

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Abiomed, Inc., Abiomed R&D, Inc., and Abiomed Europe GmbH
Petitioners

v.

Maquet Cardiovascular, LLC
Patent Owner

Case IPR2017-02151
U.S. Patent No. 9,327,068

PATENT OWNER'S EXHIBIT 2001

MAQUET
GETINGE GROUP

VIA OVERNIGHT COURIER AND EMAIL

December 15, 2015

Mr. Michael R. Minogue
Chief Executive Officer, President and Chairman
Abiomed, Inc.
22 Cherry Hill Drive
Danvers, Massachusetts 01923

Re: Maquet Cardiovascular LLC Patent Portfolio and Abiomed's Impella
Circulatory Support Systems

Dear Mr. Minogue:

Abiomed, Inc. ("Abiomed") is marketing and selling intravascular blood pumps that are known as the Impella 2.5, Impella 5.0, Impella CP, and Impella RP Circulatory Support Systems. We are writing to you because Maquet Cardiovascular LLC, a subsidiary of the Getinge Group, owns a collection of patents and pending patent applications in the United States and elsewhere that describe and claim intravascular blood pumps, and methods of using such pumps, with features such as guiding mechanisms, catheters, purge fluid lines and cannulas that we have seen in the Abiomed Impella products. Maquet proposes to discuss with Abiomed terms of a license or other agreement concerning these patents.

Maquet has retained Alston & Bird, LLP as outside counsel for the purpose of protecting Maquet's interests in its patents, and other intellectual property rights, against infringement by Abiomed.

The Maquet patent portfolio in the United States includes the following patents and applications, among others:

- U.S. Patent No. 7,022,100 ("the '100 Patent"), which issued on April 4, 2006;
- U.S. Patent No. 8,888,728 ("the '728 Patent"), which was issued on November 18, 2014; and
- Pending U.S. Patent Application No. 14/543,815 ("the '815 Application"), for which a Notice of Allowance was issued on October 5, 2015.

Maquet also owns patent applications in other jurisdictions such as Japan and Europe, including in particular Germany. The subject matter of these applications is similar to that of the U.S. patents. Copies of these U.S. and foreign patents and patent application are enclosed.

Maquet
45 Barbour Pond Dr.
Wayne, NJ 07470
Phone: 973 709 7271

Maquet's patents and pending applications have early priority claims that stem from a provisional application dated September 3, 1999 and a PCT application that was filed on September 1, 2000. The claims of these patents are entitled to broad coverage in view of the claim language and patent disclosures, and because the ventricular assist device industry was still in its infancy as of the priority dates. Enclosed for your convenience are preliminary claim charts for certain illustrative claims of the '100 patent, the '728 patent and the '815 application that compare the patent claims to the Impella product features. See Appendices A-C. As noted, these charts are illustrative only. Other claims, including dependent claims, are also infringed.

We have reviewed public information, including publications, about Abiomed's product development and are aware that the Impella products and features in the products (such as the "pigtail" a/k/a EasyGuide lumen) were reduced to practice well after the priority dates of the Maquet patents and applications. We do not believe that Abiomed could show earlier activity in the United States (or elsewhere) that would affect the validity of the Maquet patents.

We know that Abiomed has been aware of at least Maquet's '100 patent for some time because this patent was cited in patent applications prosecuted by Abiomed. Abiomed has continued its commercialization of its Impella products notwithstanding its knowledge of the Maquet patents and is therefore subject to liability for treble damages for willful infringement, and in the event of an infringement suit, to a determination of exceptional case, with attendant liability for Maquet's attorney's fees and costs.

Obviously, the United States is an important market for ventricular assist devices. In addition, we understand that Abiomed is making and selling its Impella products in Germany, and that Abiomed has recently announced its intention of entering the Japanese market with these products. Maquet's patents and applications provide Maquet, as the patent owner, with the exclusive rights to the subject devices in all of these jurisdictions.

We understand that Abiomed's marketing efforts have targeted Maquet's products as competing devices. Maquet has not been required to mark the patent information on its products because they are different from the patent claims. Thus, in the event of an infringement dispute Maquet could seek lost profits damages for up to the past six years, plus injunctive relief requiring Abiomed to stop making, using, offering for sale, selling or importing its Impella products for the remaining patent term.

A preliminary draft of a complaint for patent infringement is attached. Notwithstanding the foregoing facts, Maquet is willing to discuss entering into an agreement with Abiomed for a license to some or all of the Maquet patent portfolio. Please consider this letter as an invitation to discuss reasonable terms of a

business arrangement that we hope would be attractive to both Maquet and Abiomed. We kindly request a phone conference to discuss by January 13, 2016. Please confirm the receipt of this letter by Dec. 18.

Sincerely,



Ajey Atre
Managing Director,
Maquet Cardiovascular LLC

Enclosures:

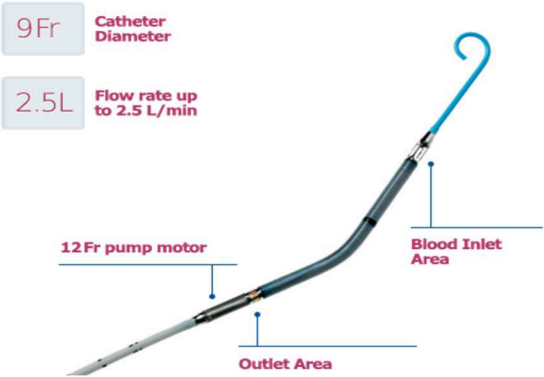
Appendices A-C (claim charts)
Draft Complaint
U.S. Patent No. 7,022,100
U.S. Patent No. 8,888,728
Allowed claims of U.S. Patent Application No. 14/543,815
EP 1207934B1
JP 4159781

APPENDIX A

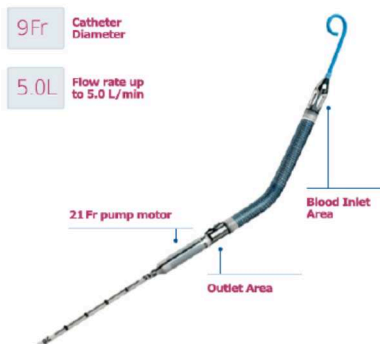
Claim Chart – U.S. Patent No. 7,022,100

Appendix A

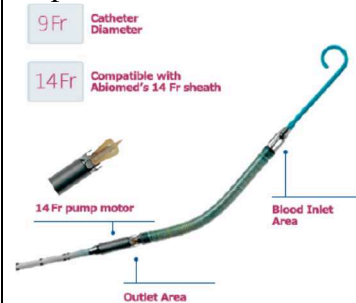
U.S. Patent No. 7,022,100

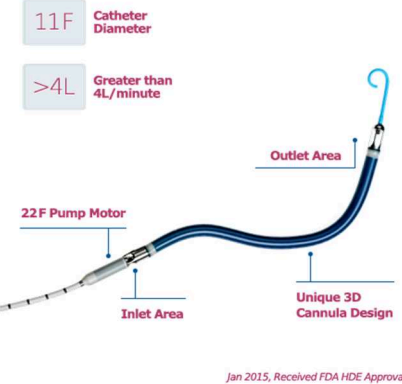
Claims	Infringement Analysis
16. An intravascular blood pump system comprising:	The Impella 2.5, Impella 5.0, Impella CP, and Impella RP are intravascular blood pumps.
an intravascular blood pump having a cannula coupled thereto,	<p>The above-identified Impella products include a cannula coupled to the blood pump.</p> <p><u>Impella 2.5</u></p> 

Impella 5.0



Impella CP



	<p>Impella RP</p>  <p>11F Catheter Diameter</p> <p>>4L Greater than 4L/minute</p> <p>22F Pump Motor</p> <p>Inlet Area</p> <p>Outlet Area</p> <p>Unique 3D Cannula Design</p> <p>Jan 2015, Received FDA HDE Approval</p>				
<p>a guide mechanism adapted to guide said intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient, and</p>	<p>The above-identified Impella blood pumps utilize a guide mechanism.</p> <p>Impella 2.5:</p> <table border="1"> <tr> <td>Pigtail</td><td>The 6 Fr pigtail is attached to the cannula at the distal end of the inlet area. It assists with stabilizing the catheter in the correct position in the left ventricle.</td></tr> <tr> <td>EasyGuide lumen</td><td>The red loading lumen, which runs from the tip of the pigtail through the outlet area of the cannula, facilitates loading the catheter onto the guidewire</td></tr> </table> <p>Impella 2.5 Manual, p. 3.4; <i>see also</i> Impella 5.0 Manual, p. 3.3 (containing the same disclosure); Impella CP Manual, p. 3.4 (containing the same), Impella RP Manual, p. 3.3 (containing the same).</p>	Pigtail	The 6 Fr pigtail is attached to the cannula at the distal end of the inlet area. It assists with stabilizing the catheter in the correct position in the left ventricle.	EasyGuide lumen	The red loading lumen, which runs from the tip of the pigtail through the outlet area of the cannula, facilitates loading the catheter onto the guidewire
Pigtail	The 6 Fr pigtail is attached to the cannula at the distal end of the inlet area. It assists with stabilizing the catheter in the correct position in the left ventricle.				
EasyGuide lumen	The red loading lumen, which runs from the tip of the pigtail through the outlet area of the cannula, facilitates loading the catheter onto the guidewire				

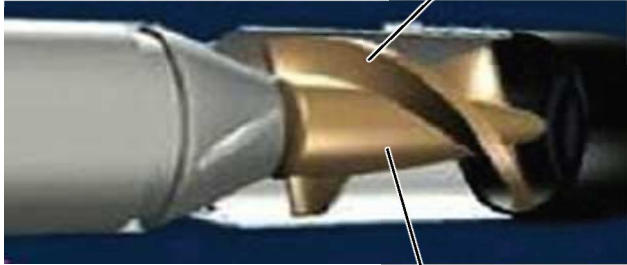
<p>a blood pressure detection mechanism to detect the pressure of the blood proximate at least one of the intravascular blood pump and cannula.</p>	<p>The above-identified Impella blood pumps include a blood pressure detection mechanism.</p> <p><u>Impella 2.5</u> “A 9 Fr catheter shaft is located between the motor housing and the red Impella® plug. The lumen of the catheter shaft contains a purge lumen, <i>a pressure measurement lumen</i>...and an electrical cable.” Impella 2.5 Manual, p. 3.5.</p> <p><u>Impella 5.0</u> “The Impella 5.0 has an electronic <i>differential pressure sensor</i> located at the proximal end of the 21 FR cannula.” Impella 5.0 Manual, p. 3.4.</p> <p><u>Impella CP</u> “The Impella® Catheter uses <i>a fluid-filled pressure lumen</i> with an inlet at the proximal end of the motor housing and the pressure sensor located in the red Impella® plug.” Impella CP Manual, p. 3.5.</p> <p><u>Impella RP</u> “The Impella RP Catheter has an electronic <i>differential pressure sensor</i> located at the proximal end of the cannula.” Impella RP Manual, p. 3.4</p>
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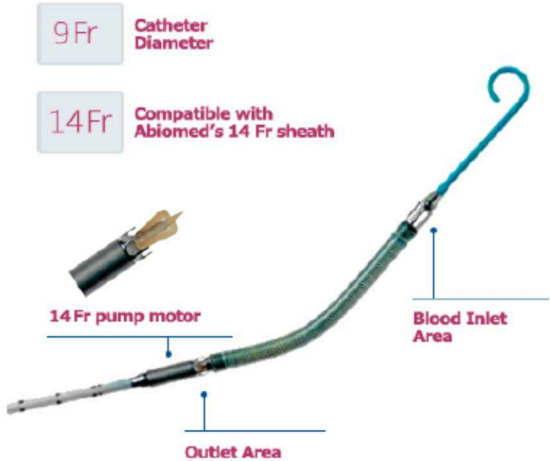
APPENDIX B

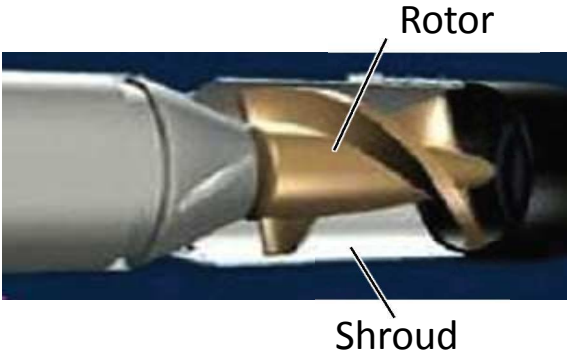
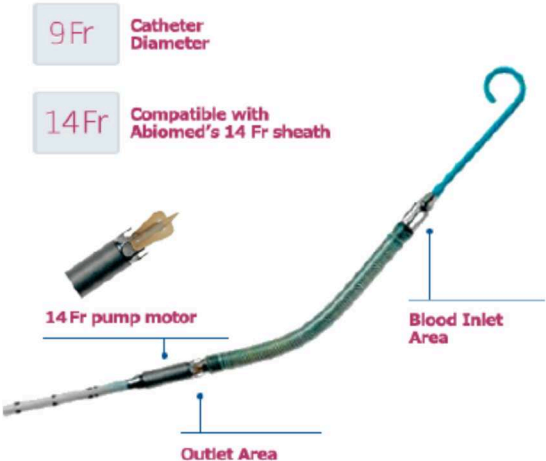
Claim Chart – U.S. Patent No. 8,888,728

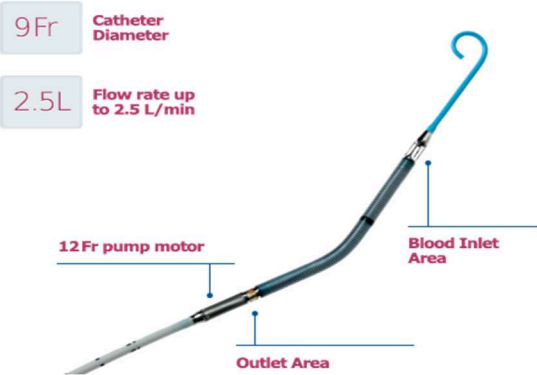
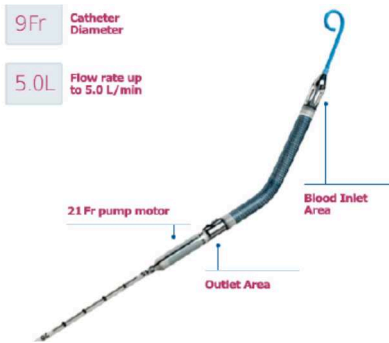
Appendix B

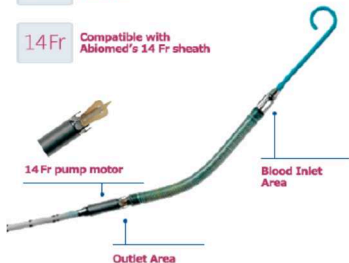
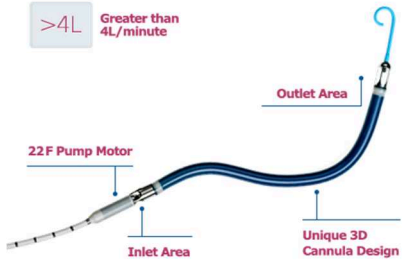
U.S. Patent No. 8,888,728

Claims	Infringement Analysis
1. An intravascular blood pump system, comprising: an intravascular blood pump comprising:	The Impella 2.5, Impella 5.0, Impella CP, and Impella RP are intravascular blood pumps.
(1a) a rotor having a rotor hub tapering in the distal direction, at least one blade extending radially outward from the rotor hub, the hub has a distal end extending distally beyond the most distal portion of the blade and	<p>The above-identified Impella blood pumps have a rotor that meets these limitations.</p> <p><u>Impella 2.5/5.0/RP</u></p> <p>Distal Direction →</p>  <p>Rotor Blade</p> <p>Rotor Hub</p>

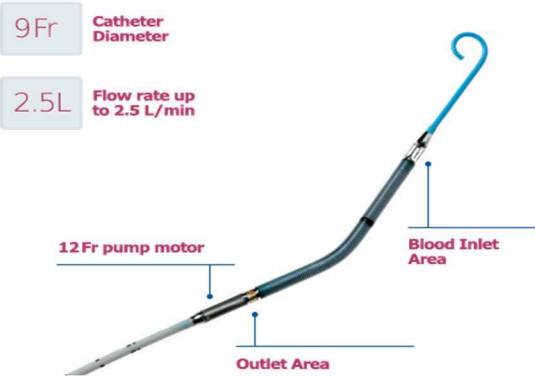
Claims	Infringement Analysis
	<p><u>Impella CP.</u></p>  <p>9 Fr Catheter Diameter</p> <p>14 Fr Compatible with Abiomed's 14 Fr sheath</p> <p>14 Fr pump motor</p> <p>Blood Inlet Area</p> <p>Outlet Area</p>
(1b) a shroud within which the rotor is rotatably disposed;	The above-identified Impella blood pumps have a rotor within a shroud.


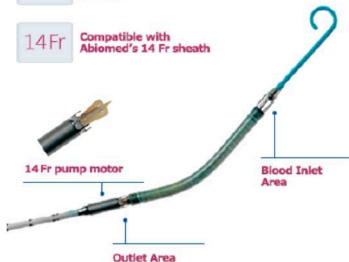
Claims	Infringement Analysis
	<p data-bbox="573 321 814 350"><u>Impella 2.5/5.0/RP</u></p>  <p data-bbox="573 776 726 805"><u>Impella CP.</u></p> 

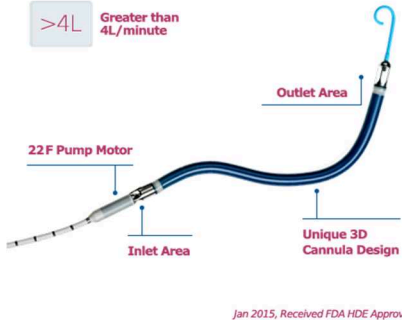
Claims	Infringement Analysis
<p>(1c) a cannula extending from the shroud and comprising an outer cannula surface, the outer cannula surface having a substantially circular cross-section along a portion of its length;</p>	<p>The above-identified Impella blood pumps include a cannula extending from a shroud as claimed.</p> <p><u>Impella 2.5</u></p>  <p><u>Impella 5.0</u></p> 

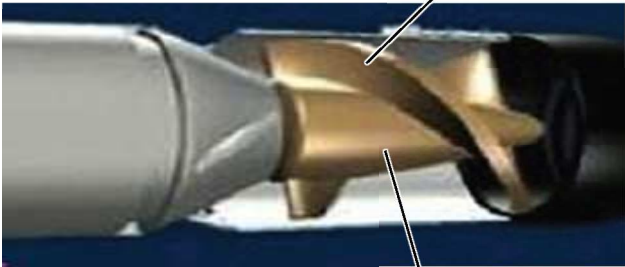
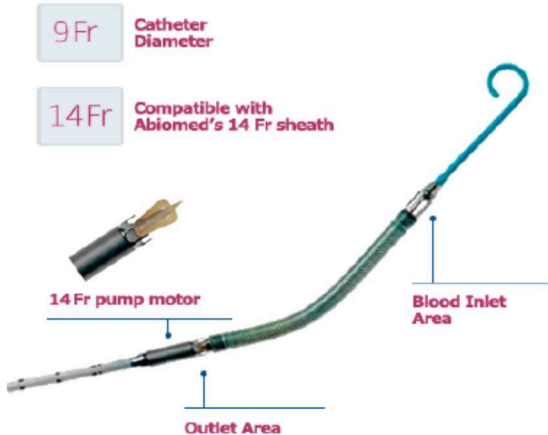
Claims	Infringement Analysis
	<p><u>Impella CP</u></p> <p>9Fr Catheter Diameter</p> <p>14Fr Compatible with Abiomed's 14 Fr sheath</p>  <p>14 Fr pump motor</p> <p>Blood Inlet Area</p> <p>Outlet Area</p> <p><u>Impella RP</u></p> <p>11F Catheter Diameter</p> <p>>4L Greater than 4L/minute</p>  <p>22F Pump Motor</p> <p>Inlet Area</p> <p>Outlet Area</p> <p>Unique 3D Cannula Design</p> <p><small>Jan 2015, Received FDA HDE Approval</small></p> <p>See also Impella 2.5 Manual, p. 3.4; Impella 5.0 Manual, p. 3.3; Impella CP Manual, p. 3.4; Impella RP Manual, p. 3.3.</p>

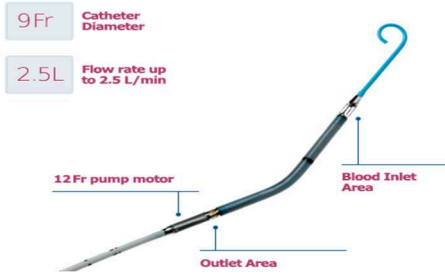
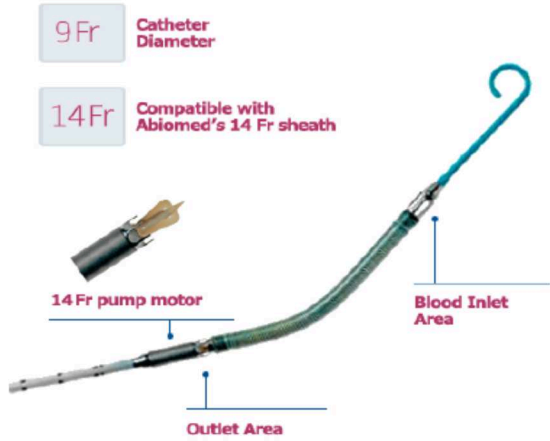
Claims	Infringement Analysis				
(1d) a first lumen in fluid communication with the intravascular blood pump and operatively arranged to deliver purge fluid to the intravascular blood pump; and	<p>The above-identified Impella blood pumps include a lumen containing a pump purge fluid.</p> <p><u>Impella 2.5</u></p> <table border="0"> <tr> <td data-bbox="569 418 884 764"><u>Catheter shaft</u></td><td data-bbox="884 418 1751 764"> <p>A 9 Fr catheter shaft is located between the motor housing and the red Impella® plug. The lumen of the catheter shaft contains a purge lumen, a pressure measurement lumen, a nitinol wire, and an electrical cable.</p> <p>The catheter shaft has longitudinal and transversal marks:</p> <ul style="list-style-type: none"> • The longitudinal mark along the inner radius shows correct position of the 0.018 inch, 260 cm placement guidewire once backloaded on the Impella® Catheter. • The transversal marks at 1 cm intervals with numbers every 5 cm aid in proper positioning. </td></tr> </table> <p>Impella 2.5 Manual, p. 3.4; <i>see also</i> Impella 5.0 Manual (stating the same), p. 3.3; Impella CP Manual, p. 3.4 (stating the same); Impella RP Manual, p. 3.3 (stating the same).</p>	<u>Catheter shaft</u>	<p>A 9 Fr catheter shaft is located between the motor housing and the red Impella® plug. The lumen of the catheter shaft contains a purge lumen, a pressure measurement lumen, a nitinol wire, and an electrical cable.</p> <p>The catheter shaft has longitudinal and transversal marks:</p> <ul style="list-style-type: none"> • The longitudinal mark along the inner radius shows correct position of the 0.018 inch, 260 cm placement guidewire once backloaded on the Impella® Catheter. • The transversal marks at 1 cm intervals with numbers every 5 cm aid in proper positioning. 		
<u>Catheter shaft</u>	<p>A 9 Fr catheter shaft is located between the motor housing and the red Impella® plug. The lumen of the catheter shaft contains a purge lumen, a pressure measurement lumen, a nitinol wire, and an electrical cable.</p> <p>The catheter shaft has longitudinal and transversal marks:</p> <ul style="list-style-type: none"> • The longitudinal mark along the inner radius shows correct position of the 0.018 inch, 260 cm placement guidewire once backloaded on the Impella® Catheter. • The transversal marks at 1 cm intervals with numbers every 5 cm aid in proper positioning. 				
(1e) 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	<p>The above-identified Impella blood pumps utilize a guide mechanism.</p> <p><u>Impella 2.5:</u></p> <table border="0"> <tr> <td data-bbox="569 1052 884 1166"><u>Pigtail</u></td><td data-bbox="884 1052 1709 1166"> <p>The 6 Fr pigtail is attached to the cannula at the distal end of the inlet area. It assists with stabilizing the catheter in the correct position in the left ventricle.</p> </td></tr> <tr> <td data-bbox="569 1166 884 1279"><u>EasyGuide lumen</u></td><td data-bbox="884 1166 1709 1279"> <p>The red loading lumen, which runs from the tip of the pigtail through the outlet area of the cannula, facilitates loading the catheter onto the guidewire</p> </td></tr> </table>	<u>Pigtail</u>	<p>The 6 Fr pigtail is attached to the cannula at the distal end of the inlet area. It assists with stabilizing the catheter in the correct position in the left ventricle.</p>	<u>EasyGuide lumen</u>	<p>The red loading lumen, which runs from the tip of the pigtail through the outlet area of the cannula, facilitates loading the catheter onto the guidewire</p>
<u>Pigtail</u>	<p>The 6 Fr pigtail is attached to the cannula at the distal end of the inlet area. It assists with stabilizing the catheter in the correct position in the left ventricle.</p>				
<u>EasyGuide lumen</u>	<p>The red loading lumen, which runs from the tip of the pigtail through the outlet area of the cannula, facilitates loading the catheter onto the guidewire</p>				

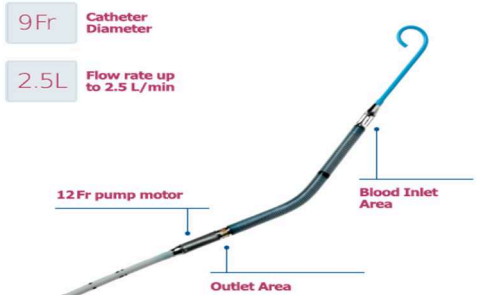
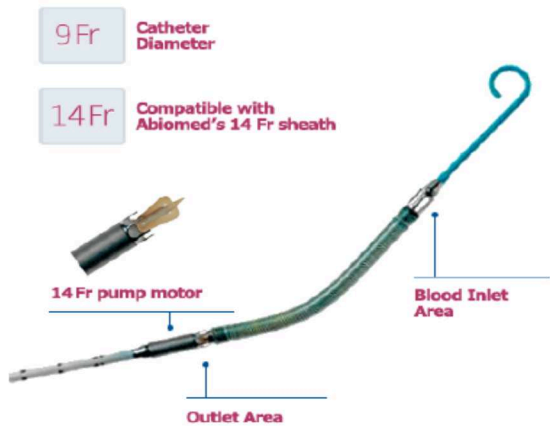
Claims	Infringement Analysis
within the circulatory system of a patient;	Impella 2.5 Manual, p. 3.4; <i>see also</i> Impella 5.0 Manual, p. 3.3 (containing the same disclosure); Impella CP Manual, p. 3.4 (containing the same), Impella RP Manual, p. 3.3 (containing the same).
(1f) wherein an axis coaxial 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.	<p>The above-identified Impella blood pumps meet this limitation.</p> <p><u>Impella 2.5</u></p> 

Claims	Infringement Analysis
	<p><u>Impella 5.0</u></p>  <p>9Fr Catheter Diameter</p> <p>5.0L Flow rate up to 5.0 L/min</p> <p>21 Fr pump motor</p> <p>Blood Inlet Area</p> <p>Outlet Area</p> <p><u>Impella CP</u></p>  <p>9Fr Catheter Diameter</p> <p>14Fr Compatible with Abiomed's 14 Fr sheath</p> <p>14 Fr pump motor</p> <p>Blood Inlet Area</p> <p>Outlet Area</p>

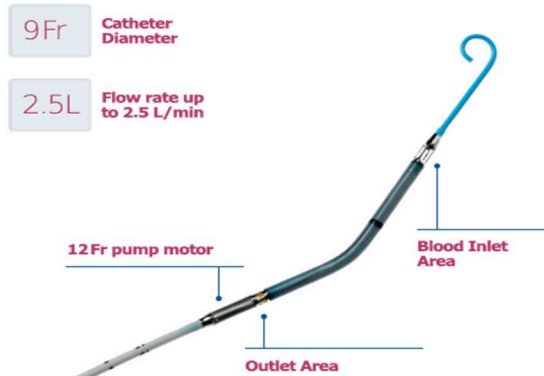
Claims	Infringement Analysis
	<p>Impella RP</p>  <p>See also, Impella 2.5 Manual, p. 513; Impella 5.0 Manual, pp. 5.14-5.15; Impella CP Manual, p. 5.13; Impella RP Manual, pp. 5.10-5.11.</p>
10. An intravascular blood pump system comprising:	The Impella 2.5 and Impella CP are intravascular blood pumps.
(10a) 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 above-identified Impella blood pumps have a rotor that meets these limitations.

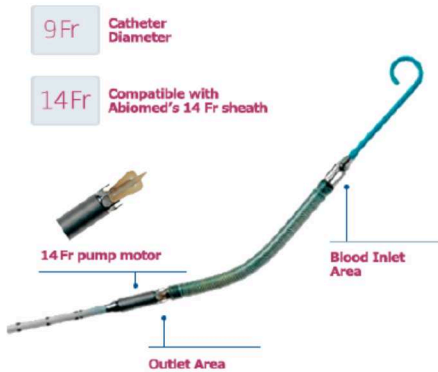
Claims	Infringement Analysis
	<p><u>Impella 2.5</u></p> <p>Distal Direction →</p>  <p>Rotor Blade</p> <p>Rotor Hub</p> <p><u>Impella CP.</u></p>  <p>9 Fr Catheter Diameter</p> <p>14 Fr Compatible with Abiomed's 14 Fr sheath</p> <p>14 Fr pump motor</p> <p>Blood Inlet Area</p> <p>Outlet Area</p>

Claims	Infringement Analysis
<p>(10b) the intravascular blood pump coupled to a catheter on a proximal end and a cannula on a distal end;</p>	<p>The above-identified Impella blood pumps meet this limitation.</p> <p><u>Impella 2.5</u></p>  <p><u>Impella CP.</u></p> 

Claims	Infringement Analysis
<p>(10c) 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;</p>	<p>The above-identified Impella blood pumps meet this limitation.</p> <p><u>Impella 2.5</u></p>  <p><u>Impella CP.</u></p> 

Claims	Infringement Analysis				
(10d) 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	<p>The above-identified Impella blood pumps utilize a guide mechanism.</p> <p><u>Impella 2.5:</u></p> <table border="1" data-bbox="573 423 1728 646"> <tr> <td data-bbox="573 423 877 532">Pigtail</td><td data-bbox="877 423 1728 532">The 6 Fr pigtail is attached to the cannula at the distal end of the inlet area. It assists with stabilizing the catheter in the correct position in the left ventricle.</td></tr> <tr> <td data-bbox="573 532 877 646">EasyGuide lumen</td><td data-bbox="877 532 1728 646">The red loading lumen, which runs from the tip of the pigtail through the outlet area of the cannula, facilitates loading the catheter onto the guidewire</td></tr> </table> <p>Impella 2.5 Manual, p. 3.4; <i>see also</i> Impella CP Manual, p. 3.4 (containing the same).</p>	Pigtail	The 6 Fr pigtail is attached to the cannula at the distal end of the inlet area. It assists with stabilizing the catheter in the correct position in the left ventricle.	EasyGuide lumen	The red loading lumen, which runs from the tip of the pigtail through the outlet area of the cannula, facilitates loading the catheter onto the guidewire
Pigtail	The 6 Fr pigtail is attached to the cannula at the distal end of the inlet area. It assists with stabilizing the catheter in the correct position in the left ventricle.				
EasyGuide lumen	The red loading lumen, which runs from the tip of the pigtail through the outlet area of the cannula, facilitates loading the catheter onto the guidewire				
(10e) a blood pressure detection mechanism comprising a fluid column configured to detect the pressure of the blood proximate the intravascular blood pump;	<p>The Impella 2.5 and CP pumps include a blood pressure detection mechanism.</p> <p><u>Impella 2.5:</u></p> <p>“A 9 Fr catheter shaft is located between the motor housing and the red Impella® plug. The lumen of the catheter shaft contains a purge lumen, <i>a pressure measurement lumen...</i> and an electrical cable.” Impella 2.5 Manual, p. 3.5.</p> <p><u>Impella CP:</u></p> <p>“The Impella® Catheter uses <i>a fluid-filled pressure lumen</i> with an inlet at the proximal end of the motor housing and the pressure sensor located in the red Impella® plug.” Impella CP Manual, p. 3.5.</p>				
(10f) wherein the elongate lumen is sized substantially smaller than an inner diameter of	The above-identified Impella blood pumps meet this limitation.				

Claims	Infringement Analysis				
the cannula and intravascular blood pump; and	<p><u>Impella 2.5</u></p> <table border="1" data-bbox="575 386 1745 605"> <tr> <td data-bbox="575 386 884 500">Pigtail</td><td data-bbox="884 386 1745 500">The 6 Fr pigtail is attached to the cannula at the distal end of the inlet area. It assists with stabilizing the catheter in the correct position in the left ventricle.</td></tr> <tr> <td data-bbox="575 500 884 605">Cannula</td><td data-bbox="884 500 1745 605">The cannula (12 Fr for the Impella® 2.5) has a spiral-shaped reinforced body that is shaped in a 145-degree angle. The cannula is made of nitinol and covered in polyurethane.</td></tr> </table> <p>Impella 2.5 Manual, p. 3.4; <i>see also</i> Impella CP Manual, p. 3.4 (stating the same).</p>	Pigtail	The 6 Fr pigtail is attached to the cannula at the distal end of the inlet area. It assists with stabilizing the catheter in the correct position in the left ventricle.	Cannula	The cannula (12 Fr for the Impella® 2.5) has a spiral-shaped reinforced body that is shaped in a 145-degree angle. The cannula is made of nitinol and covered in polyurethane.
Pigtail	The 6 Fr pigtail is attached to the cannula at the distal end of the inlet area. It assists with stabilizing the catheter in the correct position in the left ventricle.				
Cannula	The cannula (12 Fr for the Impella® 2.5) has a spiral-shaped reinforced body that is shaped in a 145-degree angle. The cannula is made of nitinol and covered in polyurethane.				
(10g) a guide wire arranged to be advanced along the lumen, wherein the lumen is arranged coaxially with at least one of a distal end or a proximal end of the cannula, and the cannula and the lumen are arranged in series longitudinally.	<p>The above-identified Impella blood pumps meet this limitation.</p> <p><u>Impella 2.5</u></p> 				

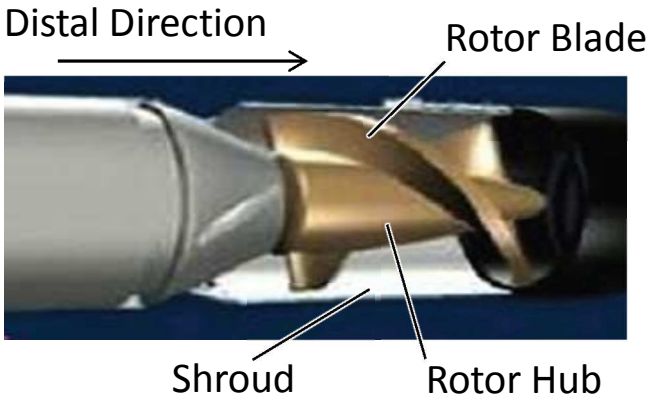
Claims	Infringement Analysis
	<p><u>Impella CP</u></p>  <p>See also, Impella 2.5 Manual, p.5.13; Impella CP Manual, p. 5.13.</p>

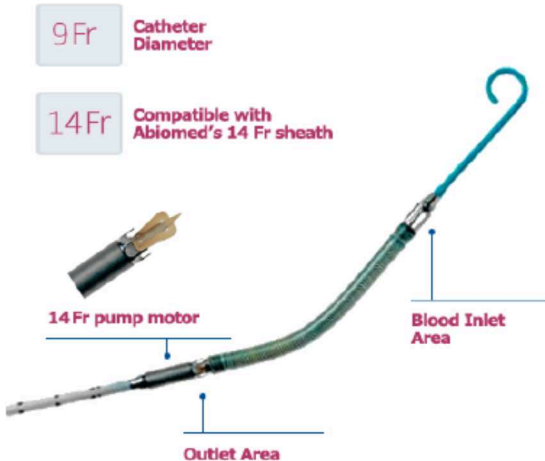
APPENDIX C

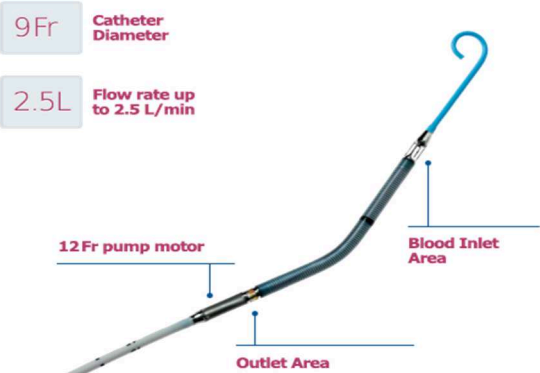
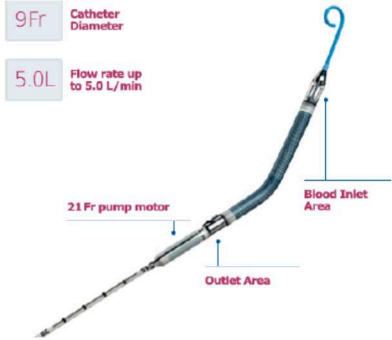
Claim Chart – U.S. Patent App. No. 14/543,815

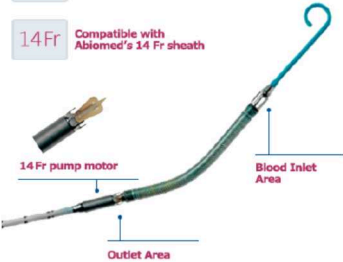
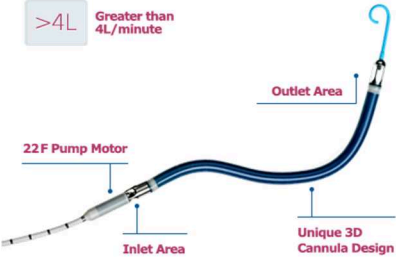
Appendix C

U.S. Patent Application No. 14/543,815

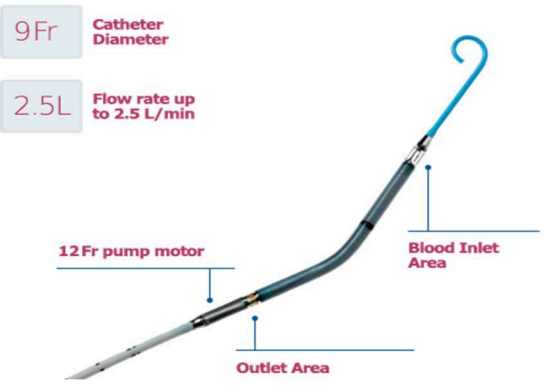
Claims	Infringement Analysis
<p>1. [24] A method for perfusing a patient with an intravascular blood pump system, the intravascular blood pump system comprising</p>	<p>The Impella 2.5, Impella 5.0, Impella CP, and Impella RP are intravascular blood pumps.</p>
<p>[1a] (i) an intravascular blood pump comprising 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;</p>	<p>The above-identified Impella blood pumps have a rotor that meets these limitations.</p> <p><u>Impella 2.5/5.0/RP</u></p> <p style="text-align: center;">  </p>


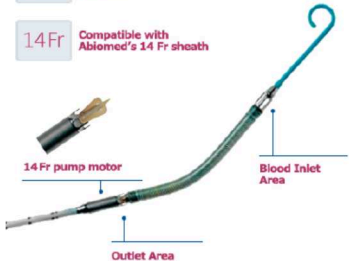
Claims	Infringement Analysis
	<p><u>Impella CP</u></p>  <p>9 Fr Catheter Diameter</p> <p>14 Fr Compatible with Abiomed's 14 Fr sheath</p> <p>14 Fr pump motor</p> <p>Blood Inlet Area</p> <p>Outlet Area</p>
<p>[1b] (ii) a cannula extending from the shroud and comprising an outer cannula surface, the outer cannula surface having a substantially circular cross-section along a portion of its length;</p>	<p>The above-identified Impella blood pumps include a cannula extending from a shroud as claimed.</p>

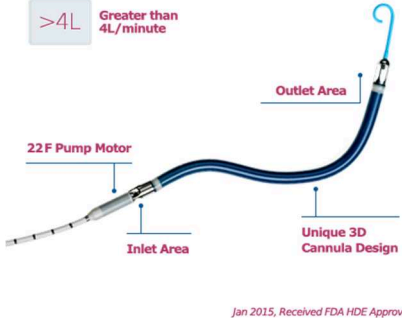
Claims	Infringement Analysis
	<p><u>Impella 2.5</u></p>  <p>See also Impella 2.5 Manual, p. 3.4</p> <p><u>Impella 5.0</u></p>  <p>See also Impella 5.0 Manual, p. 3.3.</p>

Claims	Infringement Analysis
	<p><u>Impella CP</u></p> <p>9Fr Catheter Diameter</p> <p>14Fr Compatible with Abiomed's 14 Fr sheath</p>  <p>14 Fr pump motor</p> <p>Blood Inlet Area</p> <p>Outlet Area</p> <p>See also Impella CP Manual, p. 3.4.</p> <p><u>Impella RP</u></p> <p>11F Catheter Diameter</p> <p>>4L Greater than 4L/minute</p>  <p>22 F Pump Motor</p> <p>Inlet Area</p> <p>Outlet Area</p> <p>Unique 3D Cannula Design</p> <p><small>Jan 2015, Received FDA HDE Approval</small></p> <p>See also Impella RP Manual, p. 3.3.</p>

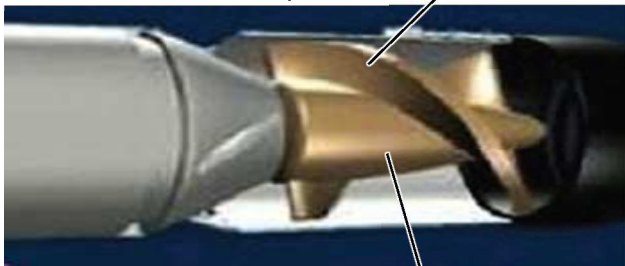
Claims	Infringement Analysis
<p>[1c] (iii) a first lumen in fluid communication with the intravascular blood pump and operatively arranged to deliver purge fluid to the intravascular blood pump; and</p>	<p>The above-identified Impella blood pumps include a lumen containing a pump purge fluid.</p> <p><u>Impella 2.5</u></p> <p><u>Catheter shaft</u></p> <p>A 9 Fr catheter shaft is located between the motor housing and the red Impella® plug. The lumen of the catheter shaft contains a purge lumen, a pressure measurement lumen, a nitinol wire, and an electrical cable. The catheter shaft has longitudinal and transversal marks:</p> <ul style="list-style-type: none"> • The longitudinal mark along the inner radius shows correct position of the 0.018 inch, 260 cm placement guidewire once backloaded on the Impella® Catheter. • The transversal marks at 1 cm intervals with numbers every 5 cm aid in proper positioning. <p>Impella 2.5 Manual, p. 3.4; <i>see also</i> Impella 5.0 Manual (stating the same), p. 3.3; Impella CP Manual, p. 3.4 (stating the same); Impella RP Manual, p. 3.3 (stating the same).</p>
<p>[1d] (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</p>	<p>The above-identified Impella blood pumps meet this limitation.</p>

