

UTILITY PATENT APPLICATION TRANSMITTAL (Only for new nonprovisional applications under 37 CFR 1.53(b))		Attorney Docket No. 06-01506US05	
		First Named Inventor Walid N. ABOUL-HOSN	
		Title GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS	
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APPLICATION ELEMENTS See MPEP chapter 600 concerning utility patent application contents.	Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450
1. ☐ Fee Transmittal Form (PTO/SB/17 or equivalent) 2. ☐ Applicant asserts small entity status. See 37 CFR 1.27 3. ☐ Applicant certifies micro entity status. See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent. 4. ☒ Specification [Total Pages 39] Both the claims and abstract must start on a new page. (See MPEP § 608.01(a) for information on the preferred arrangement) 5. ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets 18] 6. ☐ Inventor's Oath or Declaration [Total Pages _____] (including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e)) a. ☐ Newly executed (original or copy) b. ☐ A copy from a prior application (37 CFR 1.63(d)) 7. ☒ Application Data Sheet * See note below. See 37 CFR 1.76 (PTO/AIA/14 or equivalent) 8. ☐ CD-ROM or CD-R in duplicate, large table, or Computer Program (Appendix) ☐ Landscape Table on CD 9. Nucleotide and/or Amino Acid Sequence Submission (if applicable, items a. – c. are required) a. ☐ Computer Readable Form (CRF) b. ☐ Specification Sequence Listing on: i. ☐ CD-ROM or CD-R (2 copies); or ii. ☐ Paper c. ☐ Statements verifying identity of above copies	ACCOMPANYING APPLICATION PAPERS 10. ☐ Assignment Papers (cover sheet & document(s)) Name of Assignee _____ 11. ☒ 37 CFR 3.73(c) Statement ☒ Power of Attorney (when there is an assignee) 12. ☐ English Translation Document (if applicable) 13. ☒ Information Disclosure Statement (PTO/SB/08 or PTO-1449) ☐ Copies of citations attached 14. ☒ Preliminary Amendment 15. ☐ Return Receipt Postcard (MPEP § 503) (Should be specifically itemized) 16. ☐ Certified Copy of Priority Document(s) (if foreign priority is claimed) 17. ☐ Nonpublication Request Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent. 18. ☐ Other: _____ _____ _____ _____

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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 aggregation. Sublytic shear stress leads to cellular
20 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 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.

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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" 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 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.

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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 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 guide catheter, a rotor shroud, and a cannula, with the cannula and guide catheter disposed on either side of the

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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
15 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.

 In a further embodiment, a perfusion assembly is provided communicatively coupled to the guide catheter
20 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.

 In a further embodiment, the perfusion
25 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.

30 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.

 In a further embodiment, the blood pressure
35 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 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.

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 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 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 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 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 to the predetermined 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
5 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.

10 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
15 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
20 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;

25 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;

30 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;

35 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;

FIG. 15 is a cross-sectional view taken along
20 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
25 broad aspect of the present invention;

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
30 invention;

FIG. 18 is a cross-sectional view of an
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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

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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.

5 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
10 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
15 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
20 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
25 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
30 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.
35 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,
10 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
15 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
20 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
25 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
30 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
35 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, 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 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.

25 Referring to FIG. 10, shown is a guidable 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 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 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
10 surfaces on corresponding portions of the shroud 36 and 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 Touhy-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,
10 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
15 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
20 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
25 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
30 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
35 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
5 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
10 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
15 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
20 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
25 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
30 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-
35 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,
5 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
10 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
15 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
20 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
25 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
30 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
35 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:

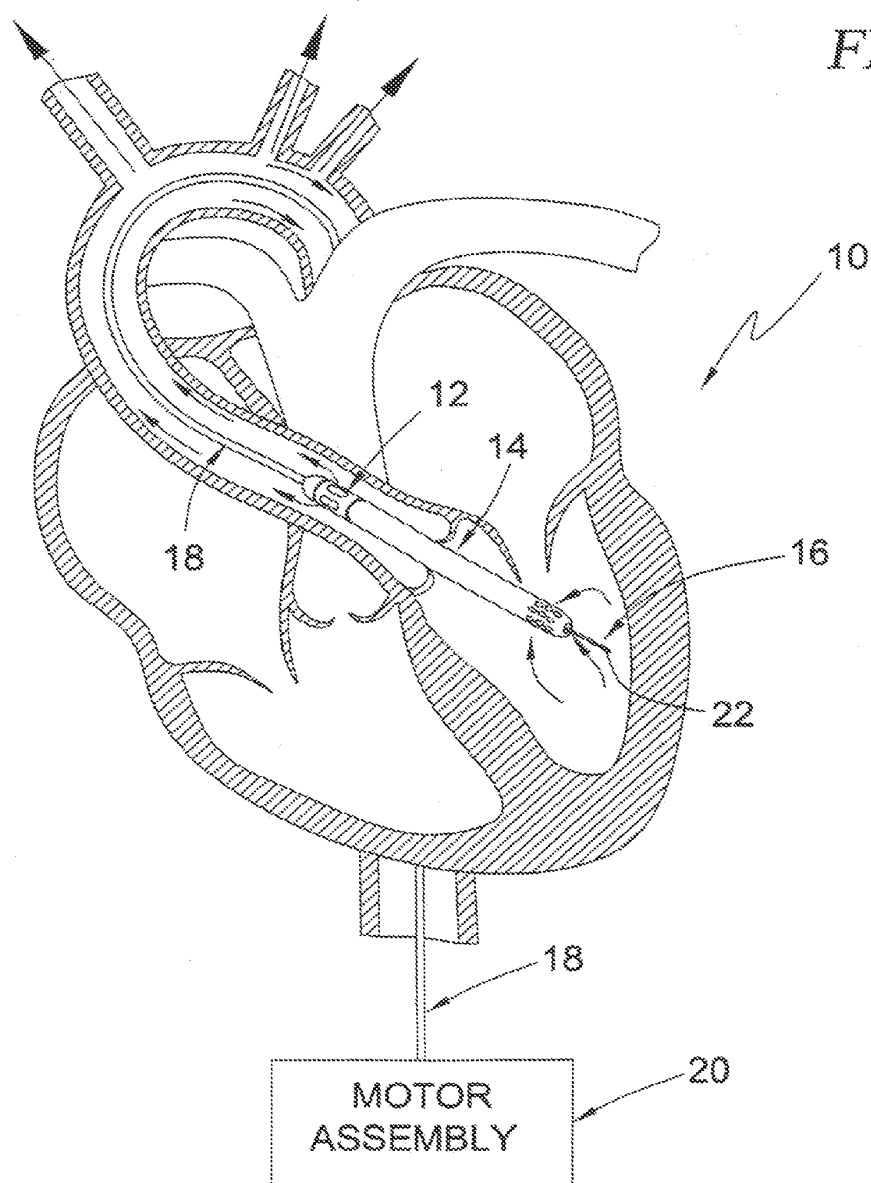
an intravascular blood pump having a cannula
5 coupled thereto; and

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.

FIG. 1



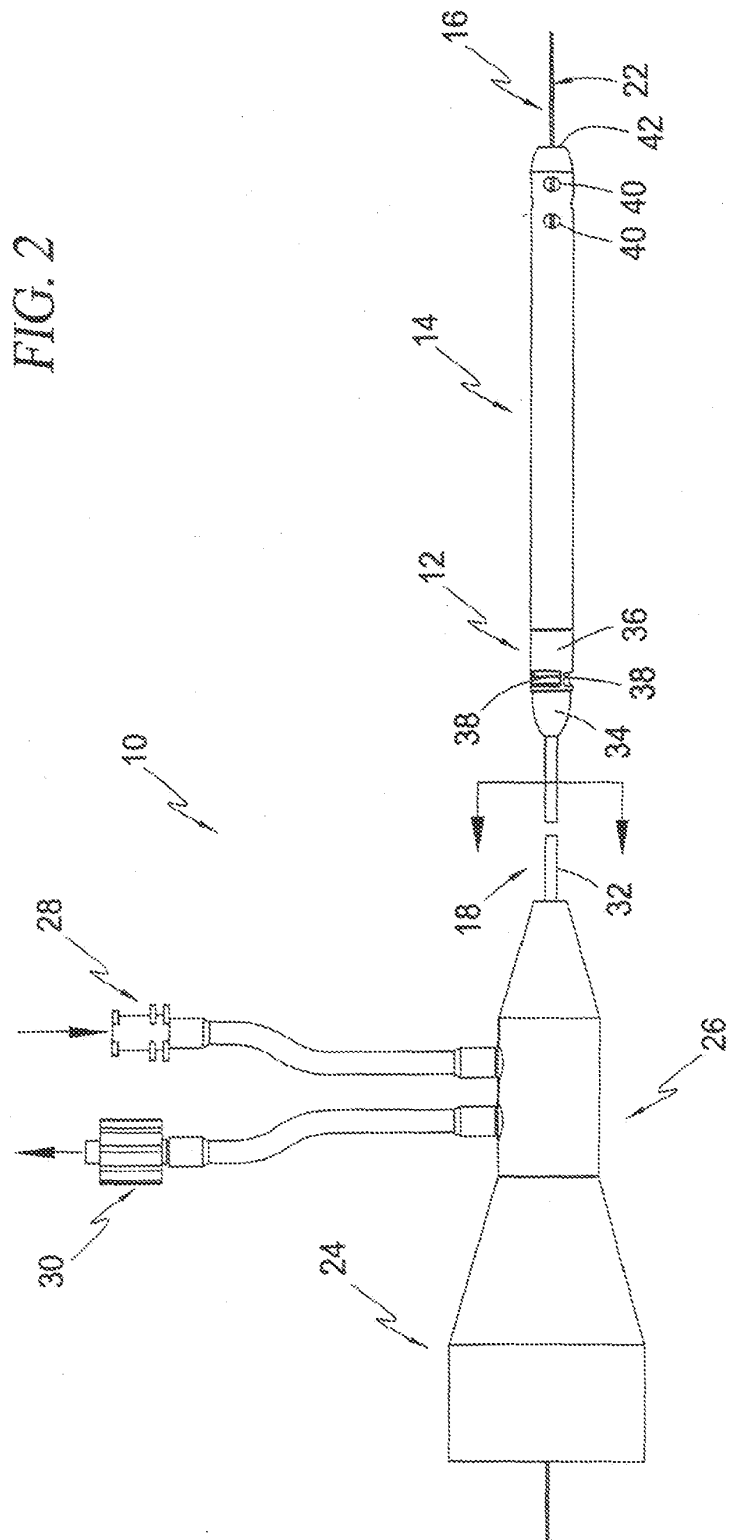
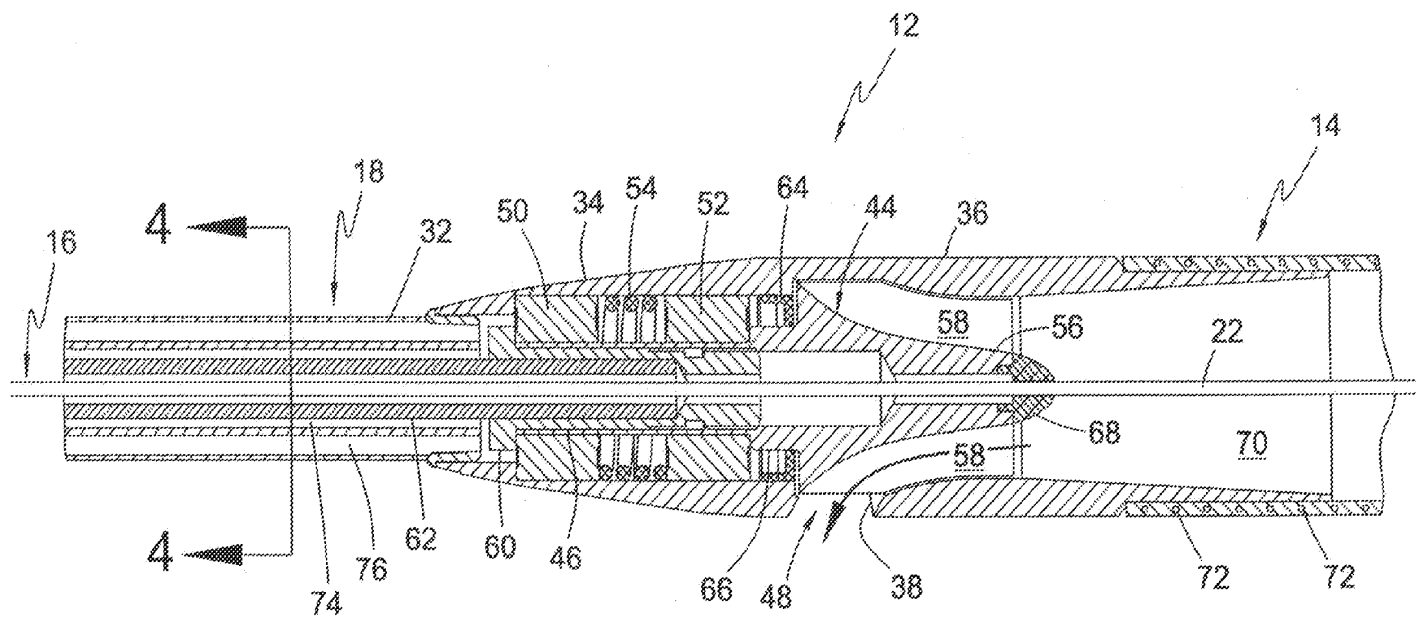


FIG. 3



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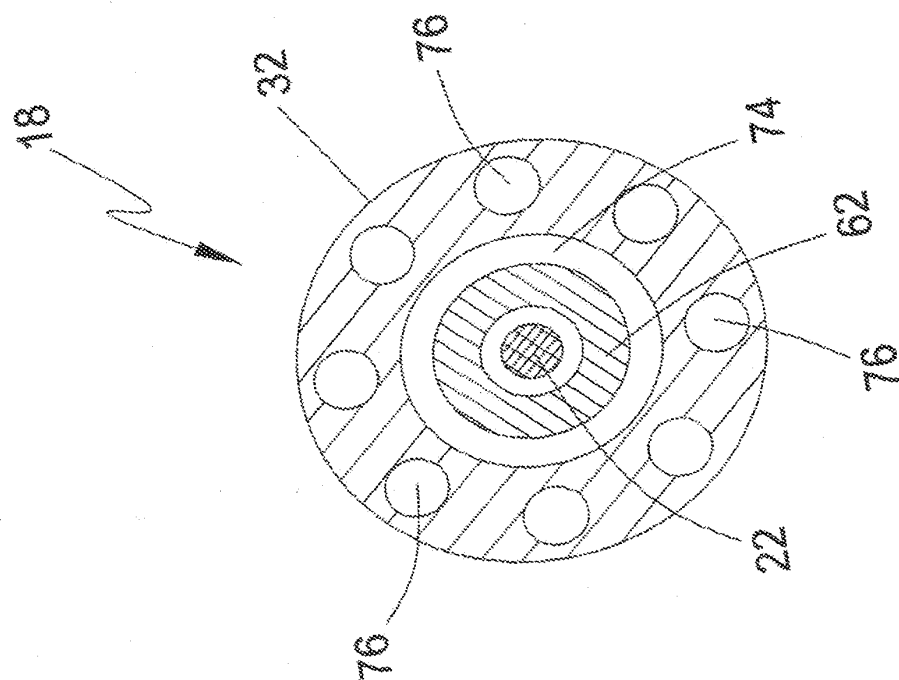


FIG. 4

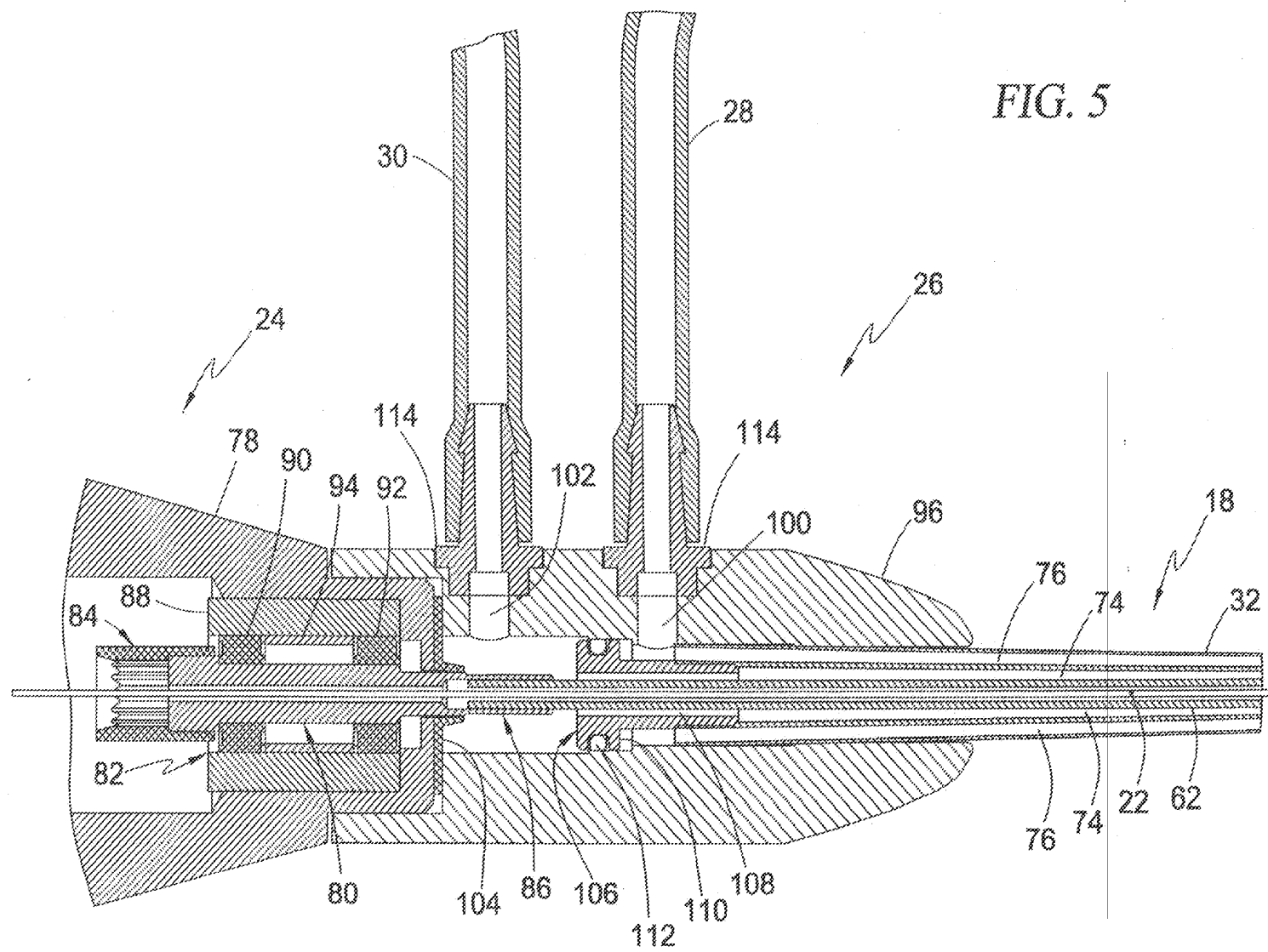


FIG. 5

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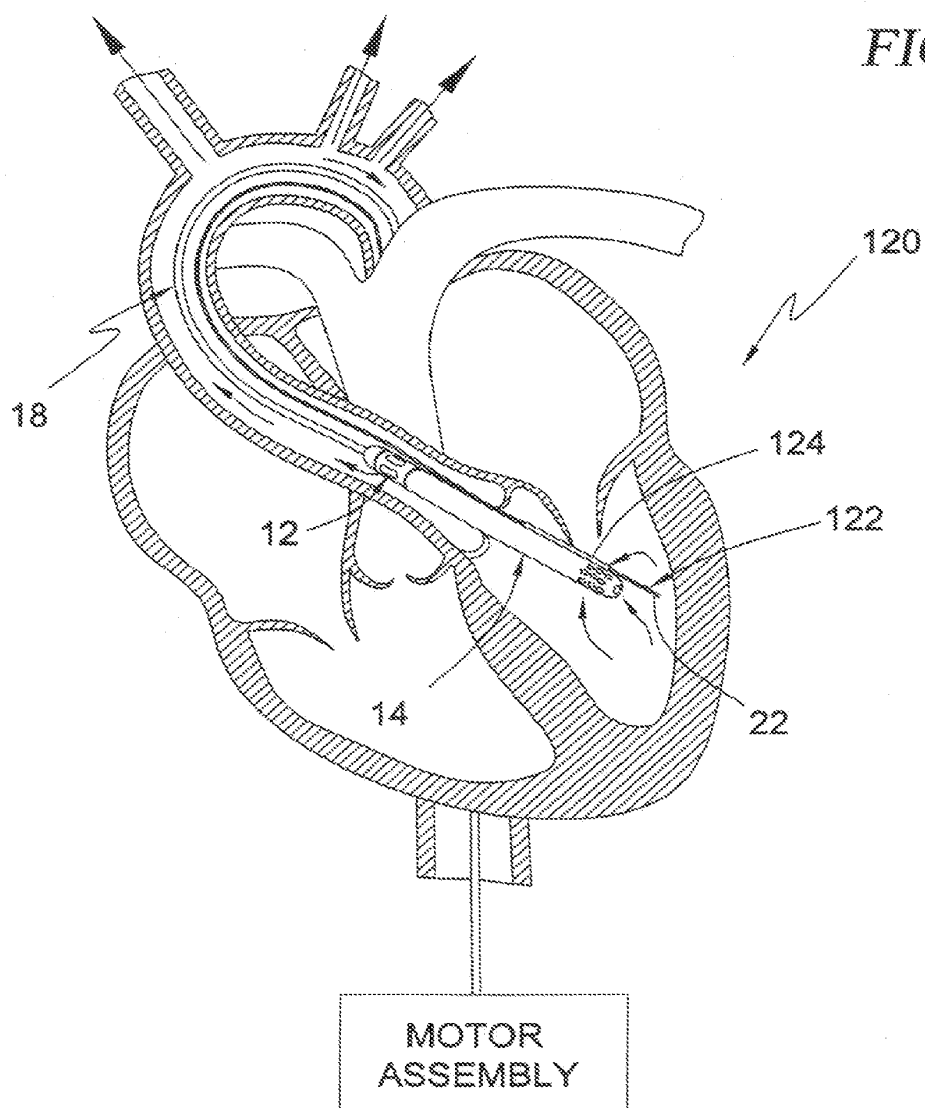
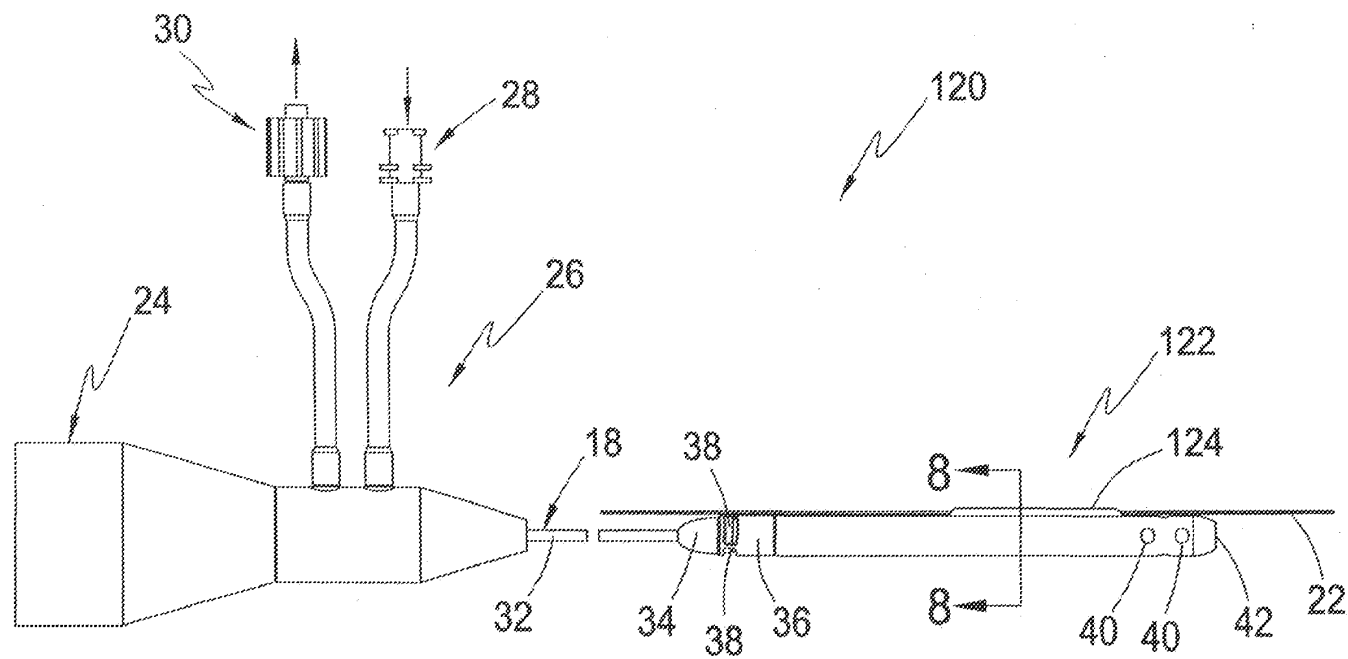


FIG. 7



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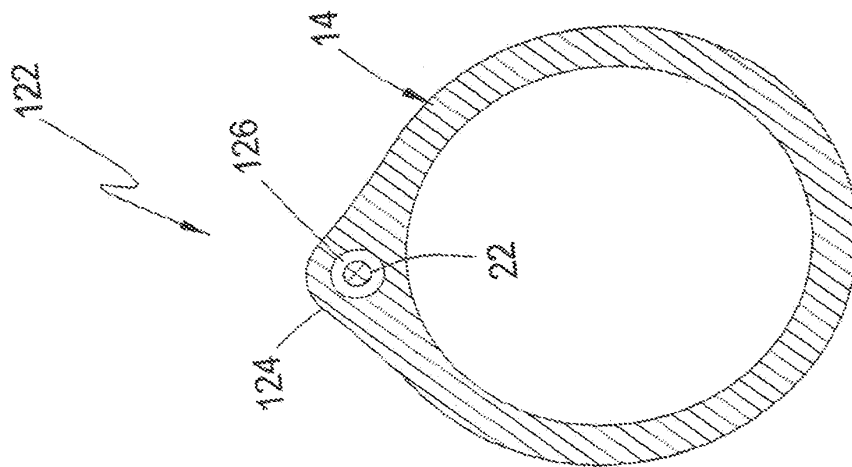


FIG 8

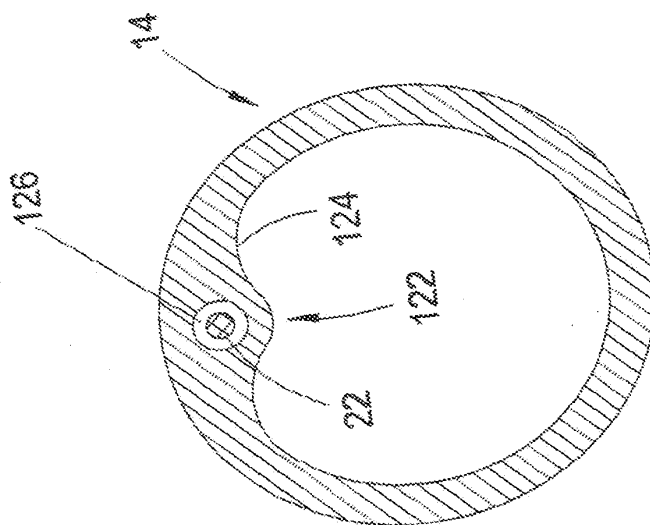
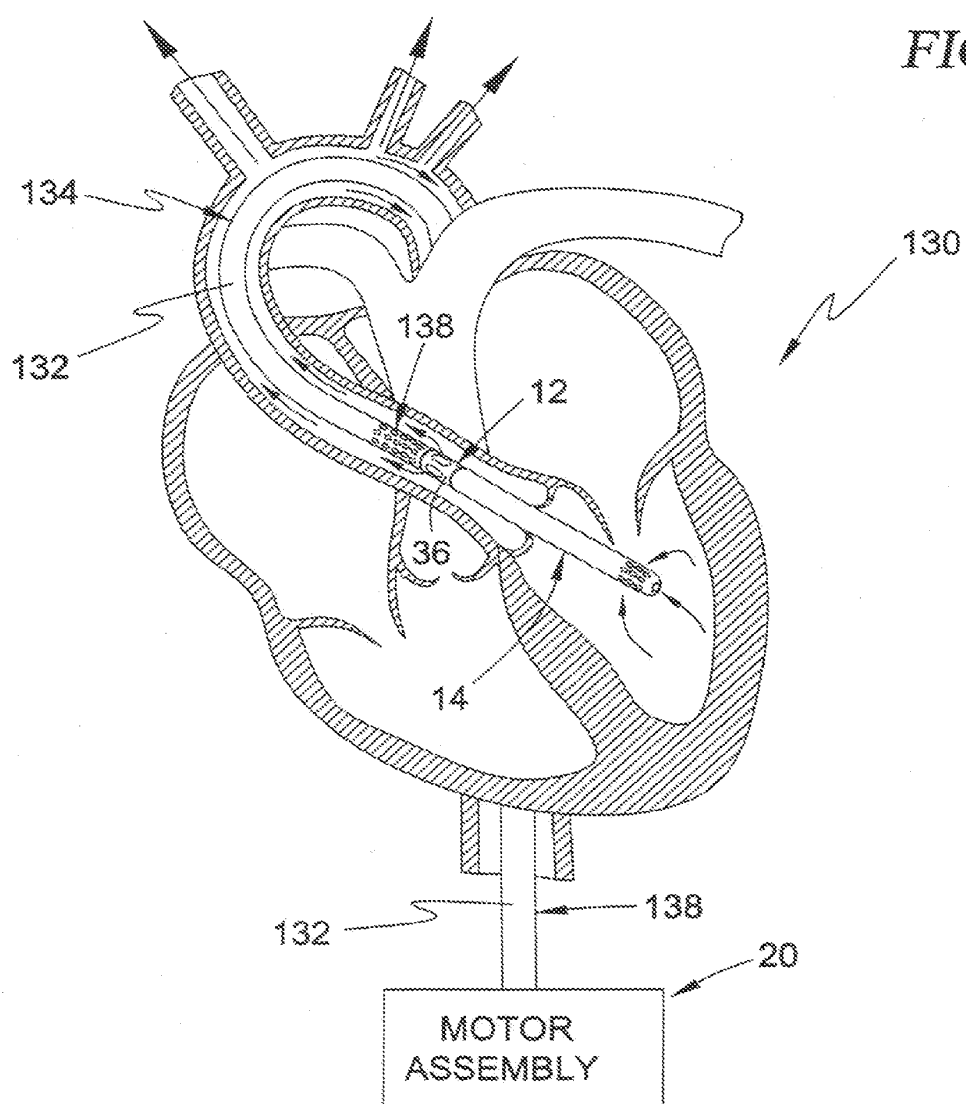
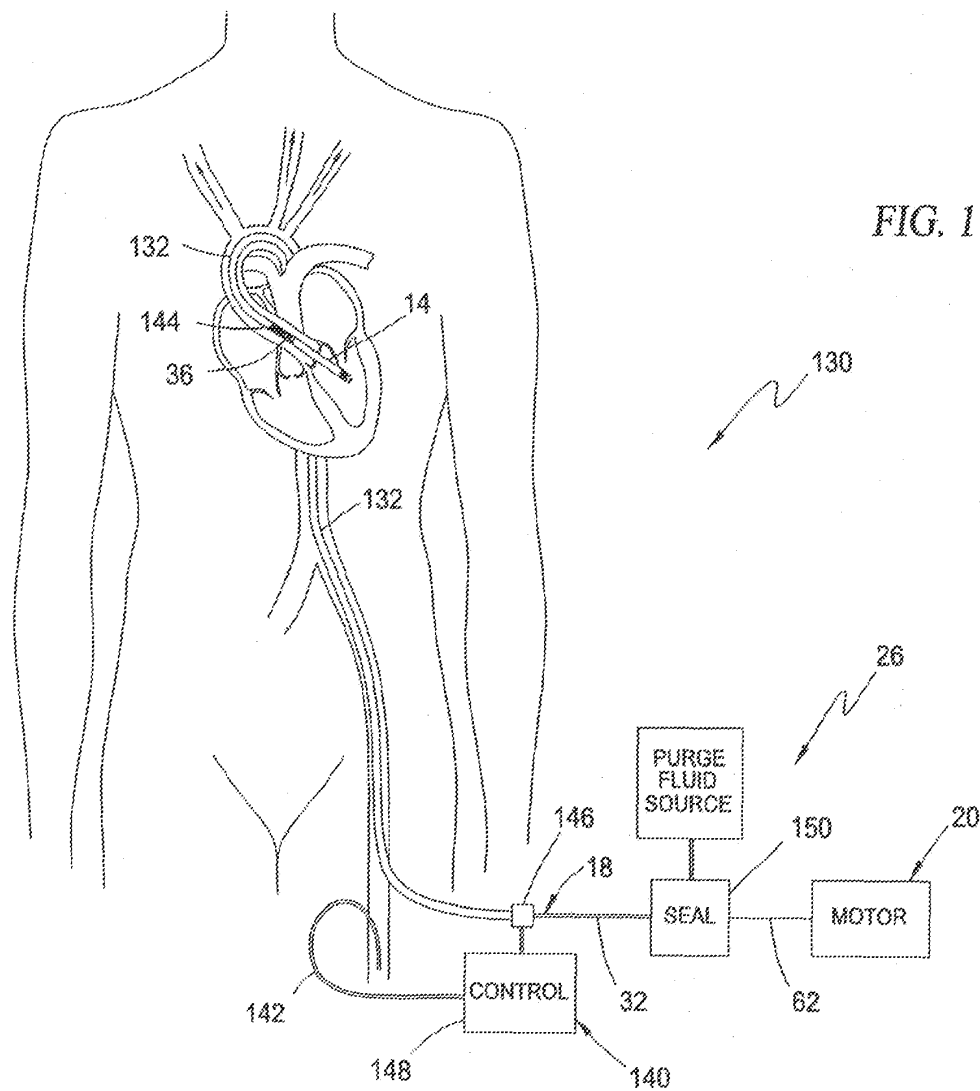


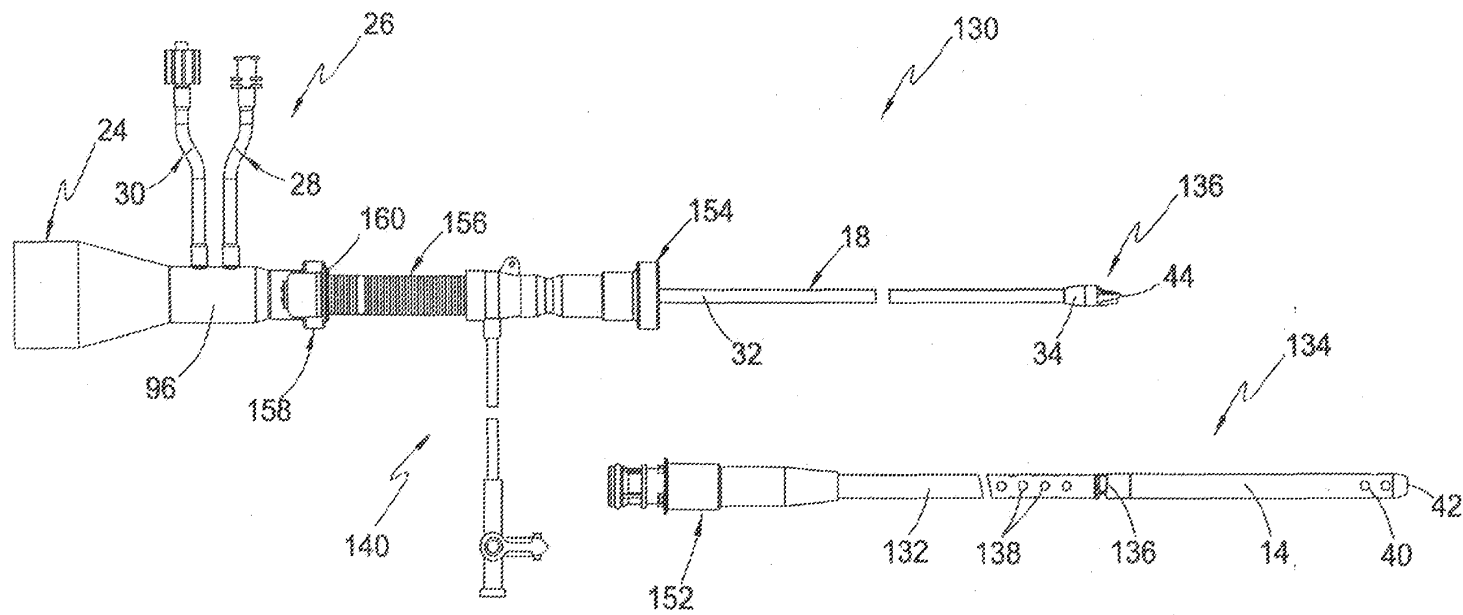
FIG 9





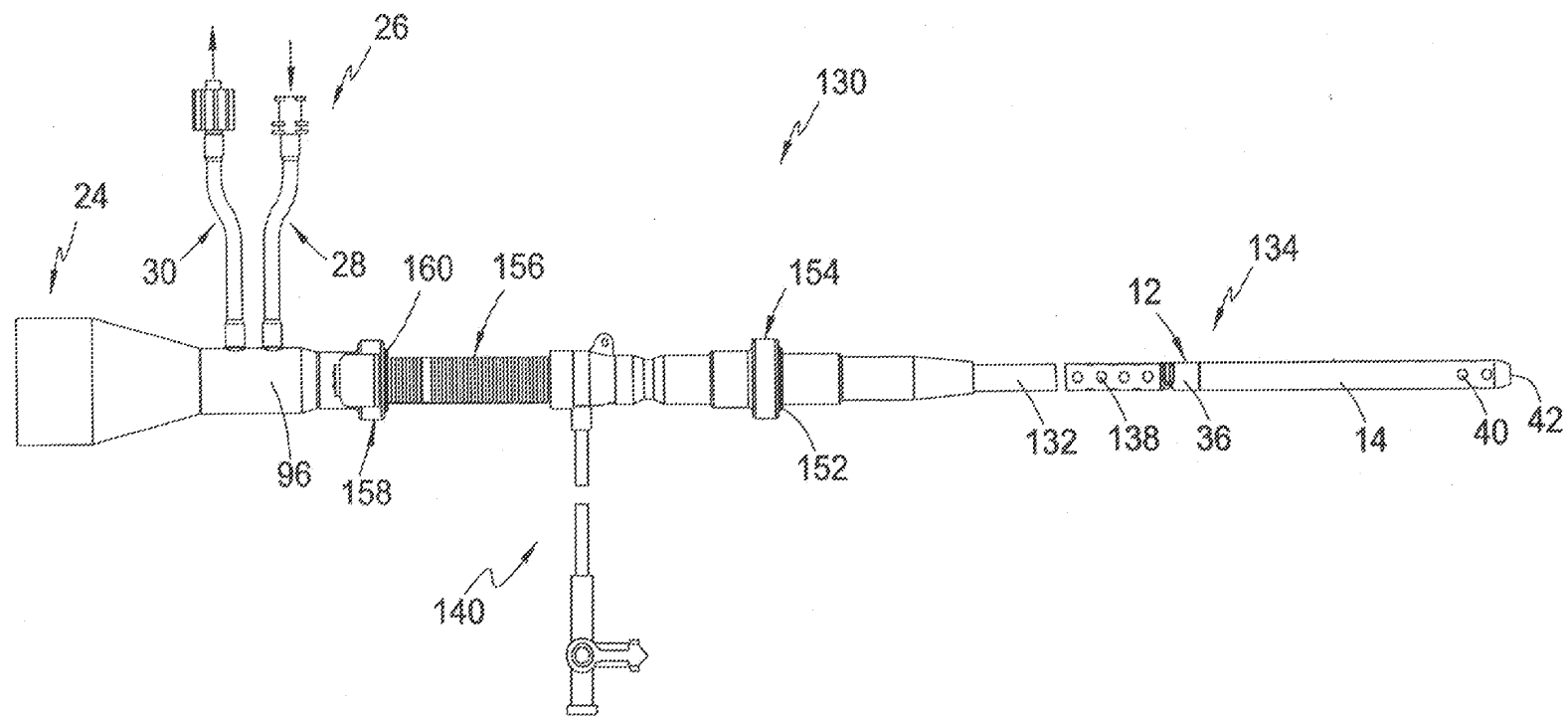
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FIG. 12



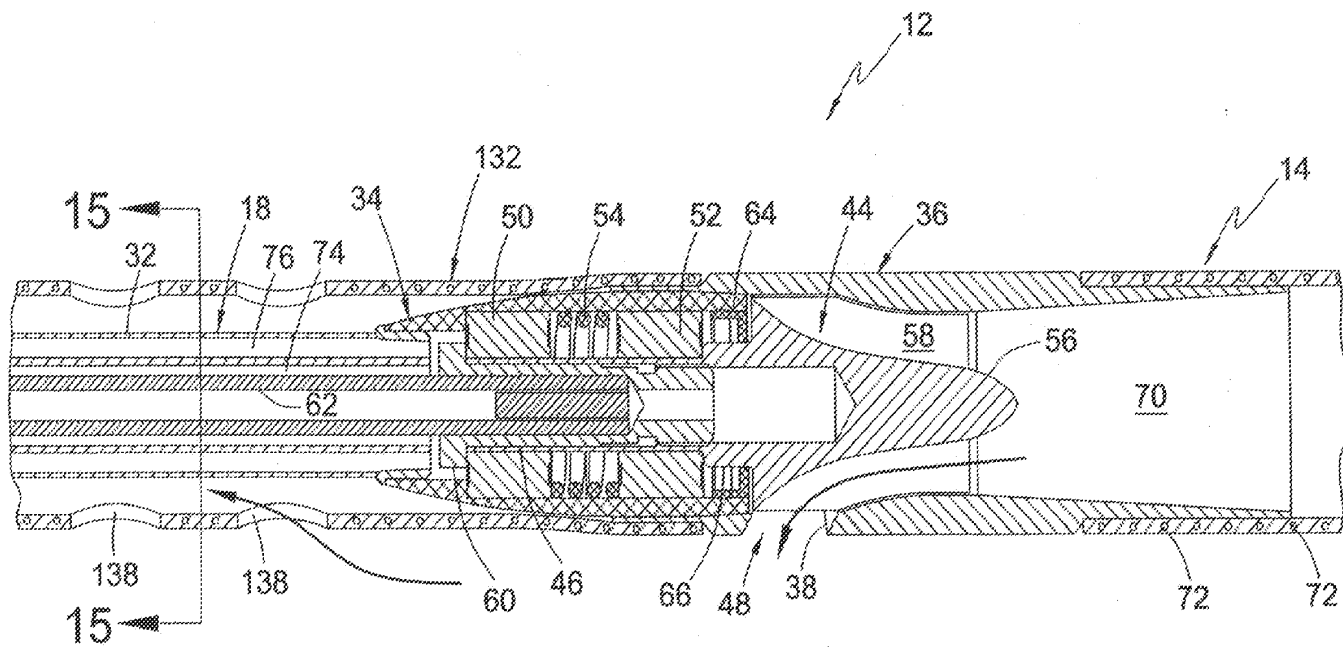
11/18

FIG 13



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FIG. 14



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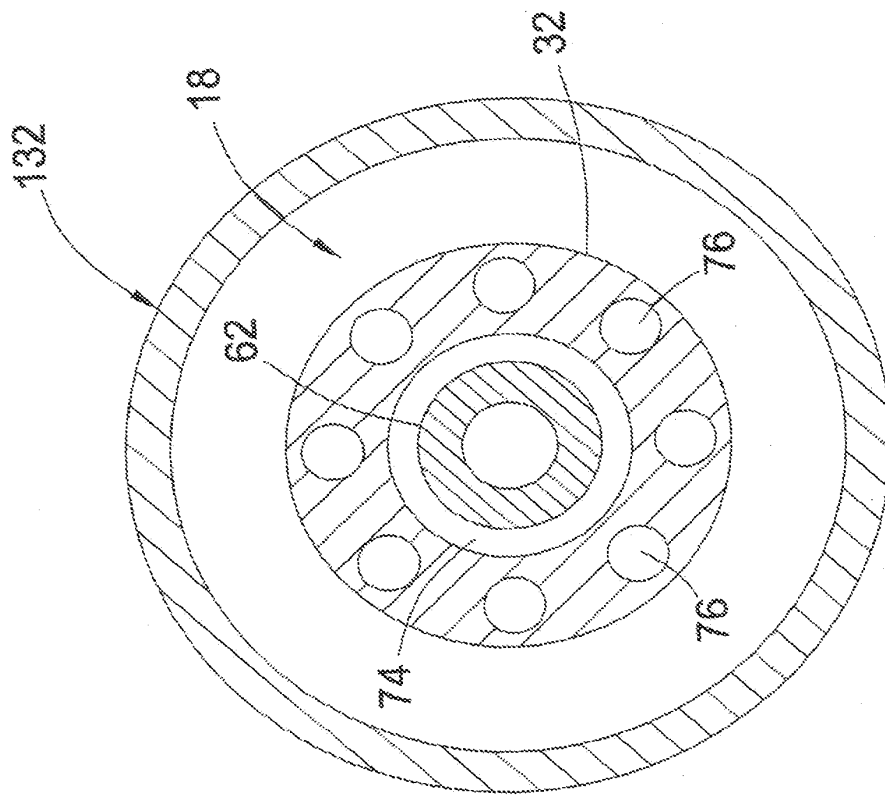


FIG. 15

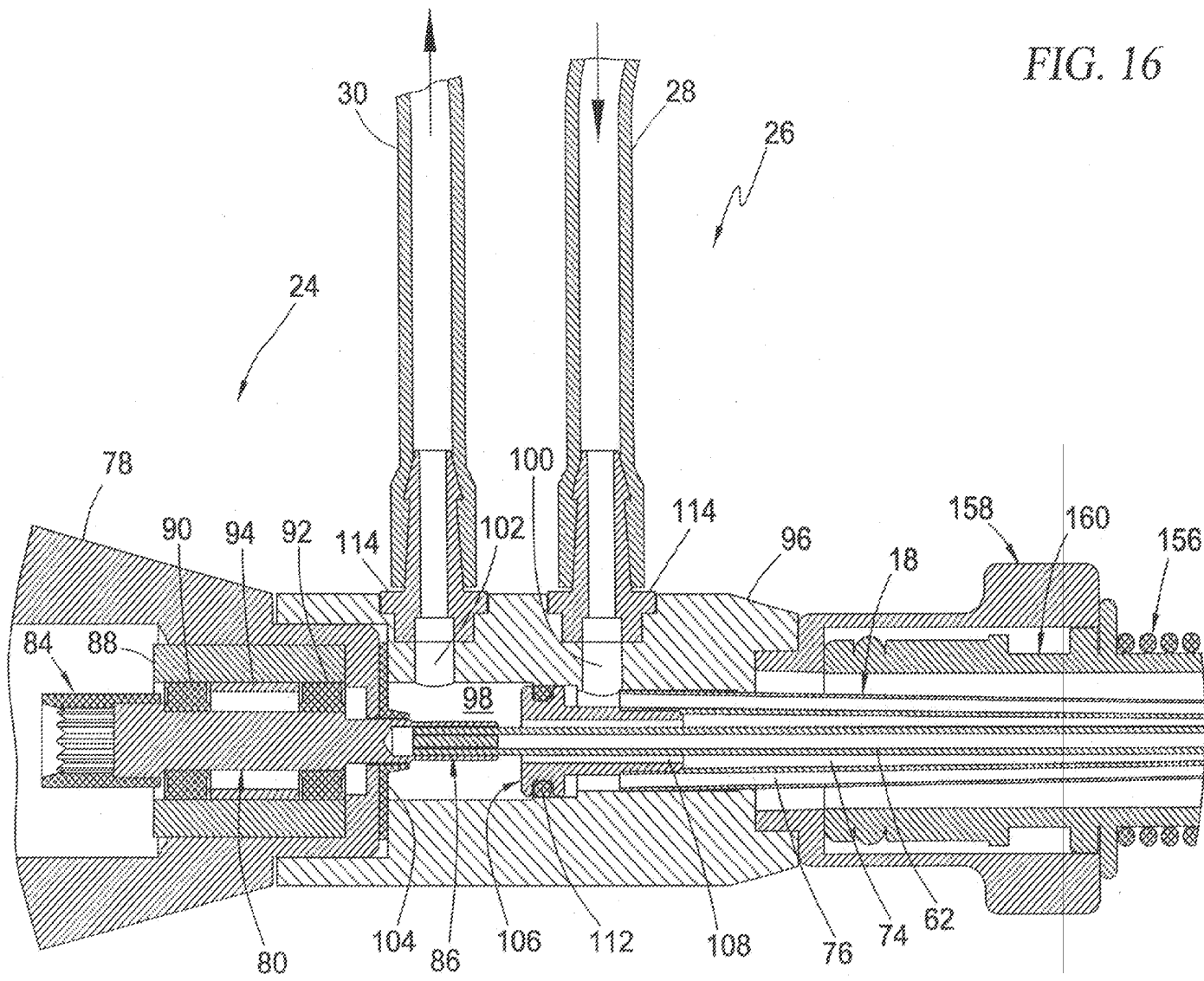


FIG. 16

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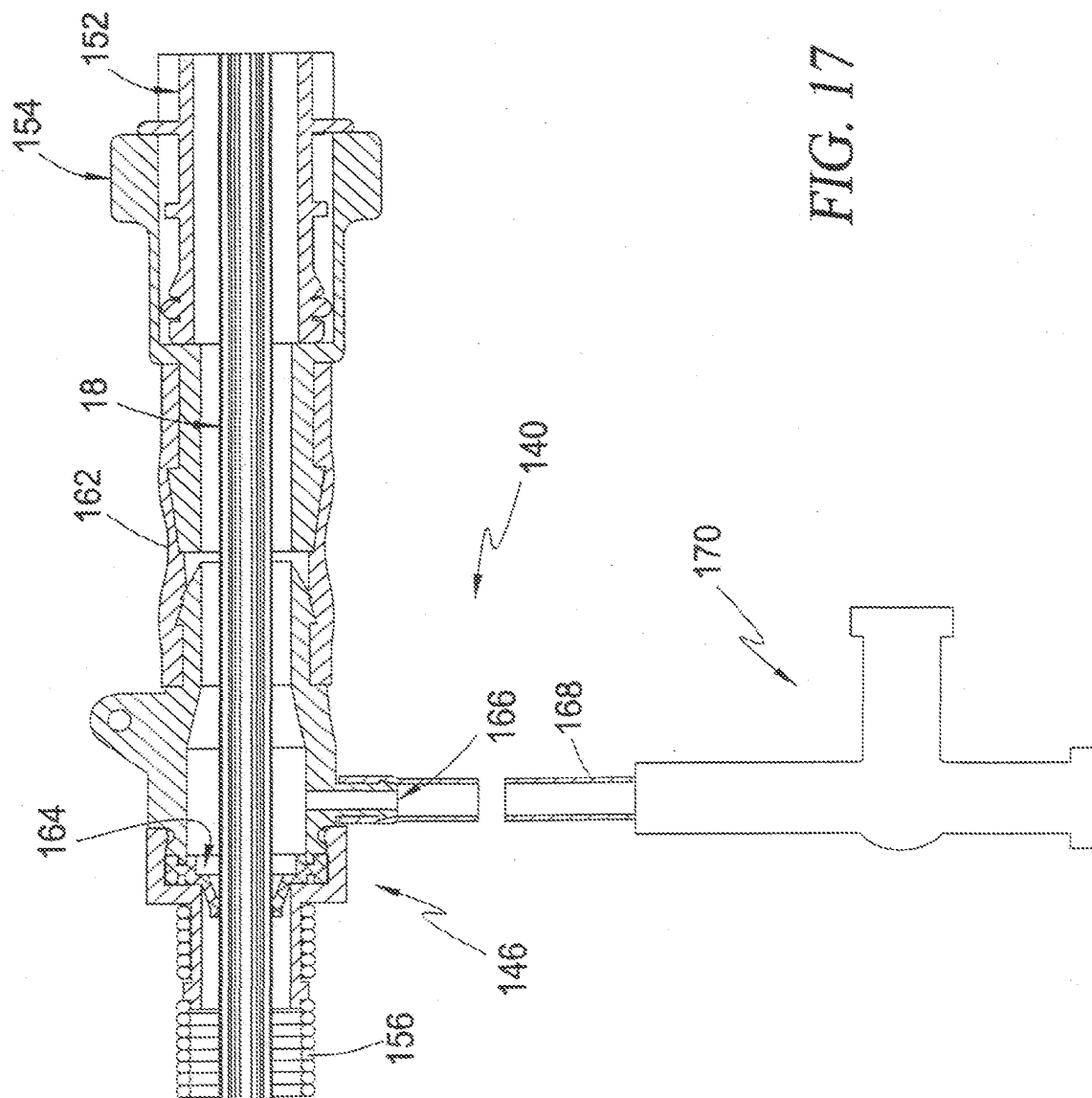
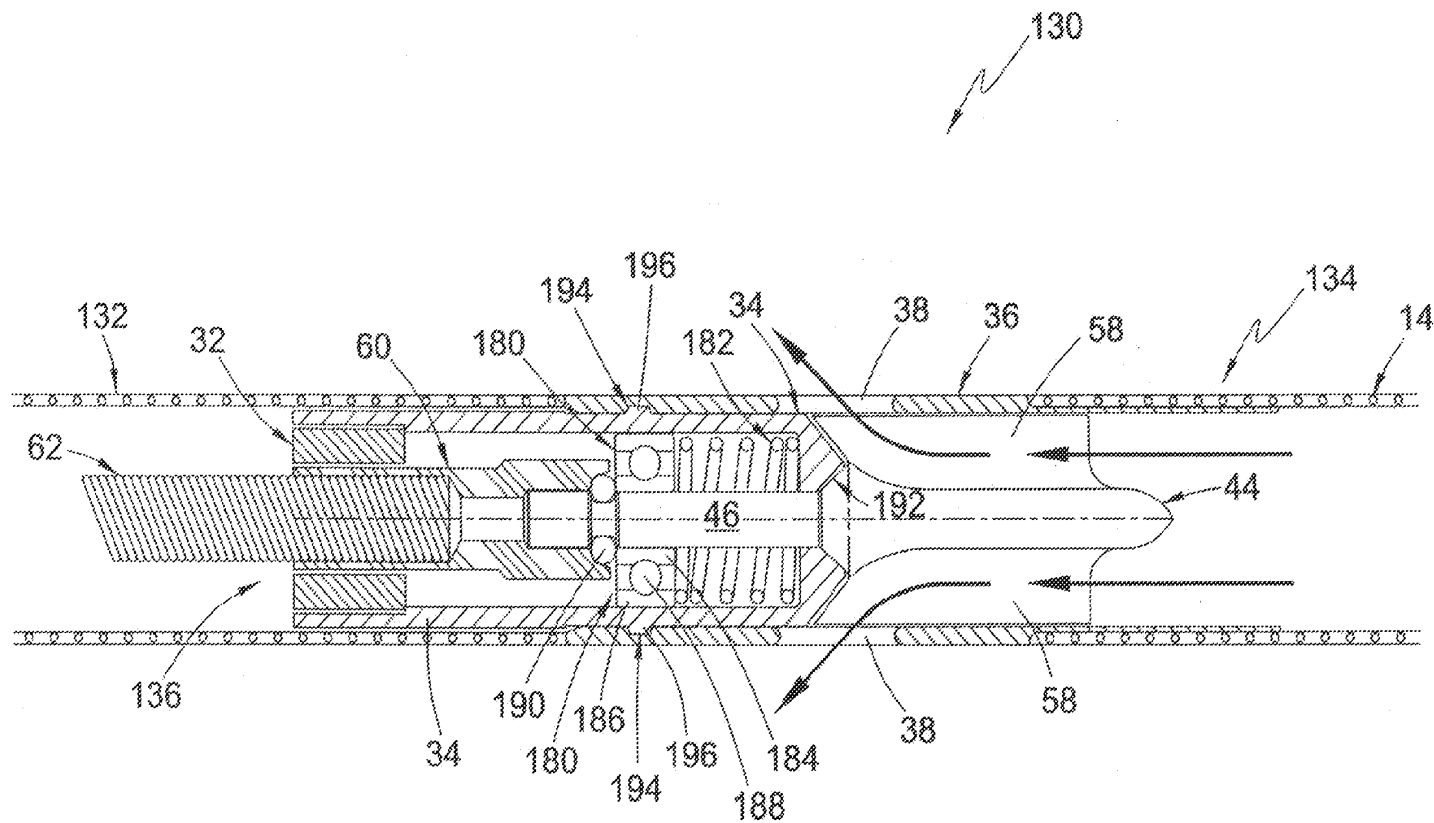
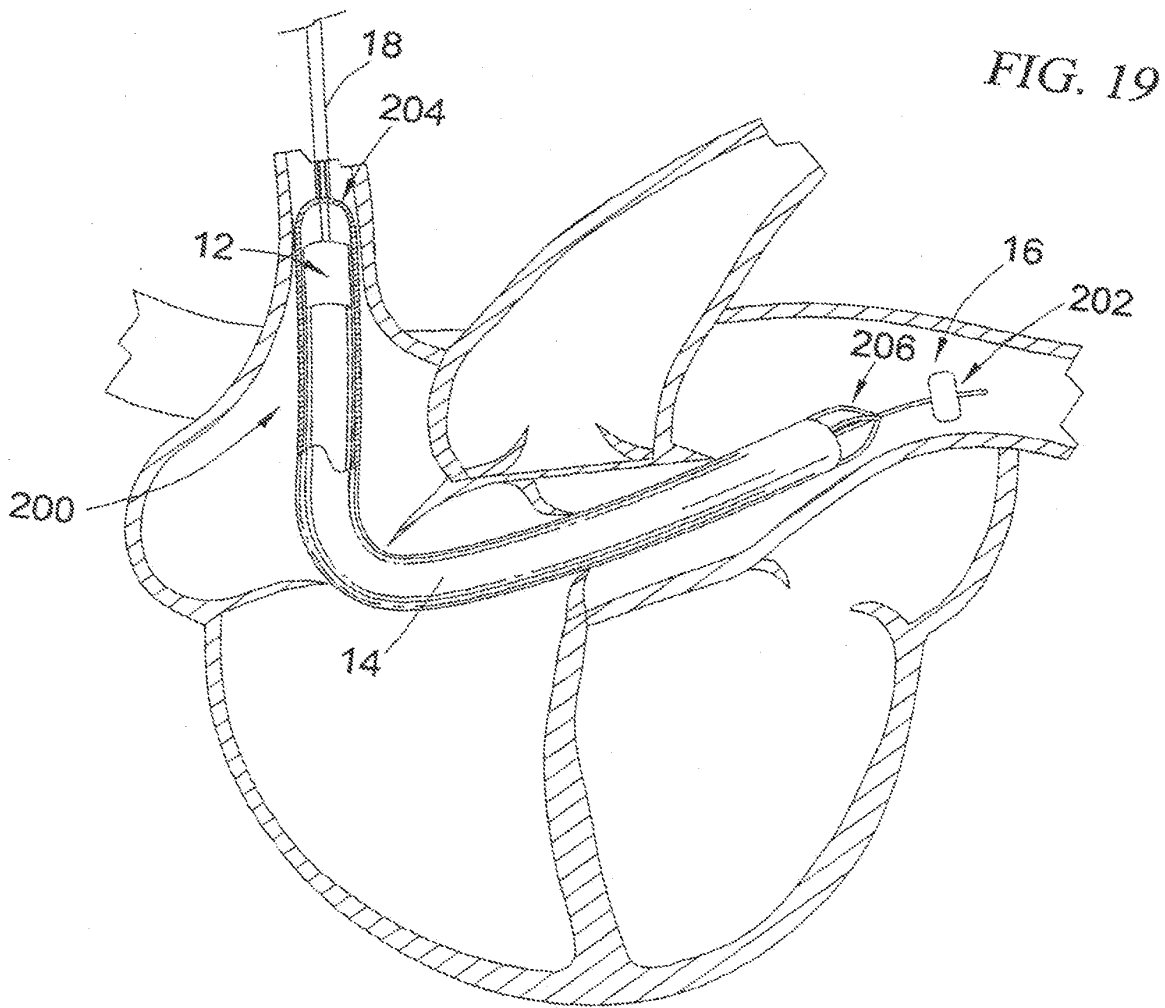


FIG. 17

FIG. 18



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

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	06-01506US05
		Application Number	
Title of Invention	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS		
The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.			

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1					Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	Walid	N.	ABOUL-HOSN			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						
City	Fair Oaks	State/Province	CA	Country of Residence i	US	
Mailing Address of Inventor:						
Address 1		4625 Chicago Avenue				
Address 2						
City	Fair Oaks	State/Province	CA			
Postal Code	94628	Country i	US			
Inventor 2					Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	William	R.	KANZ			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						
City	Sacramento	State/Province	CA	Country of Residence i	US	
Mailing Address of Inventor:						
Address 1		4695 Francis Court				
Address 2						
City	Sacramento	State/Province	CA			
Postal Code	95822	Country i	US			
Inventor 3					Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	Bruce	A.	BAKER			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						

Application Data Sheet 37 CFR 1.76		Attorney Docket Number		06-01506US05	
		Application Number			
Title of Invention	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS				
City	Placerville	State/Province	CA	Country of Residence i	US
Mailing Address of Inventor:					
Address 1	1146 Oro Loma Drive				
Address 2					
City	Placerville	State/Province	CA		
Postal Code	95667	Country i	US		
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button.					Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).		
☐ An Address is being provided for the correspondence information of this application.		
Customer Number	99185	
Email Address	legal@maquet.com	Add Email Remove Email

Application Information:

Title of the Invention	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS		
Attorney Docket Number	06-01506US05	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	18	Suggested Figure for Publication (if any)	

Filing By Reference :

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country i

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)
☐ Request Not to Publish. I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application has not and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	06-01506US05
		Application Number	
Title of Invention	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS		

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.			
Please Select One: ☒ Customer Number ☐ US Patent Practitioner ☐ Limited Recognition (37 CFR 11.9)			
Customer Number	99185		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

When referring to the current application, please leave the application number blank.

Prior Application Status	Pending		Remove		
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)		
	Continuation of	12/772810	2010-05-03		
Prior Application Status	Patented		Remove		
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
12/772810	Continuation of	11/375926	2006-03-15	7731675	2010-06-08
Prior Application Status	Patented		Remove		
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
11/375926	Division of	10/070178	2002-07-19	7022100	2006-04-04
Prior Application Status	Expired		Remove		
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)		
10/070178	a 371 of international	PCT/US2000/024515	2000-09-01		
Prior Application Status	Expired		Remove		
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)		
PCT/US2000/024515	Claims benefit of provisional	60/152249	1999-09-03		
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.					Add

Foreign Priority Information:

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	06-01506US05
		Application Number	
Title of Invention	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS		

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(d). When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX) the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(h)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove			
Application Number	Country ⁱ	Filing Date (YYYY-MM-DD)	Access Code ^j (if applicable)
Additional Foreign Priority Data may be generated within this form by selecting the Add button.			Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013. NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Authorization to Permit Access:

☐ Authorization to Permit Access to the Instant Application by the Participating Offices

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	06-01506US05
		Application Number	
Title of Invention	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS		

If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing this Authorization.

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1				Remove	
If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.					
Clear					
☒ Assignee		☐ Legal Representative under 35 U.S.C. 117		☐ Joint Inventor	
☐ Person to whom the inventor is obligated to assign.			☐ Person who shows sufficient proprietary interest		
If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:					
Name of the Deceased or Legally Incapacitated Inventor :					
If the Applicant is an Organization check here. ☒					
Organization Name		MAQUET Cardiovascular LLC			
Mailing Address Information:					
Address 1		1300 MacArthur Boulevard			
Address 2					
City		Mahwah	State/Province		NJ
Country ⁱ	US	Postal Code		07430	
Phone Number		201-995-8700	Fax Number		201-995-8910

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	06-01506US05
		Application Number	
Title of Invention	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS		
Email Address	legal@maquet.com		
Additional Applicant Data may be generated within this form by selecting the Add button.			Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Assignee 1			
Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.			
			Remove
If the Assignee or Non-Applicant Assignee is an Organization check here.			☒
Organization Name	MAQUET Cardiovascular LLC		
Mailing Address Information For Assignee including Non-Applicant Assignee:			
Address 1	1300 MacArthur Boulevard		
Address 2			
City	Mahwah	State/Province	NJ
Country i	US	Postal Code	07430
Phone Number	201-995-8700	Fax Number	201-995-8910
Email Address	legal@maquet.com		
Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.			Add

Signature:

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications					
Signature	/Kirk D. Swenson/		Date (YYYY-MM-DD)	2014-11-17	
First Name	Kirk	Last Name	Swenson	Registration Number	52265
Additional Signature may be generated within this form by selecting the Add button.				Add	

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	06-01506US05
		Application Number	
Title of Invention	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS		

This collection of information is required by 37 CFR 1.76. 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 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet 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.**

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.

POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(c).

I hereby appoint:

☒

Practitioners associated with Customer Number:

99185

OR

☐

Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number

Name	Registration Number

As attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignments documents attached to this form in accordance with 37 CFR 3.73(c).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(c) to:

☒

The address associated with Customer Number:

99185

OR

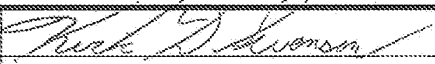
☐	Firm or Individual Name			
	Address			
	City	State	Zip	
	Country			
	Telephone	Email		

Assignee Name and Address: Maquet Cardiovascular LLC
1300 MacArthur Boulevard
Mahwah, NJ 07430

A copy of this form, together with a statement under 37 CFR 3.73(c) (Form PTO/AIA/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(c) may be completed by one of the practitioners appointed in this form, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature		Date	Sept 3, 2014
Name	Kirk D. Swenson	Telephone	201-995-8816
Title	Authorized Officer & Senior Patent Agent		

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.

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.

STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: MAQUET Cardiovascular LLC

Application No./Patent No.: Continuation of 12/772,810 Filed/Issue Date: Concurrently herewith

Titled: GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS

MAQUET Cardiovascular LLC, a limited liability company

(Name of Assignee)

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

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☒ The assignee of the entire right, title, and interest.
2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):
- ☐ The extent (by percentage) of its ownership interest is ____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.
- ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (e.g., bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

- 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 thereof is attached.
- 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.

[Page 1 of 2]

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**

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

STATEMENT UNDER 37 CFR 3.73(c)

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.

4. From: _____ To: _____

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

5. From: _____ To: _____

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

6. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, 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(c)(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.

/Kirk D. Swenson/

Signature

Kirk D. Swenson

Printed or Typed Name

November 17, 2014

Date

Patent Agent, Reg. No. 52,265

Title or Registration Number

[Page 2 of 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 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.
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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.

Customer No.: 99185

Docket No.: 06-01506US05

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Walid N. ABOUL-HOSN et al.

Serial No.:	Not Yet Assigned (continuation of 12/772,810)	Confirmation No.:	TBD
Filed:	Concurrently herewith	Group Art Unit:	TBD
For:	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS	Examiner:	TBD

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Madam:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.

In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. All listed documents were previously cited

Docket No. 06-01506US05

by or submitted to the Office in the following prior parent applications, which are relied upon under 35 U.S.C. 120:

12/772,810, filed May 3, 2010

11/375,926, filed March 15, 2006

10/070,178, filed July 19, 2002

Applicant identifies these documents by attaching hereto a fresh PTO/SB/08 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless other-wise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,

DATE: November 17, 2014

/Kirk D. Swenson/

Kirk D. Swenson
Registration No. 52,265
Agent for Applicant(s)
MAQUET Cardiovascular LLC
1300 MacArthur Boulevard
Mahwah, NJ 07430
Tel: (201) 995-8816
Fax: (866) 936-0615

Docket No. 06-01506US05

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		
	Filing Date		2014-11-17
	First Named Inventor	Walid N. ABoul-HOSN	
	Art Unit	TBD	
	Examiner Name	TBD	
	Attorney Docket Number	06-01506US05	

U.S. PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	5336184	A	1994-08-09	Teirstein	
	2	5211546	A	1993-05-18	Isaacson et al.	
	3	6245007	B1	2001-06-12	Bedingham et al.	
	4	5234407	A	1993-08-10	Teirstein et al.	
	5	3995617	A	1976-12-07	Watkins et al.	
	6	5221256	A	1993-06-22	Mahurkar	
	7	5476450	A	1995-12-19	Ruggio	
	8	5827229	A	1998-10-27	Auth et al.	

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	Art Unit	TBD		
	Examiner Name	TBD		
	Attorney Docket Number	06-01506US05		

	9	5938645	A	1999-08-17	Gordon	
	10	5965089	A	1999-10-12	Jarvik et al.	
	11	6007478	A	1999-12-28	Siess et al.	
	12	6066100	A	2000-05-23	Willard et al.	
	13	5827267	A	1998-10-27	Savage et al.	
	14	6440158	B1	2002-08-27	Saab	
	15	6849068	B1	2005-02-01	Bagaoisan et al.	
	16	7731675	B2	2010-06-08	Aboul-Hosn et al.	
	17	3585983	A	1971-06-22	Kantrowitz et al.	
	18	3602009	A	1971-08-31	Powell	
	19	3904901	A	1975-09-09	Renard et al.	

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	Examiner Name	TBD	
	Attorney Docket Number		06-01506US05

	20	4391547	A	1983-07-05	Jackson et al.	
	21	4392836	A	1983-07-12	Sugawara	
	22	4413989	A	1983-11-08	Schjeidahl et al.	
	23	4591355	A	1986-05-27	Hilse	
	24	4625712	A	1986-12-02	Wampler	
	25	4696667	A	1987-09-29	Masch	
	26	4704121	A	1987-11-03	Moise	
	27	4728319	A	1988-03-01	Masch	
	28	4817586	A	1989-04-04	Wampler	
	29	4895557	A	1990-01-23	Moise et al.	
	30	4908012	A	1990-03-13	Moise et al.	

