Title: PERCUTANEOUS-INSERTED VENTRICULAR ASSIST DEVICES AND RELATED METHODS

Abstract: According to one embodiment, a ventricular assist device is provided including an inflow cannula and a pump. The inflow cannula is adapted for receiving blood from a ventricle, an atrium, or a pulmonary vein. The pump is communicating with the inflow cannula for pumping blood through the inflow cannula. At least a portion of the ventricular assist device is adapted for extending through an inter-atrial septum wherein blood can be advanced through the inter-atrial septum.
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.
Description
PERCUTANEOUS-INSERTED VENTRICULAR ASSIST DEVICES AND RELATED METHODS

Cross-Reference to Related Application
This nonprovisional application claims the benefit of U.S. Provisional Application No. 60/512,177, filed October 17, 2003, the contents of which are incorporated herein in its entirety.

Technical Field
The subject matter disclosed herein relates to devices and methods for assisting heart function. More particularly, the subject matter disclosed herein relates to ventricular assist devices and related methods.

Background Art
Cardiac transplantation is the definitive therapy for end-stage heart failure. However, cardiac transplantation is limited by the availability of organs. A mechanical ventricular assist device (VAD) can be a life-saving form of therapy to bridge end-stage heart failure patients until a proper heart transplant is found. Many patients have shown satisfactory recovery of their ventricular function after chronic VAD unloading. VAD therapy can prolong life and provide a better quality of life. VAD patients also typically fare better during cardiac transplantation than those who do not receive VAD assistance. Some VADs are also a final form of therapy, or destination therapy, for those patients with end-stage heart failure.

VADs are typically placed with surgical techniques involving sternotomy, thoracotomy, and cardiopulmonary bypass. This type of surgery is associated with significant mortality and morbidity. Large quantities of blood products are needed because of the significant blood loss from the surgery itself and the coagulopathy that accompanies prolonged cardiopulmonary bypass. The cost of this form of therapy is also very elevated. Prolonged intensive care unit stay,
the surgery itself, and the associated morbidity all contribute to these elevated expenses.

It is therefore desirable to have an improved cardiac assist device that can be installed without need for sternotomy, thoracotomy, or cardiopulmonary bypass. Such improved cardiac assist devices can reduce blood loss, significantly reduce the time spent in intensive care, and may eliminate the need for general anesthesia. In appropriate candidates, such devices will permit significant reduction in the mortality, morbidity, and expenses of VAD therapy.

Summary

According to one embodiment, a ventricular assist device and method is disclosed including an inflow cannula and a pump. The inflow cannula can be adapted for receiving blood from a ventricle, an atrium, or a pulmonary vein. The pump can communicate with the inflow cannula for aspirating blood from the inflow cannula. At least a portion of the ventricular assist device can be adapted for extending through an inter-atrial septum wherein blood can be advanced through the inter-atrial septum.

According to a second embodiment, a ventricular assist device and method is disclosed including an inflow cannula, an outflow cannula, a pump, and a fixating device. The inflow cannula can be adapted for receiving blood from a ventricle, atrium, or a pulmonary vein. The outflow cannula can communicate with the inflow cannula and adapted to deliver blood to an artery. The pump can communicate with the inflow cannula and outflow cannula and adapted to advance blood received by the inflow cannula to the outflow cannula for delivery to the artery. The inflow cannula, the outflow cannula, or the pump can be adapted to extend through an inter-atrial septum, an atrium, a ventricle, or pulmonary vein. The fixating device can maintain an apposition of the inflow cannula, the outflow cannula, or the pump with respect to the inter-atrial septum.
According to yet another embodiment, a method of installing a ventricular assist device is disclosed. The method can include providing a ventricular assisting device. The inflow cannula can be adapted for receiving blood from a ventricle, an atrium, or a pulmonary vein. A pump can communicate with the inflow cannula for pumping blood through the inflow cannula. At least a portion of the ventricular assist device can be adapted for extending through an inter-atrial septum wherein blood can be advanced through the inter-atrial septum. The method can also include inserting the inflow cannula into the ventricle, atrium, or pulomonary vein by passing the inflow cannula through a superior vena cava, a right atrium, the inter-atrial septum, and a left atrium.

According to another embodiment, a new method for accessing the left atrium from the right atrium includes utilizing an inter-atrial puncture apparatus described herein that enables puncture from the upper body. The ventricular assist devices described herein can be placed utilizing the inter-atrial puncture apparatus.

According to yet another embodiment, implantable blood pumps are described herein including a motor and blood propelling mechanism connected via a driveline. The blood pumps can be used with a cannula for forming a percutaneous ventricular assist device.

It is therefore an object to provide novel ventricular assist devices and methods.

Brief Description of the Drawings

Exemplary embodiments of the subject matter will now be explained with reference to the accompanying drawings, of which:

Figure 1 is a front, partial view of a patient illustrating a left ventricular assist device (LVAD) coupled to the patient’s heart;

Figure 2 is a perspective view of an inflow cannula positioned in the heart (shown in vertical cross-sectional) shown in Figure 1;
Figures 3A, 3B, and 3C different views of retractable arms attached to the tubular portion of the inflow cannula shown in Figure 2;

Figures 4A and 4B are perspective end views of an inflow cannula including compliant balloons;

Figure 5 is a perspective view of another inflow cannula including a bifurcated end exiting from a right jugular vein and a right subclavian vein;

Figure 6A, 6B, and 6C are perspective views of another embodiment of an inflow cannula having bifurcated tubes showing a sequence of three representative steps for installing inflow cannula;

Figure 7 is a side elevational view of a female screw cap including a one-way valve for attaching to a male screw cap of inflow cannula;

Figure 8 is a side view of a dilator for fitting inside the inflow cannula shown in Figure 2 during installation of the inflow cannula;

Figure 9 is a partial cross-sectional view of the pump system shown in Figure 1;

Figure 10 is a perspective view of the outflow cannula shown in Figure 1;

Figure 11 is a side view of the outflow cannula shown in Figure 1 positioned in a subclavian artery near a right vertebral artery, right carotid artery, and right innominate artery of the patient shown in Figure 1;

Figure 12 is a side view of a dilator for fitting inside the outflow cannula shown in Figure 10 during installation;

Figure 13 is a perspective bottom view of female screw cap including a one-way valve for attaching to a male screw cap of an outflow cannula;

Figure 14 is a flow chart showing a method for installing the LVAD shown in Figure 1 in a patient;

Figures 15A, 15B, and 15C are perspective views of a heart showing a sequence of three representative steps for approaching left atrium by using a snaring technique;

Figure 16 is a perspective view of an exchange wire positioned in a heart (shown in vertical cross-section);
Figures 17A, 17B, and 17C are vertical cross-sectional views illustrating a sequence of three representative steps for dilating or enlarging a puncture site in an inter-atrial septum with a mitral valvulotome;

Figure 18 is a vertical cross-sectional view illustrating a step for dilating or enlarging a puncture site in an inter-atrial septum with a balloon;

Figures 19A and 19B are side elevation views of a first catheter and a second catheter, respectively, for accessing a left atrium from a right atrium;

Figure 19C is a vertical cross-sectional view of a catheter having a controllable flexible tip;

Figures 19D and 19E are vertical cross-sectional views of different catheters having two or more component catheters;

Figure 19F is a vertical cross-sectional view of a first catheter and a second catheter for deflecting a tip of catheter upwards;

Figure 19G is a side view of a flexible needle apparatus for performing inter-atrial septal puncture;

Figure 20 is a perspective view of dual catheters (shown in Figure 19C) positioned in heart (shown in vertical cross-section) for puncture of inter-atrial septum;

Figure 21A is a phantom view of a heart (shown in cross-section) coupled to another exemplary LVAD;

Figure 21B, 21C, 21D, and 21E are cross-sectional views of the exemplary LVAD shown in Figure 21A illustrating a sequence of four representative steps for installing the LVAD;

Figure 22 is another perspective view of the LVAD shown in Figure 21A;

Figure 23 is a flow chart showing a method for installing the LVAD shown in Figure 21A;

Figure 24A is a vertical cross-sectional side view showing a step of deploying snares into an inferior vena cava and advancing a trans-septal needle apparatus through deployed snares;
Figures 24B-24D are vertical cross-sectional side view showing steps during the placement of a LVAD cannula over a wire into a final intracardiac position;

Figure 25 is a vertical cross-sectional side view showing a step where a safety wire positioned from a right femoral vein through inter-atrial septum and snares tightened on a wire;

Figure 26 is a vertical cross-sectional side view showing a step of pulling snare toward right jugular vein;

Figure 27 is a vertical cross-sectional side view showing a step of extending a wire from a left atrium to a right jugular vein;

Figure 28 is a vertical cross-sectional side view showing a step of inflating an angioplasty balloon to dilate a puncture site of inter-atrial septum;

Figure 29 is a phantom view of a heart (shown in cross-section) coupled to another exemplary LVAD;

Figure 30 is a cross-sectional view of another exemplary pump system and cannula; and

Figure 31 is a cross-sectional view of another exemplary propeller system and cannula.

**Detailed Description**

Ventricular assist devices are described herein which facilitate improved methods for installing the ventricular assist devices into patients. Furthermore, improved installation devices and methods are described herein for installing ventricular assist devices. These methods and devices are described with regard to the accompanying drawings. It should be appreciated that the drawings do not constitute limitations on the scope of the disclosed devices and methods.

Following long-standing patent law convention, the terms “a”, “an”, and “the” can mean “one or more” when used in this application, including the claims.
As used herein, the term “cannula” generally means any bendable or rigid hollow tube for permitting passage of blood through the cannula, as well as the ordinary meaning as understood by those of skill in the art.

Ventricular assist devices are capable of bridging end-stage heart failure patients to transplantation and can generally be used for augmenting the operation of a weakened heart. The ventricular assist devices described herein can be installed without need for sternotomy, thoracotomy, or cardiopulmonary bypass. Additionally, methods and devices are described herein for installing these ventricular assist devices without need for sternotomy, thoracotomy, or cardiopulmonary bypass.

**First Exemplary Ventricular Assist Device**

Figure 1 illustrates a front, partial view of a patient, generally designated 100, having a heart 102 (shown in vertical cross-section) coupled to a left ventricular assist device (LVAD) 104. LVAD 104 can comprise an inflow cannula 106, a pump system 108, and an outflow cannula 110. Inflow cannula 106 can fluidly connect pump system 108 to a left ventricle 112 of heart 102 such that pump system 108 can pump blood directly from left ventricle 112, through inflow cannula 106, and to pump system 108. Outflow cannula 110 can fluidly connect pump system 108 and a right subclavian artery 114 such that blood pumped from left ventricle 112 can be delivered to the subclavian artery. Inflow cannula 106 can be inserted to extend through a right internal jugular vein 116, a right innominate vein (designated 1501 in Figure 15A), a superior vena cava 118, a right atrium 120, an inter-atrial septum 122, and left atrium 124 of patient 100 for placement as shown in Figure 1. Inflow cannula 106 can also extend into left atrium 124, pulmonic veins, or left ventricle 112. It can be appreciated by those of skill in the art that inflow cannula 106, pump system 108, and outflow cannula 110 can be manufactured together as one or more separate pieces.