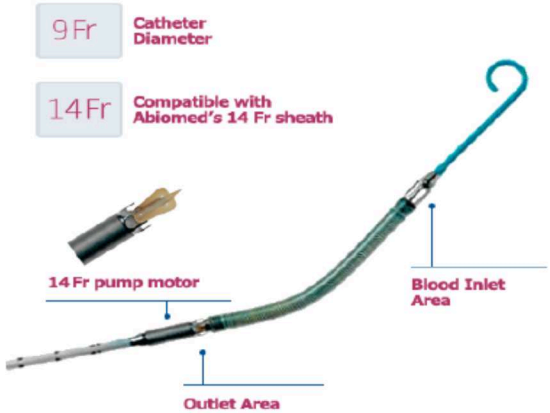
Claims	Infringement Analysis
<p>within the circulatory system of a patient, wherein an axis coaxial with and extending through a portion of said guide mechanism extends through a region delimited by the outer cannula surface, and wherein the guide mechanism is configured to allow for a guide wire to slideably advance therealong,</p>	<p><u>Impella 2.5</u></p>  <p>9Fr Catheter Diameter</p> <p>2.5L Flow rate up to 2.5 L/min</p> <p>12 Fr pump motor</p> <p>Blood Inlet Area</p> <p>Outlet Area</p> <p>Pigtail The 6 Fr pigtail is attached to the cannula at the distal end of the inlet area. It assists with stabilizing the catheter in the correct position in the left ventricle.</p> <p>EasyGuide lumen The red loading lumen, which runs from the tip of the pigtail through the outlet area of the cannula, facilitates loading the catheter onto the guidewire</p> <p>Impella 2.5 Manual, p. 3.4.</p>

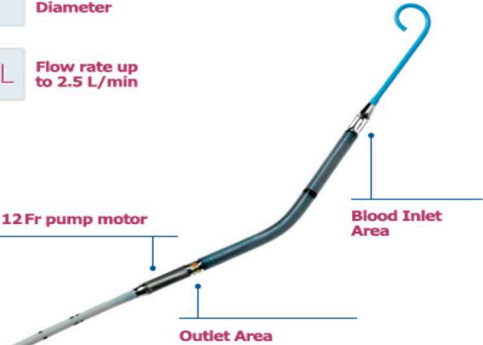
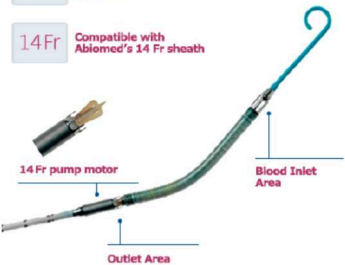
Claims	Infringement Analysis
	<p><u>Impella 5.0</u></p>  <p>See also Impella 5.0 Manual, p. 3.3.</p> <p><u>Impella CP</u></p>  <p>See also Impella CP Manual, p. 3.4.</p>

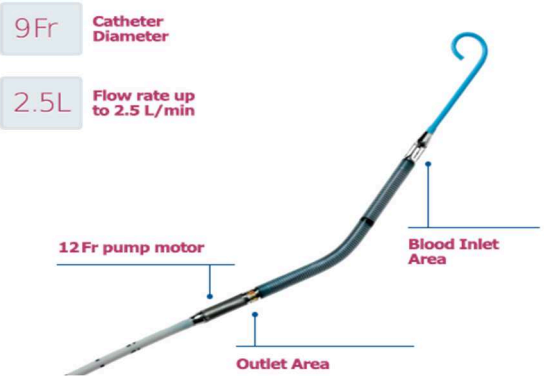
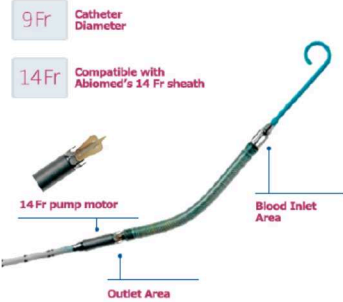
Claims	Infringement Analysis
	<p><u>Impella RP</u></p>  <p>See also Impella RP Manual, p. 3.3.</p>
[1e] the method comprising the steps of:	As discussed below, the Impella blood pumps include the additional claimed method steps.
[1f] progressing a guide wire to a predetermined location in the circulatory system of the patient; and	<p>The above-identified Impella pumps meet this limitation.</p> <p><u>Impella 2.5</u></p> <p>5. Insert a diagnostic catheter (Abiomed recommends a 6 Fr AL1 or Multipurpose without side holes or 4–5 Fr pigtail with or without side holes) over a 0.035 inch diagnostic guidewire into the introducer and advance it into the left ventricle.</p>

Claims	Infringement Analysis
	<p>6. Remove the 0.035 inch diagnostic guidewire, leaving the diagnostic catheter in the ventricle. Form a curve or bend on the end of the 0.018 inch, 260 cm placement guidewire, following the instructions and heeding the precautions described in the sidebar box.</p> <p>7. Advance the placement guidewire into the apex of the left ventricle.</p> <p>Impella 2.5 Manual, p. 5.13; <i>see also</i> Impella 5.0 Manual, pp. 5.14-5.15 (stating the same); Impella CP Manual, p. 5.13 (stating the same); Impella RP Manual, pp. 5.10-5.11.</p>
[1g] advancing the blood pump system along the guide wire to the predetermined location.	<p>The above-identified Impella pumps meet this limitation.</p> <p><u>Impella 2.5</u></p> <p>11. Advance the catheter through the hemostatic valve into the femoral artery (see Figure 5.18) and along the placement guidewire and across the aortic valve using a fixed-wire technique. Follow the catheter under fluoroscopy as it is advanced across the aortic valve, positioning the inlet area of the catheter 3.5 cm below the aortic valve annulus and in the middle of the ventricular chamber, free from the mitral valve chordae. Be careful not to coil the guidewire in the left ventricle.</p> <p>Impella 2.5 Manual, p. 5.13; <i>see also</i> Impella 5.0 Manual, pp. 5.15-5.16 (stating the same); Impella CP Manual, p. 5.13 (stating the same); Impella RP Manual, p. 5.11.</p>
10. [25] A method for perfusing a patent with an intravascular blood	<p>The Impella 2.5 and Impella CP are intravascular blood pumps.</p>

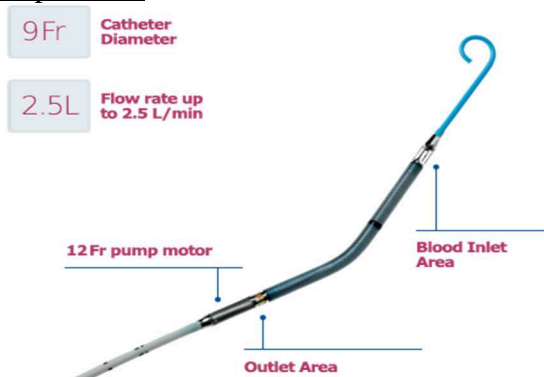
Claims	Infringement Analysis
pump system, the intravascular blood pump system comprising	
[10a] (i) an intravascular blood pump comprising a rotor having a rotor hub tapering in the distal direction and at least one blade extending radially outward from the rotor hub,	<p>The above-identified Impella blood pumps have a rotor that meets these limitations.</p> <p><u>Impella 2.5</u></p> <p>Distal Direction →</p>  <p>Rotor Blade</p> <p>Rotor Hub</p>

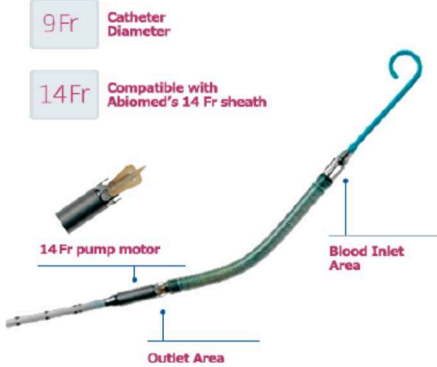
Claims	Infringement Analysis
	<p><u>Impella CP.</u></p>  <p>9 Fr Catheter Diameter</p> <p>14 Fr Compatible with Abiomed's 14 Fr sheath</p> <p>14 Fr pump motor</p> <p>Blood Inlet Area</p> <p>Outlet Area</p>
<p>[10b] the intravascular blood pump coupled to a catheter on a proximal end and a cannula on a distal end;</p>	<p>The above-identified Impella blood pumps meet this limitation.</p>

Claims	Infringement Analysis
	<p><u>Impella 2.5</u></p> <div data-bbox="562 391 1098 760"> <p>9Fr Catheter Diameter</p> <p>2.5L Flow rate up to 2.5 L/min</p>  </div> <p><i>See also Impella 2.5 Manual, p. 3.4.</i></p> <p><u>Impella CP</u></p> <div data-bbox="552 915 894 1211"> <p>9Fr Catheter Diameter</p> <p>14Fr Compatible with Abiomed's 14 Fr sheath</p>  </div> <p><i>See also Impella CP Manual, p. 3.4.</i></p>

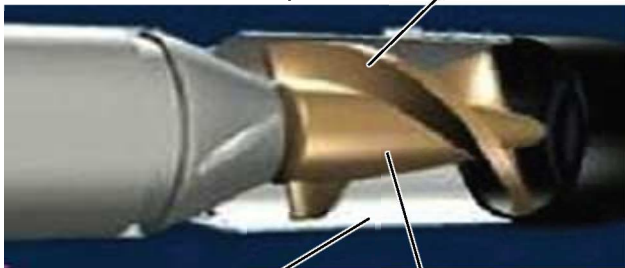
Claims	Infringement Analysis
<p>[10c] (ii) a first set and a second set of apertures establishing fluid communication between an interior of the cannula and an exterior region of the cannula, wherein the first set of apertures is located in proximity to the rotor and the second set of apertures is spaced apart from and located distal to the first set of apertures towards a distal region of the cannula;</p>	<p>The above-identified Impella blood pumps meet this limitation.</p> <p><u>Impella 2.5</u></p>  <p><u>Impella CP</u></p> 

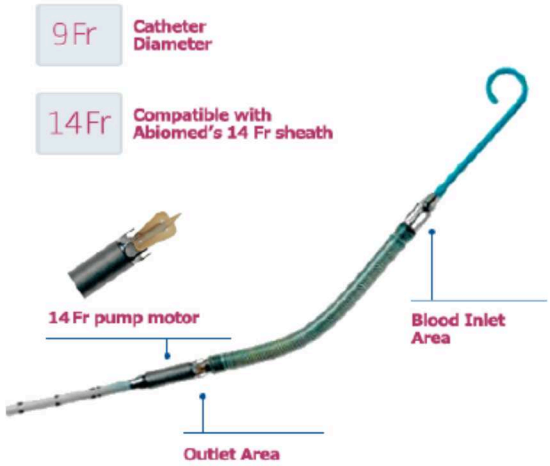
Claims	Infringement Analysis				
<p>[10d] (iii) a guide mechanism configured as an elongate lumen and adapted to guide said intravascular blood pump, cannula, and catheter to a predetermined location within the circulatory system of a patient; and</p>	<p>The above-identified Impella blood pumps utilize a guide mechanism.</p> <p><u>Impella 2.5:</u></p> <table border="1" data-bbox="552 427 1705 646"> <tr> <td data-bbox="552 427 856 532">Pigtail</td><td data-bbox="856 427 1705 532">The 6 Fr pigtail is attached to the cannula at the distal end of the inlet area. It assists with stabilizing the catheter in the correct position in the left ventricle.</td></tr> <tr> <td data-bbox="552 532 856 646">EasyGuide lumen</td><td data-bbox="856 532 1705 646">The red loading lumen, which runs from the tip of the pigtail through the outlet area of the cannula, facilitates loading the catheter onto the guidewire</td></tr> </table> <p>Impella 2.5 Manual, p. 3.4; <i>see also</i> Impella 5.0 Manual, p. 3.3 (containing the same disclosure); Impella CP Manual, p. 3.4 (containing the same), Impella RP Manual, p. 3.3 (containing the same).</p>	Pigtail	The 6 Fr pigtail is attached to the cannula at the distal end of the inlet area. It assists with stabilizing the catheter in the correct position in the left ventricle.	EasyGuide lumen	The red loading lumen, which runs from the tip of the pigtail through the outlet area of the cannula, facilitates loading the catheter onto the guidewire
Pigtail	The 6 Fr pigtail is attached to the cannula at the distal end of the inlet area. It assists with stabilizing the catheter in the correct position in the left ventricle.				
EasyGuide lumen	The red loading lumen, which runs from the tip of the pigtail through the outlet area of the cannula, facilitates loading the catheter onto the guidewire				
<p>[10e] (iv) a blood pressure detection mechanism comprising a fluid column configured to detect the pressure of the blood proximate the intravascular blood pump;</p>	<p>The above-identified Impella blood pumps include a blood pressure detection mechanism.</p> <p><u>Impella 2.5:</u></p> <p>“A 9 Fr catheter shaft is located between the motor housing and the red Impella® plug. The lumen of the catheter shaft contains a purge lumen, <i>a pressure measurement lumen...</i> and an electrical cable.” Impella 2.5 Manual, p. 3.5.</p> <p><u>Impella CP:</u></p> <p>“The Impella® Catheter uses <i>a fluid-filled pressure lumen</i> with an inlet at the proximal end of the motor housing and the pressure sensor located in the red Impella® plug.” Impella CP Manual, p. 3.5.</p>				
<p>[10f] wherein the elongated lumen (a) is</p>	<p>The above-identified Impella blood pumps meet this limitation.</p>				

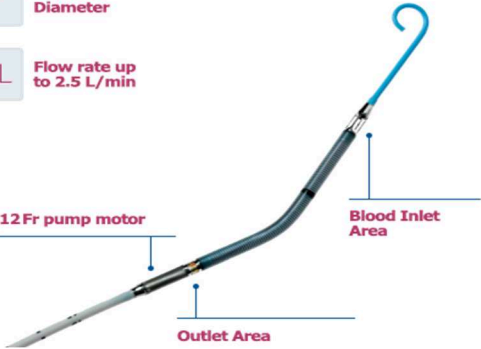
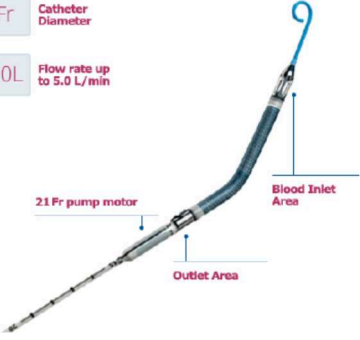
Claims	Infringement Analysis				
<p>sized substantially smaller than an inner diameter of the cannula and intravascular blood pump;</p>	<p><u>Impella 2.5</u></p> <table border="1" data-bbox="554 386 1738 605"> <tr> <td data-bbox="554 386 871 440">Pigtail</td><td data-bbox="871 386 1738 496">The 6 Fr pigtail is attached to the cannula at the distal end of the inlet area. It assists with stabilizing the catheter in the correct position in the left ventricle.</td></tr> <tr> <td data-bbox="554 496 871 605">Cannula</td><td data-bbox="871 496 1738 605">The cannula (12 Fr for the Impella® 2.5) has a spiral-shaped reinforced body that is shaped in a 145-degree angle. The cannula is made of nitinol and covered in polyurethane.</td></tr> </table> <p>Impella 2.5 Manual, p. 3.4; <i>see also</i> Impella CP Manual, p. 3.4 (stating the same).</p>	Pigtail	The 6 Fr pigtail is attached to the cannula at the distal end of the inlet area. It assists with stabilizing the catheter in the correct position in the left ventricle.	Cannula	The cannula (12 Fr for the Impella® 2.5) has a spiral-shaped reinforced body that is shaped in a 145-degree angle. The cannula is made of nitinol and covered in polyurethane.
Pigtail	The 6 Fr pigtail is attached to the cannula at the distal end of the inlet area. It assists with stabilizing the catheter in the correct position in the left ventricle.				
Cannula	The cannula (12 Fr for the Impella® 2.5) has a spiral-shaped reinforced body that is shaped in a 145-degree angle. The cannula is made of nitinol and covered in polyurethane.				
<p>[10g] (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,</p>	<p>The above-identified Impella blood pumps meet this limitation.</p> <p><u>Impella 2.5</u></p>  <p>The diagram illustrates the Impella 2.5 blood pump. It features a long, thin, curved cannula with a pigtail at the distal end. A 12Fr pump motor is attached to the proximal end of the cannula. The flow direction is indicated by arrows: from the Blood Inlet Area at the distal end, through the pump motor, and out through the Outlet Area at the proximal end. Text boxes specify the Catheter Diameter as 9Fr and the Flow rate as up to 2.5 L/min.</p>				

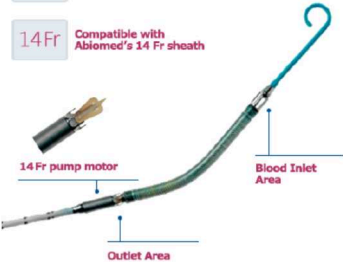
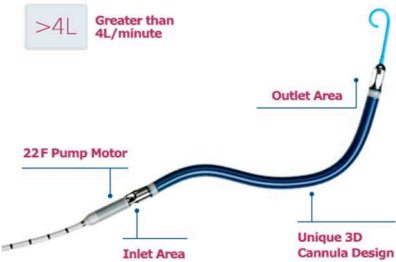
Claims	Infringement Analysis
	<p><u>Impella CP</u></p>  <p><i>See also, Impella 2.5 Manual, p.5.13; Impella CP Manual, p. 5.13.</i></p>
[10h] the method comprising:	As discussed below, the Impella blood pumps include the additional claimed method steps.
[10i] advancing a guide wire to a predetermined location in the circulatory system of the patient; and	<p>The above-identified Impella pumps meet this limitation.</p> <p><u>Impella 2.5</u></p> <p>5. Insert a diagnostic catheter (Abiomed recommends a 6 Fr AL1 or Multipurpose without side holes or 4–5 Fr pigtail with or without side holes) over a 0.035 inch diagnostic guidewire into the introducer and advance it into the left ventricle.</p>

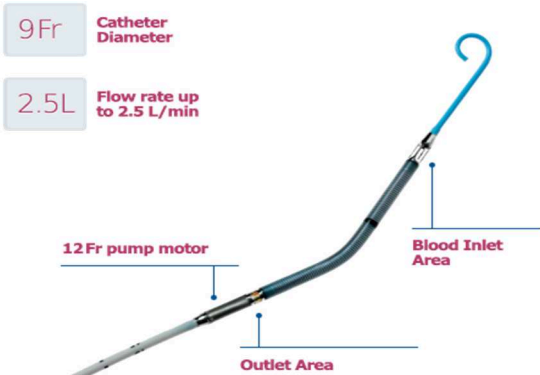
Claims	Infringement Analysis
	<p>6. Remove the 0.035 inch diagnostic guidewire, leaving the diagnostic catheter in the ventricle. Form a curve or bend on the end of the 0.018 inch, 260 cm placement guidewire, following the instructions and heeding the precautions described in the sidebar box.</p> <p>7. Advance the placement guidewire into the apex of the left ventricle.</p> <p>Impella 2.5 Manual, p. 5.13; <i>see also</i> Impella CP Manual, p. 5.13 (stating the same).</p>
<p>[10j] advancing the blood pump system along the guide wire to the predetermined location.</p>	<p>The above-identified Impella pumps meet this limitation.</p> <p><u>Impella 2.5</u></p> <p>11. Advance the catheter through the hemostatic valve into the femoral artery (see Figure 5.18) and along the placement guidewire and across the aortic valve using a fixed-wire technique. Follow the catheter under fluoroscopy as it is advanced across the aortic valve, positioning the inlet area of the catheter 3.5 cm below the aortic valve annulus and in the middle of the ventricular chamber, free from the mitral valve chordae. Be careful not to coil the guidewire in the left ventricle.</p> <p>Impella 2.5 Manual, p. 5.13; <i>see also</i> Impella CP Manual, p. 5.13 (stating the same).</p>
<p>20. [26] A method for perfusing a patient with an intravascular blood pump system, the intravascular blood pump system is configured to be</p>	<p>The Impella 2.5, Impella 5.0 and Impella CP, are intravascular blood pumps.</p>

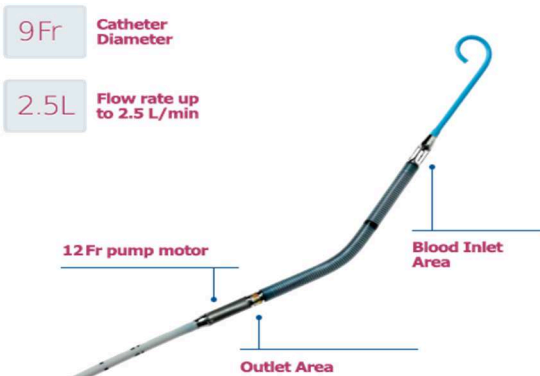
Claims	Infringement Analysis
advanced to a predetermined location in a patient's circulatory system and comprises	
(i) an intravascular blood pump, the intravascular blood pump comprising a rotor having a generally conical rotor hub tapering in the distal direction, at least two blades extending radially from the rotor hub, the generally conical rotor hub having a distal tip extending distally beyond the blades;	<p>The above-identified Impella blood pumps have a rotor that meets these limitations.</p> <p><u>Impella 2.5/5.0/RP</u></p> <p>Distal Direction →</p>  <p>Shroud Rotor Hub</p>



Claims	Infringement Analysis
	<p><u>Impella CP.</u></p>  <p>9 Fr Catheter Diameter</p> <p>14 Fr Compatible with Abiomed's 14 Fr sheath</p> <p>14 Fr pump motor</p> <p>Blood Inlet Area</p> <p>Outlet Area</p>
(ii) a cannula extending distally from the intravascular blood pump;	The above-identified Impella blood pumps meet this limitation.

Claims	Infringement Analysis
	<p data-bbox="552 321 699 354"><u>Impella 2.5</u></p> <div data-bbox="562 391 1098 764"><p data-bbox="569 399 730 431">9Fr Catheter Diameter</p><p data-bbox="569 472 758 505">2.5L Flow rate up to 2.5 L/min</p><p data-bbox="621 626 768 643">12 Fr pump motor</p><p data-bbox="968 626 1062 651">Blood Inlet Area</p><p data-bbox="800 740 894 756">Outlet Area</p></div> <p data-bbox="552 841 699 873"><u>Impella 5.0</u></p> <div data-bbox="562 911 951 1252"><p data-bbox="569 919 684 943">9Fr Catheter Diameter</p><p data-bbox="569 976 705 1008">5.0L Flow rate up to 5.0 L/min</p><p data-bbox="625 1105 741 1122">21 Fr pump motor</p><p data-bbox="863 1089 936 1114">Blood Inlet Area</p><p data-bbox="768 1179 842 1195">Outlet Area</p></div>

Claims	Infringement Analysis
	<p><u>Impella CP</u></p> <p>9Fr Catheter Diameter</p> <p>14Fr Compatible with Abiomed's 14 Fr sheath</p>  <p>14 Fr pump motor</p> <p>Blood Inlet Area</p> <p>Outlet Area</p> <p><u>Impella RP</u></p> <p>11F Catheter Diameter</p> <p>>4L Greater than 4L/minute</p>  <p>22 F Pump Motor</p> <p>Outlet Area</p> <p>Inlet Area</p> <p>Unique 3D Cannula Design</p> <p><small>Jan 2015, Received FDA HDE Approval</small></p> <p>See also Impella 2.5 Manual, p. 3.4; Impella 5.0 Manual, p. 3.3; Impella CP Manual, p. 3.4; Impella RP Manual, p. 3.3.</p>

Claims	Infringement Analysis		
<p>(iii) a plurality of ingress ports located towards the 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;</p>	<p>The above-identified Impella blood pumps meet this limitation.</p> <p><u>Impella 2.5</u></p>  <p>The diagram illustrates the Impella 2.5 catheter. It features a blue catheter with a curved tip. Labels indicate the '9Fr Catheter Diameter' and a 'Flow rate up to 2.5 L/min'. The '12Fr pump motor' is shown on the side of the catheter. The 'Blood Inlet Area' is at the distal end, and the 'Outlet Area' is located proximally to the inlet area.</p> <p><i>See also Impella 2.5 Manual, p. 3.4; Impella 5.0 Manual, p. 3.3; Impella CP Manual, p. 3.4.</i></p>		
<p>(iv) a guide wire having a cross-section substantially smaller than the cannula; and</p>	<p>The above-identified Impella blood pumps meet this limitation.</p> <p><u>Impella 2.5</u></p> <table border="1" data-bbox="558 1166 1740 1276"> <tr> <td>Pigtail</td> <td>The 6 Fr pigtail is attached to the cannula at the distal end of the inlet area. It assists with stabilizing the catheter in the correct position in the left ventricle.</td> </tr> </table>	Pigtail	The 6 Fr pigtail is attached to the cannula at the distal end of the inlet area. It assists with stabilizing the catheter in the correct position in the left ventricle.
Pigtail	The 6 Fr pigtail is attached to the cannula at the distal end of the inlet area. It assists with stabilizing the catheter in the correct position in the left ventricle.		

Claims	Infringement Analysis
	<p>Cannula The cannula (12 Fr for the Impella® 2.5) has a spiral-shaped reinforced body that is shaped in a 145-degree angle. The cannula is made of nitinol and covered in polyurethane.</p> <p>Impella 2.5 Manual, p. 3.4; <i>see also</i> Impella 5.0 Manual, p.3.3; (stating the same); Impella CP Manual, p. 3.4 (stating the same).</p>
<p>(v) an elongated lumen, the elongated 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,</p>	<p>The above-identified Impella blood pumps meet this limitation.</p> <p><u>Impella 2.5</u></p>  <p>The diagram illustrates the Impella 2.5 catheter. It features a blue curved cannula with a pigtail at the distal end. Labels indicate the '9Fr Catheter Diameter', '2.5L Flow rate up to 2.5 L/min', '12Fr pump motor', 'Blood Inlet Area', and 'Outlet Area'. A 'Pigtail' is shown at the distal end, and an 'EasyGuide lumen' is shown running through the cannula.</p> <p>Pigtail The 6 Fr pigtail is attached to the cannula at the distal end of the inlet area. It assists with stabilizing the catheter in the correct position in the left ventricle.</p> <p>EasyGuide lumen The red loading lumen, which runs from the tip of the pigtail through the outlet area of the cannula, facilitates loading the catheter onto the guidewire</p> <p>Impella 2.5 Manual, p. 3.4.</p>

Claims	Infringement Analysis
	<p><u>Impella 5.0</u></p> <p>9Fr Catheter Diameter</p> <p>5.0L Flow rate up to 5.0 L/min</p>  <p>21 Fr pump motor</p> <p>Blood Inlet Area</p> <p>Outlet Area</p> <p><i>See also Impella 5.0 Manual, p. 3.3.</i></p> <p><u>Impella CP</u></p> <p>9Fr Catheter Diameter</p> <p>14Fr Compatible with Abiomed's 14 Fr sheath</p>  <p>14 Fr pump motor</p> <p>Blood Inlet Area</p> <p>Outlet Area</p> <p><i>See also Impella CP Manual, p. 3.4.</i></p>

Claims	Infringement Analysis
the method comprising:	As discussed below, the Impella blood pumps include the additional claimed method steps.
advancing the guide wire to a predetermined location in the circulatory system of the patient; and	<p>The above-identified Impella pumps meet this limitation.</p> <p><u>Impella 2.5</u></p> <p>5. Insert a diagnostic catheter (Abiomed recommends a 6 Fr AL1 or Multipurpose without side holes or 4–5 Fr pigtail with or without side holes) over a 0.035 inch diagnostic guidewire into the introducer and advance it into the left ventricle.</p> <p>6. Remove the 0.035 inch diagnostic guidewire, leaving the diagnostic catheter in the ventricle. Form a curve or bend on the end of the 0.018 inch, 260 cm placement guidewire, following the instructions and heeding the precautions described in the sidebar box.</p> <p>7. Advance the placement guidewire into the apex of the left ventricle.</p> <p>Impella 2.5 Manual, p. 5.13; <i>see also</i> Impella 5.0 Manual, pp. 5.14-5.15 (stating the same); Impella CP Manual, p. 5.13 (stating the same).</p>
advancing the blood pump along the guide wire to the predetermined location.	The above-identified Impella pumps meet this limitation.

Claims	Infringement Analysis
	<p data-bbox="548 354 699 386"><u>Impella 2.5</u></p> <p data-bbox="575 402 1759 670">11. Advance the catheter through the hemostatic valve into the femoral artery (see Figure 5.18) and along the placement guidewire and across the aortic valve using a fixed-wire technique. Follow the catheter under fluoroscopy as it is advanced across the aortic valve, positioning the inlet area of the catheter 3.5 cm below the aortic valve annulus and in the middle of the ventricular chamber, free from the mitral valve chordae. Be careful not to coil the guidewire in the left ventricle.</p> <p data-bbox="548 695 1713 768">Impella 2.5 Manual, p. 5.13; <i>see also</i> Impella 5.0 Manual, pp. 5.15-5.16 (stating the same); Impella CP Manual, p. 5.13 (stating the same).</p>

COMPLAINT

IN THE UNITED STATES DISTRICT COURT

MAQUET Cardiovascular LLC

Plaintiff,

vs.

**Abiomed Inc., Abiomed R&D, Inc.,
Abiomed Europe GmbH**

Defendants.

CIVIL ACTION NO. _____

JURY DEMAND

COMPLAINT

Plaintiff MAQUET Cardiovascular LLC, by and through counsel, files this Complaint against Defendants Abiomed, Inc., Abiomed R&D, Inc., and Abiomed Europe GmbH (collectively “Defendants” or “Abiomed”), and alleges on personal knowledge as to its actions, and upon information and belief as to the actions of others, as follows:

THE PARTIES

1. Plaintiff MAQUET Cardiovascular LLC (“Maquet”), is a limited liability company formed and existing under the laws of Delaware having its principal place of business in Mahwah, New Jersey. Maquet is a leader in the development of medical devices. Maquet is the owner by assignment of patents and patent applications, including those that are identified below, that relate to innovative intravascular blood pumps. The patented technology concerns medical devices that can be introduced into a patient’s vascular system. These devices can be used to supplement and even fully support the circulation of blood in a patient.

2. Defendant Abiomed, Inc. is a Delaware corporation having its principal place of business at 22 Cherry Hill Dr., Danvers, MA 01923-2599. Defendant Abiomed R&D, Inc. is a

Delaware Corporation having its principal place of business at 22 Cherry Hill Dr., Danvers, MA 01923-2599. Abiomed Europe GmbH is a German Company having its principal place of business at Neuenhofer Weg 3, Aachen, Nordrhein-Westfalen 52074, Germany. Abiomed, Inc., Abiomed R&D, Inc., and Abiomed Europe GmbH are engaged in the business of manufacturing and distributing intravascular blood pumps.

JURISDICTION AND VENUE

3. This action arises under the Patent Act, Title 35 of the United States Code, and is an action for patent infringement under § 271.

4. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over the Defendants under this State's long-arm statute and consistent with the underlying due process principles of the U.S. Constitution. Upon information and belief, Defendants are doing business in this State and District, have significant contacts in this State and District, have offered for sale and sold infringing products in this State and District, and have committed acts in this State and District that are the subject of the counts set forth herein.

6. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

CLAIM I – INFRINGEMENT OF U.S. PAT. NO. 7,022,100

7. The allegations contained in Paragraphs 1 through 6 above are incorporated herein by reference.

8. On April 4, 2006, the United States Patent Office duly and lawfully issued United States Patent No. 7,022,100 entitled "Guidable Intravascular Blood Pump and Related Methods"

(“the ’100 Patent”). Maquet is the lawful owner of all right, title, and interest in and to the ’100 Patent, including the right to sue and recover for past infringement thereof. A true and correct copy of the ’100 Patent is attached hereto as Exhibit A.

9. Defendants have directly infringed, and continue to directly infringe, the claims of the ’100 Patent, including at least claim 16, in violation of 35 U.S.C. § 271(a). During the term of the ’100 Patent, Defendants have made, used, offered to sell, sold, and/or imported into the United States intravascular blood pumps including at least the Impella 2.5, the Impella 5.0, the Impella CP, and the Impella RP, and continue to do so, all without authority from the patent holder. These products include: an intravascular blood pump having a cannula coupled thereto; a guide mechanism adapted to guide said intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient; and a blood pressure detection mechanism to detect the pressure of blood proximate at least one of the intravascular blood pump and cannula.

10. Defendants have knowledge of the ’100 Patent at least by virtue of this complaint. Furthermore, on information and belief, Defendants have had knowledge of the ’100 Patent before the filing of this suit, as evidenced at least by the identification of the ’100 patent in Abiomed, Inc.’s International Patent Application No. PCT/US2011/062851 on February 20, 2012. Abomed, Inc.’s employees Zhenghong Tao, Stephen Vaughan, and Marie-Eve Mongeau are named inventors on this application. Abiomed, Inc. also disclosed the ’100 Patent in a March 11, 2014 Information Disclosure Statement by Applicant submitted during the prosecution of U.S. Patent Application No. 13/552,366, assigned to Abiomed, Inc., which names the following Abiomed, Inc. employees as inventors: Caitlyn Hastie, Frank Kirchhoff, and Thorsten Siess.

11. Despite this knowledge, Defendants' infringement has been and continues to be willful and deliberate because Defendants know, or are willfully and deliberately ignoring an objectively high risk, that each of their actions constituted infringement of the '100 Patent.

12. Defendants have also indirectly infringed, and continues to indirectly infringe, the claims of the '100 Patent, including at least claim 16, in violation of 35 U.S.C. § 271(b) and (c). During the term of the '100 Patent, Defendants' customers have infringed the patent by at least using, offering for sale or selling in the United States intravascular blood pumps including at least the Impella 2.5, the Impella 5.0, the Impella CP, and the Impella RP, and continue to do so, all without authority from the patent holder. Upon information and belief, Defendants know their customers' conduct infringes the claims of the '100 Patent, and/or Defendants are willfully and deliberately ignoring an objectively high risk that their customers' conduct infringes the claims of the '100 Patent.

13. Despite their knowledge, Defendants have encouraged and to aid and abet, and continue to encourage and aid and abet, their customers to infringe the claims of the '100 Patent.

14. Despite their knowledge, Defendants have sold and continue to sell to their customers Defendants' intravascular blood pumps including the Impella 2.5, the Impella 5.0, the Impella CP, and the Impella RP. These Impella blood pumps are a material part of the invention claimed in the '100 Patent, and the Impella blood pumps are not a stable article or commodity of commerce suitable for substantial noninfringing uses.

CLAIM II – INFRINGEMENT OF U.S. PAT. NO. 8,888,728

15. The allegations contained in Paragraphs 1 through 14 above are incorporated herein by reference.

16. On Nov. 18, 2014, the United States Patent Office duly and lawfully issued United States Patent No. 8,888,728 entitled “Guidable Intravascular Blood Pump and Related Methods” (“the ’728 Patent”). Maquet is the lawful owner of all right, title, and interest in and to the ’728 Patent, including the right to sue and recover for past infringement thereof. A true and correct copy of the ’728 Patent is attached hereto as Exhibit B.

17. Defendants have directly infringed, and continues to directly infringe, the claims of the ’728 Patent, including at least claims 1 and 10, in violation of 35 U.S.C. § 271(a). During the term of the ’728 Patent, Defendants have made, used, offered to sell, sold, and/or imported into the United States intravascular blood pumps including at least the Impella 2.5, the Impella 5.0, the Impella CP, and the Impella RP, and continue to do so, all without authority from the patent holder. These products include: 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; a cannula extending from the shroud and comprising an outer cannula surface, the outer cannula surface having a substantially circular cross-section along a portion of its length; a first lumen in fluid communication with the intravascular blood pump and operatively arranged to deliver purge fluid to the intravascular blood pump; and a guide mechanism configured as a second lumen having a proximal end and a distal end, the guide mechanism adapted to guide a distal portion of said intravascular blood pump system to a predetermined location within the circulatory system of a patient; and 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 slidably advance therealong.

18. Defendants have knowledge of the '728 Patent at least by virtue of this complaint.

19. Defendants have also indirectly infringed, and continue to indirectly infringe, the claims of the '728 Patent, including at least claims 1 and 10, in violation of 35 U.S.C. § 271(b) and (c). During the term of the '728 Patent, Defendants' customers have infringed the patent by at least using, offering for sale or selling in the United States intravascular blood pumps including at least the Impella 2.5, the Impella 5.0, the Impella CP, and the Impella RP, and continue to do so, all without authority from the patent holder. Upon information and belief, Defendants know their customers' conduct infringes the claims of the '728 Patent, and/or Defendants are willfully and deliberately ignoring an objectively high risk that its customers' conduct infringes the claims of the '728 Patent.

20. Despite their knowledge, Defendants have encouraged, and continues to encourage, its customers to infringe the claims of the '728 Patent.

21. Despite their knowledge, Defendants have sold, and continue to sell to their customers Abiomed's intravascular blood pumps including the Impella 2.5, the Impella 5.0, the Impella CP, and the Impella RP. These Impella blood pumps are a material part of the invention claimed in the '728 Patent, and the Impella blood pumps are not a stable article or commodity of commerce suitable for substantial noninfringing uses.

RELIEF SOUGHT

Plaintiff Maquet respectfully seeks that the Court grant the following relief:

A. Enter judgment for Maquet and against Defendants for infringement of the '100 Patent;

B. Enter judgment for Maquet and against Defendants for induced infringement of the '100 Patent;

C. Enter judgment for Maquet and against Defendants for contributory infringement of the '100 Patent;

D. Enter judgment that each Defendant's infringement of the '100 Patent was and is willful;

E. Enter judgment for Maquet and against Defendants for infringement of the '728 Patent;

F. Enter judgment for Maquet and against Defendants for induced infringement of the '728 Patent;

G. Enter judgment for Maquet and against Defendants for contributory infringement of the '728 Patent;

H. Preliminarily and permanently enjoin Defendants, their officers, directors, principals, agents, sales representatives, servants, employees, successors, assigns, affiliates, subsidiaries and all those acting in concert or participation with them, from directly or indirectly infringing, inducing infringement or contributing to the infringement of any claim of the '100 Patent or the '728 Patent;

I. Enter judgment in favor of Maquet and against Defendants in an amount that will adequately compensate it for Defendants' infringement, but under no circumstances an amount less than a reasonable royalty for Defendants' use of the Maquet's patented inventions;

J. Enter judgment in favor of Maquet and against each Defendant for three times the amount of damages awarded for each Defendants' infringement of the '100 Patent pursuant to 35 U.S.C. § 284 because of their willful infringement;

K. Enter judgment in favor of Maquet and against Defendants for pre-judgment interest on all damages awarded;

L. Enter judgment in favor of Maquet and against Defendants finding that this case is “exceptional” under 35 U.S.C. § 285, and enter an award to Maquet of its reasonable attorneys’ fees, expenses, and costs incurred in this action;

M. Enter judgment in favor of Maquet and against Defendants for Maquet’s costs of suit; and

N. Enter such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff Maquet requests a trial by jury.

Respectfully submitted this ____ day of December, 2015.

Alston & Bird LLP

*Attorneys for Plaintiff MAQUET Cardiovascular
LLC*

U.S. PATENT NO. 7,022,100



(12) **United States Patent**
About-Hosn et al.

(10) **Patent No.:** **US 7,022,100 B1**
(45) **Date of Patent:** **Apr. 4, 2006**

(54) **GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS**

(75) Inventors: **Walid N About-Hosn**, Fair Oaks, CA (US); **William R Kanz**, Sacramento, CA (US); **Bruce Baker**, Placerville, CA (US)

(73) Assignee: **A-Med Systems, Inc.**, W. Sacramento, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 407 days.

(21) Appl. No.: **10/070,178**

(22) PCT Filed: **Sep. 1, 2000**

(86) PCT No.: **PCT/US00/24515**

§ 371 (c)(1),
(2), (4) Date: **Jul. 19, 2002**

(87) PCT Pub. No.: **WO01/17581**

PCT Pub. Date: **Mar. 15, 2001**

Related U.S. Application Data

(60) Provisional application No. 60/152,249, filed on Sep. 3, 1999.

(51) **Int. Cl.**
A61M 37/00 (2006.01)
A61M 1/10 (2006.01)

(52) **U.S. Cl.** **604/6.11; 623/3.26**

(58) **Field of Classification Search** 604/4.01, 604/6.11, 6.16, 8, 19, 27, 28, 39-45, 151, 604/154-5; 623/3.1, 3.13, 3.26-3.28; 600/16, 600/17; 417/45, 244, 246, 348, 356, 366

See application file for complete search history.

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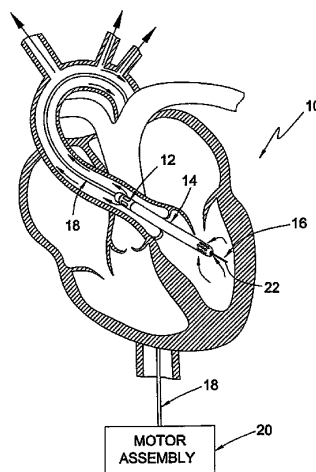
Primary Examiner—Patricia Bianco

(74) *Attorney, Agent, or Firm*—Ryan Kromholz & Manion, S.C.

(57) **ABSTRACT**

An improved intravascular blood pump system (10) and related methods involving the broad inventive concept of equipping the intravascular blood pump (12) with guiding features such that the intravascular blood pump can be selectively positioned at a predetermined location within the circulatory system of a patient.

