

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
30 October 2008 (30.10.2008)

PCT

(10) International Publication Number
WO 2008/131453 A1

(51) International Patent Classification:
A61B 17/32 (2006.01) **A61F 2/06** (2006.01)

(21) International Application Number:
PCT/US2008/061404

(22) International Filing Date: 24 April 2008 (24.04.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
11/739,151 24 April 2007 (24.04.2007) US

(71) Applicants (for all designated States except US): **EMORY UNIVERSITY** [US/US]; 1784 North Decatur Road, Atlanta, GA 30322 (US). **GEORGIA TECH RESEARCH CORPORATION** [US/US]; 505 Tenth Street, NW, Atlanta, GA 30332-0415 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **VASSILIADES, Thomas, A.** [US/US]; 530 Telford Place, N.E., Atlanta, GA 30342 (US). **YOGANATHAN, Ajit** [US/US]; 3555 Castleridge Drive, Tucker, GA 30084 (US). **JIMENEZ, Jorge, Hernan** [CO/US]; 9002 St. Clair Drive NE, Atlanta, GA 30329 (US).

(74) Agents: **KIRK, Trent, A.** et al.; Alston & Bird LLP, Bank Of America Plaza, 101 South Tryon Street, Suite 4000, Charlotte, NC 28280-4000 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(54) Title: CONDUIT DEVICE AND SYSTEM FOR IMPLANTING A CONDUIT DEVICE IN A TISSUE WALL

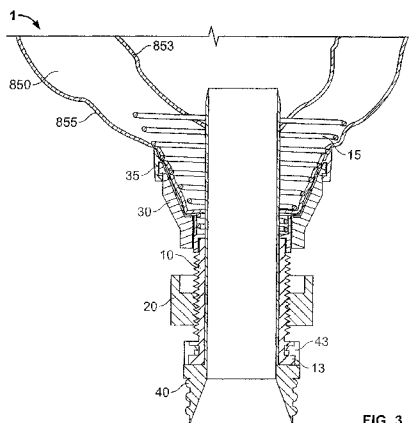


FIG. 3

(57) Abstract: Various embodiments of the present invention provide a conduit device including an attaching device configured for defining a helical pathway through a tissue wall and complementary ring in cooperation for securing the device within an aperture defined in the tissue wall. Some embodiments of the present invention further provide a system for implanting a conduit device in a tissue wall. More specifically, some embodiments provide a system including a coring device for defining an aperture in a tissue by removing and retaining a tissue core and securely implanting a conduit device therein so as to provide fluid communication between a first and second surface of the tissue wall via the conduit device.

WO 2008/131453 A1

CONDUIT DEVICE AND SYSTEM FOR IMPLANTING A CONDUIT DEVICE IN A TISSUE WALL

FIELD OF INVENTION

This invention relates to devices and methods for creating and maintaining a fluid conduit to establish fluid communication between opposing surfaces of a tissue wall.

5

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 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.

Some devices and methods have been devised to install an AAC conduit, such as those described generally in U.S. Patent Application Serial No. 11/251,100, filed on October 14, 2005, and U.S. Patent Application Serial No. 10/915,691, filed on August 11, 2004, both of which are hereby incorporated

herein in their entirety by reference. However, these AAC conduit devices and installation systems rely on the use of a flexible flange that is inserted through a pre-defined aperture in the ventricular apex. Thus, such methods require the use of a hemostatic device (such as an occlusion balloon and/or “umbrella” device) to prevent blood loss from the aperture during installation of the AAC conduit.

SUMMARY OF THE INVENTION

Various embodiments of the present invention provide an improved system and method for the insertion of a conduit (such as an AAC conduit) that will significantly 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. Various embodiments of the present invention may also provide general conduit devices (and systems for implanting) suitable for establishing fluid communication between opposing surfaces of tissue walls in a variety of applications, including the establishment of a fluid conduit through the tissue wall of a mammalian urinary bladder.

In one exemplary embodiment, a system is provided for implanting a conduit device (such as an AAC component) in a tissue wall having a first surface and an opposing second surface. According to some embodiments, the system comprises an outer tube defining a guide aperture extending axially through the outer tube and an attaching device extending from a distal end of said outer tube. The attaching device is configured for advancing along a helical path at least partially through the tissue wall such that at least a portion of the attaching device becomes disposed substantially between the first surface and the opposing second surface of the tissue wall when the outer tube is rotated relative to the first surface of the tissue wall. The attaching device, in some system embodiments, comprises at least one of a helical static coil and a helical elastic spring having a sharpened distal end adapted for piercing the tissue wall as the outer tube is rotated relative to the first surface of the tissue wall. According to some such embodiments, the attaching device may define a radially-expanding helix as the attaching device extends away from the distal end of the outer tube.

In some embodiments, the system also comprises a ring operably engaged about an outer surface of the outer tube and configured for cooperating with the attaching device such that at least a portion of the tissue wall is secured between the attaching device and the ring so as to operably engage said outer tube with the tissue wall. According to some such embodiments, the system may further comprise a plurality of ridges disposed on the outer surface of the outer tube. In such embodiments, the ring comprises at least one deformable pawl member operably engaged therewith for releasably engaging the plurality of ridges on the outer surface of the outer tube. In some other embodiments, the system may comprise threading on at least a portion of the outside surface of the outer tube and corresponding threading on at least a portion of an inside surface of the ring. The threading may thus be configured to cooperate for axially securing the ring relative to the outer tube. Furthermore, some system embodiments may further comprise a nut operably engaged about an outer surface of the outer tube and proximal to the ring. The nut may comprise threading on at least a portion on an inside surface thereof, wherein the threading may be configured for cooperating with the threading on at least a portion of the outside surface of the outer tube.

Furthermore, the nut may be configured for cooperating with the ring to advance the ring towards the distal end of the outer tube.

5 In some embodiments, various system components, such as the outer tube and the ring, may be configured to conform to and/or establish a substantially fluid-tight seal with at least a portion a surface of the tissue wall. For example, in some embodiments, the system may comprise a sealing member operably engaged with a distal end of the ring. According to such embodiments, the sealing member may be configured for establishing a substantially fluid tight seal between the ring and the first surface of the tissue wall. In some embodiments, the system may be
10 configured to cooperate and/or operably engage a tissue wall comprising a substantially curved tissue wall. According to some such embodiments, the ring may comprise a frusto-conical assembly configured for receiving at least a portion of the substantially curved tissue wall so as to form a substantially fluid-tight seal between the frusto-conical assembly and the tissue wall.

15 In some embodiments, the system further comprises an inner tube configured for insertion into the guide aperture defined by the outer tube. According to such embodiments, the inner tube defines a conduit aperture extending axially therethrough. Furthermore, in some such embodiments, the outer tube may comprise a first securing device operably engaged with a proximal end of
20 the outer tube and the inner tube may comprise a complementary second securing device operably engaged with a proximal end of said inner tube. Thus, according to such embodiments, the second securing device may be configured for selectively operably engaging the first securing device so as to operably engage the inner tube with the outer tube to install and maintain the conduit.

25 In some embodiments, the system may also comprise a coring device configured for advancing through the conduit aperture defined by the inner tube and through the tissue wall to define an aperture therein by removing a tissue core. The coring device may be further configured for carrying the inner tube through the aperture such that the inner tube extends at least partially through the aperture
30 so as to establish fluid communication between the first and second surfaces of the tissue wall. The coring device may define a coring bore extending axially therethrough and configured for receiving the tissue core removed by the coring

device. In some embodiments, the coring device may further comprise a piercing rod slidably advancable and retractable within the coring bore. The piercing rod may further comprise a retrieval device operably engaged with a distal end thereof and configured for axially retaining the tissue core removed by the coring device.

5 Thus, in some embodiments, the piercing rod may be configured for advancing so as to pierce the tissue wall prior to removal of the tissue core and/or retracting after removal of the tissue core such that the tissue core is retrievable via a proximal end of the coring device. In some such embodiments, the coring device may further comprise a handle operably engaged with the proximal end of the coring device.

10 The handle may define a tissue core chamber in communication with the coring bore, the tissue core chamber configured for receiving the tissue core retrieved by the retraction of the piercing rod. Furthermore, in some such embodiments, at least a portion of the handle may comprise a transparent material such that the tissue core received therein is visible from a position outside the handle.

15 The various embodiments of the present invention may thus be configured for implanting a conduit device that is adapted for providing a conduit for a medical procedure. Such procedures may include, but are not limited to: bypass; cardiac valve repair or replacement; attachment of a ventricular assist device; establishment of an apicoaortic conduit (AAC) and combinations of such

20 procedures.

Use of this new conduit device, system, and method will significantly improve the ease and safety of conduit insertion (such as the implantation of AAC devices, for example). For example, various embodiments of the present invention may allow the outer tube to be securely operably engaged with the tissue wall (due

25 at least in part to the cooperation of the attaching device and the ring) prior to the removal of a tissue core to define an aperture in the tissue wall. Thus, portions of the system disclosed herein may define a guide aperture extending axially through the outer tube for receiving a coring device that may be configured to be capable of efficiently removing and retrieving a tissue core while substantially simultaneously

30 operably engaging a inner tube in the guide aperture so as to establish fluid communication between first and second opposing surfaces of the tissue wall. As persons of ordinary skill in the art will readily appreciate, the various embodiments

of the present invention may also be used in a minimally invasive, endoscopically assisted approach.