Figure 2 illustrates a perspective view of inflow cannula 106 positioned in heart 102 (shown in vertical cross-section). Inflow cannula 106 can comprise a terminal end portion 200 extending from left atrium 124, across a mitral valve
and terminating at left ventricle 112. Alternatively, terminal end portion 200 can cross inter-atrial septum 122 and terminate at left atrium 124. Terminal end portion 200 can include a large opening 204 at a tip thereof and several fenestrations, or openings, 206 along its side for reducing filling resistance. Blood B can flow from left ventricle 112 and left atrium 124 into openings 204 and 206 as indicated by the direction arrows. In this embodiment, opening 204 is positioned in left ventricle 112 and fenestrations 206 are positioned in left ventricle 112 and left atrium 124 for allowing active blood aspiration from left ventricle 112 and left atrium 124. Alternatively, openings 204 and 206 can be positioned entirely in left ventricle 112 for active blood aspiration from primarily left ventricle 112. Terminal end portion 200 can induce mitral regurgitation that exposes this part of inflow cannula 106 to the contractile activity of left ventricle 112 for facilitating the fill of the inflow cannula and allowing for direct unloading of the left ventricle.

Continuing with Figure 2, inflow cannula 106 can also include a tubular portion 208 that extends from right atrium 120 to left atrium 124. As described in further detail below, inter-atrial septum 122 of heart 102 can be pierced prior to placement of tubular portion 208 across inter-atrial septum 122. Tubular portion 208 can comprise a rigid polymer, metal, or other suitable material known to those of skill in the art.

Continuing with Figure 2, tubular portion 208 can include several retractable arms, such as arms 210 and 212 that form a septum fixing device with inflow cannula 106 for fixing inflow cannula 106 to inter-atrial septum 122. Retractable arms 210 and 212 can be attached to inflow cannula 106 for fixing tubular portion 208 to inter-atrial septum 122. Arms 210 can be positioned on left atrial side 211 of inter-atrial septum 122. Arms 212 can be positioned on right atrial side 213 of inter-atrial septum 122. Arms 212 can be positioned a predetermined distance along a length of inflow cannula 106 from arms 210 such that a space can be provided for inter-atrial septum 122 between arms 210 and 212. Arms 210 and 212 can include a web, shown in Figures 3A, 3B,
and 3C for clarity and described in more detail below, attached to arms 210 and 212 for connecting them together. Arms 210 and 212 can comprise any suitable material, including but not limited to a metal material. Arms 210 and 212 can also comprise a polymer and/or metal alloy material having the ability to retain shape memory (e.g., NITINOL® available from Shape Memory Applications, Inc. of San Jose, California, U.S.A.).

Referring to Figures 3A, 3B, and 3C, different views of retractable arms 210 attached to tubular portion 208 of inflow cannula 106 (Figure 2) are illustrated. Figure 3A illustrates an end elevational view of tubular portion 208 having arms 210 extended in a deployed position at least substantially perpendicular to tubular portion 208. As stated above, arms 210 can include a web 300 that connects arms 210. Web 300 can comprise a DACRON® polyester material (available from E.I. du Pont de Nemours and Company of Wilmington, Delaware, U.S.A.), any suitable biocompatible fabric material such as HEMASHIELD® (available from Meadox Medicals, Inc. of Oakland, New Jersey, U.S.A.) or another suitable material known to those of skill in the art. When arms 210 are deployed, web 300 can provide a barrier and can reduce or eliminate blood shunting across the iatrogenically-created atrial septal defect. The fabric material can minimize any blood shunting from one atrium to the other while inflow cannula 112 is in place. Arms 210 can comprise a pull wire 302 (shown in Figure 3B) or another suitable release mechanism and springs 304. Springs 304 can bias arms 210 into a position as shown in Figure 3A. Springs 302 can maintain arms 210 in a position as shown in Figure 3B until springs 302 are activated and arms 210 are released to move into a position as shown in Figure 3A.

Figure 3B illustrates a perspective end view of tubular portion 208 and arms 210 in a position for insertion. Arms 210 can be positioned laterally against tubular portion 208 in the insertion position for facilitating insertion of inflow cannula 106 into heart 102 (shown in Figure 2). Any loose portions of web 300 can be tucked under arms 210 in the insertion position. Arms 210 can be held against tubular portion 208 with release mechanism 302. Release
mechanism 302 can be attached to arms 210 and/or inflow cannula 106 immediately distal to arms 210 for disconnecting when release mechanism 302 is activated. Release mechanism 302 can extend along the inside of inflow cannula 106 and to a position for pull by a cardiac specialist. Arms 210 can be connected to tubular portion 208 with springs 304. Springs 304 can be biased to position arms 210 in an undeployed state (i.e., an insertion position shown in Figure 3B) when restrained by release mechanism 302. When release mechanism 302 is activated, arms 210 can be released by release mechanism 302 such that springs 304 move arms 210 into a deployed position shown in Figure 3A. Figure 3C illustrates a perspective end view of arms 210 in a position between the deployed position and the insertion position.

Once the portion of inflow cannula 106 having arms 210 is positioned in a left atrium, such as left atrium 124 (shown in Figure 1), release mechanism 302 can be activated. When activated, release mechanism 302 can break at its attachment with inflow cannula 106 for releasing arms 210 to move to the deployed position shown in Figure 3A. Next, inflow cannula 106 can be retracted until resistance is met. This resistance indicates that arms 210 are opposed to inter-atrial septum 122 (shown in Figure 1).

Arms 212 (shown in Figure 2) can also be connected to a second release mechanism (not shown) for holding arms 212 in place until the second release mechanism is activated. The second release mechanism can provide separately controllable deployment of arms 212. After arms 210 are deployed and arms 212 are positioned in right atrium 120, the second release mechanism can be activated to release arms 212 for holding inflow cannula 106 against inter-atrial septum 122.

In an alternative embodiment, an inflow cannula, such as inflow cannula 106 shown in Figure 2, can include balloons for fixing the inflow cannula to an inter-atrial septum, such as inter-atrial septum 122 shown in Figure 2. Figures 4A and 4B illustrate a perspective end view of an inflow cannula 400 including compliant balloons 402 and 404 in a deflated state (Figure 4A) and an inflated state (Figure 4B), respectively, for fixing inflow cannula 106 to inter-atrial...
septum 122 (shown in Figure 4B). In the inflated state shown in Figure 4B, balloons 402 and 404 can be positioned in right atrium 120 and left atrium 124, respectively, such that the balloons press inter-atrial septum 122 between the balloons. Balloons 402 and 404 can be inflated with saline or any other suitable biocompatible material (including iodine-based contrast material or other suitable contrast material that renders the balloons visible under X-ray imaging) during placement and deflated later in the event that inflow cannula 106 is removed or replaced. Hollow plastic tubes 406 and 408 can be attached to balloons 402 and 404, respectively, and extend along inflow cannula 400 for connection to an inflation port for the independent inflation and deflation of balloons 402 and 404.

Referring particularly to Figure 4B, when balloon 310 is positioned in left atrium 312, balloon 310 can be inflated with biocompatible fluid (e.g., saline mixed with iodine contrast). Inflow cannula 306 can be pulled proximally until resistance is met. Next, balloon 402 can be inflated for fixing inflow cannula 106 to inter-atrial septum 122 by compression between balloons 402 and 404. It can be appreciated by those of skill in the art that the fixating devices can include any device adapted for maintaining a ventricular assist device (such as LVAD 104 shown in Figure 1) in position with respect to an inter-atrial septum (such as inter-atrial septum 122 shown in Figure 1). Such devices can be constructed from NITINOL® and be shaped as atrial septal defect (ASD) closure devices (such the AMPLATZER® product available from AGA Medical Corporation of Golden Valley, Minnesota, U.S.A. and the CARDIOSEAL® product available from Nitinol Medical Technologies, Inc. of Boston, Massachusetts, U.S.A.). These take advantage of the ability of NITINOL® to retain shape memory. They can be coupled to the cannula and released in sequence to fix the cannula to the inter-atrial septum as described above.

Referring again to Figure 2, inflow cannula 106 can include a flexible, tubular portion 214 for connecting tubular portion 208 to terminal end portion 200. In one embodiment, tubular portion 214 can bend approximately 90 degrees (or to other suitable angles) whereby tubular portion 208 can extend in
left atrium 124, across mitral valve 202, and into the inflow of left ventricle 112. Flexible portion 214 can also bend to accommodate variations in anatomy from subject to subject. Flexible portion 214 can comprise a polymer having the property of retaining shape memory. Flexible portion 214 can also comprise a graft material re-enforced with a metallic material. Further, flexible portion 214 can comprise a DACRON® polyester or polytetrafluoroethylene (PTFE) fabric with inlaid metal alloy such as NITINOL® alloy, which has shape memory.

Continuing with Figure 2, inflow cannula 106 can also include a long tubular portion, generally designated 216, that can have a rigid tubular portion 218 and a flexible portion 220. Long tubular portion 216 can extend through superior vena cava (shown at 118 in Figure 1) and into the proximal (in one example, the right) internal jugular vein (shown at 116 in Figure 1). Rigid tubular portion 218 can comprise a polymer or other suitable rigid material known to those of skill in the art. Flexible tubulár portion 220 can comprise a woven DACRON® polyester material for providing flexibility during torso and neck movements.

Continuing with Figure 2, inflow cannula 106 can include another flexible tubular portion 222 for connecting long tubular portion 216 to tubular portion 208. Flexible tubular portion 222 can comprise, for example, a folded sheet pattern of a rigid polymer. Flexible tubular portion 222 can allow for mobility and change in angle (over various angles, including but not limited to 90 degrees) to accommodate individual differences in anatomy.

Continuing with Figure 2, inflow cannula 106 can also include an end 224 that fluidly connects to long tubular portion 216. Further, end 224 can include a bend 226 such that end 224 can protrude from the right internal jugular vein (shown at 116 in Figure 1) and/or the right subclavian vein (shown in Figure 3) for connection to pump system 108 (Figure 1). Bend 226 can comprise a compressible material, such as a soft polymer, and can extend approximately one inch or other suitable dimension. Bend 226 can provide for clamping of inflow cannula 106 during insertion without permanent deformation. End 224 can include a male screw cap 228 for attachment to a female screw
cap, described in further detail below. Alternatively, a clip-on system can be used as known to those of skill in the art for use in cardiopulmonary bypass circuits.

According to one embodiment, inflow cannula 106 can bifurcate into two tubes at a portion near end 224. One of the bifurcated tubes can exit from internal jugular vein 116, and the other tube can exit from the right subclavian vein. Figure 5 illustrates a perspective view of another inflow cannula 500 including a bifurcated end 502 exiting from a right jugular vein 504 and a right subclavian vein 506. Bifurcated end 502 can include tubular portions 508 and 510 extending from inflow cannula 500. Tubes 508 and 510 can exit right jugular vein 504 and right subclavian vein 506, respectively, and reconnect at an end 512 for connecting to a pump system (such as pump system 108 shown in Figure 1). This embodiment allows a greater cross-sectional area for permitting greater blood flow.

Figures 6A, 6B, and 6C illustrate perspective views of another embodiment of inflow cannula, designated 600, having bifurcated tubes 602 and 604 illustrating a sequence of three representative steps for installing inflow cannula 600. Referring specifically to Figure 6A, tube 602 can be folded and placed close to body 606 of inflow cannula 600. Tube 602 can comprise a fabric material such as DACRON® material or another suitable flexible material. A wire 608 or thread can be attached to tube 602.

