(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
15 April 2010 (15.04.2010)

PCT

(10) International Publication Number
WO 2010/042812 A2

(51) International Patent Classification:
A61B 17/22 (2006.01) *A61B 18/20* (2006.01)

(21) International Application Number:
PCT/US2009/060155

(22) International Filing Date:
9 October 2009 (09.10.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/104,473 10 October 2008 (10.10.2008) US

(71) Applicant *(for all designated States except US)*: **EPITEK, INC.** [US/US]; 4801 West 81st Street, Suite 105, Bloomington, MN 55437 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **BARDSLEY, Earl** [US/US]; 39 Copley Street, Newton, MA 02458 (US). **MA, Jianlu** [CN/US]; 18431 Upper Westmont Avenue North, Maple Grove, MN 55311 (US). **SWAIN, Rob** [US/US]; 15 Pasture Lane, Bedford, NH 03110 (US). **RASSCHAERT, Jean, Paul** [US/US]; 4648 Pinetree Curve, Eagan, MN 55122 (US).

(74) Agent: **SCHUMANN, Michael, D.**; Hamre, Schumann, Mueller & Larson, P.C., P.O. Box 2902, Minneapolis, MN 55402 (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, CL, 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, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, 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, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

WO 2010/042812 A2

(54) Title: METHOD AND APPARATUS FOR PERFORMING MINIMALLY INVASIVE TRANSMYOCARDIAL REVASCULARIZATION

(57) Abstract: Methods and apparatuses for performing minimally invasive transmyocardial revascularization are described. Particularly, transmyocardial revascularization is described where laser technology is introduced through a sub-xiphoid approach to create holes in the heart for relieving angina and chest pain.

METHOD AND APPARATUS FOR PERFORMING MINIMALLY INVASIVE TRANSMYOCARDIAL REVASCULARIZATION

This application is being filed as a PCT International Patent Application in the name of EPITEK, INC. and claims the benefit of US Provisional Patent Application Number 61/104,473, filed on October 10, 2008, and titled "METHOD AND APPARATUS FOR PERFORMING MINIMALLY INVASIVE TRANSMYOCARDIAL REVASCULARIZATION", the entirety of which is incorporated herewith by reference.

Field

This disclosure generally relates to methods and devices useful for performing transmyocardial revascularization. In particular, this disclosure relates to employing methods and devices based on a sub-xiphoid approach to perform minimally invasive transmyocardial revascularization.

Background

In general, medical devices directed to treatment of the heart and other cardiac-related areas are well known. Such devices have employed various tools to access and perform such desired medical procedures.

Recently, sub-xiphoid approaches have been proposed, for example to access and close a left atrial appendage. See for example U.S. Patent 6,488,689 and U.S. Patent Application Publication 2007/0027456. In these approaches, a percutaneous penetration is first made beneath the rib cage, preferably between the xiphoid and adjacent costal cartilage, and an atrial appendage closure tool is advanced through the penetration, over the epicardial surface (in the pericardial space) to reach a location adjacent to the exterior of the left atrial appendage. The appendage is then closed using a suitable closure mechanism, for example a closure loop.

Minimally invasive access techniques have become increasingly desirable to provide less traumatic alternatives for performing medical procedures, and particularly cardiac treatments and procedures, so that a subject treated can benefit from a reduced length of hospital stay, an accelerated recovery and convalescence, and an improved overall cosmesis.

In the area of transmyocardial revascularization (TMR), severe angina or chest pain can be relieved by using laser technology to create one or more holes from the outside of the heart into the heart's pumping chamber. Such a procedure has been used, for example in patients who are at high-risk of a second by-pass surgery or angioplasty or can be used as an

alternative to, or in conjunction with, by-pass surgery or angioplasty. Oftentimes, TMR methods require a surgeon to make an incision on the left breast to expose the heart. Then, the surgeon uses a laser to drill a series of holes in the heart's pumping chamber that can be approximately 1mm in diameter. Bleeding from holes on the outside of the heart stops after a few minutes of pressure from the surgeon's finger. Such a procedure, however, does not provide a minimally invasive approach to performing TMR, as exposure of the heart is required. CardioGenesis Corporation has developed FDA approved and investigational devices directed to performing minimally invasive TMR, for example its Sologrip III™, Pearl 5.0, and Solargen™ 2100s console and cardiovascular delivery system. Such devices, however, have not been introduced using equipment or methodology based upon a sub-xiphoid approach. Rather, a side port approach is used where deflation of the lungs is necessary to gain heart access.

Despite existing technology, methods and devices relating to transmyocardial revascularization can be further improved, and particularly for performing and facilitating minimally invasive transmyocardial revascularization.

Summary

An improvement for performing transmyocardial revascularization through a sub-xiphoid approach is described.

In one embodiment, performing transmyocardial revascularization includes using a device to first access the heart through a sub-xiphoid approach. A laser delivery tool is then introduced through the device and along the path created by the device. The laser delivery tool is used to create holes in the heart to allow for blood perfusion through the myocardium.

By employing the sub-xiphoid approach, minimally invasive transmyocardial revascularization can be performed that does not require an open sternotomy procedure or exposure of the heart, and does not require deflation of the lungs such as in a side port approach.

Drawings

Fig. 1 shows an anterior view of a heart.

Fig. 2 shows a position of the heart in an associated chest cavity and illustrates a percutaneous access site for performing various access methods.

Fig. 3 shows one embodiment of a subassembly for sub-xiphoid introduction of various individual tools, for example including tools such as a laser delivery tool for TMR.

Fig. 4 is a side view in partial section of the tip of the device of Fig. 3 with individual tools retracted within a lumen tube.

