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**Vassiliades et al.**

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(54) **VASCULAR CONDUIT DEVICE AND SYSTEM FOR IMPLANTING**

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See application file for complete search history.

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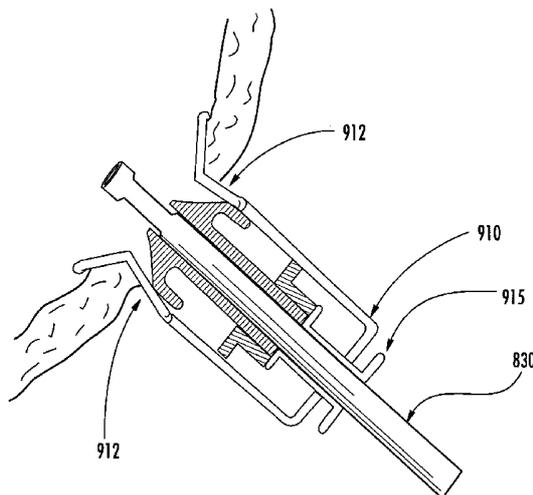
(52) **U.S. Cl.**  
CPC ..... **A61B 17/11** (2013.01); **A61F 2/064** (2013.01); **A61F 2/2493** (2013.01); **A61B 2017/00243** (2013.01); **A61B 2017/00252** (2013.01); **A61B 2017/1107** (2013.01); **A61B 2017/1135** (2013.01)

(57) **ABSTRACT**

The present invention provides a vascular conduit device including a deformable flange and complementary securing ring in cooperation for securing the device within an aperture defined in a tissue wall. The present invention further provides a system for implanting such a vascular conduit device in a tissue wall. More specifically, the present invention provides a system including a coring device for defining an aperture in a tissue wall (such as a ventricle and/or a blood vessel) and securely implanting a vascular conduit device therein so as to provide fluid communication between a first and second surface of the tissue wall via the vascular conduit device.

(58) **Field of Classification Search**  
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**31 Claims, 8 Drawing Sheets**



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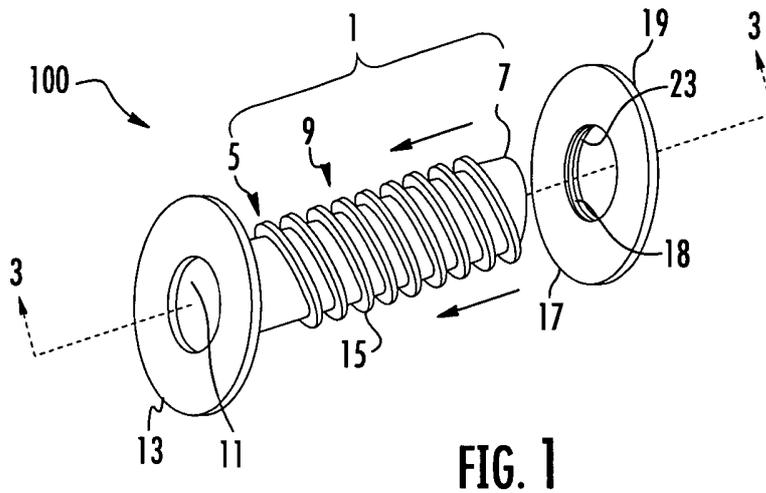