Next, referring to Figure 6B, inflow cannula 600 can be inserted into right jugular vein 610 with tube 602 positioned in a right subclavian vein 612. A snaring device 614 can be advanced from right subclavian vein 612 after cannula 600 is placed across the inter-atrial septum and then utilized for capturing wire 608. Snaring device 614 can be retracted for exteriorizing wire 608 and deploying tube 602 in subclavian vein 612.

Referring now to Figure 6C, a rigid tube 616 can be inserted into tube 602 for providing support to flexible tube 602. Rigid tube 616 can be connected to a pump system (such as pump system 108 shown in Figure 1)
together with tube 604. End 618 of rigid tube 616 can be beveled for fitting inflow cannula 600 at their junction.

Referring to Figure 7, a side elevational view of a female screw cap 700 including a one-way valve 702 for attaching to male screw cap 228 (shown in Figure 2) of inflow cannula 106 is illustrated. Valve 702 can be similar to the valves of vascular sheaths used for vascular access during angiographic procedures as known to those of skill in the art. One-way valve 702 can prevent blood from flowing out of inflow cannula 106 (Figure 1) prior to the attachment of inflow cannula 106 to pump system 108. Cap 700 can counter issues, such as air embolization, that can arise during the placement procedure. One way valves (not shown) may also be permanently incorporated within the cannula or LVAD system in order to prevent backflow of arterial blood into the heart through the cannula in case of pump failure.

Figure 8 illustrates a side view of a dilator 800 for fitting inside inflow cannula 106 (shown in Figure 2) during installation of the inflow cannula. Dilator 800 can accommodate a wire 802 having a diameter of 35 and/or 38 thousandths of an inch, in one embodiment. A wire of this width can confer a suitable flexibility for allowing it to follow an angled course while providing support for inflow cannula 106 during the placement procedure. Additionally, dilator 800 can provide for the avoidance of air embolization during insertion. Dilator 800 can comprise a soft polymer that bends freely, and dilator 800 can be discarded after placement of inflow cannula 106. Other suitable devices known to those of skill in the art can also be employed for achieving the function of installing inflow cannula 106.

According to one embodiment, an inflow cannula, such as inflow cannula 106 shown in Figure 2, can be manufactured entirely with a polymer material. The polymer material can be sufficiently flexible to allow it to fit in its final position in a subject. Additionally, the polymer material can be sufficiently rigid in order to have enough "pushability" over a guide wire. A dilator, along with the inflow cannula, can be used to confer the desired rigidity during placement. The dilator can be inserted inside the inflow cannula for providing adequate
rigidity during the placement procedure. After placement, the dilator can be withdrawn from the inflow cannula.

According to another embodiment, an inflow cannula, such as inflow cannula 106 shown in Figure 2, can be manufactured with a fabric material such as DACRON® material and/or PTFE, or another suitable material. Such materials are highly resilient and are tolerated extremely well by the human body over long time periods. NITINOL® material, stainless steel mesh, and/or other suitable materials can be inlaid in the fabric material for reinforcement. NITINOL® material has the property of being bendable and having a retaining shape memory. Therefore, an inflow cannula comprising NITINOL® mesh can be compressed and housed inside a sheath (e.g., sheaths described below) for placement. Once in place, the sheath can be withdrawn for allowing the inflow cannula to return to its original shape and dimensions.

Figure 9 illustrates a partial cross-sectional view of pump system 108. Pump system 108 can include an axial flow pump 900, such as axial flow pumps provided by MicroMed Technology, Inc. of Houston, Texas, U.S.A. and Jarvik 2000 provided by Jarvik Heart, Inc. of Houston, Texas, U.S.A. Alternatively, pump system 108 can include a centrifugal pump. In particular, pump system 108 can comprise any suitable pump having the ability to actively aspirate blood and not rely on passive filling. Pump system 108 can include a connecting tube 902 for connecting outflow cannula 110 (shown in Figures 1 and 10) to pump 900. Connecting tube 902 can include a female screw cap 904 for fitting to male screw cap 1002 of outflow cannula 110 (shown in Figure 10) for fluidly connecting pump system 108 to the outflow cannula 110. Alternatively, cap 904 and male screw cap 1002 (shown in Figures 1 and 10) can comprise other suitable connecting ends for fluidly connecting pump system 108 to outflow cannula 110. Connecting tube 902 can include a flexible bend 906 for conforming to the particular size and anatomy of patient 100 (shown in Figure 1). Flexible bend 906 can move after implantation to accommodate mobility of the neck, shoulder, and upper extremity of patient 100. Flexible bend 906 can comprise a DACRON® polyester material.
Alternatively, flexible bend 906 can comprise HEMASHIELD® material or another suitable flexible material known to those of skill in the art.

Continuing with Figure 9, pump system 108 can include another connecting tube 908 for fluidly connecting pump 900 to inflow cannula 106 (shown in Figure 2). Connecting tube 908 can include a female screw cap 910 for fitting to male screw cap 228 of inflow cannula 106 for fluidly connecting pump system 108 to inflow cannula 106. Alternatively, cap 910 can be another suitable connecting end for connecting pump 900 to inflow cannula 106. Additionally, connecting tube 908 can include a rigid bend 912 and flexible bend 914 for conforming to the particular size and anatomy of patient 100.

Continuing with Figure 9, pump 900 can also comprise a centrifugal pump, axial pump, or any other suitable pump having the ability to actively aspirate blood and of a suitable size to fit in a subclavian pocket. Pump 900 can include a power cable 916 for delivering power and control signals for operating the pump.

Figure 10 illustrates a perspective view of outflow cannula 110. Outflow cannula 110 can insert in and partially occlude subclavian artery 114 (shown in Figure 1) while maintaining upper extremity perfusion. In another embodiment, more than one additional outflow can be employed to allow higher rates of blood flow. According to one embodiment, an outflow cannula can "branch" from pump system 108 (shown in Figure 9) such that one branch is anastomosed to the right subclavian artery and another branch attaches to the right carotid artery or to any other major arteries in upper abdomen. From the subclavian artery and/or carotid artery, outflow cannula 110 can allow retrograde blood flow into the aorta and from there to the rest of the patient’s body. When outflow cannula 110 is attached to the carotid artery, direct perfusion of the patient's brain is provided. Outflow cannula 110 can include an open end portion 1000 for fitting into subclavian artery 114 to release blood advanced from pump 900 (shown in Figure 9). Open end portion 1000 is beveled in one embodiment for preventing the occlusion of the right common carotid and right vertebral arteries. Outflow cannula 110 can also include a
male screw cap 1002 for fluidly connecting to female screw cap 910 of pump system 108.

Continuing with Figure 10, outflow cannula 110 can include tube portions 1004 and 1006 for fluidly connecting cap 1002 and open end 1000. Tube portion 1004 can comprise a soft polymer for allowing clamping during insertion without permanent deformation. Tube portion 1006 can comprise a folded sheet pattern of a rigid polymer to allow outflow cannula 110 to bend as it is inserted into subclavian artery 114.

Continuing with Figure 10, outflow cannula 110 can also include a connector 1008 for connecting to a polymer de-airing tube 1010 for allowing de-airing of outflow cannula 110 prior to activation of pump system 108 (shown in Figure 10). Connector 1008 can be a side port of outflow cannula 110. De-airing tube 1010 can comprise a three-way stopcock.

Continuing with Figure 10, outflow cannula 110 can include an aperture 1012 positioned in bendable tube portion 1006. Aperture 1012 can be positioned (as shown in Figure 11) to face a direction to allow a small portion of the pump outflow to advance through subclavian artery 114 in an antegrade fashion to perfuse the patient’s arm. Pump flow can preserve adequate perfusion of the right upper extremity after insertion of the occlusive outflow cannula 110.

Figure 11 illustrates a side view of outflow cannula 110 positioned in subclavian artery 114 near a right vertebral artery 1100, right carotid artery 1102, and right innominate artery 1104 of patient 100 (shown in Figure 1). Blood B can be advanced from open end 1000 and aperture 1012 in the directions indicated by the direction arrows. Aperture 1012 is positioned at the bend of tube portion 1006 such that blood B can advance through subclavian artery 114 in an antegrade fashion. De-airing tube 1010 can be tied and clamped during installation.

In one embodiment, outflow cannula 110 can comprise a DACRON® polyester or PTFE fabric with inlaid metal alloy such as NITINOL®, which includes a retain shape memory. Outflow cannula 110 can be compressed
inside a delivery catheter and advanced over a wire into a final position during placement. Once in the final position, the sheath is withdrawn and outflow cannula 110 can expand to its final shape. According to another embodiment, a vascular graft can extend from the outflow of pump system 108 (shown in Figure 9) to the subclavian and/or carotid artery. Blood flow in the outflow of pump system 108 is under higher pressure, and thus prevents bending (unlike flow in inflow cannula 106). An end-to-side anastomosis can be used to connect biocompatible fabric grafts to the respective arteries much like what is performed during vascular bypass surgery. Banding of the subclavian artery distal to the anastomosis may be required to prevent hyper-perfusion of the right upper extremity.

Figure 12 illustrates a side view of a dilator 1200 for fitting inside outflow cannula 110 (shown in Figure 10) during installation. Dilator 1200 can accommodate a wire 1202 having a diameter of 35 and/or 38 thousandths of an inch, in one embodiment. Additionally, dilator 1200 can provide for the avoidance of air embolization during insertion. Dilator 1200 can comprise a soft polymer that bends freely. Dilator 1200 can be discarded after placement of outflow cannula 110.

Figure 13 illustrates a perspective bottom view of female screw cap 1300 including a one-way valve 1302 for attaching to a male screw cap 1002 of outflow cannula 110 (shown in Figure 10). Valve 1002 can be similar to the valves of vascular sheaths used for vascular access during angiographic procedures as known to those of skill in the art.

Installation of the First Exemplary Ventricular Assist Device

Referring now to Figure 14, a flow chart, generally designated 1400, is provided which illustrates a method for installing LVAD 104 (shown in Figure 1) in patient 100 (shown in Figure 1). The method begins at the step indicated by reference numeral 1402. In step 1404, patient 100 (shown in Figure 1) is prepared for surgery. Surgery preparation can include initializing cardiac catheterization as known to those of skill in the art. Cardiac catheterization can
include scrubbing the groin areas. Additionally, the area along the right side of the neck and the right side of the chest above and below the clavicle can be scrubbed. Patient 100 can then be draped. One or more anesthesiologists and other suitable personnel can also be made available for elective or emergency intubation.

In step 1406, right internal jugular vein 116 (shown in Figure 1), right subclavian vein 1504 (shown in Figure 15A), and right femoral vein 1508 (shown in Figure 18A) can be accessed in a manner known to those of skill in the art, such as the Seldinger technique, using local and/or general anesthesia and a sterile technique. A suitable vascular sheath can be introduced into each of the accessed veins.

Right subclavian artery 114 (shown in Figure 1) can be exposed. An incision can be performed approximately two fingers below the clavicle of patient 100 (shown in Figure 1) under local and/or general anesthesia and using sterile technique. The cut-down can be extended until an approximately one-inch long segment of right subclavian artery 114 is visualized. Afterwards, a subcutaneous pocket can be created using blunt dissection. The subcutaneous pocket should be large enough to accommodate pump system 108 (shown in Figures 1 and 9). Hemostasis can be meticulously ensured, as patient 100 is systemically anticoagulated later in the procedure. The subcutaneous pocket should be large enough to accommodate pump system 108 (shown in Figures 1 and 9). The subcutaneous pocket is then irrigated and packed with antibiotic-impregnated gauze. Next, subcutaneous tunnels can be created for connecting the other components of pump system 108 (shown in Figures 1 and 9) between the sheath in the jugular vein and the newly created pocket for connecting the inflow cannula 106 to pump 900.

