) vom hinteren Ende des Katheterschlauchs (ca. 10 cm) bis zum Beginn (der Flügel) des Pumpenrades (20) erstreckt. 15

8. Ballonkatheter nach Anspruch 4, dadurch gekennzeichnet, daß der Führungsdraht (25) im Katheterschlauch (10) und koaxial durch die Pumpe (16) verläuft. 20

9. Ballonkatheter nach einem der Ansprüche 1—8, dadurch gekennzeichnet, daß die seitlichen Einlässe (21) wenigstens teilweise bei aufgeblasenem Ballon (14) einen Abstand zur Gefäßwand aufweisen.

10. Ballonkatheter nach Anspruch 9, dadurch gekennzeichnet, daß der Abstand zwischen den seitlichen Einlässen (21) und dem Ballon (14) maximal der Länge der Flügel des Pumpenrades (20) entspricht. 25

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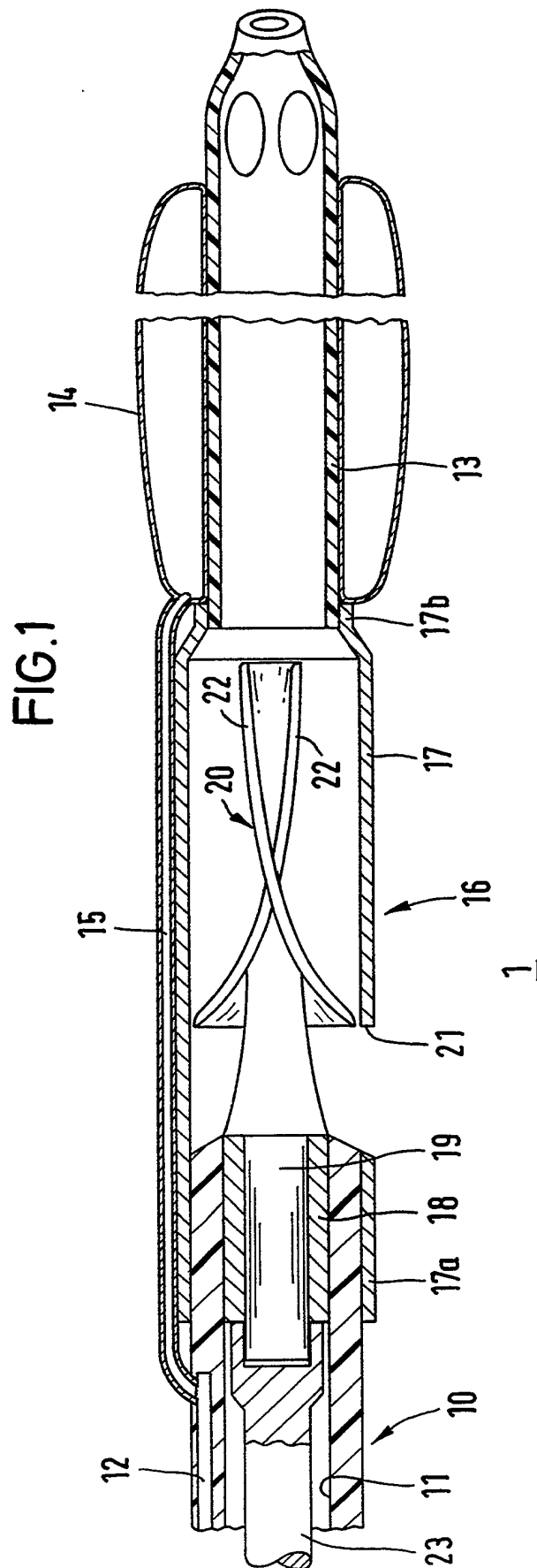
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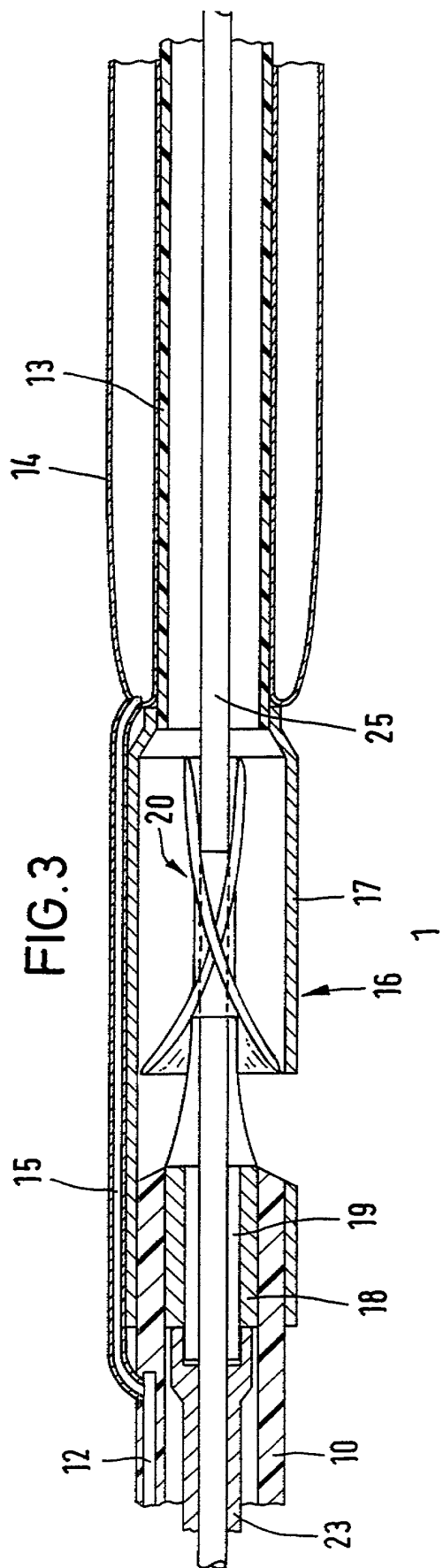
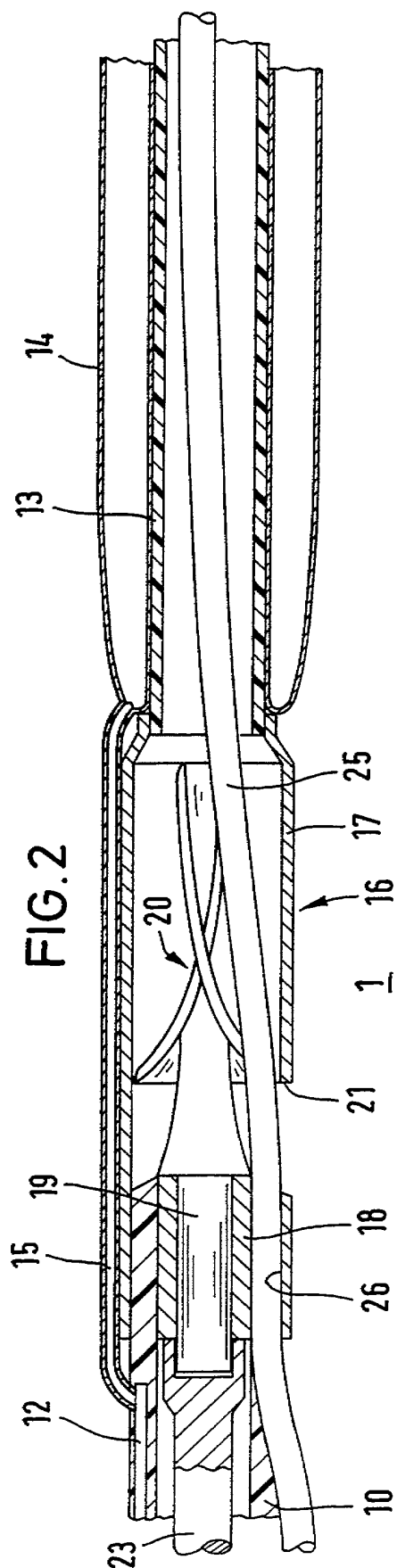
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## CLAIMS DE19622335

1.

The balloon catheter (1) comprising a catheter hose (10) and connected to the catheter tube tubular balloon support (13) carrying at least one expandable balloon (14), characterized in that in the region of the catheter tube (10) or between the same and the balloon support (13) an intravascular pump (16) is arranged, which sucks in by at least one lateral inlet (21) axially in the blood and the balloon support (13) supports.

---

Ballonkatheter (1) mit einem Katheterschlauch (10) und einem mit dem Katheterschlauch verbundenen rohrförmigen Ballonträger (13), der mindestens einen aufweitbaren Ballon (14) trägt, dadurch gekennzeichnet, dass im Bereich des Katheterschlauchs (10) oder zwischen diesem und dem Ballonträger (13) eine intravasale Pumpe (16) angeordnet ist, die durch mindestens einen seitlichen Einlass (21) Blut ansaugt und axial in den Ballonträger (13) fördert.

2.

The balloon catheter according to claim 1, characterized in that the pump (16) by a flexible shaft (23) is driven, with a proximal end of the catheter tube (10) provided for the engine is connected.

---

Ballonkatheter nach Anspruch 1, dadurch gekennzeichnet, dass die Pumpe (16) von einer

flexiblen Welle (23) angetrieben ist, die mit einem am proximalen Ende des Katheterschlauchs (10) vorgesehenen Motor verbunden ist.

3.

The balloon catheter according to claim 1, characterized in that the pump (16) is driven by a corresponding motor in the course of the catheter tube.

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Ballonkatheter nach Anspruch 1, dadurch gekennzeichnet, dass die Pumpe (16) von einem im Verlauf des Katheterschlauchs angeordneten Motor angetrieben ist.

4.

The balloon catheter of one of claims 1-3, characterized in that the pump (16) having an impeller (20) at least one vane (22) whose length is at least as large as the maximum diameter of the impeller (20).

---

Ballonkatheter nach einem der Ansprüche 1-3, dadurch gekennzeichnet, dass die Pumpe (16) ein Pumpenrad (20) mindestens einen Flügel (22) aufweist, dessen Länge mindestens so gross ist wie der maximale Durchmesser des Pumpenrades (20).

5.

Which The balloon catheter according to any one of claims 1-4, characterized in that the pump (16) having a longitudinal guide channel (26) for along the catheter hose (10) extending the guide wire (25).

---

Ballonkatheter nach einem der Ansprüche 1-4, dadurch gekennzeichnet, dass die Pumpe (16) einen längslaufenden Führungskanal (26) für einen längs des Katheterschlauchs (10) verlaufenden Führungsdraht (25) aufweist.

6.

The balloon catheter according to claim 5, characterized in that the guide wire (25) substantially outside the catheter hose (10) and the guide channel (26) leads into the interior of the pump (16).

---

Ballonkatheter nach Anspruch 5, dadurch gekennzeichnet, dass der Führungsdraht (25) weitgehend ausserhalb des Katheterschlauchs (10) verläuft und der Führungskanal (26) in das Innere der Pumpe (16) hineinführt.

7.

The balloon catheter of claim 5 or 6, characterized in that the guide channel (26) from the rear end of the catheter hose (about 10 cm) extending up to the beginning (of the blades) of the impeller (20).

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Ballonkatheter nach Anspruch 5 oder 6, dadurch gekennzeichnet, dass sich der Führungskanal (26) vom hinteren Ende des Katheterschlauchs (ca. 10 cm) bis zum Beginn (der Flügel) des Pumpenrades (20) erstreckt.

8.

The balloon catheter according to claim 4, characterized in that the guide wire (25) extends within the catheter hose (10) and coaxially through the pump (16).

---

Ballonkatheter nach Anspruch 4, dadurch gekennzeichnet, dass der Führungsdraht (25) im Katheterschlauch (10) und koaxial durch die Pumpe (16) verläuft.

9.

The balloon catheter of any of claims 1-8, characterized in that the lateral inlets (21) at least

partially in the inflated balloon (14) have a distance from the vessel wall.

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Ballonkatheter nach einem der Ansprüche 1-8, dadurch gekennzeichnet, dass die seitlichen Einlässe (21) wenigstens teilweise bei aufgeblasenem Ballon (14) einen Abstand zur Gefäßwand aufweisen.

10.

The balloon catheter according to claim 9, characterized in that the distance between the lateral inlets (21) and the balloon (14) corresponds at most to the length of the vanes of the impeller (20).

---

Ballonkatheter nach Anspruch 9, dadurch gekennzeichnet, dass der Abstand zwischen den seitlichen Einlässen (21) und dem Ballon (14) maximal der Länge der Flügel des Pumpenrades (20) entspricht.

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## DESCRIPTION DE 19622335

The invention relates to a balloon catheter according to the preamble of the claim which can be inserted into a blood vessel to expand, for example, vasoconstriction, or temporarily shutting off a part of the wall of the blood vessel from contact with the blood stream.

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Die Erfindung betrifft einen Ballonkatheter nach dem Oberbegriff des Anspruchs, der in ein Blutgefäß eingeführt werden kann, um beispielsweise Gefäßverengungen aufzuweiten oder einen Teil der Wand des Blutgefäßes vorübergehend vom Kontakt mit dem Blutstrom abzusperren.

Balloon catheters are well-known to a catheter tube which comprises a tubular balloon support at the distal end on which a ring-shaped balloon is located.

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Bekannt sind Ballonkatheter mit einem Katheterschlauch, der am distalen Ende einen rohrförmigen Ballonträger aufweist, auf welchem ein ringförmiger Ballon sitzt.

The balloon is passed through a continuous lumen through the catheter tube with an extracorporeal pressure source.

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Der Ballon steht über ein durch den Katheterschlauch hindurchgehendes Lumen mit einer

extrakorporalen Druckquelle in Verbindung.

By introducing a liquid under pressure, the balloon is expanded.

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Durch Einleiten einer Flüssigkeit unter Druck wird der Ballon aufgeweitet.

This normally occurs a total occlusion of the blood vessel, resulting in a shortage supply (ischemia) of the following organ regions.

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Dabei erfolgt normalerweise ein Totalverschluss des Blutgefäßes, mit der Folge einer Mangelversorgung (Ischämie) der nachfolgenden Organregionen.

To avoid this, perfusion (blood flow catheter) may be used.

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Um diese zu vermeiden, werden Perfusionskatheter (Durchblutungskatheter) benutzt.

These include autoperfusion catheter (DE 92 07 395 U1) having a passing through the balloon support passage so that blood flow through the interior of the annular balloon, as well as active perfusion, in which by means of an external high pressure pump, to the distal end of the catheter is connected to a continuous perfusion takes place through the catheter lumen.

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Zu diesen gehören Autoperfusionskatheter (DE 92 07 395 U1), die einen durch den Ballonträger hindurchgehenden Durchlass aufweisen, so dass eine Blutströmung durch das Innere des ringförmigen Ballons erfolgt, sowie aktive Perfusionssysteme, bei denen mit Hilfe einer externen Hochdruckpumpe, die an das distale Katheterende angeschlossen wird, eine kontinuierliche Perfusion durch das Katheterlumen erfolgt.

Unlike Autoperfusionskathetern a certain pressure is built up in the active active perfusion, which is independent of the actual blood pressure of the patient.

---

Im Gegensatz zu Autoperfusionskathetern wird bei aktiven Perfusionssystemen ein bestimmter Druck aktiv aufgebaut, der unabhängig von dem aktuellen Blutdruck des Patienten ist.

To this end, the patient, however, oxygenated blood must be removed, which is outside the body pumped into the lumen of the catheter tube.

---

Hierzu muss dem Patienten jedoch arterialisiertes Blut entnommen werden, das extrakorporal in das Lumen des Katheterschlauchs gepumpt wird.

Moreover, very high pump pressures (up to approximately 12 bar) is necessary because of the large pressure losses in the small-lumen catheter tube to approximately 40 to 60 ml / min. to promote.

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Zudem sind sehr hohe Pumpendrücke (bis ca. 12 bar) aufgrund der grossen Druckverluste im kleinumigen Katheterschlauch erforderlich, um ca. 40 bis 60 ml/min. zu fördern.

From U.S. 4,969,865 an intravascular blood pump for cardiac support is known.

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Aus US 4 969 865 ist eine intravasale Blutpumpe bei Herzunterstützung bekannt.

This blood pump may be inserted through a blood vessel and into the heart.

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Diese Blutpumpe kann durch ein Blutgefäss hindurch in das Herz eingeführt werden.

It comprises an elongate pipe in which a helical screw is arranged which is driven by a flexible shaft.

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Sie weist ein längliches Rohr auf, in dem ein schraubenförmiger Propeller angeordnet ist, der durch eine flexible Welle angetrieben wird.

This pump draws in axially and it has the opposite outlet end holes for the radial outflow on.

---

Diese Pumpe saugt axial an und sie weist am entgegengesetzten Austrittsende Löcher für das radiale Abströmen auf.

In operation, the blood pump is placed in the opening of the heart valve, wherein the suction is located in one of the ventricles of the heart, while the downstream end is positioned in the aorta.

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Im Betrieb wird die Blutpumpe in der Öffnung der Herzklappe plaziert, wobei das Ansaugende sich in einem der Herzventrikel befindet, während das Abströmende in der Aorta angeordnet ist.

The invention has for its object to provide a balloon catheter, which is a simplified active perfusion system.

---

Der Erfindung liegt die Aufgabe zugrunde, einen Ballonkatheter zu schaffen, der ein vereinfachtes aktives Perfusionssystem bildet.

The solution of this task is carried out according to the invention with the features specified in claim 1.

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Die Lösung dieser Aufgabe erfolgt erfindungsgemäss mit den im Patentanspruch 1 angegebenen Merkmalen.

The inventive balloon catheter, a pump in the course of the catheter is disposed and, although proximally of the balloon support.

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Bei dem erfindungsgemässen Ballonkatheter ist eine Pumpe im Zuge des Katheters angeordnet, und zwar proximal von dem Ballonträger.

The pump draws laterally corresponding apertures blood from the blood vessel and pumps it axially through the balloon support him.

---

Die Pumpe saugt seitlich über entsprechende Öffnungen Blut aus dem Blutgefäss an und pumpt es axial durch den Ballonträger hindurch.

Since the pump is located immediately before the balloon support, only a relatively small pump pressure is required.

---

Da die Pumpe unmittelbar vor dem Ballonträger angeordnet ist, ist nur ein relativ geringer Pumpendruck erforderlich.

The pump is so small that it can be placed directly in the area of engagement, ie in the proximity of the balloon catheter, so that the length of the through flushing lumen is short, whereby the pressure loss is kept relatively low.

---

Die Pumpe ist so klein, dass sie direkt im Bereich des Eingriffs, also in der Nähe des Ballons, im Katheter plaziert werden kann, so dass die Länge des zu durchspülenden Lumens kurz ist, wodurch der Druckverlust relativ gering gehalten wird.

The pump has a small diameter so that it can be introduced in the course of the catheter into the blood vessel without obstructing this.

---

Die Pumpe hat einen so kleinen Durchmesser, dass sie im Zuge des Katheters in das Blutgefäß eingeführt werden kann, ohne dieses zu versperren.

From a treatment with balloon catheters smaller blood vessels are usually affected.

---

Von einer Behandlung mit Ballonkathetern sind in der Regel kleinere Blutgefäße betroffen.

The maximum outer diameter of the pump should not exceed about 1.4 mm.

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Der maximale Aussendurchmesser der Pumpe sollte etwa 1,4 mm nicht übersteigen.

Such a small pump can be integrated in the catheter, so that it is immediately before the balloon support, passes through the treatment area of the blood vessel.

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Eine derartig kleine Pumpe kann in den Katheter integriert werden, so dass sie unmittelbar vor dem Ballonträger, der durch die Behandlungsstelle des Blutgefäßes hindurchgeht, liegt.

The pump draws in the flow direction of the vessel from the region of higher pressure through at least one blood inlet side and conveys it into the low-pressure region side of the inflated balloon.

---

Dabei saugt die Pumpe in Strömungsrichtung des Gefäßes aus dem Bereich höheren Drucks

Blut über mindestens einen seitlichen Einlass an und fördert dieses in den Niederdruckbereich jenseits der aufgeblasenen Ballons.

Because of the required smallness of this pump must be operated at relatively high speeds to achieve the required flow rate of eg 60 cm<sup>3</sup> / min. to reach.

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Wegen der erforderlichen Kleinheit der Pumpe muss diese mit relativ hohen Drehzahlen betrieben werden, um die erforderliche Förderleistung von beispielsweise 60 cm<sup>3</sup>/min. zu erreichen.

The pump speed is preferably in the range from 80,000 to 150,000 rev / min.

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Die Pumpendrehzahl liegt vorzugsweise im Bereich von 80.000 bis 150.000 U/min.

The balloon catheter is preferably used for the stretching of vasospasm, especially in the coronary vessel area in the carotid arteries and the like.

---

Der Ballonkatheter wird vorzugsweise für das Dehnen von Gefäßverengungen, speziell im Herzkranzgefäßbereich, in den Halsschlagadern u. dgl., eingesetzt.

It is also possible to use the balloon catheter to a wire basket (stent) for dilation of vascular constrictions to place or use a balloon catheter having a plurality of successively arranged balloons to allow between the balloons suturing of bypasses.

---

Es ist aber auch möglich, den Ballonkatheter dazu zu benutzen, einen Drahtkorb (Stent) zur Weitstellung von Gefäßverengungen zu plazieren oder einen Ballonkatheter mit mehreren hintereinander angeordneten Ballons zu verwenden, um zwischen den Ballons das Annähen von Bypässen zu ermöglichen.

The invention provides an active perfusion catheter with integrated pump.

---

Die Erfindung schafft einen aktiven Perfusionskatheter mit integrierter Pumpe.

This corresponds in its handling largely passive Autoperfusionskathetern, the active perfusion systems is in its performance but comparable.

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Dieser entspricht in seiner Handhabung weitgehend den passiven Autoperfusionskathetern, ist in seiner Leistung aber den aktiven Perfusionssystemen vergleichbar.

A further advantage is that the balloon can be realized support with a very small outer diameter of about 1 mm.

---

Ein weiterer Vorteil besteht darin, dass der Ballonträger mit einem sehr geringen Aussendurchmesser von etwa 1 mm realisiert werden kann.

Thereby is in almost all cases, even with severe stenoses, ensures that a placement of the balloon section may be performed in the stenosis.

---

Hierdurch ist in fast allen Fällen, selbst bei starken Stenosen, gewährleistet, dass eine Platzierung des Ballonbereichs in der Stenose erfolgen kann.

Preferably, the pump being driven by a flexible shaft connected with a provided at the proximal end of the catheter tube motor.

---

Vorzugsweise ist die Pumpe von einer flexiblen Welle angetrieben, die mit einem am proximalen Ende des Katheterschlauchs vorgesehenen Motor verbunden ist.

Such pumps, which consist of a pump casing and the impeller is rotatably mounted, can be manufactured with a very small outer diameter of about 1.5 mm.

---

Solche Pumpen, die nur aus einem Pumpengehäuse und dem darin rotierend angeordneten Flügelrad bestehen, können mit einem sehr geringen Aussendurchmesser von etwa 1,5 mm gefertigt werden.

Generally, it is within the scope of the invention, however, also possible to integrate a pump motor in the catheter in close proximity to the pump, wherein the motor directly drives the impeller then.

---

Generell ist es im Rahmen der Erfindung aber auch möglich, einen Pumpenmotor in den Katheter, in direkter Nähe zur Pumpe, zu integrieren, wobei der Motor dann das Pumpenrad unmittelbar antreibt.

To place a balloon catheter in a blood vessel, usually a guidewire is introduced through the catheter is then pushed.

---

Um einen Ballonkatheter in einem Blutgefäß zu platzieren, wird in der Regel ein Führungsdraht eingebracht, über den der Katheter anschliessend geschoben wird.

Such relocation of a guide wire is also possible for the inventive balloon catheter.

---

Eine derartige Verlegung mit einem Führungsdraht ist auch bei dem erfindungsgemässen Ballonkatheter möglich.

Here, the guide wire must, however, be passed through the pump.

---

Hierbei muss der Führungsdraht allerdings durch die Pumpe hindurchgeführt werden.

The impeller of the pump or the pump itself is, therefore, configured such that the passage of a guide wire having a diameter of about 0.3 mm allows.

---

Das Flügelrad der Pumpe oder die Pumpe selbst ist demnach so ausgebildet, dass es den Durchgang eines Führungsdrahtes, der einen Durchmesser von etwa 0,3 mm hat, ermöglicht.

It should be noted that the pump is put into service until after the guidewire was sufficiently far removed from the immediate pump area.

---

Zu berücksichtigen ist, dass die Pumpe erst in Betrieb genommen wird, nachdem der Führungsdraht hinreichend weit aus dem unmittelbaren Pumpenbereich herausgezogen wurde.

During installation of the catheter, it is acceptable if the guide wire blocked the impeller.

---

Während der Verlegung des Katheters ist es hinnehmbar, wenn der Führungsdraht das Pumpenrad blockiert.

In the following the invention will be explained in more detail with reference to drawings of exemplary embodiments.

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Im folgenden werden unter Bezugnahme auf die Zeichnungen Ausführungsbeispiele der Erfindung näher erläutert.

In the drawings:

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Es zeigen:

1 is a longitudinal sectional view of the distal end portion of the balloon catheter in a first embodiment,

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Fig. 1 einen Längsschnitt durch den distalen Endbereich des Ballonkatheters bei einem ersten Ausführungsbeispiel,

2 shows the balloon catheter of Figure 1 with the inserted guide wire, wherein the pump is a monorail guide and

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Fig. 2 den Ballonkatheter nach Fig. 1 mit eingeschobenem Führungsdraht, wobei die Pumpe eine Monorail-Führung bildet, und

3 shows an embodiment in which the guide wire passes coaxially through the pump.

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Fig. 3 ein Ausführungsbeispiel, bei dem der Führungsdraht koaxial durch die Pumpe

hindurchgeht.

The balloon catheter 1 shown in Figure 1 comprises an elongate catheter tube 10, the length is about 1 m and its diameter is approximately 1.3 mm.

---

Der Ballonkatheter 1 nach Fig. 1 weist einen langgestreckten Katheterschlauch 10 auf, dessen Länge etwa 1 m beträgt und dessen Durchmesser ca. 1,3 mm beträgt.

The flexible catheter tube 10 has a concentric tube lumen 11 with a diameter of about 0.8 mm.

---

Der flexible Katheterschlauch 10 weist ein zentrales Schlauchlumen 11 mit einem Durchmesser von ca. 0,8 mm auf.

Further passing through the wall of the catheter tube 10 is a further lumen 12 for supply of pressure fluid to the balloon 14

---

Ferner verläuft durch die Wand des Katheterschlauchs 10 ein weiteres Lumen 12 zur Zuleitung von Druckfluid zu dem Ballon 14.

The tubular balloon support 13 is at the catheter tip with an inner diameter of about 0.8 mm and an outer diameter of about 1.0 mm.

---

An der Katheterspitze befindet sich der rohrförmige Ballonträger 13 mit einem Innendurchmesser von ca. 0,8 mm und einem Aussendurchmesser von ca. 1,0 mm.

This balloon carrier 13 is surrounded by at least one balloon 14.

---

Dieser Ballonträger 13 ist von mindestens einem Ballon 14 umgeben.

The balloon 14 is connected via a line 15 with the lumen 12 of the catheter tube 10 in combination.

---

Der Ballon 14 steht über eine Leitung 15 mit dem Lumen 12 des Katheterschlauchs 10 in Verbindung.

The front end of the balloon member 12 is tapered and has an axial and a plurality of lateral outlet openings on blood.

---

Das vordere Ende des Ballonträgers 12 ist verjüngt ausgebildet und weist eine axiale und mehrere seitliche Blutaustrittsöffnungen auf.

The pump is located between the catheter tube 10 and the balloon support 13 16

---

Zwischen dem Katheterschlauch 10 und dem Ballonträger 13 befindet sich die Pumpe 16.

This comprises a tubular pump body 17 with an outer diameter of about 1.5 mm.

---

Diese weist ein rohrförmiges Pumpengehäuse 17 mit einem Aussendurchmesser von ca. 1,5 mm auf.

The proximal end 17a of the pump housing is secured to the end of the catheter tube 10 and the distal end 17b is connected to the balloon support 13.

---

Das proximale Ende 17a des Pumpengehäuses ist an dem Ende des Katheterschlauchs 10 befestigt und das distale Ende 17b ist mit dem Ballonträger 13 verbunden.

The pump housing 17 is made of metal and it contains a bearing 18 in which the shaft 19 of the impeller 20 is supported.

---

Das Pumpengehäuse 17 besteht aus Metall und es enthält ein Lager 18, in dem die Welle 19 des Pumpenrades 20 gelagert ist.

The end of the catheter tube 10 is fitted between the bearing 18 and the pump housing 17.

---



Das Ende des Katheterschlauchs 10 ist zwischen dem Lager 18 und dem Pumpengehäuse 17 eingepasst.

Immediately after the end of the catheter tube 10 17 lateral inlets 21 are provided on the housing, can enter radially into the pump housing 17 through the blood.

---

Unmittelbar im Anschluss an das Ende des Katheterschlauchs 10 sind an dem Gehäuse 17 seitliche Einlässe 21 vorgesehen, durch die Blut radial in das Pumpengehäuse 17 eintreten kann.

In the area in which the impeller is 20, the housing 17 is circumferentially closed.

---

In dem Bereich, in dem sich das Pumpenrad 20 befindet, ist das Gehäuse 17 umfangsmässig geschlossen.

The impeller 20 has a plurality of vanes 22 which are disposed helically about the axis and extending over an angular range of at least 150 DEG.

---

Das Pumpenrad 20 weist mehrere Flügel 22 auf, die schraubenförmig um die Achse herum angeordnet sind und sich über einen Winkelbereich von mindestens 150 DEG erstrecken.

The axial length of the impeller 20 is about twice the maximum diameter of said pump wheel.

---

Die axiale Länge des Pumpenrades 20 beträgt ca. das Doppelte des maximalen Durchmessers dieses Pumpenrades.

The impeller 20 ends immediately before the balloon support 13

---

Das Pumpenrad 20 endet unmittelbar vor dem Ballonträger 13.

The shaft 19 of the impeller 20 is connected to a flexible shaft 23 which extends inside the lumen 11 of the catheter tube 10 and is connected at the proximal end with an external electric motor, the shaft at a speed in the order of 100 000 U / min. drives.

---

Die Welle 19 des Pumpenrades 20 ist mit einer flexiblen Welle 23 verbunden, die im Innern des Lumens 11 des Katheterschlauchs 10 verläuft und am proximalen Ende mit einem externen Elektromotor verbunden ist, der die Welle mit einer Drehzahl in der Grössenordnung von 100.000 U/min. antreibt.

For example, introduced into the region of a stenosis as the balloon portion of the catheter and the balloon 14 is pressurized and expanded in the pump 16 promotes blood from inlets 21 through the balloon support 13 therethrough.

---

Während der Ballonbereich des Katheters beispielsweise in den Bereich einer Stenose eingeführt und der Ballon 14 unter Druck gesetzt und dadurch aufgeweitet wurde, fördert die Pumpe 16 Blut von den Einlässen 21 durch den Ballonträger 13 hindurch.

The distal end of the balloon carrier 13 is provided with openings or open so that blood can there emerge from the balloon member 13 into the blood vessel into it.

---

Das distale Ende des Ballonträgers 13 ist offen oder mit Öffnungen versehen, so dass das Blut dort aus dem Ballonträger 13 in das Blutgefäss hinein austreten kann.

The embodiment of Figure 2 differs from that of Figure 1 only in that, in addition, a guide wire 25 is provided which is first placed into the blood vessel and the catheter is then pushed.

---

Das Ausführungsbeispiel von Fig. 2 unterscheidet sich von demjenigen der Fig. 1 nur dadurch, dass zusätzlich ein Führungsdraht 25 vorgesehen ist, der zunächst in dem Blutgefäss plaziert wird und über den dann der Katheter geschoben wird.

This flexible guide wire 25 extends generally outside of the catheter tube 10

---

Dieser flexible Führungsdraht 25 verläuft generell ausserhalb des Katheterschlauchs 10.

At the distal end of the catheter tube, preferably in the last 10 cm of the catheter tube 10 and in a part of the pump housing 17, there is a longitudinally extending channel 26, which forms a guide

portion (Monorail) through which the guidewire 25 is guided into the pump housing 17.

---

Am distalen Ende des Katheterschlauchs, vorzugsweise auf den letzten 10 cm des Katheterschlauchs 10 und in einem Teil des Pumpengehäuses 17, befindet sich ein längslaufender Kanal 26, der einen Führungsbereich (Monorail) bildet, durch den der Führungsdraht 25 in das Pumpengehäuse 17 geleitet wird.