FIG. 1

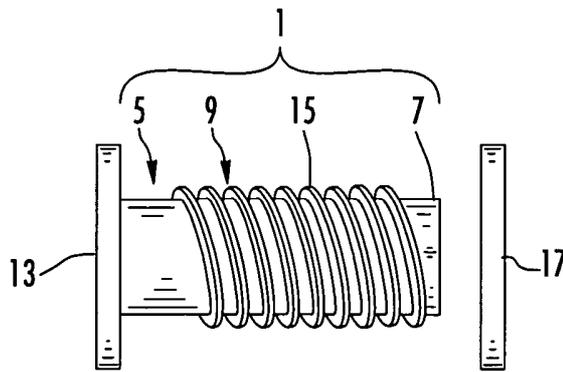


FIG. 2

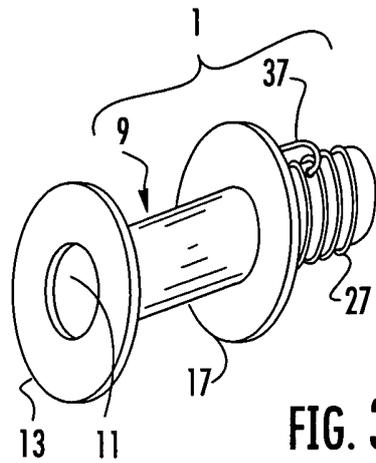


FIG. 3

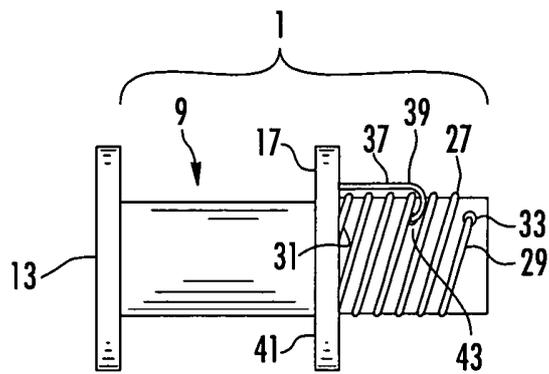


FIG. 4

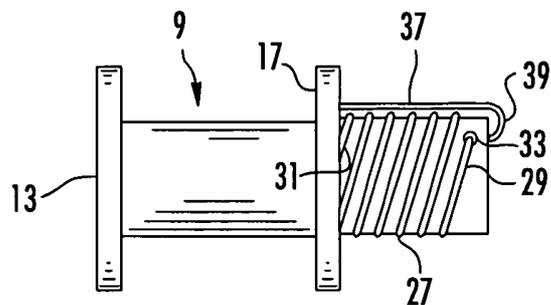


FIG. 5

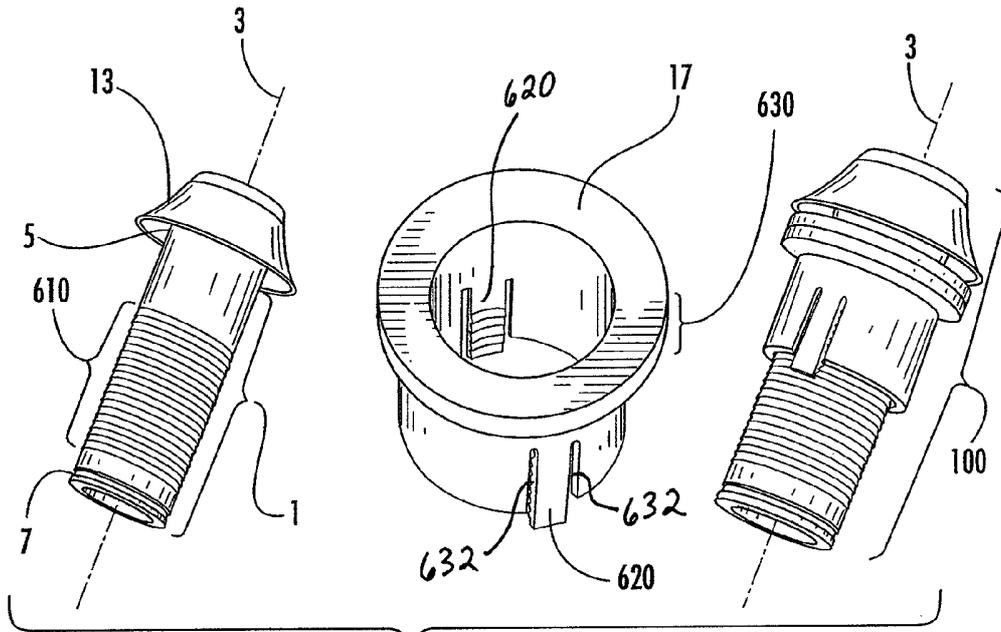


FIG. 6

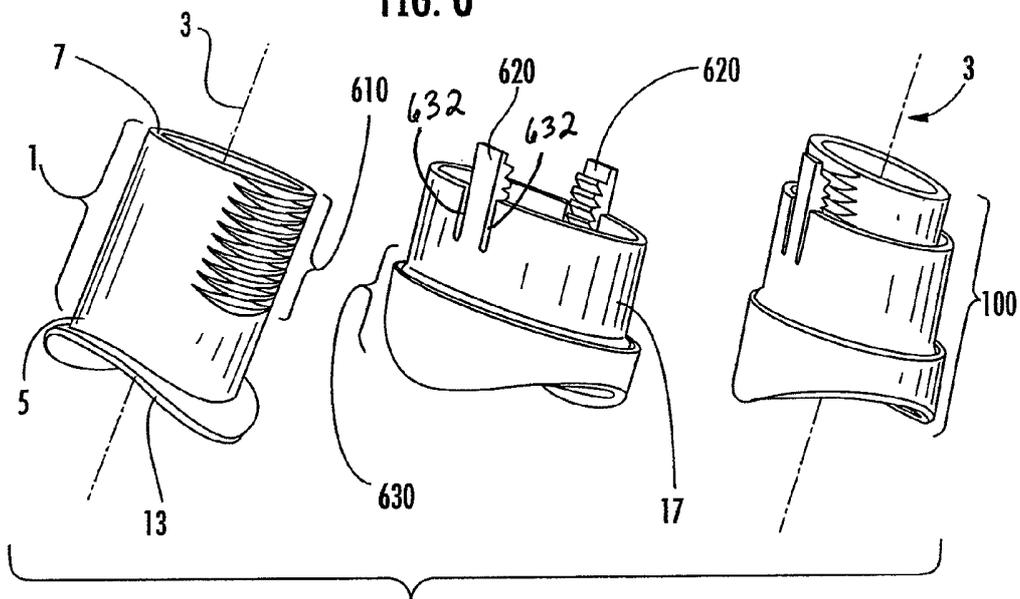
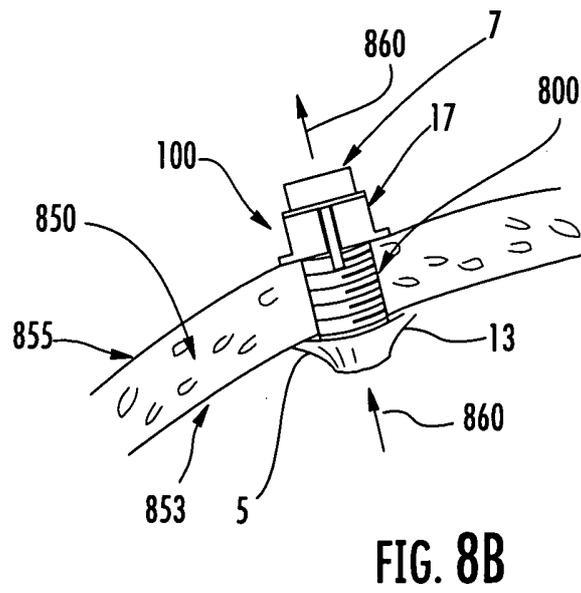
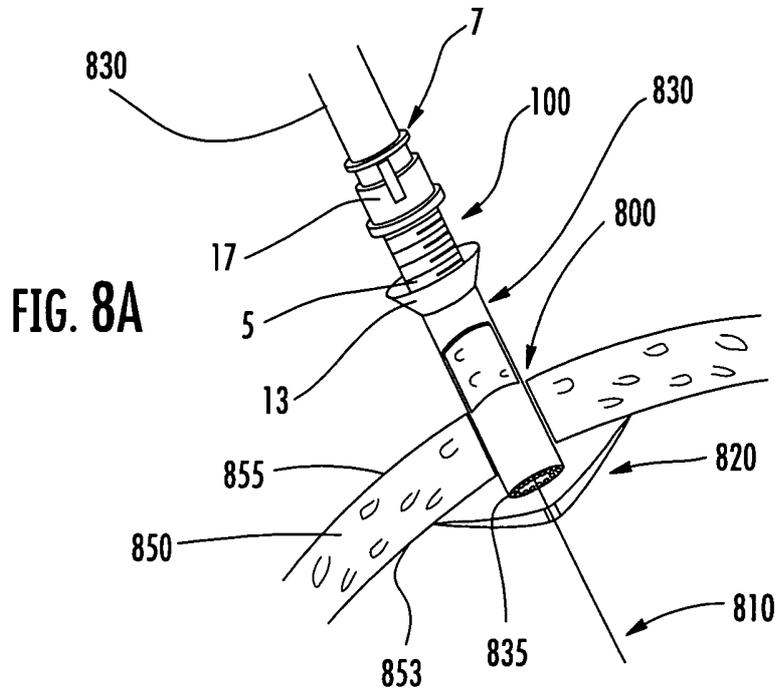


FIG. 7



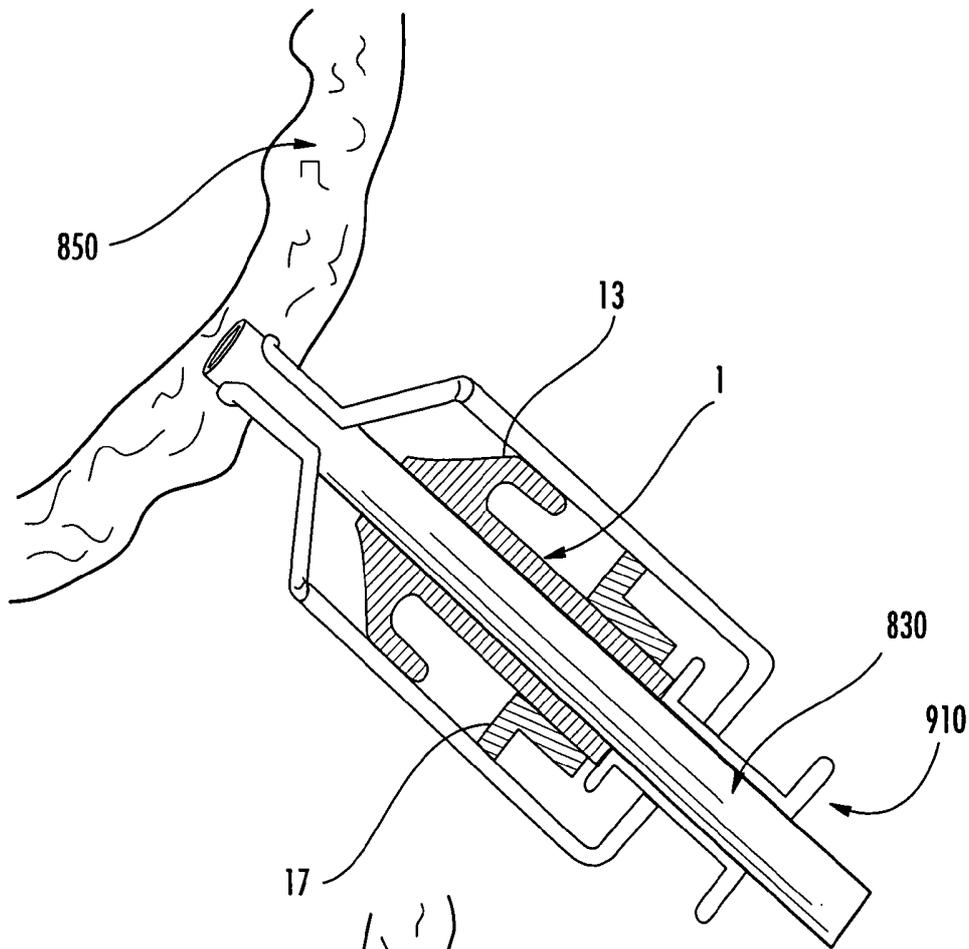


FIG. 9A

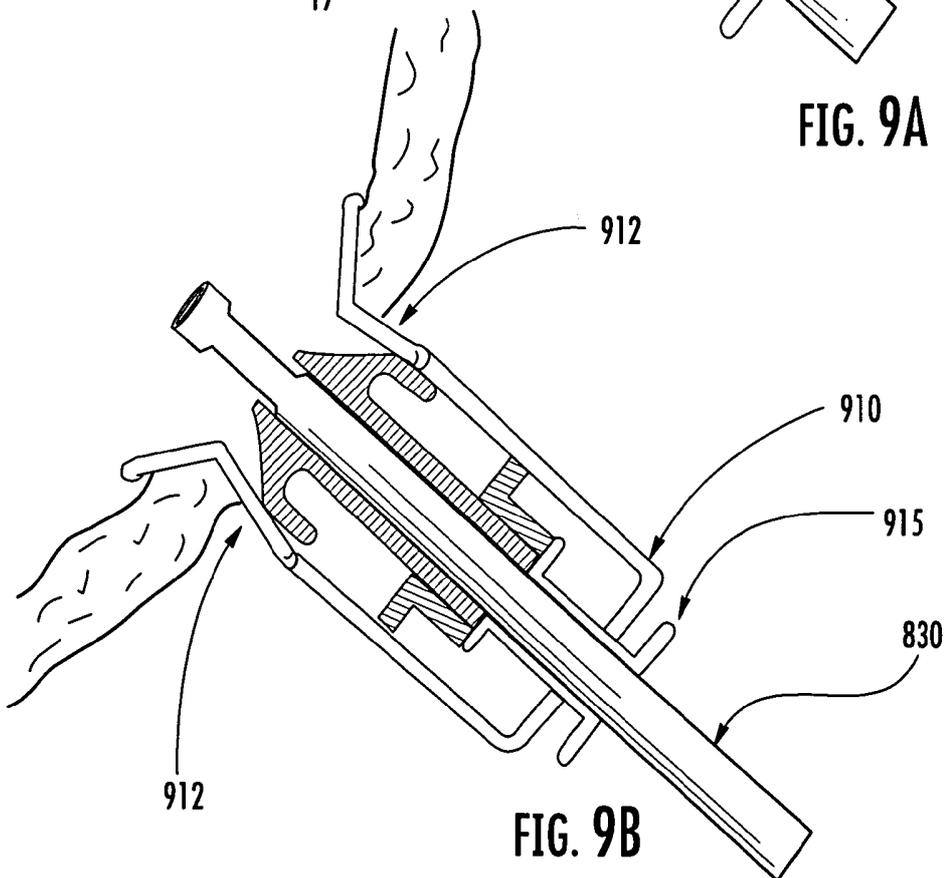
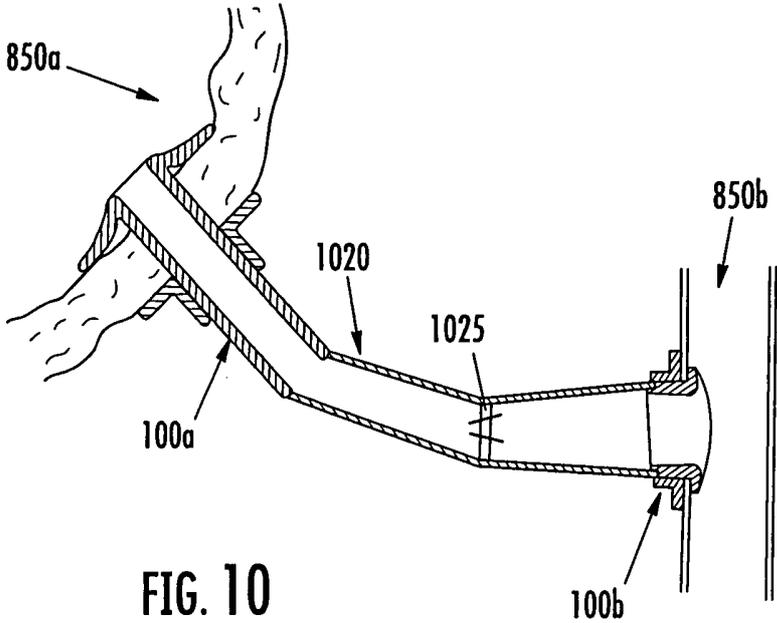