BRIEF DESCRIPTION OF THE DRAWINGS

5 Having thus described various embodiments of the invention in general terms, reference will now be made to the accompanying drawings, which are not necessarily drawn to scale, and wherein:

FIG. 1 shows a non-limiting perspective view of an exemplary system for implanting a conduit device, according to one embodiment of the present invention;

FIG. 2 shows a non-limiting side cross-sectional view of an exemplary system for implanting a conduit device, according to one embodiment of the present invention;

FIG. 3 shows a non-limiting side cross-sectional view of an exemplary conduit device implanted in a tissue wall, according to one embodiment of the present invention;

FIG. 4 shows a non-limiting side view of an exemplary system for implanting a conduit device, according to one embodiment of the present invention;

20 **FIGS. 5A-5G** show an exemplary set of views of the installation of a conduit device using an exemplary system, according to one embodiment of the present invention;

FIG. 5A shows a non-limiting side cross-sectional view of an exemplary system for implanting a conduit device comprising an attaching device at least partially implanted in a tissue wall, according to one embodiment of the present invention;

FIG. 5B shows a non-limiting side cross-sectional view of an exemplary system for implanting a conduit device comprising an attaching device and a ring cooperating to secure at least a portion of the tissue wall between the attaching device and the ring so as to operably engage said outer tube with the tissue wall, according to one embodiment of the present invention;

FIG. 5C shows a non-limiting side cross-sectional view of an exemplary

system for implanting a conduit device comprising a coring device carrying an inner tube configured for insertion into a guide aperture defined by the outer tube, wherein the coring device is advanced at least partially through the tissue wall so as to remove a tissue core thereof, according to one embodiment of the present invention;

FIG. 5D shows a non-limiting side cross-sectional view of an exemplary system for implanting a conduit device comprising a coring device carrying an inner tube configured for insertion into a guide aperture defined by the outer tube, wherein the coring bore defined by the coring device contains a tissue core removed from the tissue wall, according to one embodiment of the present invention;

FIG. 5E shows a non-limiting side cross-sectional view of an exemplary system for implanting a conduit device comprising a coring device carrying an inner tube configured for insertion into a guide aperture defined by the outer tube, wherein a piercing rod is retracted through the coring bore after removal of the tissue core such that the tissue core is retrievable via a proximal end of the coring device, according to one embodiment of the present invention;

FIG. 5F shows a non-limiting side cross-sectional view of an exemplary system for implanting a conduit device, wherein the outer tube and inner tube are installed in the tissue wall so as to establish fluid communication between the first and second surfaces of the tissue wall, according to one embodiment of the present invention;

FIG. 5G shows a non-limiting side cross-sectional view of an exemplary coring device, wherein a handle operably engaged with a proximal end of the coring device contains a tissue core removed from the tissue wall by the coring device, according to one embodiment of the present invention;

FIG. 6 shows a non-limiting side view of an exemplary coring device carrying an inner tube configured for insertion into a guide aperture defined by the outer tube, according to one embodiment of the present invention; and

FIG. 7 shows a non-limiting perspective view of an exemplary conduit device comprising an attaching device comprising a helical spring, according to one embodiment 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 conduit device 1 (see FIGS. 1 and 7, for example) and a system for implanting such a device to form an apicoaortic 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 conduit device 1 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 conduit device to form at least one 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 conduit device 1 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 conduit device 1) for selectively sealing a proximal end of the conduit device 1 such that

the inner tube **40** thereof may serve as a re-usable port for repairing and/or treating diseased portions of the cardiac anatomy. Furthermore, the conduit device **1** and system embodiments of the present invention may also be used to implant a conduit and/or port for left ventricular assist devices.

5 It should be further understood that various embodiments of the conduit device **1** described herein may also be utilized to establish fluid communication between opposing surfaces of a variety of tissue walls and/or anatomical structures. For example, in some embodiments, the conduit device **1** and system for implanting described herein may be used to establish a conduit (and consequently
10 fluid communication) between opposing surfaces of a wall of an anatomical structure that may include, but is not limited to: a urinary bladder; a gall bladder; a diaphragm; a thoracic cavity; an abdominal cavity; an intestinal structure; a cecal cavity; and other tissue wall structures.

 It should be understood that the various conduit device **1** components
15 described herein (see, for example, the components shown in FIG. 1) may comprise a variety of biocompatible materials including, but not limited to: stainless steel; titanium substantially rigid biocompatible polymers; elastomeric biocompatible polymers; and combinations of such materials. For example, in some embodiments, the outer tube **10**, ring **30**, nut **20**, and inner tube **40** may
20 comprise substantially rigid biocompatible polymers. In some embodiments, the attaching device **15** may comprise a biocompatible metal and/or metal alloy that may be embedded substantially within and/or operably engaged with an injection-molded polymer used to form the outer tube **10**. Furthermore, as described further herein, some embodiments of the present invention may further comprise a sealing
25 member **35** operably engaged with a distal end of the ring **30**. In such embodiments, the sealing member **35** may comprise a substantially compliant biocompatible polymer (such as an elastomeric polymer) that may be suitable for establishing a substantially fluid tight seal between the ring **30** a surface of the tissue wall **850**. Similarly, the various components of the coring device **2**
30 described herein may also comprise a combination of biocompatible materials suitable for removing and retaining the tissue core **850a** in order to define an aperture in the tissue wall **850** such that the inner tube **40** may be installed to

establish fluid communication between the opposing first and second surfaces **855**, **853** of the tissue wall **850** (as shown in FIG. 3, for example).

FIG. 3 shows some exemplary components of a system for implanting a conduit device **1** in a tissue wall **850** having a first surface **855** and an opposing second surface **853**. As shown generally in FIGS. 1 and 2, such a system may comprise an outer tube **10** defining a guide aperture extending axially therethrough and an attaching device **15** extending from a distal end of the outer tube **10**. As shown in FIG. 3, for example, the attaching device **15** may be configured for advancing along a helical path at least partially through the tissue wall **850** such that at least a portion of the attaching device **15** becomes disposed substantially between the first surface **855** and the opposing second surface **853** of the tissue wall **850** when the outer tube **10** is rotated relative to the first surface **855** of the tissue wall **850**. As shown generally in FIG. 2, the attaching device **15** may be integrally formed within the outer tube **10**. For example, the attaching device **15** may, in some embodiments, be placed at least partially in a mold such that the polymeric or other components of the outer tube **10** may be molded substantially around at least a portion of the attaching device **15** (which may comprise a static coil and/or elastic spring, as described further herein). In other embodiments, the attaching device **15** may be operably engaged with at least a portion of the outer tube **10** via adhesive, RF welding, and/or other attachment methods that may be suitable for securely operably engaging the attaching device **15** to the outer tube **10**.

The attaching device **15** may comprise, in some embodiments, a helical static coil having a sharpened distal end adapted for piercing the tissue wall **850** as the outer tube **10** is rotated relative to the first surface **855** of the tissue wall **850**. In other embodiments, the attaching device **15** may comprise a helical elastic spring having a sharpened end adapted for piercing the tissue wall **850** as the outer tube **10** is rotated relative to the first surface **855** of the tissue wall **850**. In some embodiments, as shown in FIG. 4, wherein the attaching device **15** comprises a helical spring and/or coil, the spring and/or coil may device a radially-expanding helix as the attaching device **15** extends away from the distal end of the outer tube **10**. In some embodiments, wherein the attaching device comprises a conical

and/or “radially-expanding” helix, the attaching device **15** may act to compress at least a portion of the tissue wall **850** radially inward and towards an outer surface of the inner tube **40** so as to establish a substantially fluid-tight seal between the outer surface of the inner tube **40** and the portion of the tissue wall **850** that has
5 been urged radially inward. Furthermore, in some such embodiments, the radially-expanding helix of the attaching device **15** may correspond, for example, to a ring **30** comprising a frusto-conical assembly configured for receiving at least a portion of a substantially curved tissue wall **850** (see, for example, FIG. **5B**) so as to form a substantially fluid-tight seal between the frusto-conical assembly of the ring **30**
10 and the tissue wall **850**.

In other embodiments, as shown generally in FIG. **7**, the attaching device **15** may comprise a helical spring and/or coil having a substantially constant helical diameter as the attaching device **15** extends away from the distal end of the outer tube **10**. The substantially consistent helical diameter of the attaching device **15**
15 shown generally in FIG. **7** may be useful for operably engaging the outer tube **10** with a substantially flat tissue wall **850**. Furthermore, as shown generally in FIG. **7**, in some embodiments, the corresponding ring **30** (and the corresponding sealing member **35** that may be operably engaged therewith) may also be configured to provide a substantially flat and/or disc-shaped sealing surface that may be suitable
20 for seating on and/or establishing a substantially fluid-tight seal with a substantially flat first tissue surface **855** that may surround an aperture defined in a correspondingly flat tissue wall **850**.

As described herein, the system may further comprise a ring **30** operably engaged about an outer surface of the outer tube **10**. As shown generally in FIGS. **3** and **5B**, the ring **30** may be configured for cooperating with the attaching device **15** such that at least a portion of the tissue wall **850** is secured between the
25 attaching device **15** and the ring **30** so as to operably engage the outer tube **10** with the tissue wall **850**. Some embodiments may further comprise a plurality of ridges **11** and/or threads disposed on the outer surface of the outer tube **10**. According to such embodiments, the ring **30** may comprise at least one deformable pawl
30 member configured for releasably engaging the plurality of ridges **11** disposed on the outer surface of the outer tube **10**. Other embodiments (as shown generally in

FIG. 2, for example), may also further comprise threading **11** on at least a portion of the outside surface of the outer tube **10** and corresponding threading on at least a portion of an inside surface of the ring **30**. The threading **11** (and corresponding threading on the inner surface of the ring **30**) may be being configured to cooperate for axially securing the ring **30** relative to the outer tube **10**. As shown generally in FIGS. **5A-5B**, some embodiments may further comprise a nut **20** operably engaged about an outer surface of the outer tube **10** and proximal to the ring **30**. According to such embodiments, the nut **20** may comprise threading on at least a portion on an inside surface of the nut **20**. The threading disposed on the inside surface of the nut **20** may be configured for cooperating with the threading **11** on at least a portion of the outside surface of the outer tube **11** for axially securing the nut **20** relative to the outer tube **10** and the adjacent ring **20**. As shown in FIGS. **5A-5B**, the nut **20** may be configured for cooperating with the ring **30** to advance the ring **30** towards the distal end of the outer tube **10**. As shown generally in FIGS. **5A-5B**, the attaching device **15** may provide counter-traction so as to allow for the rotation (and resulting advancement) of the nut **20** (and the ring **30** disposed distally thereto) such that rotation of the nut **20** (and the corresponding movement of the ring **30** toward the first tissue surface **855**) may draw at least a portion of the tissue wall **850** into engagement with an inner surface of the ring **30** such that the conduit device **1** (and particularly the outer tube **10** thereof) is stabilized, engaged in a substantially fluid tight seal, and/or operably engaged with respect to the tissue wall **850** prior to the use of a coring device **2** for removing a tissue core **850a** via the guide aperture defined axially through the outer tube **10**.

