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Aboul-Hosn et al.

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

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

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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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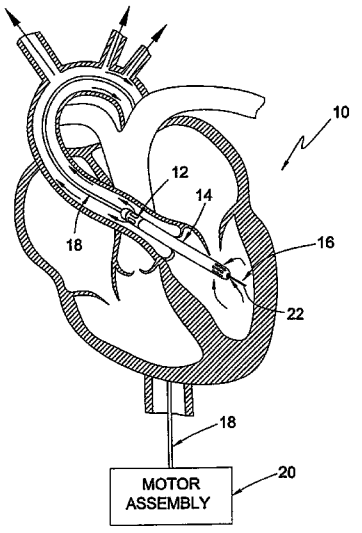
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(57) **ABSTRACT**

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



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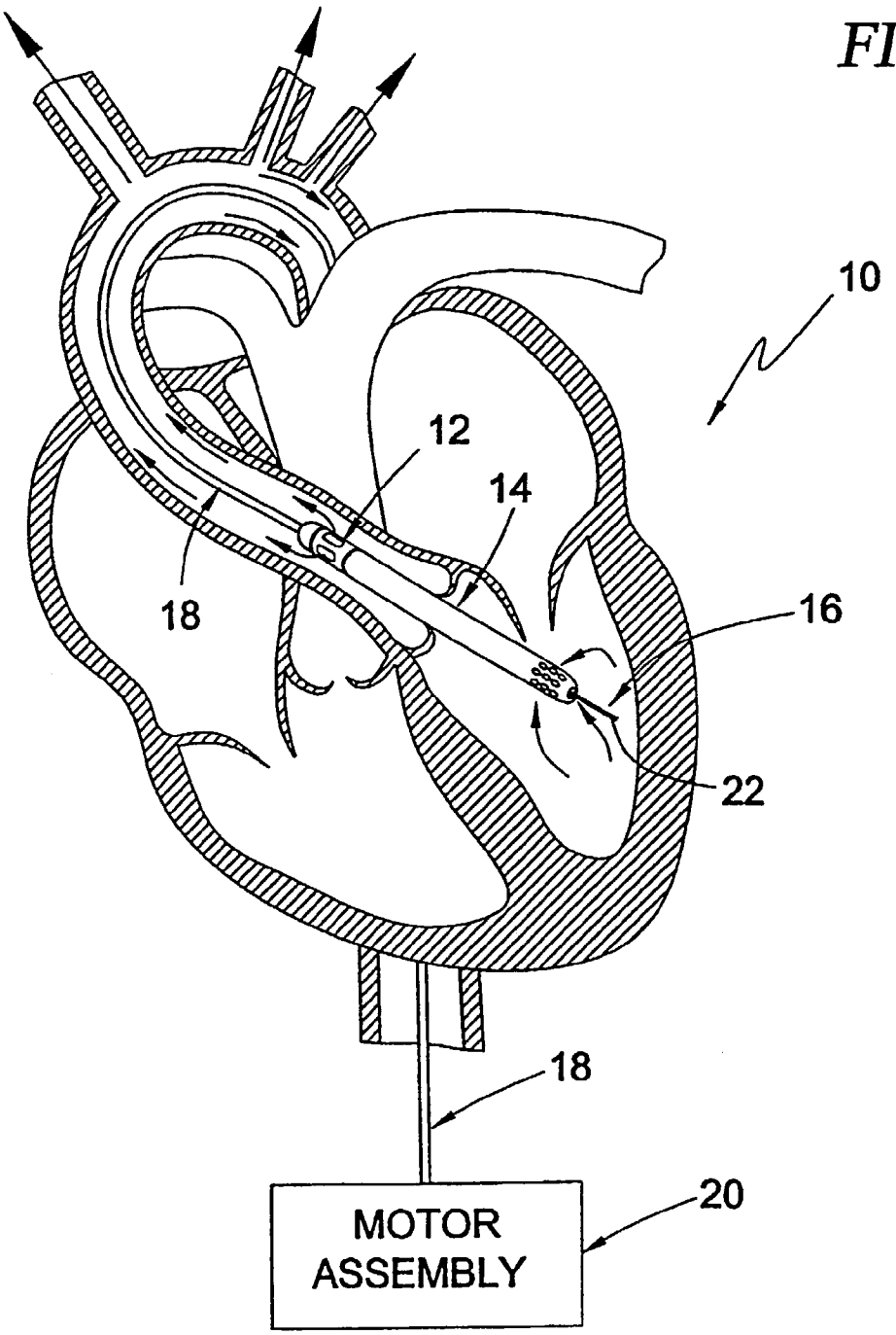
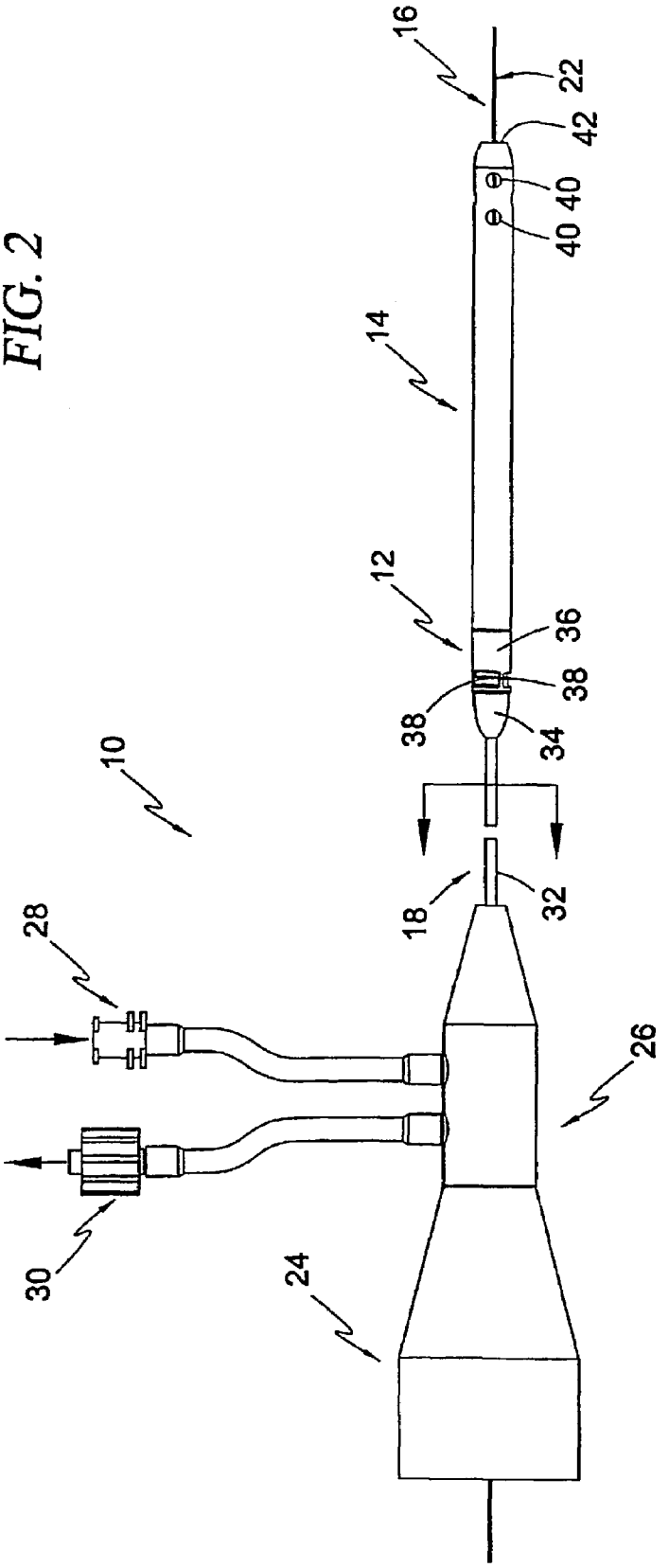


