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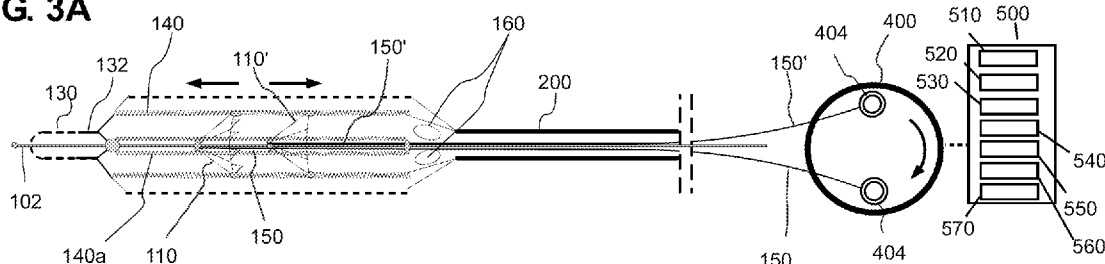
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(54) Title: HEART ASSIST SYSTEMS INCLUDING MOVING VALVE BLOOD PUMPS

FIG. 3A



(57) Abstract: A heart assist system includes a catheter and a collapsible/expandable pump connected to a distal end of the catheter. The pump includes an outer flexible conduit, a first movable check valve attached to the outer flexible conduit about the perimeter of the first movable check valve, and a second movable check valve, spaced from and in series with the first movable check valve, attached to the outer flexible conduit about the perimeter of the second movable check valve. A remotely positioned drive system is connected to the catheter. A first actuator and a second actuator are operatively connected to the drive system to transfer linear motion from the drive system to the first movable check valve and the second movable check valve, respectively.



HEART ASSIST SYSTEMS INCLUDING MOVING VALVE BLOOD
PUMPS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims benefit of U.S. Provisional Patent Application Serial No. 63/510,452, filed June 27, 2023, the disclosure of which is incorporated herein by reference.

BACKGROUND

[0002] The following information is provided to assist the reader in understanding technologies disclosed below and the environment in which such technologies may typically be used. The terms used herein are not intended to be limited to any particular narrow interpretation unless clearly stated otherwise in this document. References set forth herein may facilitate understanding of the technologies or the background thereof. The disclosure of all references cited herein are incorporated by reference.

[0003] The American Heart Association estimates that 5.7 million Americans have heart failure. The main muscle chamber of the heart is termed the left ventricle or LV. The LV functions by periodically squeezing a portion of its blood content through its outlet aortic valve into the body's aorta and arterial circulation. With a normal heartbeat rate or pulse of 72 beats per minute and a normal blood flow of 5 liters per minute, the average blood flow for each LV contraction or stroke volume will be $5,000/72$ or about ~70 milliliters (ml's or cc's) of blood. In heart failure, this 70 ml stroke volume may be reduced ~50% to ~35 ml and the person's body will suffer from serious heart failure that may be fatal. A heart transplant may be curative for ten or more years. However, yearly only approximately 2,500 such transplantable hearts are available in the United States. Cardiac assist, heart assist, and/or ventricular assist devices or VADs are available to preserve life in approximately 8,000 US cases of severe heart failure per year.

[0004] In general, a VAD is a device that helps pump blood from the lower chambers of the heart to the rest of the body. Two different VADs, the HEARTMATE 3TM (available from Abbott Laboratories of Abbott Park, Illinois) and HEARTWARE HVAD[®] (available from Medtronic of Fridley, MN) dominate the US permanently implanted VAD market. Both those VADs operate by receiving blood from the apex or tip of the LV and then pump this blood around the LV into the aorta, which is the body's main artery just beyond the LV's outlet aortic valve. The installation of those VADs requires major surgery to gain access to both the apex or tip of the LV as well as to the aorta beyond the LV. Because these rotary VADs pump blood in parallel with and around the LV, higher

rotary pump speeds have the risk of pumping the heart dry. The optimum pump speed allows blood to always flow naturally through the outlet aortic valve with each heartbeat and thereby avoid LV blood stagnation.

[0005] The pumping mechanism of both of those VADs includes a rotating impeller having metallic vanes that propel the blood against aortic pressure. This abnormal (with respect to the manner in which blood is pumped via the heart) pumping action has side effects. One side effect is the inevitable blood shear from the spinning impeller vanes damaging various blood elements including the von Willibrand factor and blood platelets leading to both the risk of abnormal blood clotting (strokes) and bleeding (gastrointestinal). To control the clotting risk, VAD patients are strongly anticoagulated with coumadin and are then at risk of bleeding. VAD patients also have an infection risk due to the skin piercing driveline in their abdominal wall. The driveline is necessary to power the VAD and power loss may be fatal. In summary, managing VADs is complicated and there are many potential adverse events. It has been reported that nearly 70% of VAD patients have one or more serious adverse events or complications in their first implant year.

[0006] A moving valve pump has, for example, been attached to an in-chest motor. Using major surgery, that pump can be placed in series with the aorta. The motive force for the valve in that moving valve pump is supplied by an electro-magnetic motor. However, having the motor as a part of the moving valve pump requires open chest surgery for installation.

[0007] There is also a need for temporary left ventricular assist. Patients having an acute heart attack from a complete or near complete coronary artery obstruction frequently undergo percutaneous coronary interventions or PCI procedures. PCI involves placing long thin tubes (catheters) through the skin and with X-ray imaging and injected fluid contrast media, attempting to open blocked coronary arteries to improve the blood supply to the heart's muscle. Cardiologists attempt to open these coronary artery obstructions with balloons and keep them open with stents. A major risk of PCI is the possibility of converting a partly occluded coronary artery into a complete occlusion resulting in a sudden total blood flow blockage. With a sudden total block of a major coronary artery, the patient will experience "shock" that is sudden loss of arterial blood pressure and possible death. Temporary VAD use may be lifesaving in this instance. As backup insurance against shock, patients are often "protected" with a temporary backup VAD. The most common temporary PCI backup VAD is the IMPELLA device (available from Abiomed of Danvers, MA). IMPELLA VADs are a family of small diameter catheters placed through the skin into the arterial system and through the aortic valve into the LV. The catheter pump is capable of moving blood from the LV through the aortic valve into the aorta. The IMPELLA pumping mechanism is a miniature screw-like impeller inside

the catheter, spinning at speeds from 20,000 to 50,000 revolutions per minute. The most commonly used IMPELLA 2.5 can provide up to 2.5 liters per minute of blood flow from the LV and, in shock, this may be lifesaving. However, because of the blood shear from the spinning impeller, use of an IMPELLA VAD is time limited to hours or at most days.

[0008] The IMPELLA 2.5 catheter pump has a 4 mm diameter and can be placed by the minimally invasive Seldinger technique including a needle skin puncture, guidewire insertion and then catheter placement over the guidewire. The IMPELLA 5.5 can pump up to 5.5 liters per minute and is 6.33 mm or 19 French in diameter. Placement of the IMPELLA 5.5 catheter pump requires a “cut down” through the skin with direct visualization and incision in the right or left axillary/subclavian artery.

[0009] In recent years, the minimally invasive transcatheter aortic valve replacement procedure or TAVAR has been developed to treat patients having stenosis or hardening of their aortic valve. Under fluoroscopic guidance and using a catheter, TAVAR valves are placed inside a patient’s defective aortic valve. The valve is expandable and becomes permanently expanded by, for example, a balloon. TAVAR valves have no pumping action but are check valves, allowing blood flow to flow only away from the LV into the aorta.

[0010] A linear, reciprocating valve pump has recently been described which is indicated to be suitable for implantation via the circulatory system of a patient to various positions for circulatory assist in stabilizing a patient to gain time for more long-term treatment. In that pump, a single valve, which is driven by a single linear motor, reciprocates within an expandable housing such that a rim thereof may form a seal with and slides along the housing. Regardless of tolerances, such sliding contact can lead to damage of various blood elements including the von Willibrand factor and blood platelets leading to both the risk of abnormal blood clotting and bleeding as described above. Further, providing a gap between such a rim and the housing of the device can lead to significant inefficiencies in pumping.

[0011] Although, there have been a number of advances in circulatory or heart assist devices such as ventricle assist devices, there is a significant need for cardiac/circulatory assist devices having improved performance, fewer risks and/or fewer other problems than currently available heart assist devices.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] FIG. 1A illustrates the left axillary (underarm) body entrance location for a pump and catheter of an embodiment of temporary heart assist system hereof.

[0013] FIG. 1B illustrates the location of the permanent implant configuration for a pump and drive system of the heart assist system hereof wherein the drive system (for example, a motor drive) is implanted subcutaneously in the lower left axillary region.