FIG. 9B



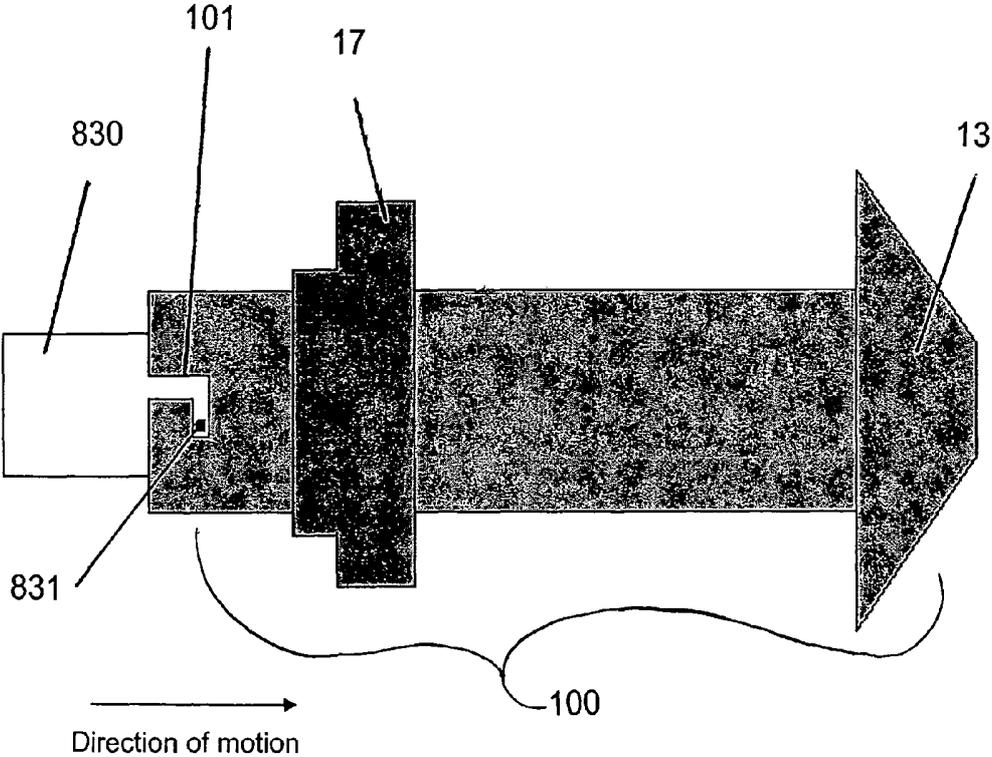
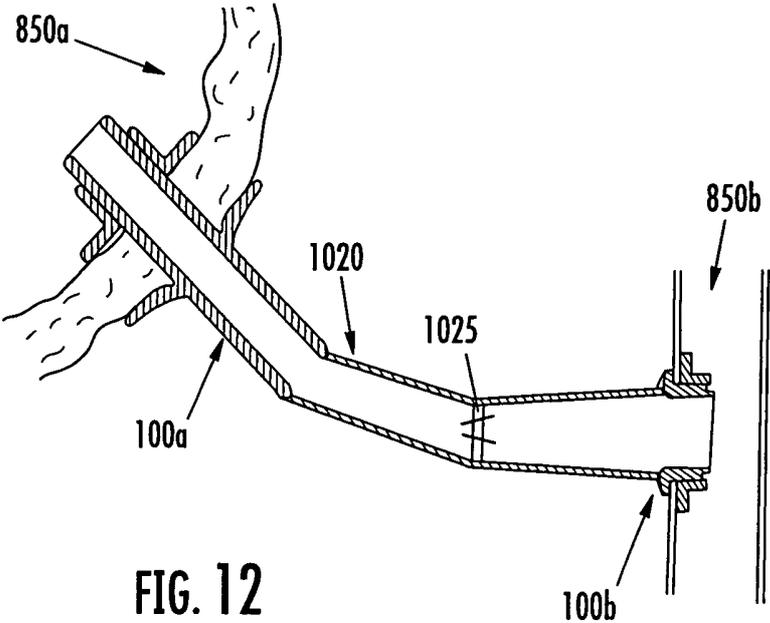


FIG. 11



## VASCULAR CONDUIT DEVICE AND SYSTEM FOR IMPLANTING

### CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of copending U.S. patent application Ser. No. 10/915,691, filed on Aug. 11, 2004, now abandoned, which is hereby incorporated herein in its entirety by reference.

### FIELD OF INVENTION

This invention relates to devices and methods for creating and maintaining a fluid conduit in a tissue wall. For example, some embodiments of the present invention may provide an alternative conduit between the left ventricle and the aorta to create a double-outlet left ventricle.

### BACKGROUND OF THE INVENTION

Construction of an alternative conduit between the left ventricle and the aorta (an apicoaortic conduit, or AAC) to create a double-outlet left ventricle (LV) has been successfully employed to treat a variety of complex congenital LV outflow obstruction (fibrous tunnel obstruction, aortic annular hypoplasia, tubular hypoplasia of the ascending aorta, and patients with diffuse septal thickening, severe LV hypertrophy and a small LV cavity) as well as adult-onset aortic stenosis in patients with complicating preoperative conditions (previous failed annular augmentation procedures, previous infection, previous CABG with patent anterior internal mammary artery grafts, and a porcelain ascending aorta).

However, the AAC insertion procedure has been poorly accepted, primarily because of early valve failures using first-generation bioprostheses as well as the success of direct LVOTO repair and aortic valve replacement. In the United States, despite an aging population, the unadjusted mortality for isolated aortic valve operations in 2001 remained under 4%. Further, the AAC insertion operation, with or without cardiopulmonary bypass, has not been as technically straightforward as direct aortic valve replacement. For most surgeons, AAC insertion is not a familiar operation and is of historical interest only.

Nonetheless, several studies have demonstrated that AAC insertion successfully lessens the LV-aortic pressure gradient, preserves or improves ventricular function and maintains normally distributed blood flow through the systemic and coronary circulation. While there have been several techniques described, the most commonly employed method is the lateral thoracotomy approach with placement of the AAC to the descending aorta. Other techniques include a median sternotomy approach with insertion of the distal limb of the AAC to the ascending aorta, to the transverse part of the aortic arch, or to the intra-abdominal supraceliac aorta.

In general, the thoracic aorta and the left ventricle apex are exposed through a left lateral thoracotomy, and a needle is passed through the apex and into the left ventricle. While the connector is still spaced apart from the apex, the sutures that will fix the connector to the apex are threaded through a cuff on the connector and through the apex in a matching pattern. The cuff is set back from the end of the connector by 1-2 centimeters to allow the end of the connector to extend through the heart muscle and into the left ventricle. Once the sutures are in place, a ventricular coring device is used to remove a core of ventricular muscle, and the pre-threaded sutures are then pulled to draw the connector into the opening

until the cuff comes to rest: on the apex. The sutures are tied off, and additional sutures may be added. Either before or after this procedure, the opposite end of the connector is attached to a valved conduit which terminates at the aorta.