In order to ensure that the ring **30** forms a substantially fluid-tight seal with the first surface **855** of the tissue wall **850** about the aperture defined therein, some embodiments (as shown in FIG. **1**, for example) may further comprise a sealing member **35** operably engaged with a distal end of the ring **30**. The sealing member **35** may comprise, for example, a gasket or other elastomeric component configured for establishing a substantially fluid tight seal between the ring **30** and the first surface **855** of the tissue wall **855**. As described herein, some embodiments of the present invention may be configured for establishing fluid communication between the opposing sides of the walls of a mammalian heart

(such as the ventricular apex, for example). In such embodiments, the conduit device **1** may be required to be operably engaged with a substantially curved tissue wall **850** (see FIG. **5A**, for example). In such embodiments, the ring **30** may comprise a frusto-conical assembly configured for receiving at least a portion of the substantially curved tissue wall **850** so as to form a substantially fluid-tight seal between the frusto-conical assembly of the ring **30** and the tissue wall **850**. As shown, for example, in FIG. **5B**, in some embodiments, the ring **30** may be urged towards a distal end of the outer tube **10** by the rotation of a nut **20** about threading **11** disposed on an outer surface of the outer tube **10**. Thus, according to some such embodiments, the cooperation of the attaching device **15** (which may comprise a piercing helical spring and/or coil, for example) with the ring **30** may act to draw at least a portion of the curved tissue wall **850** into the frusto-conical assembly of the ring **30** such that a substantially fluid-tight seal may be formed and maintained between the frusto-conical assembly of the ring **30** and the tissue wall **850**. In some conduit device **1** embodiments, as shown generally in FIG. **2**, the ring **30** may comprise a seal testing aperture **36** that may allow a clinician to selectively test whether or not a substantially fluid-tight seal has been established between the ring **30** and the first surface **855** of the tissue wall **850** when the ring **30** is moved towards the distal end of the outer tube **10** and into engagement with the tissue wall **850**. For example, a clinician may operably engage a fluid source (such as a saline solution bag) with the seal testing aperture **36** (which may comprises a luer lock connector or other connector for operably engaging the fluid source) and introducing a fluid via seal testing aperture **36** and observing the interface between the ring **30** and the first surface **855** of the tissue wall **850** to see if any substantial amount of fluid emerges. If no fluid is readily visible, a clinician may be reasonably assured that the seal formed between the ring **30** and the tissue wall **850** is substantially fluid-tight. By assessing the seal formed between the ring **30** and the tissue wall **850**, a clinician may determine if it is medically safe to introduce the coring device **2** via the guide conduit defined in the outer tube **10** (i.e. determine if blood loss is likely to occur between the ring **30** and the first surface **855** of the tissue wall **850** when the coring device **2** (and the coring cylinder **65** thereof) is advanced through the tissue wall **850** as shown in FIG. **5C**).

In some embodiments, the seal testing aperture **36** may also serve an alternative function for rotationally securing the ring **30** relative to and the first surface **855** of the tissue wall **850**. For example, a clinician may insert a needle and/or other elongate spike through the seal testing aperture **36** defined in the ring **30** and substantially into the tissue wall **850**. The interaction of the needle and/or spike with the ring **30** (via the seal testing aperture **36**) and the tissue wall **850** may thus reduce a chance that the ring **30** (and the helical attaching device **15** extending from the outer tube **10**) are rotatable relative to the tissue wall **850** such that the ring **30** and the helical attaching device **15** may be less prone to “backing out” of the tissue wall **850** once the seal is established between the ring **30** and the first surface **855** of the tissue wall **850**.

In some additional embodiments, as shown generally in FIG. 7, the ring **30** (and/or the sealing member **35** that may be operably engaged therewith) may define a substantially flat and/or disc-shaped annular sealing surface that may be configured for establishing a substantially fluid-tight seal between the ring **30** and a substantially flat first tissue surface **855** about an aperture defined in the tissue wall **850**.

Referring to FIG. 5C, for example, some embodiments may further comprise an inner tube **40** defining a conduit aperture extending axially therethrough. The inner tube **40** may be configured for insertion into the guide aperture defined by the outer tube **10**. In some embodiments, as shown in FIG. 6, the inner tube **40** may be carried by a coring device **2** that may be advanced through the guide aperture defined by the outer tube **10** and configured for substantially simultaneously removing a tissue core **850a** to define an aperture in the tissue wall **850** and operably engaging the inner tube **40** with the outer tube **10** so as to establish and/or maintain a reliable and engageable pathway for fluid communication between the first and second surfaces **855**, **853** of the tissue wall **850**. In order to facilitate the secure engagement of the outer tube **10** with the inner tube **40**, some conduit device **1** embodiments may comprise a first securing device **13** operably engaged with a proximal end of the outer tube **10** and a complementary second securing device **43** operably engaged with a proximal end of the inner tube **40**. According to such embodiments, as shown generally in FIG.

2, the second securing device **43** may be configured for selectively operably engaging the first securing device **13** so as to operably engage the inner tube **40** with the outer tube **10**. As shown generally in FIG. **6**, the second securing device **43** may comprise one or more deformable pawls configured for selectively
5 operably engaging the first securing device **13** as shown in FIG. **2** (wherein the first securing device **13** comprises one or more ridges disposed on a proximal portion of the outer surface of the outer tube **10**).

As shown generally in FIG. **6**, some system embodiments for installing a conduit device **1** may further comprise a coring device **2** configured for advancing
10 through the conduit aperture defined by the inner tube **40** and through the tissue wall **850** to define an aperture therein by removing a tissue core **850a** (see FIG. **5D**, for example, showing the coring device **2** removing a tissue core **850a** and collecting the tissue core **850a** in a coring bore defined by a coring cylinder **65**. As shown generally in FIGS. **5C** and **6**, the coring device **2** may be further configured
15 for carrying the inner tube **40** through the aperture such that the inner tube **40** extends at least partially through the aperture (see FIG. **5F**, for example) so as to establish fluid communication between the first **855** and second **853** surfaces of the tissue wall **850**. In some embodiments, as shown in the cross-sectional side view of FIG. **5D**, the coring device **2** (and/or the coring cylinder **65** thereof) defines a
20 coring bore extending axially therethrough configured for receiving the tissue core **850a** removed by the coring cylinder **65**.

As shown in FIGS. **5C-5E**, the coring device **2** may also comprise a piercing rod **60** slidably advancable and retractable within the coring bore defined by the coring device **2**. The piercing rod **60** may further comprise a retrieval
25 device **61** operably engaged with a distal end thereof and configured for axially retaining the tissue core **850a** removed by the coring cylinder **65**. In various embodiments, the retrieval device **61** may include, but is not limited to: a barb; a hook; corkscrew; expandable balloon; a self-expanding structure; and/or other device configured for initially piercing the tissue wall **850** so as to be capable of
30 retrieving the tissue core **850a** removed by the coring device **2** as described further herein. As shown generally in FIG. **5C**, the piercing rod **60** may be configured for advancing so as to pierce the tissue wall **850** prior to removal of the tissue core

850a (i.e. prior to the advancement of the coring cylinder **65** through the tissue wall **850**). Furthermore, as shown generally in FIG. **5E**, the piercing rod **60** may be further configured for retracting after removal of the tissue core **850a** such that the tissue core **850a** is retrievable via a proximal end of the coring device **2**. In some system embodiments for installing a conduit device **1**, the coring device **2** may further comprise a handle **63** operably engaged with a proximal end of the coring device **2** (and/or a proximal end of the coring cylinder **65**). According to such embodiments, as shown generally in FIG. **6**, the handle **63** may define a tissue core chamber **62** in communication with the coring bore defined by the coring cylinder **65**. As shown in FIG. **5E**, the tissue core chamber **62** may thus be configured for receiving the tissue core **850a** retrieved by retraction of the piercing rod **60** (and the retrieval device **61** operably engaged with a distal end thereof). In order to allow a clinician to positively identify and/or confirm the removal and retraction of the tissue core **850a**, in some system embodiments at least a portion of the handle **65** may be provided with a substantially transparent material (such as a transparent polycarbonate polymer, for example) such that the tissue core **850a** received by the tissue core chamber **62** may be visible (to a clinician or an endoscopic imaging device, for example) from a position substantially outside the handle **63**.

FIGS. **5A-5G** illustrate the various steps involved in the utilization of one embodiment of the system of the present invention for installing a conduit device **1** in a tissue wall **850** (such as the ventricular apex). It should be understood that various embodiments of the present invention may be utilized for installing the conduit device **1** for use in medical procedures that may include, but are not limited to: bypass; cardiac valve repair or replacement; attachment of a ventricular assist device; and combinations of such procedures. As shown in FIG. **5A**, an exemplary process for installing a conduit device **1** may begin with the implantation of the attaching device **15** in the tissue wall **850**. As described herein, the attaching device **15** may comprise a helical spring and/or coil configured for advancing along a helical path at least partially through the tissue wall **850** such that at least a portion of the attaching device **850** becomes disposed substantially between the first surface **855** and the opposing second surface **853** of the tissue

wall **850** when the outer tube **10** is rotated relative to the first surface **855** of the tissue wall **850**. In some embodiments, the attaching device **15** may be sized such that the axial length of the attaching device **15** does not extend substantially distal to the second surface **853** of the tissue wall **850**.