Referring again to Figure 14, in step 1408, pump system 108 (shown in Figure 2) can be placed in a subclavicular pocket in patient 100. As shown in Figures 1, 2, and 9, the inflow end of pump 900 connecting to tube 908 can be positioned to face laterally, and the outflow end of pump 900 connecting to bend 906 is directed medially. The outflow of pump 900 can face the exposed
part of subclavian artery 114, which can be distal to the point where the clavicle intersects with the first rib. Pump system 108 can be held in place with sutures that fix it to the pectoralis muscle fascia. Bends 904 and 906 and cap 910 can be passed through the tunnel over the clavicle in order to meet inflow cannula 106, which can be subsequently be positioned to exit jugular vein 116. The inflow part should face the sheath that marks the access site to jugular vein 116.

Power cable 916 (shown in Figure 9) can be placed during or a few days before placement of ventricular assist device 104. According to one embodiment, power cable 916 can be positioned in the subcutaneous tissue of the abdominal wall of patient 100 such that power cable 916 exits in the left or right lower quadrant of the abdomen. According to another embodiment, power cable 916 can be extended subcutaneously toward the mastoid bone, where a pedestal extends through the scalp and connects to an outside power source. This pedestal is similar to the type employed to supply electric power to implantable cochlear hearing devices.

In step 1410, outflow cannula 110 can be placed in patient 100 by any suitable approach. In one example, first, a vascular clamp can be applied to the proximal segment of subclavian artery 114 (shown in Figure 1). Two ligature loops are then wrapped around subclavian artery 114 and a needle is introduced into subclavian artery 114. A short J-tipped guide wire is then introduced and the needle withdrawn. Outflow cannula 110 and dilator 1200 (shown in Figure 12) can be advanced over the wire after incising the arterial wall to accommodate outflow cannula 110. The vascular clamp can be gradually released as outflow cannula 110 is advanced. Once outflow cannula 110 is all the way in, dilator 1200 can be withdrawn. If problems arise, the vascular clamp can be re-applied and outflow cannula 110 withdrawn in order not to jeopardize either right vertebral artery 1100 or right carotid artery 1102 (shown in Figure 11). Care must be taken not to occlude the cerebral vessels with outflow cannula 110. The beveled open end 1000 of outflow cannula 110 can be oriented in a way that the origin of carotid 1102 is not occluded by
outflow cannula 110. Outflow cannula 110 can then be carefully aspirated and flushed. Intravenous contrast is then injected briskly through the side branch and visualization of the contrast traveling antegrade through aperture 1012 (shown in Figures 10 and 11) toward the arm can be observed. At the same time, retrograde contrast flow should demonstrate patent cerebral circulation.

Outflow cannula 110 can then be clamped just distal to de-airing tube 1010 (shown in Figure 10) and female screw cap 1300 (shown in Figure 13) containing one-way valve 1302 (shown in Figure 13) is removed.

Outflow cannula 110 can then be fixed to pump system 108 (shown in Figure 9). Female screw cap 904 (shown in Figure 9) of pump system 108 outflow per se can then be screwed on male screw cap 1002 (shown in Figure 10) of outflow cannula 110. The vascular clamp is left in position in order to occlude outflow cannula 110. Alternatively, outflow cannula 110 can be fixed to pump 908 via a clip assembly.

Alternatively, pump system 108 (shown in Figure 1) can be connected to right subclavian artery 114 (shown in Figure 1) using a biocompatible vascular graft material (e.g., DACRON® material and/or PTFE). Right subclavian artery 114 can be clamped and an end-to-side anastomosis performed. Right subclavian artery 114 distal to the insertion of the graft can be banded to prevent hyper-perfusion of the upper right extremity at the expense of the rest of the body.

Further, in step 1412, puncture of inter-atrial septum 122 (shown in Figure 1) can be performed with a standard technique using a trans-septal needle such as COOK™ needle (available from Cook Incorporated of Bloomington, Indiana, U.S.A.) (shown in Figure 18A) and a trans-septal sheath such as a Mullins sheath. The Mullins sheath can be advanced into the right atrium 120 (shown in Figure 1) from right femoral vein (such as vein 1808 shown in Figure 18A) over a 0.032 inch J guide-guide wire under direct fluoroscopy. A COOK™ needle can then be advanced inside the Mullins sheath and pointed posteriorly and medially under fluoroscopy in a way to oppose the Fossa Ovalis, which is a structure of the inter-atrial septum.
Alternatively, trans-esophageal or intra-cardiac echocardiography can be employed to verify needle position.

Once the needle is in an appropriate position, the needle can be pushed through inter-atrial septum 122 (shown in Figure 2). The needle can be advanced into left atrium 124 (shown in Figure 2). The sheath can then be advanced over the needle into left atrium 124. The COOK™ needle apparatus can then be withdrawn and the sheath left in place. After sheath aspiration and flushing, patient 100 can be provided intravenous heparin in order to achieve systemic anticoagulation (with Activated Clotting Time (ACT) greater than 250 seconds). Systemic anticoagulation may be done only after successfully puncture into left atrium 124 is ensured.

After completion of the trans-septal puncture, the Mullins sheath can be replaced with a regular short sheath in the femoral vein to insure hemostasis while wire 1502 (shown in Figure 15) is left in place. Systemic anticoagulation can be maintained with boluses of intravenous heparin as dictated by periodic checks of the ACT, which should be maintained above 250 seconds.

Figures 15A, 15B, and 15C, as well as Figures 24, 25, and 26, illustrate perspective views of heart 102 illustrating a sequence of multiple representative steps for gaining access to left atrium 124 from the upper body by using a snaring technique. Referring specifically to Figure 15A, prior to performing trans-septal puncture (as described above, for example, in step 1412 of Figure 14), a first snare 1500 can be introduced from internal jugular vein 116 (shown in Figure 1) through a vascular access sheath. First snare 1500 can be advanced into superior vena cava 118, right atrium 120, and positioned in inferior vena cava 1502, just inferior to the renal veins (not shown). A second snare (not shown) can be introduced via the same sheath in the same vein or through a right subclavian vein 1504, advanced and positioned just inferior to right atrium 120 in the inferior vena cava. Next, an exchange-length wire 1506 of a trans-septal puncture apparatus can then be advanced via a right femoral vein 1508 and through an opening 1510 of first snare 1500 and an opening (not shown) of the second snare (not shown).
After trans-septal puncture, wire 1506 (e.g., 330 centimeters in length) can be positioned from right femoral vein 1508 into a left superior pulmonary vein 1512. The trans-septal needle (e.g., COOK™ needle) and Mullins sheath are withdrawn. As shown in Figure 25, first snare 2400 and the second snare 2402 can be tightened over wire 1506. The distal end of wire 1506 can then be pulled towards the upper body as shown in Figure 26. First snare 2402 can be held and fixed while second snare 2400 that is positioned inferior to renal veins (not shown) is gently pulled in the direction of arrow 2600. Second snare 2402 or distal snare can be withdrawn to the internal jugular vein and the exchange wire exteriorized. First snare 2402 that was initially used to fix the portion of wire 1506 that goes across inter-atrial septum 122 is then released and withdrawn. Figure 15C illustrates the final position of wire 1506 for allowing access to left atrium 124 from a neck vein.

Figure 16 illustrates a perspective view of exchange wire 1506 positioned in heart 102 (shown in vertical cross-section). Wire 1506 can extend into pulmonary vein 1512. Wire 1506 can include a large terminal loop, such as that used during balloon mitral valvuloplasty with the Inoue technique, and be placed in the left atrium. Wire 1506 can include wide loops at the proximal end that makes it easier for the operator to maintain position of the wire in the left atrium while manipulating the snares. Alternatively, a wire with an incorporated balloon similar to GuardWire® (available from Medtronic, Inc. of Minneapolis, Minnesota, U.S.A.) may be used. This wire terminates with a small balloon that can be inflated in the left atrium in a manner that, if tension is applied on the wire, the inflated balloon may prevent the loss of wire position from the left atrium. Next, a mitral valvulotome, a balloon, and/or trans-septal blade can be used to enlarge the puncture site in inter-atrial septum 122 (shown in Figure 2).

Referring now to Figures 17A, 17B, and 17C, vertical cross-sectional views illustrating a sequence of three representative steps for dilating or enlarging a puncture site in inter-atrial septum 122 are illustrated. Referring specifically to Figure 17A, a wire 1700 can be advanced through a mitral
valvulotome 1702 into left atrium 124 (shown in more detail in Figure 2). Mitral valvulotome 1702 can then be retracted into the inferior vena cava while wire 1700 is fixed in position. Mitral valvulotome 1702 can then be advanced over the wire into left atrium 124. Next, the blades of mitral valvulotome 1702 can be retracted (shown in Figure 17B) and pulled through inter-atrial septum 122 for enlarging puncture site 1704 (shown in Figure 17C). Alternative to mitral valvulotome 1702, a trans-septal blade can be used for enlarging puncture site 1704 in inter-atrial septum 122.

Figure 18 illustrates a vertical cross-sectional side view of a step using a balloon 1800 to enlarge a puncture site. Balloon 1800 can be advanced over wire 1802 and positioned at inter-atrial septum 122. Balloon 1800 can then be inflated to dilate or expand puncture site in inter-atrial septum 122. The puncture site can be enlarged in order to facilitate the passage of inflow cannula 106 (shown in Figure 2) from right atrium 120 to left atrium 124. The size of the passage through inter-atrial septum 122 should not be greater than the diameter of inflow cannula 106. A sizing balloon may be utilized to verify the size of the puncture site.

Referring again to Figure 16, wire 1506 is shown in position for advancement of an inflow cannula (such as inflow cannula 106 shown in Figure 2) over wire 1506. An alternative position of wire 1506 is shown in lines 1900. Wire 1506 can traverse right internal jugular vein 116 to superior vena cava 118, right atrium 120, through inter-atrial septum 122 to left atrium 124, and to left upper pulmonary vein. Wire 1900 can traverse from right subclavian vein 1514, to superior vena cava 118, right atrium 120, through inter-atrial septum 122 to left atrium 124, through mitral valve 202, and into left ventricle 112.

Wire 1506 can then be fixed and the venous sheath can be pulled out. Inflow cannula 106 (shown in Figure 2) and dilator 800 (shown in Figure 8) can be advanced over wire 1506 until opening 204 (shown in Figure 2) of inflow cannula 106 reaches left atrium 124, left ventricle 112, and/or pulmonary vein. A septum fixating device (such as arms 210 and 212 shown in Figure 2, or balloons 608 and 610 shown in Figure 6) can be deployed across the inter-
atrial septum. Dilator 800 (shown in Figure 8) can be pulled out and inflow cannula aspirated thoroughly and flushed with saline. A vascular clamp can then be applied to flexible tube portion 222 (shown in Figure 2) of inflow cannula 106 exiting from jugular vein 116. Inflow cannula 106 can then be screwed or clipped on cap 910 (shown in Figure 9) of pump system 108. At this point, pump system 108 can be connected to inflow and outflow cannulae 106 and 110, respectively.

