(19) DANMARK

(10) DK/EP 2083901 T3

(12) Oversættelse af europæisk patentskrift

Patent- og Varemærkestyrelsen

(51) Int.Cl.: ***A 61 M 29/00 (2006.01)*** ***A 61 M 1/00 (2006.01)*** ***A 61 M 3/00 (2006.01)*** ***A 61 N 1/362 (2006.01)*** *A 61 M 25/00 (2006.01)*

(45) Oversættelsen bekendtgjort den: **2018-02-26**

(80) Dato for Den Europæiske Patentmyndigheds bekendtgørelse om meddelelse af patentet: **2017-12-27**

(86) Europæisk ansøgning nr.: **07827211.9**

(86) Europæisk indleveringsdag: **2007-10-16**

(87) Den europæiske ansøgnings publiceringsdag: **2009-08-05**

(86) International ansøgning nr.: **IL2007001237**

(87) Internationalt publikationsnr.: **WO2008047354**

(30) Prioritet: **2006-10-16 US 852435 P**

(84) Designerede stater: **AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU LV MC MT NL PL PT RO SE SI SK TR**

(73) Patenthaver: **Medtronic Ventor Technologies Ltd., 14 Hamelacha Street, 42504 Netanya, Israel**

(72) Opfinder: **BENARY, Raphael, 15 Harav Ashi Street, 69395 Tel Aviv, Israel**
TUVAL, Yosi, 16 McDonald Street, 42262 Netanya, Israel

(74) Fuldmægtig i Danmark: **Zacco Denmark A/S, Arne Jacobsens Allé 15, 2300 København S, Danmark**

(54) Benævnelse: **TRANSAPIKALT AFGIVELSESSYSTEM MED VENTRIKULO-ARTERIELT OVERLØBS-BYPASS**

(56) Fremdragne publikationer:
US-A- 5 688 245
US-A1- 2004 191 116
US-B1- 6 241 699
US-B1- 6 935 344

DESCRIPTION

FIELD OF THE INVENTION

[0001] The present invention relates generally to surgical instruments, in particular to instruments for performing implantation procedures on a beating heart.

BACKGROUND OF THE INVENTION

[0002] Recently, minimally invasive approaches have been developed to facilitate catheter-based implantation of valve prostheses on the beating heart, intending to obviate the need for the use of classical sternotomy and cardiopulmonary bypass. These techniques include a transapical approach for aortic valve replacement, typically involving the use of an introducer port, i.e., a large-bore overtube, of a trocar. A crimped, stented valve prosthesis reversibly coupled to a delivery catheter is transcatheterally advanced toward the native valve, where it is either forcefully deployed using a balloon catheter, or, alternatively, passively deployed using a self-expandable system.

[0003] The need to position the crimped valve at the orifice of the native aortic valve for deployment may lead to one or more of the following complications: (1) a reduction in cardiac output secondary to the obstruction of the native valve's orifice by the crimped stented valve prosthesis, until the prosthesis is fully expanded and operative; (2) a substantial increase in left ventricular afterload caused by the obstructed aortic orifice, which may result in left ventricular pump failure; and/or (3) device embolism or migration during deployment of the prosthesis, caused by a forceful left ventricular contraction against the valve prosthesis during attempted stent expansion and deployment.

[0004] Several techniques have been used to reduce the likelihood of these complications. For example, rapid right ventricular pacing induces a transient hemodynamic cardiac arrest. This technique is intended to avoid an excessive increase in afterload during the deployment of the valve prosthesis, and also to reduce the risk of device migration during deployment. However, rapid ventricular pacing deliberately causes a drop in cardiac output, albeit temporarily, which may be poorly tolerated by patients suffering from heavily hypertrophied hearts, reduced left ventricular function, and/or coronary artery disease. Alternatively, extracorporeal or intracorporeal bypass or assist devices have been used, which may further complicate the procedure significantly due to their complexity. For example, advancing part of the tubing system of the intracorporeal bypass into the pulmonary veins requires first creating a large-bore hole in the atrial septum which later needs to be closed with an occluder device. Extracorporeal bypass systems, such as ECMO (extracorporeal membrane oxygenator) may be associated with vascular, hematological and rheological complications.

[0005] US Patent 7,201,772 to Schwammenthal et al. describes a prosthetic device including a valve-orifice attachment member attachable to a valve in a blood vessel and including a fluid inlet, and a diverging member that extends from the fluid inlet. The diverging member includes a proximal end near the fluid inlet and a distal end distanced from the proximal end. A distal portion of the diverging member has a larger cross-sectional area for fluid flow therethrough than a proximal portion thereof. The diverging member may have a diverging taper that causes fluid to flow therethrough with pressure recovery at the distal end thereof.

[0006] PCT Publication WO 06/070372 to Schwammenthal et al. describes apparatus including a prosthetic device having a single flow field therethrough, adapted for implantation in a subject, and shaped so as to define a fluid inlet and a diverging section, distal to the fluid inlet. The prosthetic device includes a plurality of axially-extending struts which extend along at least a portion of the diverging section and diverge outwardly, such that distal ends of the struts are spaced further from one another than proximal ends of the struts throughout a cardiac cycle of the subject. The diverging section includes a diverging envelope coupled to the struts, which is adapted to assume an open position thereof during systole, permitting blood flow through the device, and which is adapted to collapse to a closed position thereof during diastole, inhibiting blood flow through the device.

[0007] PCT Publication WO 05/002466 to Schwammenthal et al. describes prosthetic devices as described for use in the treatment of aortic stenosis in the aortic valve of a patient's heart. The prosthetic device has a compressed state for transarterial delivery, and is expandable to an expanded state for implantation. The prosthetic device includes an expandable metal base constructed so as to be implantable in the expanded state of the prosthetic device in the aortic annulus of the aortic valve; and an inner envelope lining tune inner surface of the metal base. The inner envelope, in the expanded state of the prosthetic device, extends into the aorta and is of a diverging conical configuration, in which its diameter gradually increases from its proximal end within the aortic annulus to its distal end extending into the aorta, such as to produce, during systole, a non-turbulent blood flow into the aorta with pressure recovery at the distal end of the inner envelope. Preferably, the distal end includes a prosthetic valve which is also concurrently implanted, but such a prosthetic valve may be implanted separately in the aorta. Also described are preferred methods of implanting such prosthetic devices.