5 In some embodiments, wherein the attaching device comprises a conical and/or “radially-expanding” helix, the attaching device **15** may act to compress at least a portion of the tissue wall **850** radially inward and towards an outer surface of the inner tube **40** so as to establish a substantially fluid-tight seal between the outer surface of the inner tube **40** and the portion of the tissue wall **850** that has
10 been urged radially inward by the conical and/or radially-expanding helix of the attaching device **15**. Furthermore, in embodiments wherein the attaching device **15** comprises a conical and/or “radially-expanding” helix, the attaching device **15** may act to compress at least a portion of the tissue wall **850** radially inward such that the portion of the tissue wall **850** may be more readily received by ring **30** (which
15 may comprise a frusto-conical structure configured for receiving the compressed portion of the tissue wall **850**). As shown in FIG. **5B**, the conduit device **1** installation process may continue with the advancement and/or tightening of the ring **30** towards a distal end of the outer tube **10**. As described herein, some conduit device **1** embodiments of the present invention may comprise a nut **20**
20 operably engaged about an outer surface of the outer tube **10** proximal to the ring **30**. In some such embodiments, the nut **20** may comprise threading on at least a portion on an inside surface thereof, wherein the threading is configured for cooperating with the threading **11** on at least a portion of the outside surface of the outer tube **10**. The nut **20** may thus be configured to cooperate with the ring **30** to
25 advance the ring **30** towards the distal end of the outer tube **10**, and therefore into contact with the first surface **855** of the tissue wall **850**. As shown generally in FIG. **5B**, once the nut **20** and ring **30** are advanced distally (which may be accomplished by hand-tightening the nut **20**), the ring **30** may cooperate with the attaching device **15** such that at least a portion of the tissue wall **850** is secured
30 between the attaching device **15** and the ring **30** so as to securely operably engage the outer tube **10** with the tissue wall **850**.

As shown in FIG. **5C**, once the outer tube **10** is stabilized relative to the

tissue wall **850**, a coring device **2** (which, in some embodiments, as shown in FIG. **6**, may be configured for carrying an inner tube **40**), may be inserted into the guide aperture defined axially within the outer tube **10**. As described herein with respect to FIG. **6**, the coring device **2** may comprise a coring cylinder **65** configured for advancing through the conduit aperture defined by the inner tube **40** and through the tissue wall **850** to define an aperture therein by removing a tissue core **850a** (see FIG. **5D**, for example). Referring again to FIG. **5C**, some embodiments may further comprise a piercing rod **60** slidably advancable and retractable within the coring bore defined by the coring cylinder **65**. The piercing rod **60** may comprise, in some embodiments, an elongate proximal end that may be manipulated (i.e. extended and/or retracted) by a clinician in order to initially pierce the tissue wall **850** and/or retract the tissue core **850a** removed therefrom (as described further herein). As shown in FIGS. **5D** and **5E**, the piercing rod **60** may further comprise a retrieval device **61** operably engaged with a distal end thereof and configured for axially retaining the tissue core **850a** removed by the coring cylinder **65**. The piercing rod **60** may be configured for advancing so as to pierce the tissue wall **850** prior to removal of the tissue core **850a** (i.e. prior to advancement of the coring cylinder **65**). Furthermore, as shown in FIG. **5E**, the piercing rod **60** may be further configured for retracting after removal of the tissue core **850a** such that the tissue core **850a** is retrievable via a proximal end of the coring device **2**.

As shown in FIGS. **5D** and **6**, the coring device **2** may be further configured for carrying the inner tube **40** through the aperture such that the inner tube **40** extends at least partially through the aperture so as to establish fluid communication between the first and second surfaces **855**, **853** of the tissue wall **850** (see also, FIG. **3**, for example). As described herein, with respect to various conduit device **1** embodiments of the present invention the outer tube **10** may comprise a first securing device **13** operably engaged with a proximal end thereof and the inner tube **40** (carried, for example, by the coring device **2** into position relative to the outer tube **10**) may comprise a complementary second securing device **43** operably engaged with a proximal end thereof. As shown generally in FIG. **3**, the second securing device **43** (which may comprise a deformable pawl, for example) may be configured for selectively operably engaging the first securing

device **13**(which may comprise a complementary at least one ridge disposed on an outer surface of the outer tube **10**) so as to positively and securely operably engage the inner tube **40** with the outer tube **10**.

Referring again to FIG. **5E**, the coring device **2** may, in some
5 embodiments, comprise a handle **63** operably engaged with a proximal end of the coring device **2**. As described herein, the handle **63** may define a tissue core chamber **62** in communication with the coring bore defined, for example, by the coring cylinder **65**. The tissue core chamber **62** may thus be configured for receiving the tissue core **850a** retrieved by retraction of the piercing rod **60** (and
10 the retrieval device **61** operably engaged with a distal end thereof). In some embodiments, the coring device **2** may also define a fill aperture configured for operably engaging a source of saline solution or other fluid that may be used to substantially flood the coring bore defined by the coring cylinder **65** and the tissue core chamber **62** so as to reduce the chance of introducing gas bubbles (i.e. air
15 bubbles) into an interior chamber defined by the tissue wall **850** when the coring device **2** is introduced via the outer tube **10**.

As described generally herein with regard to the various system embodiments of the present invention, the conduit device **1** installation process may advantageously allow a clinician to visually confirm that the tissue core **850a**
20 removed by the coring cylinder **65** has been completely and cleanly removed from the aperture defined in the tissue wall **850**. For example, in some embodiments, at least a portion of the handle **63** may comprise a transparent material such that the tissue core **850a** received within the tissue core chamber **62** may be directly visible by a clinician and/or an endoscopic imaging device from a position substantially
25 outside the handle **63**. As shown in FIGS. **5F** and **5G**, after the coring device **2** (and the tissue core **850a** retained in the handle **63** thereof) is retracted and removed from the inner tube **40**, a clamp **C** may be applied to a proximal end of a graft portion that may be operably engaged with the inner tube **40** of the conduit device **1**. In other embodiments, the inner tube **40** may comprise one or
30 more ridges defined on an outer surface of the proximal end thereof that may be configured for receiving a deformable cap or other cover for temporarily and/or semi-permanently closing the aperture defined by the installed conduit device **1**.

As described herein, the conduit device **1** may be utilized as a portion of a two-part bypass system that may comprise another corresponding conduit device **1** installed in a tissue wall **850** defining a wall of the mammalian aorta, for example. The two corresponding conduit devices **1** may then be operably engaged with one another
5 via a valve device so as to form an apicoaortic connection (AAC) in order to bypass, for example, a faulty valve or other mechanical defect present in a subject's cardiac anatomy.

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
10 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
15 descriptive sense only and not for purposes of limitation.

THAT WHICH IS CLAIMED:

1. A system for implanting a conduit device in a tissue wall having a first surface and an opposing second surface, the system comprising:
- 5 an outer tube defining a guide aperture extending axially therethrough;
an attaching device extending from a distal end of said outer tube, said attaching device configured for advancing along a helical path at least partially through the tissue wall such that at least a portion of the attaching device becomes disposed substantially between the first surface and the opposing second surface of
- 10 the tissue wall when the outer tube is rotated relative to the first surface of the tissue wall; and
- a ring operably engaged about an outer surface of said outer tube and configured for cooperating with said attaching device such that at least a portion of the tissue wall is secured between the attaching device and the ring so as to
- 15 operably engage said outer tube with the tissue wall.
2. A system according to Claim 1, further comprising a sealing member operably engaged with a distal end of said ring, said sealing member configured for establishing a substantially fluid tight seal between said ring and the
- 20 first surface of the tissue wall.
3. A system according to Claim 1, further comprising:
- an inner tube defining a conduit aperture extending axially therethrough, said inner tube configured for insertion into the guide aperture defined by said
- 25 outer tube; and
- a coring device configured for advancing through the conduit aperture defined by said inner tube and through the tissue wall to define an aperture therein by removing a tissue core, said coring device being further configured for carrying said inner tube through the aperture such that said inner tube extends at least
- 30 partially through the aperture so as to establish fluid communication between the first and second surfaces of the tissue wall.

4. A system according to Claim 3, wherein said outer tube comprises a first securing device operably engaged with a proximal end of said outer tube and wherein said inner tube comprises a complementary second securing device operably engaged with a proximal end of said inner tube, said second securing device configured for selectively operably engaging the first securing device so as to operably engage said inner tube with said outer tube.

5. A system according to Claim 1, wherein said attaching device comprises a helical static coil having a sharpened distal end adapted for piercing the tissue wall as said outer tube is rotated relative to the first surface of the tissue wall.

6. A system according to Claim 5, wherein said helical static coil defines a radially-expanding helix as said helical static coil extends away from the distal end of said outer tube.

7. A system according to Claim 1, wherein said attaching device comprises a helical elastic spring having a sharpened end adapted for piercing the tissue wall as said outer tube is rotated relative to the first surface of the tissue wall.

8. A system according to Claim 7, wherein said helical elastic spring defines a radially-expanding helix as said helical elastic spring extends away from the distal end of said outer tube.

9. A system according to Claim 6, further comprising an inner tube defining a conduit aperture extending axially therethrough, said inner tube configured for insertion into the guide aperture defined by said outer tube such that said inner tube extends at least partially through an aperture defined in the tissue wall so as to establish fluid communication between the first and second surfaces of the tissue wall, and wherein said radially-expanding helix is configured for urging at least a portion of the tissue wall radially inward towards an outer surface

of said inner tube so as to establish a substantially fluid tight seal between the at least a portion of the tissue wall and the outer surface of said inner tube.

10. A system according to Claim 8, further comprising an inner tube
5 defining a conduit aperture extending axially therethrough, said inner tube configured for insertion into the guide aperture defined by said outer tube such that said inner tube extends at least partially through an aperture defined in the tissue wall so as to establish fluid communication between the first and second surfaces of the tissue wall, and wherein said radially-expanding helix is configured for
10 urging at least a portion of the tissue wall radially inward towards an outer surface of said inner tube so as to establish a substantially fluid tight seal between the at least a portion of the tissue wall and the outer surface of said inner tube.

11. A system according to Claim 1, wherein the tissue wall comprises a
15 substantially curved tissue wall and wherein said ring comprises a frusto-conical assembly configured for receiving at least a portion of the substantially curved tissue wall so as to form a substantially fluid-tight seal between said frusto-conical assembly and the tissue wall.

20 12. A system according to Claim 1, further comprising a plurality of ridges disposed on the outer surface of said outer tube and wherein said ring comprises at least one deformable pawl member operably engaged therewith for releasably engaging the plurality of ridges.

25 13. A system according to Claim 1, further comprising threading on at least a portion of the outside surface of said outer tube and corresponding threading on at least a portion of an inside surface of said ring, the threading being configured to cooperate for axially securing said ring relative to said outer tube.