[0014] FIG. 1C illustrates a right axillary artery (in the right subclavian region) body entrance location for a pump and heart assists system hereof which may provide an advantage of a less tortuous blood vessel pathway.

[0015] FIG. 2A illustrates an embodiment of a heart assist pump hereof including two moving valves wherein the heart assist pump is compressed for insertion/removal.

[0016] FIG. 2B illustrates the pump of FIG. 2A deployed/expanded after insertion, wherein an introduction sheath is used for pump compression and is retracted from the pump to allow expansion.

[0017] FIG. 3A illustrates an embodiment including the pump of FIG. 2A wherein the valves are driven by wire actuators.

[0018] FIG. 3B illustrates an embodiment of a torque DC motor wherein the motor's rotor drives a crankshaft that includes two rotating bearings that are operatively connected to actuators to drive the valves in equal and opposite directions.

[0019] FIG. 4A illustrates a side view of an embodiment of the low flow slippage valve structure wherein five of the eight struts are shown, and wherein the struts can be compressed towards the pump's central axis to reduce the diameter of the pump and held compressed by a compression sleeve for insertion/withdrawal purposes.

[0020] FIG. 4B illustrates two axial, cross-sectional views (at different points on the axis of the valve) of the valve of FIG. 4A in the open state where the triangular shaped flaps are flexed, bent or curled to an open state.

[0021] FIG. 5 illustrates the position of a heart assist pump hereof with a distal tip of a chamber of the pump in the left ventricle and the body of the pump in the ascending aorta, wherein a bare wire

stent is deployed against the inner wall of the ascending aortic wall for grounding purposes, and wherein the pump's open wire stent allows aortic blood to flow backwards into the coronary arteries.

SUMMARY

[0022] In one aspect, a heart or circulation assist system includes a catheter and a pump connected to a distal end of the catheter. The pump includes an outer flexible conduit, a first movable check valve attached to the outer flexible conduit about the perimeter of the first movable check valve, and a second movable check valve, which is spaced from and in series with the first movable check valve, attached to the outer flexible conduit about the perimeter of the second movable check valve. The heart assist system further includes a drive system connected to the catheter and positioned remote from the first movable valve and the second movable check valve, a first actuator operatively connected to the drive system and to the first movable check valve via the catheter to transfer linear motion from the drive system to the first movable check valve, and a second actuator operatively connected to the drive system and to the second movable check valve via the catheter to transfer linear motion from the drive system to the second movable check valve. The pump is collapsible to a first, smaller-radius state in which the pump is implantable within a body of a patient via the catheter and expandable to a second, larger-radius state after implanting via the catheter to an operational position within the body of the patient. The first movable check valve may be attached to the outer flexible conduit to form a sealed attachment therewith and the second movable check valve is attached to the outer flexible conduit to form a sealed attachment therewith.

[0023] In a number of embodiments, the heart assist system further includes an inner flexible conduit having a diameter less than the outer flexible conduit. The first movable check valve may be attached to the inner flexible conduit at a position radially inward from the perimeter of the first movable check valve. The first movable check valve may be attached to the outer flexible conduit to form a sealed attachment therewith and may be attached to the inner flexible conduit to form a sealed attachment therewith. Likewise, the second movable check valve may be attached to the outer flexible conduit to form a sealed attachment therewith and may be attached to the inner flexible conduit to form a sealed attachment therewith.

[0024] The second movable check valve may be attached to the inner flexible conduit at a position radially inward from the perimeter of the second movable check valve. The first actuator and the second actuator may, for example, pass through the catheter and into a volume within the inner flexible conduit. The first actuator and the second actuator may, for example, independently include a wire or a tube.

[0025] In a number of embodiments, the heart assist system further includes a guide wire conduit passing through the catheter and through the volume within the inner flexible conduit. In a number of embodiments, at least one of the outer flexible conduit and the inner flexible conduit includes extra material in an axial direction along the length thereof. At least one of the outer flexible conduit and the inner flexible conduit may, for example, include corrugation or folds therein.

[0026] The heart assist system may further include an intake chamber at a distal end of the pump. The intake chamber, in a number of embodiments, includes one or more passages at a distal end thereof through which blood may pass to enter the pump. In a number of embodiments, the intake chamber further includes a solid surface at a proximal end thereof configured to form a seal with the aortic valve.

[0027] In a number of embodiments, the pump further includes a stent radially outward of the outer flexible conduit. When the pump is in the second, larger-radius state, the stent contacts the aortic wall and provides a mechanical ground for the pump.

[0028] In a number of embodiments, the drive system includes a motor. The motor drives the first actuator and the second actuator such that the first movable check valve and the second movable check valve are driven sinusoidally in a number of embodiments. The motor may, for example, drive the first actuator and the second actuator such that the first movable check valve and the second movable check valve are driven approximately 180 degrees out of phase.

[0029] In a number of embodiments, the drive system comprises a crank shaft in operative connection with a rotor of the motor, wherein each of the first actuator and the second actuator are operatively connected to the crank shaft. In a number of embodiments, the drive system includes two drive arms positioned approximately 180 degrees apart around a drive axle in operative connection with the rotor of the motor, each of the first actuator and the second actuator being operatively connected to a different one of the drive arms.

[0030] The motor may, for example, be configured to be positioned outside of the body of the patient and the catheter may be configured to pass percutaneously into the body of the patient. The motor may also or alternatively be configured to be positioned within the body of the patient and outside the chest cavity of the patient, and the catheter may be configured to be implanted within the body of the patient.

[0031] The first movable check valve, in a number of embodiments, includes at least one element which closes a port formed in the first movable check valve upon motion of the first movable check

valve to move blood. Similarly, the second movable check valve, in a number of embodiments, includes at least one element which closes a port formed in the second movable check valve upon motion of the second movable check valve to move blood.

[0032] In another aspect, a method of assisting the function of the heart or circulation includes placing a heart assist system as described herein in connection with a patient's circulatory system. In a number of embodiments, the pump is positioned within the ascending aorta with a distal end of the pump extending into the left ventricle. The method may include placing the heart assist system in fluid connection with the circulatory system of a patient at an operational position within the body of the patient via a catheter. The heart assist system includes a pump connected to a distal end of the catheter. The pump includes an outer flexible conduit, a first movable check valve attached to the outer flexible conduit about the perimeter of the first movable check valve, and a second movable check valve, which is spaced from and in series with the first movable check valve, attached to the outer flexible conduit about the perimeter of the second movable check valve. The pump is collapsible. The heart assist system further includes a drive system connected to the catheter and positioned remote from the first movable valve and the second movable check valve, a first actuator operatively connected to the drive system and to the first movable check valve via the catheter to transfer linear motion from the drive system to the first movable check valve, and a second actuator operatively connected to the drive system and to the second movable check valve via the catheter to transfer linear motion from the drive system to the second movable check valve. The method further includes advancing the pump to the operational position while the pump is collapsed to a first, smaller-radius state; and expanding the pump to a second, larger-radius state after upon reaching the operational position.

[0033] In another aspect, a heart or circulatory assist pump is connected to a distal end of a catheter and includes an outer flexible conduit, a first movable check valve attached to the outer flexible conduit about the perimeter of the first movable check valve, and a second movable check valve, spaced from and in series with the first movable check valve, attached to the outer flexible conduit about the perimeter of the second movable check valve. The heart assist pump further includes a first actuator operatively connected to the first movable check valve and configured to be connected to a drive system remote from the pump via the catheter to transfer linear motion from the drive system to the first movable check valve, and a second actuator operatively connected to the second movable check valve and configured to be connected to the drive system via the catheter to transfer linear motion from the drive system to the second movable check valve. The pump is collapsible to a first, smaller-radius state in which the pump is implantable within a body of a patient via the catheter and

expandable to a second, larger-radius state after implanting via the catheter to an operational position within the body of the patient. The first movable check valve may be attached to the outer flexible conduit to form a sealed attachment therewith and the second movable check valve is attached to the outer flexible conduit to form a sealed attachment therewith.

[0034] The heart assist pump may further include an inner flexible conduit having a diameter less than the outer flexible conduit. The first movable check valve being attached to the inner flexible conduit at a position radially inward from the perimeter of the first movable check valve. The first movable check valve may be attached to the outer flexible conduit to form a sealed attachment therewith and may be attached to the inner flexible conduit to form a sealed attachment therewith.