The diameter of the guide wire is approximately 0.3 mm, so that the guidewire may extend between the blades through the impeller 20.

---

Der Durchmesser des Führungsdrahtes beträgt ca. 0,3 mm, so dass der Führungsdraht durch das Pumpenrad 20 zwischen dessen Flügeln hindurch verlaufen kann.

While the guidewire 25 is located in the pump housing, there is no rotation of the impeller.

---

Während der Führungsdraht 25 sich im Pumpengehäuse befindet, erfolgt keine Rotation des Pumpenrades.

After placing the catheter, the guide wire is pulled out of the treatment at least in the pump housing.

---

Nach dem Plazieren des Katheters wird der Führungsdraht für die Behandlung mindestens an dem Pumpengehäuse herausgezogen.

Here, the channel 26 is placed and the impeller 20 is designed so that the guide wire 25 at all times after the treatment can again be slid over the stationary impeller 20 in the direction of the balloon by the balloon member 13 through to the system, again with the help of guidewire 25 to place in a changed position without having to completely withdraw the balloon catheter 1 for this.

---

Dabei ist der Kanal 26 so plazierte und das Flügelrad 20 so gestaltet, dass der Führungsdraht 25 jederzeit nach erfolgter Behandlung erneut über das stehende Flügelrad 20 in Richtung des Ballons durch den Ballonträger 13 hindurch geschoben werden kann, um das System erneut mit Hilfe des Führungsdrahtes 25 in einer veränderten Position zu plazieren, ohne den Ballonkatheter 1 hierfür völlig zurückziehen zu müssen.

In the embodiment of Figure 3, the guide wire 25 extends coaxially through the flexible shaft 23, the shaft 19 and the impeller 20.

---

Bei dem Ausführungsbeispiel von Fig. 3 verläuft der Führungsdraht 25 koaxial durch die flexible Welle 23, die Welle 19 und das Flügelrad 20 hindurch.

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These parts have respective axial channels to be slid over the guide wire to (over-the-wire-technique).

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Diese Teile haben entsprechende Axialkanäle, um über den Führungsdraht geschoben werden zu können (Over-the-Wire-Technique).

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During operation of the pump, the guide wire may be withdrawn, in order to improve the flow through the balloon support 13.

---

Während des Betriebes der Pumpe kann der Führungsdraht zurückgezogen werden, um den Durchfluss durch den Ballonträger 13 zu verbessern.

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After withdrawal of the guide wire re-feeding is possible, if the placement of the catheter is to be changed.

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Nach dem Zurückziehen des Führungsdrahtes ist ein erneutes Vorschieben möglich, wenn die Platzierung des Katheters verändert werden soll.

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For the operation of the pump, however, this is not required.

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Für die Funktion der Pumpe ist dies allerdings nicht erforderlich.

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Are located on the balloon support multiple balloons may be provided 15 via the pump 16 across each of the balloons, a hydraulic supply line.

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Befinden sich auf dem Ballonträger mehrere Ballons, so kann für jeden der Ballons eine hydraulische Zuleitung 15 über die Pumpe 16 hinweg vorgesehen werden.

However, should the catheter in its thickest portion, ie in the area of the pump 16, specifically for use in the corona region (carotenes), not significantly exceed 1.5 mm in diameter, otherwise placement of the catheter via a standard catheter with 2 mm inner diameter would no longer be possible.

---

Dennoch darf der Katheter in seinem dicksten Bereich, also im Bereich der Pumpe 16, speziell für den Einsatz im Koronabereich (Karotinen), nicht wesentlich über 1,5 mm Durchmesser hinausgehen, da sonst eine Platzierung des Katheters über einen standardmässigen Einführungskatheter mit 2 mm Innendurchmesser nicht mehr möglich wäre.

It is also necessary that the length of the pump housing 17 does not exceed about 6 mm.

---

Ferner ist es erforderlich, dass die Länge des Pumpengehäuses 17 ca. 6 mm nicht übersteigt.

The embodiments described above refer to a balloon catheter that includes a working according to the principle of low-pressure pump 16, which is so arranged in the vicinity of the balloon carrier at the end of the catheter tube.

---

Die zuvor beschriebenen Ausführungsbeispiele beziehen sich auf einen Ballonkatheter, der eine nach dem Niederdruckprinzip arbeitenden Pumpe 16 enthält, die in der Nähe des Ballonträgers, also am Ende des Katheterschlauchs, angeordnet ist.

Here, the pump only needs to produce a relatively low pressure.

---

Hierbei braucht die Pumpe nur einen relativ geringen Druck zu erzeugen.

But in the invention it is also possible to arrange an intravascular pump in the course of the catheter tube that has a greater distance from the balloon support.

---

Im Rahmen der Erfindung ist es aber auch möglich, eine intravasale Pumpe im Zuge des Katheterschlauchs anzuordnen, die einen grösseren Abstand von dem Ballonträger hat.

Such a pump has to deliver a higher pump pressure, because in the course of the catheter tube takes place a pressure drop.

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Eine solche Pumpe muss einen höheren Pumpendruck liefern, weil im Zuge des Katheterschlauchs ein Druckabfall stattfindet.

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(54)【発明の名称】 超弾性複合型ガイドワイヤ

(57)【要約】

【課題】 本発明は、操作性に問題のあった従来のガイドワイヤを改良して、従来の問題点を取り除き、潤滑性の向上したガイドワイヤを提供することを目的とする。

【解決手段】 本発明は、カテーテルを体内管腔内で誘導するのに適したガイドワイヤセクションであって、少なくとも1つの近位および遠位セクションを有する細長い可撓性のある金属ワイヤコア、および上記遠位セクションの少なくとも一部分を被覆する超弾性合金の管状編組みを備える、ガイドワイヤセクションに関する

## 【特許請求の範囲】

【請求項1】 カテーテルを体内管腔内で誘導するのに適したガイドワイヤセクションであって、少なくとも1つの近位および遠位セクションを有する細長い可撓性のある金属ワイヤコア、および該遠位セクションの少なくとも一部分を被覆する超弾性合金の管状編組みを備える、ガイドワイヤセクション。

【請求項2】 前記編組みの超弾性合金がニッケルおよびチタンを含む、請求項1に記載のガイドワイヤセクション。

【請求項3】 前記編組みの超弾性合金がニチノールを含む、請求項1に記載のガイドワイヤセクション。

【請求項4】 前記編組みの超弾性合金が、75ksi±10ksiのUP、3%ひずみで測定された25±7.5ksiのLP、および6%ひずみまで応力-ひずみ試験において測定された場合0.25%未満のPSを有する、請求項1に記載のガイドワイヤセクション。

【請求項5】 前記遠位セクションがステンレス鋼を含む、請求項1に記載のガイドワイヤセクション。

【請求項6】 前記遠位セクションが超弾性合金を含む、請求項1に記載のガイドワイヤセクション。

【請求項7】 前記遠位セクションがニッケルおよびチタンの超弾性合金を含む、請求項6に記載のガイドワイヤセクション。

【請求項8】 前記遠位セクションがニチノール超弾性合金を含む、請求項7に記載のガイドワイヤセクション。

【請求項9】 前記遠位セクションが、75ksi±10ksiのUP、3%ひずみで測定された25±7.5ksiのLP、および6%ひずみまで応力-ひずみ試験において測定された場合0.25%未満のPSを有する超弾性合金を含む、請求項1に記載のガイドワイヤセクション。

【請求項10】 前記遠位セクション上の前記編組みの少なくとも一部分の外側に位置するポリマー性結合層をさらに含む、請求項1に記載のガイドワイヤセクション。

【請求項11】 前記結合層が、ナイロン、ポリエチレン、ポリスチレン、ポリウレタン、およびポリエチレンテレフタレートのうち少なくとも1つを含む、請求項10に記載のガイドワイヤセクション。

【請求項12】 前記結合層が、ポリエチレンテレフタレートまたはポリウレタンを含む、請求項11に記載のガイドワイヤセクション。

【請求項13】 前記結合層が、ポリウレタンであり、そして遠位方向に向かって変化する硬度を有する、請求項12に記載のガイドワイヤセクション。

【請求項14】 前記ポリマー性結合層の少なくとも一部分が、潤滑性ポリマー材料でコーティングされている、請求項10に記載のガイドワイヤセクション。

【請求項15】 前記潤滑性ポリマー材料が、エチレン

オキシド；2-ビニルピリジン；N-ビニルピロリドン；モノメトキシトリエチレングリコールモノ（メタ）アクリレート、モノメトキシテトラエチレングリコールモノ（メタ）アクリレート、ポリエチレングリコールモノ（メタ）アクリレートを包含するモノアルコキシポリエチレングリコールモノ（メタ）アクリレートなどのポリエチレングリコールアクリレート；2-ヒドロキシエチルメタクリレート、グリセリルメタクリレートなどの他の親水性アクリレート；アクリル酸およびその塩；アクリルアミドおよびアクリロニトリル；アクリルアミドメチルプロパンスルホン酸およびその塩から選択されるモノマーから生成されるポリマー、セルロース、メチルセルロース、エチルセルロース、カルボキシメチルセルロース、シアノエチルセルロース、セルロースアセテートなどのセルロース誘導体、アミロース、ペクチン、アミロペクチン、アルギン酸、および架橋ヘパリンなどのポリサッカライドを包含する、請求項14に記載のガイドワイヤセクション。

【請求項16】 前記潤滑性ポリマー材料が、ポリビニルピロリドンとポリアクリルアミドとの混合物を含む、請求項14に記載のガイドワイヤセクション。

【請求項17】 前記結合層が、硫酸バリウム、三酸化ビスマス、炭酸ビスマス、タングステン、およびタンタルから選択される放射線不透過性材料をさらに含む、請求項10に記載のガイドワイヤセクション。

【請求項18】 カテーテルシースをさらに含む、請求項1に記載のガイドワイヤセクション。

## 【発明の詳細な説明】

## 【0001】

【発明の属する技術分野】本発明は、外科用器具に関する。これは、カテーテル内で使用するための複合型ガイドワイヤであり、そして被験体の体内の管腔系の標的部に到達させるために使用される。このガイドワイヤコアまたはガイドワイヤセクションは、ステンレス鋼、または好ましくは特定の物理的パラメータをも有する高弾性金属合金、好ましくはNi-Ti合金からなる。この複合型ガイドワイヤアセンブリは、末梢または軟組織の標的部に到達させるのに特に有用である。本発明の変形例としては、中間セクションまたは遠位セクションに沿って（少なくとも）超弾性遠位部分と超弾性編組み補強材とを有する多重セクションガイドワイヤアセンブリが挙げられる。本発明のガイドワイヤの変形例は、カテーテル内および血管管腔内部での使用への適性を高めるために、ワイヤを結合層でコーティングし、次いで1種またはそれ以上の潤滑性ポリマーでコーティングすることを含む。

## 【0002】

【従来の技術】体内の種々の管腔系、特に血管系を通じて到達し得るヒト体内の内的部位へ診断用および治療用の薬剤を送達する手段として、カテーテルはますます使



用される。カテーテルガイドワイヤは、体内で血管を形成する、屈曲部、ループ部および分枝部を通してカテーテルを誘導するために用いられる。これらの管腔系の曲がりくねった経路を通してカテーテルを導くためにガイドワイヤを用いるある方法は、大腿動脈などの人体のアクセス点から標的部位を含む組織領域まで1つのユニットとして導かれるトルク伝達可能なガイドワイヤを使用することを含む。ガイドワイヤは、代表的には、その遠位端で曲げられ、そして小さな血管経路に沿ってガイドワイヤを交互に回転させ前進させることにより、所望の標的まで誘導され得る。代表的には、ガイドワイヤおよびカテーテルは、以下のことを交互に行うことによって、前進させられる。すなわち、血管経路内のある距離に沿ってガイドワイヤを動かし、ガイドワイヤを適所に保持し、次いで既に体内のさらに奥に進んでいるガイドワイヤの一部分にカテーテルが到達するまで、ガイドワイヤの軸に沿ってカテーテルを前進させる。

【0003】体内の遠隔領域、すなわち末梢部または脳や肝臓などの体内の軟組織に到達させるのが困難であることは明白である。カテーテルおよびそれに付随するガイドワイヤは、この組合せが組織内を通る複雑な経路について行き得るように共に可撓性を有していなければならない。しかも医師がカテーテル遠位端を外部アクセス部位から操作し得るのに十分に堅くなければならない。カテーテルは、通常、1メートルまたはそれ以上の長さである。

【0004】ヒトの血管系を通してカテーテルを誘導するのに用いられるカテーテルガイドワイヤは、多数の様々な可撓性構造を有する。例えば、米国特許第3,789,841号、第4,545,390号および第4,619,274号は、ガイドワイヤの遠隔領域において高い可撓性を可能にするために、ワイヤの遠位端セクションを長手方向に沿ってテーパー形状にした(tapered)ガイドワイヤを示している。遠位領域は最も鋭い曲がりに出会うところであるので、このワイヤはそうように構成されている。ワイヤのテーパー状セクション(tapered section)は、ワイヤコイル、代表的にはプラチナ製コイル内にしばしば封入され、その結果、その領域内の可撓性を有意に損なうことなくテーパー形状のワイヤセクションの支柱強度(column strength)を増大させ、そしてさらに、血管系を通してガイドワイヤを微妙に操作し得るようにガイドワイヤの半径方向の能力を増大させる。

【0005】別の有効なガイドワイヤの設計は、少なくとも2つのセクションを有するガイドワイヤを示している米国特許第5,095,915号に見られる。その遠位部分は、伸長されるポリマースリーブに包まれており、そのスリーブには、スリーブの曲げ可撓性を増大させるために、軸方向に間隔をおいた溝が設けられている。

【0006】その他にも、上記の機能面での要求のいくらかを成し遂げるために、種々の超弾性合金から作られ

たガイドワイヤの使用が示唆されている。

【0007】Sakamotoらの米国特許第4,925,445号は、比較的堅い本体部分と比較的可撓性のある遠位端部分とを有する、2つの部分からなるガイドワイヤの使用を示唆している。本体部分と遠位端部分のうち少なくとも一方の部分は、超弾性金属材料から形成される。49〜58% (原子(atm)) のニッケルを含むNi-Ti合金などの多数の材料が示唆されているが、この特許では、オーステナイトとマルテンサイトの間の相転移が10℃以下で完結するNi-Ti合金が非常に好ましいとされている。その理由について、「ガイドワイヤの温度は、ガイドワイヤが体内で使用可能であるためには、低体温時における感覚喪失のため10℃から20℃でなくてはならない」と述べているが、人体の体温は通常約37℃である。

【0008】Ni-Ti超弾性合金と同一組成を有する金属合金を用いたガイドワイヤを開示する別の文献としては、W091/15152号(Sahatjianら、Boston Scientific Corp.所有)がある。その開示は、Ni-Ti弾性合金に対する前駆体から作られたガイドワイヤを示唆している。このタイプの超弾性合金は、代表的には、前駆体合金のインゴットを加熱しながら同時にそれを引き延ばすことによって製造される。室温での無応力状態では、そのような超弾性材料はオーステナイト結晶相において生じ、そしてこの材料は、応力が与えられると、非線形の弾性作用を生じる応力誘発オーステナイトマルテンサイト(SIM)結晶変態を呈する。他方では、この公開された出願に記載されたガイドワイヤは、引き延ばし工程の間に加熱を受けないとされている。ワイヤは低温で引き延ばされ、多大な労力をかけて、その製造の各段階の間、合金を300°Fよりも十分低温に維持することを確実にする。この温度制御は、ガイドワイヤを研削して種々のテーパー状セクションを形成する工程の間、維持される。

【0009】米国特許第4,665,906号は、種々の異なる医療用具における構成要素として、応力誘発マルテンサイト(SIM)合金の使用を示唆している。そのような用具は、カテーテルおよびカニューレを包含するとされている。

【0010】Sugitaらの米国特許第4,969,890号は、形状記憶合金部材を取り付けた本体を有し、そして加温した液体を供給して、その流体により加温されると形状記憶合金部材が元の形状に回復し得るための液体注入手段を有するカテーテルの製造を示唆している。

【0011】Sticeの米国特許第4,984,581号は、形状記憶合金のコアを有するガイドワイヤを示唆している。このガイドワイヤは、合金の二方向記憶特性を用いて、制御された熱刺激に反応してガイドワイヤが先端部偏向運動と回転運動の両方を起こすようにしている。この場合の制御された熱刺激は、高周波(RF)交流電流の適用を

通じて行われる。選択された合金は、36℃と45℃との間の転移温度を有する合金である。36℃という温度は、人間の体温であることから選定された。45℃は、それより高温での操作では、体内組織、特にある種の体内タンパク質を破壊し得たので選定された。

【0012】Amplatzらの米国特許第4,991,602号は、ニチノールとして知られるニッケル-チタン合金などの形状記憶合金から作られた可撓性のあるガイドワイヤを示唆している。このガイドワイヤは、その中間経路を通じて直径が単一であり、両端に向かってテーパ形状になっており、そしてそれら端部の各々にビーズまたはボールを有する。ビーズまたはボールは、カテーテルを通過して血管系内へ容易に動かし得るように選ばれる。医師がガイドワイヤのどちらの端をカテーテル内に挿入するか決める際に間違った選択をし得ないように、ガイドワイヤは対称形である。この特許は、ガイドワイヤ先端部に巻かれたワイヤコイルは望ましくないことを示唆している。さらに、この特許は、ポリマーコーティング(PTFE)および抗凝固剤の使用を示唆している。この特許は、特定のタイプの形状記憶合金、またはこれら合金の特定の化学的、もしくは物理的な変形例がある方法では有利であることを全く示唆していない。

【0013】Ni-Ti合金を用いた、別のカテーテルガイドワイヤが、Yamauchiらの米国特許第5,069,226号に記載されている。Yamauchiらは、ある量の鉄をさらに含有するNi-Ti合金を用いたカテーテルガイドワイヤを記載している。しかし、この合金は、代表的には、約37℃の温度での疑似弾性と、約80℃未満での可塑性を示す端部セクションを与えるように、約400℃から500℃の温度で熱処理される。変形例では、末端部分のみが80℃未満の温度で可塑性を有する点である。

【0014】Sagaeらの米国特許第5,171,383号は、超弾性合金から製造され、次いで、近位部分から遠位端部分へ連続的に可撓性が増大するように熱処理されるガイドワイヤを示す。熱可塑性コーティングまたはコイルスプリングが、ワイヤ材料の遠位部分上に配置され得る。一般的に言えば、ガイドワイヤの近位端部分は、比較的高い剛性を維持し、そして最遠位端部分は非常に可撓性に富む。請求の範囲では、近位端セクションは約5~7kg/mm<sup>2</sup>の降伏応力(yield stress)を有し、ガイドワイヤの中間部分は約11~12kg/mm<sup>2</sup>の降伏応力を有する。

【0015】欧州特許公開公報第0,515,201-A1号もまた、少なくとも一部分が超弾性合金から製造されたガイドワイヤを開示している。この公報には、外科的手技に使用する直前に、医師が最遠位部分を所望の形状に屈曲またはカーブさせ得るガイドワイヤが記載される。ガイドワイヤのガイド先端部の近位部は、超弾性合金からなっている。その開示で示されたクラスでは、ニッケル-チタン合金が最も望ましいとされるが、それらの合金の物理的な記載が、別の合金より特に望ましいことは開示

されていない。

【0016】欧州特許公開公報第0,519,604-A2号も同様に、ニチノールのような超弾性合金から製造され得るガイドワイヤを開示している。ガイドワイヤコアはプラスチックの皮膜物(jacket)でコーティングされ、その一部分は親水性であり得、そして他の一部分は親水性ではない。

【0017】Ni-Ti合金の例は、米国特許第3,174,851号、第3,351,463号、および第3,753,700号に開示されている。

【0018】

【発明が解決しようとする課題】上記のこれらの開示は、いずれも、下記のような本発明のガイドワイヤの構成または形状を示唆していない。

【0019】従来のガイドワイヤは、その大きさおよび操作性に問題があった。さらに、ガイドワイヤがカテーテル管腔内を通過する際の摩擦も問題になっており、カテーテル管腔を通り抜ける能力を高めるために、潤滑性の向上したガイドワイヤが求められていた。

【0020】本発明は、操作性に問題のあった従来のガイドワイヤを改良して、上記のような問題点を取り除き、潤滑性の向上したガイドワイヤを提供することを目的とする。

【0021】

【課題を解決するための手段】本発明は、カテーテルを体内管腔内で誘導するのに適したガイドワイヤセクションであって、少なくとも1つの近位および遠位セクションを有する細長い可撓性のある金属ワイヤコア、および上記遠位セクションの少なくとも一部分を被覆する超弾性合金の管状編組みを備える、ガイドワイヤセクションに関する。

【0022】好適な実施態様においては、上記編組みの超弾性合金はニッケルおよびチタンを含む。

【0023】好適な実施態様においては、上記編組みの超弾性合金はニチノールを含む。

【0024】好適な実施態様においては、上記編組みの超弾性合金は、75ksi±10ksiのUP、3%ひずみで測定された25±7.5ksiのLP、および6%ひずみまで応力-ひずみ試験において測定された場合0.25%未満のPSを有する。

【0025】好適な実施態様においては、上記遠位セクションはステンレス鋼を含む。

【0026】好適な実施態様においては、上記遠位セクションは超弾性合金を含む。

【0027】好適な実施態様においては、上記遠位セクションはニッケルおよびチタンの超弾性合金を含む。

【0028】好適な実施態様においては、上記遠位セクションはニチノール超弾性合金を含む。

【0029】好適な実施態様においては、上記遠位セクションは、75ksi±10ksiのUP、3%ひずみで測定

された $25 \pm 7.5$ ksiのLP、および6%ひずみまで応力-ひずみ試験において測定された場合0.25%未満のPSを有する超弾性合金を含む。

【0030】好適な実施態様においては、上記ガイドワイヤセクションは、上記遠位セクション上の上記編組みの少なくとも一部分の外側に位置するポリマー性結合層をさらに含む。

【0031】好適な実施態様においては、上記結合層は、ナイロン、ポリエチレン、ポリスチレン、ポリウレタン、およびポリエチレンテレフタレートのうち少なくとも1つを含む。

【0032】好適な実施態様においては、上記結合層は、ポリエチレンテレフタレートまたはポリウレタンを含む。

【0033】好適な実施態様においては、上記結合層は、ポリウレタンであり、そして遠位方向に向かって変化する硬度を有する。

【0034】好適な実施態様においては、上記ポリマー性結合層の少なくとも一部分は、潤滑性ポリマー材料でコーティングされている。

【0035】好適な実施態様においては、上記潤滑性ポリマー材料は、エチレンオキシド；2-ビニルピリジン；N-ビニルピロリドン；モノメトキシトリエチレングリコールモノ（メタ）アクリレート、モノメトキシテトラエチレングリコールモノ（メタ）アクリレート、ポリエチレングリコールモノ（メタ）アクリレートを包含するモノアルコキシポリエチレングリコールモノ（メタ）アクリレートなどのポリエチレングリコールアクリレート；2-ヒドロキシエチルメタクリレート、グリセリルメタクリレートなどの他の親水性アクリレート；アクリル酸およびその塩；アクリルアミドおよびアクリロニトリル；アクリルアミドメチルプロパンスルホン酸およびその塩から選択されるモノマーから生成されるポリマー、セルロース、メチルセルロース、エチルセルロース、カルボキシメチルセルロース、シアノエチルセルロース、セルロースアセテートなどのセルロース誘導体、アミロース、ペクチン、アミロペクチン、アルギン酸、および架橋ヘパリンなどのポリサッカライドを包含する。

【0036】好適な実施態様においては、上記潤滑性ポリマー材料は、ポリビニルピロリドンとポリアクリルアミドとの混合物を含む。

【0037】好適な実施態様においては、上記結合層は、硫酸バリウム、三酸化ビスマス、炭酸ビスマス、タングステン、およびタンタルから選択される放射線不透過性材料をさらに含む。

【0038】好適な実施態様においては、上記ガイドワイヤセクションは、カテーテルシース(sheath)をさらに含む。

【0039】本発明は、ガイドワイヤに関し、好ましくは、脳の血管系内に導入するのに適したガイドワイヤお

よびその使用方法に関する。ガイドワイヤの少なくとも1つの遠位部分は、好ましくは、特定の物理的特性を有するNi-Ti合金である超弾性合金から作られ得る。すなわち、その特定の物理的特性は、例えば、応力-ひずみの関係が6%のひずみまで測定されたとき、一方の応力-ひずみのプラトーが $75 \pm 10$ ksiであり、もう一方の応力-ひずみのプラトーが $25 \pm 7.5$ ksi（各々3%のひずみで測定）である。

【0040】本発明のガイドワイヤの高度に望ましい変形例は、近位セクション、中間セクションおよび遠位セクションを有する長いワイヤを備えている。このガイドワイヤはさらに、 $1 \pm 10^{-4}$ の偏心率を有し得る。遠位端セクションは、代表的には、最も可撓性のあるセクションであり、そしてその長さは少なくとも約3cmである。望ましくは、可撓性のある遠位端セクションは、部分的にテーパー形状になり、そしてコイルアセンブリによって覆われている。このコイルアセンブリは、ガイドワイヤの遠位端にその遠位先端部にて連結されている。このコイルアセンブリは、おそらく、金などの展性またはハンダ付け可能な金属で遠位端セクションをめっきまたはコーティングした後、ハンダ付けによって遠位先端に取り付けられ得る。

【0041】カテーテル管腔を通り抜ける能力を高めるために、ガイドワイヤは、超弾性金属のものもそうでないものも、ポリマーまたは他の材料でコーティングされ得る。潤滑性ポリマーは、コアワイヤまたは「結合(tie)」層の上に直接配置され得る。結合層は、収縮被覆されたチューブまたはプラズマ堆積物であり得るか、もしくは、適切な材料の浸漬コーティング、スプレーコーティングまたは融着スプレーコーティングであり得る。結合層もまた、放射線不透過性であり得る。

【0042】本発明のガイドワイヤは、コアの遠位部分が下記のようなタイプの超弾性合金であり、そしてそのより近位方向の1つまたは複数のセクションが、例えば、ステンレス鋼のワイヤまたはロッド、ステンレス鋼のハイボチューブ、超弾性合金のチューブ、炭素繊維のチューブなどの別の材料または形状からなるような複合体からなり得る。

【0043】本発明のガイドワイヤは、コアの遠位部分が、ステンレス鋼または超弾性合金であり、そして研削されているかまたはテーパー状になっているが、超弾性合金リボンの細いコイルまたは編組みで被覆されているような複合体からなり得る。これにより、遠位セクションにおいてテーパー形状化のため高い可撓性を有し、かつ超弾性編組みの存在のため高い支柱強度を有するガイドワイヤアセンブリが提供される。

【0044】理想的には、ガイドワイヤ上に、例えば、その遠位先端部に、および潜在的には中間セクションの長手方向に沿って、1つまたはそれ以上の放射線不透過性マーカーが配置される。これらのマーカーは、ガイド

ワイヤの放射線不透過性を高めること、および、所望の可撓性を維持したままで、近位端から遠位端へのトルク伝達能力を高めることの両方の目的で使用され得る。

【0045】本発明はまた、ガイドワイヤコアと、所望の部位への配置のためにガイドワイヤに沿って血管系を通過して前進するように設計された、壁の薄いカテーテルとから形成されるカテーテル装置を包含する。

【0046】

【発明の実施の形態】図1は、本発明により作られたガイドワイヤの拡大側面図である。ガイドワイヤ(100)は、下記の合金の、可撓性のあるトルク可能なワイヤフィラメント材料から形成されるワイヤコアからなり、そしてその全長は、代表的には約50cmと300cmとの間である。近位セクション(102)は、好ましくは、均一な直径(その長手方向に沿って)を有し、その直径は、約0.010インチから0.025インチであり、好ましくは0.010インチから0.018インチである。比較的より可撓性のある遠位セクション(104)が、ガイドワイヤ(100)の遠位端の3cmから30cm以上にわたって伸びる。中間セクション(106)が存在し得る。この中間セクションの直径は、この中間セクションに隣接するワイヤの2つの部分の直径の間の中間である。中間セクション(106)は、連続的にテーパ形状になり得るか、多数のテーパ状セクションもしくは直径の異なるセクションを有するか、あるいは、その長手方向に沿って均一な直径から構成され得る。中間セクション(106)が一般に均一な直径からなる場合、ガイドワイヤコアは、(108)に見られるように直径が狭められる。ガイドワイヤ(100)の遠位セクション(104)は、代表的には、端部キャップ(110)、細いワイヤコイル(112)、およびハンダ付け接合部(114)を有する。細いワイヤコイル(112)は、放射線不透過性であり得、そしてそれに限定されるわけではないが、プラチナおよびその合金を含む材料から作られる。端部キャップ(110)は、放射線不透過性であり得、その結果、血管系を通じてカテーテルを挿入し、そしてガイドワイヤを通らせる工程の間にコイル(112)の位置を知り得る。ガイドワイヤの可撓性または形状性に不利に影響することなくその潤滑性を改善するために、ガイドワイヤの近位セクション(102)、中間セクション(106)および遠位セクション(104)の全部または一部は、ポリマー材料の薄い層(116)でコーティングされ得る。本発明は、上記ガイドワイヤの部分(portion)またはセクション(section)を有し、このガイドワイヤは、その上に下記の注目のポリマー結合層、および滑りやすい、例えば、親水性のポリマーコーティングを有する。

【0047】図2は、本発明による複合体であるガイドワイヤの一変形例を示す。例えば、ガイドワイヤコアの遠位部分が特定の合金から作られ、そして複合体は別の

材料または形状からなる。特に、複合型ガイドワイヤ(140)は、例えば、適切なステンレス鋼、またはポリイミドのような高性能ポリマー、または本明細書中の別の箇所では説明される合金のような高弾性合金からなる小直径のチューブのセクションである近位セクション(142)から形成される。ポリマー性被覆(covering)とおそらくポリマー性内部とを有する超弾性合金リボン管状編組み(braid)のような管状複合体もまた望ましい。管状の近位セクション(142)は、ハンダ付けまたはニカワ付けもしくは接合部(144)にて含まれる材料に適した他の接合方法によって、複合型ガイドワイヤアセンブリ(140)の遠位端へ伸びて行く遠位セクション(146)に取り付けられる。近位セクション(142)は、その代わりに、ステンレス鋼のような材料からなる単一(solid)ロッド、または繊維性炭素複合体であり得る。カテーテルアセンブリ(140)の遠位先端部(148)は、本明細書中で他に記載された形状と同じ形状からなり得る。カテーテルアセンブリは、所望ならば、ポリマー材料でコーティングされ得る(150)。

【0048】図3は、遠位セクション(104)および中間セクション(106)の遠位端の一実施態様を示す部分切取図である。金属性ガイドワイヤコアは、ポリマー(116)で部分的にコーティングされ、そして遠位先端部のテーパ部分上には展性金属コーティング(118)がなされることが示される。可鍛性金属は、金などの適切な放射線不透過性材料、または銀、プラチナ、パラジウム、ロジウム、およびそれらの合金などその他のハンダ付けし易い材料から選ばれ得る。先端部もまた、放射線不透過性コイル(112)を有する。このコイルは、ハンダ付け接合部(114)によりその近位端を限られ、そして(110)において、ガイドワイヤの端部に接合される。放射線不透過性コイル(112)は、プラチナ、パラジウム、ロジウム、銀、金、および、それらの合金のような公知の適切な材料から作られ得る。好適には、プラチナと少量のタングステンを含む合金である。コイル(112)の近位端および遠位端は、ハンダ付けによってコアワイヤに固定され得る。

【0049】図4は、本発明のガイドワイヤの遠位セクション(104)の別の実施態様を示す部分切取図である。この実施態様においては、金属ガイドワイヤコアは、ハンダ接合部(114)によって2つのセクションに分かれている近位テーパ部分(120)と遠位テーパ部分(122)、および均一直径先端部(124)を有する。この遠位先端部(124)の均一直径は、代表的には約0.002インチと0.005インチとの間であり、好ましくは約0.003インチであり得る。この遠位先端部(124)の長さは、好ましくは約1cmと5cmとの間であり、より好ましくは約2cmである。しかし、均一直径部分は、ハンダ接合部(128)とハンダ

