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<input checked="" type="checkbox"/> Additional inventors are being named on the <u>1</u> separately numbered sheets attached hereto					
TITLE OF THE INVENTION (280 characters max)					
INTRAVASCULAR BLOOD PUMP					
CORRESPONDENCE ADDRESS					
Direct all correspondence to: <div style="display: flex; align-items: center;"> <input type="checkbox"/> Customer Number <input type="text"/> <div style="margin-left: 20px;">→</div> <div style="border: 1px solid black; padding: 5px; margin-left: 20px;"> Place Customer Number Bar Code Label here </div> </div>					
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ENCLOSED APPLICATION PARTS (check all that apply)					
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Respectfully submitted,

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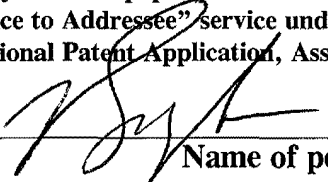
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Patent

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In re: Patent Application of)	BOX PROVISIONAL
)	PATENT APPLICATION
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Walid N. Aboul-Hosn et al.)	
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Application No.: Unassigned)	
)	
Filed: September 3, 1999)	
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For: INTRAVASCULAR)	
BLOOD PUMP)	

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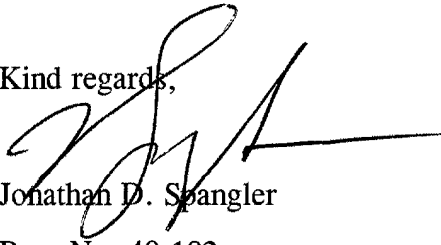
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Kind regards,

A handwritten signature in black ink, appearing to read 'J. Spangler', with a long horizontal stroke extending to the right.

Jonathan D. Spangler

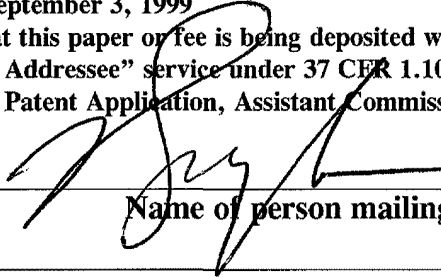
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**PROVISIONAL APPLICATION
FOR UNITED STATES LETTERS PATENT**

For:

"INTRAVASCULAR BLOOD PUMP"

By Inventors:

Walid Aboul-Hosn

Bruce Baker

William Kanz

Filed:

September 3, 1999

Assignee:

A-Med Systems, Inc.

TITLE OF THE INVENTION**INTRAVASCULAR BLOOD PUMP****BACKGROUND OF THE INVENTION****1. Field of the Invention**

The present invention relates generally to blood pumps and, more particularly, to an improved intravascular axial flow blood pump having a rotor shroud fixed along a unitary conduit which can be placed into the patient prior to the pump and rotor assembly using conventional guidance techniques such that, thereafter, the pump and rotor assembly may be backloaded into the conduit and docked with the rotor shroud for pump operation.

2. 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 introduced into the vascular system of a patient, typically to provide left and/or right heart support. One type of intravascular is an axial flow blood pump comprising an 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 which 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 wire 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, such axial flow intravascular blood pumps nonetheless suffer various drawbacks. A significant drawback is that prior art axial flow 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 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 supplement 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 axial flow intravascular pump may be introduced therein and guided while it is advanced towards the preselected 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 axial flow blood pumps.

SUMMARY OF THE INVENTION

In one broad aspect of the present invention, an intravascular blood pump assembly is provided comprising a pump assembly and a separable conduit having a rotor shroud disposed therealong. 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 conduit includes a distal cannula portion and a proximal catheter portion disposed on either side of the rotor shroud. The catheter portion of the conduit is dimensioned to receive and guide the pump

assembly to the point where the rotor docks within the rotor shroud such that axial flow pump operation may thereafter be performed. This configuration allows the conduit 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 in the desired position. This dual construction arrangement thereby provides improved placement of the pump assembly by using the conduit as a guiding mechanism.