FIG. 1

FIG. 2



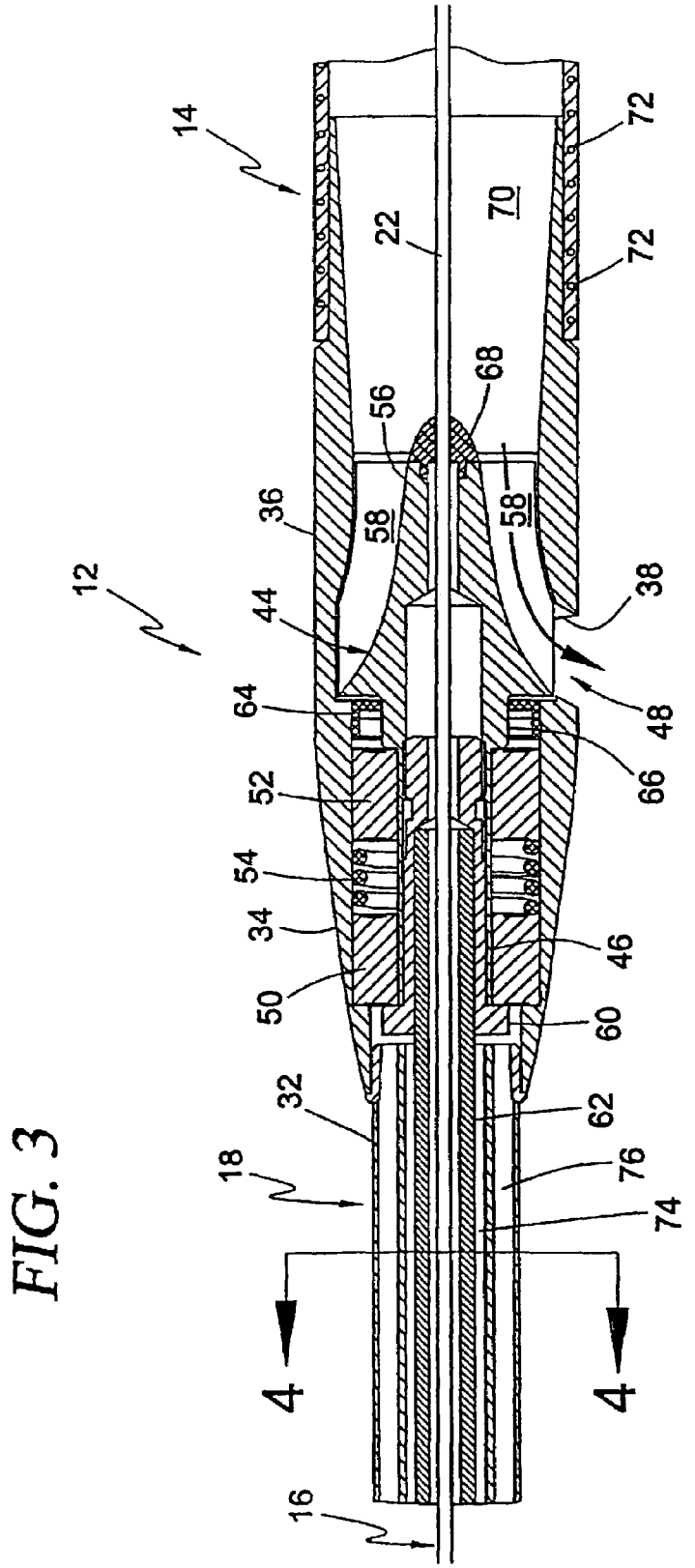

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FIG. 3

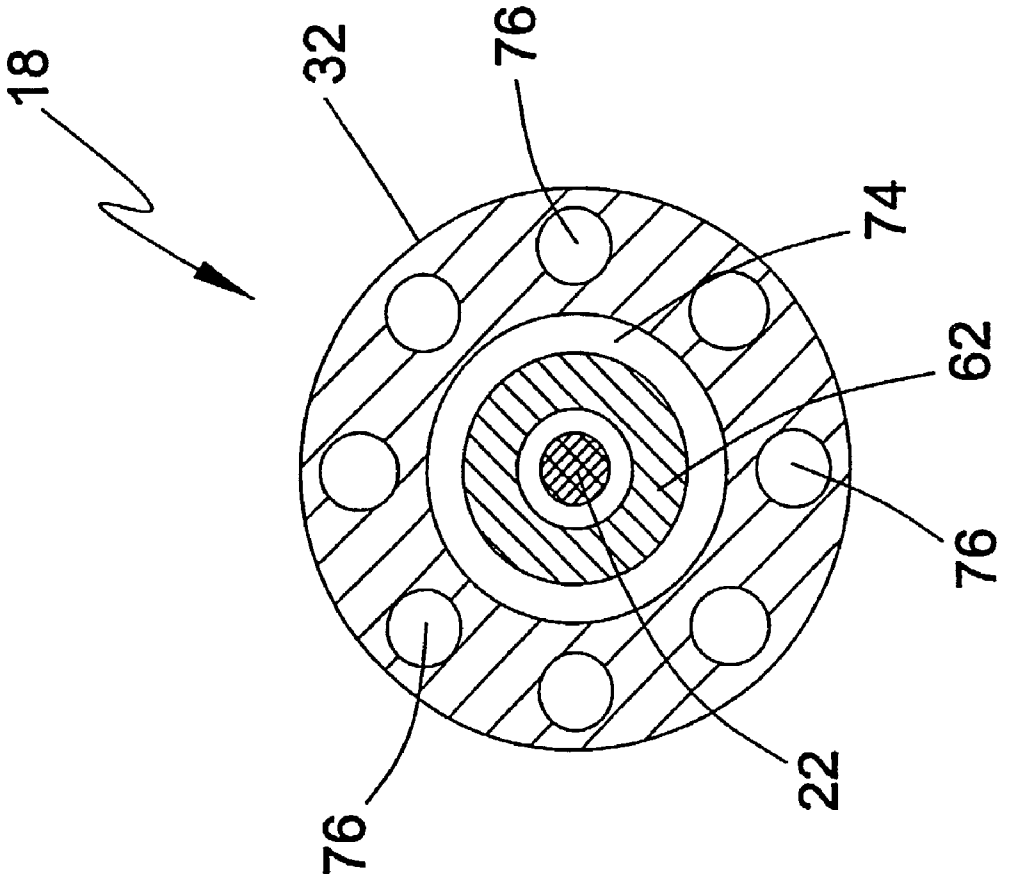
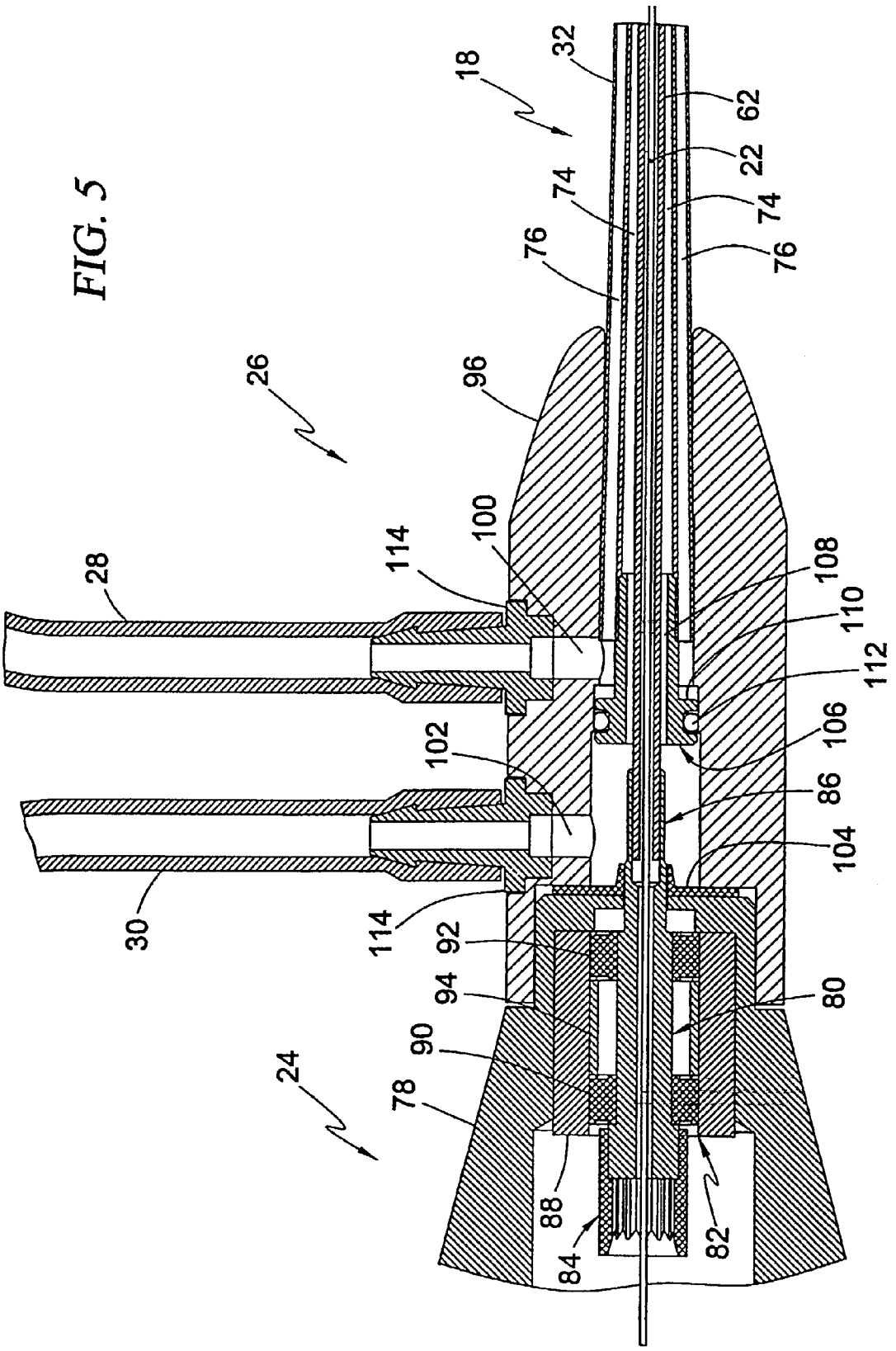