接合部(114)との間の距離の少なくとも約25%にわたって伸びる。この均一直径部分は、制御性を高めるために、遠位先端部アセンブリの端を堅くしている。遠位セクション(104)全体の長さは、望ましくは約20cmと50cmとの間であり、好ましくは約25cmである。ガイドワイヤコアの近位テーパ部分(120)の最大径は、代表的には、約0.005インチと0.020インチとの間であり、好ましくは、約0.010インチである。遠位テーパ部分(122)および遠位先端部(124)はまた、展性金属コーティング(118)と共に図示される。この展性金属コーティング(118)は、医師の形成による曲がり具合を遠位テーパ部分(122)および遠位先端部(124)が維持するように設けられている。この実施態様においては、細いワイヤコイル(112)は、ハンダ接合部(114)でその近位端を限られ、そして端部キャップ(110)でその遠位端を限られる。端部キャップ(110)は、金属性リボン(126)によって、ガイドワイヤに連結される。リボン(126)は、ステンレス鋼、プラチナ、パラジウム、ロジウム、銀、金、タングステン、およびそれらの合金、あるいは可塑性であり容易にハンダ付けされる他の材料から作られ得る。リボン(126)は、端部キャップ(110)が細いワイヤコイル(112)に対して固定されるようにして、細いワイヤコイル(112)およびガイドワイヤの遠位セクション(104)の遠位先端部(124)にハンダ接合部(128)においてハンダ付けされる。

【0050】図5Aおよび5Bは、ガイドワイヤ(100)の遠位セクション(104)の、さらに別の本発明の実施態様を示す。図5Aは、本発明のガイドワイヤの部分切取側面図である。細いワイヤコイル(112)は、コイル(112)をコアワイヤおよび端部キャップ(110)に接合するポリマー接着体(136)で限られ得、そしてさらに、ハンダ接合部(128)によってガイドワイヤコアに固定される。この実施態様においては、ガイドワイヤの遠位セクション(104)は、さらに、ポリマー接着体(136)に対して近位方向にあるテーパ部分(120)と、ポリマー接着体(136)に対して遠位方向にあるテーパ部分(122)とを有する。遠位セクション(104)はまた、必要に応じて、内部コイル(132)によって囲まれ得る小径部分(130)または「ネック部」を有する。内部コイル(132)は、好ましくはハンダ付けしやすく、好ましくは放射線不透過性である適切な金属性材料から作られ得る。これは、好ましくは、プラチナまたはステンレス鋼である。ネック部(130)を作るための1つの方法は、ネック部に対して遠位方向にあるガイドワイヤ(134)の遠位部分を平坦化し、その結果得られるスパード(134)がもはや円形断面ではなく、むしろ長方形の形状になるようにすることである。これは、図5Bに

おいて、より見やすくされている。なぜなら、この図は、図5Aに示されるガイドワイヤの切取頂面図だからである。上記の実施態様にあるように、端部キャップ(110)は、金属性リボン(126)によってガイドワイヤに固定される。ハンダ接合部(128)は、ガイドワイヤコアを内部らせん状コイル(132)に固定する。そのコイル(132)は、リボン(126)を介して端部キャップ(110)を固定し、そしてさらに、外部の細いワイヤコイル(112)を固定する。この形状は、容易にはハンダ付けできないガイドワイヤ材料により使用した場合、特に有益である。ハンダ接合部は、ガイドワイヤに密着する必要はない。しかし、内部コイル(132)、リボン(126)および外部の細いワイヤコイル(112)はすべて、単一の一体化ユニットとして維持され、そしてガイドワイヤアセンブリ上で近位方向または遠位方向に滑る可能性は全くない。

【0051】図5Aおよび5Bに関して記載される実施態様は、高弾性合金から作られるガイドワイヤについて一般的に述べたものであるが、ステンレス鋼、プラチナ、パラジウム、ロジウムなどの、ガイドワイヤおよびリボンの材料は、その実施態様に適している。

【0052】図6Aおよび6Bは、本発明のカテーテルアセンブリの変形例の遠位セクション(170)および中間セクション(172)の部分の部分断面図を示す。図6Aおよび6Bで示される変形例において、コアは、より小さい直径に研磨されてこれら領域でより高い程度の可撓性を達成する。さらなる支柱強度およびトルク可能性を提供するために、平坦化された巻きリボン(176)(図6A)またはコイル(178)(図6B)がコア上に配置される。さらに、コア(174)を構成する超弾性合金の多くは、特に放射線不透過性ではないので、医師がガイドワイヤアセンブリの位置をより多くの場合観察できるように、リボン(176)またはコイル(178)に対して放射線不透過性材料を使用することがしばしば望ましい。実際、リボン(176)またはコイル(178)が、カテーテルアセンブリの遠位先端部から25〜35cm伸びるように(コイル(112)と一緒に)伸びることは希なことではない。また、遠位コイル(112)それ自身が、10cmかそこらまでの長さであることも希ではない。最後に、より近位のコイル(178)において、遠位コイル(112)よりも小さな直径を使用して、放射線不透過性画像、およびより少ない全体重量でガイドワイヤベルトに対して増大した支柱強度を提供することが望ましい。

【0053】あるいは、リボンは、本明細書中の別の箇所で説明したように超弾性合金からなり得る。超弾性合金リボンは、(より放射線不透過性である材料と比較して)重量を少なくして支柱強度を向上させるように求められる。リボンが超弾性合金である場合、そのリボンは、望ましくは、厚さが0.0005インチと0.002

インチとの間であり、そして幅が0.002インチと0.012インチとの間であるサイズからなっている。製造を簡単にするために、リボンは、厚さが0.00075インチから0.001インチであり得、そして幅が0.003インチから0.005インチであり得る。

【0054】さらに、本発明者らは、ガイドワイヤコアの全部または一部を、ポリフルオロカーボンのような潤滑性コーティング材料を用い、または親水性ポリマーを用いてコーティングすることが（以下により詳細に考察されるように）望ましいことを見出した。以下に考察されるように、コーティング材料として親水性ポリマーを使用する場合、ガイドワイヤコア上に結合層を使用することがしばしば望ましい。このような結合層の組成もまた、以下で考察される。しかし、図6Aおよび6Bで示される変形例においては、結合層と親水性ポリマー（180）との組み合わせは、中間セクション補強材（176）および（178）を覆って配置されるとして示される。

【0055】図7は、フィラメントコア(filamentary core)（175）が、そのより遠位の領域においてテーパ状にまで研削されている本発明の変形例を示す。この局面では、このコアは、上記で説明した他の変形例とほぼ同様なものである。本変形例におけるコア（175）は、ステンレス鋼からなっているもよいし、または本明細書中の別の箇所です述べた高弾性合金のうちの1つからなっているもよい。次いで、コア（175）は、管状金属性編組み（177）で少なくとも部分的に被覆されており、この管状金属性編組み（177）は、好ましくは、コア（175）に沿って間隔をあけて、または編組みの一端から他端まで連続的にのいずれかで、接着剤またはハンダにより、あるいは溶接により、コア（175）に結合する。最も望ましい編組み（177）は、図7に示され、そして単一サイズのリボンを有するが、この編組みはそうに限定される必要はない：所望な場合、複数のサイズのリボンが用いられ得る。主に制限されるのは、単に、最終的に構築された編組み全体のサイズ（例えば、直径）、およびガイドワイヤに加えられるべき所望に加える剛直性である。

【0056】本発明において代表的に有用な編組みは、偶数個のリボンを含む：リボンの一方の半分は一方に巻き付けられており（すなわち、時計回り）、そして残りの半分は別方向に巻き付けられている。代表的な編組みは、8個から16個のリボンからなり得る。編組みは、単一のピッチを有し得、構成要素であるリボンの角度は編組みの軸に対して測定されており、あるいは編組みは、編組みの軸に沿って変化するピッチを有し得る。編組みは、ガイドワイヤコアと同様のサイズのマンドレルを覆って巻き付けられ得、そして編組みの形状を保持し、コアワイヤ上へのその後の取り付けの間に編組みがほどけるのを防ぐために、そのマンドレル上で650°

Fから750°Fの温度で1時間未満(a portion of an hour)穏やかに熱処理され得る。編組みはまた、所望であれば、コア上に直接巻き付けられ得る。

【0057】編組み（177）は、被覆されないかまたはさらに加工処理されなければ、通常は触わるとざらざらしている。ローリング(rolling)、サンディング(sanding)、またはグラインディング(grinding)のような手法が、所望であれば、編組みの表面を滑らかにするために用いられ得る。いかなる生成微粒子の除去も、もちろん必要である。編組み（177）の外表面が滑らかにされていようとなかろうと、編組みの外側に潤滑性ポリマーの外部層を配置することが非常に望ましい。図7に示される変形例は、本明細書中の別の箇所です説明した結合層（179）を用いており、そして結合層（179）の外側に配置された親水性ポリマー層の薄層を有する。親水性ポリマー層は、この層が代表的には薄すぎて見えないので、図面上には示されていない。結合層（179）およびその関連の親水性ポリマー層は、より近位のセクション上の層（181）と同じ構成からなり得る（が、同じである必要はない）。

【0058】図8は、本発明のガイドワイヤにおける中間セクション接合部の部分側面図である。本発明のガイドワイヤの多くの変形例に関して、コアの種々のセクションが（190）で見られるようなテーパ状セクションにより接合されている。これは、ガイドワイヤコアが、テーパ接合部（190）の近位端において有意により堅くなっていることを意味する。その連結部におけるガイドワイヤの全体的な堅さを低減し、しかも支柱強度を保持するために、その近位端に溝（192）を設けることが望ましい場合があることが分かった。

#### 【0059】ガイドワイヤコア

このガイドワイヤは、代表的には、近位端および遠位端を有する細長い管状部材から作られるカテーテルにおいて使用される。カテーテルの長さは、（さらに）約50cmから300cmであり、代表的には、約100cmと200cmとの間である。しばしば、カテーテルの管状部材は、カテーテルの長手方向の主要部分に沿って伸びる比較的堅い近位セクションと、1つまたはそれ以上の比較的可撓性のある遠位セクションとを有する。この遠位セクションを設けることにより、カテーテルが血管系内に見られる曲がりくねった経路を通して進められるときに会う鋭い屈曲部や曲がり目を通してガイドワイヤを追跡するカテーテルの能力が非常に高められる。長手方向に沿って異なる可撓性を有する適切なカテーテルアセンブリの構造が、米国特許第4,739,768号に記載されている。

【0060】ある種の合金、特にNi-Ti合金は、血管系内を通り抜ける間、それらの超弾性特性が保持され、しかも十分に曲げ易いことが見いだされた。そのため、ガイドワイヤを使用する医師は、「感触(feel)」ま

たはフィードバックが高められ、しかも使用中に「はねる(whip)」ことがない。すなわち、ガイドワイヤは、回されると、1ひねりの間エネルギーを蓄えて、そして「はねる」ことで急激にエネルギーを放出して蓄えた応力を素早く回復する。好適な合金は、その使用中に回復しないひずみをあまり受けない。もしワイヤの偏心、すなわち、ガイドワイヤ断面の「丸み(roundness)」(特に中間セクション)からの逸脱が非常に低い値に維持される場合は、ガイドワイヤは血管系を前進させ、または方向付けさせるのが極めて容易なこともまた見い出された。

【0061】本発明のガイドワイヤに使用される材料は、超弾性/擬弾性の形状回復特性を示す形状記憶合金からなる。これらの合金は公知である。例えば、米国特許第3,174,851号、第3,351,463号および第3,753,700号を参照のこと。しかし、米国特許第3,753,700号は、鉄の含有量の増量に起因する材料の高モジュラスのゆえに、あまり望ましくない材料を記載している。これらの金属は、オーステナイト結晶構造から応力誘発マルテンサイト(SIM)構造へ一定の温度で転移され、そして、応力が除かれたときに弾性的にオーステナイト構造に戻るという能力により特徴付けられる。これらの交互の結晶構造は、合金に超弾性特性を与える。そのような周知の合金の一つであるニチノールは、ニッケル-チタン合金である。それは、すでに市販されており、そして-20℃と30℃との間の様々な温度範囲において、オーステナイト-SIM-オーステナイトの変態を受ける。

【0062】これらの合金は、一旦応力が取り除かれると、ほとんど完全に初期の形状に弾性的に回復する能力を有するため、特に適している。代表的には、たとえ比較的高度のひずみにおいてさえも、ほとんど塑性変形がない。このため、ガイドワイヤは、人体の血管系を通る際に実質的に曲げられるようになり、しかも、一旦屈曲部を通り抜けると、ねじれ(kink)またはたわみの暗示を全く受けずに、元の形状に戻り得る。しかし、図示されている先端部はしばしば十分に可塑性を有するので、初期の先端部の形成は保持される。それにも関わらず、類似のステンレス鋼ガイドワイヤに比べると、血管内の所望の経路に沿って本発明のガイドワイヤを変形させるために、血管内壁に対して働かす力はあまり必要としない。そのため、血管の内部に対する外傷を減らし、そして同軸上のカテーテルに対する摩擦を軽減する。

【0063】ガイドワイヤは、標的部位に向かって血管系を通過する間に、数多くたわんだり、湾曲したりし得る。たわんだ遠位先端部を血管系の所望の分岐部に入れ得るために、ガイドワイヤのねじり易さを促進することは、誇張ではなく、望ましい。そのような使いやすさ、すなわちガイドワイヤの制御性を高める主要な要因は、ガイドワイヤの中間部分の断面の偏心を制御することに

あることが見い出された。ガイドワイヤの中間部分(図1の106)を偏心率 $1 \pm 10^{-4}$ に維持することで、ガイドワイヤは、この範囲外の率のものに比べて非常に制御しやすくなることが見い出された。「偏心」とは、ガイドワイヤに沿った任意の点において、その断面でのワイヤの最大直径と最小直径の比率を意味する。

【0064】担当医が使用中のフィードバックを可能にする面で見え、高い強度と向上した制御性のこれらの結果を達成するためには、合金の以下の物理的パラメータが重要であることがわかった。図9の応力-ひずみ図に示されるような応力-ひずみ試験において、上方プラトー(upper plateau)(UP)(例えば、試験の終点が約6%ひずみである場合、約3%ひずみのところで測定される)の中間点において見られる応力は、75ksi(1平方インチ当り1000ポンド) $\pm 10$ ksiの範囲、より好ましくは、75ksi $\pm 5$ ksiの範囲にあるべきである。さらに、この材料は、下方プラトー(lower plateau)(LP)の中間点において測定された、25 $\pm 7.5$ ksi、より好ましくは、20 $\pm 2.5$ ksiの下方プラトーを示すべきである。この材料は、好ましくは約0.25%以下の残留ひずみ(RS)を有し、(6%ひずみまで応力をかけ、戻した場合)、より好ましくは約0.15%以下の残留ひずみを有する。

【0065】この好適な材料は、基準としては、50.6% $\pm 0.2$ %のNiと、残りはTiである。合金は、O、C、またはNのいずれかの100万個当り約500部以下を含有するべきである。代表的には、そのような市販の材料は連続して混合 鑄造 成形され、そして別々に30-40%まで鍛えられ、焼きなまされ(annealed)、引き伸ばされる。

【0066】さらに説明すると、図9は、上記の種々のパラメータを示す定式化された応力-ひずみ図と、その図におけるそれらの測定値を示している。応力が初期に材料のサンプルに加えられる場合、オーステナイトからマルテンサイトへの相変化が(b)のところで始まるまで、ひずみは最初は、(a)において比例している。上方プラトー(UP)では、応力が加わると共に導入されたエネルギーは、準安定マルテンサイト相または応力誘発マルテンサイト(SIM)の形成の間に蓄えられる。相変化が実質的に完了すると、応力-ひずみの関係は(c)において再び比例関係に近づく。ひずみが6%に達すると、応力はもはや加えられない。測定値(UP)は、0%ひずみと6%ひずみとの間の中間点、すなわち3%ひずみのところで見られる。ひずみの別の最終状態が選ばれる場合、例えば、7%とした場合、(UP)および(LP)の測定値は、3.5%になることがわかる。

【0067】UP値の高い材料は、非常に強度があり、そして例外的に優れたトルク伝達を可能にするガイドワイヤを作り出すが、得られたガイドワイヤの「真直性

(straightness)」については、妥協的なものになる。高いLP値と共に高いUP値を有するガイドワイヤは真直とはならないことが分かる。これらのガイドワイヤは、回されると、「はねる」傾向があるために使いにくい。さらに、すなわち、ガイドワイヤは、回されると、1ひねりの間エネルギーを蓄えて、そしてそれを素早く放出する。そのようなはねるガイドワイヤを使用する難しさは明白である。上記のようなUP値を有する材料がガイドワイヤとして適している。

【0068】さらに、その上高いLP値を有する材料は真直とはならない。LP値を下げることにより、ガイドワイヤのトルク伝達能力は低下するが、真直なガイドワイヤは改善されて製造されやすくなる。しかし、LP値を下げ過ぎると、丸みはあるが触覚反応(tactile response)に乏しいガイドワイヤになってしまう。それは、使用中に、やや「漠然(vague)」とした「スープのような(soupy)」感触を与える。上記で与えられるLP値では、優れたトルク伝達性、真直性、および有用な触覚反

応が得られる。

【0069】上記の残留ひずみの値は、ガイドワイヤとして使用される際に、応力が加わった後に、ねじれないような、さもなければ「配置(set)」または形状を保持するような材料を定義している。

【0070】(実施例) どの場合も、以下の表に示されたデータを得る際に、以下の手法を用いた。基準の組成が、Ni 50.6%と残りがTi、そして直径が0.13インチ、0.16インチまたは0.18インチである市販のNi-Ti合金ワイヤに、室温で応力をかけた。どの場合も、転移温度、PS、UPおよびLPの値を測定した。さらに、上記ワイヤの数本をU字形状のTygonチューブ内に導入し、そしてワイヤの丸みおよび触覚反応の定性的な評価を可能にするためにそれをスピンさせた。その反応に対するコメントもまた以下の表に見られる。

【0071】

【表1】

| 番号             | 比較例/本発明<br>(C/I) | UP<br>(ksi) | LP<br>(ksi) | PS<br>(%) | A*<br>T°C | 定性<br>スピン試験    |
|----------------|------------------|-------------|-------------|-----------|-----------|----------------|
| 1 <sup>1</sup> | I                | 74.48       | 31.45       | 0.06      | -11       | スムーズな回転、良好な感触  |
| 2 <sup>2</sup> | I                | 76.94       | 18.90       | 0.121     | -8        | スムーズな回転、良好な感触  |
| 3 <sup>3</sup> | I                | 71.92       | 24.06       | 0.10      | 13.5      | スムーズ           |
| 4 <sup>4</sup> | C                | 78.24       | 58.82       | 0.20      | -9        | ひどく粗い回転、はねる    |
| 5 <sup>5</sup> | C                | 63.80       | 13.25       | 0.2       | 12.5      | スムーズな回り、かゆ様の感触 |
| 6 <sup>6</sup> | C                | 58.30       | 13.31       | 0.0       | -12       | 粗い回り、かゆ様の感触    |
| 7 <sup>7</sup> | C                | --          | --          | --        | --        | 回しにくい          |

1 U. S. Nitinol, Inc. より市販

2 Special Metals, Inc. より市販

3 Shape Metal Alloys, Inc. より市販

4 プラスチックでコーティングした0.13インチガイドワイヤとして、Fuji Terumo, Inc. より市販

5 ITIより市販

6 Metal Tekより市販

7 ステンレス鋼

\* 応力を加えないで室温にて測定された。

【0072】これらのデータは、本発明により作られたガイドワイヤと、比較のガイドワイヤの両方を記載している。さらに、それらは、代表的なステンレス鋼合金から作られたガイドワイヤが上記の定性試験を用いて回転させるのが非常に難しいことを示す。

【0073】ガイドワイヤコアコーティング

上記のように、ガイドワイヤコアの全てまたは一部は、ポリマー性材料の1つまたはそれ以上の層で被覆またはコーティングされ得る。コーティングは、代表的には、ガイドワイヤコアがカテーテル管腔または血管壁を通る際の潤滑性を向上させるために付与される。

【0074】コーティング材料

上記のように、ガイドワイヤコアの少なくとも一部分は、ポリスルホン；ポリフルオロカーボン（TEFLONなど）；ポリエチレン、ポリプロピレンなどのポリオレフィン、ポリエステル（ナイロン(NYLON)類などのポリアミドを含む）、およびポリウレタン；それらのブレンドならびにポリエーテルブロックアミド（例えば、PEBA X）などのそれらのコポリマー、などの材料で、浸漬法またはスプレー法により、あるいは同様の方法により簡単にコーティングされ得る。

【0075】ガイドワイヤの近位部分で上記のようなコ



ーティングを用い、そしてさらに遠位セクションで下記のようなコーティングを用いることが、しばしば望ましい。ガイドワイヤ上に様々に置かれたコーティングのあらゆる混合物が、手作業に対して選択する上で受容可能である。

【0076】ガイドワイヤコアはまた、エチレンオキシサイドおよびそのより高級な同族体；2-ビニルピリジン；N-ビニルピロリドン；モノメトキシトリエチレングリコールモノ（メタ）アクリレート、モノメトキシテトラエチレングリコールモノ（メタ）アクリレート、ポリエチレングリコールモノ（メタ）アクリレートを包含するモノアルコキシポリエチレングリコールモノ（メタ）アクリレートなどのポリエチレングリコールアクリレート；2-ヒドロキシエチルメタクリレート、グリセリルメタクリレートなどの他の親水性アクリレート；アクリル酸およびその塩；アクリルアミドおよびアクリロニトリル；アクリルアミドメチルプロパンスルホン酸およびその塩などのモノマーから生成されるポリマー、セルロース、メチルセルロース、エチルセルロース、カルボキシメチルセルロース、シアノエチルセルロース、セルロースアセテートなどのセルロース誘導体、アミロース、ベクチン、アミロベクチン、アルギン酸、および架橋ヘパリンなどのポリサッカライド；無水マレイン酸などのモノマーから生成されるポリマー；アルデヒドなどのモノマーから生成されるポリマー、を包含する他の親水性ポリマーで少なくとも部分的に被覆され得る。これらのモノマーは、ホモポリマーまたはブロックコポリマーもしくはランダムコポリマーに形成され得る。あるいは、これらのモノマーのオリゴマーをガイドワイヤのコーティングに用いてさらに重合させてもよい。好ましい前駆体としては、エチレンオキシサイド；2-ビニルピリジン；N-ビニルピロリドンならびにアクリル酸およびその塩；アクリルアミドおよびアクリロニトリルが挙げられ、それらは、ホモポリマーに、またはランダムコポリマーもしくはブロックコポリマーに（実質的な架橋で、または架橋なしで）重合される。

【0077】さらに、得られたコポリマーの親水性が、実質的に相殺されない場合には、疎水性モノマーは、得られるコポリマーの約30重量%までの量でコーティングポリマー材料に含まれ得る。適切なモノマーとしては、エチレン、プロピレン、スチレン、スチレン誘導体、アルキルメタクリレート、ビニルクロライド、ビニリデンクロライド、メタクリロニトリル、およびビニルアセテートが挙げられる。エチレン、プロピレン、スチレン、およびスチレン誘導体が好ましい。

【0078】ポリマーコーティングは、種々の技術を用いて、例えば、紫外線などの光、熱、もしくは電離放射線により、または過酸化アセチル、過酸化クミル、過酸化プロピオニル、過酸化ベンゾイルなどの過酸化物またはアゾ化合物により架橋され得る。ジビニルベンゼン、

エチレングリコールジメタクリレート、トリメチロールプロパン、ペンタエリトリールジ（またはトリもしくはテトラ）メタクリレート、ジエチレングリコール、またはポリエチレングリコールジメタクリレートなどの多官能性モノマー、およびモノマーと上記のポリマーとを結合し得る同様の多重官能性モノマー。

【0079】下記の手順を用いて適用されるポリマーまたはオリゴマーは、光学活性基または放射活性基によって活性化または官能化されて、ポリマーまたはオリゴマーと、基礎となるポリマー性表面とを反応させる。適切な活性化基としては、ベンゾフェノン、チオキサントニンなど；アセトフェノンおよび以下のように特定されるその誘導体が挙げられる：

【0080】

【化1】



【0081】ここで、 $\text{R}^1$ はHであり、 $\text{R}^2$ はOHであり、 $\text{R}^3$ はPhであり；または $\text{R}^1$ はHであり、 $\text{R}^2$ は $-\text{OCH}_3$ 、 $-\text{OC}_2\text{H}_5$ を包含するアルコキシ基であり、 $\text{R}^3$ はPhであり；または $\text{R}^1=\text{R}^2$ =アルコキシ基であり、 $\text{R}^3$ はPhであり；または $\text{R}^1=\text{R}^2$ =アルコキシ基であり、 $\text{R}^3$ はHであり；または $\text{R}^1=\text{R}^2=\text{C}1$ であり、 $\text{R}^3$ はHまたはC1である。

【0082】他の公知の活性化剤も適切である。

【0083】次に、ポリマーコーティングは、選択された活性化剤に基づいて選択される公知かつ適切な技術を用いて、例えば、紫外線、熱または電離放射線により基材に結合され得る。ここで挙げたポリマーまたはオリゴマーとの架橋は、過酸化アセチル、過酸化クミル、過酸化プロピオニル、過酸化ベンゾイルなどの過酸化物またはアゾ化合物を用いることによって成し遂げられ得る。ジビニルベンゼン、エチレングリコールジメタクリレート、トリメチロールプロパン、ペンタエリトリールジ（またはトリもしくはテトラ）メタクリレート、ジエチレングリコール、またはポリエチレングリコールジメタクリレートなどの多官能性モノマー、および上記のポリマーおよびオリゴマーを結合し得る同様の多重官能性モノマーもまた本発明に適切である。

【0084】ポリマーコーティングは、任意の種々の方法、例えば、ポリマーまたは、モノマーのオリゴマーの溶液もしくは懸濁液をガイドワイヤコア上にスプレーすることにより、またはガイドワイヤコアをこのような溶液または懸濁液に浸漬させることにより、ガイドワイヤに付与され得る。開始剤は、溶液中に含有させ得るか、個別の工程において添加され得る。ポリマーまたはオリゴマーをガイドワイヤに付与し、架橋させた後、ガイドワイヤは、連続してまたは同時に乾燥され、溶媒が除去

され得る。

【0085】ポリマーの非常に薄い層のみが付与されるべきなので、溶液または懸濁液は、非常に希釈であるべきである。溶媒に対して0.25%と5.0%（重量(wt)）との間、好ましくは0.5から2.0%（重量）の量のオリゴマーまたはポリマーが、薄くて完全な被覆を有するポリマーを得るのに優れていることが見いだされた。好ましいポリマーおよび手法を用いる場合に、この手法に対して好ましい溶媒は、水、低分子量アルコール、およびエーテルであり、特に、メタノール、プロパノール、イソプロパノール、エタノール、およびそれらの混合物である。他の水混和性溶媒、例えば、テトラヒドロフラン、メチレンジクロライド、メチルエチルケトン、ジメチルアセテート、エチルアセテートなどが、ここに挙げたポリマーに適切であり、そしてポリマーの特徴に応じて選択されなければならない。また、ポリマーおよびオリゴマーが親水性を有するのでこれらの溶媒は極性であるべきであるが、これらの材料の末端基が反応性を有するために、酸素、水酸基などにより引き起こされる公知のクエンチング効果は、ポリマーおよび溶媒系を選ぶ際に、このプロセスを実施する使用者によって認識されなければならない。

【0086】本明細書中に考察されたガイドワイヤコアのコーティングとして特に好ましいのは、ポリエチレンオキサイド；ポリ2-ビニルピリジン；ポリビニルピロリドン、ポリアクリル酸、ポリアクリルアミド、およびポリアクリロニトリルのうち少なくとも1つのホモオリゴマーの物理的混合物である。カテーテル本体または基材は、好ましくは、スプレーまたは浸漬され、乾燥され、そして照射されて、重合および架橋された上記のオリゴマーのポリマー性皮膜が形成される。

【0087】潤滑性親水性コーティングは、好ましくは、溶媒除去と架橋操作とをほぼ同時に用いることによって形成される。コーティングは、溶液が「シート状になり」得るような速度で、例えば、「たるみ(runs)」がなく、肉眼で見て滑らかな層が形成されるような速度で適用される。下記のものを含む大抵のポリマー性基材に用いられる浸漬操作において、最適なコーティング速度は、0.25インチ/秒と2.0インチ/秒との間、好ましくは0.5インチ/秒と1.0インチ/秒との間の線形除去速度であることがわかる。

【0088】溶媒の蒸発操作は、25℃と、基礎となる基材のガラス転移温度( $T_g$ )との間の温度で表面を維持するのに適切な加熱チャンバーを用いて行われ得る。好ましい温度は、50℃から125℃である。上記の好ましい溶媒系に対して最も好ましいのは、75℃から110℃の範囲である。

【0089】ポリマー前駆体を基材上に架橋させるために、紫外線源が用いられ得る。50～300mW/cm<sup>2</sup>（好ましくは、150～250mW/cm<sup>2</sup>）の照射密度を有す

る、90～375nm（好ましくは、300～350nm）の紫外線源を有する照射チャンバー中を3から7秒間移動させることが、望ましい。3から9インチの長さを有するチャンバーにおいて、ガイドワイヤコアを0.25から2.0インチ/秒（0.5から1.0インチ/秒）の速度でチャンバー中を通過させるのが適切である。電離放射線を用いる場合は、1から100kRads/cm<sup>2</sup>（好ましくは、20から50kRads/cm<sup>2</sup>）の放射密度が、ポリマー性基材上の溶液または懸濁液に適用され得る。

【0090】得られたコーティングの優れた耐久性は、浸漬／溶媒除去／照射の工程を5回まで繰り返すことによって生じる。2から4回繰り返すのが好ましい。

#### 【0091】結合層

外部ポリマー表面とガイドワイヤコアとの間にコーティングとして「結合(tie)」層を設けて、外部ポリマー表面とコアとの全体的な接着性を高めることがしばしば望ましいことが見いだされた。もちろん、これらの材料は、他の製造工程の間、ガイドワイヤおよびその構成要素に用いられる種々の他の溶媒、洗浄剤、滅菌手法などに耐えられなければならない。

【0092】図10は、金属コア(202)、ポリマー結合層(204)、および潤滑性コーティング(206)を備えた、代表的なガイドワイヤコアセクション(200)を示す。このような結合層の材料の選択は、それらの機能性によって決定される。特に、材料は、外部ポリマーの潤滑性または親水性のコーティングに対する親和性またはテナシティに対して選択される。明らかに、結合層材料が可撓性と強度を有していなければならない。結合層は、種々の方法でガイドワイヤコア上に装着される。ポリマー性材料は、押出し成形可能であり得、加熱によってガイドワイヤ上に取り付けられる収縮可能なチューブに成形され得る。結合層は、浸漬、スプレー、ポリマー性チューブの収縮被覆、または他の手法によって、ガイドワイヤコア上に装着され得る。非常に望ましい1つの手法は、融着可能なポリマー（例えば、ポリウレタン）のポリマー性チューブをガイドワイヤコア上に装着し、そして次に、ポリエチレンのような熱収縮チューブで被覆する工程を包含する。外側のチューブは収縮し、そして内側のチューブがガイドワイヤコア上に融着して、結合層を形成する。結合層は好ましくは0.0004インチから0.003インチの厚みである。結合層ポリマーの熔融温度は、望ましくは、外側のチューブの熱収縮温度で融着するように適切に選択される。次いで、外側の収縮チューブは容易に剥離され、潤滑性コーティングによる処理のために露出された結合層が残される。

【0093】種々のナイロン類、ポリエチレン、ポリスチレン、ポリウレタン、およびポリエチレンテレフタレート(PET)が、優れた結合層を形成することが見いだされた。好ましくは、ポリウレタン(Shore 80A-55D)およびPETである。最も好ましくは、ポリウレタンであ

る。異なる硬度を有する多数のポリウレタンのセクションを用いることもまた望ましい。例えば、遠位セクションは、Shore 80Aポリウレタンの結合層を有し得、近位シャフトはShore D55ポリウレタンであり得る。これらの材料は、硫酸バリウム、三酸化ビスマス、炭酸ビスマス、タングステン、タンタルなどの放射線不透過性材料を含有するように配合またはブレンドされ得る。

【0094】上記のように、結合層を付与する別の方法は、ガイドワイヤ上にチューブを熱収縮させることである。ガイドワイヤコアは、適切なサイズのチューブ内に容易に挿入される。このチューブは、いずれか一方の端部に少量の「コーキング (caulking)」をしばしば有し、流体または非滅菌の材料がチューブの下より浸入することからチューブを密閉する。チューブは、切断され、そしてサイズが十分な小さくなるまで加熱される。得られたチューブ結合層は、望ましくは、厚さが約0.0005インチと0.015インチとの間である。より薄い層は、代表的には、ポリウレタンまたはPETから製造される。次に、潤滑性ポリマーの層は、収縮したチューブの外表面上に付与される。