30 14. A system according to Claim 13, further comprising a nut operably engaged about an outer surface of said outer tube proximal to said ring, said nut comprising threading on at least a portion on an inside surface of said nut, the

threading being configured for cooperating with the threading on at least a portion of the outside surface of said outer tube, said nut being configured for cooperating with said ring to advance said ring towards the distal end of said outer tube.

5 15. A system according to Claim 3, wherein said coring device defines a coring bore extending axially therethrough configured for receiving the tissue core removed by said coring device.

10 16. A system according to Claim 15, further comprising a piercing rod slidably advancable and retractable within the coring bore defined by said coring device, said piercing rod further comprising a retrieval device operably engaged with a distal end thereof and configured for axially retaining the tissue core removed by said coring device, said piercing rod being configured for advancing so as to pierce the tissue wall prior to removal of the tissue core, said piercing rod
15 being further configured for retracting after removal of the tissue core such that the tissue core is retrievable via a proximal end of the coring device.

 17. A system according to Claim 15, further comprising a handle operably engaged with the proximal end of the coring device, said handle defining
20 a tissue core chamber in communication with the coring bore, the tissue core chamber being configured for receiving the tissue core retrieved by retraction of the piercing rod.

 18. A system according to Claim 17, wherein at least a portion of said
25 handle comprises a transparent material such that the tissue core received therein is visible from a position outside the handle.

 19. A system according to Claim 1, wherein the conduit device is adapted for providing a conduit for a medical procedure selected from the group
30 consisting of:

 bypass;
 cardiac valve repair or replacement;

attachment of a ventricular assist device; and
combinations thereof.

20. A conduit device for lining an aperture defined in a tissue wall and
5 maintaining fluid communication between a first tissue surface and a second tissue
surface of the tissue wall, the conduit device comprising:

an outer tube defining a guide aperture extending axially therethrough;
an attaching device extending from a distal end of said outer tube, said
attaching device configured for advancing along a helical path at least partially
10 through the tissue wall such that at least a portion of the attaching device becomes
disposed substantially between the first surface and the opposing second surface of
the tissue wall when the outer tube is rotated relative to the first surface of the
tissue wall;

a ring operably engaged about an outer surface of said outer tube and
15 configured for cooperating with said attaching device such that at least a portion of
the tissue wall is secured between the attaching device and the ring so as to
operably engage said outer tube with the tissue wall; and

an inner tube defining a conduit aperture extending axially therethrough,
said inner tube configured for insertion into the guide aperture defined by said
20 outer tube, said inner tube being further configured for extending at least partially
through the aperture so as to establish fluid communication between the first and
second surfaces of the tissue wall.

21. A device according to Claim 20, further comprising a sealing
25 member operably engaged with a distal end of said ring, said sealing member
configured for establishing a substantially fluid tight seal between said ring and the
first surface of the tissue wall.

22. A device according to Claim 20, wherein said outer tube comprises
30 a first securing device operably engaged with a proximal end of said outer tube and
wherein said inner tube comprises a complementary second securing device
operably engaged with a proximal end of said inner tube, said second securing

device configured for selectively operably engaging the first securing device so as to operably engage said inner tube with said outer tube.

23. A device according to Claim 20, wherein said attaching device
5 comprises a helical static coil having a sharpened distal end adapted for piercing the tissue wall as said outer tube is rotated relative to the first surface of the tissue wall.

24. A device according to Claim 23, wherein said helical static coil
10 defines a radially-expanding helix as said helical static coil extends away from the distal end of said outer tube.

25. A device according to Claim 20, wherein said attaching device
15 comprises a helical elastic spring having a sharpened end adapted for piercing the tissue wall as said outer tube is rotated relative to the first surface of the tissue wall.

26. A device according to Claim 25, wherein said helical elastic spring
20 defines a radially-expanding helix as said helical elastic spring extends away from the distal end of said outer tube.

27. A device according to Claim 20, wherein the tissue wall comprises
a substantially curved tissue wall and wherein said ring comprises a frusto-conical
assembly configured for receiving at least a portion of the substantially curved
25 tissue wall so as to form a substantially fluid-tight seal between said frusto-conical assembly and the tissue wall.

28. A device according to Claim 20, further comprising a plurality of
ridges disposed on the outer surface of said outer tube and wherein said ring
30 comprises at least one deformable pawl member operably engaged therewith for releasably engaging the plurality of ridges.

29. A device according to Claim 20, further comprising threading on at least a portion of the outside surface of said outer tube and corresponding threading on at least a portion of an inside surface of said ring, the threading being configured to cooperate for axially securing said ring relative to said outer tube.

5

30. A device according to Claim 29, further comprising a nut operably engaged about an outer surface of said outer tube proximal to said ring, said nut comprising threading on at least a portion on an inside surface of said nut, the threading being configured for cooperating with the threading on at least a portion of the outside surface of said outer tube, said nut being configured for cooperating with said ring to advance said ring towards the distal end of said outer tube.

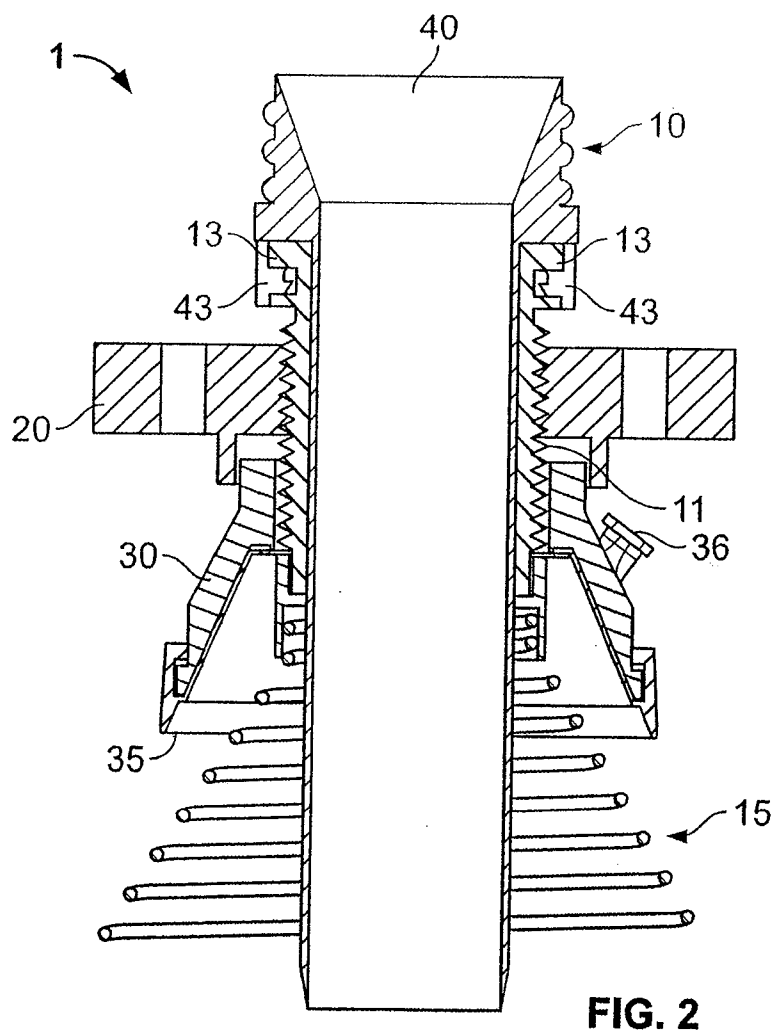
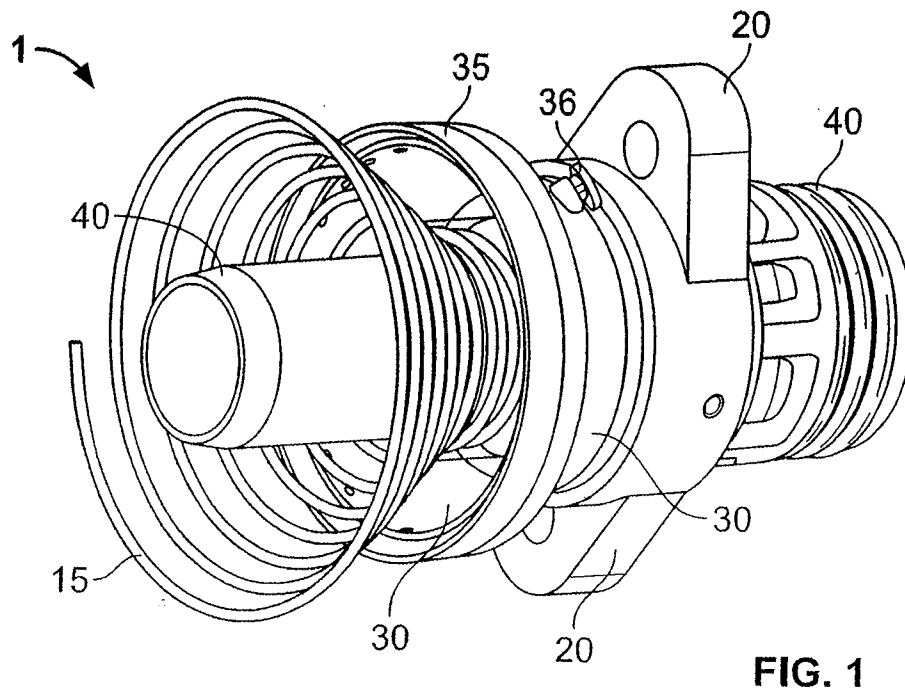
10

31. A device according to Claim 24, wherein said radially-expanding helix is configured for urging at least a portion of the tissue wall radially inward towards an outer surface of said inner tube so as to establish a substantially fluid tight seal between the at least a portion of the tissue wall and the outer surface of said inner tube.