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	Examiner Name	TBD		
	Attorney Docket Number	06-01506US05		

	31	4909781	A	1990-03-20	Husted	
	32	4917102	A	1990-04-17	Miller et al.	
	33	4919647	A	1990-04-24	Nash	
	34	4955856	A	1990-09-11	Phillips	
	35	4964839	A	1990-10-23	Gloor	
	36	5041131	A	1991-08-20	Nagase	
	37	5112349	A	1992-05-12	Summers et al.	
	38	5163910	A	1992-11-17	Schwartz et al.	
	39	5300112	A	1994-04-05	Barr	
	40	5678306	A	1997-10-21	Bozeman et al.	
	41	5692882	A	1997-12-02	Bozeman, Jr. et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		
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	Examiner Name	TBD	
	Attorney Docket Number	06-01506US05	

	42	5741234	A	1998-04-21	Aboul-Hosn	
	43	5746709	A	1998-05-05	Rom et al.	
	44	5746758	A	1998-05-05	Nordgren et al.	
	45	5776190	A	1998-07-07	Jarvik	
	46	5810088	A	1996-09-22	Lamirand et al.	
	47	5851174	A	1998-12-22	Jarvik et al.	
	48	5888241	A	1999-03-30	Jarvik	
	49	5911685	A	1999-06-15	Siess et al.	
	50	5947892	A	1999-09-07	Benkowski et al.	
	51	5957672	A	1999-09-26	Aber	
	52	6083260	A	2000-07-04	Aboul-Hosn	

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	Art Unit	TBD	
	Examiner Name	TBD	
	Attorney Docket Number	06-01506US05	

	53	6088570	A	2000-07-11	Aboul-Hosn	
	54	6093001	A	2000-07-25	Burgreen et al.	
	55	6113536	A	2000-09-05	Aboul-Hosn	
	56	6123725	A	2000-09-26	Aboul-Hosn	
	57	6123659	A	2000-09-26	Le Blanc et al.	
	58	6152704	A	2000-11-28	Aboul-Hosn et al.	
	59	6176822	B1	2001-01-23	Nix et al.	
	60	6176848	B1	2001-01-23	Rau et al.	
	61	6210133	B1	2001-04-03	Aboul-Hosn et al.	
	62	6210397	B1	2001-04-03	Aboul-Hosn et al.	
	63	6217541	B1	2001-04-17	Yu	

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	Examiner Name	TBD		
	Attorney Docket Number	06-01506US05		

	64	6228063	B1	2001-05-05	Aboul-Hosn	
	65	6234960	B1	2001-05-22	Aboul-Hosn et al.	
	66	6245007	B1	2001-06-12	Bedingham et al.	
	67	6287319	B1	2001-09-11	Aboul-Hosn et al.	
	68	6295877	B1	2001-10-02	Aboul-Hosn et al.	
	69	6336939	B1	2002-01-08	Yamazaki et al.	
	70	6346120	B1	2002-02-12	Yamazaki et al.	
	71	6395026	B1	2002-05-28	Aboul-Hosn et al.	
	72	6532964	B1	2003-03-18	Aboul-Hosn et al.	
	73	6613008	B1	2003-09-02	Aboul-Hosn et al.	
	74	6709418	B1	2004-03-23	Aboul-Hosn et al.	

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	Art Unit	TBD		
	Examiner Name	TBD		
	Attorney Docket Number	06-01506US05		

	75	7022100	B1	2006-04-04	Aboul-Hosn et al.	
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U.S.PATENT APPLICATION PUBLICATIONS

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Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20030023201	A1	2003-01-30	Aboul-Hosn et al.	
	2	20030205233	A1	2003-11-06	Aboul-Hosn et al.	

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Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ² j	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1	2002-514472	JP	A	2002-05-21	Impella Cardioteknik AG		☐
	2	97/46270	WO	A1	1997-12-11	VOELKER, Wolfram		☐
	3	19821307	DE	C1	1999-10-21	Impella Cardioteknik AG		☐
	4	1999/058170	WO	A1	1999-11-18	Impella Cardioteknik AG		☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number			
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	First Named Inventor	Walid N. ABOUL-HOSN		
	Art Unit	TBD		
	Examiner Name	TBD		
	Attorney Docket Number	06-01506US05		

	5	19622335	DE	A1	1997-12-11	VOELKER, Wolfram		☐
	6	H-0999092	JP	A	1997-04-15	Target Therapeutics Inc.		☐
	7	0916359	EP	B1	1999-05-19	Impella Cardiotech AG		☐
	8	2256427	CA	A	1998-10-08	Impella Cardiotech AG		☐
	9	89/05164	WO	A1	1989-05-15	Nimbus Medical, Inc.		☐
	10	99/02204	WO	A1	1999-01-21	A-Med Systems, Inc.		☐
	11	00/12148	WO	A1	2000-03-09	A-Med Systems, Inc.		☐
	12	00/18448	WO	A1	2000-04-06	A-Med Systems, Inc.		☐
	13	00/19097	WO	A1	2000-04-06	A-Med Systems, Inc.		☐
	14	00/37139	WO	A1	2000-06-26	A-Med Systems, Inc.		☐
	15	00/69489	WO	A1	2000-11-23	A-Med Systems, Inc.		☐

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	Art Unit	TBD		
	Examiner Name	TBD		
	Attorney Docket Number	06-01506US05		

	16	01/78807	WO	A1	2001-10-25	A-Med Systems, Inc.		☐
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	Online encyclopedia article "Pyrolytic Carbon" accessed February 19, 2009, http://en.wikipedia.org/wiki/Pyrolytic_carbon , 1 page.	☐
	2	Online encyclopedia article "Ventricular assist device, List of implantable VAD devices" accessed January 12, 2010, http://en.wikipedia.org/wiki/Ventricular_assist_device , 11 pages.	☐

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Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ 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		
	Filing Date		2014-11-17
	First Named Inventor	Walid N. ABOUL-HOSN	
	Art Unit	TBD	
	Examiner Name	TBD	
	Attorney Docket Number	06-01506US05	

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.

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

☐ A certification statement is not submitted herewith.

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	/Kirk D. Swenson/	Date (YYYY-MM-DD)	2014-11-17
Name/Print	Kirk D. Swenson	Registration Number	52265

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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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.

PRELIMINARY AMENDMENT WITH NEW FILING Address to: Mail Stop: Amendment Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450	Attorney Docket	06-01506US05
	Confirmation No.	Not yet assigned
	First Named Inventor	Walid N. ABOUL-HOSN
	Application Number	Not yet assigned
	Filing Date	November 17, 2014
	Group Art Unit	Not yet assigned
	Examiner Name	Not yet assigned
	Title	Guidable Intravascular Blood Pump and Related Methods

PRELIMINARY AMENDMENT

Madam:

This is a preliminary amendment in the above captioned application. Applicant requests entry of the amendment prior to any examination on the merits. No fees are believed to be due in association with this filing. If, however, any additional fees are required, 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 06-01506US05.

Amendments to the Specification begin on page 2.

Amendments to the Claims begin on page 3.

Remarks/Arguments begin on page 6.

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 co-pending U.S. Patent Application Serial No. 12/772,810, filed May 3, 2010, which is a continuation of U.S. Patent Application Serial No. 11/375,926, filed March 15, 2006 (now U.S. Patent No. 7,731,675, issued June 8, 2010), which is a divisional of co-pending U.S. Patent Application Serial No. 10/070,178, filed July 19, 2002, (now U.S. Patent No. 7,022,100, issued April 4, 2006) which ~~claims the benefit of~~ is a U.S. National Stage Entry of International Patent Application No. 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, all of which are hereby incorporated by reference in their entireties.

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application:

1 – 23. (Cancelled)

24. (New) A method for perfusing a patient with an intravascular blood pump system, the intravascular blood pump system comprising (i) 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 having a distal end extending distally beyond the most distal portion of the blade and a shroud within which the rotor is rotatably disposed; (ii) 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; (iii) a first lumen in fluid communication with the intravascular blood pump and operatively arranged to deliver purge fluid to the intravascular blood pump; and (iv) 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, the method comprising the steps of:

progressing a guide wire to a predetermined location in the circulatory system of the patient; and

advancing the blood pump system along the guide wire to the predetermined location.

25. (New) A method for perfusion a patient with an intravascular blood pump system, the intravascular blood pump system comprising (i) an intravascular blood pump comprising a rotor having a rotor hub tapering in the distal direction and 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; (ii) 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; (iii) 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 (iv) a blood pressure detection mechanism comprising a fluid column configured to detect the pressure of the blood proximate the intravascular blood pump; wherein the elongate lumen (a) is sized substantially smaller than an inner diameter of the cannula and intravascular blood pump; (b) is arranged coaxially with at least one of a distal end or a proximal end of the cannula, and (c) is arranged in series longitudinally with the cannula: the method comprising:

advancing a guide wire to a predetermined location in the circulatory system of the patient; and

advancing the blood pump system along the guide wire to the predetermined location.

26. (New) A method for perfusion a patient with an intravascular blood pump system,

the intravascular blood pump system is configured to be advanced to a predetermined location in a patient's circulatory system and comprises (i) 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; (ii) a cannula extending distally from the intravascular blood pump; (iii) 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; (iv) a guide wire having a cross-section substantially smaller than the cannula; and (v) an elongate lumen, the elongate lumen (a) having a luminal interior sized smaller than an inside diameter of the cannula and sufficiently large enough to accommodate the guide wire when the guide wire is advanced therealong, (b) arranged coaxially with respect to at least one of a distal end or a proximal end of the cannula, and (c) arranged in series longitudinally with the cannula, the method comprising:

advancing the guide wire to a predetermined location in the circulatory system of the patient; and

advancing the blood pump along the guide wire to the predetermined location.

REMARKS

Amendments to the specification are to correct related application data. No new matter has been added.

Please enter the above claim amendments prior to any examination on the merits. Claims 1 – 23 have been canceled without prejudice to reconsideration and resubmission. Upon entry of this amendment, claims 24 - 26 will remain pending in the application. No new matter has been added.

Applicant intends to file a supplemental preliminary amendment with addition claims and/or amendments prior to examination. Accordingly, Applicant respectfully requests that the Examiner contact Applicant's representative at the number given below if the Examiner intends to act on this application in the event the supplemental preliminary amendment with the revised set of claims has not been filed.

To the extent that any arguments and disclaimers were presented to distinguish prior art, or for other reasons substantially related to patentability, during the prosecution of any and all parent and related application(s)/patent(s), Applicant(s) hereby explicitly retracts and rescinds any and all such arguments and disclaimers in this application to recapture any disclaimed scope, and respectfully requests that the Examiner re-visit the prior art that such arguments and disclaimers were made to avoid.

If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

Respectfully submitted,

Date: November 17, 2014

By: /Kirk D. Swenson /
Kirk D. Swenson
Registration No. 52,265

Getinge US Legal Shared Services
1300 MacArthur Blvd.
Mahwah, NJ 07430
Telephone: 1-201-995-8816
Facsimile: 1-866-936-0615

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:		Kirk D. Swenson/Eunice Kim		
Attorney Docket Number:		06-01506US05		
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Utility application filing	1011	1	280	280
Utility Search Fee	1111	1	600	600
Utility Examination Fee	1311	1	720	720
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 (\$)				1600

Electronic Acknowledgement Receipt	
EFS ID:	20722514
Application Number:	14543815
International Application Number:	
Confirmation Number:	9742
Title of Invention:	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS
First Named Inventor/Applicant Name:	Walid N. ABOUL-HOSN
Customer Number:	99185
Filer:	Kirk D. Swenson/Eunice Kim
Filer Authorized By:	Kirk D. Swenson
Attorney Docket Number:	06-01506US05
Receipt Date:	17-NOV-2014
Filing Date:	
Time Stamp:	20:58:35
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$1600
RAM confirmation Number	7901
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)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)					
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File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal of New Application	Utility_Patent_Application_Transmittal-aia0015.pdf	309825 912d16b3be0bcf3eb2ee23dfc5f7aacc7b2a1310	no	2
Warnings:					
Information:					
2		Application_from_parent.pdf	1582790 36ce40be7533e62233f6219f5857d10997771d7	yes	39
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Specification		1	37	
	Claims		38	38	
	Abstract		39	39	
Warnings:					
Information:					
3	Drawings-only black and white line drawings	DRAWINGS-for-new-con_from-parent-12772810.pdf	1746495 87fb9c90002794fb1da1701102ec02291e75c3dbc	no	18
Warnings:					
Information:					
4	Application Data Sheet	Application_Data_Sheet-aia0014.pdf	1562060 2dd338392a98ef065f091355e4db6beb9818142a	no	8
Warnings:					
Information:					
5	Power of Attorney	EXECUTED_General_POA_Maquet_Cardiovascular_LLC.pdf	1087349 f5f89e1463effd2af6d4a475c9cf1c15873c21e9	no	2
Warnings:					
Information:					
6	Assignee showing of ownership per 37 CFR 3.73.	EXECUTED_Statement_under_373c-aia0096.pdf	135914 5bbdedee1e8c6038abadf537bd5a6d51071b92d65	no	3
Warnings:					

Information:					
7	Transmittal Letter	IDS_TRANSMITTAL_LETTER.pdf	22903 f7bb378d23d6c16e5c5a159a4b536600cb05f0ab	no	2
Warnings:					
Information:					
8	Information Disclosure Statement (IDS) Form (SB08)	IDS_PTOSB08.pdf	614506 b5db915465698e4c5f1336d1b3a70e72c9b305f6	no	12
Warnings:					
Information:					
9		Preliminary_Amendment.pdf	38390 baef2b8667ef05b4c4d08c9afb91b50980ad2761	yes	6
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Preliminary Amendment		1	1	
	Specification		2	2	
	Claims		3	5	
	Abstract		6	6	
Warnings:					
Information:					
10	Fee Worksheet (SB06)	fee-info.pdf	33332 1e14abf69b1af6748623b488b7f9b5d91a3d6d14	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			7133564		

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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

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Document code: WFEE

United States Patent and Trademark Office
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PATENT APPLICATION FEE DETERMINATION RECORD				Application or Docket Number		Filing Date		☐ To be Mailed	
Substitute for Form PTO-875				14/543,815		11/17/2014			
ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO									
APPLICATION AS FILED – PART I									
(Column 1)		(Column 2)							
FOR	NUMBER FILED	NUMBER EXTRA		RATE (\$)		FEE (\$)			
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A					
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A					
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A					
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		X \$ =					
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		X \$ =					
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 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).								
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))									
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL					
APPLICATION AS AMENDED – PART II									
(Column 1)		(Column 2)		(Column 3)					
AMENDMENT	11/17/2014	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 3	Minus	** 20	= 0	X \$80 =		0	
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X \$420 =		0	
	☐ Application Size Fee (37 CFR 1.16(s))								
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
TOTAL ADD'L FEE						0			
(Column 1)		(Column 2)		(Column 3)					
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =			
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =			
	☐ Application Size Fee (37 CFR 1.16(s))								
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
TOTAL ADD'L 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.									

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
14/543,815	11/17/2014	3766	1740	06-01506US05	3	3

CONFIRMATION NO. 9742

99185

Getinge US Legal Shared Services
1300 MacArthur Boulevard
Mahwah, NJ 07430

FILING RECEIPT



OC000000072144615

Date Mailed: 12/04/2014

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**

Inventor(s)

Walid N. ABOUL-HOSN, Fair Oaks, CA;
William R. KANZ, Sacramento, CA;
Bruce A. BAKER, Placerville, CA;

Applicant(s)

MAQUET Cardiovascular LLC, Mahwah, NJ

Assignment For Published Patent Application

MAQUET CARDIOVASCULAR LLC, Mahwah, NJ

Power of Attorney: The patent practitioners associated with Customer Number 99185

Domestic Priority data as claimed by applicant

This application is a CON of 12/772,810 05/03/2010 PAT 8888728
which is a CON of 11/375,926 03/15/2006 PAT 7731675
which is a DIV of 10/070,178 07/19/2002 PAT 7022100
which is a 371 of PCT/US00/24515 09/01/2000
which claims benefit of 60/152,249 09/03/1999

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

If Required, Foreign Filing License Granted: 12/02/2014

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/543,815**

Projected Publication Date: 03/12/2015

Non-Publication Request: No

Early Publication Request: No
Title

GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS

Preliminary Class

600

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

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NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 14/543,815	
APPLICATION AS FILED - PART I							
(Column 1)		(Column 2)		SMALL ENTITY		OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	280
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A	600
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	720
TOTAL CLAIMS (37 CFR 1.16(i))	3	minus 20 = *			OR	x 80 =	0.00
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3	minus 3 = *			OR	x 420 =	0.00
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 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).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
				TOTAL		TOTAL	1600
* If the difference in column 1 is less than zero, enter "0" in column 2.							
APPLICATION AS AMENDED - PART II							
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY	
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)	OTHER THAN SMALL ENTITY	
	Total (37 CFR 1.16(i))	*	Minus **	=	x	=	OR
	Independent (37 CFR 1.16(h))	*	Minus ***	=	x	=	OR
	Application Size Fee (37 CFR 1.16(s))						OR
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						OR
				TOTAL ADD'L FEE		TOTAL ADD'L FEE	
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY	
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)	OTHER THAN SMALL ENTITY	
	Total (37 CFR 1.16(i))	*	Minus **	=	x	=	OR
	Independent (37 CFR 1.16(h))	*	Minus ***	=	x	=	OR
	Application Size Fee (37 CFR 1.16(s))						OR
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						OR
				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. ** 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 found in the appropriate box in column 1.							



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/543,815	11/17/2014	Walid N. ABOUL-HOSN	06-01506US05

CONFIRMATION NO. 9742

99185

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1300 MacArthur Boulevard
Mahwah, NJ 07430

NOTICE



Date Mailed: 12/04/2014

INFORMATIONAL NOTICE TO APPLICANT

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file an oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.53(f).

The item(s) indicated below are also required and should be submitted with any reply to this notice to avoid further processing delays.

- A properly executed inventor's oath or declaration has not been received for the following inventor(s):
Walid N. ABOUL-HOSN
William R. KANZ
Bruce A. BAKER



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/543,815	11/17/2014	Walid N. ABOUL-HOSN	06-01506US05

CONFIRMATION NO. 9742

99185

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Mahwah, NJ 07430

PUBLICATION NOTICE



OC000000073922585

Title:GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS

Publication No.US-2015-0073202-A1

Publication Date:03/12/2015

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. The direct link to access the publication is currently <http://www.uspto.gov/patft/>.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently <http://pair.uspto.gov/>. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

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



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/543,815	11/17/2014	Walid N. ABOUL-HOSN	06-01506US05	9742
99185 7590 08/17/2015 Getinge US Legal Shared Services 1300 MacArthur Boulevard Mahwah, NJ 07430			EXAMINER MARCETICH, ADAM M	
			ART UNIT 3761	PAPER NUMBER
			NOTIFICATION DATE 08/17/2015	DELIVERY MODE 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

Office Action Summary	Application No. 14/543,815	Applicant(s) ABOUL-HOSN ET AL.	
	Examiner Adam Marcetich	Art Unit 3761	AIA (First Inventor to File) Status No

-- 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 MONTHS 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 November 2014.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 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) 24-26 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) 24-26 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, 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 or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 17 November 2014 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).

Priority under 35 U.S.C. § 119

- 12) ☐ 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)).

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

Attachment(s)

- | | |
|---|--|
| 1) ☒ Notice of References Cited (PTO-892) | 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date <u>1 (one)</u> . | 4) ☐ Other: ____. |

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application is being examined under the pre-AIA first to invent provisions.

Double Patenting

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).

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 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.

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).

Claims 24-26 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 10, 12 and 22 of Aboul-Hosn; Walid N. et al. (US 888728). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Regarding instant claim 24, Aboul-Hosn claims an intravascular blood pump system for perfusing a patient (claims 1, 10, 22, intravascular blood pump system), the intravascular blood pump system comprising:

(i) 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 having a distal end extending distally beyond the most distal portion of the blade (claim 1, a rotor having a rotor hub ... extending distally beyond the most distal portion of the blade); and

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

(ii) 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 (claim 1, cannula ... circular cross-section along a portion of its length);

(iii) a first lumen in fluid communication with the intravascular blood pump and operatively arranged to deliver purge fluid to the intravascular blood pump (claim 1, first lumen ... purge fluid to the intravascular blood pump); and

(iv) 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 (claim 1, guide mechanism ... 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 (claim 1, wherein an axis coaxial ... to slideably advance therealong);

the blood pump capable of performing steps of:

progressing a guide wire to a predetermined location in the circulatory system of the patient (claims 5, 12, guide catheter is configured facilitate the placement of the guide wire through the vasculature into the heart); and

advancing the blood pump system along the guide wire to the predetermined location (claim 22, intravascular blood pump system configured to be advanced to a predetermined location in a patient's circulatory system).

Aboul-Hosn does not explicitly claim a method for perfusing a patient. However, the blood pump system claimed by Aboul-Hosn will perform these steps when used as intended. Therefore, it would have been obvious to advance the pump system towards a predetermined location, in order to assist the heart by pumping blood.

Regarding instant claim 25, Aboul-Hosn claims an intravascular blood pump system for perfusing a patient (claims 1, 10, 22, intravascular blood pump system), the intravascular blood pump system comprising:

(i) an intravascular blood pump comprising a rotor having a rotor hub tapering in the distal direction and at least one blade extending radially outward from the rotor hub (claim 1, a rotor having a rotor hub ... extending distally beyond the most distal portion of the blade);

the intravascular blood pump coupled to a catheter on a proximal end and a cannula on a distal (claim 10, catheter on a proximal end and a cannula on a distal end); end

(ii) 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 (claim 10, a first set and a second set of apertures ... towards a distal region of the cannula);

(iii) 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 (claim 10, guide mechanism); and

(iv) a blood pressure detection mechanism comprising a fluid column configured to detect the pressure of the blood proximate the intravascular blood pump (claim 10, blood pressure detection mechanism comprising a fluid column);

wherein the elongate lumen (a) is sized substantially smaller than an inner diameter of the cannula and intravascular blood pump (claim 10, elongate lumen is sized substantially smaller);

(b) is arranged coaxially with at least one of a distal end or a proximal end of the cannula (claim 10, lumen is arranged coaxially ... cannula); and

(c) is arranged in series longitudinally with the cannula (claim 10, cannula and the lumen are arranged in series longitudinally);

the blood pump capable of performing steps of:

advancing a guide wire to a predetermined location in the circulatory system of the patient (claims 5, 12, guide catheter is configured facilitate the placement of the guide wire through the vasculature into the heart); and

advancing the blood pump system along the guide wire to the predetermined location (claim 22, intravascular blood pump system configured to be advanced to a predetermined location in a patient's circulatory system).

Aboul-Hosn does not explicitly claim a method for perfusing a patient. However, these steps would have been obvious to assist the heart by pumping blood as intended.

Regarding instant claim 26, Aboul-Hosn claims an intravascular blood pump system for perfusing a patient, the intravascular blood pump system is configured to be advanced to a predetermined location in a patient's circulatory system (claims 1, 10, 22, intravascular blood pump system configured to be advanced to a predetermined location in a patient's circulatory system); and

comprises:

(i) an intravascular blood pump (claim 22, 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 (claim 22, intravascular blood pump comprising ... distal tip extending distally beyond the blades);

(ii) a cannula extending distally from the intravascular blood pump (claim 22, cannula extending distally);

(iii) 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 (claim 22, a plurality of ingress ports ... steered towards the egress ports);

(iv) a guide wire having a cross-section substantially smaller than the cannula (claim 22, guide wire ... smaller than the cannula); and

(v) an elongate lumen, the elongate lumen (a) having a luminal interior sized smaller than an inside diameter of the cannula and sufficiently large enough to accommodate the guide wire when the guide wire is advanced therealong (claim 22, elongate lumen ... the guide wire is advanced therealong);

(b) arranged coaxially with respect to at least one of a distal end or a proximal end of the cannula (claim 22, lumen is arranged coaxially with respect to ... the cannula); and

(c) arranged in series longitudinally with the cannula (claim 22, lumen and the cannula are arranged in series longitudinally);

the blood pump capable of performing steps of:

advancing the guide wire to a predetermined location in the circulatory system of the patient (claims 5, 12, guide catheter is configured facilitate the placement of the guide wire through the vasculature into the heart); and

advancing the blood pump along the guide wire to the predetermined location (claim 22, intravascular blood pump system configured to be advanced to a predetermined location in a patient's circulatory system).

Aboul-Hosn does not explicitly claim a method for perfusing a patient. However, these steps would have been obvious to assist the heart by pumping blood as intended.

Conclusion

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

- Sammler; Rolf et al. US 6544216
- Hwang; Ned H. C. et al. US 5112292
- Siess; Thorsten et al. CA 2361972 A1
- Siess; T. US 6139487
- Nix; C et al. US 5964694

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

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

Notice of References Cited	Application/Control No. 14/543,815	Applicant(s)/Patent Under Reexamination ABOUL-HOSN ET AL.	
	Examiner Adam Marcetich	Art Unit 3761	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,112,292 A	05-1992	Hwang et al.	600/16
*	B	US-5,964,694 A	10-1999	Siess et al.	600/17
*	C	US-6,139,487 A	10-2000	Siess, Thorsten	600/16
*	D	US-6,544,216 B1	04-2003	Sammler et al.	604/95.03
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N	CA2361972A1	08-2000	CA	SIESS THORSTEN et al.	A61M1/10
	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.



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CA 2361972 A1 2000/08/10

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(12) **DEMANDE DE BREVET CANADIEN
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(13) **A1**

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(30) Priorité/Priority: 1999/02/06 (199 04 975.0) DE

(51) Cl.Int.⁷/Int.Cl.⁷ A61M 1/10, A61F 2/24, A61B 5/028,
A61M 29/02

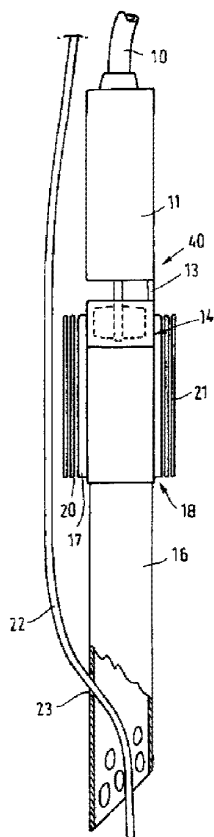
(71) Demandeur/Applicant:
IMPELLA CARDIOTECHNIK AG, DE

(72) Inventeurs/Inventors:
FLAMENG, WILLEM, BE;
SIESS, THORSTEN, DE

(74) Agent: GOWLING LAFLEUR HENDERSON LLP

(54) Titre : DISPOSITIF POUR OPERATION INTRAVASCULAIRE DE VALVULES CARDIAQUES

(54) Title: DEVICE FOR INTRAVASCULAR CARDIAC VALVE SURGERY



(57) Abrégé/Abstract:

The invention relates to a device for the treatment of cardiac valve insufficiency or cardiac valve stenosis, which consists of a microaxial pump (40). The pump part (14) of said microaxial pump comprises a dilatation device (18) which can be used to push



(57) **Abrégé(suite)/Abstract(continued):**

open a stenosed valve. The dilatation device is configured as a high-pressure balloon. During dilatation the microaxial pump (40) functions in such a way that it relieves the cardiac valve. In case of cardiac valve insufficiency a stent (21) which encloses a flexible cardiac valve prosthesis (20) is fixed to the dilatation device (17). The stent (21) is pressed against the insufficient cardiac valve by dilatation so that the cardiac valve ceases to function and the cardiac valve of the cardiac valve prosthesis is unfolded and takes over the function of the natural cardiac valve.

Abstract

A device for intravascular cardiac valve surgery

For the treatment of an insufficient cardiac valve or a cardiac valve with a stenosis, a device is provided that comprises a micro axial pump (40). The pump portion (14) of the micro axial pump carries a dilating device (18) suitable for pushing open a stenosis in a valve. The dilating device is designed as a high-pressure balloon. During dilation, the micro axial pump (40) operates so that the heart is relieved. With insufficient cardiac valves, a stent (21) is fastened to the dilating device (17), the stent surrounding a flexible cardiac valve prosthesis (20). By dilation, the stent (21) is pressed against the insufficient cardiac valve and the same is passivated. The cardiac valve of the cardiac valve prosthesis is unfolded to assume the function of the natural cardiac valve.

(Fig. 6)

A device for intravascular cardiac valve surgery

The invention refers to a device for intravascular cardiac surgery comprising a micro axial pump fastened to a catheter.

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In WO 98/43688, an intra-cardiac blood pump is described that has a motor portion and a pump portion and can be introduced into the heart through the vascular system. Such a blood pump can be positioned in the aortal valve through the aorta, for example, to pump blood from the left ventricle into the aorta. Such blood pumps are adapted to support or replace the pumping effect of the heart. They can be positioned in the heart without requiring the heart to be opened.

10

From WO 97/37697, an intravascular blood pump is known that also has a motor portion and a pump portion, which are connected to a catheter. The blood pump can be pushed through the vascular system of the patient. It is a micro axial pump with a diameter of about 7 mm at most. The pump portion is surrounded by an expandable blocking device blocking the flow path outside the pump housing. Thereby, it is made sure that all blood drawn in is conveyed past the motor portion in the flow direction and short circuits caused by the flow around the pump portion are avoided. The blocking device may be an annular balloon affixed to the pump housing or an intake hose connected to the pump housing. This blood pump is intended for use in blood vessels, the blocking device only serving the purpose of blocking the vessel lumen around the pump portion, but not of deforming the vessel wall. Therefore, the balloon of the blocking device is a low pressure balloon inflated with low pressure so as to seal against the vessel wall in a non-traumatic manner.

20

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Also known are dilating catheters having a balloon with which a vascular stenosis can be removed by pushing it open. Such dilating catheters can also be used to insert an annular stent consisting of an expandable metal structure and forming a supporting device, so as to form a permanent widening support for the stenosis. Such a dilating catheter is designed as a perfusion catheter

30

with a pump portion for conveying blood through the inflated balloon. For cardiac valve surgery, this dilating catheter is not suitable if only for its small diameter of 2 mm at most.

5 The most frequent defects of cardiac valves are valvular incompetence and valves with stenoses. In case of incompetence, the valve is unable to close fully. This causes a return flow. In general, such valves have to be replaced with artificial valves. Valves with stenoses have valve leaflets grown together at the edges, whereby the valve will not open completely and does not allow
10 the full blood flow to pass therethrough.

There are two forms of surgery on the cardiac valves: In cardiac valve replacement, the natural cardiac valve is removed and surgically replaced with a bio-prosthesis or a mechanical cardiac valve. For this type of surgery,
15 it is necessary to keep the operating area free from blood, i.e. to divert the natural blood flow. In case of a repair of the natural cardiac valve, a minimally invasive intervention can be performed using a balloon introduced into the valve. Such operations, e.g., at the aortal valve, the cardiac surgeon or the cardiologist needs great skill. Among others, the reason for this is that the
20 blood flow through the aorta has to be blocked during the breaking process so that the operation has to be made in very short time for the supply to the vessel system to be restored. Further, the pressure inside the heart rises extremely when blocking the aortal flow while its blood supply via the coronal vessels is halted.

25 It is the object of the present invention to provide a device for intravascular cardiac valve surgery with which minimally invasive valve operations can be done relatively simple and without being pressed for time.

30 The object is solved, according to the invention, with the features of claim 1.

In the present device, an intravascular micro axial pump is provided, i.e., a pump that can be pushed through the vascular system of a patient and has an correspondingly small outer diameter that does not exceed 8 mm. The pump portion of the micro axial pump bears a dilating device which is adapted to break up a stenosis in a cardiac valve if placed in the cardiac valve. This dilating device preferably comprises a high-pressure balloon whose expanded diameter is at least 15 mm and which is inflatable with at least 1.0 bar. The high-pressure balloon is positioned in the cardiac valve and expanded using a liquid so that it breaks or blows open a stenosis in the cardiac valve. The dilating device thus forms an active element for breaking up a stenosis in a cardiac valve, in particular a stenosis in an aortal valve or a bicuspid valve.

The lumen of the pump portion or of the cannula adjoining the pump portion is at least 8 mm so as to avoid a too strong local blood flow with large physiological volume flows of up to 7 l/min. Further, the carrier of the dilating device should have an outer diameter of at least 8 mm so that a sufficiently large support for the dilating device is formed and the extent of the diameter increase does not become excessive.

Further, the invention refers to a device for intravascularly placing a cardiac valve prosthesis according to the features of claim 5. This device is also provided with a micro axial pump bearing a dilating device. Moreover, a stent is provided carrying a flexible cardiac valve prosthesis on its inner side. The stent containing the cardiac valve prosthesis can be introduced into the pathogenic cardiac valve and can be expanded by the dilating device so that it presses the valve leaflets of the natural cardiac valve apart. This cardiac valve prosthesis includes a single- or multi-wing cardiac valve that automatically becomes functional and replaces the natural cardiac valve.

As the cardiac valve prosthesis, a jugular valve taken from calves or cows can be used. This would be a bio-prosthesis of natural tissue.

The following is a detailed description of embodiments of the invention with reference to the drawing.

In the figures:

5

Fig. 1 illustrates a device for removing a stenosis in a cardiac valve, introduced into the aortal valve,

10

Fig. 2 shows the device of Fig. 1 with the dilating device expanded,

Fig. 3 is a longitudinal section of a flexible cardiac valve prosthesis,

Fig. 4 illustrates the cardiac valve prosthesis of Fig. 3 in combination with an expanded stent,

15

Fig. 5 is a cross-sectional view of the pump portion with a surrounding balloon as well as a stent with a cardiac valve prosthesis contained therein that is also folded,

20

Fig. 6 is a view of the device for implanting the flexible cardiac valve prosthesis, and

Fig. 7 shows the region of the heart with the implanted cardiac valve prosthesis in an aortal position.

25

Figure 1 illustrates a part of the heart, namely the left ventricle LV, from which blood flows through the aortal valve into the aorta AO. The aortal valve has three valve leaflets projecting into the aorta AO and forming a check valve in a fluidic sense that allows passage only into the aorta.

30

To push open an aortal valve AK with a stenosis, the device illustrated in Fig. 1 is introduced into the heart through the aorta. This device comprises a catheter 10 connected with a micro axial pump 40. The pump comprises a drive portion 11 including an electric motor and driving a shaft 12 protruding from the distal end of the cylindrical drive portion 11. A holding web 13 extends axially from the drive portion 11 to the tubular pump portion 14. The pump portion 14 comprises a pump ring 15 including an impeller wheel driven by the drive shaft 12, and a cannula 16 axially continuing the pump ring 15. The entire pump device, namely the drive portion 11 and the pump portion 14, has a maximum diameter of 8 mm. The catheter 10 comprises the electric wires for the supply and the control of the micro axial pump 40 and a pressure lumen through which pressure liquid can be supplied.

An annular balloon 17 is provided on the pump portion 14 and is illustrated in Fig. 1 in a folded state. Through the pressure lumen of the catheter 10, the balloon 17 may be inflated with liquid. The balloon is a high-pressure balloon with an inflated diameter of at least 15 mm, preferably between 15 and 40 mm, and resistant to pressures up to 8 bar. The balloon 17 extends over a part of the length of the cannula 16. Its entire length may be supported by a rigid ring that prevents a compression of the cannula 16.

The pump device is introduced into the aorta by first placing a guiding wire (not illustrated) in the aorta and the left ventricle. Then the device is advanced along the guiding wire and positioned in the aortal valve AK such that the intake portion 16a is within the left ventricle LV, whereas the outlet portion 19 is within the aorta. The pump portion 15 is thus enclosed by the aortal valve AK. The pump device conveys backward, i.e., it draws axially and ejects laterally in the outlet portion 19.

After the pump device has been positioned in the way illustrated in Fig. 1, the drive portion 11 is activated so that the pump conveys blood from the

left ventricle LV into the aorta AO. Thereby, the heart is relieved in terms of volume and pressure and is calmed down. Then, the balloon 17 forming the dilating device 18 is inflated and expanded in the middle of the aortal valve AK. By the high-pressure inflated balloon 17, the valve leaflets of the aortal valve AK are pushed open and possible adhesions to the commissures are broken. In this manner a valve with a stenosis is pushed open far enough to reassume a completely open state. With the pump device, this form of valve operation can be performed in a calmed environment and without haste since, for the duration of the surgery, the cardiac output (l/min) is conveyed by the pump device through the dilating device. In a similar manner, the above described dilating device can be used to break open a natural bicuspid valve with a stenosis.

Figures 3 to 7 refer to a device with which an insufficient valve is replaced with a valve prosthesis. To this end, generally the same device as described with reference to Figures 1 and 2 is used. This device is illustrated in Figure 6. Situated on the deflated and folded dilating device 18 is a flexible cardiac valve prosthesis 20 above which a compressed spiral-shaped stent 21 is located.

Figure 6 further illustrates the guiding wire 22 that serves to advance the device with the catheter 10 and to place it in the correct position. The guiding wire 22 projects from the distal end of the cannula 16. It passes through a lateral hole 23 in the cannula and extends outside the pump portion 14 and the drive portion 11 along the catheter 10.

The flexible cardiac valve prosthesis 20 is illustrated in Figure 3. It is a bio-prosthesis that has been taken from a cow or a calf. For this purpose, a section 24 of a blood vessel including a vascular valve 25 was removed. This valve 24 may be a single-wing or a three-wing valve. According to Figure 4, this valve prosthesis 20 is placed within a stent 21. The stent 21 is a tubular element of metal rods which, in the present example, are bent meander-like and allow

for an axial compression or radial expansion. Other stent structures could also be used, such as, for example, a cell structure of stretch material. It is essential that the stent can reliably assume a compressed tubular shape and an expanded tubular shape. The hose-shaped wall 24 of the vascular prosthesis 20 is sewed to the rods of the stent 21. Thus, the vascular prosthesis 20 is fastened to the inner side of the stent 21 so that after implantation of the vascular prosthesis, the stent rests between the natural cardiac valve and the bio-prosthesis and has no contact with the blood. Thus, the stent does not require the application of anti-coagulants against thrombosis.

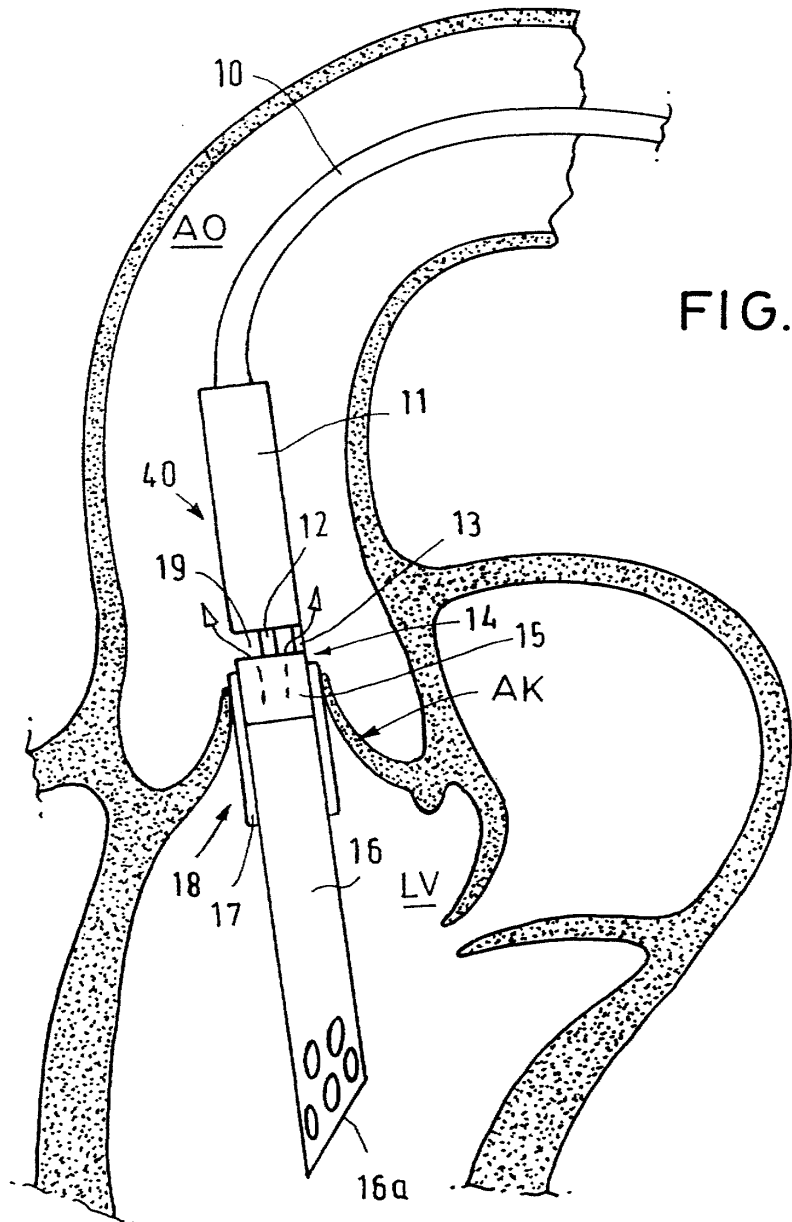
Figure 5 illustrates the pump portion 14 with the pump ring 15. The balloon of the dilating device 18 and the valve prosthesis 20 are folded in a plurality of loops around the pump ring 15, the valve prosthesis being affixed to the rods of the stent 21. In this state, the balloon, the valve prosthesis 20 and the stent 21 form a flat package surrounding the pump portion 14. This package is positioned in the natural cardiac valve AK. Thereafter, the pump is activated and the dilating device 17 is inflated with the pump operating. The stent 21 is dilated, widening the cardiac valve prosthesis 24 and pressing the leaflets of the natural aortal valve AK outward into the open position (systolic valve position, as illustrated in Figure 7. Thereby, the aortal valve AK is passivated. The stent 21 remains in the cardiac valve opening. In the stent, there is the cardiac valve prosthesis 24 enlarged to its original state and including the valve leaflets 25. This cardiac valve now assumes the function of the natural aortal valve AK.

To avoid displacement of the cardiac valve prosthesis, the stent 21 or the cardiac valve prosthesis 20 can be fixed in the annulus 26 surrounding the natural cardiac valve. This is a strong ring of cartilage suitable for use as a holder of a cardiac valve prosthesis.

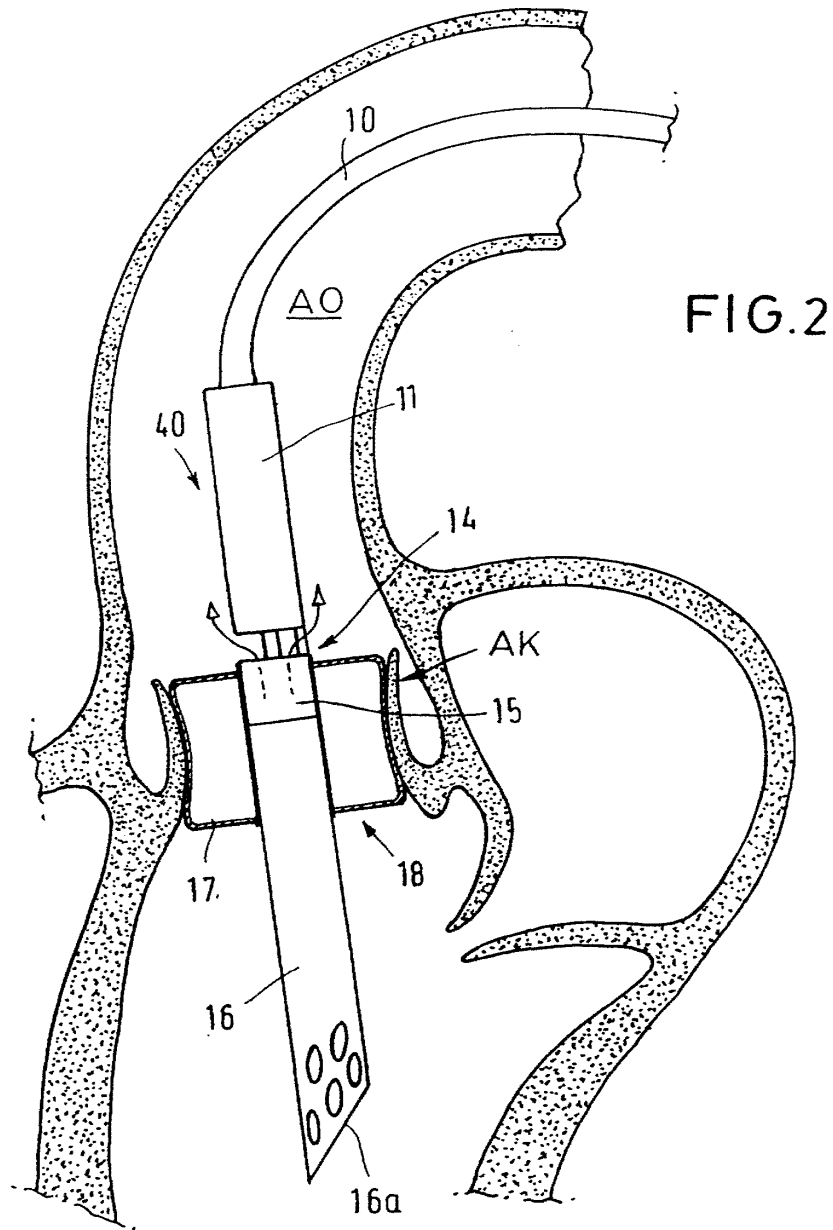
Claims

1. A device for intravascular cardiac valve surgery comprising a micro axial pump (40) fastened to a catheter (10) and having a tubular pump portion (14), and a dilating device (18) surrounding the pump portion (14) which dilating device is suitable for breaking a stenosis of a cardiac valve when positioned in said cardiac valve (AK).
2. The device of claim 1, characterized in that the dilating device (18) consists of an annular high-pressure balloon inflatable with at least 1.0 bar.
3. The device of claim 1 or 2, characterized in that the pump portion (14) comprises a pump ring (15) and a tubular cannula (16) connected therewith.
4. The device of one of claims 1-3, wherein the high-pressure balloon sits on a rigid annular support.
5. A device for intravascular cardiac valve surgery comprising a micro axial pump (40) fastened to a catheter (10) and having a tubular pump portion (14), a dilating device (18) for expanding a stent (21), and a stent (21) carrying a folded flexible cardiac valve prosthesis (20) and being adapted to be expanded by the dilating device (17).
6. The device of claim 5, wherein the cardiac valve prosthesis (20) is sewn to the stent (21).
7. The device of claim 5 or 6, wherein the cardiac valve prosthesis (20) has a hose-shaped wall (24) that is folded together with a balloon wall of the dilating device (17).

-1/5-



-2/5-



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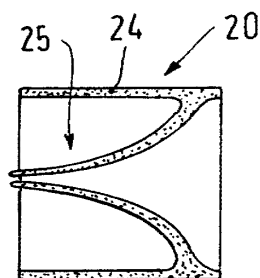


FIG. 3

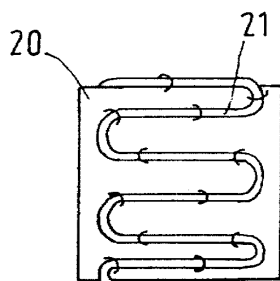


FIG. 4

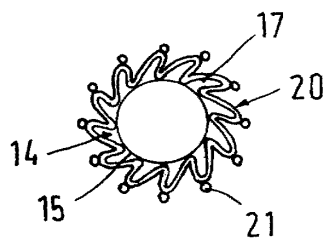


FIG. 5

- 4/5 -

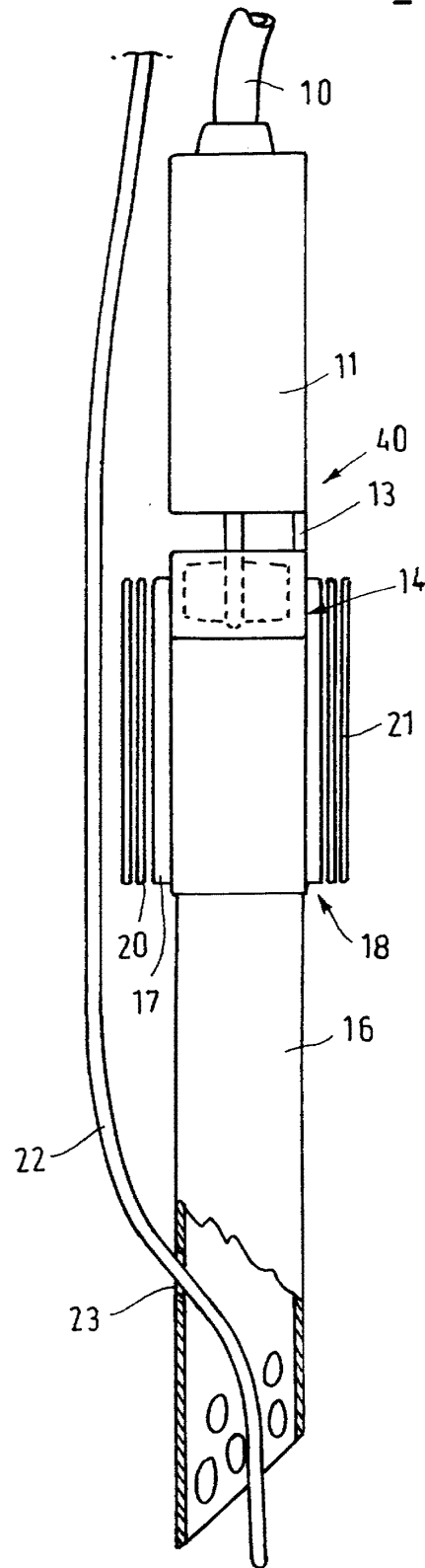
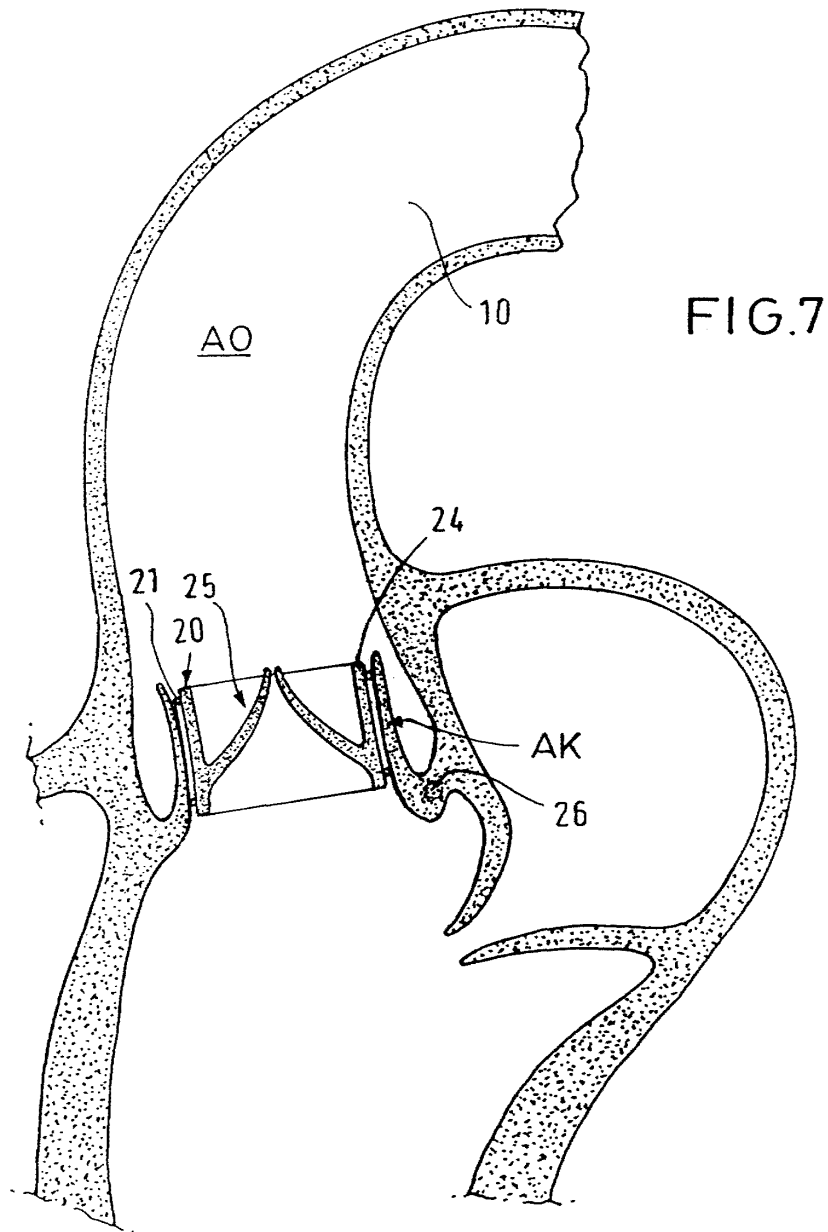


FIG.6

-5/5-



Search Notes 	Application/Control No. 14543815	Applicant(s)/Patent Under Reexamination ABOUL-HOSN ET AL.
	Examiner ADAM MARCETICH	Art Unit 3761

CPC- SEARCHED		
Symbol	Date	Examiner
A61M1/101; A61M1/102; A61M1/1034; A61M1/125; A61M1/1029; A61M1/1086; A61M25/09; Y10S415/90	08/10/2015	AMM

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor search: PALM and EAST (US-PGPUB, USPAT, USOCR)	08/10/2015	AMM
Review cited art for parent cases 10/070,178; 11/375,926; 12/772,810	08/10/2015	AMM

INTERFERENCE SEARCH			
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SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.		
14/543,815	11/17/2014	604	3761	06-01506US05		
APPLICANTS MAQUET Cardiovascular LLC, Mahwah, NJ; INVENTORS Walid N. ABOUL-HOSN, Fair Oaks, CA; William R. KANZ, Sacramento, CA; Bruce A. BAKER, Placerville, CA; ** CONTINUING DATA ***** This application is a CON of 12/772,810 05/03/2010 PAT 8888728 which is a CON of 11/375,926 03/15/2006 PAT 7731675 which is a DIV of 10/070,178 07/19/2002 PAT 7022100 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 ** 12/02/2014						
Foreign Priority claimed ☐ Yes ☒ No 35 USC 119(a-d) conditions met ☐ Yes ☒ No Verified and Acknowledged <u>/Adam Marcetich/</u> Examiner's Signature		☐ Met after Allowance Initials	STATE OR COUNTRY CA	SHEETS DRAWINGS 18	TOTAL CLAIMS 3	INDEPENDENT CLAIMS 3
ADDRESS Getinge US Legal Shared Services 1300 MacArthur Boulevard Mahwah, NJ 07430 UNITED STATES						
TITLE GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS						
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	Filing Date		2014-11-17
	First Named Inventor	Walid N. ABoul-HOSN	
	Art Unit	TBD	
	Examiner Name	TBD	
	Attorney Docket Number	06-01506US05	

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	2	97/46270	WO	A1	1997-12-11	VOELKER, Wolfram		☐
	3	19821307	DE	C1	1999-10-21	Impella Cardiotechnik AG		☐
	4	1999/058170	WO	A1	1999-11-18	Impella Cardiotechnik AG		☐

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AM/

Receipt date: 11/17/2014

14543815 - GAU: 3761

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

Application Number		14543815 - GAU: 3761	
Filing Date		2014-11-17	
First Named Inventor		Walid N. ABOUL-HOSN	
Art Unit		TBD	
Examiner Name		TBD	
Attorney Docket Number		06-01506US05	

	5	19622335	DE	A1	1997-12-11	VOELKER, Wolfram		☐
	6	H-0999092	JP	A	1997-04-15	Target Therapeutics Inc.		☐
	7	0916359	EP	B1	1999-05-19	Impella Cardiotech AG		☐
	8	2256427	CA	A	1998-10-08	Impella Cardiotech AG		☐
	9	89/05164	WO	A1	1989-05-15	Nimbus Medical, Inc.		☐
	10	99/02204	WO	A1	1999-01-21	A-Med Systems, Inc.		☐
	11	00/12148	WO	A1	2000-03-09	A-Med Systems, Inc.		☐
	12	00/18448	WO	A1	2000-04-06	A-Med Systems, Inc.		☐
	13	00/19097	WO	A1	2000-04-06	A-Med Systems, Inc.		☐
	14	00/37139	WO	A1	2000-06-26	A-Med Systems, Inc.		☐
	15	00/69489	WO	A1	2000-11-23	A-Med Systems, Inc.		☐

EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AM/

Receipt date: 11/17/2014

14543815 - GAU: 3761

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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Application Number		14543815 - GAU: 3761	
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First Named Inventor	Walid N. ABOUL-HOSN		
Art Unit	TBD		
Examiner Name	TBD		
Attorney Docket Number	06-01506US05		

	16	01/78807	WO	A1	2001-10-25	A-Med Systems, Inc.	☐
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Add

NON-PATENT LITERATURE DOCUMENTS

Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	Online encyclopedia article "Pyrolytic Carbon" accessed February 19, 2009, http://en.wikipedia.org/wiki/Pyrolytic_carbon , 1 page.	☐
	2	Online encyclopedia article "Ventricular assist device, List of implantable VAD devices" accessed January 12, 2010, http://en.wikipedia.org/wiki/Ventricular_assist_device , 11 pages.	☐

If you wish to add additional non-patent literature document citation information please click the Add button

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EXAMINER SIGNATURE

Examiner Signature	/ADAM MARCETICH/	Date Considered	08/10/2015
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AM/

Receipt date: 11/17/2014

14543815 - GAU: 3761

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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Application Number	14543815 - GAU: 3761		
Filing Date	2014-11-17		
First Named Inventor	Walid N. ABOUL-HOSN		
Art Unit	TBD		
Examiner Name	TBD		
Attorney Docket Number	06-01506US05		

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.

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

☐ A certification statement is not submitted herewith.

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	/Kirk D. Swenson/	Date (YYYY-MM-DD)	2014-11-17
Name/Print	Kirk D. Swenson	Registration Number	52265

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.**

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.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L17	63	I16 and (pump\$3 rotor\$1 blade\$1 foil\$1 propeller\$1).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/08/10 16:43
L16	475	ABOUL-HOSN-WALI D\$.in. KANZ-WILLIAM\$.in. BAKER-BRUCE\$.in.	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/08/10 16:43
L15	77	I13 and (pump\$3 rotor\$1 blade\$1 foil\$1 propeller\$1)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/08/10 16:40
L14	40	I13 and (pump\$3 rotor\$1)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/08/10 16:40
L13	531	I4 and (wire guidewire) near5 (carriage lumen path passage passageway hole aperture) not (I5 I6 I8 I9 I10)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/08/10 16:36
L11	42	(I8 I9 I10) and (wire guidewire)	US-PGPUB; USPAT; USOCR	OR	OFF	2015/08/10 16:26
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L7	2	("6176822" "6139487").pn.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/08/10 16:22
L6	24	I4 and ((intra inter) adj cardiac intracardiac intercardiac)and pump\$3 not I5	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/08/10 16:20
L5	246	I4 and (IVD VAD intravascular (intra inter) adj (vascular venous arterial atrial ventricular) and pump\$3	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/08/10 16:15
L4	4989	(A61M1/101 A61M1/102 A61M1/1034 A61M1/125 A61M1/1029 A61M1/1086 A61M25/09 Y10S415/90).cpc. and @ad< "20000901"	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT;	OR	ON	2015/08/10 16:14

			IBM_TDB			
L3	5	(10/070,178 11/375,926 12/772,810).app.	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/08/10 14:14
L2	2	12/772,810.app.	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/08/10 13:46
L1	1	14/543815.app.	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/08/10 13:45

EAST Search History (Interference)

<This search history is empty>

8/ 10/ 2015 4:44:16 PM**H:\ EAST searches\ workspaces\ 14543815 CON.wsp**

<i>Index of Claims</i> 	Application/Control No. 14543815	Applicant(s)/Patent Under Reexamination ABOUL-HOSN ET AL.
	Examiner ADAM MARCETICH	Art Unit 3761

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47										
CLAIM		DATE								
Final	Original	08/10/2015								
	1									
	2	-								
	3	-								
	4	-								
	5	-								
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	16	-								
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	19	-								
	20	-								
	21	-								
	22	-								
	23	-								
	24	✓								
	25	✓								
	26	✓								

TERMINAL DISCLAIMER TO OBTAIN A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) 06-01506US05
In re Application of: Walid N. ABOUL-HOSN, et al. Application No.: 14/543,815 Filed: November 17, 2014 For: GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS The applicant, <u>MAQUET Cardiovascular LLC</u>, owner of <u>100</u> percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent No. <u>8,888,728</u> as the term of said prior patent is presently shortened by any terminal disclaimer. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns. In making the above disclaimer, the applicant does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later: - expires for failure to pay a maintenance fee; - is held unenforceable; - is found invalid by a court of competent jurisdiction; - is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321; - has all claims canceled by a reexamination certificate; - is reissued; or - is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer. Check either box 1 or 2 below, if appropriate. 1. ☐ The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee. I hereby acknowledge that any willful false statements made are punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both. 2. ☒ The undersigned is an attorney or agent of record. Reg. No. <u>47,395</u> <u>/Wesley Scott Ashton/</u> Signature <u>9/10/15</u> Date <u>Wesley Scott Ashton</u> Typed or printed name <u>Patent Attorney</u> Title <u>(201) 378-8419</u> Telephone Number ☒ Terminal disclaimer fee under 37 CFR 1.20(d) included. 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.	

This collection of information is required by 37 CFR 1.321. 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.**

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

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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.

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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.

AMENDMENT AND RESPONSE Address to: Mail Stop: Amendment Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450	Attorney Docket	06-01506US05
	Confirmation No.	9742
	First Named Inventor	Walid N. ABOUL-HOSN
	Application Number	14/543,815
	Filing Date	November 17, 2014
	Group Art Unit	3761
	Examiner Name	MARCETICH, ADAM M
	Title	Guidable Intravascular Blood Pump and Related Methods

AMENDMENT IN RESPONSE TO THE OFFICE ACTION OF AUGUST 17, 2015

Sir:

In response to the non-final Office Action mailed from the U.S. Patent and Trademark Office on August 17, 2015 with respect to the above-captioned application, please amend the application identified above as follows.

Other than the excess claim fees provided herewith and any fees associated with the terminal disclaimer, no additional fees are believed to be due in association with this filing. If, however, any additional fees are required, 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 06-01506US05.

Amendments to the Specification begin on page 2.

Amendments to the Claims begin on page 3.

Remarks/Arguments begin on page 9.

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 co-pending U.S. Patent Application Serial No. 12/772,810, filed May 3, 2010 (now U.S. Patent No. 8,888,728), which is a continuation of U.S. Patent Application Serial No. 11/375,926, filed March 15, 2006 (now U.S. Patent No. 7,731,675, issued June 8, 2010), which is a divisional of U.S. Patent Application Serial No. 10/070,178, filed July 19, 2002, (now U.S. Patent No. 7,022,100, issued April 4, 2006) which is a U.S. National Stage Entry of International Patent Application No. 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, all of which are hereby incorporated by reference in their entireties.

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application:

1 – 23. (Cancelled)

24. (Previously Presented) A method for perfusing a patient with an intravascular blood pump system, the intravascular blood pump system comprising (i) 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 having a distal end extending distally beyond the most distal portion of the blade and a shroud within which the rotor is rotatably disposed; (ii) 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; (iii) a first lumen in fluid communication with the intravascular blood pump and operatively arranged to deliver purge fluid to the intravascular blood pump; and (iv) 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, the method comprising the steps of:

progressing a guide wire to a predetermined location in the circulatory system of the patient; and

advancing the blood pump system along the guide wire to the predetermined location.

25. (Previously Presented) A method for perfusion a patient with an intravascular blood pump system, the intravascular blood pump system comprising (i) an intravascular blood pump comprising a rotor having a rotor hub tapering in the distal direction and 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; (ii) 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; (iii) 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 (iv) a blood pressure detection mechanism comprising a fluid column configured to detect the pressure of the blood proximate the intravascular blood pump; wherein the elongate lumen (a) is sized substantially smaller than an inner diameter of the cannula and intravascular blood pump; (b) is arranged coaxially with at least one of a distal end or a proximal end of the cannula, and (c) is arranged in series longitudinally with the cannula: the method comprising:

advancing a guide wire to a predetermined location in the circulatory system of the patient; and

advancing the blood pump system along the guide wire to the predetermined location.

26. (Currently Amended) A method for perfusion a patient with an intravascular

blood pump system, the intravascular blood pump system is configured to be advanced to a predetermined location in a patient's circulatory system and comprises (i) 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; (ii) a cannula extending distally from the intravascular blood pump; (iii) a plurality of ingress ports located towards the ~~proximal~~-distal 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; (iv) a guide wire having a cross-section substantially smaller than the cannula; and (v) an elongate lumen, the elongate lumen (a) having a luminal interior sized smaller than an inside diameter of the cannula and sufficiently large enough to accommodate the guide wire when the guide wire is advanced therealong, (b) arranged coaxially with respect to at least one of a distal end or a proximal end of the cannula, and (c) arranged in series longitudinally with the cannula, the method comprising:

advancing the guide wire to a predetermined location in the circulatory system of the patient; and

advancing the blood pump along the guide wire to the predetermined location.

27. (New) The method of claim 24, wherein the rotor comprises a second blade extending radially from the rotor hub and the rotor hub is generally conical.

28. (New) The method of claim 24, 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.

29. (New) The method of claim 24, 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.

30. (New) The method of claim 24, wherein the second lumen has an inner diameter along a portion of its length that is substantially smaller than an outer diameter of the outer cannula surface, and the length of the second lumen is substantially longer than the inner diameter of the second lumen.

31. (New) The method of claim 24, further comprising a guide catheter, wherein the guide catheter is configured to facilitate the placement of the guide wire into the heart.

32. (New) The method of claim 24, 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.

33. (New) The method of claim 24, wherein the cannula is operatively arranged to bend at a location between distal and proximal ends thereof.

34. (New) The method of claim 24, 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.

35. (New) The method of claim 25, further comprising a guide wire and a guide catheter, wherein the guide catheter is configured to facilitate the placement of the guide wire through the vasculature into the heart.

36. (New) The method of claim 25, wherein the cannula comprises an outer cannula surface having a substantially circular cross-section along a portion of its length, and the cannula is reinforced with a spiral wire.

37. (New) The method of claim 25, 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. (New) The method 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 method of claim 25, 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. (New) The method of claim 25, wherein the central lumen extends through the cannula and blood pump.

41. (New) The method of claim 25, wherein the lumen of the central lumen is proximal to the cannula.

42. (New) The method of claim 25, wherein the cannula is operatively arranged to bend at a location between distal and proximal ends thereof.

43. (New) The method of claim 25, wherein the distal end of the cannula is open to enable the guide wire to pass axially through the distal end of the cannula.

44. (New) The method of claim 26, wherein the lumen is proximal with respect to the cannula.

45. (New) The method of claim 26, 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

Amendments to the specification are to update the related application data. No new matter has been added.

Please enter the above claim amendments and new claims.

Claims 1 – 23 have been previously canceled without prejudice to reconsideration and resubmission. Claim 26 has been amended. Claims 27 through 45 are new.

Support for new claims 27 through 45 and the amendment to claim 26 can be found throughout the specification and drawings as originally filed. Upon entry of this amendment, claims 24 - 45 will remain pending in the application.

No new matter has been added.

A. The Rejections

Claims 24-26 stand allegedly rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 10, 12 and 22 of Aboul-Hosn; Walid N. et al. (US 8,888,728).

B. Applicants' Arguments

Applicants traverse the Examiner's rationale for the nonstatutory obviousness-type double patenting rejection, however, purely in the interest of expediting prosecution, Applicants file herewith a terminal disclaimer in compliance with 37 C.F.R. § 1.321 (c) with respect to U.S. Patent 8,888,728. Therefore, the Examiner's obviousness-type double patenting rejection has been overcome and should be withdrawn.

CONCLUSION

In light of the terminal disclaimer filed herewith, Claims 24 – 45 are in condition for allowance, and a prompt notice of allowance is earnestly solicited.

Applicants believe that no additional fee is due for the response other than the fee for two additional dependent claims and any fees associated with the terminal disclaimer. However, if

an additional fee is due, or if any extensions of time are required to maintain the application, then please charge the required fees to Deposit Account No. 04-0170, order number 06-01506US05.

If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

Respectfully submitted,

Date: September 10, 2015

By: /Kirk D. Swenson /
Kirk D. Swenson
Registration No. 52,265

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1300 MacArthur Blvd.
Mahwah, NJ 07430
Telephone: 1-201-995-8816
Facsimile: 1-866-936-0615

Electronic Patent Application Fee Transmittal				
Application Number:		14543815		
Filing Date:		17-Nov-2014		
Title of Invention:		GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS		
First Named Inventor/Applicant Name:		Walid N. ABOUL-HOSN		
Filer:		Kirk D. Swenson/Kathleen Andree		
Attorney Docket Number:		06-01506US05		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Claims in Excess of 20	1202	2	80	160
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Statutory or Terminal Disclaimer	1814	1	160	160
Total in USD (\$)				320

Electronic Acknowledgement Receipt	
EFS ID:	23457264
Application Number:	14543815
International Application Number:	
Confirmation Number:	9742
Title of Invention:	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS
First Named Inventor/Applicant Name:	Walid N. ABOUL-HOSN
Customer Number:	99185
Filer:	Kirk D. Swenson/Kathleen Andree
Filer Authorized By:	Kirk D. Swenson
Attorney Docket Number:	06-01506US05
Receipt Date:	10-SEP-2015
Filing Date:	17-NOV-2014
Time Stamp:	16:22:31
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$ 320
RAM confirmation Number	3351
Deposit Account	040170
Authorized User	SWENSON, KIRK
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 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer Filed	2015-09-10_PTO_AIA_26_Terminal_Disclaimer.pdf	160511 57606adb8bd1017cd24c5b346489477773fdee26	no	2
Warnings:					
Information:					
2		2015-09-10_RESPONSE_TO_NO N- FINAL_OFFICE_ACTION_AS_FIL ED.pdf	56222 af419b05e2a00e9910952c7387362adf90f50700	yes	10
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Applicant Arguments/Remarks Made in an Amendment		1	1	
	Specification		2	2	
	Claims		3	8	
	Applicant Arguments/Remarks Made in an Amendment		9	10	
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	32461 13aea893f0706fde075127e744f35014457b6cd3	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			249194		

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.

Application Number 	Application/Control No. 14/543,815	Applicant(s)/Patent under Reexamination ABOUL-HOSN ET AL.	
Document Code - DISQ		Internal Document – DO NOT MAIL	

TERMINAL DISCLAIMER	☒ APPROVED	☐ DISAPPROVED
Date Filed : 9/10/15	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:

Lawana Hixon

U.S. Patent and Trademark Office



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NOTICE OF ALLOWANCE AND FEE(S) DUE

99185 7590 10/05/2015
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1300 MacArthur Boulevard
Mahwah, NJ 07430

EXAMINER

MARCETICH, ADAM M

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 10/05/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/543,815	11/17/2014	Walid N. ABOUL-HOSN	06-01506US05	9742

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	01/05/2016

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)

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Mahwah, NJ 07430

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.

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.
14/543,815	11/17/2014	Walid N. ABOUL-HOSN	06-01506US05	9742

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	01/05/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
MARCETICH, ADAM M	3761	600-016000

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. _____



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/543,815	11/17/2014	Walid N. ABOUL-HOSN	06-01506US05	9742
99185	7590	10/05/2015	EXAMINER	
Getinge US Legal Shared Services 1300 MacArthur Boulevard Mahwah, NJ 07430			MARCETICH, ADAM M	
			ART UNIT	PAPER NUMBER

3761

DATE MAILED: 10/05/2015

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.

<i>Notice Requiring Inventor's Oath or Declaration</i>	Application No. 14/543,815	Applicant(s) Walid N. ABOUL-HOSN	
	Examiner MARCETICH, ADAM M	Art Unit 3761	

This notice is an attachment to the Notice of Allowability (PTOL-37), or the Notice of Allowability For A Design Application (PTOL-37D).

An inventor's oath or declaration in compliance with 37 CFR 1.63 or 1.64 executed by or with respect to each inventor has not yet been submitted.

An oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each inventor (for any inventor for which a compliant oath, declaration, or substitute statement has not yet been submitted) **MUST** be filed no later than the date on which the issue fee is paid. See 35 U.S.C. 115(f). Failure to timely comply will result in ABANDONMENT of this application.

A properly executed inventor's oath to declaration has not been received for the following inventor(s):

If applicant previously filed one or more oaths, declarations, or substitute statements, applicant may have received an informational notice regarding deficiencies therein.

The following deficiencies are noted:

INFORMAL ACTION PROBLEMS

- A properly executed inventor's oath or declaration has not been received for the following inventor(s): **Walid N. ABOUL-HOSN, William R. KANZ, and Bruce A. BAKER.**

Applicant may submit the inventor's oath or declaration at any time before the Notice of Allowance and Fee(s) Due, PTOL-85, is mailed.

Questions relating to this Notice should be directed to the Application Assistance Unit at 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.

Notice of Allowability	Application No. 14/543,815	Applicant(s) ABOUL-HOSN ET AL.	
	Examiner Adam Marcetich	Art Unit 3761	AIA (First Inventor to File) Status 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 10 September 2015.
☐ 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 24-45. 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 or send an inquiry to 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. ☐ Notice of References Cited (PTO-892)	5. ☒ Examiner's Amendment/Comment
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____	6. ☒ Examiner's Statement of Reasons for Allowance
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material	7. ☐ Other _____
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____	

/Adam Marcetich/ Primary Examiner, Art Unit 3761	
---	--

EXAMINER'S COMMENT / AMENDMENT / 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

The amended paragraph filed 10 September 2015 is acceptable and has been entered.

Terminal Disclaimer

The terminal disclaimer filed on 10 September 2015 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Aboul-Hosn; Walid N. et al. (US 8888728) has been reviewed and is accepted. The terminal disclaimer has been recorded.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kirk D. Swenson on Tuesday, 22 September 2015.

Claims 27, 40 and 41 are amended as follows. **[[Deletions are in double brackets]]** and **additions are underlined**. Ellipsis ... designates unchanged portions of claims which have been omitted for brevity.

27. (Currently Amended) The method of claim 24, wherein the rotor comprises a second blade extending radially from the rotor hub and the **[[rotar]] rotor** hub is generally conical.

40. (New) The method of claim 25, wherein the **[[central]] elongate** lumen extends **centrally** through the cannula and blood pump.

41. (New) The method of claim 25, wherein the **elongate** lumen **[[of the central lumen]]** is proximal to the cannula.

Allowable Claims

Claims 24-45 are allowed.

Reasons for Allowance

Applicant's arguments filed 10 September 2015 regarding Aboul-Hosn have been considered and are persuasive. Examiner advances additional reasons for allowance.

Sammler; Rolf et al. (US 6544216), the closest art of record, discloses an intracardiac blood pump and method of using (col. 1, lines 3-7; col. 3, lines 16-22, blood pump 10), comprising:

(i) an intravascular blood pump comprising a rotor, tapered rotor hub, blade and shroud (col. 3, lines 20-24, drive section 11 and a pump section 12 as described in Siess; Thorsten et al. (WO 9737696 A1));

(ii) a cannula extending from the shroud and comprising an outer cannula surface (col. 3, lines 36-44, Figs. 1, 2, pump hose 14).

However, Sammler lacks several critical feature of the invention. Sammler lacks both a first lumen arranged to deliver purge fluid, and a guide mechanism configured as an elongate lumen. Significantly, Sammler relies on the motor-driven pump of Siess to move blood through vessels (Siess, Figs. 2, 3). Since the motor of Siess occupies the entire cross-section of the lumen, no space remains for a lumen to pass a guide wire or purge fluid.

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

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.

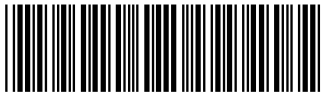
/Adam Marcetich/
Primary Examiner, Art Unit 3761

Issue Classification 	Application/Control No. 14543815	Applicant(s)/Patent Under Reexamination ABOUL-HOSN ET AL.	
	Examiner ADAM MARCETICH	Art Unit 3761	

CPC					
Symbol				Type	Version
A61M		1	125	F	2014-02-04
A61M		2025	0183	A	2013-01-01
A61M		2025	0177	A	2013-01-01
A61M		1	101	I	2013-01-01
Y10S		415	90	A	2013-01-01
A61M		1	102	I	2014-02-04
A61M		1	1034	I	2014-02-04
A61M		1	1029	I	2014-02-04
A61M		1	1086	I	2013-01-01
A61M		25	09	I	2013-01-01

CPC Combination Sets						
Symbol			Type	Set	Ranking	Version

NONE		Total Claims Allowed:	
(Assistant Examiner)		22	
(Date)			
/ADAM MARCETICH/	09/22/2015	O.G. Print Claim(s)	O.G. Print Figure
Primary Examiner.Art Unit 3761		1	1
(Primary Examiner)	(Date)		

Issue Classification 	Application/Control No. 14543815	Applicant(s)/Patent Under Reexamination ABOUL-HOSN ET AL.
	Examiner ADAM MARCETICH	Art Unit 3761

US ORIGINAL CLASSIFICATION						INTERNATIONAL CLASSIFICATION													
CLASS		SUBCLASS				CLAIMED					NON-CLAIMED								
600		16				A	6	1	M	1 / 10 (2006.01.01)									
CROSS REFERENCE(S)						A	6	1	M	25 / 09 (2006.01.01)									
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)																		
604	8	164.13																	
623	3.15	3.1																	

NONE		Total Claims Allowed:	
		22	
(Assistant Examiner)	(Date)		
/ADAM MARCETICH/ Primary Examiner.Art Unit 3761	09/22/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

Issue Classification 	Application/Control No. 14543815	Applicant(s)/Patent Under Reexamination ABOUL-HOSN ET AL.
	Examiner ADAM MARCETICH	Art Unit 3761

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1		17	8	33										
	2		18	9	34										
	3		19	11	35										
	4		20	12	36										
	5		21	13	37										
	6		22	14	38										
	7		23	15	39										
	8	1	24	16	40										
	9	10	25	17	41										
	10	20	26	18	42										
	11	2	27	19	43										
	12	3	28	21	44										
	13	4	29	22	45										
	14	5	30												
	15	6	31												
	16	7	32												

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 22	
/ADAM MARCETICH/ Primary Examiner.Art Unit 3761 (Primary Examiner) _____ (Date) _____		O.G. Print Claim(s) 1	O.G. Print Figure 1



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BIB DATA SHEET

CONFIRMATION NO. 9742

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.		
14/543,815	11/17/2014	604	3761	06-01506US05		
APPLICANTS MAQUET Cardiovascular LLC, Mahwah, NJ; INVENTORS Walid N. ABOUL-HOSN, Fair Oaks, CA; William R. KANZ, Sacramento, CA; Bruce A. BAKER, Placerville, CA; ** CONTINUING DATA ***** This application is a CON of 12/772,810 05/03/2010 PAT 8888728 which is a CON of 11/375,926 03/15/2006 PAT 7731675 which is a DIV of 10/070,178 07/19/2002 PAT 7022100 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 ** 12/02/2014						
Foreign Priority claimed ☐ Yes ☒ No 35 USC 119(a-d) conditions met ☐ Yes ☒ No Verified and Acknowledged /Adam Marcetich/ Examiner's Signature		☐ Met after Allowance Initials	STATE OR COUNTRY CA	SHEETS DRAWINGS 18	TOTAL CLAIMS 22	INDEPENDENT CLAIMS 3
ADDRESS Getinge US Legal Shared Services 1300 MacArthur Boulevard Mahwah, NJ 07430 UNITED STATES			total claims: 22 independent: 3 updated Tue 22 Sep 2015 /AMM/			
TITLE GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS						
FILING FEE RECEIVED 1900	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:			☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit		

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L15	11	WO adj "9737696"	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/09/22 08:20
L10	248	I9 and (wire guidewire)	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/09/22 07:18
L9	807	I8 and (rotor rotar rotat\$3 spin\$1 spinn\$3 turn\$3 motor)	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/09/22 07:17
L8	1150	I7 and pump\$3 with (cardiac intracardiac heart intravascular vascular vasculature vessel\$1 vein\$1 arter\$3 venous veinous)	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/09/22 07:17
L7	10115	(A61M1/101 A61M1/102 A61M1/1034 A61M1/125 A61M1/1029 A61M1/1086 A61M25/09 A61M25/09041 A61M2025/0183 A61M2025/0177 A61B5/021 A61B5/0215 Y10S415/90).cpc. and @ad<"20000901"	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/09/22 07:16
L6	249	(A61M2025/0177).cpc. and @ad<"20000901"	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/09/22 07:08
L5	875	I4 and (wire guidewire)	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/09/22 07:04
L4	1631	(A61M2025/0183).cpc. and @ad<"20000901"	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/09/22 07:04
L3	79	(US-20060161095-\$ or US-20060155158-\$ or US-20050165269-\$ or US-	US-PGPUB; USPAT;	OR	OFF	2015/09/22 06:58

		20030023201-\$ or US-20150073202-\$ or US-20100210895-\$).did. or (US-7731675-\$ or US-7022100-\$ or US-6976996-\$ or US-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-\$ 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-\$ or US-6007478-\$ or US-6176822-\$ or US-3995617-\$ or US-5965089-\$ or US-5921913-\$ or US-5964694-\$ or US-6139487-\$ or US-6058593-\$ or US-4964864-\$ or US-7066924-\$ or US-6066122-\$ or US-5234407-\$).did. or (US-6295877-\$ or US-6387125-\$ or US-6716189-\$ or US-6346120-\$ or US-6176848-\$ or US-6135729-\$ or US-5851174-\$ or US-4969865-\$ or US-4846152-\$ or US-5211546-\$ or US-5336184-\$ or US-5527159-\$ or US-8888728-\$ or US-6544216-\$ or US-5112292-\$).did. or (CA-2361972-\$).did. or (WO-8905668-\$ or US-5741234-\$ or WO-9843689-\$ or WO-9843688-\$).did.	FPRS; DERWENT			
L2	1	14/543,815.app.	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/09/22 06:14

EAST Search History (Interference)

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L12	109	l11 and (wire guidewire).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2015/09/22 07:22
L11	3925	pump\$3 with (cardiac intracardiac heart	US-	OR	ON	2015/09/22

	intravascular vascular vasculature vessel\$1 vein\$1 arter\$3 venous veinous).clm. and @ad<"20000901"	PGPUB; USPAT; UPAD		07:21
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9/ 22/ 2015 8:31:50 AM
H:\ EAST searches\ workspaces\ 14543815 CON.wsp

AMENDMENTS TO THE SPECIFICATION:

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

OK TO ENTER: /AMM/

/AMM/ {09/30/2015}

This application is a continuation of co-pending U.S. Patent Application Serial No. 12/772,810, filed May 3, 2010 (now U.S. Patent No. 8,888,728), which is a continuation of U.S. Patent Application Serial No. 11/375,926, filed March 15, 2006 (now U.S. Patent No. 7,731,675, issued June 8, 2010), which is a divisional of U.S. Patent Application Serial No. 10/070,178, filed July 19, 2002, (now U.S. Patent No. 7,022,100, issued April 4, 2006) which is a U.S. National Stage Entry of International Patent Application No. 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, all of which are hereby incorporated by reference in their entireties.

Search Notes 	Application/Control No. 14543815	Applicant(s)/Patent Under Reexamination ABOUL-HOSN ET AL.
	Examiner ADAM MARCETICH	Art Unit 3761

CPC- SEARCHED		
Symbol	Date	Examiner
A61M1/101; A61M1/102; A61M1/1034; A61M1/125; A61M1/1029; A61M1/1086; A61M25/09; Y10S415/90	08/10/2015	AMM
A61M1/101; A61M1/102; A61M1/1034; A61M1/125; A61M1/1029; A61M1/1086; A61M25/09; A61M25/09041; A61M2025/0183 ; A61M2025/0177	09/22/2015	AMM
A61B5/021; A61B5/0215; Y10S415/90	09/22/2015	AMM

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor search: PALM and EAST (US-PGPUB, USPAT, USOCR)	08/10/2015	AMM
Review cited art for parent cases 10/070,178; 11/375,926; 12/772,810	08/10/2015	AMM
search update	09/22/2015	AMM

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
	claim keyword search	09/22/2015	AMM

	/ADAM MARCETICH/ Primary Examiner.Art Unit 3761
--	--

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

Application Number	14/543,815	Filing Date	2014-11-17	Docket Number (if applicable)	06-01506US05	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, to any international application that does not comply with the requirements of 35 U.S.C. 371, 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 Submitted after Notice of Allowance issued (October 5, 2015)

☒ 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 040170

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

Applicant Signature

Doc code: RCEX

Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (07-14)

Approved for use through 07/31/2016. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

Signature of Registered U.S. Patent Practitioner			
Signature	Kirk D. Swenson/	Date (YYYY-MM-DD)	2016-01-05
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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT Substitute for Form PTO-1449 (Not for submission under 37 CFR 1.99)	Complete If Known	
	Attorney Docket	06-01506US05
	Confirmation No.	9742
	First Named Inventor	Walid N. ABOUL-HOSN
	Application Number	14/543,815
	Filing Date	November 17, 2014
	Group Art Unit	3761
	Examiner Name	MARCETICH, ADAM M
Title		Guidable Intravascular Blood Pump and Related Methods
Sheet 1 of 5		

U.S. PATENTS						
Examiner Initial*	Cite No. (A1, A2, ...An)	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
				YYYY-MM-DD		
	A1	4769005	A	1988-09-06	Ginsburg et al.	
	A2	4846152	A	1989-07-11	Nimbus Medical Inc.	
	A3	4944722	A	1990-07-31	Nimbus Medical Inc.	
	A4	5092879	A	1992-03-03	Jarvik, Robert K.	
	A5	5106363	A	1992-04-21	Terumo Kabushiki Kaisha	
	A6	5108411	A	1992-04-28	Cardiovascular Imaging Systems Inc.	
	A7	5137513	A	1992-08-11	Advanced Cardiovascular Systems Inc.	
	A8	5334142	A	1994-08-02	New York University	

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT Substitute for Form PTO-1449 (Not for submission under 37 CFR 1.99)	Complete If Known	
	Attorney Docket	06-01506US05
	Confirmation No.	9742
	First Named Inventor	Walid N. ABOUL-HOSN
	Application Number	14/543,815
	Filing Date	November 17, 2014
	Group Art Unit	3761
	Examiner Name	MARCETICH, ADAM M
	Title	Guidable Intravascular Blood Pump and Related Methods
Sheet 2 of 5		

	A9	5516336	A	1996-05-14	Advanced Cardiovascular Systems Inc.	
	A10	5697948	A	1997-12-16	Endovascular Systems Inc.	
	A11	5746575	A	1998-05-05	Baxter International Inc.	
	A12	5824070	A	1998-10-20	Jarvik, Robert	
	A13	5851174	A	1998-12-22	Jarvik Robert	
	A14	5911702	A	1999-06-15	Heartport Inc.	
	A15	6007478	A	1999-12-28	Impella Cardiatechnik Aktiengesellschaft	
	A16	6071093	A	2000-06-06	Abiomed Inc.	
	A17	6116862	A	2000-09-12	MEDOS Medizintechnik GmbH	
	A18	6136025	A	2000-10-24	Barbut et al.	
	A19	6146354	A	2000-11-14	Horizon Medical Products	
	A20	6176848	B1	2001-01-23	Impella Cardiatechnik GmbH	

Examiner Signature		Date Considered	
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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.

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT Substitute for Form PTO-1449 (Not for submission under 37 CFR 1.99)	Complete If Known	
	Attorney Docket	06-01506US05
	Confirmation No.	9742
	First Named Inventor	Walid N. ABOUL-HOSN
	Application Number	14/543,815
	Filing Date	November 17, 2014
	Group Art Unit	3761
	Examiner Name	MARCETICH, ADAM M
	Title	Guidable Intravascular Blood Pump and Related Methods
Sheet 3 of 5		

	A21	6197001	B1	2001-03-06	Becton Dickinson and Company	
	A22	6248091	B1	2001-06-19	Voelker, Wolfram	
	A23	6290689	B1	2001-09-18	Corazón Technologies Inc.	
	A24	6354814	B1	2002-03-12	Kaufmann et al.	
	A25	6544216	B1	2003-04-08	Impella Cardiatechnik Aktiengesellschaft	
	A26	6572530	B1	2003-06-03	JMS Co. Ltd.	
	A27	6592567	B1	2003-07-15	CHF Solutions Inc.	
	A28	6673040	B1	2004-01-06	Cardeon Corporation	
	A29	6733459	B1	2004-05-11	Aisin Seiki Kabushiki Kaisha	
	A30	7517352	B2	2009-04-14	Bacchus Vascular Inc.	
	A31	7998054	B2	2011-08-16	Thoratec Corporation	
	A32	8545447	B2	2013-10-01	Demarais et al.	

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

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	Attorney Docket	06-01506US05
	Confirmation No.	9742
	First Named Inventor	Walid N. ABOUL-HOSN
	Application Number	14/543,815
	Filing Date	November 17, 2014
	Group Art Unit	3761
	Examiner Name	MARCETICH, ADAM M
	Title	Guidable Intravascular Blood Pump and Related Methods
Sheet 4 of 5		

U.S. PATENT APPLICATION PUBLICATIONS						
Examiner Initial*	Cite No. (B1, B2, ...Bn)	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
				YYYY-MM-DD		
	B1	20010027287	A1	2001-10-04	Trans Vascular Inc.	
	B2	20030088151	A1	2003-05-08	Kung et al.	
	B3	20030100816	A1	2003-05-29	Siess, Thorsten	
	B4	20030187322	A1	2003-10-02	Siess, Thorsten	
	B5	20040097995	A1	2004-05-20	Nash et al.	
	B6	20050049696	A1	2005-03-03	Siess et al.	
	B7	20090024212	A1	2009-01-22	Siess et al.	
	B8	20130304158	A1	2013-11-14	Zarinetchi et al.	

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT Substitute for Form PTO-1449 (Not for submission under 37 CFR 1.99)	Complete If Known	
	Attorney Docket	06-01506US05
	Confirmation No.	9742
	First Named Inventor	Walid N. ABOUL-HOSN
	Application Number	14/543,815
	Filing Date	November 17, 2014
	Group Art Unit	3761
	Examiner Name	MARCETICH, ADAM M
Sheet 5 of 5	Title	Guidable Intravascular Blood Pump and Related Methods

FOREIGN PATENT DOCUMENTS								
Examiner Initial*	Cite No. (C1, C2, ...Cn)	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date YYYY-MM-DD	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵

NON PATENT LITERATURE DOCUMENTS			
Examiner Initial*	Cite No. (D1, D2, ...Dn)	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	D1		

Examiner Signature		Date Considered	
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.			
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Customer No.: 99185

Docket No.: 06-01506US05

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re

application of: Walid N. ABOUL-HOSN et al.

Serial No.: 14/543,815

Confirmation No.: 9742

Filed: November 17, 2014

Group Art Unit: 3761

For: GUIDABLE INTRAVASCULAR
BLOOD PUMP AND
RELATED METHODS

Examiner: MARCETICH, Adam

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir/Madam:

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 Supplemental Information Disclosure Statement (SIDS) 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.

Docket No. 06-01506US05

The filing of this Supplemental Information Disclosure Statement and the enclosed SDS 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.

1. ☒ This Information Disclosure Statement is being filed before the mailing of a first office action after filing of a request for continued examination.

2. ☒ 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.

Docket No. 06-01506US05

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 Deposit Account No. 04-0170, reference number 06-01506US05. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account 04-0170.

Respectfully submitted,

DATE: January 5, 2016

/Kirk D. Swenson/

Kirk D. Swenson
Registration No. 52,265
Agent for Applicant(s)
MAQUET Cardiovascular LLC
1300 MacArthur Boulevard
Mahwah, NJ 07430
Tel: (201) 995-8816
Fax: (866) 936-0615

Docket No. 06-01506US05

Electronic Patent Application Fee Transmittal				
Application Number:		14543815		
Filing Date:		17-Nov-2014		
Title of Invention:		GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS		
First Named Inventor/Applicant Name:		Walid N. ABOUL-HOSN		
Filer:		Kirk D. Swenson		
Attorney Docket Number:		06-01506US05		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Request for Continued Examination	1801	1	1200	1200
Total in USD (\$)				1200

Electronic Acknowledgement Receipt	
EFS ID:	24535565
Application Number:	14543815
International Application Number:	
Confirmation Number:	9742
Title of Invention:	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS
First Named Inventor/Applicant Name:	Walid N. ABOUL-HOSN
Customer Number:	99185
Filer:	Kirk D. Swenson
Filer Authorized By:	
Attorney Docket Number:	06-01506US05
Receipt Date:	05-JAN-2016
Filing Date:	17-NOV-2014
Time Stamp:	20:20:15
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$1200
RAM confirmation Number	5663
Deposit Account	040170
Authorized User	SWENSON, KIRK
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 CFR 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	Request for Continued Examination (RCE)	2016-01-05_RCE_sb0030efs.pdf	1363858 44cd7685790acf8b4d06fab19030e953a21f8ea	no	3
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	06-01506US05_1.pdf	167097 b2469e18504b692976ebf15f7093f11d73cd5b60	no	5
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Transmittal Letter	2016_01_05_TRANSMITTAL_LETTER_1.pdf	74194 6c17515bb7a299e344c620d37895889525191c20	no	3
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	30786 f168ce8512a47dc34b0554c2f041dfd7608e1773	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			1635935		

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.

UTILITY PATENT APPLICATION TRANSMITTAL <i>(Only for new nonprovisional applications under 37 CFR 1.53(b))</i>	Attorney Docket No.	06-01506US05
	First Named Inventor	Walid N. ABOUL-HOSN
	Title	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS
	Express Mail Label No.	FILED ELECTRONICALLY via EFS WEB

APPLICATION ELEMENTS <i>See MPEP chapter 600 concerning utility patent application contents.</i>	Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450
1. ☐ Fee Transmittal Form (PTO/SB/17 or equivalent) 2. ☐ Applicant asserts small entity status. See 37 CFR 1.27 3. ☐ Applicant certifies micro entity status. See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent. 4. ☐ Specification [Total Pages _____] Both the claims and abstract must start on a new page. (See MPEP § 608.01(a) for information on the preferred arrangement) 5. ☐ Drawing(s) (35 U.S.C. 113) [Total Sheets _____] 6. ☐ Inventor's Oath or Declaration [Total Pages <u>3</u>] (including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e)) a. ☒ Newly executed (original or copy) b. ☐ A copy from a prior application (37 CFR 1.63(d)) 7. ☐ Application Data Sheet * See note below. See 37 CFR 1.76 (PTO/AIA/14 or equivalent) 8. ☐ CD-ROM or CD-R in duplicate, large table, or Computer Program (Appendix) ☐ Landscape Table on CD 9. Nucleotide and/or Amino Acid Sequence Submission (if applicable, items a. – c. are required) a. ☐ Computer Readable Form (CRF) b. ☐ Specification Sequence Listing on: i. ☐ CD-ROM or CD-R (2 copies); or ii. ☐ Paper c. ☐ Statements verifying identity of above copies	ACCOMPANYING APPLICATION PAPERS 10. ☐ Assignment Papers (cover sheet & document(s)) Name of Assignee _____ 11. ☐ 37 CFR 3.73(c) Statement ☐ Power of Attorney (when there is an assignee) 12. ☐ English Translation Document (if applicable) 13. ☐ Information Disclosure Statement (PTO/SB/08 or PTO-1449) ☐ Copies of citations attached 14. ☐ Preliminary Amendment 15. ☐ Return Receipt Postcard (MPEP § 503) (Should be specifically itemized) 16. ☐ Certified Copy of Priority Document(s) (if foreign priority is claimed) 17. ☐ Nonpublication Request Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent. 18. ☐ Other: _____ _____ _____ _____ _____

***Note:** (1) Benefit claims under 37 CFR 1.78 and foreign priority claims under 1.55 **must** be included in an Application Data Sheet (ADS).
(2) For applications filed under 35 U.S.C. 111, the application must contain an ADS specifying the applicant if the applicant is an assignee, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter. See 37 CFR 1.46(b).

19. CORRESPONDENCE ADDRESS					
☒ The address associated with Customer Number: 99185 OR ☐ Correspondence address below					
Name _____					
Address _____					
City _____		State _____		Zip Code _____	
Country _____		Telephone _____		Email _____	
Signature		/Kirk D. Swenson/		Date	
				January 5, 2016	
Name (Print/Type)		Kirk D. Swenson		Registration No. (Attorney/Agent)	
				52,265	

This collection of information is required by 37 CFR 1.53(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.**

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 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.
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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	
EFS ID:	24525881
Application Number:	14543815
International Application Number:	
Confirmation Number:	9742
Title of Invention:	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS
First Named Inventor/Applicant Name:	Walid N. ABOUL-HOSN
Customer Number:	99185
Filer:	Kirk D. Swenson/Kathleen Andree
Filer Authorized By:	Kirk D. Swenson
Attorney Docket Number:	06-01506US05
Receipt Date:	05-JAN-2016
Filing Date:	17-NOV-2014
Time Stamp:	11:53:49
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

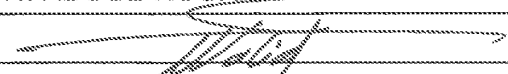
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Oath or Declaration filed	FULLY_EXECUTED_DEC_aia0001.pdf	1049756 160e1d98e62b4fe9caf4c034f3552eb450010d4	no	3

Warnings:

Information:

2	Transmittal Letter	2016-01-05_Transmittal_of_Oa ths_aia0015.pdf	275263 626b2970a06bc72c1781cb1a611522de9d5 d1328	no	2
Warnings:					
Information:					
Total Files Size (in bytes):				1325019	
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. <u>New Applications Under 35 U.S.C. 111</u> 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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.					

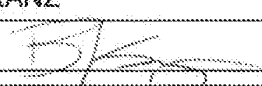
**DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN
APPLICATION DATA SHEET (37 CFR 1.76)**

Title of Invention	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS
As the below named inventor, I hereby declare that: This declaration is directed to: ☐ The attached application, or ☒ United States application or PCT international application number <u>14/543,815</u> filed on <u>November 17, 2014</u> The above-identified application was made or authorized to be made by me. I believe that I am the original inventor or an original joint inventor of a claimed invention in the application. I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both. WARNING: Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available. LEGAL NAME OF INVENTOR Inventor: <u>Walid N. ABOUL-HOSN</u> Date (Optional): <u>Jan 9 2016</u> Signature:  Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.	

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1 minute 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.

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS
As the below named inventor, I hereby declare that: This declaration is directed to: ☐ The attached application, or ☒ United States application or PCT international application number <u>14/543,815</u> filed on <u>November 17, 2014</u> The above-identified application was made or authorized to be made by me. I believe that I am the original inventor or an original joint inventor of a claimed invention in the application. I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both. WARNING: Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.	
LEGAL NAME OF INVENTOR Inventor: <u>William R. KANZ</u> Date (Optional): <u>12/11/2015</u> Signature: <u></u>	
Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.	

This collection of information is required by 35 U.S.C. 116 and 37 CFR 1.63. 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 1 minute 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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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of
Invention

GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS

As the below named inventor, I hereby declare that:

This declaration
is directed to:

☐

The attached application, or

☒

United States application or PCT international application number 14/543,815

filed on November 17, 2014

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

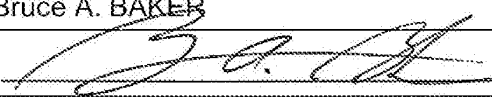
WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Bruce A. BAKER

Date (Optional): 22 FEB, 2015

Signature: 

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT Substitute for Form PTO-1449 (Not for submission under 37 CFR 1.99)	Complete If Known	
	Attorney Docket	06-01506US05
	Confirmation No.	9742
	First Named Inventor	Walid N. ABOUL-HOSN
	Application Number	14/543,815
	Filing Date	November 17, 2014
	Group Art Unit	3761
	Examiner Name	MARCETICH, ADAM M
Title		Guidable Intravascular Blood Pump and Related Methods
Sheet 1 of 5		

U.S. PATENTS						
Examiner Initial*	Cite No. (A1, A2, ...An)	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
				YYYY-MM-DD		
	A1	3966358	A	1976-06-29	Medac Gesellschaft fur Klinische Spezialpraparate mbH	

U.S. PATENT APPLICATION PUBLICATIONS						
Examiner Initial*	Cite No. (B1, B2, ...Bn)	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
				YYYY-MM-DD		

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

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	Filing Date	November 17, 2014
	Group Art Unit	3761
	Examiner Name	MARCETICH, ADAM M
	Title	Guidable Intravascular Blood Pump and Related Methods
Sheet 2 of 5		

FOREIGN PATENT DOCUMENTS								
Examiner Initial*	Cite No. (C1, C2, ...Cn)	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
					YYYY-MM-DD			
	C1	764448	EP	A2	1997-03-26	United States Surgical Corporation		
	C2	1222862	CN	A	1999-07-14	IMPELLA CARDIOTECHNIK GMBH		√
	C3	2349483	CA	A1	2000-06-08	IMPELLA CARDIOTECHNIK AKTIENGESELLSCHAFT		
	C4	2352234	CA	A1	2000-06-08	IMPELLA CARDIOTECHNIK AG		

Examiner Signature		Date Considered	
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.			
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	First Named Inventor	Walid N. ABOUL-HOSN
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	Examiner Name	MARCETICH, ADAM M
	Title	Guidable Intravascular Blood Pump and Related Methods
Sheet 3 of 5		

	C5	2355966	DE	A1	1975-05-22	Heimes et al.		√
	C6	4016013	DE	A1	1991-11-21	Knierbein et al.		√
	C7	4105278	DE	A1	1992-08-27	Rau et al.		√
	C8	10017147	DE	A1	2001-10-18	Voelker Wolfram		√
	C9	10018424	DE	A1	2001-10-25	Impella Cardiotechnik AG		√
	C10	19626224	DE	A1	1998-01-02	Rau et al.		√
	C11	29604787	DE	U1	1996-10-02	Hutzenlaub et al.		√
	C12	200000007	CZ	A3	2000-05-17	SAMMLER ET AL.		√
	C13	2000029056	WO	A3	2001-01-04	CORVASCULAR INC.		
	C14	2000029056	WO	A2	2000-05-25	CORVASCULAR INC.		
	C15	2000033047	WO	A1	2000-06-08	IMPELLA CARDIOTECHNIK AG		√

Examiner Signature		Date Considered	
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	Group Art Unit	3761
	Examiner Name	MARCETICH, ADAM M
Title		Guidable Intravascular Blood Pump and Related Methods
Sheet 4 of 5		

	C16	2000037139	WO	A1	2000-06-29	A-MED SYSTEMS INC.		
	C17	2000053240	WO	A1	2000-09-14	ABIOMED INC.		
	C18	2000074748	WO	A1	2000-12-14	GOLDOWSKY Michael P.		
	C19	2001039817	WO	A3	2002-1-10	IMPELLA CARDIOTECHNIK AG		√
	C20	2001039817	WO	A2	2001-06-07	IMPELLA CARDIOTECHNIK AG		√
	C21	2042827	CA	A1	1991-11-19	Forschungsges ellschaft fur Biomedizinisch e technik e.V.		

NON PATENT LITERATURE DOCUMENTS				
Examiner Initial*	Cite No. (D1, D2, ...Dn)	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.		
	D1	T. Siess et al., "Concept, Realization, and First In Vitro Testing of an Intraarterial Microaxial Blood Pump", Artificial Organs, Volume 19, Issue 7, pages 644-652, July 1995.		

Examiner Signature		Date Considered	
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	Group Art Unit	3761
	Examiner Name	MARCETICH, ADAM M
Title	Guidable Intravascular Blood Pump and Related Methods	
Sheet 5 of 5		

	D2	K.C. Butler et al., "The Hemopump - a New Cardiac Prosthesis Device", IEEE Trans Biomed Eng. 1990;37:193-196.	
	D3	T. Siess, "System Analysis and Development of Intravascular Rotary Pumps to Support the Heart" (original title in German Systemanalyse und Entwicklung intravasaler Rotationspumpen zur Herzunterstützung), Shaker, 189 pages, 1999.	√
	D4	Kirsten-Treptow, P., & Sieß, T. (2000). The intracardiac pump system – High-tech product and Technology Platform (original title in German "Das intrakardiale Pumpsystem - Hightech-Produkt und Technologie-Plattform"). Kardiotechnik, 9(3), pp. 77 - 80.	√
	D5	H. Reul et al., "Artificial Heart and Assist Device: New Developments at the Helmholtz Institute", Chapter from <u>Heart Replacement</u> , publ. Springer (Japan), pages 201-227, 1996.	
	D6	B. Meyns et al., "Coronary Artery Bypass Graft with Biventricular Microaxial Pumps", Journal of Perfusion. 1999 Jul;14(4):pages 287-290.	
	D7	B. Meyns et al., Micro pumps to Support the Heart During CABG, European Journal of Cardiothorac Surg (2000) 17 (2): pages 169-174.	
	D8	Reul et al., "Rotary Blood Pumps in Circulatory Assist", Perfusion, 1995 May; 10(3); pp 153 – 168.	
	D9	U. Lonn et al., "Beating Heart Coronary Surgery Supported by an Axial Blood Flow Pump", The Annals of Thoracic Surgery, January 1999, Vol. 67, Issue 1, pp 99-104.	

Examiner Signature		Date Considered	
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.			
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Customer No.: 99185

Docket No.: 06-01506US05

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re

application of: Walid N. ABOUL-HOSN et al.

Serial No.: 14/543,815

Confirmation No.: 9742

Filed: November 17, 2014

Group Art Unit: 3761

For: GUIDABLE INTRAVASCULAR
BLOOD PUMP AND
RELATED METHODS

Examiner: MARCETICH, Adam

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir/Madam:

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 Supplemental Information Disclosure Statement (SIDS) 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.

Docket No. 06-01506US05

The filing of this Supplemental Information Disclosure Statement and the enclosed SDS 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.

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. ☒ Documents Not in English. Documents C1, C3, C4, C13, C14, C16, C17, C18, and C20 are submitted in English.

- a. ☒ English-language Abstracts of the non-English language references are attached hereto. See item(s) C6, C8, C9, C10, C12, C15, C19. A

Docket No. 06-01506US05

DERWENT Abstract is included for reference C5. For those abstracts that were translated via a machine, Applicant does not attest to the accuracy of the machine translation.

b. ☒ A machine translation of document(s) C5, C7, and C11 is included, as translated by “Google Translate.” Applicant does not attest to the accuracy of the machine translation.

c. ☒ Other:

- i. Document C21 is believed to be an English equivalent of reference C6.
- ii. Document C1 is believed to be an English equivalent of reference C15.
- iii. Document A1 is believed to be an English equivalent of reference C5.

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 Deposit Account No. 04-0170, reference number 06-01506US05. However,

Docket No. 06-01506US05

the Commissioner is not authorized to charge the cost of the issue fee to the Deposit
Account 04-0170.

Respectfully submitted,

DATE: January 11, 2016

/Kirk D. Swenson/

Kirk D. Swenson
Registration No. 52,265
Agent for Applicant(s)
MAQUET Cardiovascular LLC
1300 MacArthur Boulevard
Mahwah, NJ 07430
Tel: (201) 995-8816
Fax: (866) 936-0615

Docket No. 06-01506US05



(12)EUROPEAN PATENT APPLICATION

(43) Date of publication:26.03.1997 Bulletin 1997/13

(51) Int. Cl.⁶: A61M 1/12

(21) Application number: 96115148.7

(22) Date of filing: 20.09.1996

(84) Designated Contracting States:
DE ES FR GB IT

(30) Priority: 22.09.1995 US 4184

(71) Applicants:

- United States Surgical Corporation
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(72) Inventors:

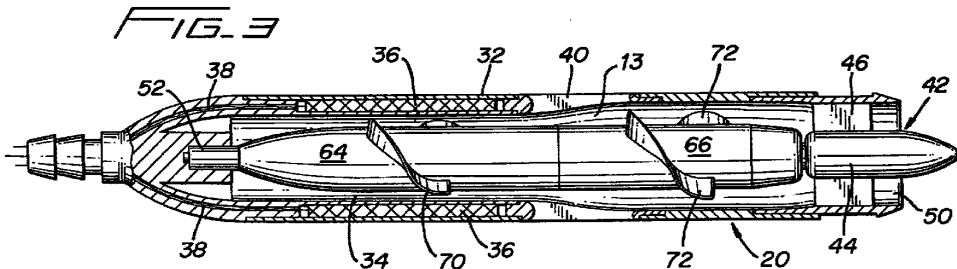
- Jarvik, Robert
New York, NY 10023 (US)
- Alesi, Daniel E.
Sherman, CT 06784 (US)

(74) Representative: Marsh, Roy David et al
Hoffmann Eitle & Partner
Patent- und Rechtsanwälte
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81925 München (DE)

(54) Cardiac support device

(57) An apparatus for pumping blood includes an elongated housing dimensioned to be at least partially positioned within the heart of a patient, a rotating member supported for rotational movement within the elongated housing and a drive mechanism for imparting rotational movement to the rotating member. The elongated housing includes an outer wall, a first inlet port for permitting blood to enter the elongated housing through a first end of the elongated housing and a second inlet port defined in the outer wall of the elongated housing for permitting blood to enter through the outer wall. The rotating member is rotatable to impart pumping energy to the blood entering through the first and second inlet ports to direct the blood through an outlet opening of the

elongated housing. The rotating member preferably includes first and second blood pumping blade arrangements. The first blade arrangement is dimensioned to impart pump energy to the blood entering the elongated housing through the first inlet port. The second blade arrangement is dimensioned to at least impart pump energy to the blood entering the elongated housing through the second inlet port. The electric motor stator and rotor define a space therebetween through which blood entering the first inlet passes. The motor is an ironless core copper electromagnetic windings which provides a sufficiently large air space for blood flow.



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Description**SUMMARY****BACKGROUND****1. Field of the Disclosure**

The present disclosure relates generally to cardiac support devices, and, more particularly, to a cannula pump which is implantable in the heart.

2. Description of the Relevant Art

Mechanical blood pumps are commonly utilized to temporarily support or substitute the pumping function of the heart during heart surgery or during periods of heart failure. The most widely applied blood pumps include roller pumps and centrifugal pumps. Typically, these pumps are a component of a cardiopulmonary bypass system (e.g., a heart-lung machine) which includes an oxygenator, a heat exchanger, blood reservoirs and filters, and tubing which transports the blood from the patient through the bypass system and back to the patient. With these systems, blood is withdrawn from the patient via an uptake cannula positioned within the vena cavae and atria or ventricles of the heart, transported through the bypass system located outside the patient's body, and pumped back into the pulmonary artery and aorta via a return cannula.

Although these cardiopulmonary bypass systems have been generally effective, they are subject to certain disadvantages. In particular, these bypass systems are relatively complicated and expensive to manufacture, expose the blood to a high surface area of foreign materials which ultimately damages the blood, require full anticoagulation, and require considerable set up time and continual management by a skilled technician (perfusionist), which also adds to the expense of the procedure.

PCT WO 94/09835 to Robert Jarvik discloses a cannula pump for temporary cardiac support. The Jarvik cannula pump includes an elongated cannula housing having a miniature rotary pump disposed therein and an electric motor which drives the rotary pump via a small shaft. The rotary pump is mounted for rotational movement about blood-immersed mechanical bearings. The cannula pump is inserted into one of the ventricles of the heart through a small incision. In one embodiment, the electric motor is miniaturized to be positioned within the heart.

Although the Jarvik cannula pump has shown great potential as a device to supplement or replace the total pumping function of the heart during, e.g., bypass surgery, the present disclosure is directed to further improvements of the Jarvik cannula pump whereby the pumping capacity is improved by, for example, the provision of two pumping sections and where concerns regarding sealing between the stationary and moving parts are essentially eliminated by directing the blood flow through the sealed electric motor.

The present disclosure relates to an apparatus for pumping blood comprising an elongated housing dimensioned to be at least partially positioned within the heart of a patient, a rotating member supported for rotational movement within the elongated housing and a drive mechanism for imparting rotational movement to the rotating member. The elongated housing includes an outer wall, at least a first inlet port for permitting blood to enter the elongated housing through a first end of the elongated housing and at least a second inlet port defined in the outer wall of the elongated housing for permitting blood to enter through the outer wall. The rotating member is rotatable to impart pumping energy to the blood entering through the first and second inlet ports to direct the blood through an outlet opening of the elongated housing.

The rotating member preferably includes first and second blood pumping blade arrangements (although one blade arrangement is also contemplated). The first blade arrangement is dimensioned to impart pump energy to the blood entering the elongated housing through the first inlet port. The second blade arrangement is dimensioned to impart pump energy to the blood entering the elongated housing through the second inlet port as well as the first inlet port.

The drive mechanism of the apparatus may be enclosed within the elongated housing. The drive mechanism preferably includes an electric motor incorporating a magnetically actuated rotor and a motor stator where the rotor is embedded within the rotatable member. The motor stator and the rotatable member define an annular space therebetween through which blood entering the first inlet passes and is acted upon by the first blade arrangement.

A method for supporting all or part of the pumping function of a heart by endoscopically inserting the apparatus is also disclosed.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the disclosure are described hereinbelow with reference to the drawings wherein:

FIG. 1 is a perspective view of the cardiac support device in accordance with the principles of the present disclosure;

FIG. 2 is a cross-sectional view of the cardiac support device taken along lines 2-2 of FIG. 1;

FIG. 3 is a side plan view of the cardiac support device in partial cross-section illustrating one embodiment of the configuration of the impeller blades of the rotating member (with the flexible cannula removed);

FIG. 4 is a cross-sectional view of the cardiac support device taken along lines 4-4 of FIG. 2;

FIG. 5 is a cross-sectional view of the cardiac support device taken along lines 5-5 of FIG. 2;

FIG. 6 is a cross-sectional view of the cardiac support device taken along lines 6-6 of FIG. 2;

FIG. 7 is a perspective view of the impeller blade structure of the cardiac support device of FIG. 2;

FIG. 8 is a perspective view of an alternate impeller blade structure;

FIG. 9 is a perspective view of another alternate impeller blade structure;

FIG. 10A is an axial cross-sectional view of the motor unit of the cardiac support device with the impeller blades removed to illustrate the cross-sectional area of the motor air gap provided with a motor unit having an iron core;

FIG. 10B is a view similar to the view of FIG. 10A illustrating the relatively enlarged cross-sectional area of the motor air gap as provided through the incorporation of an ironless core motor unit;

FIG. 10C is a view similar to the view of FIG. 10B illustrating an alternate embodiment of the ironless core motor unit where the diameter of the rotor is reduced to further increase the cross-sectional area of the motor air gap;

FIG. 11 is a schematic drawing of the heart illustrating a first cardiac support device inserted through the apex of the left ventricle with the out-flow across the aortic valve into the aorta and a second cardiac support device inserted across the apex of the right ventricle with the outflow across the pulmonic valve into the pulmonary artery;

FIG. 12 is a view illustrating an alternate method for applying the cardiac support device where endoscopic techniques are incorporated, illustrating a first endoscopic portal for delivering the device and a second endoscopic portal for permitting the introduction of an endoscopic viewing apparatus;

FIG. 13 is a view illustrating the cardiac support device introduced through the endoscopic portal to be positioned within the apex of the heart;

FIG. 14 illustrates an alternate method for applying the cardiac support device utilizing endoscopic techniques where the aorta is accessed and the cardiac support device is inserted within the aorta for positioning within the heart;

FIG. 15 is a side plan view in partial cross-section of an alternate embodiment of the cardiac support device of FIG. 1; and

FIG. 16 is a cross-sectional view of the cardiac support device of FIG. 15 taken along lines 16-16.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT(S)

Referring now in detail to the drawings wherein like reference numerals identify similar or like components throughout the several views, FIGS. 1-2 illustrate a preferred embodiment of the cardiac support device or cannula heart pump in accordance with the principles of the present disclosure. Support device 10 may be used to supplement or totally replace the pumping function of the heart during cardiac surgery, during temporary periods of heart failure and during medical emergencies involving severe heart failure. Support device 10 is advantageously dimensioned to be positioned within either the left or right ventricle of a patient's heart and preferably has a length ranging from about 2 to about 3 inches and a diameter ranging from about 9 to 12 millimeters, and is more preferably 2 inches in length with a diameter of 10 mm. Flexible cannula 11, only a portion of which is illustrated in Fig. 1, is placed over support device 10, and preferably has a length of 1-4 inches and substantially the same diameter as the device 10.

Support device 10 includes generally cylindrically-shaped cannula housing 12 having an elongated opening or axial bore 13 and a rotating member 14 coaxially mounted within the bore 13. Cannula housing 12 has three component parts or sections integrally connected to each other by conventional means to form a single cannula unit. The sections include first or inlet section 16, second or intermediate section 18 and third or exit section 20.

Inlet section 16 includes a central hub 22, and a plurality of spokes 26 (e.g., four) extending contiguously from the cylindrical portion 24 interconnecting central hub 22 and cylindrical portion 24. Central hub 22 houses stationary bearing pin 28 which supports the proximal end of rotating member 14. A plurality of axial openings 30 (FIG. 1) defined between adjacent spokes 26 form blood inlet ports to permit the axial inflow of blood into cannula housing 12 as will be discussed below.

Referring now to FIGS. 2-3, in conjunction with the axial cross-sectional view of FIG. 4, intermediate section 18 of cannula housing 12 accommodates the drive mechanism or electric motor unit of the device 10 and includes an outer tube 32 and an inner tube 34 coaxially mounted within the outer tube 32. Outer tube 32 and inner tube 34 define a generally annular space therebetween which accommodates and effectively seals the electromagnetic wire windings 36 of the motor unit. In a preferred embodiment, electromagnetic wire windings 36 are fabricated from copper and the motor is an iron-

less core design for reasons which will be discussed below. Electromagnetic windings 36 are in electrical contact with a plurality of electrical wires 38 which supply the electric current necessary to generate the electromagnetic fields required to rotate rotating member 14. Electrical wires 38 are embedded within spokes 26 of housing 12 and extend from the spokes 26 to an electric source located outside the body.

Referring now to FIGS. 1-3, in conjunction with the axial cross-sectional view of FIG. 5, third section 20 of cannula housing 14 defines the pump chamber or pump housing of device 10 and has a plurality of elongated axial slots 40 formed in its outer surface at a location adjacent second section 18. Although four axial slots 40 are shown, a different number of slots as well as slots of different configurations are also contemplated. Axial slots 40 are preferably equidistantly spaced and serve as side inlet ports to permit the entry of blood through the side of cannula housing 12 and into exit section 20. Exit section 20 also includes a pump stator housing 42 possessing central hub 44 and pump stator blades 46 integrally connected to the central hub 44 and the outer wall of the exit section as shown in FIG. 6. Central hub 44 possesses stationary bearing pin 48 (FIG. 2) which is fixedly secured to the central hub 44 and serves to rotatably support the distal end of rotatable member 14. Exit section 20 also defines an axial opening or outlet port 50 to permit the pumped blood which entered through side ports 40 as well through openings 30 to exit cannula housing 12.

Flexible cannula 11 is preferably in the form of a tube placed over device 10 at the distal end to carry the pumped blood further in the artery. The cannula 11 preferably has a soft tip to avoid damage to the valve during insertion of the pump. The cannula optionally terminates in a solid hub and a plurality of spaced apart spokes similar to inlet section 16. It is preferably frictionally fit over device 10 although other modes of attachment are also contemplated.

Referring now to FIGS. 2-3, the motor unit of cannula pump 10 will be described. Rotating member 14 is supported for rotational movement within cannula housing 12 at one end by rotatable journal bearing 52 which is mounted about stationary bearing pin 28 and at the other end by rotatable journal bearing 54 which is mounted about stationary bearing pin 48. Journal bearings 52, 54 are fixedly secured within respective recesses 56, 58 formed in rotating member 14 and, thus, rotate with rotating member 14 about their respective stationary bearing pins 26, 48. Journal bearings 52, 54 are intended to absorb the thrust loads exerted by the action of rotating member 14 against the blood and are fabricated from a suitable material for this purpose such as ceramic or pyrolytic carbon.

Rotating member 14 has two sections, namely, rotor section 64 and impeller section 66. Rotor section 64 and impeller section 66 may be two separate components bonded to each other along adjacent end surfaces, as shown in the FIGS., or, in the alternative, may

be a single component. Rotor section 64 has a built-in high energy bar or motor magnet 68 which cooperates with the magnetic fields produced by electromagnetic windings 36 to effectuate rotational movement of rotating member 14. The preferred materials of fabrication for rotor magnet 68 includes samarium-cobalt, neodymium-iron-boron, or any other suitable magnetizable material.

Referring still to FIGS. 2-3, rotating member 14 has a first or proximal set of blades 70 on rotor section 64 and a second or distal set of blades 72 on impeller section 66. In one embodiment shown in FIGS. 2, 3, and 7, each set of blades 70, 72 includes two diametrically opposed blades which provide for an axial flow type pumping action on the blood. In FIG. 7, only the impeller section 66 of rotating member 14 is shown since the blades 70 on rotor section 64 are identical. The blades 70, 72 preferably wrap about the perimeter of rotating member 14 for a distance between about 1/4-3/4 of the circumference of rotating member 14. Other blade arrangements are possible as well, particularly that of only a single blade configuration placed either at the rotor section 64 or impeller section 66. In particular, depending on the pumping parameters desired, the blade structure could be modified to provide a mixed flow (i.e., a blood flow having both an axial component and a centrifugal component). In addition, the number of blades in first and second sets of blades 70, 72 could be increased to three, for example, as shown in FIG. 8 or reduced to one single blade as shown in FIG. 9 to regulate the flow rate and back pressure of blood pumped by the cardiac support device. The direction of rotation and direction of blood flow is indicated by the arrows in FIGS. 7-9. Although shown as identical, it is also contemplated that the blade design for the rotor section 64 and the impeller section 66 could be different. The flow rate, typically referenced in liters/minute, is measured by the product of the velocity and cross-sectional area divided by the time. The velocity is measured as: meters/second.

In operation, the proximal set of blades 70 impart a pumping action to the blood entering into cannula housing 12 through axial inlet ports 30 and passing through the annular motor gap, referred to as the air gap, defined between rotor section 64 and inner tube 34 of cannula housing 12. The distal set of blades 72 impart mechanical energy to the blood entering cannula housing 12 through side inlet ports 40 and blood exiting the motor air gap and pumped by proximal blades 70. Thus, blood entering cannula housing 14 through axial inlet ports 30 initially passes over the proximal set of blades 70 within the motor chamber and then over the distal set of blades 72 within the pump chamber. Blood entering side inlet ports 42 passes over only the distal set of blades 72.

In a preferred embodiment, the volume of blood flow entering axial inlet ports 30 and passing through the motor air gap constitutes approximately 1/4 - 1/3 of the total volume pumped (e.g., approximately 1-2 lit-

ers/min. out of total pump flow of 4-6 liters/min.) by device 10. The remaining blood flow enters side inlet ports 40 of cannula housing 12 to be directed over and acted upon by blades 72. Clearly other volume ratios of blood entry through the axial and side ports are contemplated.

Although the volume of blood flowing through the motor chamber in the preferred embodiment accounts for only 1/4-1/3 of the total volume pumped by cardiac support device 10, this is a relatively significant amount of blood to pass through the motor air gap. The capability to accommodate a relatively large volume of blood through the motor air gap is attributed to the use of an ironless core copper electromagnetic windings 36 as opposed to employing copper windings supported by an iron core. The motor is a brushless motor to avoid mechanical failure of the brushes, e.g. arcing or wearing out, and to enable performance feedback, for better controlling the operation of the motor. Thus, the ironless core copper electromagnetic windings 36 occupy a significantly smaller cross-sectional area in the motor unit than a conventional iron core electromagnet winding, thereby increasing the total cross-sectional area of the motor air gap, i.e., the area defined between rotor section 64 and inner tube 34 of housing 12. As a result of this enlarged area of the air gap as provided through the incorporation of an ironless core copper electromagnetic windings 36, the following benefits are realized: 1) the motor unit can accommodate a greater volume of blood flow; 2) damage to the blood flowing through the motor is minimized since shearing of the blood with surfaces of the support device 10 is reduced; 3) a larger diameter rotor or rotor section 64 can be utilized which results in an increased cross-sectional area and an increase in blood flow; 4) sealing concerns of the motor and the moving components is essentially eliminated due to the aforementioned increase in the rate of blood flow through the device 10 and the motor air gap, which prevents blood from clotting within the motor without the need for dilution of the blood with saline or other fluids; 5) the blood constantly flows past the motor thereby eliminating any stagnation points which could result in blood clotting; and 6) the constant blood flow dissipates heat generated by the motor which could otherwise damage the blood.

FIG. 10A is an axial cross-sectional view of the motor unit of the support device 10 with the first set of blades 70 of the motor section removed for illustrative purposes. In FIG. 10A, the motor unit is shown incorporating an iron core with conventional electromagnetic windings 36. FIG. 10B is a view similar to the view of FIG. 10A and illustrates the motor unit incorporating ironless core copper electromagnetic windings 36 in accordance with the preferred embodiment of the present disclosure. In both FIGS. 10A and 10B, the electromagnetic forces produced by the respective windings are comparable and the distance between rotor section 64 and inner tube 34, i.e., the distance "d" of the motor air gap, is identical. However, as can be

seen by comparing FIGS. 10A and 10B, the ironless core copper windings 36 of the embodiment of FIG. 10B occupy a significantly smaller cross-sectional area than that occupied by the conventional windings of FIG. 10A.

Thus, as can be seen, the motor unit incorporating ironless core copper windings defines a motor air gap (space) with a greater total cross-sectional area to thereby accommodate a greater volume of blood and improve the pumping capabilities of the support device. As also depicted in the drawings, since the ironless core copper electromagnetic windings 36 (FIG. 10B) occupy a smaller area, a larger diameter rotor section or rotor 64 can be employed while maintaining the same distance "d" of the motor air gap, thus, further increasing the pumping capabilities of the device 10.

By way of example, a working embodiment of the motor unit of FIG. 10A has a rotor section 64 with a diameter of .165 inches and a motor air gap distance "d" of 0.025 inches. That is, the area A1 of the air gap in Fig. 10A is defined by;

$A1 = \pi r_1^2 - \pi r_2^2$, where r_1 is the distance from the center of the motor to the inner wall of the inner tube 34; and r_2 is the distance from the center of the motor to the outer wall of the rotor magnet 68.

By way of example, in a working embodiment of the motor unit of FIG. 10B incorporating copper windings 36, the diameter of rotor section 64 is .230 inches and the distance "d" of the motor air gap is identical to that of the motor unit of FIG. 10A, i.e., .025 inches.

The area A2 of the air gap in Fig. 10B is defined by;

$A2 = \pi r_3^2 - \pi r_4^2$, where r_3 is the distance from the center of the motor to the inner wall of the inner tube 34; and r_4 is the distance from the center of the motor to the outer wall of the rotor magnet 68.

To show by way of example the increased cross-sectional area of air gap Fig. 10B utilizing e.g. ironless core copper windings compared to Fig. 10A utilizing windings with an iron core; if $r_1 = .145$ inches and $r_2 = .115$ inches, the air gap area A1 would be .030 inches and the cross-sectional area of the air gap would be .0175 in². If, for comparative purposes, $r_3 = .108$ inches, and $r_4 = .078$ inches, the air gap A2 would be .030 inches and the cross-sectional area would be .025 in². Thus by keeping the overall diameter of the motor unit constant, e.g. at .402 inches, cross-sectional area of the air gap is increased by approximately 40%.

FIG. 10C depicts an alternate configuration of the motor unit of FIG. 10B. In this embodiment, the diameter of rotor section 64 is reduced to even further increase the cross-sectional area of the air gap between the motor stator and rotor section 64. Although in this embodiment the magnetic field as generated by ironless core copper electromagnetic windings 36 is further from rotor magnet 68 of rotor section 64, the magnetic flux losses would be compensated by the longer moment

arm as provided by the relatively long diameter of the rotor section 64 as compared to the diameter of the rotor for the stainless steel or iron core stator of FIG. 10A. Thus, the motor unit of FIG. 10C can accommodate an even larger volume of blood. By way of example, a working embodiment of the motor unit of FIG. 10C utilizes a rotor having a radius of .105 inches and provides a distance "d" of the motor air gap of .040 inches. The total cross-sectional area of the motor air gap is approximately .031 inches ($1r5^2 - 1r6^2$). This represents an increase in cross-sectional area of approximately 80% over that of the iron core motor stator of FIG. 10A.

Referring now to FIG. 11, a generally schematic view of the heart showing two devices 10 of the present disclosure inserted for support of both the left heart function and the right heart function is illustrated. It should be understood that in the alternative, only one support device can be used to support either the left or the right heart function. In the illustrated embodiment, the left ventricle, generally indicated at A, contains one device 10 and the right ventricle, indicated at B, contains another device 10. The outflow portions of the support devices 10 deliver blood respectively from the left ventricle A into the aorta C, and from the right ventricle B into the pulmonary artery D. As previously described, the blood enters through axial ports 30 and side ports 40 as indicated by the directional arrows 25, 27 and is emitted through the outflow opening 50 as shown. Thus, the support devices 10 intake blood from both ventricles A, B and pump the blood into the two main arteries C, D. Since the entire volume of blood within the support device 10 remains within the ventricles or arteries, it is appropriate to consider that the priming blood volume of this pump is essentially zero. That is, no blood need be withdrawn from the cardiovascular system to fill the pump and tubing circuit with this embodiment.

Each device 10 is respectively inserted through a small incision in the apex of either ventricle and may be held there by a purse-string suture (not shown). Since in this embodiment the devices 10 are inserted when the patient's open chest is open and the heart is exposed, the surgeon can readily feel the heart and easily ascertain that the tip of the flexible cannula 11 has passed across the proper valve, i.e., the aortic valve or pulmonary artery valve, and into the aorta or pulmonary artery as desired, rather than across an inflow valve and into the left atrium or right atrium, which would be improper. The anatomy of the heart makes proper placement relatively simple and direct path from the apex to the aorta and to the pulmonary artery. With support devices 10 inserted in the fashion shown in Figure 11, the outflow valve, that is the aortic valve or pulmonary valve, is able to close around the outside of the flexible cannula 11 thereby permitting a sufficient seal to prevent major leakage back from the artery into the respective ventricle A,B. Thus, support devices 10 may be applied and sealed by the aortic or pulmonary valves thereby leaving the valves undamaged.

It is also to be appreciated that in the alternative,

the entire support device 10 can be positioned within the heart.

Referring now to FIGS. 12-13, there is illustrated an alternate method for positioning support device 10 within the patient's heart. In accordance with this method, support device 10 is inserted utilizing endoscopic (thoracoscopic) surgical techniques. In endoscopic procedures, surgery is performed in the body through narrow endoscopic tubes or portals inserted through small entrance wounds in the skin. Endoscopic procedures, by being less invasive, have the advantage of reducing the patient's recovery time and thereby reducing costs.

In accordance with the endoscopic method, an endoscopic tube or portal 80 is positioned within the patient's chest cavity to access the heart area as shown. The endoscopic tube 80 may be positioned proximal to the abdominal cavity and within adjacent ribs to access the open area of the heart. In this application, the endoscopic portal 80 would be in an offset position as shown in FIG. 12 to avoid the sternum bone. Typically, at least a second endoscopic portal 82 would be positioned within the chest cavity to permit the insertion of an endoscope to view the procedure being performed. It is also envisioned that additional endoscopic portals may be utilized to permit the introduction of endoscopic surgical instrumentation into the chest cavity to assist the surgeon in accessing the heart and positioning the support device 10 within the heart. Further, another endoscopic tube 84 would be utilized if two support devices 10, one for each side of the heart, are to be used. A cuff 86 may also be utilized to restrict blood flow when the support device 10 is inserted. Cuff 86 has a flexible tube portion 87 configured to receive the support device 10 and a flange 88 which is attached to the apex by glue, staples or other fastening means. The endoscopic portal 80 is inserted through cuff 86 to provide an access port for the support device 10. The support device 10 is inserted through the port 80 and cuff 86. A similar cuff can be utilized in conjunction with endoscopic portal 84 if a second support device 10 is utilized.

With the endoscopic portals and instrumentation appropriately placed, the support device 10 is inserted through endoscopic portal 80 to a position adjacent the apex of the heart as shown in FIG. 13. The heart is accessed by, e.g., making an incision in the heart wall by an appropriate incising instrument inserted through an endoscopic tube, and the support device 10 is placed within the ventricle of the heart. The support device 10 is preferably positioned within the heart as illustrated in FIG. 11 whereby the outlet port 50 of the support device 10 is adjacent the corresponding artery. The support device 10 may be secured in place with the use of purse string stitches or the like as mentioned above. If two pumps are to be inserted, one in each ventricle, an access port for each device 10 would be required.

FIG. 14 illustrates another endoscopic method for

applying the cardiac support device 10. In accordance with this method, an endoscopic portal 80 is positioned to access the aorta C. Preferably, the portal 80 is positioned under the clavicle between the first and second ribs. Thereafter, the device 10 is inserted within the portal 80 and advanced to the aorta C. A cuff such as that described above could be utilized and attached to the device 10, i.e., the end having the motor unit, inserted within the aorta through, for example, an incision formed in the outer wall of the aorta by an incising instrument inserted through an endoscopic port and maneuvered down into the left ventricle through the aorta C to any of the positions shown in FIG. 11. The device 10 is oriented within portal 80 such that the rear end of the device 10, i.e., the end having the motor unit, exits the portal 80 first and is dropped down into the left ventricle. In this manner, the outlet port 50 is adjacent the aorta C as shown in FIG. 11. It could alternatively be inserted into the left subclavian artery. It is also envisioned that the pulmonary artery could be accessed and the device 10 maneuvered into the right ventricle B in a similar manner.

Referring now to FIG. 15, an alternate embodiment of the cardiac support device of the present disclosure is illustrated. Cardiac support device 100 includes cannula housing 102 having motor section 104 and pump section 106. Motor section 104 defines a tapered portion 108 of reduced cross-section at one end which is connected to the impeller section 106 by support pins 110. Support pins 110 are preferably embedded within each section 104, 106 to fixedly connect the two components. A plurality of inlet ports 112 are defined about tapered portion 108 of motor section 104 between adjacent support pins 110 to permit the direct entry of blood within impeller section 106 of cannula housing 102. Inlet ports 112 are generally axially disposed openings and, thus, provide an axial path for blood to enter cannula housing 102 at this intermediate location. Pump section 106 possesses pump stator housing 114 having central hub 116 and pump stator blades 118.

Rotating member 120 of device 10 includes rotor section 122 and impeller section 124 connected to the rotor section 122 by rotating drive shaft 126. Drive shaft 126 is securely connected to each section 122, 124 thus providing for corresponding rotational movement of the two components. Rotor section 122 includes rotor magnet 128 (as shown in phantom) and rotor blade 130 (also shown in phantom). Impeller section 124 includes impeller blade 132. Rotating member 120 is supported for rotational movement in a manner similar to that described in connection with the embodiment of FIG. 1.

An elongated cannula portion 134 is connected to pump section 104 of device 100 and extends beyond pump stator housing 114. Elongated cannula portion 134 is typically at least partially positioned within a respective artery associated with either the left or right ventricles to ensure the outlet opening of cannula housing 102 is disposed within the artery.

As previously described, rotor section 122 and

impeller section 124 each includes only one blade member, i.e., rotor blade 130 and impeller blade 132. As best shown in the cross-sectional view of FIG. 16, rotor blade 130 extends about rotating member 120 for a distance of about 1/3 or less of the circumference of the rotating member 120. Impeller blade 132 extends about rotating member 120 for a distance of about 2/3 or more of the circumference of the rotating member 120. Rotor blade 130 can possess this relatively small dimension since the volume of blood pumped by this blade 130 is small compared to the total volume pumped by device 10 (i.e., 1-2 liters/min. of 4-6 liters/min.). The two blades 130, 132 are preferably disposed substantially opposite each other or diametrically opposed on their respective sections 122, 124 of rotating member 114 so as to minimize the radial imbalance of the rotating member 114. Other blade configurations are envisioned as well including the blade configurations of FIGS. 7-9.

Blood entering cannula housing 102 through axial inlet ports 30 defined between adjacent spokes 26 of cannula housing 102 passes through the motor air gap defined between inner tube 34 and rotor section 122 of rotating member 114 where the blood is acted upon by single rotor blade 130. The blood is then directed through the interior of tapered portion 108 within an annular space defined between rotating drive shaft 126 and the inner wall of the tapered portion 108 and released through an exit opening of the tapered portion into pump section 106 of cannula housing 102. Impeller blade 126 imparts mechanical energy to the blood and directs the blood over stator blades 126 through the longitudinal opening of cannula portion 134.

Blood entering directly through inlet ports 112 is acted upon by impeller blade 132 of impeller section 124 and pumped through cannula portion 134. Since inlet ports 112 are generally axial openings, the blood entering the ports 112 takes a direct axial path into cannula housing 102 coincident with the path the blood takes through pump section 106 across impeller blade 132, thus, enhancing the pumping capabilities of support device 100. This device 100 can be inserted into the heart in similar ways as the device 10 discussed above.

The support devices of FIGS. 1 and 15 can be fabricated utilizing primarily injection-molded, polymeric materials permitting low cost and disposability of the cannula housings and pumps themselves. The electric motors may be provided in a reusable configuration or may be made very inexpensive to make it economically feasible to dispose of the motors after use.

While the above description contains many specifics, these specifics should not be construed as limitations, on the scope, but merely as an exemplification of a preferred embodiment thereof. For example, the blade arrangement of the embodiment of FIG. 15 can be incorporated in the embodiment of FIG. 1. Those skilled in the art will envision other possible variations that are within the scope and spirit of the claims appended hereto.

Claims**1. An apparatus for pumping blood, which comprises:**

a) an elongated housing dimensioned to be at least partially positioned within the heart of a patient, the elongated housing including an outer wall, a first inlet port for permitting blood to enter the elongated housing through a first end of the elongated housing and a second inlet port defined in the outer wall of the elongated housing for permitting blood to enter through the outer wall;

b) a rotating member supported for rotational movement within the elongated housing and rotatable to impart pumping energy to the blood entering through the first and second inlet ports to direct the blood through an outlet opening of the elongated housing; and

c) a drive mechanism for imparting rotational movement to the rotating member.

2. The apparatus according to claim 1 wherein the first end of the elongated housing is open and wherein the first inlet port is the first end.**3. The apparatus according to any of the preceding claims including a plurality of second inlet ports defined in the outer wall of the cannula housing and the first and second inlet ports are axially displaced relative to each other.****4. The apparatus according to any of the preceding claims wherein the rotating member includes first and second blood pumping blade arrangements, the first blade arrangement dimensioned to impart pump energy to the blood entering the elongated housing through the first inlet port, the second blade arrangement dimensioned to at least impart pump energy to the blood entering the elongated housing through the second inlet port.****5. The apparatus according to any of the preceding claims wherein the first and second blade arrangements each include at least one blade mounted to the rotatable member and wherein the first blade arrangement includes a first blade which extends about 1/3 the distance of the periphery of the rotating member and wherein the second blade arrangement includes a second blade which extends about 2/3 the distance of the periphery of the rotating member, the positions of the first and second blade being substantially opposite one another so as to minimize radial imbalance of the rotating member.****6. The apparatus according to any of the preceding**

claims wherein the drive mechanism is enclosed within the cannula housing and wherein the drive mechanism includes an electric motor, the electric motor including a magnetically actuated rotor and a motor stator.

7. The apparatus according to any of the preceding claims wherein the rotor of the electric motor is embedded within the rotatable member.**8. The apparatus according to any of the preceding claims wherein the rotatable member and the motor stator define an annular space therebetween through which blood entering the first inlet passes.****9. The apparatus according to any of the preceding claims wherein the motor stator includes ironless core copper electromagnetic windings.****10. An apparatus for pumping blood, which comprises:**

a) an elongated housing defining a generally longitudinal axis and having at least one opening at a first location to permit blood to enter the elongated housing at the first location and at least one opening at a second location axially displaced from the first location to permit blood to enter the elongated housing at the second location;

b) a rotating member supported for rotational movement within the elongated housing, the rotating member including first and second blood pumping blade arrangements, the first blade arrangement imparting pump energy to the blood entering the elongated housing through the at least one opening at the first location and the second blade arrangement imparting pump energy to at least the blood entering the elongated housing through the one at least opening at the second location; and

c) a drive mechanism disposed within the elongated housing for imparting rotational movement to the rotating member.

11. The apparatus according to claim 10 wherein the one opening at the first axial location is an open end of the elongated housing and the first and second blade arrangements are substantially identical in configuration.**12. An apparatus for pumping blood, which comprises:**

an elongated housing member including a motor chamber and a pump chamber, the housing member having at least a first opening to permit blood to enter the motor chamber and

at least a second opening to permit blood to enter the pump chamber, the housing member further including an outflow opening to permit blood to exit the housing member;

5

a rotatable member supported for rotational movement within the housing to impart pumping energy to blood entering the motor and pump chambers through respective first and second openings of the housing member; and

10

an electric motor disposed within the motor chamber for imparting rotational movement to the rotatable member, the electric motor including a magnetically actuated rotor mounted to the rotatable member and a motor stator, the rotatable member and the motor stator defining a space therebetween through which blood entering the first opening passes through the motor chamber.

15

20

13. The apparatus according to any of the preceding claims wherein the rotatable member traverses at least portions of the motor chamber and the pump chamber.

25

14. The apparatus according to any of the preceding claims wherein the motor unit includes an ironless core motor with copper windings.

30

15. The apparatus according to any of the preceding claims wherein the rotatable member includes a first blade arrangement for imparting pump energy to blood entering the first opening and passing through the motor chamber within the space defined between the rotor blade member and the motor stator and a second blade arrangement for imparting pump energy to blood both entering the second opening and exiting the motor chamber.

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16. The apparatus according to any of the preceding claims wherein the cross-sectional area of the space between the rotatable member and the motor stator ranges from approximately .025 in² to approximately .031 in².