【0095】ポリマー、好ましくは潤滑性、生体適合性、および親水性のポリマーをその後コーティングする前にガイドワイヤを調製または前処理するための別の手法は、プラズマ流を用いて炭化水素またはフルオロカーボン残基を堆積 (deposit) させることである。この手法は、以下のように行われる。すなわち、ガイドワイヤコアは、プラズマチャンバー内に配置し、そして酸素プラズマエッチングで洗浄する。次に、ガイドワイヤコアを、炭化水素プラズマに曝し、プラズマ重合された結合層をガイドワイヤコア上に堆積させて前処理を完了する。炭化水素プラズマは、メタン、エタン、プロパン、イソブタン、ブタンなどの低分子量（または気体の）アルカン；エテン、プロペン、イソブテン、ブテンなどの低分子量アルケン；テトラフルオロメタン、トリクロロフルオロメタン、ジクロロジフルオロメタン、トリフルオロクロロメタン、テトラフルオロエチレン、トリクロロフルオロエチレン、ジクロロジフルオロエチレン、トリフルオロクロロエチレンなどの気体状フルオロカーボンおよび他の同様な材料を包含し得る。これらの材料の混合物もまた受容可能である。結合層は、明らかに、外部親水性ポリマーコーティングに対するその後の共有結合のためのC-C結合を提供する。炭化水素のプラズマチャンバーへの好ましい流速は、500 c.c./分から2000 c.c./分の範囲であり、そしてチャンバー内にガイドワイヤを保持する時間は、選択された炭化水素およびプラズマチャンバー動作パラメータに応じて、1〜20分の範囲である。プラズマチャンバーの電力は、200Wから1500Wの範囲に設定されるのが好ましい。

【0096】10オングストロームオーダーの厚みを有するプラズマ生成炭化水素残基の結合層は、コアとコー

ティングとの間に堆積される。この工程では、代表的には、厚さが約1000オングストローム未満、そしてより代表的には約100オングストローム未満の炭化水素残基の層が形成される。結合層は、ガイドワイヤの大きさをほんの少ししか増加させずに、外部層をガイドワイヤコアへ効果的に結合させる。従って、本発明によって形成されるガイドワイヤでは、従来技術のガイドワイヤの有していた大きさおよび操作性の問題が解消される。

【0097】前処理されたガイドワイヤは、上記のような手法を用いてポリマーによりコーティングされ得る。例えば、前処理されたガイドワイヤは、光学活性親水性ポリマーシステム、すなわち、親水性ポリマーに共有結合した潜在性光反応性結合基の溶液中に浸漬され得る。乾燥後、コーティングされたガイドワイヤは、UV光に露光させることによって硬化される。UV光は、光学活性ポリマーシステム内の潜在性反応性基を活性化して、炭化水素残基の結合層内の架橋C-C結合と共有結合を形成する。浸漬および硬化の工程は、好ましくは何度も十分に繰り返して、代表的には2回繰り返して、適切な厚みの親水性コーティング層が達成される。

【0098】本発明の特に好ましい変形例の1つは、好ましくは直径0.010インチから0.025インチのステンレス鋼またはニチノールで形成された金属コアを有するガイドワイヤを伴う。ガイドワイヤの外表面は、光学活性結合剤に結合したポリアクリアミド/ポリビニルピロリドン混合物の生体適合性コーティングである。好ましいコーティングは、以下の実施例に記載のBio-Metric Systems PA03およびPV05（またはPV01）結合系の混合物から形成される。

【0099】この好ましい実施態様の光学活性親水性ポリマーシステムは、Bio-Metric Systems PA03ポリアクリルアミド/結合剤システムと、Bio-Metric Systems PV05ポリビニルピロリドンシステムとの混合物である。ポリアクリルアミドシステムは潤滑性を与え、そしてポリビニルピロリドンシステムは、潤滑性および耐久性のための結合を与える。2つのシステムの正確な割合はその適用に適するように変化し得る。しかし、これに代わるものとして、親水性生体適合性コーティングは、ポリアクリルアミド単独、ポリビニルピロリドン単独、ポリエチレンオキシド、または当該分野において公知の任意の適切なコーティングであり得る。さらに、ヘパリン、アルブミン、または他のタンパク質のコーティングが、当該分野において公知の方法で、親水性コーティングを覆って堆積され、さらに生体適合性の特徴を与え得る。

【0100】ガイドワイヤまたは他の用具は、酸素プラズマエッチングの代わりにアルゴンプラズマエッチングを用いて洗浄され得る。プラズマ重合された結合層の厚さはまた、本発明の範囲を逸脱しない程度に様々であり得る。

【0101】以下の実施例は、本発明の物品および方法をさらに例示するものである。本発明はこれらの実施例に限定されない。

【0102】

【実施例】

(実施例) 直径0.016インチのニチノールガイドワイヤをPlasma Etch MK IIプラズマチャンバー内に配置し、そして酸素プラズマで10分間洗浄した。2000 c.c./分の速度で流れるメタンをチャンバー内に入れ、そして400Wの電力設定で2分間チャンバーを作動して、炭化水素残基をワイヤの表面上に堆積させた。ワイヤの約6インチを除くすべてを、67%のBSI PV01および33%のBSI PA03の混合物のポリビニルピロリドン/ポリアクリルアミド (PVP/PA) 光架橋性溶液中に浸漬した。次に、コーティングしたガイドワイヤを乾燥し、そして、紫外線(325nm)に8秒間露光させた。浸漬、乾燥、および露光の工程を2回繰り返した。得られたワイヤは、湿ると潤滑性を帯び、0.018インチのIDカテーテルを通して引っ張るのに、コーティングされていないワイヤよりも少量の力しか必要としなかった。

【0103】(実施例) 直径0.016インチのニチノールガイドワイヤをPlasma Etch MK IIプラズマチャンバー内に配置し、そして酸素プラズマで10分間洗浄した。1500 c.c./分の速度で流れるメタンをチャンバー内に入れ、そして600Wの電力設定で5分間チャンバーを作動して、ワイヤの表面上の炭化水素残基内にメタンをプラズマ処理した。ワイヤの約6インチを除くすべてを、50%のBSI PV01および50%のBSI PA03の混合物から本質的になるポリビニルピロリドン/ポリアクリルアミド (PVP/PA) 光架橋性溶液中に浸漬した。次に、コーティングしたガイドワイヤを乾燥し、そして紫外線(325nm)に8秒間露光させた。浸漬、乾燥、および露光の工程を繰り返した。得られたワイヤは、湿ると潤滑性を帯び、0.018インチのIDカテーテルを通して引っ張るのにコーティングされていないワイヤよりも少量の力しか必要としなかった。

【0104】(実施例) 直径0.016インチのニチノールガイドワイヤをPlasma Etch MK IIプラズマチャンバー内に配置し、そして酸素プラズマで10分間洗浄した。900 c.c./分の速度で流れるエタンをチャンバー内に入れ、そして600Wの電力設定で10分間チャンバーを作動して、炭化水素残基をワイヤの表面上に堆積させた。ワイヤの約6インチを除くすべてを、33%のBSI PV01および67%のBSI PA03の混合物のポリビニルピロリドン/ポリアクリルアミド (PVP/PA) 光架橋性溶液中に浸漬した。次に、コーティングしたガイドワイヤを乾燥し、そして紫外線(325nm)に8秒間露光した。浸漬、乾燥、および露光の工程を2回繰り返した。得られたワイヤは、湿ると潤滑性を帯び、0.018インチのIDカテーテルを通して引っ張るのにコーティングさ

れていないワイヤよりも少量の力しか必要としなかった。

【0105】(実施例) 直径0.013インチのニチノールガイドワイヤコアを洗浄し、そして壁厚0.0015インチのポリウレタンチューブ(Shore 80Aデュロメータ硬度)内に導入した。次いで、この組合せを熱収縮性ポリエチレンチューブ内に導入した。次いで、この2層チューブを350°Fから400°Fまで加熱し、そのためにポリエチレンチューブが収縮し、そしてポリウレタンチューブがワイヤコアに融着した。次いで、ポリエチレンチューブを剥離した。

【0106】次に、このポリウレタン-金属コアを上記のBio-Metric Systems PA03/PA05材料の8層でコーティングした。次いで、コーティングされたガイドワイヤに、潤滑性の喪失について反復試験を行った。試験は、水浴内に設置した0.028インチのIDカテーテル(長さ150cm)内にガイドワイヤを導入することを伴った。このカテーテルの遠位端は、血管網に似せたガラスの迷路に連結した。

【0107】次に、ガイドワイヤを距離1インチで特定の回数(この場合30ストローク)往復させ、そして摩擦を測定した。このカテーテルの測定された摩擦を図11に示す。摩擦の絶対値は示さない。摩擦が増大しないという事実が図11からわかる。このことは、外部潤滑性層が試験の間に劣化されなかったことを示す。

【0108】本発明の好ましい実施態様を説明したが、様々な変更、適応、および改変が、本発明の精神および以下の請求の範囲から逸脱せずに行われ得ることが理解されるべきである。

【0109】

【発明の効果】本発明の複合型ガイドワイヤは、好ましくは、脳の血管系内に導入するのに適している。本発明の複合型ガイドワイヤにおいて、その遠位部分が超弾性合金の編組みで被覆されているため、高い可撓性を有する遠位セクションに対して高い支柱強度を与える。従って、本発明の複合型ガイドワイヤを用いることにより、従来のガイドワイヤの有していた操作性の問題点が解消され得る。

【図面の簡単な説明】

【図1】本発明のガイドワイヤの主要な構成要素を示す略側面図(縮尺は一定せず)である。

【図2】本発明による、高弾性合金の遠位部分を有する複合型ガイドワイヤの部分切取側面図である。

【図3】図1の器具の遠位先端部の一実施態様を示す、部分切取側面図である。

【図4】図1の器具の遠位先端部の第二の実施態様を示す、部分切取側面図である。

【図5】Aは、図1の器具の遠位先端部の第三の実施態様を示す、部分切取側面図である。Bは、Aに示す実施態様の部分切取頂面図である。

【図6】AおよびBは、本発明のガイドワイヤの中間セクションの変形例を示す部分断面図である。

【図7】編組み補強材を有するガイドワイヤを示す部分側面図である。

【図8】本発明のガイドワイヤの中間セクションの接合部を示す部分側面図である。

【図9】本発明のガイドワイヤに使用する合金の客観的選定基準を示す、Ni-Ti合金の代表的な応力-ひずみ図である。

【図10】ガイドワイヤセクションの部分断面図である。

【図11】本発明によって作製されたガイドワイヤの試験における摩擦を示すグラフである。

【符号の説明】

100 ガイドワイヤ

102、142 近位セクション

104、146、170 遠位セクション

106、172 中間セクション

108、174、175 コア

110 端部キャップ

112 ワイヤコイル

114、128 ハンド接合部

116、150、180 ポリマー

118 展性金属コーティング

120 近位テーパ部分

122 遠位テーパ部分

124 遠位先端部

126 金属性リボン

132 内部コイル

136 ポリマー接着体

140 複合型ガイドワイヤ

144 接合部

148 遠位先端部

176、178 中間セクション補強材

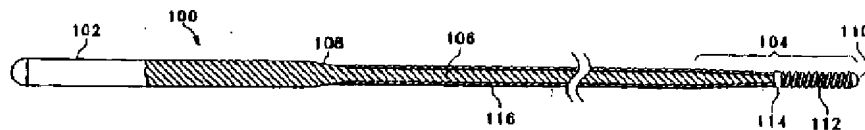
177 編組み

179 結合層

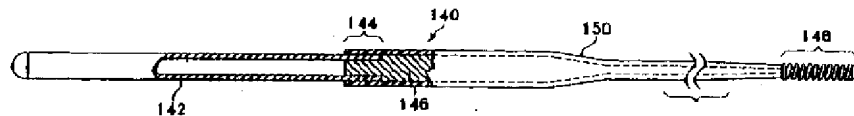
190 テーパー接合部

192 溝

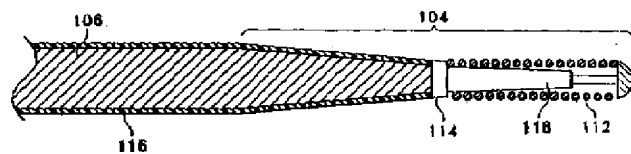
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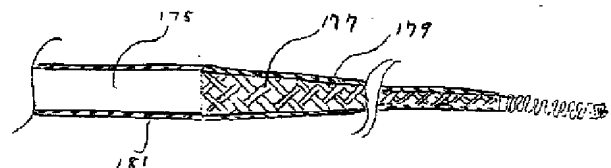
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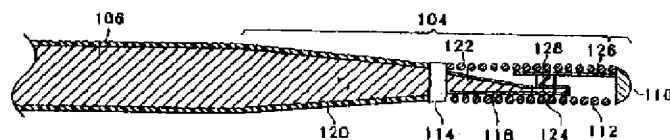
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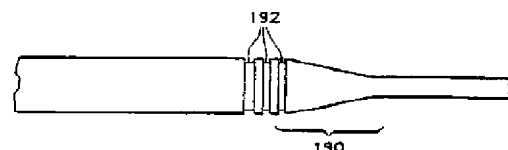
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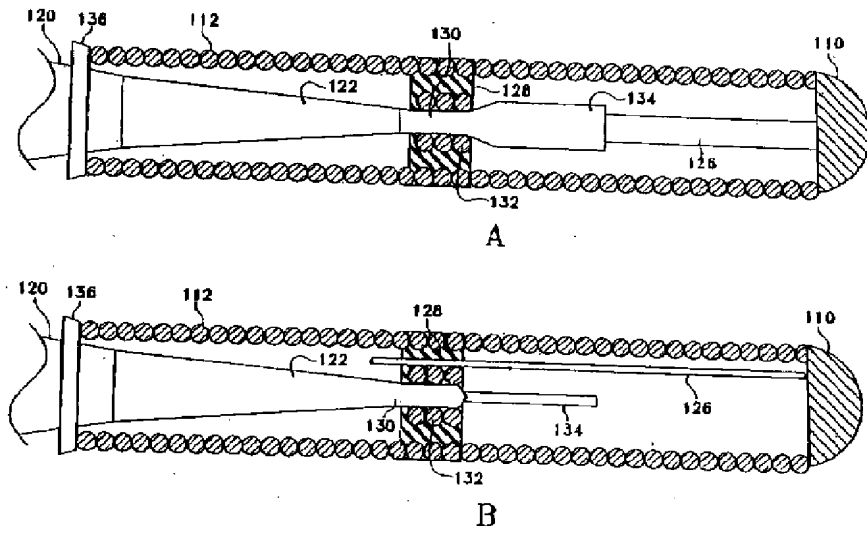
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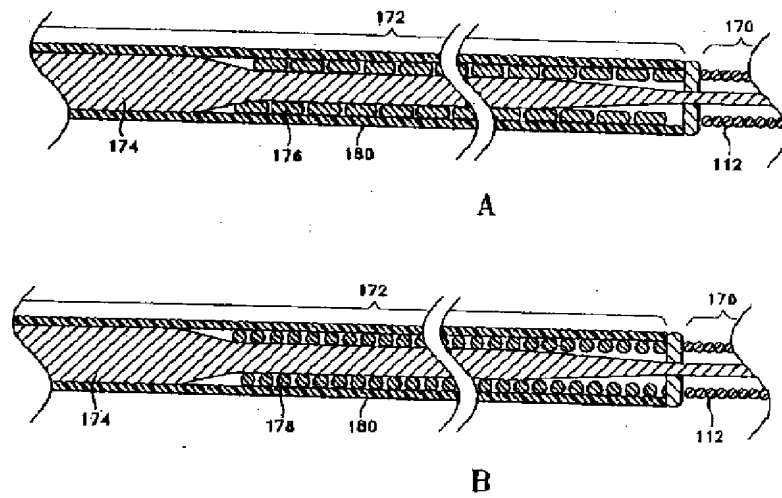
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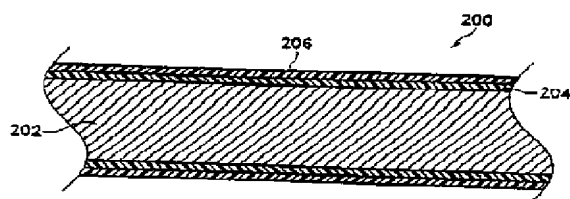
【図5】



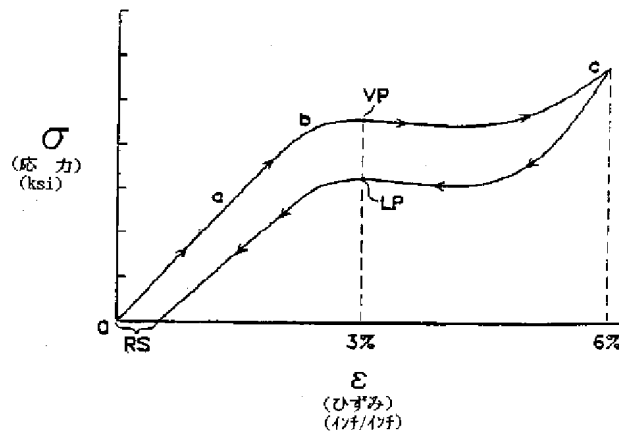
【図6】



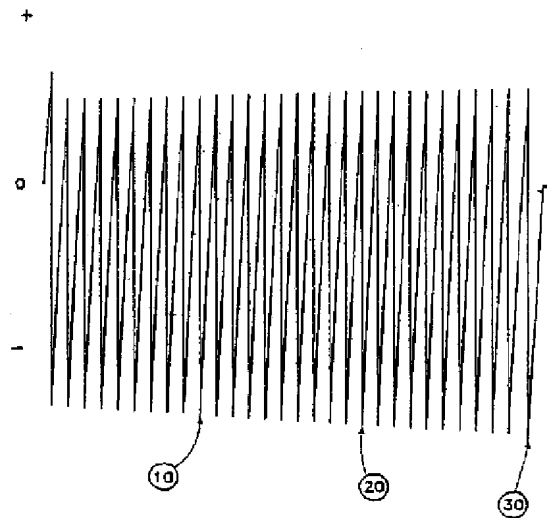
【図10】



【図9】



【図11】



フロントページの続き

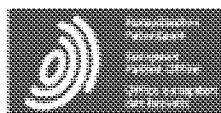
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**Espacenet****Description: JPH0999092 (A) — 1997-04-15**

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**SUPERELASTIC COMPOUND TYPE GUIDE WIRE****Description not available for JPH0999092 (A)****Description of corresponding document: EP0744186 (A1)**

The EPO does not accept any responsibility for the accuracy of data and information originating from other authorities than the EPO; in particular, the EPO does not guarantee that they are complete, up-to-date or fit for specific purposes.

[0001] This invention is a surgical device. It is a composite guidewire for use in a catheter and is used for accessing a targeted site in a lumen system of a patient's body. The guidewire core or guidewire section may be of a stainless steel or a high elasticity metal alloy, preferably a Ni-Ti alloy, also preferably having specified physical parameters. The composite guidewire assembly is especially useful for accessing peripheral or soft tissue targets. Variations of the invention include multi-section guidewire assemblies having (at least) super-elastic distal portions and super-elastic braided reinforcements along the mid or distal sections. A variation of the inventive guidewire includes the coating of the wire with a tie layer and then with a one or more lubricious polymers to enhance its suitability for use within catheters and with the interior of vascular lumen.

[0002] Catheters are used increasingly as a means for delivering diagnostic and therapeutic agents to internal sites within the human body that can be accessed through the various of the body's lumen systems, particularly through the vasculature. A catheter guidewire is used for guiding the catheter through the bends, loops, and branches forming the blood vessels within the body. One method of using a guidewire to direct the catheter through the torturous paths of these systems of lumen involves the use of a torqueable guidewire which is directed as a unit from a body access point such as the femoral artery to the tissue region containing the target site. The guidewire is typically bent at its distal end, and may be guided by alternately rotating and advancing the guidewire along the small vessel pathway to the desired target. Typically the guidewire and the catheter are advanced by alternately moving the guidewire along a distance in the vessel pathway, holding the guidewire in place, and then advancing the catheter along the axis of the guidewire until it reaches the portion of the guidewire already advanced farther into the human body.

[0003] The difficulty in accessing remote body regions, the body's periphery or the soft tissues within the body such as the brain and the liver, are apparent. The catheter and



its attendant guidewire must be both flexible, to allow the combination to follow the complicated path through the tissue, and yet stiff enough to allow the distal end of the catheter to be manipulated by the physician from the external access site. It is common that the catheter is as long as a meter or more.

[0004] The catheter guidewires used in guiding a catheter through the human vasculature have a number of variable flexibility constructions. For instance, U.S. Patent Nos 3,789,841; 4,545,390; and 4,619,274 show guidewires in which the distal end section of the wire is tapered along its length to allow great flexibility in that remote region of the guidewire. This is so, since the distal region is where the sharpest turns are encountered. The tapered section of the wire is often enclosed in a wire coil, typically a platinum coil, to increase the column strength of the tapered wire section without significant loss of flexibility in that region and also to increase the radial capacity of the guidewire to allow fine manipulation of the guidewire through the vasculature.

[0005] Another effective guidewire design is found in U.S. Patent No. 5,095,915 which shows a guidewire having at least two sections. The distal portion is encased in an elongated polymer sleeve having axially spaced grooves to allow increased bending flexibility of the sleeve.

[0006] Others have suggested the use of guidewires made of various super-elastic alloys in an attempt to achieve some of the noted functional desires.

[0007] U.S. Patent 4,925,445, to Sakamoto et al., suggests the use of a two-portion guidewire having a body portion relatively high in rigidity and a distal end portion which is comparatively flexible. At least one portion of the body and the distal end portions is formed of super-elastic metallic materials. Although a number of materials are suggested, including Ni-Ti alloys of 49 to 58% (atm) nickel, the patent expresses a strong preference for Ni-Ti alloys in which the transformation between austenite and martensite is complete at a temperature of 100C or below. The reason given is that "for the guidewire to be useable in the human body, it must be in the range of 100 to 200C due to anesthesia at a low body temperature. The temperature of the human body is typically about 37C.

[0008] Another document disclosing a guidewire using a metal alloy having the same composition as a Ni-Ti super-elastic alloy is WO91/15152 (to Sahatjian et al. and owned by Boston Scientific Corp.). That disclosure suggests a guidewire made of the precursor to the Ni-Ti elastic alloy. Super-elastic alloys of this type are typically made by drawing an ingot of the precursor alloy while simultaneously heating it. In the unstressed state at room temperature, such super-elastic materials occur in the austenite crystalline phase and, upon application of stress, exhibit stress-induced austenite-martensite (SIM) crystalline transformations which produce nonlinear elastic behavior. The guidewires described in that published application, on the other hand, are said not to undergo heating during the drawing process. The wires are cold-drawn and great pains are taken to assure that the alloy is maintained well below 3000F during each of the stages of its manufacture. This temperature control is maintained during the step of grinding the guidewire to form various of its tapered sections.

[0009] U.S. Patent 4,665,906 suggests the use of stress-induced martensite (SIM) alloys as constituents in a variety of different medical devices. Such devices are said to include catheters and cannulas.

[0010] U.S. Patent 4,969,890 to Sugita et al., suggests the production of a catheter having a main body fitted with a shape memory alloy member, and having a liquid injection means to supply a warming liquid to allow the shape memory alloy member to recover its original shape upon being warmed by the fluid.

[0011] U.S. Patent 4,984,581, to Stice, suggests a guidewire having a core of a shape memory alloy, the guidewire using the two-way memory properties of the alloy to provide both tip-deflecting and rotational movement to the guidewire in response to a controlled thermal stimulus. The controlled thermal stimulus in this instance is provided through application of an RF alternating current. The alloy selected is one that has a transition temperature between 360C and 450C. The temperature 360C is chosen because of the temperature of the human body; 450C is chosen because operating at higher temperatures could be destructive to body tissue, particularly some body proteins.

[0012] U.S. Patent 4,991,602 to Amplatz et al., suggests a flexible guidewire made up of a shape memory alloy such as the nickel-titanium alloy known as nitinol. The guidewire is one having a single diameter throughout its midcourse, is tapered toward each end, and has a bead or ball at each of those ends. The bead or ball is selected to allow ease of movement through the catheter into the vasculature. The guidewire is symmetrical so that a physician cannot make a wrong choice in determining which end of the guidewire to insert into the catheter. The patent suggests that wound wire coils at the guidewire tip are undesirable. The patent further suggests the use of a polymeric coating (PTFE) and an anticoagulant. The patent does not suggest that any particular type of shape memory alloy or particular chemical or physical variations of these alloys are in any manner advantageous.

[0013] Another catheter guidewire using Ni-Ti alloys is described in U.S. Patent No. 5,069,226, to Yamauchi, et al. Yamauchi et al describes a catheter guidewire using a Ni-Ti alloy which additionally contains some iron, but is typically heat-treated at a temperature of about 4000 to 5000C so as to provide an end section which exhibits pseudo-elasticity at a temperature of about 370C and plasticity at a temperature below about 800C. A variation is that only the end portion is plastic at the temperatures below 800C.

[0014] U.S. Patent No. 5,171,383, to Sagae, et al., shows a guidewire produced from a super-elastic alloy which is then subjected to a heat treatment such that the flexibility is sequentially increased from its proximal portion to its distal end portions. A thermoplastic coating or coil spring may be placed on the distal portion of the wire material. Generally speaking, the proximal end portion of the guidewire maintains a comparatively high rigidity and the most distal end portion is very flexible. The proximal end section is said in the claims to have a yield stress of approximately five to seven kg/mm<sup>2</sup> and an intermediate portion of the guidewire is shown in the claims to have a yield stress of approximately 11 to 12 kg/mm<sup>2</sup>.

[0015] Published European Patent Application 0,515,201-A1 also discloses a guidewire produced at least in part of a super-elastic alloy. The publication describes a guidewire in which the most distal portion can be bent or curved into a desired shape by a physician immediately prior to use in a surgical procedure. Proximal of the guide tip, the guidewire is of a super-elastic alloy. Although nickel-titanium alloys are said to be most desirable of the class shown in that disclosure, no particular physical description of those alloys is disclosed to be any more desirable than another.

[0016] Published European Patent Application 0,519,604-A2 similarly discloses a guidewire which may be produced from a super-elastic material such as nitinol. The guidewire core is coated with a plastic jacket, a portion of which may be hydrophilic and a portion of which is not.

[0017] Examples of Ni-Ti alloys are disclosed in U.S. Patent Nos. 3,174,851; 3,351,463; and 3,753,700.

[0018] None of these disclosures suggest the guidewire composition or configuration described below.

[0019] This invention is a guidewire, preferably a guidewire suitable for introduction into the vasculature of the brain. At least a distal portion of the guidewire may be of a super-elastic alloy which preferably is a Ni-Ti alloy having specific physical characteristics, e.g., a stress-strain plateau at about 75 +/- 10 ksi and another at 25 +/- 7.5 ksi (each measured at 3% strain) when the stress-strain relationship is measured to a strain of 6%.

[0020] A highly desirable variation of the inventive guidewire comprises a long wire having a proximal section, an intermediate section, and a distal section. The guidewire further may have an eccentricity ratio of  $1 \pm 10^{-4}$ . The distal end section is typically the most flexible of the sections and is at least about three centimeters long. Desirably, the flexible distal end section is partially tapered and is covered by a coil assembly which is connected to the distal end of the guidewire at its distal tip. The coil assembly may be attached to the distal tip by soldering, perhaps after plating or coating the distal end section with a malleable or solderable metal, such as gold.

[0021] The guidewire, whether of a super-elastic metal or not, may be coated with a polymer or other material to enhance its ability to traverse the lumen of the catheter. A lubricious polymer may be placed directly upon the core wire or upon a "tie" layer. The tie layer may be a shrink-wrap tubing or a plasma deposition or may be a dip, spray, or fusion spray coating of an appropriate material. The tie layer may also be radio opaque.

[0022] The guidewire of this invention may be of a composite in which a distal portion of the core is a super-elastic alloy of the type described below and the more proximal section or sections are of another material or configuration, e.g., stainless steel wire or rod, stainless steel hypotube, super-elastic alloy tubing, carbon fiber tubing, etc.

[0023] The guidewire of this invention may be of a composite in which a distal portion of the core is a stainless steel or super-elastic alloy and is ground or tapered but is

jacketed with a thin coil or braid of a super-elastic alloy ribbon. This provides the guidewire assembly with high flexibility in the distal section due to the tapering and high column strength due to the presence of the super-elastic braid.

[0024] Ideally there will be one or more radiopaque markers placed upon the guidewire, e.g., at its distal tip and potentially along the length of the intermediate section. These markers may be used both to enhance the guidewire's radiopacity and its ability to transmit torque from the proximal end to the distal end while maintaining a desired flexibility.

[0025] This invention also includes a catheter apparatus made up of the guidewire core and a thin-walled catheter designed to be advanced along the guidewire through the vasculature for positioning at a desired site.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0026] Figure 1 shows a schematic side view (not to scale) of the major components of the inventive guidewire.

[0027] Figure 2 is a partial cutaway, side view of composite guidewire according to this invention having a distal portion of a highly elastic alloy.

[0028] Figure 3 is a partial cutaway side view of one embodiment of the distal tip of the Figure 1 device.

[0029] Figure 4 is a partial cutaway side view of a second embodiment of the distal tip of the Figure 1 device.

[0030] Figure 5A is a partial cutaway side view of a third embodiment of the distal tip of the Figure 1 device.

[0031] Figure 5B is a partial cutaway top view of the embodiment shown in Figure 5A.

[0032] Figures 6A and 6B show midsection variations, in fragmentary cross-section, of the invention guidewire.

[0033] Figure 7 is a partial side view of a guidewire having a braided reinforcement distally.

[0034] Figure 8 is a partial side view of a midsection joint in the inventive guidewire.

[0035] Figure 9 shows a typical stress-strain diagram for a Ni-Ti alloy displaying objective criteria for selection of alloys for the inventive guidewire.

[0036] Figure 10 is a partial cross-section of a guidewire section.

[0037] Figure 11 is a graph showing friction on a guidewire test, the guidewire being made according to this invention.

[0038] Figure 1 shows an enlarged side view of a guidewire made according to the invention. The guidewire (100) is made up of the wire core formed of a flexible torqueable wire filament material, of the alloys described below, and has a total length typically between about 50 and 300 centimeters. The proximal section (102) preferably has a uniform diameter (along its length) of about 0.010 to 0.025 inches, preferably 0.010 to 0.018 inches. The relatively more flexible distal section (104) extends for 3 to 30 centimeters or more of the distal end of the guidewire (100). There may be a middle section (106) having a diameter intermediate between the diameter of the two portions of the wire adjoining the middle section. The middle section (106) may be continuously tapered, may have a number of tapered sections or sections of differing diameters, or may be of a uniform diameter along its length. If middle section (106) is of a generally uniform diameter, the guidewire core will neck down as is seen at (108). The distal section (104) of the guidewire (100) typically has an end cap (110), a fine wire coil (112), and a solder joint (114). The fine wire coil (112) may be radiopaque and made from materials including but not limited to platinum and its alloys. The end cap (110) may be radiopaque to allow knowledge of the position of the coil (112) during the process of inserting the catheter and traversal of the guidewire through the vasculature. All or part of the guidewire proximal section (102) and middle section (106) and distal section (104) may be coated with a thin layer (116) of polymeric material to improve its lubricity without adversely affecting the flexibility or shapeability of the guidewire. This invention includes portions or sections of the guidewire described above having the noted polymeric tie layer described below and a slippery, e.g., a hydrophilic polymeric coating thereon.

[0039] Figure 2 shows a variation of the inventive guidewire which is a composite, e.g., a distal portion of the guidewire core is produced of the specified alloy and the composite is of another material or configuration. In particular, the composite guidewire (140) is made up of a proximal section (142) that is a section of small diameter tubing of, e.g., an appropriate stainless steel or a high performance polymer such as a polyimide or a high elasticity alloy such as those discussed elsewhere herein. Tubular composites such as super-elastic alloy ribbon tubular braids having polymeric coverings and perhaps polymeric interiors are also desirable. The tubular proximal section (142) is attached by soldering or by gluing or by other joining method suitable for the materials involved at the joint (144) to a distal section (146) that extends to the distal end of the composite guidewire assembly (140). The proximal section (142) may instead be a solid rod of a material such as stainless steel or a fibrous carbon composite. The distal tip (148) of the catheter assembly (140) may be of the same configuration as those otherwise described herein. The catheter assembly may be coated (150) with polymeric material, as desired.