Referring to Figure 14, inflow cannula 106 can be placed (step 1414) and de-airing can be performed to address the risk of air embolism (step 1416). First, inflow cannula 106 can be unclamped and pump 900 run at minimal speed while the outflow cannula remains clamped. Blood can be aspirated from left atrium 124 and ejected from connector 1008 to de-air tube 1010 of outflow cannula 110 (shown in Figure 10). Once all the air that was present in pump 900 is safely evacuated, the clamp occluding outflow canula 110 can be released, thus allowing blood flow into the arterial circulation. Connector 1008 can be tied upon itself, clipped, and discarded. Pump speed can be slowly increased while all hemodynamic parameters are monitored, such as right ventricular function and cardiac rhythm. The manipulation of the atrium may give rise to atrial arrhythmias. Once the hemodynamic parameters and the general condition of the patient are considered satisfactory, the pocket and skin tunnel are closed in layers and patient 100 sent for recovery. The sheath in the right femoral vein can be removed and pressure applied to achieve hemostasis. Systemic anticoagulation with un-fractioned or low-molecular weight heparin is started as early as possible after adequate hemostasis is ensured. Oral anticoagulation with warfarin may then be initiated. The process then stops at step 1418.

Alternative Methods and Devices for Accessing the Left Atrium Via Inter-Atrial Septal Puncture

Several devices and methods are provided herein for accessing a left atrium (such as left atrium 124 shown in Figure 1) from a right atrium (such as
right atrium 120 shown in Figure 1). Figures 19A and 19B illustrate side
elevation views of a first catheter 1900 and a second catheter 1902,
respectively, for accessing a left atrium from a right atrium. Referring to
Figures 19A and 19B, first and/or second catheters 1900 and 1902 can be
introduced from a vein in the upper body and shaped in a manner that would
allow their tips to face the Fossa Ovalis once the catheter is advanced into the
right atrium from the upper body veins. Catheters 1900 and 1902 may have a
primary curve, generally designated 1904 and 1906, respectively, at an end
portion 1908. Catheters 1900 and 1902 can also include one or more
secondary curves, generally designated 1910.

Either of catheters 1900 and 1902 may be advanced with a dilator over a
wire in a manner known to those of skill in the art of angiography and
percutaneous vascular intervention. Access may first be obtained with a
needle or by direct visualization of an upper body vein (e.g., the right internal
jugular vein), and a wire is advanced into the right atrium. One of catheters
1900 and 1902 and a dilator (similar to that used in all vascular access sheaths
known to those of skill in the art) can be advanced over each wire. Once the tip
of the catheter is in the right atrium, the dilator is withdrawn and the tip of the
catheter is shaped in a manner for contact with the Fossa Ovalis.
Transesophageal or the intracardiac echocardiography may be employed to
guide the catheter into position. Once the catheter tip faces or touches the
Fossa Ovalis, a flexible puncture apparatus is advanced through the catheter to
perform puncture. Alternatively, the catheter tip may be utilized to perform
puncture.

After successful access to the left atrium, first catheter 1900 or second
catheter 1902 is advanced into the left atrium. The needle is withdrawn and a
wire is advanced into the catheter into the left atrium in order to secure access.
A balloon or trans-septal blade, mitral valvulotome or other suitable device can
be advanced over the wire in order to dilate the inter-atrial septal puncture as
described above. Positioning of the inflow cannula follows as described in the
method above. Catheters 1900 and 1902 can be built in different sizes to accommodate different patients.

According to another embodiment, the catheter may include a flexible end portion or tip that can be controlled with a remote control mechanism. Figure 19C illustrates a vertical cross-sectional view of a catheter 1912 having a controllable flexible end portion or tip 1914. One or more wires 1916 would be attached to the distal tip of the catheter and be extended along the length of catheter 1912. The proximal end of each wire 1916 exits at the proximal end of catheter 1912. Pulling on one of wires 1916 deflects the tip of the catheter in the direction of that wire. For example, catheter 1912 can be moved from a position designated A to a position designated B in a position where a tip 1918 of catheter 1912 is indicated by broken lines. By pulling on the wire, an operator can deflect catheter 1912 in a desired direction and degree for opposing tip 1914 of catheter 1912 to the Fossa Ovalis. Imaging techniques such as transesophageal or intra-cardiac echocardiography may be utilized in addition to fluoroscopy.

According to another embodiment, a catheter includes two or more component catheters that connect to one another. Figures 19D and 19E illustrate vertical cross-sectional views of different catheters, 1920 and 1922 having two or more component catheters. Each component catheter can have its own distal curve. Advancing or retracting the catheters relative each other can change the overall curve of the catheter in a way that would provide the operator with control over the direction of the tip of the catheter.

Figure 19F illustrates a vertical cross-sectional view of a first catheter 1924 and a second catheter 1926 for deflecting a tip 1928 of catheter 1924 upwards. Tip 1928 is shown in a position A prior to deflection upwards and in an upward position B (indicated by broken lines). Once tip 1928 of catheter 1924 faces the Fossa Ovalis, a flexible needle apparatus (such as needle 1930 shown in Figure 19G) or the catheter may be used to perform the inter-atrial septal puncture. Alternatively, inter-atrial septal puncture can be performed utilizing a radiofrequency or electro-cauterization catheter. Next, catheter 1928
is advanced into the left atrium. A wire is then advanced through the catheter into the left atrium to secure access. The following steps are similar to the ones described above and result to the final positioning of the inflow cannula.

Figure 19G illustrates a side view of a flexible needle apparatus 1930 for performing inter-atrial septal puncture. A flexible needle apparatus can be useful for following the curves of a catheter, such as catheter 1928 shown in Figure 19F. The catheter can provide support to the flexible needle apparatus 1930 that punctures the inter-atrial septum. According to one embodiment, a straight or curved catheter can be utilized. This catheter can be similar to that used in the manufacture of right heart catheterization catheters 1451. Needle apparatus 1930 can be made of DACRON® material. A small rim of sharp metal or a needle tip 1932 can be fixed to the distal tip of the catheter, thus making it a cutting catheter. Once needle tip 1932 is opposite to the Fossa Ovalis, flexible needle apparatus 1930 can be advanced for puncturing the inter-atrial septum under echocardiographic guidance or another suitable guidance system. The core of the catheter may be solid or hollow to allow a wire 1934 disposed therein to be advanced therein.

Another embodiment of a catheter (such as catheter 1928 shown in Figure 19C) can include a long needle made of a flexible metal (such as thin stainless steel). Once the catheter tip faces the Fossa Ovalis, the needle on the catheter can be used to perform the puncture. After successful puncture, a wire may be advanced into the left atrium through the core of the needle apparatus. If the needle apparatus is manufactured without a hollow core, the catheter may be advanced into the left atrium over the needle apparatus.

Figure 20 illustrates a perspective view of dual catheters 1924 and 1926 (shown in Figure 19F) positioned in heart 2000 (shown in vertical cross-section) for puncture of inter-atrial septum 2002. Catheters 1924 and 1926 can be advanced into a right atrium 2004 from a superior vena cava 2006. Catheter 1926 may be positioned in the roof of right atrium 2004 and catheter 1924 is manipulated to face Fossa Ovalis 2008 in inter-atrial septum 2002. Flexible puncture needle 1930 (shown in Figure 19G) can be advanced and used to
perform the trans-septal puncture of inter-atrial septum \textbf{2002}. Wire \textbf{1934} (shown in Figure 19G) can be advanced within the lumen of flexible puncture needle \textbf{1930} into a left atrium \textbf{2010}.

\textbf{Second Exemplary Ventricular Assist Device}

Figure 21A illustrates a phantom view of a heart \textbf{2100} (shown in cross-section) coupled to another exemplary LVAD \textbf{2102}. LVAD \textbf{2102} can comprise an inflow cannula \textbf{2104}, a pump system \textbf{2106}, and an outflow cannula \textbf{2108}. Inflow cannula \textbf{2104} can fluidly connect pump system \textbf{2106} to a left ventricle \textbf{2110}, left atrium \textbf{2112}, or left pulmonary vein \textbf{2114} of heart \textbf{2100} such that pump system \textbf{2106} can pump blood directly from left ventricle \textbf{2110}, left atrium \textbf{2112}, or left pulmonary vein \textbf{2114}, and through inflow cannula \textbf{2104} and outflow cannula \textbf{2108}. Outflow cannula \textbf{2108} can fluidly connect pump system \textbf{2106} and a right subclavian artery \textbf{2116} and/or a right carotid artery \textbf{2118} such that blood pumped from left ventricle \textbf{2110} can be delivered to arteries \textbf{2116} and \textbf{2118}. As shown, pump system \textbf{2106} can extend across an inter-atrial septum \textbf{2120}. Alternatively, pump system \textbf{2106} can be placed in a superior vena cava \textbf{2122} and/or a right atrium \textbf{2124}.

Figure 21A illustrates LVAD \textbf{2102} prior to deployment of fixating devices \textbf{2126} and \textbf{2128} for attaching LVAD \textbf{2102} to inter-atrial septum \textbf{2120}. Figures 21B-21E are cross-sectional views of LVAD \textbf{2102} illustrating a sequence of four representative steps for installing LVAD \textbf{2102} in heart \textbf{2100} (shown in cross-section). Referring specifically to Figure 21B, fixating device \textbf{2128} is positioned inside left atrium \textbf{2112} such that fixating device \textbf{2128} can be deployed. Figure 21C shows fixating device \textbf{2128} deployed in left atrium \textbf{2112}. Next, Figure 21D shows fixating device \textbf{2128} position against the left atrium side of inter-atrial septum \textbf{2120}. LVAD \textbf{2102} can be pulled in the direction of the right atrium side of inter-atrial septum \textbf{2120} to position fixating device \textbf{2128} against the left atrium side of inter-atrial septum \textbf{2120}. Referring now to Figure 21E, fixating device \textbf{2126} can be deployed for fixing LVAD \textbf{2102} to inter-atrial septum \textbf{2120}.
Figure 22 illustrates another perspective view of LVAD 2102. Inflow cannula 2104 can connect to pump 2106 and comprise a terminal end portion 2200 adapted to extend from a left atrium 2112 (Figure 21A), across a mitral valve 2130 (Figure 21A), and terminate at left ventricle 2110 (Figure 21A). Alternatively, terminal end portion 2200 can terminate at left atrium 2112. Terminal end portion 2200 can include a large opening 2202 at a tip thereof for receiving blood B1 in the direction indicated by the direction arrow. Inflow cannula 2104 can comprise flexible and/or rigid material for placement between pump 2106 and left atrium 2112 and/or left ventricle 2110.

Pump 2106 can be positioned to extend across inter-atrial septum 2120. As described herein, septum 2120 can be pierced for placement of pump 2106 across septum 2120. Pump 2106 can comprise an axial pump or another suitable pump of a suitable size for extending across septum 2120. In the alternative, pump 2106 can be located elsewhere in the body along the track of inflow cannula 2104 and outflow cannula 2108. For example, pump 2106 can be located within subclavian artery 2116, superior vena cava 2122, a right jugular vein 2132 (Figure 21A), or right atrium 2124. In these examples, inflow cannula 2104 and outflow cannula 2108 can be suitably increased or decreased in size for connecting to pump 2106 at its placement. Further, in these cases, either inflow cannula 2104 and/or outflow cannula 2108 may extend across septum 2120.