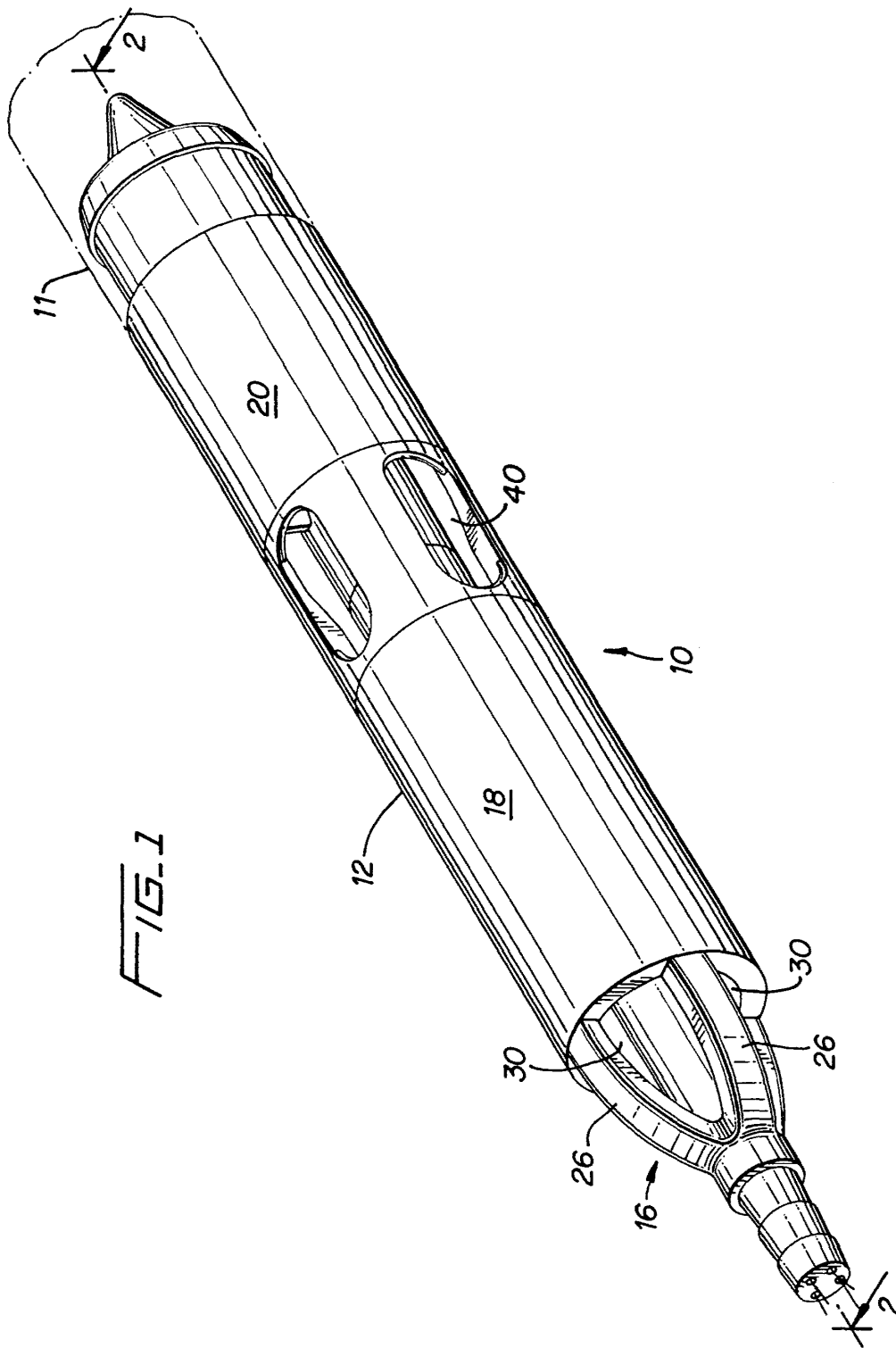
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17. The apparatus according to any of the preceding claims wherein the first and second openings in the elongated housing member are generally axial openings.

50

18. The apparatus according to any of the preceding claims including a cannula portion connected to the housing member adjacent the outflow opening, the cannula portion dimensioned to be placed in an artery associated with a patient's heart and defining a longitudinal opening therethrough to permit blood to pass.

55



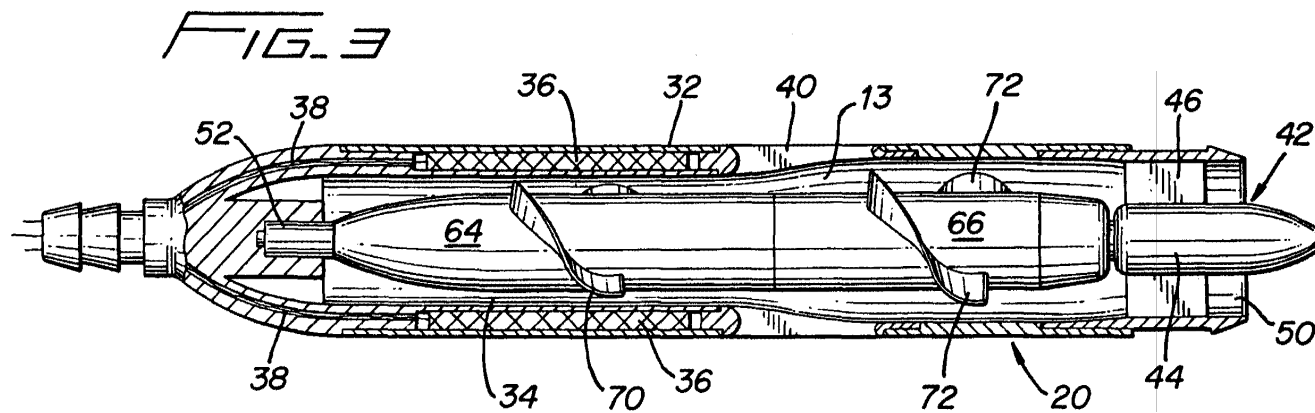
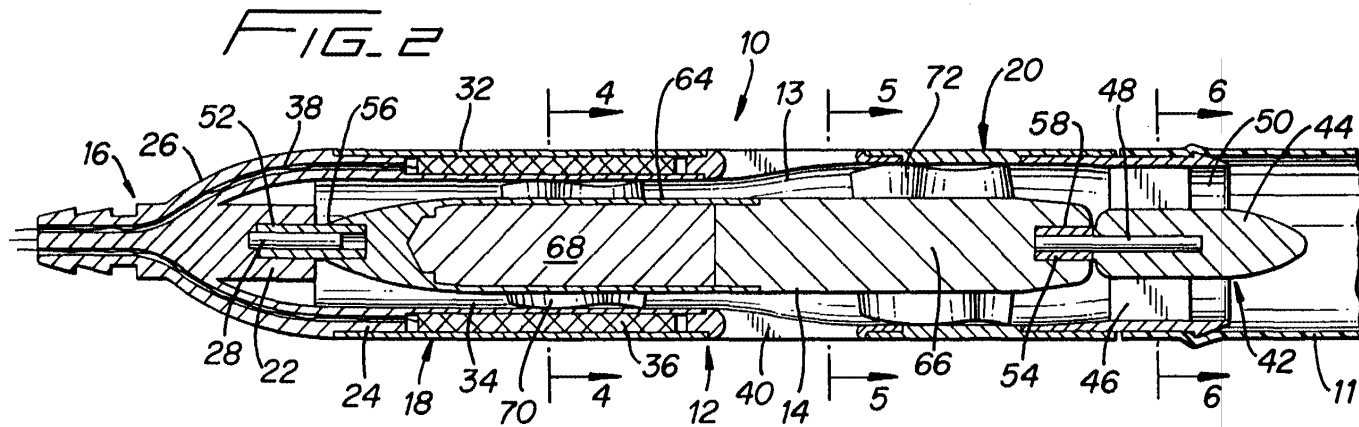


FIG. 4

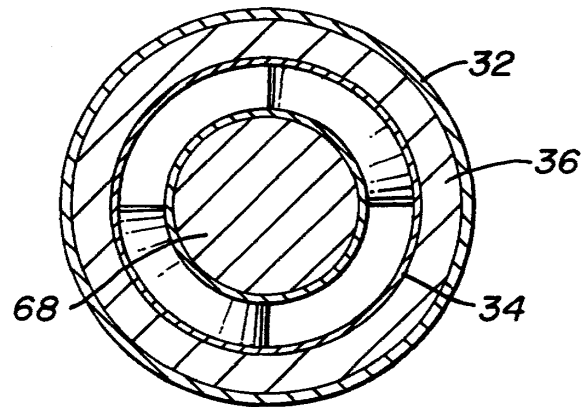


FIG. 5

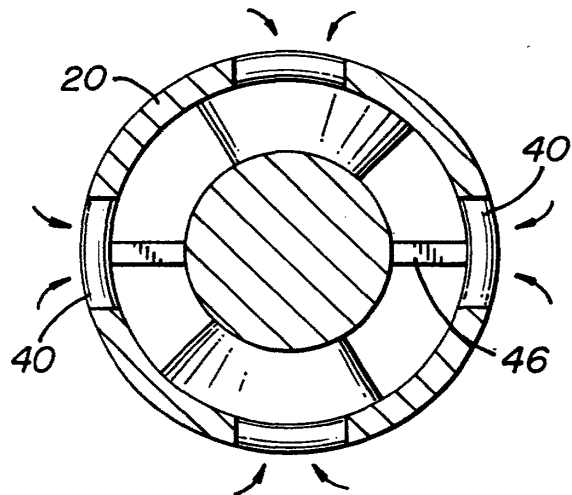
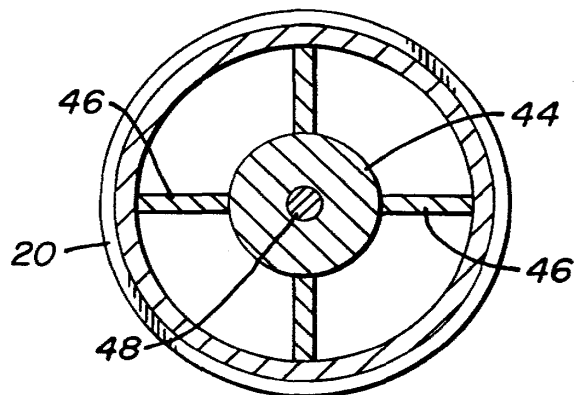
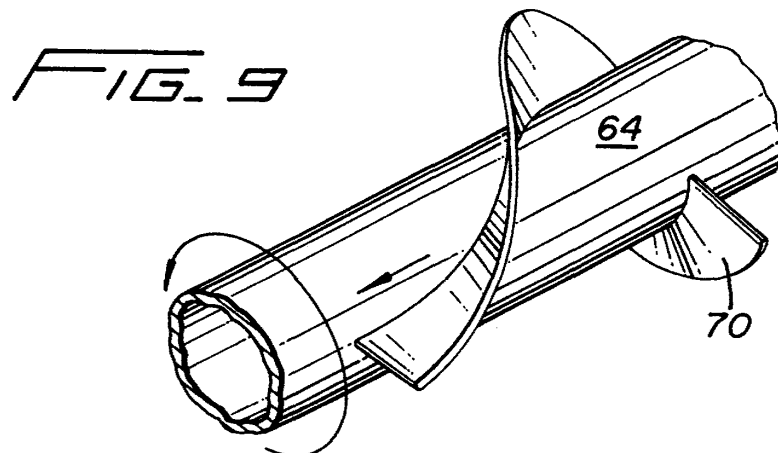
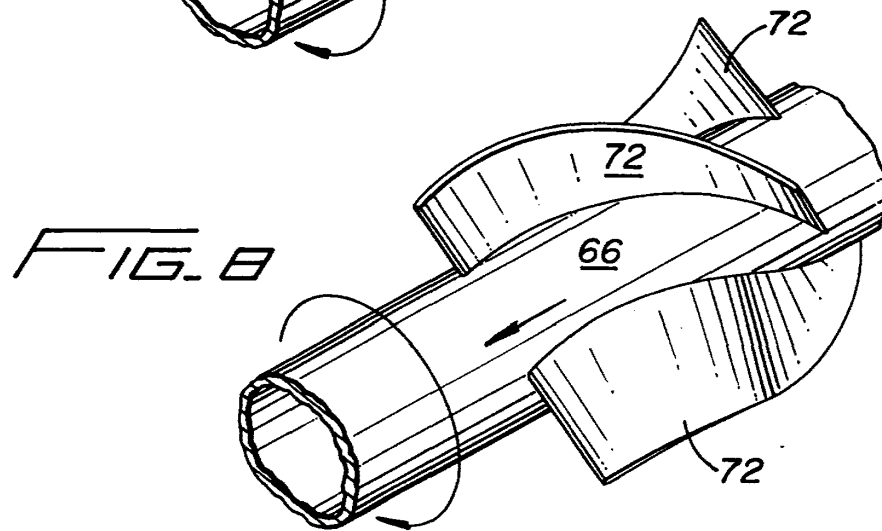
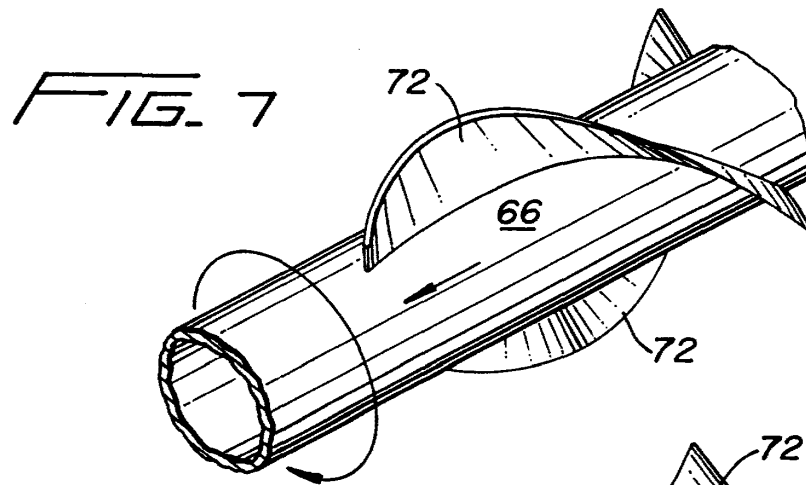
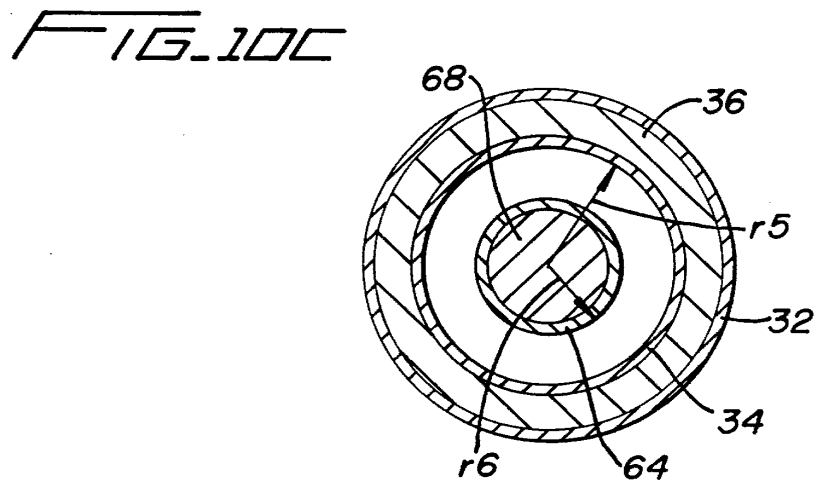
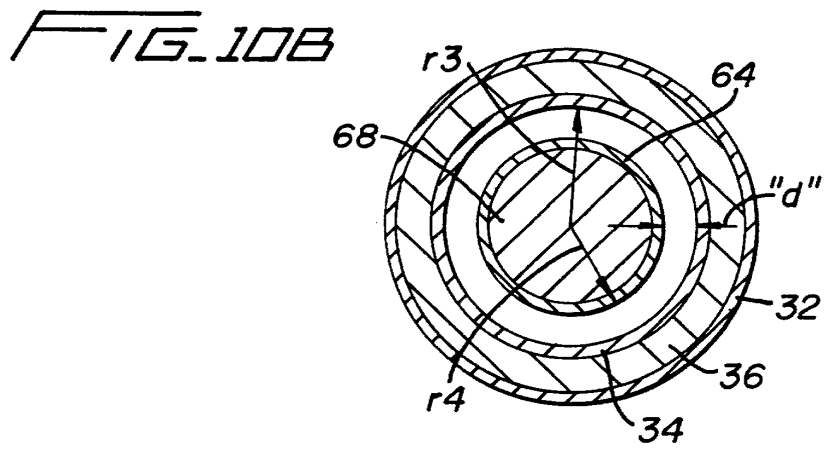
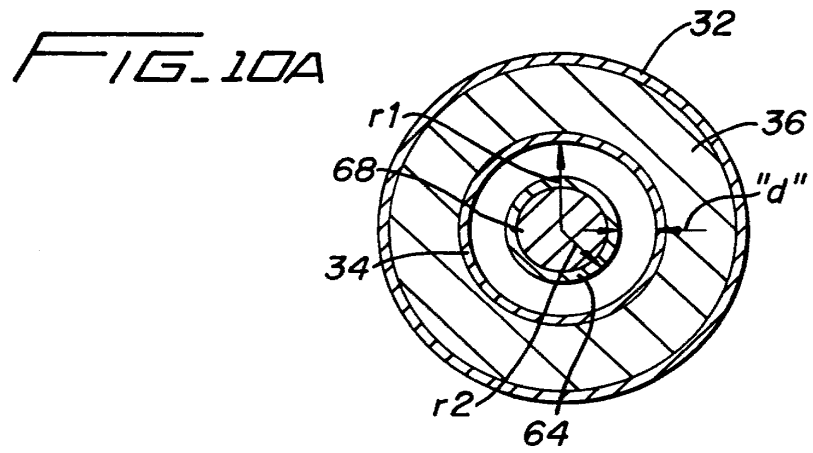


FIG. 6







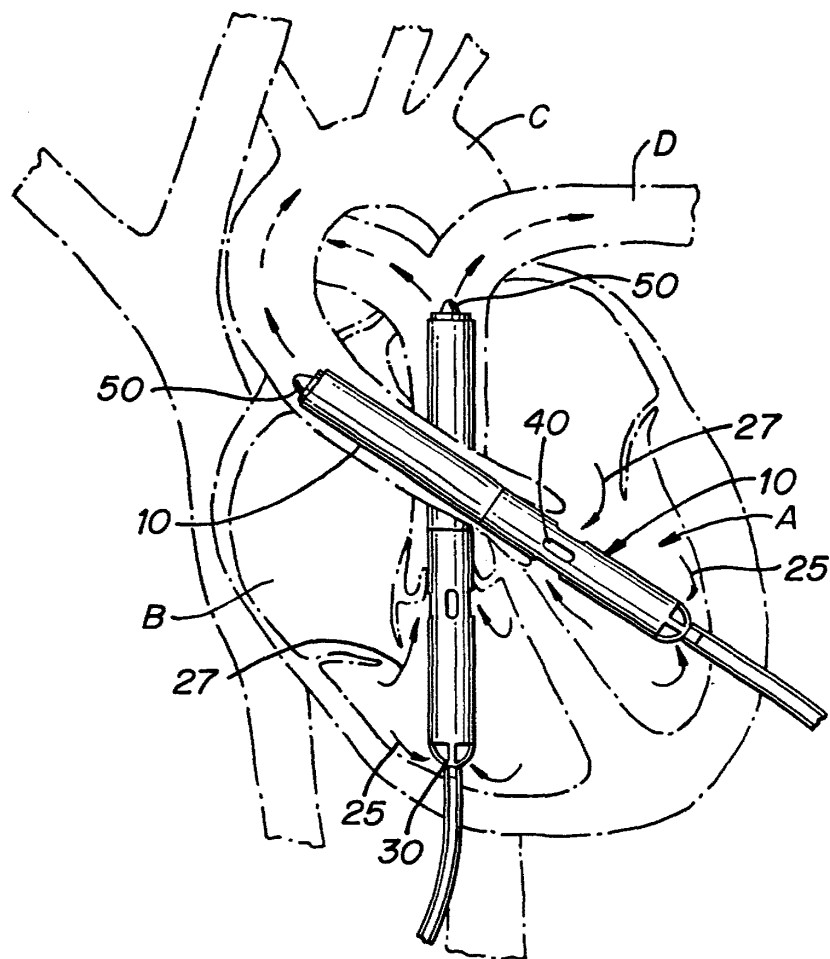
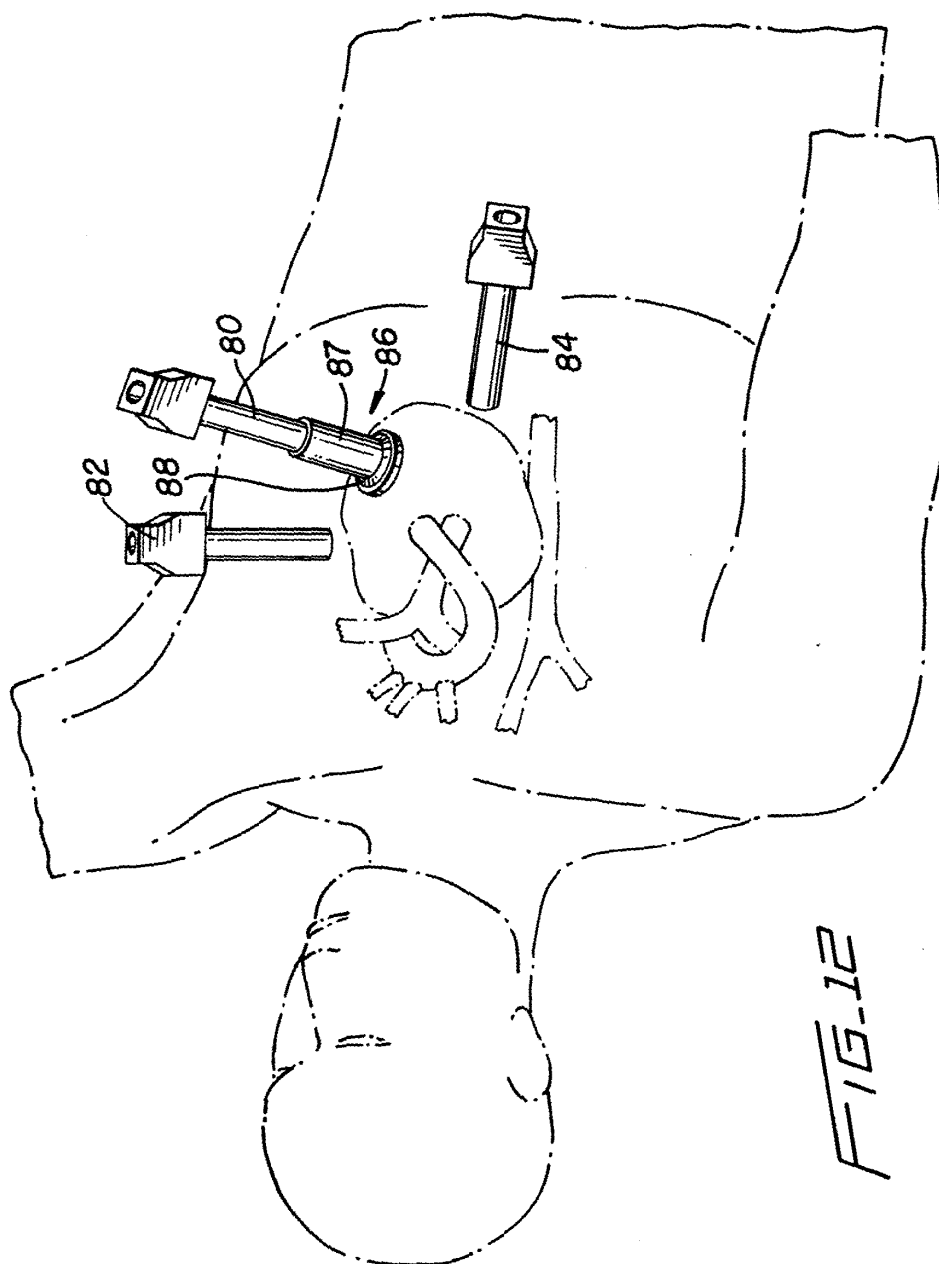


FIG. 11



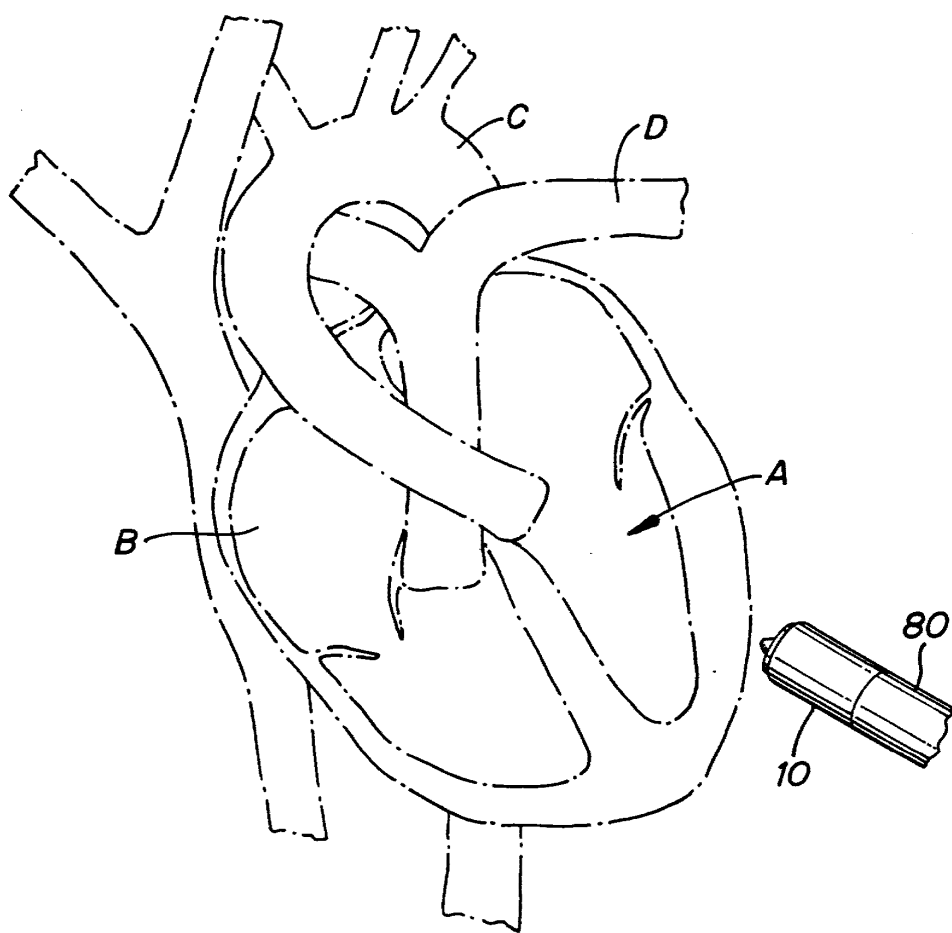


FIG. 13

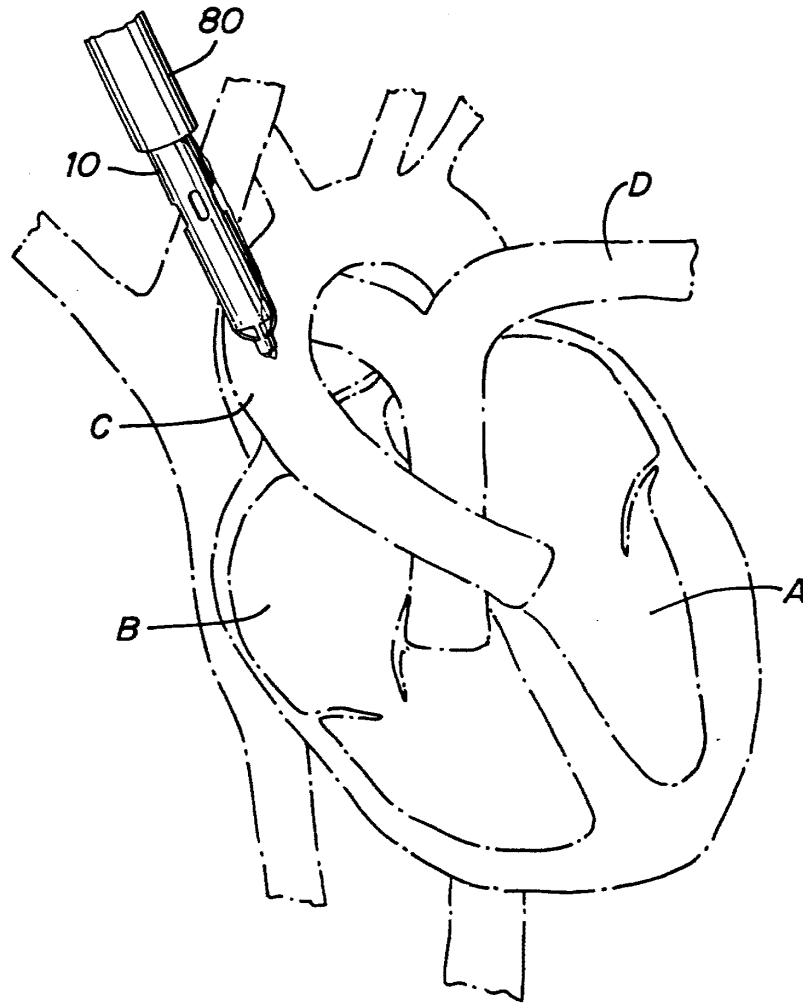
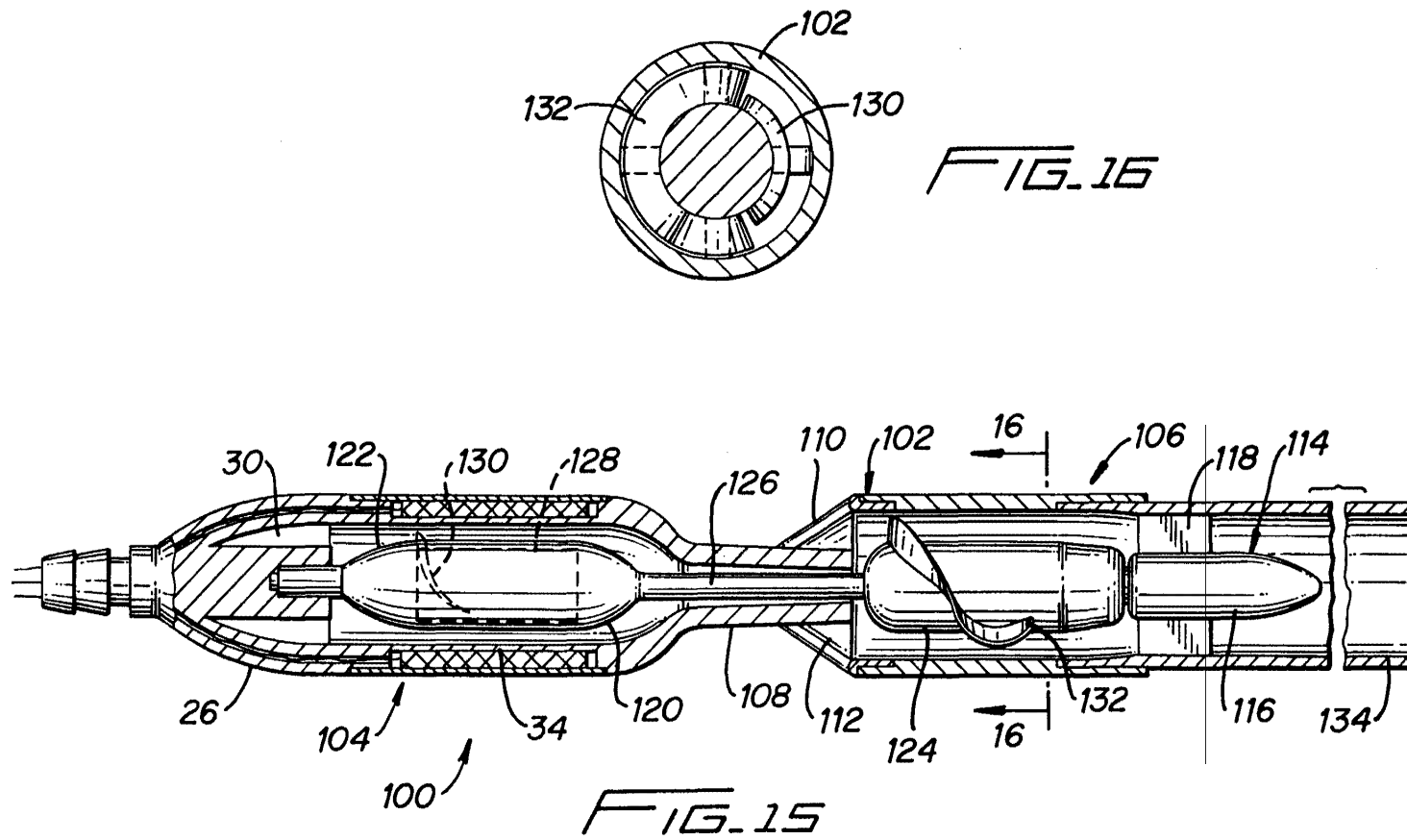


FIG. 14





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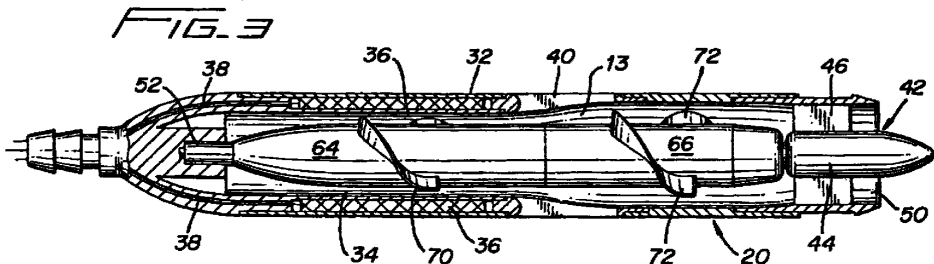
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(84) Designated Contracting States: DE ES FR GB IT (30) Priority: 22.09.1995 US 4184 (71) Applicants: - United States Surgical Corporation Norwalk, Connecticut 06856 (US) - JARVIK, Robert K. New York, NY 10023 (US)	(72) Inventors: - Jarvik, Robert New York, NY 10023 (US) - Alesi, Daniel E. Sherman, CT 06784 (US) (74) Representative: Marsh, Roy David et al Hoffmann Eitle & Partner Patent- und Rechtsanwälte Arabellastrasse 4 81925 München (DE)
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(54) Cardiac support device

(57) An apparatus for pumping blood includes an elongated housing dimensioned to be at least partially positioned within the heart of a patient, a rotating member supported for rotational movement within the elongated housing and a drive mechanism for imparting rotational movement to the rotating member. The elongated housing includes an outer wall, a first inlet port for permitting blood to enter the elongated housing through a first end of the elongated housing and a second inlet port defined in the outer wall of the elongated housing for permitting blood to enter through the outer wall. The rotating member is rotatable to impart pumping energy to the blood entering through the first and second inlet ports to direct the blood through an outlet opening of the

elongated housing. The rotating member preferably includes first and second blood pumping blade arrangements. The first blade arrangement is dimensioned to impart pump energy to the blood entering the elongated housing through the first inlet port. The second blade arrangement is dimensioned to at least impart pump energy to the blood entering the elongated housing through the second inlet port. The electric motor stator and rotor define a space therebetween through which blood entering the first inlet passes. The motor is an ironless core copper electromagnetic windings which provides a sufficiently large air space for blood flow.



EP 0 764 448 A3



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 96 11 5148

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	US 4 964 864 A (SUMMERS ET AL.) * column 3, line 28 - column 5, line 27 * * figures 1,3,4 *	1-4,10	A61M1/12 A61M1/10 F04D3/00
Y	---	6-9, 12-15	
Y	WO 90 01347 A (NIMBUS MEDICAL) * page 3, line 32 - page 5, line 11 * * figure 1 *	6-9, 12-15	
A	---	4,5,11	
A,D	WO 94 09835 A (JARVIK) * page 15, line 19 - line 23 * * page 16, line 15 - line 20 * * figure 8 * -----	17,18	
			TECHNICAL FIELDS SEARCHED (Int.Cl.6)
			A61M F04D
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 2 April 1997	Examiner Schönleben, J
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

EPO FORM 1503 01.82 (P04C01)

The invention relates to a pump device comprising a first pump (10a) and a second pump (10b). The suction end of the first pump (10a) can be introduced into the left ventricle (42) of the heart, whilst the delivery end is positioned in the aorta (40), and the suction end of the second pump (10b) is arranged in the right atrium (43) whilst the delivery end is positioned in the pulmonary artery (47). Both pumps (10a, 10b) are driven interdependently by a single control unit, the first pump (10a) assumes a lead function while the second pump (10b) only pumps around 90 % of the volume flow of said first (10a) pump. Pressure sensors on the pumps serve to detect the pressure difference between the suction end and the delivery end of a pump and to determine the volume flow. Both pumps are introduced into the heart without the ventricle having to be opened.

[19]中华人民共和国国家知识产权局

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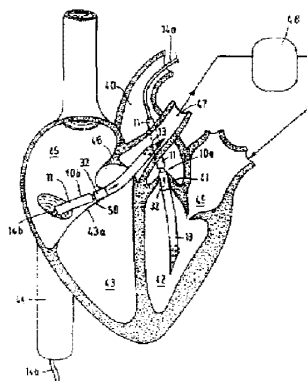
代理人 顾红霞

权利要求书 2 页 说明书 8 页 附图页数 5 页

[54]发明名称 心内泵装置

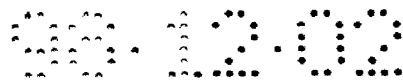
[57]摘要

一种泵装置,有一个可将其取血端插入心脏的左心室(42)的第一泵(10a),而供血端位于主动脉(40)内,和一个取血端安排在右心房(43)内,而供血端有肺动脉(47)内。一公共控制单元相互依从地驱动两泵,第一泵(10a)起主导作用,而第二泵(10b)只泵出第一泵流量的90%左右。泵上的传感器起测定泵的取血端和供血端差压的作用并测定血流量。两泵都可以在不切开心室的情况下插入心脏。



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权 利 要 求 书

5 1. 用于置入心脏的带有两个泵(10a, 10b)的心内泵装置, 每个泵有一个驱动部(11)和一个与之刚性连接的泵部(12), 其特征为, 一个公共控制单元(66)相互依从地控制两泵(10a, 10b)。

10 2. 权利要求 1 所述的泵装置, 其特征为, 一个泵(10a)为用于右心室(43)的右心泵, 而另一个泵(10b)为用于左心室(42)的左心泵, 并且两泵的流量都由公共控制单元控制, 使左心泵(10b)的血流量大于右心泵(10a)的血流量。

3. 权利要求 2 所述的泵装置, 其特征为, 左心泵(10b)的血流量比右心泵(10a)的血流量大预定的百分比, 最好约 10 %。

15 4. 权利要求 1-3 之一所述的泵装置, 其特征为, 为每一个泵(10a, 10b)提供一个流量测量装置以测定各泵的血流量(V), 测量装置与控制单元(66)联通。

20 5. 权利要求 4 所述的泵装置, 其特征为, 流量测量装置含有至少一个测定泵的入口端和出口端间的压力差($\Delta P1$, $\Delta P2$)的差压测量装置, 设置该装置用于由差压($\Delta P1$, $\Delta P2$)和泵的转速确定流量(V)。

25 6. 权利要求 1-5 之一所述的泵装置, 其特征为, 泵(10a, 10b)每一个都有一个由可控频率交流电驱动的电马达。

7. 权利要求 1-6 之一所述的泵装置, 其特征为, 每一个泵(10a, 10b)上至少设有一个绝对压力传感器(60, 61, 62, 63), 当压力过高或者过低时传感器引起流量减少或者增加。

30 8. 权利要求 1-7 之一所述的泵装置, 其特征为, 泵(10a, 10b)在主



一从控制下驱动，左心泵(10a)起主作用，而右心泵(10b)跟随。

5 9. 权利要求 1-7 之一所述的血泵，其特征为，设有测定两个泵(10a, 10b)在各自的工作条件下哪个表现出较弱的传输性能以及向它指派主控功能的装置。

10 10. 权利要求 1-9 之一所述的泵装置，其特征为至少一个泵(10a, 10b)的至少一个参数被测量并相应于设定值被控制。

10 11. 权利要求 10 所述的泵装置，其特征为，该参数是泵的取血端和供血端之间的差压。

心内泵装置

5 本发明涉及有两个泵的心内泵装置，可用于插入心脏，以辅助自然心脏的泵功能或者连续运转代替自然心脏泵功能。

WO 94/09835(Jajvik)公布了一种支持心脏的泵装置。该泵装置有两个独立的泵，各有一个泵部以及与之刚性联接的驱动部。一个泵的泵部
10 经过心尖的手术开口插入左心室，使之由左心室向主动脉供血。另一个泵部由另一个手术开口导入右心室，使之由右心室向肺动脉供血。该系统还有控制和显示模块，它们小得足以被消毒并用于消毒的手术环境。该系统可包括带有控制及监测算法的微处理器以控制血流量和血压，或者把血流量及血压参数送往数据库，其值是由传感器测出的，或者是通过
15 比较流速和能耗的测量值计算出的。这些称作导管泵的泵可设有内装压力传感器或者流量测量装置以就地测取这些患者护理参数。

本发明的一个目的是提供一个至少具有两个泵的心内泵装置，该泵装置可以通过适当地确定两泵的工作条件达到有效地支持心脏。

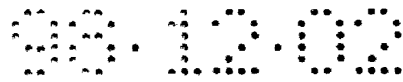
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本发明心内泵装置有两个置入心内的泵，它们各有一个驱动部和一个与之刚性联接的泵部。两个泵凭借一公共控制装置相互依赖地受到驱动。根据本发明，两泵不是独立地受驱动，两泵中对泵的运转重要的参数是相互适应的。从而避免了两泵工作干扰，并且防止了心脏及外周器官中发生反自然的血压条件和抽吸条件。

25

本发明中，“心内”一词指的是心室、心房以及邻接血管。

心内血泵的一个基本参数是单位时间输送的血流量。两个泵的控制
30 相互调制，使血流量有预定的相互关系。当一个泵用作右心泵，另一个



5 用作左心泵，从流向上看，两泵都向互相串联的液流系统供血，肺的供血系统先灌流，该系统与右心室直接血液流通。血液在肺中氧合后返回心脏，即返回左心室。由左心室血液被泵入主动脉。然而由于分流和所谓“泄露”外周血管系统中的血容量要减少约 10 %。右心泵的流量比左心泵的流量少一个预定的百分数，最好是 10 %。血流量变化时，这个固定的百分数保持不变，亦即，两个泵都以同样的百分数改变流量。

10 两泵的公共控制单元还可以具有相互联系的不同控制装置，从而一个泵的流量变化能够自动地引起另一个泵的流量的相应变化。

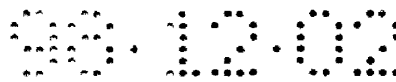
最好，两个泵在主一从控制下工作，左心泵往往起主泵作用。左心泵是提供最大心输出量的泵，承受最高的抗压，这就是为什么它承受最大的工作负载。

15 两个泵可有相同的设计，从而可有同样的结构和相同的工作特性。

20 最好，这些泵设计成 WO97/37696 所述的血管内泵（公布于后）。这种血管内血液泵与导管相连。它小得足以经过血管推进到要求它工作的位置，或者，也可以在血管中工作。这类血管内血泵中，泵部和驱动部基本上直径相同，不大于约 5 至 7 毫米，因为人体外周区域血管宽度最多稍大于 7 毫米。这种泵的刚性长度不应超过 35 毫米左右，这样泵才能设法通过血管的转折。然而泵可以靠挠性管进一步延长，由挠性管增加泵的有效长度。

25 另一方面，有可能经过近心血管系统把泵手术导入心脏。无论如何，该泵小得足以配合到心脏内，包括心房及邻接血管，并且可以在泵的任何部分都不超出心脏的情况下在心脏内工作。如果泵有任何部分超出心脏的话，那就是从心脏导出的与泵联接的导管。该导管不仅含有向泵供电能的导线，还含有从泵的传感器通向体外控制单元的信号导线。

30



下面参照附图对本发明实施方案进行详细说明。

图中：

图 1 所示为心内血液泵一个实施方案的纵剖面示意图；

5 图 2 所示为两血管内泵的心内执行实施案；

图 3 所示为经血管壁手术插入心脏的两泵执行实施方案；

图 4 为解释两个泵运转的示意图；

图 5 为表示血流量对泵的进血端与出血端压差的依从性的图解；

图 6 表示两泵控制部分的方框图，而

10 图 7 为表示心脏内不同时间压力变化的图解。

图 1 所示为血管内血泵 10，也就是一种可以经过患者的血管系统推进最终抵达心脏内的血泵。但是这种泵的外径无处大于 7 毫米。

15 泵 10 有一个驱动部 11 和一个刚性联接的泵部 12。驱动部 11 有一个容纳一个电马达 21 的细长圆柱壳 20。在后端，壳 20 由端壁 22 关闭，端壁 22 后接装封闭其的挠性导管 14。电动马达 21 的供电和控制电导线 23 以及联接泵 10 传感器的另外导线 23a 经该导管 14 伸出。

20 作为典型，马达的定子 24 具有多个沿圆周分布的线圈和一个纵向安排的磁轭，它牢固地与马达壳 20 连接。定子 24 包围着与马达轴 25 相联的转子 26，转子 26 由在活性方向上磁化的永久磁体制成。轴承 27 在马达壳或者说端壁 22 处支承马达轴的尾端。马达轴穿越马达壳 20 的全长并由马达壳向前方伸出。

25 马达壳的前罩由一个管形的静止轴套构件 30 形成，该构件尾端位于马达壳 20 的直径缩小的突出部 20a 中。轴套构件的外径向前端逐渐变细，支承马达轴 25 的轴承 33 位于轴套构件的前端。该轴承同时设计为轴封。

30



5 马达轴 25 向前穿出轴套构件 30，在穿出处装有叶轮 34，叶轮的轴套 35 处于轴端，其上伸出叶片 36 或称泵叶，叶片相对于叶轮 34 的轴线倾斜。叶轮 34 容纳在圆柱形泵壳 32 中，泵壳由三个沿圆周分布的连接肋 38 连接在马达壳 20 上。马达壳 20 和泵壳 32 靠环 38 相互刚性连接，而且外径相同。泵 10 的直径无超出该外径处。

10 当叶轮 34 旋转时，血液经过泵壳 32 的进血口 37 抽入后被轴向向后迫入泵壳 32。血流经过泵壳 32 和马达壳 20 之间的环状间隙沿轴套构件 30 向外进一步沿马达壳 20 流动。这样，驱动器产生的热量被带走，而血流不会由于马达壳 20 的表面温度（41℃ 以上）过高而被破坏。

也可以设计供血方向相反的泵部 12，血液沿马达壳抽入并轴向地在前端开口 27 放出。

15 图 2 所示为一个实施方案，其中两个图 1 所示的结构基本相同的泵 10a、10b 用于心脏中以支持心脏，或者在心脏停跳时替代心脏的泵功能。泵 10a、10b 分别与导管 14a、14b 相连。导管被经皮（穿刺）置入，在左心泵 10a 的导管 14a 经主动脉 40 伸入后延伸泵 10a 的软管 13 穿过主动脉瓣 41 进入左心室。这里泵部 12 被与泵壳 32 相连的挠性软管 13 延长，软管的端部和/或侧壁上设有使血液流入泵 10a 的开孔。泵 20 10a 经软管 13 进血并向主动脉 40 供血，同时主动脉瓣 41 从外侧贴靠在泵壳 32 或者软管 13 上。这样，在左心室 42 中，泵 10a 以轴向流入的左心泵工作。

25 另一泵 10b 以右心泵方式工作，与右心室 43 血液流通。导管 14b 经上腔静脉或下腔静脉 44 进入右心房 45。泵 10b 的软管 13 经由三尖瓣 43a 和肺动脉瓣 46 进入肺动脉 47，血液由肺动脉流向肺 48 进行氧合。氧合后的血液流入左心房 49 再流入左心室 42。

30 泵 10b 经径向入口 50 取血然后经过软管 13 轴向把血液输入肺动脉



47。这样泵 10b 与泵 10a 反相地工作。

两个泵 10a、10b 导入心脏都不需要把任一个心室手术切开。

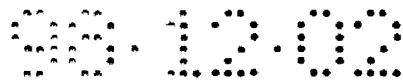
5 图 3 所示为另一种把两泵置入心脏的可能性，它能够支持心脏，或者完全地取代心脏的泵功能。与图 2 不同，两泵 10a 和 10b 经过血管系统上手术植入，左心泵 10a 的导管 14a 经过主动脉壁 52，而右心泵 10b 的导管 14b 穿过 53 处的肺动脉 47 的壁。左心泵 10a 的软管 13 安排在左心室 42 中并由主动脉瓣 41 在远端从出口 51 处封合。右心泵 10b 的软管 13 安排在右心室 43 中并被肺动脉瓣 46 包围。两个泵 10a、10b 工作时由其软管 13 取血，并经出口 50 和 51 供血。

15 图 4 为带有各种传感器的上述实施方案两泵 10a、10b 的示意图。特别地，在驱动单元 11 的外表面上设有一个位置靠近径向开口 51 的第一压力传感器 60，而第二压力传感器 61 设在泵壳入口附近。传感器的引线 23a 整合进泵的元件并且与电源线 23 一起经导管 14 引出。压力传感器 60 的传感面在马达壳的外表面。相反，压力传感器 61 的传感面设在软管 13 的内表面。另外，在驱动部可设一个温度传感器以监测马达温度。

20 相似地，在泵 10b 中，第一压力传感器 62 设在马达壳的外表面上，而另一个压力传感器 63 设在软管 13 的内表面上。这些传感器的引线也是经导管 14 引出。导管 14 上设有氧传感器 64，提供血液氧合信息。

25 电源线 23 和导线 23a 与体外接口 65 相联。接口把传感器发出的信号提供给控制单元 66，后者评估信号并据此控制泵 10a、10b。控制单元 66 上联有带开关板的显示器装置 67 以输入及显示信息。

30 利用传感器提供的信息可以确定泵相对于外部封闭的构件，例如心脏瓣膜的位置。如果泵的入口和出口在封闭构件的不同侧面，由于压力



条件不同，压力传感器上会出现不同的压力。心脏跳动时，该差压也随时间发生变化。另一方面，相同的测出压力值表明泵的位置不正确，因为两个压力传感器测出了同样的压力。对两个压力传感器提供的数据的评估，参考马达的电流，提供出有关泵位置以及泵运转的重要信息。靠比较差压与马达即时电流关系，还能够确定阻塞状况及涡空现象。

泵的入口压力和出口压力信息，与电动马达功耗信息一起为泵装置的功能提供重要鉴定信息。它们还提供血流量的实时指示并且使泵能够在没有 X 光透视或超声扫描的控制下定位。还有，可以有效地实时监视流入血流受阻的情况，例如，阻尼可以来自心室衰竭、血栓、软管阻塞或者心脏组织吸入。再有，传感器使之可以监测轴承磨损、马达故障或者预告这些事故。而且，在要求的使用期间，泵的运转可以被保持在可接受的总溶血率上，并保持每分钟 3.6 至 5 升的血流量。可以显示并分析数小时运转的各种参数性能趋势，检测出要求立即处理的情况可以报警，不必人工永久守候。另外不用取出泵就可以监视患者的心脏。安置两个配有仪器的泵时，向控制单元提供一个泵给出的局部信息以控制另一泵的工作，从而使整个系统性能理想化。

控制单元 66 控制两个泵 10a、10b 使每一泵供出一定的血流量（单位时间血量）。如此工作中，右心泵 10b 以预定的左心泵 10a 血流量的百分比泵血，例如 90 %。右心泵血流量总是低于左心泵的血流量。首先，控制左心泵 10a 的泵血功率使得维持预定的血流量。接着把右心泵 10b 的泵血能力当作左心泵的函数进行控制。这就是主从运转，此处左心泵 10a 常常为主，而右心泵 10b 为从。

泵由同步电动机驱动，由控制单元 66 给出要求的驱动频率，或转速 n 。每个泵的流量都是转速 n 的函数。

图 5 所示为泵的流量 V 对各种不同转速 n 时泵的入血端与供血端间差压 ΔP 的依从关系。每条平行的直线对应于一个特定的转速 n 。显



然，转速 n 已知时，可由差压 ΔP 计算出流量 V 。马达 21 是电换向同步电动机。因为转速是由控制单元预设的，故转速已知。差压 ΔP 分别靠传感器 60 和 61 或者 62 和 63 确定。当然，还对压力的绝对值进行测定和评估。

5

当泵经径向入口 50 或 51 取血并向软管 13 输血时，软管端压力传感器 61 或 63 处的压力分别大于取血端压力传感器 60 或 62 处的压力。

10 然而，当泵沿相反方向泵血时，亦即通过软管 13 取血时，压力传感器 60 或 62 处的压力分别大于压力传感器 61 和 63 处的压力。

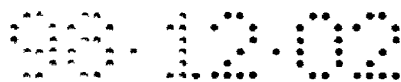
15 图 6 说明如何确定血流量 V_1 和 V_2 。测定出第一泵的差压 ΔP_1 和第二泵的差压 ΔP_2 。把泵 10a 的转速 n_1 和差压 ΔP_1 送到第一评估装置 70。第二泵 10b 的转速 n_2 和第二泵的差压 ΔP_2 送到第二评估装置 71。然后，根据图 5 所示评估装置 70、71 向控制装置 72 提供第一泵和第二泵的流量 V_1 和 V_2 ，据此控制装置设定转速 n_1 和 n_2 ，使流量 V_1 和 V_2 取预定的值。在所述实施方案中，两泵的流量值相互依从，使血流量 V_2 为血流量 V_1 的 90 %。每个泵的血流量独立维持和调节。

20 可能发生这样的情况，两泵之一完全由于泵吸吮心脏组织或者瓣膜器官部分或者完全地阻塞。这时，压力传感器给出不正常值。各自泵的转速就会在一定时间内降低使心脏组织自行脱开，再接着重新增加到要求的数值。当测出绝对压力值过高时，控制单元 66 会发出一个流量极限，需要时降低流量，以免破坏下游的器官（肺）。

25

压力测量还提供监护作用。右心室或肺动脉内血压不得超过一定的值，而左心室或主动脉的血压不得低于一定的值。检测到相应压力偏离，就发出警报，或者作出调节。

30 图 7 表示心脏跳动时，在收缩期 S 和舒张期 D 左心室压力变化 P_1 。



可看到强劲的脉动压力，在收缩期 S 之间有急剧的下降。图中还表示了主动脉的压力变化 P2。主动脉压力也可脉动，尽管不脉动在很窄的压力范围。差压 ΔP 由 $P2 - P1$ 确定。在泵上设有压力传感器时，该差压可由之测定。

5

上述的传感器 61 — 63 是绝对压力传感器。也可在泵壳 32 上设置薄膜形式的差压传感器，以获得其内外侧的压力差。这样，就可用单个传感器测量差压。

10

对于把泵插到心脏中的正确位置，测量压力和差压尤其重要。插入时泵可以不转动或者低转速运转，而心脏不停跳动。当一个压力传感器检测出强脉动压力变化 P1 而另一个压力传感器检测出弱脉的压力变化 P2，泵定位就正确。

15

然而定位并不必需测量压力。此外，定位还可以靠泵的电流变化来监视。只要泵的入口和出口在同一个空间，两口就都受到同样的压力。如果以一定的速度驱动泵，泵电流的时间变化就是恒定的。然而，如果泵的出口和入口在压力随时间变化的不同的空间，就会得到不平滑的、脉动的泵电流。因此可以根据泵电流判定心脏瓣膜是否正确地封闭泵壳或者软管使得泵的入口位于心室或者心房，而出口位于主动脉或者肺动脉。

20

说明书附图

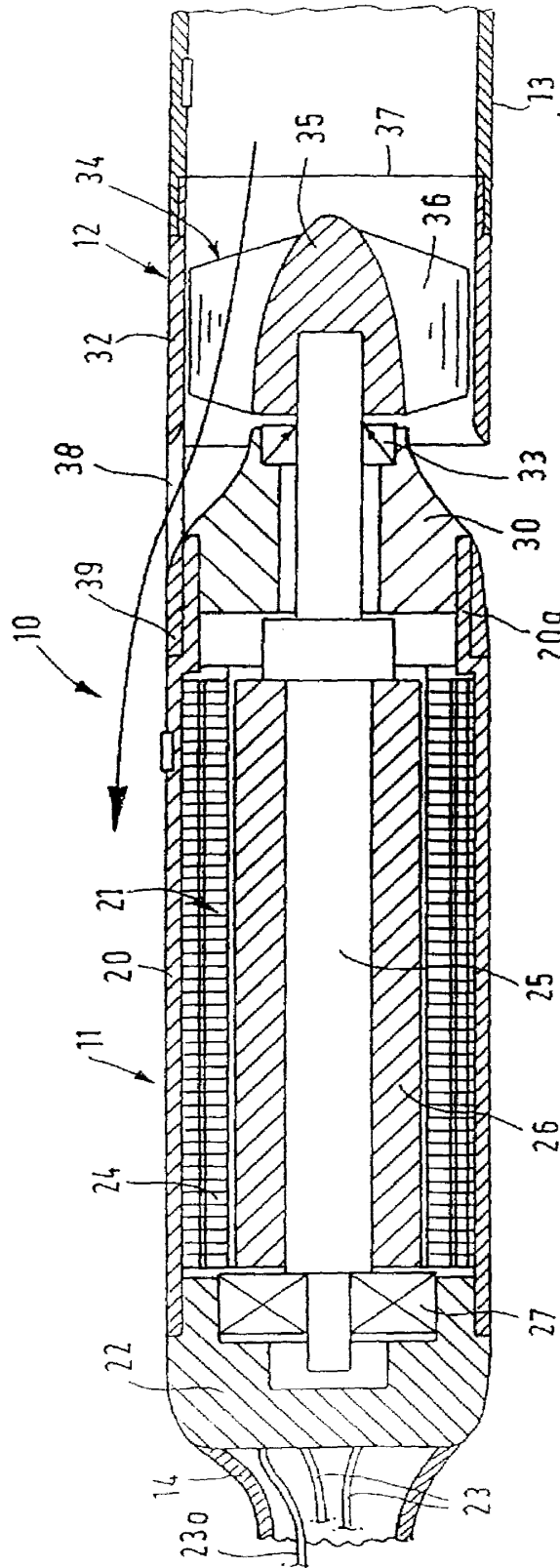


图 1

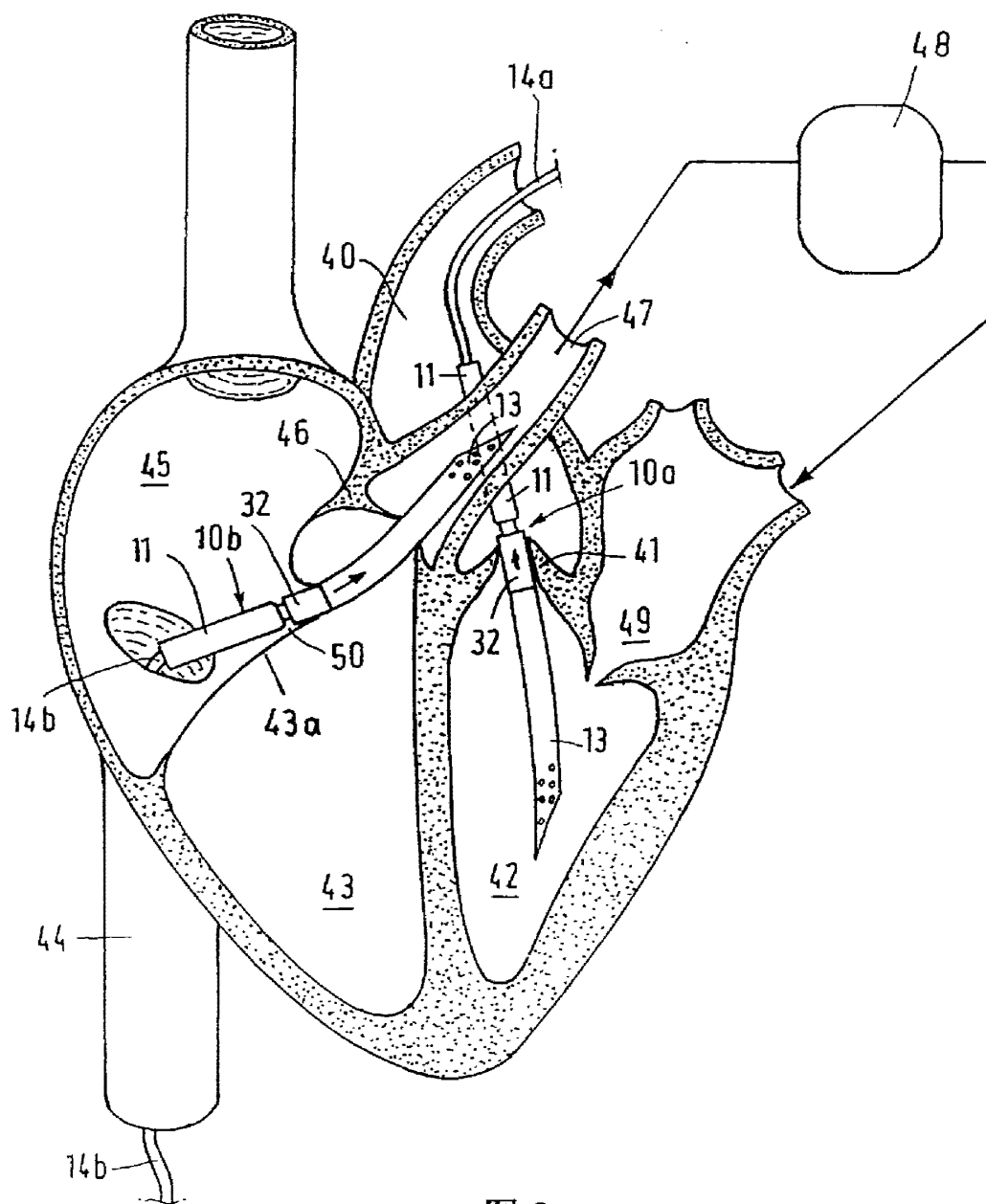


图 2

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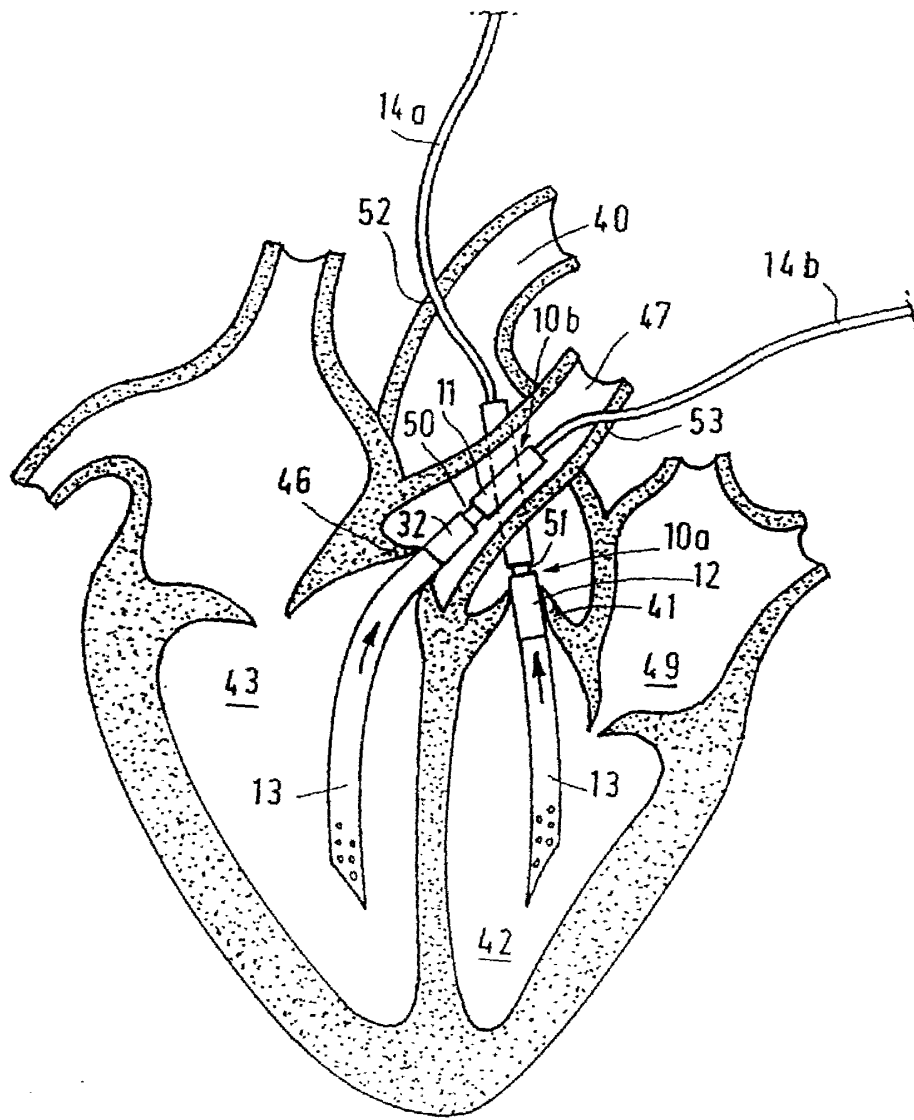


图 3

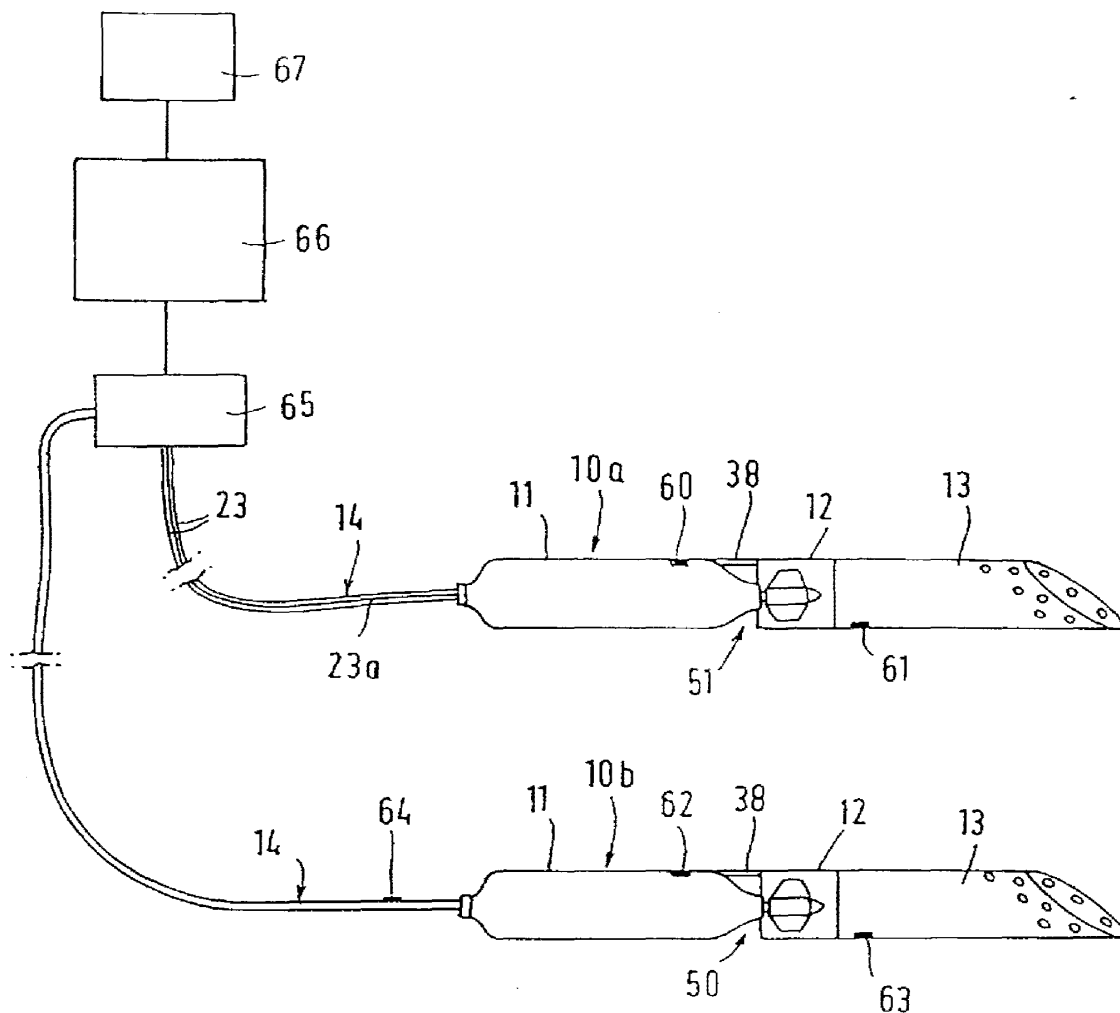


图 4

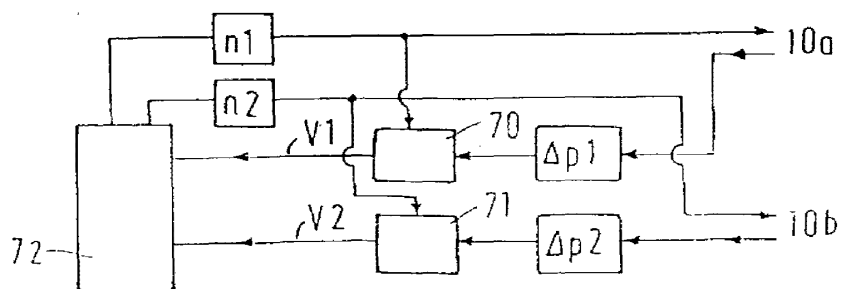


图 6

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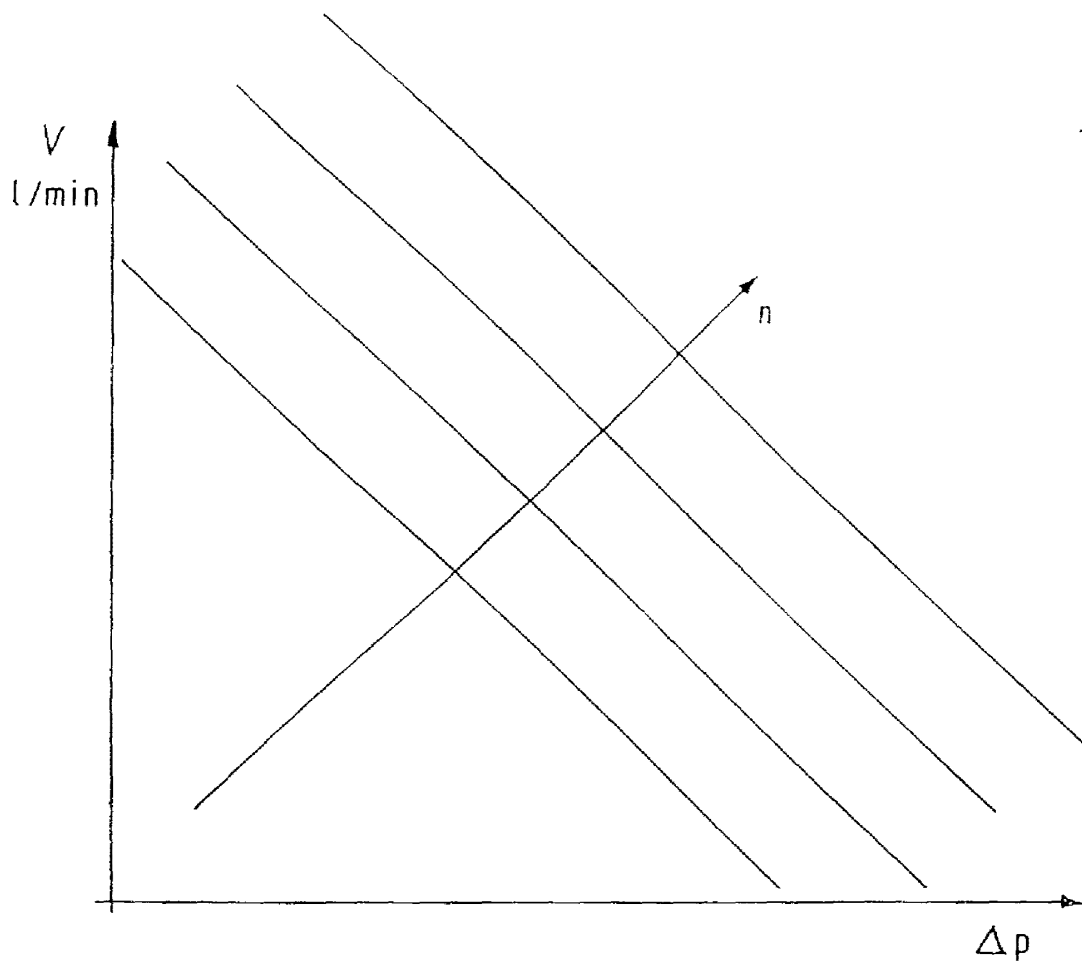


图 5

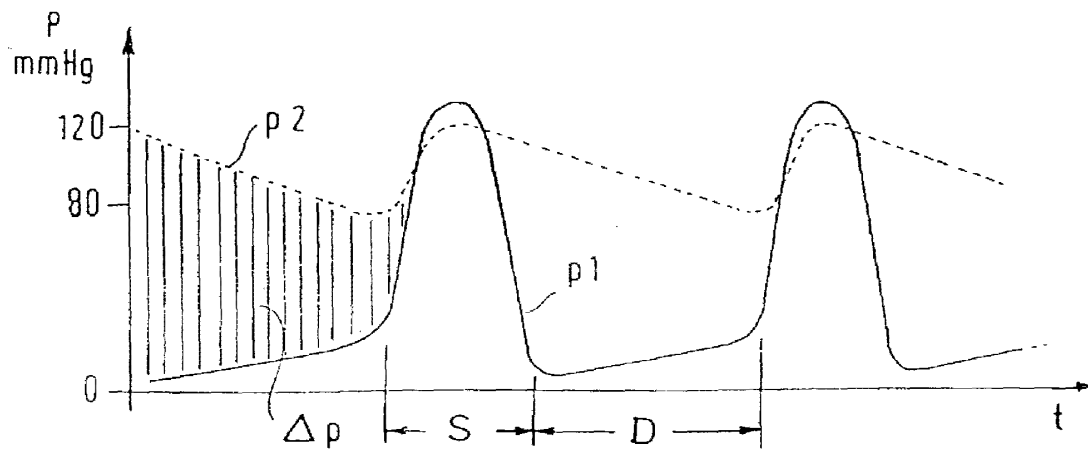


图 7

(12)

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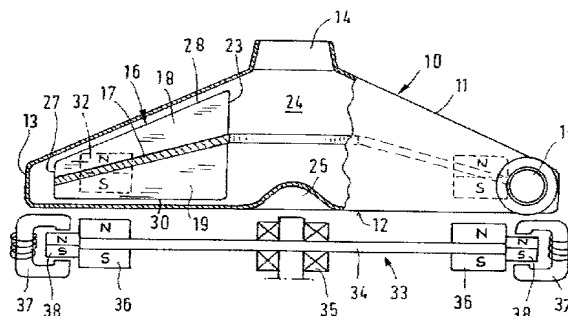
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(54) **POMPE A SANG SANS PALIER**
(54) **BLOOD PUMP WITHOUT BEARING**

(57)

Disclosed is a blood pump having a pump housing (10) in which an impeller (16) is arranged without housing. An external magnetic drive device (33) turns the impeller (16) via a magnetic coupling (32, 36). The lower side (30) of the wings (19) of the impeller is configured as a support surface (30) which slopes at the following end. A hydrodynamic supporting effect is thus obtained during rotation. Said effect raises the impeller (17) from the bottom surface of the pump housing (10). As the pump housing does not comprise bearings and seals, the thrombosis risk and the danger of penetration of foreign bodies into the blood by attrition is reduced.