[0008] The following patents may be of interest:

US Patent 6,395,026 to Aboul-Hosn et al.

US Patent 6,935,344 to Aboul-Hosn et al.

US Patent 6,532,964 to Aboul-Hosn et al.

[0009] US 2009/0191116 describes a circulatory support system.

[0010] US 6,241,699 describes a catheter system and method for posterior epicardial revascularization and intracardiac surgery on a beating heart.

SUMMARY OF THE INVENTION

[0011] Claim 1 defines the scope of the invention and the dependent claims disclose the preferred embodiment. In some embodiments of the present invention, a delivery system housing a valvular prosthetic device is configured to allow blood to bypass the aortic valve during the advancement of the delivery system through the aortic valve. Typically, the system comprises a delivery catheter, e.g., a trocar tube, which houses the prosthesis in a compressed state at a distal end of the tube. The trocar tube is typically transapically advanced into the heart of the patient. In some embodiments, however, the trocar tube is configured for transmyocardial advancement at locations other than the apex of the heart. For example, the trocar tube may be introduced anterior and superior to the apex of the heart at the left ventricle. During delivery of the prosthesis to the aortic surface of the native aortic valve, a distal portion of the trocar tube is advanced through the aortic valve, thereby creating a temporary blockage at the aortic valve.

[0012] Typically, a ventricular portion of the tube is shaped to provide a plurality of holes configured to drain the blood from the left ventricle. In order to bypass the temporary blockage at the aortic valve, the trocar tube is configured to direct blood flow from the left ventricle to one or more arteries downstream of the aorta (e.g., the femoral arteries, the common iliac arteries, or the descending aorta) rather than through the aortic valve. The bypass (a) helps maintain normal cardiac output (or prevent a critical drop in output), and (b) helps reduce the possibility of an excessive increase in contractile resistance of the left ventricle against pressure generated by the blockage.

[0013] Typically, an extracardiac portion of the tube is shaped to provide at least one port which is coupled to a bypass tube at a first end thereof. The second end of the bypass tube is configured to be disposed within one of the abovementioned arteries. The bypass tube is configured to direct blood from the left ventricle into the artery. The bypass tube typically comprises a mechanical valve mechanism that facilitates unidirectional blood flow from the left ventricle to the arteries. Thus, when a prosthetic device is inserted into the aorta, the system creates a bypass flow pathway from the left ventricle into the downstream arteries by bypassing the temporary blockage of the aortic valve created by the trocar tube.

[0014] In some embodiments of the present invention, the distal end of the trocar tube remains within the left ventricle and is not advanced through the native aortic valve. In such an embodiment, the prosthetic device is typically surrounded by a sheath which prevents expansion of the compressed prosthesis during the advancement of the prosthesis through the valve. The sheath is removed once the prosthesis is advanced through the valve, allowing the prosthesis to expand. Alternatively, the prosthesis is not self-expandable, and is instead expanded by inflating a balloon disposed within the prosthesis. Since the distal end of the

trocar tube remains disposed within the left ventricle in this embodiment, the blood is allowed to flow through the trocar tube from the left ventricle to one or more extracardiac arterial sites that are downstream of the left ventricle. In such an embodiment, the trocar tube typically (but not necessarily) does not provide the plurality of holes described hereinabove.

[0015] In an embodiment of the present invention, a transmyocardial approach is used in order to introduce a cardiopulmonary bypass system into the right ventricle of the patient. In another embodiment of the present invention, the cardiopulmonary bypass system is introduced through the right ventricular apex. In either embodiment, the cardiopulmonary bypass system comprises a delivery catheter, e.g., a trocar tube (as described hereinabove), which houses a prosthesis configured to be advanced through the native pulmonary valve. As the device is positioned in the vicinity of the pulmonary valve, the delivery catheter creates a temporary blockage at the pulmonary valve. Sheaths coupled to extracardiac portions of the trocar tube direct blood from the right ventricle to the pulmonary arteries at a site downstream of the pulmonary valve, in a manner as described hereinabove with respect to the aortic valve bypass system.

[0016] In embodiments in which a system as described is advanced either into the left ventricle or into the right ventricle, the system is configured to passively induce blood flow through the trocar tube in response to the natural pressure force exerted on the blood by the ventricular contractile force. In other embodiments, the system is coupled to an active assist pump (e.g., a roller pump), in order to direct the blood flow through the trocar tube. For embodiments in which the pump is used, the system may also serve as a left ventricular assist device (LVAD) in acute left ventricular failure patients, particularly when combined with the transmyocardial and/or transapical approach to insert the system into the patient's heart. For some applications, the delivery system is configured to provide another ventriculoarterial bypass, such as ventriculo-brachial or ventriculoaortic bypass.

[0017] There is therefore provided, in accordance with an embodiment of the present invention, apparatus for implanting a prosthetic device in a patient, the apparatus including:

a trocar tube,

a first portion of which is configured to be placed in a left ventricle of the patient during a procedure for implantation of the prosthetic device, and

a second portion of which is configured to be placed in an extracardiac location during the procedure, the first portion being shaped so as to define at least one.opening to an interior thereof; and

one or more flexible bypass tubes, each of which is coupled to the second portion, and each of which is configured to be coupled to at least one artery of the patient, so as to create a blood flow bypass path during the procedure, from the left ventricle, via the opening and the bypass tubes, to the at least one artery.

[0018] In an embodiment, the apparatus includes one or more unidirectional valves configured to prevent backflow of blood into the left ventricle.

[0019] A distal end of the first portion is shaped so as to define the at least one opening therethrough to the interior of the first portion, and the trocar tube is configured to enable introduction of the prosthetic device via the at least one opening.

[0020] In an embodiment, the apparatus is configured to allow for passive blood flow through the at least one opening of the trocar tube in response to force generated by the left ventricle.

[0021] In an embodiment, the apparatus includes an external source of power, the source of power is configured to facilitate active blood flow through the at least one opening of the trocar tube.