20 Claims, 18 Drawing Sheets



US 7,022,100 B1

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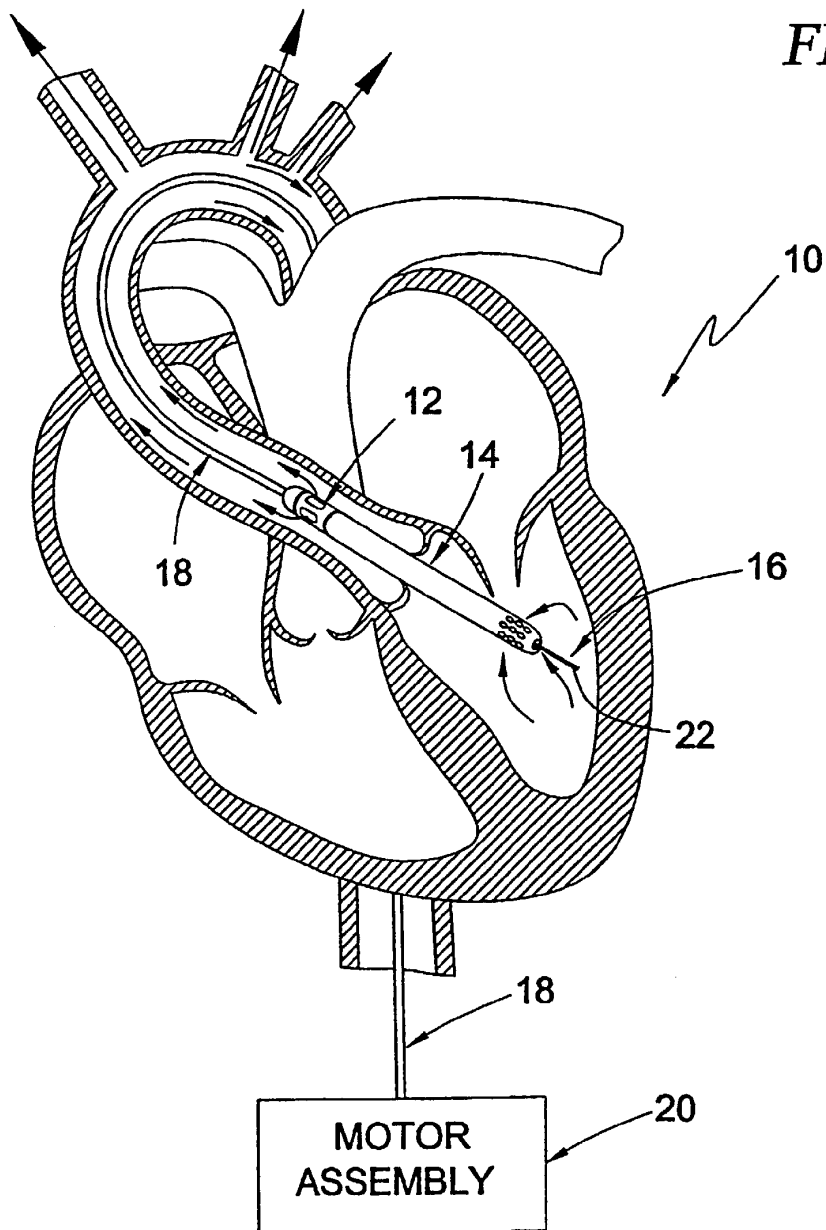
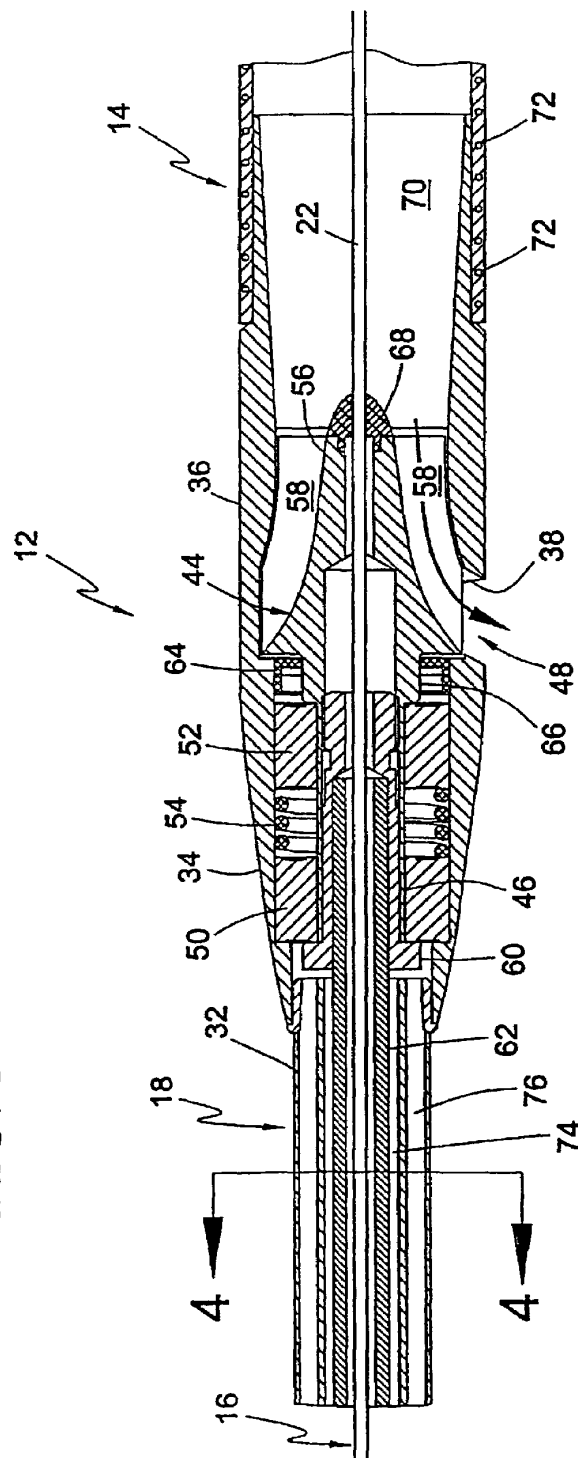


FIG. 3



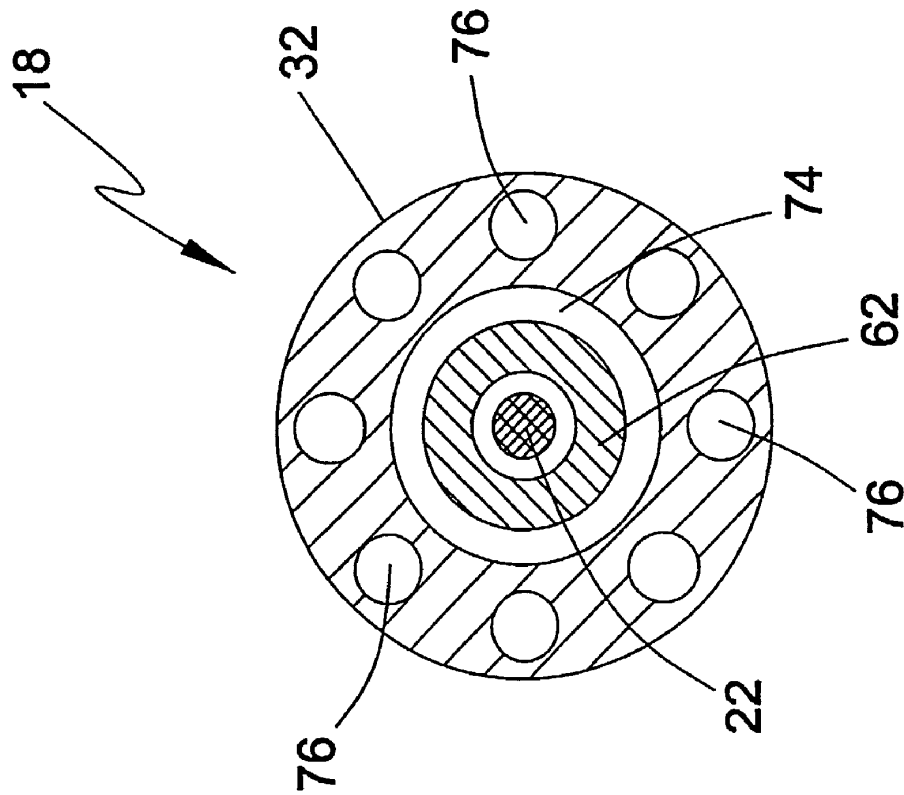
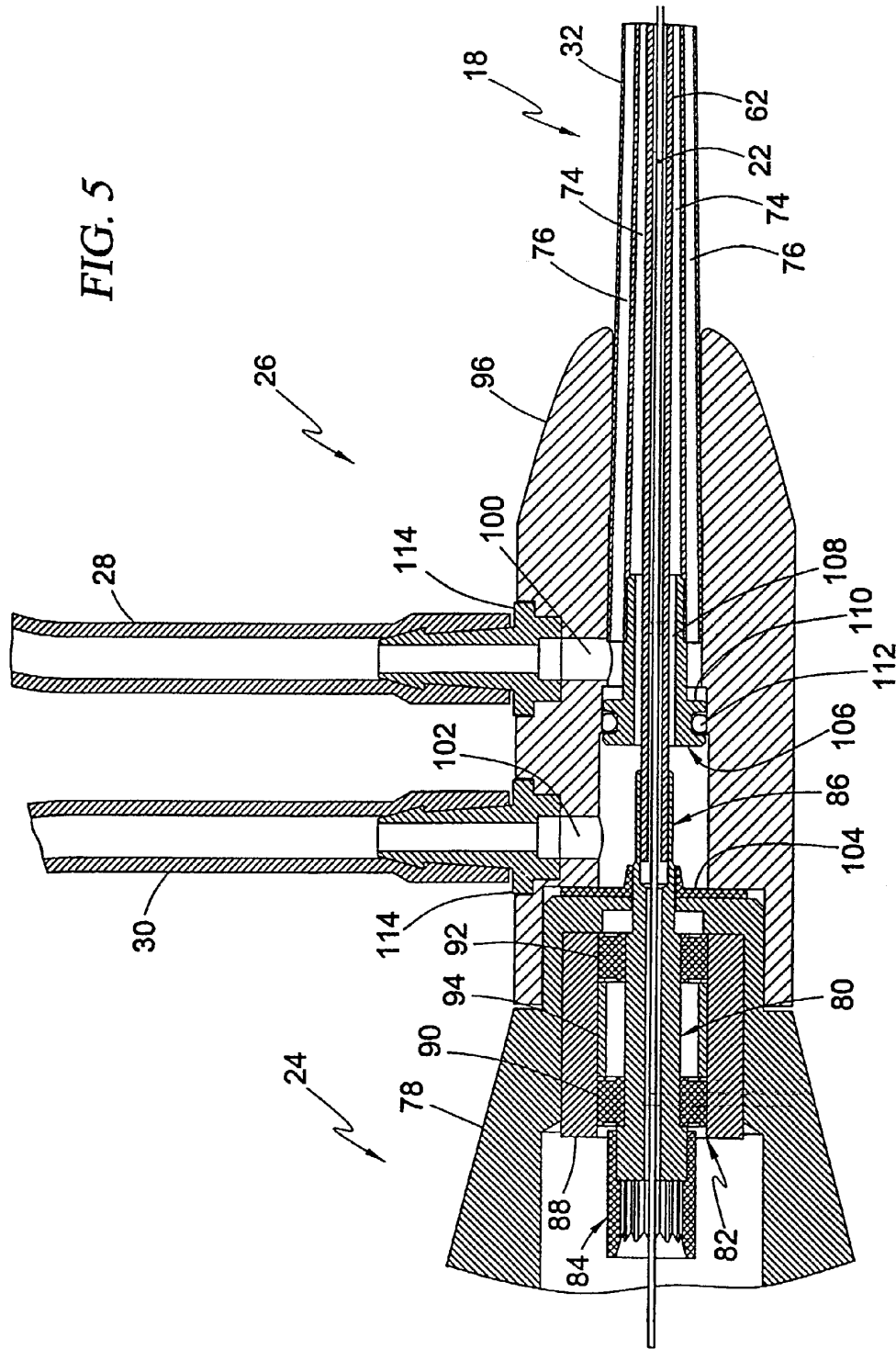


FIG. 4



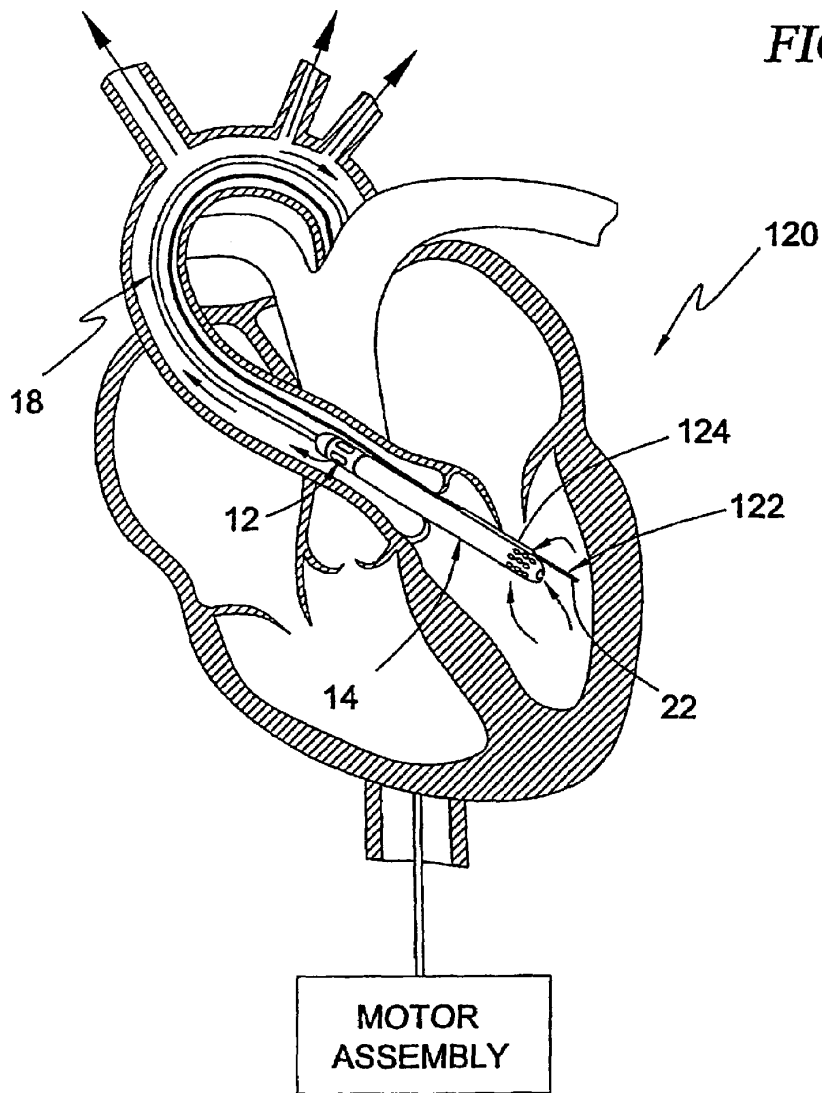
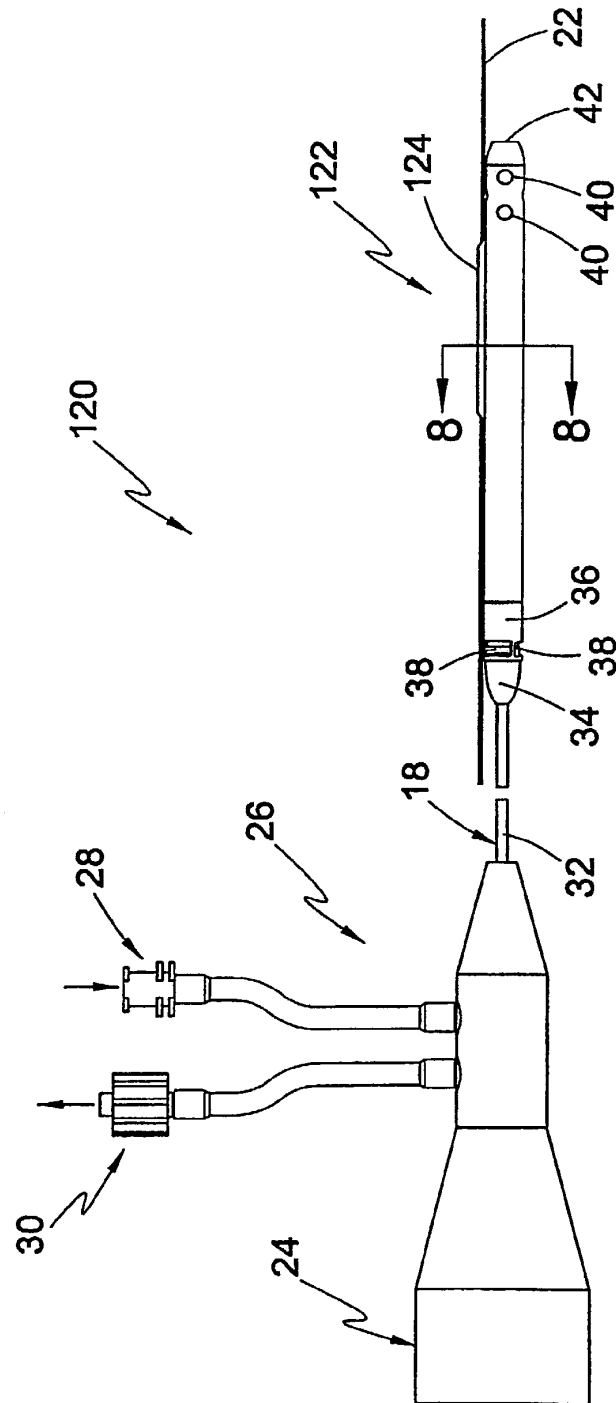


FIG. 7



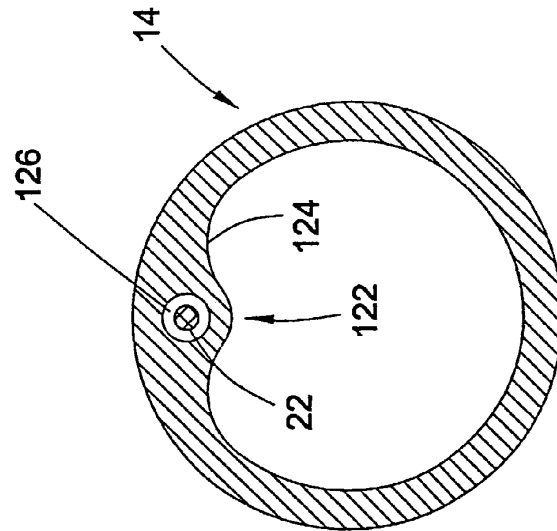


FIG 9

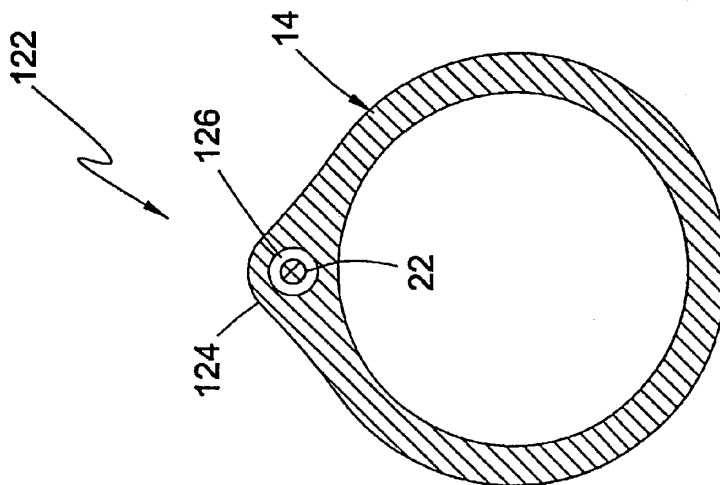


FIG 8

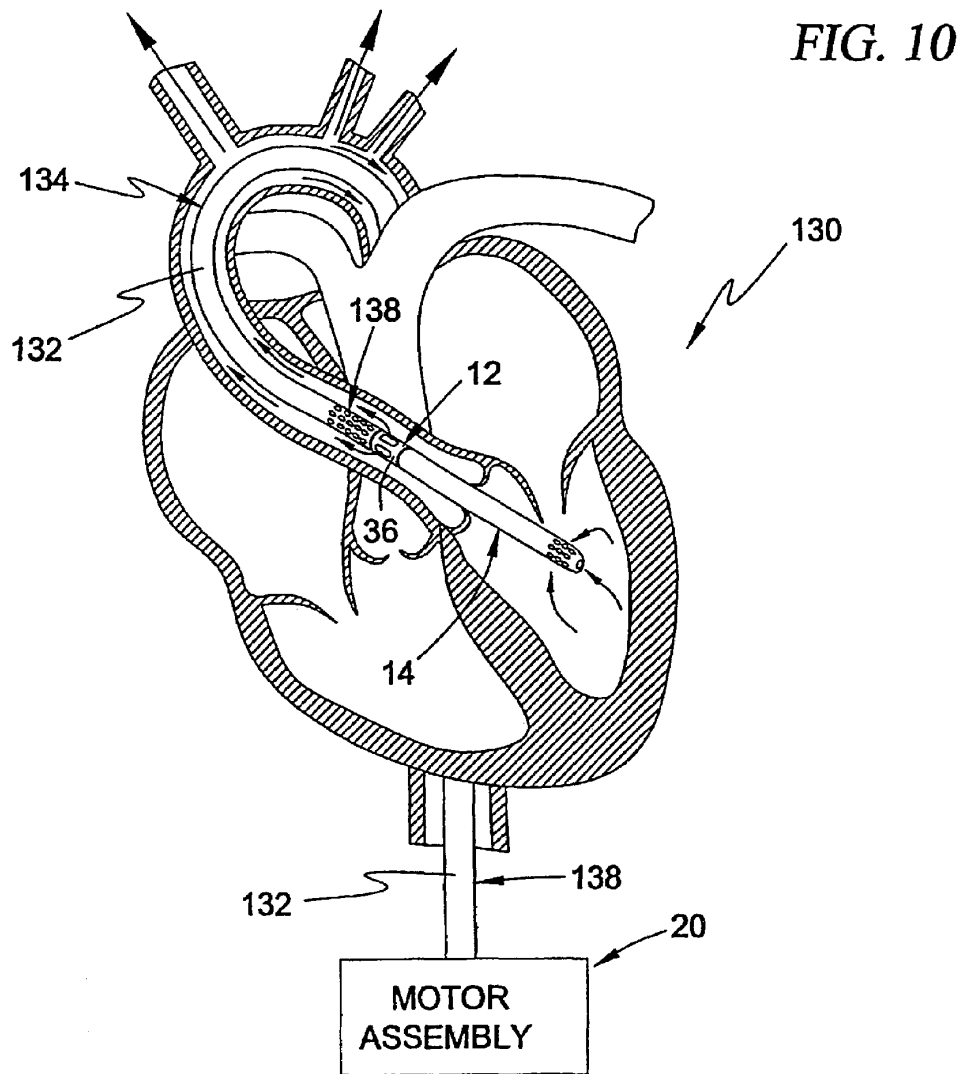


FIG. 12

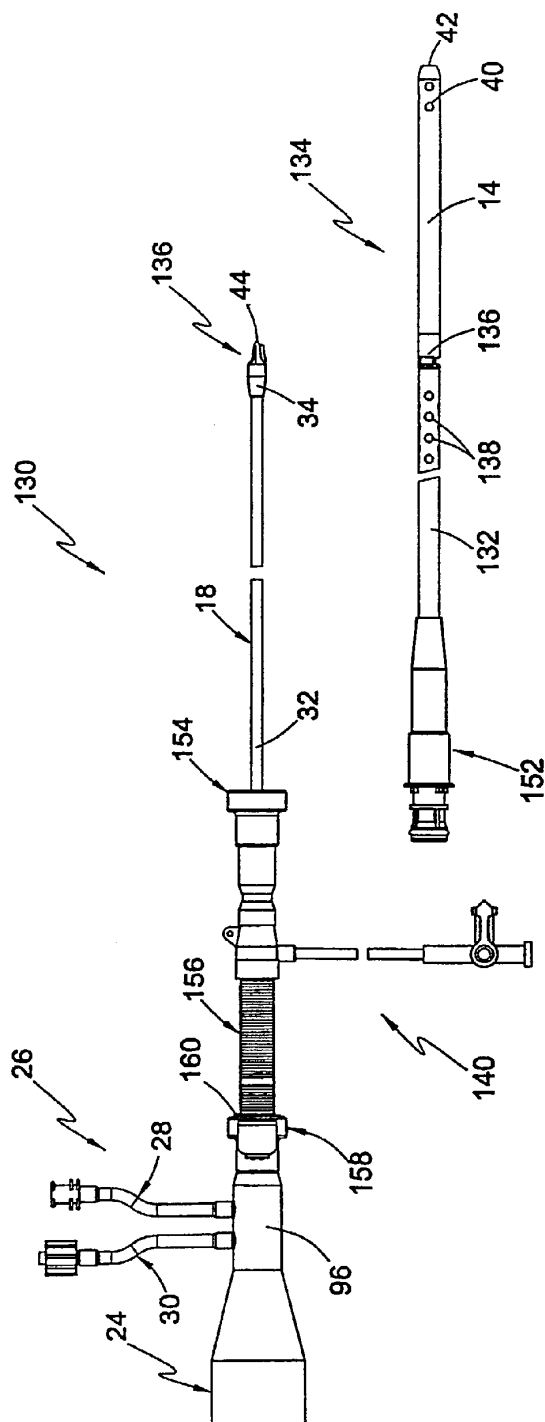


FIG 13

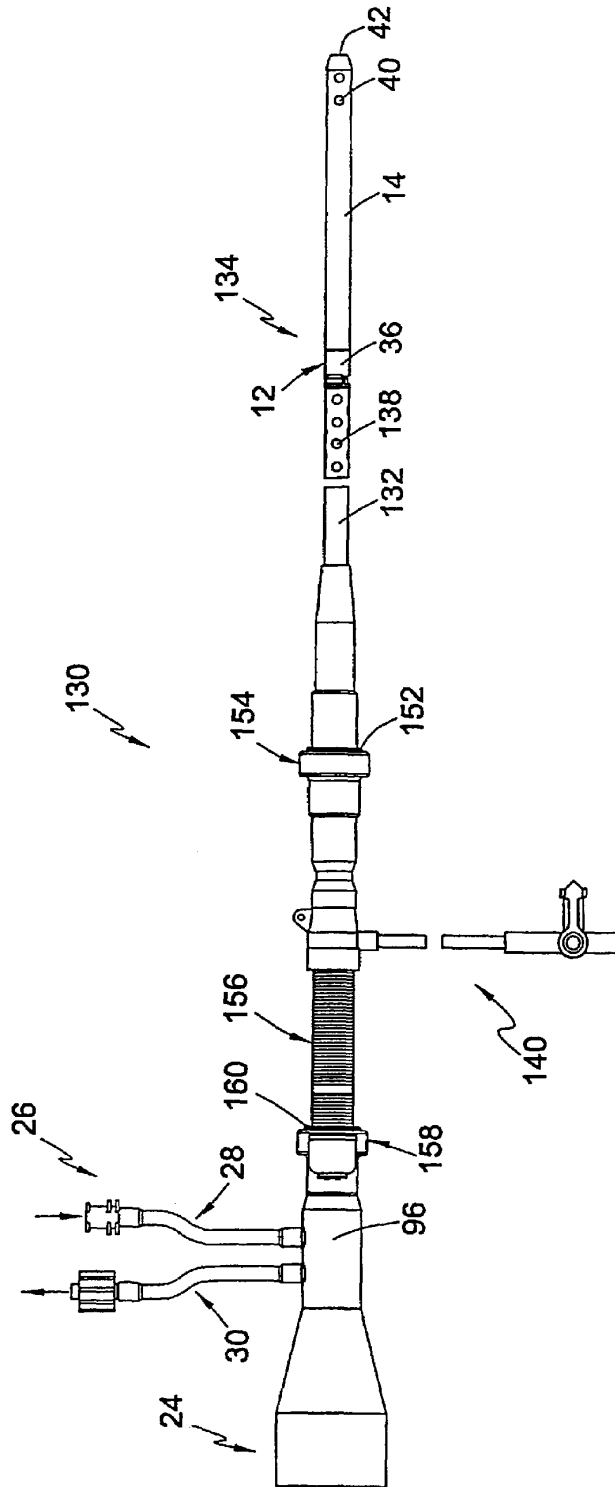
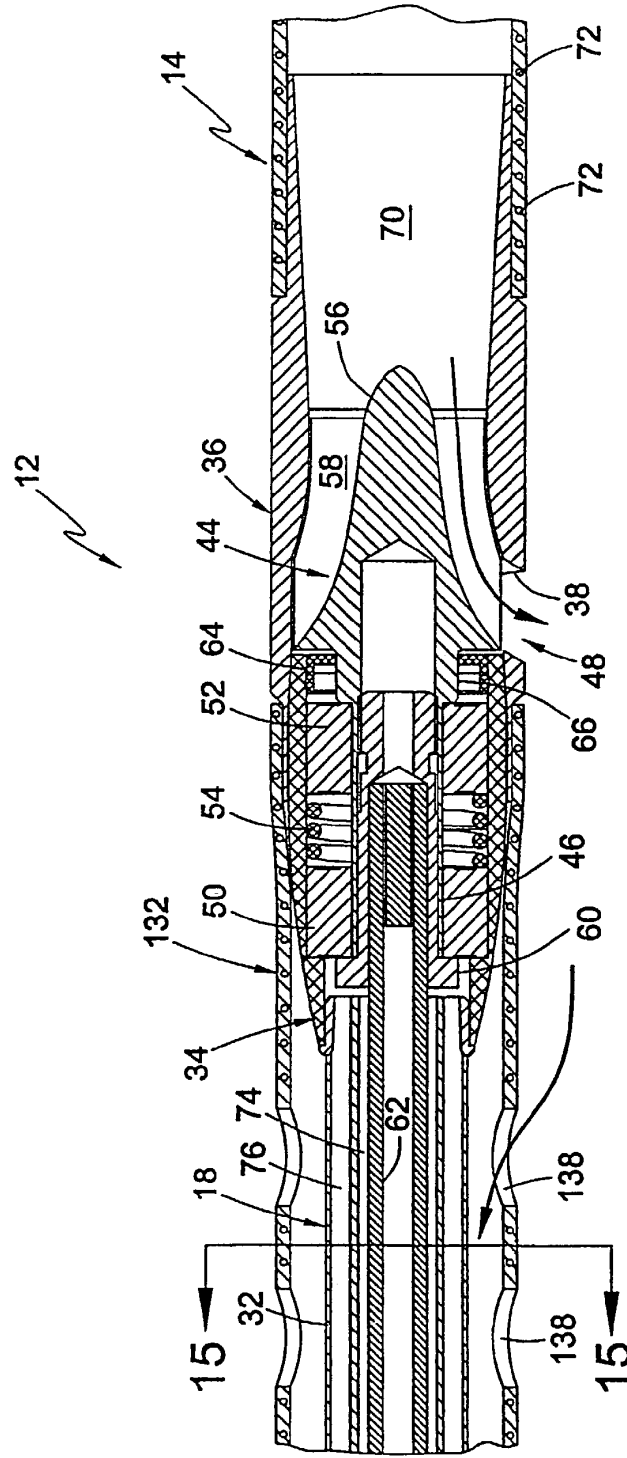


FIG. 14



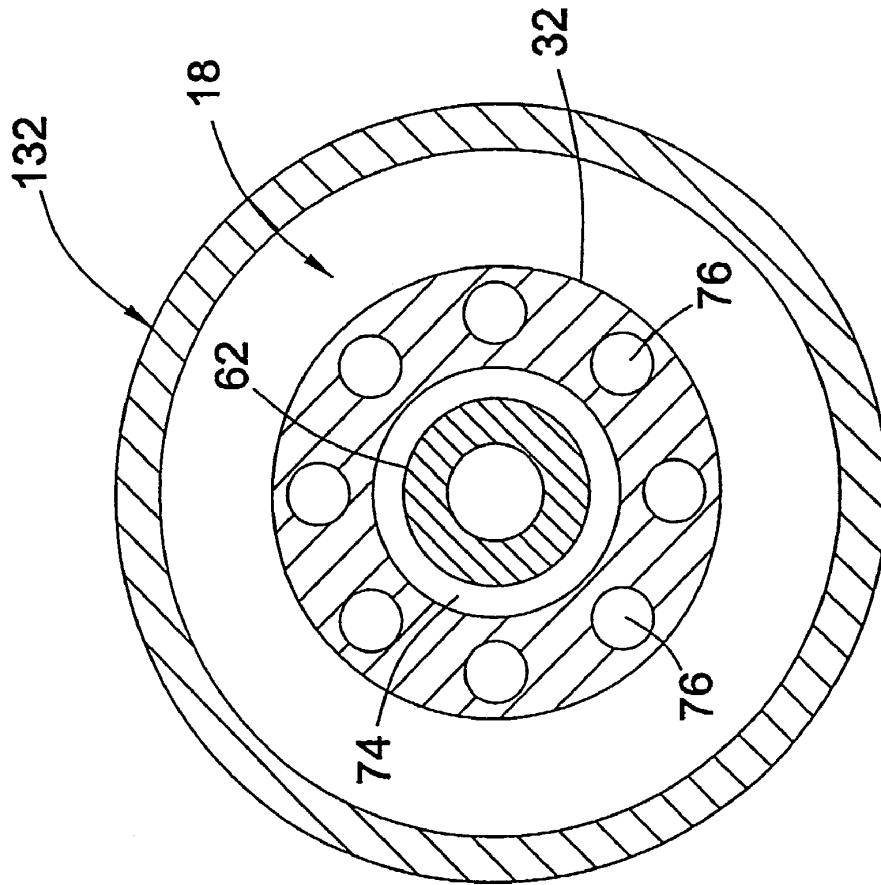
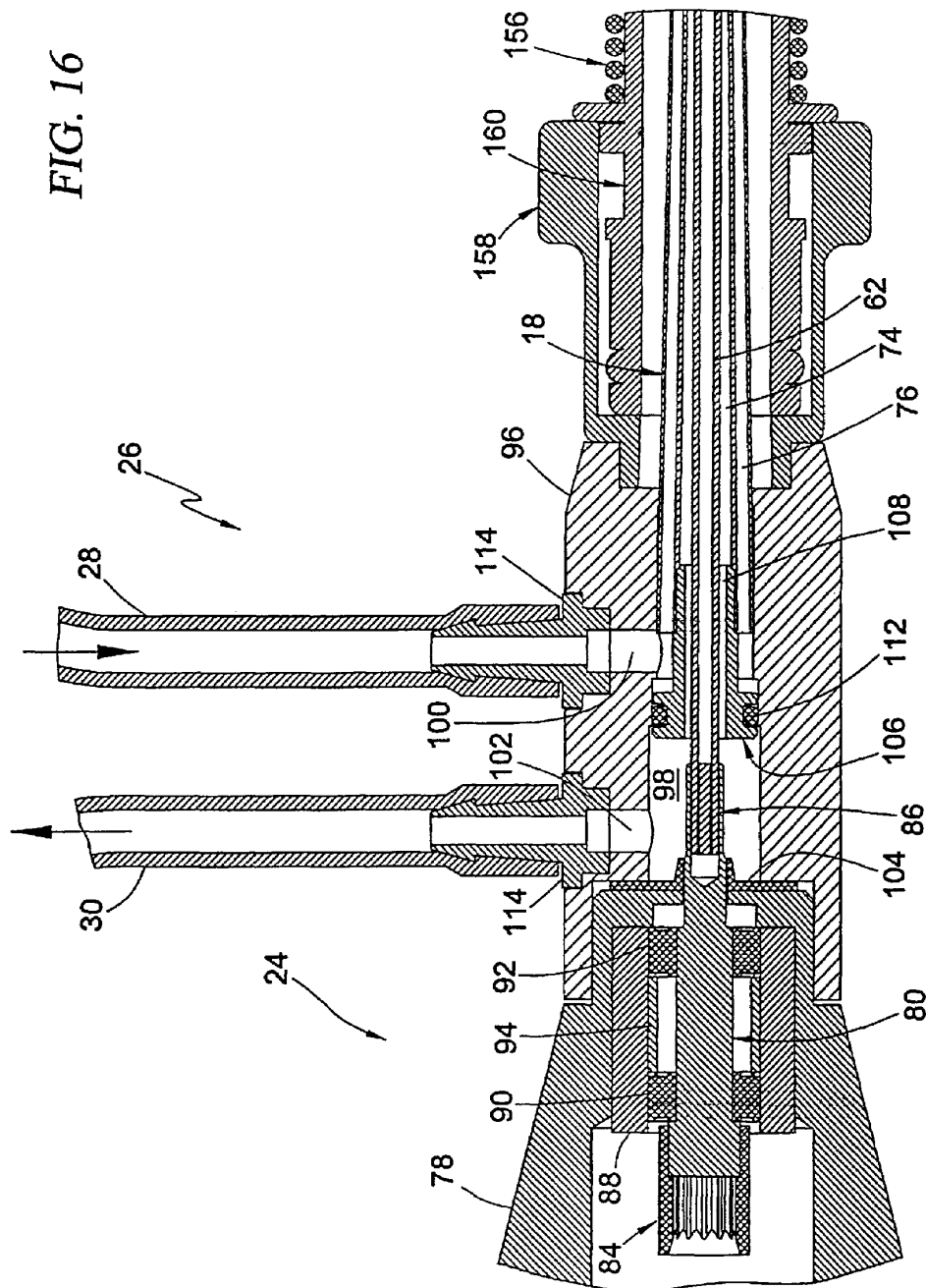


FIG. 15

FIG. 16



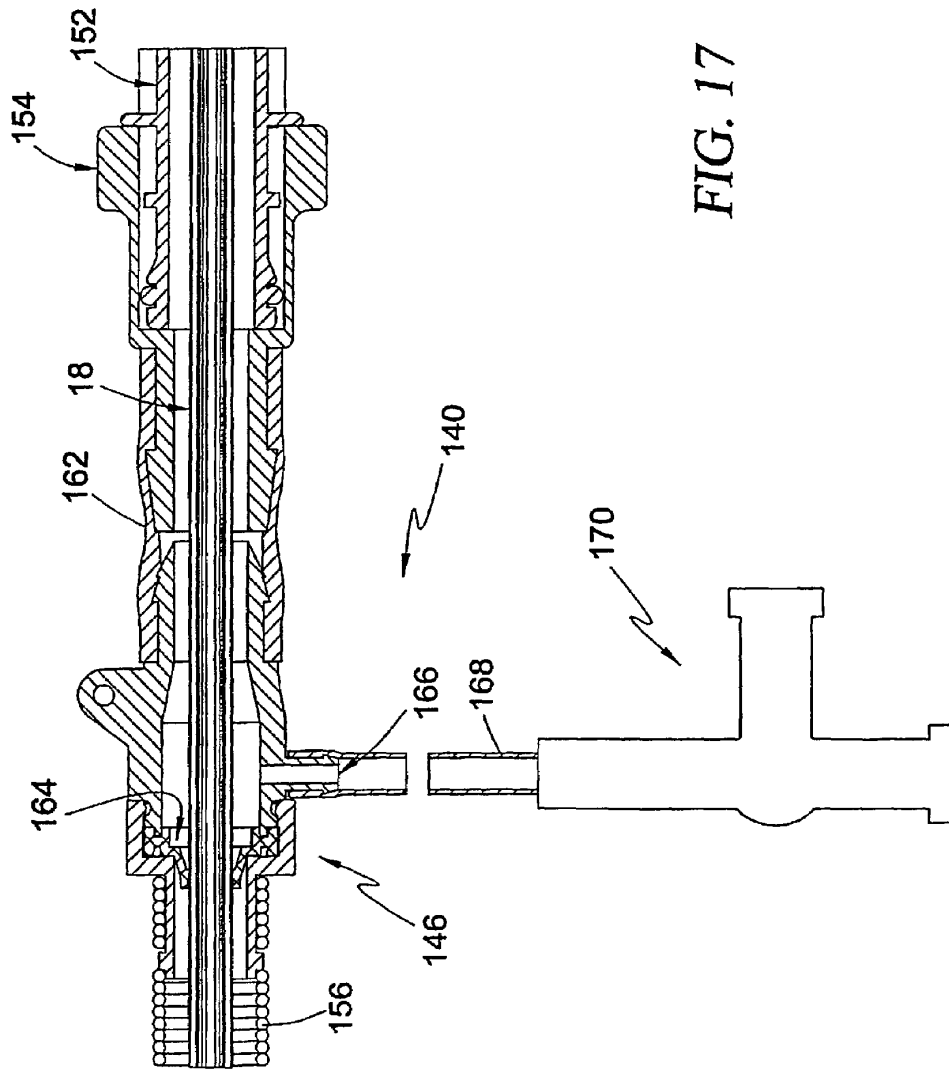
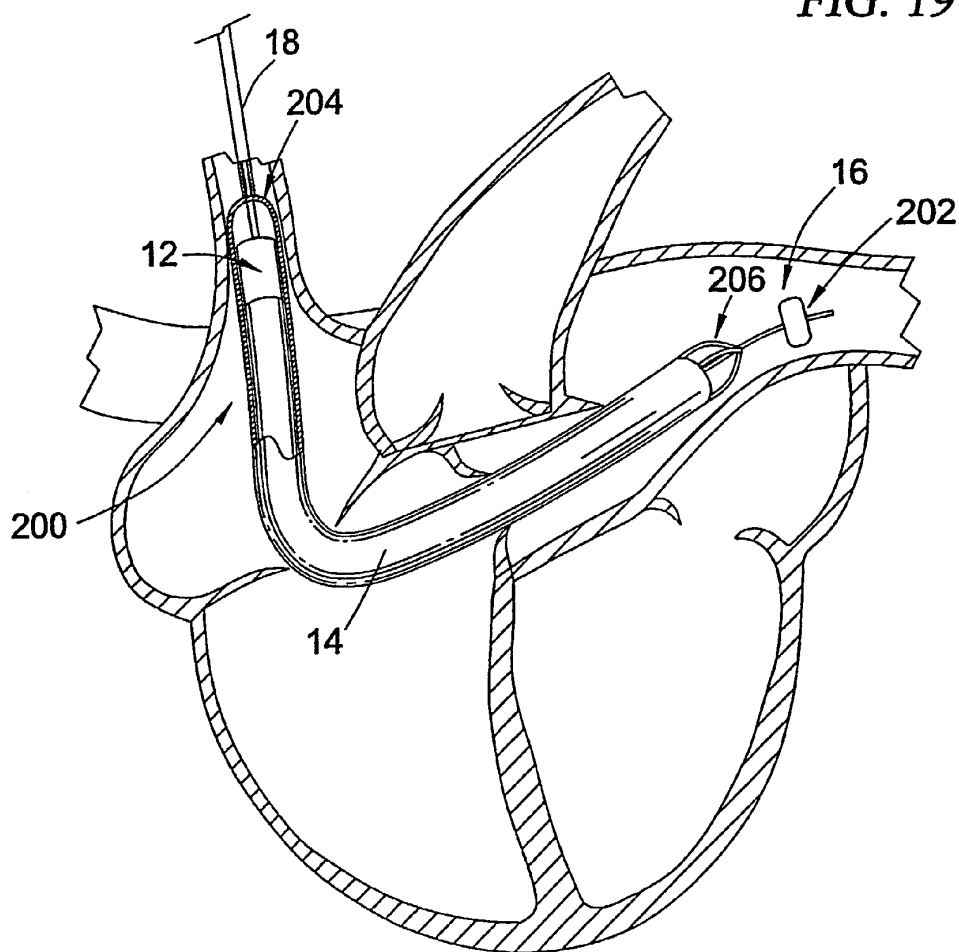


FIG. 19



1

GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS

RELATED APPLICATIONS

This application is a 371 of PCT/US00/24515 filed 1 Sep. 2000, which claims the benefit of provisional U.S. patent application Ser. No. 60/152,249, filed 3 Sep. 1999.

FIELD OF THE INVENTION

The present invention relates generally to blood pumps and, more particularly, to an improved intra-vascular 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.

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 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 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 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 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 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 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 particu-

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lar 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 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 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 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

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 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.

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 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

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intravascular blood pump and cannula may thereafter be advanced along the guide element to the desired location.

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.

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 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.

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.

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

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

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

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

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 detection mechanism comprises at least one of fluid filled column disposed within at least a portion of the cannula, a piezo-electric 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 vasculature of the patient.