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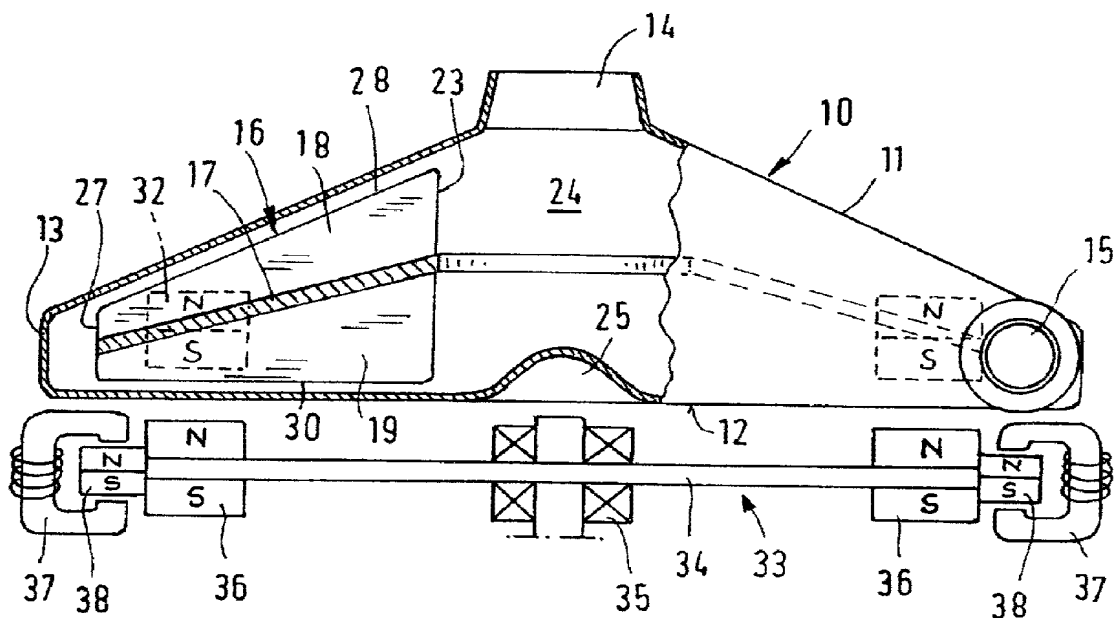
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(54) Title: BLOOD PUMP WITHOUT BEARING



(57) Abrégé/Abstract:

Disclosed is a blood pump having a pump housing (10) in which an impeller (16) is arranged without housing. An external magnetic drive device (33) turns the impeller (16) via a magnetic coupling (32, 36). The lower side (30) of the wings (19) of the impeller is configured as a support surface (30) which slopes at the following end. A hydrodynamic supporting effect is thus obtained during rotation. Said effect raises the impeller (17) from the bottom surface of the pump housing (10). As the pump housing does not comprise bearings and seals, the thrombosis risk and the danger of penetration of foreign bodies into the blood by attrition is reduced.

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ABSTRACT**Blood pump without bearing**

The blood pump comprises a pump casing (10) in which an impeller (16) is installed without any bearing. Said impeller (16) is rotated via a magnetic coupling (32,36) by an external magnetic driving means (33). The impeller is radially centered via the magnetic coupling (32,36). The lower side (30) of the blades (19) of the impeller is configured as supporting surface (30) sloping towards the trailing end. In this way a hydrodynamical supporting effect is attained during rotation such that the impeller (16) raises from the bottom surface (12) of the pump casing (10). Since no bearings and sealings are provided on the pump casing the danger of thrombosis and the danger of penetration of foreign bodies in the form of abrasive particles into the blood is reduced.

(Fig. 1)

Sg/Schm

Blood pump without bearing

The invention relates to a blood pump without bearing, operating according to the rotary pump principle, for temporary or long-term blood conveyance.

5

For temporary short-term blood conveyance extracorporeal blood pumps are used which comprise a rotationally driven impeller. Said impeller is supported on bearings in the pump casing. Examples of such blood pumps are described in EP 0 451 376 B1 and DE 43 21 260 C1. The impeller is driven via a mag-
10 netic coupling by a rotating rotor located outside the pump casing. The bearings supporting the impeller pose a problem in connection with the blood pump since thrombosis may occur at the bearings. Further, there is the danger of abrasive particles of the bearings contaminating the blood. Seals designed to protect the bearings against penetration of blood have also turned
15 out to be unsuitable for the medium-term to long-term use (days to years). Blood pumps with mechanical support of the impeller are not suited for the long-term use for the aforementioned reasons. Pump systems having magnetic bearings (US 5 385 581 A, DE 196 13 388 A1) which contactlessly support the impeller in an electromagnetic bearing means require a considerable
20 controlling effort and a voluminous configuration because of the complex supporting structure where additional energy must be supplied to a large extent due to the active impeller centering.

It is an object of the invention to provide a blood pump having a rotor rotating in a pump casing where the danger of blood contamination and thrombo-
25 sis minimized.

This object is solved according to the invention with the features stated in claim 1.

30

The blood pump according to the invention is a blood pump without bearing which is not provided with any mechanical bearings. The impeller is freely movable within a limited clearance in the pump casing. The impeller is rotated

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- by an external magnetic driving means thus being self-centering. At least a front side of the blades comprises supporting surfaces which hydrodynamically lift the impeller during rotation. The static force of attraction of the permanent magnets in the impeller and the driving means tends to press the impeller against the pump casing wall facing the driving means. However, the supporting surfaces in the impeller cause the impeller to be lifted from the bottom surface during rotation such that the impeller slides on a blood cushion thus being kept at a distance from the wall. The impeller without bearing is passively centered in the pump casing via permanent magnets in combination with hydrodynamically acting driving forces. The lateral centering of the impeller is also effected by the magnets cooperating with the driving means. In this way it is possible to create a blood pump without bearing and shaft where the impeller is suspended in the pump casing.
- 15 The blood pump without bearing according to the invention offers the advantage that due to the fact that no bearings and sliding seals are provided the risk of thrombosis of the blood and penetration of foreign bodies into the blood is reduced. Thus the blood pump according to the invention cannot only be used as an extracorporeal blood pump for short-term application but also as an implantable blood pump for long-term operation. The blood pump is operable with high efficiency due to the low centering-induced losses wherein the required capacity lies in the range of 6 W under physiologically relevant operating conditions such that the pump has a long service life even when configured as a battery-operated portable device.
- 25 The impeller may comprise a straight continuous passage extending from the inlet to a bottom wall of the pump casing. Thus the impeller is provided with vanes on both sides.
- 30 Preferably, the impeller blades are arranged such that they protrude to opposite sides from the circumferential wall of a disk-shaped or cone-shaped supporting body. The impeller does not form a disk which would, together with

3

the bottom wall of the pump casing, define a narrow gap. This also reduces the risk of thrombosis. In all areas of the pump casing a blood flow is maintained without there being the danger of dead water areas.

- 5 As seen from the top the blades are of essentially triangular configuration and comprise the blade-side magnets. The triangular form of the blades allows the blade volume to increase with increasing radius such that the fluid passage area available between the blades can be kept constant on all radii. Thus the conicality of the pump casing, which would be required to ensure that on all
10 circumferential circles approximately the same volume is available, is reduced or eliminated.

- The blood pump according to the invention is a centrifugal pump where the outlet is arranged essentially tangentially to the outer edge of the pump cas-
15 ing. Since the maximum pressure prevails in the outlet a radial force is produced which tends to press the impeller away from the outlet. To counteract this decentering force a peripheral ring diffuser is provided on the pump casing according to a preferred aspect of the invention, the ring diffuser ending in a tangential outlet. Said ring diffuser is a helical duct which causes the
20 pressure prevailing in the outlet to be distributed over the circumference of the pump casing thus having a centering effect on the impeller.

Hereunder embodiments of the invention are explained in detail with reference to the drawings in which:

25

Fig. 1 shows a schematic longitudinal section across a first embodiment of the blood pump,

30

Fig. 2 shows a perspective view of the pump casing of the blood pump shown in Fig. 1,

Fig. 3 shows a view of the impeller of the pump shown in Fig. 1,

4

Fig. 4 shows another perspective view of the impeller of the pump shown in Fig. 1,

5 Fig. 5 shows a second embodiment of the blood pump,

Fig. 6 shows a perspective view of the pump casing of the pump shown in Fig. 5,

10 Fig. 7 shows a perspective view of the impeller of the pump shown in Fig. 5,

Fig. 8 shows a third embodiment of the blood pump,

15 Fig. 9 shows the pump casing of the blood pump shown in Fig. 8, and

Fig. 10 shows the impeller of the blood pump shown in Fig. 8.

20 The blood pump shown in Fig. 1 comprises a pump casing 10 having a truncated circumferential wall 11, an essentially flat bottom wall 12 and a peripheral cylindrical wall 13 extending between said bottom wall 12 and said circumferential wall 11. The blood is supplied via the axial inlet 14 to the pump casing and leaves the latter via the tangential outlet 15 on the outer casing circumference.

25

In the pump casing 10 an impeller 16 is rotatably arranged. Said impeller comprises a truncated supporting body 17 whose slope is approximately half as large as that of the circumferential wall 11. The supporting body 17 is made of surface material of approximately identical thickness at all locations.

30 On the supporting body 17 blades 18,19 protruding to the top and to the bottom are arranged wherein the upper blades 18 and the lower blades 19 are congruent as seen from the top, i. e. they have the same projection surfaces.

Said blades 18,19 are of triangular configuration as seen from the top and comprise a convex circumferential surface 20 coinciding with the circumferential circle of the supporting body 17, a convex leading surface 21 leading in the direction of rotation, and a concave inner surface 22. Said convex leading surface 21 coincides with the concave inner surface 22 at the inner edge 23. The circle on, which lie the inner edges 23 of the three blade pairs, form the limit of a circular passage 24 arranged in axial extension of the inlet 14. This means that the impeller 16 is open in its center such that a direct axial passage 24 extends down to the bottom wall 12 wherein a central raised portion 25 extending into said passage 24 is provided in the bottom wall 12. The cross-section of the passage 24 is at least as large as that of the inlet 14.

When the impeller rotates, the respective inner edge 23 precedes the outer edge 26 of the same leading surface 21. This means that the leading surface 21 presses the medium radially to the outside by setting said medium into a swirling motion. The trailing edge 27 moves along the same path as the leading edge 26.

The upper side 28 of the upper blades 18 moves in a truncated plane having the same cone angle as the circumferential surface 11 of the pump casing. Between the upper sides 28 of the blades and the conical circumferential surface 11 of the pump casing a gap is formed which provides the play required for axial movement of the impeller.

The lower sides of the lower blades 19 form supporting surfaces 30 which lift the impeller from the bottom wall 12 of the pump casing when the impeller rotates in the direction indicated by arrow 31. Said supporting faces are formed in that on the lower side of the blade the lower edge of the leading surface 21 is positioned at a larger distance to the bottom wall 12 than at the trailing end, namely at the edge 27. In this way a gap is formed between the supporting surface 30 and the bottom wall 12, the gap decreasing towards the trailing end such that fluid in the gap tends to lift the impeller. Further, the

6

vertical height of the gap above the bottom wall increases from the inner edge 23 towards the outside whereby the impeller is also radially centered. The inclination angle α of the supporting surface 30 in the circumferential direction is approximately 2 to 4°.

5

The blades 18,19 which are of triangular configuration as seen from the top are each provided with a magnet 32 with north pole N and south pole S. Said magnet extends through the two blades 18,19.

- 10 The blood pump is driven by an external magnetic driving means 33 onto which the pump casing 10 is placed. Said driving means comprises a rotor 34 supported in bearings 35 and being provided with magnets 36 on its circumference. Each of said magnets 36 attracts a magnet 32 located in the pump casing 10. The rotor 34 is rotated by stationary electromagnets 37. Each elec-
- 15 tromagnet 37 comprises a U-shaped yoke through which passes a magnet 38 arranged on the circumference of the rotor 34. The poles of the electromagnets 37 are cyclically changed such that they generate a rotating magnetic field carrying along the rotor 34. Via the magnetically coupled magnets 32 and 36 the rotor 34 rotates the impeller 16. All parts of the impeller 16, with
- 20 the exception of the magnets 32, are made of plastic material or another nonmagnetic material.

- The type of magnet arrangement of the rotor magnet 32 at the drive magnet 36 results in a radial centering of the impeller 16. Thus 2 cartesian axes and 3
- 25 rotating axes are defined. The last remaining degree of freedom in the direction of magnetic attraction is fixed by the convergent gap formed between the supporting wall 30 and the bottom wall 12 and extending in circumferential direction. Thus the impeller, when rotating, raises from the bottom wall 12 against the magnetic attraction. When a sufficient circumferential velocity of
- 30 the impeller has been reached, a blood film capable of bearing forms in the convergent gap and the impeller is suspended in the pump casing without mixed friction.

7

In the embodiment shown in Fig. 5 the casing 10a comprises a flat bottom wall 11 and a flat upper wall 11a extending essentially in parallel to the former. The supporting body 17a, from which the blades 18,19 protrude to the top and to the bottom, is a flat disk.

According to Fig. 5 the external driving means 33a comprises electromagnets 40 distributed on the circumference of the pump casing 10a and generating a peripheral magnetic field. The yokes of the electromagnets 40 directly act upon the magnets 32 of the impeller 16a. Here, too, the magnets do not only carry out the rotary drive of the impeller but also its radial centering. For axial centering of the impeller the blades are provided with an inclined supporting surface 30 on their lower side and with an inclined supporting surface 41 on their upper side, said supporting surfaces forming, together with the upper wall 11a of the pump casing, a convergent centering gap.

The blades 18,19 have the blade form shown in Fig. 7 deviating from that of the first embodiment in that the vanes are curved in forward direction as seen in the direction of rotation. In all cases the blades extend up to the passage 24 and the blade width (in circumferential direction) increases from the passage 24 towards the outside such that each blade has its maximum width at the edge of the supporting body 17 and 17a, respectively.

According to Fig. 6 the pump casing 10a generally has the form of a flat cylinder with a flat upper wall 11a and a cylindrical circumferential wall 13. Since during rotation of the impeller 16a the maximum pressure builds up in the outlet 15 it may happen that this pressure presses the impeller against the pump casing side located opposite to the outlet. To compensate for this pressure force a ring diffuser 44 extends around the circumference of the pump casing, said ring diffuser 44 completely enclosing the circumference of the pump casing and being configured as a helical bulge whose cross-section continuously enlarges from the inlet end 44a towards the outlet 15.

8

The embodiment shown in Figs. 8 to 10 corresponds to a large extent to that shown in Figs. 5 to 7. The pump casing 10b is essentially configured as a flat cylinder with a flat upper side 11a and a flat bottom wall 12. The lower side of the lower blades 19 forms a hydrodynamical supporting surface 30 which increases, as in the previous embodiments, towards the leading edge. Further, the supporting surface 30 shown in Fig. 8 increases towards the outside.

The driving means 33b comprises a disk rotor motor 45 supported in bearings 35 and being provided with magnets 36 which cooperate with the magnets 32 of the impeller 16b.

CLAIMS

1. Blood pump without bearing, having a pump casing (10) comprising an axial inlet (14) and an outlet (15) disposed on its circumference, and having an impeller (16) rotatably arranged in said pump casing (10), said impeller (16) being provided with magnets (32) adapted to cooperate with an external magnetic driving means (33), wherein the impeller (16) is freely movable within a limited clearance in the pump casing (10), and the blades (19) on the lower side of the impeller (16) facing the driving means (33) comprise hydrodynamically lifting supporting surfaces (30),

characterized in that

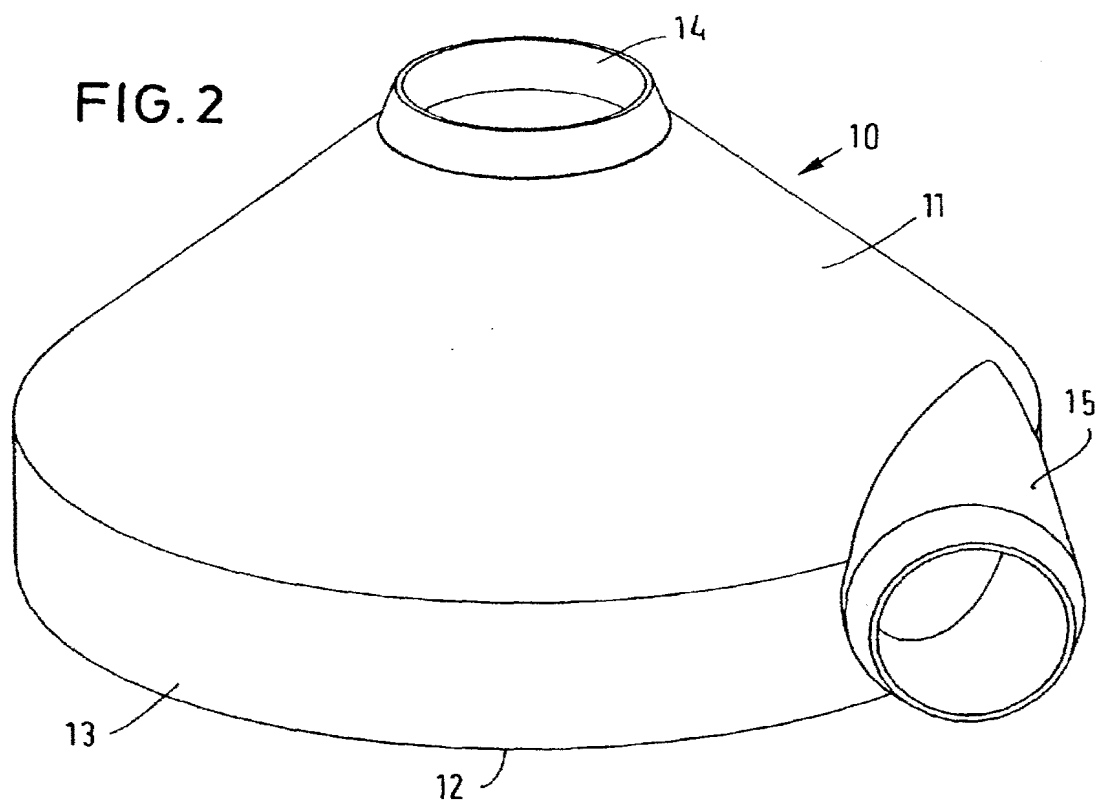
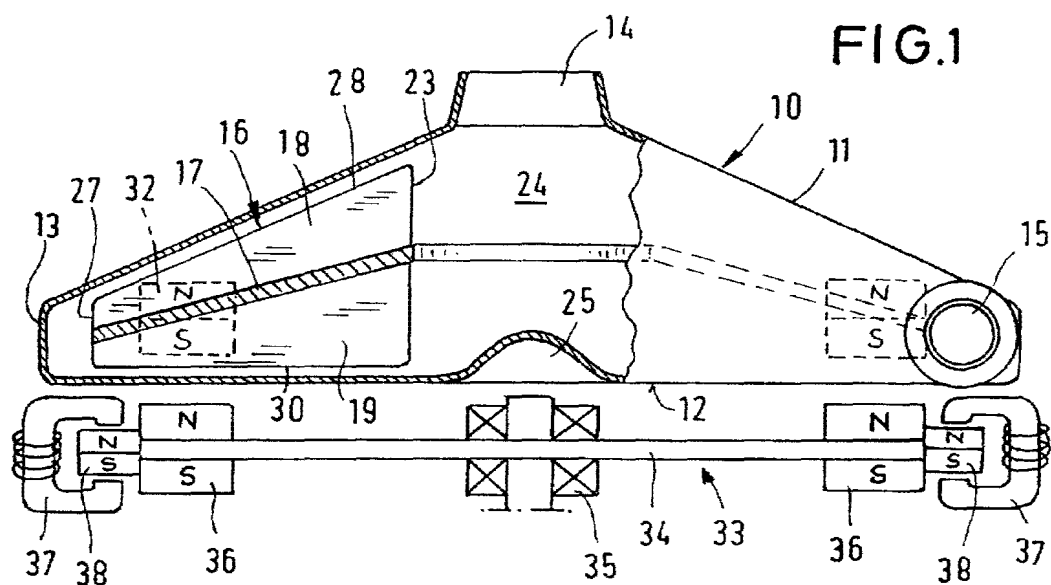
the impeller (16) is positioned without any bearings involved and comprises a passage (24) in extension of the axial inlet (14) of the pump casing (10).

2. Blood pump according to claim 1, characterized in that the impeller (16) has no shaft and comprises a straight continuous passage (24) extending from the inlet (14) to a bottom wall (12).
3. Blood pump according to claim 1 or 2, characterized in that the blades (18,19) are arranged such that they protrude to opposite sides from the surface wall of a disk-shaped or truncated supporting body (17).
4. Blood pump according to one of claims 1 to 3, characterized in that, as seen from the top, the blades (18,19) are of essentially triangular configuration, wherein the blade width increases with increasing radius.

10

5. Blood pump according to one of claims 1 to 4, characterized in that the blades (18,19) comprise the magnets (32).
6. Blood pump according to claim 4, characterized in that the blades (18, 19) have a convex outer surface (20) on the circular border of the supporting body (17).
7. Blood pump according to claim 5 or 6, characterized in that the supporting surfaces (30) of the blades (19) slope towards a trailing edge (27) of the triangular shape.
8. Blood pump according to one of claims 1 to 7, characterized in that a peripheral ring diffuser (44) is provided on the pump casing (10a), the ring diffuser (44) ending in the tangential outlet (15).

- 1 / 6 -



- 2 / 6 -

FIG. 3

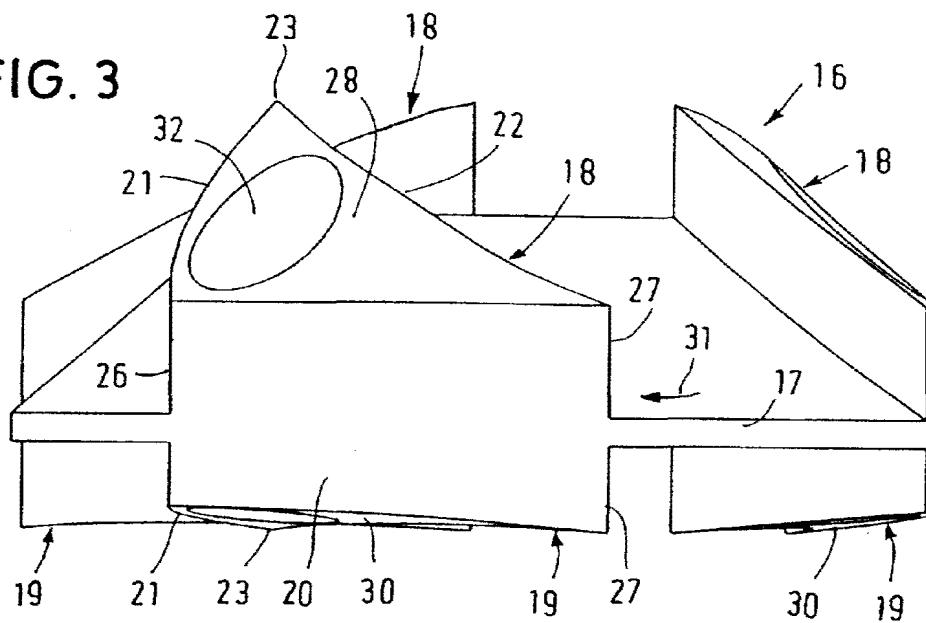
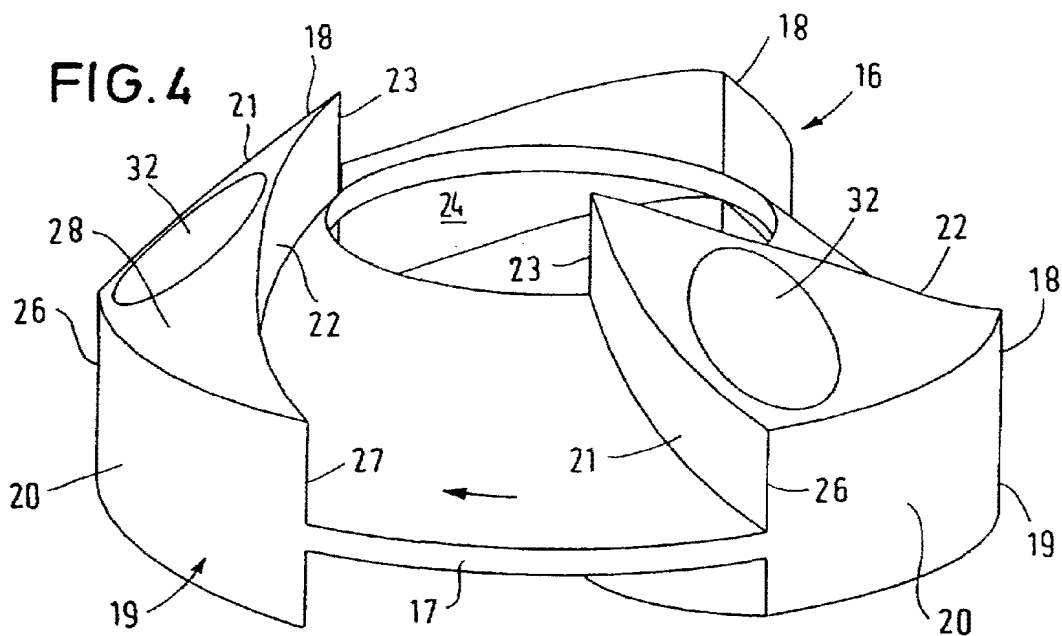


FIG. 4



- 3 / 6 -

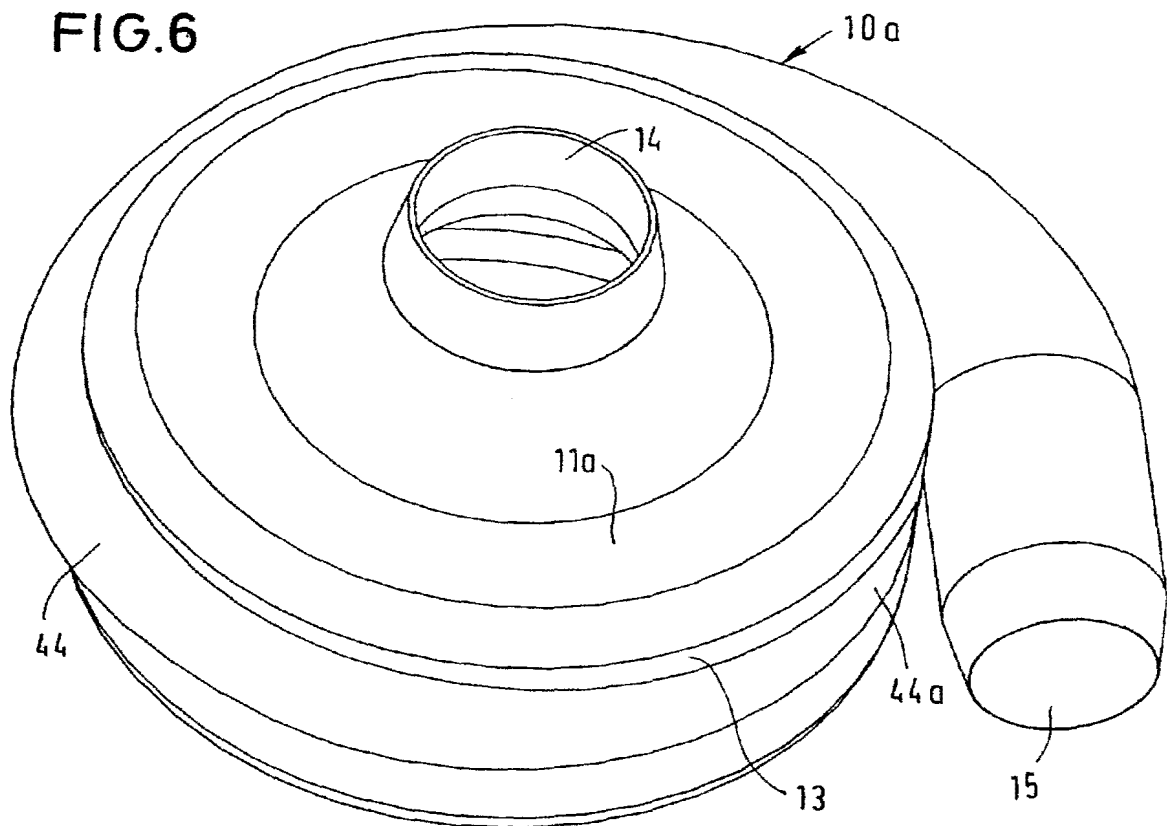
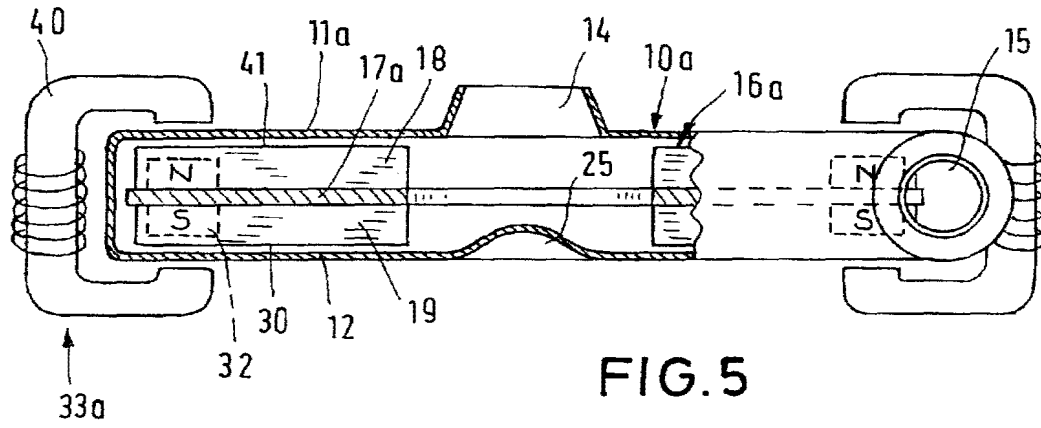
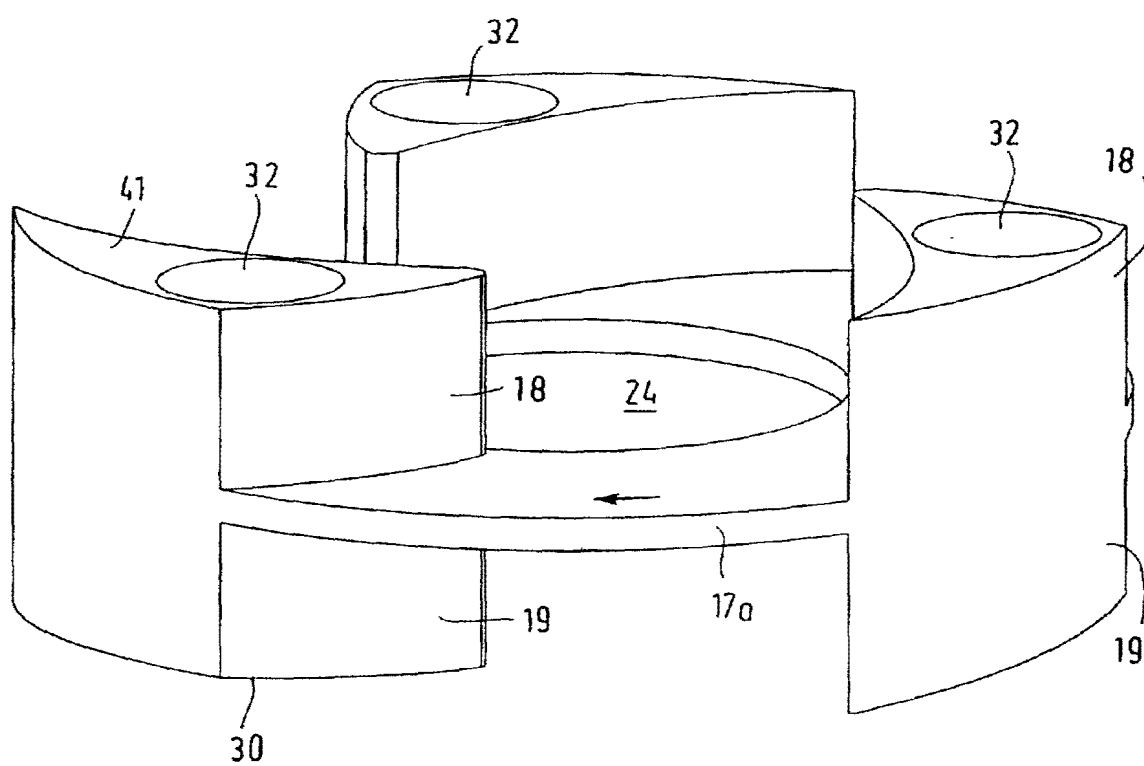


FIG. 7



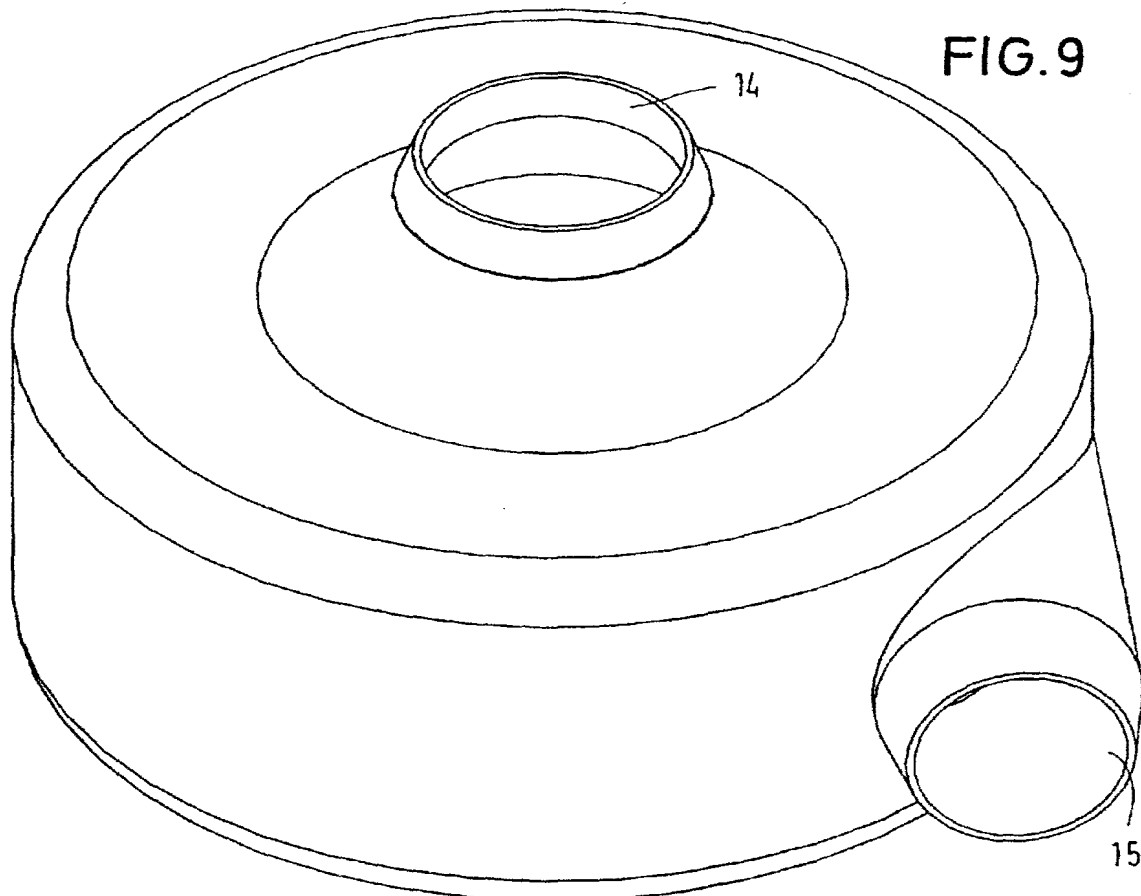
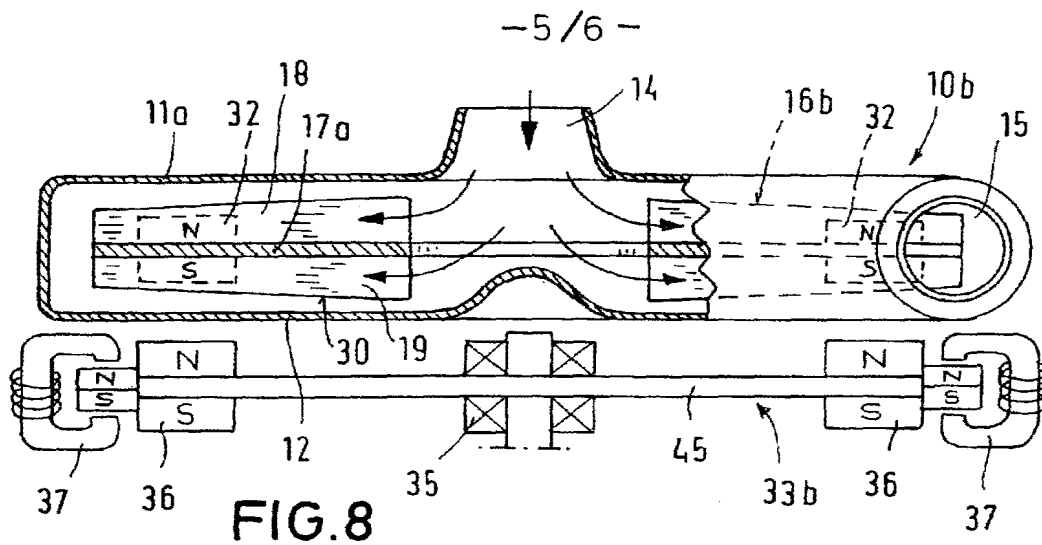
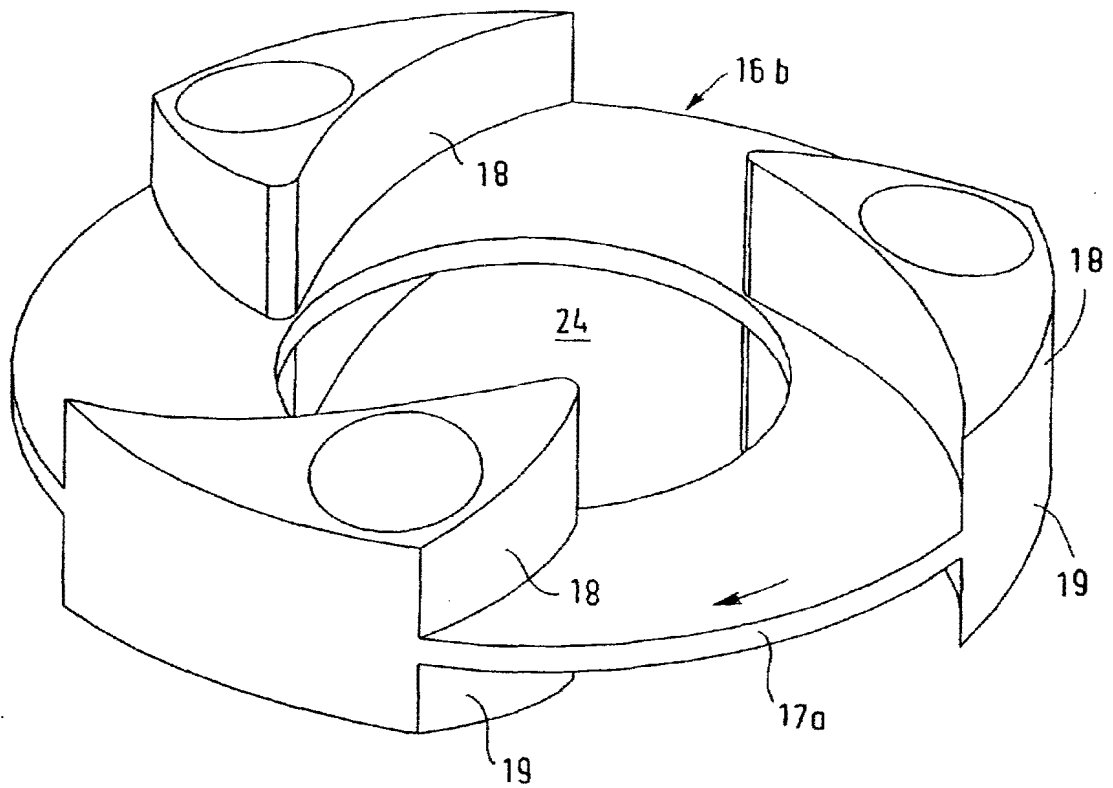


FIG. 10



(12)

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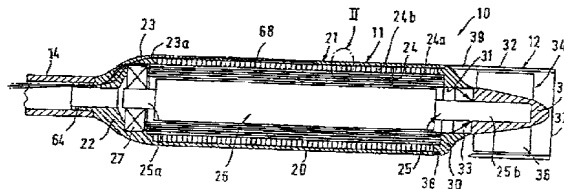
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(54) **MOTEUR ELECTRIQUE REFROIDI PAR UN LIQUIDE ET A PUISSANCE VOLUMIQUE ELEVEE**

(54) **ELECTRIC MOTOR COOLED BY A FLUID AND HAVING HIGH SPECIFIC POWER**

(57)

Disclosed is a micromotor with a motor housing (20) formed of polymer material. Said motor housing (20) surrounds the stator (24). The motor drives a pump part (12), which pushes fluid along the motor housing (20). The polymer material of the motor housing (20) contains an electrically isolating filler having caloric conductivity, especially Al₂O₃. Thereby, the temperatures arising in the motor housing are reduced. Furthermore, the hollow spaces of the coils (24a) of the stator can be filled up with a polymer material which contains a filler with caloric conductivity. The internal temperature of the motor is reduced as a result of the heat carried away to the fluid flowing around the motor. The micromotor is particularly useful for an intravascular blood pump.





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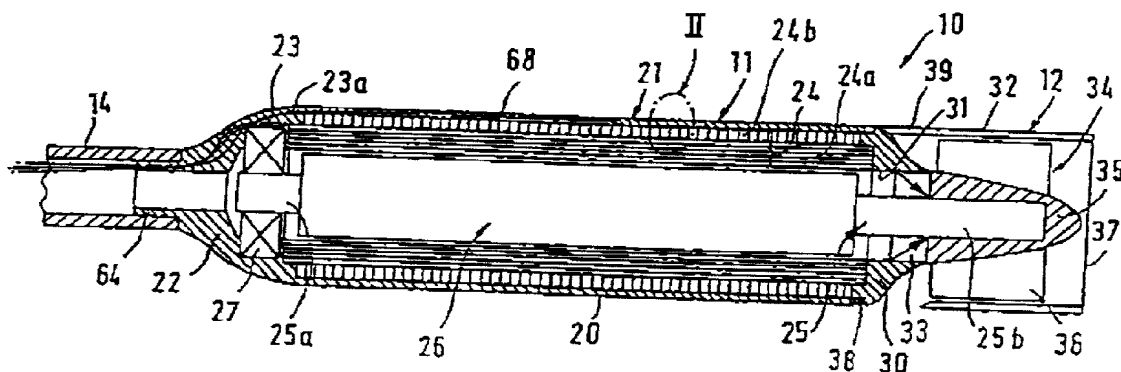
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(54) Titre : MOTEUR ELECTRIQUE REFROIDI PAR UN LIQUIDE ET A PUISSANCE VOLUMIQUE ELEVEE
(54) Title: ELECTRIC MOTOR COOLED BY A FLUID AND HAVING HIGH SPECIFIC POWER



(57) Abrégé/Abstract:

Disclosed is a micromotor with a motor housing (20) formed of polymer material. Said motor housing (20) surrounds the stator (24). The motor drives a pump part (12), which pushes fluid along the motor housing (20). The polymer material of the motor housing (20) contains an electrically isolating filler having caloric conductivity, especially Al_2O_3 . Thereby, the temperatures arising in the motor housing are reduced. Furthermore, the hollow spaces of the coils (24a) of the stator can be filled up with a polymer material which contains a filler with caloric conductivity. The internal temperature of the motor is reduced as a result of the heat carried away to the fluid flowing around the motor. The micromotor is particularly useful for an intravascular blood pump.

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Abstract

Disclosed is a micromotor with a motor housing (20) formed of polymer material. Said motor housing (20) surrounds the stator (24). The motor drives a pump part (12) which pushes fluid along the motor housing (20). The polymer material of the motor housing (20) contains an electrically isolating filler having caloric conductivity, especially Al_2O_3 . Thereby, the temperatures arising in the motor housing are reduced. Furthermore, the hollow spaces of the coils (24a) of the stator can be filled up with a polymer material which contains a filler with caloric conductivity. The internal temperature of the motor is reduced as a result of the heat carried away to the fluid flowing around the motor. The micromotor is particularly useful for an intravascular blood pump.

Electric motor cooled by a fluid and having high specific power

The invention refers to a fluid-cooled electric motor with high specific power comprising a motor housing injection molded from a polymer material and enclosing a stator, and in particular to a micromotor that can be introduced
5 into the vascular system of a body to drive a blood pump situated within the body.

WO 98/44619 describes a micromotor that is part of a blood pump to be
10 introduced into the body of a patient. The micromotor has a motor housing injection molded from polymer material and having an outer diameter no larger than 8.0 mm. The motor is part of a blood pump pumping blood in the vascular system of a patient, the blood flowing along the motor housing, thereby cooling the motor. A relatively high temperature is generated in the motor housing,
15 since polymer material has poor thermal conductivity. Due to the thermos bottle effect, temperatures of 60° C occur. Although the motor housing is cooled by the blood flowing along the same at a temperature of 37° C, the shaft extending from the motor housing has a higher temperature. There is a risk that the temperature-critical medium blood is damaged by too high a shaft
20 temperature. Seals sealing a shaft having a high temperature are subject to greater wear, thereby reducing the service life of the micromotor. Further, consideration must be given to the fact that the efficiency decreases at a high inner temperature within the motor. With micromotors in particular, which often rely on battery power for operation, a high efficiency is important. An
25 excessive inner temperature in the motor and the accompanying deterioration of efficiency, the mechanically available power is also reduced.

It is the object of the invention to provide a fluid-cooled micromotor with improved thermal dissipation.
30

According to the invention, the object is solved with the features mentioned in claim 1. In the present micromotor, the polymer material of the motor housing includes a thermally conductive electrically insulating filler. This filler

causes the motor housing to have a high conductivity so that the heat occurring inside the housing can be transferred better into the surrounding blood. Preferably, the filler is a ceramic material, in particular Al_2O_3 . Due to this material, given a corresponding filling amount, the thermal conductivity of thermoplastics or duroplastics can be increased significantly from a typical 0.05 W/mK to up to 2 W/mK without the electric conductivity increasing. It has been found that at a fluid temperature of 37° C, the internal temperature of the motor can be reduced from an initial 60° C to between 40° C and 45° C. Within the motor, no thermal build-up occurs, since the thermally conductive motor housing provides for a better transfer of the heat to the blood. Therefore, the components of the electric motor are subjected to a lesser thermal stress and, thus, also to a lesser wear. Moreover, the motor can be operated with improved efficiency.

The length of the motor housing is at least twice the outer diameter of this housing. Thus, it is an elongate motor housing with a small diameter. Such motor housing has a large surface relative to the volume. The thermally conductive filler contained in the housing wall, in combination with the large housing surface, allows for an effective thermal transfer to a medium flowing along the housing. Preferably, the length of the motor housing is at least 2.5 times, in particular at least three times, the outer diameter.

The filler is also advantageous in the manufacture of the micromotor by injection molding or in vacuum molding, since a large amount of filler reduces the curing time of a duromer because of the lesser duromer thicknesses and the improved thermal conductivity. Thus, the heat curing time in an oven is significantly reduced.

The amount of filler should be at least 40 percent by weight to achieve a significant increase in the thermal conductivity of the matrix material. The

filler, initially present as a fine powder, is mixed into the liquid polymer material, whereupon the forming is done by injection molding, drenching, and the like.

5 An important insulator within a micromotor is formed by the wire coils. Cavities filled with air exist between the windings, which form an ideal heat insulator. Moreover, the individual wires are coated with insulating sheaths that also present good thermal insulators. According to a preferred embodiment of the invention, which is of independent importance, the cavities of the stator coils are filled with a polymer material including a thermally conductive filler.
10 Thereby, the coils become good thermal conductors, where the current-induced heat generated in the coils is dissipated to the yoke and/or the motor housing with little thermal resistance. The polymer material filling the cavities causes an improved heat transfer to the iron yoke sheet arrangement which in turn passes the heat on to the motor housing. Introducing the filler-loaded polymer
15 material into the cavities of the coils is suitably done by drenching or by casting under a combination of vacuum and pressure, where all cavities are intentionally filled with thermally conductive polymer material.

20 The following is a detailed description of an embodiment of the invention taken in conjunction with the drawings.

In the Figures:

25 Fig. 1 is a longitudinal section of the micromotor and the pump connected thereto, and

Fig. 2 is an enlarged representation of the detail II of Fig. 1.

30 Fig. 1 described below already forms subject matter of WO 98/44619.

Fig. 1 illustrates an intravascular blood pump 10, i.e. a blood pump that can be pushed through the blood vessels of a patient so as to arrive in the heart. In general, the outer diameter of such a blood pump is nowhere larger than 8 mm.

5

The pump 10 has a drive portion 11 and a pump portion 12 rigidly connected thereto. The drive portion 11 includes an electric micromotor 21 with an elongate cylindrical housing 20. At the rear end, the housing 20 is closed by an end wall adjoined in a sealing manner by a flexible catheter 14. Electric wires 23 for power supply to and control of the electric motor 21 extend through the catheter 14, together with further wires 23a connected to sensors of the blood pump 10.

In a conventional manner, the stator 24 of the motor has a plurality of circumferentially distributed coils 24a, as well as a magnetic yoke 24b made of metal sheets and extending longitudinally. It is extrusion-coated with the motor housing 20. The stator 24 encloses the rotor 26 connected to the motor shaft 25 and consisting of permanent magnets magnetized in the direction of action. A bearing 27 supports the rear end of the motor shaft in the motor housing or the end wall 22. The shaft extends along the entire length of the motor housing 20 and projects forward therefrom.

The front end of the motor housing is formed by a stationary hub member 30 that is an integral part of the housing 20. The outer diameter of the hub member tapers towards the front end where a bearing 33 for supporting the motor shaft 25 is provided. This bearing is simultaneously designed as a shaft seal.

The motor shaft 25 protrudes forward from the hub member 30 and carries an impeller wheel 34 with a hub 35 sitting on the shaft end and blades 36 or pump vanes projecting therefrom and being inclined with respect to the

axis of the impeller wheel 34. The impeller wheel 34 is contained in a cylindrical pump housing 32 that is connected to a ring 38 on the hub member 30, the connection being established through three circumferentially distributed webs 39. It is visible that the motor housing 20 and the pump housing 32 are rigidly connected and have the same outer diameter, and that the diameter of the pump 10 is nowhere larger than this outer diameter.

During the rotation of the impeller wheel 34, blood is taken in through the take-in port 37 of the pump housing 32 and driven to the rear in the axial direction within the pump housing 32. Through the annular gap between the pump housing 32 and the motor housing 20, the blood flows outward along the hub member 30 to flow further along the motor housing 20. This guarantees the dissipation of the heat generated in the drive, without any damage to the blood caused by excessive surface temperatures (above 41° C) on the motor housing 20.

It is also possible to operate the pump portion 12 with the supply direction reversed, where the blood is drawn along the motor housing and exits axially from the front end opening 37.

A pressure sensor 68 is embedded in the circumferential wall of the motor housing 20, which communicates with a line 23a. This line 23a is encapsulated in the motor housing 20 and extends through the front wall 22 into the catheter 14. At the proximal end of the catheter, the line 23a and the wire 23 may be connected to an extracorporeal control device that controls the operation of the pump 10.

The micromotor 21 is manufactured by injection molding using an injection mold into which a mandrel is inserted that carries the stator components 24a, 24b. Polymer material is then injected into the mold. Thereafter, the injection

mold and the mandrel are removed from the motor housing 20 and the rotor 26 is finally mounted through the opening 31 of the hub member 30.

5 The polymer material used is preferably a liquid epoxy resin including a filler percentage of at least 40% by weight. The filler used is a fine powder of Al_2O_3 .

10 The current-induced heat generated in the coils 24a of the stator 24 is first transferred to the yoke arrangement 24b and, through heat transfer, from there to the motor housing 20. Since the motor housing 20 has a good heat conductivity, there is a low temperature gradient to the blood flowing around the motor housing at a temperature of 37° C.

15 Fig. 2 illustrates the wire windings 40 of a coil 24a, where each wire is provided with an insulating sheath 41. The spaces between the wire windings or their insulations are filled with polymer material 42 containing Al_2O_3 as a filler. Again the filler amount is at least 40% by weight. The polymer material 42 filling the cavities is in full surface contact with the yoke sheet arrangement 24b, which is in full surface contact with the motor housing 20.

20 Due to the improved cooling, a high mechanical power output of 5 W can be achieved at $n = 30,000$ rpm. Because of the substantially improved thermal conductivity in all motor components and the substantially improved heat coupling at the transition between coil, yoke and motor housing, the temperature inside the motor can be reduced significantly.

25 Thus, in the structure described, the transfer of 10 W of heat from within the motor to the outside requires a mere driving temperature difference of $\Delta\theta = 5 - 8$ K opposed to $\Delta\theta = 18 - 25$ K when using a non-filled polymer.

30 The complete filling of all winding cavities with polymer material 42 further allows for a smooth and insulating coil coating 43 on the inner surface of the

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coil. When the motor is designed as a brush-less synchronous machine, it is possible to drive the motor filled with liquid on the inside, provided the coils are fully encapsulated.

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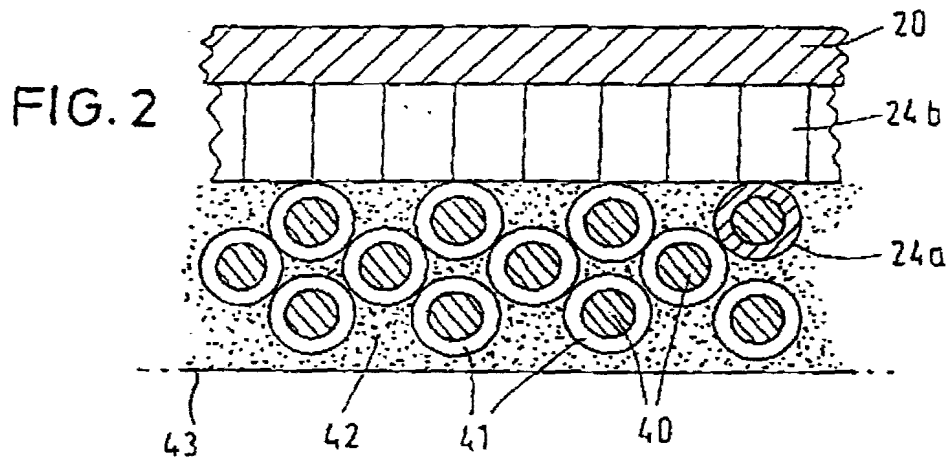
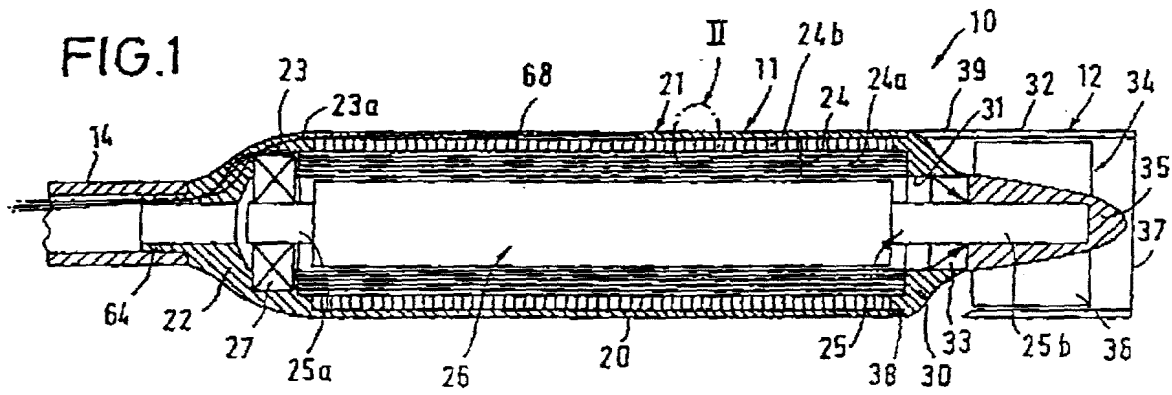
Claims

1. A fluid-cooled electric motor with a motor housing (20) made of polymer material and enclosing a stator (24), the length of the motor housing being at least twice the outer diameter of the motor housing,

characterized in that

the polymer material of the motor housing (20) contains a thermally conductive, electrically insulating filler in an amount of at least 40 percent by weight.
2. The electric motor of claim 1, wherein the filler comprises Al_2O_3 .
3. The electric motor in particular of claim 1 or 2, wherein the stator (24) comprises coils whose cavities are filled with a polymer material (42) including a thermally conductive filler.
4. The electric motor of claim 3, wherein the polymer material (42) filling the cavities is in thermally conductive contact with a surrounding yoke sheet arrangement (24b).
5. The electric motor of one of claims 1 to 4, wherein a pump portion (12) driven by the motor also includes filler.
6. The electric motor of claim 3 or 4, wherein the coil has a smooth insulating inner surface (43) made of said polymer material.

1/1



54. displacement to promote blood

57

There are described for their preparation, a positive displacement pump for conveying blood and a method. The pump has a pump housing, in that the housings of the inlet and outlet valve are seamlessly integrated. Thereby seam or joints can be avoided with their adverse effects on the blood. In the manufacturing method for the positive displacement pump, the pump housing is produced together with the two flaps enclosures in a single molding operation. In further process steps, the flaps closing body and the blood side
Formed membrane seamlessly



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DEUTSCHLAND



DEUTSCHES
PATENTAMT

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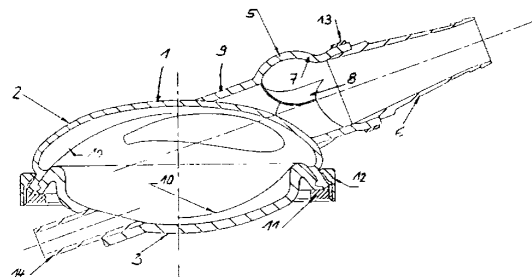
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⑤4 Verdrängerpumpe zur Förderung von Blut

⑤7 Es werden eine Verdrängerpumpe zur Förderung von Blut und ein Verfahren zu deren Herstellung beschrieben. Die Pumpe besitzt ein Pumpengehäuse, in das die Gehäuse der Einlaß- und Auslaßklappe nahtlos integriert sind. Hierdurch werden Naht- bzw. Stoßstellen mit ihren nachteiligen Auswirkungen auf das Blut vermieden. Bei dem Herstellverfahren für die Verdrängerpumpe wird das Pumpengehäuse zusammen mit den beiden Klappengehäusen in einem einzigen Formvorgang hergestellt. In weiteren Verfahrensschritten werden die Klappenschließkörper und die blutseitige Membran nahtlos angeformt.



DE 40 16 013 A 1

Die vorliegende Erfindung betrifft eine Verdrängerpumpe zur Förderung von Blut mit einem Pumpengehäuse, einer als Förderorgan dienenden, im Pumpengehäuse angeordneten Membran, die das Pumpengehäuse in eine Blutkammer und eine Kammer für das Fördermedium unterteilt, einem Einlaßstutzen am Pumpengehäuse und einem Auslaßstutzen am Pumpengehäuse.

Derartig ausgebildete Blutpumpen sind bekannt. Sie arbeiten mit einem gasförmigen oder flüssigen Antriebsmedium, das durch die flexible Membran vom Blut getrennt ist. Diese Membran ist schlauchförmig, flach, halbkugelförmig oder sackförmig ausgebildet und so in dem festen Pumpengehäuse untergebracht, daß das Blut von dem antriebsseitig ein- bzw. ausströmenden Antriebsmedium verdrängt bzw. angesaugt wird.

Derartige Blutpumpen werden mit separat ausgebildeten Ein- und Auslaßklappen betrieben, für die üblicherweise Herzklappenprothesen eingesetzt werden. Die Klappen werden dabei am Einlaß- und Auslaßstutzen des Pumpengehäuses befestigt.

Für alle Verdränger-Blutpumpen sind die Ein- und Auslaßklappen von entscheidender strömungsmechanischer bzw. hämodynamischer Bedeutung. Aus der Befestigung der Klappen an den Stutzen des Pumpengehäuses resultieren jedoch zwangsläufig Übergangs- bzw. Stoßstellen, die entsprechende strömungsmechanische bzw. hämodynamische Nachteile mit sich bringen. So resultieren thrombotische Ablagerungen, so daß beim Einsatz von derartigen Pumpen permanent gerinnungshemmende Mittel eingesetzt werden müssen. Es liegen somit keine übergangsfreien und stoßarmen Oberflächen vor, was zu entsprechenden Blutschädigungen führt.

Der Erfindung liegt die Aufgabe zugrunde, eine Verdrängerpumpe zur Förderung von Blut der angegebenen Art zu schaffen, die auf der Blutseite besonders strömungsgünstig ausgebildet ist.

Diese Aufgabe wird erfindungsgemäß bei einer Verdrängerpumpe der gattungsgemäßen Art dadurch gelöst, daß der Einlaßstutzen mit dem Gehäuse einer Einlaßklappe und der Auslaßstutzen mit dem Gehäuse einer Auslaßklappe einstückig ausgebildet sind.

Bei der erfindungsgemäßen Lösung sind somit beide Klappengehäuse unmittelbar in das Pumpengehäuse integriert, so daß sich zwischen Ein- und Auslaßstutzen einerseits und den Klappengehäusen andererseits keine Stoß- und Übergangsstellen mehr ergeben. Es liegen daher im Übergangsbereich zwischen Klappe und Stutzen ablösungsfreie Störungsverhältnisse vor, die zu keinen Blutschädigungen, insbesondere thrombotischen Ablagerungen, führen. Die beiden Klappengehäuse bilden daher Verlängerungen des Einlaß- und Auslaßstutzens.

Bei einer speziellen Ausführungsform der erfindungsgemäßen Pumpe sind die Einlaß- und Auslaßklappe als Bulbenklappen ausgebildet, wobei die jeweiligen Bulben einstückig mit dem Einlaß- und Auslaßstutzen ausgebildet sind. Hierbei bilden die Klappengehäuse bulbenförmige Ausbauchungen der jeweiligen Stutzen. Auch hier sind glatte Übergangsflächen zwischen Klappengehäuse und Stutzen vorgesehen, was die vorstehend geschilderten Vorteile mit sich bringt.

Bei den heute im Handel erhältlichen Blutpumpen werden nahezu ausschließlich mechanische Kippscheibenklappen verwendet, die nicht für diesen speziellen Anwendungsfall entwickelt wurden. Durch die unphy-

siologische Strömungsführung im Klappenbereich wird das Blut infolge überhöhter Schubspannungen sowohl hämolytisch geschädigt als auch präthrombotisch gereizt. Der in solchen Fällen typische Weg des Blutes führt aus Bereichen hoher Schubspannungen in Reizulationsgebiete (Totwassergebiete). Diese fluiddynamisch zeitweise abgeschlossenen Räume ermöglichen analog einem Reagenzgefäß die Durchmischung ohne Verdünnung von geschädigten und intakten Plättchen und bilden so die Grundlage zum thrombotischen Entstehungsprozeß. In ungestörter laminarer Strömung würde diese verhältnismäßig kleine Blutschädigung infolge rascher Verdünnung der aktivierenden Mediatoren ohne Folgen bleiben. Mit anderen Worten, auch durch die Art der bisher verwendeten Klappen, insbesondere die Ausbildung des Schließkörpers, wird das Blut geschädigt. Ein weiterer Nachteil von derartigen mechanischen Klappen sind das harte Schließen und die damit verbundenen Quer- und Längsbeschleunigungen der gesamten Pumpe sowie eine entsprechende Geräuscentwicklung.

Zur Behebung dieser Nachteile wird in Weiterbildung der Erfindung vorgeschlagen, daß der Schließkörper der Klappe an das zugehörige Klappengehäuse angeformt ist. Hierdurch wird auch zwischen Klappengehäuse und Schließkörper ein glatter Übergang erreicht, so daß die vorstehend aufgezeigten Nachteile, insbesondere das Entstehen von Totwassergebieten, vermieden werden. Bei dieser Ausführungsform sind somit Pumpengehäuse, Klappengehäuse und Schließkörper der Klappe einstückig ausgebildet.

Die Klappe weist als Schließkörper vorzugsweise mindestens ein Klappensegel auf. Bei einer besonders bevorzugten Ausführungsform sind drei Klappensegel vorhanden, die jeweils an die Innenseite des Klappengehäuses angeformt sind. Eine solche Klappe zeichnet sich durch besonders gute Strömungscharakteristika aus. Bei einer Bulbenklappe sind dabei die Segel vorzugsweise an der Übergangsstelle zwischen dem Bulbus und dem zylindrischen Gehäusestutzen angeformt.

Zur Vereinfachung der Herstellung ist das Pumpengehäuse zweckmäßigerweise zweigeteilt, wobei beide Gehäusehälften über eine Spanneinrichtung miteinander verbunden sind. Dabei weist vorzugsweise die obere Gehäusehälfte die mit den integrierten Klappen versehenen Stutzen für die Blutzuführung und Blutabführung auf, während die untere Gehäusehälfte vorzugsweise einen Stutzen zur Zu- und Abführung des Fördermediums (Luft) besitzt. Als Spanneinrichtung findet vorzugsweise eine auf einen Gewindering aufgeschraubte Spannmutter Verwendung, die zwei Ringflansche der Gehäusehälften gegeneinander preßt. Durch diesen Preßvorgang wird zweckmäßigerweise die Membran mit eingepreßt, indem deren radial äußere Bereiche mit Feder-Nut-Verbindungen zwischen die beiden Gehäuseflansche geführt sind.

Die das Pumpengehäuse unterteilende Membran besitzt zweckmäßigerweise eine blutseitige Lage und eine dem Fördermedium zugewandte Lage. Beide Lagen sind vorzugsweise voneinander getrennt und liegen nur lose aneinander an, wobei zwischen beiden eine Gleitschicht, beispielsweise aus Graphit, angeordnet ist. Dabei kann die dem Fördermedium zugewandte Lage aus dem gleichen Material wie das Pumpengehäuse bestehen, während die blutseitige Lage aus einem speziellen biokompatiblen Material besteht.

Wie bereits vorstehend erläutert, wird die Membran vorzugsweise dadurch gehalten, daß sie zwischen die

beiden Gehäusehälften eingespannt ist. Dies betrifft in Weiterbildung der Erfindung nur die dem Fördermedium zugewandte Lage der Membran, während die blutseitige Membranlage an die Innenseite des Pumpengehäuses angeformt ist. Bei dieser Ausführungsform ist daher auch die blutseitige Membranlage einstückig mit dem Pumpengehäuse ausgebildet. Pumpengehäuse, Stutzen, Klappengehäuse, Klappenschließkörper und blutseitige Membran bilden dabei hierbei eine Einheit.