15

32. A device according to Claim 26, wherein said radially-expanding helix is configured for urging at least a portion of the tissue wall radially inward towards an outer surface of said inner tube so as to establish a substantially fluid tight seal between the at least a portion of the tissue wall and the outer surface of said inner tube

20



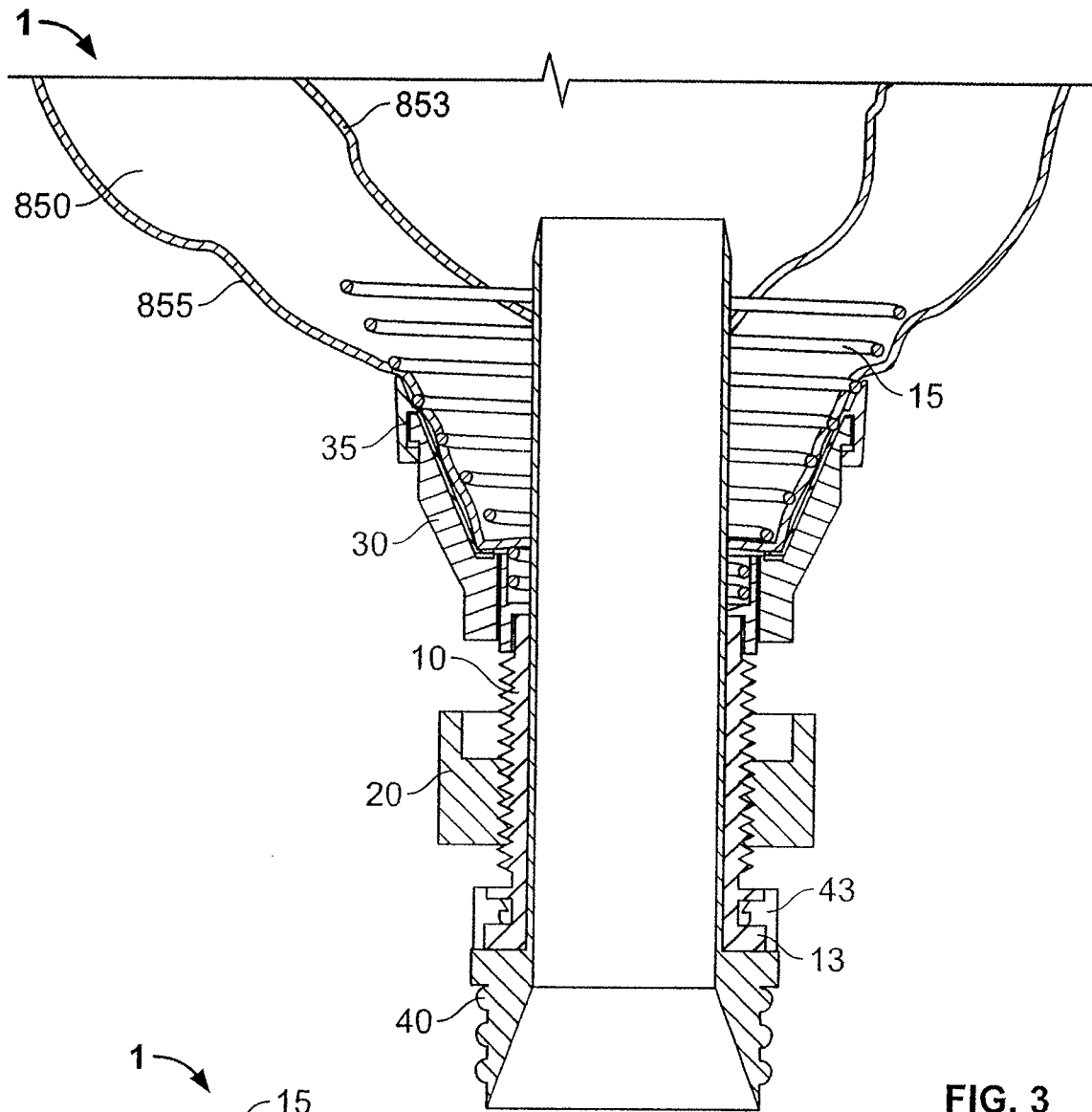


FIG. 3

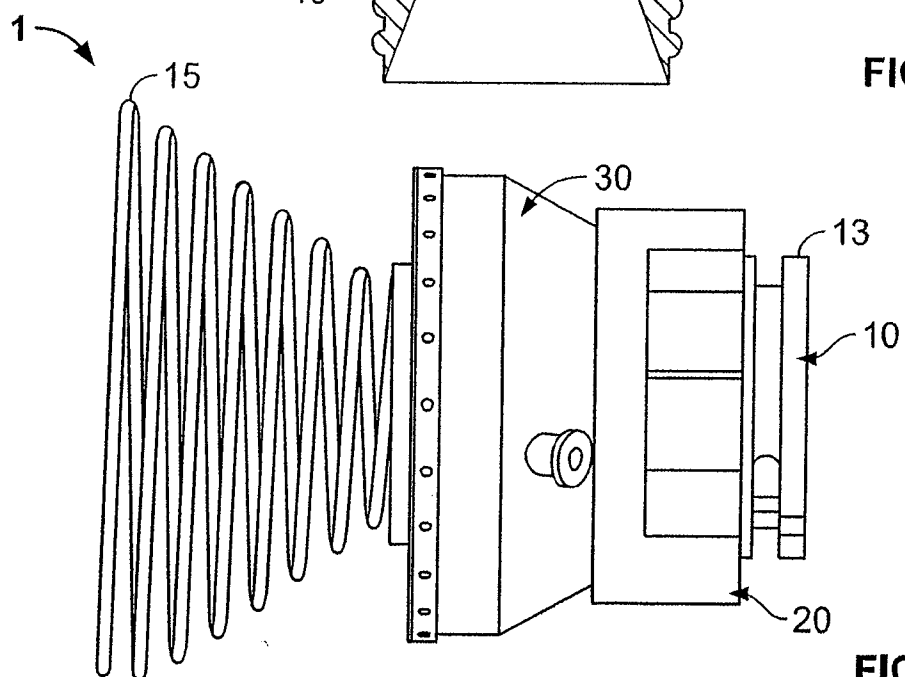


FIG. 4

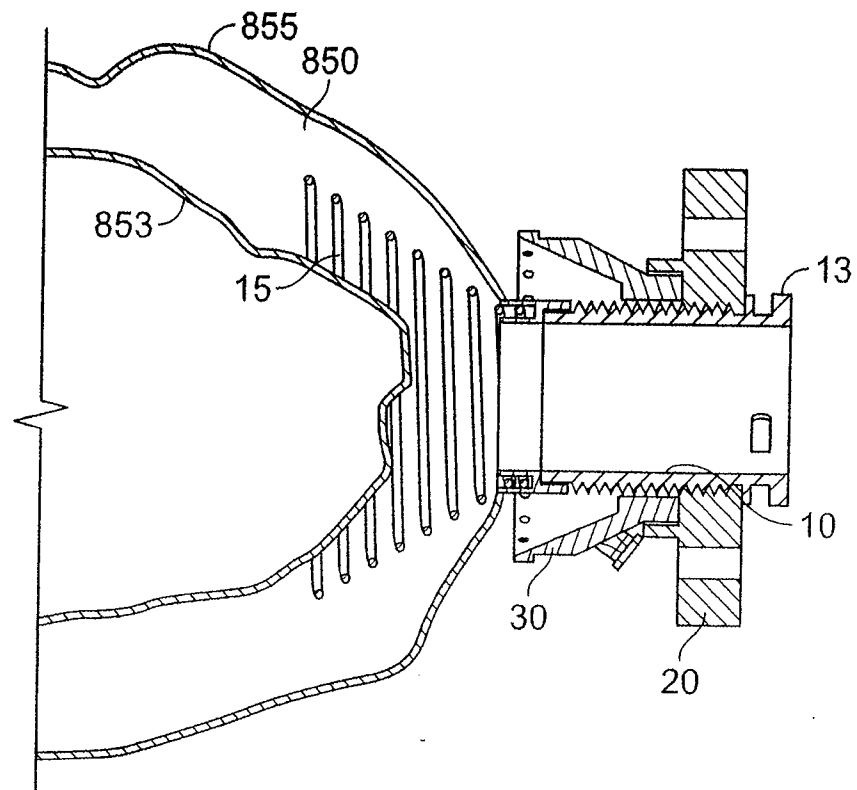


FIG. 5A

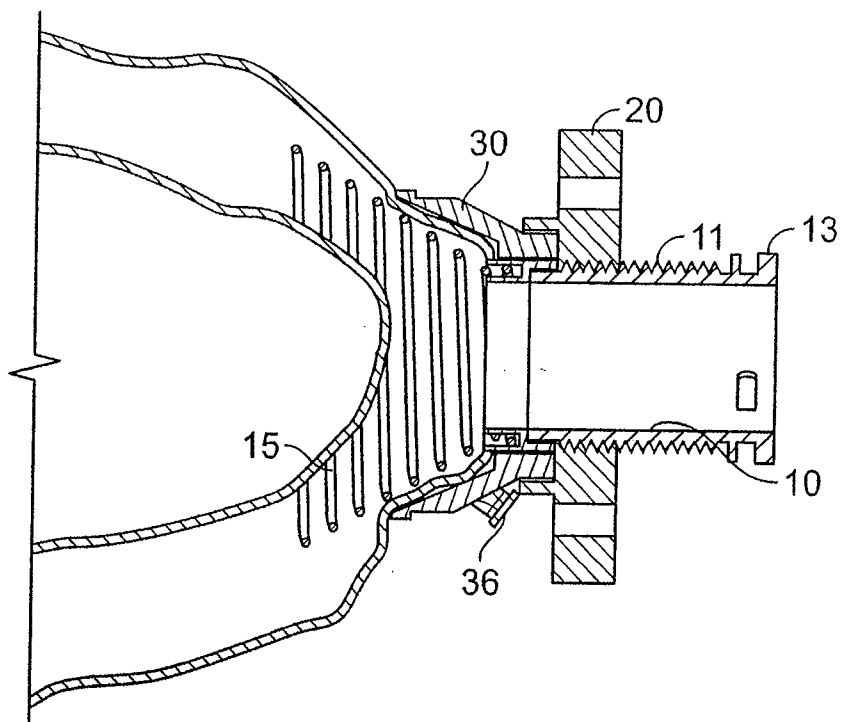


FIG. 5B

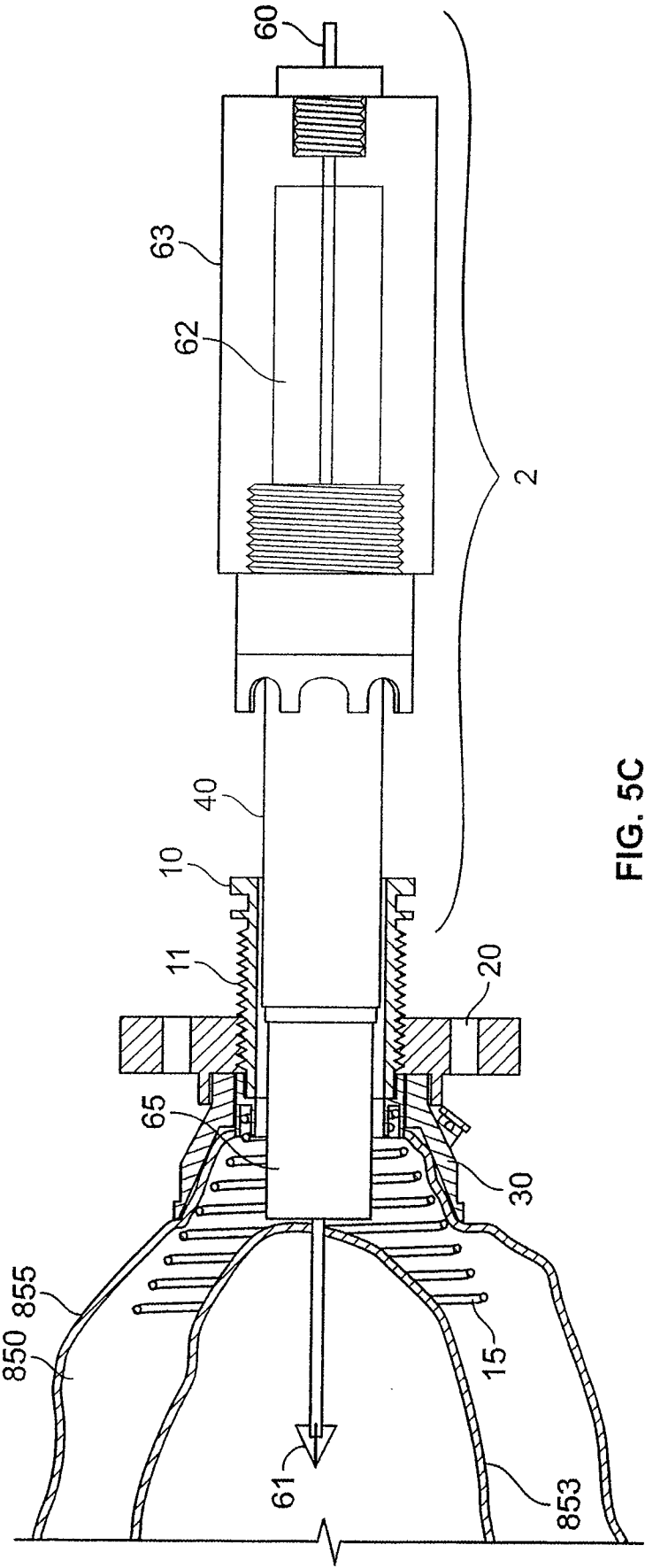
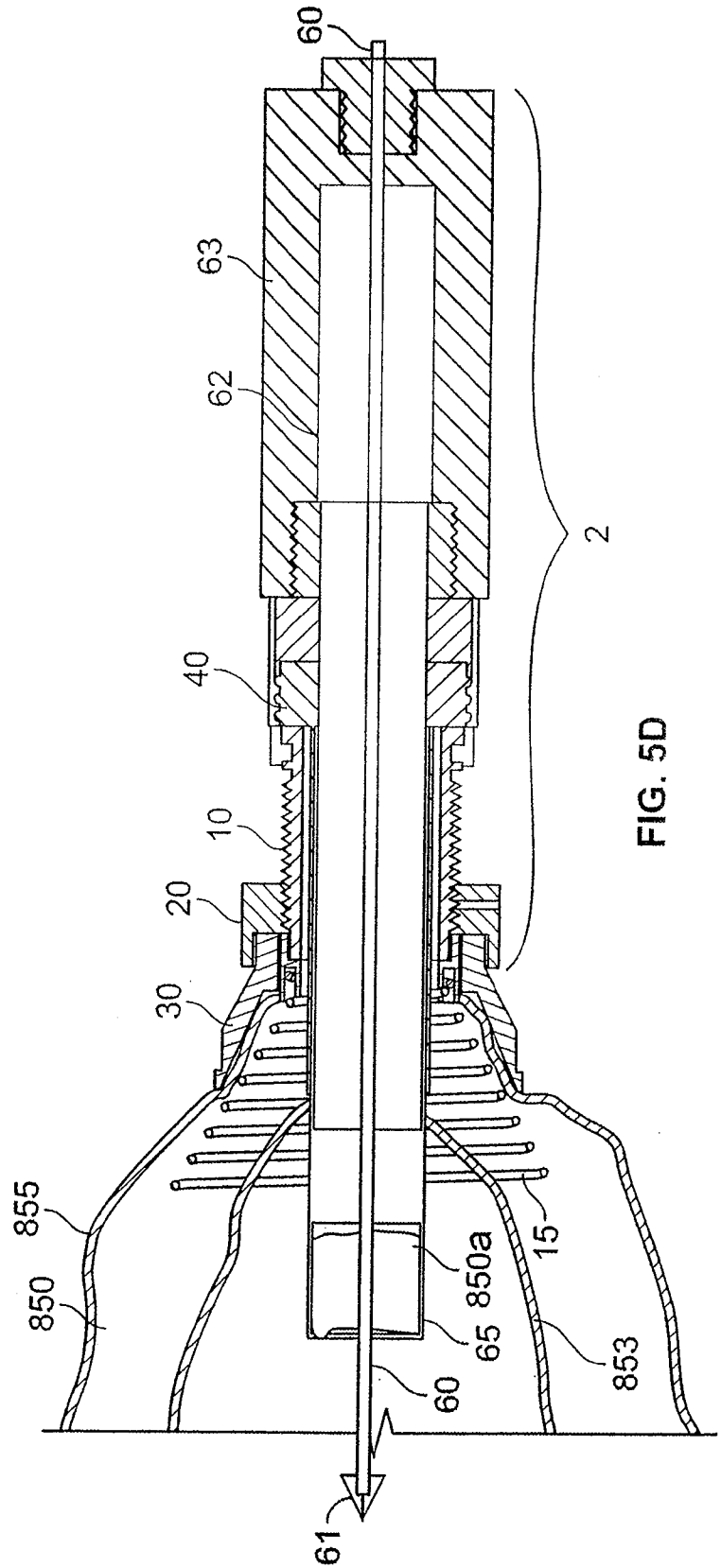