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 an axial partial cross sectional view of an intravascular blood pump assembly provided in accordance with one embodiment of the present invention;

FIG. 2 is a schematic view of a human heart generally in the plane of the aorta, illustrating an intravascular blood pump assembly of the present invention positioned in a trans-valvular fashion for cardiac assist purposes;

FIG. 3 is a schematic view of a human being illustrating an intravascular blood pump assembly of the present invention inserted through the femoral artery and positioned in a trans-valvular fashion for cardiac assist purposes; and

FIG. 4 is a flow diagram illustrating the method steps involved in practicing the intravascular blood pump of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The present invention involves an intravascular pump assembly for use in a number of broad ranging applications involving the augmentation of blood flow within the circulatory system of a patient. 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 ventricular assist applications.

Referring to FIG. 1, shown is an intravascular blood pump assembly 10 according to one embodiment of the present invention. The intravascular blood pump assembly 10 includes a pump assembly 12 disposed within a conduit assembly 14. The conduit assembly 14 includes a shroud 16 disposed between a cannula section 18 and a catheter section 20. The term "cannula" as used herein is to be defined as a hollow conduit designed to be introduced into a body cavity for the purpose of transporting fluid. The term "catheter" as used herein is to be defined as a hollow conduit designed to be introduced into a body cavity for the purpose of guiding or directing other devices or components within the body.

In an important aspect of the present invention, the pump assembly 12 and conduit assembly 14 are provided as two separate units. This dual-construction forms a significant feature of the present invention because it provides the ability to position the blood pump assembly 10 in a patient using two separate and distinct steps. The first step involves positioning the conduit assembly 14 within a patient such that the shroud 16 and cannula section 18 are each disposed in a predetermined desired location, such as a transvalvular

configuration for cardiac assist procedures. In an important aspect, the task of positioning the conduit assembly 14 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 ultrasound or fluoroscopy. The second step in providing the intravascular blood pump assembly 10 of the present invention involves introducing and advancing the pump assembly 12 through the conduit assembly 14 such that the rotor 22 of the pump assembly 12 docks within the shroud 16 to form an operational pumping system. The dual-construction of the present invention makes the intravascular blood pump 10 far easier to use and position than prior art intravascular blood pumps having the shroud permanently fixed to the pump assembly 12. In a preferred embodiment, the outer diameter of the conduit assembly 14 is approximately 14 French, although it is contemplated that this diameter could be reduced to around 9 French and further under the dual-construction arrangement between the pumping assembly 12 and conduit assembly 14 of the present invention.

The pump assembly 12 includes a rotor 22 coupled to a drive cable 24 via a cable adapter 26. Pump assembly 12 also includes a pump 28 comprising a pump body 30, a seal spring 32, and a ball bearing assembly 34. The ball bearing assembly 34 includes an inner race 36, an outer race 38, and a plurality of balls 40 which enable the inner race 36 to rotate along with the rotor shaft 42 while the outer race 38 remains in a static and fixed position relative to an inner surface of the pump body 30. An O-ring 44 is disposed within a groove formed in the rotor shaft 42 so as to maintain the ball bearing assembly 34 against the seal spring 32. The O-ring 44 is further secured within the groove in the rotor shaft 42 via a contoured lip portion extending from the distal end of the cable adapter 26. The proximal end of the cable adapter 26 flushly engages the drive cable 24. During manufacture, an adhesive may be introduced along the interior of the cable adapter 26 to securely fasten the cable adapter 26 to both the shaft 42 of the rotor 22 and the drive cable 24. It will be recognized that a variety of other attachment methods may be employed to fix the cable adapter 26 to the shaft 42, including but not limited to laser welding. In a preferred embodiment, the drive cable 24 is rotatably disposed within a protective sheath

46. Although not fully shown, the protective sheath 46 extends proximally away from the pump 28 the entire length of the drive cable 24. As will be explained in more detail below, pressurized fluid (namely, fluid pressurized to some level elevated above the blood pressure in the surrounding artery) is injected in between the drive cable 24 and the interior of the protective sheath 46 during operation. This serves to reduce any frictional heating that exists between the drive cable 24 and sheath 46. The pressurized fluid also flows through the interior of the pump 28 such that, if the seal at 48 is broken, the pressurized fluid will flow past the open seal 48 and onward through the blood flow ports 50 formed in the shroud 16. This serves to keep blood from entering the pump 28 in an effort to avoid clotting and/or damaging the pump 28.