[0035] In another aspect, a method of assisting the function of the heart or circulation includes placing a pump as described herein in connection with a patient's circulatory system. In a number of embodiments, the pump is positioned within the ascending aorta with a distal end of the pump extending into the left ventricle. The method may include placing a heart assist pump in fluid connection with the circulatory system of a patient at an operational position within the body of the patient via a catheter. The heart assist pump includes an outer flexible conduit, a first movable check valve attached to the outer flexible conduit about the perimeter of the first movable check valve, and a second movable check valve, spaced from and in series with the first movable check valve, attached to the outer flexible conduit about the perimeter of the second movable check valve, a first actuator operatively connected to the first movable check valve and configured to be connected to a drive system remote from the heart assist pump via the catheter to transfer linear motion from the drive system to the first movable check valve, and a second actuator operatively connected to the second movable check valve and configured to be connected to the drive system via the catheter to transfer linear motion from the drive system to the second movable check valve. The heart assist pump is collapsible to a first, smaller-radius state in which the heart assist pump is implantable within the body of the patient via the catheter and expandable to a second, larger-radius state after implanting via the catheter to an operational position within the body of the patient. The method further includes advancing the heart assist pump to the operational position through while the heart assist pump is collapsed to a first, smaller-radius state and expanding the heart pump to a second, larger-radius state after upon reaching the operational position.

[0036] In another aspect, a heart assist system includes a catheter, and a pump connected to a distal end of the catheter. The pump includes an outer flexible conduit, a first movable check valve attached to the outer flexible conduit about the perimeter of the first movable check valve. The heart assist system further include a drive system connected to the catheter and positioned remote from the first

movable valve and the second movable check valve and a first actuator operatively connected to the drive system and to the first movable check valve via the catheter to transfer linear motion from the drive system to the first movable check valve. The pump is collapsible to a first, smaller-radius state in which the pump is implantable within a body of a patient via the catheter and expandable to a second, larger-radius state after implanting via the catheter to an operational position within the body of the patient. The first movable check valve may be attached to the outer flexible conduit to form a sealed attachment therewith.

[0037] The heart assist system may further include an inner flexible conduit having a diameter less than the outer flexible conduit. The first movable check valve may be attached to the inner flexible conduit at a position radially inward from the perimeter of the first movable check valve. The first movable check valve may be attached to the outer flexible conduit to form a sealed attachment therewith and may be attached to the inner flexible conduit to form a sealed attachment therewith.

[0038] In another aspect, a method of assisting the function of the heart or circulation includes placing a heart assist system as described above in connection with a patient's circulatory system. In a number of embodiments, the pump is positioned within the ascending aorta with a distal end of the pump extending into the left ventricle.

[0039] In a further aspect, a heart assist pump, which is connectable to a catheter, includes an outer flexible conduit, a first movable check valve attached to the outer flexible conduit about the perimeter of the first movable check valve, and a first actuator operatively connected to the first movable check valve and configured to be connected to a drive system remote from the heart assist pump via the catheter to transfer linear motion from the drive system to the first movable check valve. The heart assist pump is collapsible to a first, smaller-radius state in which the heart assist pump is implantable within a body of a patient via the catheter and expandable to a second, larger-radius state after implanting via the catheter to an operational position within the body of the patient. The first movable check valve may be attached to the outer flexible conduit to form a sealed attachment therewith.

[0040] The heart assist pump may further include an inner flexible conduit having a diameter less than the outer flexible conduit. The first movable check valve may be attached to the inner flexible conduit at a position radially inward from the perimeter of the first movable check valve. The first movable check valve may be attached to the outer flexible conduit to form a sealed attachment therewith and may be attached to the inner flexible conduit to form a sealed attachment therewith.

[0041] In still a further aspect, a method of assisting the function of the heart or circulation includes placing a heart assist pump as described above in connection with a patient's circulatory system. In a number of embodiments, the pump is positioned within the ascending aorta with a distal end of the pump extending into the left ventricle.

[0042] The present devices, systems, and methods, along with the attributes and attendant advantages thereof, will best be appreciated and understood in view of the following detailed description taken in conjunction with the accompanying drawings.

DETAILED DESCRIPTION

[0043] It will be readily understood that the components of the embodiments, as generally described and illustrated in the figures herein, may be arranged and designed in a wide variety of different configurations in addition to the described representative embodiments. Thus, the following more detailed description of the representative embodiments, as illustrated in the figures, is not intended to limit the scope of the embodiments, as claimed, but is merely illustrative of representative embodiments.

[0044] Reference throughout this specification to “one embodiment” or “an embodiment” (or the like) means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment. Thus, the appearance of the phrases “in one embodiment” or “in an embodiment” or the like in various places throughout this specification are not necessarily all referring to the same embodiment.

[0045] Furthermore, described features, structures, or characteristics may be combined in any suitable manner in one or more embodiments. In the following description, numerous specific details are provided to give a thorough understanding of embodiments. One skilled in the relevant art will recognize, however, that the various embodiments can be practiced without one or more of the specific details, or with other methods, components, materials, et cetera. In other instances, well known structures, materials, or operations are not shown or described in detail to avoid obfuscation.

[0046] As used herein and in the appended claims, the singular forms “a,” “an,” and “the” include plural references unless the context clearly dictates otherwise. Thus, for example, reference to “a moving valve” includes a plurality of such moving valves and equivalents thereof known to those skilled in the art, and so forth, and reference to “the moving valve” is a reference to one or more such moving valves and equivalents thereof known to those skilled in the art, and so forth. Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually

to each separate value falling within the range. Unless otherwise indicated herein, each separate value, as well as intermediate ranges, are incorporated into the specification as if individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contraindicated by the text.

[0047] The terms “electronic circuitry”, “circuitry” or “circuit,” as used herein include, but are not limited to, hardware, firmware, software, or combinations of each to perform a function(s) or an action(s). For example, based on a desired feature or need, a circuit may include a software controlled microprocessor, discrete logic such as an application specific integrated circuit (ASIC), or other programmed logic device. A circuit may also be fully embodied as software. As used herein, “circuit” is considered synonymous with “logic.” The term “logic”, as used herein includes, but is not limited to, hardware, firmware, software, or combinations of each to perform a function(s) or an action(s), or to cause a function or action from another component. For example, based on a desired application or need, logic may include a software controlled microprocessor, discrete logic such as an application specific integrated circuit (ASIC), or other programmed logic device. Logic may also be fully embodied as software.

[0048] The term “processor,” as used herein includes, but is not limited to, one or more of virtually any number of processor systems or stand-alone processors, such as microprocessors, microcontrollers, central processing units (CPUs), and digital signal processors (DSPs), in any combination. The processor may be associated with various other circuits that support operation of the processor, such as random access memory (RAM), read-only memory (ROM), programmable read-only memory (PROM), erasable programmable read only memory (EPROM), clocks, decoders, memory controllers, or interrupt controllers, etc. These support circuits may be internal or external to the processor or its associated electronic packaging. The support circuits are in operative communication with the processor. The support circuits are not necessarily shown separate from the processor in block diagrams or other drawings.

[0049] The term “controller,” as used herein includes, but is not limited to, any circuit or device that coordinates and controls the operation of one or more input and/or output devices. A controller may, for example, include a device having one or more processors, microprocessors, or central processing units capable of being programmed to perform functions.

[0050] The term “software,” as used herein includes, but is not limited to, one or more computer readable or executable instructions that cause a computer or other electronic device to perform functions, actions, or behave in a desired manner. The instructions may be embodied in various forms

such as routines, algorithms, modules, or programs including separate applications or code from dynamically linked libraries. Software may also be implemented in various forms such as a stand-alone program, a function call, a servlet, an applet, instructions stored in a memory, part of an operating system or other type of executable instructions. It will be appreciated by one of ordinary skill in the art that the form of software is dependent on, for example, requirements of a desired application, the environment it runs on, or the desires of a designer/programmer or the like.

[0051] The heart assist and pump devices, systems, and methods hereof achieve a number of desirable results in left ventricular assist. For example, the heart assist systems provide blood movement with less shear than currently available systems. The pump systems hereof reduce shear by pushing blood without shearing it as rotary pumps do. Moreover, the heart assist system hereof may be temporarily or permanently implanted without major surgery. Heart assist system hereof may, for example, be implanted without the requirement for opening the chest cavity. Moreover, the heart assist systems hereof may be used to move/pump blood in-series with the LV instead of pumping around and competing with the LV.