Fig. 5 is a side view in partial section of the tip of the device of Fig. 3 with some of the individual tools extended from the tip.

Fig. 6 is a perspective view of one embodiment of a multi-lumen tube of the device of Fig. 3.

Fig. 7 is an embodiment of an endoscope extending through the multi-lumen tube of Fig. 6.

Fig. 8 shows one embodiment of an access sheath together with one embodiment of an expander sub-assembly.

Fig. 9 shows the tip of the expander sub-assembly with one embodiment of an expander tool covered by a loading sheath.

Figs. 10A-C are cross-sectional views of the expander sub-assembly.

Fig. 11 shows one embodiment of a laser delivery tool for TMR

Fig. 12 is another embodiment of a laser delivery tool, and for use with the device of Fig. 13.

Fig. 13 is one embodiment of a medical device for sub-xiphoid introduction of various individual tools including for example a laser delivery tool.

Detailed Description

An improvement for performing transmyocardial revascularization (TMR) using a sub-xiphoid approach is described. Generally, performing TMR includes using a device to first access the heart through a sub-xiphoid approach. A laser delivery tool is then introduced through the device and along the path created by the device. The laser delivery tool is used to create holes in the heart to allow for blood perfusion through the myocardium.

By employing a sub-xiphoid approach, minimally invasive TMR can be performed that does not require an open sternotomy procedure or exposure of the heart, and does not require deflation of the lungs such as in a side port approach.

Fig. 1 is an anterior view of a heart H illustrating the right ventricle RV, the left ventricle LV, and the left atrial appendage LAA. In one preferred example, the methods and devices described herein are intended to first access the heart and then deliver various tools including a laser delivery tool to the heart, particularly the myocardium over the pumping chambers of the heart (e.g. RV and LV). Referring to Fig. 2, the heart is located within the pericardial space PS located beneath the patient's rib cage RC. The sternum S is located in the center of the rib cage RC and terminates at its lower end in the xiphoid X. On either side of the xiphoid are the costal cartilage CC, and the percutaneous access points for performing sub-xiphoid procedures are shown located beneath the rib cage RC, for example between the

xiphoid X and an adjacent costal cartilage CC at an access location AL shown by a broken line.

Turning now to the TMR method and structures for implementing the method, one embodiment for accessing the heart includes accessing the pericardial space PS and then introducing a device through a sub-xiphoid approach such as shown in Fig. 2 to obtain access to the myocardium. After obtaining access of the myocardium, a laser delivery tool can be introduced or passed over the sub-xiphoid device to a desired location of the heart. The laser delivery tool can then be used to create holes in the myocardium to allow for blood perfusion from the outside of the heart through the myocardium and into the heart's pumping chambers.

Regarding accessing the pericardial space, it will be appreciated that various access devices can be employed. As one approach, accessing the pericardial space is performed through the sub-xiphoid approach so as to achieve a minimally invasive result. A variety of instruments or tools may be employed to access the pericardial space using the sub-xiphoid approach. For example, a needle is introduced by itself or through a catheter, suitable lumen tube, or introducer to puncture the pericardial sac and then dilators can subsequently be introduced to achieve a desired size opening for introduction. In some embodiments, dilators or a balloon dilatation system are used to size the opening for passage of devices. Such tools and instruments can be obtained through various commercially available and off the shelf products.

Regarding introducing a device through the sub-xiphoid approach, it will be appreciated that a variety of instruments or tools may be employed to access, locate, and work within areas of the heart. For example, such suitable instruments and tools which can be used are found in U.S. Patent 6,488,689 and U.S. Patent Application Publication 2007/0027456, as well as in the Left Atrial Appendage devices described in copending US Application No. 12/119008 (filed on May 12, 2008), published on December 18, 2008 as US 2008-0312664 A1, and US Application No. US 12/183345 (filed on July 31, 2008) published on November 27, 2008 as US 2008-0294175 A1, all of which are herewith incorporated by reference in their entirety.

Referring to Figs. 3-7 and 13 (in operation, a medical device 10 such as disclosed in copending US Application No. 12/119008 can be used for minimally invasive access and closure of a left atrial appendage 2 of a human heart 4. The device 10 is configured for use in a sub-xiphoid procedure for left atrial appendage closure, but could be used in other procedures as well. That is, it is to be understood that the device 10 and individual components of the device 10 discussed below are not necessarily limited to left atrial

appendage closure applications. The medical device 10 can be used in a number of differing medical applications and clinical procedures, including where one or more of non-traumatic grasping, manipulation, closure, and inspection of anatomical tissue is required.

For example, the device 10 (see e.g. Fig. 13) can be leveraged for use in the pericardial space to perform TMR, where holes are created through the myocardium of the heart 2 to allow direct blood flow to the heart's pumping chambers. The device 10 can be adapted for suitably introducing a laser delivery tool (further described below).

With some specific reference to Figs. 3-7, the medical device 10 generally includes a sub-assembly 5 of various tools and an implementation of delivering the tools. Figs. 8-10C generally show an expander sub-assembly 6, and an introducer sheath 7. In one embodiment, the sub-assemblies 5, 6 and the sheath 7 together form the medical device, and are configured to be used together during the TMR procedure as needed.