[0040] Figure 3 shows a partial cutaway of one embodiment of the distal section (104) and the distal end of the intermediate section (106). The metallic guidewire core is shown partially coated with polymer (116) and a malleable metal coating (118) on the tapered portion of the distal tip. The malleable metal may be selected from suitable radiopaque materials such as gold or other easily solderable materials such as silver, platinum, palladium, rhodium, and alloys of the above. The tip also includes a radiopaque coil (112) which is bounded on its proximal end by a solder joint (114) and is joined with the end of the guidewire at (110). The radiopaque coil (112) may be made of known suitable materials such as platinum, palladium, rhodium, silver, gold,

and their alloys. Preferred is an alloy containing platinum and a small amount of tungsten. The proximal and distal ends of coil (112) may be secured to the core wire by soldering.

[0041] Figure 4 shows a partial cutaway of another embodiment of the distal section (104) of the inventive guidewire. In this embodiment, the metal guidewire core has a proximal tapered portion (120), a distal tapered section (122) with a solder joint (114) separating the two sections, and a constant diameter tip (124). The distal tip (124) may have constant diameter typically between about 0.002 and 0.005 inches, preferably about 0.003 inches. The distal tip (124) is preferably between about 1 and 5 cm in length, preferably about 2 cm but the portion of constant diameter extends for at least about 25% of the distance between the solder joint (128) and the solder joint (114). This constant diameter section marginally stiffens the distal tip assembly for enhanced control. The entire distal section (104) desirably is between about 20 and 50 cm, preferably about 25 cm in length. The maximum diameter of the proximal tapered portion (120) of the guidewire core typically is between about 0.005 and 0.020 inches, preferably about 0.010 inches. The distal tapered portion (122) and distal tip (124) are again shown with a malleable metal coating (118) such that the distal tapered portion (122) and distal tip (124) stay bent upon forming by the physician. In this embodiment, the fine wire coil (112) is bounded on its proximal end by a solder joint (114) and on its distal end by an end cap (110). The end cap (110) is connected to the guidewire by means of a metallic ribbon (126). The ribbon (126) may be made of stainless steel, platinum, palladium, rhodium, silver, gold, tungsten, and their alloys or other materials which are plastic and that are easily soldered. The ribbon (126) is soldered to the fine wire coil (112) and to the distal tip (124) of the distal section (104) of the guidewire at a solder joint (128) such that the end cap (110) is secured against the fine wire coil (112).

[0042] Figures 5A and 5B show yet another inventive embodiment of the distal section (104) of the guidewire (100). Figure 5A shows a side view, partial cutaway of the inventive guidewire. The fine wire coil (112) may be bounded by a polymer adhesive (136) that joins the coil (112) to the core wire and an end cap (110) and further secured to the guidewire core by a solder joint (128). In this embodiment, the distal section (104) of the guidewire again comprises a tapered portion (120) that is proximal to the polymer adhesive (136) and a tapered portion (122) that is distal to the polymer adhesive (136). The distal section (104) also comprises a smaller diameter portion (130) or "neck" that may be surrounded by optional inner coil (132). The inner coil (132) may be made of a suitable metallic material preferably that is easy to solder and preferably radiopaque. It is preferably platinum or stainless steel. One way to produce neck (130) is to flatten the distal portion of the guidewire (134) distal to the neck so that the resulting spade (134) is no longer of circular cross-section but rather is of rectangular shape. This may be more easily visualized in Figure 5B since that Figure shows a cutaway top view of the guidewire shown in Figure 5A. As in above-described embodiments, the end cap (110) is secured to the guidewire by a metallic ribbon (126). The solder joint (128) secures the guidewire core to the inner helical coil (132) which secures the end cap (110) via the ribbon (126) and further secures the outer fine wire coil (112). This configuration is especially valuable for use with guidewire materials which are not easily solderable. The solder joint need not adhere to the guidewire and yet the inner coil (132), ribbon (126); and outer fine wire coil (112) all are maintained as

a single integral unit and have no chance of slipping proximally or distally on the guidewire assembly.

[0043] Although the embodiment described with reference to Figures 5A and 5B speaks generally of a guidewire made of a high elasticity alloy, materials for the guidewire and the ribbon such as stainless steel, platinum, palladium, rhodium and the like are suitable with that embodiment.

[0044] Figures 6A and 6B show partial fragmentary cross-sections of portions of the distal section (170) and the midsection (172) of a variation of the inventive catheter assembly. In the variations shown in Figures 6A and 6B, the core is ground to a smaller diameter to achieve a higher degree of flexibility in those regions. To provide additional column strength and torqueability, a flat wound ribbon (176) (in Figure 6A) or coil (178) (in Figure 6B) is placed on the core. In addition, since many of the super-elastic alloys making up core (174) are not particularly radiopaque, it is often desirable to use radiopaque materials for the ribbon (176) or coil (178) so to permit the physician to observe the position of the guidewire assembly with greater ease. Indeed, it is not uncommon for the ribbons (176) or coils (178) to extend (in conjunction with the coils (112)) to extend 25-35 cm. from the distal tip of the catheter assembly. Again, it is not uncommon for the distal coil (112) to be itself up to 10 cm. or so in length. Finally, it is desirable to use a smaller diameter wire in the more proximal coil (178) than the distal coil (112) to provide a radiopaque view and enhanced column strength to the guidewire belt with lower overall mass.

[0045] Alternatively, the ribbon may be of a super-elastic alloy as described elsewhere herein. A super-elastic alloy ribbon is used to provide enhanced column strength at a reduced weight (as compared to the more radiopaque materials). When the ribbon is a super-elastic alloy, it desirably is of a size between 0.0005" and 0.002" (thickness) and 0.002" and 0.012" (width). For ease of fabrication, the ribbon may be 0.00075" to 0.001" in thickness and 0.003" to 0.005" in width.

[0046] In addition, we have found it desirable to coat all or part of the guidewire core (as will be discussed in more detail below) with a lubricious coating material such as polyfluorocarbons or with hydrophilic polymers. As is discussed below, when using hydrophilic polymers as the coating material, it is often desirable to use a tie layer on the guidewire core. The composition of such tie layers will be also discussed below. However, in the variation shown in Figures 6A and 6B, the combination of tie layer and hydrophilic polymer (180) is shown as being placed over the midsection stiffeners (176) and (178).

[0047] Figure 7 shows a variation of the invention in which the filamentary core (175) has been ground to a taper in its more distal regions. In this aspect, the core is much like other variations which have been discussed above. The core (175) in this variation may be of a stainless steel or of one of the high elasticity alloys noted elsewhere herein. The core (175) is then at least partially jacketed with a tubular metallic braid (177) which preferably is bonded to the core (175), by adhesives or solder or by welding, either at intervals along the core (175) or continuously from one end of the braid to the other. Although the braid (177) most desired is shown in Figure 7 and has a single size of ribbon, the braid need not be so limited; multiple sizes of ribbon may

be used as desired. The major limitations are simply the size, e.g., diameter, of the overall braid as finally constructed and the desired added stiffness to be added to the guidewire.

[0048] The braids typically useful in this invention comprise an even number of ribbons: one half of the ribbons wound one way, i.e., clockwise, and the remainder are wound the other way. A typical braid will be of eight to 16 ribbons. The braid may have a single pitch, an angle of a constituent ribbon measured against the axis of the braid, or it may have a pitch which varies along the axis of the braid. The braid may be wound over a mandrel of a size similar to the guidewire core and gently heat-treated on that mandrel at temperature of 6500 to 7500F for a portion of an hour to preserve the shape of the braid and to prevent its unwinding during subsequent installation on the core wire. The braid may also be wound directly onto the core if so desired.

[0049] The braid (177) is usually rough to the touch if not covered or further processed. Procedures such as rolling, sanding, or grinding may be used to smooth the surface of the braid if so desired. Removal of any produced particulates is, of course, necessary. Whether the outer surface of the braid (177) is smoothed or not, it is quite desirable to place an outer layer of a lubricious polymer on the exterior of the braiding. The variation shown in Figure 7 utilizes the tie layer (179) discussed elsewhere herein and has a thin layer of a hydrophilic polymeric layer placed on the exterior of the tie layer (179). The hydrophilic polymeric layer is not depicted on the drawing because the layer is typically too thin to see. The tie layer (179) and its associated hydrophilic polymeric layer may be (but need not be) of the same composition as a layer (181) on the more proximal section.

[0050] Figure 8 is a partial side view of a midsection joint in the inventive guidewire. On many variations of the inventive guidewire, various sections of the core are joined by tapered sections such as seen at (190). This means that the guidewire core is significantly stiffer at the proximal end of the tapered joint (190). We have found that it is sometimes desirable to place grooves (192) in that proximal end to lower the overall stiffness of the guidewire at that junction and yet retain the columnar strength.

## GUIDEWIRE CORE

[0051] This guidewire is typically used in a catheter which is made up of an elongate tubular member having proximal and distal ends. The catheter is (again) about 50 to 300 centimeters in length, typically between about 100 and 200 centimeters in length. Often, the catheter tubular member has a relatively stiff proximal section which extends along a major portion of the catheter length and one or more relatively flexible distal sections which provide greater ability of the catheter to track the guidewire through sharp bends and turns encountered as the catheter is advanced through the tortuous paths found in the vasculature. The construction of a suitable catheter assembly having differential flexibility along its length is described in U.S. Patent No. 4,739,768.

[0052] We have found that certain alloys, particularly Ni-Ti alloys, retain their super-elastic properties during traversal through the vasculature and yet are sufficiently pliable that they provide the physician using the guidewire with enhanced "feel" or



feedback and yet do not "whip" during use. That is to say, as a guidewire is turned it stores energy during as a twist and releases it precipitously as it "whips" to quickly recover the stored stress. The preferred alloys do not incur significant unrecovered strain during use. We have also found that if the eccentricity of the wire, i.e., the deviation of the cross-section of the guidewire from "roundness" (particularly in the middle section) is maintained at a very low value, the guidewire is much easier to steer or direct through the vasculature. The material used in the guidewires of this invention are of shape memory alloys which exhibit super-elastic/pseudo-elastic shape recovery characteristics. These alloys are known. See, for instance, U.S. Patent Nos. 3,174,851 and 3,351,463 as well as 3,753,700; however, the '700 patent describes a less desirable material because of the higher modulus of the material due to an increased iron content. These metals are characterized by their ability to be transformed from an austenitic crystal structure to a stress-induced martensitic (SIM) structure at certain temperatures, and return elastically to the austenitic structure when the stress is removed. These alternating crystalline structures provide the alloy with its super-elastic properties. One such well-known alloy, nitinol, is a nickel-titanium alloy. It is readily commercially available and undergoes the austenite-SIM-austenite transformation at a variety of temperature ranges between -200C and 300C.

[0053] These alloys are especially suitable because of their capacity to elastically recover almost completely to the initial configuration once the stress is removed. Typically there is little plastic deformation, even at relatively high strains. This allows the guidewire to undertake substantial bends as it passes through the body's vasculature, and yet return to its original shape once the bend has been traversed without retaining any hint of a kink or a bend. However, the tips shown are often sufficiently plastic that the initial tip formation is retained. Nevertheless, compared to similar stainless steel guidewires, less force need be exerted against the interior walls of the vessels to deform the guidewire of the invention along the desired path through the blood vessel thereby decreasing trauma to the interior of the blood vessel and reducing friction against the coaxial catheter.

[0054] A guidewire, during its passage through the vasculature to its target site, may undertake numerous bends and loops. The desirability of enhancing the ease with which a guidewire may be twisted to allow the bent distal tip to enter a desired branch of the vasculature cannot be overstated. We have found that a major factor in enhancing such ease of use, that is, in enhancing the controllability of the guidewires is by controlling the eccentricity of the cross-section of the middle portion of the guidewire. We have found that by maintaining the middle portion of the guidewire (106 in Figure 1) to an eccentricity ratio of  $1 \pm 10^{-4}$ , the guidewire is significantly more controllable than those which fall outside this ratio. By "eccentricity", we mean that at any point along the guidewire the ratio of the largest diameter at that cross-section to the smallest diameter of the wire at that cross-section.

[0055] To achieve these results of high strength and enhanced control even while allowing feedback to the attending physician during use, we have found that the following physical parameters of the alloy are important. In a stress-strain test as shown on a stress-strain diagram such as that found in Figure 9, the stress found at the midpoint of the upper plateau (UP) (measured, e.g. at about 3% strain when the test end point is about 6% strain) should be in the range of 75 ksi (thousand pounds

per square inch)  $\pm$  10 ksi and, preferably, in the range of 75 ksi  $\pm$  5 ksi. Additionally, this material should exhibit a lower plateau (LP) of 25  $\pm$  7.5 ksi, preferably 20  $\pm$  2.5 ksi, measured at the midpoint of the lower plateau. The material preferably has no more than about 0.25% residual strain (RS) (when stressed to 6% strain and allowed to return) and preferably no more than about 0.15% residual strain

[0056] The preferred material is nominally 50.6%  $\pm$  0.2% Ni and the remainder Ti. The alloy should contain no more than about 500 parts per million of any of O, C, or N. Typically such commercially available materials will be sequentially mixed, cast, formed, and separately co-worked to 30-40%, annealed and stretched.

[0057] By way of further explanation, Figure 9 shows a stylized stress-strain diagram showing the various parameters noted above and their measurement on that diagram. As stress is initially applied to a sample of the material, the strain is at first proportional (a) until the phase change from austenite to martensite begins at (b). At the upper plateau (UP), the energy introduced with the applied stress is stored during the formation of the quasi-stable martensite phase or stress-induced-martensite (SIM). Upon substantial completion of the phase change, the stress-strain relationship again approaches a proportional relationship at (c). The stress is no longer applied when the strain reaches 6%. The measured value (UP) is found at the midpoint between zero and 6% strain, i.e., at 3% strain. If another terminal condition of strain is chosen, e.g., 7%, the measured value of (UP) and (LP) would be found at 3.5%.

[0058] Materials having high UP values produce guidewires which are quite strong and allow exceptional torque transmission but cause a compromise in the resulting "straightness" of the guidewire. We have found that guidewires having high UP values in conjunction with high LP values are not straight. These guidewires are difficult to use because of their tendency to "whip" as they are turned. Again, that is to say, as a guidewire is turned it stores energy during as a twist and releases it quickly. The difficulty of using such a whipping guidewire should be apparent. Materials having UP values as noted above are suitable as guidewires.

[0059] Furthermore, materials having values of LP which are high, again, are not straight. Lowering the value of LP compromises the ability of the guidewire to transmit torque but improves the ease with which a straight guidewire may be produced. Lowering the LP value too far, however, results in a guidewire which, although round, has poor tactile response. It feels somewhat "vague" and "soupy" during its use. The LP values provided for above allow excellent torque transmission, straightness, and the valuable tactile response.

[0060] The values of residual strain discussed above define a materials which do not kink or otherwise retain a "set" or configuration after stress during use as a guidewire.

#### EXAMPLE

[0061] In each instance, the following procedure was used in producing the data displayed in the table which follows: commercial Ni-Ti alloy wires having a nominal composition of 50.6% Ni and the remainder Ti, and diameters of 0.13", 0.16", or 0.18" were stressed at room temperature. In each instance, values for transition

temperature, PS, UP, and LP were measured. Additionally, several of the noted wires were introduced into a U-shaped Tygon tube and spun to allow qualitative evaluation of the roundness and tactile response of the wires. Comments on that response are also found in the following table.

[0062] These data describe both guidewires made according to the invention and comparative guidewires. Additionally, they show that guidewire made from a typical stainless steel alloy is very difficult to turn using the qualitative test described above.

## GUIDEWIRE CORE COATINGS

[0063] As mentioned above, all or part of the guidewire core may be covered or coated with one or more layers of a polymeric material. The coating is applied typically to enhance the lubricity of the guidewire core during its traversal of the catheter lumen or the vascular walls.

### Coating Materials

[0064] As noted above, at least a portion of the guidewire core may simply be coated by dipping or spraying or by similar process with such materials as polysulfones, polyfluorocarbons (such as TEFLON), polyolefins such as polyethylene, polypropylene, polyesters (including polyamides such as the NYLON's), and polyurethanes; their blends and copolymers such as polyether block amides (e.g., PEBAX).

[0065] It is often desirable to utilize a coating such as discussed just above on the proximal portion of the guidewire and a coating such as discussed below on the more distal sections. Any mixture of coatings placed variously on the guidewire is acceptable as chosen for the task at hand.

[0066] The guidewire core may also be at least partially covered with other hydrophilic polymers including those made from monomers such as ethylene oxide and its higher homologs; 2-vinyl pyridine; N-vinylpyrrolidone; polyethylene glycol acrylates such as mono-alkoxy polyethylene glycol mono(meth) acrylates, including mono-methoxy triethylene glycol mono (meth) acrylate, mono-methoxy tetraethylene glycol mono (meth) acrylate, polyethylene glycol mono (meth) acrylate; other hydrophilic acrylates such as 2-hydroxyethylmethacrylate, glycerylmethacrylate; acrylic acid and its salts; acrylamide and acrylonitrile; acrylamidomethylpropane sulfonic acid and its salts cellulose, cellulose derivatives such as methyl cellulose ethyl cellulose, carboxymethyl cellulose, cyanoethyl cellulose, cellulose acetate, polysaccharides such as amylose, pectin, amylopectin, alginic acid, and cross-linked heparin; maleic anhydride; aldehydes. These monomers may be formed into homopolymers or block or random copolymers. The use of oligomers of these monomers in coating the guidewire for further polymerization is also an alternative. Preferred precursors include ethylene oxide; 2-vinyl pyridine; N-vinylpyrrolidone and acrylic acid and its salts; acrylamide and acrylonitrile polymerized (with or without substantial crosslinking) into homopolymers, or into random or block copolymers.

[0067] Additionally, hydrophobic monomers may be included in the coating polymeric material in an amount up to about 30% by weight of the resulting copolymer so long as the hydrophilic nature of the resulting copolymer is not substantially compromised. Suitable monomers include ethylene, propylene, styrene, styrene derivatives, alkylmethacrylates, vinylchloride, vinylidenechloride, methacrylonitrile, and vinyl acetate. Preferred are ethylene, propylene, styrene, and styrene derivatives.

[0068] The polymeric coating may be cross-linked using various techniques, e.g., by light such as ultraviolet light, heat, or ionizing radiation, or by peroxides or azo compounds such as acetyl peroxide, cumyl peroxide, propionyl peroxide, benzoyl peroxide, or the like. A polyfunctional monomer such as divinylbenzene, ethylene glycol dimethacrylate, trimethylolpropane, pentaerythritol di- (or tri- or tetra-) methacrylate, diethylene glycol, or polyethylene glycol dimethacrylate, and similar multifunctional monomers capable of linking the monomers and polymers discussed above.

[0069] Polymers or oligomers applied using the procedure described below are activated or functionalized with photoactive or radiation-active groups to permit reaction of the polymers or oligomers with the underlying polymeric surface. Suitable activation groups include benzophenone, thioxanthone, and the like; acetophenone and its derivatives specified as:

where

R<1> is H, R<2> is OH, R<3> is Ph; or

R<1> is H, R<2> is an alkoxy group including -OCH<sub>3</sub>, -OC<sub>2</sub>H<sub>3</sub>, R<3> is Ph, or

R<1> = R<2> = an alkoxy group, R<3> is Ph; or

R<1> = R<2> = an alkoxy group, R<3> is H; or

R<1> = R<2> = Cl, R<3> is H or Cl. Other known activators are suitable.

[0070] The polymeric coating may then be linked with the substrate using known and appropriate techniques selected on the basis of the chosen activators, e.g., by ultraviolet light, heat, or ionizing radiation. Crosslinking with the listed polymers or oligomers may be accomplished by use of peroxides or azo compounds such as acetyl peroxide, cumyl peroxide, propionyl peroxide, benzoyl peroxide, or the like. A polyfunctional monomer such as divinylbenzene, ethylene glycol dimethacrylate, trimethylolpropane, pentaerythritol di- (or tri- or tetra-) methacrylate, diethylene glycol, or polyethylene glycol dimethacrylate, and similar multifunctional monomers capable of linking the polymers and oligomers discussed above is also appropriate for this invention.

[0071] The polymeric coating may be applied to the guidewire by any of a variety of methods, e.g., by spraying a solution or suspension of the polymers or of oligomers of the monomers onto the guidewire core or by dipping it into the solution or suspension. Initiators may be included in the solution or applied in a separate step. The guidewire may be sequentially or simultaneously dried to remove solvent after application of the polymer or oligomer to the guidewire and crosslinked.

[0072] The solution or suspension should be very dilute since only a very thin layer of

polymer is to be applied. We have found that an amount of oligomer or polymer in a solvent of between 0.25% and 5.0% (wt), preferred is 0.5 to 2.0% (wt), is excellent for thin and complete coverage of the resulting polymer. Preferred solvents for this procedure when using the preferred polymers and procedure are water, low molecular weight alcohols, and ethers, especially methanol, propanol, isopropanol, ethanol, and their mixtures. Other water miscible solvents, e.g., tetrahydrofuran, methylene dichloride, methylethylketone, dimethylacetate, ethyl acetate, etc., are suitable for the listed polymers and must be chosen according to the characteristics of the polymer; they should be polar because of the hydrophilic nature of the polymers and oligomers but, because of the reactivity of the terminal groups of those materials, known quenching effects caused by oxygen, hydroxyl groups and the like must be recognized by the user of this process when choosing polymers and solvent systems.

[0073] Particularly preferred as a coating for the guidewire cores discussed herein are physical mixtures of homo-oligomers of at least one of polyethylene oxide; poly 2-vinyl pyridine; polyvinylpyrrolidone, polyacrylic acid, polyacrylamide, and polyacrylonitrile. The catheter bodies or substrates are preferably sprayed or dipped, dried, and irradiated to produce a polymerized and crosslinked polymeric skin of the noted oligomers.

[0074] The lubricious hydrophilic coating is preferably produced using generally simultaneous solvent removal and crosslinking operations. The coating is applied at a rate allowing "sheeting" of the solution, e.g., formation of a visibly smooth layer without "runs". In a dipping operation for use with most polymeric substrates including those noted below, the optimum coating rates are found at a linear removal rate between 0.25 and 2.0 inches/see, preferably 0.5 and 1.0 inches/see.

[0075] The solvent evaporation operations may be conducted using a heating chamber suitable for maintaining the surface at a temperature between 250C and the glass transition temperature (T<sub>g</sub>) of the underlying substrate. Preferred temperatures are 500C to 1250C. Most preferred for the noted and preferred solvent systems is the range of 750 to 1100C.

[0076] Ultraviolet light sources may be used to crosslink the polymer precursors onto the substrate. Movement through an irradiation chamber having an ultraviolet light source at 90-375nm (preferably 300-350nm) having an irradiation density of 50-300 mW/cm<sup>2</sup> (preferably 150-250 mW/cm<sup>2</sup>) for a period of three to seven seconds is desired. Passage of a guidewire core through the chamber at a rate of 0.25 to 2.0 inches/second (0.5 to 1.0 inches/second) in a chamber having three to nine inches length is suitable. When using ionizing radiation, a radiation density of 1 to 100 kRads/cm<sup>2</sup> (preferably 20 to 50 kRads/cm<sup>2</sup>) may be applied to the solution or suspension on the polymeric substrate. Exceptional durability of the resulting coating is produced by repetition of the dipping/solvent removal/irradiation steps up to five times. Preferred are two to four repetitions.

#### Tie Layers

[0077] We have found that it is often desirable to incorporate a "tie" layer as a coating between the outer polymeric surface and the guidewire core to enhance the overall

adhesion of the outer polymeric surface to the core. Of course, these materials must be able to tolerate the various other solvents, cleaners, sterilization procedures, etc. to which the guidewire and its components are placed during other production steps.

[0078] Figure 10 shows a typical guide wire core section (200) having a metallic core (202), a polymeric tie layer (204), and a lubricious coating (206).

[0079] Choice of materials for such tie layers is determined through their functionality. Specifically, the materials are chosen for their affinity or tenacity to the outer polymeric lubricious or hydrophilic coating. Clearly, the tie layer material must be flexible and strong. The tie layers may be placed onto the guidewire core in a variety of ways. The polymeric material may be extrudable and made into shrinkable tubing for mounting onto the guidewire through heating. It may be placed onto the guidewire core by dipping, spraying, shrink wrapping of polymeric tubing or other procedure. One quite desirable procedure involves the placement of a polymeric tubing of a fusible polymer, e.g., polyurethane, on the guidewire core which, in turn, is covered with a heat shrink tubing such as polyethylene. The outer tubing is shrunk down and the inner tubing is fused onto the guidewire core to form a tie layer. The tie layer is preferably 0.0004" to 0.003" in thickness. The melt temperature of the tie layer polymer desirably is appropriately chosen to fuse at the heat shrink temperature of the outer tubing. The outer shrink tubing is then simply peeled off, leaving the tie layer exposed for treatment with the lubricious coating.

[0080] We have found that various NYLON's, polyethylene, polystyrene, polyurethane, and polyethylene terephthalate (PET) make excellent tie layers. Preferred are polyurethane (Shore 80A-55D) and PET. Most preferred is polyurethane. It is additionally desirable to use a number of sections of polyurethane having differing hardnesses. For instance, the distal section may have a tie layer of Shore 80A polyurethane; the proximal shaft might be Shore D55 polyurethane. These materials may be formulated or blended to include radio opaque materials such as barium sulfate, bismuth trioxide, bismuth carbonate, tungsten, tantalum or the like.

[0081] As noted above, another manner of applying a tie layer is by heat-shrinking the tubing onto the guidewire. The guidewire core is simply inserted into a tubing of suitable size -- often with a small amount of a "caulking" at either end to seal the tubing from incursion of fluids or unsterile materials from beneath the tubing. The tubing is cut to length and heated until it is sufficiently small in size. The resulting tubing tie layer desirably is between about 0.0005 and 0.015 inches in thickness. The thinner layers are typically produced from polyurethane or PET. The layer of lubricious polymer is then placed on the outer surface of the shrunk tubing.

[0082] Another procedure for preparing or pretreating guidewires prior to receiving a subsequent coating of a polymer, preferably a polymer which is lubricious, biocompatible, and hydrophilic, is via the use of a plasma stream to deposit a hydrocarbon or fluorocarbon residue. The procedure is described as follows: the guidewire core is placed in a plasma chamber and cleaned with an oxygen plasma etch. The guidewire core is then exposed to a hydrocarbon plasma to deposit a plasma-polymerized tie layer on the guidewire core to complete the pretreatment. The hydrocarbon plasma may comprise a lower molecular weight (or gaseous) alkanes

such as methane, ethane, propane, isobutane, butane or the like; lower molecular weight alkenes such as ethene, propene, isobutene, butene or the like or; gaseous fluorocarbons such as tetrafluoromethane, trichlorofluoromethane, dichlorodifluoromethane, trifluorochloromethane, tetrafluoroethylene, trichlorofluoroethylene, dichlorodifluoroethylene, trifluorochloroethylene and other such materials. Mixtures of these materials are also acceptable. The tie layer apparently provides C-C bonds for subsequent covalent bonding to the outer hydrophilic polymer coating. Preferred flow rates for the hydrocarbon into the plasma chamber are in the range of 500 c.c./min. to 2000 c.c./min. and the residence time of the guidewire in the chamber is in the range of 1-20 minutes, depending on the chosen hydrocarbon and the plasma chamber operating parameters. Power settings for the plasma chamber are preferably in the range of 200W to 1500W.

[0083] A tie layer of plasma-produced hydrocarbon residue having a thickness on the order of 10/ thick is disposed between core and coating. This process typically produces layers of hydrocarbon residue less than about 1000/ in thickness, and more typically less than about 100/. Tie layer effectively bonds the outer layer to the guidewire core while adding very little additional bulk to the guidewire. Guidewires made according to this invention therefore avoid the size and maneuverability problems of prior art guidewires.

[0084] The pretreated guidewire may be coated by a polymer using a procedure such as described above. For example, the pretreated guidewire may be dipped in a solution of a photoactive hydrophilic polymer system, i.e., a latently photoreactive binder group covalently bonded to a hydrophilic polymer. After drying, the coated guidewire is cured by exposing it to UV light. The UV light activates the latently reactive group in the photoactive polymer system to form covalent bonds with crosslinked C-C bonds in the hydrocarbon residue tie layer. The dipping and curing steps are preferably repeated often enough, typically twice, to achieve the appropriate thickness of the hydrophilic coating layer.

[0085] One highly preferred variation of the invention involves a guidewire with metal core, preferably 0.010" to 0.025" diameter stainless steel or nitinol. The exterior surface of guidewire is a biocompatible coating of a polyacrylamide/polyvinylpyrrolidone mixture bonded to a photoactive binding agent. The preferred coating is made from a mixture of Bio-Metric Systems PA03 and PV05 (or PVO1) binding systems according to the Examples below.

[0086] The photoactive hydrophilic polymer system of this preferred embodiment is a mixture of Bio-Metric Systems PA03 polyacrylamide/binder system and Bio-Metric Systems PV05 polyvinylpyrrolidone system. The polyacrylamide system provides lubricity, and the polyvinylpyrrolidone system provides both lubricity and binding for durability. The exact proportions of the two systems may be varied to suit the application. As an alternative, however, the hydrophilic biocompatible coating may be polyacrylamide alone, polyvinylpyrrolidone alone, polyethylene oxide, or any suitable coating known in the art. In addition, a coating of heparin, albumin or other proteins may be deposited over the hydrophilic coating in a manner known in the art to provide additional biocompatibility features.

[0087] The guidewire or other device may be cleaned by using an argon plasma etch in place of the oxygen plasma etch. The thickness of the plasma-polymerized tie layer may also vary without departing from the scope of this invention.

[0088] The following examples are further illustrative of the articles and methods of this invention. The invention is not limited to these examples.

#### Example

[0089] A 0.016" diameter nitinol guidewire was placed in a Plasma Etch MK II plasma chamber and cleaned with an oxygen plasma for 10 minutes. Methane flowing at a rate of 2000 c.c./min. was admitted into the chamber, and the chamber operated at a power setting of 400W for 2 minutes to deposit a hydrocarbonaceous residue onto the surface of the wire. All but approximately six inches of the wire was dipped in a polyvinylpyrrolidone/polyacrylamide (PVP/PA) photocrosslinkable solution of a mixture of 67% BSI PV01 and 33% BSI PA03. The coated guidewire was then dried and exposed to an ultraviolet light (325 nm.) for 8 seconds. The dipping, drying, and exposing steps were repeated twice. When wetted, the resulting wire felt lubricious and required less force to pull through an 0.018" ID catheter than an uncoated wire.

#### Example

[0090] A 0.016" diameter nitinol guidewire was placed in a Plasma Etch MK II plasma chamber and cleaned with an oxygen plasma for 10 minutes. Methane flowing at a rate of 1500 c.c./min. was admitted into the chamber, and the chamber was operated at a power setting of 600W for 5 minutes to plasma-treat the methane into a hydrocarbonaceous residue on the surface of the wire. All but approximately six inches of the wire was dipped in a polyvinylpyrrolidone/polyacrylamide (PVP/PA) photocrosslinkable solution consisting essentially a mixture of 50% BSIPV01 and 50% BSIPA03. The coated guidewire was then dried and exposed to an ultraviolet light (325 nm.) for 8 seconds. The dipping, drying, and exposing steps were repeated. When wetted, the resulting wire felt lubricious and required less force to pull through an 0.018" ID catheter than an uncoated wire.

#### Example

[0091] A 0.016" diameter nitinol guidewire was placed in a Plasma Etch MK II plasma chamber and cleaned with an oxygen plasma for 10 minutes. Ethane flowing at a rate of 900 c.c./min. was admitted into the chamber, and the chamber was operated at a power setting of 600W for 10 minutes to deposit a hydrocarbon residue onto the surface of the wire. All but approximately six inches of the wire was dipped in a polyvinyl-pyrrolidone/polyacrylamide (PVP/PA) photocrosslinkable solution of a mixture of 33% BSI PV01 and 67% BSI PA03. The coated guidewire was then dried and exposed to an ultraviolet light (325 nm.) for 8 seconds. The dipping, drying, and exposing steps were repeated twice. When wetted, the resulting wire felt lubricious and required less force to pull through an 0.018" ID catheter than an uncoated wire.

#### Example



[0092] A 0.013" diameter nitinol guidewire core was cleaned and introduced into a polyurethane tube (Shore 80A durometer hardness) having a 0.0015" wall thickness. The combination was then introduced into a heat-shrinkable polyethylene tubing. The dual layers of tubing were then heated to 3500 to 4000F whereupon the polyethylene tubing shrunk and the polyurethane tubing was fused to the wire core. The polyethylene tubing was then peeled off.