FIG. 4

FIG. 5


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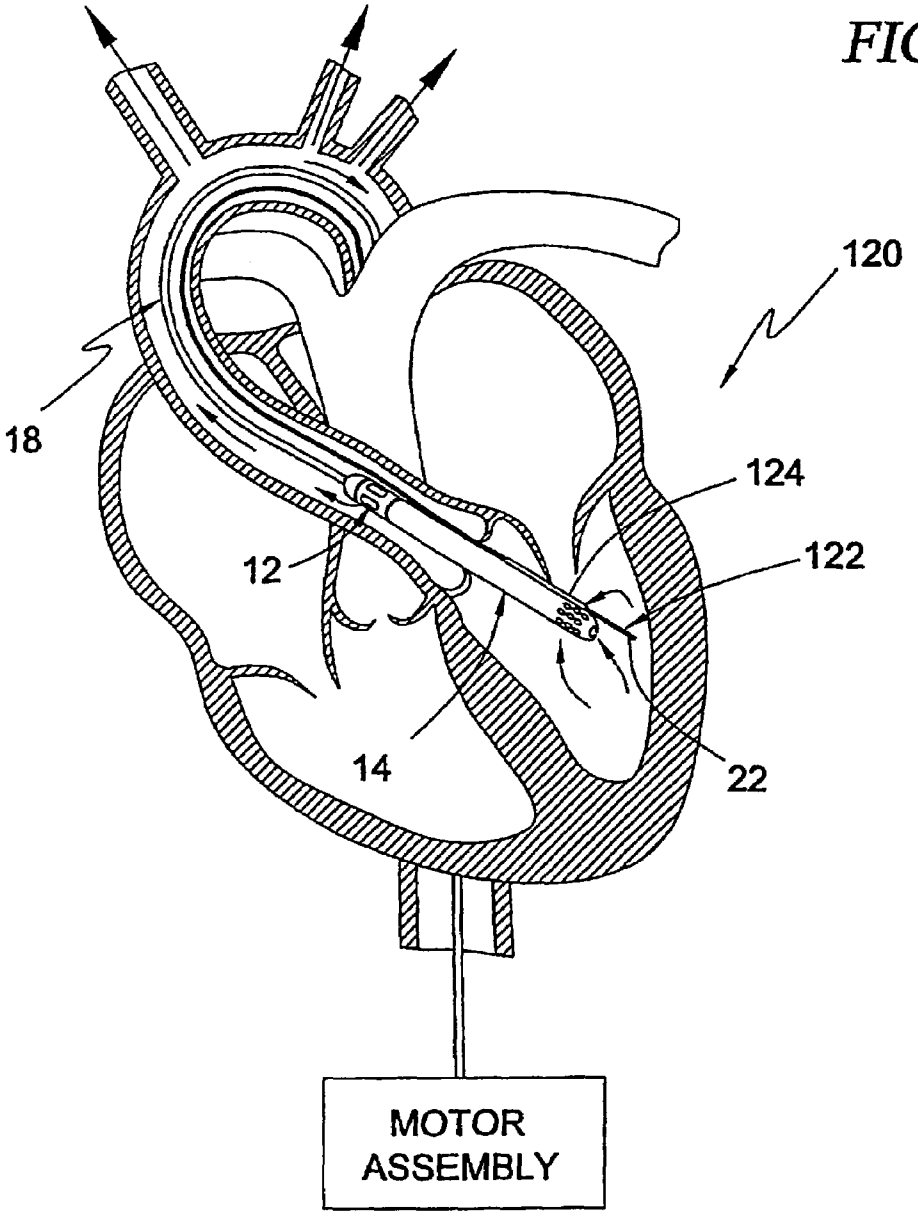
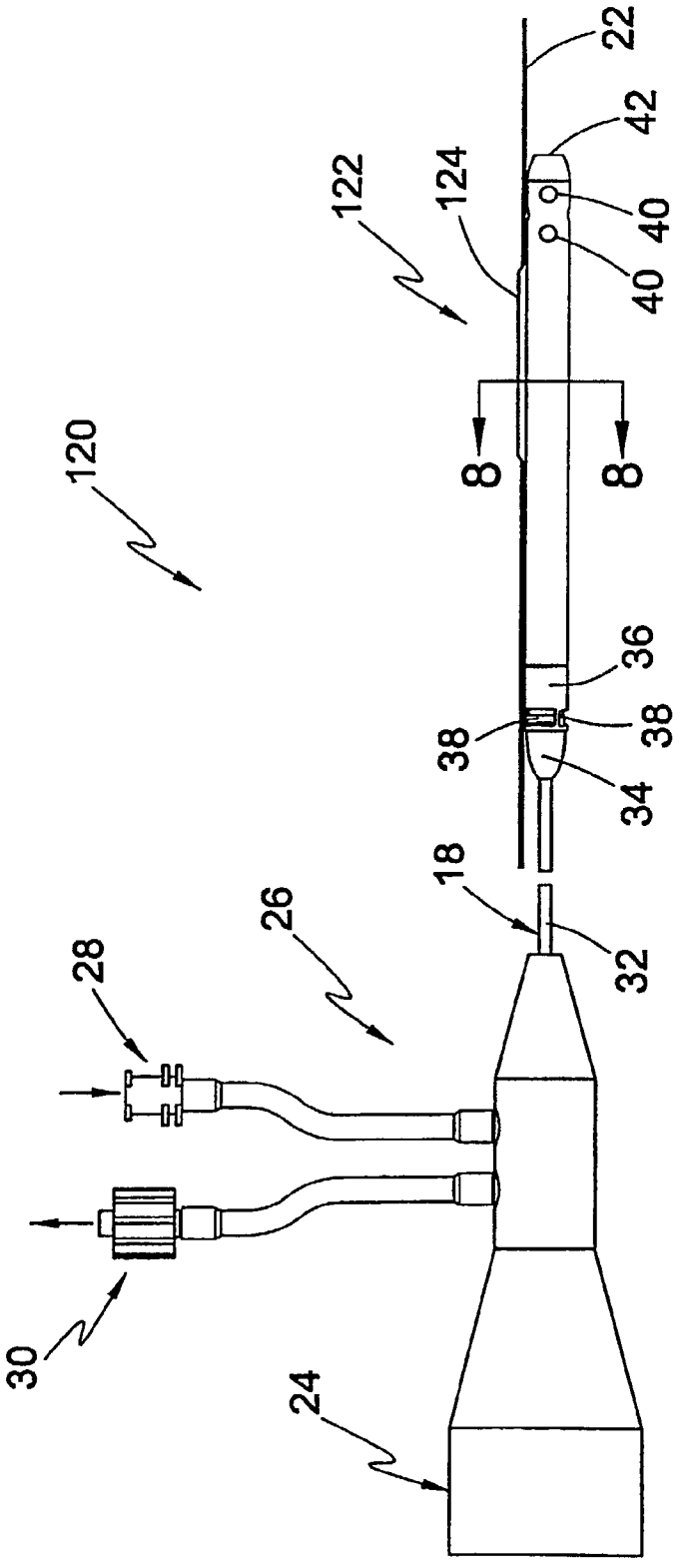