[0052] In a number of embodiments, heart assist systems hereof include a heart assist pump which is remotely activated/driven via a drive system located outside the chest wall. The pump can, for example, include one or more moving valves and may provide a solution for various shortcomings of currently available assist devices such as VADs. In a number of embodiments hereof, a dual moving valve (that is, a two-moving-valve) pump is discussed as a representative example. However, one skilled in the art appreciates that a single moving valve or more than two moving valves may be provided in various embodiments of a heart assist pump hereof. Advantages of the heart assist systems hereof include, but are not limited to, installing an assist device/VAD minimally invasively; pushing blood rather than slicing blood; having a blood pumping mechanism that will satisfy both short- and long-term needs; pumping blood in series with the left ventricle; and having an assist device mechanism that is failsafe. To implant minimally invasively, embodiments of moving valve pumps hereof are catheter-based with a compressed diameter (for example, approximately 7 mm). Further, when located with a distal end in the LV, moving valve pumps hereof are deployable to a larger diameter (for example, approximately 16 mm or larger) while leaving space between the catheter-delivered pump and the aortic wall for blood to flow backwards into the coronary arteries. To enable a small insertion diameter, the drive system (including, for example, a motor) may be positioned external to the rib cage and either outside the body for temporary use or subcutaneously for permanent use. Linear actuators may be used to control valve position and velocity. To minimize shear, in a number of embodiments, the pumps hereof pump blood by collapsing an annular shaped

elastic chamber in the axial/linear direction. To improve pumping efficiency, two moving-valve controlled collapsing chambers may be employed in series which may, for example, be operated or of phase. In a number of embodiments, the two moving valves are operated approximately 180 degrees (that is, within 5 degrees of 180 degrees) out of phase in a number of embodiments. To minimize vibration, the cycling speed may be reduced or minimized by increasing/maximizing the cross-sectional area of the moving valve(s).

[0053] In theory, a dual valve assisted flow will be that of a rectified sine wave with almost constant forward flow. However, if the valves are driven with constant motor power, the flow will be smoother because a valve's motion will speed up when doing less work during valve switching. As a general rule, noisy or vibrating devices that are in, on, or near a patient are problematic with regard to the patient's comfort and peace of mind. Likewise, a vibrating device that is continuously sensed in or on the body is very undesirable. A target flow rate for a heart assist device may, for example, be a blood flowrate produced by a normal heart, namely 5,000 milliliters (ml's) or cubic centimeters (cc's) per minute. If one assumes that a single moving valve pump has a 5 cm stroke and a cross sectional area of 3.1 centimeters squared (20 mm diameter) producing a stroke volume of 15.5 cc per stroke cycle, the stroke frequency for 5,000 cc per minute will be 5+ cycles per second. To simulate the pulsatile action of the heart that pumps roughly half the time, the stroke frequency would have to double to 10 to 11 strokes per second. The preceding calculation neglects the possibility of backflow that will occur when the moving valve is returning to its most distal position. To the extent that backflow exists, the stroke frequency will need to be increased to maintain the targeted flowrate. With moving valve cycling frequencies in the 5 to 15 Hertz range there is a substantial risk of the patient sensing the moving valve motion, especially if such motion is jerky (that is, exhibiting rapid changes in velocity and acceleration). In that regard, valve motion jerkiness is the opposite of smooth valve motion in which rapid changes in velocity and acceleration are absent. As clear to one skilled in the art, the valve of a reciprocating, moving valve pump must travel forward, slow down, stop, move in reverse, stop and then move forward again. By controlling a valve to provide generally sinusoidal motion, jerkiness is at a minimum and the motion is not likely to be sensed by the patient. Providing a plurality of (for example, two) valves results in additional smoothness. For example, one may control such valves such that the two valves travel in generally equal and opposite directions, thereby balancing the motion (momentum) of the two valves. Furthermore, having two (or more) valves sharing the pumping work will provide nearly continuous flow at a much lower cycling rate than the case of a single valve. Thus, in a number of embodiments of systems hereof two moving valves are provided in series and are operated or cycled such that the valves are approximately 180

degrees out of phase as described above. Moving valves in a pump including three moving valves may, for example, be cycled approximately 120 degrees out of phase.

[0054] For a fully implanted moving valve pump requiring battery power for patient mobility purposes, energy efficiency is very important. In that regard, there is a safe limit for transcutaneous energy transmission to an implanted pump. Bench testing has demonstrated that energy requirement is exponentially related to cycling rate. A multi-valve (for example, dual-valve) pump will operate at a fraction (for example, roughly half for a dual-valve pump) the cycling rate required of a single valve pump for the same assisted flow rate, significantly reducing the required energy transmission. Transcutaneous energy transmission to an implanted pump is, for example, described in U.S. Patent No. 8,764,621, the disclosure of which is incorporated herein by reference.

[0055] In a number of embodiments, the generally cylindrical wall of pump systems hereof is flexible in at least the axial direction. By attaching or sealing at least a portion of the periphery of the valve(s) of the pump systems hereof to the cylindrical wall, blood shear can be greatly reduced, minimized or completely eliminated. Moving valve pumps hereof will certainly have much less blood shear than the high speed (30,000 to 50,000 RPM) Archimedes screw type pumps. Moreover, to minimize blood shear for a moving valve pump such as a catheter-based moving valve pump, it is desirable that valve perimeter or rim does not slide on/relative to the inside surface of its outside containment wall, tube, conduit or housing. Such sliding action will inevitably produce substantial blood shear and associated shear-induced blood damage.

[0056] In a number of embodiments, extra material is provided in the length of the conduit to which the movable valve rim is attached (that is, in an axial direction, and between attachment points for such material) such that the reciprocal motion of the movable valve does not result in significant (or any) stretching of the material (for example, elongation of a polymer material) of the wall. In that regard, the extra or excess material of the conduit enables the material to move with the moving valve(s) with little or no stretching of that material. As used herein, significant stretching refers to an extension strain of X% or more. Minimizing or eliminating such stretching assists in reducing or minimizing the force/energy required to move the valve(s). In addition to increasing energy/force, stretching of a conduit wall also introduces the risk of wall breakage as a result from material fatigue. In a number of embodiments, the generally cylindrical conduit wall of assist systems or devices hereof is corrugated or has accordion-like folds therein to provide extra material between attachment points such that very little energy is required to extend the length of the conduit wall and the risk of failure as a result of fatigue is minimized or eliminated.

[0057] It is desirable to locate the drive system/motor at a position remote from the valves (and outside the chest wall). As described above, out-of-phase cycling of, for example, two moving valves substantially reduces vibration that could be sensed by the patient as well as nearly doubling the flow output of the pump compared to a pump with a single moving valve. The drive system/methodology for providing remote motive power for two or more moving valves may, for example, include a single rotating motor and rotor placed outside the chest cavity. Such a remote drive system may, for example, drive the moving valves of the pump (which may be positioned inside the aorta as described further below) using two linear actuators (for a dual valve pump) that are attached proximally to the motor's rotor and distally to the valves. The actuators could, for example, include linear actuators such as independent wires or tubes. If the actuators include tubes, one tube could be placed inside the other. The actuator(s) could be a combination of a wire and a tube that would facilitate the wire/tube within a tube feature. The valve actuators may be sufficiently laterally flexible to negotiate the curvature of the arterial tree but sufficiently axially/linearly stiff to efficiently transmit energy to the valves.

[0058] The ascending aorta is a thick-walled fibrous structure that can provide a mechanical ground for the contracting LV to push blood through its attached aortic valve. A moving valve pump hereof can benefit from a mechanical ground attached to the ascending aortic wall to assure that the distal end of the moving valve pump may be stabilized inside the LV. In a number of embodiments, the cross-sectional area or CSA of the dual valve pump is smaller than the CSA of the ascending aorta so that during the LV's diastolic or resting period, blood from the aorta can flow backwards and around the pump to supply blood to the LV's coronary arteries. The entrances for the two coronary arteries may be aside the aortic valve but effectively above the aortic valve. In one embodiment, a mechanical ground for the dual valve pump is provided by an expandable, open wire stent positioned between the moving valve pump and the inside wall of the ascending aorta. Coronary artery blood flow could then be provided through the open bare wire stent while the stent provides a mechanical ground for the moving valve pump.

[0059] Embodiments of a moving valve pump hereof may, for example, operate in two ways. For example, the pump can be operated to cycle continuously to minimize its cycle speed or it can be operated during systole only when the heart is contracting to provide pulsatile blood flow. Operating during systole only mimics natural blood flow from the LV, which many experts in the field believe is beneficial. The assisted flow output from a moving valve pump hereof will depend on its cycle rate combined with its cross-sectional area or CSA. For a given desired flow assist rate, the needed flow rate will be inversely related to the pump's effective CSA multiplied by its cycle rate. In a number

of embodiments, one full pump cycle results from one full rotation of the motor's rotor driving the linear actuators for the valve(s). An adjustment to the flow calculation may be made for that motion required to close the valves as well as for discounting a portion of the CSA used for the CSA overheads of, for example, a guidewire lumen, the blood sealing bellows sections defined by the valve positions, and the valve actuators in a number of embodiments as described further below. In a representative example, for a deployed 16 mm OD pump including two movable valves, the CSA overhead or CSA discount may, for example, be approximately 20%.