[0022] In an embodiment, the trocar tube is configured for transmyocardial delivery through a free wall of a heart of the patient.

[0023] In an embodiment, the trocar tube is configured for transapical delivery through an apex of a heart of the patient, into the left ventricle of the patient.

[0024] In an embodiment, the valve includes an aortic valve, and the one or more bypass tubes are configured to create a blood flow bypass to a descending aorta of the patient.

[0025] In an embodiment, the valve includes an aortic valve, and the one or more bypass tubes are configured to create a blood flow bypass to a femoral artery of the patient.

[0026] In an embodiment, the valve includes an aortic valve, and the one or more bypass tubes are configured to create a blood flow bypass to an iliac artery of the patient.

[0027] In an embodiment, the first portion is shaped to define a wall, the wall being shaped so as to define the at least one opening to the interior of the first portion.

[0028] In an embodiment, the wall of the first portion is shaped to provide a plurality of openings.

[0029] In an embodiment, the first portion of the trocar tube is configured to house therein the prosthetic device in a compressed state thereof.

[0030] In an embodiment, the prosthetic device is configured to be pushed through a valve of the patient from within the first portion.

[0031] In an embodiment, the prosthetic device is configured to expand from the compressed state once the prosthetic device is pushed through the valve.

[0032] In an embodiment, a portion of the first portion is configured to be advanced through a valve of the subject, and the prosthetic device is configured to be pushed from within the first portion once the first portion is advanced through the valve.

[0033] In an embodiment, the prosthetic device is configured to expand from the compressed state once the prosthetic device is pushed from within the first portion of the tube.

[0034] In an embodiment, the prosthetic device includes a prosthetic valve.

[0035] In an embodiment, the prosthetic valve is configured to be advanced through a native valve of the patient.

[0036] In an embodiment, the one or more bypass tubes are configured to create the blood flow bypass path during advancement of the prosthetic valve through the native valve of the patient.

[0037] There is further described an exemplary method for implanting a prosthetic device in a patient, the method including:

transmyocardially advancing a trocar tube housing a prosthesis into a left ventricle of a subject;

advancing the prosthesis through a valve of the patient; and

during the advancing of the prosthesis, providing a blood flow bypass path from the left ventricle of the patient, through at least a portion of the trocar tube, and to an extracardiac arterial site downstream from the valve.

[0038] Advancing the prosthesis may include pushing a distal end of the trocar tube through the valve of the patient.

[0039] The method may include allowing the prosthesis to expand following the advancing of the prosthesis through the valve.

[0040] The valve may include an aortic valve, advancing the prosthesis through the valve includes advancing the prosthesis through the aortic valve, and providing the blood flow bypass path includes providing the blood flow bypass path from the left ventricle to a descending aorta of the patient.

[0041] The valve may include an aortic valve, advancing the prosthesis through the valve includes advancing the prosthesis through the aortic valve, and providing the blood flow bypass path includes providing the blood flow bypass path from the left ventricle to a femoral artery of the patient.

[0042] The valve may include an aortic valve, advancing the prosthesis through the valve includes advancing the prosthesis through the aortic valve, and providing the blood flow bypass path includes providing the blood flow bypass path from the left ventricle to an iliac artery of the patient.

[0043] The method may include restricting blood flow through the valve during the advancing of the prosthesis therethrough.

[0044] Providing a blood flow bypass path may include draining blood from the left ventricle to the extracardiac site in response to the restricting.

[0045] Draining the blood may include actively draining the blood.

[0046] Restricting the blood flow may include increasing a contractile force of the left ventricle, and draining the blood includes allowing the blood to be passively drained through the trocar tube in response to the increasing.

[0047] There is yet further provided, in accordance with an embodiment of the present invention, apparatus for implanting a prosthetic device in a patient, the apparatus including:

a trocar tube,

a first portion of which is configured to be placed in a right ventricle of the patient during a procedure for implantation of the prosthetic device, and

a second portion of which is configured to be placed in an extracardiac location during the procedure, the first portion being shaped so as to define at least one opening to an interior thereof; and

one or more flexible bypass tubes, each of which is coupled to the second portion, and each of which is configured to be coupled to at least one artery of the patient, so as to create a blood flow bypass path during the procedure, from the right ventricle, via the opening and the bypass tubes, to the at least one artery.

[0048] In an embodiment, the apparatus includes one or more unidirectional valves configured to prevent backflow of blood into the right ventricle.

[0049] A distal end of the first portion is shaped so as to define the at least one opening therethrough to the interior of the first portion, and the trocar tube is configured to enable introduction of the prosthetic device via the at least one opening.

[0050] In an embodiment, the apparatus is configured to allow for passive blood flow through the at least one opening of the trocar tube in response to force generated by the right ventricle.

[0051] In an embodiment, the apparatus includes an external source of power, the source of power is configured to facilitate active blood flow through the at least one opening of the trocar tube.

[0052] In an embodiment, the trocar tube is configured for transmyocardial delivery through a free wall of a heart of the patient.

[0053] In an embodiment, the trocar tube is configured for transapical delivery through a right ventricular apex of a heart of the patient, into the right ventricle of the patient.

[0054] In an embodiment, the valve includes a pulmonary valve, and the one or more bypass tubes are configured to create a blood flow bypass to a pulmonary artery of the patient.

[0055] In an embodiment, the first portion is shaped to define a.wall, the wall being shaped so as to define the at least one opening to the interior of the first portion.

[0056] In an embodiment, the wall of the first portion is shaped to provide a plurality of openings.

[0057] In an embodiment, the first portion of the trocar tube is configured to house therein the prosthetic device in a compressed state thereof.

[0058] In an embodiment, the prosthetic device is configured to be pushed through a valve of the patient from within the first portion.

[0059] In an embodiment, the prosthetic device is configured to expand from the compressed state once the prosthetic device is pushed through the valve.

[0060] In an embodiment, a portion of the first portion is configured to be advanced through a valve of the subject, and the prosthetic device is configured to be pushed from within the first portion once the first portion is advanced through the valve.

[0061] In an embodiment, the prosthetic device is configured to expand from the compressed state once the prosthetic device is pushed from within the first portion of the tube.