FIG. 6

FIG. 7



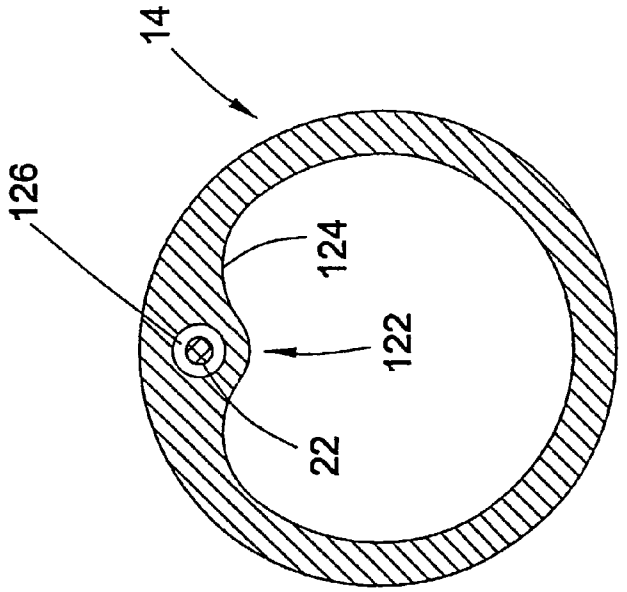


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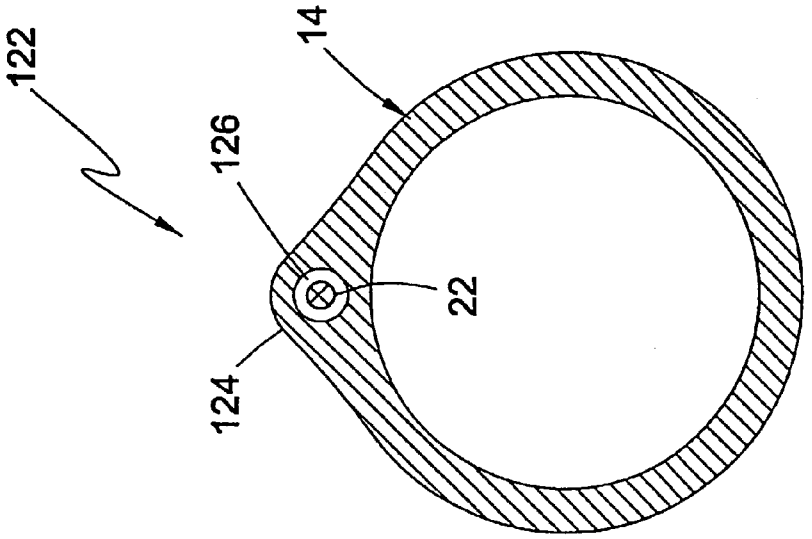


FIG 8

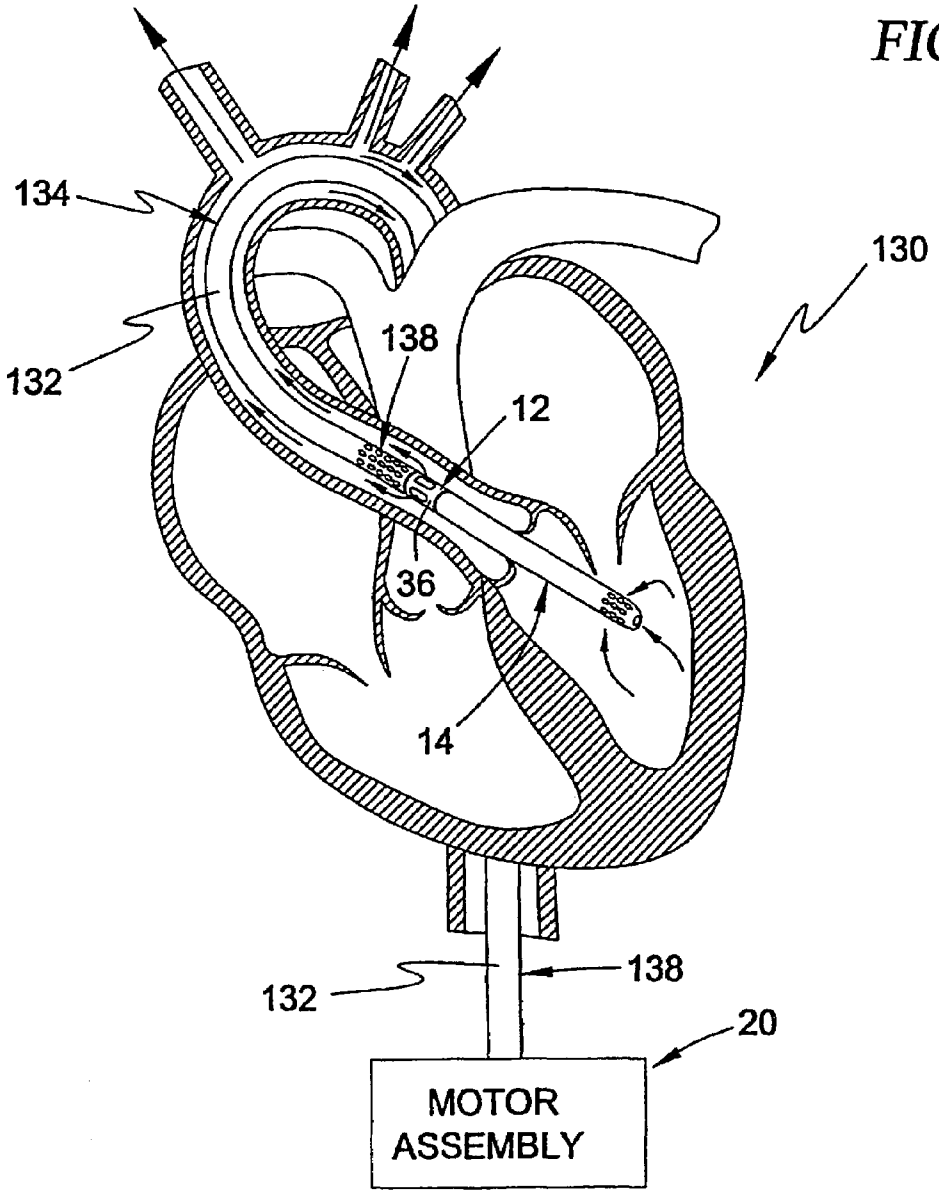
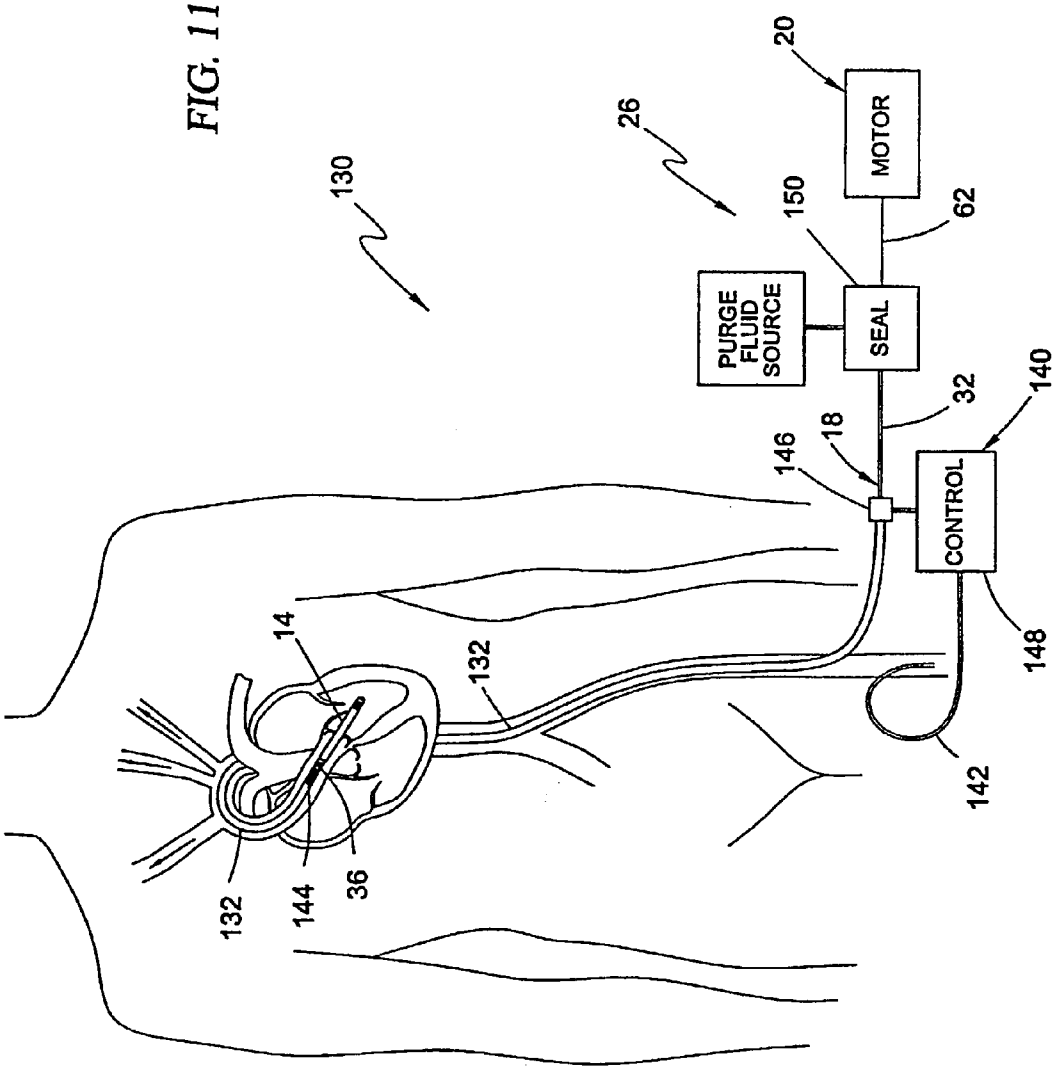