[0060] Blood flow in rotary VADs is generally continuous and dependent on both pump pressure differential and cycle rate. This will not be true for moving valve pumps hereof because such pumps are essentially positive displacement pumps. For example, assuming that a moving valve pump has an effective diameter of 1.6 cm, the CSA is the product of the 0.8 centimeter radius squared multiplied by π which is 2 cm^2 . Discounting for an overhead of 20% results in an effective CSA of 1.6 cm^2 . Further, assuming each valve's effective linear stroke is 2 cm after the valve has closed, then for two moving valves, the theoretical stroke volume per pump cycle becomes 2 valves multiplied 1.6 cm^2 per valve and multiplied by 2 cm per stroke, resulting in a stroke volume of approximately 6.4 cm^3 or ml per cycle. If the desired assisted output from the pump is half of the normal 70 ml heart stroke volume, then $35 \text{ ml}/6.4 \text{ ml per stroke}$ results in 5 to 6 cycles needed from the dual valve pump for each heartbeat. At a heart rate of 72 BPM, the pump cycle rate becomes 72 multiplied by 6 or 432 revolutions per minute. For motor efficiency purposes, a motor speed reducer may be beneficial. However, for simplicity and sound/vibration reduction purposes, elimination of a speed reducer is beneficial. Smaller CSAs will require proportionally higher motor speeds.

[0061] To reduce any thromboembolic risk to the brain arising from a moving valve pump placed in the ascending aorta, the moving valve pump may, for example, include thromboresistant surfaces combined with some degree of anticoagulant medication. There are a variety of such thromboresistant surfaces available as coatings such as heparin, 2-methacryloyloxyethyl phosphorylcholine (MPC) or hyaluronic acid coatings. Copolymers of polyurethane and silicon (for example, copolymers of methylene diphenyl diisocyanate (MDI) based polyurethanes and hydroxyl-terminated polydimethyl siloxane) available as ElastEonTM from, for example, RUA Biomaterials of Irvine, Ayrshire Scotland, have been shown to be highly thromboresistant and suitable for long-term implantable medical devices. Such polymers provide high mechanical performance while being non-thrombogenic, biostable, non-calcific, abrasion resistant and fatigue resistant. Non-thrombogenic or thromboresistant properties may, for example, be important in managing the risk of embolic clots coming from the moving valve pump.

[0062] In a number of embodiments, the moving valve(s) of the pumps hereof operate as check valve(s). In general, check valves allow flow in one direction but not, or minimally, in the opposite direction through the valve. The valves hereof are desirably passive in a number of embodiments. In that regard, such valves require no energy to open or close other than energy harvested from the fluid flowing through the valve itself. Within the valve(s), a closing element or elements is present that closes the valve in response to valve backflow. Many types of valve closing elements are known. Representative examples include, but are not limited to, flexible cusps such as the three cusps of a natural aortic valve, flaps as described further below in a representative embodiment hereof, hinged element or doors that function similarly to flaps but include a combination of a flexible hinge and a rigid surface, and flexible membranes (for example, a conically shaped but flexible membrane). All such closure elements operate to close or open the valve's CSA in response to the valve's flow direction. In a number of embodiments, moving valves hereof minimize backflow closing volumes to improve forward stroke efficiency, minimize any blood shear causing obstructions, and maximize the valve's cross-sectional area or CSA to operate near the minimum effective speed.

[0063] Unlike currently available permanent VADs, the remotely driven/actuated moving valve pumps hereof provide failsafe operation in the sense that, in the case of pump power loss, the heart will be able to pump blood through the pump hereof, although heart failure may return. Permanent VAD power loss is often fatal as a result of unrestricted backflow.

[0064] FIGS. 1A through 1C illustrate a representative embodiment of a dual valve pump 100 of a heart assist system 50 and 50a, respectively, located in ascending aorta 10 with the distal end or tip of pump 100 extending into left ventricle 20. For temporary use (that is, hours or days), catheter portion 200 of pump 100 of dual valve heart assist system 50 exits the body from the left axillary region in the illustrated embodiment of FIG. 1A to interface with external motor drive system 300. In a representative embodiment of an implantation method using a cutdown procedure, the physician visualizes the left axillary artery. Using fluoroscopic visualization and contrast media injections as needed, the blood flow pathway from the axillary artery to the subclavian artery and then the aortic arch may be visualized. A flexible guidewire 102 (see, FIGS. 2A and 2B) having a diameter of, for example, 18 to 25 mils may first be inserted through an arteriotomy and threaded through the arterial tree and aortic valve into left ventricle 20. Dual valve pump 100 may then be threaded over guidewire 102 using the guidewire lumen 104 (see, FIGS. 2A and 2B) within pump 100. In a number of embodiments, a compression sleeve 106 is used to maintain pump 100 in a compressed state during insertion. When pump 100 is properly placed in the heart, compression sleeve 106 is withdrawn from pump 100 a specific distance to allow pump 100 to expand its cross-sectional area

until bare metal stent 108 contacts the inner wall of ascending aorta 10. A moving valve pump hereof such as dual valve pump 100 may also be installed from the right side with a sub clavicular cutdown as illustrated in FIG. 1C using the analogous procedure except that the arterial tree pathway will include the innominate artery.

[0065] For a long-term or permanent installation of a moving valve pump hereof (such as dual valve pump 100 in heart assist system 50a) as illustrated in the embodiment of FIG. 1B or 1C, motor drive system 300a is miniaturized and encased in, for example, a titanium shell. An axillary incision is enlarged, and a subcutaneous pocket is created to house encased motor drive system 300a.

[0066] As set forth above, FIGS. 2A and 2B illustrate pumping mechanism or pump 100 of dual valve heart assist system 50 and 50a. FIG. 2A illustrates pump 100 in a compressed state in which the compressed diameter may, for example, be between 5 and 10 mm. Compression sleeve 106 holds valves 110, 110' in the compressed state. When sleeve 106 is withdrawn from the length of the pump 100 as illustrated in FIG. 2B, pump 100 expands/springs outwardly to, for example, a diameter of 15 to 20 mm. Valves 110, 110' may, for example, be formed of a polymeric material which is, for example, thermally formed in the uncompressed state such that valves 110, 110' are biased to the uncompressed state. In the illustrated embodiment, bare metal stent 108, which is positioned inside compression sleeve 106, will also expand/spring radially outwardly when compression sleeve 106 is withdrawn from pump 100. The deployed diameter of stent 108 will become the width of ascending aorta 10 and deployed stent 108 will become mechanical ground for system 50, 50a.

[0067] At the distal end of pump 100 in the illustrated embodiment is a cylindrical chamber or basket or cage 130 (see FIG. 1C) that is designed to reside in the LV. Chamber 130 may, for example, be constructed from a soft polymer such as low durometer polyurethane. In the illustrated embodiment, the most distal portion of chamber 130 is perforated to allow blood intake when pumping. A proximal portion of chamber 130 has a solid wall (that is, not perforated) that functions as a seal within the aortic valve. When deployed as shown in FIG. 2B, two pumping chambers (as formed or defined by valves 110, 110') reside in the space between two thin-walled, flexible elastic conduits or tubes 140 and 140a, both of which may be convoluted or accordion-like. A function of inner tube 140a is to create a sealed, blood-free space of volume 145 for the valve actuators 150, 150' and guidewire lumen wall 104. Seals 148 (see, for example, FIG. 2B) may be provided to prevent blood from entering into the space around actuators 150, 150'. Outer pumping chamber wall/flexible elastic tube 140 is sealed to a perimeter of each valve 110, 110' to assist in assuring a pushing rather than sliding action on the blood as described above. The cross-sectional area of the space between the inner and outer elastic tubes 140a and 140, respectively, is the effective pumping cross sectional area.

Multiplying the effective pumping area by the stroke length of valves 110, 110' yields the stroke volume as described above. Valves 110 and 110' may be alternated during pumping action with one valve retracting while the other is pumping. Valve actuators 150 and 150' in FIG. 2A are shown schematically as tubes, while valve actuators 150 and 150' in FIG. 2B are shown schematically as wires. Blood exits pump 100 via outlet ports or openings 160 formed in a proximal portion of flexible tube 140 as illustrated in FIG. 2B and 3A. The shaded ovals 148 in FIGS. 2A and 2B function as connection nodes and seals. Guidewire lumen wall 104 is shown in FIG. 2A but, to avoid confusion, is not shown in FIG. 2B.

[0068] As described above, each of inner and outer walls, conduits, tubes or housings 140 and 140a, respectively can include extra material or slack in an axial direction such that the reciprocal motion of the movable valves does not result in significant (or any) stretching/elongation of the material forming the wall of the conduits. In a number of embodiments, such conduits may be corrugated or have accordion-like folds therein to provide extra material in an axial direction (between attachment points) such that very little energy is required to move valves 110 and 110'.