As stated above, pump 2106 can include fixing devices 2126 and 2128 for attaching pump 2106 to septum 2120. For example, fixing devices 2126 and 2128 can be retractable arms and/or balloons for fixing pump 2106 to septum 2120. Exemplary retractable arms and balloons can be similar in structure and operation to retractable arms 210 and 212 (shown in Figure 2) and balloons 402 and 404 (shown in Figures 4A and 4B). An exemplary process for attaching pump 2106 to septum 2120 with fixing devices 2126 and 2128 is described in further detail hereinbelow.
Outflow cannula 2108 can fluidly connect to pump 2106 and extend from pump 2106 through right atrium 2124 (Figure 21A) and superior vena cava 2122 (Figure 21A), and to the junction of right jugular vein 2132 (Figure 21A) and a right subclavian vein 2134 (Figure 21A). According to one embodiment, outflow cannula 2108 can bifurcate into two tubes 2204 and 2206 at an end portion 2208. Tube 2204 can extend into right carotid artery 2118 (Figure 21A). Tube 2206 can extend into right subclavian artery 2116 (Figure 21A). In addition, tube 2204 can include an opening 2210 for positioning in carotid artery 2118 (Figure 21A), and tube 2206 can include an opening 2212 for positioning in right subclavian artery 2116 (Figure 21A). As a result, pump 2106 can advance blood B2 into the arterial system of the subject in the direction indicated by the directions arrows. As a result, pump 2106 can at least partially relieve left ventricle 2112 (Figure 21A) of the function of advancing blood from left ventricle 2112 to the arterial system. Outflow cannula 2108 may also include a small tube (not shown) for de-airing.

Installation of the Second Exemplary Ventricular Assist Device

Referring to Figure 23, a flow chart, generally designated 2300, is provided which illustrates a method for installing LVAD 2102 as shown in Figure 21A. The method begins at the step indicated by reference numeral 2302. In step 2304, the patient is prepared for surgery. Implantation can be performed under fluoroscopic guidance in a catherization laboratory. In addition, transesophageal or intra-cardiac echocardiographic guidance can be utilized. Next, the area along the right side of the neck and the right side of the chest above and below the clavicle can be scrubbed. The patient can be prepped and draped in a sterile manner known to those of skill in the art. Anesthesia personnel can be made available for elective or emergency intubation.

In step 2306, right subclavian artery 2116 (Figure 21A), right jugular vein 2132 (Figure 21A), right subclavian vein 2134 (Figure 21A), right carotid artery 2118 (Figure 21A), and a right femoral vein 2136 (Figure 21A) can be exposed
from an incision at the base of the neck, extending about 1-2 inches into the
shoulder above the clavicle using local and/or general anesthesia and a sterile
technique. A vascular sheath can be placed in right femoral vein 2136. The
junction of right carotid artery 2118 and right subclavian artery 2116 as well as
the junction of right jugular vein 2132 and right subclavian vein 2134 can be
exposed. Clavicular head of sternocleidomastoid muscle may be detached
from its insertion and may be sacrificed.

In step 2308, two gooseneck snares can be deployed through superior
vena cava 2122 (Figure 21A) and right atrium 2124 (Figure 21A) to an inferior
vena cava 2138 (Figure 21A). Referring to Figure 24A, a vertical cross-
sectional side view showing a step of deploying snares 2400 and 2402 into
inferior vena cava 2140 is illustrated. Snare 2400 can be deployed in inferior
vena cava 2138 below the renal veins. Snare 2402 can be deployed in inferior
vena cava 2138 just below right atrium 2122. Snares 2400 and 2402 can be
inserted by placing one or two sheaths in right jugular vein 2132 (Figure 21A)
and/or right subclavian vein 2134 (Figure 21A). Snares 2400 and 2402 can then
be advanced through the sheaths to the positions shown in Figure 24A.

In step 2310 of Figure 23, inter-atrial septum 2120 (Figure 21A) can be
punctured. Inter-atrial trans-septal puncture is performed using the standard
technique described above. An exchange length (e.g., 330 centimeters)
straight wire or a large loop wire similar to that used during balloon mitral
valvuloplasty can be advanced from the right femoral artery and into left atrium
2112 across inter-atrial septum 2120 (step 2312). Full systemic anticoagulation
can be administered. Referring to Figure 25, a vertical cross-sectional side
view showing a step where a safety wire 2500 positioned from right femoral
vein 2136 (Figure 21A) through inter-atrial septum 2120 is illustrated. Snares
2400 and 2402 can be tightened around wire 2500 as shown in Figure 25.

Referring again to Figure 23, in step 2314, the distal end of safety wire
2500 can be pulled from right femoral vein 2136 (Figure 21A) towards superior
vena cava 2122 (Figure 21A) and out of right jugular vein 2132 (Figure 21A).
Snare 2402 can be fixed in place while snare 2400 is slowly pulsed toward right
jugular vein 2132. Referring to Figure 26, a vertical cross-sectional side view showing a step of pulling snare 2400 toward right jugular vein 2132 is illustrated. Continued pulling of snare 2400 in a direction indicated by direction arrow 2600 can result in a distal end of wire 2500 being exteriorized from right jugular vein 2132. Next, snares 2400 and 2402 can be loosened and removed. Figure 27 illustrates a vertical cross-sectional side view showing a step of extending wire 2500 from left atrium 2112 to right jugular vein 2132 (Figure 21A).

In step 2316, the puncture site of inter-atrial septum 2120 can be dilated with an angioplasty balloon. The balloon can be advanced over wire 2500 (Figure 27) into the puncture site across septum 2120. Next, the balloon can be inflated to dilate the puncture site. Figure 28 illustrates a vertical cross-sectional side view showing a step of inflating an angioplasty balloon 2800 to dilate a puncture site of inter-atrial septum 2120. Next, balloon 2800 can be deflated for withdrawal from the subject.

In step 2318, LVAD 2102 can be advanced to the operating position as shown in Figure 21A. In order to advance LVAD, one or more sheaths in the right side of the neck can be removed and an incision made in the vein. In addition, serial dilators or any suitable dilator 2404 (shown in Figure 24B) can be advanced over wire 2400 and into superior vena cava 2406 to facilitate passage of LVAD cannula 2408 (Figure 24D). A dilator of a size to match the width of pump can be advanced over wire 2400 before advancing LVAD cannula 2408. Next, the dilators can be removed while wire 2400 is held in position (as shown in Figure 24C) and then LVAD cannula 2408 with or without an incorporated pump system) can be advanced over wire 2400 and across septum 2120 (Figure 24D). The assist device assembly would have a specialized lumen that would accommodate the wire so that the wire may guide the assist device assembly into position.

In step 2320, pump 2106 (Figure 21) or other part of the cannula can be attached to septum 2120. First, the device can be positioned such that fixating devices 2204 and 2206 (Figure 22) are positioned on opposing sides of septum.
2120. For example, device 2204 can be positioned in right atrium 2124 (Figure 21), and device 2206 can be positioned in left atrium 2112 (Figure 21). Device 2206 can be activated prior to device 2204. Next, device 2206 can be pulled until it is against septum 2120. Secondly, device 2204 can be activated such that pump 2106 is attached to septum 2120.

In step 2322, outflow cannula 2108 (Figure 21A) can be fluidly connected to right subclavian artery 2114 and carotid artery 2118. In particular, tubes 2214 and 2216 (Figure 22) can be connected to arteries 2114 and 2118, respectively. Next, wire 2500 (Figures 27 and 28) can be removed. In addition, a subcutaneous tunnel can be created for placement of a power line 2218 (Figure 22) for powering pump 2106 (Figure 22).

Pump 2106 (Figure 22) can be activated at low speed to de-air VLAD 2102 (Figure 22). After thorough de-airing, the outflow of pump 2106 can be released and full support can be initiated. The incisions can be closed in layers after adequate hemostasis and the subject is transferred to recovery. The right femoral venous sheath can be removed when ACT is less than 150 seconds. Systemic anticoagulation can be started after documentation of adequate sheath/incision hemostasis. The process can stop at step 2324.

Alternatively, another method for placement of percutaneous LV assist system utilizing a method for inter-atrial trans-septal puncture can be applied as described above.

Third Exemplary Ventricular Assist Device

Figure 29 illustrates a phantom view of a heart 2900 (shown in cross-section) coupled to another exemplary LVAD 2902. LVAD 2902 can include a cannula 2904 that connects the left side of the heart (e.g., a left atrium 2906, a left ventricle 2908, and/or pulmonary vein) to the arterial circulation (e.g., right carotid artery 2910 and/or right subclavian artery 2912 or other artery). Cannula 2904 incorporates a propeller mechanism 2914 to push blood from the left side of the heart into the arterial circulation. According to one embodiment, propeller mechanism 2914 can be coated with a material for preventing blood
clot formation or minimizing damage to blood cells. Cannula 2904 also incorporates one or more fixing devices 2916 for fixing cannula 2904 to an inter-atrial septum 2918. Fixating device 2916 include fixing arms or balloons as described above. Cannula 2904 may also incorporate a small lumen tube (not shown) for de-airing.

Propeller mechanism 2914 can be attached via a driveline 2920 to motor 2922 that is physically distinct from cannula 2904. In this example, motor 2922 is placed in a subclavicular pocket similar to the one used in the placement of permanent transvenous pacemakers. Motor 2922 can be connected to a power source (not shown) via a power line 2924. Motor 2922 transmits energy to propeller mechanism 2914 that ejects oxygenated blood from heart 2900 and into the arterial system via the driveline 2920. Driveline 2920 can be contained in a protective housing such as a solid tube 2926 in order to allow it unhindered gyration once inside the body. In this embodiment, motor 2922, propeller mechanism 2914, and driveline 2920 are distinct components. Motor 2922 is not incorporated within cannula 2904 but is in conjunction with it. This provides a larger space within the lumen of cannula 2904 for blood flow.

It is important to note that the exemplary LVAD systems described herein are not mutually exclusive. As patients differ in body habitus and in anatomy, they may be better accommodated by one system or the other.

Cannula 2904 may be similar to the one illustrated in the second exemplary LVAD above. The difference is the presence of a propeller mechanism in conjunction with the cannula instead of a whole pump. The propeller mechanism 2914 can be similar to that employed in temporary left ventricular assist devices such as the HEMOPUMP® device available from Nimbus, Inc. of Rancho Cordova, California, U.S.A. Alternatively, different suitable designs may be utilized. One such propeller would have a design that minimizes non-motile parts. This may minimize the areas in cannula 2904 where blood can stagnate due to flow turbulence. This, in turn, can minimize the probability of the formation of blood clots, or thrombi, within the cannula
itself. The formation of blood clots within the assist device is a potential side effect of all known assist devices.

A device that minimizes non-motile parts in a propeller assembly is one that eliminates the need for an axis of rotation. This can be achieved by shaping the propeller into one or more spiraling ribbons. Figure 30 illustrates a cross-sectional view of another exemplary pump system 3000 and cannula 3002. Pump system 3000 can include a driveline 3004 for rotating a ribbon 3006 in the direction of arrow 3008. Movement of ribbon 3006 in the direction of arrow 3008 moves blood inside cannula 3002 from the inflow towards the outflow in the direction of arrow 3010. Ribbon 3006 may be manufactured of metal such as titanium or other suitable metallic or non-metallic synthetic material.