Vorzugsweise sind Pumpengehäuse, Stutzen und Klappengehäuse auf ihren mit Blut in Berührung tretenden Flächen mit einem biokompatiblen Material beschichtet. Wenn auch die Klappenschließkörper (Segel) aus einem biokompatiblen Material bestehen, sind somit sämtliche mit Blut in Berührung tretenden Flächen der Verdrängungspumpe einschließlich der Klappen mit biokompatiblen Material versehen, so daß sich das Material der Pumpe nicht schädigend auf das Blut auswirkt.

Zweckmäßigerweise bestehen die relativ festen Bestandteile der Pumpe, nämlich das Pumpengehäuse, die Stutzen und die Klappengehäuse, aus thermoplastischem Polyurethan, das sich für diesen Einsatzzweck als besonders geeignet erwiesen hat. Als biokompatibles Material für die Herstellung der blutseitigen Membranlage und der Klappenschließkörper sowie für die Beschichtung der übrigen mit Blut in Kontakt tretenden Flächen kommt vorzugsweise in einem geeigneten Lösungsmittel lösbares biokompatibles Polyurethan zum Einsatz.

Insgesamt wird somit erfindungsgemäß eine Verdrängerpumpe mit nahtlos integrierten Ein- und Auslaßklappengehäusen sowie insbesondere mit nahtlos integrierter blutseitiger Membranlage und nahtlos integrierten Klappenschließkörpern vorgeschlagen. Die Blutpumpe ist auf der Blutseite besonders strömungsgünstig ausgebildet und weist insbesondere weichschließende Klappen auf. Alle blutführenden Bauteile können mit ein und demselben biokompatiblen flexiblen Material beschichtet oder aus diesem hergestellt sein.

Die Erfindung betrifft ferner ein Verfahren zur Herstellung einer Verdrängerpumpe der erfindungsgemäßen Art.

Wie erwähnt, ist es bekannt, für derartige Verdrängerpumpen separat hergestellte Klappen zu verwenden und diese Klappen mit den beiden Stutzen des Pumpengehäuses zu verbinden, beispielsweise zu verklemmen oder zu verkleben. Das erfindungsgemäße Verfahren wendet sich von dieser bekannten Lehre ab und schlägt in seiner allgemeinsten Ausführungsform die Herstellung des Pumpengehäuses mit den Klappengehäusen in einem einzigen Formvorgang vor.

Das Gehäuse wird dabei vorzugsweise über eine Positivform, die im Stutzenbereich die Gehäuse für die Aufnahme der Klappenschließorgane besitzt, in einem Arbeitsgang geformt, vorzugsweise thermogeformt.

In Weiterbildung umfaßt das erfindungsgemäße Verfahren des weiteren den Schritt des Anformens der Klappenschließorgane durch Antauchen. Hierbei wird zweckmäßigerweise gleichzeitig mit dem Anformen des Einlaßklappenschließorgans die Innenseite des Pumpengehäuses mit dem Material für die Klappenschließorgane beschichtet. Wie vorstehend erwähnt, handelt es sich hierbei um ein biokompatibles Material.

Ähnlich wie bei dem Einlaßklappenschließorgan wird auch das Auslaßklappenschließorgan durch Antauchen an das entsprechende Klappengehäuse angeformt.

Die blutseitige Membranlage wird vorzugsweise durch Anformen an das Pumpengehäuse hergestellt.

Bei einer besonders bevorzugten Ausführungsform des erfindungsgemäßen Verfahrens wird in der folgenden Reihenfolge vorgegangen: Zuerst wird das Pumpengehäuse mit integrierten Klappengehäusen geformt, wonach das Einlaßklappenschließorgan durch Antauchen hergestellt und an das Einlaßklappengehäuse angeformt wird. Hierbei erfolgt gleichzeitig eine Beschichtung der Innenseite des Pumpengehäuses. Im nächsten Verfahrensschritt wird das Auslaßklappenschließorgan durch Antauchen hergestellt und an das Auslaßklappengehäuse angeformt, wonach an die mit den fertigen Klappen versehene Pumpengehäusehälfte im nächsten Fertigungsschritt die blutseitige Membran angetaucht wird. Die Klappen müssen hierfür abgedeckt werden, um eine Beschädigung durch die Lösungsmittelatmosphäre beim Antauchvorgang zu unterbinden. Die Membran selbst wird durch mehrfaches Tauchen einer Kugelkalotte vorgefertigt. Beim letzten Tauchvorgang wird die Membran im feuchten Zustand mit der anderen Gehäusehälfte gefügt. Dies geschieht in Verbindung mit dem Einspannen der luftseitigen Membran und dem Festspannen der beiden Gehäusehälften gegeneinander.

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Das Pumpengehäuse wird zweckmäßigerweise in zwei Hälften hergestellt, wobei die beiden Hälften nach der Anbringung der Klappenschließorgane und der Membran miteinander verspannt werden. Wenn die Membran aus einer blutseitigen Lage und einer dem Fördermedium zugewandten Lage besteht, wird hierbei zweckmäßigerweise so vorgegangen, daß die dem Fördermedium zugewandte Membranlage zuerst einseitig eingespannt wird, während die blutseitige Membranlage ebenfalls zuerst einseitig angeformt wird. Es erfolgt dann ein Zusammenfügen der beiden Gehäusehälften, wobei die andere Seite der dem Fördermedium zugewandten Membranlage eingespannt und die andere Seite der blutseitigen Membranlage im noch feuchten Zustand mit dem Gehäuse gefügt wird.

Die Erfindung wird nachfolgend anhand eines Ausführungsbeispiels in Verbindung mit der Zeichnung im einzelnen erläutert. Es zeigt

Fig. 1 eine Draufsicht auf eine Ausführungsform einer Verdrängerpumpe mit integrierten Klappen; und

Fig. 2 einen Schnitt durch die Verdrängerpumpe der **Fig. 1** entlang Linie A-A in **Fig. 1**.

Die in den Figuren dargestellte Verdrängerpumpe zur Förderung von Blut besteht aus einem Pumpengehäuse 1, das sich aus einer oberen und einer unteren Gehäusehälfte 2, 3 zusammensetzt. Das Pumpengehäuse ist mit einer nahtlos integrierten Einlaß- und Auslaßklappe 4, 5 versehen. An diese Klappen sind entspre-

chende Reduzierstücke 6 angeschlossen, die mit entsprechenden Leitungen in Verbindung gebracht werden können.

Fig. 2 zeigt den Aufbau des Pumpengehäuses 1 im einzelnen. Die beiden Hälften 2, 3 des Pumpengehäuses, die jeweils etwa halbkugelförmig ausgebildet sind, sind mit Endflanschen versehen, die aneinander liegen. Der Endflansch der oberen Hälfte 2 weist dabei eine Feder auf, die in eine entsprechende Nut des Endflansches der unteren Hälfte 3 eingreift. Diese beiden Endflansche sind mit Hilfe eines Gewinderings 11 und einer Spannmutter 12 gegeneinander verspannt, so daß eine dichte Gehäuseeinheit gebildet wird. Mit zwischen die Flansche eingespannt ist eine Membran 10, die die Pumpenkammer im Gehäuse 1 in zwei Hälften unterteilt. Die Membran ist in der Figur links in ihrem endsystolischen und in der Figur rechts in ihrem enddiastolischen Zustand dargestellt.

Die Membran 10 unterteilt die Pumpenkammer in eine Luftkammer und eine Blutkammer. In die Luftkammer mündet ein Luftstutzen 14, mittels dem wechselweise Druck- und Unterdruck auf die Luftseite der Membran geführt werden. Auf diese Weise erfolgt eine Förderung des durch die Blutkammer strömenden Blutes. Die Blutkammer steht dabei über einen Einlaßstutzen und einen Auslaßstutzen 9 und die entsprechende Einlaß- und Auslaßklappe 4, 5 mit einem blutführenden Leitungssystem in Verbindung.

Wie man Fig. 2 entnehmen kann, ist das Gehäuse 7 der Auslaßklappe 5 zusammen mit dem Auslaßstutzen und der oberen Hälfte 2 des Pumpengehäuses 1 einstückig ausgebildet, so daß keine Naht- bzw. Stoßstelle dazwischen vorhanden ist. Gleiches trifft auf das Gehäuse der Einlaßklappe zu, das einstückig mit dem Einlaßstutzen und der oberen Hälfte 2 des Pumpengehäuses ausgebildet ist. Bei der hier dargestellten Ausführungsform sind Einlaß- und Auslaßklappe als Bulbenklappe ausgebildet, so daß die entsprechenden Klappengehäuse gegenüber den zugehörigen Stutzen erweitert sind. Als Schließkörper der Klappen finden drei Segel 8 Verwendung. Auch die Schließkörper sind nahtlos in das jeweilige Klappengehäuse integriert. Dies trifft auch auf die blutseitige Lage der Membran 10 zu, die an die Innenseite des Pumpengehäuses angeformt ist.

Die beiden Reduzierstücke 6 sind über einen geeigneten Schlauchbinder 13 mit dem zugehörigen Klappengehäuse verbunden.

Zur Herstellung der Pumpe mit integrierten Klappen wird wie folgt vorgegangen:

Zuerst wird die obere Gehäusehälfte 2 zusammen mit den beiden Klappengehäusen in einem Arbeitsgang thermogeformt. Hierzu wird eine mehrfach zerlegbare Positivform verwendet, die im Stutzenbereich die Bulben für die Aufnahme der Klappensegel besitzt.

In entsprechender Weise wird die untere Gehäusehälfte 3 geformt.

Die fertiggeformte Gehäusehälfte 2 wird dann von Materialresten freigeschnitten, auf einen Ring gespannt und fixiert. An diesem Ring wird das Tauchwerkzeug für die Segel der Einlaßklappe befestigt. Durch Ausschwenken mit PUR-Lösung werden sowohl die Klappensegel hergestellt als auch das Pumpengehäuse von innen beschichtet. Der Abfluß der überschüssigen Kunststofflösung erfolgt dabei durch die Auslaßöffnung, die z. T. abgedeckt wird, um dort die Bulbenkontur durch die mehrfachen Beschichtungen nicht zu verändern.

Nach Austrocknung werden die Segelkanten der Einlaßklappe aufgeschnitten oder aufgeschmolzen, um

dann das Klappenwerkzeug zu entfernen. Dies kann auch durch Laserschneiden geschehen.

Hiernach erfolgt die Fertigung der Auslaßklappensegel. Ähnlich wie bei der Einlaßklappe kann nun das Klappenwerkzeug am Ring im Auslaßbulbus befestigt werden. Durch Ausschwenken des Bulbus und anschließendes Taumeln können nun ähnlich wie bei der bisherigen Klappe die Segel hergestellt werden. Nach der Trocknung werden die Segelkanten aufgeschnitten bzw. aufgeschmolzen, und das Klappenwerkzeug wird entfernt.

An die mit den fertigen Klappen versehenen Pumpengehäusehälfte wird im nächsten Fertigungsschritt die blutseitige Membran angetaucht. Die Klappen müssen hierfür abgedeckt werden, um eine Beschädigung durch die Lösungsmittelatmosphäre beim Antauchvorgang zu unterbinden. Die Membran selbst wird durch mehrfaches Tauchen einer Kugelkalotte vorgefertigt. Beim letzten Tauchvorgang wird die Membran im feuchten Zustand mit der anderen Gehäusehälfte gefügt. Dies geschieht in Verbindung mit dem Einspannen der luftseitigen Membran und dem Festspannen der beiden Gehäusehälften gegeneinander.

Patentansprüche

1. Verdrängerpumpe zur Förderung von Blut mit einem Pumpengehäuse, einer als Förderorgan dienenden, im Pumpengehäuse angeordneten Membran, die das Pumpengehäuse in eine Blutkammer und eine Kammer für das Fördermedium unterteilt, einem Einlaßstutzen am Pumpengehäuse und einem Auslaßstutzen am Pumpengehäuse, **dadurch gekennzeichnet**, daß der Einlaßstutzen mit dem Gehäuse einer Einlaßklappe (4) und der Auslaßstutzen (9) mit dem Gehäuse (7) einer Auslaßklappe (5) einstückig ausgebildet sind.
2. Verdrängerpumpe nach Anspruch 1, dadurch gekennzeichnet, daß Einlaß- und Auslaßklappe (4, 5) als Bulbenklappen ausgebildet sind, wobei die jeweiligen Bulben einstückig mit dem Einlaß- und Auslaßstutzen (9) ausgebildet sind.
3. Verdrängerpumpe nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß der Schließkörper (8) der jeweiligen Klappe (4, 5) an das zugehörige Klappengehäuse (7) angeformt ist.
4. Verdrängerpumpe nach Anspruch 3, dadurch gekennzeichnet, daß die Klappe (5) als Schließkörper (8) mindestens ein Klappensegel aufweist.
5. Verdrängerpumpe nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, daß das Pumpengehäuse (1) zweigeteilt ist, wobei beide Gehäusehälften (2, 3) über eine Spanneinrichtung (11, 12) miteinander verbunden sind.
6. Verdrängerpumpe nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, daß die Membran (10) eine blutseitige Lage und eine dem Fördermedium zugewandte Lage aufweist.
7. Verdrängerpumpe nach Anspruch 6, dadurch gekennzeichnet, daß die blutseitige Membranlage an die Innenseite des Pumpengehäuses (1) angeformt ist.
8. Verdrängerpumpe nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, daß Pumpengehäuse (1), Stutzen (9) und Klappengehäuse (7) auf ihren mit Blut in Berührung tretenden Flächen mit einem biokompatiblen Material beschichtet sind.

9. Verdrängerpumpe nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, daß die Klappenschließkörper (8) aus biokompatiblen Material bestehen.
10. Verdrängerpumpe nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, daß Pumpengehäuse (1), Stutzen (9) und Klappengehäuse (7) aus thermoplastischem Polyurethan bestehen. 5
11. Verfahren zur Herstellung der Verdrängerpumpe nach einem der Ansprüche 1 bis 10, dadurch gekennzeichnet, daß Pumpengehäuse mit Stutzen und Klappengehäuse gemeinsam in einem Formvorgang hergestellt werden. 10
12. Verfahren nach Anspruch 11, dadurch gekennzeichnet, daß der Formvorgang ein Thermoformvorgang ist. 15
13. Verfahren nach Anspruch 11 oder 12, dadurch gekennzeichnet, daß es des weiteren den Schritt des Anformens der Klappenschließorgane durch Antauchen umfaßt. 20
14. Verfahren nach Anspruch 13, dadurch gekennzeichnet, daß gleichzeitig mit dem Anformen des Einlaßklappenschließorgans die Innenseite des Pumpengehäuses mit dem Material für die Klappenschließorgane beschichtet wird. 25
15. Verfahren nach einem der Ansprüche 11 bis 14, dadurch gekennzeichnet, es des weiteren den Schritt des Anformens der blutseitigen Membranlage durch Antauchen umfaßt.
16. Verfahren nach Anspruch 15, gekennzeichnet durch die in der nachfolgend weitergegebenen Reihenfolge ablaufenden Schritte: 30
- Formen des Pumpengehäuses mit integrierten Klappengehäusen;
- Antauchen des Einlaßklappenschließorgans mit gleichzeitiger Beschichtung der Innenseite des Pumpengehäuses; 35
- Antauchen des Auslaßklappenschließorgans; und
- Antauchen der blutseitigen Membranlage.
17. Verfahren nach einem der Ansprüche 11 bis 16, dadurch gekennzeichnet, daß das Pumpengehäuse in zwei Hälften hergestellt wird und daß die beiden Hälften nach der Anbringung der Klappenschließorgane und der Membran miteinander verspannt werden. 40

Hierzu 2 Seite(n) Zeichnungen

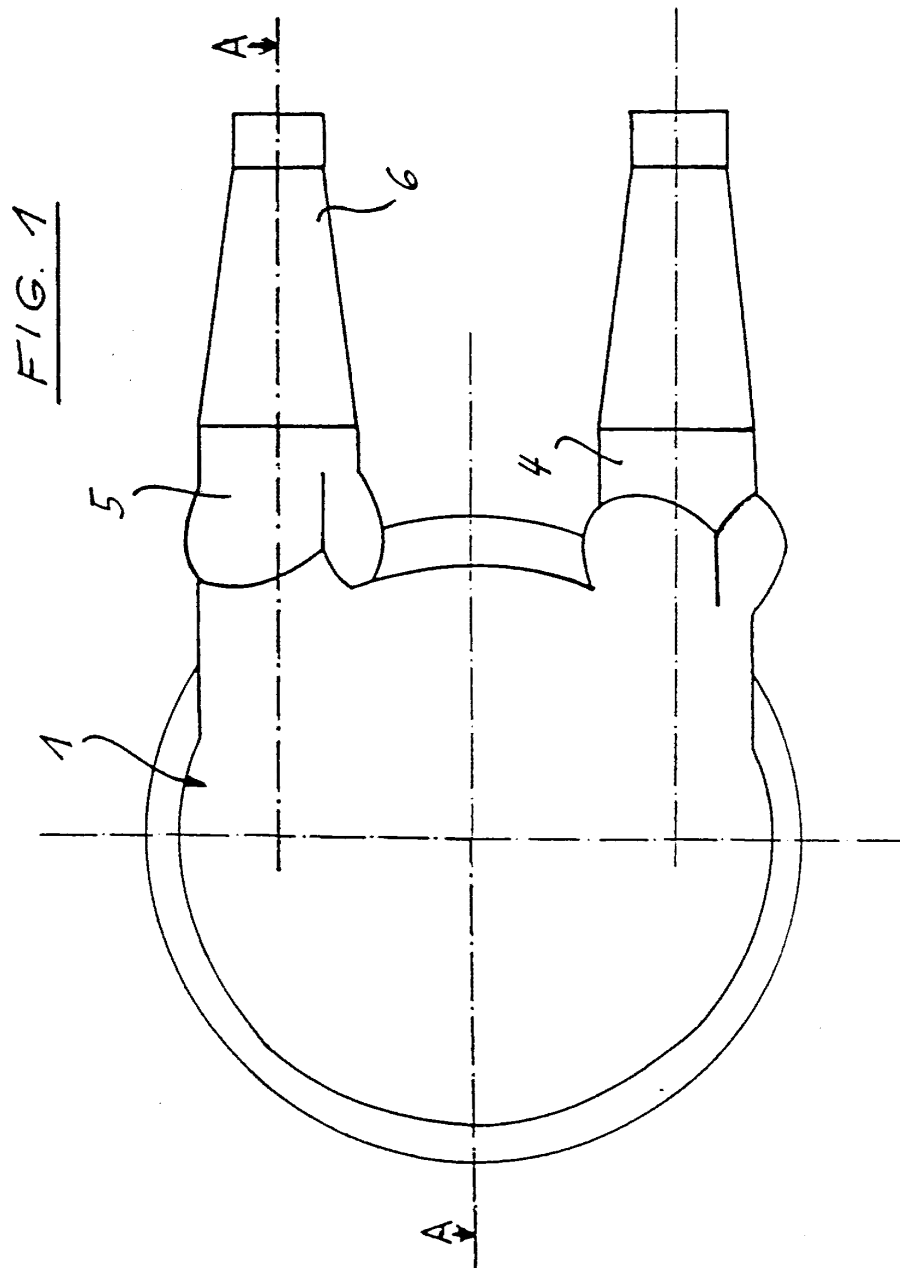
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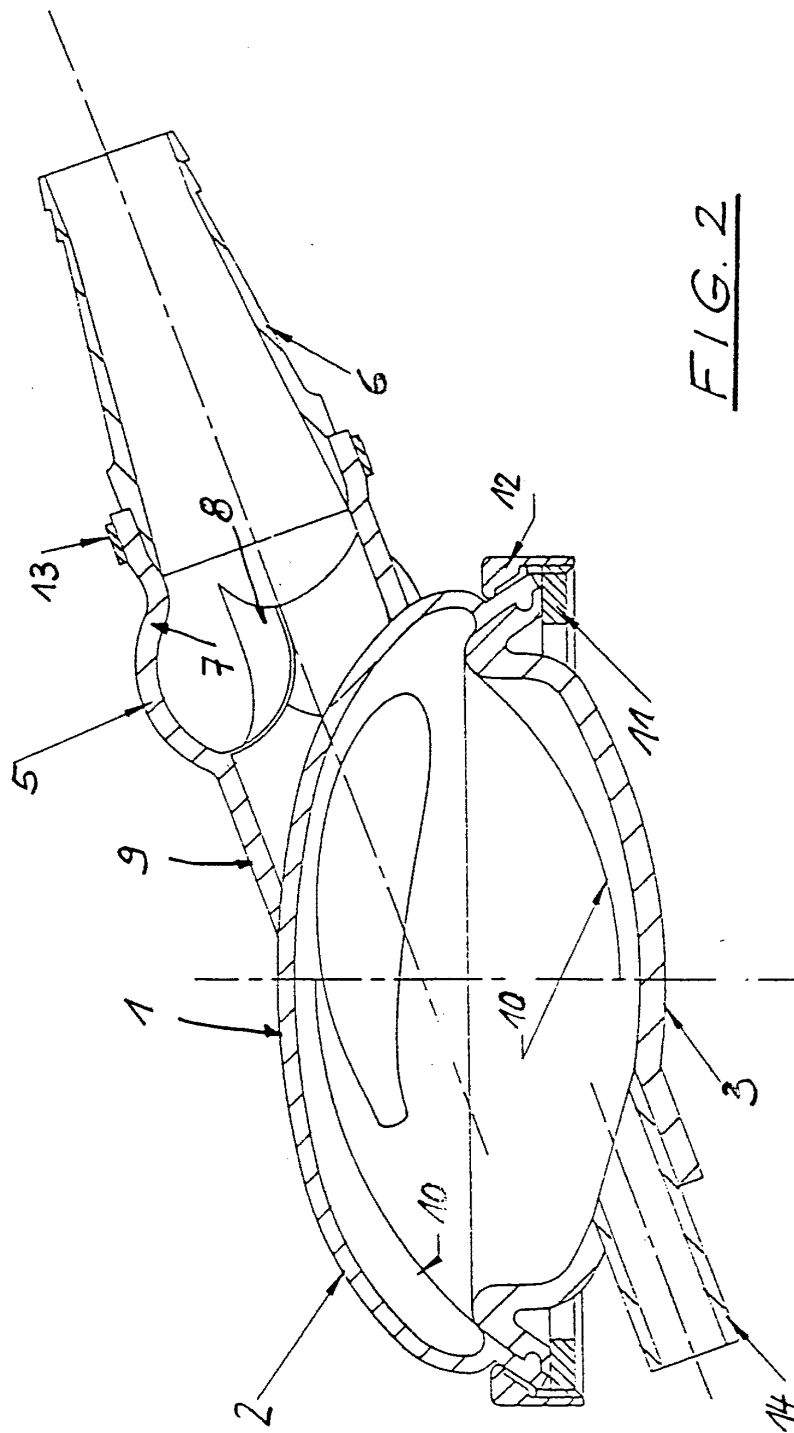


FIG. 2

DWPI Abstract (DE2355966A1)

Novelty

The pump is used for circulating human blood and has an externally controllable volume-and pressure-time relationship for the fluid fed from the pump. The pump is coupled with a programmable store which is programmed according to the desired volume and/or pressure-time relationship and can be sensed in a time controlled manner. The pump is hydraulically driven and is connected with a servo valve which feeds hydraulic fluid to the pump according to the stored programme. A digital-analogue converter is connected after the store and its output signal controls the servo valve. There is an interpolator, connected to a maximum decoder and a command amplifier which passes commands on to the servo valve.

Original Title:

Pump arrangement, in particular for blood pumps

For gesteaerten operation of the stepping motor 25 according to the stored program read out from the memory 6, binary coded signals to a parallel-serial converter 26 is supplied, whose output ~ series signals reach a Impalswandler 7, and then via the power amplifier 28 the stepper motor 25 to . Floating

To the rotary actuator tune; the Schri'ttmotors 25 according to the Proe; Ramm fe'stzu-lee; s is a Drehrichtungskennanc 29 connected to the memory 6, which operates via an electronic switch 30 to the pulse transformer 27 and ensures the correct direction of rotation of the stepping motor 25th

Deviations of the stepping motor of the actual position warden erkompensation about the pedometer control 31 and the Schrittfelh ~. 32 applied to the address counter 8 which produces a corresponding correction of the scan of the memory 6.

If the blood pump 1 'for the operation of an artificial - heart used • as the systole and diastole must be determined.

For controlling the duration of systole is an oxygen sensor 33 is used, which operates through an amplifier 34 to a frequency switch 35. This frequency switch determines the beat frequency in response to the output of the oxygen sensor 33rd

A pressure sensor 36 monitors the pressure in the atrium of the artificial heart, and controls over the frequency switch 35 to the timing generator 7, so that the atrial pressure can not be negative.

A pressure sensor 36 monitors the pressure in the atrium of the artificial heart, and controls over the frequency switch 35 to the timing generator 7, so that the atrial pressure can not be negative.

The control portion of the pump arrangement according to Figure 3 can be, indicated by dashed lines UEE, build in the form of an integrated circuit, which is fed by a power source 37 which also energizes the stepping motor 25th

In a modification of the pump arrangement according to Figure 3 can the memory 6 a Generator.126 with digital frequency selection are downstream, as is indicated in FIG. 4 This generator produces in accordance with the binary coded outputs of the memory 6 different frequencies which are supplied to the pulse transformer 127, which drives the stepping motor with Seisen output pulses.

Another possibility for driving the pump is the use of a directly working on the pump piston 201 linear motor 225. The opposite figure 3 modified part of the arrangement shown in Figure 5 • schematically. In this arrangement, the output signals of the memory 6 to a generator 226 with digital F ~ equenzwahl supplied whose changing output frequencies a turn ~ omgenerator 227 control which drives the linear motor 225 via the power amplifier 228th To control the direction of movement of Linearmotdtrs serves a phase switch 230, the paired with the memory 6 ~ lt.

While it has been assumed above assumes that the memory 6, a digital memory is of the digital or essentially binary coded output • providing signals of the memory can also be constructed so that its output signal is substantially in analog form. An example of this is shown in Figure 6. This memory schematically shown in Figure 6 has the form of a function generator and contains a number of resistors RP1 to RPm 'which are preferably adjustable. This counterclaim states, are at one end to a voltage source and the other end at the output of a demultiplexer 300, whose inputs are connected to the exits a- binary counter 301 •.

When using this memory in a pump assembly for a blood pump, the binary counter 301 is input with a frequency

finely $1/t \cdot 1/m$

operated, where t is the duration of the heartbeat period and m the number of resistors Rp is. The counter 301 then supplies during a flapping period m meter readings, which are the de-multiplexer 300 fed laying successively via its outputs resistors RPi to RPm to voltage. The voltage drop across this resistor is s an integrator 302 is supplied via a resistor for each singles g provided resistance whose A sgangssignale then the adjusted means of the lviderstände Rp program corresponds.

A memory according to Figure 6 can be used to control the servo valve in the Pumpenan? Rdnung according to Figure 1 in spielsvmise without using a digital to analog \ vandlers.

Claims:

1. A pump assembly comprising a pump with an externally controllable volume and / or pressure-time behavior of the pump for the fluid to be conveyed; characterized ge particular for blood pumps, ennzeichnet that the pump (1,1 ') with a programmable memory (6) is coupled, which is per rammiert corresponding to the desired volume and / or pressure-time behavior and timed scanned.
2. Pump arrangement according to claim 1, characterized in that the Pu pe (1) is connected hydraulically driven, and a servo valve (2) that the P MPE (1) in Abhäne; accuracy from the stored ProR; supplying ram hydraulic fluid..
3. Pump arrangement according to claim 2, characterized in that the memory (6), a digital-to-analog converter (11) is connected downstream whose Ause; angssignal'im substantially controls the servo valve (2).
4. Pump arrangement according to claim 3, characterized in that the output signal of the digital-to-analog converter (11) a maximum decoder (12 ') for generating a signal upon occurrence of the maximum amplitude of the output signal can be fed.
5. Pump arrangement according to claim 1, characterized in that the pump (1 ') of a program corresponding to the stored controllable stepper motor (25) is drivable.
6. A pump assembly according to claim 1, characterized in that the pump is a piston pump whose piston antreibbarist (201) of a program corresponding to the stored controllable linear motor (225).
7. A pump assembly according to one of claims 1 to 6, characterized by a controllable timing generator (7) which is ver via an address counter (8) for temporal Abtastune the program stored to the memory (6) connected.
8. A pump assembly according to claims 4 and 7, characterized in that the signal to the timing generator (7) can be fed.
9. A pump assembly according to one of claims 1 to 8, characterized in that the actual pump is vereleichbar position with the target position and that the pump Vergleichssiñal determined to control the pump entsegen a deviation from the target is .verwendbar Pumpenstellunc.
10. A pump assembly according to one of claims 1 to 9, characterized in that the memory (6) is a semiconductor memory.
11. A pump assembly according to one of claims 1 to 9, characterized in that the memory contains a plurality of sequentially controllable resistors (Rp1. •• rpm), whose dimensions corresponds to the program, and sequentially that the .Hiderstände plexer of a demuxer (300) can be controlled, in time sequence to the output signals of a binary counter (301) can be fed.
12. A pump assembly according to one of claims 1 to 11, characterized in that the memory (6) contains several programs for the volume undbder • nuck-time behavior and can be switched to the desired program.
13. A pump assembly according to claim 12, characterized by a zero detector (23) for the output signal of the memory (6), the output to switch to another Program memory (6) coupled thereto.

⑤1

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Pumpenanordnung, insbesondere für Blutpumpen

⑦1

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Hamburg, 5. November 1973

Pumpenanordnung, insbesondere für

Blutpumpen

Die Erfindung bezieht sich auf eine Pumpenanordnung mit einer Pumpe mit einem extern steuerbaren Volumen- und/oder Druck-Zeit-Verhalten für das von der Pumpe zu fördernde Fluid, insbesondere für Blutpumpen.

Pumpen mit extern steuerbarem Volumen- und/oder Druck-Zeit-Verhalten sind beispielsweise für die Kraftstoffzufuhr zu Verbrennungsmotoren bekannt. Bei diesen Pumpenanordnungen erfolgt die Steuerung des Volumen- und/oder Druck-Zeit-Verhaltens üblicherweise rein mechanisch, und eine Steuerung ist üblicherweise nur in Abhängigkeit von der Drehzahl des Verbrennungsmotors möglich.

Es gibt jedoch viele Anwendungsfälle, bei denen während eines Arbeitszyklus der Pumpe eine bestimmte Förder- oder Druckkurve erwünscht ist. Ein derartiger Anwendungsfall ergibt sich beispielsweise bei einer Blutpumpe, die insbesondere dann, wenn sie mit einem künstlichen Herzen zusammenarbeitet, möglichst genau die "Pumpcharakteristik;"

des natürlichen Herzens nachahmen soll. Ferner sind derartige Pumpanordnungen unter anderem für Beatmungsgeräte, Dialysegeräte, Herz-Lungen-Maschinen u.ä. sowie auch für andere technische Gebiete erwünscht.

Um bei einer Pumpanordnung der eingangs erwähnten Art ein gewünschtes Volumen- und/oder Druck-Zeit-Verhalten innerhalb des jeweiligen Zyklus der Pumpe, also eine bestimmte Pumpencharakteristik zu erreichen, ist die Pumpe erfindungsgemäß mit einem programmierbaren Speicher gekoppelt, der entsprechend dem gewünschten Volumen- und/oder Druck-Zeit-Verhalten programmiert und zeitlich gesteuert abtastbar ist.

In einen programmierbaren Speicher, der beispielsweise ein Halbleiterspeicher sein oder der eine Anzahl von nacheinander ansteuerbaren Widerständen enthalten kann, deren Dimensionierung dem Programm entspricht, wobei die Widerstände nacheinander von einem Demultiplexer ansteuerbar sind, dem in zeitlicher Folge Ausgangssignale von einem Binärzähler zuführbar sind, läßt sich die gewünschte Pumpencharakteristik eingeben, so daß die Pumpe das zu fördernde Fluid innerhalb eines Arbeitszyklus entsprechend dem eing gespeicherten Programm fördert.

Für die Steuerung einer Blutpumpe läßt sich dadurch die Pumpcharakteristik des Herzens sehr genau nachahmen, so daß

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die sonst möglichen Schädigungen der Mikrozirkulation (vgl. NAS Publication No. 1283) vermieden werden.

Die zu verwendende Pumpe kann hydraulisch antreibbar und mit einem Servoventil verbunden sein, das der Pumpe in Abhängigkeit vom gespeicherten Programm Hydraulikflüssigkeit zuführt.

Es ist jedoch auch möglich, die Pumpe von einem entsprechend dem gespeicherten Programm steuerbaren Schrittmotor antreiben zu lassen, oder eine Kolbenpumpe zu verwenden, deren Kolben von einem entsprechend dem gespeicherten Programm steuerbaren Linearmotor antreibbar ist.

Um das Programm des Speichers in dem gewünschten zeitlichen Ablauf auslesen und zur Steuerung der Pumpe verwenden zu können, kann ein steuerbarer Zeitgenerator vorgesehen sein, der über einen Adreßzähler zur zeitlichen Abtastung des gespeicherten Programms mit dem Speicher verbunden ist.

Zur Erzielung des gewünschten Zeitablaufes können dem Zeitgenerator besondere Steuersignale zugeführt werden, die z.B. aus Meßwerten gewonnen werden. Bei einer Blutpumpe können die Meßwerte aus dem Sauerstoffgehalt des Blutes und dem

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Vorhofdruck des künstlichen Herzens gewonnen werden, so daß auf diese Weise der zeitliche Ablauf des gespeicherten Programms beeinflußt und verändert werden kann.

Gegebenenfalls kann der Speicher auch verschiedene Programme für das Volumen- und/oder Druck-Zeit-Verhalten aufweisen, und es kann auf das gewünschte Programm geschaltet werden. In diesem Fall kann in Abhängigkeit vom Ausgangssignal des Speichers, beispielsweise beim Null-Durchgang des Ausgangssignals, auf ein anderes Programm im Speicher umgeschaltet werden.

Wird eine hydraulisch antreibbare und mit einem Servoventil verbundene Pumpe benutzt, so kann dem Speicher ein Digital-Analog-Wandler nachgeschaltet sein, dessen Ausgangssignal im wesentlichen das Servoventil steuert.

Das Ausgangssignal des Digital-Analog-Wandlers kann einem Maximum-Dekodierer zur Erzeugung eines Signals beim auftreten der maximalen Amplitude des Ausgangssignals zugeführt werden. Ein derartiges Signal ist dann besonders vorteilhaft, wenn die Pumpenanordnung im Zusammenhang mit einer Blutpumpe zur Unterstützung des natürlichen Blutkreis-

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laufs benutzt wird, da dann das Signal zu einer Anpassung des Betriebs der beiden Pumpmechanismen dienen kann.

Die Erfindung wird im folgenden anhand der schematischen Ausführungsbeispiele zeigenden Figuren näher erläutert.

Figur 1 zeigt in einem Blockschaltbild eine Pumpenanordnung gemäß der Erfindung mit einer Blutpumpe mit Servoventil.

Figur 2 zeigt schematisch die Pumpe mit dem mit ihr verbundenen Servoventil.

Figur 3 zeigt in einem Blockschaltbild eine andere Pumpenanordnung gemäß der Erfindung.

Figur 4 zeigt die dem Speicher nachgeschalteten Elemente für eine Abwandlung der Pumpenanordnung gemäß Figur 3.

Figur 5 zeigt in einem Blockschaltbild die Änderungen in der Pumpenanordnung gemäß Figur 3 bei Verwendung einer von einem Linearmotor angetriebenen Kolbenpumpe.

Figur 6 zeigt schematisch ein Ausführungsbeispiel für einen

in der Pumpenanordnung verwendbaren, programmierbaren Speicher.

In dem Ausführungsbeispiel gemäß Figur 1 ist eine Pumpenanordnung mit einer Blutpumpe 1 gezeigt, die von einem Servoventil 2 über einen Servozylinder 3 und eine Fluidpumpe 4 getrieben wird. Der Aufbau dieses mechanischen Teils wird anhand von Figur 2 erläutert werden. Das Servoventil 2 und der Servozylinder 3 sind außerdem mit einer Quelle 5 für Hydraulikfluid verbunden.

Zur Steuerung der Blutpumpe dient als wesentliches Element ein programmierbarer Speicher 6, der von bekannter Bauart sein kann, also z.B. ein Halbleiterspeicher, ein Kernspeicher o.ä. In diesen Speicher wird der gewünschte Verlauf des Volumen- und/oder Druck-Zeit-Verhaltens der Pumpe eingespeichert, so daß die Pumpe durch Auslesen des Speichers 6 entsprechend gesteuert werden kann. Um den programmierten Speicher in zeitlicher Abhängigkeit auszulesen, ist ein Zeitgenerator 7 vorgesehen, der über einen Adreßzähler 8 und eine X-Anzeige 9 den Speicher in vom Zeitgenerator vorgegebener Zeitfolge abfragt und so entsprechend dieser Zeitfolge den programmierten Verhaltensverlauf über eine Y-Anzeige 10 an einen Digital-Analog-Wandler 11 gibt.

Das aus sich un~~st~~etig ändernden Größen bestehende Ausgangssignal dieses Wandlers 11 wird zur Erzeugung eines sich nicht sprunghaft ändernden Kurvenlaufes einem Interpolator 12 zugeführt, dessen Ausgangssignal über einen Regelverstärker 13 zur Steuerung des Servoventils 2 dient.

Bei Verwendung eines Ventils, wie es schematisch in Figur 2 dargestellt ist, ergibt sich dann die folgende Arbeitsweise. Das mit der Pumpe 1 verbundene Servoventil 2 führt von der Quelle 5 (Figur 1) entsprechend der Ansteuerung vom Regelverstärker 13 (Figur 1) dem Servozylinder 3 über den Verbindungskanal 16 oder 17 Hydraulikfluid zu, so daß der Pumpenkolben 4 in Figur 2 nach rechts oder links verschoben wird. Nimmt man hierzu an, daß ausgehend von der Darstellung in Figur 2 Hydraulikfluid über den Kanal 17 zugeführt wird, so bewegt sich der Kolben 4 nach rechts und mit ihm der mit zwei gegeneinander geschalteten Rollmembranen 14 und 15 abgedichtete Kolben der Blutpumpe 1, d.h. es erfolgt ein Ansaugvorgang. Diese Bewegung des Kolbens 4 nach rechts erfolgt entsprechend dem im Speicher 6 (Figur 1) enthaltenen Programm, d.h. die Bewegung des Kolbens nach rechts kann sich zeitlich ändern, also in einzelnen Abschnitten schneller oder langsamer erfolgen, was durch eine entsprechende Zufuhr von Hydraulikfluid erreicht wird. Als Folge davon bewegt sich auch der

Kolben der Blutpumpe entsprechend dem Programm im Speicher 6. Wie ohne weiteres klar ist, läßt sich ein entsprechender Bewegungsablauf auch bei einer Bewegung des Kolbens 4 nach links erreichen, indem das Hydraulikfluid vom Servoventil 2 gesteuert mittels des Programms aus dem Speicher 6 über den Kanal 16 zugeführt wird.

Im allgemeinen muß überwacht werden, ob die Bewegung des Kolbens im Servozylinder auch entsprechend dem vorgegebenen Programm erfolgt, d.h. ob der Ist-Wert mit dem Soll-Wert übereinstimmt. Hierzu kann der Servozylinder 3 mit einem Weggeber 18 (Figur 1 und 2) verbunden sein, dessen Ausgangssignal dem Regelverstärker zugeführt wird, so daß bei Abweichung des Ist-Wertes vom Soll-Wert eine Regelung in Richtung auf den Soll-Wert, also eine Korrektur erfolgt.

Wie bereits erwähnt, kann die Pumpenanordnung gemäß Figur 1 in Zusammenhang mit einer Blutpumpe benutzt werden. Hierbei können besondere Betriebsfälle auftreten, die in der Pumpenanordnung berücksichtigt werden sollten.

So ändert sich das Verhältnis der systolischen Zeit zur diastolischen Zeit des Herzens mit wachsender Schlagfrequenz

in Richtung zu kürzeren Diastolenzeiten, d.h. daß im Speicher 6 enthaltene Programm muß an die Schlagfrequenz angepaßt bzw. mit dieser geändert werden. Hierzu kann man dem Zeitgenerator 7 der Schlagfrequenz entsprechende Signale sowie Signale entsprechend der Systole und der Diastole zuführen, so daß die zeitliche Abtastung des Speichers 6 mittels des Zeitgenerators 7 entsprechend der Schlagfrequenz geändert wird, also bei wachsender Schlagfrequenz eine Berücksichtigung der sich verkürzenden Diastolenzeiten erfolgt. Es ist daher nicht erforderlich, das Programm im Speicher zu ändern, sondern es genügt, wenn die zeitliche Ansteuerung des Speichers 6 zur Auslesung des Programms entsprechend verändert wird.

Die Blutpumpenanordnung gemäß der Erfindung kann auch benutzt werden, um die Blutpumpe unterstützend für den natürlichen Blutkreislauf einzusetzen. Hierzu kann ein Elektrokardiogramm dienen, das über einen Differenzverstärker 19, einen Trigger 20 und eine Verzögerungsstufe 21 auf den Zeitgenerator 7 arbeitet und so den zeitlichen Ablauf der Auslesung des Programms im Speicher 6 steuert.

Für Modelluntersuchungen o.ä. ist es häufig erwünscht, zwischen verschiedenen Programmen für den Betrieb der Pumpe umschalten

zu können, wobei vorzugsweise die verschiedenen Programme bereits im Speicher 6 enthalten sind. Für diese Umschaltung ist ein Programmschalter 22 vorgesehen, bei dessen Betätigung von einem Programm zu einem anderen Programm übergegangen wird.

Um jedoch zu verhindern, daß dieser Übergang zu einer sprunghaften Zustandsänderung im Pumpkreislauf führt, kann an den Digital-Analog-Wandler 11 ein Nullpunktsdetektor 23 angeschlossen sein, der den Nulldurchgang des Ausgangssignals vom Speicher 6 feststellt, d.h. den Totpunkt im Betrieb der Pumpe ermittelt und dann bei diesem Totpunkt über einen Zwischenspeicher 24 die Programmumschaltung im Speicher 6 bewirkt, falls der Programmschalter 22 zuvor betätigt wurde.

Figur 3 zeigt in einem Blockschaltbild ein etwas abgewandeltes Ausführungsbeispiel der Erfindung, wobei wiederum eine Blutpumpe in Abhängigkeit von einem im Speicher 6 gespeicherten Programm gesteuert wird. Diese Blutpumpe 1' wird in diesem Fall von einem Schrittmotor 25 angetrieben, der sich in Abhängigkeit vom Programm schrittweise bewegt und so ein entsprechendes Volumen- und/oder Druck-Zeit-Verhalten der Pumpe hervorruft.

Zum gesteuerten Betrieb des Schrittmotors 25 entsprechend dem gespeicherten Programm werden die aus dem Speicher 6 ausgelesenen, binär kodierten Signale einem Parallel-Serien-Umsetzer 26 zugeführt, dessen Ausgangs-Seriensignale in einen Impulswandler 27 gelangen, um dann über die Endstufe 28 den Schrittmotor 25 zu treiben.

Um die Drehrichtung des Schrittmotors 25 entsprechend dem Programm festzulegen, ist an den Speicher 6 eine Drehrichtungskennung 29 angeschlossen, die über einen elektronischen Schalter 30 auf den Impulswandler 27 arbeitet und die richtige Drehrichtung des Schrittmotors 25 sicherstellt.

Abweichungen des Schrittmotors von der Ist-Stellung werden über die Schrittzählerkontrolle 31 und die Schrittfehlerkompensation 32 an den Adreßzähler 8 gegeben, der eine entsprechende Korrektur über die Abtastung des Speichers 6 bewirkt.

Wird die Blutpumpe 1' für den Betrieb eines künstlichen Herzens eingesetzt, so müssen die Systole und die Diastole bestimmt werden.

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Zur Steuerung der Dauer der Systole wird ein Sauerstoff-Fühler 33 verwendet, der über einen Verstärker 34 auf einen Frequenzschalter 35 arbeitet. Dieser Frequenzschalter bestimmt die Schlagfrequenz in Abhängigkeit vom Ausgangssignal des Sauerstoff-Fühlers 33.

Ein Druckfühler 36 kontrolliert den Druck im Vorhof des künstlichen Herzens und steuert über den Frequenzschalter 35 den Zeitgenerator 7 an, so daß der Vorhofdruck nicht negativ werden kann.

Der Steuerteil der Pumpenanordnung gemäß Figur 3 läßt sich, wie gestrichelt angedeutet, in Form einer integrierten Schaltung aufbauen, die von einer Energiequelle 37 gespeist wird, welche außerdem den Schrittmotor 25 erregt.

In Abwandlung der Pumpenanordnung gemäß Figur 3 kann dem Speicher 6 auch ein Generator 126 mit digitaler Frequenzwahl nachgeschaltet werden, wie dies in Figur 4 angedeutet ist. Dieser Generator erzeugt entsprechend den binär kodierten Ausgangssignalen des Speichers 6 unterschiedliche Frequenzen, die dem Impulswandler 127 zugeführt werden, der mit seinen Ausgangsimpulsen den Schrittmotor treibt.

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Eine weitere Antriebsmöglichkeit für die Pumpe besteht in der Verwendung eines unmittelbar auf den Pumpenkolben 201 arbeitenden Linearmotors 225. Der gegenüber Figur 3 abgeänderte Teil der Anordnung ist in Figur 5 schematisch gezeigt. In dieser Anordnung werden die Ausgangssignale des Speichers 6 einem Generator 226 mit digitaler Frequenzwahl zugeführt, dessen sich ändernde Ausgangsfrequenzen einen Drehstromgenerator 227 steuern, der über die Endstufe 228 den Linearmotor 225 treibt. Zur Steuerung der Bewegungsrichtung des Linearmotors dient ein Phasenschalter 230, der mit dem Speicher 6 gekoppelt ist.

Während vorstehend davon ausgegangen wurde, daß der Speicher 6 ein digitaler Speicher ist, der im wesentlichen digitale bzw. binär kodierte Ausgangssignale liefert, kann der Speicher auch so aufgebaut sein, daß sein Ausgangssignal im wesentlichen analoge Form hat. Ein Beispiel hierfür ist in Figur 6 dargestellt.

Dieser in Figur 6 schematisch dargestellte Speicher hat die Form eines Funktionsgenerators und enthält eine Anzahl von Widerständen R_{P1} bis R_{Pm} , die vorzugsweise regelbar sind. Diese Widerstände liegen mit einem Ende an einer Spannungsquelle und mit dem anderen Ende am Ausgang eines Demultiplexers 300, dessen Eingänge mit den Ausgängen eines Binärzählers 301 verbunden sind.

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Bei Verwendung dieses Speichers in einer Pumpenanordnung für eine Blutpumpe wird der Binärzähler 301 mit einer Eingangsfrequenz

$$f_{\text{ein}} = \frac{1}{t} \cdot \frac{1}{m}$$

betrieben,

wobei t die Dauer der Herzschlagperiode und m die Anzahl der Widerstände R_p ist. Der Zähler 301 liefert dann während einer Schlagperiode m Zählerstände, die dem Demultiplexer 300 zugeführt werden, der nacheinander über seine Ausgänge die Widerstände R_{p1} bis R_{pm} an Spannung legt. Der Spannungsabfall an diesen Widerständen wird über einen für jeden Widerstand gesondert vorgesehenen Widerstand R_s einem Integrator 302 zugeführt, dessen Ausgangssignale dann dem mittels der Widerstände R_p eingestellten Programm entspricht.

Ein Speicher gemäß Figur 6 kann benutzt werden, um beispielsweise ohne Verwendung eines Digital-Analog-Wandlers das Servoventil in der Pumpenanordnung gemäß Figur 1 zu steuern.

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Patentansprüche:

1. Pumpenanordnung mit einer Pumpe mit einem extern steuerbaren Volumen- und/oder Druck-Zeit-Verhalten für das von der Pumpe zu fördernde Fluid, insbesondere für Blutpumpen, dadurch gekennzeichnet, daß die Pumpe (1,1') mit einem programmierbaren Speicher (6) gekoppelt ist, der entsprechend dem gewünschten Volumen- und/oder Druck-Zeit-Verhalten programmiert und zeitlich gesteuert abtastbar ist.
2. Pumpenanordnung nach Anspruch 1, dadurch gekennzeichnet, daß die Pumpe (1) hydraulisch antreibbar und mit einem Servoventil (2) verbunden ist, das der Pumpe (1) in Abhängigkeit vom gespeicherten Programm Hydraulikfluid zuführt.
3. Pumpenanordnung nach Anspruch 2, dadurch gekennzeichnet, daß dem Speicher (6) ein Digital-Analog-Wandler (11) nachgeschaltet ist, dessen Ausgangssignal im wesentlichen das Servoventil (2) steuert.
4. Pumpenanordnung nach Anspruch 3, dadurch gekennzeichnet, daß das Ausgangssignal des Digital-Analog-Wandlers (11) einem Maximum-Dekodierer (12') zur Erzeugung eines Signals beim Auftreten der maximalen Amplitude des Ausgangssignals zuführbar ist.

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5. Pumpenanordnung nach Anspruch 1, dadurch gekennzeichnet, daß die Pumpe (1') von einem entsprechend dem gespeicherten Programm steuerbaren Schrittmotor (25) antreibbar ist.
6. Pumpenanordnung nach Anspruch 1, dadurch gekennzeichnet, daß die Pumpe eine Kolbenpumpe ist, deren Kolben (201) von einem entsprechend dem gespeicherten Programm steuerbaren Linearmotor (225) antreibbar ist.
7. Pumpenanordnung nach einem der Ansprüche 1 bis 6, gekennzeichnet durch einen steuerbaren Zeitgenerator (7), der über einen Adreßzähler (8) zur zeitlichen Abtastung des gespeicherten Programms mit dem Speicher (6) verbunden ist.
8. Pumpenanordnung nach den Ansprüchen 4 und 7, dadurch gekennzeichnet, daß das Signal dem Zeitgenerator (7) zuführbar ist.
9. Pumpenanordnung nach einem der Ansprüche 1 bis 8, dadurch gekennzeichnet, daß die Ist-Pumpenstellung mit der Soll-Pumpenstellung vergleichbar ist und daß das ermittelte Vergleichssignal zur Steuerung der Pumpe entgegen einer Abweichung von der Soll-Pumpenstellung verwendbar ist.

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10. Pumpenanordnung nach einem der Ansprüche 1 bis 9, dadurch gekennzeichnet, daß der Speicher (6) ein Halbleiterspeicher ist.
11. Pumpenanordnung nach einem der Ansprüche 1 bis 9, dadurch gekennzeichnet, daß der Speicher eine Anzahl von nacheinander ansteuerbaren Widerständen ($R_{P1} \dots R_{Pm}$) enthält, deren Dimensionierung dem Programm entspricht, und daß die Widerstände nacheinander von einem Demultiplexer (300) ansteuerbar sind, dem in zeitlicher Folge Ausgangssignale von einem Binärzähler (301) zuführbar sind.
12. Pumpenanordnung nach einem der Ansprüche 1 bis 11, dadurch gekennzeichnet, daß der Speicher (6) verschiedene Programme für das Volumen- und/oder Druck-Zeit-Verhalten enthält und auf das gewünschte Programm schaltbar ist.
13. Pumpenanordnung nach Anspruch 12, gekennzeichnet durch einen Nullpunkt-Detektor (23) für das Ausgangssignal des Speichers (6), dessen Ausgang zur Umschaltung auf ein anderes Programm im Speicher (6) mit diesem gekoppelt ist.

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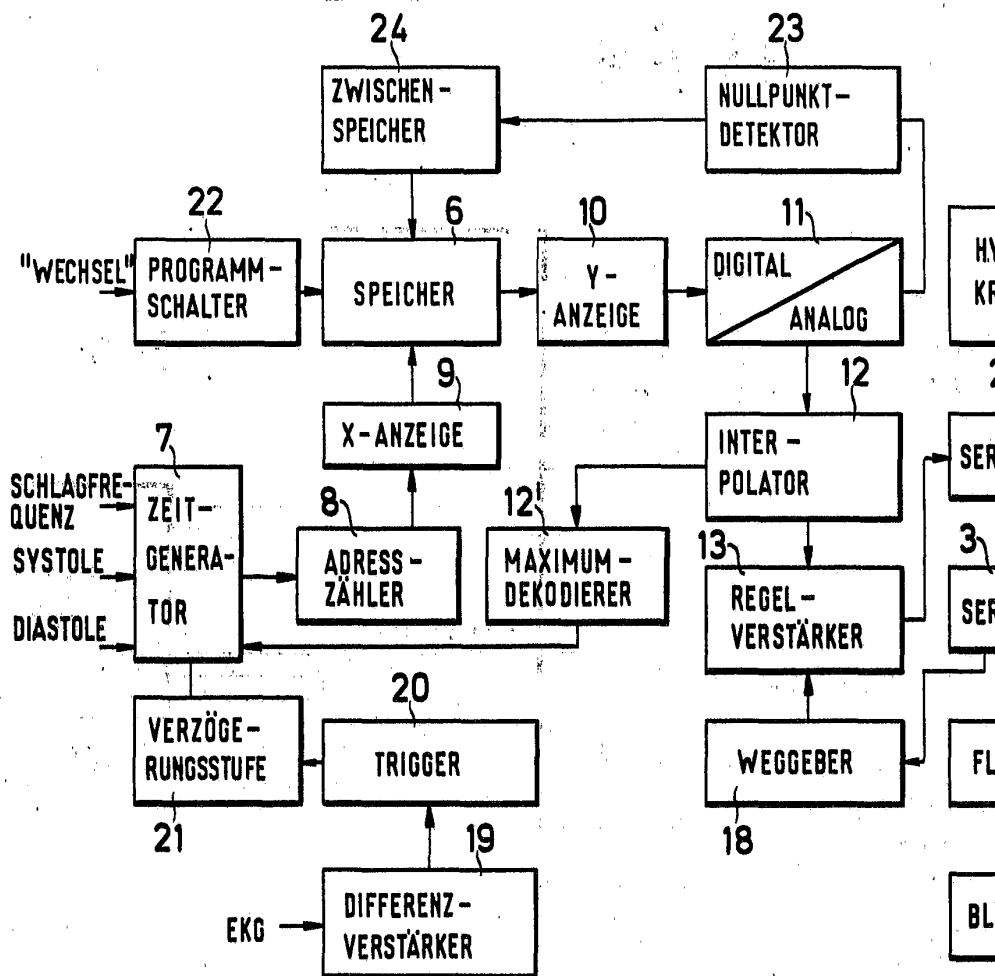
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Fig.1

FO4B 49-00 AT: 09.11.197 OT: 22.05.1975 HS

509821/0059

ORIGINAL INSPECTED



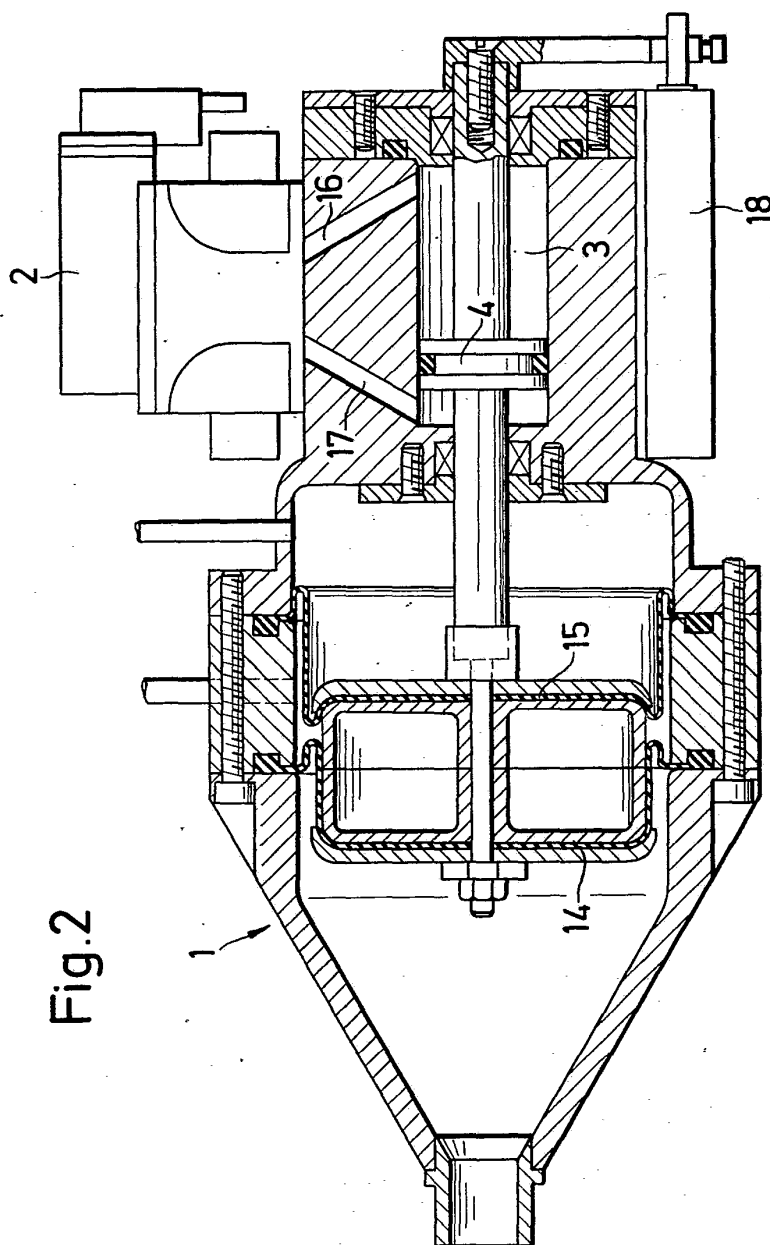
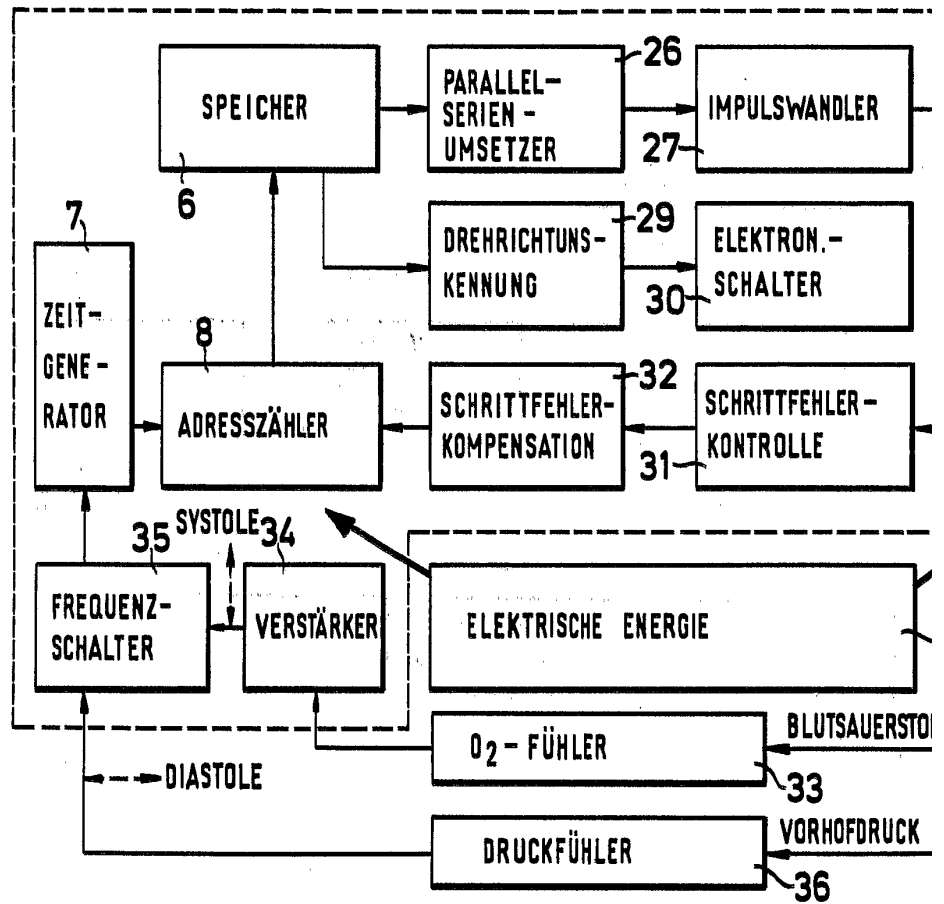


Fig. 2

Fig.3



509821/0059

Fig.4

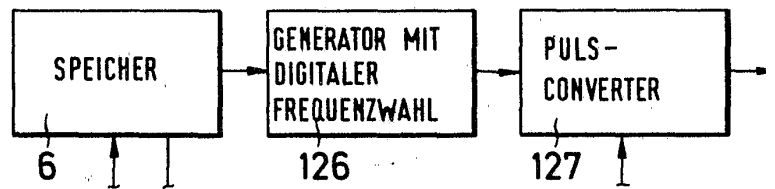
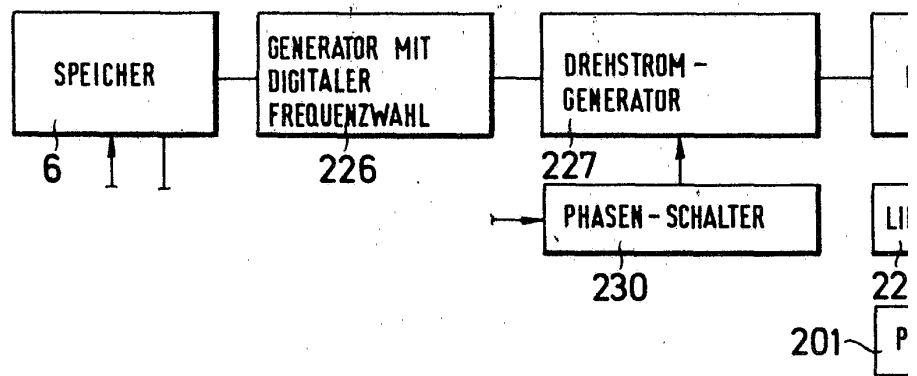
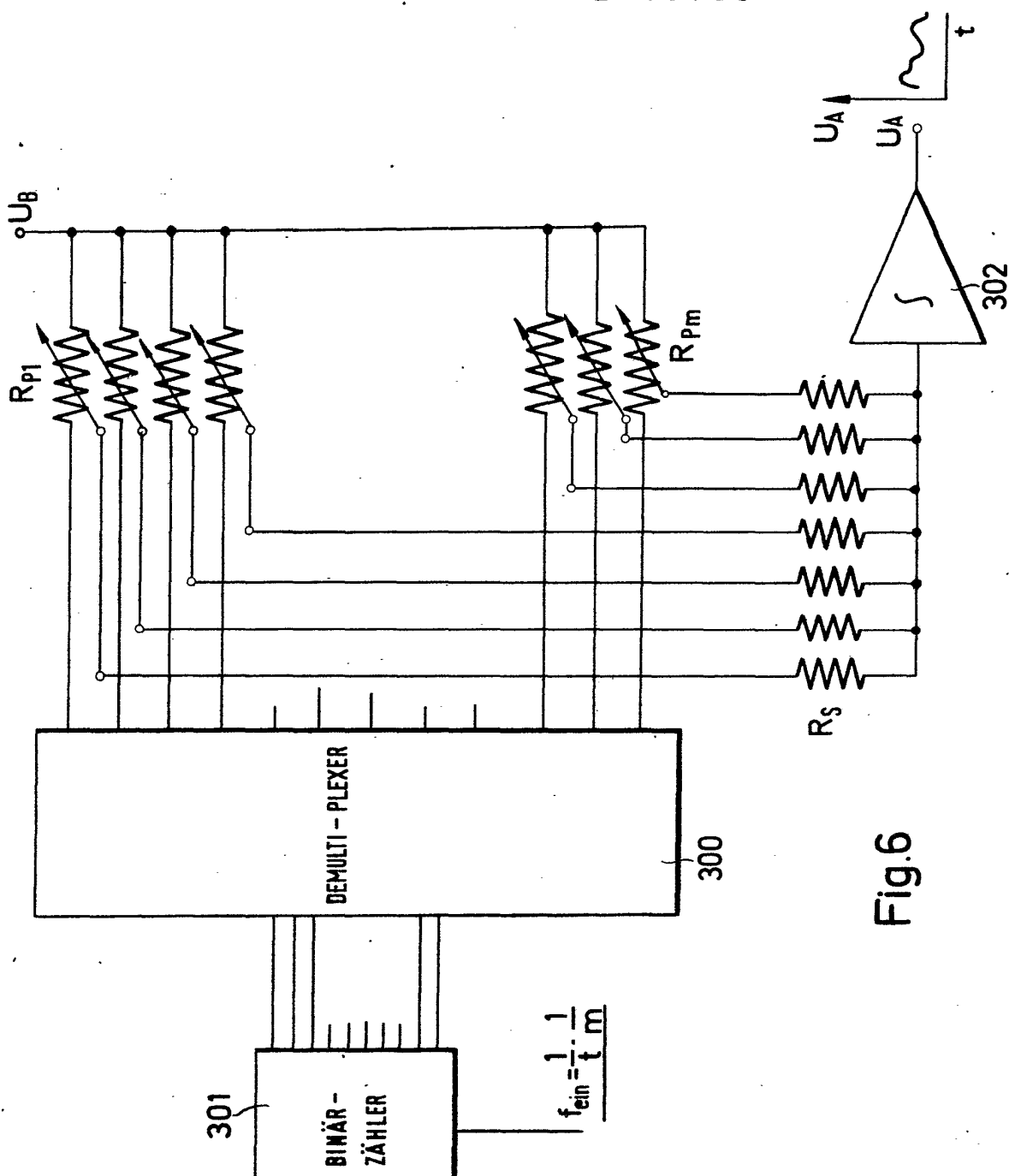


Fig.5





[DE] blood pump as a centrifugal pump

[EN] centrifugal pump used as blood pump - uses fluid pressure bearing to hold impeller in required position

[EN] The centrifugal pump is used as a blood pump. It has a housing (10) forming the pump chamber (13) Which has to inlet (11) and at outlet (13).

The pumping chamber encloses vanes of the impeller (15) Which is equipped with (14) and is mounted on bearings (17). The bearing system supports the impeller (15) so did a gap (21) is FORMED Between the impeller and the housing (10). This gap is filled with a special fluid Supplied from a source (30).

A sensor (33) senses the boundary between the fluid and the special blood and controls the pressure of the fluid source in order to keep the boundary between blood and fluid in a defined position. USE / ADVANTAGE - Blood pump, with impellers supported in a fluid bearing with separate fluid to reduce friction and Minimise damage to blood.

The blood pump comprises a closed pump housing (10) having an inlet (11) and an outlet (13). In the housing there is an external rotation of the drive driven rotor (15) supporting the impeller (14). Those parts of the rotor, which are in mechanical contact with other parts, are included in a cavity (18). A fluid source (30) provides a displacement fluid (F) under pressure into a gap system (21) that surrounds the rotor. The displacing fluid displaces blood and keeps the blood from those components remotely, where wall friction.

A sensor (33) detects the limit (G) between the blood (B) and displacement fluid (F) in the gap system (21) and regulates the fluid source (30) so that said limit (G) assumes a defined position.

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Page 2 --- (DE)

[0001] The invention relates to a blood pump as centrifugal pump, comprising a rotating impeller in umpenraum which conveys the blood from an inlet to an outlet.

[0002] In centrifugal pumps which have a rotor with vane, a part of the pumped medium with bearings or seals come into contact.

If such centrifugal pumps used as a blood pump for pumping blood from a patient, then the contact of blood with bearings or shaft seals cause blood damage by damaging blood cells are destroyed or get in foreign materials of bearings or seals in the blood. Furthermore, blood clots can occur in the seal area, which lead to dysfunction of the blood pump and the patient at risk by local temperature increases or dead spots.

[0003] WO 85/01 436, a blood pump is known, a continuous current flows in along the shaft carrying the impeller from a blood-compatible purge fluid, which opens at the shaft end in the pump chamber. The cleaning fluid keeps impurities away from the blood and flushes the annular gap surrounding the shaft. A disadvantage is that the cleaning fluid passes into the blood and thus the blood that necessarily foreign materials are supplied.

[0004] The invention has for its object to provide a blood pump in which no rubbing parts are present, which may come into contact with the blood, and in which the possibility of the penetration of a foreign fluid in the blood is reduced to a minimum ,

[0005] This object is achieved according to the invention with the features specified in claim. 1

[0006] In the blood pump of the invention, those parts which are in rubbing contact during pump operation, such. As the pivot bearing device, separated by a gap system of the pump chamber. In this system a gap displacement fluid is directed from the outside, which forms a generally fixed phase boundary between fluid and blood, which keeps the blood from the related frictional parts.

This phase boundary is only very small contact surfaces inside the gap system with the blood into contact, so that the risk of ingress of foreign substances in the blood is very low. It should be noted that the phase boundary is stationary and that take place on the border between blood and displacement fluid practically no radial movements. Nevertheless, the displacement fluid should be blood compatible. When displacement fluid are liquids or gases, eg. As saline, carbon dioxide or helium are suitable. The blood comes into contact only with walls that are not in frictional contact with any point, so that no damage to the blood are to be feared by shear stresses of the blood or entries of foreign bodies in the blood. There is also no constant flow of displacement fluid and in particular no permanent insertion of a foreign fluid in the blood.

[0007] The blood pump according to the invention is particularly suitable as a disposable item that is discarded after use. The pump housing is, except for the ports for the blood and for the displacement fluid, completely encapsulated. The drive of the rotor from the outside by magnetic coupling. In this way, the blood pump can be manufactured without the associated drive device as a very cost-effective one-off items, consisting only of the pump housing, the rotor therein with impeller and the rotary bearing device. The rotor body includes for Drive coupling required magnets.

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[0008] Advantageously, a sensor device is provided which detects the boundary between displacement fluid and blood in the gap system and regulates the fluid source such that the limit always remains in the area of ??the sensor device. In this way it is ensured by adding or removing fluid displacement that penetrates the blood within the gap system down to a precisely defined point.

[0009] The rotational supporting means is located inside the rotor in a cavity which faces away from the impeller. This cavity can be sealed by a seal against the invading into it fixed to the housing shaft carrying the rotor. The seal is also located in the protected from the blood by the displacement fluid region.

[0010] The invention is applicable to any type of centrifugal pumps, namely, radial, axial or diagonal pump.

[0011] In the following is explained in detail with reference to the single figure of the drawing shows an embodiment of the invention.

[0012] The drawing shows a schematic longitudinal section through the blood pump.

[0013] The blood pump shown comprises a closed pump housing 10, which is substantially cylindrical and has at one end an axial inlet 11. The inlet 11 leads into the pump chamber 12, branches off from the radial outlet 13. In the pump chamber 12 is located the impeller 14, which is part of the rotor 15, which is rotatably supported in the pump housing. The rotor 15 is supported by a shaft 16 which is fixedly attached to the pump housing 10 and projects into the housing interior. The shaft 16 transmits the rotational bearing means 17, which store consists of a ball or a slide bearing and disposed in a cavity 18 of the rotor 15. The cavity 18 is a blind hole, which is open only to the rear of the rotor 15 back, so to that side which is the inlet 11 and the impeller 14 turned away. The cavity 18 is there by a ring 19 containing a seal 20 closed. The seal 20 provides the sealing of the cavity 18 to the passage of the shaft 16.