[0069] FIG 3A illustrates an embodiment of a system and method that may be used to activate valve motion. In the embodiment of FIG. 3A, the proximal ends of the valve actuators 150 and 150' are placed in operative connection with a crankshaft 400 via rotating bearings 404 positioned apart or spaced 180° around crankshaft 400. Crankshaft 400 may, for example, include a centered axel 410 that may operatively connect to (for example, snap into an opening in) a rotor 310 of a DC torque motor 300 as illustrated in FIG. 3B. In another embodiment, rotating axle operatively connected to motor 300 may be connected with two equal and oppositely positioned drive arms. Each drive arm may have an end including a rotating bearing that connects independently to one of linear actuators 150, 150' to control the oscillating motion of each of two moving valves 110, 110'. Bearings (for example, miniature ball bearings) may also be used in connection with linear actuators 150, 150' to, for example, reduce friction and associated frictional heating. When valve 110' is moved in a proximal direction (away from the heart) to pump blood, valve 110 will be moved in a distal direction (toward the heart). In this arrangement, the flow output from dual valve pump 100 will be a direct function of the cycle rate of motor 300.

[0070] FIG. 4A is a sideview of an embodiment of a valve structure for valve 110 (which may be identical to valve 100') showing five of eight struts 112 that each support valve flaps 114 as shown in FIG. 4B. The valve structure may be micromachined or molded from a hard but bendable material such as high durometer polyurethane. Struts 112 may be compressed to the diameter of actuating rod 116, 116' via which they connect to actuators 150, 150 in the embodiment illustrated for

valve 110. In the illustrated embodiment, valve flaps 114 are generally triangularly shaped when in a closed position. Each flap 114 may, for example, be solvent bonded to the surface of strut 114 to which flap 114 is connected. This configuration results in reduced/minimum flow slippage when an open state of valve 100 changes to a closed state. Minimizing flow slippage maximizes the forward flow stroke efficiency of valves 100, 100. In the embodiment of FIG. 4B., valve flaps 114 are oversized for the aperture space between struts 112 and functionally close valve 100 (by closing ports between struts 112) when they contact and overlap on the surfaces of adjacent struts 112. Flaps 114 may, for example, be formed to be in a curved open state as illustrated in FIGS. 4A and 4B and close (that is, by flexing to come into contact against an adjacent strut 112) under the force exerted by blood upon flaps 114 when valve 110 is moved in a proximal direction to move blood.

[0071] FIG. 5 illustrates schematically the spatial relationship of dual valve pump 100, LV 20, aortic valve 12 and ascending aorta 10 in a representative position of an assist system of the device hereof. Chamber/basket 130 extends into LV 20 and seals within aortic valve 12. Bare wire stent 108 expands against the wall of ascending aorta 20. The pumping portion of dual valve pump 100 (wherein, valves 110, 110' are represented by a dual or double arrow) resides in ascending aorta 20. As described above, drive catheter 200 for pump 100 has been introduced from the patient's left axilla through left subclavian artery 30.

[0072] As illustrated schematically in FIG. 3A, pump system 100 hereof may be in communicative/electrical connection with electronic circuitry 500 for power and control thereof. Electronic circuitry 500 may be positioned external to the body, internal to the body, or be distributed in position depending upon the manner in which pump system 100 is deployed. As appreciated by those skilled in the computer and control arts, electronic circuitry 500 may, for example, include processor system 510 (which may, for example, include one or more processors and/or microprocessors) in operative connection with a memory system 520. Memory system 520 may, for example, include software including one or more algorithms stored therein and executable by processor system 510 to operate as a control system or controller to control operation of pump system 100 (for example, of drive system 300, 300a of pump system 100). Electronic circuitry 500 may further include a sensor system 530 in communicative connection with processor system 510 to measure data such as physiological data (for example, ECG data), data on the operation of pump system 100, and/or other data. Such data may, for example, be used in control of pump system 100 via, for example, feedback control as known in the control arts. As known in the computer arts, an input/output system 540 may be in operative connection with processor system 510 and memory system 510, for example, to acquire data (for example, signals from sensor system 530 and other

sources) and/or to enable output of data/information. A communication system 550 may be in communicative connection with processor system 510 for wired and/or wireless communication between various system components as well as to one or more communication devices positioned remote from pump system 100 and electronic circuitry 500. A user interface system 560 as known in the computer arts may be in operative connection with processor system 510. Further a power system 570 (for example, including a battery pack system, a transcutaneous energy transmission system (TETS) as described above, etc.) is in electrical connection with processor system 510 and other powered components of electronic circuitry 500 and pump system 100.

[0073] The foregoing description and accompanying drawings set forth a number of representative embodiments at the present time. Various modifications, additions and alternative designs will, of course, become apparent to those skilled in the art in light of the foregoing teachings without departing from the scope hereof, which is indicated by the following claims rather than by the foregoing description. All changes and variations that fall within the meaning and range of equivalency of the claims are to be embraced within their scope.

WHAT IS CLAIMED IS:

1. A heart assist system, comprising:

a catheter,

a pump connected to a distal end of the catheter and comprising:

an outer flexible conduit,

a first movable check valve attached to the outer flexible conduit about the perimeter of the first movable check valve, and

a second movable check valve, which is spaced from and in series with the first movable check valve, attached to the outer flexible conduit about the perimeter of the second movable check valve,

a drive system connected to the catheter and positioned remote from the first movable valve and the second movable check valve,

a first actuator operatively connected to the drive system and to the first movable check valve via the catheter to transfer linear motion from the drive system to the first movable check valve, and

a second actuator operatively connected to the drive system and to the second movable check valve via the catheter to transfer linear motion from the drive system to the second movable check valve,

wherein the pump is collapsible to a first, smaller-radius state in which the pump is implantable within a body of a patient via the catheter and expandable to a second, larger-radius state after implanting the pump via the catheter to an operational position within the body of the patient.

2. The heart assist system of claim 1 further comprising an inner flexible conduit having a diameter less than the outer flexible conduit, the first movable check valve being attached to the inner flexible conduit at a position radially inward from the perimeter of the first movable check valve, the second movable check valve being attached to the inner flexible conduit at a position radially inward from the perimeter of the second movable check valve.

3. The heart assist system of claim 2 wherein the first actuator and the second actuator pass through the catheter and into a volume within the inner flexible conduit.

4. The heart assist system of claim 3 further comprising a guide wire conduit passing through the catheter and through the volume within the inner flexible conduit.

5. The heart assist system of claim 3 wherein at least one of the outer flexible conduit and the inner flexible conduit includes extra material in an axial direction along the length thereof.

6. The heart assist system of claim 5 wherein the at least one of the outer flexible conduit and the inner flexible conduit includes corrugation or folds therein.

7. The heart assist system of claim 6 wherein the first actuator and the second actuator independently comprise a wire or a tube.

8. The heart assist system of claim 5 further comprising an intake chamber at a distal end of the pump, the intake chamber comprising one or more passages at a distal end thereof through which blood may pass to enter the pump.

9. The heart assist system of claim 8 wherein the intake chamber further comprises a solid surface at a proximal end thereof configured to form a seal with the aortic valve.

10. The heart assist system of claim 5 wherein the pump further comprises a stent radially outward of the outer flexible conduit, which, when the pump is in the second, larger-radius state, contacts the aortic wall and provides a mechanical ground for the pump.

11. The heart assist system of claim 8 wherein the pump further comprises a stent radially outward of the outer flexible conduit, which, when the pump is in the second, larger-radius state, contacts the aortic wall and provides a mechanical ground for the pump.

12. The heart assist system of any one of claims 1 through 11 wherein the drive system comprises a motor.

13. The heart assist system of claim 12 wherein the motor drives the first actuator and the second actuator such that the first movable check valve and the second movable check valve are driven sinusoidally.

14. The heart assist system of claim 13 wherein the motor drives the first actuator and the second actuator such that the first movable check valve and the second movable check valve are driven approximately 180 degrees out of phase.

15. The heart assist system of claim 14 wherein the drive system comprises a crank shaft in operative connection with a rotor of the motor, each of the first actuator and the second actuator being operatively connected to the crank shaft.

16. The heart assist system of claim 14 wherein the drive system comprises two drive arms positioned approximately 180 degrees apart around a drive axle in operative connection with a rotor of the motor, each of the first actuator and the second actuator being operatively connected to a different one of the drive arms.

17. The heart assist system of claim 14 wherein the motor is configured to be positioned outside of the body of the patient and the catheter is configured to pass percutaneously into the body of the patient.