[0093] The polyurethane-metal core was then coated with eight layers of the Bio-Metric Systems PAO3/PAO5 material discussed above. The coated guidewire was then subjected to repetitive testing for loss of lubricity. The test involved introduction of the guidewire into a 0.028" ID catheter (150 cm length) situated in a water bath, the distal end of the catheter being connected to a glass labyrinth analogous to a vascular network.

[0094] The guidewire was then stroked over a 1" distance for a specified number of times--in this case, 30 strokes--and the friction measured. The measured friction on this catheter is shown in Figure 11. The absolute value of the friction is not shown; the fact that the friction did not increase is to be noticed in Figure 11. This demonstrates that the outer lubricious layer did not degrade during the test.

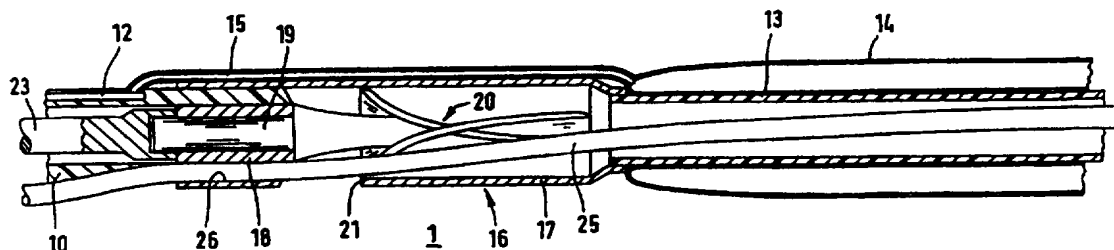
[0095] Although preferred embodiments of the present invention have been described, it should be understood that various changes, adaptations, and modifications may be made therein without departing from the scope of the claims which follow.



|                                                                                                                                                                                                                                                                                                                                                                                                                                                   |           |                                                                                                                                                                                                                                                                                                                                                                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>(51) Internationale Patentklassifikation <sup>6</sup> :</b><br><b>A61M 1/10</b>                                                                                                                                                                                                                                                                                                                                                                | <b>A1</b> | <b>(11) Internationale Veröffentlichungsnummer:</b> <b>WO 97/46270</b><br><b>(43) Internationales Veröffentlichungsdatum:</b> 11. Dezember 1997 (11.12.97)                                                                                                                                                                                                     |
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**(54) Title:** BALLOON CATHETER

**(54) Bezeichnung:** BALLONKATHETER



**(57) Abstract**

The balloon catheter has a catheter pipe (10) and a hydraulically expandable balloon (14) on a balloon support (13). Between the catheter pipe (10) and the balloon support (13) there is a small-diameter pump (16) which takes blood in through lateral inlets (21) and pumps it through the tubular balloon support (13). The pump (16) is driven via a flexible shaft (23) running through the catheter pipe (10) or by a directly integrated micromotor.

**(57) Zusammenfassung**

Der Ballonkatheter weist einen Katheterschlauch (10) und einen auf einem Ballonträger (13) sitzenden hydraulisch aufweitbaren Ballon (14) auf. Zwischen dem Katheterschlauch (10) und dem Ballonträger (13) ist eine Pumpe (16) von kleinem Durchmesser angeordnet, die Blut durch seitliche Einlässe (21) einsaugt und es durch den rohrförmigen Ballonträger (13) pumpt. Die Pumpe (16) wird über eine flexible Welle (23), die durch den Katheterschlauch (10) verläuft oder mittels direkt integriertem Mikromotor, angetrieben.

### LEDIGLICH ZUR INFORMATION

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### Ballonkatheter

Die Erfindung betrifft einen Ballonkatheter, der in ein Blutgefäß eingeführt werden kann, um beispielsweise Gefäßverengungen aufzuweiten oder einen Teil der Wand des Blutgefäßes vorübergehend vom Kontakt mit dem Blutstrom abzusperren.

Bekannt sind Ballonkatheter mit einem Katheterschlauch, der am distalen Ende einen rohrförmigen Ballonträger aufweist, auf welchem ein ringförmiger Ballon sitzt. Der Ballon steht über ein durch den Katheterschlauch hindurchgehendes Lumen mit einer extrakorporalen Druckquelle in Verbindung. Durch Einleiten einer Flüssigkeit unter Druck wird der Ballon aufgeweitet. Dabei erfolgt normalerweise ein Totalverschluß des Blutgefäßes, mit der Folge einer Mangelversorgung (Ischämie) der nachfolgenden Organregionen. Um diese zu vermeiden, werden Perfusionskatheter (Durchblutungskatheter) benutzt. Zu diesen gehören Autoperfusionskatheter (DE 92 07 395 U1), die einen durch den Ballonträger hindurchgehenden Durchlaß aufweisen, so daß eine Blutströmung durch das

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Innere des ringförmigen Ballons erfolgt, sowie aktive Perfusionssysteme, bei denen mit Hilfe einer externen Hochdruckpumpe, die an das distale Katheterende angeschlossen wird, eine kontinuierliche Perfusion durch das Katheterlumen erfolgt. Im Gegensatz zu Autoperfusionskathetern wird bei aktiven Perfusionssystemen ein bestimmter Druck aktiv aufgebaut, der unabhängig von dem aktuellen Blutdruck des Patienten ist. Hierzu muß dem Patienten jedoch arterialisiertes Blut entnommen werden, das extrakorporal in das Lumen des Katheterschlauchs gepumpt wird. Zudem sind sehr hohe Pumpendrucke (bis ca. 12 bar) aufgrund der großen Druckverluste im kleinelumigen Katheterschlauch erforderlich, um ca. 40 bis 60 ml/min. zu fördern.

Aus US 4 969 865 ist eine intravasale Blutpumpe bei Herzunterstützung bekannt. Diese Blutpumpe kann durch ein Blutgefäß hindurch in das Herz eingeführt werden. Sie weist ein längliches Rohr auf, in dem ein schraubenförmiger Propeller angeordnet ist, der durch eine flexible Welle angetrieben wird. Diese Pumpe saugt axial an und sie weist am entgegengesetzten Austrittsende Löcher für das radiale Abströmen auf. Im Betrieb wird die Blutpumpe in der Öffnung der Herzklappe plaziert, wobei das Ansaugende sich in einem der Herzventrikel befindet, während das Abströmende in der Aorta angeordnet ist.

Der Erfindung liegt die Aufgabe zugrunde, einen Ballonkatheter zu schaffen, der ein vereinfachtes aktives Perfusionssystem bildet.

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Die Lösung dieser Aufgabe erfolgt erfindungsgemäß mit den im Patentanspruch 1 angegebenen Merkmalen.

Bei dem erfindungsgemäßen Ballonkatheter ist eine Pumpe im Zuge des Katheters angeordnet, und zwar proximal von dem Ballonträger. Die Pumpe saugt seitlich über entsprechende Öffnungen Blut aus dem Blutgefäß an und pumpt es axial durch den Ballonträger hindurch. Da die Pumpe unmittelbar vor dem Ballonträger angeordnet ist, ist nur ein relativ geringer Pumpendruck erforderlich. Die Pumpe ist so klein, daß sie direkt im Bereich des Eingriffs, also in der Nähe des Ballons, im Katheter platziert werden kann, so daß die Länge des zu durchspülenden Lumens kurz ist, wodurch der Druckverlust relativ gering gehalten wird. Die Pumpe hat einen so kleinen Durchmesser, daß sie im Zuge des Katheters in das Blutgefäß eingeführt werden kann, ohne dieses zu versperren. Von einer Behandlung mit Ballonkathetern sind in der Regel kleinere Blutgefäße betroffen. Der maximale Außendurchmesser der Pumpe sollte etwa 1,4 mm nicht übersteigen. Eine derartig kleine Pumpe kann in den Katheter integriert werden, so daß sie unmittelbar vor dem Ballonträger, der durch die Behandlungsstelle des Blutgefäßes hindurchgeht, liegt. Dabei saugt die Pumpe in Strömungsrichtung des Gefäßes aus dem Bereich höheren Drucks Blut über mindestens einen seitlichen Einlaß an und fördert dieses in den Niederdruckbereich jenseits der aufgeblasenen Ballons.

Wegen der erforderlichen Kleinheit der Pumpe muß diese mit relativ hohen Drehzahlen betrieben werden, um die erforderliche Förderleistung von beispielsweise 60

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cm<sup>3</sup>/min. zu erreichen. Die Pumpendrehzahl liegt vorzugsweise im Bereich von 80.000 bis 150.000 U/min.

Der Ballonkatheter wird vorzugsweise für das Dehnen von Gefäßverengungen, speziell im Herzkranzgefäßbereich, in den Halsschlagadern u.dgl., eingesetzt. Es ist aber auch möglich, den Ballonkatheter dazu zu benutzen, einen Drahtkorb (Stent) zur Weitstellung von Gefäßverengungen zu platzieren.

Ein anderer Aspekt der Erfindung betrifft einen Perfusionskatheter, der mehrere hintereinander angeordnete Ballons aufweist. Die Ballons dichten einen Längenabschnitt des Gefäßes vorübergehend ab, um in diesem Bereich einen Bypass annähen zu können. Das Blut strömt weiterhin durch den rohrförmigen Ballonträger, während der abgedichtete Gefäßabschnitt für operative Eingriffe zur Verfügung steht.

Die Erfindung schafft einen aktiven Perfusionskatheter mit integrierter Pumpe. Dieser entspricht in seiner Handhabung weitgehend den passiven Autoperfusionskathetern, ist in seiner Leistung aber den aktiven Perfusionssystemen vergleichbar. Ein weiterer Vorteil besteht darin, daß der Ballonträger mit einem sehr geringen Außendurchmesser von etwa 1 mm realisiert werden kann. Hierdurch ist in fast allen Fällen, selbst bei starken Stenosen, gewährleistet, daß eine Platzierung des Ballonbereichs in der Stenose erfolgen kann.

Vorzugsweise ist die Pumpe von einer flexiblen Welle angetrieben, die mit einem am proximalen Ende des Katheterschlauchs vorgesehenen Motor verbunden ist. Sol-

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che Pumpen, die nur aus einem Pumpengehäuse und dem darin rotierend angeordneten Flügelrad bestehen, können mit einem sehr geringen Außendurchmesser von etwa 1,5 mm gefertigt werden. Generell ist es im Rahmen der Erfindung aber auch möglich, einen Pumpenmotor in den Katheter, in direkter Nähe zur Pumpe, zu integrieren, wobei der Motor dann das Pumpenrad unmittelbar antreibt.

Um einen Ballonkatheter in einem Blutgefäß zu platzieren, wird in der Regel ein Führungsdraht eingebracht, über den der Katheter anschließend geschoben wird. Eine derartige Verlegung mit einem Führungsdraht ist auch bei dem erfindungsgemäßen Ballonkatheter möglich. Hierbei muß der Führungsdraht allerdings durch die Pumpe hindurchgeführt werden. Das Flügelrad der Pumpe oder die Pumpe selbst ist demnach so ausgebildet, daß es den Durchgang eines Führungsdrahtes, der einen Durchmesser von etwa 0,3 mm hat, ermöglicht. Zu berücksichtigen ist, daß die Pumpe erst in Betrieb genommen wird, nachdem der Führungsdraht hinreichend weit aus dem unmittelbaren Pumpenbereich herausgezogen wurde. Während der Verlegung des Katheters ist es hinnehmbar, wenn der Führungsdraht das Pumpenrad blockiert.

Im folgenden werden unter Bezugnahme auf die Zeichnungen Ausführungsbeispiele der Erfindung näher erläutert.

Es zeigen:

Fig. 1 einen Längsschnitt durch den distalen Endbereich des Ballonkatheters bei einem ersten Ausführungsbeispiel,



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Fig. 2 den Ballonkatheter nach Fig. 1 mit eingeschobenem Führungsdraht, wobei die Pumpe eine Monorail-Führung bildet, und

Fig. 3 ein Ausführungsbeispiel, bei dem der Führungsdraht coaxial durch die Pumpe hindurchgeht.

Der Ballonkatheter 1 nach Fig. 1 weist einen langgestreckten Katheterschlauch 10 auf, dessen Länge etwa 1 m beträgt und dessen Durchmesser ca. 1,3 mm beträgt. Der flexible Katheterschlauch 10 weist ein zentrales Schlauchlumen 11 mit einem Durchmesser von ca. 0,8 mm auf. Ferner verläuft durch die Wand des Katheterschlauchs 10 ein weiteres Lumen 12 zur Zuleitung von Druckfluid zu dem Ballon 14.

An der Katheterspitze befindet sich der rohrförmige Ballonträger 13 mit einem Innendurchmesser von ca. 0,8 mm und einem Außendurchmesser von ca. 1,0 mm. Dieser Ballonträger 13 ist von mindestens einem Ballon 14 umgeben. Der Ballon 14 steht über eine Leitung 15 mit dem Lumen 12 des Katheterschlauchs 10 in Verbindung. Das vordere Ende des Ballonträgers 13 ist verjüngt ausgebildet und weist eine axiale und mehrere seitliche Blutaustrittsöffnungen auf.

Zwischen dem Katheterschlauch 10 und dem Ballonträger 13 befindet sich die Pumpe 16. Diese weist ein rohrförmiges Pumpengehäuse 17 mit einem Außendurchmesser von ca. 1,5 mm auf. Das proximale Ende 17a des Pumpengehäuses ist an dem Ende des Katheterschlauchs 10 befestigt und das distale Ende 17b ist mit dem Ballonträger 13 verbunden. Das Pumpengehäuse 17 besteht aus Metall und

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es enthält ein Lager 18, in dem die Welle 19 des Pumpenrades 20 gelagert ist. Das Ende des Katheterschlauchs 10 ist zwischen dem Lager 18 und dem Pumpengehäuse 17 eingepaßt. Unmittelbar im Anschluß an das Ende des Katheterschlauchs 10 sind an dem Gehäuse 17 seitliche Einlässe 21 vorgesehen, durch die Blut radial in das Pumpengehäuse 17 eintreten kann. In dem Bereich, in dem sich das Pumpenrad 20 befindet, ist das Gehäuse 17 umfangsmäßig geschlossen. Das Pumpenrad 20 weist mehrere Flügel 22 auf, die schraubenförmig um die Achse herum angeordnet sind und sich über einen Winkelbereich von mindestens 150° erstrecken. Die axiale Länge des Pumpenrades 20 beträgt ca. das Doppelte des maximalen Durchmessers dieses Pumpenrades. Das Pumpenrad 20 endet unmittelbar vor dem Ballonträger 13.

Die Welle 19 des Pumpenrades 20 ist mit einer flexiblen Welle 23 verbunden, die im Innern des Lumens 11 des Katheterschlauchs 10 verläuft und am proximalen Ende mit einem externen Elektromotor verbunden ist, der die Welle mit einer Drehzahl in der Größenordnung von 100.000 U/min. antreibt.

Während der Ballonbereich des Katheters beispielsweise in den Bereich einer Stenose eingeführt und der Ballon 14 unter Druck gesetzt und dadurch aufgeweitet wurde, fördert die Pumpe 16 Blut von den Einlässen 21 durch den Ballonträger 13 hindurch. Das distale Ende des Ballonträgers 13 ist offen oder mit Öffnungen versehen, so daß das Blut dort aus dem Ballonträger 13 in das Blutgefäß hinein austreten kann.

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Das Ausführungsbeispiel von Fig. 2 unterscheidet sich von demjenigen der Fig. 1 nur dadurch, daß zusätzlich ein Führungsdraht 25 vorgesehen ist, der zunächst in dem Blutgefäß plaziert wird und über den dann der Katheter geschoben wird. Dieser flexible Führungsdraht 25 verläuft generell außerhalb des Katheterschlauchs 10. Am distalen Ende des Katheterschlauchs, vorzugsweise auf den letzten 10 cm des Katheterschlauchs 10 und in einem Teil des Pumpengehäuses 17, befindet sich ein längslaufender Kanal 26, der einen Führungsbereich (Monorail) bildet, durch den der Führungsdraht 25 in das Pumpengehäuse 17 geleitet wird. Der Durchmesser des Führungsdrahtes beträgt ca. 0,3 mm, so daß der Führungsdraht durch das Pumpenrad 20 zwischen dessen Flügeln hindurch verlaufen kann. Während der Führungsdraht 25 sich im Pumpengehäuse befindet, erfolgt keine Rotation des Pumpenrades. Nach dem Plazieren des Katheters wird der Führungsdraht für die Behandlung mindestens an dem Pumpengehäuse herausgezogen. Dabei ist der Kanal 26 so plaziert und das Flügelrad 20 so gestaltet, daß der Führungsdraht 25 jederzeit nach erfolgter Behandlung erneut über das stehende Flügelrad 20 in Richtung des Ballons durch den Ballonträger 13 hindurch geschoben werden kann, um das System erneut mit Hilfe des Führungsdrahtes 25 in einer veränderten Position zu plazieren, ohne den Ballonkatheter 1 hierfür völlig zurückziehen zu müssen.

Bei dem Ausführungsbeispiel von Fig. 3 verläuft der Führungsdraht 25 koaxial durch die flexible Welle 23, die Welle 19 und das Flügelrad 20 hindurch. Diese Teile haben entsprechende Axialkanäle, um über den Führungsdraht geschoben werden zu können (Over-the-Wire-Techni-

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que). Während des Betriebes der Pumpe kann der Führungsdraht zurückgezogen werden, um den Durchfluß durch den Ballonträger 13 zu verbessern. Nach dem Zurückziehen des Führungsdrahtes ist ein erneutes Vorschieben möglich, wenn die Platzierung des Katheters verändert werden soll. Für die Funktion der Pumpe ist dies allerdings nicht erforderlich.

Befinden sich auf dem Ballonträger mehrere Ballons, so kann für jeden der Ballons eine hydraulische Zuleitung 15 über die Pumpe 16 hinweg vorgesehen werden. Dennoch sollte der Katheter in seinem dicksten Bereich, also im Bereich der Pumpe 16, speziell für den Einsatz im Koronarbereich (Karotinen), nicht wesentlich über 1,5 mm Durchmesser hinausgehen, da sonst eine Platzierung des Katheters über einen standardmäßigen Einführkatheter mit 2 mm Innendurchmesser nicht mehr möglich wäre. Ferner ist es erforderlich, daß die Länge des Pumpengehäuses 17 ca. 6 mm nicht übersteigt.

Die zuvor beschriebenen Ausführungsbeispiele beziehen sich auf einen Ballonkatheter, der eine nach dem Niederdruckprinzip arbeitenden Pumpe 16 enthält, die in der Nähe des Ballonträgers, also am Ende des Katheterschlauchs, angeordnet ist. Hierbei braucht die Pumpe nur einen relativ geringen Druck zu erzeugen. Im Rahmen der Erfindung ist es aber auch möglich, eine intravasale Pumpe im Zuge des Katheterschlauchs anzuordnen, die einen größeren Abstand von dem Ballonträger hat. Eine solche Pumpe muß einen höheren Pumpendruck liefern, weil im Zuge des Katheterschlauchs ein Druckabfall stattfindet.

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**PATENTANSPRÜCHE**

1. Ballonkatheter (1) mit einem Katheterschlauch (10) und einem mit dem Katheterschlauch verbundenen rohrförmigen Ballonträger (13), der mindestens einen aufweitbaren Ballon (14) trägt,

d a d u r c h   g e k e n n z e i c h n e t ,

daß im Bereich des Katheterschlauchs (10) oder zwischen diesem und dem Ballonträger (13) eine intravasale Pumpe (16) angeordnet ist, die durch mindestens einen seitlichen Einlaß (21) Blut ansaugt und axial in den Ballonträger (13) fördert.

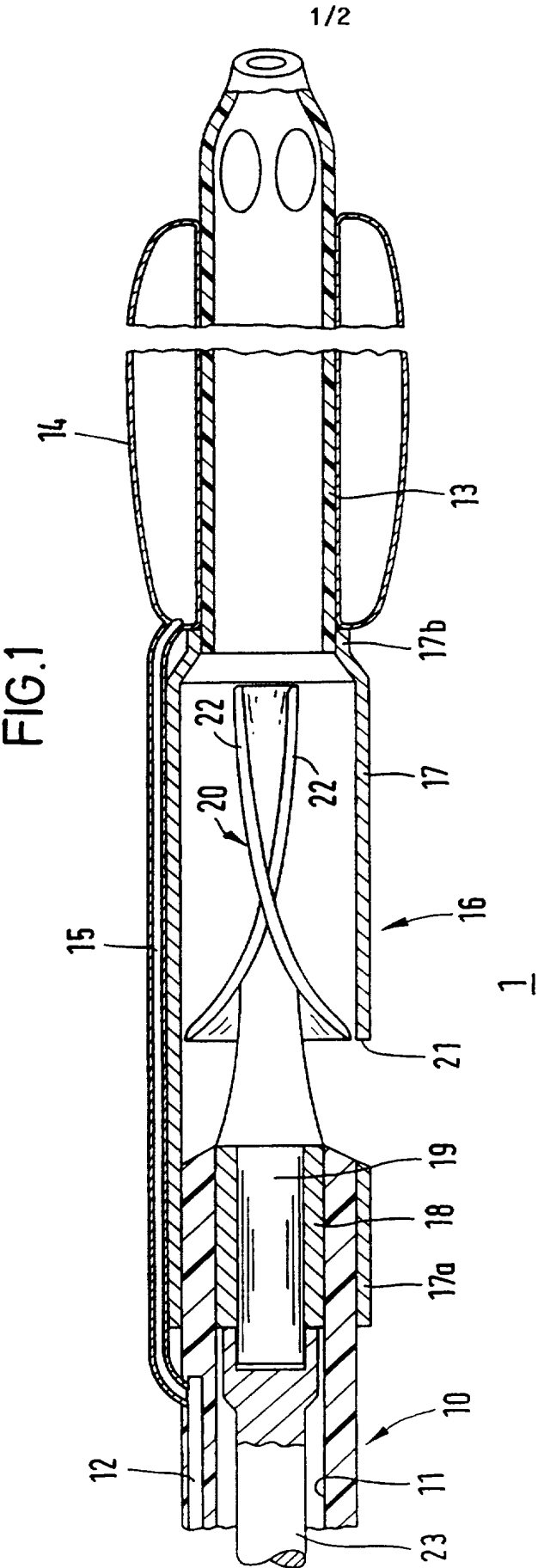
2. Ballonkatheter nach Anspruch 1, dadurch gekennzeichnet, daß die Pumpe (16) von einer flexiblen Welle (23) angetrieben ist, die mit einem am proximalen Ende des Katheterschlauchs (10) vorgesehenen Motor verbunden ist.
3. Ballonkatheter nach Anspruch 1, dadurch gekennzeichnet, daß die Pumpe (16) von einem im Verlauf des Katheterschlauchs angeordneten Motor angetrieben ist.
4. Ballonkatheter nach einem der Ansprüche 1-3, dadurch gekennzeichnet, daß die Pumpe (16) ein Pumpenrad (20) mindestens einen Flügel (22) aufweist, dessen Länge mindestens so groß ist wie der maximale Durchmesser des Pumpenrades (20).

- 11 -

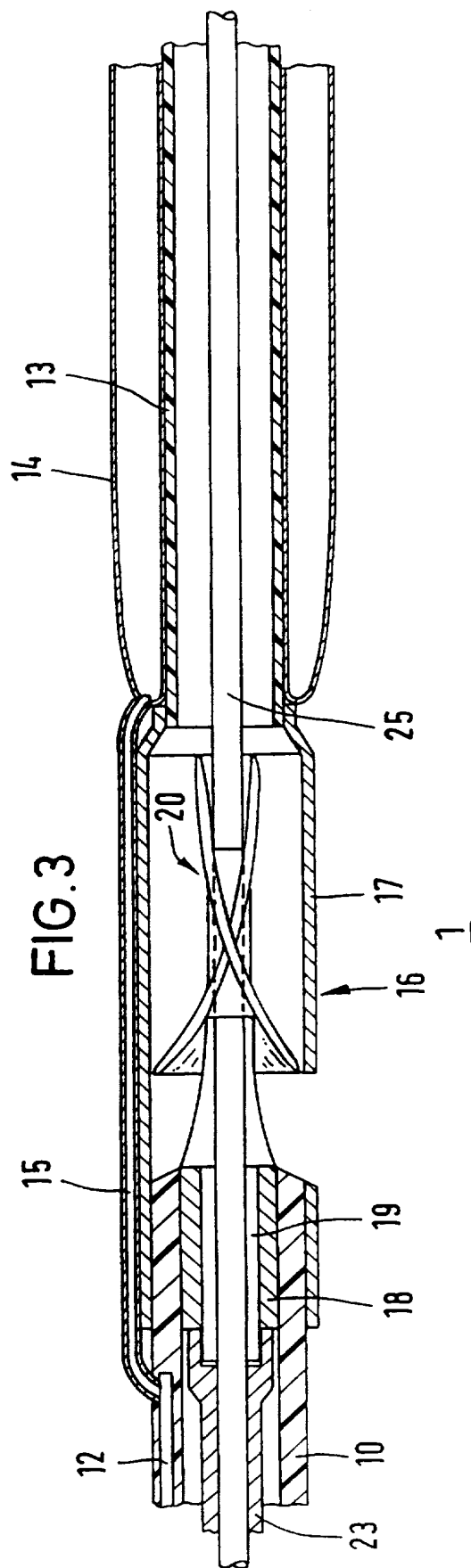
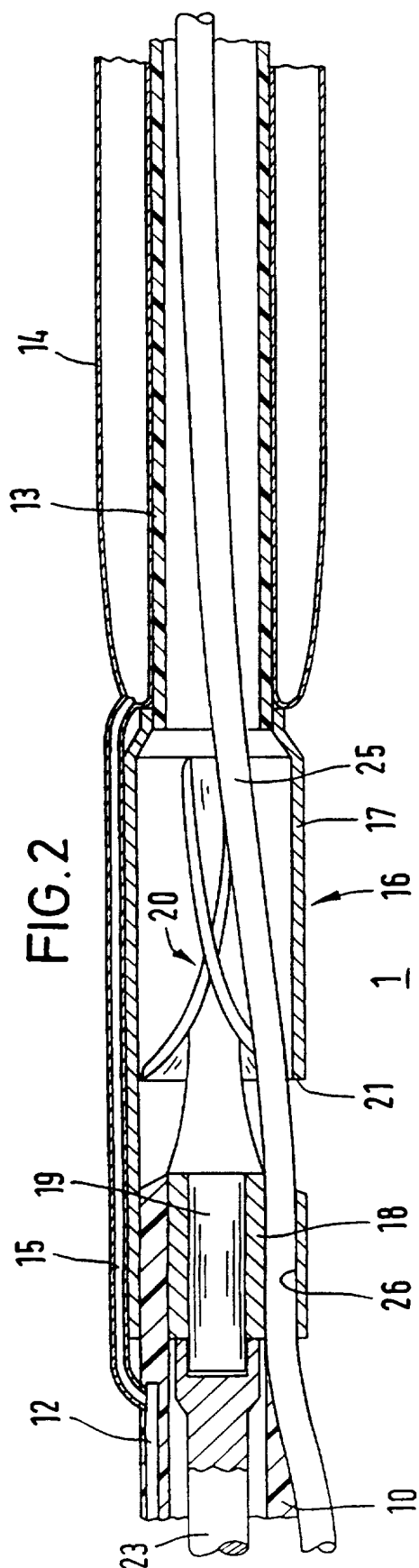
5. Ballonkatheter nach einem der Ansprüche 1-4, dadurch gekennzeichnet, daß die Pumpe (16) einen längslaufenden Führungskanal (26) für einen längs des Katheterschlauchs (10) verlaufenden Führungsdraht (25) aufweist.
6. Ballonkatheter nach Anspruch 5, dadurch gekennzeichnet, daß der Führungsdraht (25) weitgehend außerhalb des Katheterschlauchs (10) verläuft und der Führungskanal (26) in das Innere der Pumpe (16) hineinführt.
7. Ballonkatheter nach Anspruch 5 oder 6, dadurch gekennzeichnet, daß sich der Führungskanal (26) vom hinteren Ende des Katheterschlauchs (ca. 10 cm) bis zum Beginn (der Flügel) des Pumpenrades (20) erstreckt.
8. Ballonkatheter nach Anspruch 4, dadurch gekennzeichnet, daß der Führungsdraht (25) im Katheterschlauch (10) und koaxial durch die Pumpe (16) verläuft.
9. Ballonkatheter nach einem der Ansprüche 1-8, dadurch gekennzeichnet, daß die seitlichen Einlässe (21) wenigstens teilweise bei aufgeblasenem Ballon (14) einen Abstand zur Gefäßwand aufweisen.
10. Ballonkatheter nach Anspruch 9, dadurch gekennzeichnet, daß der Abstand zwischen den seitlichen Einlässen (21) und dem Ballon (14) maximal der Länge der Flügel des Pumpenrades (20) entspricht.

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11. Ballonkatheter, insbesondere nach einem der Ansprüche 1-10, dadurch gekennzeichnet, daß auf dem Ballonträger mindestens zwei Ballons mit gegenseitigem Abstand angeordnet sind.







# INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 97/02864

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61M1/10

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category * | Citation of document, with indication, where appropriate, of the relevant passages                              | Relevant to claim No. |
|------------|-----------------------------------------------------------------------------------------------------------------|-----------------------|
| X          | US 5 163 910 A (SCHWARTZ) 17 November 1992<br>see the whole document<br>---                                     | 1,2,4,5,<br>7-11      |
| A          | US 4 753 221 A (KENSEY) 28 June 1988<br>see column 3, line 11 - column 8, line 7;<br>figures<br>---             | 1,2,4,5,<br>9,10      |
| A          | WO 93 05712 A (DU-MED) 1 April 1993<br>see abstract; figure 1<br>---                                            | 3                     |
| P,X        | US 5 628 719 A (HASTINGS) 13 May 1997<br>see column 19, line 21 - column 20, line<br>58; figures 21-23<br>----- | 1,3,5-7,<br>11        |



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

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Date of the actual completion of the international search

4 September 1997

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# INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 97/02864

| Patent document<br>cited in search report | Publication<br>date | Patent family<br>member(s) | Publication<br>date |
|-------------------------------------------|---------------------|----------------------------|---------------------|
| US 5163910 A                              | 17-11-92            | US 5092844 A               | 03-03-92            |
| US 4753221 A                              | 28-06-88            | NONE                       |                     |
| WO 9305712 A                              | 01-04-93            | US 5240003 A               | 31-08-93            |
|                                           |                     | DE 69216842 D              | 27-02-97            |
|                                           |                     | DE 69216842 T              | 22-05-97            |
|                                           |                     | EP 0605573 A               | 13-07-94            |
|                                           |                     | US 5375602 A               | 27-12-94            |
| US 5628719 A                              | 13-05-97            | NONE                       |                     |

# INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen  
PCT/EP 97/02864

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES  
IPK 6 A61M1/10

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Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)  
IPK 6 A61M

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C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

| Kategorie* | Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile                   | Betr. Anspruch Nr. |
|------------|----------------------------------------------------------------------------------------------------------------------|--------------------|
| X          | US 5 163 910 A (SCHWARTZ) 17.November 1992<br>siehe das ganze Dokument<br>---                                        | 1,2,4,5,<br>7-11   |
| A          | US 4 753 221 A (KENSEY) 28.Juni 1988<br>siehe Spalte 3, Zeile 11 - Spalte 8, Zeile 7; Abbildungen<br>---             | 1,2,4,5,<br>9,10   |
| A          | WO 93 05712 A (DU-MED) 1.April 1993<br>siehe Zusammenfassung; Abbildung 1<br>---                                     | 3                  |
| P,X        | US 5 628 719 A (HASTINGS) 13.Mai 1997<br>siehe Spalte 19, Zeile 21 - Spalte 20, Zeile 58; Abbildungen 21-23<br>----- | 1,3,5-7,<br>11     |



Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen



Siehe Anhang Patentfamilie

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Datum des Abschlusses der internationalen Recherche

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Bevollmächtigter Bediensteter

Kousouretas, I

# INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen

PCT/EP 97/02864

| Im Recherchenbericht<br>angeführtes Patentdokument | Datum der<br>Veröffentlichung | Mitglied(er) der<br>Patentfamilie | Datum der<br>Veröffentlichung |
|----------------------------------------------------|-------------------------------|-----------------------------------|-------------------------------|
| US 5163910 A                                       | 17-11-92                      | US 5092844 A                      | 03-03-92                      |
| US 4753221 A                                       | 28-06-88                      | KEINE                             |                               |
| WO 9305712 A                                       | 01-04-93                      | US 5240003 A                      | 31-08-93                      |
|                                                    |                               | DE 69216842 D                     | 27-02-97                      |
|                                                    |                               | DE 69216842 T                     | 22-05-97                      |
|                                                    |                               | EP 0605573 A                      | 13-07-94                      |
|                                                    |                               | US 5375602 A                      | 27-12-94                      |
| US 5628719 A                                       | 13-05-97                      | KEINE                             |                               |

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## DESCRIPTION WO9746270

Balloon catheter

---

Ballonkatheter

The invention relates to a balloon catheter that can be inserted into a blood vessel to expand, for example, vasoconstriction, or temporarily shutting off a part of the wall of the blood vessel from contact with the blood stream.