The pump assembly 12 may be docked within the conduit assembly 14 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. 1 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 12 within the conduit assembly 14. The only requirement is that the pump assembly 12 and conduit assembly 14 dock such that the rotor 22 is disposed within the shroud 16 to provide the desired axial flow through the cannula section 18 and out the shroud 16. In FIG. 1, the exemplary docking scheme involves forming an annular engagement groove 52 along the interior of the shroud 16, and forming a complementary annular ridge 54 along the exterior surface of the pump body 30. During insertion, the pump assembly 12 will be advanced into the conduit assembly 14 until the annular ridge 54 on the pump body 30 engages within the groove 52 formed in the shroud 16. This docking scheme is generally advantageous in that the engagement action between the annular ridge 54 and groove 52 will provide tactile feedback to the physician during the process of inserting the pump assembly 12 into the conduit assembly 14 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 54 and engagement groove 52 may be varied such that they are disposed closer or farther

away from the flow apertures 50. It may be advantageous to form these docking structures close to the flow apertures 50 in an effort to thwart the ingress of blood into the junction extending between the interior of the shroud 16 and the exterior surface of the pump body 30. It is also contemplated to employ selectively inflatable structures, such as balloons, in an effort to temporarily engage or dock the pump assembly 12 within the conduit assembly 14. In this regard, one or more lumens may be formed within the pump body 30 extending from the interior of the pump body 30 in fluid communication with a balloon disposed along the exterior surface of the pump body 30. The pressurized fluid flowing within the interior of the pump body 30 may then be used to inflate the balloon, which will then engage within an annular groove in the shroud 16, such as at 52 in FIG. 1. Of course, the engagement structures may also be reversed without departing from the scope of the present invention. For example, the shroud 16 may be equipped with a fluid delivery lumen therein for inflating a balloon disposed on the interior surface of the shroud 16, which may in turn be disposed within an annular engagement groove formed along the exterior surface of the pump body 30.

FIGS. 2 and 3 illustrate an exemplary application of the intravascular blood pump assembly 10 of the present invention. The blood pump assembly 10 is shown by way of example in a trans-valvular configuration within a human heart 60 for left-heart cardiac assist. The blood pump assembly 10 is preferably introduced into the vascular system of the patient through the femoral artery 62. The conduit assembly 14 is disposed within the patient such that the cannula section 18 extends through the aortic valve 66 into the left ventricle 64. The shroud 16 is preferably disposed in the ascending aorta 68. The catheter section 20 extends proximally from the shroud 16 for extracorporeal attachment to a motor system 70. Motor system 70, which is set forth by way of example only, includes a hemostasis valve 72, a motor 74, and a fluid delivery system 76. The hemostasis valve 72 is common in the art and designed to allow the passage of the intravascular pump 10 of the present invention into the femoral artery 62 without blood seepage or the introduction of air into the circulatory system. The motor 74 may be any number of commercially available motors capable of driving the drive cable 24 at high speeds, including but not limited to

motors capable of operating at speeds of between 25,000 and 45,000 rpm. The fluid delivery system 76 is representative of any and all mechanisms or methods for delivering pressurized fluid in between the drive cable 24 and the interior surface of the drive cable sheath 46. Such fluid delivery systems may include, but are not necessarily limited to, the use of a syringe, an inflator, or a fluid delivery pump. It is also contemplated as part of the present invention to employ an accumulator arrangement to provide the requisite delivery of pressurized fluid.