FIG. 10

FIG. 11


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MOTOR
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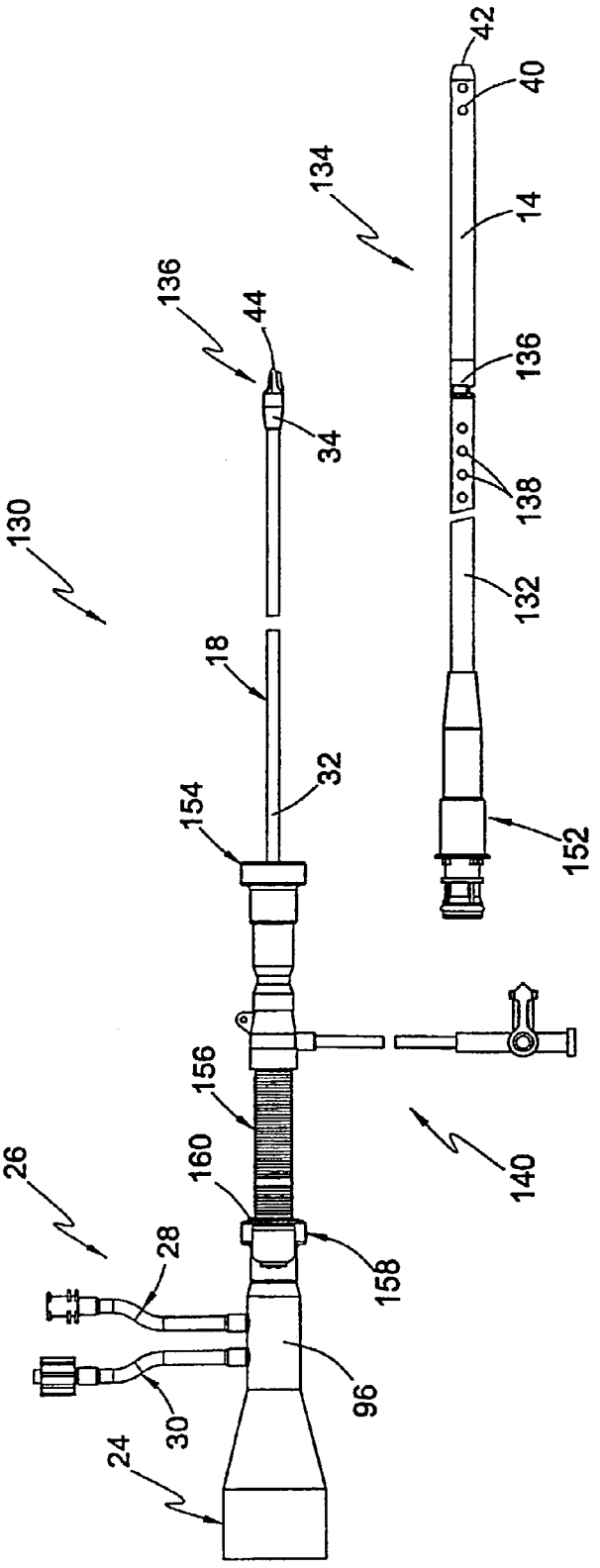