[0062] In an embodiment, the prosthetic device includes a prosthetic valve.

[0063] In an embodiment, the prosthetic valve is configured to be advanced through a native valve of the patient.

[0064] In an embodiment, the one or more bypass tubes are configured to create the blood flow bypass path during advancement of the prosthetic valve through the native valve of the patient.

[0065] There is additionally described an exemplary method for implanting a prosthetic device in a patient, the method including:

transmyocardially advancing a trocar tube housing a prosthesis into a right ventricle of a patient;

advancing the prosthesis through a valve of the patient; and

during the advancing of the prosthesis, providing a blood flow bypass path from the right ventricle of the patient, through at least a portion of the trocar tube, and to an extracardiac arterial site downstream from the valve.

[0066] Transmyocardially advancing the trocar tube may include transmyocardially advancing the trocar tube through a free wall of the heat.

[0067] Transmyocardially advancing the trocar tube may include transapically advancing the tube through a right ventricular apex and into the right ventricle of the patient.

[0068] Advancing the prosthesis may include pushing a distal end of the trocar tube through the valve of the patient.

[0069] The method may include allowing the prosthesis to expand following the advancing of the prosthesis through the valve.

[0070] The valve may include a pulmonary valve, advancing the prosthesis through the valve includes advancing the prosthesis through the pulmonary valve, and providing the blood flow bypass path includes providing the blood flow bypass path from the right ventricle to a pulmonary artery of the patient.

[0071] The method may include restricting blood flow through the valve during the advancing of the prosthesis therethrough.

[0072] Providing a blood flow bypass path may include draining blood from the right ventricle to the extracardiac site in response to the restricting.

[0073] Draining the blood may include actively draining the blood.

[0074] Restricting the blood flow may include increasing a contractile force of the right ventricle, and draining the blood includes allowing the blood to be passively drained through the trocar tube in response to the increasing.

[0075] There is also provided, in accordance with an embodiment of the present invention, apparatus for implanting a prosthetic device in a patient, the apparatus including:

a trocar tube,

a first portion of which is configured to be placed in a left ventricle of the patient during a procedure for implantation of the prosthetic device, and

a second portion of which is configured to be placed in an extracardiac location during the procedure,

wherein the first portion is shaped so as to define at least one opening to an interior thereof; and,

one or more flexible bypass tubes, each of which is coupled to the second portion, and each of which is configured to be coupled to at least one artery of the patient, so as to create a blood flow bypass path during the procedure, from the left ventricle, via the opening and the bypass tubes, to the at least one artery.

[0076] In an embodiment, the apparatus includes one or more one-way valves configured to prevent backflow of blood into the left ventricle.

[0077] A distal end of the first portion is shaped so as to define the at least one opening therethrough to the interior of the first portion, and the trocar tube is configured enable introduction of the prosthetic device via the at least one opening.

[0078] For some applications, the apparatus is configured such that blood flow through the bypass is driven only by force generated by the left ventricle: Alternatively, the apparatus is configured such that blood flow through the bypass is at least in part driven by an external source of power.

[0079] The present invention will be more fully understood from the following detailed description of embodiments thereof, taken together with the drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

[0080]

Fig. 1 is a schematic illustration of a bypass device and delivery system therefor, in accordance with an embodiment of the present invention;

Fig. 2 is a schematic illustration of a trocar tube of the delivery system of Fig. 1, within a left ventricle of a patient, in accordance with an embodiment of the present invention;

Fig. 3 is a schematic illustration of a prosthesis emerging from within the trocar tube of Fig. 2, in accordance with an embodiment of the present invention;

Fig. 4 is a schematic illustration of a portion of the bypass device within a descending aorta of the patient, in accordance with an embodiment of the present invention;

Fig. 5 is a schematic illustration of a portion of the bypass device inserted into a downstream artery of the aorta, in accordance with an embodiment of the present invention; and

Fig. 6 is a schematic illustration of a bypass device and delivery system therefor, in accordance with another embodiment of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS

[0081] Fig. 1 is a schematic illustration of a prosthetic device delivery system 100, in accordance with an embodiment of the present invention. Delivery system 100 comprises a trocar tube 101 housing a prosthetic valvular device 108 at a distal end of tube 101. Typically, prosthetic device 108 comprises a self-expanding, biocompatible, resilient material, e.g., nitinol, stainless steel, or other such materials known in the art. The distal end of trocar tube 101 is configured to be advanced toward leaflets 11 of a native aortic valve of the patient. In some embodiments, the distal end of tube 101 is configured to be advanced through leaflets 11 to a site within the ascending aorta 10, downstream of leaflets 11. During advancement of prosthetic device 108 through leaflets 11, system 100 creates a temporary blockage at the aortic valve. In order to supply blood to arteries downstream of the heart during the advancement and subsequent implantation of prosthetic device 108, system 100 provides a bypass mechanism configured to supply blood from left ventricle 12 to one or more arteries 30 downstream of aorta 10.

[0082] Trocar tube 101 is shaped so as to define a plurality of holes 102 at a ventricular portion of tube 101. The ventricular portion of tube 101 is configured to be disposed in left ventricle 12 as prosthetic device 108 is delivered to the aortic surface of leaflets 11. Typically, prosthetic device 108 is advanced through the aortic valve as the heart is beating. The distal end of tube 101 occludes the aortic valve during the delivery of device 108 therethrough. The blockage, in combination with contractile force of left ventricle 12 against the occluded valve, forces the blood to passively flow from ventricle 12 into holes 102 of tube 101.

[0083] Delivery system 100 further comprises one or more flexible bypass tubes 103 and 104, which are coupled to an extracardiac portion of trocar tube 101. Typically, tubes 103 and 104 comprise a flexible material, e.g., silicone, rubber, or polyvinyl chloride (PVC). First ends of tubes 103 and 104 are coupled to extracardiac portions of tube 101, as shown, via holes in the extracardiac portions of tube 101. During the percutaneous delivery of system 100, portions of bypass tubes 103 and 104 remain disposed outside the body of the patient, while the first ends of tubes 103 and 104 are advanced toward the heart along with the advancement of system 100. Once the intracardiac portion of system 100 is positioned in left ventricle 12 of the heart, second ends of tubes 103 and 104 are introduced within artery 30 of the patient, typically via

percutaneous incisions in the vicinity of artery 30. As shown, tube 103 is placed in a first branch 20 of artery 30, while tube 104 is placed in a second branch 21 of artery 30. In some embodiments of the present invention, artery 30 includes a femoral artery. In some embodiments, artery 30 includes an iliac artery. In some embodiments, artery 30 includes a descending aorta, as shown hereinbelow with reference to Fig. 4.