With reference to Fig. 3, the sub-assembly 5 is illustrated. The sub-assembly 5 includes a tube 11 composed of a multi-lumen tube 12 having a proximal end 14, and a lumen tube 13, which may be a single or multi-lumen tube as further described below, that is connected to an end of the multi-lumen tube 12, with the lumen tube 13 having a distal end 16. A number of tools, the purpose, construction and function of which are described below, extend through the multi-lumen tube 12 and the lumen tube 13. At the proximal end 14, a number of actuators 18 are provided that are connected to the tools for manipulating the tools. The actuators 18 can include, for example, an actuator 20 for actuating a grasping tool, and an actuator 22 for actuating a closure member. A viewing scope (shown in Fig. 7 for example) connected to a camera can also be disposed at the proximal end 14. In addition, a free end 28 of a pull suture 30 can extend from the proximal end 14 and can act as an actuator for contracting a closure member, if a procedure calls for closure or further manipulation of a certain structure.

As will be described below, many of the tools of the sub-assembly 5 are mounted within the tubes 12, 13 to permit independent operation, including axial movement relative to the tubes 12, 13, actuated by the respective actuators. Furthermore, one or more of the tools of the sub-assembly are intended to be exchangeable with other tools, as needed to perform TMR on a desired location of the myocardium.

Fig. 3 illustrates the distal end 16 of the tube 13 with the tools fully retracted, or in a stowed position, within the end of the tube 13. Figs. 3 and 5 illustrate a grasping tool 32 and a constricting tool 34 advanced axially by the respective actuators 20 and 22 relative to the tube 13 so that they extend beyond the distal end 16 (i.e. a deployed position).

A ring 36 is connected near the end 16 of the tube 13, as shown in Fig. 3 The ring 36 is used for visualization, for example using fluoroscopy, of the end 16 of the tube 13 during a procedure to be able to determine the location of the end 16 in the pericardial space.

With reference now to Figs. 6 and 7, details of the multi-lumen tube 12 will now be discussed. The multi-lumen tube 12 includes the proximal end 14 and a second end 40 to which will be connected an end 42 of the tube 13. The tubes 12, 13 can have a diameter suitable for its intended purpose. For procedures to be performed on the heart, for example, the tubes 12, 13 can have a maximum diameter of about 5.9-8.6 mm or 18-26 Fr. The tube 12 comprises a polymer extrusion, for example Pebax®, urethane, nylon, polyethylene, or polypropylene, defining a plurality of separate and distinct lumens. In the illustrated embodiment, the tube 12 has for example 5 lumens. A larger or smaller number of lumens can be used depending upon the number of tools to be used in the device 10. In the illustrated embodiment, the tube 12 includes for example a guidewire lumen 48, a suction lumen 50, an endoscope lumen 52, a grasper lumen 54, and a closure deploying lumen 56. The lumens 48-56 extend from the end 14 to the end 40.

The tube 13 is also a polymer extrusion, for example Pebax®, urethane, nylon, polyethylene, or polypropylene, defining less lumens than the multi-lumen tube, preferably having one or two lumens. The tube 13 can be a clear or transparent material, and can be employed to create a field of view for a visualization or scoping device. The tube 13 is joined to the end 40 of the tube 12 at juncture 44 (Fig. 3) in a suitable manner, for example using a thermal bond or an adhesive bond. In some embodiments, the tube 13 has a single lumen 66 that extends from the end 42 to the end 16. The space defined by the lumen 66 is large enough to receive portions of the grasping tool 32, the constricting tool 34, and other tools used during the procedure when they are retracted or stowed, as shown in Fig. 4. In embodiments where a guidewire is used, the tube 13 also includes a guidewire lumen that extends from the end 42 to the end 16 and which is aligned with the guidewire lumen 48 of the tube 12 when the tubes 12, 13 are connected.

With respect to the entire tube 11, it will be appreciated that both the multi-lumen tube 12 and the lumen tube 13 may be formed of a single lumen, where various instruments and treatment materials are not compartmentalized into separate and distinct lumens or channels.

When a guidewire is used, the guidewire lumen 48 of the tube 12 and the guidewire lumen in the tube 13 allow the sub-assembly 5 to be inserted over a guidewire, and through an access or introducer sheath when employed (see e.g. Figs. 8-10C below), to where the end

of the guidewire has previously been positioned at a desired location of the heart. This facilitates positioning of the end 16 of the tube 13 adjacent the desired location of the heart, and helps ensure that the proper position of the sub-assembly 5 is maintained. A guidewire also can help maintain and/or regain access to the heart if the device 10 or another instrument is needed to be withdrawn and/or re-introduced. It will be appreciated that guidewires are well known and are commercially available.

The suction lumen 50 allows removal of blood and other fluids and tissue from the pericardial space to improve visibility during the TMR procedure. For example, removal of bleeding caused by use of the laser delivery tool is desired for visibility. Suction can be applied through the lumen 50, or via a suction device that can be introduced through the lumen 50.

The endoscope lumen 52 is used to introduce an endoscope through the sub-assembly 5 to allow visualization of the pericardial space and desired heart structure for treatment. The endoscope that is used can be a single use, disposable endoscope that is devoid of steering, and can include a lens, vision and light fibers, each of which are conventional in construction. In this embodiment, the endoscope would be discarded after use along with the remainder of the closure sub-assembly 5. The disposable endoscope can be built into the closure sub-assembly 5 so that it is in the optimal position to provide the required direct vision of the desired heart structure. However, the operator will have the ability to unlock the endoscope and reposition it if the procedure requires.

Alternatively, the endoscope can be a commercially available reusable endoscope currently used in the medical field. However, many commercial endoscopes are too large for the direct vision requirements of the device 10 and its tools, because they contain features, for example steering, excessive light and vision fibers, and working channels, which are unnecessary for the device 10 disclosed herein. Further, the field of view and the working distance of the lens of many commercially available endoscopes may be wrong for use in the pericardial sac and through the sub-xiphoid approach. Further, reusable endoscopes are often damaged either in use or during reprocessing so that they are not available for use when needed.