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FIG. 12

FIG 13

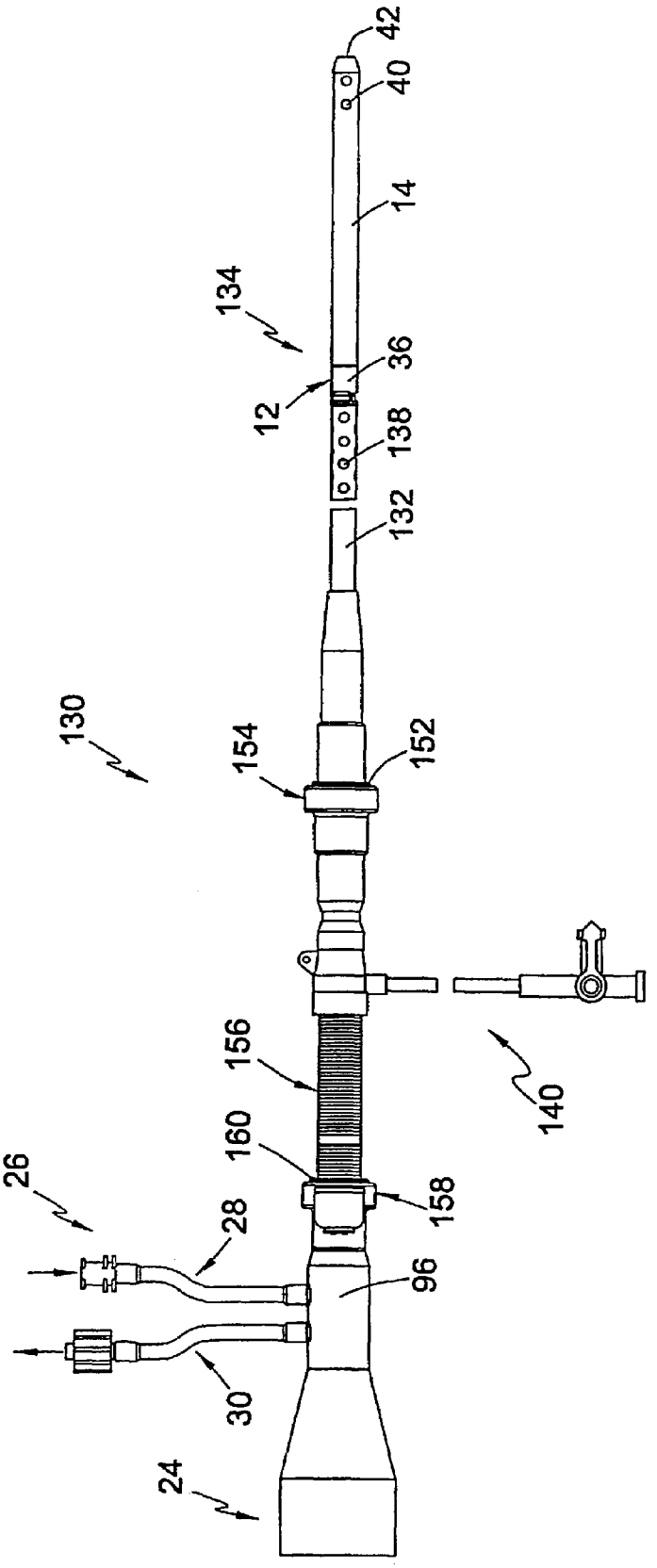
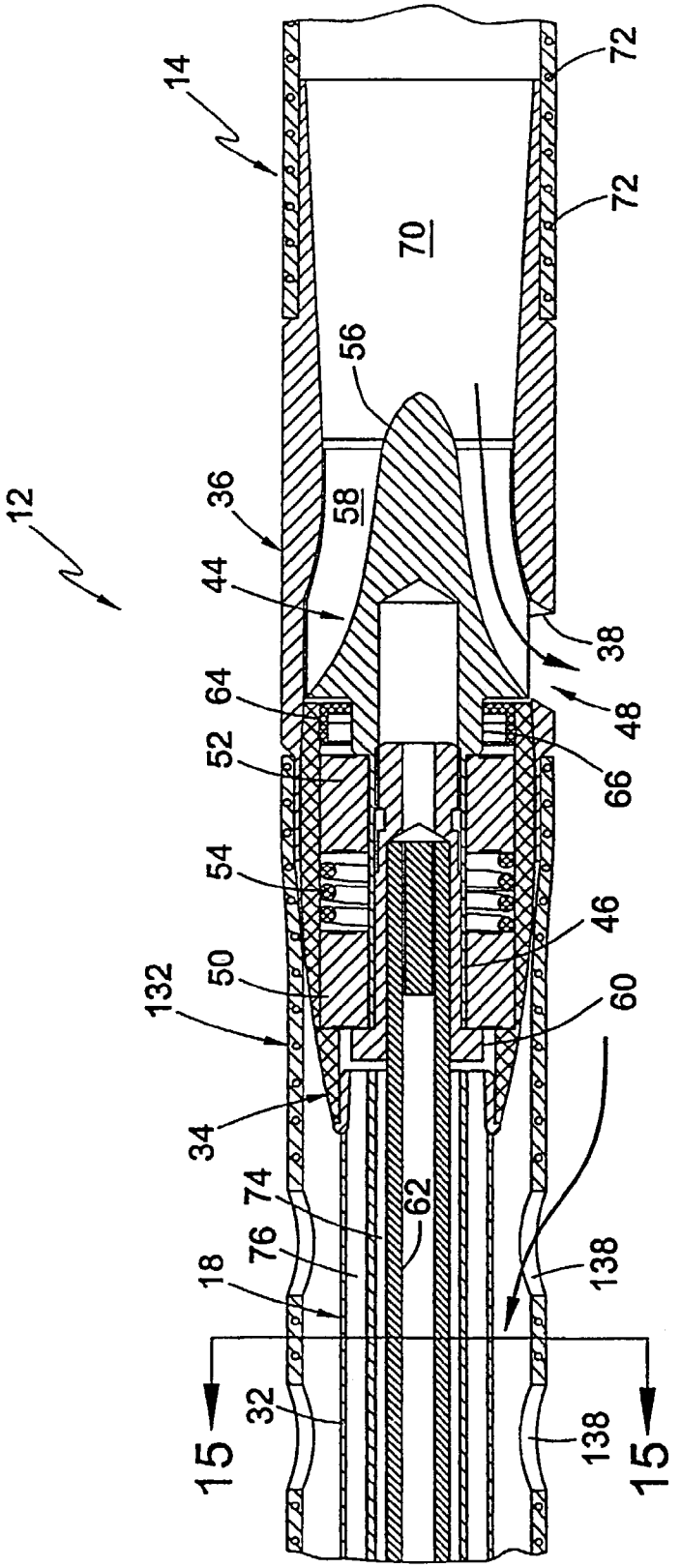

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FIG. 14


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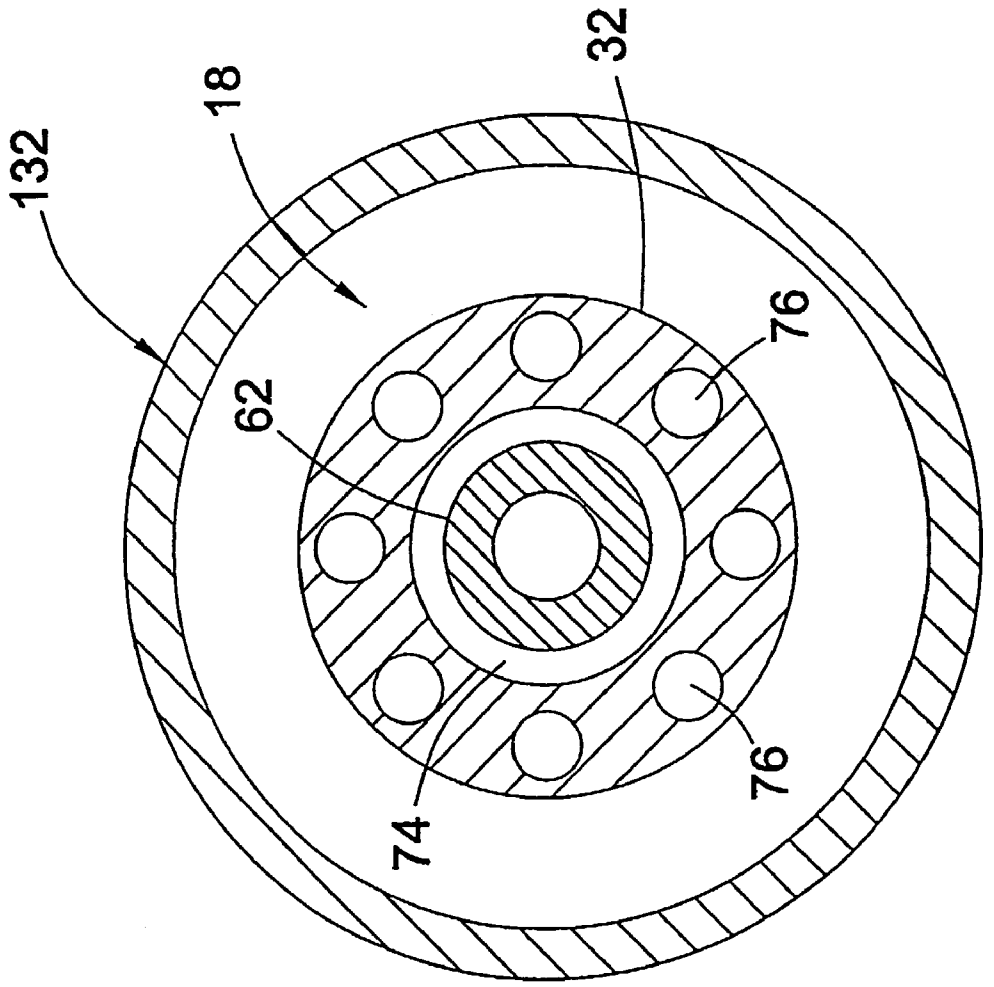
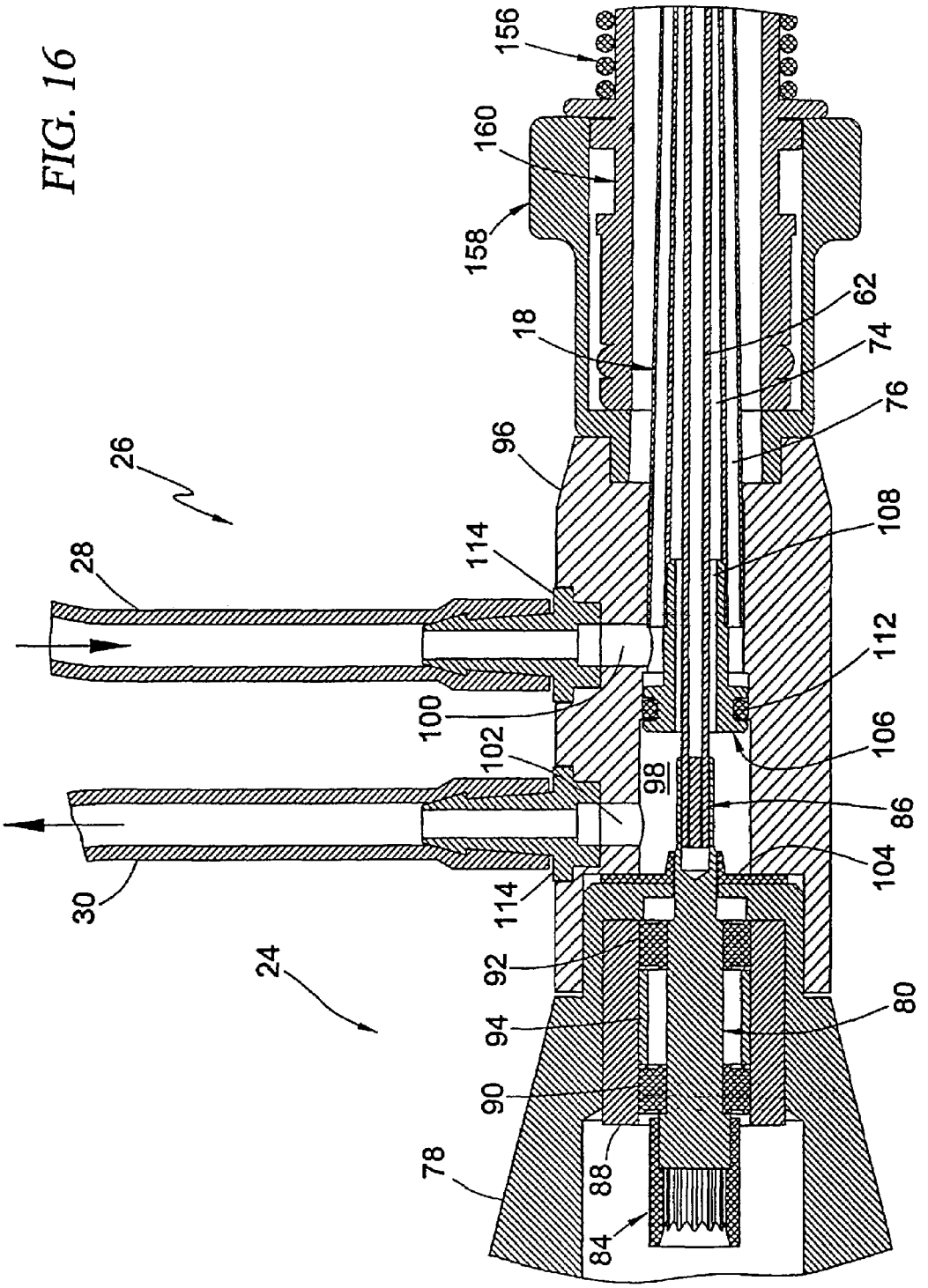