18. The heart assist system of claim 14 wherein the motor is configured to be positioned within the body of the patient and outside the chest cavity of the patient and the catheter is configured to be implanted within the body of the patient.

19. The heart assist system of any one of claims 5 through 11 wherein the first movable check valve comprises at least one element which closes a port formed in the first movable check valve upon motion of the first movable check valve to move blood, and the second movable check valve comprises at least one element which closes a port formed in the second movable check valve upon motion of the second movable check valve to move blood.

20. The heart assist system of claim 1 wherein the first movable check valve is attached to the outer flexible conduit to form a sealed attachment therewith and the second movable check valve is attached to the outer flexible conduit to form a sealed attachment therewith.

21. The heart assist system of claim 2 wherein the first movable check valve is attached to the outer flexible conduit to form a sealed attachment therewith and is attached to the inner flexible conduit to form a sealed attachment therewith and the second movable check valve is attached to the outer flexible conduit to form a sealed attachment therewith and is attached to the inner flexible conduit to form a sealed attachment therewith.

22. A method of providing heart assist, comprising:

placing a heart assist system in fluid connection with the circulatory system of a patient at an operational position within the body of the patient via a catheter, the heart assist system, including:

a pump connected to a distal end of the catheter and comprising:

an outer flexible conduit,

a first movable check valve attached to the outer flexible conduit about the perimeter of the first movable check valve, and

a second movable check valve, which is spaced from and in series with the first movable check valve, attached to the outer flexible conduit about the perimeter of the second movable check valve,

a drive system connected to the catheter and positioned remote from the first movable valve and the second movable check valve,

a first actuator operatively connected to the drive system and to the first movable check valve via the catheter to transfer linear motion from the drive system to the first movable check valve, and

a second actuator operatively connected to the drive system and to the second movable check valve via the catheter to transfer linear motion from the drive system to the second movable check valve,

wherein the pump is collapsible,

advancing the pump to the operational position while the pump is collapsed to a first, smaller-radius state; and

expanding the pump to a second, larger-radius state after upon reaching the operational position.

23. The method of claim 22 wherein the operational position of the pump is within the ascending aorta.

24. The method of claim 23 wherein a distal end of the pump extends into the left ventricle.

25. A heart assist pump, which is connectable to a catheter, comprising:

an outer flexible conduit,

a first movable check valve attached to the outer flexible conduit about the perimeter of the first movable check valve, and

a second movable check valve, which is spaced from and in series with the first movable check valve, attached to the outer flexible conduit about the perimeter of the second movable check valve,

a first actuator operatively connected to the first movable check valve and configured to be connected to a drive system remote from the heart assist pump via the catheter to transfer linear motion from the drive system to the first movable check valve, and

a second actuator operatively connected to the second movable check valve and configured to be connected to the drive system via the catheter to transfer linear motion from the drive system to the second movable check valve,

wherein the heart assist pump is collapsible to a first, smaller-radius state in which the heart assist pump is implantable within a body of a patient via the catheter and expandable to a second, larger-radius state after implanting via the catheter to an operational position within the body of the patient.

26. A method of providing heart assist, comprising: placing a heart assist pump in fluid connection with the circulatory system of a patient at an operational position within the body of the patient via a catheter, the heart assist pump including:

an outer flexible conduit,

a first movable check valve attached to the outer flexible conduit about the perimeter of the first movable check valve, and

a second movable check valve, spaced from and in series with the first movable check valve, attached to the outer flexible conduit about the perimeter of the second movable check valve,

a first actuator operatively connected to the first movable check valve and configured to be connected to a drive system remote from the heart assist pump via the catheter to transfer linear motion from the drive system to the first movable check valve, and

a second actuator operatively connected to the second movable check valve and configured to be connected to the drive system via the catheter to transfer linear motion from the drive system to the second movable check valve,

wherein the heart assist pump is collapsible to a first, smaller-radius state in which the heart assist pump is implantable within the body of the patient via the catheter and expandable to a second, larger-radius state after implanting via the catheter to an operational position within the body of the patient,

advancing the heart assist pump to the operational position while the heart assist pump is collapsed to a first, smaller-radius state; and

expanding the heart assist pump to a second, larger-radius state after upon reaching the operational position.

27. The method of claim 26 wherein the operational position of the pump is within the ascending aorta.

28. The method of claim 27 wherein a distal end of the pump extends into the left ventricle.

29. A heart assist system, comprising:

a catheter,

a pump connected to a distal end of the catheter and comprising:

an outer flexible conduit, and

a first movable check valve attached to the outer flexible conduit about the perimeter of the first movable check valve,

a drive system connected to the catheter and positioned remote from the first movable valve, and

a first actuator operatively connected to the drive system and to the first movable check valve via the catheter to transfer linear motion from the drive system to the first movable check valve,

wherein the pump is collapsible to a first, smaller-radius state in which the pump is implantable within a body of a patient via the catheter and expandable to a second, larger-radius state after implanting via the catheter to an operational position within the body of the patient.

30. The heart assist system of claim 29 further comprising an inner flexible conduit having a diameter less than the outer flexible conduit, the first movable check valve being attached to the inner flexible conduit at a position radially inward from the perimeter of the first movable check valve.

31. The heart assist system of claim 29 wherein the first movable check valve is attached to the outer flexible conduit to form a sealed attachment therewith.

32. The heart assist system of claim 30 wherein the first movable check valve is attached to the outer flexible conduit to form a sealed attachment therewith and is attached to the inner flexible conduit to form a sealed attachment therewith.

33. A heart assist pump, which is connectable to a distal end of a catheter, comprising:
an outer flexible conduit,
a first movable check valve attached to the outer flexible conduit about the perimeter of the first movable check valve, and

a first actuator operatively connected to the first movable check valve and configured to be connected to a drive system remote from the heart assist pump via the catheter to transfer linear motion from the drive system to the first movable check valve,

wherein the heart assist pump is collapsible to a first, smaller-radius state in which the heart assist pump is implantable within a body of a patient via the catheter and expandable to a second, larger-radius state after implanting via the catheter to an operational position within the body of the patient.

34. The heart assist pump of claim 33 further comprising an inner flexible conduit having a diameter less than the outer flexible conduit, the first movable check valve being attached to the inner flexible conduit at a position radially inward from the perimeter of the first movable check valve.

35. The heart assist pump of claim 33 wherein the first movable check valve is attached to the outer flexible conduit to form a sealed attachment therewith.

36. The heart assist pump of claim 34 wherein the first movable check valve is attached to the outer flexible conduit to form a sealed attachment therewith and is attached to the inner flexible conduit to form a sealed attachment therewith.