[0084] Typically, bypass tubes 103 and 104 comprise one or more unidirectional valves 105 that prevent retrograde flow of blood into left ventricle 12. In some embodiments, trocar tube 101 comprises at least one valve 105.

[0085] During the advancement and subsequent implantation of prosthetic device 108 at the aortic valve, holes 102 drain blood from ventricle 12 during contraction thereof. System 100 thereby facilitates a bypass flow of the blood from ventricle 12, into tube 101, through bypass tubes 103 and 104, and ultimately into downstream artery 30. In such an embodiment, blood is generally not passed directly through the aortic valve and into aorta 10.

[0086] It is to be noted that the use of two bypass tubes 103 and 104 is shown by way of illustration and not limitation, and that one or more bypass tubes may be used.

[0087] Once the distal end of tube 101 is advanced through leaflets 11, prosthetic device 108 is pushed from within tube 101 by a prosthetic device delivery shaft 109 (Fig. 3).

[0088] It is to be noted that although blood is directed away from aorta 10 during systole, coronary ostia 13 are still supplied blood during retroperfusion of the blood within the arteries during the cardiac cycle.

[0089] Fig. 2 is a schematic illustration of the distal end of trocar tube 101 being placed within left ventricle 12 of the patient, in accordance with an embodiment of the present invention. During advancement of system 100 toward the aortic valve, prosthetic device 108 is disposed in a compressed state within trocar tube 101.

[0090] Fig. 3 is a schematic illustration of the advancement of prosthetic device 108 through leaflets 11 of the aortic valve, in accordance with an embodiment of the present invention. As shown, the distal end of trocar tube 101 is configured to remain upstream of valve leaflets 11 in a ventricular vicinity of leaflets 11. In some embodiments, the distal end of tube 101 may be advanced at least in part, but typically not fully, through the native valve.

[0091] During advancement of prosthetic device 108 and prosthetic device delivery shaft 109 toward the aortic valve, the presence of device 108 within the distal end of tube 101 restricts drainage of blood from the left ventricle into tube 101. Once the distal end of tube 101 reaches the ventricular surface of the aortic valve, prosthetic device 108 is pushed from within tube 101 by pushing on the prosthesis delivery shaft 109. Pushing prosthesis 108 from within tube 101 frees an opening at the distal end of tube 101, thereby allowing blood from ventricle 12 to drain into the interior of tube 101. (Alternatively or additionally, holes 102 allow such drainage of

blood.)

[0092] Prosthetic device 108 is further advanced through the aortic valve and is allowed to self-expand once inside aorta 10. In some embodiments, a balloon is disposed within the compressed prosthesis during the advancement of prosthetic device 108 toward the aortic valve of the patient. Once prosthetic device 108 is positioned at the aortic surface of the aortic valve, prosthetic device 108 is made to expand by inflating the balloon.

[0093] As shown, the distal end of trocar tube 101 is typically not advanced through the native valve. Instead, once prosthetic device 108 is advanced through native aortic valve leaflets 11, blood is allowed to passively flow around the prosthetic device shaft 109, and into an opening at the distal end of trocar tube 101. In such an embodiment, trocar tube 101 is not shaped so as to define holes 102, as described hereinabove with reference to Figs. 1 and 2. However, in some embodiments, trocar tube 101 is shaped so as to define holes 102. In such an embodiment, blood flows through holes 102 as well as through the opening at the distal end of tube 101.

[0094] As described hereinabove with reference to Fig. 1, system 100 bypasses blood from left ventricle 12 to any suitable downstream artery 30.

[0095] Fig. 4 is a schematic illustration of the bypass blood flow from left ventricle 12 to one or more extracardiac sites that are downstream of left ventricle 12, as described hereinabove with reference to Figs. 1-3, with the exception that a portion of system 100 is inserted into the descending aorta of the patient, in accordance with an embodiment of the present invention. As shown, blood travels unidirectionally from within tube 101 and into a bypass tube 106 via valve 105. Bypass tube 106 diverts the blood from ventricle 12 into downstream artery 30, the descending aorta (as shown). Bypass tube 106 is inserted into the body of the patient as described hereinabove with reference to tubes 103 and 104, with the exception that the second end of bypass tube 106 is inserted, via a percutaneous incision, into the descending aorta.

[0096] Fig. 5 is a schematic illustration of system 100 described hereinabove with reference to Fig. 1, with the exception that system 100 comprises an arterial introducer sheath 110, in accordance with an embodiment of the present invention. The second end of bypass tube 103 is inserted into downstream artery 30 via arterial introducer sheath 110. Sheath 110 is configured to generate a smooth flow of blood from within bypass tube 103 into artery 30. For clarity of illustration, the continuation of bypass tube 104 is not shown. It is to be noted that arterial sheath 110 may be used in combination with any of the tubes described herein.

[0097] Reference is now made to Fig. 6, which is a schematic illustration of system 100 comprising a cardiopulmonary bypass system, in accordance with an embodiment of the present invention. Typically, trocar tube 101 is advanced into a right ventricle 31 using a transmyocardial approach, whereby tube 101 is advanced through the right ventricular apex of the heart. Using some embodiments, tube 101 is advanced through any portion of the free wall

of the heart using a transmyocardial approach (embodiment not shown).

[0098] Once the distal end of tube 101 is advanced through the pulmonary valve, blood is drained through holes 102 of tube 101, through tube 101, and subsequently into bypass tubes 103 and 104. The distal end of tube 101 occludes the pulmonary valve as it is advanced through the pulmonary valve. The blockage, in combination with contractile force of right ventricle 31 on the blood, forces the blood to passively flow from ventricle 31 into holes 102 of tube 101. In a manner as described hereinabove with reference to Fig. 1, a second end of tube 103 is disposed within a left branch 24 of pulmonary artery 23, and a second end of tube 104 is disposed within a right branch 25 of pulmonary artery 23. Such a configuration diverts blood from ventricle 31 and into branches 24 and 25 of pulmonary artery 23.