FIG. 15

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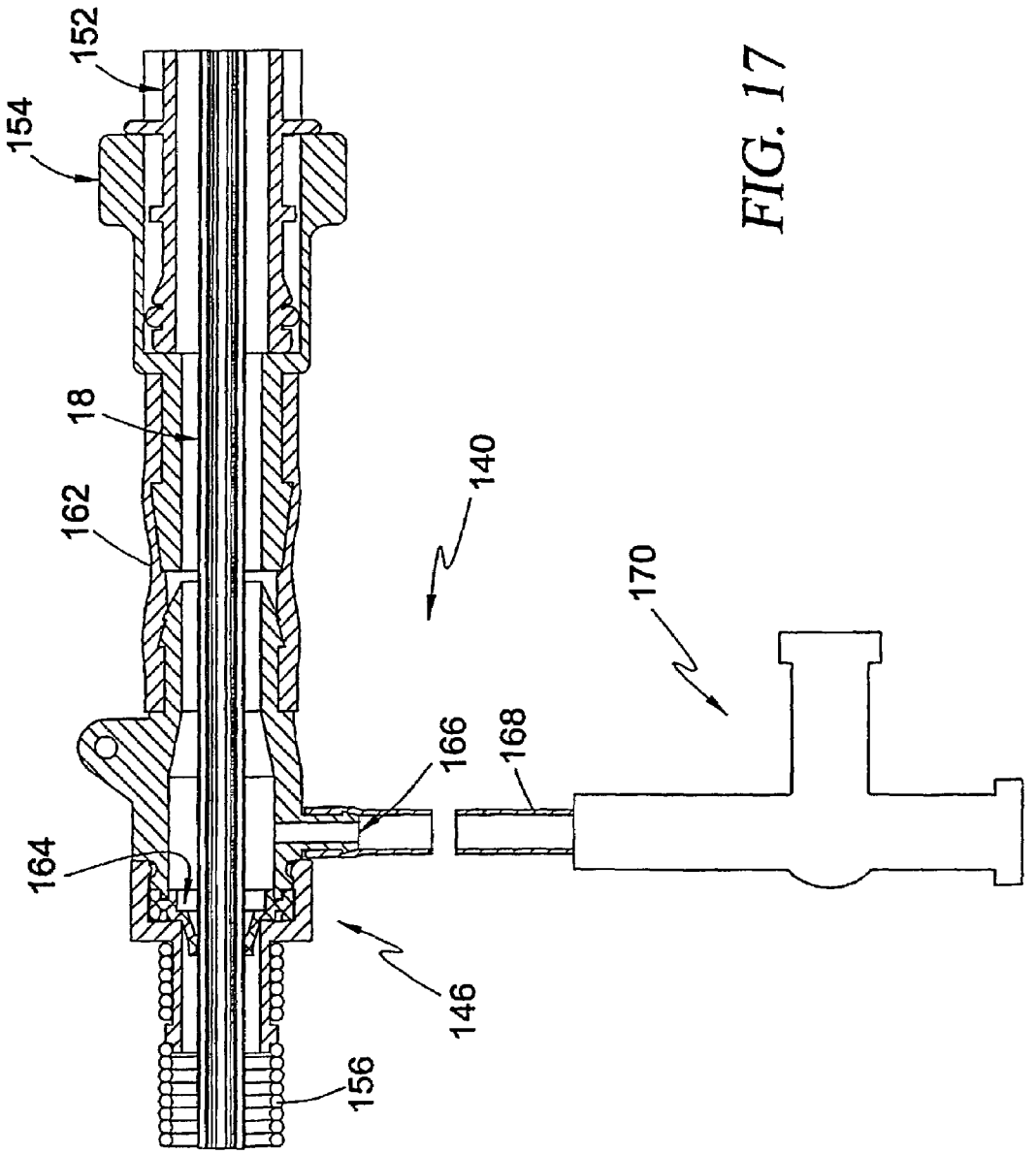