The current techniques and technology available to perform AAC insertion were originally designed to be performed on-pump; either with an arrested or fibrillating heart. While off-pump cases have been described, they can be technically difficult due to the shortcomings of presently available vascular conduits and systems for installing such conduits. For example, because existing conduits require the use of sutures to reliably secure the connector in place, it is often difficult for surgeons or other clinicians to insert such sutures reliably in active cardiac and/or vascular tissue.

### SUMMARY OF THE INVENTION

This invention describes an improved system and method for the insertion of a vascular conduit (such as an AAC) that will significantly improve and simplify the in vivo insertion of a graft into the beating cardiac apex or other tissue walls (such as other areas of the heart including the anterior, lateral, posterior walls of the left or right ventricle, the left or right atrium, the aortic wall, ascending, transverse, or descending, or other blood vessel walls), such that vascular conduit insertions (including AAC procedures) may be rendered far more attractive to clinicians. Because vascular conduits and systems of the present invention may be used to create alternate outflow tracts in "off-pump" procedures, the embodiments of the present invention may effectively reduce and/or negate the detrimental effects of both cardio-pulmonary by-pass (CPB) and global cardiac ischemia. Additionally, because some conduit embodiments of the present invention (for AAC procedures, for example) may be inserted into a ventricular or atrial free wall or cardiac apex, the conduction system of the heart may be avoided, along with the native coronary arteries and grafts from previous surgical revascularization. In some embodiments of the present invention, wherein the system is used to implant an AAC, a small size valve (19 to 21 mm for typical adult body surface areas) is usually adequate; as the effective postoperative orifice is the sum of the native and prosthetic aortic valves. Further, the present invention provides vascular conduits that may be compatible with newer generation biologic valves, such that valved conduit failure is far less likely.

In one embodiment, the present invention provides a system for implanting a vascular conduit device (such as an AAC component). According to some embodiments, the system comprises a coring device for defining an aperture in a tissue wall (such as a cardiac free wall or apex and/or the aorta) having a first tissue surface and a second tissue surface. The coring device may define a lumen adapted to be capable of receiving a guide wire for directing the coring device to the first or second tissue surface, depending upon whether the approach is intra- or extra-vascular, respectively. The system may also comprise a conduit device for lining the aperture defined in the tissue wall and maintaining fluid communication between the first and second tissue surfaces of the tissue wall. The conduit device may be adapted to be capable of being advanced over the guide wire and/or the coring device so as to be guided to the aperture defined by the coring device. The conduit device may comprise, in some embodiments: a tube having proximal and distal ends, and inside and outside surfaces; a flexible flange disposed at or near the distal end, wherein the flexible flange is adapted to be capable of operably engaging the first tissue surface; and a securing ring adapted to fit over the tube and adapted to be capable of

operably engaging the second tissue surface and cooperating with the flexible flange so as to secure the conduit device within the aperture.

According to some embodiments of the present invention, the system may also comprise a hemostatic device for selectively deploying so as to temporarily occlude the aperture (so as to prevent the passage of blood through the aperture and into an adjacent body cavity, for example). The hemostatic device may also be adapted to be capable of being advanced over the guide wire and/or within the lumen of the coring device such that the hemostatic device may be accurately guided to the site of the newly-formed aperture created by the coring device. The hemostatic device may comprise at least one of an "umbrella" occlusion device, a dilation balloon, and/or combinations of such devices. Furthermore, according to various system embodiments of the present invention, the coring device may comprise at least one of: a pulsed laser scalpel; a continuous wave laser scalpel; a mechanical coring device; a device employing ultrasonic energy (such as high-frequency focused ultra-sound); and/or combinations of such coring devices. Some embodiments of the present invention may also provide a specialized delivery device for enclosing the conduit device and selectively implanting the conduit device within the aperture. The delivery device may be operably engaged with an outer surface of the coring device and may comprise one or more retracting arms for dilating the aperture prior to and/or simultaneously with the implantation of the conduit device.

Some additional system embodiments of the present invention may also comprise a guiding catheter defining a guiding lumen for receiving and directing the coring device and the conduit device to the tissue wall via an endovascular pathway. Thus, according to various system embodiments of the present invention, the system may be used to implant the conduit device via an endovascular pathway such that the conduit may be implanted from inside the left ventricle and/or inside another blood vessel.

Other embodiments of the present invention provide a vascular conduit device for lining an aperture defined in a tissue wall (such as the cardiac wall, apex and/or a blood vessel wall) and maintaining fluid communication between a first tissue surface and a second tissue surface of the tissue wall. According to some embodiments, the vascular conduit device may comprise a tube having proximal and distal ends, and inside and outside surfaces, wherein the outside surface of the tube defines a plurality of ridges. The vascular conduit device may further comprise a flexible flange disposed at or near the distal end for operably engaging the first tissue surface and a securing ring adapted to fit over the tube for operably engaging the second tissue surface. The securing ring may also comprise at least one deformable pawl member for releasably engaging the plurality of ridges defined by the outer surface of the tube such that the securing ring cooperates with the flexible flange so as to secure the vascular conduit device within the aperture.

According to some embodiments, the flexible flange and/or securing ring may define complementary concave and/or convex profiles so as to conform more completely to the first and second tissue surfaces. Furthermore, the flexible flange may comprise a frusto-conical assembly such that the flange may be more easily inserted into the aperture. According to various other embodiments of the present invention, the outside surface of the tube may comprise threading on at least a portion of the outside surface of the tube and corresponding threading on an inside diameter of the securing ring such that the securing ring may be secured with respect to the flange and the tissue wall held there between.

According to some embodiments of the present invention, the flexible flange may be soft and thin enough to bend backwards so that it can be pushed through the aperture defined in the tissue wall, but rigid enough to flex back to its original position and hold its shape once it emerges along a first tissue surface of the tissue wall. The tube of the vascular conduit device may then be drawn back so that the flexible flange presses against the first tissue surface of the tissue wall. The securing ring may then be deployed over the body of the connector and against the second tissue surface of the tissue wall. Various vascular conduit device embodiments are described herein to secure the position of the second ring against a surface of the tissue wall such that no sutures may be required. Such embodiments may include, but are not limited to: the ridge and pawl mechanism described above, a threaded surfaces disposed on the tube and an inner surface of the securing ring, a biasing device for biasing the securing ring toward the flange; and/or combinations of such securing devices.

According to one embodiment for using the new system and/or vascular conduit device of the present invention, a needle is passed through a tissue wall (such as the wall of the cardiac apex) to provide access to the first tissue surface (defining the interior of the left ventricle, for example). A guide wire may then be inserted into the opening and, following dilation of the opening, an occlusion device may be threaded over the wire and into a cavity defined by the tissue wall and deployed. A coring device may then be threaded in-line over the guide wire such that a core of tissue may be removed to form an aperture in the tissue wall. While the occlusion device maintains hemostasis, the coring device may be removed and the vascular conduit device of the present invention may be mounted on a dilator and introduced over the guide wire and occlusion device catheter. As the vascular conduit device is introduced into the aperture, the flexible flange retracts. Furthermore, as discussed above, as the vascular conduit device enters the aperture, it may displace the occlusion device to allow the flange to resume its normal shape. As discussed above, the vascular conduit device may then be drawn tight against the first tissue wall such that the securing ring may be deployed over the body of the vascular conduit device to fit snugly against the second tissue surface. Once the connector is firmly in place, the occlusion device may be withdrawn and the vascular conduit device may be clamped shut while its free end is connected to a vascular graft or valved conduit that may terminate at another tissue wall (such as a blood vessel wall, for example).

Use of this new vascular conduit device, system, and method will significantly improve the ease and safety of vascular conduit insertion (such as the implantation of AAC devices). As persons of ordinary skill would readily appreciate, this method can also be, used in a minimally invasive, endoscopically assisted approach.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be better understood by reference to the Detailed Description of the Invention when taken together with the attached drawings, wherein:

FIG. 1 is a perspective view of a first embodiment of an LV apical connector according to the invention;

FIG. 2 is a side view of the embodiment shown in FIG. 1;

FIG. 3 is a perspective view of a second embodiment of an LV apical connector according to the invention;

FIG. 4 is a side view of the embodiment shown in FIG. 3;

FIG. 5 is a side view of a third embodiment of an LV apical connector according to the invention.

FIG. 6 is a perspective view of a vascular conduit device, including a tube, flexible flange, and securing ring, according to one embodiment of the present invention.

FIG. 7 is a perspective view of a vascular conduit device, including a tube, flexible flange, and securing ring, according to one embodiment of the present invention, wherein the flexible flange and securing rings define convex and concave profiles, respectively.

FIG. 8A is a cross-sectional view of a tissue wall and aperture defined therein in relation to one system embodiment of the present invention including a coring device for defining an aperture and a vascular conduit device for defining and maintaining the aperture.

FIG. 8B is a cross-sectional view of a tissue wall and aperture defined therein including a side view of a vascular conduit device, according to one embodiment of the present invention, implanted in the aperture.

FIG. 9A is a cross-sectional side view of a system according to one embodiment of the present invention including a delivery device for enclosing and selectively delivering the conduit device.