[0014] Around the periphery of the rotor 15 extends, the cleavage system 21, which consists of the space between the rotor periphery and the inner wall of the pump housing 10. This splitting system 21, which is in communication with the pump chamber 12, the rotor 15 surrounds on all sides.

Only the shaft 16 bridges this gap system at one location. The splitting system 21 forms the periphery of the rotor a meandering path, caused by the fact that the rotor 15 has a radially extending flange 22 which dips into an inner groove 23 of the pump housing. The splitting system 21 extends around the flange 22 around the pump room 12th

[0015] At the rear side remote from the impeller 14 of the rotor 15 are inserted in these magnets 24. Comprises the drive of the rotor 15 is effected by the external rotary drive 26, the magnets 27 and is rotated by a (not shown) motor. The magnets 27 pull at her round the magnets 24 with, thereby causing a magnetic coupling between the rotary drive 26 and the rotor 15. The wall of the pump housing 10 is for magnetic fields

Page 3 --- (CL, DE)

permeable, ie, the pump housing is z. B. plastic.

[0016] The splitting system 21 has a pump housing provided at the terminal 28, which is connected via a hose 29 with an external fluid source 30. This fluid source is in the illustrated embodiment consists of a syringe pump 31, at which a syringe 32 is mounted. The syringe plunger is pushed forward by the syringe pump 31 (or withdrawn), while the syringe barrel is retained. In this way, fluid can be withdrawn from the 32befindet in the syringe, pumped into the gap 21 or system.

[0017] In the region of the groove 23 10 is located in the wall of the pump housing, a sensor 33, which can distinguish between blood and fluid displacement. The output of the sensor 33 is a controller 34 is supplied, which the fluid source 30 controls such that the boundary G is always equal to the sensor 33 between blood B and displacement fluid F.

[0018] The fluid source 30 delivers to the splitting system 21 displacement fluid under pressure. This displacement fluid drives the blood system in the gap as far forward (toward the pump chamber 12), until the limit G adjusts to the height of the sensor 33rd If the blood pump is set in function, so the rotor 15 is driven by the rotary drive 26, the blood pump pumps blood from the inlet 11 to the outlet 13. The front portion of the rotor 15, including the front side of the flange 22, communicates with the blood B in touch, while the rear portion of the

Rotor solely with the displacement fluid F comes into contact. The only parts of the rotor 15 where wall friction may occur, the bearings of the rotation-support apparatus 17 are and the seal 20. Of these parts, the blood is kept out by the displacement fluid.

[0019] The system 21 the gap forming gaps have a width such that in them no blood damage can be done by shear stresses, ie a minimum width of about 0.5 mm.

[0020] can be used either a liquid or a gas as a displacement fluid. If the displacement fluid is a gas, this should be a gas whose penetration is harmless in the blood, eg. As carbon dioxide or helium.

Having the first blood pump as centrifugal pump with a pump housing (10) having a pump chamber (12) having an inlet (11) and an outlet (13), one in the pump chamber (12) rotating impeller (14) and one of the pump housing (10) enclosed and connected to the impeller (14) rotor (15) with a rotary bearing device (17) is mounted on the pump housing, characterized in that the rotary bearing device (17) of the pump chamber (12) through a gap system (21) separately and in that the cracking system is connected to a fluid source (30), giving it a displacement fluid to (F) and in a phase boundary between the blood and the fluid for keeping the blood (B) of the rotary bearing device (17) maintains. 2. The blood pump according to claim 1, characterized in that the splitting system (21) at least one border (G) between blood (B) and displacement fluid (F) declaratory sensor (33) which regulates the fluid source (30) such that the limit (G) in the range of the sensor (33) remains. 3. The blood pump according to claim 2, characterized in that the sensor (33) in the region of radial branch of the gap system (21) is arranged between an annular groove (23) of the pump housing (10) and one from the rotor (15) projecting

Flange (22) is formed. 4. The blood pump according to any one of claims 1 to 3, characterized in that the rotor (15) arranged with an outside of the pump housing (10), rotary drive (26) is coupled through a housing wall through magnetic and that the pump housing (10), with the exception the connections for blood and fluid displacement, is completely encapsulated. 5. The blood pump of one of claims 1 to 4, characterized in that the rotary bearing device (17) in a cavity (18) at the impeller (14) facing away from the rotor (15) is arranged. 6. The blood pump according to one of claims 1 to 5, characterized in that the containing of the rotary bearing device (17) cavity (18) with a seal (20) against the rotary bearing device (17) carrying the axle (16) is sealed. 7. The blood pump of one of claims 1 to 6, characterized in that the rotary bearing device (17) on a pump casing (10) fixed axis (16) sits. 8. The blood pump of one of claims 1 to 7, characterized in that the gap system (21) of the inner wall of the pump housing and the outer surface of the rotor (15) is limited.

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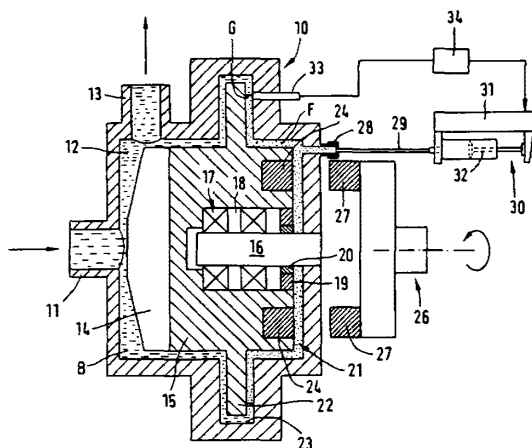
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Antrag auf Nichtnennung

54 Blutpumpe als Kreislumppe

57 Die Blutpumpe weist eine geschlossenes Pumpengehäuse (10) auf, mit einem Einlaß (11) und einem Auslaß (13). In dem Gehäuse befindet sich der von einem externen Rotationsantrieb angetriebene Rotor (15), der das Flügelrad (14) trägt. Diejenigen Teile des Rotors, die in mechanischer Berührung mit anderen Teilen stehen, sind in einem Hohlraum (18) enthalten. Eine Fluidquelle (30) liefert ein Verdrängungsfluid (F) unter Druck in ein Spaltsystem (21), das den Rotor umgibt. Das Verdrängungsfluid verdrängt Blut und hält das Blut von denjenigen Komponenten fern, an denen Wandreibung auftritt. Ein Sensor (33) ermittelt die Grenze (G) zwischen Blut (B) und Verdrängungsfluid (F) im Spaltsystem (21) und regelt die Fluidquelle (30) so, daß die Grenze (G) eine definierte Position annimmt.



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Die Erfindung betrifft eine Blutpumpe als Kreiselpumpe, mit einem im Pumpenraum rotierenden Flügelrad, welches das Blut von einem Einlaß zu einem Auslaß befördert.

Bei Kreiselpumpen, die einen Rotor mit Flügelrad aufweisen, kommt ein Teil des Fördermediums mit Lagern oder Dichtungen in Berührung. Werden solche Kreiselpumpen als Blutpumpe zum Fördern von Blut eines Patienten eingesetzt, so kann die Berührung des Blutes mit Lagern oder Wellendichtungen zu Blutschädigungen führen, indem Blutzellen zerstört werden oder Fremdmaterialien von Lagern oder Dichtungen in das Blut hineingelangen. Ferner können durch lokale Temperaturerhöhungen oder Totwassergebiete Thromben im Dichtungsbereich auftreten, die zu Funktionsstörungen an der Blutpumpe und zur Gefährdung des Patienten führen.

Aus WO 85/01 436 ist eine Blutpumpe bekannt, bei der entlang der das Flügelrad tragenden Welle ein kontinuierlicher Strom aus einem blutkompatiblen Reinigungsfluid fließt, der am Wellenende in den Pumpenraum einmündet. Das Reinigungsfluid hält Verunreinigungen vom Blut fern und spült den die Welle umgebenden Ringspalt. Nachteilig ist, daß das Reinigungsfluid in das Blut gelangt und daß somit dem Blut notwendigerweise Fremdstoffe zugeführt werden.

Der Erfindung liegt die Aufgabe zugrunde, eine Blutpumpe zu schaffen, bei der keine reibenden Teile vorhanden sind, die mit dem Blut in Berührung kommen können, und bei dem die Möglichkeit des Eindringens von fremdem Fluid in das Blut auf ein Mindestmaß verringert ist.

Die Lösung dieser Aufgabe erfolgt erfindungsgemäß mit den im Patentanspruch 1 angegebenen Merkmalen.

Bei der erfindungsgemäßen Blutpumpe sind diejenigen Teile, die beim Pumpenbetrieb in reibender Berührung stehen, wie z. B. die Drehlagereinrichtung, durch ein Spaltsystem von dem Pumpenraum getrennt. In dieses Spaltsystem wird von außen her ein Verdrängungsfluid geleitet, das eine generell feststehende Phasengrenze zwischen Fluid und Blut bildet, welches das Blut von den in Reibberührung stehenden Teilen fernhält. Diese Phasengrenze kommt nur an sehr kleinen Berührungsflächen innerhalb des Spaltsystems mit dem Blut in Kontakt, so daß die Gefahr des Eindringens von Fremdstoffen in das Blut sehr gering ist. Dabei ist zu berücksichtigen, daß die Phasengrenze stationär ist und daß an der Grenze zwischen Blut und Verdrängungsfluid praktisch keine radialen Bewegungen stattfinden. Dennoch sollte das Verdrängungsfluid blutkompatibel sein. Als Verdrängungsfluid eignen sich Flüssigkeiten oder Gase, z. B. Kochsalzlösung, Kohlendioxid oder Helium. Das Blut kommt nur mit solchen Wänden in Berührung, die nicht in Reibkontakt mit irgendeiner Stelle stehen, so daß keine Blutschädigungen durch Scherbeanspruchungen des Blutes oder Eintragen von Fremdkörpern in das Blut zu befürchten sind. Es erfolgt auch keine ständige Strömung des Verdrängungsfluids und insbesondere kein ständiges Eintragen eines Fremdfluids in das Blut.

Die erfindungsgemäße Blutpumpe eignet sich besonders als Einmalartikel, der nach Gebrauch entsorgt wird. Das Pumpengehäuse ist, mit Ausnahme der Anschlüsse für Blut und für das Verdrängungsfluid, vollständig gekapselt. Der Antrieb des Rotors erfolgt von außen durch magnetische Kopplung. Auf diese Weise kann die Blutpumpe ohne die zugehörige Antriebsvorrichtung

als sehr kostengünstiger Einmalartikel hergestellt werden, der nur aus dem Pumpengehäuse, dem darin enthaltenen Rotor mit Flügelrad und der Drehlagereinrichtung besteht. Der Rotorkörper enthält die für die Antriebskopplung erforderlichen Magnete.

Zweckmäßigerweise ist eine Sensoreinrichtung vorgesehen, die die Grenze zwischen Verdrängungsfluid und Blut in dem Spaltsystem feststellt und die die Fluidquelle derart regelt, daß die Grenze stets im Bereich der Sensoreinrichtung verbleibt. Auf diese Weise wird durch Zuführen oder Abführen von Verdrängungsfluid sichergestellt, daß das Blut innerhalb des Spaltsystems bis zu einer genau definierten Stelle vordringt.

Die Drehlagereinrichtung befindet sich im Innern des Rotors in einem Hohlraum, der dem Flügelrad abgewandt ist. Dieser Hohlraum kann durch eine Dichtung gegenüber dem in ihn eindringenden gehäusefesten Schaft, der den Rotor trägt, abgedichtet sein. Die Dichtung befindet sich ebenfalls in dem durch das Verdrängungsfluid vor dem Blut geschützten Bereich.

Die Erfindung ist bei jeder Art von Kreiselpumpen anwendbar, nämlich bei Radial-, Axial- oder Diagonalspumpen.

Im folgenden wird unter Bezugnahme auf die einzige Figur der Zeichnung ein Ausführungsbeispiel der Erfindung näher erläutert.

Die Zeichnung zeigt einen schematischen Längsschnitt durch die Blutpumpe.

Die dargestellte Blutpumpe weist ein geschlossenes Pumpengehäuse 10 auf, das im wesentlichen zylindrisch ist und an einem Ende einen axialen Einlaß 11 hat. Der Einlaß 11 führt in den Pumpenraum 12 hinein, von dem radial der Auslaß 13 abgeht. In dem Pumpenraum 12 befindet sich das Flügelrad 14, das Bestandteil des Rotors 15 ist, welcher im Pumpengehäuse drehbar gelagert ist. Der Rotor 15 wird von einem Schaft 16 getragen, der am Pumpengehäuse 10 fest angebracht ist und in das Gehäuseinnere hineinragt. Der Schaft 16 trägt die Drehlagereinrichtung 17, die aus Kugellagern oder einem Gleitlager besteht und in einem Hohlraum 18 des Rotors 15 angeordnet ist. Der Hohlraum 18 ist ein Sackloch, das nur zur Rückseite des Rotors 15 hin offen ist, also zu derjenigen Seite, die dem Einlaß 11 und dem Flügelrad 14 abgewandt ist. Der Hohlraum 18 ist dort durch einen Ring 19, der eine Dichtung 20 enthält, verschlossen. Die Dichtung 20 bewirkt die Abdichtung des Hohlraums 18 gegen den Durchgang des Schafts 16.

Um den Umfang des Rotors 15 erstreckt sich das Spaltsystem 21, das aus dem Zwischenraum zwischen dem Rotorumfang und der Innenwand des Pumpengehäuses 10 besteht. Dieses Spaltsystem 21, das mit dem Pumpenraum 12 in Verbindung steht, umgibt den Rotor 15 allseitig. Nur der Schaft 16 überbrückt an einer Stelle dieses Spaltsystems. Das Spaltsystem 21 bildet am Umfang des Rotors einen mäanderförmigen Weg, der dadurch entsteht, daß der Rotor 15 einen radial abstehenden Flansch 22 aufweist, der in eine innere Nut 23 des Pumpengehäuses eintaucht. Das Spaltsystem 21 verläuft um den Flansch 22 herum zum Pumpenraum 12.

An der dem Flügelrad 14 abgewandten Rückseite des Rotors 15 sind in diesen Magnete 24 eingelassen. Der Antrieb des Rotors 15 erfolgt durch den externen Rotationsantrieb 26, der Magnete 27 aufweist und von einem (nicht dargestellten) Motor gedreht wird. Die Magnete 27 ziehen bei ihrem Umlauf die Magnete 24 mit und bewirken dadurch eine magnetische Kopplung zwischen dem Rotationsantrieb 26 und dem Rotor 15. Die Wand des Pumpengehäuses 10 ist für magnetische Fel-

der durchlässig, d. h. das Pumpengehäuse besteht z. B. aus Kunststoff.

Das Spaltsystem 21 weist einen am Pumpengehäuse vorgesehenen Anschluß 28 auf, der über eine Schlauchleitung 29 mit einer externen Fluidquelle 30, verbunden ist. Diese Fluidquelle besteht bei dem dargestellten Ausführungsbeispiel aus einer Spritzenpumpe 31, an welcher eine Spritze 32 befestigt wird. Der Spritzenkolben wird von der Spritzenpumpe 31 vorgeschoben (oder zurückgezogen), während der Spritzenzylinder festgehalten wird. Auf diese Weise kann Fluid, das sich in der Spritze 32 befindet, in das Spaltsystem 21 eingepumpt oder aus diesem abgezogen werden.

Im Bereich der Nut 23 befindet sich in der Wand des Pumpengehäuses 10 ein Sensor 33, der zwischen Blut und Verdrängungsfluid unterscheiden kann. Das Ausgangssignal des Sensors 33 wird einem Regler 34 zugeführt, welcher die Fluidquelle 30 derart steuert, daß sich die Grenze G zwischen Blut B und Verdrängungsfluid F stets in Höhe des Sensors 33 befindet.

Die Fluidquelle 30 liefert in das Spaltsystem 21 Verdrängungsfluid unter Druck. Dieses Verdrängungsfluid treibt das Blut in dem Spaltsystem so weit nach vorne (in Richtung auf den Pumpenraum 12), bis sich die Grenze G auf die Höhe des Sensors 33 einstellt. Wird die Blutpumpe in Funktion gesetzt, also der Rotor 15 durch den Rotationsantrieb 26 angetrieben, so fördert die Blutpumpe Blut von dem Einlaß 11 zum Auslaß 13. Der vordere Bereich des Rotors 15, einschließlich der Vorderseite des Flansches 22, steht mit dem Blut B in Berührung, während der rückwärtige Bereich des Rotors ausschließlich mit dem Verdrängungsfluid F in Berührung kommt. Die einzigen Teile des Rotors 15, an denen Wandreibung auftreten kann, sind die Lager der Drehlagervorrichtung 17 und die Dichtung 20. Von diesen Teilen wird das Blut durch das Verdrängungsfluid ferngehalten.

Die das Spaltsystem 21 bildenden Spalte haben eine solche Breite, daß in ihnen keine Blutschädigung durch Scherbeanspruchungen erfolgen kann, d. h. eine Mindestbreite von etwa 0,5 mm.

Als Verdrängungsfluid kann entweder eine Flüssigkeit oder ein Gas benutzt werden. Sofern das Verdrängungsfluid ein Gas ist, sollte dieses ein Gas sein, dessen Eindringen in das Blut unschädlich ist, z. B. Kohlendioxid oder Helium.

Patentansprüche

1. Blutpumpe als Kreislumpumpe mit einem Pumpengehäuse (10), das einen Pumpenraum (12) mit einem Einlaß (11) und einem Auslaß (13) aufweist, einem in dem Pumpenraum (12) rotierenden Flügelrad (14) und einem von dem Pumpengehäuse (10) umschlossenen, mit dem Flügelrad (14) verbundenen Rotor (15), der mit einer Drehlagereinrichtung (17) am Pumpengehäuse gelagert ist, **dadurch gekennzeichnet**, daß die Drehlagereinrichtung (17) von dem Pumpenraum (12) durch ein Spaltsystem (21) getrennt ist und daß das Spaltsystem an eine Fluidquelle (30) angeschlossen ist, die ihm ein Verdrängungsfluid (F) zuführt und dadurch eine Phasengrenze zwischen Blut und Fluid zum Fernhalten des Blutes (B) von der Drehlagereinrichtung (17) aufrechterhält.

2. Blutpumpe nach Anspruch 1, dadurch gekennzeichnet, daß das Spaltsystem (21) mindestens einen die Grenze (G) zwischen Blut (B) und Verdrän-

gungsfluid (F) feststellenden Sensor (33) aufweist, der die Fluidquelle (30) derart regelt, daß die Grenze (G) im Bereich des Sensors (33) verbleibt.

3. Blutpumpe nach Anspruch 2, dadurch gekennzeichnet, daß der Sensor (33) im Bereich eines radialen Zweiges des Spaltsystems (21) angeordnet ist, der zwischen einer Ringnut (23) des Pumpengehäuses (10) und einem vom Rotor (15) abstehenden Flansch (22) gebildet ist.

4. Blutpumpe nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß der Rotor (15) mit einem außerhalb des Pumpengehäuses (10) angeordneten Rotationsantrieb (26) durch eine Gehäusewand hindurch magnetisch gekoppelt ist und daß das Pumpengehäuse (10), mit Ausnahme der Anschlüsse für Blut und Verdrängungsfluid, vollständig gekapselt ist.

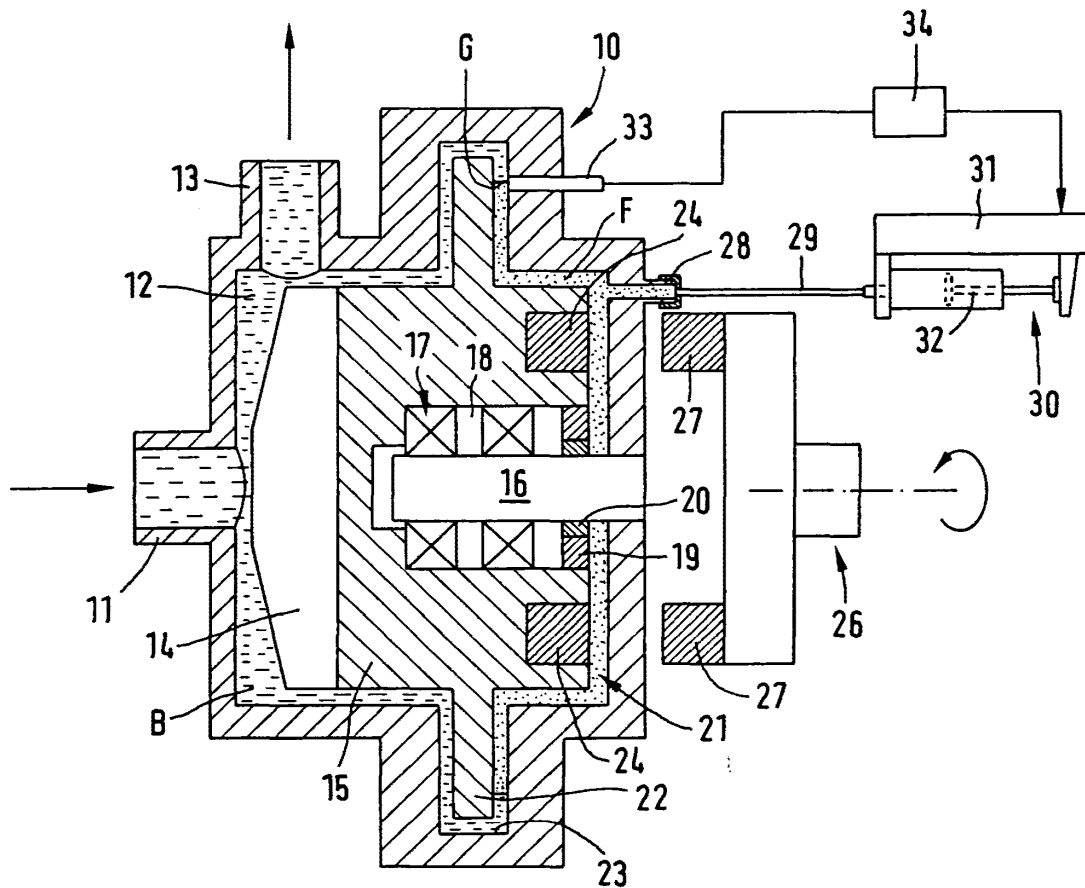
5. Blutpumpe nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß die Drehlagereinrichtung (17) in einem Hohlraum, (18) an der dem Flügelrad (14) abgewandten Seite des Rotors (15) angeordnet ist.

6. Blutpumpe nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, daß der die Drehlagereinrichtung (17) enthaltende Hohlraum (18) mit einer Dichtung (20) gegen eine die Drehlagereinrichtung (17) tragende Achse (16) abgedichtet ist.

7. Blutpumpe nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, daß die Drehlagereinrichtung (17) auf einer am Pumpengehäuse (10) befestigten Achse (16) sitzt.

8. Blutpumpe nach einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, daß das Spaltsystem (21) von der Innenwand des Pumpengehäuses und der Außenfläche des Rotors (15) begrenzt ist.

Hierzu 1 Seite(n) Zeichnungen



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[DE]Blutpumpe als Kreislumppe

[EN]Centrifugal pump used as blood pump - uses fluid pressure bearing to hold impeller in required position

[EN]The centrifugal pump is used as a blood pump. It has a housing (10) forming the pump chamber (13) which has an inlet (11) and an outlet (13). The pump chamber encloses an impeller (15) which is equipped with vanes (14) and is mounted on bearings (17). The bearing system supports the impeller (15) so that a gap (21) is formed between the impeller and the housing (10). This gap is filled with a special fluid supplied from a source (30). A sensor (33) senses the boundary between the special fluid and the blood and controls the pressure of the fluid source in order to keep the boundary between blood and fluid in a defined position. USE/ADVANTAGE - Blood pump, with impeller supported in a fluid bearing with separate fluid to reduce friction and minimise damage to blood.

Die Blutpumpe weist eine geschlossenes Pumpengehäuse (10) auf, mit einem Einlaß (11) und einem Auslaß (13). In dem Gehäuse befindet sich der von einem externen Rotationsantrieb angetriebene Rotor (15), der das Flügelrad (14) trägt. Diejenigen Teile des Rotors, die in mechanischer Berührung mit anderen Teilen stehen, sind in einem Hohlraum (18) enthalten. Eine Fluidquelle (30) liefert ein Verdrängungsfluid (F) unter Druck in ein Spaltsystem (21), das den Rotor umgibt. Das Verdrängungsfluid verdrängt Blut und hält das Blut von denjenigen Komponenten fern, an denen Wandreibung auftritt. Ein Sensor (33) ermittelt die Grenze (G) zwischen Blut (B) und Verdrängungsfluid (F) im Spaltsystem (21) und regelt die Fluidquelle (30) so, daß die Grenze (G) eine definierte Position annimmt.

Seite 1 --- (BI, AB)

Seite 2 --- (DE)

[0001] Die Erfindung betrifft eine Blutpumpe als Kreislumppe, mit einem im Pumpenraum rotierenden Flügelrad, welches das Blut von einem Einlaß zu einem Auslaß befördert.

[0002] Bei Kreislumpen, die einen Rotor mit Flügelrad aufweisen, kommt ein Teil des Fördermediums mit Lagern oder Dichtungen in Berührung. Werden solche Kreislumpen als Blutpumpe zum Fördern von Blut eines Patienten eingesetzt, so kann die Berührung des Blutes mit Lagern oder Wellendichtungen zu Blutschädigungen führen, indem Blutzellen zerstört werden oder Fremdmaterialien von Lagern oder Dichtungen in das Blut hineingelangen. Ferner können durch lokale Temperaturerhöhungen oder Totwassergebiete Thromben im Dichtungsbereich auftreten, die zu Funktionsstörungen an der Blutpumpe und zur Gefährdung des Patienten führen.

[0003] Aus WO 85/01 436 ist eine Blutpumpe bekannt, bei der entlang der das Flügelrad tragenden Welle ein kontinuierlicher Strom aus einem blutkompatiblen Reinigungsfluid fließt, der am Wellenende in den Pumpenraum einmündet. Das Reinigungsfluid hält Verunreinigungen vom Blut fern und spült den die Welle umgebenden Ringspalt. Nachteilig ist, daß das Reinigungsfluid in das Blut gelangt und daß somit dem Blut notwendigerweise Fremdstoffe zugeführt werden.

[0004] Der Erfindung liegt die Aufgabe zugrunde, eine Blutpumpe zu schaffen, bei der keine reibenden Teile vorhanden sind, die mit dem Blut in Berührung kommen können, und bei dem die Möglichkeit des Eindringens von fremdem Fluid in das Blut auf ein Mindestmaß verringert ist.

[0005] Die Lösung dieser Aufgabe erfolgt erfindungsgemäß mit den im Patentanspruch 1 angegebenen Merkmalen.

[0006] Bei der erfindungsgemäßen Blutpumpe sind diejenigen Teile, die beim Pumpenbetrieb in reibender Berührung stehen, wie z. B. die Drehtagereinrichtung, durch ein Spaltsystem von dem Pumpenraum getrennt. In dieses Spaltsystem wird von außen her ein Verdrängungsfluid geleitet, das eine generell feststehende Phasengrenze zwischen Fluid und Blut bildet, welches das Blut von den in Reibberührung stehenden Teilen fernhält. Diese Phasengrenze kommt nur an sehr kleinen Berührungsflächen innerhalb des Spaltsystems mit dem Blut in Kontakt, so daß die Gefahr des Eindringens von Fremdstoffen in das Blut sehr gering ist. Dabei ist zu berücksichtigen, daß die Phasengrenze stationär ist und daß an der Grenze zwischen Blut und Verdrängungsfluid praktisch keine radialen Bewegungen stattfinden. Dennoch sollte das Verdrängungsfluid blutkompatibel sein. Als Verdrängungsfluid eignen sich Flüssigkeiten oder Gase, z. B. Kochsalzlösung, Kohlendioxid oder Helium. Das Blut kommt nur mit solchen Wänden in Berührung, die nicht in Reibkontakt mit irgendeiner Stelle stehen, so daß keine Blutschädigungen durch Scherbeanspruchungen des Blutes oder Eintragen von Fremdkörpern in das Blut zu befürchten sind. Es erfolgt auch keine ständige Strömung des Verdrängungsfluids und insbesondere kein ständiges Eintragen eines Fremdfluids in das Blut.

[0007] Die erfindungsgemäße Blutpumpe eignet sich besonders als Einmalartikel, der nach Gebrauch entsorgt wird. Das Pumpengehäuse ist, mit Ausnahme der Anschlüsse für Blut und für das Verdrängungsfluid, vollständig gekapselt. Der Antrieb des Rotors erfolgt von außen durch magnetische Kopplung. Auf diese Weise kann die Blutpumpe ohne die zugehörige Antriebsvorrichtung als sehr kostengünstiger Einmalartikel hergestellt werden, der nur aus dem Pumpengehäuse, dem darin enthaltenen Rotor mit Flügelrad und der Drehtagereinrichtung besteht. Der Rotorkörper enthält die für die Antriebskopplung erforderlichen Magnete.

[0008] Zweckmäßigerweise ist eine Sensoreinrichtung vorgesehen, die die Grenze zwischen Verdrängungsfluid und Blut in dem Spaltsystem feststellt und die die Fluidquelle derart regelt, daß die Grenze stets im Bereich der Sensoreinrichtung verbleibt. Auf diese Weise wird durch Zuführen oder Abführen von Verdrängungsfluid sichergestellt, daß das Blut innerhalb des Spaltsystems bis zu einer genau definierten Stelle vordringt.

[0009] Die Drehlagereinrichtung befindet sich im Innern des Rotors in einem Hohlraum, der dem Flügelrad abgewandt ist. Dieser Hohlraum kann durch eine Dichtung gegenüber dem in ihn eindringenden gehäusefesten Schaft, der den Rotor trägt, abgedichtet sein. Die Dichtung befindet sich ebenfalls in dem durch das Verdrängungsfluid vor dem Blut geschützten Bereich.

[0010] Die Erfindung ist bei jeder Art von Kreiselpumpen anwendbar, nämlich bei Radial-, Axial- oder Diagonalpumpen.

[0011] Im folgenden wird unter Bezugnahme auf die einzige Figur der Zeichnung ein Ausführungsbeispiel der Erfindung näher erläutert.

[0012] Die Zeichnung zeigt einen schematischen Längsschnitt durch die Blutpumpe.

[0013] Die dargestellte Blutpumpe weist ein geschlossenes Pumpengehäuse **10** auf, das im wesentlichen zylindrisch ist und an einem Ende einen axialen Einlaß **11** hat. Der Einlaß **11** führt in den Pumpenraum **12** hinein, von dem radial der Auslaß **13** abgeht. In dem Pumpenraum **12** befindet sich das Flügelrad **14**, das Bestandteil des Rotors **15** ist, welcher im Pumpengehäuse drehbar gelagert ist. Der Rotor **15** wird von einem Schaft **16** getragen, der am Pumpengehäuse **10** fest angebracht ist und in das Gehäuseinnere hineinragt. Der Schaft **16** trägt die Drehlagereinrichtung **17**, die aus Kugellagern oder einem Gleitlager besteht und in einem Hohlraum **18** des Rotors **15** angeordnet. Der Hohlraum **18** ist ein Sackloch, das nur zur Rückseite des Rotors **15** hin offen ist, also zu derjenigen Seite, die dem Einlaß **11** und dem Flügelrad **14** abgewandt ist. Der Hohlraum **18** ist dort durch einen Ring **19**, die eine Dichtung **20** enthält, verschlossen. Die Dichtung **20** bewirkt die Abdichtung des Hohlraums **18** gegen den Durchgang des Schafts **16**.

[0014] Um den Umfang des Rotors **15** erstreckt sich das Spaltsystem **21**, das aus dem Zwischenraum zwischen dem Rotorumfang und der Innenwand des Pumpengehäuses **10** besteht. Dieses Spaltsystem **21**, das mit dem Pumpenraum **12** in Verbindung steht, umgibt den Rotor **15** allseitig. Nur der Schaft **16** überbrückt an einer Stelle dieses Spaltsystems. Das Spaltsystem **21** bildet am Umfang des Rotors einen mäanderförmigen Weg, der dadurch entsteht, daß der Rotor **15** einen radial abstehenden Flansch **22** aufweist, der in eine innere Nut **23** des Pumpengehäuses eintaucht. Das Spaltsystem **21** verläuft um den Flansch **22** herum zum Pumpenraum **12**.

[0015] An der dem Flügelrad **14** abgewandten Rückseite des Rotors **15** sind in diesen Magnete **24** eingelassen. Der Antrieb des Rotors **15** erfolgt durch den externen Rotationsantrieb **26**, der Magnete **27** aufweist und von einem (nicht dargestellten) Motor gedreht wird. Die Magnete **27** ziehen bei ihrem Umlauf die Magnete **24** mit und bewirken dadurch eine magnetische Kopplung zwischen dem Rotationsantrieb **26** und dem Rotor **15**. Die Wand des Pumpengehäuses **10** ist für magnetische Felder

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durchlässig, d. h. das Pumpengehäuse besteht z. B. aus Kunststoff.

[0016] Das Spaltsystem **21** weist einen am Pumpengehäuse vorgesehenen Anschluß **28** auf, der über eine Schlauchleitung **29** mit einer externen Fluidquelle **30**, verbunden ist. Diese Fluidquelle besteht bei dem dargestellten Ausführungsbeispiel aus einer Spritzenpumpe **31**, an welcher eine Spritze **32** befestigt wird. Der Spritzenkolben wird von der Spritzenpumpe **31** vorgeschoben (oder zurückgezogen), während der Spritzenzylinder festgehalten wird. Auf diese Weise kann Fluid, das sich in der Spritze **32** befindet, in das Spaltsystem **21** eingepumpt oder aus diesem abgezogen werden.

[0017] Im Bereich der Nut **23** befindet sich in der Wand des Pumpengehäuses **10** ein Sensor **33**, der zwischen Blut und Verdrängungsfluid unterscheiden kann. Das Ausgangssignal des Sensors **33** wird einem Regler **34** zugeführt, welcher die Fluidquelle **30** derart steuert, daß sich die Grenze G zwischen Blut B und Verdrängungsfluid F stets in Höhe des Sensors **33** befindet.

[0018] Die Fluidquelle **30** liefert in das Spaltsystem **21** Verdrängungsfluid unter Druck. Dieses Verdrängungsfluid treibt das Blut in dem Spaltsystem so weit nach vorne (in Richtung auf den Pumpenraum **12**), bis sich die Grenze G auf die Höhe des Sensors **33** einstellt. Wird die Blutpumpe in Funktion gesetzt, also der Rotor **15** durch den Rotationsantrieb **26** angetrieben, so fördert die Blutpumpe Blut von dem Einlaß **11** zum Auslaß **13**. Der vordere Bereich des Rotors **15**, einschließlich der Vorderseite des Flansches **22**, steht mit dem Blut B in Berührung, während der rückwärtige Bereich des Rotors ausschließlich mit dem Verdrängungsfluid F in Berührung kommt. Die einzigen Teile des Rotors **15**, an denen Wandreibung auftreten kann, sind die Lager der Drehlagereinrichtung **17** und die Dichtung **20**. Von diesen Teilen wird das Blut durch das Verdrängungsfluid ferngehalten.

[0019] Die das Spaltsystem **21** bildenden Spalte haben eine solche Breite, daß in ihnen keine Blutschädigung durch Scherbeanspruchungen erfolgen kann, d. h. eine Mindestbreite von etwa 0,5 mm.

[0020] Als Verdrängungsfluid kann entweder eine Flüssigkeit oder ein Gas benutzt werden. Sofern das Verdrängungsfluid ein Gas ist, sollte dieses ein Gas sein, dessen Eindringen in das Blut unschädlich ist, z. B. Kohlendioxid oder Helium.

1. Blutpumpe als Kreiselpumpe mit einem Pumpengehäuse (**10**), das einen Pumpenraum (**12**) mit einem Einlaß (**11**) und einem Auslaß (**13**) aufweist, einem in dem Pumpenraum (**12**) rotierenden Flügelrad (**14**) und einem von dem Pumpengehäuse (**10**) umschlossenen, mit dem Flügelrad (**14**) verbundenen Rotor (**15**), der mit einer Drehlagereinrichtung (**17**) am Pumpengehäuse gelagert ist, **dadurch gekennzeichnet**, daß die Drehlagereinrichtung (**17**) von dem Pumpenraum (**12**) durch ein Spaltsystem (**21**) getrennt ist und daß das Spaltsystem an eine Fluidquelle (**30**) angeschlossen ist, die ihm ein Verdrängungsfluid (F) zuführt und dadurch eine Phasengrenze zwischen Blut und Fluid zum Fernhalten des Blutes (B) von der Drehlagereinrichtung (**17**) aufrechterhält. 2. Blutpumpe nach Anspruch 1, dadurch gekennzeichnet, daß das Spaltsystem (**21**) mindestens einen die Grenze (G) zwischen Blut (B) und Verdrängungsfluid (F) feststellenden Sensor (**33**) aufweist, der die Fluidquelle (**30**) derart regelt, daß die Grenze (G) im Bereich des Sensors (**33**) verbleibt. 3. Blutpumpe nach Anspruch 2, dadurch gekennzeichnet, daß der Sensor (**33**) im Bereich eines radialen Zweiges des Spaltsystems (**21**) angeordnet ist, der zwischen einer Ringnut (**23**) des Pumpengehäuses (**10**) und einem vom Rotor (**15**) abstehenden Flansch (**22**) gebildet ist. 4. Blutpumpe nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß der Rotor (**15**) mit einem außerhalb des Pumpengehäuses (**10**) angeordneten Rotationsantrieb (**26**) durch eine Gehäusewand hindurch magnetisch gekoppelt ist und daß das Pumpengehäuse (**10**), mit Ausnahme der Anschlüsse für Blut und Verdrängungsfluid, vollständig gekapselt ist. 5. Blutpumpe nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß die Drehlagereinrichtung (**17**) in einem Hohlraum, (**18**) an der dem Flügelrad (**14**) abgewandten Seite des Rotors (**15**) angeordnet ist. 6. Blutpumpe nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, daß der die Drehlagereinrichtung (**17**) enthaltende Hohlraum (**18**) mit einer Dichtung (**20**) gegen eine die Drehlagereinrichtung (**17**) tragende Achse (**16**) abgedichtet ist. 7. Blutpumpe nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, daß die Drehlagereinrichtung (**17**) auf einer am Pumpengehäuse (**10**) befestigten Achse (**16**) sitzt. 8. Blutpumpe nach einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, daß das Spaltsystem (**21**) von der Innenwand des Pumpengehäuses und der Außenfläche des Rotors (**15**) begrenzt ist.

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Abstract

The guide wire is inserted with the inner wire (13) completely accommodated inside the outer cover (10) until it is blocked by the narrowing or obstruction of the coronary artery. The outer cover is pulled back, exposing the inner wire equipped with a tip designed as a ball (16) of the same diameter as the inner wire (14) attached to a narrower transition area (15). The forces created by the blood streaming around the ball shaped tip move the tip towards and finally through the narrowing followed by the outer cover.



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54 Führungsdraht für einen Katheter

57 Der Führungsdraht besteht aus einem äußeren Drahtstrang (10), der als Hohlstrang ausgebildet ist und einem darin verschiebbaren Innenstrang (13). Der Drahtstrang (10) hat an seinem distalen Ende eine gebogene Führungsspitze (11), die bei der Verlegung des Führungsdrahtes als Steuerungselement oder Wegfinder wirkt. Bei Erreichen einer Gefäßverengung, die von dem äußeren Drahtstrang nicht ohne weiteres passiert werden kann, wird der äußere Drahtstrang (10) zurückgezogen. An dem nun aus dem Drahtstrang herausragenden Vorderabschnitt (15) des Innenstranges befindet sich ein Kopf (16), an dem die Strömungskraft des Blutstromes angreift. Dadurch kann eine komplexe und enge Stenose von dem Führungsdraht durchdrungen werden, ohne dass die Gefahr einer Beschädigung des Blutgefäßes oder des Ablösens von Ablagerungen besteht.



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[0001] Die Erfindung betrifft einen Führungsdraht für einen Katheter mit einem langgestreckten Drahtstrang, der am distalen Ende eine Führungsspitze aufweist.

[0002] Es ist bekannt, Koronarstenosen durch perkutane Dilatation mit einem Ballonkatheter zu erweitern oder zu beseitigen. Voraussetzung für die erfolgreiche Durchführung einer Ballondilatation ist, dass zunächst ein dünner Führungsdraht durch die Stenose hindurchgeschoben wird. Dies kann insbesondere bei langstreckigen, hochgradigen und unregelmäßig konturierten Stenosen schwierig sein. Es gibt Fälle, in denen es auch bei Verwendung unterschiedlicher Führungsdrähte nicht möglich ist, eine Stenose zu passieren. Manchmal kommt es bei dem Versuch der Rekanalisation einer komplexen Stenose zu einem Eindringen des Führungsdrahtes in die Gefäßwand, zu einem Ablösen eines Teiles der Gefäßwand (Dissektion) oder zum Verschluss des Gefäßes. Dies birgt die Gefahr eines Myokardinfarktes oder sogar des Todes des Patienten.

[0003] Die zum Legen eines Ballonkatheters üblichen Führungsdrähte bestehen aus einem Drahtstrang, der etwa 1,40 m lang ist und einen Durchmesser von etwa 0,35 mm (= 0,014 inch) hat. Am distalen Ende des Drahtstranges befindet sich eine weichelastische Führungsspitze oder eine plastisch verformbare Führungsspitze, die es erlaubt, an Verzweigungen des Blutgefäßsystems durch Drehen des Führungsdrahtes den gewünschten Weg zu verfolgen. Bekannt ist ferner ein Führungsdraht, der als Rekanalisationsdraht verwendet wird und an seinem distalen Ende einen Kopf in Form einer kleinen Olive trägt. Die Olive wird als stumpfer Stößel zum Aufstoßen von Hindernissen benutzt.

[0004] Der Erfindung liegt die Aufgabe zugrunde, einen Führungsdraht zu schaffen, der imstande ist, auch komplexe Stenosen zu passieren.

[0005] Die Lösung dieser Aufgabe erfolgt erfindungsgemäß mit den im Anspruch 1 angegebenen Merkmalen. Hiernach ist der Führungsdraht zweiteilig ausgebildet. Er besteht aus einem als Hohlstrang ausgebildeten äußeren Drahtstrang und einem darin längsverschiebbaren Innenstrang. Am distalen Ende des Innenstranges befindet sich ein verdickter Kopf. Die proximale Fläche dieses Kopfes dient als Strömungsangriffsfläche für den in dem Blutgefäß strömenden Blutstrom. Die auf diese Weise auf den Kopf ausgeübte Strömungskraft ermöglicht ein passives Einschwemmen des Innenstranges zum Passieren der Stenose. Hierbei kann der Außenstrang mitgenommen oder auch nachträglich nachgeschoben werden. Die Erfindung erleichtert das Platzieren eines Führungsdrahtes, über den ein Ballonkatheter geschoben werden soll, in der Stenose eines Blutgefäßes. Dabei wird die Kraft des Blutstromes ausgenutzt, damit der Innenstrang die Stenose passieren kann. Die Verlegung des Führungsdrahtes erfolgt ohne stocherndes Anstoßen an die Gefäßwand oder die Stenose, so dass nicht die Gefahr von Gefäßverletzungen oder Materialablösungen besteht. Der Führungsdraht wird vollkommen atraumatisch eingeführt, da er nicht aktiv durch Manipulation bewegt wird sondern an den entscheidenden Stellen passiv im Blutstrom mitschwimmt. Der Führungsdraht ist daher ein "passiver" oder "einschwemmbarer" Führungsdraht.

[0006] Gemäß einer bevorzugten Ausgestaltung der Erfindung ist der Vorderabschnitt, an dem der Kopf angeordnet ist, weicher als der übrige Innenstrang. Der Vorderabschnitt kann aus einem sehr dünnen Zugdraht bestehen oder aus einer sich zu dem Kopf hin verjüngenden Spitze. Der Durchmesser des Kopfes ist vorzugsweise etwa so groß wie derjenige des übrigen Innenstranges (mit Ausnahme des Vorderabschnitts). Der Vorderabschnitt bildet einen Abschnitt ver-

ringerten Durchmessers, damit an der Rückfläche des Kopfes die Strömungskraft des Blutstromes angreifen kann.

[0007] Die Führungsspitze wird von dem äußeren Drahtstrang gebildet. Die Führungsspitze, die vorgebogen ist, ermöglicht es, den Führungsdraht bei zurückgezogenem Innenstrang in üblicher Weise zu platzieren. Erst wenn die zu passierende Stenose erreicht ist, wird der Innenstrang aus dem äußeren Drahtstrang ausgefahren, vorzugsweise um die Länge des verjüngten Vorderabschnitts. Dann greift an dem Kopf die Kraft der Blutströmung an, die den Innenstrang durch die Stenose hindurchspült.

[0008] Im folgenden wird unter Bezugnahme auf die Zeichnungen ein Ausführungsbeispiel der Erfindung näher erläutert.

[0009] Es zeigen:

[0010] Fig. 1 einen schematischen Längsschnitt durch den Führungsdraht, und

[0011] Fig. 2 den distalen Bereich des Führungsdrahtes nach dem Zurückziehen des äußeren Drahtstranges.

[0012] Der dargestellte Führungsdraht weist einen als Hohlstrang ausgebildeten äußeren Drahtstrang 10 auf, der eine Länge von etwa 1,40 m und einen Außendurchmesser von etwa 0,35 mm hat. Der Drahtstrang 10 besteht vorzugsweise aus einem schraubenförmig gewickelten dünnen Draht. Das vordere Ende des Drahtstranges 10 ist als Führungsspitze 11 ausgebildet. Es ist formbar, so dass es möglich ist, den Draht bis vor der kritischen Stenose aktiv zu steuern. Der Hauptteil 12 des Drahtstranges 10 ist gerade, jedoch so flexibel, dass er sich Biegungen des Gefäßsystems anpassen kann.

[0013] In dem äußeren Drahtstrang 10 verläuft ein Innenstrang 13 aus einem dünnen Draht, der in dem Drahtstrang verschiebbar ist. Der Innenstrang 13 besteht aus einem langgestreckten Hauptteil 14 und einem Vorderabschnitt 15 veringerten Durchmessers. Der Vorderabschnitt 15 endet in einem Kopf 16, der hier als Kugel ausgebildet ist. Der Durchmesser des Kopfes 16 ist gleich dem Durchmesser des Hauptteils 14, so dass der gesamte Innenstrang in dem Lumen des äußeren Drahtstranges 12 verschoben werden kann. Der Vorderabschnitt 15 hat hier einen konischen Verlauf. Seine Länge beträgt 10–20 mm. Der Kopf 16 befindet sich an dem dünnen Ende. Der Vorderabschnitt 15 ist wesentlich weicher als der Hauptteil 14 des Innenstranges 13.

[0014] Der zweiteilige Führungsdraht wird in dem in Fig. 1 dargestellten Zustand percutan in das Gefäßsystem des Patienten eingeführt. Dabei ist der Vorderabschnitt des Innenstranges hinter die Führungsspitze 11 zurückgezogen. Die Führungsspitze 11 ist daher in diesem Zustand unverstärkt und die gebogene, Führungsspitze dient als Wegfinder für den Führungsdraht.

[0015] Wenn die Führungsspitze 11 eine Stenose erreicht hat, die sie nicht durchdringen kann, wird der äußere Drahtstrang 10, aus dem proximalen Ende der Innenstrang 14 herausragt, zurückgezogen, so dass die Führungsspitze 11 gestreckt wird und der Vorderabschnitt 15 des Innenstranges 13 aus dem äußeren Drahtstrang 10 heraus vorsteht. Der den Führungsdraht umspülende Blutstrom greift nun an dem verdickten Kopf 16 an und zieht den Innenstrang 13 durch die Stenose. Anschließend kann der äußere Drahtstrang 10 nachgeschoben werden. Über den äußeren Drahtstrang 10 wird anschließend ein (nicht dargestellter) Ballonkatheter geschoben. Der Ballonkatheter kann für die Dilatation des Blutgefäßes oder auch zum Setzen eines Stents benutzt werden.

Patentansprüche

1. Führungsdraht für einen Katheter, mit einem lang-

gestreckten Drahtstrang (10), der am distalen Ende eine Führungsspitze (11) aufweist, **dadurch gekennzeichnet**, dass der Drahtstrang (10) als Hohlstrang ausgebildet ist und einen längsverschiebbaren Innenstrang (13) enthält, und dass am distalen Ende des Innenstranges (13) ein Kopf (16) angeordnet ist. 5

2. Führungsdraht nach Anspruch 1, dadurch gekennzeichnet, dass der Kopf (16) an einem Vorderabschnitt (15) des Innenstranges (13) von gegenüber dem Innenstrang (13) verkleinertem Durchmesser angeordnet ist. 10

3. Führungsdraht nach Anspruch 2, dadurch gekennzeichnet, dass der Vorderabschnitt (15) weicher ist als der Hauptteil (14) des Innenstranges (13).

4. Führungsdraht nach einem der Ansprüche 1–3, dadurch gekennzeichnet, dass die Führungsspitze (11) 15 aus einem formbaren Drahtabschnitt besteht.

5. Führungsdraht nach einem der Ansprüche 1–4, dadurch gekennzeichnet, dass der Außendurchmesser des Drahtstranges (10) maximal 0,5 mm beträgt.

Hierzu 1 Seite(n) Zeichnungen

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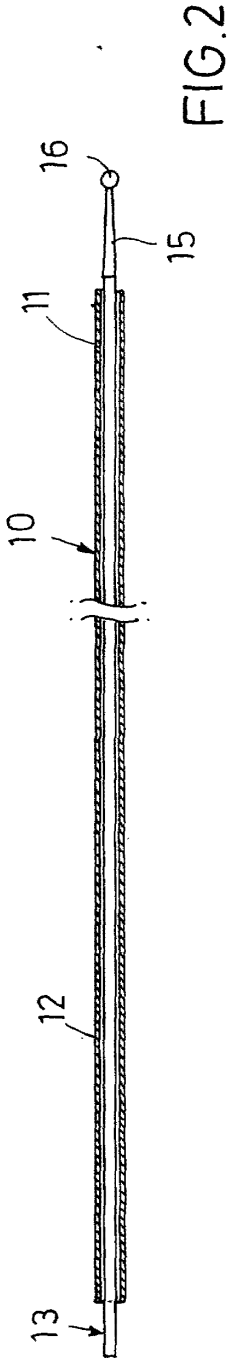
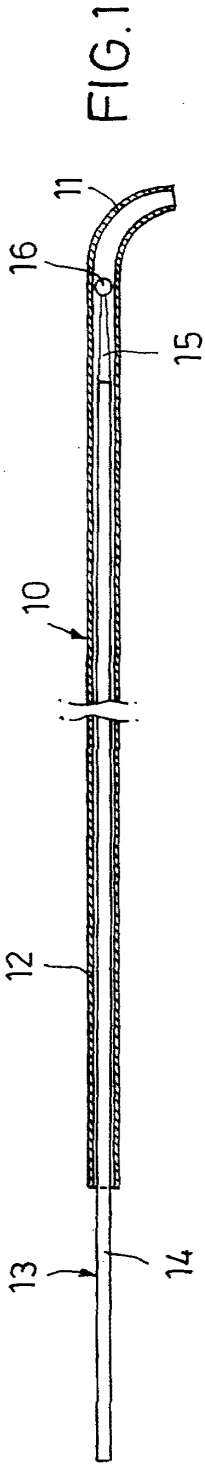
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Abstract

The device has a heart catheter (10) with a dilation balloon at the far end, a guide wire movable within a catheter main lobe, a balloon lobe passing through the catheter and joined to the dilation balloon and a high pressure pump (31) connected to the main lobe for generating a pressure of 5 bar maximum. The pump is connected to a fluid source (33, 34) that delivers an artificial blood product enriched with oxygen. Independent claims are also included for the following: a method of dilating a constriction in a coronary vessel.



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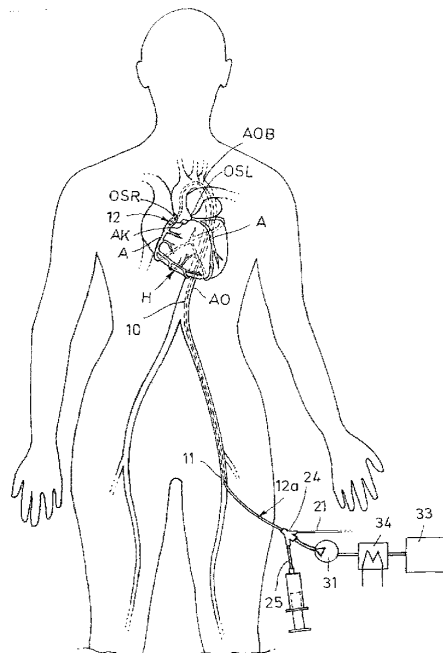
56 Entgegenhaltungen:
DE 694 06 118 T2
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Die folgenden Angaben sind den vom Anmelder eingereichten Unterlagen entnommen

Prüfungsantrag gem. § 44 PatG ist gestellt

54 Dilatationsvorrichtung für Herzkranzgefäße

57 Ein Herzkatheter (10), der an seinem distalen Ende einen Dilatationsballon trägt, wird durch die Aorta (AO) bis in eine Herzkranzarterie hinein vorgeschoben. Dort wird der Dilatationsballon zur Beseitigung einer Stenose inflatiert. Zur Perfusion des Herzkranzgefäßes wird mit einer Hochdruckpumpe (31) eine Blutersatzflüssigkeit, die in einem Oxygenator (34) mit Sauerstoff angereichert wurde, in das Hauptlumen des Herzkatheters (10) gepumpt. Der Blutersatzstoff kann mit erheblich geringerer Flußmenge zugeführt werden als Blut, weil er eine höhere Sättigungskapazität mit Sauerstoff hat. Es kann eine gleiche Oxygenierung des Herzmuskels bei halber oder noch weiter verringerter Flußmenge erzielt werden. Die Gefahr einer Hämatombildung durch Hochdruckperfusion wird verringert.



DE 100 18 424 A 1

[0001] Die Erfindung betrifft eine Dilatationsvorrichtung für Herzkranzgefäße, mit einem Herzkatheter, der einen Dilatationsballon trägt und zur Durchführung einer aktiven Hochdruckperfusion geeignet ist.

[0002] Bei der Perkutanen Transluminalen Coronaren Angioplastie (PTCA) wird ein Herzkatheter, der einen Ballon aufweist, in ein Herzkranzgefäß eingeführt, um durch Inflation des Ballons eine im Herzkranzgefäß vorhandene Stenose aufzuweiten. Zur Vermeidung des unmittelbaren Recoils ist es weitgehend üblich geworden, einen aufweitbaren Stent in das Gefäß einzubringen. Dieser Stent stützt die Stenose ab und stellt ein im Körper verbleibendes Implantat dar. Obwohl das Gefäß durch einen Stent im dilatierten Bereich stark aufgedehnt werden kann, kommt es in erheblichem Maße zu Restenosen. Auch andere Behandlungsmethoden haben nicht zu hinreichend sicheren Therapien geführt. Als beste Therapieform gilt immer noch die klassische PTCA, die aber weiter verfeinert werden muss, um die Restenoserate von 40 bis 60% zu reduzieren. Bei längeren Dilatationszeiten von bis zu 15 Minuten wird erwartet, dass bei der PTCA das Recoilrisiko deutlich reduziert werden kann. Dies setzt voraus, dass eine Perfusion des distalen Herzmuskels erreicht werden kann.

[0003] Zur Aufrechterhaltung der Durchblutung (Autoperfusion) gibt es Autoperfusionskatheter, die den Blutfluß im behandelten Blutgefäß fortsetzen und dabei den inflatierten Ballon überbrücken. Solche Katheter haben einen großen Durchmesser im Ballonbereich und lassen nur relativ geringe Durchflußraten von weniger als 10 ml/min zu.

[0004] Aus DE 196 22 335 C2 ist ein Perfusionskatheter mit integrierter Miniatur-Niederdruckpumpe bekannt. Ein solcher Katheter erfordert einen hohen technischen Aufwand. Infolge der an der Miniatur-Pumpe auftretenden hohen Scherkräfte besteht die Gefahr der Blutschädigung.

[0005] Eine dritte Form der Perfusion ist die Hochdruckperfusion. Hierbei wird von einer Perfusionsquelle, die am proximalen Katheterende extrakorporal angeordnet ist, Blut mit hohem Druck in den Herzkatheter gepumpt. Das Blut wird als arterialisiertes Blut aus der Leistengegend des Patienten entnommen und in eine Hochdruckpumpe eingebracht. Die erforderlichen Drücke betragen bis zu 12 bar. Mit einer derartigen Hochdruckperfusion können Flußraten um 40 ml/min erreicht werden, jedoch besteht wegen des erforderlichen hohen Druckes die Gefahr der Hämatombildung im Koronarbereich oder einer anderweitigen Blutschädigung.

[0006] Der Erfindung liegt die Aufgabe zugrunde, eine Dilatationsvorrichtung mit aktiver Hochdruckperfusion zu schaffen, die mit relativ geringen Volumenströmen eine ausreichende Sauerstoffversorgung der distalen Herzmuskulatur sicherstellt.

[0007] Die Lösung dieser Aufgabe erfolgt erfindungsgemäß mit den im Patentanspruch 1 angegebenen Merkmalen. Hiernach ist die Hochdruckpumpe, die mit dem proximalen Ende des Herzkatheters verbunden ist, an eine Fluidquelle angeschlossen, die einen mit Sauerstoff angereicherten Blutersatzstoff liefert. Blutersatzstoffe können eine zweifach bis dreifach höhere Sättigungskapazität mit Sauerstoff, als Blut aufweisen. Entsprechend kann eine gleiche Oxygenierung des Herzmuskels bei halber oder gedritelter Flußmenge erzielt werden. Dies bedeutet, dass für eine ausreichende Perfusion ein wesentlich geringerer Durchfluß durch den Herzkatheter erforderlich ist. Unter einer Hochdruckpumpe ist eine Pumpe zu verstehen, die einen Druck von mindestens 0,5 bar liefert.

[0008] Ein Vorteil besteht darin, dass bei einem spontanen

Gefäßverschluß die Gefahr der Druckerhöhung verringert ist, weil der Blutersatzstoff in geringerem Volumenstrom zugeführt wird. Günstig ist ferner, dass kein arterialisiertes Blut aus der Leiste des Patienten entnommen werden muss. Die Vorrichtung ist wie ein üblicher PTCA-Herzkatheter zu bedienen und verfügt über ein zentrales Hauptlumen, das genauso klein ist wie bei einem Standardkatheter, nämlich einen Durchmesser von 0,2 bis 0,5 mm auf Höhe des Ballonträgers und proximal des Ballonträgers von 1,0 bis 1,4 mm hat. Damit können bei einem Durchfluß von 15 bis 20 ml/min die Druckverluste im Katheter gering bleiben.

[0009] Als künstlicher Blutersatzstoff können Hämoglobine, die sich in Lösung befinden (stromafräies Hämoglobin oder konjugierte und versetzte Hämoglobine) oder mittels Liposomenmembranen verkapselte Hämoglobine eingesetzt werden. Besser eignen sich aufgrund der hohen erreichbaren Sauerstofflöslichkeit (bis an 40 Vol) noch die perfluorierten Kohlene. Diese Substanzen stellen zyklische oder linearkettige Kohlenwasserstoffverbindungen dar, bei denen eine vollständige Substitution des Wasserstoffs durch Fluor erfolgt ist. Aufgrund der bipolaren Charakteristik und der daraus resultierenden Unlöslichkeit in Wasser werden die perfluorierten Kohlene emulgiert.

[0010] Solche Blutersatzstoffe können künstlich gewonnen werden und stehen in steriler Form zur Verfügung. Der Blutersatzstoff wird aus einem sterilen Gefäß zunächst einem Oxygenator zugeführt, oder er ist bereits im sterilen Gefäß stark mit Sauerstoff angereichert. Danach wird die Lösung einer Hochdruckpumpe zugeführt und in den Herzkatheter eingespeist. Als Hochdruckpumpen können Zahnradpumpen, Spritzenpumpen, Rollpumpen o. dgl. eingesetzt werden, ohne dass auf die Vermeidung von Blutschädigungen geachtet werden mußte. Die kleine während der Therapie zu applizierende Menge (< 150 ml) reduziert zudem die anderweitig für den Blutersatzstoff beschriebenen Nebenwirkungen.

[0011] Der Herzkatheter enthält in üblicher Weise einen Führungsdraht. Dieser Führungsdraht kann dazu benutzt werden, einen am distalen Ende des Herzkatheters vorgesehenen Abschnitt verringerten Querschnittes durch den Führungsdraht im wesentlichen zu verschließen oder zu öffnen. Geöffnet wird dieser Abschnitt dann, wenn der Führungsdraht in proximaler Richtung zurückgezogen wird und dann den engen Abschnitt zur Perfusion freigibt. Auf diese Weise ist mit Hilfe des Führungsdrahtes eine Steuerung der Perfu-sionsrate möglich.

[0012] Im folgenden wird unter Bezugnahme auf die Zeichnungen ein Ausführungsbeispiel der Erfindung näher erläutert.

[0013] Es zeigen:

[0014] Fig. 1 die Anwendung der Dilatationsvorrichtung bei einem Patienten,

[0015] Fig. 2 einen schematischen Längsschnitt durch Aorta bei Verlegung eines Führungskatheters, in den später der Herzkatheter eingeschoben wird,

[0016] Fig. 3 einen Längsschnitt durch das distale Ende des Herzkatheters, und

[0017] Fig. 4 eine Ansicht des proximalen Endes des Herzkatheters, teilweise geschnitten.

[0018] Fig. 1 zeigt die Verlegung eines Herzkatheters 10 zur Dilatation eines verengten Herzkranzgefäßes. Der Herzkatheter 10 tritt durch einen perkutanen Zugang 11 in der Leistengegend in den Körper des Patienten ein und verläuft durch das Arteriensystem in die Aorta AO und durch den Aortenbogen AOB zur Aortenklappe AK, von der die Ostien OS abzweigen, die zu den Herzkranzarterien A führen. Dabei wird unterschieden zwischen rechtem Ostium OSR und linken Ostium OSL.

[0019] Der Herzkatheter 10 hat ein distales Ende 12, das in der Koronararterie A plaziert wird und ein proximales Ende 12a, das sich außerhalb des Patientenkörpers befindet. Der Herzkatheter hat eine Länge von etwa 100 cm. Er besteht aus einem Schlauch mit einem Außendurchmesser von maximal 2,0 mm.

[0020] Der Herzkatheter 10 wird durch einen Führungskatheter 13 hindurchgeschoben, der zunächst in der Aorta AO verlegt wird. Der Außendurchmesser des Führungskatheters 13 beträgt maximal 3,0 mm und sein Innendurchmesser beträgt maximal etwa 2,5 mm. Der Führungskatheter 13 hat eine abgebogene elastische Katheterspitze 14, die durch Drehen und Verschieben des Katheters in das betreffende Ostium OSR oder OSL eingeführt werden kann. In den Führungskatheter 13 wird dann der Herzkatheter 10 eingeführt. Fig. 3 zeigt das distale Ende 12 des Herzkatheters 10. Der Herzkatheter weist ein Hauptlumen 15 auf, das sich im wesentlichen über die gesamte Länge des Herzkatheters erstreckt und einen Innendurchmesser von 1,0 bis 1,4 mm aufweist. Parallel zum Hauptlumen verläuft ein Ballonlumen 16, dessen Durchmesser 0,1 bis 0,2 mm beträgt.

[0021] Am proximalen Ende des Herzkatheters 10 befindet sich ein Abschnitt 17 verringerten Querschnitts, der das Hauptlumen 15 fortsetzt. In dem Abschnitt 17 beträgt der Lumendurchmesser 0,2 bis 0,5 mm. Der Abschnitt 17 ist von einem Ballon 18 umgeben, der durch Flüssigkeit, die durch das Ballonlumen 16 zugeführt wird, aufgeblasen werden kann. Der Ballon 18 bildet den mit dem Ballonlumen 16 in Verbindung stehenden Dilatationsballon.

[0022] Am distalen Ende des Abschnitts 17 befindet sich die Katheterspitze 19 mit einer axialen Durchtrittsöffnung und zusätzlichen seitlichen Perfusionsöffnungen 20.

[0023] In dem Hauptlumen 15 befindet sich ein Führungsdraht 21, der verschoben werden kann und der durch die axiale Öffnung 19 hindurchragen kann. Das distale Ende 12 des Führungsdrahtes 21 ist als weichelastische Spitze ausgebildet und als Wegfinder vorgebogen.

[0024] Der Führungsdraht 21 hat einen Durchmesser von 0,3 mm. Der Abschnitt 17 hat im deflatiert anliegenden Ballon einen Außendurchmesser von etwa 1 mm und ist somit so klein im Profil wie PTCA-Ballons der neuestens Generation. Der Innendurchmesser ist so groß, dass der Führungsdraht 21 in dem Abschnitt 17 verschoben werden kann, jedoch ist der um den Führungsdraht verbleibende Ringspalt so eng, dass praktisch kein Durchfluß von Blut oder Blutersatzstoff durch diesen Ringspalt stattfindet. Der Ballon 18 hat eine Länge von 10 bis 40 mm und im aufgeweiteten Zustand einen Durchmesser von 2 bis 5 mm.

[0025] An der Stelle 23, an der der Abschnitt 17 beginnt, erweitert sich das Lumen um mehr als das Doppelte der Querschnittsfläche. Das erweiterte Lumen bildet das Hauptlumen 15. Wird der Führungsdraht 21 in das Hauptlumen 15 zurückgezogen, so dass er die in Fig. 3 mit 21a bezeichnete Position einnimmt, dann wird der Abschnitt 17 zum Durchströmen frei. Im Hauptlumen 15 kann Perfusionsflüssigkeit an dem in der Position 21a befindlichen Führungsdraht vorbeiströmen. Die Perfusionsflüssigkeit tritt aus den Öffnungen der Katheterspitze 19 aus.

[0026] Fig. 4 zeigt das proximale Ende 12a des Herzkatheters 10. Dort befindet sich ein Verzweigungsstück 24, von dem ein mit dem Ballonlumen 16 verbundener Schlauch 25 abzweigt. Am Ende dieses Schlauchs befindet sich ein Luer-Lock-Konnektor 26 für den Anschluß einer Ballondruckquelle.

[0027] Von dem Verzweigungsstück 24 zweigt ein weiterer Schlauch 27 aus dem Hauptlumen 15 ab, durch den der Führungsdraht 21 verläuft. Am Ende dieses Schlauchs 27 befindet sich ein Dichtelement 28 mit einer Überwurfmutter,

die unter Zusammendrückung einer Dichtung 29 festgeschraubt werden kann, um den Eintritt des Führungsdrahtes 21 in den Schlauch 27 abzudichten und zugleich den Führungsdraht 21 gegen Längsverschiebung zu sichern.

[0028] Das Hauptlumen 15 setzt sich proximal von dem Verzweigungsstück 24 in einem Schlauch 30 fort, der den gleichen Innendurchmesser hat wie das Hauptlumen. Dieser Schlauch 30 ist an eine Hochdruckpumpe 31 angeschlossen, deren Sauganschluß mit einer Fluidquelle 32 verbunden ist. Die Fluidquelle 32 enthält ein Reservoir 33 mit einer Blutersatzflüssigkeit, beispielsweise ölgebundenes Hämoglobin oder fluorierte Kohlenwasserstoffverbindungen. Diese Blutersatzflüssigkeit wird über einen Oxygenator 34 der Saugseite der Hochdruckpumpe 31 zugeführt. Im Oxygenator 34 erfolgt eine Anreicherung der Blutersatzflüssigkeit mit Sauerstoff.

[0029] Die Hochdruckpumpe 31 pumpt den oxygenierten Blutersatzstoff in einem Volumenstrom von 10 bis 20 ml/min bei einem Druck von maximal etwa 5 bar in das Hauptlumen 15. Infolge der Strömungsverluste im Verlauf des Herzkatheters verringert sich der Druck so, dass er an der Katheterspitze schließlich nur noch etwa 0,08 bar beträgt.

[0030] Wenn der Herzkatheter 10 durch den Führungskatheter 13 hindurch geschoben wird, befindet sich der Ballon 18 im deflatierten Zustand, d. h. er liegt flach am Umfang des Abschnitts 17 an. Wenn der Abschnitt 17 des Herzkatheters die verengte Stelle des Herzkranzgefäßes erreicht hat, wird der Führungsdraht 21 in die Position 21a zurückgezogen. Der Ballon 18 wird mit einer Flüssigkeit inflatiert, während gleichzeitig die Hochdruckpumpe 31 oxygenierten Blutersatzstoff in den Katheter pumpt. Der Blutersatzstoff passiert durch den Abschnitt 17 hindurch den aufgeblasenen Ballon 18, so dass durch diesen Abschnitt eine Perfusion des blockierten Gefäßes erfolgt. Dabei ist der für eine ausreichende Versorgung der Herzkranzarterie erforderliche Volumenstrom viel geringer als bei einer Perfusion mit Blut.

[0031] Im Falle eines vorübergehenden Gefäßverschlusses 8a, wie er zyklisch im Herzrhythmus stattfinden kann, kann der Perfusionsstrom durch den Herzkatheter gestoppt werden. Eine zyklische Förderung des Blutersatzstoffes kann druckgesteuert erfolgen, wobei die hierfür notwendige Druckerfassungsvorrichtung sich in Ballonnähe im Herzkatheter 10 oder auf dem Führungsdraht 2 befindet. Erfolgt während eines Gefäßverschlusses im distalen Gefäßbett eine kontinuierliche Förderung des Blutersatzstoffes, so baut sich der von der Hochdruckpumpe 31 erzeugte Druck über die gesamte Länge des Herzkatheters auf. Wegen der relativ geringen Förderrate der Hochdruckpumpe 31 und der Elastizität des distalen Gefäßbettes erstreckt sich dieser Druckaufbau über einen Zeitraum von mehreren Sekunden, so dass kein plötzliches Aufsprengen der Gefäßwand mit nachfolgender Hämatombildung zu befürchten ist, zumal die Verschlusszeiten weniger als 1 s betragen.

[0032] An dem Herzkatheter ist ein (nicht dargestellter) Drucksensor vorgesehen, der den Druck an einer Stelle des Hauptlumens 15 in Nähe des Ballons 18 mißt. Dieser Drucksensor bewirkt dann, wenn der Druck einen Grenzwert übersteigt, das Öffnen eines Entlastungsventils, wodurch der von der Hochdruckpumpe aufgebaute Druck 31 schnell entweicht.