[0099] It is to be noted that system 100 shown in Fig. 6 without prosthetic device 108 is shown by way of illustration and not limitation, and that the distal end of tube 101 typically houses device 108.

[0100] It is to be further noted that the cardiopulmonary bypass system described with reference to Fig. 6 may be used independently of or in combination with techniques and apparatus described hereinabove with reference to Figs. 1-5. For example, the distal end of tube 101 is configured to remain within right ventricle 31 while not being advanced through the pulmonary valve, as described hereinabove with reference to Fig. 3. In such an embodiment, blood is drained from ventricle 31 into tube 101 through the opening at the distal end of tube 101.

[0101] In either embodiment in which tube 101 is advanced into either left ventricle - 12 or right ventricle 31, blood is caused to passively flow through trocar 101 tube in response to the natural pressure force exerted on the blood by the ventricular contractile force. Alternatively, in some embodiments, system 100 is coupled to an active assist pump (e.g., a roller pump) in order to direct the blood flow through trocar tube 101.

[0102] The scope of the present invention includes embodiments described in the following patent and patent applications, which are assigned to the assignee of the present application. In an embodiment, techniques and apparatus described in one or more of the following patent and patent applications are combined with techniques and apparatus described herein:

- US Patent 7,201,772, filed December 30, 2004;
- International Patent Application PCT/IL2005/01399, filed December 29, 2005;
- International Patent Application PCT/IL2004/000601, filed July 6, 2004, and US Patent Application 10/563,384, filed January 5, 2006 in the national stage thereof; and/or
- US Patent Application 11/728,253, filed March 23, 2007, entitled, "Valve prosthesis fixation techniques using sandwiching."

[0103] For some applications, techniques described herein are practiced in combination with

techniques described in one or more of the references cited in the Cross-references section or Background section of the present patent application.

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US7201772B **[0005] [0102]**
- WO06070372A **[0006]**
- WO05002466A **[0007]**
- US6395026B **[0008]**
- US6935344B **[0008]**
- US6532964B **[0008]**
- US20090191116A **[0009]**
- US6241699B **[0010]**
- IL200501399W **[0102]**
- IL2004000601W **[0102]**
- US10563384B **[0102]**
- US11728253B **[0102]**

PATENTKRAV

1. Apparat til implantering af en proteseindretning hos en patient, hvilket apparat omfatter:

et trokartrør (101),

en første del af hvilken er konfigureret til at blive placeret i en venstre (højre) ventrikel (12) hos patienten under et indgreb til implantering af proteseindretningen, og en anden del af hvilken er konfigureret til at blive placeret på en ekstrakardial lokalitet under indgrebet, idet den første del er formet med henblik på at definere mindst én åbning til et indre deraf; og

ét eller flere bøjelige bypass-rør (103, 104), hvert af hvilke er sammenkoblet med den anden del, og hvert af hvilke er konfigureret til at blive sammenkoblet med mindst én arterie (30) hos patienten med henblik på at skabe en blodgennemstrømnings-bypass-vej under indgrebet fra den venstre (højre) ventrikel (12) via åbningen og bypass-rørene til den mindst ene arterie, hvor en distal ende af den første del er formet med henblik på at definere den mindst ene åbning derigennem til det indre af den første del, og hvor trokartrøret (101) er konfigureret til at muliggøre indføring af proteseindretningen via den mindst ene åbning.

2. Apparat ifølge krav 1, der omfatter én eller flere envejsventiler (105), som er konfigureret til at forhindre tilbagestrømning af blod ind i den venstre (højre) ventrikel.

3. Apparat ifølge krav 1, hvor apparatet er konfigureret til at muliggøre passiv blodgennemstrømning gennem trokartrørets mindst ene åbning som reaktion på kraft genereret af den venstre (højre) ventrikel.

4. Apparat ifølge krav 1, der endvidere omfatter en ekstern kraftkilde, hvor kraftkilden er konfigureret til at facilitere aktiv blodgennemstrømning gennem trokartrørets mindst ene åbning.

5. Apparat ifølge krav 1, hvor trokartrøret er konfigureret til transmyokardiel afgivelse

gennem en fri væg i et hjerte hos patienten.

6. Apparat ifølge krav 1, hvor trokartrøret er konfigureret til transapikal afgivelse gennem en apex i et hjerte hos patienten og ind i den venstre (højre) ventrikel hos patienten.

7. Apparat ifølge et hvilket som helst af kravene 1-6, hvor den første del er formet med henblik på at definere en væg, idet væggen er formet med henblik på at definere den mindst ene åbning til den indre af den første del.

8. Apparat ifølge krav 7, hvor væggen i den første del er formet med henblik på at tilvejebringe en flerhed af åbninger (102).

9. Apparat ifølge et hvilket som helst af kravene 1-6, der endvidere omfatter proteseindretningen (108), hvor den første del af trokartrøret er konfigureret til deri at rumme proteseindretningen (108) i komprimeret tilstand deraf.

10. Apparat ifølge krav 9, hvor proteseindretningen (108) er konfigureret til at blive skubbet gennem en ventil hos patienten indefra den første del.

11. Apparat ifølge krav 10, hvor proteseindretningen (108) er konfigureret til at ekspandere fra den komprimerede tilstand, når først proteseindretningen er skubbet gennem ventilen.

12. Apparat ifølge krav 9, hvor en del af den første del er konfigureret til at blive bevæget fremad gennem en ventil hos patienten, og hvor proteseindretningen (108) er konfigureret til at blive skubbet indefra den første del, når først den første del er bevæget fremad gennem ventilen.

13. Apparat ifølge krav 12, hvor proteseindretningen (108) er konfigureret til at ekspandere fra den komprimerede tilstand, når først proteseindretningen er skubbet

indefra den første del af røret.

14. Apparat ifølge et hvilket som helst af kravene 1-6, der endvidere omfatter proteseindretningen (108), hvor proteseindretningen (108) omfatter en proteseventil.