Referring to Figure 30, driveline 3004 may enter cannula 3002 retrograde from the outflow part and may or may not be in contact with blood. As it exits cannula 3002, it courses in a subcutaneous channel to connect with the motor unit. Driveline 3004 can be housed within a protective tubing 3012 while in the subcutaneous channel in order to protect the body structures from the gyration of driveline 3004 and to protect driveline 3004 from the scarring process that the body initiates in response to foreign material. Driveline 3004 can be inserted into a motor unit (not shown) that powers movement in the direction of arrow 3008. Before implantation, driveline 3004 can be attached to ribbon 3006 inside cannula 3002. It can be manufactured such that it allows easy and reversible "plugging" of driveline 3004 into the motor unit. Driveline 3004 may be secured with a screw or any other mechanical method into the motor unit.

Figure 31 illustrates a cross-sectional view of another exemplary propeller system 3100 and LVAD cannula 3102. Propeller system 3100 can be connected to a motor unit (not shown) via a driveline 3104. A connection 3106 of propeller 3100 with driveline 3104 is located outside the lumen proper of LVAD cannula 3102. The connection point of driveline 3104 to propeller 3100 is a potential nidus for the formation of blood clots because of blood stasis at or
around the connection point. Placing this connection point outside the lumen proper of the LVAD cannula would prevent these clots from reaching the arterial circulation. During operation, propeller 3102 can move blood B in the direction of direction arrow 3108 and out of bifurcated tubes 3110 and 3112.

Installation of the Third Exemplary Ventricular Assist Device

Installation of LVAD 2902 shown in Figure 29 can include the following steps: (1) installation of cannula 2904 (Figure 29) and driveline 2920 (Figure 29); and (2) installation of motor 2922 (Figure 29). First, a small incision can be made below the clavicle and a pocket can be created to accommodate motor 2922. Motor 2922 can then be placed in the pocket. Motor 2922 can be fixed to the pectoralis muscle using sutures or it can be placed in a subpectoral pocket. Alternatively, motor 2922 can then be placed elsewhere in the body and connected to cannula 2904 with driveline 2920. In addition, motor 2922 can also be positioned in a left subclavicular pocket or in the abdomen.

Power line 2924 can be tunneled subcutaneously and exteriorized in the abdomen. An incision can then be made next at the right base of the neck and the internal jugular and right subclavian veins, as well as the right carotid and the right subclavian arteries may be exposed down to their origin. A subcutaneous tunnel can be created between the motor pocket and the neck incision. Next, cannula 2904 can be placed as described above and kept clamped. After the successful anastomosis of the outflow part of cannula 2904 to the arterial system, driveline 2920 is placed in the subcutaneous tunnel and is connected to motor 2922. Cannula 2904 is de-aired and motor 2922 activated. The incisions are closed in layers and the patient taken to recovery. Hemodynamic parameters can be monitored and systemic anticoagulation initiated.
Preoperative Evaluation and Contraindications

In preparation for the installation of a ventricular assist device, certain precautionary procedures can be performed. These procedures can include the following:

1. A transesophageal echocardiography to rule in or out any intracardiac thrombi, to evaluate the mitral valve, and to evaluate the ascending aorta and arch for atherosclerotic disease.

2. Angiography, CT scan, MRI, or other imaging modality of the carotid, vertebral, innominate, and right subclavian arteries can be performed to rule out significant cerebral atherosclerotic disease and to assess diameter of these vessels.

3. Angiography, CT scan, MRI or other imaging modality of the superior vena cava can be performed to assess the diameter of these vessels.


5. Baseline renal and hepatic function tests can be performed.

The installation of a ventricular assist device can be inadvisable for patients having the one of the following conditions:

1. Intra cardiac thrombi other than small, old, layered left ventricular apical thrombi.

2. Significant occlusions to the venous or arterial vasculature of the thorax, neck, or right upper extremity.

3. Severe aortic atherosclerotic disease.

4. Severe blood dyscrasias.

5. Presence of more than mild aortic valve regurgitation.

It will be understood that various details of the subject matter can be changed without departing from the scope of the subject matter. Furthermore, the foregoing description is for the purpose of illustration only, and not for the purpose of limitation.
CLAIMS

What is claimed is:

1. A ventricular assist device, comprising:
   (a) an inflow cannula adapted for receiving blood from a ventricle, an atrium, or a pulmonary vein;
   (b) a pump communicating with the inflow cannula for pumping blood through the inflow cannula; and
   (c) at least a portion of the ventricular assist device being adapted for extending through an inter-atrial septum wherein blood can be advanced through the inter-atrial septum.

2. The ventricular assist device of claim 1, wherein the inflow cannula is adapted to extend through the inter-atrial septum, an atrium, a ventricle, or a pulmonary vein.

3. The ventricular assist device of claim 1, wherein the inflow cannula comprises one or more balloons for fixing the inflow cannula to the inter-atrial septum.

4. The ventricular assist device of claim 3, wherein the balloon can move between a first and second position, wherein the balloon is deflated in the first position for insertion of the inflow cannula and the balloon through the inter-atrial septum, and wherein the balloon is inflated in the second position for preventing the inflow cannula from moving through the inter-atrial septum.

5. The ventricular assist device of claim 3, wherein the balloon is a first balloon, wherein the inflow cannula comprises a second balloon for fixing the inflow cannula to the inter-atrial septum, and wherein the second balloon is positioned a predetermined distance along the length of the inflow cannula from the first balloon and nearer the right atrium.

6. The ventricular assist device of claim 1, wherein the inflow cannula comprises an arm for fixing the inflow cannula to the inter-atrial septum.

7. The ventricular assist device of claim 6, wherein the arm can move between a first and second position, wherein the arm is substantially
parallel to the inflow cannula in the first position for insertion of the inflow cannula and the arm through the inter-atrial septum, and wherein the arm extends substantially perpendicular to the inflow cannula in the second position for preventing the inflow cannula from moving through the inter-atrial septum.

8. The ventricular assist device of claim 7, comprising a spring coupled to the arm and inflow cannula for biasing the arm in the position extending substantially perpendicular to the inflow cannula.

9. The ventricular assist device of claim 6, wherein the arm comprises a material that retains shape memory.

10. The ventricular assist device of claim 6, comprising a release connected to the arm for maintaining the arm in the first position until the release is pulled for releasing the arm such that the spring moves the arm to the second position.

11. The ventricular assist device of claim 6, wherein the arm is a first arm wherein the inflow cannula comprises a second arm for fixing the inflow cannula to the inter-atrial septum, and wherein the second arm is positioned a predetermined distance along the length of the pump from the first arm.

12. The ventricular assist device of claim 6, wherein the arm is a first arm, wherein the inflow cannula comprises a second arm, and comprising a web connected to the first and second arms.

13. The ventricular assist device of claim 12, wherein the web comprises a material selected from the group consisting of a polymer, metal alloy, and biocompatible fabric.

14. The ventricular assist device of claim 1, wherein the inflow cannula comprises a terminal end portion adapted to extend into the ventricle, atrium, or pulmonary vein and comprising an opening for receiving blood from the ventricle, atrium, or pulmonary.
15. The ventricular assist device of claim 14, wherein the terminal end portion comprises a plurality of fenestrations positioned along a length of the terminal end portion.

16. The ventricular assist device of claim 14, wherein the inflow cannula comprises a tubular portion adapted to extend across the inter-atrial septum.

17. The ventricular assist device of claim 16, wherein the first tubular portion comprises a material selected from the group consisting of polymer, metal alloy, and fabric.

18. The ventricular assist device of claim 16, wherein the inflow cannula comprises a flexible portion coupled between the terminal end portion and the tubular portion and adapted to bend such that the terminal end portion inserts into the ventricle, atrium, or pulmonary vein and the tubular portion extends across the inter-atrial septum.

19. The ventricular assist device of claim 1, wherein the inflow cannula comprises a tubular portion adapted to extend through a jugular vein, subclavian vein, or innominate vein.

20. The ventricular assist device of claim 19, wherein the tubular portion comprises a material consisting from the group of polymer, fabric, and metal alloy.

21. The ventricular assist device of claim 1, wherein the pump is adapted to extend through the inter-atrial septum, an atrium, a ventricle, or pulmonary vein.

22. The ventricular assist device of claim 1, wherein the pump comprises a pump selected from the group consisting of an axial flow pump and a centrifugal flow pump.

23. The ventricular assist device of claim 1, wherein the pump comprises a propeller attached to a motor via a driveline for powering the propeller.

24. The ventricular assist device of claim 23, wherein the propeller comprising a material coating the propeller for minimizing blood clot formation or damage to blood cells.
25. The ventricular assist device of claim 1, wherein the pump comprises one or more balloons for fixing the pump to the inter-atrial septum.

26. The ventricular assist device of claim 25, wherein the balloon can move between a first and second position, wherein the balloon is deflated in the first position for insertion of the pump and the balloon through the inter-atrial septum, and wherein the balloon is inflated in the second position for preventing the pump from moving through the inter-atrial septum.

27. The ventricular assist device of claim 25, wherein the balloon is a first balloon, wherein the pump comprises a second balloon for fixing the pump to the inter-atrial septum, and wherein the second balloon is positioned a predetermined distance along the length of the pump from the first balloon and nearer the right atrium.

28. The ventricular assist device of claim 1, wherein the pump comprises an arm for fixing the pump to the inter-atrial septum.

29. The ventricular assist device of claim 28, wherein the arm can move between a first and second position, wherein the arm is substantially parallel to the pump in the first position for insertion of the pump and the arm through the inter-atrial septum, and wherein the arm extends substantially perpendicular to the pump in the second position for preventing the pump from moving through the inter-atrial septum.

30. The ventricular assist device of claim 29, comprising a spring coupled to the arm and pump for biasing the arm in the position extending substantially perpendicular to the pump.

31. The ventricular assist device of claim 28, wherein the arm comprises a material that retains shape memory.

32. The ventricular assist device of claim 28, comprising a release connected to the arm for maintaining the arm in the first position until the release is pulled for releasing the arm such that the spring moves the arm to the second position.
33. The ventricular assist device of claim 28, wherein the arm is a first arm wherein the pump comprises a second arm for fixing the pump to the inter-atrial septum, and wherein the second arm is positioned a predetermined distance along the length of the pump from the first arm.

34. The ventricular assist device of claim 28, wherein the arm is a first arm, wherein the pump comprises a second arm, and comprising a web connected to the first and second arms.

35. The ventricular assist device of claim 34, wherein the web comprises a material selected from the group consisting of a polymer, metal alloy, and biocompatible fabric.

36. The ventricular assist device of claim 1, comprising an outflow cannula adapted to extend through the inter-atrial septum, an atrium, a ventricle, or pulmonary vein.

37. The ventricular assist device of claim 36, wherein the outflow cannula comprises one or more balloons for fixing the outflow cannula to the inter-atrial septum.

38. The ventricular assist device of claim 37, wherein the balloon can move between a first and second position, wherein the balloon is deflated in the first position for insertion of the outflow cannula and the balloon through the inter-atrial septum, and wherein the balloon is inflated in the second position for preventing the outflow cannula from moving through the inter-atrial septum.

39. The ventricular assist device of claim 36, wherein the outflow cannula comprises an arm for fixing the outflow cannula to the inter-atrial septum.