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

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

BRIEF DESCRIPTION OF THE DRAWINGS

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

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

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

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

FIG. 4 is a cross-sectional view taken along lines 4—4 of FIG. 3 illustrating an exemplary construction of the drive cable assembly and guide mechanism according to the first broad aspect of the present invention;

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;

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 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 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;

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;

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;

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 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 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 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 lines 15—15 of FIG. 14 illustrating an exemplary construction of the drive cable assembly and guide catheter according to the third broad aspect of the present invention;

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

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

FIG. 18 is a cross-sectional view of an 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

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-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 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 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 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 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 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), cardiopulmonary 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 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 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 done using the control features of the guide wire 22 itself, or may be facilitated through the use of any number of supplemental guidance mechanisms or techniques to ensure the proper and efficient placement of the guide wire 22. Such supplemental guidance techniques may include, but are not necessarily limited to, guide catheters and/or techniques involving ultrasound or fluoroscopy. 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 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 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 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 coupler 24 and, as will be described in greater detail below, a purge fluid delivery system 26 for providing a two-way fluid flow within the drive cable assembly 18 during pump operation. The purge fluid delivery system 26 includes a fluid inlet conduit 28 for introducing pressurized purge fluid from a fluid source (not shown) for delivery into the blood pump 12, and a fluid outlet conduit 30 to withdraw a return flow of purge fluid from the blood pump 12. The motor coupler 24 establishes a mechanical connection between a motor (not shown) and

a drive cable (not shown) for providing motive force to the blood pump 12 for pump operation. The drive cable assembly 18 includes a drive cable sheath 32 which, in addition to serving a purge fluid delivery function, also serves as a protective housing for the drive cable (not shown). Although shown in broken form for clarity, it will be appreciated that the drive cable assembly 18 (and all components thereof) may be provided in any suitable length sufficient for intravascular applications. That is to say, the length of the drive cable assembly 18 must be enough to reach between the motor coupler 24 and purge fluid delivery system 26, located outside the patient, and the desired location within the patient's circulatory system where the blood pump 12 is to be positioned.

The intravascular blood pump 12 is shown (by way of example only) as an axial flow intravascular blood pump. The blood pump 12 includes pump body 34, a rotor shroud 36 having flow ports 38, and an internally disposed rotor (not shown) having a shaft rotatably disposed within the pump body 34 and an impeller rotatably disposed within the rotor shroud 36. The cannula 14 is fixedly attached to the rotor shroud 36 and may extend any suitable length therefrom depending upon the particular intravascular application. The cannula 14 preferably includes a plurality of ports or fenestrations 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 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 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 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.

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 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 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 bearing assemblies 50, 52 are well known in the art, each comprising an inner race which rotates along with the rotor shaft 46, an outer race which remains in a static and fixed position against the inner surface of the pump body 34, and a plurality of ball bearings disposed between the inner and outer races. The spring 54 biases each bearing assembly 50, 52 axially away from one another to reduce axial play during pump operation. The shaft 46 is generally hollow and dimensioned to receive a cable adapter 60 therein for the purpose of coupling the rotor 44 to a drive cable 62 forming part of the drive cable assembly 18. The drive cable 62 may be secured to the cable adapter 60 in any number of suitable fashions, including but not limited to the use of adhesives, crimping, and laser welding. These same techniques may be used to secure the cable adapter 60 within the shaft 46 of the rotor 44. A radial seal 64 is provided in between the wall of the pump body 34 and a distal stepped region 66 on the rotor shaft 46, the function of which will be described below.

The impeller 48 includes a hub 56 and a plurality of blades 58 extending therefrom. The hub 56 is generally conical and, according to the first broad aspect of the present invention, is hollow throughout to form part of the central lumen of the guide mechanism 16. In this regard, the hub 56 is preferably provided with a gasket or seal member 68 at its distal tip. The seal member 68 may be made of any suitable sealing material (including but not limited to silicone) such that the pump 12 and cannula 14 may be easily progressed along the guide wire 22 for delivery to a desired circulatory site. The seal member 68 should also be robust enough to prevent the ingress of blood into the interior of the rotor hub 56 during pump operation, whether the guide wire 22 remains in place or is fully withdrawn. The blades 58 are dimensioned to reside in close tolerance with the interior surface of the shroud 36. In operation, the blades 58 impart both an axial and radial vector on the blood which causes it to flow outward through the flow ports 38 formed in the shroud 36. As used herein, the term “axial flow” is deemed to include flow characteristics like that shown in FIG. 3, which include both an axial and slight radial component. It is to be readily appreciated that, although shown as an axial flow type, blood pump 12 may comprise any number of suitable types of intravascular blood pumps, including but not limited to so-called “mixed flow” intravascular blood pumps without departing from the scope of the present invention.

The cannula 14 is coupled at its proximal end to the rotor shroud 36. This may be accomplished in any number of fashions, including but not limited to the use of adhesives. This may also be facilitated by dimensioning the shroud 36 to include a narrow inlet region 70 capable of being received flushly within the proximal end of the cannula 14. The inlet region 70 of the shroud 36 should preferably have a tapered interior surface for establishing a smooth flow transition between the cannula 14 and the region containing the impeller blades 58. Although shown as a single integral element, it is to be understood that the pump body 34 and

shroud 36 may comprise two separate (and sometimes separable) components, the significance of which will become apparent below. The pump body 34 and shroud 36 may be constructed from any number of suitable materials, including but not limited to stainless steel or other medical grade compositions or alloys. The cannula 14 may also be constructed from any number of suitable materials, including but not limited to medical grade plastics. As shown, the cannula 14 may also be fortified with spiral-wound reinforcement wire 72 within the walls of the cannula 14.

The drive cable assembly 18 includes the drive cable 62 and the drive cable sheath 32. The drive cable 62 is coupled to the rotor 44 via the cable adapter 60. The drive cable sheath 32 includes a central lumen 74 and a plurality of side lumens 76. The central lumen 74 serves as a protective covering for the drive cable 62. The central lumen 74, along with the side lumens 76, also forms part of the purge fluid delivery system 26 shown above in FIG. 2, which will be described in greater detail below. The side lumens 76 are provided in fluid communication with the fluid inlet conduit 28, while the 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 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 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 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 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 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 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. The spring 94 is provided to bias each bearing assembly 90, 92 axially away from one another to reduce axial play during operation.

The purge fluid delivery system 26 includes a housing 96 having a central lumen 98, an inflow port 100, and an outflow port 102. The housing 96 is also dimensioned to matingly receive a portion of the motor coupler 24. In this regard, a seal element 104 is provided sandwiched in between the housing 96 and housing 78 and including an aperture which extends about the drive shaft adapter 80 as it exits the housing 78 to prevent the ingress of purge fluid into the motor coupler 24. A fluid guide structure 106 is also provided within the central lumen 98 for the purpose of separating the inflow and outflow ports 100, 102. The fluid guide structure 106 includes a central lumen 108 through which the drive cable 62 extends, and an elevated portion 110 that retains an O-ring 112 against the inner surface of the central lumen 98 of the housing 96. The drive cable sheath 32 is secured to the housing 96 such that the inflow port 100 is communicatively coupled to the side lumens 76, and the outflow port 102 is communicatively coupled to the central lumen 74. In this fashion, pressurized purge fluid may be introduced through the inflow port 100 via inflow conduit 28, and removed through the outflow port 102 via outflow conduit 30. By way of example, the inflow conduit 28 and outflow conduit 30 may be coupled to their respective ports 100, 102 via barbed connectors 114. Similarly, the inflow and outflow conduits 28, 30 may be equipped with any number of suitable connectors (such as those illustrated by way of example in FIG. 2) for establishing fluid communication with a source of pressurized fluid (not shown). The pressurized fluid source (not shown) may include, but is not necessarily limited to, the use of a syringe, an inflater, 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 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 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 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 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 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 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 "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 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 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 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 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 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 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.

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

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to include such central lumens as was required with the intravascular blood pump system 10 set forth above.

Referring to FIG. 10, shown is a guidable 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 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 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, 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 cannula 14 coupled to the rotor shroud 36. 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 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) 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 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 fluoroscopy. 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

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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.

An exemplary docking arrangement will now be described with reference to FIG. 14. In a preferred embodiment, the rotor 44 may be properly and accurately docked within the shroud 36 by forming angled mating surfaces on corresponding portions of the shroud 36 and 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 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 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

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blood pump 12. 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 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 spring 156 is provided in between the perfusion assembly 140 and the housing 96 of the purge fluid delivery system 26. The bias spring 156 is preferably dimensioned so as to be in tension when the male quick-connect 152 is engaged within the female quick-connect 154 as part of the docking process of the present invention. As such, the bias spring 156 serves to maintain the pump assembly 136 in the docked position within the rotor shroud 36. The bias spring 156 may be coupled to the housing 96 of the purge fluid delivery system 26 in any number of suitable fashions. One such coupling arrangement may comprise a female quick-connect coupling 158 attached to the housing 96 and a male quick-connect coupling 160 attached to the bias spring 156.

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

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

FIG. 18 illustrates an alternate configuration of the intra-vascular blood pump system 130 of the third broad aspect of the present invention having an alternate bearing assembly, purge fluid delivery, and docking scheme. The bearing assembly includes a seal spring 182 and a bearing assembly 180. The bearing assembly 180 includes an inner race 184, an outer race 186, and a plurality of balls 188 which enable the inner race 184 to rotate along with the rotor shaft 46 while the outer race 186 remains in a static and fixed position relative to an inner surface of the pump body 34. An O-ring 190 is disposed within a groove formed in the rotor shaft 46 so as to maintain the bearing assembly 180 against

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the seal spring 182. The O-ring 190 is further secured within the groove in the rotor shaft 46 via a contoured lip portion extending from the distal end of the cable adapter 60. The proximal end of the cable adapter 60 flushly engages the drive cable 62.

The purge fluid delivery system of the embodiment shown in FIG. 18 provides for a one way delivery of purge fluid to the blood pump 12. That is, pressurized fluid (namely, fluid pressurized to some level elevated above the blood pressure in the surrounding vessel) is injected in between the drive cable 62 and the interior of the protective sheath 32 during operation. This serves to reduce any frictional heating that exists between the drive cable 62 and sheath 32. The pressurized fluid also flows through the interior of the pump 12 such that, if the seal at 192 is broken, the pressurized fluid will flow past the open seal 192 and onward through the blood flow ports 38 formed in the shroud 36. This serves to keep blood from entering the pump 12 in an effort to avoid clotting and/or damaging the pump 12.

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

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

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disposed within an annular engagement groove formed along the exterior surface of the pump body 34.

While this invention has been shown in use largely in during left-heart applications, it is to be readily appreciated that this does not limit the applications of this invention for use in left heart support only. Rather, the guidable intravascular blood pump of the present invention can be utilized in right-heart support applications and a wide variety of other applications apparent to those skilled in the art. For example, with reference to FIG. 19, shown is an intravascular blood pump 200 (of the type shown and described above with reference to FIGS. 2-5) configured 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 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 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 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 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 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 over the balloon catheter 202 until the fluid inlet 204 is disposed within the vena cava (or right atrium) and the fluid outlet 206 is positioned within the pulmonary artery. The pump 12 may then be selectively (i.e. automatically or on-demand) controlled to transport blood from the vena cava (or right atrium) in a trans-valvular fashion through the tricuspid valve, the right ventricle, and the pulmonary valve for deposit within the pulmonary artery. Providing right-heart support during beating heart surgery advantageously overcomes conditions where cardiac output may become compromised during beating heart surgery, such as when the heart is lifted to gain access to posterior vessels, thereby avoiding the need for cardiopulmonary bypass.

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

Those skilled in the art will also appreciate that, although shown and described above in terms of "axial flow," the

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

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

It is also contemplated to incorporate various pressure sensing and/or guidability features into at least one of the cannula 14 and pump 12. Such features may include, but are not necessarily limited to, those shown and described in commonly-owned and co-pending U.S. patent application Ser. No. 09/280,988 (filed Mar. 30, 1999) entitled "Steerable Cannula," and U.S. patent application Ser. No. 09/280,970 (filed Mar. 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 intravascular blood pump system comprising:
an intravascular blood pump having a cannula coupled thereto, said intravascular blood pump including a rotor, a shroud for receiving said rotor, and a drive

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cable coupled to said rotor for driving said rotor within said shroud, said cannula being coupled to said shroud of said intravascular blood pump, and

a guide mechanism adapted to guide said intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient, wherein said guide mechanism comprises a guide catheter coupled to said shroud.

2. The intravascular blood pump system of claim 1 and further, wherein a perfusion assembly is provided communicatively coupled to said guide catheter for selectively rerouting blood from within said guide catheter to a point downstream from the introduction site of said guide catheter into the vasculature of said patient.

3. The intravascular blood pump system of claim 2 and further, wherein said perfusion assembly includes a first conduit communicatively coupled to said guide catheter, a second conduit dimensioned to be introduced into the vasculature of the patient, and a selectively operable valve disposed in between said first conduit and said second conduit.

4. The intravascular blood pump system of claim 1 and further, wherein said guide mechanism further includes guide element for passage through the guide catheter to facilitate placement of said shroud and said cannula at said predetermined location within the vasculature of the patient.

5. The intravascular blood pump system of claim 4 and further, wherein said guide element comprises at least one of a guide wire and a balloon catheter.

6. The intravascular blood pump system of claim 1 and further, wherein said guide mechanism further includes a guide element for passage through a side lumen formed along at least a portion of said guide catheter.

7. The intravascular blood pump system of claim 6 and further, wherein said guide element comprises at least one of a guide wire and a balloon catheter.

8. The intravascular blood pump system of claim 1 and further, wherein said guide catheter may be used to guide said shroud and cannula to said predetermined location within the circulatory system of said patient, after which point said rotor and drive cable of said intravascular blood pump may be docked within said shroud for pump operation.

9. An intravascular blood pump system comprising:
an intravascular blood pump having a cannula coupled thereto, said intravascular blood pump including a rotor, a shroud for receiving said rotor, and a drive cable coupled to said rotor for driving said rotor within said shroud, and

a guide mechanism adapted to guide said intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient, wherein a drive cable sheath is provided having a central lumen for receiving said drive cable, and wherein a purge fluid delivery system is coupled to said drive cable sheath to deliver purge fluid to said rotor.

10. The intravascular blood pump system of claim 9 and further, wherein said guide mechanism comprises a guide element disposed at least partially within said cannula.

11. The intravascular blood pump system of claim 10 and further, wherein said guide element comprises a guide wire for passage through a side lumen formed in said cannula.

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12. The intravascular blood pump system of claim 11 and further, wherein said intravascular blood pump and cannula may be selectively advanced to said predetermined location within the vasculature of the patient by first passing said guide wire to said predetermined location and thereafter sliding said intravascular blood pump and cannula along said guide wire to said predetermined location.

13. The intravascular blood pump system of claim 10 and further, wherein said guide element comprises a selectively deformable element disposed at least partially within said cannula.

14. The intravascular blood pump system of claim 9 and further, wherein said drive cable sheath includes at least one side lumen for delivering said purge fluid towards said rotor.

15. The intravascular blood pump system of claim 14 and further, wherein a portion of said purge fluid is delivered through said at least one side lumen and past said rotor, and a portion of purge fluid is rerouted back from said rotor through said central lumen of said drive cable.

16. An intravascular blood pump system comprising:
an intravascular blood pump having a cannula coupled thereto,

a guide mechanism adapted to guide said intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient, and a blood pressure detection mechanism to detect the pressure of the blood proximate at least one of the intravascular blood pump and cannula.

17. The intravascular blood pump system of claim 16 and further, wherein said blood pressure detection mechanism comprises at least one of fluid filled column disposed within at least a portion of said 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.

18. The intravascular blood pump system of claim 16 and further, wherein said blood pressure detection mechanism involves calculating blood pressure based on the relationship between the torque and motor current of a motor used to drive said rotor.

19. An intravascular blood pump system comprising:
an intravascular blood pump having a cannula coupled thereto, said intravascular blood pump including a rotor, a shroud for receiving said rotor, and a drive cable coupled to said rotor for driving said rotor within said shroud, and

a guide mechanism adapted to guide said intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient, said guide element comprising a guide wire for passage through a lumen extending through said drive cable and rotor.

20. The intravascular blood pump system of claim 19 and further, wherein said intravascular blood pump and cannula may be selectively advanced to said predetermined location within the vasculature of the patient by first passing said guide wire to said predetermined location and thereafter sliding said intravascular blood pump and cannula along said guide wire to said predetermined location.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

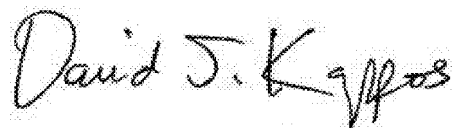
PATENT NO. : 7,022,100 B1
APPLICATION NO. : 10/070178
DATED : April 4, 2006
INVENTOR(S) : Aboul-Hosn et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 4, line 55, please delete “predetermine” and insert --predetermined--;
Column 7, line 19, please delete “slideably” and insert --slidably--;
Column 8, line 49, please delete “slideably” and insert --slidably--;
Column 9, line 11, please delete “Ball bearings” and insert --Ball bearing--;
Column 10, line 47, please delete “slideably” and insert--slidably--;
Column 17, line 3-4, please delete “in during” and insert --during--;
Column 17, line 37, please delete “involve advanced” and insert --involve advancement--;
Column 17, line 38, please delete “overt” and insert --over--;
Column 20, line 59, please delete “predetermine” and insert --predetermined--;

Signed and Sealed this
Twenty-eighth Day of December, 2010

A handwritten signature in black ink that reads "David J. Kappos". The signature is written in a cursive, flowing style with a large initial "D" and a stylized "K".

David J. Kappos
Director of the United States Patent and Trademark Office

Maquet, Ex. 2001-93
IPR2017-02151

U.S. PATENT NO. 8,888,728



US00888728B2

(12) **United States Patent**
Aboul-Hosn et al.

(10) **Patent No.:** **US 8,888,728 B2**
(45) **Date of Patent:** **Nov. 18, 2014**

(54) **GUIDABLE INTRAVASCULAR BLOOD PUMP
AND RELATED METHODS**

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(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 98 days.

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(22) Filed: **May 3, 2010**

(65) **Prior Publication Data**
US 2010/0210895 A1 Aug. 19, 2010

Related U.S. Application Data

(60) Continuation of application No. 11/375,926, filed on
Mar. 15, 2006, now Pat. No. 7,731,675, which is a
division of application No. 10/070,178, filed as
application No. PCT/US00/24515 on Sep. 1, 2000,
now Pat. No. 7,022,100.

(60) Provisional application No. 60/152,249, filed on Sep.
3, 1999.

(51) **Int. Cl.**
A61M 1/12 (2006.01)
A61M 1/10 (2006.01)

(52) **U.S. Cl.**
CPC **A61M 1/101** (2013.01); **A61M 1/102**
(2013.01); **A61M 1/1034** (2013.01); **A61M**
1/125 (2013.01); **Y10S 415/90** (2013.01)
USPC **604/6.11**; 623/3.1; 623/3.13; 623/3.15;
415/900

(58) **Field of Classification Search**

CPC A61M 1/10; A61M 1/12; A61M 1/101;
A61M 2001/10; A61M 2001/12; A61M
2001/122; A61M 2001/125; A61M
2001/1034; A61M 25/0015; A61M 25/0052;
A61M 25/0169; A61M 25/0172; A61M
2025/0079; A61M 2039/0235
USPC 604/43, 156, 158, 540; 623/3.1; 600/16
See application file for complete search history.

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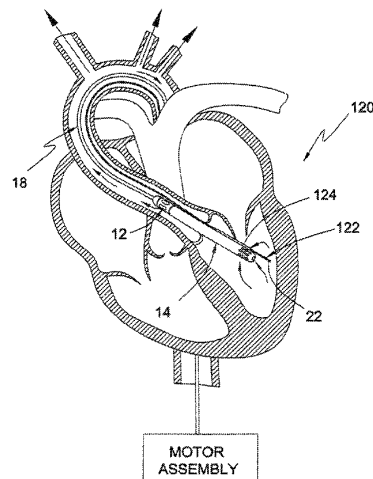
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Primary Examiner — Adam Marcetich

(57) **ABSTRACT**

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

24 Claims, 18 Drawing Sheets



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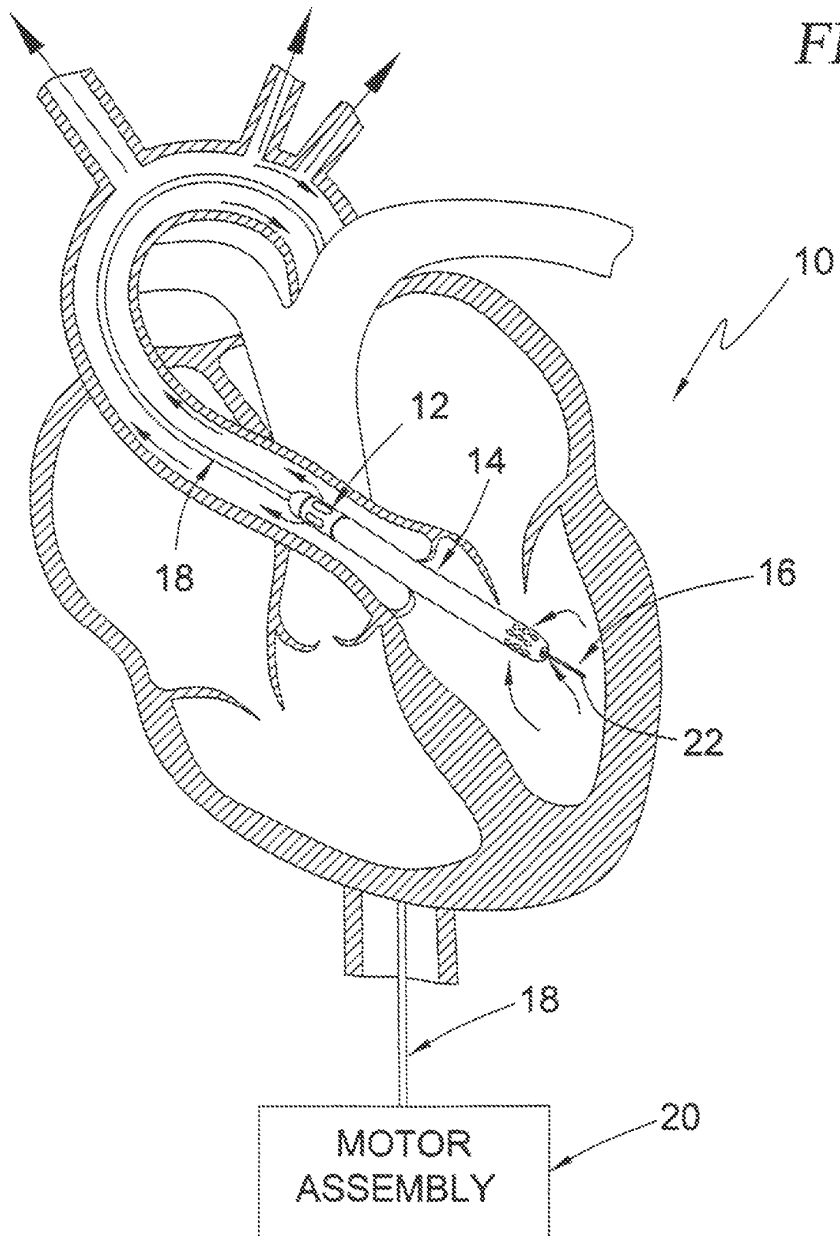


FIG. 2

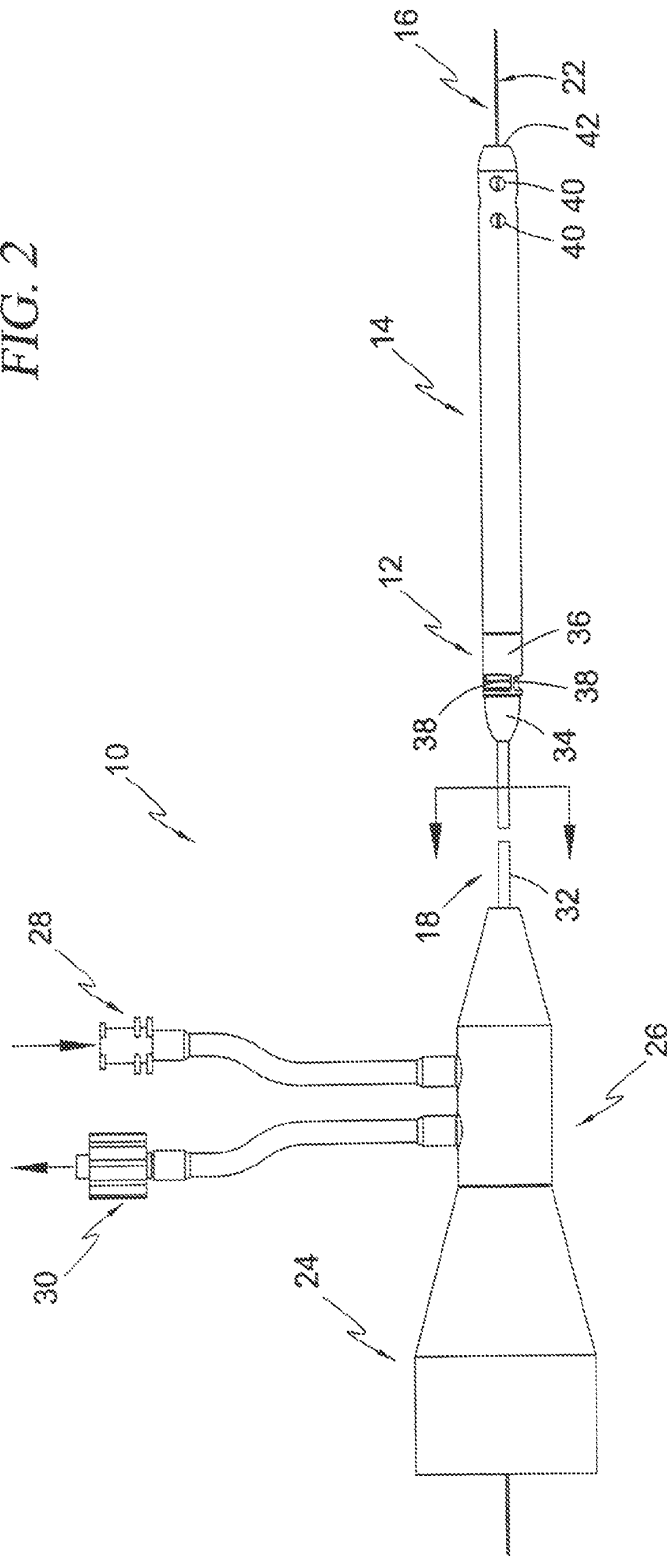
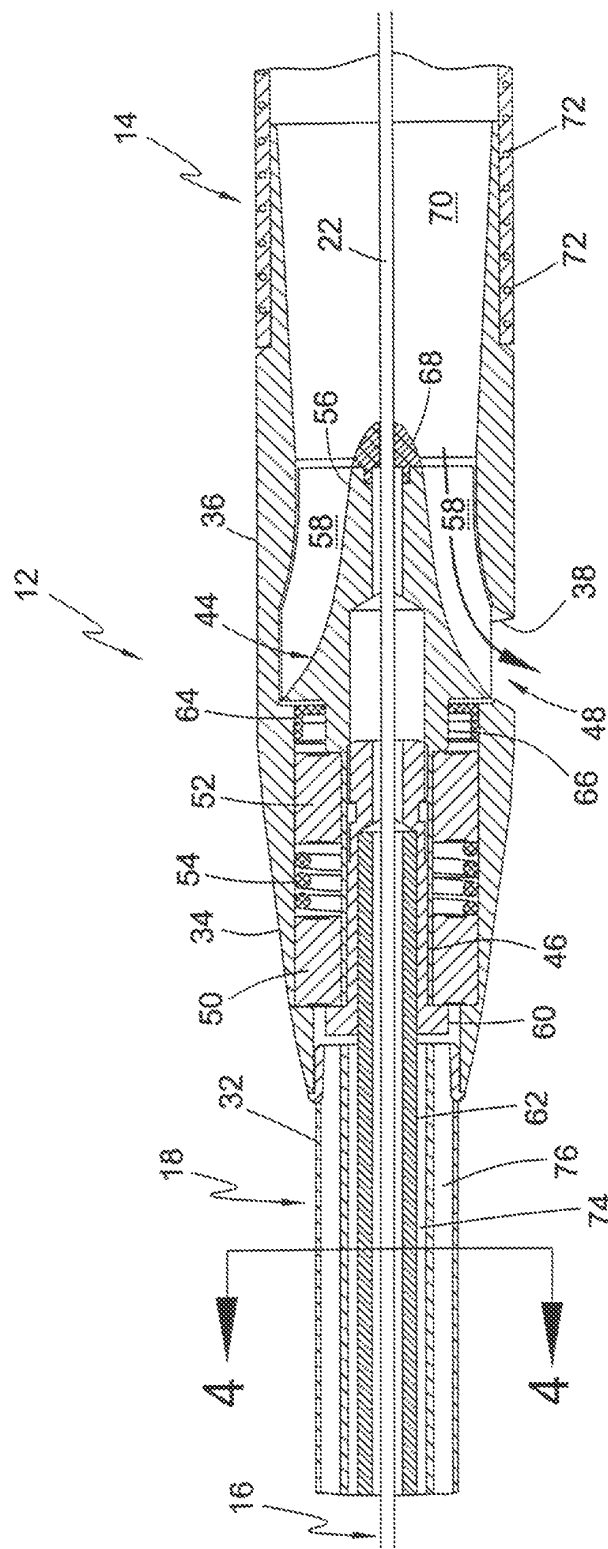


FIG. 3



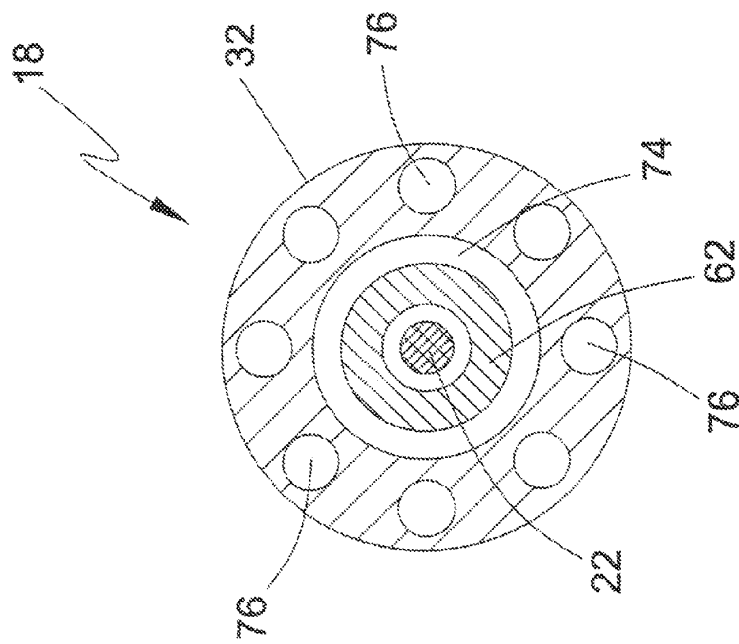


FIG. 4

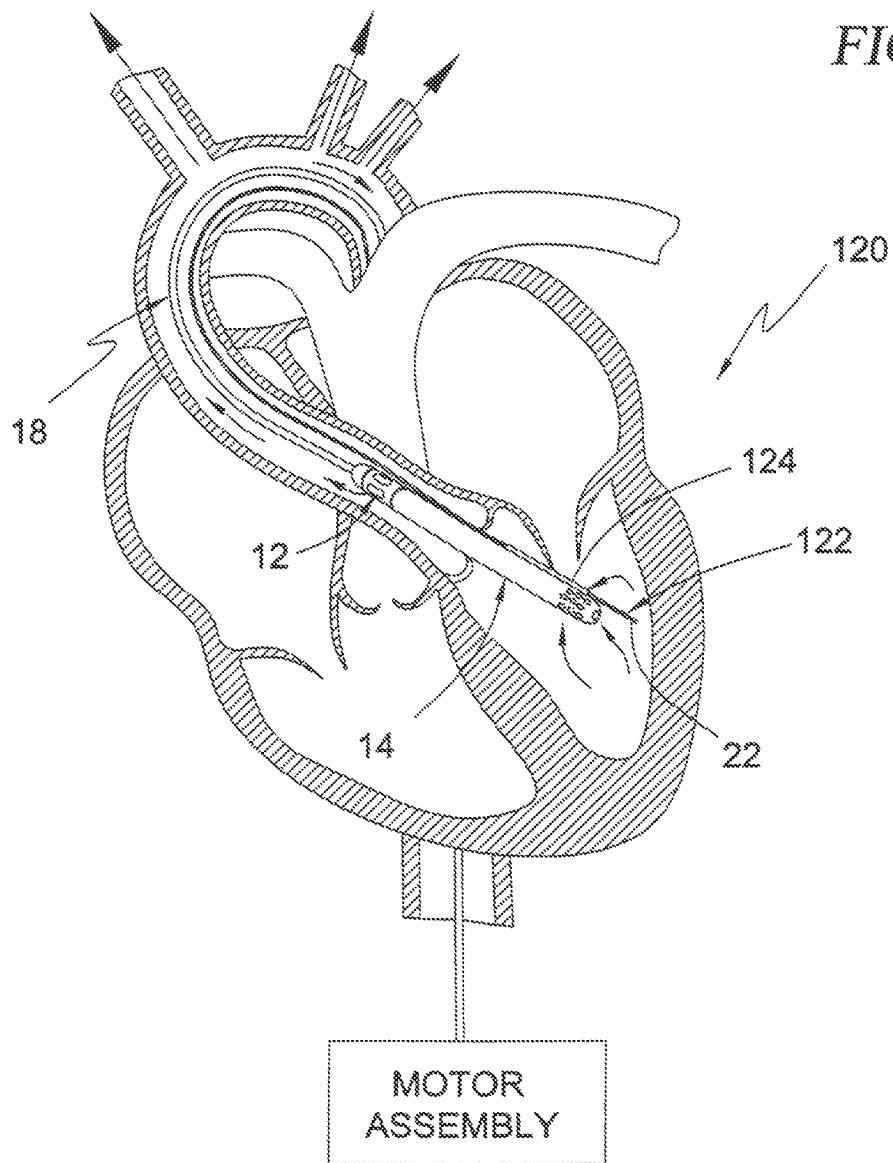
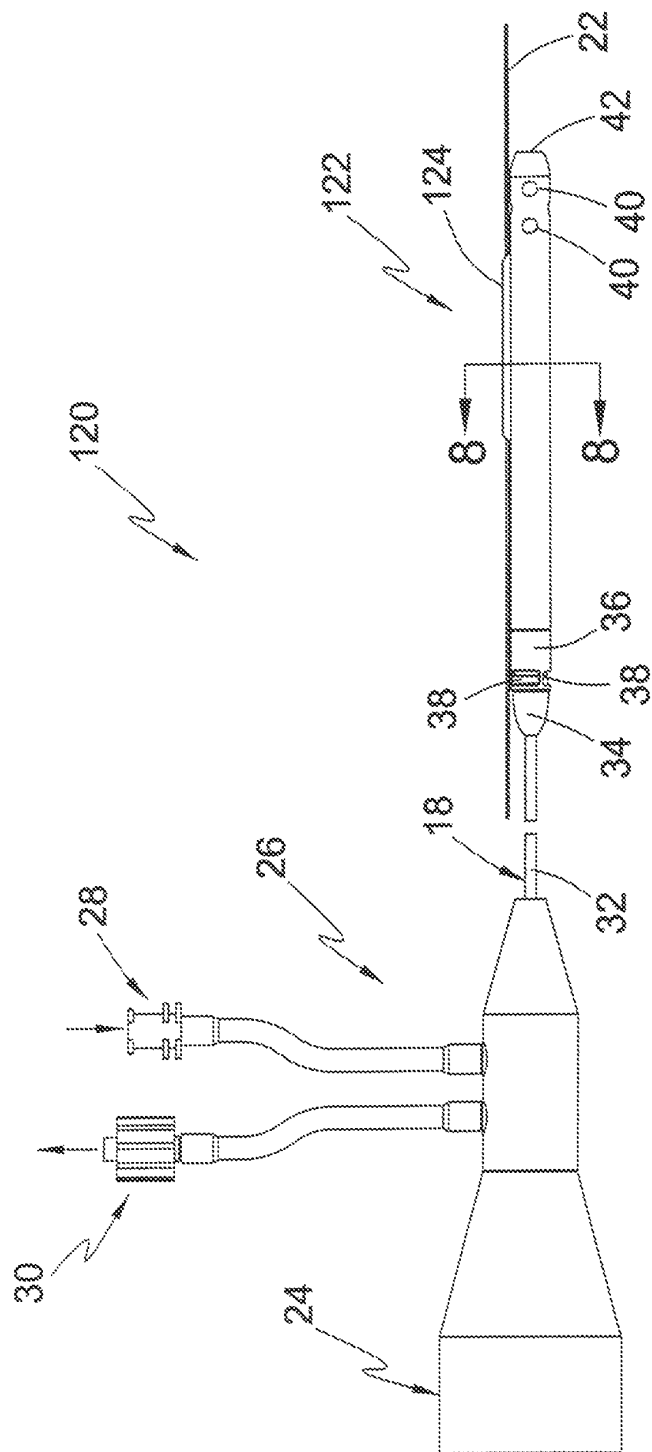