FIG. 9B is a cross-sectional side view of a system according to one embodiment of the present invention including a delivery device comprising a pair of retracting arms for dilating the aperture during implantation of the conduit device.

FIG. 10 is a cross-sectional side view of an exemplary apico-aortic connection (AAC) constructed using some embodiments of the present invention.

FIG. 11 is a side view of an exemplary embodiment of the conduit device of the present invention including a notch and pin arrangement for selectively engaging the conduit device with a coring device.

FIG. 12 is a cross-sectional side view of an exemplary apico-aortic connection (AAC) inserted via endovascular methods using system embodiments of the present invention.

#### DETAILED DESCRIPTION OF THE INVENTION

The present inventions now will be described more fully hereinafter with reference to the accompanying drawings, in which some, but not all embodiments of the inventions are shown. Indeed, these inventions may be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will satisfy applicable legal requirements. Like numbers refer to like elements throughout. The singular forms “a,” “an,” and “the” include plural referents unless the context clearly dictates otherwise.

Although some embodiments of the invention described herein are directed to a vascular conduit device **100** and a system for implanting such a device to form an apico-aortic connector (AAC) between the cardiac apex and the aorta, it will be appreciated by one skilled in the art that the invention is not so limited. For example, aspects of the vascular conduit device **100** and systems of the present invention can also be used to establish and/or maintain conduits in a variety of tissue structures using minimally-invasive and/or invasive delivery techniques. Furthermore, while the embodiments of the invention described herein are directed to the thoracoscopic implantation of the vascular conduit device to form at least one vascular port for establishing an AAC, it should be understood that the system and/or vascular conduit device embodiments of the present invention may be used to establish valved and/or open conduits (including bypass conduits) to augment native blood vessels in order to treat a variety of vascular conditions including, but not limited to: aortic valvular disease, congestive heart failure, left ventricle outflow

tract obstructions (LVOTO), peripheral arterial obstructions, small vessel obstructions, and/or other conditions. Furthermore, the vascular conduit device and system of the present invention may also be used to establish a port for inter-ventricular repairs such as, for example, valve repair and/or replacement or ablation procedures. Thus, the vascular conduit device **100** described in further detail below may also comprise a threaded fluid-tight cap, and/or a cap having at least one pawl member (for engaging corresponding ridges defined on an outer surface of the vascular conduit device **100**) for selectively sealing the proximal end **7** of the vascular conduit device **100** such that the tube **1** may serve as a reusable port for repairing and/or treating diseased portions of the cardiac anatomy. Furthermore, the vascular conduit device **100** and system embodiments of the present invention may also be used to implant a conduit and/or port for left ventricular assist devices.

Furthermore, (as shown generally in FIG. 12) some system embodiments of the present invention may also be used “from the inside out”, such that the coring device **830** and conduit device **100** may be passed from through an intravascular space (percutaneously). For example, in one possible embodiment, the system embodiments of the present invention may be used to establish an apico-aortic conduit (AAC) percutaneously (see FIG. 12). The system components may be introduced (via methods that will be appreciated by one skilled in the art) into the femoral vein, across the atrial septum, through the mitral valve and out the ventricular free wall. Therefore, the ventricular conduit device (see element **100a**, FIG. 12) would be placed from inside the vasculature (via a guiding catheter, for example). In similar fashion, the aortic conduit device (see element **100b**, FIG. 12) may be passed retrograde in the femoral artery (via guide wire and/or guiding catheter) or other blood vessel and implanted using the systems of the present invention from the luminal side of the aorta. The two connectors would then be joined with a valved conduit introduced from either end of the system (see FIG. 12).

As shown in FIGS. 1 and 2, the vascular conduit device **100** according to one embodiment of the present invention includes tube (or conduit) **1** having an axis **3**, distal end **5**, a proximal end **7**, an outer surface **9** and an inner surface **11**. Distal end **5** is provided with a flange **13** extending from outer surface **9** in a direction away from axis **3**. Flange **13** may be integrally formed with tube **1**, or it may be formed separately and permanently attached to distal end **5** of tube **1** by known means. Tube **1** should be sufficiently rigid to maintain its shape so as not to occlude the passage of blood and/or other fluids therethrough during use (see generally, element **860**, FIG. 8B). Flange **13** may be sufficiently flexible to allow introduction of the distal end **5** of the vascular conduit device **100** into an aperture **800** (see FIG. 8A) having a diameter equal to or slightly less than the diameter of outer surface **9**, but have sufficient stiffness and/or shape memory to flex back to its original position once it has passed through the aperture **800** (which may be defined in a tissue wall **850**, as shown generally in FIGS. 8A-8B).

As shown generally in FIGS. 8A-8B, the vascular conduit device **100** may maintain and/or provide a lining for an aperture **800** defined in a tissue wall **850** so as to maintain fluid communication **860** between a first tissue surface **853** and a second tissue surface **855** of the tissue wall **850**. As described generally above, and as shown in FIGS. 6 and 7, the vascular conduit device **100** may comprise a tube **1** having proximal **7** and distal **5** ends, and inside and outside surfaces, wherein the outside surface of the tube **1** defines a plurality of ridges **610**. According to some embodiments, the vascular conduit device

**100** may also comprise a flexible flange **13** disposed at or near the distal end **5** for operably engaging the first tissue surface **853** (see FIG. **8B**). As shown in FIGS. **6** and **7**, the vascular conduit device **100** may also comprise a securing ring **17** adapted to fit over the tube **1** and having a flange **630** for operably engaging the second tissue surface **855**. The securing ring **17** may also comprise at least one deformable pawl member **620** for releasably engaging the plurality of ridges **610** defined by the outer surface of the tube **1** such that the securing ring **17** cooperates with the flexible flange **13** so as to secure the vascular conduit device **100** within the aperture **800**. In one embodiment, the securing ring **17** comprises a flange **630** configured to engage the second tissue surface **855**, and the deformable pawl member **620** extends axially along the axis **3** of the tube **1** at an opposite end of the flange. According to one aspect, the securing ring **17** has a wall thickness, and the deformable pawl member is defined by a pair of slots **632** formed through the wall thickness as shown in FIGS. **6** and **7**.

As shown generally in FIG. **8B**, once the vascular conduit device **100** is secured within the aperture **800** defined in the tissue wall **850**, the vascular conduit device **100** may define a pathway for fluid communication (and/or a pathway for thoracoscopic instruments or other surgical tools) between a first tissue surface **853** and a second tissue surface **855**. Furthermore, the proximal end **7** of the vascular conduit device **100** may be configured to receive a number of different valved and/or open conduits for creating, for example, vascular bypasses or other alternate fluid pathways within a living organism. For example, according to apico-aortic conduit embodiments of the present invention (see FIG. **10**), a first vascular conduit device **100a** (shown generally in FIG. **6**) may be implanted and/or secured in the apex **850a** of the left ventricle, and a second vascular conduit device **100b** (shown generally in FIG. **7**) may be implanted and/or secured within a wall **850b** of the aorta. The two devices may then be connected via a commercially-available valved conduit device **1020** (including a one-way valve **1025**) in order to create an alternative valved pathway for blood in order to augment a diminished flow of blood that may be passing through a diseased and/or damaged aortic valve. Thus, according to some embodiments, the proximal end **7** of the tube **1** defining the fluid pathway through the vascular conduit device **100** may be formed so as to be compatible with one or more existing valved conduit devices **1020**. Furthermore, according to some embodiments, the vascular conduit device **100** may be fitted with an adapter sleeve (not shown) such that the proximal end **7** of the tube may be connected in a fluid-tight manner with one or more commercially-available conduit devices **1020** for establishing a bypass and/or alternate pathway between two body cavities or blood vessels. Furthermore, the vascular conduit device **100** of the present invention may be used to bypass and/or repair a variety of diseased and/or damaged blood vessels. For example, some embodiments of the present invention may be used to bypass an abdominal aortic aneurysm (AAA) by providing two aortic vascular conduit devices **100b** (see FIG. **7**) for example connected by a section of conduit **1020** spanning the diseased and/or damaged portions of the abdominal aorta.

As discussed below, the flexible flange **13** and tube **1** of various embodiments of the vascular conduit device **100** may be altered so as to be compatible with various tissue walls **850**. For example, the vascular conduit device **100** shown in FIG. **7** may be suited for use in defining and maintaining an aperture in a large blood vessel having a curved tissue wall (such as the aorta). Furthermore, the vascular conduit device **100** shown in FIG. **6** may be suited for use in defining and

maintaining an aperture in a body cavity having a relatively thick and/or muscular tissue wall (such as the cardiac muscle of the left ventricle).