During a left-heart cardiac assist procedure, the intravascular blood pump 10 of the present invention serves to withdraw blood from the left ventricle under the direction of the rotor assembly 78 formed by docking the rotor 22 within the shroud 16. More specifically, axial rotation of the rotor 22 within the shroud 16 causes the blood to be drawn into blood inlet apertures 80 formed in the distal end of the cannula section 18 and to flow in a generally axial fashion towards the rotor 22. As best seen in FIG. 1, the blades 82 of the rotor 22 impart both an axial and radial vector on the blood which causes it to flow outward through the flow apertures 50 formed in the shroud 16. As used herein, the term "axial flow" is deemed to include flow characteristics like that shown in FIG. 1, which include both an axial and slight radial component. With combined reference to FIGS. 1 and 2, it will be appreciated that the blood passing through the apertures 50 in the shroud 16 in turn flows past the exterior surface of the catheter section 20 in a substantially axial fashion for arterial distribution throughout the body.

FIG. 4 illustrating typical steps involved in using the intravascular pump 10 of the present invention. Step 100 involves positioning the conduit assembly 14 to a predetermined location within the patient. In a typical cardiac application, this involves introducing the conduit assembly 14 into the vascular system of the patient, such as through the use of the well known Seldinger technique, and advancing it within the patient to the predetermined location within the circulatory system of the patient. For left-heart cardiac assist, for example, this is accomplished by passing the conduit assembly 14 through the femoral artery and onward to position the end of the cannula section 18 within the left

ventricle and the shroud 16 within the ascending aorta. Any number of different guidance mechanisms or techniques may be employed to ensure the proper and efficient placement of the conduit assembly 14 in the circulatory system of the patient, including but not limited to guide wires, balloon catheters, imaging wires, guide catheters, and/or techniques involving ultra-sound or fluoroscopy. The second step 110 involves introducing and advancing the pump assembly 12 through the conduit assembly 14 such that the rotor 22 of the pump assembly 12 docks within the shroud 16 to form an operational pumping system. As noted above, the task of docking the pump assembly 12 with the shroud 16 may be accomplished in any number of different fashions without departing from the scope of the present invention. The last step 120 involves operating the pump 10, which includes the steps of coupling the drive cable 24 to the motor 74, in addition to the well known techniques involving the use of the hemostasis valve 72 (to avoid the introduction of air or contaminants into the blood stream and to prevent blood leakage /loss) and the fluid delivery system 76 (to cool heating between the drive cable and drive cable sheath, and to thwart the ingress of blood into the pump).

A major advantage of the present invention is that the dual-construction of the present invention makes the intravascular blood pump 10 far easier to use and position than prior art intravascular blood pumps having the shroud permanently fixed to the pump assembly 12. With the rotor shroud fixed in position with the rotor, such prior art pumps do not provide the guidability offered by the present invention. Employing supplemental guidance devices with the prior art intravascular pumps may provide improved guidability (i.e. by using a guide catheter); however, this would necessarily cause an increase in the size of the device being introduced into the body because such a guide catheter would have to be larger in diameter than the pump in order to provide adequate movement within the guide catheter. By employing the dual-construction of the present invention to facilitate guidance of both the conduit assembly and the pump assembly, the intravascular pumps disclosed herein would not need a supplemental guide catheter type device. As will be appreciated, the intravascular axial flow pump of the present invention therefore facilitates

miniaturization which advantageously translates into an increase in the amount of space available for blood flow past the conduit assembly.

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. For example, while this invention has been described for use for left heart support, this does not limit the applications of this invention for use in left heart support only; rather, the intravascular blood pump of the present invention can be utilized in a wide variety of other applications apparent to those skilled in the art. Moreover, it is contemplated to provide guide structures to the intravascular pump of the present invention. For example, lumens may be provided within such structures as the pump body 30, the cable drive sheath 46, the catheter section 20 of the conduit assembly 14, etc... in order to receive wires for fashioning certain guidance characteristics, as well for receiving expandable balloon structures for venous applications. It is understood that this invention is not limited to the particular embodiments disclosed.