FIG. 7



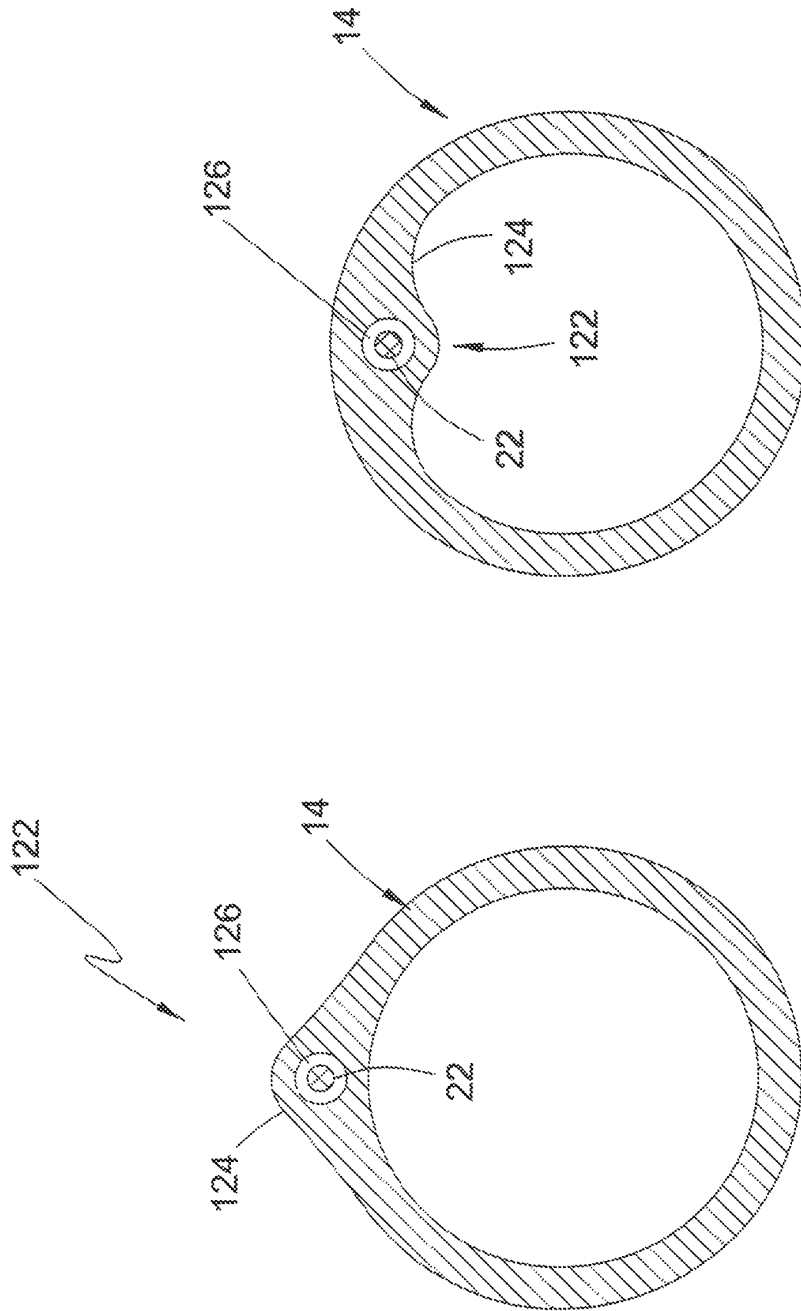


FIG 9

FIG 8

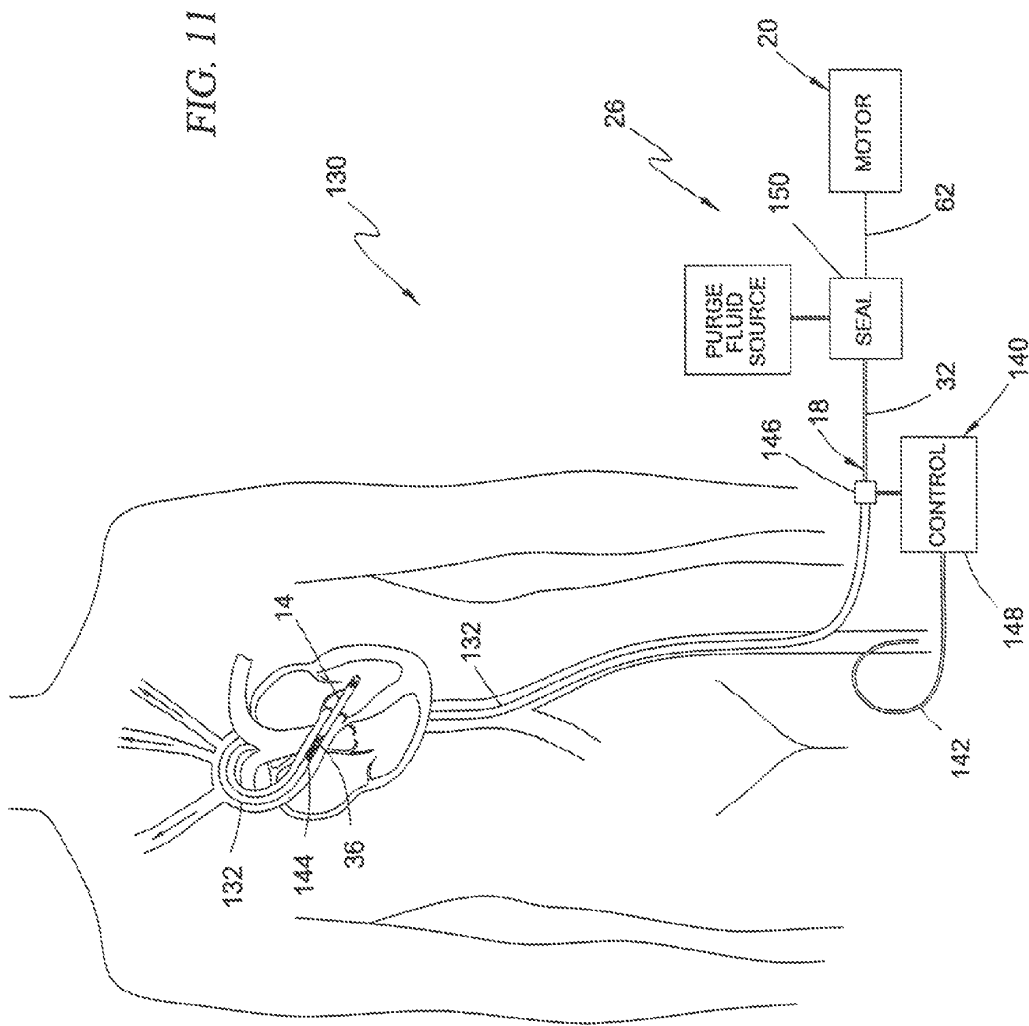


FIG 13

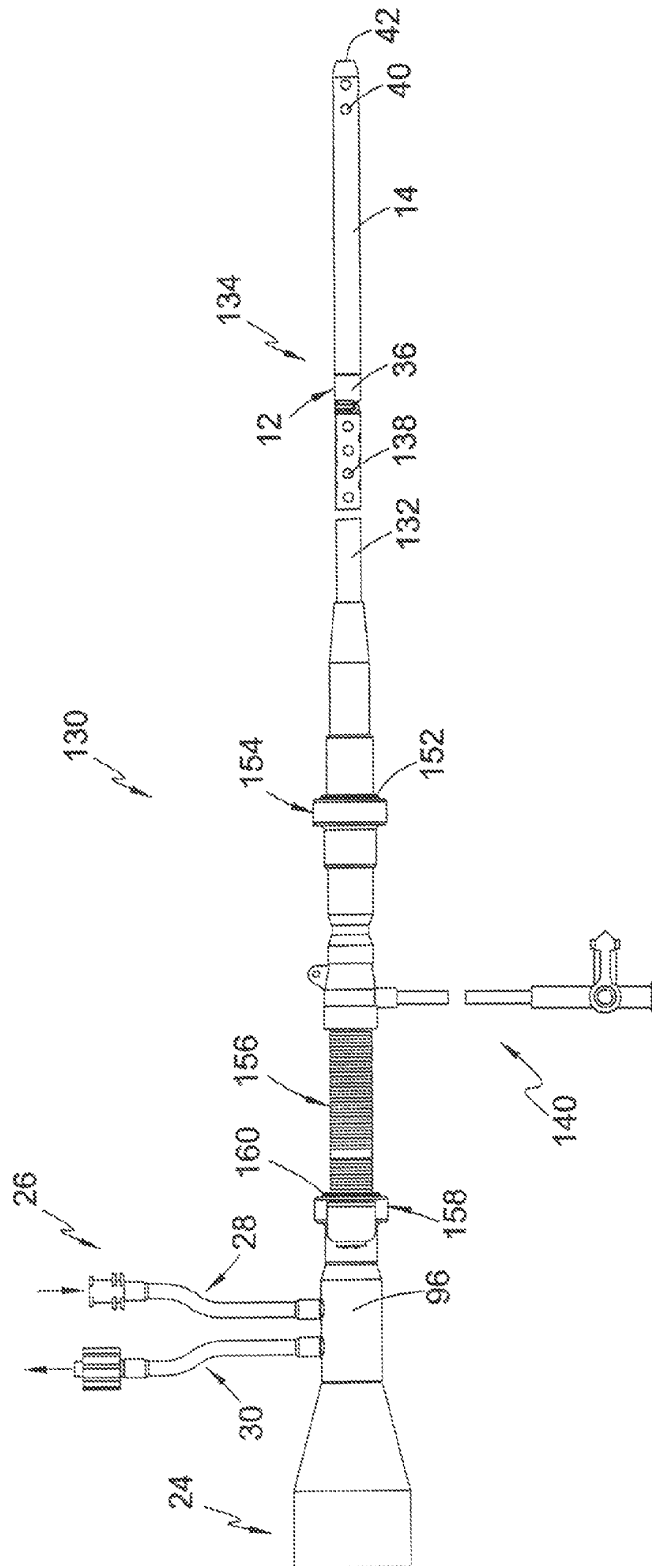
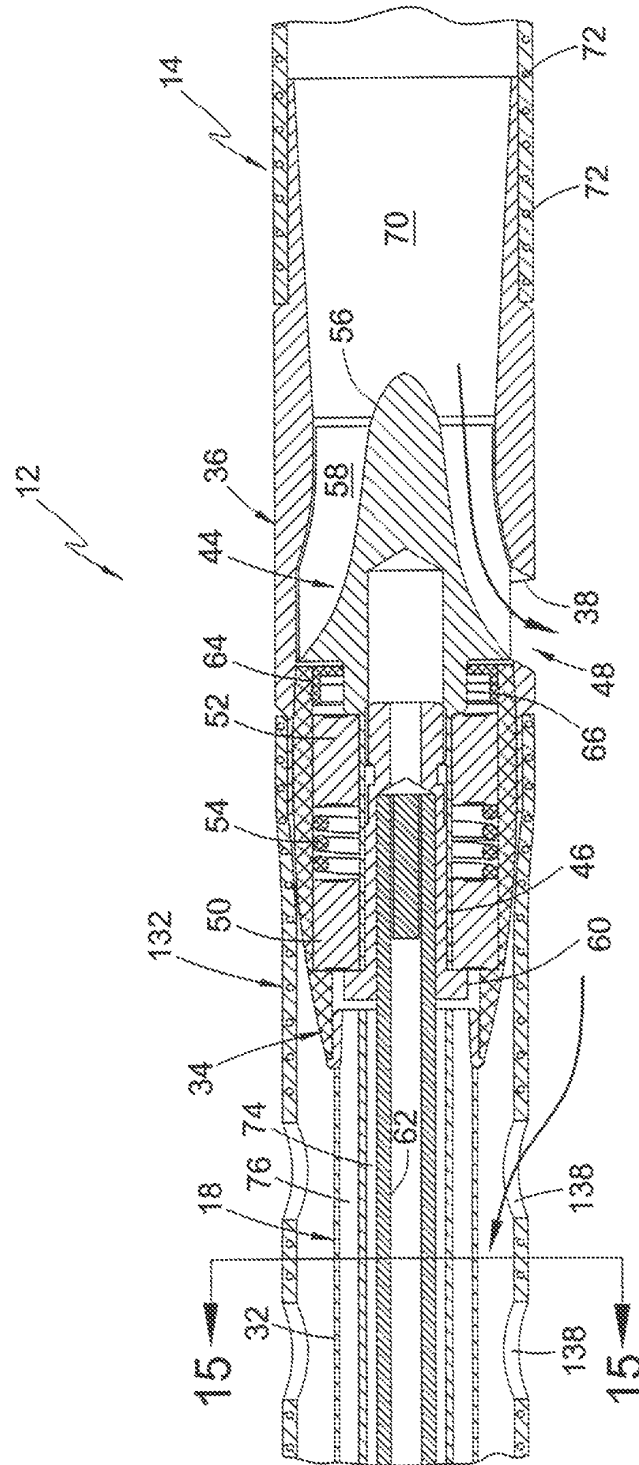


FIG. 14



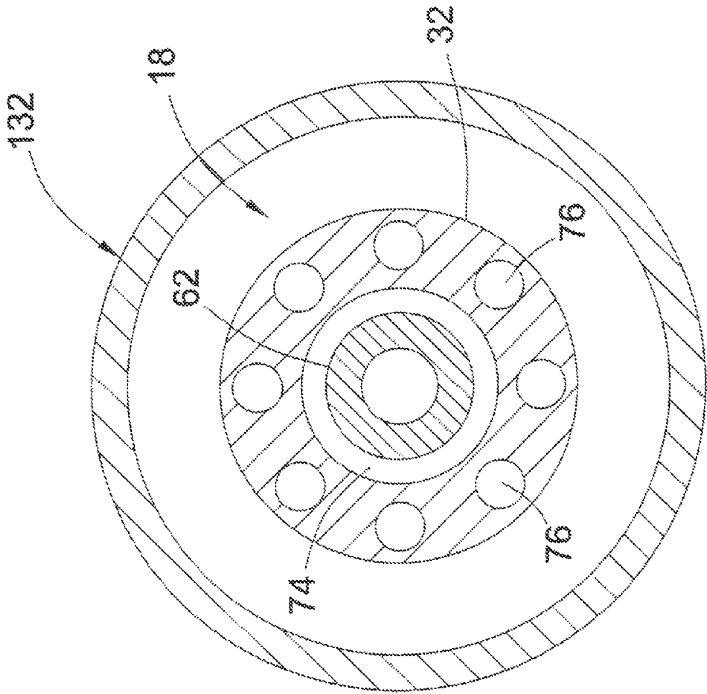
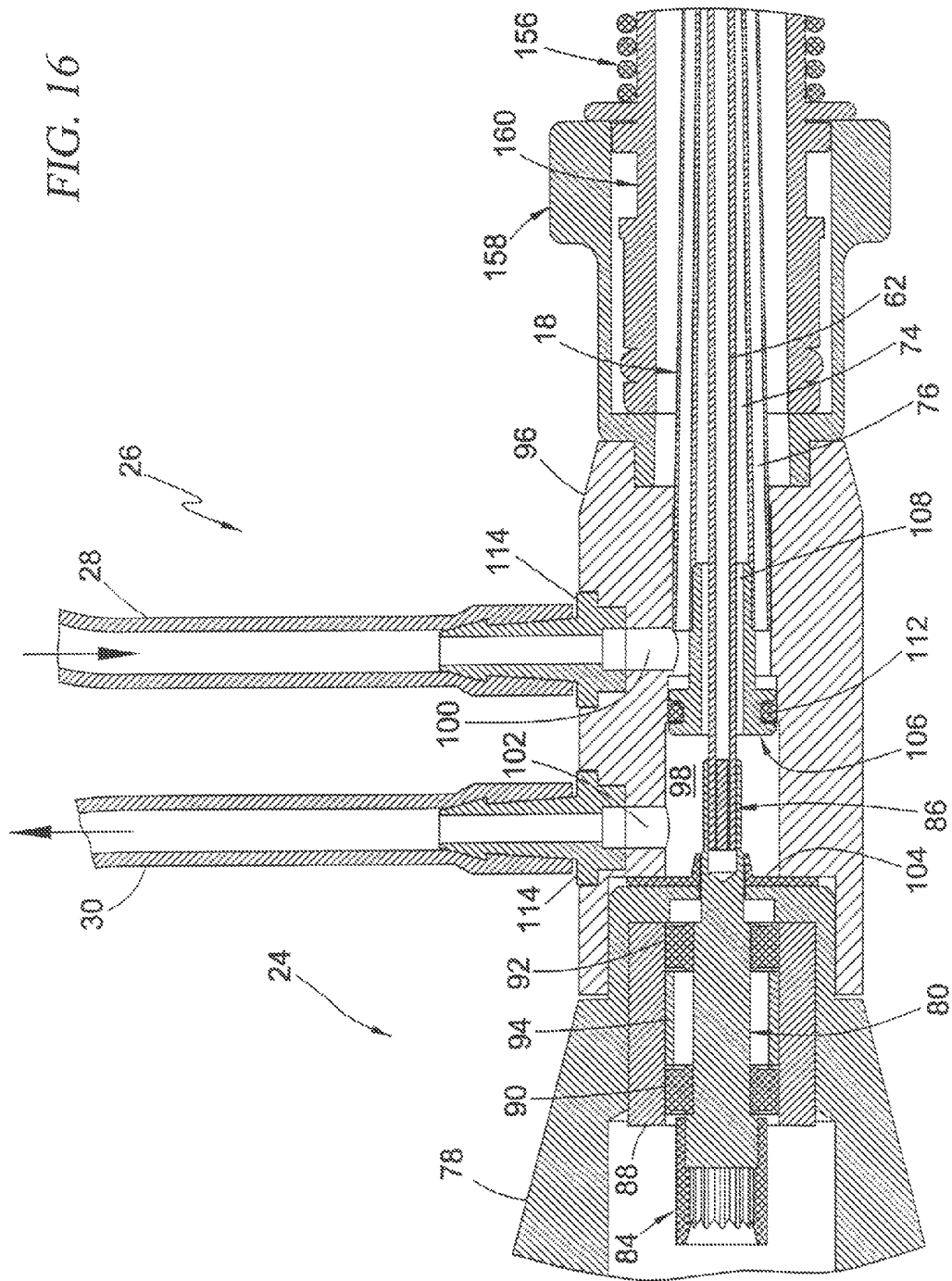


FIG. 15



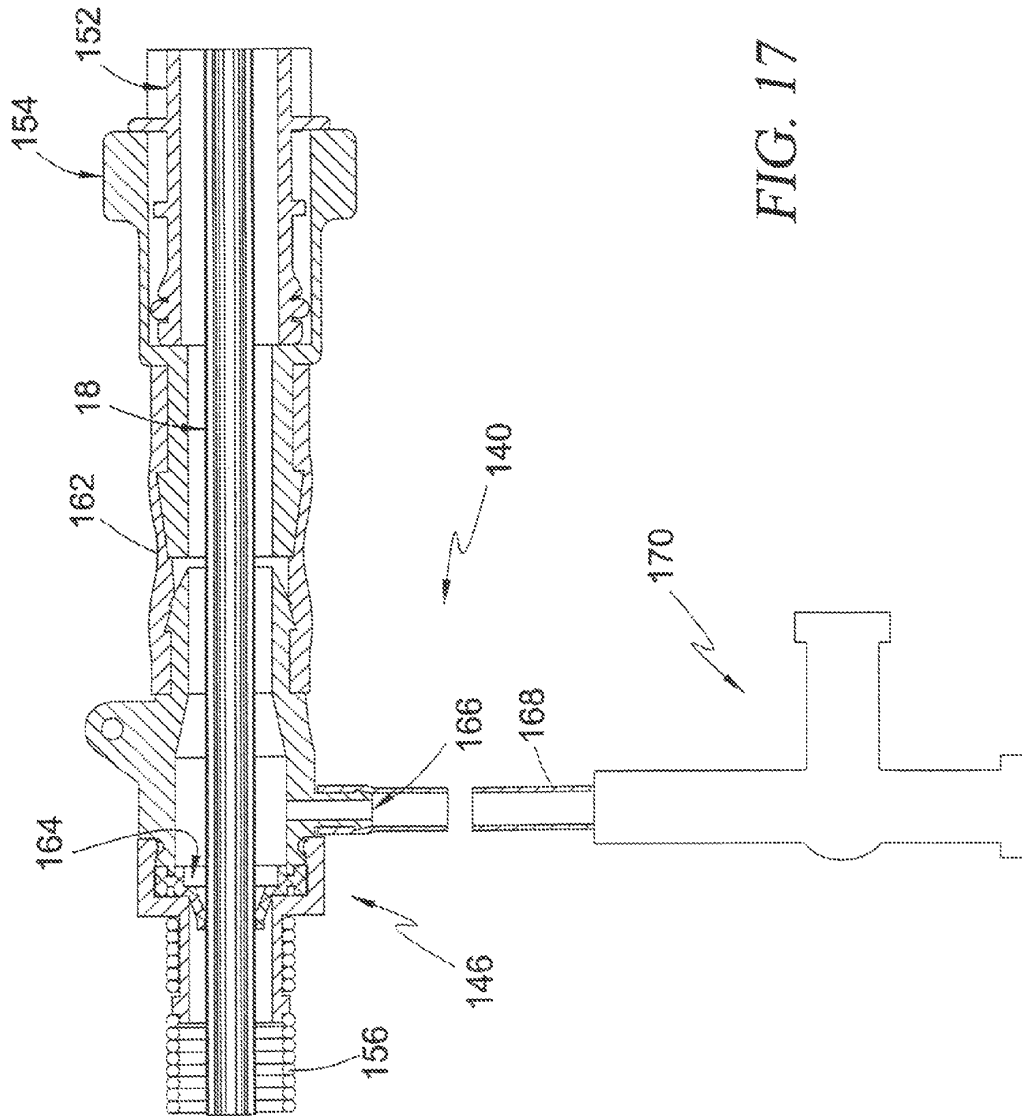
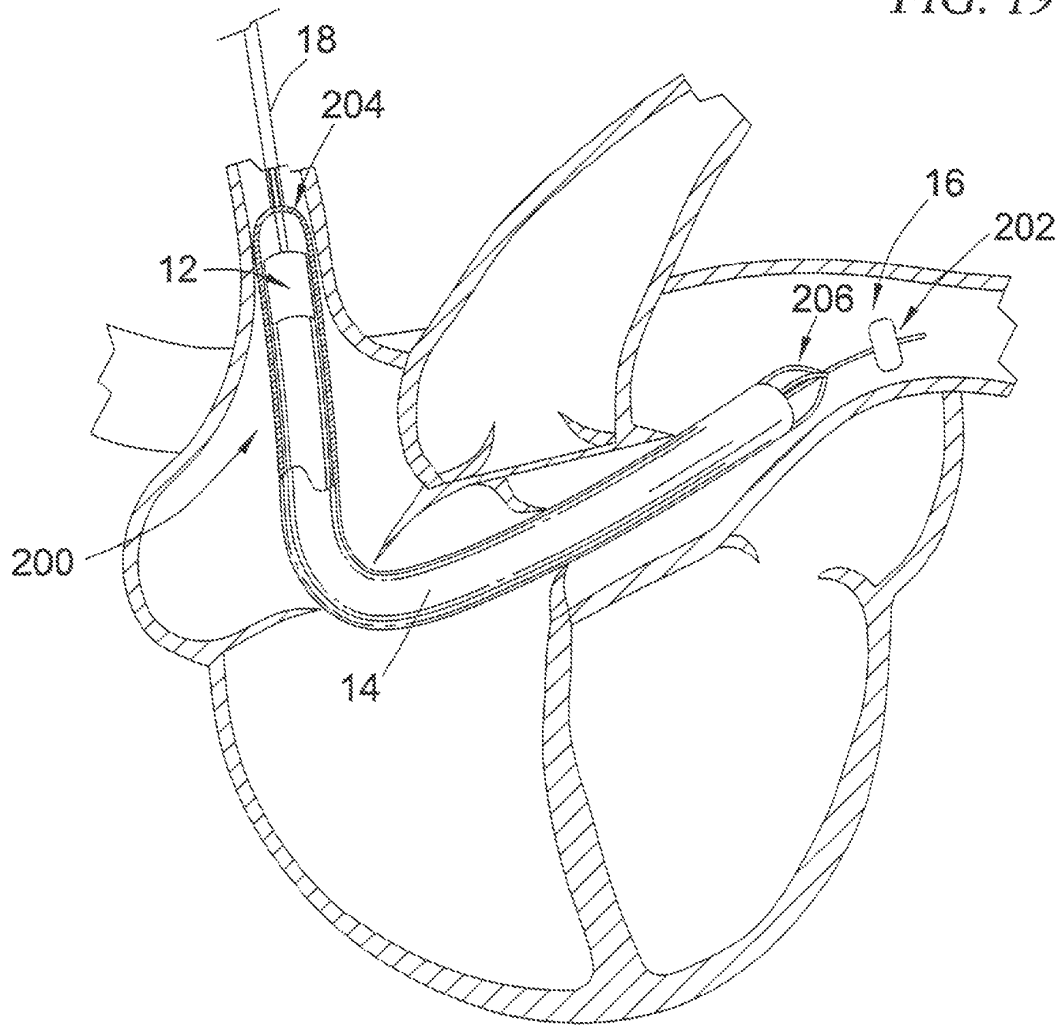


FIG. 19



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GUIDABLE INTRAVASCULAR BLOOD PUMP AND RELATED METHODS

RELATED APPLICATIONS

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

FIELD OF THE INVENTION

The present invention relates generally to blood pumps and, more particularly, to an improved intra-vascular 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.

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 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 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 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 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 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 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

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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 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 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 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

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 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.

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 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

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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.

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.

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 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.

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.

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

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

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

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

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 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 predetermine location.

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

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

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

BRIEF DESCRIPTION OF THE DRAWINGS

Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in

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conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

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

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

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

FIG. 4 is a cross-sectional view taken along lines 4-4 of FIG. 3 illustrating an exemplary construction of the drive cable assembly and guide mechanism according to the first broad aspect of the present invention;

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;

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 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 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;

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;

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;

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 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 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 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;

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

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

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

FIG. 18 is a cross-sectional view of an 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

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-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 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 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 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 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 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 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 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 done using the control features of the guide wire 22 itself, or may be facilitated through the use of any number of supplemental guidance mechanisms or techniques to ensure the proper and efficient placement of the guide wire 22. Such supplemental guidance techniques may include, but are not necessarily limited to, guide catheters and/or techniques involving ultra-sound or fluoroscopy. 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 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 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 detail below, a purge fluid distribution throughout the body.

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

length of the drive cable assembly 18 must be enough to reach between the motor coupler 24 and purge fluid delivery system 26, located outside the patient, and the desired location within the patient's circulatory system where the blood pump 12 is to be positioned.

The intravascular blood pump 12 is shown (by way of example only) as an axial flow intravascular blood pump. The blood pump 12 includes pump body 34, a rotor shroud 36 having flow ports 38, and an internally disposed rotor (not shown) having a shaft rotatably disposed within the pump body 34 and an impeller rotatably disposed within the rotor shroud 36. The cannula 14 is fixedly attached to the rotor shroud 36 and may extend any suitable length therefrom depending upon the particular intravascular application. The cannula 14 preferably includes a plurality of ports or fenestrations 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 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 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 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.

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 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 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 bearing assemblies 50, 52 are well

known in the art, each comprising an inner race which rotates along with the rotor shaft 46, an outer race which remains in a static and fixed position against the inner surface of the pump body 34, and a plurality of ball bearings disposed between the inner and outer races. The spring 54 biases each bearing assembly 50, 52 axially away from one another to reduce axial play during pump operation. The shaft 46 is generally hollow and dimensioned to receive a cable adapter 60 therein for the purpose of coupling the rotor 44 to a drive cable 62 forming part of the drive cable assembly 18. The drive cable 62 may be secured to the cable adapter 60 in any number of suitable fashions, including but not limited to the use of adhesives, crimping, and laser welding. These same techniques may be used to secure the cable adapter 60 within the shaft 46 of the rotor 44. A radial seal 64 is provided in between the wall of the pump body 34 and a distal stepped region 66 on the rotor shaft 46, the function of which will be described below.

The impeller 48 includes a hub 56 and a plurality of blades 58 extending therefrom. The hub 56 is generally conical and, according to the first broad aspect of the present invention, is hollow throughout to form part of the central lumen of the guide mechanism 16. In this regard, the hub 56 is preferably provided with a gasket or seal member 68 at its distal tip. The seal member 68 may be made of any suitable sealing material (including but not limited to silicone) such that the pump 12 and cannula 14 may be easily progressed along the guide wire 22 for delivery to a desired circulatory site. The seal member 68 should also be robust enough to prevent the ingress of blood into the interior of the rotor hub 56 during pump operation, whether the guide wire 22 remains in place or is fully withdrawn. The blades 58 are dimensioned to reside in close tolerance with the interior surface of the shroud 36. In operation, the blades 58 impart both an axial and radial vector on the blood which causes it to flow outward through the flow ports 38 formed in the shroud 36. As used herein, the term "axial flow" is deemed to include flow characteristics like that shown in FIG. 3, which include both an axial and slight radial component. It is to be readily appreciated that, although shown as an axial flow type, blood pump 12 may comprise any number of suitable types of intravascular blood pumps, including but not limited to so-called "mixed flow" intravascular blood pumps without departing from the scope of the present invention.

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

The drive cable assembly 18 includes the drive cable 62 and the drive cable sheath 32. The drive cable 62 is coupled to

the rotor 44 via the cable adapter 60. The drive cable sheath 32 includes a central lumen 74 and a plurality of side lumens 76. The central lumen 74 serves as a protective covering for the drive cable 62. The central lumen 74, along with the side lumens 76, also forms part of the purge fluid delivery system 26 shown above in FIG. 2, which will be described in greater detail below. The side lumens 76 are provided in fluid communication with the fluid inlet conduit 28, while the 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 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 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 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 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 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 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

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

The purge fluid delivery system 26 includes a housing 96 having a central lumen 98, an inflow port 100, and an outflow port 102. The housing 96 is also dimensioned to matingly receive a portion of the motor coupler 24. In this regard, a seal element 104 is provided sandwiched in between the housing 96 and housing 78 and including an aperture which extends about the drive shaft adapter 80 as it exits the housing 78 to prevent the ingress of purge fluid into the motor coupler 24. A fluid guide structure 106 is also provided within the central lumen 98 for the purpose of separating the inflow and outflow ports 100, 102. The fluid guide structure 106 includes a central lumen 108 through which the drive cable 62 extends, and an elevated portion 110 that retains an O-ring 112 against the inner surface of the central lumen 98 of the housing 96. The drive cable sheath 32 is secured to the housing 96 such that the inflow port 100 is communicatively coupled to the side lumens 76, and the outflow port 102 is communicatively coupled to the central lumen 74. In this fashion, pressurized purge fluid may be introduced through the inflow port 100 via inflow conduit 28, and removed through the outflow port 102 via outflow conduit 30. By way of example, the inflow conduit 28 and outflow conduit 30 may be coupled to their respective ports 100, 102 via barbed connectors 114. Similarly, the inflow and outflow conduits 28, 30 may be equipped with any number of suitable connectors (such as those illustrated by way of example in FIG. 2) for establishing fluid communication with a source of pressurized fluid (not shown). The pressurized fluid source (not shown) may include, but is not necessarily limited to, the use of a syringe, an inflator, 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 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 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 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 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 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 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

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through the guide carriage 124. The "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 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 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 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 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 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 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.

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.

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 blood pumps described above are hereby incorporated into the discussion of the intravascular blood pump system 130.

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In its most general form, the intravascular blood pump system 130 of this third broad aspect of the 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, 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 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 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) 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 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 fluoroscopy. 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

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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.

An exemplary docking arrangement will now be described with reference to FIG. 14. In a preferred embodiment, the rotor 44 may be properly and accurately docked within the shroud 36 by forming angled mating surfaces on corresponding portions of the shroud 36 and 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 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 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. 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 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 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

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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.

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

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

The purge fluid delivery system of the embodiment shown in FIG. 18 provides for a one way delivery of purge fluid to the blood pump 12. That is, pressurized fluid (namely, fluid pressurized to some level elevated above the blood pressure in the surrounding vessel) is injected in between the drive cable 62 and the interior of the protective sheath 32 during operation. This serves to reduce any frictional heating that exists between the drive cable 62 and sheath 32. The pressurized fluid also flows through the interior of the pump 12 such that, if the seal at 192 is broken, the pressurized fluid will flow past the open seal 192 and onward through the blood flow ports 38 formed in the shroud 36. This serves to keep blood from entering the pump 12 in an effort to avoid clotting and/or damaging the pump 12.

The pump assembly 136 may be docked within the conduit assembly 134 in any number of different fashions without departing from the scope of the present invention. That is to

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say, the docking scheme shown in FIG. 18 is set forth by way of example only and is not to be deemed limiting or restrictive as to numerous ways to temporarily engage or "dock" the pump assembly 136 within the conduit assembly 134. The only requirement is that the pump assembly 136 and conduit assembly 134 dock such that the rotor 44 is disposed within the shroud 36 to provide the desired axial flow through the cannula 14 and out the shroud 36. The exemplary docking scheme involves forming an annular engagement groove 194 along the interior of the shroud 36, and forming a complementary annular ridge 196 along the exterior surface of the pump body 34. During insertion, the pump assembly 136 will be advanced into the conduit assembly 134 until the annular ridge 196 on the pump body 34 engages within the groove 194 formed in the shroud 36. This docking scheme is generally advantageous in that the engagement action between the annular ridge 196 and groove 194 will provide tactile feedback to the physician during the process of inserting the pump assembly 136 into the conduit assembly 134 such that the physician will be able to determine when the docking has been completed.

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

While this invention has been shown in use largely in during left-heart applications it is to be readily appreciated that this does not limit the applications of this invention for use in left heart support only. Rather, the guidable intravascular blood pump of the present invention can be utilized in right-heart support applications and a wide variety of other applications apparent to those skilled in the art. For example, with reference to FIG. 19, shown is an intravascular blood pump 200 (of the type shown and described above with reference to FIGS. 2-5) configured 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 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 the art based on the broad principles enumerated in this application, are contemplated as being within the scope of the present invention.

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The intravascular blood pump system **200** is shown positioned within the heart, such as may be 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 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 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** over the balloon catheter **202** until the fluid inlet **204** is disposed within the vena cava (or right atrium) and the fluid outlet **206** is positioned within the pulmonary artery. The pump **12** may then be selectively (i.e. automatically or on-demand) controlled to transport blood from the vena cava (or right atrium) in a trans-valvular fashion through the tricuspid valve, the right ventricle, and the pulmonary valve for deposit within the pulmonary artery. Providing right-heart support during beating heart surgery advantageously overcomes conditions where cardiac output may become compromised during beating heart surgery, such as when the heart is lifted to gain access to posterior vessels, thereby avoiding the need for cardiopulmonary bypass.

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

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

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

It is also contemplated to incorporate various pressure sensing and/or guidability features into at least one of the cannula, **14** and pump **12**. Such features may include, but are not necessarily limited to, those shown and described in commonly-owned and co-pending U.S. patent application Ser. No. 09/280,988 (filed Mar. 30, 1999) entitled "Steerable Cannula," and U.S. patent application Ser. No. 09/280,970 (filed

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Mar. 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 intravascular blood pump system, comprising:

an intravascular blood pump comprising:

a rotor having a rotor hub tapering in the distal direction, at least one blade extending radially outward from the rotor hub, the hub has a distal end extending distally beyond the most distal portion of the blade and a shroud within which the rotor is rotatably disposed;

a cannula extending from the shroud and comprising an outer cannula surface, the outer cannula surface having a substantially circular cross-section along a portion of its length;

a first lumen in fluid communication with the intravascular blood pump and operatively arranged to deliver purge fluid to the intravascular blood pump; and

a guide mechanism configured as a second lumen having a proximal end and a distal end, the guide mechanism adapted to guide a distal portion of said intravascular blood pump system to a predetermined location within the circulatory system of a patient;

wherein an axis coaxial with and extending through a portion of said guide mechanism extends through a region delimited by the outer cannula surface, and wherein the guide mechanism is configured to allow for a guide wire to slideably advance therealong.

2. The intravascular blood pump system of claim 1, wherein the rotor comprises a second blade extending radially from the rotor hub.

3. The intravascular blood pump system of claim 1, wherein the rotor hub is generally conical.

4. The intravascular blood pump system of claim 1, wherein the guide mechanism is configured such that the guide wire passes through the region delimited by the outer

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cannula surface at a location proximal to where the guide wire establishes slidable contact with the guide mechanism.

5. The intravascular blood pump system of claim 1, further comprising a guide catheter, wherein the guide catheter is configured to facilitate the placement of the guide wire into the heart.

6. The intravascular blood pump system of claim 1, 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.

7. The intravascular blood pump system of claim 1, wherein the cannula is operatively arranged to bend at a location between distal and proximal ends thereof.

8. The intravascular blood pump system of claim 1, 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.

9. The intravascular blood pump system of claim 1, 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.

10. An intravascular blood pump system comprising:

an intravascular blood pump comprising a rotor having a rotor hub tapering in the distal direction, at least one blade extending radially outward from the rotor hub, the intravascular blood pump coupled to a catheter on a proximal end and a cannula on a distal end;

a first set and a second set of apertures establishing fluid communication between an interior of the cannula and an exterior region of the cannula, wherein the first set of apertures is located in proximity to the rotor and the second set of apertures is spaced apart from and located distal to the first set of apertures towards a distal region of the cannula;

a guide mechanism configured as an elongate lumen and adapted to guide said intravascular blood pump, cannula, and catheter to a predetermined location within the circulatory system of a patient; and

a blood pressure detection mechanism comprising a fluid column configured to detect the pressure of the blood proximate the intravascular blood pump;

wherein the elongate lumen is sized substantially smaller than an inner diameter of the cannula and intravascular blood pump; and

a guide wire arranged to be advanced along the lumen, wherein the lumen is arranged coaxially with at least one of a distal end or a proximal end of the cannula, and the cannula and the lumen are arranged in series longitudinally.

11. The intravascular blood pump system of claim 10, wherein the cannula is reinforced with a spiral wire.

12. The intravascular blood pump system of claim 10, further comprising a guide wire and a guide catheter, wherein the guide catheter is configured facilitate the placement of the guide wire through the vasculature into the heart.

13. The intravascular blood pump system of claim 10, wherein the rotor comprises a second blade extending radially from the rotor hub.

14. The intravascular blood pump system of claim 10, wherein the cannula comprises an outer cannula surface hav-

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ing a substantially circular cross-section along a portion of its length, the distal region of the outer cannula surface is distally tapered about its circumference.

15. The intravascular blood pump system of claim 10, 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.

16. The intravascular blood pump system of claim 15, 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.

17. The intravascular blood pump system of claim 10, 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.

18. The intravascular blood pump system of claim 10, wherein the central lumen extends through the cannula and blood pump.

19. The intravascular blood pump system of claim 10, wherein the lumen of the central lumen is proximal to the cannula.

20. The intravascular blood pump system of claim 10, wherein the cannula is operatively arranged to bend at a location between distal and proximal ends thereof.

21. The intravascular blood pump system of claim 10, wherein the distal end of the cannula is open to enable the guide wire to pass axially through the distal end of the cannula.

22. An intravascular blood pump system configured to be advanced to a predetermined location in a patient's circulatory system, the intravascular blood pump system comprising:

an intravascular blood pump, the intravascular blood pump comprising a rotor having a generally conical rotor hub tapering in the distal direction, at least two blades extending radially from the rotor hub, the generally conical rotor hub having a distal tip extending distally beyond the blades;

a cannula extending distally from the intravascular blood pump;

a plurality of ingress ports located towards the proximal region of the cannula and a plurality of egress ports located in proximity to the blood pump such that movement of fluid proximally through an interior region of the cannula is steered towards the egress ports;

a guide wire having a cross-section substantially smaller than the cannula;

and

an elongate lumen having a luminal interior sized (i) smaller than an inside diameter of the cannula and (ii) sufficiently large enough to accommodate the guide wire when the guide wire is advanced therealong, wherein the lumen is arranged coaxially with respect to at least one of a distal end or a proximal end of the cannula, and the lumen and the cannula are arranged in series longitudinally.

23. The intravascular blood pump system of claim 22, wherein the lumen is proximal with respect to the cannula.

24. The intravascular blood pump system of claim 22, wherein the distal end of the cannula is open to enable the guide wire to pass axially through the distal end of the cannula.

* * * * *

U.S. PATENT APP. NO. 14/543,815



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

99185 7590 10/05/2015
Getinge US Legal Shared Services
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)

99185 7590 10/05/2015
Getinge US Legal Shared Services
1300 MacArthur Boulevard
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,
- (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.

1 _____
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			MARCETICH, ADAM M	
1300 MacArthur Boulevard			ART UNIT	
Mahwah, NJ 07430			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. <input type="checkbox"/> Notice of References Cited (PTO-892)	5. <input checked="" type="checkbox"/> Examiner's Amendment/Comment
2. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date ____	6. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance
3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material	7. <input type="checkbox"/> Other ____.
4. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date ____ .	

/Adam Marcetich/ Primary Examiner, Art Unit 3761	
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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

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant <input type="checkbox"/> CPA <input checked="" type="checkbox"/> T.D. <input type="checkbox"/> R.1.47															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
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	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

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 rotar 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.

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WO 2001/017581 (15.03.2001 Gazette 2001/11)

(54) **GUIDABLE INTRAVASCULAR BLOOD PUMP**

LENKBARE INTRAVASKULARE BLUTPUMPE

POMPE A SANG INTRAVASCULAIRE POUVANT ETRE GUIDEE

(84) Designated Contracting States:

**AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU
MC NL PT SE**

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US-A- 5 746 709	US-A- 5 746 709

Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

Description

Field of the Invention

[0001] The present invention relates generally to blood pumps and, more particularly, to an improved intra-vascular 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

[0002] 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.

[0003] 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 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 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 alterations and direct activation and aggregation of platelets and white blood cells.

[0004] Intravascular blood pumps comprise miniaturized blood pumps capable of being percutaneously or surgically introduced into the vascular system of a 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 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 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.

[0005] 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.

[0006] 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 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 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 accessing the vessel.

[0007] DE 196 22 335 discloses a balloon catheter comprising a catheter hose, a balloon support connected to the catheter hose and an expandable balloon carried on the balloon support. A small diameter pump is disposed between the catheter hose and the balloon support for pumping blood.

[0008] WO 89/05164 discloses an inflow cannula for retrograde insertion of the blood intake for an intravascular blood pump through the aortic valve. The cannula comprises a stiff body section adapted to be attached at its trailing end to the intake of the blood pump and a substantially soft, flexible, resilient tip section at the lead-

ing end of the body section.

[0009] EP-A-0,916,359 discloses a cannula device for use on the inflow end of an implantable heart pump.

[0010] 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

[0011] The present invention provides an intravascular blood pump system for ventricular assist according to claim 1.

[0012] 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 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.

[0013] 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 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 wire may be progressed therethrough and advanced to the predetermined location in the circulatory system of the patient. After the guide wire is advanced to this desired location, the intravascular blood pump and cannula may thereafter be advanced along the guide wire to the desired location.

[0014] 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 wire may be advanced to the predetermined location in the circulatory system of the patient. After the guide wire is advanced to this desired location, the intravascular blood pump and cannula may thereafter be advanced along the guide wire to the desired location.

[0015] 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.

[0016] In a further embodiment, the cannula is coupled to the shroud of the intravascular blood pump.

[0017] 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.

[0018] In a further embodiment, the drive cable sheath includes at least one side lumen for delivering the purge fluid towards the rotor.

[0019] In a further embodiment, a portion of the purge fluid is delivered through the at least one side lumen and past the rotor, and a portion of purge fluid is rerouted back from the rotor through the central lumen of the drive cable.

[0020] 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.

[0021] The blood pressure detection mechanism comprises a fluid filled column, e.g., disposed within at least a portion of the cannula.

[0022] In a further embodiment, the guide wire is disposed at least partially within the cannula.

[0023] In a further embodiment, the guide wire is for passage through a side lumen formed in the cannula.

[0024] In a further embodiment, the guide element comprises a selectively deformable element disposed at least partially within the cannula.

[0025] 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.

[0026] In a further embodiment, the guide wire is for passage through a lumen extending through the drive cable and rotor.

[0027] 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.

[0028] In a further embodiment, the guide element comprises a guide wire and a balloon catheter.

Brief Description of the Drawings

[0029] Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

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

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

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

FIG. 4 is a cross-sectional view taken along lines 4-4 of FIG. 3 illustrating an exemplary construction of the drive cable assembly and guide mechanism according to the first broad aspect of the present invention;

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;

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 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 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;

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, and

FIG. 10 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-valvular configuration to provide right-heart assist.

Detailed Description of the Invention

[0030] Illustrative embodiments of the invention are described below. In the interest of clarity, not all features of an actual implementation may be described in 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 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 disclosure.

[0031] 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 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 predetermined location within the circulatory system of a patient without the need for bulky supplemental guide mechanisms, such as a separate guide catheter.

[0032] 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.

[0033] Referring to FIG. 1, shown is a guidable intravascular 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. The guide element is shown as a guide wire 22. According to the present invention, the "over-the-wire" guide mechanism 16 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.

[0034] To accomplish this, the guide wire 22 is first 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 done using the control features of the guide wire 22 itself, or may be facilitated through the use of any number of supplemental guidance mechanisms or techniques to ensure the proper and efficient placement of the guide wire 22. Such supplemental guidance techniques may include, but are not necessarily limited to, guide catheters and/or techniques involving ultra-sound or fluoroscopy. 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 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 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 distribution throughout the body.

[0035] 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 coupler 24 and, as will be described in greater detail below, a purge fluid 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.

[0036] The intravascular blood pump 12 is shown (by way of example only) as an axial flow intravascular blood pump. The blood pump 12 includes pump body 34, a rotor shroud 36 having flow ports 38, and an internally disposed rotor (not shown) having a shaft rotatably disposed within the pump body 34 and an impeller rotatably disposed within the rotor shroud 36. The cannula 14 is fixedly attached to the rotor shroud 36 and may extend

any suitable length therefrom depending upon the particular intravascular application. The cannula 14 preferably includes a plurality of ports or fenestrations 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 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 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 for intravascular applications. For example, the range of sizes may include, but is not necessarily limited to, 3 to 10 mm (9 French to 30 French), although the range is more preferably from 4.7 to 8 mm (14 French to 24 French), and most preferably from 6 to 6.7 mm (18 French to 20 French).

[0037] 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 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 has been so positioned using conventional guidance techniques. It is to be readily understood that, while shown as a conventional guide wire 22, imaging wires may be used.

[0038] 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.

[0039] 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.

[0040] The cannula 14 is coupled at its proximal end to the rotor shroud 36. This may be accomplished in any number of fashions, including but not limited to the use of adhesives. This may also be facilitated by dimensioning the shroud 36 to include a narrow inlet region 70 capable of being received flushly within the proximal end of the cannula 14. The inlet region 70 of the shroud 36 should preferably have a tapered interior surface for establishing a smooth flow transition between the cannula 14 and the region containing the impeller blades 58. Although shown as a single integral element, it is to be understood that the pump body 34 and shroud 36 may comprise two separate (and sometimes separable) components, the significance of which will become apparent below. The pump body 34 and shroud 36 may be constructed from any number of suitable materials, including but not limited to stainless steel or other medical grade compositions or alloys. The cannula 14 may also be constructed from any number of suitable materials, including but not limited to medical grade plastics. As shown, the cannula 14 may also be fortified with spiral-wound reinforcement wire 72 within the walls of the cannula 14.

[0041] The drive cable assembly 18 includes the drive cable 62 and the drive cable sheath 32. The drive cable

62 is coupled to the rotor 44 via the cable adapter 60. The drive cable sheath 32 includes a central lumen 74 and a plurality of side lumens 76. The central lumen 74 serves as a protective covering for the drive cable 62. The central lumen 74, along with the side lumens 76, also forms part of the purge fluid delivery system 26 shown above in FIG. 2, which will be described in greater detail below. The side lumens 76 are provided in fluid communication with the fluid inlet conduit 28, while the 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 drive cable 62.

[0042] 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 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 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 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.

[0043] The "over-the-wire" guide mechanism 16 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 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.

[0044] Referring to FIG. 5, the motor coupler 24 in-

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

[0045] The purge fluid delivery system 26 includes a housing 96 having a central lumen 98, an inflow port 100, and an outflow port 102. The housing 96 is also dimensioned to matingly receive a portion of the motor coupler 24. In this regard, a seal element 104 is provided sandwiched in between the housing 96 and housing 78 and including an aperture which extends about the drive shaft adapter 80 as it exits the housing 78 to prevent the ingress of purge fluid into the motor coupler 24. A fluid guide structure 106 is also provided within the central lumen 98 for the purpose of separating the inflow and outflow ports 100, 102. The fluid guide structure 106 includes a central lumen 108 through which the drive cable 62 extends, and an elevated portion 110 that retains an O-ring 112 against the inner surface of the central lumen 98 of the housing 96. The drive cable sheath 32 is secured to the housing 96 such that the inflow port 100 is communicatively coupled to the side lumens 76, and the outflow port 102 is communicatively coupled to the central lumen 74. In this fashion, pressurized purge fluid may be introduced through the inflow port 100 via inflow conduit 28, and removed through the outflow port 102 via outflow conduit 30. By way of example, the inflow conduit 28 and outflow conduit 30 may be coupled to their respective ports 100, 102 via barbed connectors 114. Similarly, the inflow and outflow conduits 28, 30 may be equipped with any number of suitable connectors (such as those illustrated by way of example in FIG. 2) for establishing fluid communication with a source of pressurized fluid (not shown). The pressurized fluid source (not shown) may include, but is not necessarily limited to, the use of a syringe, an inflator, 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 cooling the

blood pump 12 and preventing the ingress of blood past the radial seal 64 and into blood pump 12.