---

Die Erfindung betrifft einen Ballonkatheter, der in ein Blutgefäß eingeführt werden kann, um beispielsweise Gefäßverengungen aufzuweiten oder einen Teil der Wand des Blutgefäßes vorübergehend vom Kontakt mit dem Blutstrom abzusperren.

Balloon catheters are well-known to a catheter tube which comprises a tubular balloon support at the distal end on which a ring-shaped balloon is located.

---

Bekannt sind Ballonkatheter mit einem Katheterschlauch, der am distalen Ende einen rohrförmigen Ballonträger aufweist, auf welchem ein ringförmiger Ballon sitzt.

The balloon is connected via a through going through the catheter tube lumen with an extracorporeal pressure [not] source in conjunction.

---

Der Ballon steht über ein durch den Katheterschlauch hindurchgehendes Lumen mit einer extrakorporalen Druck[not] quelle in Verbindung.

By introducing a liquid under pressure, the balloon is expanded.

---

Durch Einleiten einer Flüssigkeit unter Druck wird der Ballon aufgeweitet .

This normally occurs a total occlusion of the blood vessel, resulting in a shortage supply (ischaemia) according to the [not] following organ regions.

---

Dabei erfolgt normalerweise ein Totalverschluss des Blutgefäßes, mit der Folge einer Mangelversorgung (Ischämie) der nach[not] folgenden Organregionen.

To avoid this, perfusion (blood flow catheter) may be used.

---

Um diese zu vermeiden, werden Perfusionskatheter (Durchblutungskatheter) benutzt.

These include autoperfusion catheter (DE 92 07 395 UI) having a passing through the balloon support passage so that blood flow through the interior of the annular balloon, as well as active perfusion, in which by means of an external high pressure pump, distal to the end of the catheter is [not] connected will be a continuous perfusion is performed through the catheter lumen.

---

Zu diesen gehören Autoperfusionskatheter (DE 92 07 395 UI) , die einen durch den Ballonträger hindurchgehenden Durchlass aufweisen, so dass eine Blutströmung durch das Innere des ringförmigen Ballons erfolgt, sowie aktive Perfusionssysteme, bei denen mit Hilfe einer externen Hochdruckpumpe, die an das distale Katheterende ange[not] schlossen wird, eine kontinuierliche Perfusion durch das Katheterlumen erfolgt.

Unlike Autoperfusionskathetern a certain pressure is built up in the active active perfusion, which is independent of the actual blood pressure of the patient.

---

Im Gegensatz zu Autoperfusionskathetern wird bei aktiven Perfusionssystemen ein bestimmter Druck aktiv aufgebaut, der unabhängig von dem aktuellen Blutdruck des Patienten ist.

To this end, the patient, however, oxygenated blood must be removed, which is outside the body pumped into the lumen of the catheter tube.

---

Hierzu muss dem Patienten jedoch arterialisiertes Blut entnommen werden, das extrakorporal in das Lumen des Katheterschlauchs gepumpt wird.

In addition, very high pump [not] are pressures (up to about 12 bar) due to the large Druckver[not] losses in small-lumen catheter tube required about 40 to 60 ml / min. to promote.

---

Zudem sind sehr hohe Pumpen[not] drücke (bis ca. 12 bar) aufgrund der grossen Druckver[not]luste im kleinumigen Katheterschlauch erforderlich, um ca. 40 bis 60 ml/min. zu fördern.

From U.S. 4,969,865 an intravascular blood pump for cardiac support is known.

---

Aus US 4 969 865 ist eine intravasale Blutpumpe bei Herzunterstützung bekannt.

This blood pump may be inserted through a blood vessel and into the heart.

---

Diese Blutpumpe kann durch ein Blutgefäss hindurch in das Herz eingeführt werden.

It has an elongated tube, in which a screw [not] benförmiger propeller is arranged, which is driven by a flexible shaft.

---

Sie weist ein längliches Rohr auf, in dem ein schrau[not] benförmiger Propeller angeordnet ist, der durch eine flexible Welle angetrieben wird.

This pump sucks axi [not] al and it has the opposite outlet end holes for the radial outflow on.

---

Diese Pumpe saugt axi[not] al an und sie weist am entgegengesetzten Austrittsende Löcher für das radiale Abströmen auf .

In operation, the blood pump is placed in the opening of the heart valve, the suction is located in one of the ventricles of the heart, while the downstream end in the aorta arranged [not] is net.



---

Im Betrieb wird die Blutpumpe in der Öffnung der Herzklappe plaziert, wobei das Ansaugende sich in einem der Herzventrikel befindet, während das Abströmende in der Aorta angeord[not] net ist.

The invention is based is to provide a balloon [not] catheter, which forms a simplified active perfusion system the task.

---

Der Erfindung liegt die Aufgabe zugrunde, einen Ballon[not] katheter zu schaffen, der ein vereinfachtes aktives Perfusionssystem bildet.

The solution of this task is carried out according to the invention with the features specified in claim 1.

---

Die Lösung dieser Aufgabe erfolgt erfindungsgemäss mit den im Patentanspruch 1 angegebenen Merkmalen.

The inventive balloon catheter, a pump in the course of the catheter is disposed and, although proximally of the balloon support.

---

Bei dem erfindungsgemässen Ballonkatheter ist eine Pumpe im Zuge des Katheters angeordnet, und zwar proximal von dem Ballonträger.

The pump sucks the side of via appropriate [not] speaking openings blood from the blood vessel and pumps it axially through the balloon support him.

---

Die Pumpe saugt seitlich über ent[not] sprechende Öffnungen Blut aus dem Blutgefäss an und pumpt es axial durch den Ballonträger hindurch.

Since the pump is located immediately before the balloon support, only a relatively small pump pressure is required.

---

Da die Pumpe unmittelbar vor dem Ballonträger angeordnet ist, ist nur ein relativ geringer Pumpendruck erforderlich.

The pump is so small that it can be placed directly in the area of engagement, ie in the vicinity of the balloon catheter, so that the length of the through-spacer [not] lumen is short, causing the pressure loss relative [not] to be small.

---

Die Pumpe ist so klein, dass sie direkt im Bereich des Eingriffs, also in der Nähe des Ballons, im Katheter platziert werden kann, so dass die Länge des zu durchspülenden Lumens kurz ist, wodurch der Druckverlust relativ gering gehalten wird.

The pump has such a small [not] tube diameter that it can be introduced in the course of the catheter into the blood vessel, without having to lock this to [not] the vessel.

---

Die Pumpe hat einen so kleinen Durchmesser, dass sie im Zuge des Katheters in das Blutgefäß eingeführt werden kann, ohne dieses zu ver[sperren].

From a treatment with balloon catheters smaller blood vessels are usually affected.

---

Von einer Behandlung mit Ballonkathetern sind in der Regel kleinere Blutgefäße betroffen.

The maximum [not] outer diameter of the pump should not exceed about 1.4 mm.

---

Der maximale Aussendurchmesser der Pumpe sollte etwa 1,4 mm nicht übersteigen.

Such a small pump can be integrated in the catheter, so that it is immediately before the balloon support, passes through the treatment area of the blood vessel.

---

Eine derartig kleine Pumpe kann in den Katheter integriert werden, so dass sie unmittelbar vor dem Ballonträger, der durch die Behandlungsstelle des Blutgefäßes hindurchgeht, liegt.

The pump sucks in the flow direction of the vessel from the field height [not] the blood pressure on at least one lateral inlet and feeds this into the low pressure area [not] part of the inflated balloon.

---

Dabei saugt die Pumpe in Strömungsrichtung des Gefäßes aus dem Bereich höherem Drucks Blut über mindestens einen seitlichen Einlass an und fördert dieses in den Niederdruckbereich jenseits der aufgeblasenen Ballons.

Because of the required smallness of this pump must be operated at relatively high speeds to achieve the required flow rate of eg 60 cm<sup>3</sup> / min reach The pump speed is present preferably in the range 80000-150000 V / mm.

---

Wegen der erforderlichen Kleinheit der Pumpe muss diese mit relativ hohen Drehzahlen betrieben werden, um die erforderliche Förderleistung von beispielsweise 60 cm<sup>3</sup>/min zu erreichen Die Pumpendrehzahl liegt vorzugsweise im Bereich von 80.000 bis 150.000 U/mm.

The balloon catheter is etc. preferably for stretching of Gefassverengungen, especially in Herzkranzgefäßbereich, in the carotid arteries., Used but it is also possible to use the balloon catheter to an extension wire basket (stent) to the far position of Gefassverengungen conditions to place.

---

Der Ballonkatheter wird vorzugsweise für das Dehnen von Gefassverengungen, speziell im Herzkranzgefäßbereich, in den Halsschlagadern u.dgl., eingesetzt Es ist aber auch möglich, den Ballonkatheter dazu zu benutzen, einen Drahtkorb (Stent) zur Weitstellung von Gefassverengungen zu platzieren.

Em Another aspect of the invention relates to a perfusion comprising a plurality of balloons arranged one behind the other.

---

Em anderer Aspekt der Erfindung betrifft einen Perfusionskatheter, der mehrere hintereinander angeordnete Ballons aufweist.

The balloons seal a longitudinal section of the vessel from temporary to make this possible to approach a bypass.

---

Die Ballons dichten einen Längenschnitt des Gefäßes vorübergehend ab, um in diesem Bereich einen Bypass annehmen zu können.

The blood continues to flow through the tubular balloon exchanger, is available during the sealed vessel section for surgical interventions.

---

Das Blut strömt weiterhin durch den rohrförmigen Ballonträger, während der abgedichtete Gefäßabschnitt für operative Eingriffe zur Verfügung steht.

The invention provides an active perfusion catheter with integrated pump.

---

Die Erfindung schafft einen aktiven Perfusionskatheter mit integrierter Pumpe.

This corresponds to its handling largely passive Autoperfusionskathetern, the active perfusion is in its performance but version systems comparable.

---

Dieser entspricht in seiner Handhabung weitgehend den passiven Autoperfusionskathetern, ist in seiner Leistung aber den aktiven Perfusionsystemen vergleichbar.

Another advantage is that the balloon transmitter can be realized in a diameter of about 1 mm with a very small length.

---

Ein weiterer Vorteil steht darin, dass der Ballonträger mit einem sehr geringen Außendurchmesser von etwa 1 mm realisiert werden kann.

It is thereby almost in all cases, even with severe stenoses, ensures that a positioning of the balloon portion can be carried out in the stenosis.

---

Hierdurch ist in fast allen Fällen, selbst bei starken Stenosen, gewährleistet, dass eine Platzierung des Ballonbereichs in der Stenose erfolgen kann.

Preferably, the pump being driven by a flexible shaft connected with a motor provided at the proximal end of the catheter tube.

---

Vorzugsweise ist die Pumpe von einer flexiblen Welle angetrieben, die mit einem am proximalen Ende des Katheterschlauchs vorgesehenen Motor verbunden ist.

Sol before pumps, which consist only of a pump casing and the impeller is rotatably arranged, can be manufactured with a very small outer diameter of about 1.5 mm.

---

Sol ehe Pumpen, die nur aus einem Pumpengehäuse und dem darin rotierend angeordneten Flügelrad bestehen, können mit einem sehr geringen Aussendurchmesser von etwa 1,5 mm gefertigt werden.

It's generally in the context of He [not] also making possible a pump motor in the catheter to integrate in close proximity to the pump, wherein the engine then the pump directly drives [not].

---

Generell ist es im Rahmen der Er[not]findung aber auch möglich, einen Pumpenmotor in den Katheter, in direkter Nähe zur Pumpe, zu integrieren, wobei der Motor dann das Pumpenrad unmittelbar an[not]treibt.

To a balloon catheter into a blood vessel to place [not] reindeer, usually a guide wire is introduced, through which the catheter is then pushed.

---

Um einen Ballonkatheter in einem Blutgefäß zu platzie[not]ren, wird in der Regel ein Führungsdraht eingebracht, über den der Katheter anschliessend geschoben wird.

Such relocation of a guide wire is also possible for the inventive balloon catheter.

---

Eine derartige Verlegung mit einem Führungsdraht ist auch bei dem erfindungsgemässen Ballonkatheter möglich.

Here [not] be, however, passed through the pump when must the guide wire.

---

Hier[not] bei muss der Führungsdraht allerdings durch die Pumpe hindurchgeführt werden.

The impeller of the pump or the pump itself is, therefore, configured such that the passage of a guide wire having a diameter of about 0.3 mm allows.

---

Das Flügelrad der Pumpe oder die Pumpe selbst ist demnach so ausgebildet, dass es den Durchgang eines Führungsdrahtes, der einen Durchmesser von etwa 0,3 mm hat, ermöglicht.

---

It should be noted that the pump is put into service until after [not] the guide wire was pulled sufficiently far from the immediate pump area.

---

Zu berücksichtigen ist, dass die Pumpe erst in Betrieb genommen wird, nach[not] dem der Führungsdraht hinreichend weit aus dem unmittelbaren Pumpenbereich herausgezogen wurde.

---

During installation of the catheter, it is acceptable if the guide wire blocked the impeller.

---

Während der Verlegung des Katheters ist es hinnehmbar, wenn der Führungsdraht das Pumpenrad blockiert.

---

The following conditions embodiments of the invention are explained in detail with reference to the drawings [not].

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Im folgenden werden unter Bezugnahme auf die Zeichnung[not] gen Ausführungsbeispiele der Erfindung näher erläutert.

---

In the drawings:

---

Es zeigen:

---

Figure 1 embodiment a longitudinal section through the distal end region [not] area of the balloon catheter at a first from [not], Figure 2, the balloon catheter of FIG 1 with the schobe [not] nem guidewire, wherein the pump is a monorail guide and

---

Fig. 1 einen Längsschnitt durch den distalen Endbereich des Ballonkatheters bei einem ersten Ausführungsbeispiel, Fig. 2 den Ballonkatheter nach Fig. 1 mit eingeschobenem Führungsdraht, wobei die Pumpe eine Monorail-Führung bildet, und

Figure 3 shows an embodiment in which the Führungsdraht coaxially passes through the pump.

---

Fig. 3 ein Ausführungsbeispiel, bei dem der Führungsdraht koaxial durch die Pumpe hindurchgeht

---

The balloon catheter 1 according to Figure 1, a long stretched catheter tube 10 whose length is about 1 m and its diameter is about 1.3 mm.

---

Der Ballonkatheter 1 nach Fig. 1 weist einen langen gestreckten Katheterschlauch 10 auf, dessen Länge etwa 1 m beträgt und dessen Durchmesser ca. 1,3 mm beträgt.

---

The flexible catheter tube 10 has a concentric tube lumen 11 with a diameter of about 0,8 mm.

---

Der flexible Katheterschlauch 10 weist ein zentrales Schlauchlumen 11 mit einem Durchmesser von ca. 0,8 mm auf.

---

Further passing through the wall of the catheter tube 10 is a further lumen 12 for supply of pressure fluid to the balloon 14

---

Ferner verläuft durch die Wand des Katheterschlauchs 10 ein weiteres Lumen 12 zur Zuleitung von Druckfluid zu dem Ballon 14.

---

The tubular balloon support 13 is at the catheter tip with an inner diameter of about 0.8 mm and an outer diameter of about 1.0 mm.

---

An der Katheterspitze befindet sich der rohrförmige Ballonträger 13 mit einem Innendurchmesser von ca. 0,8 mm und einem Aussendurchmesser von ca. 1,0 mm.

This balloon member 13 is passed by at least one balloon 14 to [not].

---

Dieser Ballonträger 13 ist von mindestens einem Ballon 14 um[not] geben.

---

The balloon 14 is connected via a line 15 with the lumen 12 of the catheter tube 10 in combination.

---

Der Ballon 14 steht über eine Leitung 15 mit dem Lumen 12 des Katheterschlauchs 10 in Verbindung.

---

The front end of the balloon member 12 is tapered out [not] forms and has an axial and a plurality of lateral blood outlet openings.

---

Das vordere Ende des Ballonträgers 12 ist verjüngt ausge[not] bildet und weist eine axiale und mehrere seitliche Blutaustrittsöffnungen auf.

---

The pump is located between the catheter tube 10 and the balloon support 13 16

---

Zwischen dem Katheterschlauch 10 und dem Ballonträger 13 befindet sich die Pumpe 16.

---

This includes a rohrförmig [not] Miges pump housing 17 having an outer diameter of about 1.5 mm.

---

Diese weist ein rohrförmig[not] miges Pumpengehäuse 17 mit einem Aussendurchmesser von ca. 1,5 mm auf.

---

The proximal end 17a of the Pumpengehäuse [not] ses is attached to the end of the catheter tube 10 and the distal end 17b is connected to the balloon support 13.

---

Das proximale Ende 17a des Pumpengehäuses[not] ses ist an dem Ende des Katheterschlauchs 10 befestigt und das distale Ende 17b ist mit dem Ballonträger 13 verbunden.

---

The pump housing 17 is made of metal and it contains a bearing 18 in which the shaft 19 of the



pump [not] penrades 20 is supported.

---

Das Pumpengehäuse 17 besteht aus Metall und es enthält ein Lager 18, in dem die Welle 19 des Pum[not] penrades 20 gelagert ist.

---

The end of the catheter [not] hose 10 is provided between the bearing 18 and the pump [not] housing 17 is fitted.

---

Das Ende des Katheter[not] schlauchs 10 ist zwischen dem Lager 18 und dem Pumpen[not] gehäuse 17 eingepasst.

---

Immediately after the end of the catheter tube 10 17 lateral inlets 21 are provided on the housing, can enter radially into the pump housing 17 through the blood.

---

Unmittelbar im Anschluss an das Ende des Katheterschlauchs 10 sind an dem Gehäuse 17 seitliche Einlasse 21 vorgesehen, durch die Blut radial in das Pumpengehäuse 17 eintreten kann.

---

In the area in which the impeller is 20, the housing 17 is moderately extensive closed.

---

In dem Bereich, in dem sich das Pumpenrad 20 befindet, ist das Gehäuse 17 umfangsmässig geschlossen.

---

The impeller 20 has a plurality of vanes 22 which are disposed helically about the axis and extending over an angular range of at least 150 [deg.].

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Das Pumpenrad 20 weist mehrere Flügel 22 auf, die schraubenförmig um die Achse herum angeordnet sind und sich über einen Winkelbereich von mindestens 150[deg.] erstrecken.

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The axial length of the impeller 20 is about twice the maximum diameter of said pump wheel.

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Die axiale Länge des Pumpenrades 20 beträgt ca. das Doppelte des maximalen Durchmessers dieses Pumpenrades.

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The impeller 20 ends immediately before the balloon support 13

---

Das Pumpenrad 20 endet unmittelbar vor dem Ballonträger 13.

The shaft 19 of the impeller 20 is connected to a flexible shaft 23 which extends inside the lumen 11 of the catheter tube 10 and is connected at the proximal end with an external electric motor, the shaft at a speed in the order of 100 000 U / min. drives.

---

Die Welle 19 des Pumpenrades 20 ist mit einer flexiblen Welle 23 verbunden, die im Innern des Lumens 11 des Katheterschlauchs 10 verläuft und am proximalen Ende mit einem externen Elektromotor verbunden ist, der die Welle mit einer Drehzahl in der Grössenordnung von 100.000 U/min. antreibt.

For example, introduced into the region of a stenosis as the balloon portion of the catheter and the balloon 14 is pressurized and expanded in the pump 16 promotes blood from inlets 21 through the balloon support 13 therethrough.

---

Während der Ballonbereich des Katheters beispielsweise in den Bereich einer Stenose eingeführt und der Ballon 14 unter Druck gesetzt und dadurch aufgeweitet wurde, fördert die Pumpe 16 Blut von den Einlassen 21 durch den Ballonträger 13 hindurch.

The distal end of Bal [not] lonträgers 13 is provided with openings or open so that blood can there emerge from the balloon support 13 in the blood [not] vascular into it.

---

Das distale Ende des Bal[not] lonträgers 13 ist offen oder mit Öffnungen versehen, so dass das Blut dort aus dem Ballonträger 13 in das Blut[not] gefäss hinein austreten kann.

The embodiment of Figure 2 differs from that of Figure 1 only in that, in addition, a guide wire 25 is provided, which is initially placed in the blood vessel, and is then slid over the Ka [not] catheter.

---

Das Ausführungsbeispiel von Fig. 2 unterscheidet sich von demjenigen der Fig. 1 nur dadurch, dass zusätzlich ein Führungsdraht 25 vorgesehen ist, der zunächst in dem Blutgefäss plaziert wird und über den dann der Ka[not] theter geschoben wird.

This flexible guide wire 25 extends generally outside of the catheter tube 10

---

Dieser flexible Führungsdraht 25 verläuft generell ausserhalb des Katheterschlauchs 10.

---

At the distal end of the catheter tube, preferably in the last 10 cm of the catheter tube 10 and in a part of the pump housing 17, there is a longitudinally extending channel 26, which forms a guide portion (Monorail) through which the guidewire 25 is guided into the pump housing 17.

---

Am distalen Ende des Katheterschlauchs, vorzugsweise auf den letzten 10 cm des Katheterschlauchs 10 und in einem Teil des Pumpengehäuses 17, befindet sich ein längslaufender Kanal 26, der einen Führungsbereich (Monorail) bildet, durch den der Führungsdraht 25 in das Pumpengehäuse 17 geleitet wird.

---

The diameter of the guide wire is about 0.3 mm, so that the guide [not] ing wire through the pump 20 between its wing [not] rules can pass therethrough.

---

Der Durchmesser des Führungsdrahtes beträgt ca. 0,3 mm, so dass der Füh[not] rungsdraht durch das Pumpenrad 20 zwischen dessen Flü[not] geln hindurch verlaufen kann.

---

While the guide wire 25 is located in the pump housing, no Rota [not] tion of the impeller.

---

Während der Führungsdraht 25 sich im Pumpengehäuse befindet, erfolgt keine Rota[not] tion des Pumpenrades.

---

After placing the catheter, the guide wire is pulled out of the treatment at least in the pump housing.

---

Nach dem Plazieren des Katheters wird der Führungsdraht für die Behandlung mindestens an dem Pumpengehäuse herausgezogen.

---

Here, the channel 26 is placed and the impeller 20 is designed so that the guide wire 25 at all times after the treatment can again be slid over the stationary impeller 20 in the direction of the balloon by the balloon member 13 through to the system, again with the help of the guide [ not] ing wire 25 decorate in a changed position to plan [not] without pulling back the balloon catheter 1 of this completely [not].

---

Dabei ist der Kanal 26 so plaziert und das Flügelrad 20 so gestaltet, dass der Führungsdraht 25 jederzeit nach erfolgter Behandlung erneut über das stehende Flügelrad 20 in Richtung des Ballons durch den Ballonträger 13 hindurch geschoben werden kann, um das System erneut mit Hilfe des Füh[not] rungsdrahtes 25 in einer veränderten Position zu pla[not] zieren, ohne den Ballonkatheter 1 hierfür völlig zu[not] rückziehen zu müssen.

In the embodiment of Figure 3, the guide wire 25 extends coaxially through the flexible shaft 23, the shaft 19 and the impeller 20.

---

Bei dem Ausführungsbeispiel von Fig. 3 verläuft der Führungsdraht 25 koaxial durch die flexible Welle 23, die Welle 19 und das Flügelrad 20 hindurch.

These parts have corresponding axial channels to be pushed over the Führungsdraht can (over-the-wire Techni que).

---

Diese Teile haben entsprechende Axialkanäle, um über den Führungsdraht geschoben werden zu können (Over-the-Wire-Techni que) .

During operation of the pump, the guide [not] be withdrawn tion wire to improve the flow through the balloon support 13.

---

Während des Betriebes der Pumpe kann der Füh[not] rungsdraht zurückgezogen werden, um den Durchfluss durch den Ballonträger 13 zu verbessern.

After retracting [not] hen the guidewire re-feeding is possible if the placement of the catheter to be changed.

---

Nach dem Zurückzie[not] hen des Führungsdrahtes ist ein erneutes Vorschieben möglich, wenn die Plazierung des Katheters verändert werden soll.

For the operation of the pump, this is all [not] not necessary, however.

---

Für die Funktion der Pumpe ist dies aller[not] dings nicht erforderlich.

Are located on the balloon support multiple balloons may be provided 15 via the pump 16 across each of the balloons, a hydraulic supply line.

---

Befinden sich auf dem Ballonträger mehrere Ballons, so kann für jeden der Ballons eine hydraulische Zuleitung 15 über die Pumpe 16 hinweg vorgesehen werden.

---

However, should the catheter in its thickest portion, ie in the area of the pump 16, specifically for use in the coronary (carotenes), not significantly exceed 1.5 mm in diameter, otherwise placement of the catheter via a standard catheter with 2 mm inner diameter would no longer be possible.

---

Dennoch sollte der Katheter in seinem dicksten Bereich, also im Bereich der Pumpe 16, speziell für den Einsatz im Koronarbereich (Karotinen) , nicht wesentlich über 1,5 mm Durchmesser hinausgehen, da sonst eine Platzierung des Katheters über einen standardmässigen Einführungskatheter mit 2 mm Innendurchmesser nicht mehr möglich wäre.

---

Fer [not] ner, it is necessary that the length of Pumpengehäu [not] ses does not exceed 17 about 6 mm.

---

Fer[not] ner ist es erforderlich, dass die Länge des Pumpengehäu[not] ses 17 ca. 6 mm nicht übersteigt.

---

The above-described embodiments relate to a balloon catheter containing one after the Never [not] derdruckprinzip operating pump 16 which is disposed in the vicinity of the balloon carrier, at the end of the catheter [not] terschlauchs.

---

Die zuvor beschriebenen Ausführungsbeispiele beziehen sich auf einen Ballonkatheter, der eine nach dem Nie[not] derdruckprinzip arbeitenden Pumpe 16 enthält, die in der Nähe des Ballonträgers, also am Ende des Kathe[not] terschlauchs, angeordnet ist.

---

Here, the pump only needs to produce a relatively low pressure.

---

Hierbei braucht die Pumpe nur einen relativ geringen Druck zu erzeugen.

---

But in the invention it is also possible to arrange an intravascular pump in the course of the catheter tube that has a greater distance from the balloon support.

---

Im Rahmen der Erfindung ist es aber auch möglich, eine intravasale Pumpe im Zuge des Katheterschlauchs anzuordnen, die einen grösseren Abstand von dem Ballonträger hat.

Such a pump has to deliver a higher pump pressure, because in the course of the catheter tube takes place a pressure drop.

---

Eine solche Pumpe muss einen höheren Pumpendruck liefern, weil im Zuge des Katheterschlauchs ein Druckabfall stattfindet.

## Electronic Patent Application Fee Transmittal

|                                                |                                                       |                 |               |                             |
|------------------------------------------------|-------------------------------------------------------|-----------------|---------------|-----------------------------|
| <b>Application Number:</b>                     | 12772810                                              |                 |               |                             |
| <b>Filing Date:</b>                            | 03-May-2010                                           |                 |               |                             |
| <b>Title of Invention:</b>                     | Guidable Intravascular Blood Pump and Related Methods |                 |               |                             |
| <b>First Named Inventor/Applicant Name:</b>    | Walid N. Aboul-Hosn                                   |                 |               |                             |
| <b>Filer:</b>                                  | Kurt Raymond Denniston                                |                 |               |                             |
| <b>Attorney Docket Number:</b>                 | 06-01506US04                                          |                 |               |                             |
| Filed as Large Entity                          |                                                       |                 |               |                             |
| <b>Utility under 35 USC 111(a) Filing Fees</b> |                                                       |                 |               |                             |
| <b>Description</b>                             | <b>Fee Code</b>                                       | <b>Quantity</b> | <b>Amount</b> | <b>Sub-Total in USD(\$)</b> |
| <b>Basic Filing:</b>                           |                                                       |                 |               |                             |
| <b>Pages:</b>                                  |                                                       |                 |               |                             |
| <b>Claims:</b>                                 |                                                       |                 |               |                             |
| <b>Miscellaneous-Filing:</b>                   |                                                       |                 |               |                             |
| <b>Petition:</b>                               |                                                       |                 |               |                             |
| <b>Patent-Appeals-and-Interference:</b>        |                                                       |                 |               |                             |
| <b>Post-Allowance-and-Post-Issuance:</b>       |                                                       |                 |               |                             |
| <b>Extension-of-Time:</b>                      |                                                       |                 |               |                             |

| Description                      | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
|----------------------------------|----------|----------|--------|----------------------|
| <b>Miscellaneous:</b>            |          |          |        |                      |
| RCE - 2nd and Subsequent Request | 1820     | 1        | 1700   | 1700                 |
| <b>Total in USD (\$)</b>         |          |          |        | <b>1700</b>          |



## Electronic Acknowledgement Receipt

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| <b>EFS ID:</b>                              | 19511200                                              |
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| <b>International Application Number:</b>    |                                                       |
| <b>Confirmation Number:</b>                 | 4661                                                  |
| <b>Title of Invention:</b>                  | Guidable Intravascular Blood Pump and Related Methods |
| <b>First Named Inventor/Applicant Name:</b> | Walid N. Aboul-Hosn                                   |
| <b>Customer Number:</b>                     | 99185                                                 |
| <b>Filer:</b>                               | Kurt Raymond Denniston                                |
| <b>Filer Authorized By:</b>                 |                                                       |
| <b>Attorney Docket Number:</b>              | 06-01506US04                                          |
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| <b>Application Type:</b>                    | Utility under 35 USC 111(a)                           |

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| Page 613 of 628 |                      |           |                                     |                      |                     |

|                                                 |                                                    |                                                               |                                          |    |    |
|-------------------------------------------------|----------------------------------------------------|---------------------------------------------------------------|------------------------------------------|----|----|
| 1                                               | Request for Continued Examination (RCE)            | sb0030e_fill.pdf                                              | 697650                                   | no | 3  |
|                                                 |                                                    |                                                               | 412c7112da53f853da64e156eb1fa3e4b0709366 |    |    |
| Warnings:                                       |                                                    |                                                               |                                          |    |    |
| Information:                                    |                                                    |                                                               |                                          |    |    |
| 2                                               | Miscellaneous Incoming Letter                      | IDS_Cover_Sheet.pdf                                           | 69337                                    | no | 3  |
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| Warnings:                                       |                                                    |                                                               |                                          |    |    |
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| 3                                               | Information Disclosure Statement (IDS) Form (SB08) | Form_SB08.pdf                                                 | 68308                                    | no | 1  |
|                                                 |                                                    |                                                               | d64ecdd4486523c0d84e4def30d3046f841e45a5 |    |    |
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| 4                                               | Foreign Reference                                  | C1_JP2002514472A.pdf                                          | 764517                                   | no | 19 |
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| Information:                                    |                                                    |                                                               |                                          |    |    |
| 5                                               | Foreign Reference                                  | C3_DE000019821307C1_original_with_english_translation.pdf     | 615399                                   | no | 38 |
|                                                 |                                                    |                                                               | 9b60b1edefa55811892f2b74a044119bd317c3c2 |    |    |
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| 6                                               | Foreign Reference                                  | C4_WO1999058170A1_original_with_english_claims_and_spec.pdf   | 1161012                                  | no | 58 |
|                                                 |                                                    |                                                               | 9d96a7a5fef62d68354ce6261cc4706ea1dc7a5  |    |    |
| Warnings:                                       |                                                    |                                                               |                                          |    |    |
| Information:                                    |                                                    |                                                               |                                          |    |    |
| 7                                               | Foreign Reference                                  | C5_DE000019622335A1_original_with_english_claims_and_spec.pdf | 499601                                   | no | 27 |
|                                                 |                                                    |                                                               | 601f79b0471a47e8bd341fee1813efd3f1b68388 |    |    |
| Warnings:                                       |                                                    |                                                               |                                          |    |    |
| Information:                                    |                                                    |                                                               |                                          |    |    |
| 8                                               | Foreign Reference                                  | C6_JPH0999092A_combined.pdf                                   | 1202183                                  | no | 35 |
|                                                 |                                                    |                                                               | 32190760254aba26a0e0bce5153202732fac4aa7 |    |    |
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| 9                                               | Foreign Reference                                  | C2_WO1997046270A1.pdf                                         | 728432                                   | no | 37 |
|                                                 |                                                    |                                                               | a0e0756fe13df8b059e636d27fa1fa8856953145 |    |    |

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| <b>Warnings:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                      |              |                                          |         |   |
| <b>Information:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                      |              |                                          |         |   |
| 10                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Fee Worksheet (SB06) | fee-info.pdf | 30364                                    | no      | 2 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                      |              | 87a981c95a111df6052e7d9165db4e7a48c1938c |         |   |
| <b>Warnings:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                      |              |                                          |         |   |
| <b>Information:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                      |              |                                          |         |   |
| Total Files Size (in bytes):                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                      |              |                                          | 5836803 |   |
| <p><b>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</b></p> <p><b><u>New Applications Under 35 U.S.C. 111</u></b><br/> <b>If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</b></p> <p><b><u>National Stage of an International Application under 35 U.S.C. 371</u></b><br/> <b>If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</b></p> <p><b><u>New International Application Filed with the USPTO as a Receiving Office</u></b><br/> <b>If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</b></p> |                      |              |                                          |         |   |



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Walid N. Aboul-Hosn

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TITLE OF INVENTION: GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS

| APPLN. TYPE    | ENTITY STATUS | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE   |
|----------------|---------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | UNDISCOUNTED  | \$960         | \$0                 | \$0                  | \$960            | 10/21/2014 |

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.**

**THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.**

### HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

## PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**  
**Commissioner for Patents**  
**P.O. Box 1450**  
**Alexandria, Virginia 22313-1450**  
**or Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

99185 7590 07/21/2014  
**MAQUET Cardiovascular LLC**  
**1300 MacArthur Boulevard**  
**Mahwah, NJ 07430**

## Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

|                    |
|--------------------|
| (Depositor's name) |
| (Signature)        |
| (Date)             |

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 12/772,810      | 05/03/2010  | Walid N. Aboul-Hosn  | 06-01506US04        | 4661             |

TITLE OF INVENTION: GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS

| APPLN. TYPE    | ENTITY STATUS | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE   |
|----------------|---------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | UNDISCOUNTED  | \$960         | \$0                 | \$0                  | \$960            | 10/21/2014 |

| EXAMINER          | ART UNIT | CLASS-SUBCLASS |
|-------------------|----------|----------------|
| MARCETICH, ADAM M | 3761     | 604-006110     |

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) The names of up to 3 registered patent attorneys or agents OR, alternatively, 1 \_\_\_\_\_
- (2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 \_\_\_\_\_
- 3 \_\_\_\_\_

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies \_\_\_\_\_

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
- ☐ Applicant asserting small entity status. See 37 CFR 1.27
- ☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature \_\_\_\_\_

Date \_\_\_\_\_

Typed or printed name \_\_\_\_\_

Registration No. \_\_\_\_\_



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
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www.uspto.gov

|                 |             |                      |                     |                  |
|-----------------|-------------|----------------------|---------------------|------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 12/772,810      | 05/03/2010  | Walid N. Aboul-Hosn  | 06-01506US04        | 4661             |

|                           |      |            |
|---------------------------|------|------------|
| 99185                     | 7590 | 07/21/2014 |
| MAQUET Cardiovascular LLC |      |            |
| 1300 MacArthur Boulevard  |      |            |
| Mahwah, NJ 07430          |      |            |

|                   |
|-------------------|
| EXAMINER          |
| MARCETICH, ADAM M |

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
| 3761     |              |

  
DATE MAILED: 07/21/2014

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

## OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

### Privacy Act Statement

**The Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

|                               |                                      |                                          |                                                  |
|-------------------------------|--------------------------------------|------------------------------------------|--------------------------------------------------|
| <b>Notice of Allowability</b> | <b>Application No.</b><br>12/772,810 | <b>Applicant(s)</b><br>ABOUL-HOSN ET AL. |                                                  |
|                               | <b>Examiner</b><br>ADAM MARCETICH    | <b>Art Unit</b><br>3761                  | <b>AIA (First Inventor to File) Status</b><br>No |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 07/07/2014.  
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on \_\_\_\_.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 15,23-27,29,31,33,35-39,41-45 and 48-52. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see [http://www.uspto.gov/patents/init\\_events/pph/index.jsp](http://www.uspto.gov/patents/init_events/pph/index.jsp) or send an inquiry to [PPHfeedback@uspto.gov](mailto:PPHfeedback@uspto.gov).
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

**Certified copies:**

- a) ☐ All    b) ☐ Some    \*c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_.