Patentansprüche

1. Dilatationsvorrichtung für Herzkranzgefäße, mit einem Herzkatheter (10), der am distalen Ende (12) einen Dilatationsballon (18) aufweist, einem in einem Hauptlumen (15) des Herzkatheters verschiebbaren Führungsdraht (21), wobei das Hauptlumen distal vom Di-

latationsballon (18) offen ist, einem durch den Herzkatheter (10) verlaufenden, mit dem Dilatationsballon (18) verbundenen Ballonlumen (16) und einer an das Hauptlumen (15) angeschlossenen Hochdruckpumpe (31) zur Erzeugung eines Druckes von maximal 5 bar, **dadurch gekennzeichnet**, dass die Hochdruckpumpe (31) an eine Fluidquelle (32) angeschlossen ist, die einen mit Sauerstoff angereicherten künstlichen Blutersatzstoff liefert.

2. Dilatationsvorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass die Fluidquelle (32) ein den Blutersatzstoff enthaltendes Reservoir (33) und einen Oxygenator (34) aufweist.

3. Dilatationsvorrichtung nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass das Hauptlumen (15) am distalen Ende (12) einen Abschnitt (17) verringerten Querschnitts aufweist, durch den der Führungsdraht (21) hindurchpaßt.

4. Dilatationsvorrichtung nach Anspruch 3, dadurch gekennzeichnet, dass der Querschnitt in dem Abschnitt (17) kleiner ist als die halbe Querschnittsfläche des proximalen Bereichs des Hauptlumens (15).

5. Dilatationsvorrichtung nach Anspruch 3 oder 4, dadurch gekennzeichnet, dass der Abschnitt (17) von dem Dilatationsballon (18) bedeckt ist und dass der Außendurchmesser des Abschnittes einschließlich des deflatierten Ballon kleiner ist als derjenige des Hauptteils des Herzkatheters (10).

6. Dilatationsvorrichtung nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, dass ein den Druck im Hauptlumen (15) messender Drucksensor vorgesehen ist.

7. Dilatationsvorrichtung nach einem der Ansprüche 1–6, dadurch gekennzeichnet, dass die Hochdruckpumpe in Abhängigkeit von dem Gefäßdruck in der Nähe des Dilationsballons (18) geregelt ist.

8. Dilatationsvorrichtung nach Anspruch 7, dadurch gekennzeichnet, dass die Regelung der Hochdruckpumpe zyklisch im Herzrhythmus erfolgt.

9. Verfahren zum Dilatieren einer Stenose in einem Herzkranzgefäß mit den Schritten:

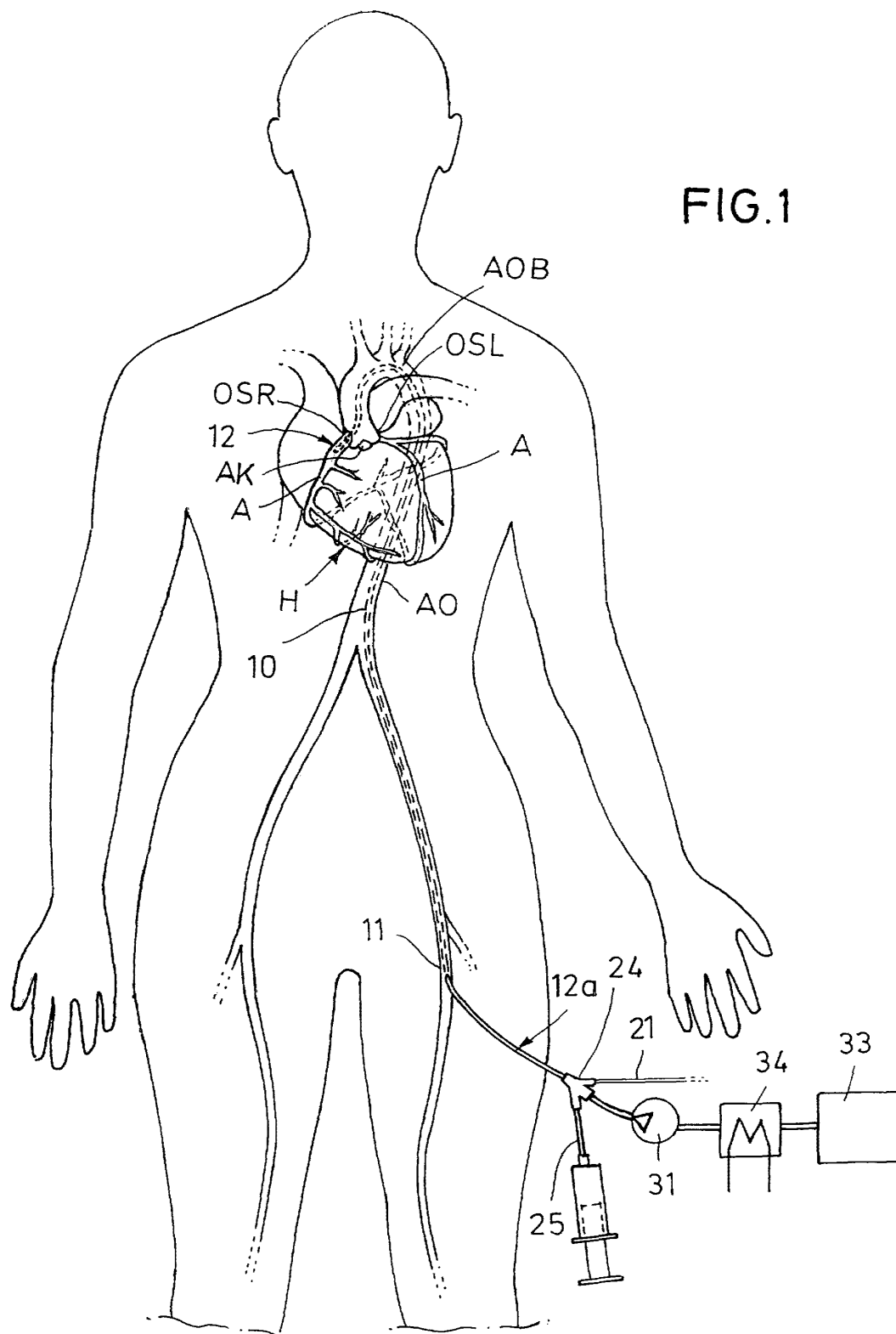
- Einführen eines Führungskatheters (13) in eine Arterie und Verschieben des Führungskatheters bis in das Herzkranzgefäß,
- Einführen eines Führungsdrahts (21) in das Herzkranzgefäß bis die Spitze des Führungsdrahts (21) die verengte Stelle im Herzkranzgefäß passiert hat,
- Einführen eines Herzkatheters (10), der am distalen Ende (12) einen Dilatationsballon (18) aufweist, in den Führungskatheter (13) und Herauschieben des den Dilatationsballon (18) tragenden Abschnitts (17) des Herzkatheters aus dem Führungskatheter (13) in den Bereich der Stenose,
- Rückzug des Führungsdrahts in eine Rückzugsposition (21a),
- Inflatieren des Dilatationsballons (18) zur Aufweitung der Stenose,
- Einführen eines mit Sauerstoff angereicherten flüssigen Blutersatzstoffes in das proximale Ende (12a) des Herzkatheters (10) und Herauslassen des Blutersatzstoffes distal von dem Dilatationsballon (18).

Hierzu 3 Seite(n) Zeichnungen

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- Leerseite -

FIG.1



101 430/285

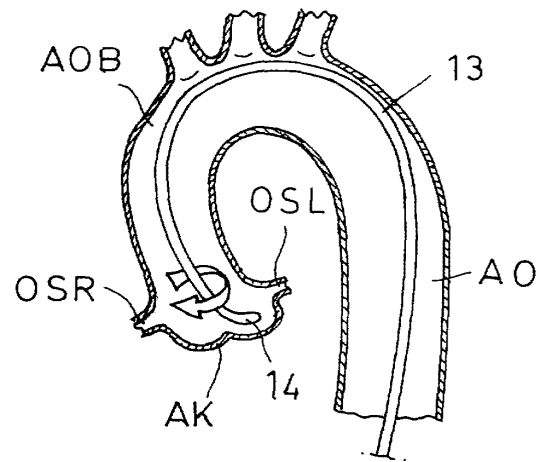


FIG. 2

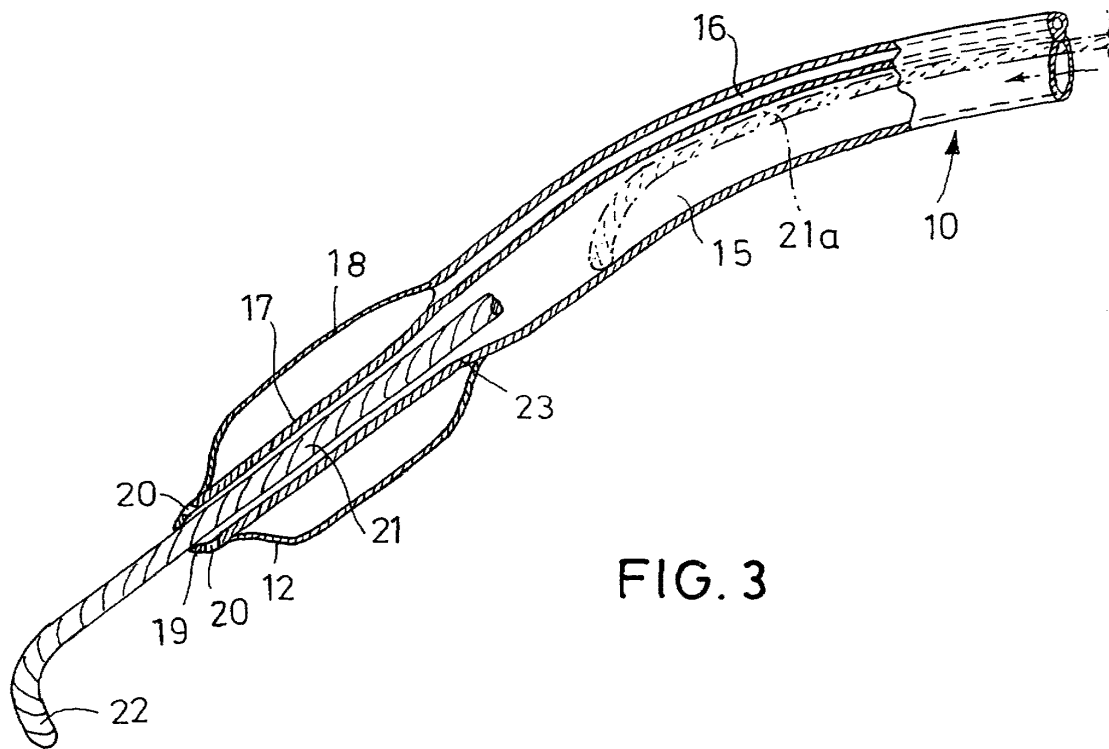
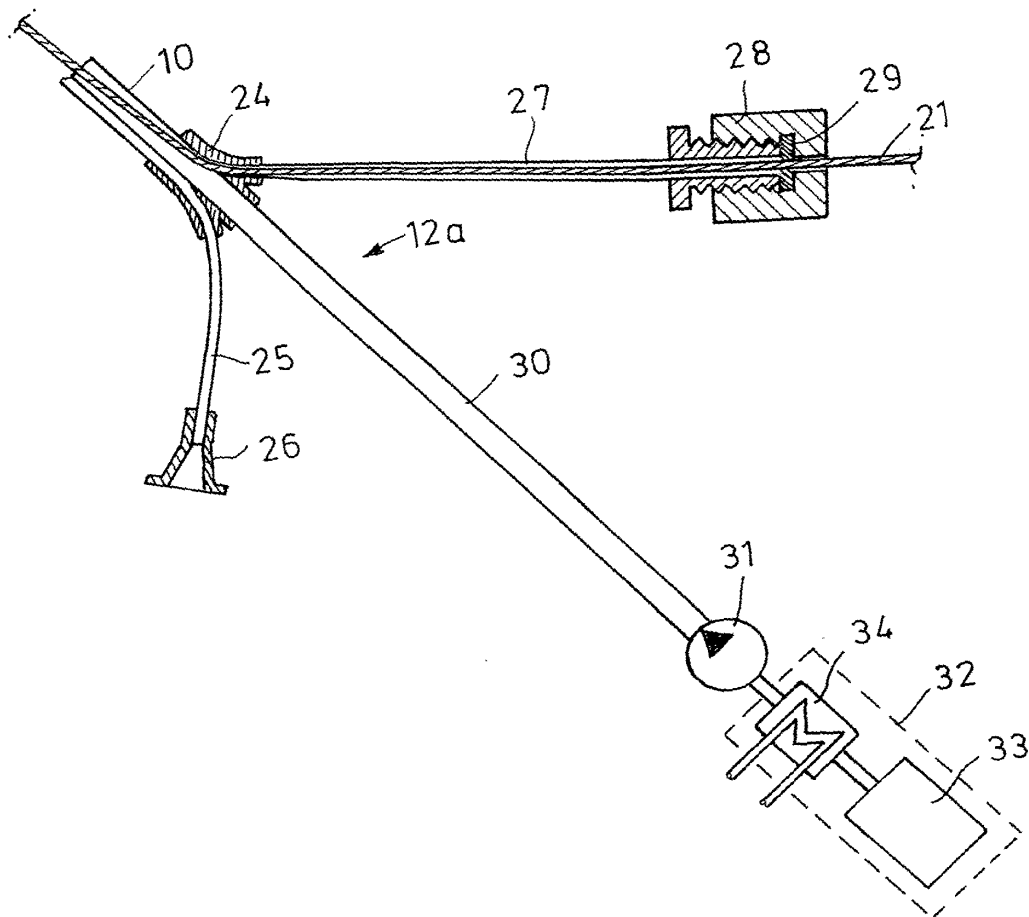


FIG. 3

FIG. 4



Abstract

The blood pump has a channel (32) running centrally through the impeller (22) connecting the rear side of the impeller (22) with the suction side (40). Blood is continually pumped through the channel (32) so that no dead water areas can form in unbladed areas of the impeller (22). The rear side of the impeller (22) is fitted with auxiliary blades (62) which produce a current parallel to the main current.



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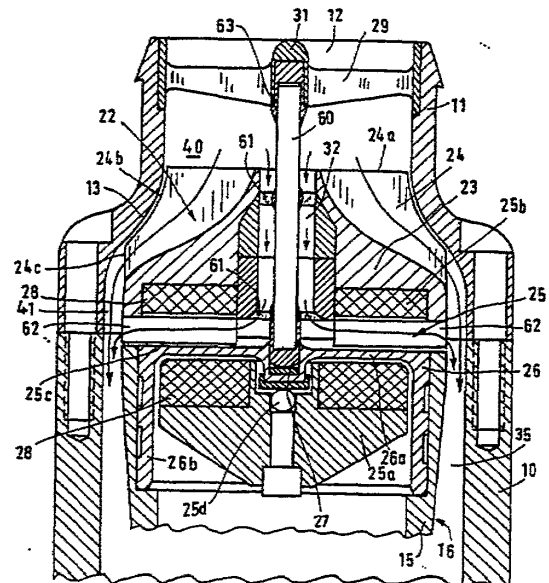
Patentanwälte von Kreisler, Selting, Werner et col.,
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gleich Anmelder

54 Blutpumpe nach dem Rotationspumpenprinzip

57 Die Blutpumpe weist einen zentrisch durch das Pumpenrad (23) hindurchgehenden Kanal (32) auf, der die Rückseite des Pumpenrades (23) mit der Saugseite (40) verbindet. Durch den Kanal (32) wird ständig Blut hindurchgepumpt, so daß sich an den unbeschaufelten Bereichen des Pumpenrades (22) keine Totwasserbereiche bilden können. An der Rückseite des Pumpenrades (22) sind Hilfsschaufeln (62) vorgesehen, die einen Parallelstrom zum Hauptstrom erzeugen.



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Die folgenden Angaben sind den vom Anmelder eingereichten Unterlagen entnommen

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Die Erfindung betrifft eine Blutpumpe nach dem Rotationsprinzip, also eine Blutpumpe mit einem rotierenden Pumpenrad.

Bei Blutpumpen besteht generell das Problem der Thrombenbildung durch Agglomeration von Blutteilchen. Dieses Problem besteht auch bei Blutpumpen nach dem Rotationsprinzip, insbesondere im Bereich des Pumpenrades, wenn dort enge Spalte sind, in denen Totwasserbildung auftreten kann.

Der Erfindung liegt die Aufgabe zugrunde, eine Blutpumpe nach dem Rotationsprinzip zu schaffen, bei der die Gefahr von Thrombenbildung im Bereich des Pumpenrades weitgehend vermieden wird.

Die Lösung dieser Aufgabe erfolgt erfindungsgemäß mit den im Patentanspruch 1 angegebenen Merkmalen.

Bei der erfindungsgemäßen Blutpumpe weist das Pumpenrad einen axialen Kanal auf, der die Saugseite des Pumpenrades mit dessen Rückseite hydraulisch verbindet. So kann Blut in den rückseitigen Spalt des Pumpenrades gelangen und diesen spülen. Durch die Druckdifferenz zwischen Druck- und Saugseite des Pumpenrades erfolgt somit eine Umspülung aller ungeschaukelten Flächen des Pumpenrades.

Gemäß einer bevorzugten Weiterbildung der Erfindung ist das Pumpenrad auf seine der Anströmseite abgewandten Rückseite mit radialfördernden Hilfsschaufeln versehen. Diese Hilfsschaufeln bewirken eine verstärkte aktive Durchströmung des axialen Kanals und der Rückseite des Pumpenrades in Hauptströmungsrichtung. Dadurch wird ein Bypassstrom erzeugt, der anschließend der Hauptströmung wieder zugeführt wird.

Bei der erfindungsgemäßen Blutpumpe ist ein zweiter Strömungsweg durch das Pumpenrad hindurch vorgesehen. Dieser zweite Strömungsweg, bei dem es sich um einen achsnahen reinen Spülweg handelt, wird entweder im Gegenstrom zum Hauptstrom durchströmt, wenn keine Hilfsbeschaufelung vorhanden ist, oder als Bypass in gleicher Strömungsrichtung wie der Hauptstrom. In jedem Fall werden Totwasserbereiche an der Rückseite des Schaufelrades wirksam vermieden.

Die Erfindung ist bei jeder Form von Rotationspumpen verwendbar, wie z. B. Axialpumpen, Radialpumpen und Diagonalpumpen.

Im folgenden wird unter Bezugnahme auf die Zeichnung ein Ausführungsbeispiel der Erfindung näher erläutert.

Es zeigt:

Fig. 1 einen Längsschnitt durch eine Ausführungsform der Blutpumpe.

Die Blutpumpe BP nach Fig. 1 weist ein langgestrecktes, rohrförmiges Pumpengehäuse 10 auf, das an einem Ende mit einem Einlaßteil 11 versehen ist. Der Einlaßteil 11 weist einen Einlaß 12 auf, dessen Innendurchmesser kleiner ist als der Innendurchmesser des Pumpengehäuses 10. Im Einlaßteil 11 ist ein ringförmiger Übergangsteil 13 ausgebildet, der bogenförmig gestaltet ist und in einer S-förmigen Krümmung von dem Durchmesser des Einlasses 12 auf den Innendurchmesser des Pumpengehäuses 10 glatt und knickfrei überleitet.

In dem Pumpengehäuse 10 ist coaxial das Motorgehäuse 15 eines Motors 16 befestigt, bei dem es sich um einen Elektromotor handelt. Das Motorgehäuse ist vollständig abgedichtet.

In dem Einlaßteil 11 des Pumpengehäuses 10 ist ein Pumpenrad 22 angeordnet. Dieses besteht aus einer Na-

be 23, von der Schaufeln 24 abstehen. Der Antrieb des Pumpenrades 22 erfolgt von dem Motor 16 über eine magnetische Kupplung, die als Stirndrehkupplung 25 oder Zentralsdrehkupplung ausgebildet sein kann. Diese weist ein erstes Kupplungsteil 25a auf, das mit dem Rotor des Motors 16 verbunden und im Innern des Motorgehäuses 15 gekapselt angeordnet ist, und ein zweites Kupplungsteil 25b, das in der Nabe 23 des Pumpenrades 22 angeordnet ist. Beide Kupplungsteile 25a, 25b haben Magnete 28, die bewirken, daß bei einer Drehung des ersten Kupplungsteils 25a das zweite Kupplungsteil 25b mitdreht.

Das Motorgehäuse 15 ist mit einer amagnetischen nichtleitenden Kappe 26 verschlossen, an welcher ein kombiniertes Axial/Radiallager 27 in Form einer Kugel abgestützt ist. Dieses Lager 27 stützt seinerseits die Nabe des Pumpenrades 22 ab. Die Magnete 28 der Stirndrehkupplung 25 erzeugen eine axiale Haltekraft, die größer ist als die beim Drehen des Pumpenrades 22 erzeugte Reaktionskraft, so daß das Pumpenrad 22 durch die Magnetkraft in Richtung auf den Motor 16 gezogen und gegen das Lager 27 gedrückt wird. Die axiale Haltekraft der Kupplung 25 wird zentral auf der Kappe 26 durch eine weitere axiale Lagerabstützung 25d in Verbindung mit dem Lager 27 kompensiert, so daß weder die Lager des Motors 26 noch die dünne Kappe 26 diese Kraft in ihrer Umfangswand 26b und auf der Stirnfläche 26a aufnehmen müssen.

Zur Zentrierung des Pumpenrades 22 auf der Einlaßseite ist in dem Einlaß 12 ein Armstern 29 befestigt. An dem Armstern 29 befindet sich ein zentrisches Kopfstück 31, das den Lagerzapfen 60 umgibt und die axial einströmende Strömung geringfügig radial in Richtung der Nabe 23 ableitet. Ferner enthält die Nabe 23 einen axialen Spülkanal 32, der zum Lager 27 führt. Der Leckagestrom durch den Spülkanal 32 bewirkt eine ständige Umspülung des Spaltes 25c zwischen der Achse 60 und dem Pumpenrad 22, um Thrombenbildung zu vermeiden.

Die Leitschaufeln 24 des Pumpenrades 22 haben an dem Anströmende 24a einen Außendurchmesser, der im wesentlichen dem Durchmesser des Einlasses 12 entspricht, so daß das Pumpenrad hier den gesamten Durchmesser des Einlaßkanals erfaßt. Im Anschluß an die Einlaßkanten 24a erfolgt ein konkav-bogenförmiger Umfangsbereich 24b, der dem Übergangsteil 13 des Pumpengehäuses mit geringem Abstand folgt. Daran anschließend haben die Pumpenschaufeln 24 einen Bereich 24c, dessen Durchmesser etwa so groß ist wie der Außendurchmesser des Motorgehäuses 15 an demjenigen Ende, das dem Pumpenrad 22 zugewandt ist. Der Außendurchmesser der diagonalen Pumpenschaufeln 24 wird so groß ausgeführt, wie es der Gesamtdurchmesser des Übergangsteils 13 erlaubt. Hierdurch kann die erforderliche, hydraulische Leistung bei einer vergleichsweise geringen Drehzahl (beispielhaft $n \approx 7000$ U/min für $V/t \approx 51$ /min und $\Delta P \approx 100$ mmHg) erzielt werden, was die Standzeiten der lagernden Komponenten der Pumpe erhöht.

Zwischen dem Pumpengehäuse 10 und dem Motorgehäuse 15 besteht ein Ringkanal 35, der sich in Längsrichtung erstreckt. Dieser Ringkanal 35 ist als Diffusor ausgebildet, indem sich seine Querschnittsfläche vom Einlaß zum Auslaß vergrößert. Dadurch entsteht eine Verlangsamung des Blutflusses und somit eine Druckerhöhung. Die Erweiterung der Querschnittsfläche des Ringkanals 35 wird durch entsprechende Veränderung der Wandstärken von Pumpengehäuse 10 und Motorgehäu-

se 15 erreicht.

Der Motor 16 bewirkt eine Rotation des Pumpenrades 22, dessen Schaufelräder 24 schraubenförmig gestaltet sind. Dadurch wird Blut von der Saugseite 40 axial angesaugt und zur Druckseite 41 und von dort und mit einer rotierenden Umfangskomponente in den Ringkanal 25 gefördert.

Das Pumpenrad 22 ist mit einer Achse 60 versehen, die an einem Ende in dem Lager 27 der das Motorgehäuse 15 verschließenden Kappe 26 und am anderen Ende in dem Armstern 29 über ein Radiallager 63 gelagert ist. Der ringförmige Längskanal 32 der Nabe 23 ist durch Stege 61 überbrückt, die die Nabe 23 an der Achse 60 festhalten. An dem dem Motor zugewandten Ende der Nabe 23 befinden sich Hilfsschaufeln 62, die die durch den Längskanal 32 einströmende Flüssigkeit radial nach außen pumpen und sie dem von den Pumpenschaufeln 24 erzeugten Hauptstrom zuführen. Durch die Hilfsschaufeln wird erreicht, daß der Spalt zwischen dem Pumpenrad 22 und dem Motorgehäuse 15 ständig durchströmt ist, so daß sich dort keine Thromben bilden können. Der Längskanal 32 ist so bemessen, daß der durch ihn hindurchgehende Blutstrom deutlich geringer ist als der von den Pumpenschaufeln 24 erzeugte Hauptstrom. Die Lager 27 und 63 sind derart angeordnet, daß sie einen ausreichenden Abstand zum Kanal 32 aufweisen. Obwohl der Übergang zwischen dem stationären und dem rotierenden Teil der Lager 27 und 63 integral — ohne große Stoßkante — erfolgt, an der sich Thromben anlagern könnten, muß davon ausgegangen werden, daß sich gegebenenfalls kleine Ringthromben an der Übergangsstelle bilden. Verschließen diese bei entsprechendem Abstand den Kanal 32 nicht, so kann ein degressives Thrombenwachstum aufgrund hinreichender Umspülung mit letztendlich stabiler Größe erreicht werden.

Patentansprüche

1. Blutpumpe nach dem Rotationspumpenprinzip, mit einem in Blut laufenden Pumpenrad (22), dadurch gekennzeichnet, daß das Pumpenrad (22) einen die Saugseite (40) mit der Rückseite verbindenden durchgehenden Kanal (32) aufweist.
2. Blutpumpe nach Anspruch 1, dadurch gekennzeichnet, daß das Pumpenrad (22) an seiner Rückseite mit radial fördernden Hilfsschaufeln (62) verbunden ist.
3. Blutpumpe nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß das Pumpenrad (22) eine in Lagern (27, 63) gelagerte Achse (60) aufweist, wobei die Lager (27, 63) zur Vermeidung von größeren Thromben direkt von Blut umströmt sind und der Übergang zwischen stationärem und rotierendem Lagerteil kontinuierlich und frei von Stoßkanten ausgeformt ist.
4. Blutpumpe nach Anspruch 3, dadurch gekennzeichnet, daß die Lager (27, 63) im Abstand von dem zentral angeordneten axialen Kanal (32) angeordnet sind, so daß kleine Thromben im Lagerbereich den Kanal (32) nicht versperren können.

Hierzu 1 Seite(n) Zeichnungen

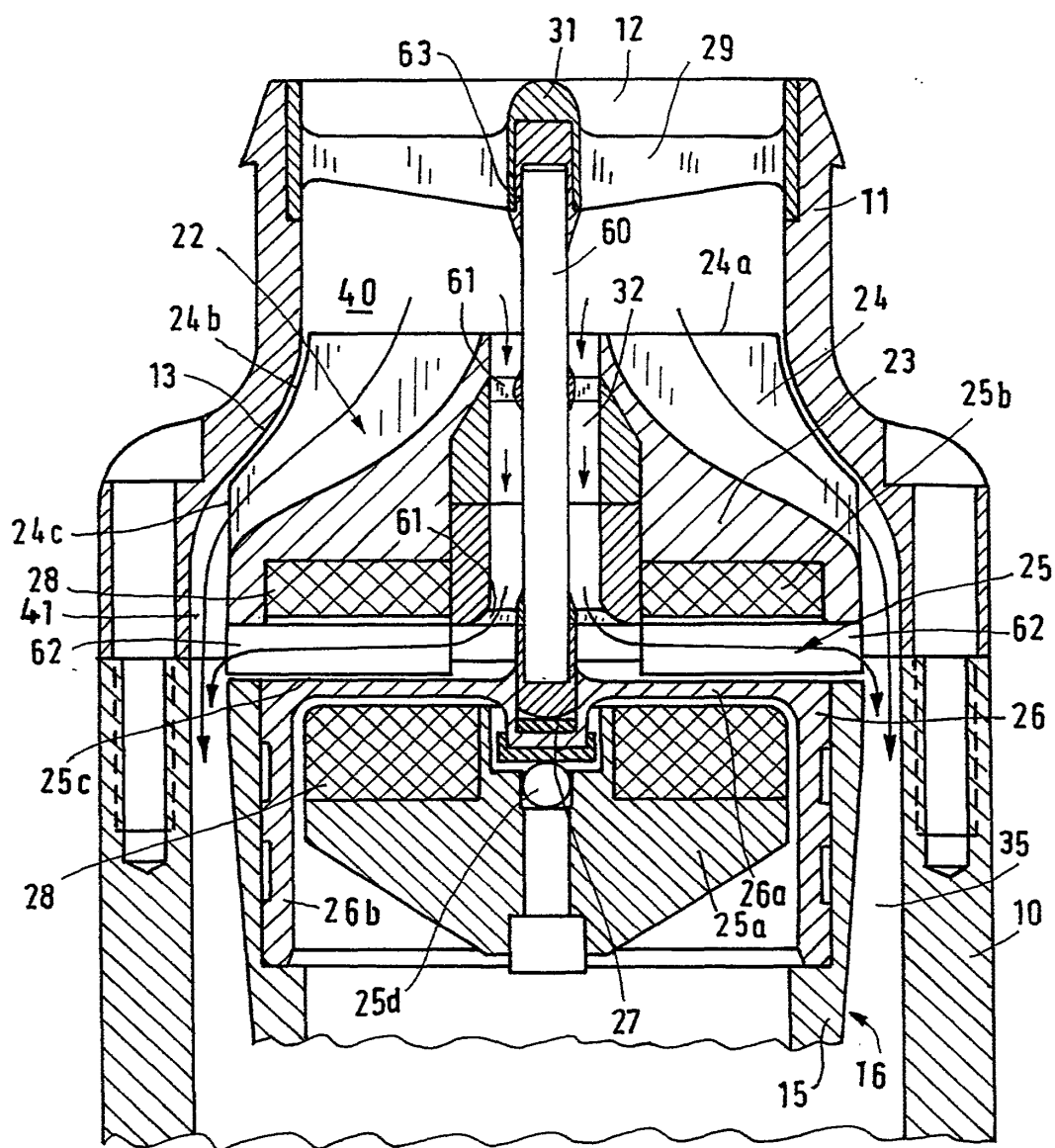


FIG.1

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Spiral bending wire in medical cannulas and catheters

General;

Like many areas of daily life, as well as the medicine in recent years and decades has made great strides. This is based not least on the developments and achievements of modern medical technology. Especially here, the microelectronics and the development of biocompatible materials in a very special way have proved to be engines of progress. So nowadays are not only open-heart surgery surgical standards, but also the use of special blood pump for the medium and long-term use is increasingly on the rise. These are usually used as a bridge to heart transplantation as long as there is no suitable Spenderherz available.

Such blood pumps are usually the result of many years of research, since very high and varied demands are placed on such pumps.

So they need to be not only extremely biocompatible and reliable, but also have a very low blood damage. This is the product of trönmungsführung and tolerability of the blood contacting surfaces. Only when all factors are right, is from the technical side, an insert which extends over several weeks or even months justifiable.

Due to the increasing number of uses of such systems more insights from practice are also increasingly. So turns out that one aspect in recent years too little attention has been paid: The cannulation. Thus, the connection between the body and the blood pump is meant, which is prepared by means of cannulae.

Thus, the respective cannulae are sewn on the one side to the diseased heart and connected on the other side to the pump. For this purpose, cannulas are also used today for the most part, as they have been used several decades ago. This are usually anatomically shaped low PVC - hoses. These have a number of disadvantages that often cause that is called into question the success of the whole blood pump insert. Thus, these needles are not only very rigid and can not be adapted to place the respective anatomical conditions, but often have a bad Oberflächeneinfluß on the blood.

A better blood behavior have here cannulas made of polyurethane (PU). This is known for its excellent biocompatibility. Unfortunately PU is still stiffer than PVC normally, the connection is often reminiscent of rigid pipes. For this reason, cannulas are inserted silicone rubber by some surgeons. This is characterized by its special flexibility. Unfortunately, silicone rubber has to have two not insignificant disadvantages: First, there is the very poor tear resistance, which has the consequence that when damage in the cannula is present,

this very quickly

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continue to tear and thus resulting in total loss. This property of the silicone rubber is prevented by relatively thick wall thickness prior to the cannula, which increase on the other hand, the rigidity strong again. The other disadvantage of silicone cannulas is the relatively poor blood compatibility of Oberflächen.

Although silicone rubber is not toxic, however, enabled certain defensive reactions of the blood, which makes them less suitable for a longer-term use.

Another problem that the surgeon is often during surgery is that due to anatomy variations or modified operations performed the connection of a cannula has to be carried out differently than initially foreseen. One way to address such a situation is the Bevorratung of various needles in size and geometry. This means that the surgeon Having regard to the circumstances of a present offer selects the most appropriate cannula.

For the hospital, however, the consequence that they must have a relatively large stock of needles, as well as many special sizes and shapes need to be permanently available, which are only very rarely needed. For the surgeon, this practice as a restriction, because it is only dependent on the available supply.

In view of these problems, some manufacturers offer cannulas, in whose wall a plastically deformable wire is embedded so that it is possible to easily deform the cannula binding by hand. Thus, the stockpiling of various geometries cannula omitted. The surgeon, the cannula can always turn optimally cope in the present case. This can happen even in the patient's body.

The prerequisite for such a cannula is not only the sufficient rigidity of the bending wire, but also a sufficient flexibility of the cannula itself.

All cannulas of this type available on the market have one thing in common: the bending wire runs just as straight wire parallel to

Cannula axis. However, this arrangement has some drawbacks. Thus, a bending of the cannula in only one plane is possible, because the wire is not stretch can still upsetting.

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Thus, the wire must always stored to the; are neutral fiber "of the cannula If it is in compressed or stretched area, so for this.

quickly became a kinking of the cannula, which usually also means that closes the cannula thereby.

The surgeon is thus always obliged to pay special attention to a corresponding behavior of the cannula, so as not to

Impairments in the function occurs. However, such needles are used because there is not yet an ideal cannula.

However, the problem described here is only lately especially through the increased use of long-term blood pumps

emerged. For this reason, just Efforts increased lately, being able to offer a better product on the market here. Such an improvement is Page 4 --- (DE)

Presented in the following arrangement of a bending wire, preferably in a soft cannula is.

Description:

The present invention relates to the arrangement of a bending wire which is embedded in a cannula wall. As can be easily show

it is much more meaningful, not straight and parallel to place the bending line to the cannula axis but helically to wrap around the cannula.

This wire is then, as the just previously also coated with a layer of plastic, so that it is fixed properly and no contact with body tissues or fluids has.

Such a cannula has significantly better bending properties than previous. Thus one can thus turn a cannula at any point in any direction without

Running the risk of this kinking due to the bending wire. Further, this arrangement can be also three-dimensional shapes turn, which is not readily possible in a straight bending wire.

The pitch of the helical wire has proven with an angle of approximately 45 ° to the axis of the cannula to be favorable. The wire must have a sufficient

thickness to accommodate the deforming forces on the cannula can. This applies, however, for a straight bending wire.

It proves to be useful to form the end portions of the wire so that it at least once without significant slope to the cannula

are looped. The ends tend otherwise uproot this, since relatively large forces occur and the wire ends quickly the plastic layer can pierce.

Unlike needles with straight bending wire to make in this case meaning arrangements in which two or more wires (possibly are distributed correspondingly thinner) at different locations (preferably symmetrically) over the cross section.

The manufacturing effort for a described cannula is slightly higher than with conventional due to be executed coiling Bending needles, but the significantly better handling characteristics and enhanced reliability to justify all the small

More effort.

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LIST OF REFERENCE NUMBERS

Example cannula

1. Inlet area
2. initial portion bending wire
3. bending wire
4. cannula wall
5. end bending wire
6. non-compliant cannula area

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· sigma ;:

Protection claims

First bending wire assembly with cannulas and catheters, characterized in that a plastically deformable bending wire is disposed spirally around the cannula / catheter.

Second bending wire assembly according to claim 1, characterized in that a plurality of plastically deformable bending wires arranged spirally around the cannula / catheter.

3. bending wire assembly according to claim 1 + 2., Characterized in that the one or more wires with vözugweise plastic coated.

4. bending wire assembly according to claim 1.-3., Characterized in that the end areas of the / of the wires with little or no slope at the cannula / catheter are wound.

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⑤④ Spiralförmiger Biegedraht in medizinischen Kanülen und Kathetern

DE 296 04 787 U 1

15.03.98

Spiralförmiger Biegedraht in medizinischen Kanülen und Kathetern

Allgemeines:

Wie viele Bereiche des täglichen Lebens, so hat auch die Medizin in den letzten Jahren und Jahrzehnten große Fortschritte gemacht. Diese beruhen nicht zuletzt auf den Weiterentwicklungen und Errungenschaften der modernen Medizintechnik. Speziell hier haben sich die Mikroelektronik und die Entwicklung biokompatibler Materialien in ganz besonderer Weise als Motoren des Fortschrittes erwiesen. So sind heutzutage nicht nur Operationen am offenen Herzen chirurgischer Standart, sondern auch der Einsatz von speziellen Blutpumpen für den mittel- und langfristigen Einsatz ist zunehmend auf dem Vormarsch. Diese werden in der Regel als Überbrückung zur Herztransplantation verwendet, solange noch kein geeignetes Spenderherz zur Verfügung steht.

Solche Blutpumpen sind meist das Ergebnis langjähriger Forschung, da an solche Pumpen sehr hohe und vielfältige Anforderungen gestellt werden. So müssen sie nicht nur besonders bioverträglich und zuverlässig sein, sondern auch eine sehr geringe Blutschädigung aufweisen. Diese ist das Produkt aus Strömungsführung und Verträglichkeit der blutberührenden Oberflächen. Erst wenn alle Faktoren stimmen, ist von der technischen Seite ein Einsatz, der sich über mehrere Wochen oder gar Monate erstreckt verantwortbar.

Aufgrund der steigenden Einsatzzahlen solcher Systeme liegen auch zunehmend mehr Erkenntnisse aus der Praxis vor. So zeigt sich, daß einem Aspekt in den letzten Jahren zu wenig Aufmerksamkeit geschenkt wurde: Die Kanülierung. Damit ist die Verbindung zwischen Körper und Blutpumpe gemeint, die mittels Kanülen hergestellt wird. So werden die entsprechenden Kanülen auf der einen Seite an das kranke Herz genäht und auf der anderen Seite an die Pumpe angeschlossen. Hierfür werden auch heute noch größtenteils Kanülen verwendet, wie sie schon vor Jahrzehnten eingesetzt wurden. Diese sind in der Regel anatomisch günstig geformte PVC - Schläuche. Diese weisen eine Reihe von Nachteilen auf, die oft dazu führen, daß der Erfolg des gesamten Blutpumpeinsatzes in Frage gestellt ist. So sind diese Kanülen nicht nur sehr steif und können nicht an Ort und Stelle den jeweiligen anatomischen Gegebenheiten angepaßt werden, sondern haben oft auch einen schlechten Oberflächeneinfluß auf das Blut. Ein besseres Blutverhalten haben hier Kanülen aus Polyurethan (PU). Dieses ist für seine sehr gute Biokompatibilität bekannt. Leider ist PU in der Regel noch steifer als PVC, so daß die Verbindung oft an starre Rohre erinnert. Aus diesem Grunde werden von manchen Chirurgen Kanülen aus Silikonkautschuk eingesetzt. Dieses zeichnet sich durch seine besondere Flexibilität aus. Leider hat Silikonkautschuk auch zwei nicht unbedeutende Nachteile aufzuweisen: Da ist zum einen die sehr schlechte Weiterreißfestigkeit, die zur Folge hat, daß wenn eine Beschädigung in der Kanüle vorliegt, diese sehr schnell

weiterreißt und damit zum Totalausfall führt. Dieser Eigenschaft des Silikonkautschuk beugt man durch relativ dicke Wandstärken der Kanüle vor, welche auf der anderen Seite die Steifigkeit wieder stark erhöhen. Der andere Nachteil von Silikonkanülen ist die verhältnismäßig schlechte Blutverträglichkeit der Oberflächen. Silikonkautschuk ist zwar nicht giftig, aktiviert jedoch gewisse Abwehrreaktionen des Blutes, was sie für einen längerfristigen Einsatz eher ungeeignet macht.

Ein weiteres Problem, daß sich dem Chirurgen während einer Operation oft stellt ist, daß auf Grund von Anatomieschwankungen oder modifiziert durchgeführter Operationen der Anschluß einer Kanüle anders durchgeführt werden muß als ursprünglich vorgesehen. Eine Möglichkeit solch einer Situation zu begegnen ist die Bevorratung von diversen Kanülen hinsichtlich Größe und Geometrie. Dieses bedeutet, daß der Chirurg nach Kenntnisnahme der Gegebenheiten aus einem präsenten Angebot die geeignetste Kanüle auswählt.

Für die Klinik hat das jedoch zur Folge, das sie ein verhältnismäßig großes Lager an Kanülen haben muß, da auch viele Sondergrößen und Formen ständig verfügbar sein müssen, die nur sehr selten benötigt werden. Auch für den Chirurg stellt diese Praxis eine Einschränkung da, da er lediglich auf das vorhandene Angebot angewiesen ist.

Vor dem Hintergrund dieser Problematik bieten einige Hersteller Kanülen an, in deren Wand ein plastisch verformbarer Draht eingebettet ist, so das die Möglichkeit besteht, die Kanüle einfach mit der Hand bleibend zu verformen. Somit entfällt die Bevorratung verschiedener Kanülengeometrien. Der Chirurg kann sich die Kanüle immer optimal für den vorliegenden Fall zurecht biegen. Dieses kann auch noch im Körper des Patienten geschehen.

Die Voraussetzung für solch eine Kanüle ist nicht nur die ausreichende Steifigkeit des Biegedrahtes, sondern auch eine ausreichende Flexibilität der Kanüle selbst.

Alle auf dem Markt erhältlichen Kanülen dieser Art weisen eine Gemeinsamkeit auf: Der Biegedraht verläuft einfach als gerader Draht parallel zur Kanülenachse. Diese Anordnung bietet jedoch einige Nachteile. So ist ein Biegen der Kanüle nur in einer Ebene möglich, da sich der Draht weder dehnen noch stauchen läßt.

Der Draht muß also immer in der „neutralen Faser“ der Kanüle liegen. Befindet er sich im gestauchten oder gedehnten Bereich, so für dieses schnell zu einem Abknicken der Kanüle, was in der Regel auch bedeutet, daß sich die Kanüle dabei verschließt.

Der Chirurg ist also immer gezwungen in besonderer Weise auf ein entsprechendes Verhalten der Kanüle zu achten, damit es nicht zu Beeinträchtigungen in der Funktion kommt. Dennoch werden solche Kanülen verwendet, da es die ideale Kanüle noch nicht gibt.

Die hier beschriebene Problematik ist jedoch auch erst in letzter Zeit durch den vermehrten Einsatz von Langzeitblutpumpen besonders hervorgetreten. Aus diesem Grund werden gerade in letzter Zeit vermehrt Anstrengungen unternommen, hier ein besseres Produkt auf dem Markt anbieten zu können. Eine solche Verbesserung stellt

die im folgenden vorgestellte Anordnung eines Biegedrahtes. in einer vorzugsweise weichen Kanüle dar.

Beschreibung:

Die vorliegende Erfindung bezieht sich auf die Anordnung eines Biegedrahtes, der in eine Kanülenwand eingelassen ist. Wie sich einfach zeigen läßt, ist es sehr viel sinnvoller, den Biegedraht nicht gerade und parallel zur Kanülenachse anzuordnen, sondern spiralförmig um die Kanüle zu wickeln.

Dieser Draht wird dann, wie der gerade bisher auch, mit einer Kunststoffschicht beschichtet, so daß er gut fixiert ist und keine Berührung mit Körpergewebe oder Flüssigkeiten hat.

Solch eine Kanüle hat deutlich bessere Biegeeigenschaften als bisherige. So kann man so eine Kanüle an jeder Stelle in jede Richtung biegen, ohne Gefahr zu laufen diese aufgrund des Biegedrahtes abzuknicken. Ferner lassen sich durch diese Anordnung auch dreidimensionale Formen biegen, was bei einem geraden Biegedraht nicht ohne weiteres möglich ist.

Die Steigung des spiralförmigen Drahtes hat sich mit einem Winkel von ca. 45° zur Kanülenachse als günstig erwiesen. Der Draht muß über eine ausreichende Dicke verfügen, um auch die verformenden Kräfte an der Kanüle aufnehmen zu können. Dieses gilt jedoch auch für einen geraden Biegedraht.

Es erweist sich als sinnvoll, die Endbereiche des Drahtes so zu formen, daß sie mindestens einmal ohne nennenswerte Steigung um die Kanüle geschlungen sind. Die Enden neigen sonst dazu auszureißen, da hier relativ große Kräfte auftreten und die Drahtenden schnell die Kunststoffschicht durchstoßen können.

Im Gegensatz zu Kanülen mit geradem Biegedraht machen in diesem Fall auch Anordnungen Sinn, bei denen zwei oder mehr Drähte (evtl. entsprechend dünner) an verschiedenen Stellen (vorzugsweise symmetrisch) über den Querschnitt verteilt angeordnet sind.

Der Fertigungsaufwand für eine hier beschriebenen Kanüle liegt aufgrund der auszuführenden Wendelung etwas höher, als bei herkömmlichen Biegekanülen, aber die deutlich besseren Handhabungseigenschaften und die gesteigerte Funktionssicherheit rechtfertigen allemal den geringen Mehraufwand.

15.03.95

Bezugzeichenliste

Beispielkanüle

1. Einlaufbereich
2. Anfangsbereich Biegedraht
3. Biegedraht
4. Kanülenwand
5. Endbereich Biegedraht
6. Nichtverformbarer Kanülenbereich

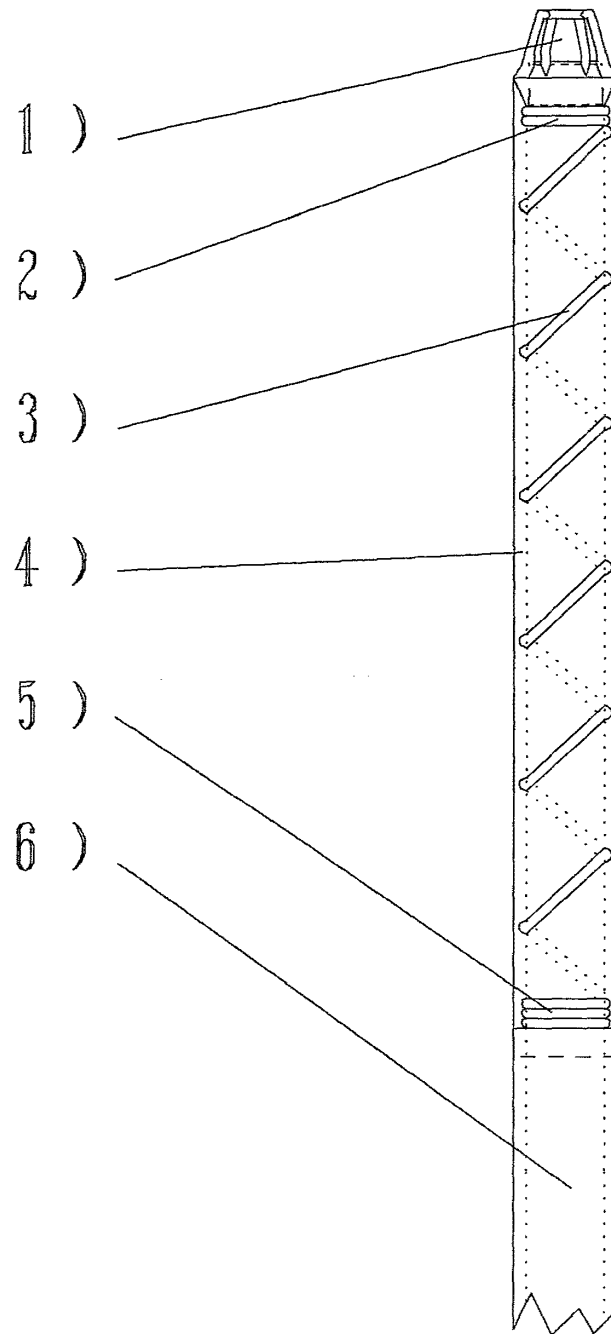
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Schutzansprüche

1. Biegedrahtanordnung bei Kanülen und Kathetern, dadurch gekennzeichnet, daß ein plastisch verformbarer Biegedraht spiralförmig um die Kanüle / den Katheter angeordnet ist.
2. Biegedrahtanordnung gemäß Anspruch 1., dadurch gekennzeichnet, daß mehrere plastisch verformbare Biegedrähte spiralförmig um die Kanüle / den Katheter angeordnet sind.
3. Biegedrahtanordnung gemäß Anspruch 1.+2., dadurch gekennzeichnet, daß der oder die Drähte mit vorzugsweise Kunststoff beschichtet sind.
4. Biegedrahtanordnung gemäß Anspruch 1.-3., dadurch gekennzeichnet, daß die Endbereiche des/der Drähte mit keiner oder geringer Steigung um die Kanüle / den Katheter gewickelt sind.

15.03.98

Beispielzeichnung



Intracardiac blood pump (10) has a drive portion (11) and a suction portion (12). The suction part (12) is connected a flexible hose (14) of the pump (10). For stretching of the hose (14) of the pump (10) from the right atrium (21) to the pulmonary artery (26) at the distal end of the hose (14) of the pump (10) is positioned a balloon (35) which acts in the bloodstream as a guide element and srháván is behind a stream of blood. This simplifies the positioning of the blood pump (10) in the heart.

PŘÍHLÁŠKA VYNÁLEZU

zveřejněná podle § 31 zákona č. 527/1990 Sb.

(19)
ČESKÁ
REPUBLIKA



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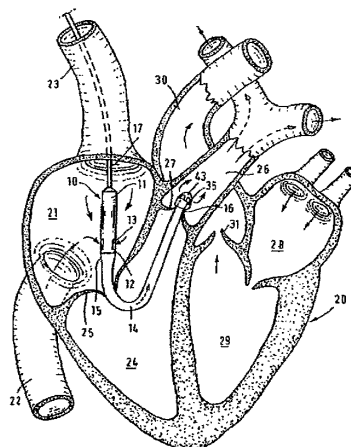
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Intrakardiální krevní čerpadlo

(57) Anotace:

Intrakardiální krevní čerpadlo (10) má hnací část (11) a nasávací část (12). K nasávací části (12) je připojena ohebná hadice (14) čerpadla (10). Pro protažení hadice (14) čerpadla (10) od pravé předsíně (21) k pulmonální arterii (26), je na distálním konci hadice (14) čerpadla (10) umístěn balonek (35), který působí v proudu krve jako vodící prvek a je srháván sebou proudem krve. Tím se zjednoduší polohování krevního čerpadla (10) v srdci.



CZ 2000 - 7 A3

Intrakardiální krevní čerpadlo

Oblast techniky

Vynález se týká intrakardiálního krevního čerpadle, a zejména pak krevního čerpadla, které se může zavádět přes sousedící cévy do srdce, aby se podpořila přirozená srdeční funkce nebo aby se tato nahradila kontinuálním provozem čerpadla.

Dosavadní stav techniky

Jedno z takovýchto čerpadel, sloužící pro podporu srdce je popsáno ve WO 94/09835 /Jervik/. Toto čerpací zařízení je opatřeno na sobě nezávislými čerpadly, které sestávají z části čerpadla a s ní na tuho spojené hnací části. Čerpací část jednoho z čerpadel se zavádí přes apekální operační otvor tak do levé komory, aby se přes levou komoru zavedla do aorty. Druhá část čerpadla se dalším, s výhodou apekálním otvorem, zavádí do pravé komory tak, aby se z pravé předsíně dopravila do pulmonální tepny. Čerpadla jsou na svém výstupu prodloužena hadicovou výstupní kanylou, která se může zavádět skrz stávající srdeční chlopeň.

Intrakardiální krevní čerpadlo, které se zavádí z aorty přes chlopeň aorty do levé předsíně, je známo z WO 97/37696 /Rau et al./. U tohoto je výstupní část čerpadla prodloužena hadicí, která prochází skrz chlopeň aorty.

Z WO 97/37697 /Rau et al./ je známo intrakardiální krevní čerpadlo, které se může zasouvat cévou. I tato krevní čerpadlo je na svém výstupním konci prodlou-

ženo sací hadicí. Tato sací hadice je opatřena nafouknutelným balonkem, který slouží jako uzavírací zařízení, aby se zabránilo toku krve bočně okolo sací hadice.

Konečně je z US patentu 4 753 221 /Kenney et al./ znám čerpací katetr, který má čerpadlo, která se dá umístit v srdci. Toto čerpadlo sestává z oběžného kola a tělesa čerpadla, které obklopuje oběžné kolo. Těleso čerpadla se může umístit do srdce ve ztlačeném stavu a potom rozvinout nafouknutím pomocí balonku, který je spojen s tělesem čerpadla.

Dále jsou pro diagnostické účely známé maloprůměrové katetry, sloužící pro zjišťování tlaku proudu a objemu proudu, které mají na distálním konci katetru nafouknutelný balon. Tento balon se pro umístění špičky katetru používá v pulmonální arterii.

U intrakardiálních krevních čerpadel, která se zavádí do srdce přes cévu, je obtížné umístit krevní čerpadlo v srdci přesně. Zejména, když se krevní čerpadlo zavádí skrz horní dutou žílu, aby se krev čerpala z pravé před síně do pulmonální arterie, je přesné umístění krevního čerpadla obtížné, neboť čerpadlo musí provést změnu směru okolo téměř 180°, aby nasávací otvor ležel v pravé přesíni a vypouštěcí otvor v pulmonální arterii. K tomu přistupuje ještě to, že v pravé předíni jsou četné vazivové nitky a svaly, které drží trojčípou chlopuň a zajišťují cípy chlopně vůči proražení a zajišťují tvarovou stálost srdce. Mezi takovými vazivovými nitkami a svaly se musí zavádět krevní čerpadlo, které se zavádí přes dutou žílu.

Vynález si klade za základní úlohu vytvořit intrakardiální čerpadlo, které se může relativně snadno umístit v srdci.

Podstata vynálezu

Řešení této úlohy se podle vynálezu provádí znaky uvedenými v patentovém nároku 1.

U krevního čerpadla podle vynálezu je na výtlak čerpadla nasazena ohebná hadice, jejíž distální konec nese balonek, působící v proudu krve jako vodící prvek. Vynález využívá tu okolnost, že přirozený proud krve v srdci vede od hlavní žíly do pravé předsíně skrz pravou komoru do pulmonální arterie. Krevní čerpadlo, které má na distálním konci hadici s balonkem, se zavádí podél této cesty, přičemž balonek, pohybující se krevním proudem najde automaticky svou cestu od pravé předsíně do pulmonální arterie. Výstupní část hadice se nakonec stabilizuje v pulmonální arterii, zatím co se čerpací část nachází v pravé předsíni. Hadice čerpadla se při tom ohne přibližně o 180°. Tímto způsobem se podaří umístit konečně hadici čerpadla přesně v srdci, aniž by se muselo provádět dotykové pokusné narážení výstupní části hadice na stěny srdeční komory, nebo aby byl nezbytný pomocný diagnostický prostředek / rentgen nebo ultrazvuk/.

Intrakardiálně zahrnuje ve smyslu předloženého vynálezu srdeční komory /ventrikuly/, předsíně a hraničící pahýly cév.

Je výhodné, když hadice čerpadla je v souladu se svou konečnou polohou, kterou zaujímá v srdci, předem ohnu-

ta. Toto vyžaduje ohyb minimálně o asi 150° . Hadici musí být sice pro zavádění skrz dutou žílu propůjčena schopnost se narovnat, ale ve stavu rozpínání by měla zaujmout tvar písmene U nebo písmene V. Obzvláště je výhodné, když hadice čerpadla má tuhost v ohybu, která se od proximálního konce k distálnímu konci zmenšuje. Tímto způsobem se distální konec může snadno pohybovat jako hledač cesty, takže balonek může lépe sledovat přirozené proudění krve.

Balonek nemusí být nutně umístěn přímo na hadici čerpadla. Může být upěvněn na katetru, který je součástí hadice čerpadla a může probíhat skrz tuto uvnitř nebo vně. V každém případě k balonku probíhat vnitřní průměr /světlost/, kterým se balonek může nafouknout. Dodatečně může být uspořádána druhá světlost, do které se zavádí vodící drát, pomocí něhož se posouvání hadice čerpadla dopředu skrz systém cév usnadní. Po odstranění vodícího drátu se tato druhá světlost může používat jako světlost pro tlakové čidlo.

Podle výhodné formy provedení je to uspořádáno tak, že balonek obklopuje hadici čerpadla jako prstěncový balonek. To má tu výhodu, že distální konec hadice má v důsledku balonku zvětšený vnější průměr, a tím může být pevně držen pulmonální chlopní. Tímto způsobem přispívá balonek k zakotvení konce hadice na pulmonální chlopní, zatím co se výstup hadice nachází v pulmonální arterii. Tím se zabrání tomu, aby výstupní část hadice vyklouzla z pulmonální arterie. Další předností je to, že prstěncový balonek tvoří zaoblený tupý konec hadice čerpadla, takže se hadicí

čerpádla nemůže způsobit žádné poranění stěn cév a srdce nebo jiných částí srdce. Konečně se také zabrání tomu aby se konec hadice zasekl o okraj chlopně nebo sva-
lech v srdci.

Vzhledem k tomu, že se část krve čerpádla napumpuje do hadice čerpádla, udržuje se hadice čerpádla samočin-
ně otevřená. Jako hadice čerpádla se proto může použít kolabující hadice, například fóliová hadice, jejíž stě-
na není tvarově stálá. Skrz tuto hadici může probíhat katetr k balonku uspořádaném na distálním konci.

U intrakardiálního krevního čerpádla s ohebnou ha-
dicí čerpádla existuje nebezpečí, že krev vytékající z
výstupní části hadice vyvolává na hadici zpětný náraz,
který může mít za následek zpětné posunutí hadice. Tím-
to způsobem se může stát, že hadice vyklouzne z pulmo-
nální chlopně. Vynález si proto klade za další základní
úlohu vytvořit intrakardiální krevní čerpadlo, u kte-
rého by se zabránilo posunutí hadice v důsledku hydrau-
lických reakčních sil.

Řešení této úlohy se provádí podle vynálezu znaky
patentového nároku 13. Podle toho je na distálním konci
hadice upevněn tažný prvek, který je naplavován čerpa-
ným proudem. U tohoto tažného prvku se může jednat o
plachtu nebo o balonek. Proud krve, vystupující z konce
hadice, naráží proti tažnému prvku, čímž vzniká síla
směřující dopředu, působící proti vratné síle hadice.
Tímto způsobem slouží tažný prvek ke stabilizaci poloho-
vání hadice čerpádla.

Přehled obrázků na výkresech

Dále jsou s odkazem na výkresy níže vysvětleny příklady provedení vynálezu

Obr. ukazují:

Obr. 1 průřez znázorněním srdce s krevním čerpadlem umístěným v srdci,

obr. 2 znázornění krevního čerpadla z obr. 1,

obr. 3 řez podrobností III z obr. 2,

obr. 4 druhý příklad provedení krevního čerpadla,

obr. 5 třetí příklad provedení a

obr. 6 znázornění katetru z příkladu provedení podle obr. 5 ve zvětšeném měřítku.

Příklady provedení vynálezu

Podle obr. 1 je krevní čerpadlo 10 intravazální krevní čerpadlo, tedy krevní čerpadlo, které se může zasouvat systémem krevních cév pacienta, tak aby proniklo až dovnitř srdce. Vnější průměr takového krevního čerpadla není na žádném místě větší než 8 mm. Čerpadlo 10 má hnací část 11 a s ní na tuho spojenou čerpací část 12. Čerpadlo 10 odpovídá například čerpadlům z WO 97/37696, takže jeho vnitřní stavba zde není blíže vysvětlena. V přechodové oblasti mezi hnací částí 11 a čerpací částí 12 se nacházejí sací otvory 13, jimiž je krev nasávána radiálně zvenčí dovnitř. Čerpací část 12 obsahuje / neznázorněné/ oběžné kolo, které pohání krev v axiálním směru. Na výstupní části 12 čerpadla je připojena hadice 14 čerpadla. Tato má proximální konec 15, spojený s výstupem čerpadla 10 a distální konec 16 tvořící výstupní část hadice 14.

Proximální konec čerpadla 10 je spojen s katetrem 17, který také obsahuje elektrická zásobovací vedení pro hnací část 11. Dále má katetr 17 světlost, která se může připojit ke zdroji tlakového vzduchu.

Hadice 14 čerpadla 10 a katetr 17 jsou ohebné. Rigidní délka čerpadla 10 není větší než 35 mm, aby čerpadlo 10 prošlo zakřiveními systému krevních cév. Délka hadice 14 čerpadla 10 je při nejmenším dvakrát tak velká jako rigidní délka čerpadla 10. Hadice 14 čerpadla 10 má délku asi 12 cm a vnější průměr asi 8 mm. Tloušťka její stěny je 0,05 mm až 0,2 mm. Poloměr zakřivení ohybu hadice 14 je 40 mm až 60 mm.

Na obr. 1 je znázorněn průřez srdcem 20. Do pravé přesíně 21 ústí dolní dutá žíla 21 a horní dutá žíla 23. Mezi pravou přesíní 21 a pravou komorou 24 se nachází trojcípá chlopeč 25. Mezi pravou komorou 24 a pulmonální arterií 26 se nachází pulmonální chlopeč 27. Od pulmonální arterie 26 teče krev k plicím a odtud zpět do levé přesíně 28 a k levé komoře 29. Mezi levou komorou 29 a aortou 30 se nachází aortální chlopeč 31.

Čerpadlo 10 se jako čerpadlo pravého srdce umístí tak, že dopravováno od pravé přesíně 21 do pulmonální arterie 26. Za tím účelem je u znázorněné formy provedení prostrčeno horní dutou žílou 23. Bylo by také možné, provést zavedení dolní dutou žílou 22. Během zavádění čerpadla 10 je hadice 14 čerpadla 10 umístěna před čerpadlem 10, to znamená, že leží ve směru proudu krve obklopující čerpadlo 10 po proudu směrem od čerpadla 10.

Na distálním konci 16 hadice 14 čerpadla 10 se nachází balonek 35, který je zde podle obr. 2 a obr. 3

vytvořen jako prstěncový balonek. Balonek 35, nafouknutý plynem /například vzduchem, heliem, CO_2 /

nebo kapalinou má vnější průměr větší než hadice 14 čerpadla 10. Následně tvoří balonek 35 vodící prvek, na kterém působí přirozený proud krve, a táhne se sebou vodící prvek. Tím se balonek 35 oplachuje nejdříve do pravé komory 24 a potom do pulmonální arterie 26.

Balonek 35 se nafukuje tím, že se v průměr vnitřního tlakového kanálku 36 je přes otvory 37 spojen s vnitřkem prstěncového balonku 35. V hadici 14 čerpadla 10 teče krev vnitřním kanálkem 38 pro krev, jehož průřez je podstatně větší než průměr vnitřního tlakového kanálku 36. Vnitřní tlakový kanálek 36 je připojen k odpovídajícímu vnitřnímu tlakovému kanálku proximálního katetru 17, takže se jeho tlak může řídit mimotělně.

Hadice 14 čerpadla 10 je na obr. 2 znázorněna v rozepnutém stavu. Hadice 14 čerpadla 10 je ohnuta do tvaru písmene U nebo do tvaru písmene V, to znamená, že má tvarovou paměť, takže není v srdci vystavena žádnému podstatnému nucení a sama o sobě také nevyvolává žádné podstatné nucení na srdce. Na obr. 2 ukazuje začernění puntíkové oblasti tuhost hadice 14 čerpadla 10. Na proximálním konci 15 je tato tuhost velmi velká a směrem k distálnímu konci 16 se potom stále snižuje. To znamená, že distální konec 16, na které se nachází balonek 35, se může pomocí balonku 35 volně pohybovat a být vedena.

Jak vyplývá z obr. 3, přečnívá balonek 35 na distálním konci přes konec 39 hadice 14 čerpadla 10, takže balonek 35 tvoří zaoblený konec 40 hadice 14, který nevytváří nebezpečí zaháknutí na překážkách. Na proximálním konci balonku 35 tvoří tento prsténkové podříznutí 41, do kterého mohou vniknout cípy pulmonální chlopně 27, takže pulmonální chlopeň 27 zabráňuje zpětnému couvnutí konce hadice.

Jak je znázorněno na obr. 2 a 3, napíná se přes výstupní část 42 hadice 14 tažný prvek 43 ve formě kopulovité plachty. Tento tažný prvek 43 sestává z tenké ohebné kůže, která je upevněna můstky 44 na balonku 35. Krev, vytékající z výstupní části 42 hadice 14 proudí proti tažnému prvku 43 a působí tedy na hadici 14 čerpadla tahem, který kladé odpor proti zpětnému nárazu. Tím se zabrání tomu, aby distální konec 16 hadice 14 čerpadla 10 se v důsledku hydraulického zpětného nárazu posunul a eventuálně aby vyklouzl z pulmonální chlopně 27.

Hadice 14 čerpadla 10 sestává s výhodou z polyurethanu, který se projevil jako obzvláště výhodný.

U příkladu provedení podle obr. 4 je k čerpadlu 10 připojena hadice 14a, která obsahuje pružnou opěrnou strukturu 45 ve formě šroubovice z karbonu nebo kovu. Tato opěrná struktura 45 udržuje hadici 14a čerpadla otevřenou a působí požadovanou tuhost a ohybu, která se rovněž může měnit pomocí délky hadice 14a. Hadicí 14a čerpadla probíhá katetr 46, která má na distálním konci balonek 35a. Tento balonek 35a tvoří

vodící prvek pro hadici 14a čerpadla. Katetr 46 obsahuje vnitřní tlakový kanálek. Jeho vnější průměr je podstatně menší než průměr hadice 14a čerpadla, takže v hadici 14a čerpadla je k dispozici dostatečně velký průřez pro tok krve. Katetr 46 je spojen s katetrem 17.

Jako tažný prvek 43a je uspořádána koule umístěná v odstupu za výstupem 42 hadice 14a a je upevněna na katetru 46. Proud krve tlačící proti tažnému prvku 43a zabraňuje zpětnému couvnutí distálního konce 16 hadice 14a k čerpadlu 10. Hadice 14a čerpadla 10 je zakotvena pomocí přídržného zařízení 47 na tažném prvku 43a.

U příkladu provedení podle obr. 5 a 6 je hadice 14b čerpadla 10 smrštitelná hadice 14b čerpadla 10, která je z tenkého fóliového materiálu, který nemá žádnou vlastní tvarovou stálost. Hadicí 14b čerpadla 10 probíhá katetr 48, který nese na svém distálním konci balonek 35a. Tento katetr 48 je spojen s katetrem 17. Distální konec 16 hadice 14b čerpadla 10 je spojena s katetrem 48 a hadice 14b čerpadla 10 má výstupní otvory 49 pro výstup krve. Při zavádění čerpadla 10 podle obr. 5 není čerpadlo 10 v provozu, takže hadice 14b čerpadla 10 je smrštěná. Pomocí balonku 35a se zavede měkký a ohebný katetr 48 do srdce, přičemž tento je polohován v hadici 14b čerpadla 10. Jestliže se potom čerpadlo 10 uvede do provozu, tak se hadice 14b čerpadla 10 rozšíří.

Pro usnadnění polohování může katetr 36, 48 podle obr. 6 mít kromě vnitřního tlakového kanálku 49, vedoucího k balonku 35a, mít další vnitřní kanálek 50, který

je určen pro pojmnutí vodícího drátu 51 a po odstranění vodícího drátu 51 je určen pro externí měření tlaku. Tento vodící drát 51, který vede také katetrem 17 a čerpadlem 10, umožňuje operujícímu lékaři, aby ovlivnil řízeně položení hadice 14b čerpadla 10. Potom se vodící drát 51 vytáhne.

Podle obr. 6 může být na kateru 48 vytvořen otvor 52, který je spojen s vnitřním kanálkem 50 a je uzavřen vodícím drátem 51. Poté co se vodící drát 51 vytáhne z vnitřního kanálku 50, vniká otvorem 52 krev do vnitřního kanálku 50. Vnitřní kanálek 50 může být spojen s tlakovým čidlem pro měření tlaku krve, aby se takto mohl krevní tlak měřit během čerpání v pulmonální arterii a popřípadě se mohl ovlivnit.

Jestliže se polohování hadice 14b čerpadla 10 provádí bez vodícího drátu 51, tak se může pomocí měřitelných průběhů tlaku v dalším vnitřním kanálku 50 měřit tlak na místě 52. Z průběhů tlaku se může zjistit přesná poloha distální špičky hadice 14b čerpadla 10.

Průměr balonku nesmí být tak velký, aby podstatně bránil průtoku pulmonální arterií 26 nebo dokonce pulmonální arterii 26 uzavřel. Zpravidla nesmí být jeho průměr větší než 30 mm. Dále by balonek měl být vysoce pružný, na rozdíl od dilatačního balonku. Jako materiál balonku se proto z důvodů pružných vlastností hodí silikon, latek, a s výhodou polyurethan.

Balonek se může, zatím co tento plave jako vodící prvek pro hadici katetru v proudu krve, být nafukován velkým tlakem a konečně zmenšen pomocí snížení tlaku, aby působil jako tažný prvek, který je naplávován proudem z čerpadla.

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P A T E N T O V É N Á R O K Y

1. Intrakardiální krevní čerpadlo s radiálně nasávající a axiálně dopravující částí /11/ čerpadla /10/, která je spojena s katetrem /17/, a ohebnou hadicí /14/ čerpadla /10/ spojenou s s výstupem čerpadla /10/, která má proximální konec /15/ hraničící s výstupem čerpadla /10/ a distální konec /16/, tvořící výstupní část hadice /14/, v y z n a č u j í c í s e t í m , že hadice /14/ čerpadla /10/ má blízko svého distálního konce /16/ balonek /35/, strhávaný proudem krve a působící jako vodící prvek.

2. Krevní čerpadlo podle nároku 1, v y z n a č u j í c í s e t í m , že hadice /14/ čerpadla /10/ je předem ohnuta o více než 100° , s výhodou asi o 150° ,

3. Krevní čerpadlo podle nároku 1 nebo 2, v y z n a č u j í c í s e t í m , že hadice /14/ čerpadla /10/ má pevnost v ohybu, která se ve směru od proximálního konce /15/ k distálnímu konci /16/ snižuje.

4. Krevní čerpadlo podle jednoho z nároků 1 až 3, v y z n a č u j í c í s e t í m , že hadice /14/ čerpadla /10/ má uvnitř nebo vně katetr /46,48/, který přečnívá přes distální konec /16/ hadice /14/ čerpadla /10/ a na straně distálního konce /16/ nese balonek /35a/.

5. Krevní čerpadlo podle jednoho z nároků 1 až 3, v y z n a č u j í c í s e t í m , že balonek /35/