FIG. 17

FIG. 18

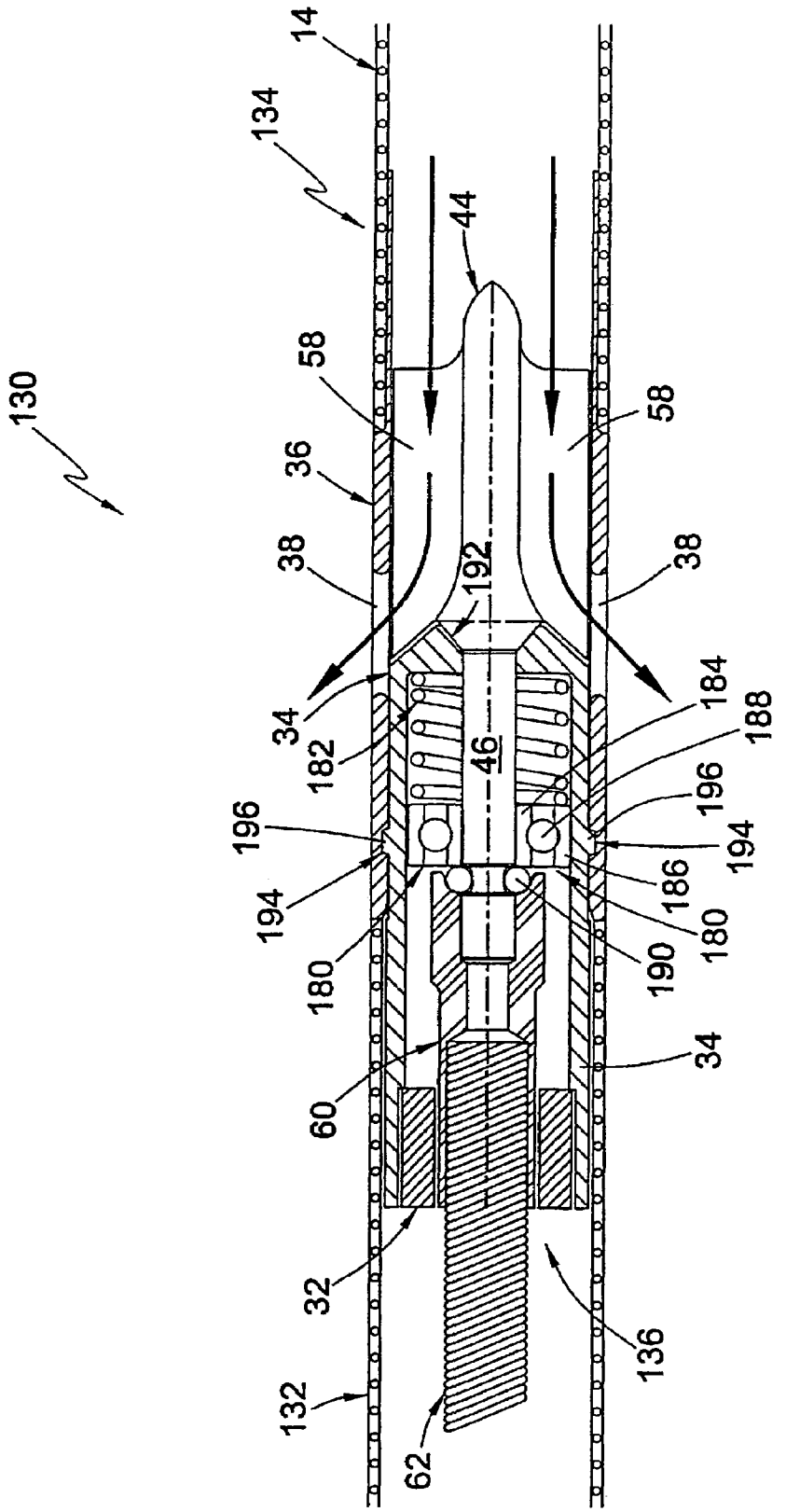
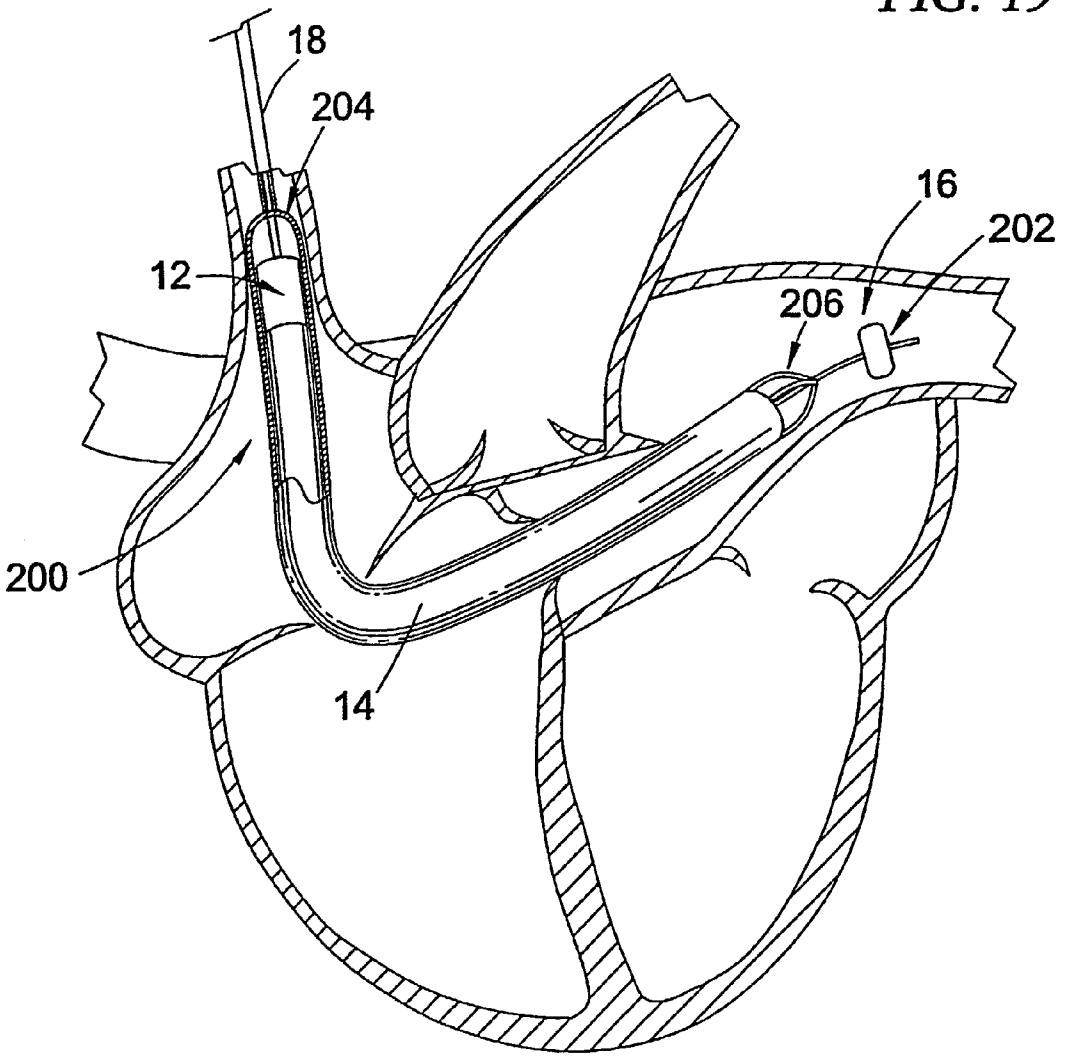

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FIG. 19



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 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 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.

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 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 flouroscopy. Once the guide wire **22** is positioned at the desired location (such as in left ventricle as shown), the blood pump **12** and cannula **14** may thereafter be 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 bearings assemblies **50**, **52** are well known in the art, each comprising an inner race which rotates along with the rotor shaft **46**, an outer race which remains in a static and fixed position against the inner surface of the pump body **34**, and a plurality of ball bearings disposed between the inner and outer races. The spring **54** biases each bearing assembly **50**, **52** axially away from one another to reduce axial play during pump operation. The shaft **46** is generally hollow and dimensioned to receive a cable adapter **60** therein for the purpose of coupling the rotor **44** to a drive cable **62** forming part of the drive cable assembly **18**. The drive cable **62** may be secured to the cable adapter **60** in any number of suitable fashions, including but not limited to the use of adhesives, crimping, and laser welding. These same techniques may be used to secure the cable adapter **60** within the shaft **46** of the rotor **44**. A radial seal **64** is provided in between the wall of the pump body **34** and a distal stepped region **66** on the rotor shaft **46**, the function of which will be described below.

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

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

The drive cable assembly **18** includes the drive cable **62** and the drive cable sheath **32**. The drive cable **62** is coupled to the rotor **44** via the cable adapter **60**. The drive cable sheath **32** includes a central lumen **74** and a plurality of side lumens **76**. The central lumen **74** serves as a protective covering for the drive cable **62**. The central lumen **74**, along with the side lumens **76**, also forms part of the purge fluid delivery system **26** shown above in FIG. **2**, which will be described in greater detail below. The side lumens **76** are provided in fluid communication with the fluid inlet conduit **28**, while the 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 **0.94** 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 indeflator, a fluid delivery pump, or an accumulator arrangement to provide the requisite delivery of pressurized fluid. The purge fluid delivery system **26** thus provides a two-way transmission of purge fluid within the drive cable sheath **32** for the purposes of 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 **20** 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

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 flouroscopy. The second step in providing the intravascular blood pump system **130** of the present invention involves advancing the pump assembly **136** through the conduit assembly **134** such that the rotor **44** docks within the shroud **36** to form the pump **12** at the desired location.

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

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 Touehy-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 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.

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** overt 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 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. Nitonol).

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

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.

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 predetermine 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.

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

David J. Kappos

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