40. The ventricular assist device of claim 39, wherein the arm can move between a first and second position, wherein the arm is substantially parallel to the outflow cannula in the first position for insertion of the outflow cannula and the arm through the inter-atrial septum, and wherein the arm extends substantially perpendicular to the outflow
cannula in the second position for preventing the outflow cannula from moving through the inter-atrial septum.

41. The ventricular assist device of claim 40, comprising a spring coupled to the arm and outflow cannula for biasing the arm in the position extending substantially perpendicular to the outflow cannula.

42. The ventricular assist device of claim 40, wherein the arm comprises a material that retains shape memory.

43. The ventricular assist device of claim 39, comprising a release connected to the arm for maintaining the arm in the first position until the release is pulled for releasing the arm such that the spring moves the arm to the second position.

44. The ventricular assist device of claim 1, wherein the outflow cannula comprises a beveled open end adapted to couple to the artery.

45. The ventricular assist device of claim 1, wherein the outflow cannula comprises a vascular graft material adapted to couple to the artery.

46. The ventricular assist device of claim 1, wherein the outflow cannula comprises an aperture for allowing blood to advance through the artery in an antegrade fashion.

47. The ventricular assist device of claim 1, wherein the outflow cannula comprises a bifurcated outflow cannula.

48. The ventricular assist device of claim 1, wherein the outflow cannula comprises at least two tubes.

49. The ventricular assist device of claim 46, wherein the at least two tubes are positioned in two different arteries.

50. A ventricular assist device, comprising:

(a) an inflow cannula adapted for receiving blood from a ventricle, an atrium, or a pulmonary vein;

(b) an outflow cannula communicating with the inflow cannula and adapted to deliver blood to an artery;

(c) a pump communicating with the inflow cannula and outflow cannula and adapted to advance blood received by the inflow
cannula to the outflow cannula for delivery to the artery, wherein the inflow cannula, the outflow cannula, or the pump is adapted to extend through an inter-atrial septum; and

(d) a fixating device for maintaining a position of the inflow cannula, the outflow cannula, or the pump with respect to the inter-atrial septum.

51. The ventricular assist device of claim 50, wherein the pump comprises a propeller attached to a motor via a driveline for powering the propeller.

52. The ventricular assist device of claim 51, wherein the propeller comprising a material coating the propeller for minimizing blood clot formation or damage to blood cells.

53. The ventricular assist device of claim 50, wherein the fixating device comprises an arm.

54. The ventricular assist device of claim 50, wherein the fixating device comprises a balloon.

55. A ventricular assist device, comprising:
(a) an inflow cannula for receiving blood from a ventricle, an atrium, or a pulmonary vein;
(b) an outflow cannula communicating with the inflow cannula and adapted to deliver blood to an artery; and
(c) a pump communicating with the inflow cannula and outflow cannula and adapted to advance blood received by the inflow cannula to the outflow cannula for delivery to the artery, wherein the inflow cannula, the outflow cannula, or the pump is adapted to extend through an inter-atrial septum.

56. A method of installing a ventricular assist device, the method comprising:
(a) providing a ventricular assisting device, comprising:
   (i) an inflow cannula adapted for receiving blood from a ventricle, an atrium, or a pulmonary vein;
(ii) a pump communicating with the inflow cannula for pumping blood through the inflow cannula; and

(iii) at least a portion of the ventricular assist device being adapted for extending through an inter-atrial septum wherein blood can be advanced through the inter-atrial septum; and

(b) inserting the inflow cannula into the ventricle, atrium, or pulomony vein by passing the inflow cannula through a superior vena cava, a right atrium, the inter-atrial septum, and a left atrium.

57. The method of claim 56, wherein the inflow cannula or the pump comprises a balloon for fixing the inflow cannula or the pump to the inter-atrial septum.

58. The method of claim 57, wherein inserting the inflow cannula comprises inflating the balloon in the left atrium.

59. The method of claim 57, wherein the balloon is a first balloon, wherein the inflow cannula or the pump comprises a second balloon for fixing the inflow cannula or the pump to the inter-atrial septum, and wherein the second balloon is positioned a predetermined distance along the length of the inflow cannula or the pump from the first balloon and nearer the right atrium.

60. The method of claim of claim 59, wherein inserting the inflow cannula comprises:

(a) inflating the first balloon in the left atrium; and

(b) inflating the second balloon in the right atrium.

61. The method of claim 52, wherein inserting the inflow cannula comprises inserting the inflow cannula through a catheter.

62. The method of claim 61, wherein the catheter comprises a flexible tip.

63. The method of claim 62, wherein the flexible tip is operable to be moved by a remote control mechanism.
64. The method of claim 52, wherein the inflow cannula or the pump comprises an arm for fixing the inflow cannula or the pump to the inter-atrial septum.

65. The method of claim 64, wherein inserting the inflow cannula comprises deploying the arm in the left atrium.

66. The method of claim 64, wherein the arm is a first arm, wherein the inflow cannula or the pump comprises a second arm for fixing the inflow cannula or the pump to the inter-atrial septum, and wherein the second arm is positioned a predetermined distance along the length of the inflow cannula or the pump from the first balloon and nearer the right atrium.

67. The method of claim 59, wherein inserting the inflow cannula comprises:
   (a) deploying the first arm in the left atrium; and
   (b) deploying the second arm in the right atrium.

68. The method of claim 52, wherein the step of inserting the inflow cannula comprises accessing a vein for routing the inflow cannula through the vein to the ventricle, atrium, or pulmonary vein.

69. The method of claim 68, wherein the step of inserting the inflow cannula comprises puncturing the inter-atrial septum for providing passage for the inflow cannula or the pump through the inter-atrial septum.

70. The method of claim 69, wherein puncturing the inter-atrial septum comprises utilizing a catheter.

71. The method of claim 69, wherein the catheter is selected from a group consisting of a radiofrequency catheter and an electro-cauterization catheter.

72. The method of claim 69, wherein puncturing the inter-atrial septum comprises utilizing a flexible needle.

73. The method of claim of claim 69, comprising dilating the inter-atrial septum with a device selected from the group consisting of a valvulotome, septal blade, and balloon.
74. The method of claim 56, wherein the step of inserting the inflow cannula comprises routing a sheath through the jugular vein and to a right atrium to provide a passage for advancing the inflow cannula through the jugular vein and into the right atrium.

5 75. The method of claim 74, wherein the sheath comprises a J-tipped sheath.

76. The method of claim 74, wherein the sheath is a first sheath, and comprising routing a second sheath through the first sheath, the inter-atrial septum, the left atrium, the left ventricle, or the pulmonary vein.

10 77. The method of claim 76, wherein the second sheath comprises a body portion and an end angled from the body portion.

78. The method of claim 76, wherein inserting the inflow cannula comprises routing the inflow cannula through the second sheath and into the left ventricle.

15 79. The method of claim 77, comprising directing a wire from the right atrium to the left atrium from a point of access above the heart with the first and second sheaths.

80. The method of claim 79, wherein inserting the inflow cannula comprises routing the inflow cannula or the pump over the wire and into the left atrium, left ventricle, or pulmonary vein.

20 81. The method of claim 80, wherein inserting the inflow cannula comprises routing the inflow cannula or the pump over the wire and into the left atrium, left ventricle, or pulmonary vein.

82. The method of claim 56, comprising directing a wire from the femoral vein through the inter-atrial septum.

25 83. The method of claim 82, comprising snaring the wire with a snare advanced from the jugular vein, subclavian vein, or innominate vein for pulling an end of the wire upward and allowing the wire to protrude from the jugular vein, subclavian vein, or innominate vein.

30 84. The method of claim 56, comprising inserting the pump subcutaneously into a patient.
85. A method of installing a ventricular assist device, the method comprising:
   (a) providing a ventricular assist device, comprising:
       (i) an inflow cannula adapted for receiving blood from a ventricle, an atrium, or a pulmonary vein;
       (ii) a pump communicating with the inflow cannula for pumping blood through the inflow cannula; and
       (iii) at least a portion of the ventricular assist device being adapted for extending through an inter-atrial septum wherein blood can be advanced through the inter-atrial septum;
   (b) puncturing the inter-atrial septum to provide passage for the inflow cannula, the outflow cannula, or the pump through the inter-atrial septum;
   (c) routing a first sheath through a vein for gaining access to the right atrium;
   (d) routing a second sheath through the first sheath, the inter-atrial septum, the left atrium, the left ventricle, or the pulmonary vein;
   (e) routing the inflow cannula or the pump through the second sheath and into the left ventricle; and
   (f) inserting the outflow cannula into the artery.

86. The method of claim 85, wherein the ventricular assist device comprises a fixating device for maintaining a position of the inflow cannula or the pump with respect to the inter-atrial septum.

87. The method of claim 86, wherein the fixating device comprises an arm.

88. The method of claim 86, wherein the fixating device comprises a balloon.

89. The method of claim 85, wherein inserting the inflow cannula comprises inserting the inflow cannula through a catheter.

90. The method of claim 89, wherein the catheter comprises a flexible tip.
91. The method of claim 85, wherein the flexible tip is operable to be moved by a remote control mechanism.

92. A method of installing a ventricular assist device, the method comprising:

5
(a) providing a ventricular assist device, comprising:

(i) an inflow cannula adapted for receiving blood from a ventricle, an atrium, or a pulmonary vein;

(ii) a pump communicating with the inflow cannula for pumping blood through the inflow cannula; and

10
(iii) at least a portion of the ventricular assist device being adapted for extending through an inter-atrial septum wherein blood can be advanced through the inter-atrial septum;

(b) directing a wire from a femoral vein through the inter-atrial septum to provide passage for the inflow cannula, the outflow cannula, or the pump through the inter-atrial septum;

(c) snaring the wire with a snare advanced from the jugular vein, subclavian vein, or innominate vein for pulling an end of the wire upward and allowing the wire to protrude from the jugular vein, subclavian vein, or innominate vein;

15
(d) routing the inflow cannula or the pump along the wire across the inter-atrial septum; and

(e) inserting the outflow cannula into the artery.

93. The method of claim 92, wherein the inflow cannula comprises at least two tubes.

94. The method of claim 93, comprising inserting the inflow cannula into a first vein.
**Fig. 7**

**Fig. 8**
START

PREPARE FOR SURGERY

ACCESS RIGHT INTERNAL JUGULAR, SUBCLAVIAN, AND FEMORAL VEINS

PLACE PUMP SYSTEM IN POCKET

PLACE OUTFLOW CANNULA

PUNCTURE INTER-ATRIAL SEPTUM

PLACE INFLOW CANNULA

PERFORM DE-AIRING

STOP

Fig. 14
Fig. 18
2302 START

2304 PREPARE PATIENT FOR SURGERY

2306 ACCESS VEINS AND ARTERIES

2308 DEPLOY SNARES

2310 PUNCTURE INTER-ATRIAL SEPTUM

2312 EXTEND WIRE ACROSS SEPTUM

2314 PULL DISTAL END OF WIRE FROM FEMORAL VEIN TO JUGULAR VEIN

2316 DILATE PUNCTURE SITE

2318 ADVANCE LVAD TO OPERATING POSITION

2320 ATTACH LVAD TO SEPTUM

2322 CONNECT OUTFLOW CANNULA TO ARTERIES

2324 STOP

Fig. 23