[0046] Referring to FIG. 6, shown is a guidable intravascular blood pump system 120 according to a second broad aspect of the present invention. As will be 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 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 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.

[0047] In its most general form, the intravascular 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 exchange" or "side-rigger" guide mechanism 122 includes a guide carriage 124 formed along at least a portion of the cannula 14, and a guide wire 22 dimensioned to pass slidably through a lumen (not shown) extending through the guide carriage 124. The "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 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 positioned in the trans-valvular configuration shown for providing left-heart assist.

[0048] 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 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 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 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 ac-

cording to the present invention. The guide wire 22 may thereafter be withdrawn from the patient. If 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.

[0049] 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.

[0050] While this invention has been shown in use largely in during left-heart applications, it is to be readily appreciated that this does not limit the applications of this invention for use in left heart support only. Rather, the guidable intravascular blood pump of the present invention can be utilized in right-heart support applications and a wide variety of other applications apparent to those skilled in the art. For example, with reference to FIG. 10, shown is an intravascular blood pump 200 (of the type shown and described above with reference to FIGS. 2-5) configured 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 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 the art based on the broad principles enumerated in this application, are contemplated as being within the scope of the present invention.

[0051] The intravascular blood pump system 200 is shown positioned within the heart, such as may be 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 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 advanced over the balloon catheter 202 and guided into a desired arrangement. For right heart support, this would involve advancing the pump 12 and cannula 14 over the balloon catheter 202 until the fluid inlet 204 is disposed within the vena cava (or right atrium) and the fluid outlet 206 is positioned within the pulmonary artery. The pump 12 may then be selectively (i.e. automatically or on-demand) controlled to transport blood from the vena cava (or right atrium) in a trans-valvular fashion through the tricuspid valve, the right ventricle, and the pulmonary valve for deposit within the pulmonary artery. Providing right-heart support during beating heart surgery advantageously overcomes conditions where cardiac output may become compromised during beating heart surgery, such as when the heart is lifted to gain access to posterior vessels, thereby avoiding the need for cardiopulmonary bypass.

[0052] It is also contemplated as part of the present invention that the guidable intravascular blood pump systems can be introduced into the patient's vasculature to achieve the intravascular access into the right or left heart through any number of access points, including but not limited to the internal jugular vein, the brachiocephalic vein, carotid artery, axillary artery, femoral vein, femoral artery, and subclavian artery. The intravascular blood pump systems of the present invention may also be introduced via direct introduction, such as into the aorta, the atria, and the ventricles. As is well known in the art, such intravascular access may be achieved percutaneously through the use of the Seldinger technique or directly through the use of minimally invasive access techniques.

[0053] Those skilled in the art will also appreciate that, although shown and described above in terms of "axial flow," the present invention is not limited to the axial flow type intravascular blood pumps. Rather, the intravascular blood pumps 12 may comprise any number of suitable types of intravascular blood pumps, including but not limited to so-called "mixed flow" intravascular blood pumps, without departing from the scope of the present invention.

[0054] With regard to the arrangements 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).

[0055] 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 pressure sensing in the system of the invention includes the use of a fluid-filled lumen. The guidability features may include, but are not necessarily limited to, the use of side lumens and deformable materials (i.e. Nitinol).

[0056] 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.

Claims

1. An intravascular blood pump system for ventricular assist comprising:

an intravascular blood pump (12) having a cannula (14) coupled distally thereto, the intravascular blood pump (12) including a pump body (34), a rotor shroud (36) having flow ports (38) and an internally disposed rotor (44) having a shaft rotatably disposed within the pump body (34) and an impeller rotatably disposed within the rotor shroud (36); wherein the cannula (14) comprises a plurality of ports (40) about its distal region, and an end port (42); a blood pressure sensing feature incorporated into at least one of the intravascular blood pump (12) and the cannula (14), wherein said blood

pressure sensing feature comprises at least one of a fluid filled lumen, a piezo-electric pressure sensing element, a strain gauge, and analysis of the torque/current relationship based on the dynamic pressure differential between the inlet and outlet of the blood pump (12); a guide wire (22) capable of being introduced into the vascular system of a patient; and a guide mechanism (16), adapted to guide said intravascular blood pump and cannula to a predetermined location within the circulatory system of a patient, which is

- (a) an "over-the-wire" guide mechanism wherein a central lumen is formed through at least a portion of the intravascular blood pump (12) such that the guide wire (22) may be progressed therethrough; or
- (b) a "rapid exchange" guide mechanism wherein a side lumen is formed along a length of at least one of the intravascular blood pump (12) and the cannula (14) and is dimensioned to slideably receive the guide wire (22), such that the blood pump and cannula may be advanced along the guide wire (22).

2. The intravascular blood pump system of Claim 1 and further, wherein said cannula (14) is coupled to said shroud (36) of said intravascular blood pump (12)
3. The intravascular blood pump system of Claim 1 and further, wherein said intravascular blood pump (12) and cannula (14) may be selectively advanced to said predetermined location within the vasculature of the patient by first passing said guide wire (22) to said predetermined location and thereafter sliding said intravascular blood pump (12) and cannula (14) along said guide wire (22) to said predetermined location.
4. The intravascular blood pump system of Claim 1, wherein the cannula (14) is reinforced with a spiral wound wire embedded in a wall of the cannula (14).
5. The intravascular blood pump system of Claim 1, wherein the cannula (14) is configured to be placed in a trans-valvular position for left-heart ventricular assist procedures.
6. The Intravascular blood pump system of Claim 1, wherein said cannula (14) comprises a diameter from 3 millimeters (9 French) to 10 millimeters (30 French).
7. The intravascular blood pump system of Claim 1, wherein the lumen of the guide mechanism is formed within a wall of the cannula (14).

8. The intravascular blood pump of claim 1, wherein the guide mechanism (16) is the "over-the-wire" guide mechanism.
9. The intravascular blood pump of claim 8, wherein the central lumen extends through the blood pump (12), cannula (14), and a drive cable (18). 5
10. The intravascular blood pump system of Claim 1, wherein the guide mechanism (16) is a rapid exchange guide mechanism (122). 10
11. The intravascular blood pump system of claim 10, wherein the guide mechanism includes a guide carriage(124) formed along at least a portion of the cannula (14) and through which the lumen extends. 15

Patentansprüche

1. Intravaskuläres Blutpumpensystem zur ventrikulären Unterstützung, umfassend: 20

eine intravaskuläre Blutpumpe (12) mit einer distal an diese gekoppelten Kanüle (14), wobei die intravaskuläre Blutpumpe (12) ein Pumpengehäuse (34), eine Rotorumhüllung (36) mit Fließöffnungen (38) und einen im Inneren angeordneten Rotor (44) enthält, der eine Welle hat, die drehbar innerhalb des Pumpengehäuses (34) angeordnet ist, sowie ein Flügelrad, das drehbar innerhalb der Rotorumhüllung (36) angeordnet ist, 25

wobei die Kanüle (14) eine Vielzahl von Öffnungen (40) um ihren distalen Bereich herum und eine Endöffnung (42) umfasst, 30

ein Blutdruckmessmerkmal, das in mindestens einem Element ausgewählt aus der intravaskulären Blutpumpe (12) und der Kanüle (14) aufgenommen ist, wobei das genannte Blutdruckmessmerkmal mindestens ein Element ausgewählt aus einem fluidgefüllten Lumen, einem piezoelektrischen Druckmesselement, einem Dehnungsmessstreifen und einer Analyse des Drehmoment/Strom-Verhältnisses basierend auf dem dynamischen Druckdifferential zwischen dem Einlass und dem Auslass der Blutpumpe (12) umfasst, 35

einen Führungsdraht (22), der dazu geeignet ist, in das vaskuläre System eines Patienten eingeführt zu werden, und 40

einen Führungsmechanismus (16), der dazu geeignet ist, die genannte intravaskuläre Blutpumpe und Kanüle zu einer vorgegebenen Stelle innerhalb des Blutkreislaufsystems eines Patienten zu führen, wobei der Mechanismus 45

(a) ein "Over-the-Wire"-Führungsmecha-

nismus ist, wobei ein zentrales Lumen durch mindestens einen Abschnitt der intravaskulären Blutpumpe (12) hindurch ausgebildet ist, derart, dass der Führungsdraht (22) durch dieses fortbewegt werden kann, oder 5

(b) ein "Schnellwechsel"-Führungsmechanismus, wobei ein Seitenlumen entlang einer Länge mindestens eines Elements ausgewählt aus der intravaskulären Blutpumpe (12) und der Kanüle (14) ausgebildet und so bemessen ist, dass es den Führungsdraht (22) verschiebbar aufnimmt, derart, dass die Blutpumpe und die Kanüle entlang des Führungsdrahtes (22) vorgeschoben werden können. 10

2. Intravaskuläres Blutpumpensystem nach Anspruch 1, und wobei ferner die genannte Kanüle (14) mit der genannten Umhüllung (36) der genannten intravaskulären Blutpumpe (12) gekoppelt ist. 20
3. Intravaskuläres Blutpumpensystem nach Anspruch 1, und wobei ferner die genannte intravaskuläre Blutpumpe (12) und die Kanüle (14) selektiv zu der genannten vorgegebenen Stelle innerhalb des Gefäßsystems des Patienten vorgeschoben werden können, indem zunächst der genannte Führungsdraht (22) zu der genannten vorgegebenen Stelle geführt wird und daraufhin die genannte intravaskuläre Blutpumpe (12) und die Kanüle (14) entlang dem genannten Führungsdraht (22) zu der genannten vorgegebenen Stelle geschoben werden. 25
4. Intravaskuläres Blutpumpensystem nach Anspruch 1, wobei die Kanüle (14) mit einem spiralgewickelten Draht verstärkt ist, der in einer Wand der Kanüle (14) eingebettet ist. 30
5. Intravaskuläres Blutpumpensystem nach Anspruch 1, wobei die Kanüle (14) derart konfiguriert ist, dass sie in einer transvalvulären Position für linksventrikuläre Unterstützungsverfahren platziert werden kann. 35
6. Intravaskuläres Blutpumpensystem nach Anspruch 1, wobei die genannte Kanüle (14) einen Durchmesser von 3 Millimeter (9 Charriäre) bis 10 Millimeter (30 Charriäre) umfasst. 40
7. Intravaskuläres Blutpumpensystem nach Anspruch 1, wobei das Lumen des Führungsmechanismus innerhalb einer Wand der Kanüle (14) ausgebildet ist. 45
8. Intravaskuläres Blutpumpensystem nach Anspruch 1, wobei der Führungsmechanismus (16) der sogenannte "Over-the-Wire"-Führungsmechanismus ist. 50
9. Intravaskuläres Blutpumpensystem nach Anspruch 8, 55

wobei sich das zentrale Lumen durch die Blutpumpe (12), die Kanüle (14) und ein Antriebskabel (18) erstreckt.

10. Intravaskuläres Blutpumpensystem nach Anspruch 1, wobei der Führungsmechanismus (16) der Schnellwechsel-Führungsmechanismus (122) ist. 5
11. Intravaskuläres Blutpumpensystem nach Anspruch 10, wobei der Führungsmechanismus einen Führungsschlitten (124) enthält, der entlang wenigstens eines Abschnitts der Kanüle (14) ausgebildet ist und durch den sich das Lumen erstreckt. 10

Revendications

1. Système de pompe à sang intra-vasculaire pour assistance ventriculaire, comprenant 15
- une pompe à sang intra-vasculaire (12) munie d'une canule (14) couplée à celle-ci de manière distale, la pompe à sang intra-vasculaire (12) comportant un corps de pompe (34), une enveloppe de rotor (36) présentant ports d'écoulement (38) et un rotor (44) disposé à l'intérieur possédant un arbre disposé pour tourner à l'intérieur du corps de pompe (34) et une hélice disposée pour tourner à l'intérieur de l'enveloppe de rotor (36) ; 20
 - dans lequel la canule (14) comprend une pluralité de ports (40) au niveau de sa région distale, et un port d'extrémité (42) ; 25
 - un instrument de mesure de la tension artérielle intégré dans au moins l'une de la pompe à sang intra-vasculaire (12) et de la canule (14), dans lequel ledit instrument de mesure de la tension artérielle comprend au moins l'un parmi une lumière remplie de fluide, un élément de détection de pression piézo-électrique, une jauge de contraintes et une analyse de la relation couple/courant en se fondant sur le différentiel de pression dynamique entre l'entrée et la sortie de la pompe à sang (12), 30
 - un fil guidage (22) apte à être introduit dans le système vasculaire d'un patient ; et 35
 - un mécanisme de guidage (16) adapté à guider ladite pompe à sang intra-vasculaire et ladite canule jusqu'à un emplacement prédéterminé, à l'intérieur du système circulatoire d'un patient, qui est 40
- (a) un mécanisme de guidage « à passage de guide-fil » dans lequel une lumière centrale est formée à travers au moins une portion de la pompe à sang intra-vasculaire (12), de telle sorte que le fil de guidage (22) puisse progresser à travers celle-ci ; ou 45
 - (b) un mécanisme de guidage « à échange rapide » dans lequel une lumière latérale est formée sur une longueur d'au moins l'une de la pompe à sang intra-vasculaire (12) et de la canule (14) et est dimensionnée de manière à recevoir, par glissement, le fil de guidage (22), de telle sorte que la pompe à sang et la canule puissent être avancées le long du fil de guidage (22). 50
2. Système de pompe à sang intra-vasculaire selon la revendication 1 et, en outre, dans lequel ladite canule (14) est couplée à ladite enveloppe (36) de ladite pompe à sang intra-vasculaire (12). 55
3. Système de pompe à sang intra-vasculaire selon la revendication 1 et, en outre, dans lequel ladite pompe à sang intra-vasculaire (12) et ladite canule (14) peuvent être avancées, de manière sélective, jusqu'au dit emplacement prédéterminé à l'intérieur des vaisseaux du patient en faisant tout d'abord passer ledit fil de guidage (22) jusqu'au dit emplacement prédéterminé et ensuite en faisant glisser ladite pompe à sang intra-vasculaire (12) et ladite canule (14) le long dudit fil de guidage (22) jusqu'au dit emplacement prédéterminé.
4. Système de pompe à sang intra-vasculaire selon la revendication 1, dans lequel la canule (14) est renforcée par un fil enroulé en spirale intégré dans une paroi de la canule (14).
5. Système de pompe à sang intra-vasculaire selon la revendication 1, dans lequel la canule (14) est configurée de manière à être placée dans une position trans-valvulaire pour des procédures d'assistance sur le ventricule gauche.
6. Système de pompe à sang intra-vasculaire selon la revendication 1, dans lequel ladite canule (14) présente un diamètre compris entre 3 millimètres (9 sur la jauge française) et 10 millimètres (30 sur la jauge française).
7. Système de pompe à sang intra-vasculaire selon la revendication 1, dans lequel la lumière du mécanisme de guidage est formée à l'intérieur d'une paroi de la canule (14).
8. Système de pompe à sang intra-vasculaire selon la revendication 1, dans lequel le mécanisme de guidage (16) est le mécanisme de guidage « à passage de guide-fil ».
9. Système de pompe à sang intra-vasculaire selon la revendication 8, dans lequel la lumière centrale s'étend à travers la pompe à sang (12), la canule (14) et un câble d'entraînement (18).

10. Système de pompe à sang intra-vasculaire selon la revendication 1, dans lequel le mécanisme de guidage (16) est le mécanisme de guidage à échange rapide (122).

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11. Système de pompe à sang intra-vasculaire selon la revendication 10, dans lequel le mécanisme de guidage inclut un support de guidage (124) formé le long d'au moins une portion de la canule (14) et à travers lequel s'étend la lumière.

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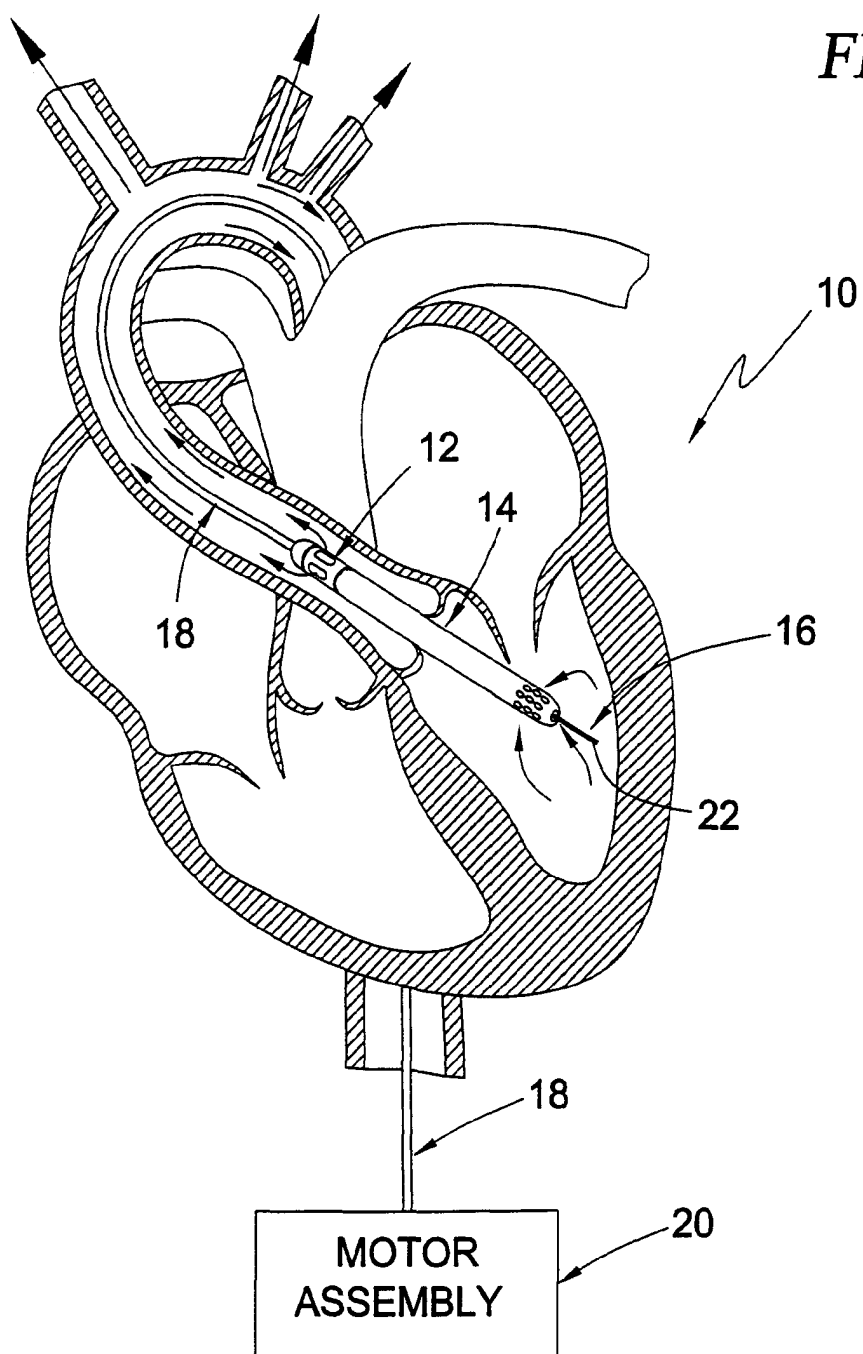
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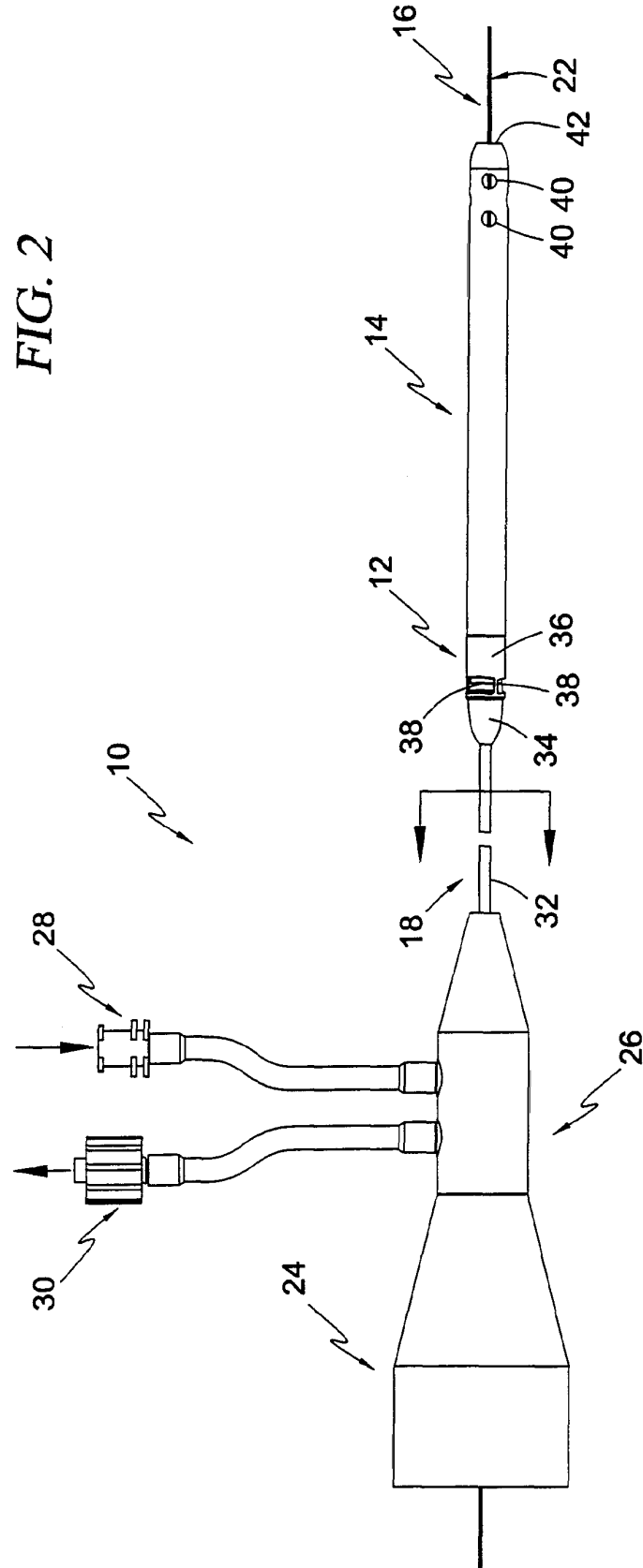
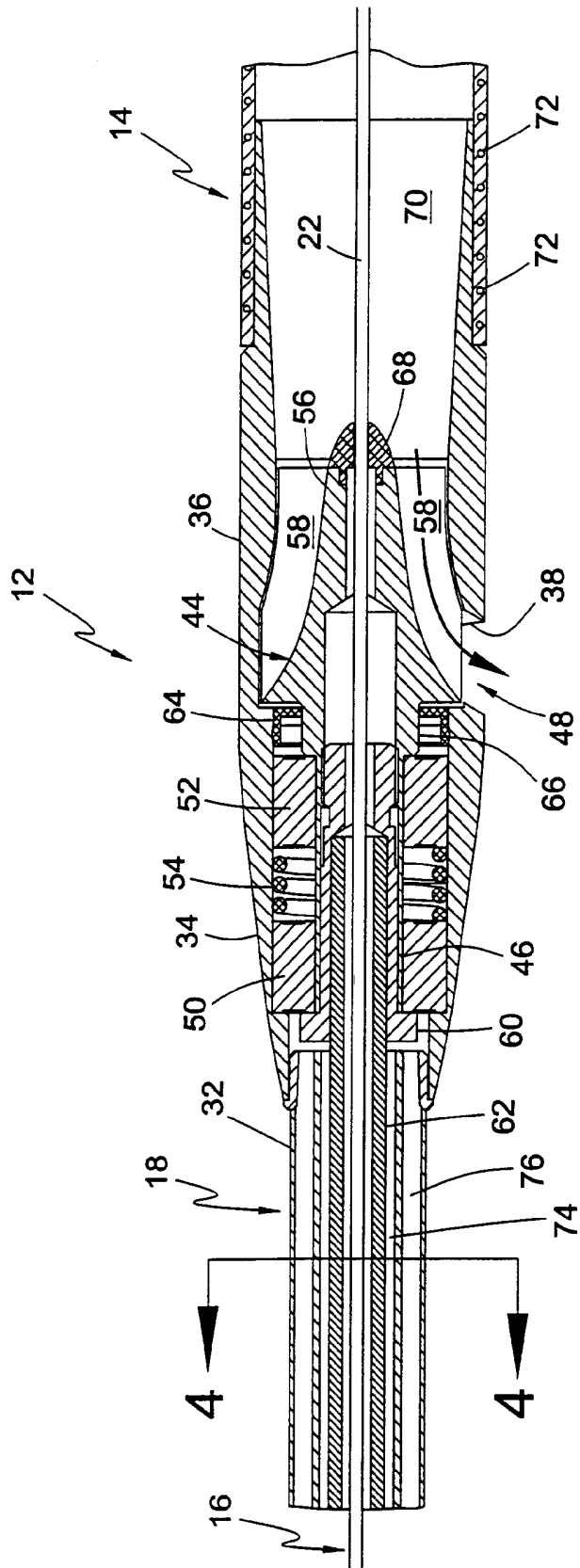


FIG. 3



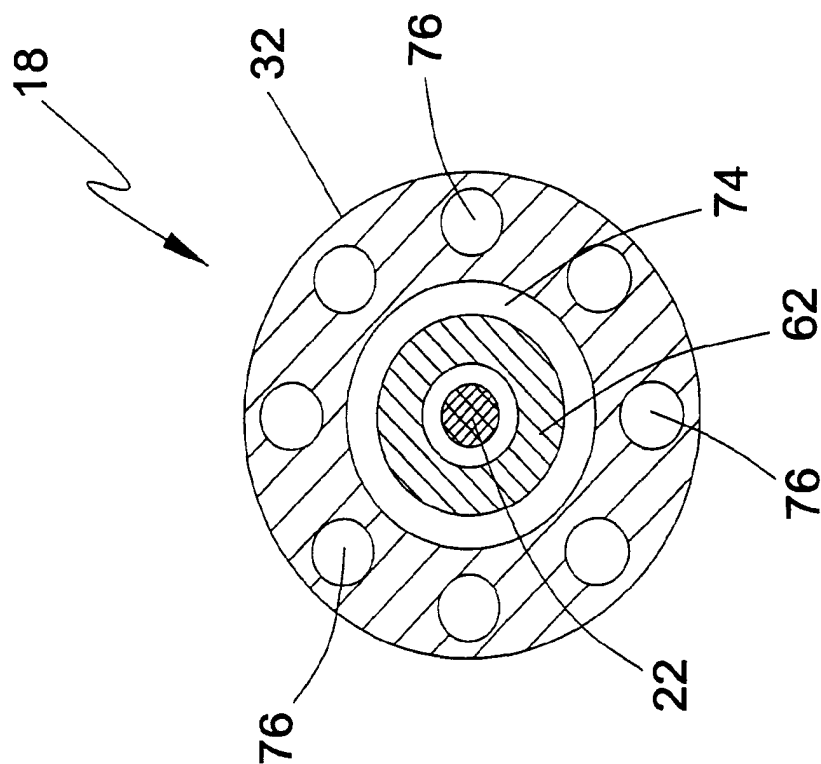
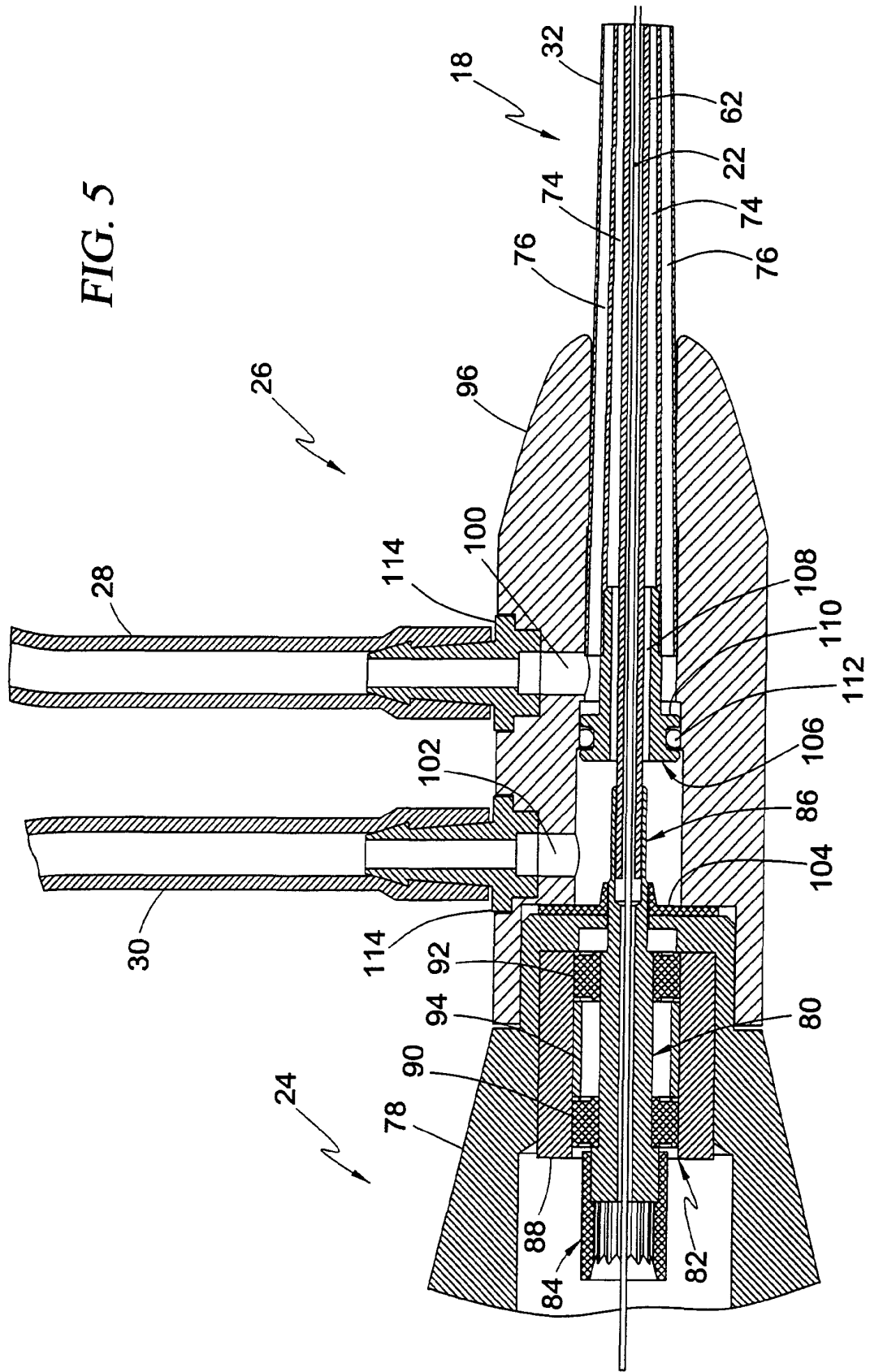


FIG. 4



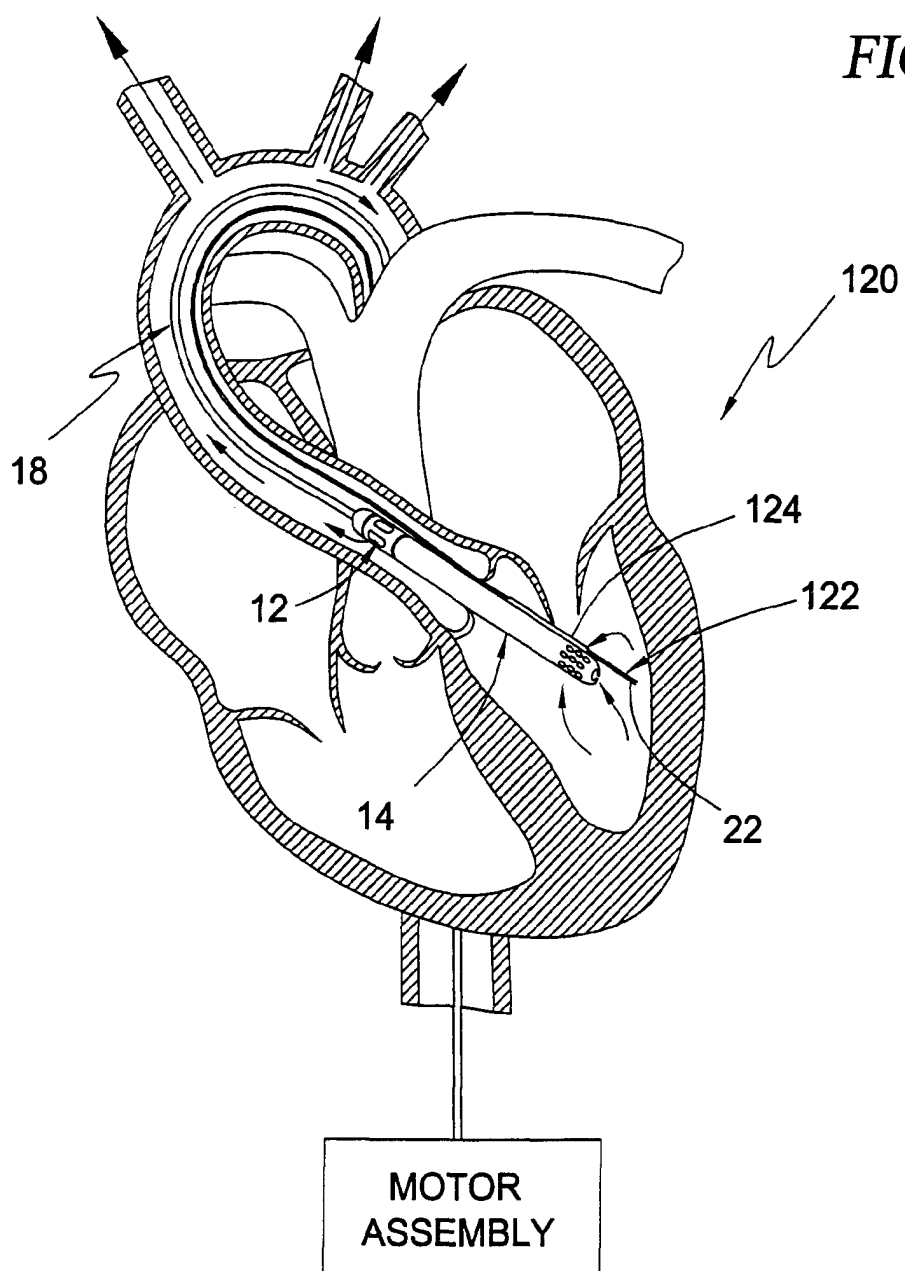
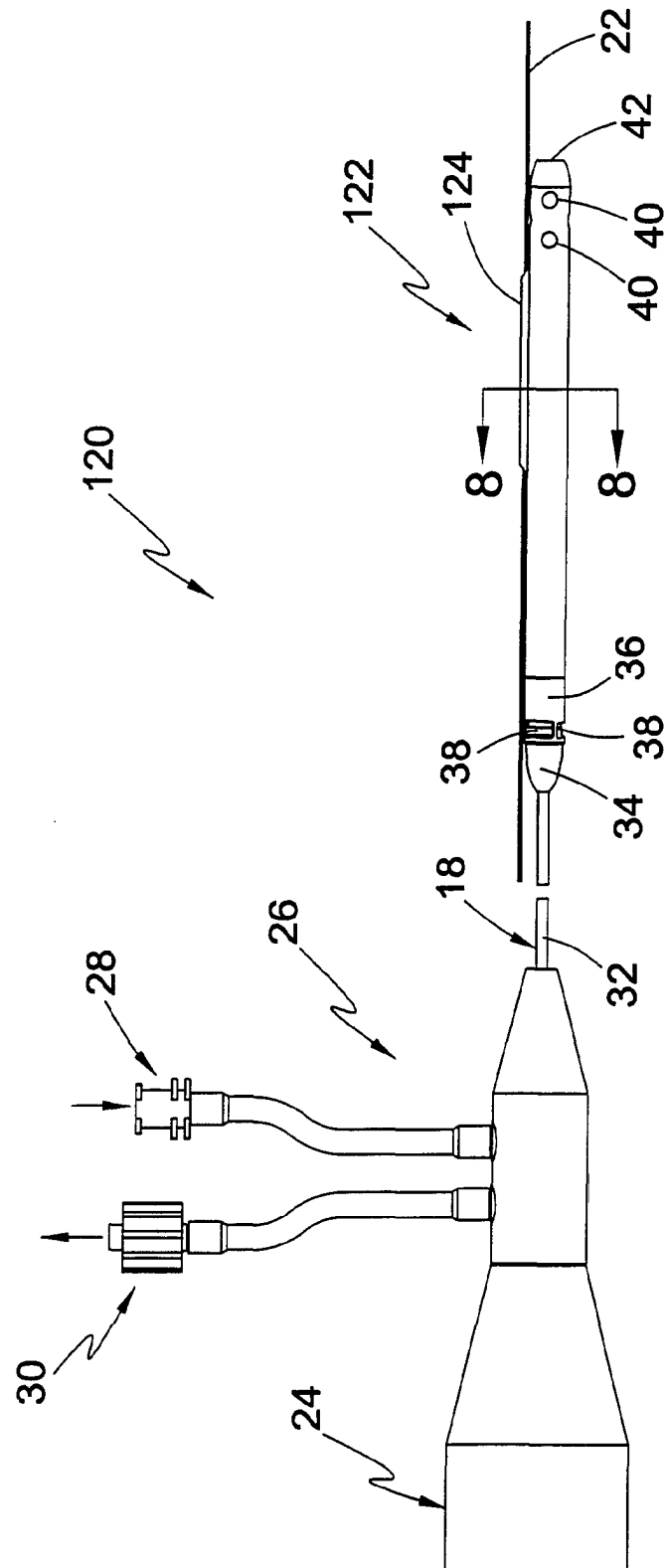


FIG. 7



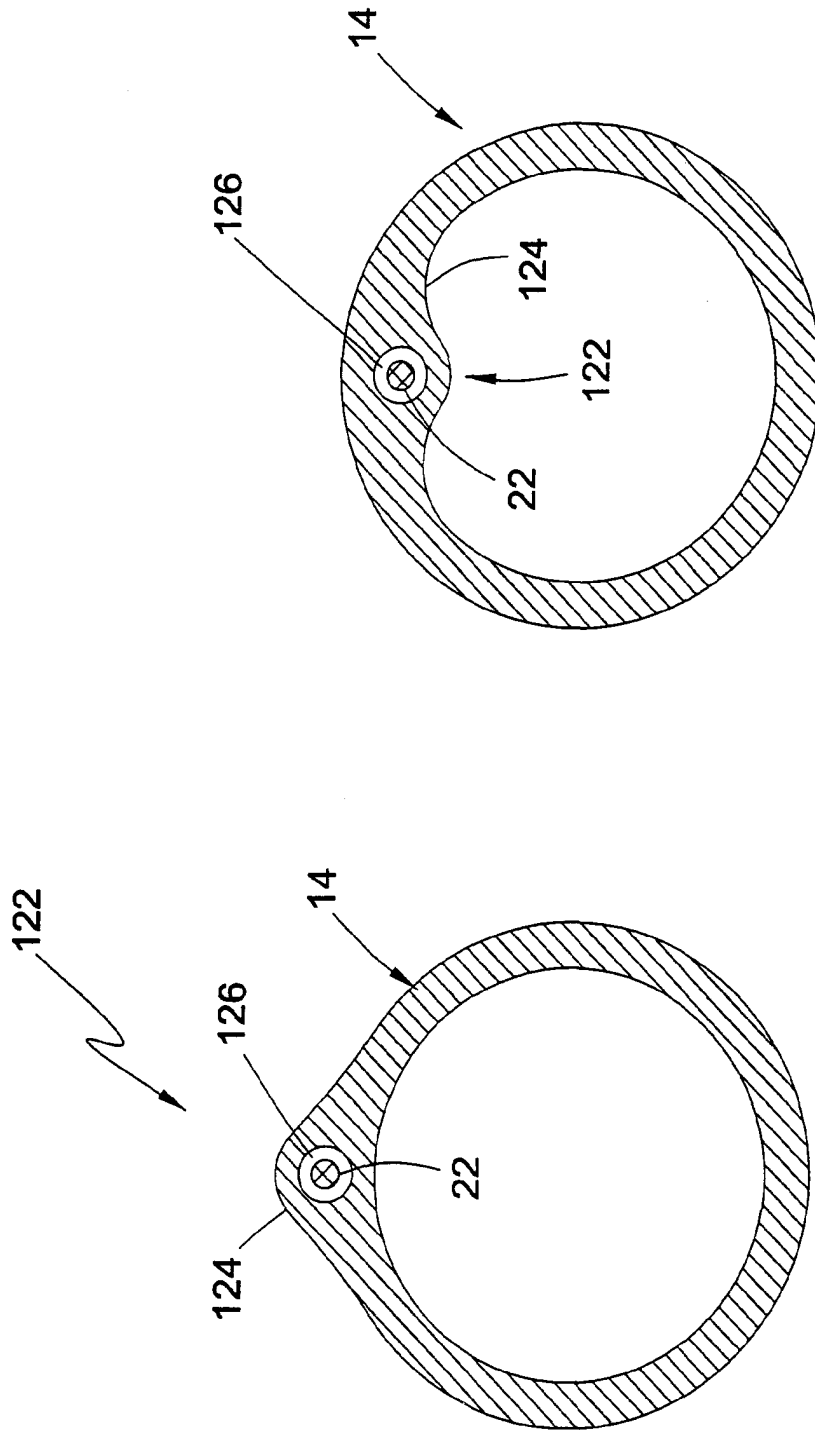
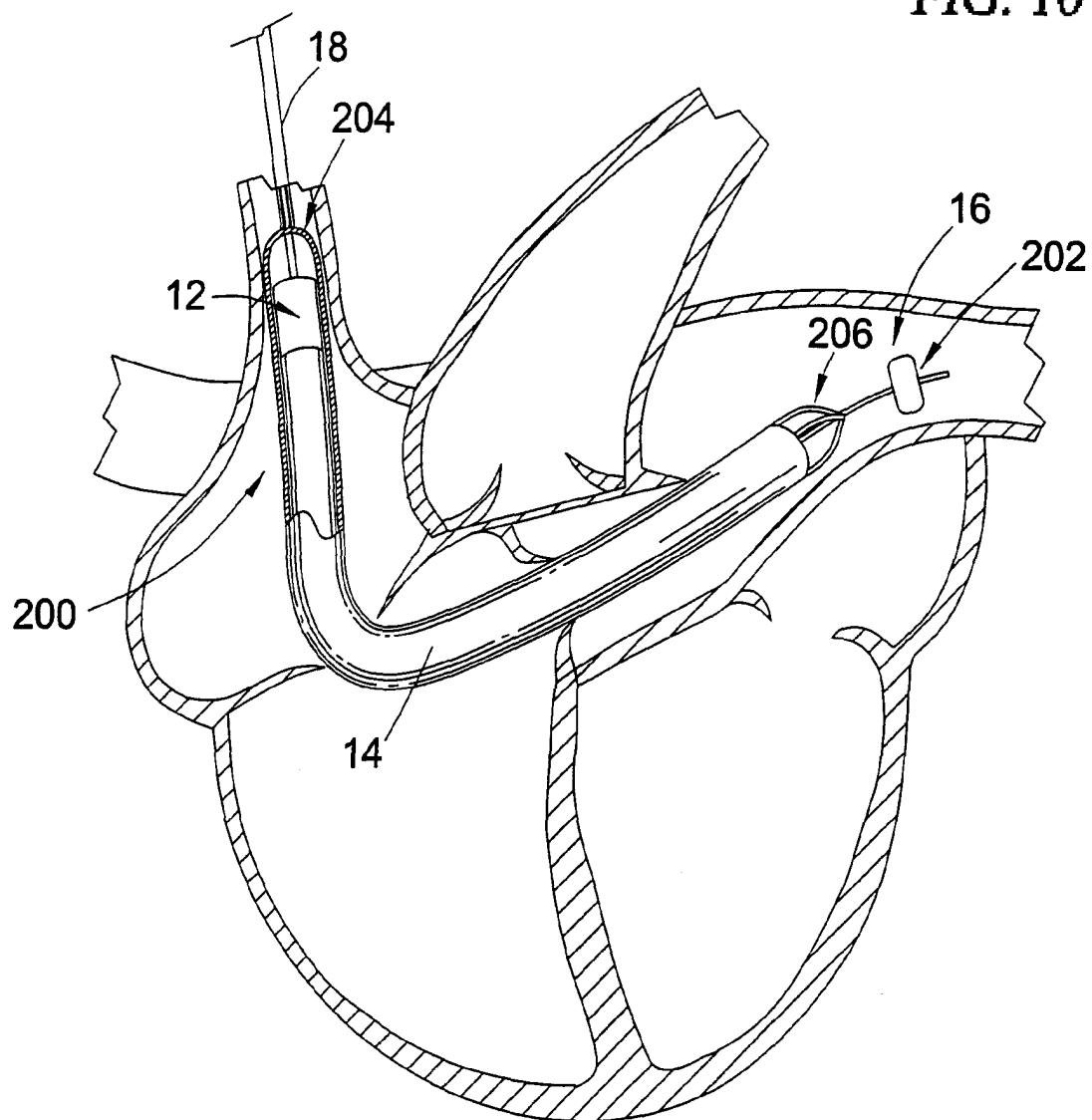