Therefore, as shown in FIG. **7**, the flexible flange **13** may define, in some embodiments, a convex profile with respect to the proximal end **7** of the tube **1** so as to be capable of conforming to a curved first tissue surface **853** (such as a tissue surface defined by the inner wall surface of a blood vessel (such as the aorta)). Furthermore, in some embodiments, the securing ring **17** may also include a flange **630** defining a corresponding concave profile such that the securing ring **17** may be capable of operably engaging a curved and/or contoured second tissue surface **855** and be better capable of cooperating with the flexible flange **13** so as to secure the vascular conduit device **100** within the aperture **800**. Furthermore, as shown generally in FIG. **6**, the flexible flange **13** may also comprise a frusto-conical assembly such that the insertion of the flexible flange **13** into a relatively narrow tissue aperture **800** may be more easily accomplished (see generally FIG. **8A**). Furthermore, the frusto-conical assembly of some flexible flange **13** embodiments of the present invention may also prevent and/or minimize the occurrence of the accidental removal of the vascular conduit device **100** from the second tissue surface **855** of the tissue wall **850**. The relative thicknesses of the materials used to form the flexible flange **13** may also be varied so as to allow the flange **13** to be optimized based on the expected type of tissue wall **850** it may be used to engage. For example, a relatively thin and/or contoured flexible flange **13** (as shown generally in FIG. **7**) may be used to secure vascular conduit devices **100** within more fragile and/or thin blood vessels. Furthermore, the relatively thick and robust frusto-conical flexible flange **13** (shown generally in FIG. **6**) may be used to secure vascular conduit devices **100** within more substantial tissue walls (such as cardiac muscle).

Tube **1** and flange **13** may be made of any suitable biocompatible material. Alternatively, tube **1** and flange **13** may be coated with a biocompatible material. According to one exemplary embodiment, the tube **1** may comprise a first polymer material having a first hardness and the flange **13** may comprise a second polymer material having a second hardness, wherein the first hardness is greater than the second hardness. Thus, according to some such embodiments, the flange **13** may be easily deformable as it is inserted into the aperture **800** defined in the tissue wall **850**, but the tube **1** may remain relatively rigid so as to maintain a path for fluid communication (see element **860**, FIG. **8B**) between the surfaces **853**, **855** of the tissue wall **850**.

According to some other embodiments, at least a portion of the outer surface **9** of tube **1** may be threaded. Threading **15** may extend the entire length of tube **1**, or extend over only a portion thereof. According to one exemplary embodiment, threading **15** may be absent from a length of the distal end **5** of the tube **1** that is slightly less than the thickness of the tissue wall **850**. This alternative embodiment may serve to prevent over-tightening of the vascular conduit device **100**, which may, in some case lead to damage and/or rupture of portions of the tissue wall **850** near the aperture **800** defined therein. According to another embodiment, threading **15** may not extend all the way to the proximal end **7** such that the tube **1** (and the resulting vascular conduit device **100**) may be used to provide a conduit through tissue walls having a variety of thicknesses.

External ring **17** (or securing ring **17**) may be provided with an inner diameter **18** and an outer diameter **19**. Inner diameter **18** may further define threads **23** to correspond to the threading **15** on the outer surface **9** of tube **1**. The outer diameter **19**

of external ring 17 may have any shape suitable to the designer, including circular or hexagonal. According to one embodiment of the invention, external ring 17 may be adapted to be engaged by a tightening device (not shown) for tightening external ring 17 on tube 1. As discussed above with respect to the tube 1, the external ring 17 may be made of any suitable biocompatible material. Alternatively, external ring 17 may be coated with a biocompatible material.

For embodiments wherein the tube defines threading 15 and wherein the complementary external ring 17 defines threads 23, the tightening device may comprise a specialized wrench device for rotating the external ring 17 relative to the tube 1. Furthermore, in other embodiments (such as those shown generally in FIGS. 6 and 7) the tightening device may comprise a simple push tool capable of encircling a coring device 830 (see discussion below of FIG. 8A) and pushing the external ring 17 towards the distal end 5 of the tube 1 such that the at least one pawl member 620 of the external ring 17 may be engaged with the plurality of ridges 610 defined on an outer surface of the tube 1. According to some embodiments of the present invention, as shown generally in FIG. 11, the vascular conduit device 100 may be selectively secured to the coring device 830 (or, in some embodiments, the delivery device 910, discussed below) by a pin 831 and notch 101 arrangement. For example, as shown in FIG. 11 a pin 831 may extend from an external surface of the coring device 830 (or the delivery device 910) and be operably engaged with a complementary notch 101 defined in the proximal end of the vascular conduit device 100. Thus, a clinician may use the coring device 830 (or the delivery device 910) to advance the vascular conduit device 100 to the aperture 800 and into an implanted position (see FIG. 8B, for example) and subsequently apply counter-traction to the vascular conduit device 100 (via the pin 831) such that the external ring 17 may be advanced and secured relative to the vascular conduit device 100. In some embodiments, the clinician may then rotate the coring device 830 (and/or the delivery device 910) to release the pin 831 from the notch 101 and retract the coring device 830, leaving the vascular conduit device 100 securely implanted (as shown generally in FIG. 8B). Furthermore, in some embodiments, the hemostatic device 820 (see FIG. 8A) may also be used to apply counter-traction force to hold the tube 1 and flexible flange 13 in place within the aperture 800 as the external ring 17 is engaged with respect to the second tissue surface 855 from a proximal position.

According to the embodiment shown in FIGS. 3 and 4, tube 1 of the vascular conduit device 100 may also be provided with an external ring 17 that is biased toward flange 13 by a biasing device 27 (such as a spring device), having proximal end 29 and distal end 31. The biasing device 27 may be configured so as to tend to force external ring 17 into contact with flange 13. As shown in FIGS. 4-6, the biasing device 27 may be a spring in compression. As one of ordinary skill in the art will appreciate, any biasing device may be used, including one or more flexible bands or rods. Furthermore, tube 1 may be provided with and/or define an engagement feature 33, such as a ring, slot or bore, to engage the proximal end 29 of the biasing device 27. Likewise, external ring 17 may be provided with an engagement feature (not shown) adapted to receive the distal end 31 of the biasing device 27.

According to some embodiments, release device 37 may also be provided to releasably hold external ring 17 and biasing device 27 in pre-deployment configuration, with biasing device 27 in compression, until such a time as the flange 13 has been placed in the interior of a cavity defined by the tissue wall 850 (such as the interior of the ventricle) and the external ring 17 is ready to be deployed against the outer

tissue surface 855 of the heart muscle (see generally FIG. 8B, showing the vascular conduit device 100 secured within the aperture 800).

According to the embodiment shown in FIGS. 1 and 4, release device 37 may include one or more hooks 39 extending from the proximal surface 41 of the external ring 17 and adapted to releasably engage an engagement feature 43; for example, a slot or bore, defined in tube 1. Alternatively, as shown in FIG. 5, the release device 37 may extend to and hook over the proximal end 7 of tube 1.

In some additional embodiments, a portion of tube 1 may be threaded and the inside diameter of external ring 17 threaded to permit further tightening of external ring 17 on tube 1 after deployment of the external ring 17 following removal of the release device 37.

Some embodiments of the present invention, as shown generally in FIG. 8A, further provide a system for implanting a vascular conduit device 100, wherein the system comprises a coring device 830 for defining an aperture 800 in a tissue wall 850 having a first tissue surface 853 and a second tissue surface 855. The various components of the system embodiments of the present invention may be inserted into a patient (via, for example, a thoracoscopic, endovascular, and/or percutaneous procedure) such that a guide catheter (not shown) and/or guide wire 810 (see FIG. 8B) may be inserted into the thoracic cavity of a patient in order to gain access to diseased vasculature and/or the heart. Furthermore, according to some embodiments, the system of the present invention may be used to implant a vascular conduit device 100 via more invasive surgical procedures that will be appreciated by one skilled in the art. Furthermore, as shown generally in FIG. 12, the vascular conduit device 100 may also be delivered and implanted endovascularly from the inside (and/or from a first tissue surface 853) of the ventricle and/or aorta.

As shown in FIG. 8A, the coring device 830 may define a lumen adapted to be capable of receiving a guide wire 810 for directing the coring device 830 to the second tissue surface 855. Furthermore, the system of the present invention may also comprise a conduit device 100 (such as the vascular conduit device discussed above) for lining the aperture 800 defined in the tissue wall 850 and maintaining fluid communication between the first 853 and second tissue 855 surfaces of the tissue wall 850. The conduit device 100 may be adapted to be capable of being advanced over the guide wire 810 and coring device 830. As described above with respect to FIGS. 1-5, the vascular conduit device 100 may comprise: a tube 1 having proximal 7 and distal 5 ends, and inside and outside surfaces; a flexible flange 13 disposed at or near the distal end 5; and a securing ring 17 (or external ring 17) adapted to fit over the tube 1 and adapted to be capable of operably engaging the second tissue surface 855 and cooperating with the flexible flange 13 so as to secure the conduit device 100 within a tissue aperture 800.