Fig. 7 shows a schematic illustration of an endoscope 52a extending through the endoscope lumen 52 of multi-lumen tube 12. Like reference numbers as in Fig. 6 are not further described. It will be appreciated that the endoscope 52a is structured and functions as described above so as to be suitable for use with the device.

The grasper lumen 54 and the closure deploying lumen 56 of the tube 12 open into the lumen 66 (Fig. 4) that is formed in the tube 13. The grasping tool 32 extends through the grasper lumen 54 and into the lumen 66, and the constricting tool 34 extends through the closure deployment lumen 56 and into the lumen 66.

With reference to Figures 3-5, the grasping tool 32 comprises a clamp device 170 formed by two jaw members 172a, 172b that are pivotally connected to each other at pivot 174. A flexible support 176 is connected to the clamp device 170 and extends through the tubes 12, 13 to the actuator 20. The support 176 is used to axially advance the clamp device 170 past the end 16 of the tube 13 from the stowed position shown in Fig. 4 to the extended position shown in Figs. 3 and 5. The flexible support 176 can bend during use. Actuating wires 178 extend through the support 176 and are connected at one end of the jaw members 172a, 172b and at their opposite ends to the actuator 20. The actuating wires 178 are used to open and close the jaw members 172a, 172b for clamping and releasing various heart tissue(s), by pivoting the jaw members 172a, 172b relative to each other.

The jaw members 172a, 172b each include front teeth and a rear portion 180 formed without teeth to provide an open space between the jaw members. This improves clamping by the jaw members, by allowing desired tissue, such as the left atrial appendage, to be disposed in the space between the jaw members at the rear, while the front teeth of the jaw members clamp directly onto the desired tissue.

The constricting tool 34 can take on a number of configurations. Generally, the tool 34 includes a closure member that is designed to constrict around certain tissue such as the left atrial appendage and to close such tissue if it is desired. The constricting tool 34 includes at least one tool to deploy, control, and position the closure member.

The tool 34 is visible in Fig. 3-5. The tool 34 includes a support encased in a polymer sleeve. In addition, the sleeve substantially encapsulates the closure member, which may be a snare 76. A slit or thin film can formed in the sleeve through which the snare 76 can be pulled out of the sleeve when the snare 76 is constricted.

The support, which is connected to the actuator 22, for instance through mechanism 82, is used to axially advance and retract the constricting tool between the positions shown in Figs. 4 and 5. The snare support is formed from a suitable shape memory material, for example nitinol or other metal or polymer material which can provide a suitable level of elastic deformation. The snare support expands to generally the shape shown in Figs. 3 and 5 when extended from the tube 13 in order to expand the snare 76 and maintain the profile of the snare loop. The snare support should expand sufficiently to open the snare 76 sufficiently

to ensure a large enough loop so that the snare can fit around the desired tissue (e.g. the left atrial appendage). The polymer sleeve prevents the snare support from damaging tissue of the patient during use. The sleeve need only encase those portions of the snare support that in use will project past the end 16 of the tube 13.

The snare 76 can be made of any material suitable for encircling and constricting anatomical tissue, and that is biologically compatible with the tissue. For example, the snare 76 can be made of polyester or polypropylene. The snare material can have a diameter of, for example, 0.5 Fr.

The snare 76 includes a pre-tied knot 78, and a mechanism 82 is provided for engaging the knot 78 during tightening or constricting of the snare 76 and cutting the snare 76. The knot 78 can be any suitable knot that allows tightening of the snare 76 by pulling on the suture pull wire 30 that is connected to the snare 76. For example, a knot 78 commonly used in endoscopic surgery, for example a locking slip knot called a Meltzer's knot, can be employed.

The construction of the tool 34 provides a number of advantages. For example, the loop formed by the snare support permits approach of tissue from different angles, with the loop and the snare 76 being maintained in their fully expanded condition at all angles of approach. In addition, when the snare 76 is constricted and pulls out of the sleeve, no other material or portion of the snare holding structure gets pinned between tissue and the snare 76 when the snare is constricted. In such a configuration, loosening of the constricted snare does not occur, for instance, when the snare holding structure is retracted.

Entering the pericardial sac via the sub-xiphoid can include various other sub-assemblies and introducer sheath/access device principles. Such exemplary implementations of pericardial access devices which may be used are described in US Patent No. 6,423,051 (issued on July 23, 2002) and in copending US Application No. 12/118915 (filed on May 12, 2008), published on November 27, 2008 as US 2008-0294174 A1, both of which are titled "Methods and Apparatus for Pericardial Access" and both of which are herewith incorporated by reference in their entirety. An example of expander subassemblies and introducer sheaths are described in US Application No. 12/119026 and titled "Introducer Sheath" (filed on May 12, 2008), published on December 11, 2008 as US 2008-0306442 A1, which also is incorporated by reference in its entirety.

These references also are illustrative of the various other devices and tools that may be employed for accessing the pericardial space PS and creating a path to introduce various tools which can be used to perform TMR.

For example, referring to Figs. 8-10C, the expander sub-assembly 6 and the introducer sheath 7 are shown. The introducer sheath 7 is used to create a working channel in a sub-xiphoid procedure for introducing the expander sub-assembly 6 and the sub-assembly 5 of various tools into the patient. Further details on the introducer sheath 7 can be found in U.S. Patent Application No. 12/119026 incorporated by reference above.

The expander sub-assembly 6 is designed to be introduced through the sheath 7 and into the pericardial space for expanding the pericardial space during the TMR procedure. Once in position, the expander sub-assembly 6 and the introducer sheath 7 can be locked relative to one another using a locking mechanism 200, the details and operation of which are described in U.S. Patent Application No. 12/119026 incorporated by reference above.