FIG 9

FIG 8

FIG. 10



REFERENCES CITED IN THE DESCRIPTION

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(54) 【発明の名称】 ガイド可能血管内血液ポンプおよび関連する方法

(57) 【特許請求の範囲】

【請求項 1】

改良された血管内血液ポンプシステムであって、以下：

血管内血液ポンプであって、該血管内血液ポンプに連結されたカニューレを備える、血
管内血液ポンプ；およびガイド機構であって、該血管内血液ポンプおよびカニューレを患者の循環器系内の所定
の位置にガイドするように適合された、ガイド機構、
を備え、該血管内血液ポンプは、ローター、該ローターを受容するシュラウド、および該シュラ
ウド内の該ローターを駆動するために該ローターに連結された駆動ケーブルを備え、

該カニューレは、該血管内血液ポンプの該シュラウドに連結されており、

該ガイド機構は、該シュラウドに連結されたガイドカテーテルを備え、

該血管内血液ポンプシステムは、

血液を該ガイドカテーテル内から、該患者の血管構造内への該ガイドカテーテルの導入
部位よりも下流の点に選択的に向けるために、該ガイドカテーテルに連絡して連結された
灌流アセンブリ

をさらに備え、

該灌流アセンブリは、該ガイドカテーテルに連絡して連結された第1導管、該患者の血
管構造に導入されるような寸法にされた第2導管、および該第1導管と該第2導管との間
に配置された止血バルブアセンブリを備える、

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血管内血液ポンプシステム。

【請求項 2】

請求項 1 に記載の血管内血液ポンプシステムであって、さらに、前記ガイドカテーテルが、前記シュラウドおよびカニューレを前記患者の循環器系内の前記所定の位置にガイドするために使用され得、その後、該血管内血液ポンプの前記ローターおよび駆動ケーブルが、ポンプ操作のために該シュラウド内に入れられ得る、血管内血液ポンプシステム。

【請求項 3】

請求項 1 に記載の血管内血液ポンプシステムであって、さらに、前記駆動ケーブルを受容するための中心管腔を有する駆動ケーブルシースを備え、そしてパージ流体送達システムが、パージ流体を前記ローターに送達するために該駆動ケーブルシースに連結されている、血管内血液ポンプシステム。

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【請求項 4】

請求項 3 に記載の血管内血液ポンプシステムであって、さらに、前記駆動ケーブルシースが、前記パージ流体を前記ローターに送達するために少なくとも 1 つの側部管腔を備える、血管内血液ポンプシステム。

【請求項 5】

請求項 4 に記載の血管内血液ポンプシステムであって、さらに、前記パージ流体の一部が、前記少なくとも 1 つの側部管腔を通り前記ローターを通過して送達され、そしてパージ流体の一部が、該ローターから前記駆動ケーブルの前記中心管腔を通して戻される、血管内血液ポンプシステム。

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【請求項 6】

請求項 1 に記載の血管内血液ポンプシステムであって、さらに、該血管内血液ポンプおよび前記カニューレのうちの少なくとも 1 つの近位において血圧を検出するための血圧検出機構を備える、血管内血液ポンプシステム。

【請求項 7】

請求項 6 に記載の血管内血液ポンプシステムであって、さらに、前記血圧検出機構が、前記カニューレの少なくとも一部の中に配置された流体充填カラム；該血管内血液ポンプおよび該カニューレのうちの少なくとも 1 つに連結された圧電素子；ならびに該血管内血液ポンプおよび該カニューレのうちの少なくとも 1 つに連結されたひずみゲージ；のうちの少なくとも 1 つを備える、血管内血液ポンプシステム。

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【請求項 8】

請求項 6 に記載の血管内血液ポンプシステムであって、さらに、前記血圧検出機構が、前記ローターを駆動するために使用されるモーターのトルクとモーター電流との間の関係に基づいて、血圧を計算する工程を包含する、血管内血液ポンプシステム。

【請求項 9】

請求項 1 に記載の血管内血液ポンプシステムであって、さらに、前記ガイド機構が、前記患者の血管構造内の前記所定の位置への前記シュラウドおよび前記カニューレの配置を容易にするために、前記ガイドカテーテルを通る通過のためのガイド要素をさらに備える、血管内血液ポンプシステム。

【請求項 10】

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請求項 9 に記載の血管内血液ポンプシステムであって、さらに、前記ガイド要素が、ガイドワイヤおよびバルーンカテーテルのうちの少なくとも 1 つを備える、血管内血液ポンプシステム。

【請求項 11】

請求項 1 に記載の血管内血液ポンプシステムであって、さらに、前記ガイド機構が、前記ガイドカテーテルの少なくとも一部に沿って形成される側部管腔を通る通過のためのガイド要素を備える、血管内血液ポンプシステム。

【請求項 12】

請求項 11 に記載の血管内血液ポンプシステムであって、さらに、前記ガイド要素が、ガイドワイヤおよびバルーンカテーテルのうちの少なくとも 1 つを備える、血管内血液ポ

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ンプシステム。

【発明の詳細な説明】

【0001】

(発明の分野)

本発明は、通常、血液ポンプに関し、そしてより具体的には、ガイド機構を有する、改良された血管内血液ポンプに関し、このガイド機構は、患者の循環器系内の所望の位置に血管内ポンプを選択的にガイドする能力を提供する。

【0002】

(関連技術の記述)

数年にわたって、損傷したまたは病気の心臓の血液を送り込む機能を補強または置換する目的のために、種々の型の血液ポンプが開発されてきた。血液ポンプは、一般に、(1) 心臓-肺手術の間の急なサポートのため；(2) 手術からの心臓の回復を待つ間の、短期間のサポートのため；または(3) 心臓移植を待つ間、患者を生存させておくためのつなぎとして、の3つの状況に使用される。ポンプは、右および／または左の心室補助を提供するように設計され得る。もともと、左の心室補助は、右心室よりも、左心室が病気になったりまたは損傷したりすることがずっとより一般的なので、最も一般的な適用である。

【0003】

血液ポンプは、漏れのない操作を提供しなくてはならず、そしてポンプの構成要素および外の環境による流体の汚染を避けなければならない。このようなポンプはまた、流体に過剰なレイノルズ剪断応力を与えることなく、適切な速さで流体を送り込まなくてはならない。細胞溶解または細胞破壊が、細胞膜に剪断応力を与えることによって生じることは、当業者に周知である。赤血球の細胞膜は、細胞の形を保持するための強化細胞骨格を含まないので、赤血球は、特に剪断応力損傷を被り易い。白血球および血小板の細胞溶解もまた、高い剪断応力を与えることによって起こる。赤血球の細胞溶解は、細胞内容物の放出を引き起こし得、この細胞内容物は、引き続いて、血小板の凝縮を誘導し得る。準溶解性剪断応力は、細胞の変化、そして、血小板および白血球の、活性化および凝集を引き起こす。

【0004】

血管内血液ポンプは、典型的に、左および／または右の心臓のサポートを提供するために、患者の血管系へ、経皮的または外科的に導入され得る、小型化された血液ポンプを含む。血管内ポンプの1つの型は、保護シュラウドに囲まれた、ケーブルを搭載したローターを含む軸方向流血液ポンプである。ポンプは、ローターおよびシュラウドと共に、伸長された可撓性カテーテルの端に搭載される。このカテーテルは、離れた入口点(例えば、大腿動脈へのアクセスを提供する単径部の下の切開)から大動脈へ挿入される。次いで、カテーテルは、心臓近くの上行大動脈に達するまで、下行大動脈を通過する。カテーテルデバイスは、回転する駆動ケーブルを含み、このケーブルは、一方の端でインペラブレードに連結し、そして他方の端で、患者の単径部近くの、カテーテルの露出端から現れる。この駆動ケーブルの露出端は、患者の体の外側に設置されたデバイスを用いて、機械的に回転され、カテーテルの長さによって回転力を伝達し、インペラを、心臓の近くで高速でスピンさせる。この型の血液ポンプは、手術の間の心室の補助を提供するか、または患者が危機を切り抜けるのを助けるための一時的なつなぎのサポートを提供する際に、特別な適用が見い出される。

【0005】

先行技術の血管内血液ポンプは、通常、心室補助機能を提供する際に、効果的であるが、それにもかかわらず、種々の欠陥を有する。重要な欠陥は、先行技術の血管内血液ポンプは、患者の循環器系内の適切な位置にガイドすることが難しい、ということである。これは、伸長されたカテーテルが、心臓まで、そして心臓内へと続く蛇行する経路を通して、このポンプに容易に扱うために必要な程度の制御を提供し得ない、という事実に大きく起因する。血液ポンプを、弁を横切る(trans-valvular)配置(この配置は、入口を左心室に、そしてポンプ出口を上行大動脈に有する)において設置しようとする

場合、カテーテルが真っ直ぐのままとどまろうとする自然の傾向によって、ポンプは、不注意にも頸動脈口に配置され得、このことは、ポンプが脳からの血液を回収するように操作されると、危険となり得る。

【 0 0 0 6 】

これらの困難性を克服するために、特定のガイド機構は、医者が、循環器系内の適切な位置にポンプを配置するのを補助するために利用され得る。1つの型の補助的ガイド機構は、ガイドカテーテルである。ガイドカテーテルは、医者が、ガイドカテーテルを血管構造または心臓内に、比較的容易に、選択的に配置し得るように、特定のガイド可能性を特徴として有して設計される。中心管腔は、血管内ポンプが、ガイドカテーテル内に導入され、そして所定の循環部位に向かって進む間、ガイドされ得るように、ガイドカテーテル内に提供される。このような補助的ガイド機構を利用することは、通常、このような血管内血液ポンプに対してガイドする特徴を提供する場合に効果的であるが、それにもかかわらず、このような補助的ガイド機構が血管内の貴重な空間を占領するという点で不利である。例えば、ガイドカテーテルは、ポンプおよび保護シュラウドの構成要素の十分な通過を提供するために、これらの直径よりも、直径が必ず大きい。理解されるように、このことは、血液が特定の血管内で流れるために利用可能な空間の体積を制限し、そして血管にアクセスするために必要とされる刺創のサイズを大きくする。

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【 0 0 0 7 】

本発明は、先行技術の血管内血液ポンプの前述する欠陥の影響を取り除き、および／または減らすことに向けられる。

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【 0 0 0 8 】

(本発明の要旨)

本発明は、患者の循環器系（すなわち、心臓および／または血管構造）内の、所定の位置に、血管内血液ポンプを選択的にガイドするための統合された特徴を備えた、改良された血管内血液ポンプを提供することによって、先行技術の欠陥を克服する。このようにする際に、本発明の血管内血液ポンプは、補助的なガイド機構（例えば、先行技術で使用されるような分離した、大きな直径のガイドカテーテル）に対する必要性を取り除く。

【 0 0 0 9 】

本発明の第1の広範な局面において、血管内血液ポンプシステムは、血管内血液ポンプであって、それに連結されたカニューレを有する血管内血液ポンプ、および、患者の循環器系内の所定の位置に、血管内血液ポンプおよびカニューレを選択的に配置するための、「オーバーワイヤ（over-the-wire）」型のガイド機構を含んで、提供される。これを確立するために、中心管腔は、血管内血液ポンプシステムの少なくとも一部分を通じて形成され、その結果、ガイドワイヤのようなガイド要素は、その部分を通して前に進められ、そして患者の循環器系の所定の位置まで推し進められ得る。このガイド要素は、このような所望の位置に進められた後、血管内血液ポンプおよびカニューレは、その後、ガイド要素に沿って所望の位置まで進められ得る。

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【 0 0 1 0 】

本発明の第2の広範な局面としては、血管内血液ポンプシステムは、血管内血液ポンプであって、それに連結されたカニューレを有する血管内血液ポンプ、および、患者の循環器系内の所定の位置に、血管内血液ポンプおよびカニューレを選択的に配置するための、「側部装備（side-rigger）」または「迅速交換（rapid exchange）」型のガイド機構を含んで、提供される。これを確立するために、側部管腔は、血管内血液ポンプおよびカニューレの少なくとも一部分の長さに沿って形成される。ガイドワイヤのようなガイド要素は、患者の循環器系内の所定の位置に進められ得る。ガイド要素がこのような所望の位置に進められた後、血管内血液ポンプおよびカニューレは、その後、ガイド要素に沿って所望の位置まで進められ得る。

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【 0 0 1 1 】

本発明の第3の広範な局面としては、血管内血液ポンプシステムは、血管内血液ポンプであって、それに連結されたカニューレを有する血管内血液ポンプ、および、患者の循環器

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系内の所定の位置に、血管内血液ポンプおよびカニユーレを選択的に配置するための、「ガイドカテーテル (guide catheter)」型のガイド機構を含んで、提供される。この広範な局面のポンプシステムは、導管アセンブリおよび分離したポンプアセンブリを含む。導管アセンブリは、ガイドカテーテル、ローターシュラウド、およびカニユーレ（このカニユーレおよびガイドカテーテルは、ローターシュラウドのいずれかの端に配置されている）を備える。ポンプアセンブリは、ローター、ローターに連結された駆動部材、およびローターと駆動部材との間に配置されたポンプを備える。ガイドカテーテルは、使用できる血液ポンプを形成するために、ポンプアセンブリを受容し、そしてローターシュラウド内にローターがドッキングする点まで、ポンプアセンブリをガイドするように寸法決めされる。この配置は、導管アセンブリが、介入的心臓病学において周知の、従来のガイド技術の使用を通じて、体内の所望の位置へ正確かつ効果的にガイドされるのを可能とする。その後、ポンプアセンブリは、導管へ導入され、ポンプアセンブリがローターシュラウド内でドッキングされるまで、導管内でガイドされ得る。この二重の構築アレンジメントは、ガイド機構として導管を使用することによって、ポンプアセンブリの改良された配置を提供する。

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【0012】

本発明の前述される広範な局面は、以下の詳述に従って明らかにされ得る。

【0013】

本発明の第1の広範な詳述によると、血管内血液ポンプシステムは、血管内血液ポンプに連結されたカニユーレを有する血管内血液ポンプ、および、患者の循環器系内の所定の位置に、血管内血液ポンプおよびカニユーレをガイドするために適合されるガイド機構を含んで、提供される。

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【0014】

さらなる実施形態において、血管内血液ポンプは、ローター、ローターを受容するためのシュラウド、およびシュラウド内でローターを駆動するための、ローターに連結した駆動ケーブルを備える。

【0015】

さらなる実施形態において、カニユーレは、血管内血液ポンプのシュラウドに連結される。

【0016】

さらなる実施形態において、ガイド機構は、シュラウドに連結されたガイドカテーテルを備える。

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【0017】

さらなる実施形態において、ガイドカテーテルは、患者の循環器系内の所定の位置に、シュラウドおよびカニユーレをガイドするために使用され得、その後、血管内血液ポンプのローターおよび駆動ケーブルは、ポンプ操作のために、シュラウド内でドッキングされ得る。

【0018】

さらなる実施形態において、駆動ケーブルシースは、駆動ケーブルを受容するための中心管腔を有して、提供され、そしてここで、パージ流体送達システムが、駆動ケーブルシースに連結され、ローターにパージ流体を送達する。

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【0019】

さらなる実施形態において、駆動ケーブルシースは、パージ流体をローターに送達するための少なくとも1つの側部管腔を備える。

【0020】

さらなる実施形態において、一部分のパージ流体は、少なくとも1つの側部管腔を介して、そしてローターを経て送達され、そして一部分のパージ流体はローターから駆動ケーブルの中心管腔を介して経路変更されて戻る。

【0021】

さらなる実施形態において、灌流アセンブリは、ガイドカテーテル内から、患者の血管構

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造へのガイドカテーテルの導入位置から下流の位置まで、血液を選択的に経路変更するために、ガイドカテーテルに相互連絡して連結されて、提供される。

【0022】

さらなる実施形態において、灌流アセンブリは、ガイドカテーテルに相互連絡して連結された第1の導管、患者の血管構造へ導入されるように寸法決めされた第2の導管、ならびに、第1の導管と第2の導管との間に配置された選択的に操作可能な弁を備える。

【0023】

さらなる実施形態において、血管内血液ポンプおよびカニューレの少なくとも1つに近接する、血液の圧力を検出するために、血圧検出機構が提供される。

【0024】

さらなる実施形態において、血圧検出機構は、カニューレの少なくとも一部分内に配置された、液体充填カラム、血管内血液ポンプおよびカニューレの少なくとも1つに連結された圧電素子、および血管内血液ポンプおよびカニューレの少なくとも1つに連結されたひずみゲージを含む。

【0025】

さらなる実施形態において、血圧検出機構は、ローターを駆動するために使用されるモーターのトルクとモーター電流との間の関係に基づいて、血圧を計算することを包含する。

【0026】

さらなる実施形態において、ガイド機構は、カニューレ内に少なくとも部分的に配置されたガイド要素を含む。

【0027】

さらなる実施形態において、ガイド機構は、カニューレ内に形成された側部管腔を通過するためのガイドワイヤを含む。

【0028】

さらなる実施形態において、ガイド要素は、カニューレ内に少なくとも部分的に配置された、選択的に変形可能な要素を含む。

【0029】

さらなる実施形態において、血管内血液ポンプおよびカニューレは、まず、所定の位置までガイドワイヤを通し、その後、血管内血液ポンプおよびカニューレをガイドワイヤに沿って所定の位置まで滑らせることによって、患者の血管構造内の所定の位置まで、選択的に進められ得る。

【0030】

さらなる実施形態において、ガイド要素は、駆動ケーブルおよびローターを介して延びる管腔を通る通路のためのガイドワイヤを含む。

【0031】

さらなる実施形態において、血管内血液ポンプおよびカニューレは、血管内血液ポンプおよびカニューレは、まず、所定の位置までガイドワイヤを通し、その後、血管内血液ポンプおよびカニューレをガイドワイヤに沿って所定の位置まで滑らせることによって、患者の血管構造内の所定の位置まで、選択的に進められ得る。

【0032】

さらなる実施形態において、ガイド機構は、患者の血管構造内の所定の位置へのシュラウドおよびカニューレの配置を容易にするために、ガイドカテーテルを通過するためのガイド要素をさらに含む。

【0033】

さらなる実施形態において、ガイド機構は、ガイドカテーテルの少なくとも一部分に沿って形成された側部管腔を通過するためのガイド要素をさらに含む。

【0034】

さらなる実施形態において、ガイド要素は、ガイドワイヤおよびバルーンカテーテルの少なくとも1つを含む。

【0035】

(発明の詳細な説明)

本発明の例示的实施形態が以下に記載される。明瞭性の目的で、実際の実施の全ての特徴が本明細書に記載され得るわけではない。もちろん、任意のこのような実際の実施形態の開発において、多くの実施特異的決定が、開発者の特定の目的（例えば、システム関連の制限および商業関連の制限（これらは実施間で異なる）に従う）を達成するためになされなければならないことが理解される。さらに、このような開発の努力は、複雑で時間を消費し得るが、それにもかかわらず本開示の利益を有する当業者が慣用的に行うことが理解される。

【0036】

本発明は、患者の循環器系内の血流の増強を含む多くの幅広い範囲の適用における使用のための血管内ポンプシステムを含む。以下に記載されるように、本発明の血管内血液ポンプシステムは、血管内血液ポンプの一部としてガイド機構を提供することによって先行技術の欠点を克服する。これによって、血管内血液ポンプが、かさ高い補足ガイド機構（例えば、別のガイドカテーテル）の必要なしに患者の循環器系内の所定の位置に選択的にガイドされ得る。

【0037】

本発明の血管内ポンプアセンブリは、弁を横切る使用（例えば、左心室および／または右心室補助処置）に特に適する。単なる例示として、このような心室補助処置は、冠状動脈バイパス移植（GABG）、心肺バイパス（CPB）、開胸および非開胸（最小限の侵襲性）手術、移植への橋渡しの状況および／またはバイパスから離すことの失敗の状況が挙げられるがこれらに限定されない心臓手術において使用され得る。さらに、左心臓補助適用に関して大いに例示および記載されているが、本発明の原理が右心臓補助適用に関して等しく適用されることが容易に理解され、これは、本発明の範囲内として意図される。これらおよび他の変更およびさらなる特徴は、全体を通して記載される。

【0038】

図1を参照すると、単なる例示として示されるヒトの心臓内の左心臓補助構成で、本発明の最初の幅広い局面に従ったガイド可能血管内血液ポンプシステム10が示される。システム10は、血管内血液ポンプ12、カニューレ14、および「オーバーワイヤ」型のガイド機構16を備える。駆動ケーブルアセンブリ18およびモーターアセンブリ20は、血管内血液ポンプ12を駆動するために提供される。「オーバーワイヤ」ガイド機構16は、駆動ケーブル18、血液ポンプ12、およびカニューレ14を通して伸長する中心管腔をスライド可能に通過する寸法にされた適切なガイド要素を備える。適切なガイド要素には、多数の従来のガイドデバイス（心臓病学に使用されるデバイスを含むがこれに限定されない）が挙げられ得る。単なる例示として、ガイド要素は、ガイドワイヤ22として示される。本発明に従って、「オーバーワイヤ」ガイド機構16は、患者の循環器系内の所定の位置（例えば、示される弁を横切る位置）に血液ポンプ12およびカニューレ14を選択的にガイドする能力を提供する。

【0039】

これを達成するために、ガイドワイヤ22は、最初に任意の適切なアクセスポイントを通して患者の血管系に導入される（例えば、周知のセルディング技術を使用する）。次いで、ガイドワイヤ22は、患者の循環器系内の所望の位置に患者内を進み得る。これは、ガイドワイヤ22自身の制御特徴を使用してなされ得るか、またはガイドワイヤ22の適切かつ効率的な配置を確実にするために多数の補足ガイダンス機構または技術の使用によって容易にされ得る。このような補足ガイダンス技術には、ガイドカテーテルおよび／または超音波またはX透視検査を含む技術が挙げられえが、必ずしもこれらに限定されない。一旦、ガイドワイヤ22が所望の位置（例えば、示されるような左心室）に配置されると、血液ポンプ12およびカニューレ14は、その後、ガイドワイヤ22に沿って進められ得、そして示される弁を横切る構成で位置付けられ得る。モーターアセンブリ20の操作下において、血液ポンプ12は、血液ポンプ12に形成される拍出装置を通して外側に送達するために左心室から（カニューレ14の内側を通して）血液を選択的に引き込む

ことによって左心臓補助に使用され得る。血液ポンプ 12 からのこの拍出は、身体中を通して動脈分布について実質的な軸様式で駆動ケーブルアセンブリ 18 の外側に沿って流れる。

【0040】

図 2～5 を参照すると、図 1 の血管内血液ポンプシステム 10 の例示的な実施形態がここで記載される。図 2 に示されるように、血管内血液ポンプシステム 10 は、モーター連結器 24、および以下にさらに詳細に記載されるように、ポンプ操作の間、駆動ケーブルアセンブリ 18 内に二通路流体フローを提供するためのパージ流体送達システム 26 を備える。パージ流体送達システム 26 は、血液ポンプ 12 への送達のための流体供給源（図示せず）からの加圧パージ流体を導入するための流体入口導管 28、および血液ポンプ 12 からパージ流体の戻りのフローを引き込むための流体出口導管 30 を備える。モーター連結器 24 は、ポンプ操作のために血液ポンプ 12 に起動力を提供するためにモーター（図示せず）と駆動ケーブル（図示せず）との間に機械的接続を確立する。駆動ケーブルアセンブリ 18 は、駆動ケーブルシース 32 を備え、これはまた、パージ流体送達機能を提供することに加えて、駆動ケーブル（図示せず）に対する保護性のハウジングとして役立つ。明瞭性のために分解されて示されるが、駆動ケーブルアセンブリ 18（およびその全ての構成要素）は、血管内適用に十分な任意の適切な長さで提供され得る。すなわち、駆動ケーブルアセンブリ 18 の長さは、患者の外側に配置されるモーター連結器 24 およびパージ流体送達システム 26 と血液ポンプ 12 が配置される患者の循環器系内の所望の位置との間に達するのに十分でなければならない。

【0041】

血管内血液ポンプ 12 は、軸方向フロー血管内血液ポンプとして（例示として）示される。血液ポンプ 12 は、ポンプ本体 34、フローポート 38 を有するローターシュラウド 36、ならびにポンプ本体 34 内に回転可能に配置されるシャフトおよびローターシュラウド 36 内に回転可能に配置されるインペラーを有する内部に配置されたローター（図示せず）を備える。カニューレ 14 は、ローターシュラウド 36 に固定的に接続され、そして特定の血管内適用に依存してそこから任意の適切な長さで伸長し得る。カニューレ 14 は、好ましくは、その遠位領域のあたりに複数のポートまたは窓（*f e n e s t r a t i o n*）40、ならびに端部ポート 42（これは血液ポンプ 12 の操作に依存して血液をカニューレ 14 に入れるかまたはカニューレ 14 から出すことを可能にする）を備える。すなわち、ポンプ 12 が、図 1 に示される左心臓補助のために構成される場合、ポート 40、42 が、左心室からカニューレ 14 へ血液が入ることを可能にする。他方で、血液ポンプ 12 が右心臓補助のために構成される（すなわち、ポンプ 12 が右心房に配置され、そしてカニューレ 14 の遠位端が肺動脈内に配置される）場合、ポート 40、42 は、カニューレ 14 から肺動脈へ血液が入ることを可能にする。（右心臓補助適用についての詳細は、以下にさらに詳細に議論される）。ポンプ 12 およびカニューレ 14 は、血管内適用に適切な任意の直径の寸法であり得る。例えば、サイズの範囲は、9 *F r e n c h*～30 *F r e n c h* を含み得るが、これらに必ずしも限定されない。その範囲は、好ましくは 14 *F r e n c h*～24 *F r e n c h*、最も好ましくは 18 *F r e n c h*～20 *F r e n c h* である。

【0042】

「オーバーワイヤ」型ガイド機構 16 は、ガイドワイヤ 22 を備え、以下にさらに詳細に説明されるように、カニューレ 14 を通って伸長する中心管腔、血液ポンプ 12、駆動ケーブルアセンブリ 18、パージ流体送達システム 26、およびモーター連結器 24 を備える。上で示すように、中心管腔は、ガイドワイヤ 22 をスライド可能に受容するような寸法であり、その結果、ガイドワイヤ 22 が従来のガイドランス技術を使用して位置付けられた後に、血液ポンプ 12 およびカニューレ 14 がガイドワイヤ 22 に沿って患者の循環器系内の所望の位置にスライド可能に進み得る。従来のガイドワイヤ 22 として示されるが、本発明のガイド機構 16 の一部を形成するガイド要素が、適用（中心管腔を通してスライド可能に受容されるような寸法のバルーンカテーテル、イメージングワイヤ、およびガ

イドカテーテルを含むがこれらに限定されない)に依存して多数の周知のガイダンス機構を備え得ることが容易に理解される。例えば、逆行性の進行(例えば、図1に示される左心臓適用)に適切ではないが、バルーンカテーテルは、右心臓補助適用に適切なガイダンス機構であり得る。このような場合、バルーンは、カテーテルを所望の位置(例えば、肺動脈)に向けるように膨張されそして「セイル(sail)」として使用され得、その後、血液ポンプ12およびカニューレ14が、血液ポンプ12が右心房にあり、そしてカニューレ14のポート38、40が肺動脈にある弁を横切る構成にカテーテルを越えて進み得る。

【0043】

図3および4は、さらに血液ポンプ12、カニューレ14、駆動ケーブルアセンブリ18、および「オーバーワイヤ」ガイド機構16の構成を詳述する。血液ポンプ12は、シャフト46を有するローター44およびインペラー48を備える。シャフト46は、例示としてボールベアリングアセンブリ50、52およびバネ54を含むベアリングパックによってポンプ本体34内に回転可能に配置される。ボールベアリングアセンブリ50、52は、当該分野において周知であり、それぞれローターシャフト46に沿って回転する内側レース、ポンプ本体34の内側表面に対して静的かつ固定された位置に保持する外側レース、および内側レースと外側レースの間に配置される複数のボールベアリングを備える。バネ54は、ポンプ操作の間の軸方向のあそびを減少するために互いに軸方向に離れるように各ベアリングアセンブリ50、52を付勢する。シャフト46は、一般的に中空であり、そして駆動ケーブルアセンブリ18の一部を形成する駆動ケーブル62にローター44を連結するために、このシャフト内にケーブルアダプタ60を受容するような寸法である。駆動ケーブル62は、多数の適切な形式(接着剤、クリンピング、およびレーザー溶接の使用を含むがこれらに限定されない)でケーブルアダプタ60に固定され得る。これらの同じ技術を使用して、ローター44のシャフト46内にケーブルアダプタ60を固定し得る。ラジアルシール64は、ポンプ本体34の壁とローターシャフト46の遠位段状領域66との間に提供され、その機能は、以下に記載される。

【0044】

インペラー48は、ハブ56およびそこから伸びる複数のブレード58を備える。ハブ56は、ほぼ円錐形であり、本発明の第1の幅広い局面に従って、ガイド機構16の中心管腔の一部を形成するために全体にわたって中空である。これに関して、ハブ56は、好ましくは、その遠位先端においてガスケットまたはシール部材68を備える。シール部材68は、任意の適切なシール材料(シリコーンを含むがこれに限定されない)から形成され得、その結果、ポンプ12およびカニューレ14は、所望の循環部位への送達のためにガイドワイヤ22に沿って容易に進み得る。シール部材68はまた、ガイドワイヤ22が適所のままにあるか、または完全に引き抜かれるかにかかわらず、ポンプ操作の間、ローターハブ56の内側への血液の侵入を妨げるのに十分丈夫であるべきである。ブレード58は、シュラウド36の内側表面と近い許容差(tolerance)であるような寸法である。操作において、ブレード58は、血液に軸方向ベクトルと半径方向ベクトルとの両方を与え、これによって、血液はシュラウド36に形成されるフローポート38を通して外に流れる。本明細書中で使用されるように、用語「軸方向フロー」は、図3に示されるようなフロー特徴を含むと考えられ、これは、軸方向成分と少しの半径方向成分の両方を含む。軸方向フロー型として示されているが、血液ポンプ12は、本発明の範囲から離れることなく、多数の適切な型の血管内血液ポンプを含み得る(これには、いわゆる「混合フロー」血管内血液ポンプが挙げられるが、これには限定されない)ことが容易に理解される。

【0045】

カニューレ14は、その近位端において、ローターシュラウド36に接続される。これは、接着剤の使用が挙げられるがこれに限定されない、多数の様式で達成され得る。これはまた、シュラウド36を、カニューレ14の近位端の内部に同一面に受容され得る狭い入口領域70を含むような寸法にすることによって、容易にされ得る。シュラウド36の入

口領域 70 は、カニューレ 14 とインペラブレード 58 を含む領域との間の滑らかなフロー移行を確立するために、好ましくは、テーパ状の内部表面を有するべきである。単一の一体的な要素として示されるが、ポンプ本体 34 およびシュラウド 36 は、2つの別個の（そして時々分離可能な）構成要素を備え得ることが、理解されるべきである。このことの重要性は、以下で明らかとなる。ポンプ本体 34 およびシュラウド 36 は、多数の適切な材料（ステンレス鋼または他の医療等級の組成物もしくはアロイが挙げられるがこれらに限定されない）から構成され得る。カニューレ 14 もまた、多数の適切な材料（医療等級のプラスチックが挙げられるがこれに限定されない）から構成され得る。示されるように、カニューレ 14 はまた、カニューレ 14 の壁の内部の螺旋状に巻かれた補強ワイヤ 72 で強化され得る。

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【0046】

駆動ケーブルアセンブリ 18 は、駆動ケーブル 62 および駆動ケーブルシース 32 を備える。駆動ケーブル 62 は、ケーブルアダプタ 60 を介してローター 44 に接続される。駆動ケーブルシース 32 は、中心管腔 74 および複数の側部管腔 76 を備える。中心管腔 74 は、駆動ケーブル 62 のための保護的カバリングとして働く。中心管腔 74 はまた、側部管腔 76 とともに、上記図 2 に示すパージ流体送達システム 26 の一部を形成し、このことは、以下でさらに詳細に記載される。側部管腔 76 は流体入口導管 28 と流体連絡して提供され、一方で中心管腔 74 は、流体出口導管 30 と流体連絡して提供される。従って、側部管腔 76 は、パージ流体をポンプ 12 内へと駆動するよう構成され、一方で中心管腔 74 は、パージ流体を駆動ケーブル 62 の長さに沿ってポンプ 12 から離れるように

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【0047】

側部管腔 76 の内部の加圧されたパージ流体は、ポンプ 12 に入る際に、2つの流路のうち的一方をとり得る。一方の流路は、ポンプ 12 の内部を通過し、そしてラジアルシール 64 を外向きに通過して、ポンプの作動中に血液がポンプ本体 34 に入ることを防止する。より具体的には、パージ流体は、ケーブルアダプタ 10 の周囲を遠位方向に流れ、ボールベアリングアセンブリ 50、52 を通過し、そしてラジアルシール 64 を外向きに通過する。このようにパージ流体を強制的にラジアルシール 64 を通過させることは、血液がラジアルシール 64 を通過して入ることを効果的に妨害するよう制御され得る。血液が入ることは、妨害されない場合には、凝固および／またはポンプの損傷を引き起こし得る。外側の流路は、流体出口導管 30 に送達するために、中心管腔 74 の外側を戻るよう指向される。このようにする際に、この流路は、ポンプ 12 および／または駆動ケーブル 62 の構成要素を浸漬し、これによって、ポンプの作動中に、ポンプ 12 および／またはシース 32 の中心管腔 74 の内部の摩擦加熱を減少させる。

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【0048】

「オーバーワイヤ」ガイド機構 16 は、中心管腔を備え、この管腔を通して、ガイドワイヤ 22 が、血液ポンプ 12 およびカニューレ 14 を患者の循環器系内の所望の位置にスライド可能に進めるために、延び得る。示される実施形態において、この中心管腔は、駆動ケーブル 62、ケーブルアダプタ 60、ローター 44 のシャフト 46 およびハブ 56、ならびにカニューレ 14 の各々の内部に個々の中心管腔を形成し、そしてこれらの中心管腔をとともに整列させることによって、確立される。この点に関して、駆動ケーブル 62 は、好ましくは、内部に中心管腔が形成された巻かれたワイヤの構成である。ケーブルアダプタ 60、ローター 44、およびガスケット 68 の内部の中心管腔は、機械加工プロセスまたは成形プロセスによって、形成され得る。これらの中心管腔は、好ましくは、ポンプの作動中に、これらに沿ったポンプ 12 およびカニューレ 14 のスライド可能な通過を可能にするが、ガイドワイヤ 22 がガイドワイヤ 22 の不注意による回転を引き起こすことを妨害も制限もしないような大きさにされるべきである。上記のように、ポンプ 12 およびカニューレ 14 が患者内で適切に配置された後に、ガイドワイヤ 22 を取り除くこともまた、意図される。この場合には、ハブ 56 のガスケットまたはシール 68 は、ガイドワイヤ 22 が引き抜かれた後に再シールし、そして血液がローター 44 の内部に入ることを防

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止するよう十分に丈夫であるべきである。

【0049】

図5を参照すると、モーター連結器24は、ハウジング78、駆動シャフトアダプタ80、およびベアリングアセンブリ82を備える。駆動シャフトアダプタ80は、駆動シャフト連結器84および駆動ケーブル連結器86を備え、この駆動シャフト連結器84は、モーター（図示せず）の駆動シャフトを受容するような寸法にされ、そしてこの駆動ケーブル連結器86は、駆動ケーブル62を受容するような寸法にされる。種々の取り付け技術（接着剤、圧着、およびレーザー溶接が挙げられるが、これらに限定されない）の任意のものを使用して、駆動ケーブル62を駆動ケーブル連結器86にしっかりと固定し得る。駆動シャフトアダプタ80は、ベアリングアセンブリ82によって、ハウジング78の内部に回転可能に配置される。ベアリングアセンブリ82は、ボールベアリングアセンブリ90、92の対、および上記の型のバネ94を保持するための、スリーブ88を備える（あるいは、このスリーブ88は、ハウジング78の一体的な部分として形成され得る）。すなわち、各ベアリングアセンブリ90、92は、一般に、内側レース、外側レース、および複数のボールベアリングを備え、この内側レースは、駆動シャフトアダプタ80とともに回転し、そして外側レースは、静止したままであり、そして保持スリーブ88の内側表面に対して固定されて位置し、そして複数のボールベアリングは、内側レースと外側レースとの間に配置される。バネ94は、各ベアリングアセンブリ90、92を互いに軸方向に離して付勢するために提供され、これによって作動中の軸方向の遊びを減少させる。

【0050】

ページ流体送達システム26は、中心管腔98、流入ポート100、および流出ポート102を有するハウジング96を備える。ハウジング96はまた、モーター連結器24の一部を嵌合して受容するような寸法にされる。この点に関して、シール要素104が、ハウジング96とハウジング78との間に挟まれて提供され、そして開口部を有し、この開口部は、駆動シャフトアダプタ80がハウジング78を出るにつれて、駆動シャフトアダプタ80の周囲に延びて、ページ流体がモーター連結器24に入ることを防止する。流体ガイド構造体106もまた、流入ポート100および流出ポート102を分離するために、中心管腔98の内部に提供される。流体ガイド構造体106は、中心管腔108および上昇部分110を備え、この中心管腔108を通して、駆動ケーブル62が延び、そしてこの上昇部分110は、Oリング112を、ハウジング96の中心管腔98の内側表面に対して保持する。駆動ケーブルシース32は、ハウジング96に固定され、その結果、流入ポート100が、側部管腔76と連絡して接続され、そして流出ポート102が、中心管腔74と連絡して接続される。この様式で、加圧されたページ流体は、流入導管28を通して流入ポート100へと導入され得、そして流出ポート102を通して流出導管30を通して除去され得る。例示として、流入導管28および流出導管30は、それらのそれぞれのポート100、102に、鉤付きコネクタ114を介して接続され得る。同様に、流入導管28および流出導管30は、加圧された流体の供給源（図示せず）との流体連絡を確立するための、任意の数の適切なコネクタ（例えば、図2に例示として示されるもの）を備え得る。加圧された流体の供給源（図示せず）としては、加圧された流体の必要な送達を提供するための、シリンジ、インデフレーター（indeflator）、流体送達ポンプ、またはアキュムレータ配置の使用が挙げられ得るが、これらに必ずしも限定されない。従って、ページ流体送達システム26は、血液ポンプ12を冷却し、そして血液がラジアルシール64を通過して血液ポンプ12に入ることを防止する目的で、駆動ケーブルシース32の内部に、ページ流体の2方向伝達を提供する。

【0051】

図6を参照すると、本発明の第二の広い局面による、ガイド可能な血管内血液ポンプシステム120が示される。本明細書中以下に記載されるように、血管内血液ポンプシステム120は、利用されるガイド機構の型に関してのみ、上記血管内血液ポンプシステム10と異なる。ここで、明瞭さおよび一貫性のために、類似の参照番号は類似の要素を示すために使用され、そして必要である場合に、違いを指摘する。さらに、両方の血管内血液ポ

ンプシステム 10、120 において使用される原理の共通性に起因して、上記の細部のレベルの議論は、血管内血液ポンプシステム 120 に関しては、必要であるとはみなされない。その代わりに、血管内血液ポンプ 10 と共通の局面を、ここで血管内血液ポンプシステム 120 の議論に援用する。

【0052】

その最も一般的な形態において、本発明のこの第二の広い局面の血管内血液ポンプシステム 120 は、血液ポンプ 12 およびカニューレ 14 の配置を備え、ここで、カニューレ 14 は、「側部装備 (side-rigger)」または「迅速交換」ガイド機構 122 を備える。本発明の重要な局面において、「迅速交換」または「側部装備」ガイド機構 122 は、ガイドキャリッジ 124 および適切なガイド要素 (例えば、ガイドワイヤ 22) を備え、ここで、このガイドキャリッジ 124 は、カニューレ 14 の少なくとも一部に沿って形成され、そしてこのガイド要素は、ガイドキャリッジ 124 を通って延びる管腔 (図示せず) をスライドして通過する寸法にされる。これによって、「迅速交換」ガイド機構 122 は、血液ポンプ 12 およびカニューレ 14 を、上記様式で、患者の循環器系内の所定の位置に選択的にガイドするための能力を提供する。すなわち、ガイドワイヤ 22 は、任意の適切なアクセスポイントを通して患者の血管系に最初に導入され、そしてこの患者の循環器系内の所望の位置 (すなわち、図示されるような左心室) にガイドされ得る。その後、血液ポンプ 12 およびカニューレ 14 は、ガイドワイヤ 22 に沿って進められ得、そして左心の補助を提供するために、示される弁を通過する構成に配置され得る。