15. Apparat ifølge krav 14, hvor proteseventilen er konfigureret til at blive bevæget fremad gennem en nativ ventil hos patienten.

16. Apparat ifølge krav 15, hvor det ene eller flere bypass-rør (103, 104, 106) er konfigureret til at skabe blodgennemstrømnings-bypass-vejen under fremføring af proteseventilen gennem den native ventil hos patienten.

17. Apparat ifølge krav 12, hvor den første del er konfigureret til at blive placeret i en venstre ventrikel, og ventilen indbefatter en aortaventil, og hvor det ene eller flere bypass-rør er konfigureret til at skabe en blodgennemstrømnings-bypass til en descenderende aorta eller en arteria femoralis eller en arteria iliaca hos patienten.

18. Apparat ifølge krav 12, hvor den første del er konfigureret til at blive placeret i en højre ventrikel, og ventilen indbefatter en lungeventil, og hvor det ene eller flere bypass-rør er konfigureret til at skabe en blodgennemstrømnings-bypass til en arteria pulmonalis hos patienten.

DRAWINGS

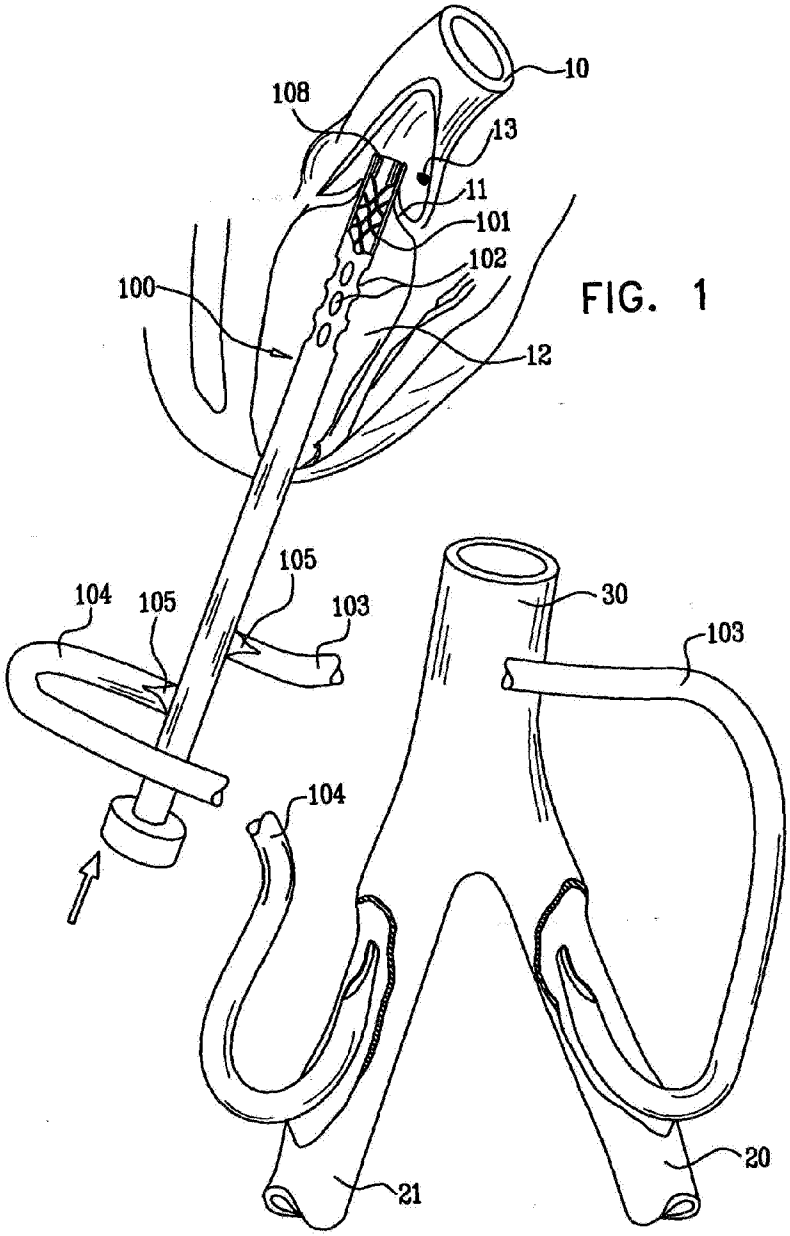
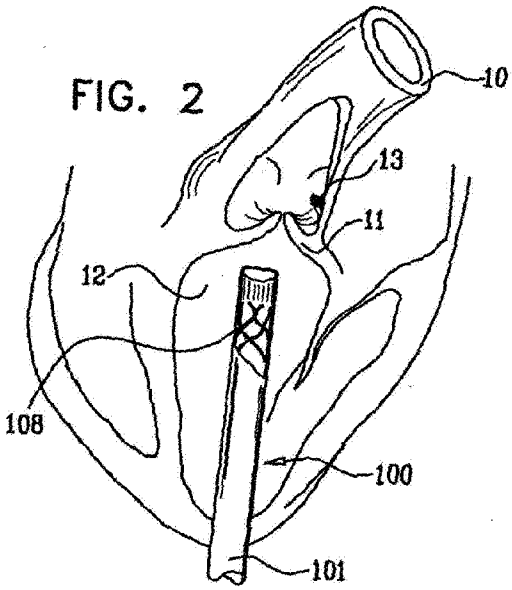