ABSTRACT OF THE DISCLOSURE

An intravascular axial flow blood pump and related methods involving the novel concept of providing a rotor shroud fixed along a unitary conduit which can be placed into the patient prior to the pump and rotor assembly using conventional guidance techniques such that, thereafter, the pump and rotor assembly may be backloaded into the conduit and docked with the rotor shroud for pump operation.

FIG. 1

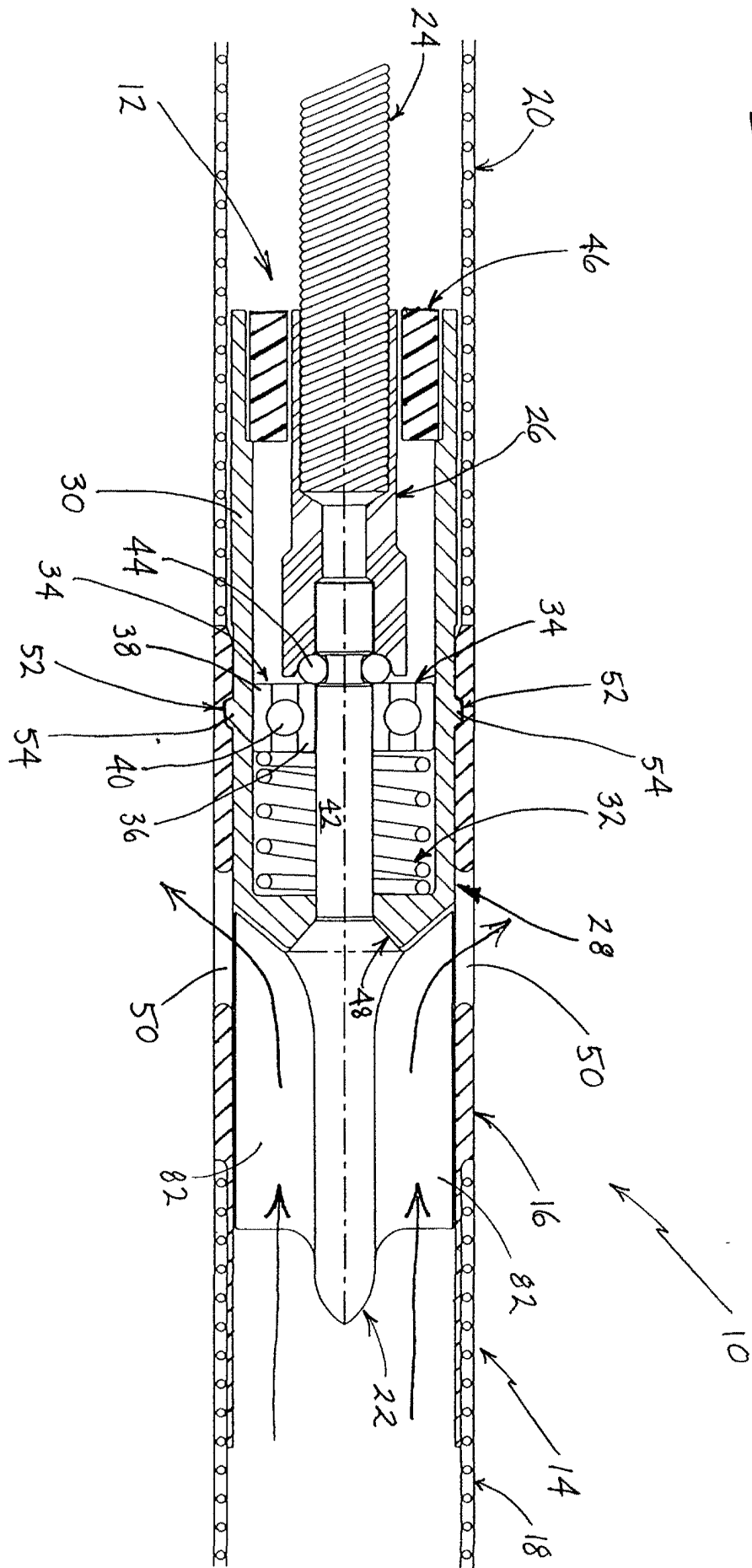


FIG. 2

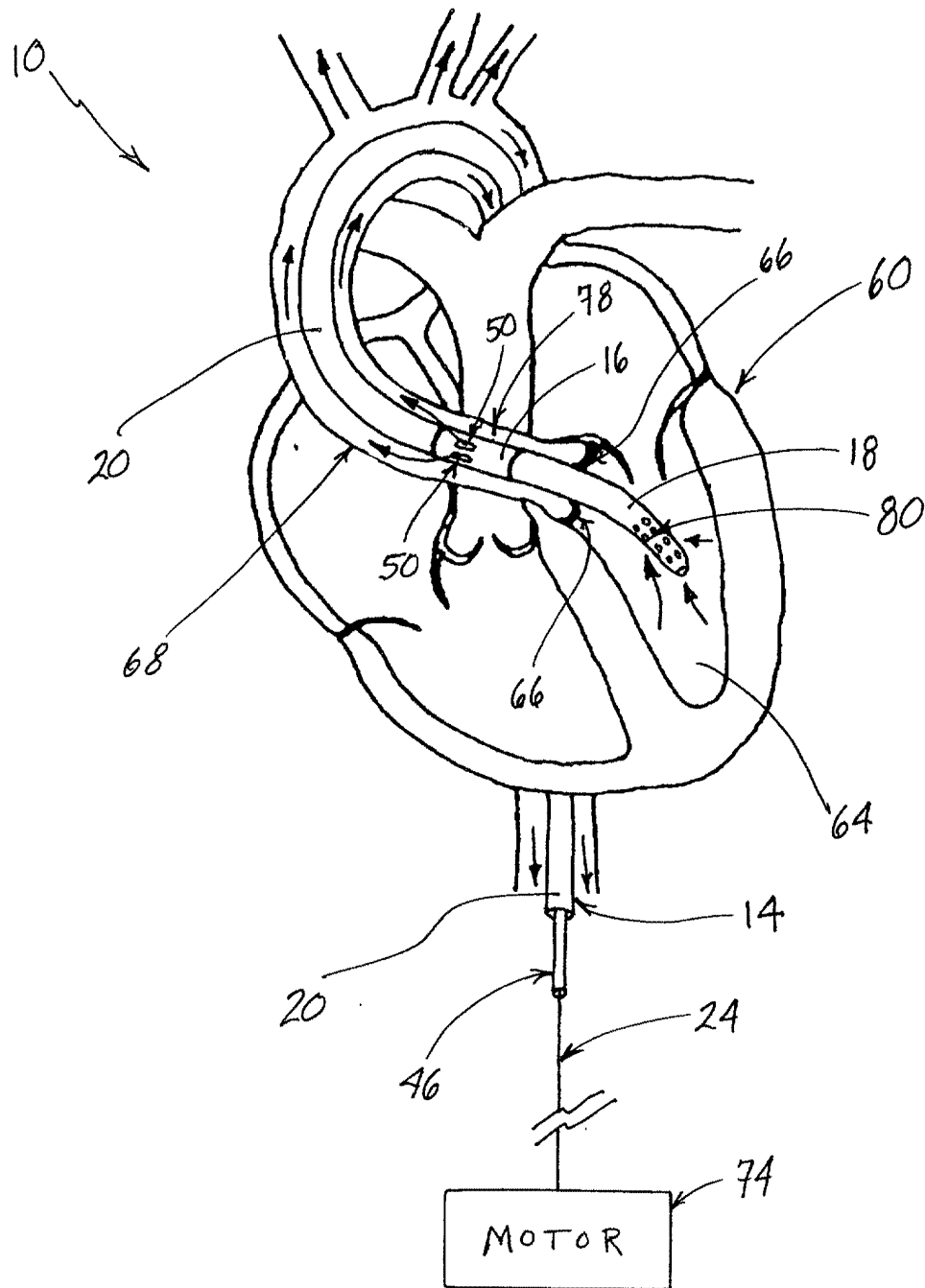


FIG. 3

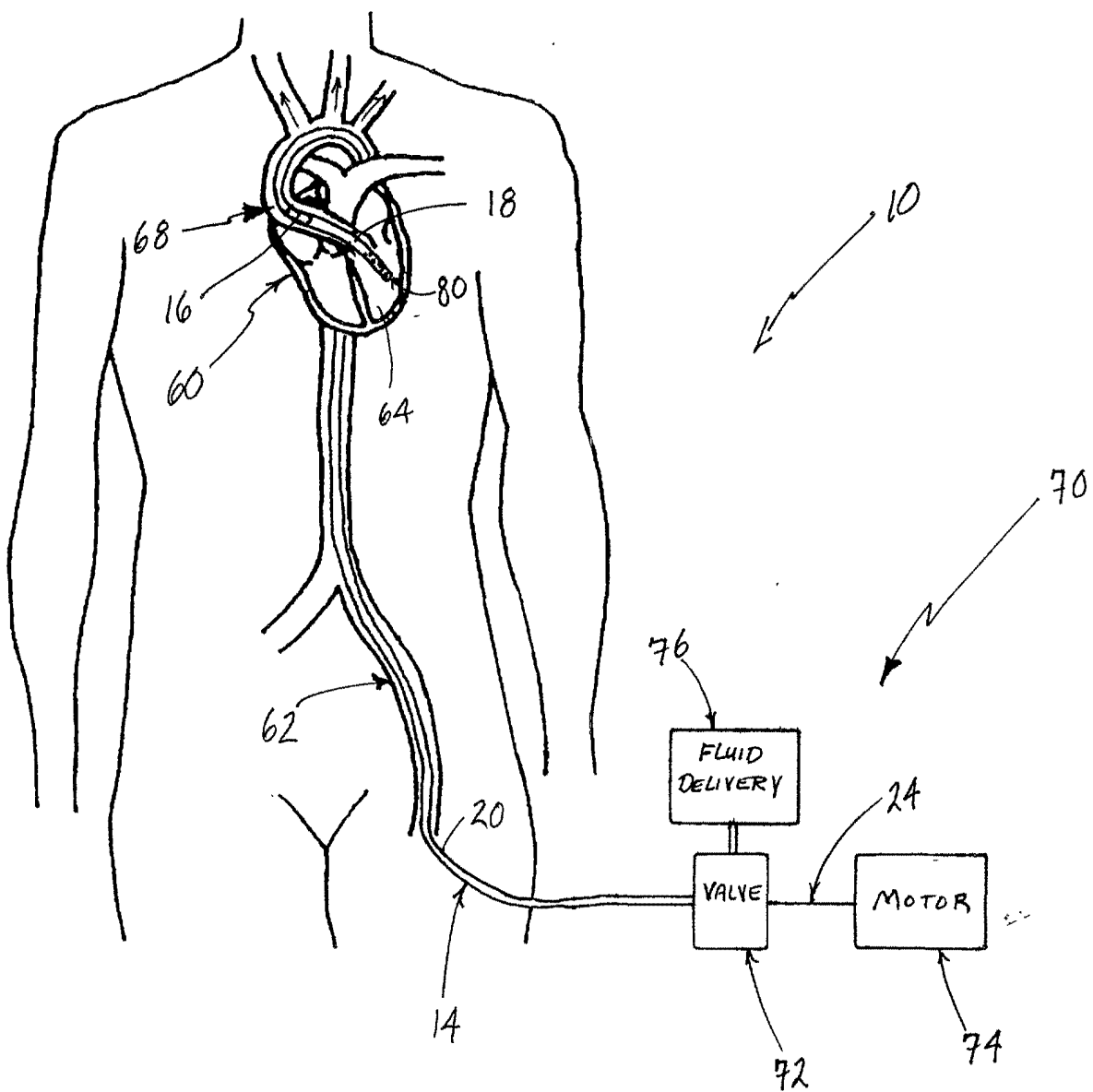


FIG. 4