【0053】

図 7～9 は、本発明のこの第二の広い局面の「側部装備」または「迅速交換」ガイド機構 122 をさらに説明する。好ましい実施形態において、「側部装備」ガイド機構 122 は、ガイドキャリッジ 124 の内部に形成された管腔 126 を備える。ガイドキャリッジ 124 は、好ましくは、カニューレ 14 の壁の一体的な拡張部として形成される。図 7 および 8 は、図 6 に示す実施形態と一致する。すなわち、カニューレ 14 の外側表面に沿って形成されるガイドキャリッジ 124 を示す。図 9 は、ガイドキャリッジ 124 は、カニューレ 14 の内側表面に沿って形成され得る、代替の実施形態を示す。いずれの場合においても、ガイドワイヤ 22 は、患者の血管構造内の所望の位置に進められ、その時点の後に、血液ポンプ 12 およびカニューレ 14 は、本発明に従って、所望の位置へと送達するために、このガイドワイヤ 22 に沿ってスライド可能に進められ得る。ガイドワイヤ 22 は、その後、患者から引き抜かれ得る。ガイドキャリッジ 124 がカニューレ 14 の外側表面に沿って形成される (図 7～8 に示すように) 場合には、カニューレ 14 は、好ましくは、ガイドキャリッジ 124 が弁を通過する様式で延びないように、配置されるべきである。例えば、図 6 を参照して、ガイドキャリッジ 124 は、心拍手順の間の拍動性血流が側部管腔 126 を不注意に通過せず、そして大動脈弁を通過するように、左心室の完全に内部に位置するべきである。

【0054】

血管内血液ポンプシステム 120 は、上で示し、そして説明した血管内血液ポンプシステム 10 と、それぞれのガイド機構 16、122 の位置を除いて実際的に同じ様式で構成される。より具体的には、ガイド機構 122 は、カニューレ 14 の側部に沿って配置されるので、血管内血液ポンプシステム 10 に関して上に詳述したように、血液ポンプ 12、駆動ケーブルアセンブリ 18、パージ流体送達システム 26、およびモーター連結器 24 を通って延びる中心管腔を形成する必要がない。それ自体で、これらの構成要素は、上記血管内血液ポンプシステム 10 に関して必要であったような中心管腔を含むように、特に機械加工または成形される必要がない。

【0055】

図 10 を参照すると、本発明の第三の広い局面によるガイド可能な血管内血液ポンプシステム 130 が示される。再度、上記血管内血液ポンプシステムと血管内血液ポンプシステム 130 との間の、多くの同じ構成要素および特徴の共通性に起因して、類似の参照番号は、類似の要素を表すために使用され、そして必要な場合に、違いを指摘する。以下にさ

らに詳細に説明されるように、血管内血液ポンプシステム１３０は、本発明による、独
かつ有用な別個のガイド機構を使用する。しかし、多くの同じ構成要素が使用されてい
るので、上記の細部のレベルの議論は、血管内血液ポンプシステム１３０に関しては、必
要であるとはみなされない。その代わりに、上記の血管内血液ポンプと共通の局面を、こ
こで、血管内血液ポンプシステム１３０の議論に援用する。

【００５６】

その最も一般的な形態において、本発明のこの第三の広い局面の血管内血液ポンプシス
テム１３０は、血液ポンプ１２およびカニューレ１４の配置を備え、ここで、「ガイドカテ
ーテル」１３２が、ポンプ１２およびカニューレ１４を患者の循環器系の内部の所望の位
置に配置するためのガイド機構として、提供される。より具体的には、図１２を簡単に参
照して、血管内血液ポンプシステム１３０は、本発明に従って、２つの別個のアセンブリ
に形成される：導管アセンブリ１３４およびポンプアセンブリ１３６である。その最も基
本的な形態において、導管アセンブリ１３４は、ガイドカテーテル１３２およびカニュー
レ１４を備え、これらは、ローターシュラウド３６に接続される。ポンプアセンブリ１３
６は、ポンプ本体３４およびローター４４が、ローターシュラウド２６から脱係合され、
そして導管アセンブリ１３４から完全に取り外されるように、構成される。再度図１０を
参照すると、この二重の構成は、本発明の有意な特徴を形成する。なぜならこれは、血
液ポンプ１２を、患者の所望の位置において、２つの別個のかつ区別された工程を使用し
て、形成する能力を提供するからである。第一の工程は、シュラウド３６およびカニュー
レ１４が各々所望の位置（例えば、心臓補助手順については弁を通過する配置）に配置さ
れるように、導管アセンブリ１３４を（ポンプアセンブリ１３６が取り外された状態で）患
者内に配置する工程を包含する。重要な局面において、導管アセンブリ１３４を患者の内
部で配置する作業は、多数の周知の案内機構（ガイドワイヤ、バルーンカテーテル、画像
化ワイヤ、ガイドカテーテル、および／または超音波もしくは蛍光透視法を含む技術が挙
げられるが、これらに限定されない）の使用によって、有利に容易にされ得る。本発明の
血管内血液ポンプシステム１３０を提供する工程における第二工程は、ローター４４がシ
ュラウド３６の内部に合体して所望の位置でポンプ１２を形成するように、ポンプアセン
ブリ１３６を導管アセンブリ１３４に通して進める工程を包含する。

【００５７】

説明として、用語「カニューレ」とは、カニューレ１４を表すために使用される。なぜな
ら、このカニューレが、血液ポンプ１２の内部に流体を移送するために主として働くから
である。一方で、用語「カテーテル」とは、カテーテル１３２を表すために使用される。
なぜなら、このカテーテルが、デバイスまたは構成要素（すなわち、ポンプアセンブリ１
３６）を身体内の所望の位置に案内または指向するために主として働くからである。しか
し、これらの用語は、本発明の範囲から逸脱することなく、カニューレ１４が特定のガイ
ド機構を果たし得、そしてカテーテル１３２が特定の流体移送機能を果たし得るように、
簡便なため、および一般的な様式でのみに使用されることが、容易に理解されるべきで
ある。例えば、カニューレ１４は、種々のガイド機構（例えば、ガイドワイヤ、バルーンカ
テーテル、Nitinolのような選択的に変形可能な要素など）を受容するための専用の
管腔を備え得る。類似の様式で、ガイドカテーテル１３２を使用して、例えば、開口部
１３８をカテーテル１３２の所定の領域に沿って提供することによって、流体を患者へお
よび／または患者から送達し得る。

【００５８】

図１１は、患者におよび／または患者から流体を輸送するためのガイドカテーテル１３２
の使用を包含する、本発明の有意な特徴を例示する。任意の灌流アセンブリ１４０は、本
発明の血管内血液ポンプシステム１３０の一部として提供される。この灌流アセンブリ１
４０は、開口１３８と流体連絡した導管１４２を備え、この場合、この導管は血液ポンプ
１２から短距離下流のガイドカテーテル１３２の遠位領域付近で形成される。使用中、血
液は身体全体にわたる分配のためのガイドカテーテル１３２の外部に沿って通過し、開口
１３８を通過した後ガイドカテーテル１３２の内部内を通過する。灌流アセンブリ１４０

は、次いで、ガイドカテーテル 1 3 2 内から、ガイドカテーテル 1 3 2 が身体に入る点から下流の患者の血管内の点に血液を選択的に再変更するために用いられ得る。灌流アセンブリ 1 4 0 の止血バルブアセンブリ 1 4 6 により、駆動ケーブルアセンブリ 1 8 は、灌流アセンブリ 1 4 0 以外に血液が流れるのを防止しつつ、パージ流体送達システム 2 6 まで通過し得る。パージ流体送達システム 2 6 のシールアセンブリ 1 5 0 によって、駆動ケーブル 6 2 は、パージ流体送達システム 2 6 へおよびこれから以外のパージ流体の流れを防止しつつ、モーター 2 0 まで通過し得る。灌流アセンブリ 1 4 0 は、灌流アセンブリ 1 4 0 から患者への灌流血流の分配を選択的に制御するための制御機構 1 4 8 を備える。この制御機構 1 4 8 は、特定のフィードバック基準に基づいて自動化されるか、または手動で作動され得る。

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【 0 0 5 9 】

図 1 2 ～ 1 7 は、本発明の第 3 の広範な局面に従う血管内血液ポンプシステム 1 3 0 の代表的な構成を例示する。図 1 2 に示されるように、導管アセンブリ 1 3 4 は、この導管アセンブリからポンプアセンブリ 1 3 6 を取り外すように選択的に外され得る。本発明によると、導管アセンブリ 1 3 4 は、患者の循環器系に導入され（ポンプアセンブリ 1 3 6 を使用することなく）、そしてローターシュラウド 3 6 およびカニユーレ 1 4 が所望の位置に配置されるように、選択的にガイドされ得る。その後、ポンプアセンブリ 1 3 6 は、導管アセンブリ 1 3 4 に選択的に導入され得る。このような「バックローディング（back-loading）」配置における挑戦は、ポンプアセンブリ 1 3 6 が概してローターシュラウド 3 6 内でドッキングし、そして得られたポンプ 1 2 の作動中、適切な係合を維持されることを保証することである。

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【 0 0 6 0 】

代表的なドッキング配置は、ここで図 1 4 に関して記載される。好ましい実施形態において、このローター 4 4 は、シュラウド 3 6 およびポンプ本体 3 4 の対応する位置上に角度付けした接合表面を形成することによって、シュラウド 3 6 内で適切かつ正確にドッキングされ得る。より詳細には、この角度を付けられた接合表面は、フロー開口 3 8 から近位に伸長している部分に沿ってローターシュラウド 3 6 の内面上に形成され得る。対応する角度をつけられた接合表面は、その遠位部分に沿ったポンプ本体 3 4 の外面に沿って設けられる。図 1 4 に示される接合表面は、好ましくは、約 2° ～ 約 1 0° の範囲で形成され、そしてより好ましくは、約 3° ～ 約 6° の範囲で形成される。これらの範囲内の接合角は、図 1 4 に示されるようなフロー開口 3 8 の近位端とほぼ同一平面にある点まで、ポンプ本体 3 4 の遠位端をガイドするのに適切である。この様式において、ポンプアセンブリ 1 3 6 およびローターシュラウド 3 6 が結合して、血液ポンプ 1 2 を形成する。より重要なことに、このドッキングは、ローター 4 4 およびローターブレード 5 8 が、効果的かつ安全なポンプ作動のために適切な位置に維持されるように行われる。

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【 0 0 6 1 】

ポンプアセンブリ 1 3 6 をこのドッキングされた関係に維持するための例示的な付勢スキームは、ここで、図 1 2 ～ 1 3 および 1 6 ～ 1 7 に関して記載される。導管アセンブリ 1 3 4 には、好ましくは、本発明の灌流アセンブリ 1 4 0 の一部を形成する雌型クイックコネクト継手 1 5 4 と係合し得る雄型クイックコネクト継手 1 5 2 が装着される。バイアスパネ 1 5 6 は、灌流アセンブリ 1 4 0 とパージ流体送達システム 2 6 のハウジング 9 6 との間に備えられる。このバイアスパネ 1 5 6 は、好ましくは、この雄型クイックコネクト継手 1 5 2 が、本発明のドッキングプロセスの一部として雌型クイックコネクト継手 1 5 4 と係合した場合の張力となるように寸法決めされる。このように、バイアスパネ 1 5 6 は、ローターシュラウド 3 6 内のドッキング位置にポンプアセンブリ 1 3 6 を維持するように働く。このバイアスパネ 1 5 6 は、任意の数の適切な様式で、パージ流体送達システム 2 6 のハウジング 9 6 と連結され得る。1 つのこのような連結配置は、ハウジング 9 6 に取り付けられた雌型クイックコネクト継手 1 5 8、およびバイアスパネ 1 5 6 に取り付けられた雄型クイックコネクト継手 1 6 0 を備え得る。

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【 0 0 6 2 】

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灌流アセンブリ 140 の例示的な実施形態は、図 12 ～ 13 および 17 に関して示される。示される灌流アセンブリ 140 は、雌型クイックコネクタ継手 154 に連結された止血バルブ 146 を備える。ある長さのチューブ 162 は、止血バルブ 146 の対立するパーブコネクタと雌型クイックコネクタ継手 154 との間を伸長する。雄型クイックコネクタ継手 152 の内側、雌型クイックコネクタ継手 154、チューブ 162、および止血バルブ 146 を通って伸長する連続管腔が、形成される。駆動ケーブルアセンブリ 18 は、この連続管腔を通して伸長し、T o u e h y - B o r s t 止血シール 164（これは、灌流アセンブリ 140 の近位端からの血液の移動を防ぐ）を通して出る。側部ポート 166 は、灌流アセンブリ 140 の中心管腔と流体連絡して配置される。一実施形態において、この側部ポート 166 には、止め栓 170 に連結された灌流導管（すなわち、図 11 の導管 142）を通る血液の分配を選択的に制御するための止め栓 170 を有する導管 168 が備えられる。患者を選択的に灌流するためのこの型の手動制御システムは、灌流の速度を自動的に制御するための制御回路と置き換えられ得る。このような自動還流は、同時フィードバックまたは予めプログラムされた閾値に基づく制御アルゴリズムに依存し得る。

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【0063】

前記の議論は、本発明の一部を形成する本発明の多数の局面を詳述する。広範な本発明の概念から逸脱することなく、変更が上記の実施形態において行われ得ることが当業者に理解される。例示の目的のみで、以下の証拠の様々なさらなる局面が本発明の一部を形成する。

【0064】

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図 18 は、代替のベアリングアセンブリ、パージ流体送達、およびドッキングスキームを有する本発明の第 3 の広範な局面の血管内血液ポンプシステムの代替の構成を例示する。このベアリングアセンブリは、シールバネ 182 およびベアリングアセンブリ 180 を備える。このベアリングアセンブリ 180 は、内側レース 184、外側レース 186、および複数のボール 188（これにより、この内側レース 184 はローターシャフト 46 と共に回転し得、一方、外側レース 186 はポンプ本体 34 の内面に対して静的な固定された位置に維持され得る）を備える。リング 190 は、ベアリングアセンブリ 180 をシールバネ 182 に対して維持するようにローターシャフト 46 内に形成された溝部に配置される。このリング 190 は、ケーブルアダプタ 60 の遠位端から伸長している湾曲したリップ部分を介してローターシャフト 46 内の溝部にさらに固定される。ケーブルアダプタ 60 の近位端は、駆動ケーブル 62 と同一平面で係合する。

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【0065】

図 18 に示される実施形態のパージ流体送達システムは、血液ポンプ 12 へのパージ流体の 1 つの送達方法を提供する。すなわち、加圧流体（すなわち、周囲容器内の血圧より上に上昇されたあるレベルまで加圧された流体）は、作動中、駆動ケーブル 62 と保護シース 32 の内側との間に注入される。これは、駆動ケーブル 62 とシース 32 との間に存在する任意の摩擦熱を減少するように働く。この加圧流体はまた、シールが 192 で破壊した場合、この加圧流体が開口シール 192 を通過しシュラウド 36 内に形成される血流ポート 38 を通って前向きに流れるように、ポンプ 12 の内部を通して流れる。このことは、凝固および／またはポンプ 12 の破損を回避するために、血液がポンプ 12 に入らないように働く。

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【0066】

ポンプアセンブリ 136 は、本発明の範囲から逸脱することなく、任意の数の異なる様式で、導管アセンブリ 134 内でドッキングされ得る。すなわち、図 18 に示されるドッキングスキームは、例示のみのために記載され、そして導管アセンブリ 134 内でポンプアセンブリ 136 と一時的に係合または「ドッキング」する多数の方法を制限または制約することを意図しない。唯一の要件は、ポンプアセンブリ 136 および導管アセンブリ 134 が、ローター 44 がシュラウド 36 内に配置されて、カニューレ 14 を通りシュラウド 36 から出る所望の軸方向フローを提供するようにドッキングすることである。例示的なドッキングスキームは、シュラウド 36 の内部に沿ってカニューレ係合溝部 194 を形成

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する工程、およびポンプ本体 3 4 の外面に沿って相補的環状リッジ 9 6 を形成する工程を包含する。挿入中、ポンプアセンブリ 1 3 6 は、ポンプ本体 3 4 上の環状リッジ 1 9 6 が、シュラウド 3 6 内で形成される溝部 1 9 4 内で係合するまで、導管アセンブリ 1 3 4 内に押し進められる。このドッキングスキームは、一般的に、ポンプアセンブリ 1 3 6 を導管アセンブリ 1 3 4 に挿入するプロセスの間、環状リッジ 1 9 6 と溝部 1 9 4 との間の係合作用が医師に触覚フィードバックを提供するという点において有利であり、その結果、この医師は、ドッキングがいつ完了したかを決定し得る。

【 0 0 6 7 】

当業者に理解されるように、環状リッジ 1 9 6 および係合溝部 1 9 6 の位置は、これらがフロー開口 3 8 に接近してかまたはさらに離れて配置されるように変動し得る。シュラウド 3 6 の内面とポンプ本体 3 4 の外面との間を伸長する接合部に血液が侵入するのを妨げるために、これらのドッキング構造をフロー開口 3 8 に接近して形成することが有利であり得る。ポンプアセンブリ 1 3 6 を導管アセンブリ 1 3 4 内で一時的に係合またはドッキングするために、選択的に膨張可能な構造体（例えば、バルーン）を用いることもまた企図される。この点において、1 つ以上の管腔が、ポンプ本体 3 4 の外面に沿って配置されたバルーンと流体連絡したポンプ本体 3 4 の内部から伸長するポンプ本体 3 4 内で形成される。ポンプ本体 3 4 の内側を流れる加圧流体は、次いで、バルーンを膨張するため使用され、このバルーンは次いで、シュラウド 3 6 内の環状溝部（例えば、1 9 4）内で係合する。もちろん、係合構造は、本発明の範囲から逸脱することなく入れ替えられ得る。例えば、シュラウド 3 6 は、その中に、シュラウド 3 6 の内面上に配置されたバルーンを膨張するための流体送達管腔を備えられ、これは次いで、ポンプ本体 3 4 の外面に沿って形成される環状係合溝部内に配置され得る。

【 0 0 6 8 】

本発明は、大部分が左心臓適用の間における使用において示されてきたが、これは本発明の適用を左心臓支持のみにおける使用に制限しないことが容易に理解されるべきである。さらに本発明のガイド可能な血管内血液ポンプは、右心臓支持適用および当業者に明らかな広範な他の適用において利用され得る。例えば、図 1 9 に関して、右心臓支持適用における使用のために構成された（図 2 ～ 5 に関して上記に示されそして記載される型の）血管内血液ポンプ 2 0 0 が示される。この実施形態において、血管内血液ポンプシステム 2 0 0 は、例えば、バルーンカテーテル 2 0 2 を備える「オーバーワイヤ（o v e r - t h e - w i r e）」ガイド機構 1 6 を装着される。図 2 ～ 5 に示される型の実施形態の観点において以下で示されそして記載されてきたが、本明細書中で開示される血管内血液ポンプシステム 1 2 0、1 3 0 はまた、右心臓適用において使用するために構成され得ることが容易に理解されるべきである。このような右心臓構成、および本願に列挙される広範な原理に基づく当業者に明らかな他の構成は、本発明の範囲内にあることが意図される。

【 0 0 6 9 】

心臓内に配置された血管内血液ポンプシステム 2 0 0 が、示され、拍動心臓手術の間に右心臓の支持を提供するのに利点があり得る。これは、本発明に従って右心臓にガイド可能な血管内血液ポンプシステム 2 0 0 を配置するために、適切なガイド要素（例えば、バルーンカテーテル 2 0 2）は、膨張可能なバルーンの「セイル（s a i l）」作動を介して心臓内の所望の位置にまず進められる。このバルーンカテーテル 2 0 2 は、所望の位置（例えば、示されるような肺動脈）内に位置決めされた後、本発明に従う血管内血液ポンプシステム 2 0 0 は、バルーンカテーテル 2 0 2 によって進められ、そして所望の配置にガイドされ得る。右心臓の支持のために、流体入口 2 0 4 が大静脈（または右心房）内に配置され、そして流体出口 2 0 6 が肺動脈内に配置されるまで、バルーンカテーテル 2 0 2 によってポンプ 1 2 およびカニューレ 1 4 を進めることを包含する。次いで、このポンプ 1 2 は、肺動脈内の沈着物のために、三尖弁、右心室、および肺動脈弁を介して弁を横切る様式（t r a n s - v a l v u l a r f a s h i o n）で、血液を大動脈（または右心房）から輸送するために選択的（すなわち、自動的にまたは必要なときに）制御され得る。拍動心臓手術の間に右心臓の支持を提供することは、心拍出量が拍動心臓手術の間に

下がり得る状態を有利に克服し、例えば、心臓が、後部の血管へのアクセスを得るために持ち上げられる場合、これにより、心肺バイパスの必要性が避けられる。

【0070】

このガイド可能な血管内血液ポンプシステムが患者の血管系に導入され、任意の数のアクセスポイントを介して右心臓または左心臓に血管内アクセスを達成し得ることはまた、本発明の一部として意図される。このアクセスポイントには、内頸静脈、腕頭静脈、頸動脈、腋窩動脈、大腿静脈、大腿動脈、および鎖骨下動脈が挙げられるが、これらに限定されない。本発明の血管内血液ポンプシステムはまた、直接的な導入を介して、例えば、大動脈、心房、および心室へ導入され得る。当該分野で周知であるが、このような血管内アクセスは、セルディング技術の使用して皮膚を介して、または手動浸襲性アクセス技術の使用を直接的に介して達成され得る。

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【0071】

当業者はまた、用語「軸方向フロー (axial flow)」について上で示しそして議論したが、本発明は、軸方向フロー型血管内血液ポンプに限定されないことが理解される。むしろ、この血管内血液ポンプ12は、任意の数の適切な型の血管内血液ポンプを含み得、このポンプは、本発明の範囲から逸脱しない、いわゆる「混合流 (mixed flow)」血管内血液ポンプを含むが、これに限定されない。

【0072】

図10～17に示される実施形態に関して、ポンプアセンブリ136が患者の循環器系内の所望の位置において、ポンプ12を形成するためにシュラウド36内に搭載された後、ガイドカテーテル132は、導管アセンブリ134から分離され得ることがさらに意図される。これは、任意の数の適切な配置を介して、検出可能な様式でガイドカテーテル132を提供することによって達成され得る。ポンプ12を構築した後、ガイドカテーテル132を取り外すことによって、患者の血管内へのアクセスポイントでの創傷管理が改善され得る。これは、部分的に、患者へ延びるデバイス（すなわち、より大きな直径のガイドカテーテル132に対向するようなドライブケーブルアセンブリ18）のサイズの実質的な減少に起因する。

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【0073】

種々の圧力検出および／またはガイド可能な特徴を少なくとも1つのカニューレ14およびポンプ12に取り込むことがまた、意図される。このような特徴としては、共有であり、かつ同時係属中の以下に示されそして記載される特徴が挙げられるが、これらに必ずしも限定されるわけではない：1999年3月30日出願の米国特許出願第09/280,988（表題「Steerable Cannula」）、1999年3月30日出願の米国特許出願第09/280,970（表題「Pressure Sensing Cannula」）（これらの開示は、本明細書中でその全体を記載する場合に参考として明確に援用される）。これらの圧力検出特徴には、流体充填管腔の使用、圧電検出要素、ストレインゲージ、およびトルク／電流の関係の分析（ポンプの入口と出口との間の動的圧力差に基づく）の使用が挙げられるが、これらに限定されない。ガイド可能な特徴には、スライド管腔および変形可能材料（すなわち、Nitonol）の使用が挙げられるが、これらに必ずしも限定されるわけではない。

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【0074】

種々のポンプおよびカニューレ配置は、右心臓および／または左心臓の支持を提供するために上に記載および示されており、ここで、血液を、故意に経路を再び決定させ、特定の心室によって汲み上げられる血液の容積を減少させる試みにおいて、右心室および／または左心室を通過させる。この様式で心室に「未充填」とは、特定の例において好ましいが、本明細書中に記載されるポンプおよびカニューレ配置はまた、心室に「予充填」するために使用され得ることが容易に理解され得る。血管内予充填は、ポンプから所定の心室に流出カニューレを配置することによって達成され得、ポンプは、心室を血液で充填または予充填するために使用され得る。これは、右心室で特に有用であり得る。時々、右心室は、右心房から十分なレベルの血液を供給されず、その結果、収縮の際、右心室は、肺動脈

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に不十分な量の血液を供給する。右心室および／または左心房が、手術の間に圧迫された状態または変形された状態にある場合に、これが生じ得る。予充填は、血液を右心室に活動的に供給することによってこの問題を克服し、これにより、血液の肺動脈への送達を容易にする。この同一の技術を使用して左心室を予充填し、次いで、左心室から大動脈への血液の送達を容易にし得る。

【 0 0 7 5 】

本発明の多くの利点は、添付の図面と組み合わせて本明細書を読んで当業者に明らかであり、ここで、同様な参照番号は、同様な要素に適用される。

【図面の簡単な説明】

【図 1】 図 1 は、例示として、左心臓補助を提供するために弁を横切る構成で位置付けられる本発明の第 1 の幅広い局面に従って「オーバーワイヤ」型ガイド機構を有する血管内血液ポンプシステムを例示するヒト心臓の部分断面図である。

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【図 2】 図 2 は、本発明の例示の実施形態に従うモーター連結器およびパージ流体送達システムを含む図 1 に示される型のガイド可能血管内血液ポンプシステムの側面図である。

【図 3】 図 3 は、本発明の第 1 の幅広い局面に従う、血管内血液ポンプシステムの血液ポンプ、駆動ケーブルアセンブリ、およびカニユーレの例示的な構成を例示する断面図である。

【図 4】 図 4 は、本発明の第 1 の幅広い局面に従う、駆動ケーブルアセンブリおよびガイド機構の例示的構成を示す図 3 の線 4 - 4 に沿って取られた断面図である。

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【図 5】 図 5 は、本発明の第 1 の幅広い局面に従う、モーター連結器およびパージ流体送達システムの例示的構成を例示する断面図である。

【図 6】 図 6 は、例示として、左心臓補助を提供するために弁を横切る構成で位置付けられる本発明の第 2 の幅広い局面に従って「迅速交換」または「側部装備」型ガイド機構を有する血管内血液ポンプシステムを例示するヒト心臓の部分断面図である。

【図 7】 図 7 は、本発明の例示の実施形態に従うモーター連結器およびパージ流体送達システムを含む図 6 に示される型のガイド可能血管内血液ポンプシステムの側面図である。

【図 8】 図 8 は、本発明の第 2 の幅広い局面に従う、「側部装備」または「迅速交換」型ガイド機構を示す図 7 の線 8 - 8 に沿って取られた断面図である。

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【図 9】 図 9 は、本発明の第 2 の幅広い局面に従う、ガイド機構の代替の構成を示す図 8 に示される型の断面図である。

【図 10】 図 10 は、例示として、左心臓補助を提供するために弁を横切る構成で位置付けられる本発明の第 3 の幅広い局面に従って「ガイドカテーテル」型ガイド機構を有する血管内血液ポンプシステムを例示するヒト心臓の部分断面図である。

【図 11】 図 11 は、大腿動脈を通して挿入され、そしてガイドカテーテルが大腿動脈に入る切開部位から下流の血管構造を灌流するための任意の灌流アセンブリを含む、図 10 に示される型の血管内血液ポンプシステムを例示するヒトの概略図である。

【図 12】 図 12 は、本発明の第 3 の幅広い局面に従う、血管内血液ポンプシステムを集成的に形成するポンプアセンブリおよび導管アセンブリの分離可能な性質を例示する図 10 ~ 11 に示される血管内血液ポンプシステムの側面図である。

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【図 13】 図 13 は、本発明の第 3 の幅広い局面に従う、導管アセンブリにドッキングされたポンプアセンブリを有する図 12 に示される血管内血液ポンプシステムを例示する側面図である。

【図 14】 図 14 は、図 13 に示される血管内血液ポンプシステムの血液ポンプ、駆動ケーブル、カニユーレ、およびガイドカテーテルの例示的な構成を例示する断面図である。

【図 15】 図 15 は、本発明の第 3 の幅広い局面に従う、駆動ケーブルアセンブリおよびガイドカテーテルの例示的構成を例示する図 14 の線 15 ~ 15 に沿って取られた断面図である。

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【図 1 6】 図 1 6 は、本発明の第 3 の幅広い局面に従う、モーター連結器、ページ流体送達システム、およびガイドカテーテル付勢アセンブリの近位部分の例示的構成を例示する断面図である。

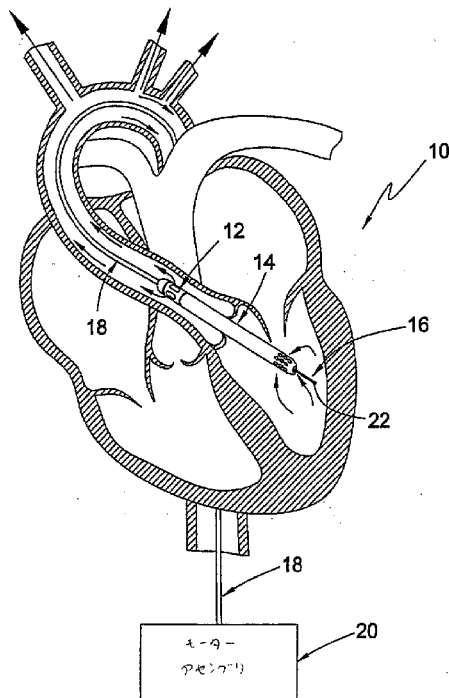
【図 1 7】 図 1 7 は、本発明の第 3 の幅広い局面に従う、灌流アセンブリおよびガイドカテーテル付勢アセンブリの遠位部分の例示的な構成を例示する断面図である。

【図 1 8】 図 1 8 は、本発明の原理に従う、シュラウド内にローターをドッキングするための代替の構成を有する、図 1 2 ～ 1 3 に示される型の血管内血液ポンプシステムの断面図である。

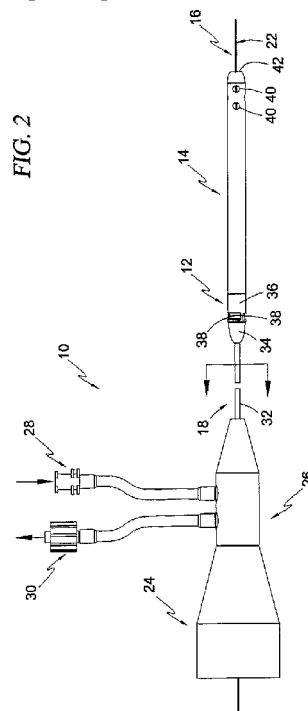
【図 1 9】 図 1 9 は、例示として、右心臓補助を提供するために弁を横切る構成で位置付けられる本発明の第 1 の幅広い局面に従って「オーバーワイヤ」型ガイド機構を有する代替の血管内血液ポンプシステムを例示するヒト心臓の部分断面図である。

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【図 1】



【図 2】



【図 3】

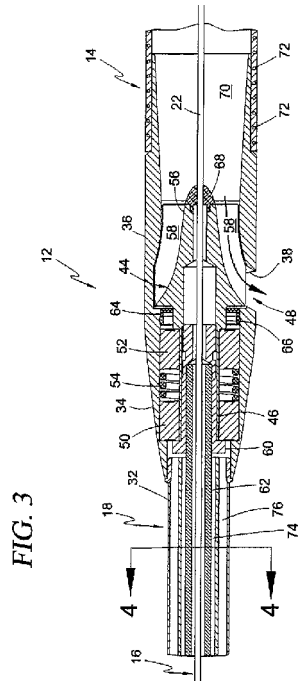


FIG. 3

【図 4】

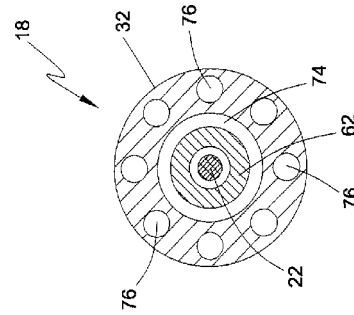


FIG. 4

【図 5】

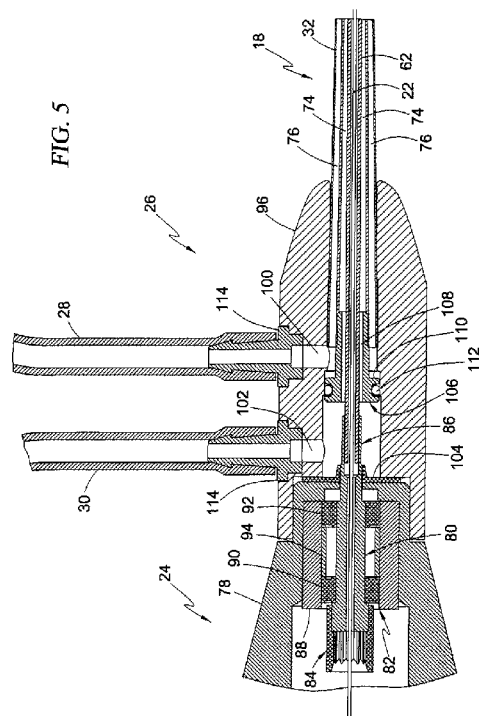
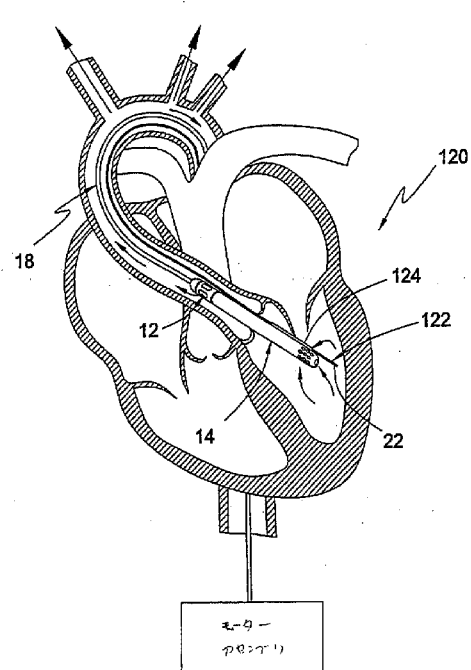


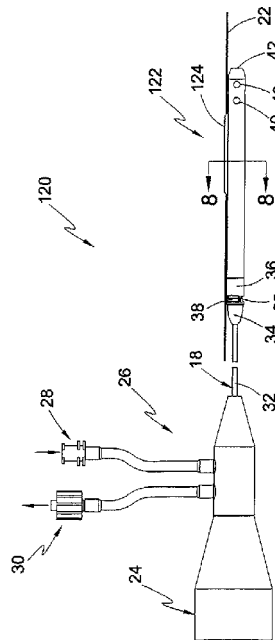
FIG. 5

【図 6】



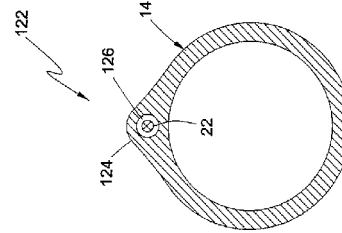
【図 7】

FIG. 7



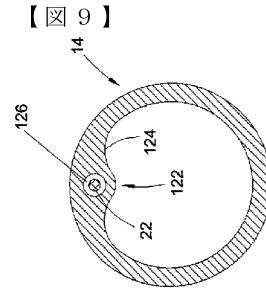
【図 8】

FIG 8



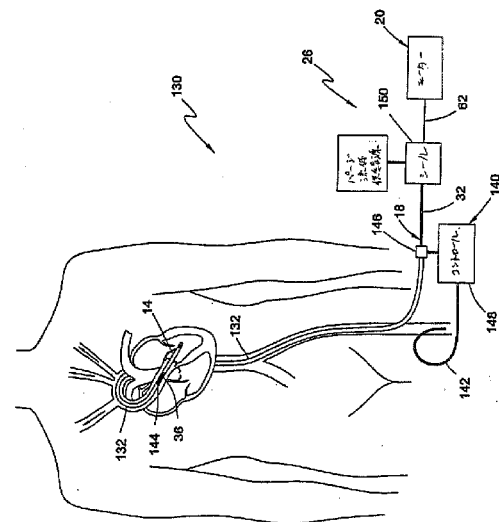
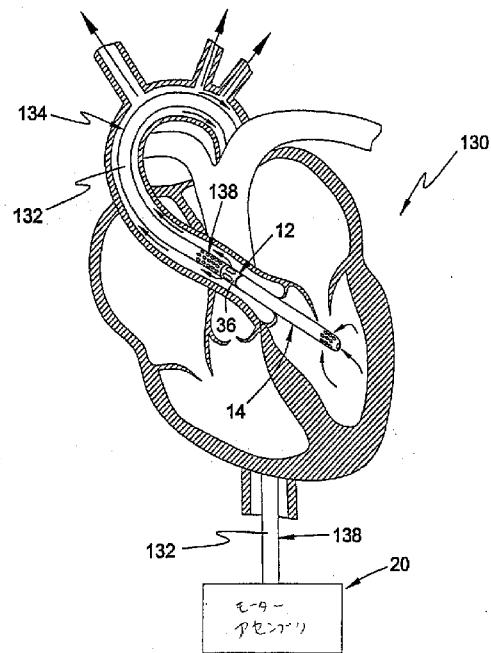
【図 9】

FIG 9

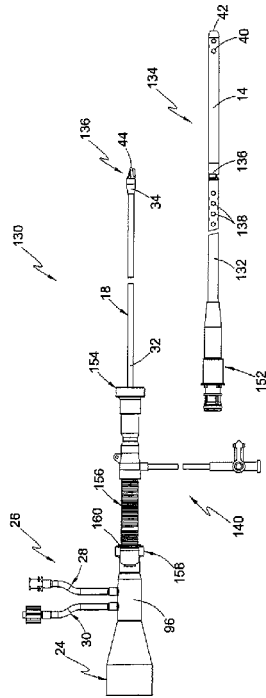


【図 10】

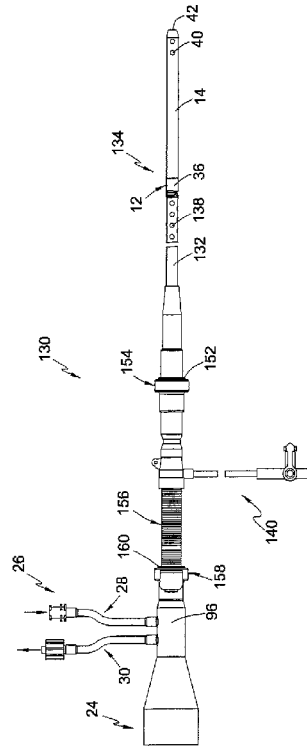
【図 11】



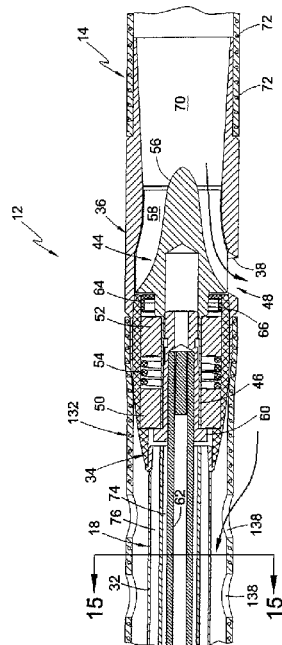
【図 1 2】



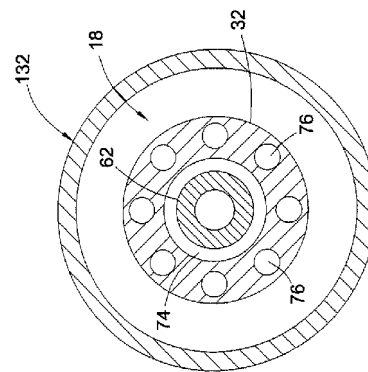
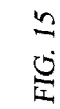
【 図 1 3 】



【図 14】

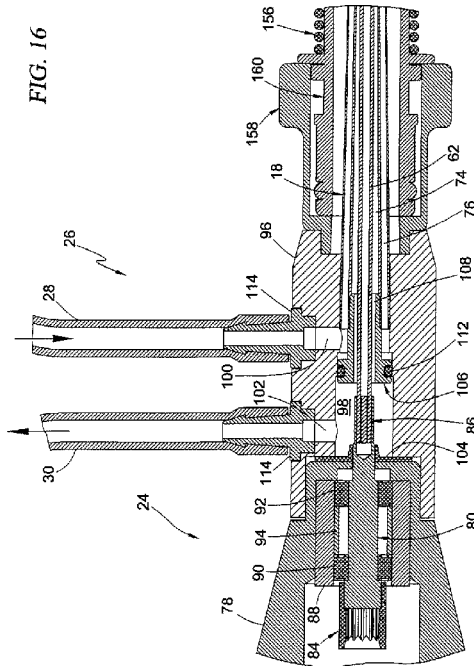


【 図 1 5 】



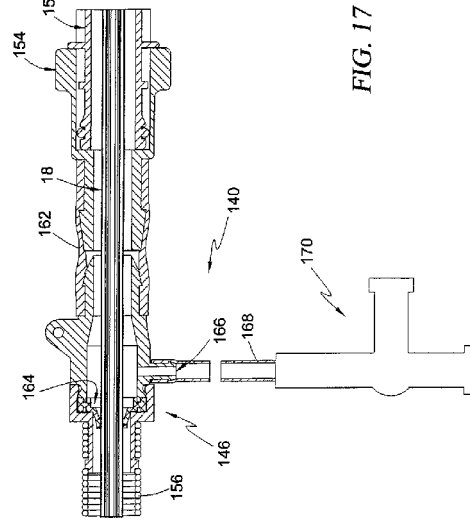
【図 16】

FIG. 16



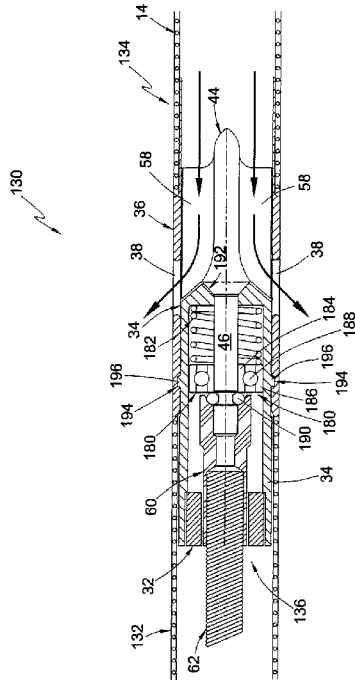
【図 17】

FIG. 17



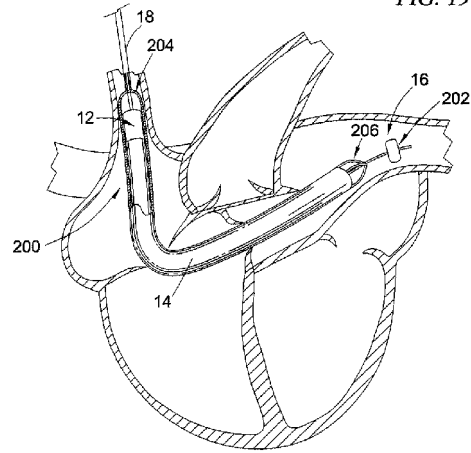
【図 18】

FIG. 18



【図 19】

FIG. 19



フロントページの続き

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			F 0 4 D	29/00	Z

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A61M 1/10

A61M 25/00

A61M 25/01

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F04B 15/02

F04D 7/02

F04D 29/00