FIG. 1A

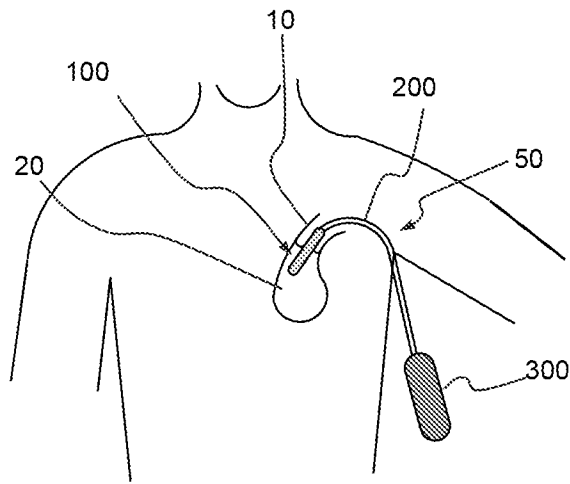


FIG. 1B

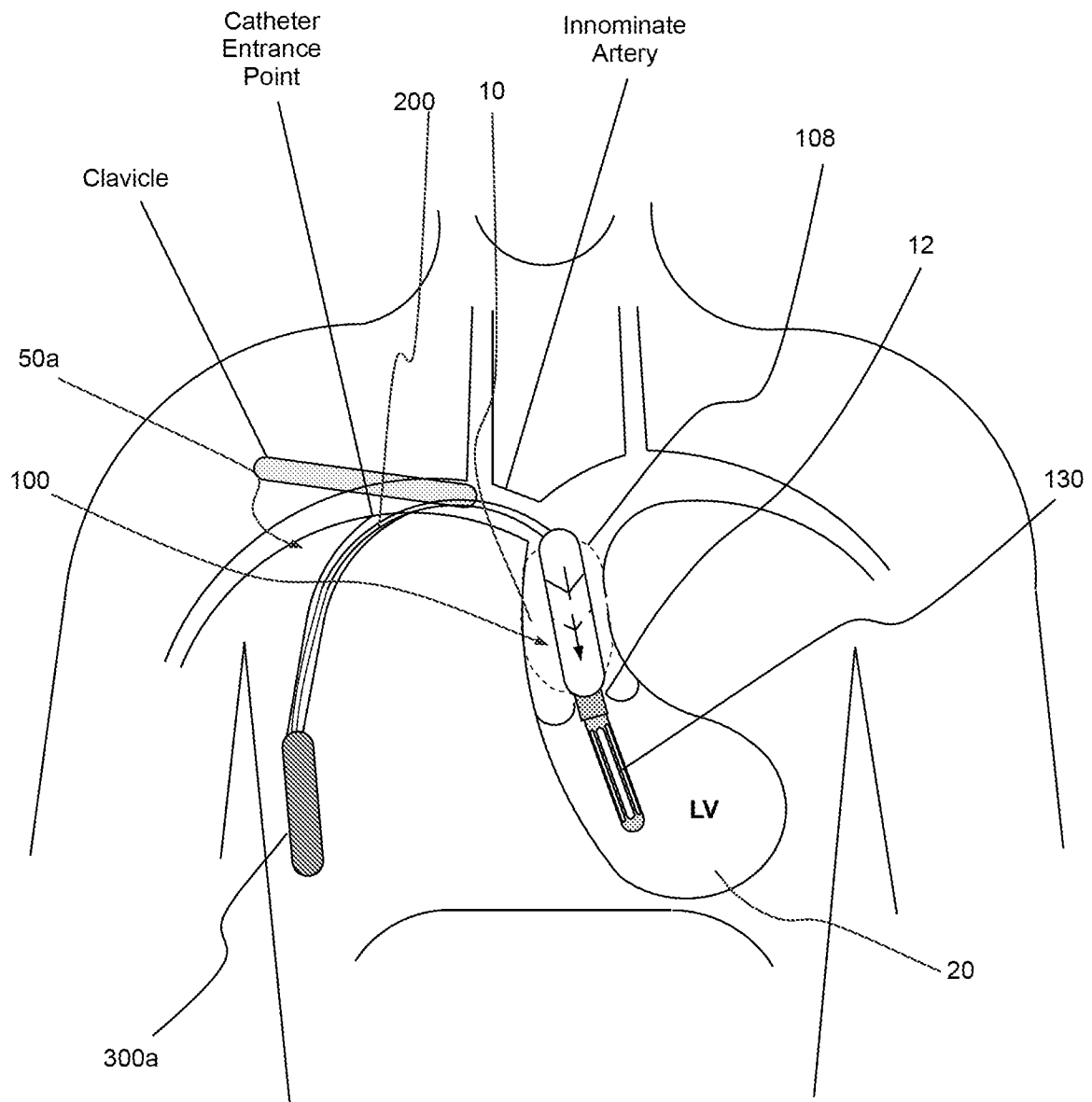
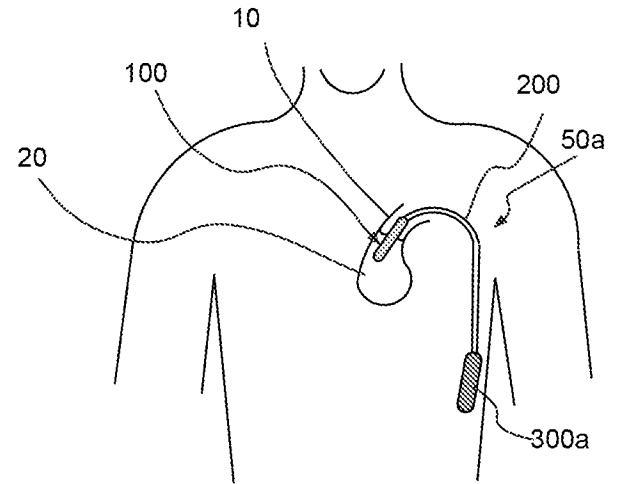


FIG. 1C

FIG. 2A

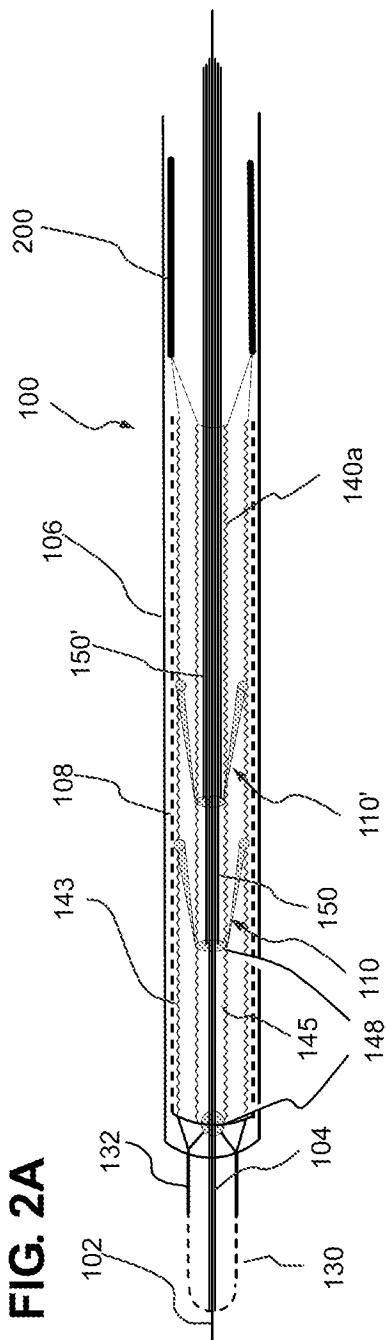


FIG. 2B

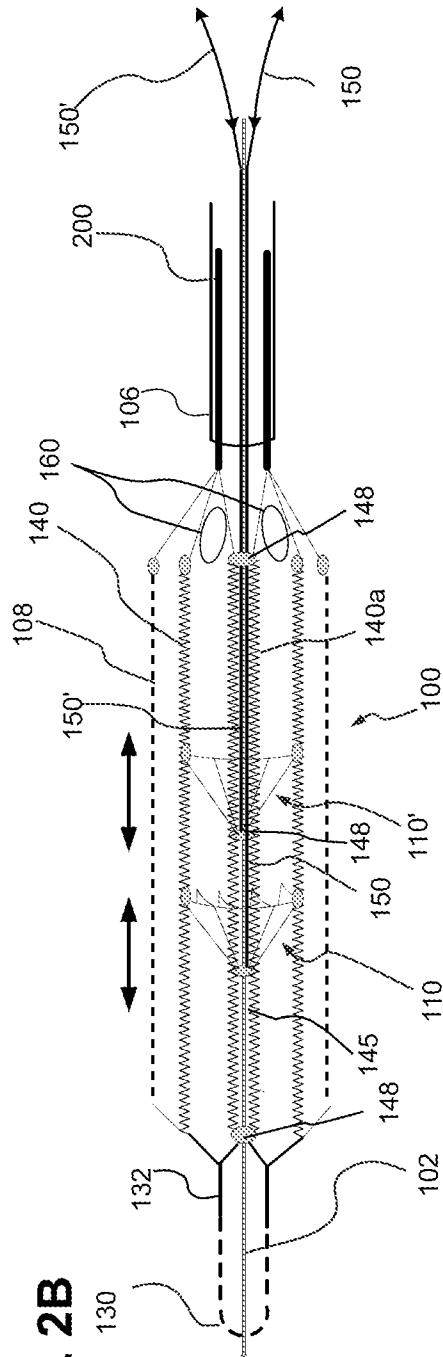
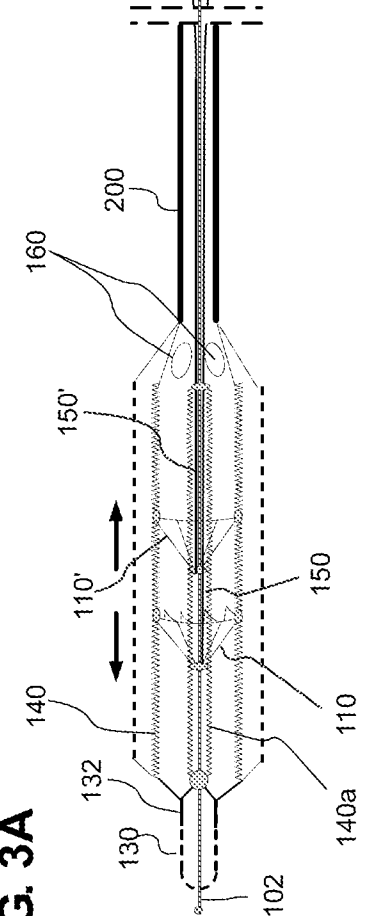


FIG. 3A



FILE 3B