According to various embodiments of the system of the present invention, the coring device 830 may comprise at least one of: a pulsed laser scalpel; a continuous wave laser scalpel; a mechanical coring device (such as, for example, a rotoblator catheter or other mechanical and/or catheter-based mechanical cutting device); an ultrasonic coring device (such as high-frequency focused ultra-sound); and combinations thereof. For example, in one exemplary embodiment, the coring device 830 may comprise a pulsed excimer laser device having a light pulse duration that is less than the tissue wall's 850 time of thermal diffusion (defining how quickly the laser's imparted heat spreads to adjacent tissue) so as to provide a relatively "cool" cutting method (i.e. less than about 50 degrees C.). Furthermore, the pulsed laser may be pro-

vided with a relatively shallow cutting depth (i.e. less than about 50  $\mu\text{m}$ ) such that the coring device **830** may be precisely controlled. The use of a pulsed laser scalpel as the coring device **830** may thus result in minimal damage to tissue adjacent the targeted aperture **800** area, which may be especially advantageous in embodiments wherein the system is used to implant a vascular conduit device **100** in the ventricular apex, as the cardiac tissue of the left ventricle contains tissues that are vital for maintaining the electrical pacing of the heart.

Some system embodiments of the present invention (as shown generally in FIG. **8A**) may further comprise a hemostatic device **820** for selectively deploying so as to temporarily occlude the aperture **800**. As one skilled in the art will appreciate, the hemostatic device **820** may be adapted to be capable of being advanced over the guide wire **810** within the lumen of the coring device **830**. Furthermore, according to some embodiments, the hemostatic device **820** may be delivered via a delivery catheter defining a lumen for receiving the guide wire **810** and having a sufficiently small outer diameter to be guided within the lumen defined by the coring device **830**. According to various embodiments of the present invention, the hemostatic device **830** may comprise at least one of: an “umbrella” occlusion device; a dilation balloon; and/or combinations thereof. According to some embodiments, the hemostatic device **820** (as shown in FIG. **8A**) may be used to maintain “traction” for the advance of the coring device **830** (which, in pulsed excimer laser embodiments, may comprise a circular array **835** of lasers that must be advanced into the tissue wall **850** in order to core the wall and define an aperture **800** therein). Thus, in some embodiments, a clinician may deploy the hemostatic device **820** proximal to the first tissue surface **853** of the tissue wall **850** and exert a force (using the deployed hemostatic device) against the first tissue surface **853** such that the laser array **835** of the coring device **830** may be advanced to define the aperture **800** in the tissue wall **850**. The exertion of such “traction” forces using the hemostatic device **820** may be useful in instances wherein the tissue wall **850** is in motion (such as is the case with the cardiac muscle defining the walls of the left ventricle). Thus, embodiments of the present invention may be successfully employed in “off-pump” procedures wherein the heart is left beating during the course of the procedure for implanting the vascular conduit device **100**.

Following the coring process, the vascular conduit device **100** (as described in its various embodiments above) may be advanced along the outer surface of the coring device **830** and into position within the aperture (as shown generally in FIG. **8B**) so as to define a pathway for fluid flow **860** through the tissue wall **850**. According to some embodiments, a dilator device (not shown) may be introduced (over the guide wire **810**, for example) for dilating the initial aperture **800** defined by the coring device **830**. The dilator device may also be used to advance the vascular conduit device **100** into its final implanted position (see FIG. **8B**) by at least partially expanding the dilator device within the inner surface **11** of the tube **1** so as to carry the vascular conduit device **100** with the partially-expanded portion of the dilator device. The dilator device may comprise, in various embodiments, a dilation balloon, a multi-arm endoscopic and/or thoracoscopic retractor device, and/or other types of dilator devices that will be appreciated by one skilled in the art.

For example, as shown generally in FIGS. **9A** and **9B**, some embodiments of the present invention may comprise a dilator device that may serve as a delivery device **910** for dilating the aperture **800** formed by the coring device **830** and for percutaneously and/or thoracoscopically delivering the

vascular conduit device **100** to a secured position (see FIG. **8A**, for example) relative to the aperture **800** defined in the tissue wall **850**. The delivery device **910** may be operably engaged with an outer surface of the coring device **830** and may comprise two or more retractor arms **912** that may be opened as the vascular conduit device **100** is pushed out from the delivery device **810** by applying an opening force to a plunger **915**. Thus, as shown in FIG. **9B**, the delivery device **910** may be configured to simultaneously dilate the aperture **800** (using the retractor arms **912**) and deliver the vascular conduit device **100**. As shown in FIG. **9B** the flexible flange **13** of the vascular conduit device **100** may urge the retractor arms **912** to an open position as the plunger **915** pushes the vascular conduit device **100** outward and into the aperture **800**. The retractor arms **912**, when deployed as shown in FIG. **9B** may also serve to provide “counter-traction” such that the clinician may apply a distally-acting force on the plunger **915**, a clinician may deploy the securing ring **17** relative to the tube **1** of the vascular conduit device **100** in order to secure the vascular conduit device **100** within the aperture **800** (as shown in FIG. **8B**, for example).

As described above (see FIG. **8A**, for example) the hemostatic device **820** may also be deployed in order to provide additional “counter-traction” such that the distal end of the vascular conduit device **100** (once implanted in the aperture **800**) may contact the expanded hemostatic device **820**. Thus, by applying a distally-acting force on the plunger **915**, a clinician may deploy the securing ring **17** relative to the tube **1** of the vascular conduit device **100** in order to secure the vascular conduit device **100** within the aperture **800** (as shown in FIG. **8B**, for example).

According to one exemplary embodiment, the system of the present invention (shown generally in FIGS. **8B** and **10**) may be used to implant vascular conduit devices **100a**, **100b** to serve as the terminal points for an apico-aortic conduit. According to such embodiments, a thoracoscopic procedure may be used to insert a needle through the apex and into the left ventricle **850a**. A guide wire **810** may then inserted into the opening and, following dilation of the opening (using a dilation device, for example), an hemostatic device **820** may be threaded over the wire **810** and into the left ventricle and deployed proximal to an first tissue surface **853** thereof. The hemostatic device **820** may comprise, for example, known occlusion devices such as an occlusion balloon, the Guidant Heartstring™, or the Baladi inverter, disclosed in U.S. Patent Nos. 5,944,730 and 6,409,739. As described above, and as shown generally in FIG. **12**, the vascular conduit devices **100a**, **100b** may also be implanted endovascularly (i.e. from the inside of the left ventricle and/or the aorta) by introducing the system embodiments of the present invention through the vasculature via guidewire and/or guiding catheter. For example, the aortic conduit **100b** may be introduced via the system embodiments of the present invention (including a guiding catheter) inserted in the femoral artery. In addition, the ventricular conduit **100a** may be introduced via the systems of the present invention (including a guiding catheter) inserted into the femoral vein, across the atrial septum, through the mitral valve and out the ventricular free wall.

A ventricular coring device **830** may then be threaded in-line over the hemostatic device **820** and a core of ventricular muscle is removed from the tissue wall **850** of the apex in order to form an aperture **800**. In addition to known coring techniques, an annular contact laser (and in some embodiments a “cool” cutting pulsed excimer laser, having elements arranged in a circular array **835**) may be used to vaporize the tissue along the perimeter of the core. The cored tissue may then be removed according to known methods. According to

a further alternative embodiment, a contact laser may be used to vaporize the entire area of the core, eliminating the need to remove cored tissue. In yet another embodiment, a mechanical coring device (such as a catheter-based rotoblator device) or an ultrasonic coring device, may be used to form the aperture **800**. No matter the method of coring, once coring has been-completed, the coring device **830** may be removed while the occlusion device maintains hemostasis, and the vascular conduit device **100** of the present invention may be mounted on a dilator and-introduced over the guide wire **810** and hemostatic device **820**. As the vascular conduit device **100** is introduced into the aperture **800** in the apex, the flexible flange **13** may deform and/or retract. As the vascular conduit device **100** enters the-left ventricle, it may displace the hemostatic device **820** to allow the flexible flange **13** to resume its normal shape. As discussed above the vascular conduit device **100** may then be drawn tight against the first tissue surface **853** of the wall **850** of the left ventricle. According to a first embodiment, external ring **17** is threaded onto the tube **1** and tightened until it is snug against the second tissue surface **855** of the ventricular apex.

According to it second embodiment, once the flexible flange **13** has been introduced into the ventricle and pulled back to engage the first tissue surface **853**, release-device **37** is released, allowing biasing device **27** to force the external ring **17** against the second tissue surface **855** of the ventricular apex. According to a further aspect of this embodiment of the invention, threads on the inside diameter of external ring **17** may be made to engage threads on the outer surface of the tube **1** to further secure external ring **17** against the tissue wall **850** of the ventricular apex.

Once the vascular conduit device **100** is firmly in place (see generally FIG. **8B**), the occlusion device **820** may be retracted and withdrawn. The vascular conduit device **100** may then be clamped shut and/or capped while its free end (defined by the proximal end **7** of the tube **1**) is connected to a valved conduit and/or graft which may terminate at a complementary vascular conduit device **100** implanted in the aorta (see FIG. **7** showing an exemplary embodiment of a vascular conduit device **100** suited for implantation in the tissue wall **850** of the aorta).

Many modifications and other embodiments of the inventions set forth herein will come to mind to one skilled in the art to which these inventions pertain having the benefit of the teachings presented in the foregoing descriptions and the associated drawings. Therefore, it is to be understood that the inventions are not to be limited to the specific embodiments disclosed and that modifications and other embodiments are intended to be included within the scope of the appended claims. Although specific terms are employed herein, they are used in a generic and descriptive sense only and not for purposes of limitation.