The expander sub-assembly 6 is illustrated in Figs. 8-10C. The expander sub-assembly 6 includes an expanding structure 902 that is a collapsible tool that is self-expanding, collapsible, and constructed of a material utilizing an elastic property. The expander sub-assembly 6 provides key functions in that the expanding structure 902 is retractable and is self-expanding once it is released. In one example, the expanding structure 902 can be configured as a self-expanding shape memory material, which can also be temporarily collapsed when confined. In one embodiment, the expanding structure 902 is a cylindrically hollow part when in an expanded configuration. In this configuration, the expanding structure 902 can allow the constricting tool 34 and the grasping tool 32 to be passed into and through the hollow part of the expanding structure 902, such as when it is expanded.

The material of the expanding structure 902 allows it to be collapsed on itself, when it is not deployed. When the expanding structure 902 is not to be deployed, it can be collapsed into a smaller dimension or diameter by being retracted within the elongated body of the introducer sheath 7 (i.e. the shaft structure of the sheath). In operation, the expander sub-assembly 6 can be delivered to a target site of the heart, such as by extending the expanding structure 902 from the distal end of the elongated body of the introducer sheath, or by retracting the sheath 7 to expose the expanding structure 902. As one example, the expanding structure 902 can be delivered by using a shaft portion 904 that is connected to the end of the expanding structure. The shaft portion 904 is hollow and has an outer diameter that is slightly smaller than the inner diameter of the introducer sheath 7. In this configuration, the shaft portion 904 can be inserted into the sheath and be longitudinally moved within the sheath. As the shaft portion 904 is hollow, the tools and lumens of the sub-assembly 5 can be passed therethrough.

As shown in Figs. 8 and 9, the expanding structure 902 is initially held in its collapsed configuration via a loading sheath 910. This permits the expander sub-assembly 6 to be inserted into the introducer sheath 7 as shown in Fig. 8. Once in the sheath 7, the loading sheath 910 is removed or pulled back to free the expanding structure 902. Since the sub-assembly is in the introducer sheath 7, the introducer sheath 7 will hold the expanding structure 902 in its collapsed configuration until the expanding structure 902 is advanced beyond the end of the sheath 7.

The shaft portion 904 can be moved relative to the introducer sheath 7 to extend and retract the expanding structure 902. In the expanded configuration, the expanding structure 902 would be extended past the end of the sheath 7 by pushing it forward relative to the introducer sheath 7, or by pulling the introducer sheath back relative to the expanding structure 902. That is, the introducer sheath can act to cover and uncover the expanding structure 902 based on relative movement of the introducer sheath and expanding structure. In either configuration, the expanding structure 902 can extend from the distal end of the elongated body of the introducer sheath 7. In the non-expanded configuration, the expanding structure 902 could be collapsed by pulling the expanding structure back inside the introducer sheath 7 through the distal end of the elongated body, or could be collapsed by pushing the introducer sheath over the expanding structure 902 to cover it.

When the expanding structure 902 is extended from the sheath, the material of the expanding structure 902 is such that it self-expands to create a working space. That is, due to the expanding structure's propensity to expand when the expanding structure 902 is not contained/retracted inside the access sheath, a space inside a patient can be expanded by the expanding structure.

The expanding structure 902 may be a flexible material with an elastic-like quality, and that includes a self-expanding force that can sufficiently open a working space in the body of a patient. As one example, the expanding structure 902 may be a nitinol cage-like structure. It will be appreciated that the expanding structure 902 may be made of materials other than nitinol, for example elastic resins or plastics. It further will be appreciated that the expanding structure 902 may be constructed as a combination of materials, rather than as one material. Likewise, the shaft portion 904 may be sufficiently flexible or have varied flexibility, as necessary or desired, and so as to be suitable for use with the introducer sheath.

Figures 10A-C illustrate side views of the expander sub-assembly 6 in operation with the introducer sheath 7. Figure 10A shows the sub-assembly 6 in a non-expanded configuration inside the introducer sheath 7. Figure 10B shows the sub-assembly being

advanced axially in the direction of the arrow, with the expanding structure 902 in a partially expanded configuration and partially extended from the sheath 7. Figure 10C shows the sub-assembly 6 advanced further axially, with the expanding structure 902 in a fully expanded configuration.

In operation for example, when using the device 10 for left atrial appendage closure, the device 10 can be introduced using a sub-xiphoid approach similar to that described in US Patent 6,488,689. In use, once the sheath 7 is in place in the patient, the expander sub-assembly 6 is introduced into the sheath 7. The loading sheath 910 is then removed or pulled back to free the expanding device 902, and the sub-assembly 6 is advanced further axially toward the end of the introducer sheath 7 and the pericardial space. Once it is determined that the end of the sheath 7 is positioned properly, the expander sub-assembly 6 is advanced further until the expanding structure 902 extends past the end of the sheath 7. The expanding structure 902 self-expands to increase the working space. The sub-assembly 5 is then introduced through the expander sub-assembly 6 and advanced toward the pericardial space. Once the closure sub-assembly 5 is fully inserted, a locking mechanism can be used to lock the sub-assemblies 5 and 6 together. The locking mechanism can be similar to the locking mechanism 200. The constricting tool 34 and the grasping tool 32 can then be actuated as discussed above to achieve manipulation and/or closure of a desired tissue (e.g. left atrial appendage). The procedure can be reversed to remove the device and other sub-assemblies from the patient.