FIG. 1

FIG. 2



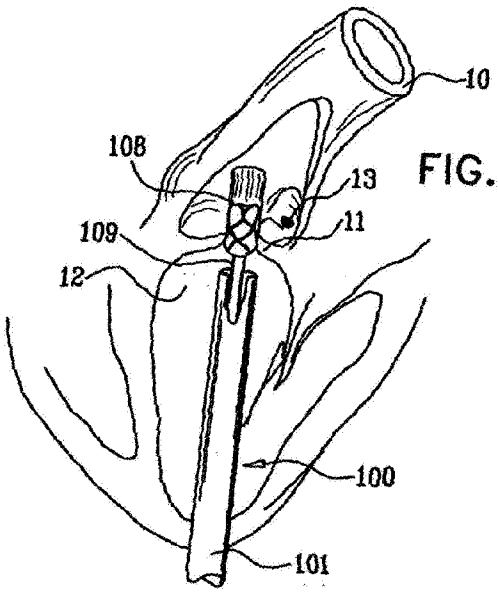


FIG. 3

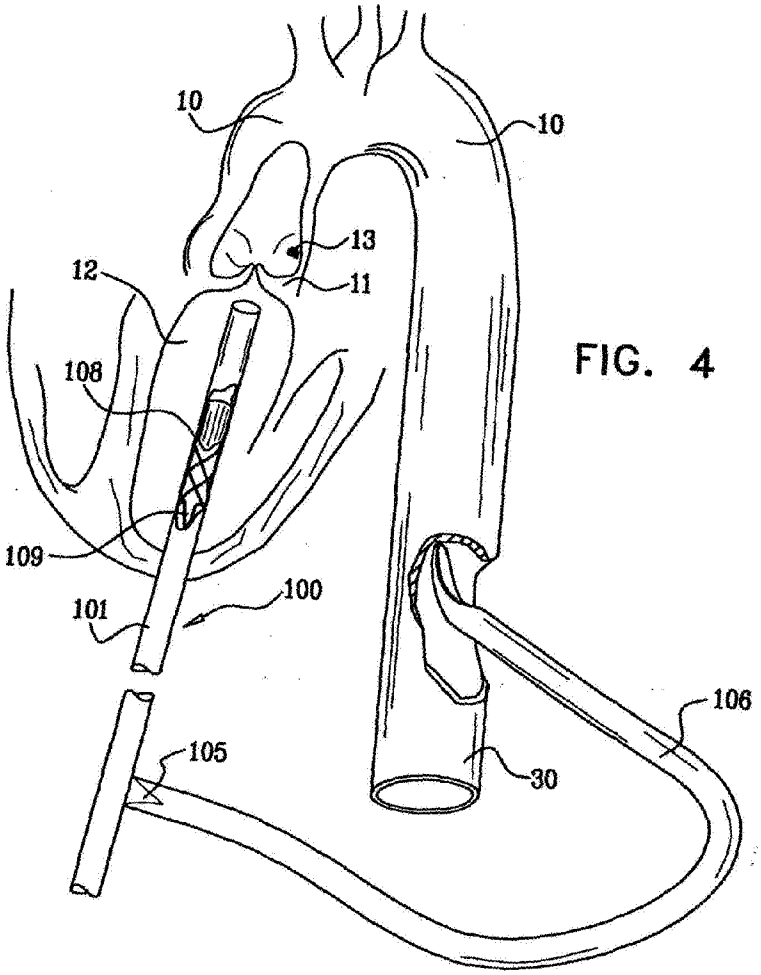


FIG. 4

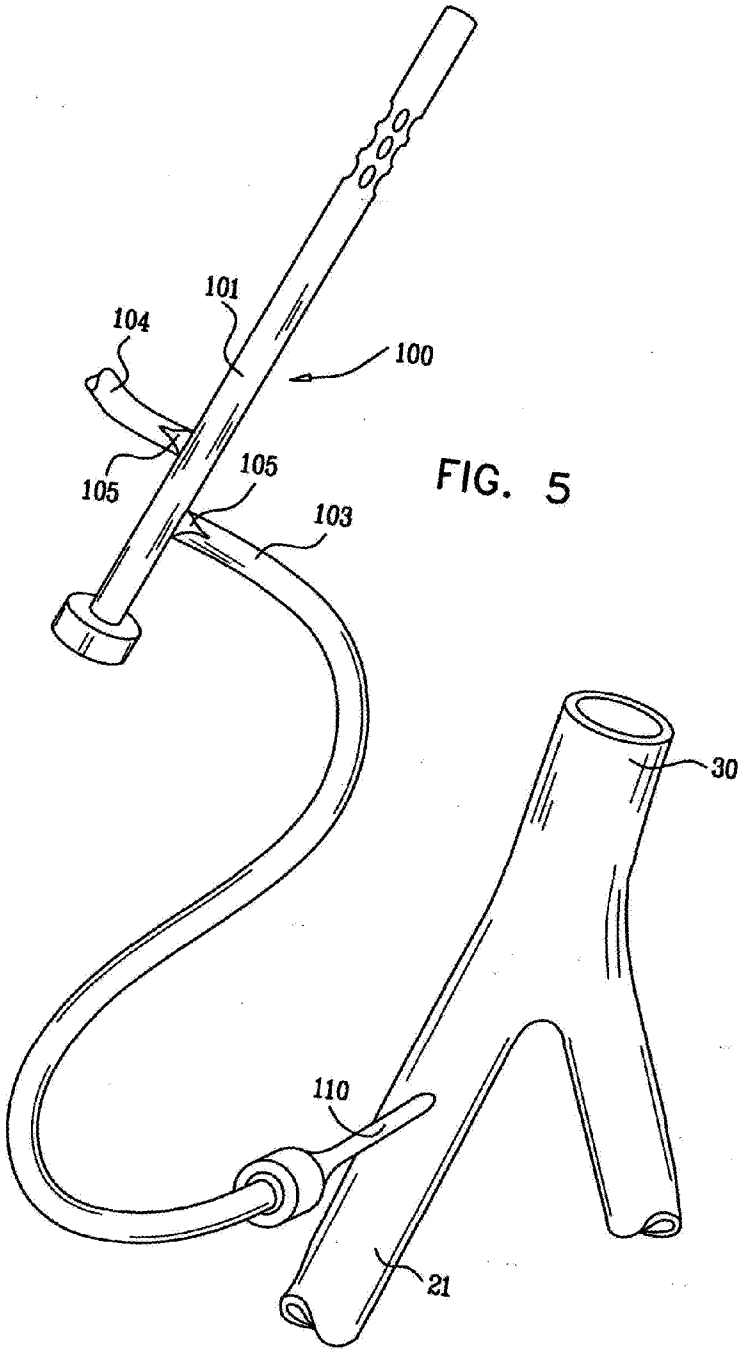


FIG. 5

FIG. 6