Applicant has **THREE MONTHS FROM THE "MAILING DATE"** of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.  
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |                                                                                                                                |                                                                                      |
|--------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)                                                               | 5. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                  |
| 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date <u>07/07/2014</u> | 6. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                     | 7. <input type="checkbox"/> Other ____.                                              |
| 4. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date ____.                                          |                                                                                      |

/ADAM MARCETICH/  
Primary Examiner, Art Unit 3761



## **EXAMINER'S COMMENT / REASONS FOR ALLOWANCE**

### ***Notice of Pre-AIA or AIA Status***

The present application is being examined under the pre-AIA first to invent provisions.

### ***Examiner's Comment***

Rejection of claims 30 and 46 under 35 U.S.C. 112 (pre-AIA), first paragraph and rejection of claim 49 under 35 U.S.C. 112 (pre-AIA), second paragraph are withdrawn in view of the amendments filed 29 March 2014.

### ***Allowable Claims***

Claims 15, 23-27, 29, 31, 33, 35-39, 41-45 and 48-52 are allowed.

### ***Reasons for Allowance***

All references listed on the IDS filed 07 July 2014 have been considered.

Völker, Wolfram (WO 9746270, machine translation), the closest art of record, discloses an intravascular blood pump system (p. 4, ¶ 4, pump in the course of the catheter, p. 11; ¶ 4, Figs. 1-3, pump is located between the catheter tube 10 and the balloon support 13 16; p. 11, ¶ 5, Figs. 1-3, this includes a pump housing 17;), comprising:

a rotor having a rotor hub and at least one blade (p. 12, ¶ 5, the impeller 20 has a plurality of vanes 22);

a guide mechanism (p. 13, ¶ 5, a guide wire 25 is provided, which is initially placed in the blood vessel, and is then slid over the catheter).

However, Völker lacks several features of the invention, namely a hub tapering in the distal direction, a hub distal end extending distally beyond the blade and a guide mechanism configured as a second lumen. Instead, vanes 22 extend along the full length of impeller 20. Additionally, Völker does not provide a separate second lumen for the guide mechanism. Instead, Völker threads guidewire 25 through the pump housing, which temporarily prevents the rotor from turning (p. 14, ¶ 4, while the guide wire 25 is located in the pump housing, no Rotation of the impeller). Therefore, Völker fails to teach or suggest the side-rigger or coaxial guide mechanisms of claims 15, 29 or 45.

Also cited on the IDS, Sammler, Rolf et al. (DE 19821307, machine translation) discloses an intravascular blood pump system (p. 1, ¶ 2, intracardiac blood pump; p. 12, ¶ 6, Fig. 1, blood pump 10), comprising:

a guide mechanism configured as an elongate lumen for a guide wire (p. 21, ¶ 1, 3, 5, Fig. 4, catheter 48; p. 22, ¶ 4, 6, Fig. 5, catheter 48).

However, Sammler lacks a blood pressure detection mechanism comprising a fluid column. Additionally, Sammler is silent whether the lumen for catheters 46/48 is arranged coaxially with the distal or proximal end of the cannula, and whether the blood pump comprises a generally conical rotor hub. Sammler does not disclose enough detail in order to modify any of the art of record with a coaxial elongate lumen for passing a guidewire.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Tel (571)272-2590  
Fax 571-273-2590  
Email [Adam.Marcetich@uspto.gov](mailto:Adam.Marcetich@uspto.gov)

The Examiner can be reached 8:00am to 4:00pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/  
Primary Examiner, Art Unit 3761

|                                                                                                                                         |                          |                     |
|-----------------------------------------------------------------------------------------------------------------------------------------|--------------------------|---------------------|
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>Substitute for Form PTO-1449<br>( Not for submission under 37 CFR 1.99) | <b>Complete If Known</b> |                     |
|                                                                                                                                         | Application Number       | 12/772,810          |
|                                                                                                                                         | Filing Date              | 05-03-2010          |
|                                                                                                                                         | First Named Inventor     | Walid N. Aboul-Hosn |
|                                                                                                                                         | Art Unit                 | 3761                |
|                                                                                                                                         | Examiner Name:           | MARCTICH, ADAM M    |
|                                                                                                                                         | Attorney Docket Number:  | 06-01506US04        |
|                                                                                                                                         | Confirmation Number      | 4661                |
| <b>Sheet 1 of 1</b>                                                                                                                     |                          |                     |

| FOREIGN PATENT DOCUMENTS |                          |                                      |                           |                        |                  |                                                 |                                                                          |                |
|--------------------------|--------------------------|--------------------------------------|---------------------------|------------------------|------------------|-------------------------------------------------|--------------------------------------------------------------------------|----------------|
| Examiner Initial*        | Cite No. (C1, C2, ...Cn) | Foreign Document Number <sup>3</sup> | Country Code <sup>2</sup> | Kind Code <sup>4</sup> | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear | T <sup>5</sup> |
|                          |                          |                                      |                           |                        | YYYY-MM-DD       |                                                 |                                                                          |                |
|                          | C1                       | 2002514472                           | JP                        | A                      | 2002-05-21       |                                                 |                                                                          |                |
|                          | C2                       | 9746270                              | WO                        | A1                     | 1997-12-11       | VOELKER, WOLFRAM                                |                                                                          |                |
|                          | C3                       | 19821307                             | DE                        | C1                     | 1999-10-21       | IMPELLA CARDIOTECHNIK GMBH                      |                                                                          |                |
|                          | C4                       | 1999058170                           | WO                        | A1                     | 1999-11-18       | IMPELLA CARDIOTECH AG                           |                                                                          |                |
|                          | C5                       | 19622335                             | DE                        | A1                     | 1997-12-11       | VOELKER, WOLFRAM                                |                                                                          |                |
|                          | C6                       | H0999092                             | JP                        | A                      | 1997-04-15       | TARGET THERAPEUTICS INC                         |                                                                          |                |

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.M./

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                  |                        |            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|------------------------|------------|
| <b>Examiner Signature</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | /Adam Marcetich/ | <b>Date Considered</b> | 07/16/2014 |
| <b>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</b>                                                                                                                                                                                                                                                                                                                                  |                  |                        |            |
| <sup>1</sup> See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached. |                  |                        |            |

|                                                                                                              |                                                |                                                                         |
|--------------------------------------------------------------------------------------------------------------|------------------------------------------------|-------------------------------------------------------------------------|
| <b>Search Notes</b><br><br> | <b>Application/Control No.</b><br><br>12772810 | <b>Applicant(s)/Patent Under Reexamination</b><br><br>ABOUL-HOSN ET AL. |
|                                                                                                              | <b>Examiner</b><br><br>ADAM MARCETICH          | <b>Art Unit</b><br><br>3761                                             |

| CPC- SEARCHED                                                                                      |            |          |
|----------------------------------------------------------------------------------------------------|------------|----------|
| Symbol                                                                                             | Date       | Examiner |
| A61M1/10; A61M1/12; A61M1/101; A61M2001/10; A61M2001/12; A61M2001/122; A61M2001/125                | 11/19/2013 | AMM      |
| A61M1/10; A61M1/12; A61M1/101; A61M2001/10; A61M2001/12; A61M2001/122; A61M2001/125; A61M2001/1034 | 04/01/2014 | AMM      |
| A61M25/0015; A61M25/0052; A61M25/0169; A61M25/0172; A61M2025/0079; A61M2039/0235                   | 04/01/2014 | AMM      |
| search update                                                                                      | 07/16/2014 | AMM      |

| CPC COMBINATION SETS - SEARCHED |      |          |
|---------------------------------|------|----------|
| Symbol                          | Date | Examiner |
|                                 |      |          |

| US CLASSIFICATION SEARCHED |                |            |          |
|----------------------------|----------------|------------|----------|
| Class                      | Subclass       | Date       | Examiner |
| 604                        | 43,156,158,540 | 2/3/2012   | AMM      |
| 623                        | 3.1            | 2/3/2012   | AMM      |
| 600                        | 16             | 2/3/2012   | AMM      |
|                            | search update  | 8/17/2012  | AMM      |
|                            | search update  | 05/02/2013 | AMM      |
|                            | search update  | 11/19/2013 | AMM      |
|                            | search update  | 04/01/2014 | AMM      |
|                            | search update  | 07/16/2014 | AMM      |

| SEARCH NOTES                                                                              |          |          |
|-------------------------------------------------------------------------------------------|----------|----------|
| Search Notes                                                                              | Date     | Examiner |
| Inventor search: PALM and EAST (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT, IBM_TDB) | 2/3/2012 | AMM      |
| Review PLUS search results returned Friday, 3 February 2012                               | 2/3/2012 | AMM      |
| Review cited art for related cases 11/375926, 10/070178                                   | 2/3/2012 | AMM      |
| Review ISR for PCT/US00/24515 performed 19 March 2001, Angie Sykes USPTO                  | 2/3/2012 | AMM      |

|  |                                                    |
|--|----------------------------------------------------|
|  | /ADAM MARCETICH/<br>Primary Examiner.Art Unit 3761 |
|--|----------------------------------------------------|

## SEARCH NOTES

| Search Notes  | Date       | Examiner |
|---------------|------------|----------|
| search update | 8/17/2012  | AMM      |
| search update | 05/02/2013 | AMM      |
| search update | 11/19/2013 | AMM      |
| search update | 04/01/2014 | AMM      |

## INTERFERENCE SEARCH

| US Class/<br>CPC Symbol | US Subclass / CPC Group                                                                                  | Date       | Examiner |
|-------------------------|----------------------------------------------------------------------------------------------------------|------------|----------|
|                         | A61M1/10; A61M1/12; A61M1/101; A61M2001/10;<br>A61M2001/12; A61M2001/122; A61M2001/125;<br>A61M2001/1034 | 04/01/2014 | AMM      |
|                         | A61M25/0015; A61M25/0052; A61M25/0169;<br>A61M25/0172; A61M2025/0079; A61M2039/0235                      | 04/01/2014 | AMM      |
|                         | search update                                                                                            | 07/16/2014 | AMM      |

/ADAM MARCETICH/  
Primary Examiner.Art Unit 3761



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## BIB DATA SHEET

CONFIRMATION NO. 4661

| SERIAL NUMBER                                                                                                                                                                                                                                                                 | FILING or 371(c)<br>DATE                                                                                          | CLASS                             | GROUP ART UNIT                                                                                                                                                                                                                                                            | ATTORNEY DOCKET<br>NO.                      |                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|-----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|-------------------------------------------------|
| 12/772,810                                                                                                                                                                                                                                                                    | 05/03/2010                                                                                                        | 604                               | 3761                                                                                                                                                                                                                                                                      | 06-01506US04                                |                                                 |
| <b>APPLICANTS</b><br><b>INVENTORS</b><br>Walid N. Aboul-Hosn, Fair Oaks, CA;<br>William R. Kanz, Sacramento, CA;<br>Bruce A. Baker, Placerville, CA;                                                                                                                          |                                                                                                                   |                                   |                                                                                                                                                                                                                                                                           |                                             |                                                 |
| <b>** CONTINUING DATA *****</b><br>This application is a CON of 11/375,926 03/15/2006 PAT 7731675<br>which is a DIV of 10/070,178 07/19/2002 PAT 7022100<br>which is a 371 of PCT/US00/24515 09/01/2000<br>which claims benefit of 60/152,249 09/03/1999                      |                                                                                                                   |                                   |                                                                                                                                                                                                                                                                           |                                             |                                                 |
| <b>** FOREIGN APPLICATIONS *****</b>                                                                                                                                                                                                                                          |                                                                                                                   |                                   |                                                                                                                                                                                                                                                                           |                                             |                                                 |
| <b>** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **</b><br>05/11/2010                                                                                                                                                                                                        |                                                                                                                   |                                   |                                                                                                                                                                                                                                                                           |                                             |                                                 |
| Foreign Priority claimed <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No<br>35 USC 119(a-d) conditions met <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No<br>Verified and /ADAM M<br>MARCETICH/<br>Acknowledged Examiner's Signature | <input type="checkbox"/> Met after Allowance<br>Initials                                                          | <b>STATE OR<br/>COUNTRY</b><br>CA | <b>SHEETS<br/>DRAWINGS</b><br>18                                                                                                                                                                                                                                          | <b>TOTAL<br/>CLAIMS</b><br><del>24</del> 24 | <b>INDEPENDENT<br/>CLAIMS</b><br><del>3</del> 3 |
| <b>ADDRESS</b><br>MAQUET Cardiovascular LLC<br>1300 MacArthur Boulevard<br>Mahwah, NJ 07430<br>UNITED STATES                                                                                                                                                                  |                                                                                                                   |                                   | total claims: 24<br>independent: 3<br>updated 16 July 2014<br>/AMM/                                                                                                                                                                                                       |                                             |                                                 |
| <b>TITLE</b><br>Guidable Intravascular Blood Pump and Related Methods                                                                                                                                                                                                         |                                                                                                                   |                                   |                                                                                                                                                                                                                                                                           |                                             |                                                 |
| <b>FILING FEE<br/>RECEIVED</b><br>1390                                                                                                                                                                                                                                        | FEES: Authority has been given in Paper<br>No. _____ to charge/credit DEPOSIT ACCOUNT<br>No. _____ for following: |                                   | <input type="checkbox"/> All Fees<br><input type="checkbox"/> 1.16 Fees (Filing)<br><input type="checkbox"/> 1.17 Fees (Processing Ext. of time)<br><input type="checkbox"/> 1.18 Fees (Issue)<br><input type="checkbox"/> Other _____<br><input type="checkbox"/> Credit |                                             |                                                 |

|                                                                                                                 |                                            |                                                                     |  |
|-----------------------------------------------------------------------------------------------------------------|--------------------------------------------|---------------------------------------------------------------------|--|
| <b>Issue Classification</b><br> | <b>Application/Control No.</b><br>12772810 | <b>Applicant(s)/Patent Under Reexamination</b><br>ABOUL-HOSN ET AL. |  |
|                                                                                                                 | <b>Examiner</b><br>ADAM MARCETICH          | <b>Art Unit</b><br>3761                                             |  |

| CPC    |  |     |   |      |      |            |
|--------|--|-----|---|------|------|------------|
| Symbol |  |     |   |      | Type | Version    |
| A61M   |  | 1   | / | 101  | F    | 2013-01-01 |
| A61M   |  | 1   | / | 102  | I    | 2014-02-04 |
| A61M   |  | 1   | / | 1034 | I    | 2014-02-04 |
| A61M   |  | 1   | / | 125  | I    | 2014-02-04 |
| Y10S   |  | 415 | / | 90   | A    | 2013-01-01 |
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| CPC Combination Sets |      |     |         |         |
|----------------------|------|-----|---------|---------|
| Symbol               | Type | Set | Ranking | Version |
|                      |      |     |         |         |
|                      |      |     |         |         |

|                                                                                                  |                                |                              |                   |
|--------------------------------------------------------------------------------------------------|--------------------------------|------------------------------|-------------------|
| NONE                                                                                             |                                | <b>Total Claims Allowed:</b> |                   |
|                                                                                                  |                                | 24                           |                   |
| (Assistant Examiner)<br>/ADAM MARCETICH/<br>Primary Examiner.Art Unit 3761<br>(Primary Examiner) | (Date)<br>07/16/2014<br>(Date) | O.G. Print Claim(s)          | O.G. Print Figure |
|                                                                                                  |                                | 1                            | 6                 |





|                                                                                                                 |                                            |                                                                     |
|-----------------------------------------------------------------------------------------------------------------|--------------------------------------------|---------------------------------------------------------------------|
| <b>Issue Classification</b><br> | <b>Application/Control No.</b><br>12772810 | <b>Applicant(s)/Patent Under Reexamination</b><br>ABOUL-HOSN ET AL. |
|                                                                                                                 | <b>Examiner</b><br>ADAM MARCETICH          | <b>Art Unit</b><br>3761                                             |

| <input type="checkbox"/> Claims renumbered in the same order as presented by applicant |          |       |          |       |          |       |          |       |          |       |          |       |          |       |          |
|----------------------------------------------------------------------------------------|----------|-------|----------|-------|----------|-------|----------|-------|----------|-------|----------|-------|----------|-------|----------|
| <input type="checkbox"/> CPA                                                           |          |       |          |       |          |       |          |       |          |       |          |       |          |       |          |
| <input type="checkbox"/> T.D.                                                          |          |       |          |       |          |       |          |       |          |       |          |       |          |       |          |
| <input type="checkbox"/> R.1.47                                                        |          |       |          |       |          |       |          |       |          |       |          |       |          |       |          |
| Final                                                                                  | Original | Final | Original | Final | Original | Final | Original | Final | Original | Final | Original | Final | Original | Final | Original |
|                                                                                        | 1        |       | 17       | 12    | 33       | 8     | 49       |       |          |       |          |       |          |       |          |
|                                                                                        | 2        |       | 18       |       | 34       | 9     | 50       |       |          |       |          |       |          |       |          |
|                                                                                        | 3        |       | 19       | 13    | 35       | 21    | 51       |       |          |       |          |       |          |       |          |
|                                                                                        | 4        |       | 20       | 14    | 36       | 24    | 52       |       |          |       |          |       |          |       |          |
|                                                                                        | 5        |       | 21       | 15    | 37       |       |          |       |          |       |          |       |          |       |          |
|                                                                                        | 6        |       | 22       | 16    | 38       |       |          |       |          |       |          |       |          |       |          |
|                                                                                        | 7        | 2     | 23       | 17    | 39       |       |          |       |          |       |          |       |          |       |          |
|                                                                                        | 8        | 3     | 24       |       | 40       |       |          |       |          |       |          |       |          |       |          |
|                                                                                        | 9        | 4     | 25       | 18    | 41       |       |          |       |          |       |          |       |          |       |          |
|                                                                                        | 10       | 5     | 26       | 19    | 42       |       |          |       |          |       |          |       |          |       |          |
|                                                                                        | 11       | 6     | 27       | 7     | 43       |       |          |       |          |       |          |       |          |       |          |
|                                                                                        | 12       |       | 28       | 20    | 44       |       |          |       |          |       |          |       |          |       |          |
|                                                                                        | 13       | 10    | 29       | 22    | 45       |       |          |       |          |       |          |       |          |       |          |
|                                                                                        | 14       |       | 30       |       | 46       |       |          |       |          |       |          |       |          |       |          |
| 1                                                                                      | 15       | 11    | 31       |       | 47       |       |          |       |          |       |          |       |          |       |          |
|                                                                                        | 16       |       | 32       | 23    | 48       |       |          |       |          |       |          |       |          |       |          |

|                                                    |            |                                    |                        |
|----------------------------------------------------|------------|------------------------------------|------------------------|
| NONE                                               |            | <b>Total Claims Allowed:</b><br>24 |                        |
| (Assistant Examiner)                               | (Date)     |                                    |                        |
| /ADAM MARCETICH/<br>Primary Examiner.Art Unit 3761 | 07/16/2014 | O.G. Print Claim(s)<br>1           | O.G. Print Figure<br>6 |
| (Primary Examiner)                                 | (Date)     |                                    |                        |

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**Courtesy Reminder for  
Application Serial No: 12/772,810**

Attorney Docket No: 06-01506US04

Customer Number: 99185

Date of Electronic Notification: 07/21/2014

This is a courtesy reminder that new correspondence is available for this application. If you have not done so already, please review the correspondence. The official date of notification of the outgoing correspondence will be indicated on the form PTOL-90 accompanying the correspondence.

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Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**  
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99185 7590 07/21/2014  
**MAQUET Cardiovascular LLC**  
**1300 MacArthur Boulevard**  
**Mahwah, NJ 07430**

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

|                          |                    |
|--------------------------|--------------------|
| Eunice Kim (via EFS-web) | (Depositor's name) |
| /Eunice Kim/             | (Signature)        |
| October 17, 2014         | (Date)             |

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 12/772,810      | 05/03/2010  | Walid N. Aboul-Hosn  | 06-01506US04        | 4661             |

TITLE OF INVENTION: GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS

| APPLN. TYPE    | ENTITY STATUS | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE   |
|----------------|---------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | UNDISCOUNTED  | \$960         | \$0                 | \$0                  | \$960            | 10/21/2014 |

| EXAMINER          | ART UNIT | CLASS-SUBCLASS |
|-------------------|----------|----------------|
| MARCETICH, ADAM M | 3761     | 604-006110     |

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

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- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

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- (1) The names of up to 3 registered patent attorneys or agents OR, alternatively, 1 \_\_\_\_\_
- (2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 \_\_\_\_\_
- 3 \_\_\_\_\_

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

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(B) RESIDENCE: (CITY and STATE OR COUNTRY)

**MAQUET Cardiovascular LLC**

**Mahwah, NJ**

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

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- ☐ Applicant asserting small entity status. See 37 CFR 1.27
- ☐ Applicant changing to regular undiscounted fee status.

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NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Kurt R. Denniston/

Date October 17, 2014

Typed or printed name Kurt R. Denniston

Registration No. 59,605

## Electronic Patent Application Fee Transmittal

|                                                |                                                       |                 |               |                             |
|------------------------------------------------|-------------------------------------------------------|-----------------|---------------|-----------------------------|
| <b>Application Number:</b>                     | 12772810                                              |                 |               |                             |
| <b>Filing Date:</b>                            | 03-May-2010                                           |                 |               |                             |
| <b>Title of Invention:</b>                     | GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS |                 |               |                             |
| <b>First Named Inventor/Applicant Name:</b>    | Walid N. Aboul-Hosn                                   |                 |               |                             |
| <b>Filer:</b>                                  | Kurt Raymond Denniston/Eunice Kim                     |                 |               |                             |
| <b>Attorney Docket Number:</b>                 | 06-01506US04                                          |                 |               |                             |
| Filed as Large Entity                          |                                                       |                 |               |                             |
| <b>Utility under 35 USC 111(a) Filing Fees</b> |                                                       |                 |               |                             |
| <b>Description</b>                             | <b>Fee Code</b>                                       | <b>Quantity</b> | <b>Amount</b> | <b>Sub-Total in USD(\$)</b> |
| <b>Basic Filing:</b>                           |                                                       |                 |               |                             |
| <b>Pages:</b>                                  |                                                       |                 |               |                             |
| <b>Claims:</b>                                 |                                                       |                 |               |                             |
| <b>Miscellaneous-Filing:</b>                   |                                                       |                 |               |                             |
| <b>Petition:</b>                               |                                                       |                 |               |                             |
| <b>Patent-Appeals-and-Interference:</b>        |                                                       |                 |               |                             |
| <b>Post-Allowance-and-Post-Issuance:</b>       |                                                       |                 |               |                             |
| Utility Appl Issue Fee                         | 1501                                                  | 1               | 960           | 960                         |
| <b>Extension of Time:</b><br>Page 633 of 638   |                                                       |                 |               |                             |
| ABIOMED Ex. 1036                               |                                                       |                 |               |                             |

| Description       | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
|-------------------|----------|----------|--------|----------------------|
| Miscellaneous:    |          |          |        |                      |
| Total in USD (\$) |          |          |        | 960                  |

## Electronic Acknowledgement Receipt

|                                             |                                                       |
|---------------------------------------------|-------------------------------------------------------|
| <b>EFS ID:</b>                              | 20446908                                              |
| <b>Application Number:</b>                  | 12772810                                              |
| <b>International Application Number:</b>    |                                                       |
| <b>Confirmation Number:</b>                 | 4661                                                  |
| <b>Title of Invention:</b>                  | GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS |
| <b>First Named Inventor/Applicant Name:</b> | Walid N. Aboul-Hosn                                   |
| <b>Customer Number:</b>                     | 99185                                                 |
| <b>Filer:</b>                               | Kurt Raymond Denniston/Eunice Kim                     |
| <b>Filer Authorized By:</b>                 | Kurt Raymond Denniston                                |
| <b>Attorney Docket Number:</b>              | 06-01506US04                                          |
| <b>Receipt Date:</b>                        | 17-OCT-2014                                           |
| <b>Filing Date:</b>                         | 03-MAY-2010                                           |
| <b>Time Stamp:</b>                          | 14:24:44                                              |
| <b>Application Type:</b>                    | Utility under 35 USC 111(a)                           |

### Payment information:

|                                          |                 |
|------------------------------------------|-----------------|
| Submitted with Payment                   | yes             |
| Payment Type                             | Deposit Account |
| Payment was successfully received in RAM | \$960           |
| RAM confirmation Number                  | 606             |
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## File Listing:

| Document Number | Document Description        | File Name                            | File Size(Bytes)/ Message Digest         | Multi Part /.zip | Pages (if appl.) |
|-----------------|-----------------------------|--------------------------------------|------------------------------------------|------------------|------------------|
| 1               | Issue Fee Payment (PTO-85B) | 2014-10-17-Issue-Fee-Transmittal.pdf | 916232                                   | no               | 1                |
|                 |                             |                                      | 38aa555df14cb246f55b1c976de2ca2828a57280 |                  |                  |

### Warnings:

### Information:

|   |                      |              |                                          |    |   |
|---|----------------------|--------------|------------------------------------------|----|---|
| 2 | Fee Worksheet (SB06) | fee-info.pdf | 30679                                    | no | 2 |
|   |                      |              | 41ed6642275d68233be90c00a59c5b12c35b9b21 |    |   |

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#### New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

#### National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

#### New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.





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| APPLICATION NO. | ISSUE DATE | PATENT NO. | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|------------|------------|---------------------|------------------|
| 12/772,810      | 11/18/2014 | 8888728    | 06-01506US04        | 4661             |

99185 7590 10/29/2014  
Getinge US Legal Shared Services  
1300 MacArthur Boulevard  
Mahwah, NJ 07430

## ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

### **Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)** (application filed on or after May 29, 2000)

The Patent Term Adjustment is 98 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

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AO 120 (Rev. 08/10)

|                                                                                                                                               |                                                                                                                         |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
| <b>TO: Mail Stop 8</b><br><b>Director of the U.S. Patent and Trademark Office</b><br><b>P.O. Box 1450</b><br><b>Alexandria, VA 22313-1450</b> | <b>REPORT ON THE</b><br><b>FILING OR DETERMINATION OF AN</b><br><b>ACTION REGARDING A PATENT OR</b><br><b>TRADEMARK</b> |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been  
filed in the U.S. District Court District of Massachusetts on the following

☐ Trademarks or ☒ Patents. ( ☐ the patent action involves 35 U.S.C. § 292.):

|                            |                                |                                                  |
|----------------------------|--------------------------------|--------------------------------------------------|
| DOCKET NO.<br>16-cv-10914  | DATE FILED<br>5/19/2016        | U.S. DISTRICT COURT<br>District of Massachusetts |
| PLAINTIFF<br>ABIOMED INC.  |                                | DEFENDANT<br>MAQUET CARDIOVASCULAR LLC           |
| PATENT OR<br>TRADEMARK NO. | DATE OF PATENT<br>OR TRADEMARK | HOLDER OF PATENT OR TRADEMARK                    |
| 1 7,022,100                | 4/4/2006                       | Maquet Cardiovascular LLC                        |
| 2 8,888,728                | 11/18/2014                     | Maquet Cardiovascular LLC                        |
| 3 9,327,068                | 5/3/2016                       | Maquet Cardiovascular LLC                        |
| 4                          |                                |                                                  |
| 5                          |                                |                                                  |

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

|                            |                                                                                                                                                               |                               |
|----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| DATE INCLUDED              | INCLUDED BY<br><input type="checkbox"/> Amendment <input type="checkbox"/> Answer <input type="checkbox"/> Cross Bill <input type="checkbox"/> Other Pleading |                               |
| PATENT OR<br>TRADEMARK NO. | DATE OF PATENT<br>OR TRADEMARK                                                                                                                                | HOLDER OF PATENT OR TRADEMARK |
| 1                          |                                                                                                                                                               |                               |
| 2                          |                                                                                                                                                               |                               |
| 3                          |                                                                                                                                                               |                               |
| 4                          |                                                                                                                                                               |                               |
| 5                          |                                                                                                                                                               |                               |

In the above—entitled case, the following decision has been rendered or judgement issued:

|                    |
|--------------------|
| DECISION/JUDGEMENT |
|--------------------|

|       |                   |      |
|-------|-------------------|------|
| CLERK | (BY) DEPUTY CLERK | DATE |
|-------|-------------------|------|

Copy 1—Upon initiation of action, mail this copy to Director    Copy 3—Upon termination of action, mail this copy to Director  
Copy 2—Upon filing document adding patent(s), mail this copy to Director    Copy 4—Case file copy