Alternative embodiments are possible. It will be appreciated that the expander sub-assembly is not limited to the specific structure shown and described, and that other expander constructions and modifications may be employed that are equally or more suitable. For instance, other implementations may include inflatable expanders such as inflatable balloons, or general injection of air into the pericardial space (e.g. CO_2). The use of gas, for example, can allow for an expanded operating cavity. The introduction of gas can be performed using the sub-xiphoid approach and delivered through the medical device 10. By way of example, a syringe or fluid line or catheter as may be known in the art can be used to deliver the gas to the heart through the device 10. It will be appreciated that any gas(es) (e.g. CO_2) that are biologically suitable for use and performance of medical procedures within the body may be employed.

It further will be appreciated that any expander structure as may be known in the art may be suitably adapted for performing procedures on the heart and via a sub-xiphoid, minimally invasive approach.

As described above, the medical device 10, including its sub-assemblies and introducer sheath, could be used in procedures other than left atrial appendage closure. That is, the device 10 and individual components of the device 10 are not necessarily limited to left atrial appendage closure applications, and can be used in a number of differing medical applications and clinical procedures, including where one or more of non-traumatic grasping, manipulation, closure, and inspection of anatomical tissue is required.

In general, the device 10 can deliver various tools into the pericardial space through a single shaft, catheter-like structure, which allows an operator to pass various other tools and devices to a target site of the heart for treatment. For example, the device 10 can be used in the pericardial space to perform TMR, where holes are created through the myocardium of the heart to allow direct blood to perfuse into the heart's pumping chambers. The device 10 can be suitably adapted for introducing a laser delivery tool (see Fig. 11, described below) through the sub-xiphoid approach.

As described, the device 10 includes a scope (e.g. endoscope 52a), suction or aspiration capability (e.g. suction lumen 50), a grasper (e.g. grasping tool 32), and a snare (e.g. snare 76). In one implementation of the device 10, the scope can provide visualization while performing TMR and the suction capability can allow for aspirating fluid (e.g. blood) from the pericardial sac to further assist with visualization during the TMR procedure. Further, the grasper and snare structures can be used to manipulate and maneuver various cardiac tissue and structures as needed to obtain clearance to the area of the heart targeted for TMR.

In general, a device such as device 10 can be configured to allow various devices and tools to be passed through its lumen structure (e.g. multi-lumen), so as to offer an operator greater flexibility to perform the TMR procedure. The device 10 is intended to be suitable for allowing adaptation and exchangeability of tools through the lumen structure of the device 10, so that TMR can be easily and safely performed. For example, one or more of the tools discussed above for device 10 may be changed out so that the lumen structure can support introduction of other tools needed during performance of the TMR procedure. It also will be appreciated that the lumen structure can be adapted to have additional lumens and/or be sized to support all of the tools needed for the TMR procedure.

It further will be appreciated, however, that the device 10 for introducing a laser delivery tool is meant to represent an example of such a device to introduce such tools associated with TMR through a single tube, catheter-like structure, and that various modifications and changes may be made as needed and/or desired.

With regard to the laser delivery tool, Fig. 11 illustrates one example of a laser delivery tool 100. Generally, the laser delivery tool 100 includes a handle 102, a shaft 104, and a distal tip 106. The laser delivery tool 100 is connected to a console 110, which provides control and setting features for the laser delivery tool 100. The laser delivery tool 100 is connected to the console 110 through connection structure 120. In one example, the connection 120 can be a wired connection to deliver the laser capability to the laser delivery tool 100 from the console 110.

In TMR, the laser delivery tool 100 is used to create holes in through the myocardium to allow blood to perfuse through the myocardium in the pumping chambers of the heart. The handle 102 can include an actuator to activate the laser capability of the tool. The distal tip 106 provides the emission point of the tool, for example, where a laser beam can be emitted from the tool to burn or drill one or more holes through desired areas of the myocardium. The shaft 104 connects the distal tip 106 to the handle 102 and provides an overall length to the tool that is suitable for the distal tip to be navigated, moved, and positioned to its desired location of the heart (e.g. the structures of the myocardium and its pumping chambers).

In one embodiment, the laser delivery tool 100 can be delivered through ports that are about 12-15mm, or about 8mm, and even about 5mm. The shaft 104 can be a guideshaft that is about 20cm to 50cm in length, and can be constructed of a flexible or adjustable material. The distal tip 106 can be deflectable and include stabilizing features to hold it in a desired deflecting position. It will be appreciated that the handle 102 is configured to include the necessary actuators to deflect and stabilize the distal tip 106.

With reference to the console 110, the console 110 includes the control and setting features for the laser delivery tool 100. In one embodiment, the console 110 is equipped with suitable laser capability for performing TMR. As one example, the console can include a contact laser system having a pulsed, solid state holmium, yttrium aluminium garnet (YAG) laser, with a wavelength of about 2.1microns, at mid-infrared (about 2100nm), and a pulse width of about 200 microseconds nominal and pulse rate of 5 hertz (pulses per second). It will be appreciated that the laser delivery tool 100 can be set and controlled through the console 110, and that the laser capability can be configured so that a desired and/or needed diameter and depth of the holes can be created. It also will be appreciated that the laser capability can be modified as desired and/or necessary.

Laser delivery tools and control consoles have been known and are available. As discussed above, CardioGenesis Corporation has developed FDA approved and

investigational devices directed to performing minimally invasive TMR. For example, its Sologrip III™, Pearl 5.0, Pearl 8.0, and Solargen™ 2100s console and cardiovascular delivery system are examples of technology in this area. Such devices have not yet been introduced using equipment or methodology based upon a sub-xiphoid approach. However, it is intended that such tools developed by CardioGenesis Corporation can be used or adapted for use with a device (e.g. device 10) for TMR under the sub-xiphoid approach. That is, one implementation of the inventive concepts herein is that any of the devices by CardioGenesis Corporation above can be used and/or suitably adapted to be used in conjunction with the device 10 to carry out the TMR procedure. It will be appreciated that modifications can be made, such as to the sizing, so as to be compatible for use in the sub-xiphoid approach.