That which is claimed:

**1.** A system for implanting a vascular conduit device, the system comprising:

a coring device for defining an aperture in a tissue wall having a first tissue surface and a second tissue surface, the coring device defining a lumen adapted to receive a guide for directing the coring device to the second tissue surface;

an articulating device for selectively deploying through the tissue wall and proximate the first tissue surface, the articulating device adapted to provide counter-traction for advancing the coring device into the tissue wall and to selectively occlude the aperture;

a sutureless conduit device for lining the aperture and maintaining fluid communication between the first and

second tissue surfaces of the tissue wall, the sutureless conduit device adapted to be separably positioned over and coaxial with the coring device and to be advanced over the coring device and into the aperture, the sutureless conduit device comprising a tube having proximal and distal ends, and inside and outside surfaces, the inside surface of the tube adapted to slidably contact an outer surface of the coring device when the sutureless conduit device is positioned over the coring device; and a delivery device for selectively deploying the sutureless conduit device into the aperture, the delivery device comprising a plurality of retractor arms adapted to engage the tissue wall and to provide counter-traction for advancing the sutureless conduit device into the aperture.

**2.** The system according to claim **1**, wherein the coring device is selected from the group consisting of:

a pulsed laser scalpel;

a continuous wave laser scalpel;

a mechanical coring device;

an ultrasonic coring device; and

combinations thereof.

**3.** The system according to claim **1**, wherein the articulating device comprises an umbrella occlusion device.

**4.** The system according to claim **1**, wherein the sutureless conduit device is further adapted to implant a ventricular assist device in the tissue wall.

**5.** The system according to claim **1**, wherein the sutureless conduit device further comprises at least one flexible flange disposed at or near the distal end of the tube, the flexible flange having a larger outer diameter than the tube and adapted to operably engage the first tissue surface.

**6.** The system according to claim **5**, wherein the flexible flange has a frusto-conical shape.

**7.** The system according to claim **5**, wherein the flexible flange is adapted to deform sufficiently to allow the distal end of the tube and the flange to be inserted through the aperture defined in the tissue wall, the aperture having a diameter equal to or less than the diameter of the tube.

**8.** The system according to claim **7**, wherein the flexible flange has sufficient shape memory that once deformed to allow insertion of the distal end of the tube and the flange through the aperture, the flange will return to a larger original shape.

**9.** The system according to claim **5**, wherein the flexible flange extends about an entire circumference of the tube.

**10.** The system according to claim **1**, wherein the sutureless conduit device is further adapted for the passage of medical or surgical instruments during an intervention through the tissue wall.

**11.** The system according to claim **1**, further comprising a guiding wire or a guiding catheter for directing the coring device and the sutureless conduit device to the tissue wall via an endovascular pathway.

**12.** The system according to claim **1**, wherein a proximal end of the sutureless conduit device is operably engaged with the coring device.

**13.** The system according to claim **1**, wherein the delivery device further comprises a plunger adapted to be slidably disposed with respect to the coring device and to advance the sutureless conduit device over the coring device and into the aperture, and wherein the retractor arms are adapted to engage the tissue wall while the plunger advances the conduit device over the coring device and into the aperture.

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14. The system according to claim 13, wherein the retractor arms are adapted to dilate the aperture while the plunger advances the conduit device over the coring device and into the aperture.

15. The system according to claim 1, further comprising a valve adapted to control fluid flow through the sutureless conduit device.

16. The system according to claim 15, wherein the valve is adapted for the passage of medical or surgical instruments.

17. The system according to claim 1, wherein the articulating device is adapted to be advanced over the guide and within the lumen of the coring device.

18. The system according to claim 1, wherein the articulating device is adapted to be advanced over the guide and within the lumen of the sutureless conduit device.

19. The system according to claim 1, wherein the retractor arms are adapted to dilate the aperture.

20. The system according to claim 1, wherein the retractor arms are flexible.

21. The system according to claim 1, wherein the retractor arms are adapted to move from a closed position to an open position as the sutureless conduit device is advanced over the coring device and into the aperture.

22. The system according to claim 1, wherein the sutureless conduit device is adapted to move the retractor arms from a closed position to an open position as the sutureless conduit device is advanced over the coring device and into the aperture.

23. The system according to claim 1, wherein the retractor arms extend over the sutureless conduit device.

24. A system for implanting a vascular conduit device, the system comprising:

a coring device for defining an aperture in or near a ventricular apex of a heart tissue wall having an inner first tissue surface and an outer second tissue surface, the coring device defining a lumen adapted to receive a guide for directing the coring device to the second tissue surface, the coring device adapted to remove and capture a core of tissue from the heart tissue wall to define the aperture;

an articulating device for selectively deploying through the heart tissue wall and proximate the first tissue surface, the articulating device adapted to provide a hemostatic surface about the first tissue surface when the articulating device is in an expanded configuration, to provide counter-traction for advancing the coring device into the heart tissue wall and to selectively occlude the aperture;

a sutureless conduit device for lining the aperture and maintaining fluid communication between the first and second tissue surfaces of the heart tissue wall, the sutureless conduit device adapted to be separably positioned over and coaxial with the coring device and to be advanced over the coring device and into the aperture, the sutureless conduit device comprising:

a tube having proximal and distal ends, and inside and outside surfaces, the inside surface of the tube adapted to slidably contact an outer surface of the coring device when the sutureless conduit device is positioned over the coring device;

a flexible flange disposed at or near the distal end of the tube, the flexible flange having a frusto-conical shape expanding from a distal end to a proximal end thereof, the flexible flange adapted to deform sufficiently to be inserted through the aperture and to operably engage the first tissue surface; and

a securing ring adapted to selectively engage the outer surface of the tube and to advance over the tube to

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operably engage the second tissue surface so as to secure the sutureless conduit device in the aperture; and

a delivery device for selectively deploying the sutureless conduit device into the aperture, the delivery device comprising:

a plurality of retractor arms adapted to engage the tissue wall and to provide counter-traction for advancing the sutureless conduit device into the aperture; and

a plunger adapted to advance the sutureless conduit device over the coring device and into the aperture.

25. The system according to claim 24, wherein the sutureless conduit device is further adapted to implant a ventricular assist device in the tissue wall.

26. The system according to claim 24, wherein the retractor arms are adapted to engage the tissue wall while the plunger advances the sutureless conduit device over the coring device and into the aperture.

27. The system according to claim 24, wherein the articulating device comprises an umbrella occlusion device.

28. The system according to claim 24, further comprising a valve adapted to control fluid flow through the sutureless conduit device.

29. The system according to claim 28, wherein the valve is adapted for the passage of medical or surgical instruments.

30. A system for implanting a vascular conduit device, the system comprising:

a coring device for defining an aperture in a tissue wall having a first tissue surface and a second tissue surface, the coring device defining a lumen adapted to receive a guide for directing the coring device to the second tissue surface, the coring device adapted to remove and capture a core of tissue from the tissue wall to define the aperture;

a sutureless conduit device for lining the aperture and maintaining fluid communication between the first and second tissue surfaces of the tissue wall, the sutureless conduit device adapted to be separably positioned over and coaxial with the coring device and to be advanced over the coring device and into the aperture, the sutureless conduit device comprising a tube having proximal and distal ends, and inside and outside surfaces, the inside surface of the tube adapted to slidably contact an outer surface of the coring device when the sutureless conduit device is positioned over the coring device; and

a delivery device for selectively deploying the sutureless conduit device into the aperture, the delivery device comprising:

a plurality of retractor arms adapted to engage the tissue wall and to provide counter-traction for advancing the sutureless conduit device into the aperture; and

a plunger adapted to advance the sutureless conduit device over the coring device and into the aperture.

31. A system for implanting a vascular conduit device, the system comprising:

a coring device for defining an aperture in or near a ventricular apex of a heart tissue wall having a first tissue surface and a second tissue surface, the coring device adapted to be advanced over a guidewire and to remove a core of tissue from the heart tissue wall to define the aperture;

a sutureless conduit device for lining the aperture and maintaining fluid communication between the first and second tissue surfaces of the heart tissue wall, the sutureless conduit device adapted to be advanced over the coring device and into the aperture;

a valve adapted to control blood flow through the sutureless conduit device; and  
a delivery device for selectively deploying the sutureless conduit device into the aperture, the delivery device comprising a plurality of retractor arms adapted to 5 engage the tissue wall and to provide counter-traction for advancing the sutureless conduit device into the aperture.

\* \* \* \* \*

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摘要(译)

本发明提供了一种血管导管装置，其包括可变形凸缘和互补固定环，用于将该装置固定在限定在组织壁中的孔内。本发明还提供了一种用于将这种血管导管装置植入组织壁的系统。更具体地，本发明提供了一种系统，该系统包括用于限定组织壁（例如心室和/或血管）中的孔并在其中牢固地植入血管导管装置的取芯装置，以便在第一个之间提供流体连通。组织壁的第二表面通过血管导管装置。