FIG. 5C



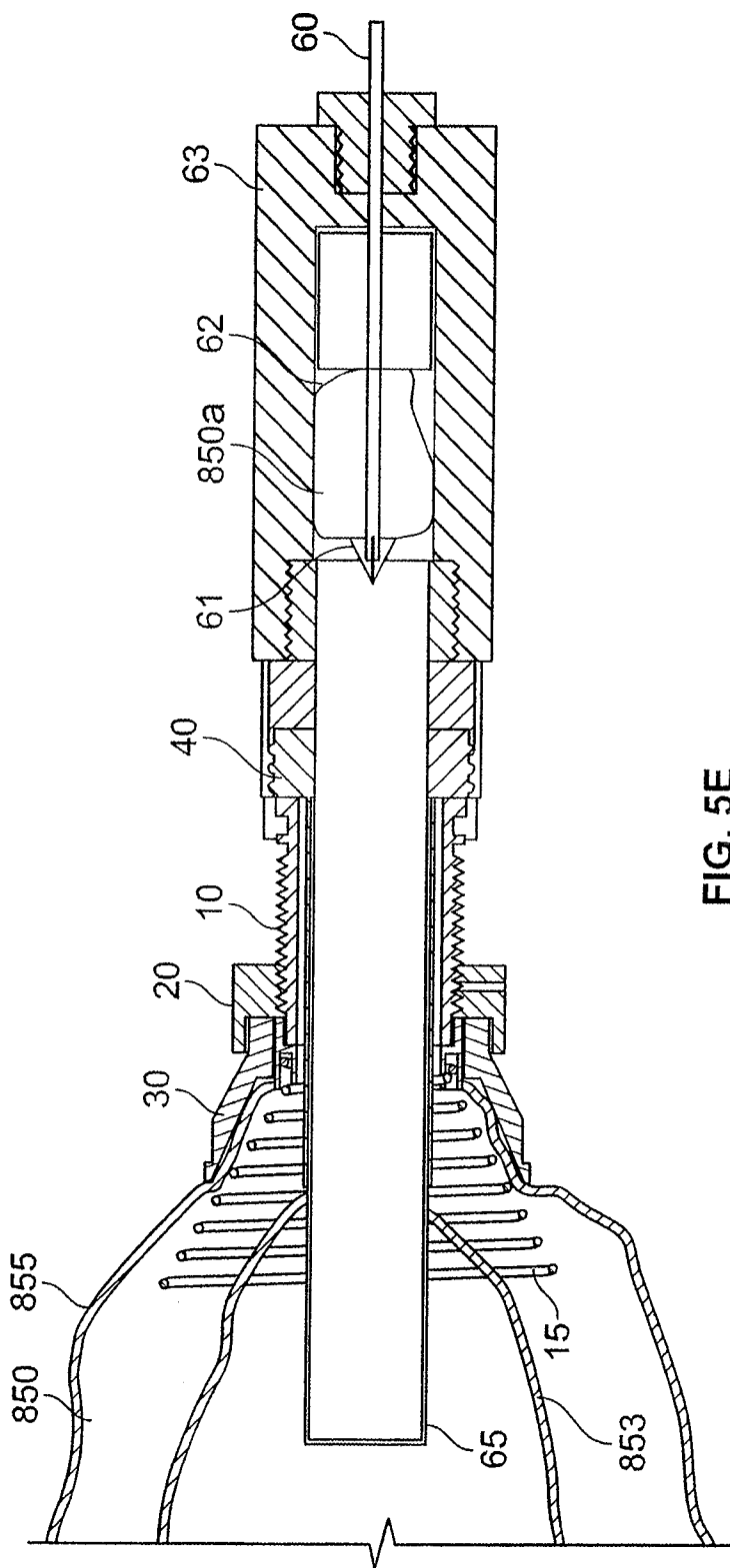


FIG. 5E

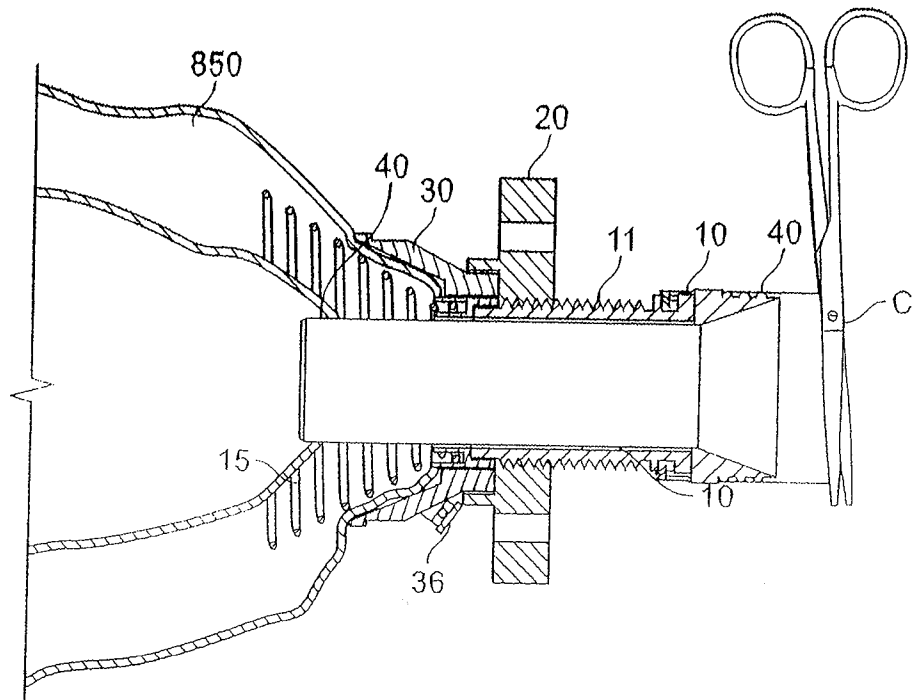


FIG. 5F

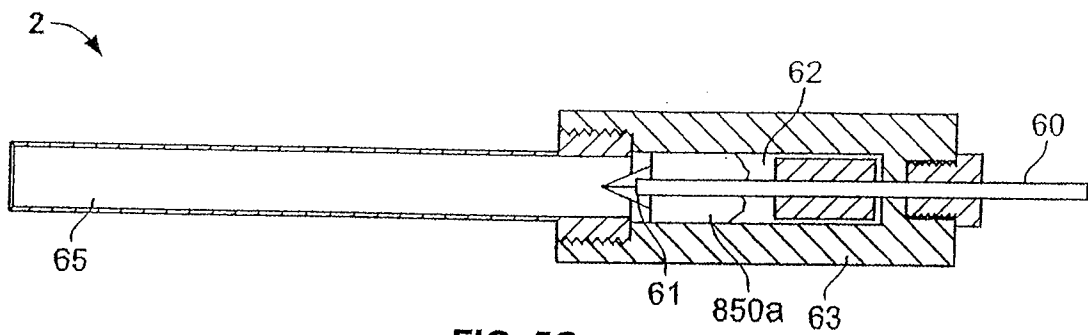


FIG. 5G

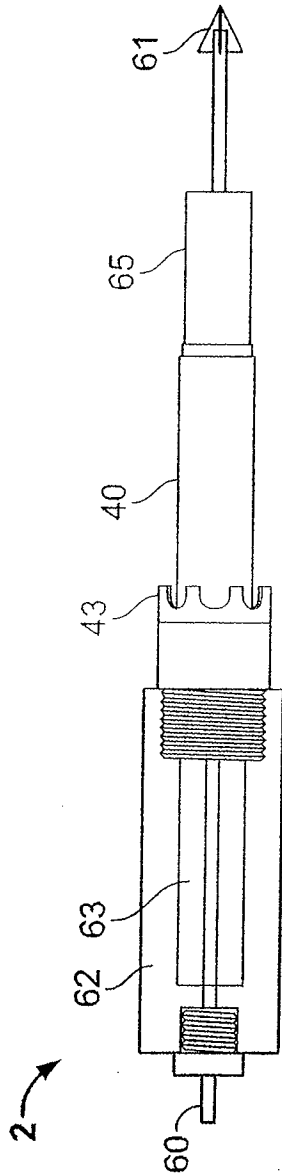


FIG. 6

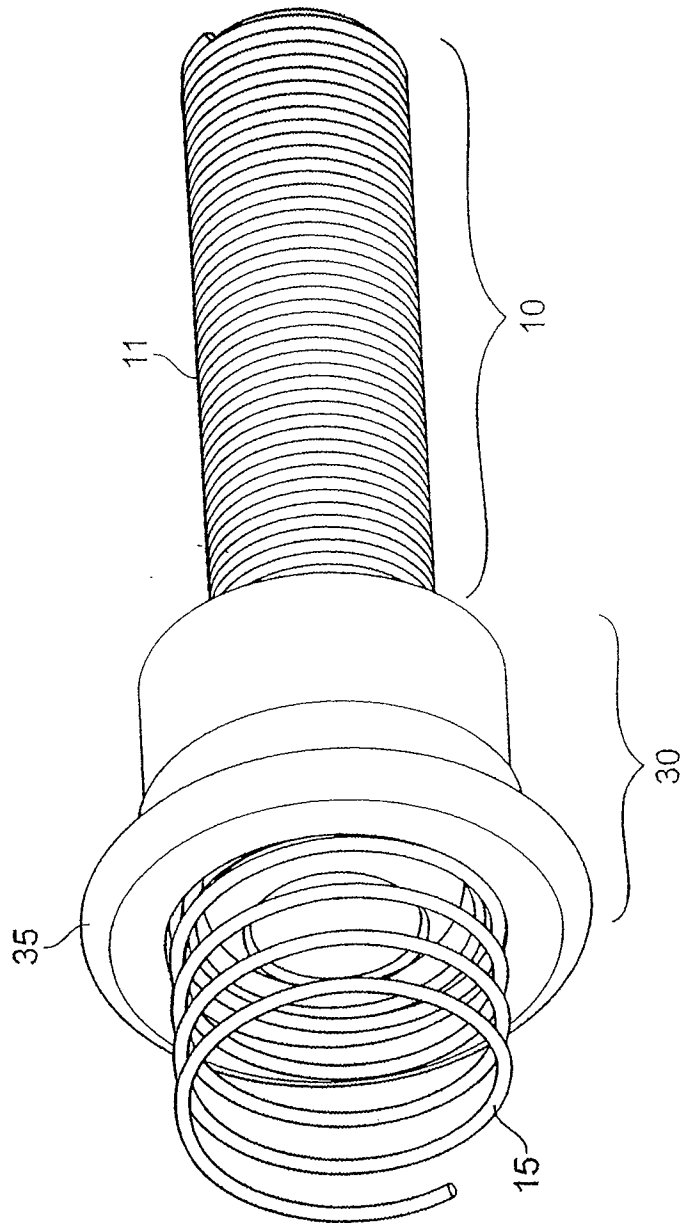


FIG. 7

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2008/061404

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/32 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/032462 A1 (HOUSER RUSSELL A [US] ET AL) 14 March 2002 (2002-03-14) paragraphs [0093], [0095] figures 16D, 16E, 17A, 17B	1, 2, 12-14, 19-21, 28-30
Y		5-11, 23-27, 31, 32
Y	WO 2006/093970 A (ST JUDE MEDICAL [US]; BRENZEL MICHAEL P [US]; DALE THEODORE P [US]; CO) 8 September 2006 (2006-09-08) paragraph [0052] figure 10	5-10, 23-26, 31, 32



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

8 August 2008

Date of mailing of the international search report

19/08/2008

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Chevalot, Nicolas

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2008/061404

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 366 819 A (KASTER ROBERT L [US]) 4 January 1983 (1983-01-04) column 8, lines 31-39 figure 3	11,27
X	US 5 755 697 A (JONES CALVIN E [US] ET AL) 26 May 1998 (1998-05-26) column 5, line 2 - column 6, line 41 column 8, lines 47-64 figures 1,17	1,2,20, 22
Y		3,4, 15-18
Y	US 6 699 256 B1 (LOGAN JOHN [US] ET AL) 2 March 2004 (2004-03-02) column 13, lines 1-44 figures 20-24	3,4, 15-18
X	WO 00/41759 A (A MED SYSTEMS INC [US]; ABOUL HOSN WALID N [US]; KANZ WILLIAM R [US];) 20 July 2000 (2000-07-20) page 12, line 19 - page 13, line 8 figure 5	1,13
A	WO 2004/026147 A (NMT MEDICAL INC [US]) 1 April 2004 (2004-04-01) paragraph [0059] figures 6A,6B	1,5-8, 20,23-26

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2008/061404

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2002032462 A1	14-03-2002	NONE	
WO 2006093970 A	08-09-2006	EP 1804679 A1 US 2006196137 A1	11-07-2007 07-09-2006
US 4366819 A	04-01-1983	CA 1175726 A1 EP 0064535 A1 WO 8201644 A1	09-10-1984 17-11-1982 27-05-1982
US 5755697 A	26-05-1998	NONE	
US 6699256 B1	02-03-2004	US 2002082614 A1	27-06-2002
WO 0041759 A	20-07-2000	AU 2848900 A US 6210397 B1	01-08-2000 03-04-2001
WO 2004026147 A	01-04-2004	AT 379991 T AU 2003272323 A1 CA 2499753 A1 EP 1542593 A2 ES 2298556 T3	15-12-2007 08-04-2004 01-04-2004 22-06-2005 16-05-2008