Fig. 12 illustrates another example of a laser delivery tool 200. The laser delivery tool 200 can be configured much like the laser delivery tool 100. Generally, the laser delivery tool 200 includes a shaft 204, and a distal tip 206. It will be appreciated that the laser delivery tool 200 can include a proximate end that can have an actuator and handle (e.g. handle 102) or that can be adapted to operate with one of the actuators on the handle of the device 10. As with laser deliver tool 100, laser delivery tool 200 also can be connected to a console (e.g. console 110), which provides control and setting features for the laser delivery tool 200. The laser delivery tool 200 can be connected to the console through connection structure similar to connections structure 120 and can be a wired connection to deliver the laser capability of the console to the laser delivery tool 200.

Fig. 12 shows one illustration, where a laser delivery tool is incorporated with the device 10. In a TMR procedure, for example, Fig. 12 shows the laser delivery tool 200 inserted through the tube 11 of subassembly 5, with its lumen structure configured by the lumen tubes 12, 13. Fig. 12 shows the laser delivery tool 200 in operation after access of the myocardium M (e.g. pericardial sac access is obtained), along with use of the endoscope 52a, and while the grasper 32 is mainly retracted into the tube 13. The shaft 204 provides an overall length to the tool 200, and it will be appreciated that the shaft 204 can be configured for steering, navigation, movement, and positioning, so that the distal tip 206 can reach its desired location of the myocardium. In some examples, the shaft 204 can be deflectable and include stabilizing features to hold it in a desired deflecting position. It will be appreciated that any necessary actuators to deflect and stabilize the laser delivery tool may be employed on the proximate end of the laser delivery tool or on the device 10.

The invention may be embodied in other forms without departing from the spirit or novel characteristics thereof. The embodiments disclosed in this application are to be

considered in all respects as illustrative and not limitative. The scope of the invention is indicated by the appended claims rather than by the foregoing description; and all changes which come within the meaning and range of equivalency of the claims are intended to be embraced therein.

Claims

1. A method of transmyocardial revascularization comprising:

accessing the pericardial space of the heart through a sub-xiphoid approach by delivering a device through a port in the sub-xiphoid of a subject and along a path to the pericardial space;

locating a desired tissue location of the heart by navigating the device;

introducing a laser delivery tool through the device and along the path created by the device; and

creating holes in the heart with the laser delivery tool to allow for blood perfusion through the myocardium into chambers of the heart.

2. The method of claim 1, wherein the step of introducing a laser delivery tool comprises navigating and positioning the laser delivery tool to the desired tissue location of the heart.

3. The method of claim 1, wherein the step of creating holes in the heart comprises setting and controlling a diameter and depth of the holes to be created through a console.

4. A transmyocardial revascularization device comprising:

a device having one or more tools configured to access the pericardial space through the sub-xiphoid; and

a laser delivery tool insertable through a lumen of the device under a sub-xiphoid approach, the laser delivery tool configured to create one or more holes through the myocardium of the heart when the laser delivery tool is activated.

5. The device of claim 4, wherein the laser delivery tool comprises a handle, a shaft, and a distal tip, the shaft having a length that is suitable for the distal tip to be navigated to a desired location of the heart.

6. The device of claim 5, wherein the shaft is a flexible material that allows for deflectable adjustment.

7. The device of claim 4, wherein the distal tip includes an emission point of the tool.

8. The device of claim 4, further comprising a console connected to the tool, the console provides control and setting features of the tool.

9. The device of claim 8, wherein the console is connected to the tool via a wired connection.

10. The device of claim 8, wherein the console includes a contact laser system having a pulsed, solid state, holmium, yttrium, aluminum garnet laser.

Fig. 1

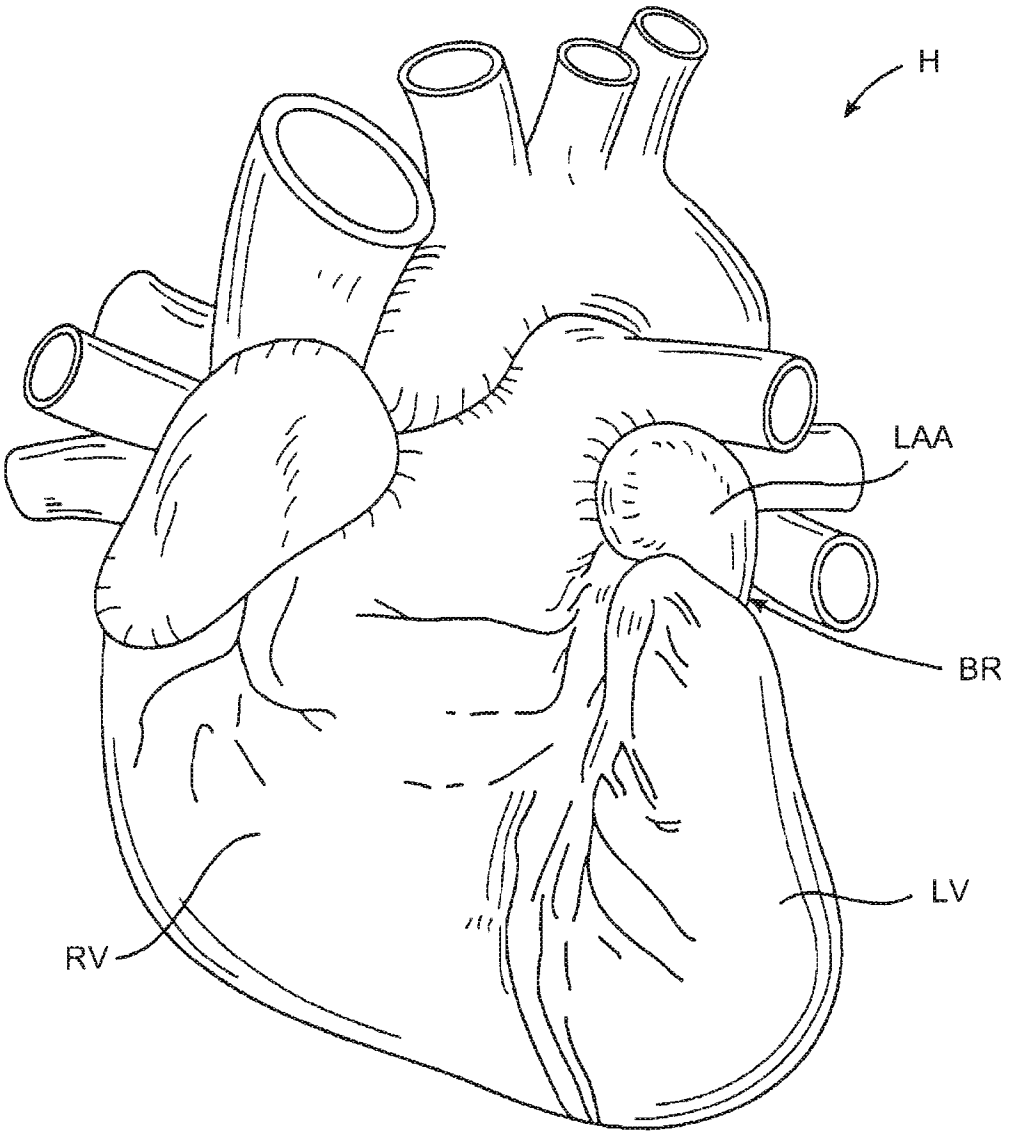
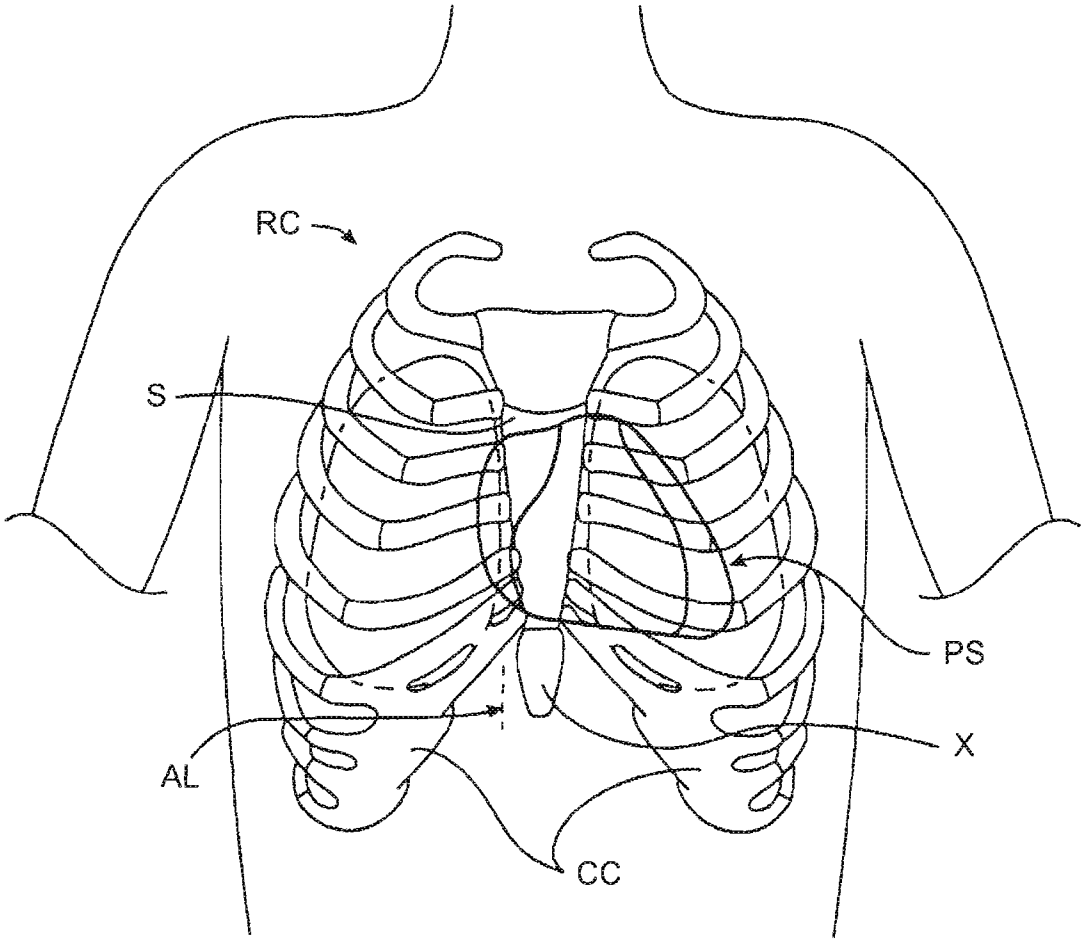


Fig. 2



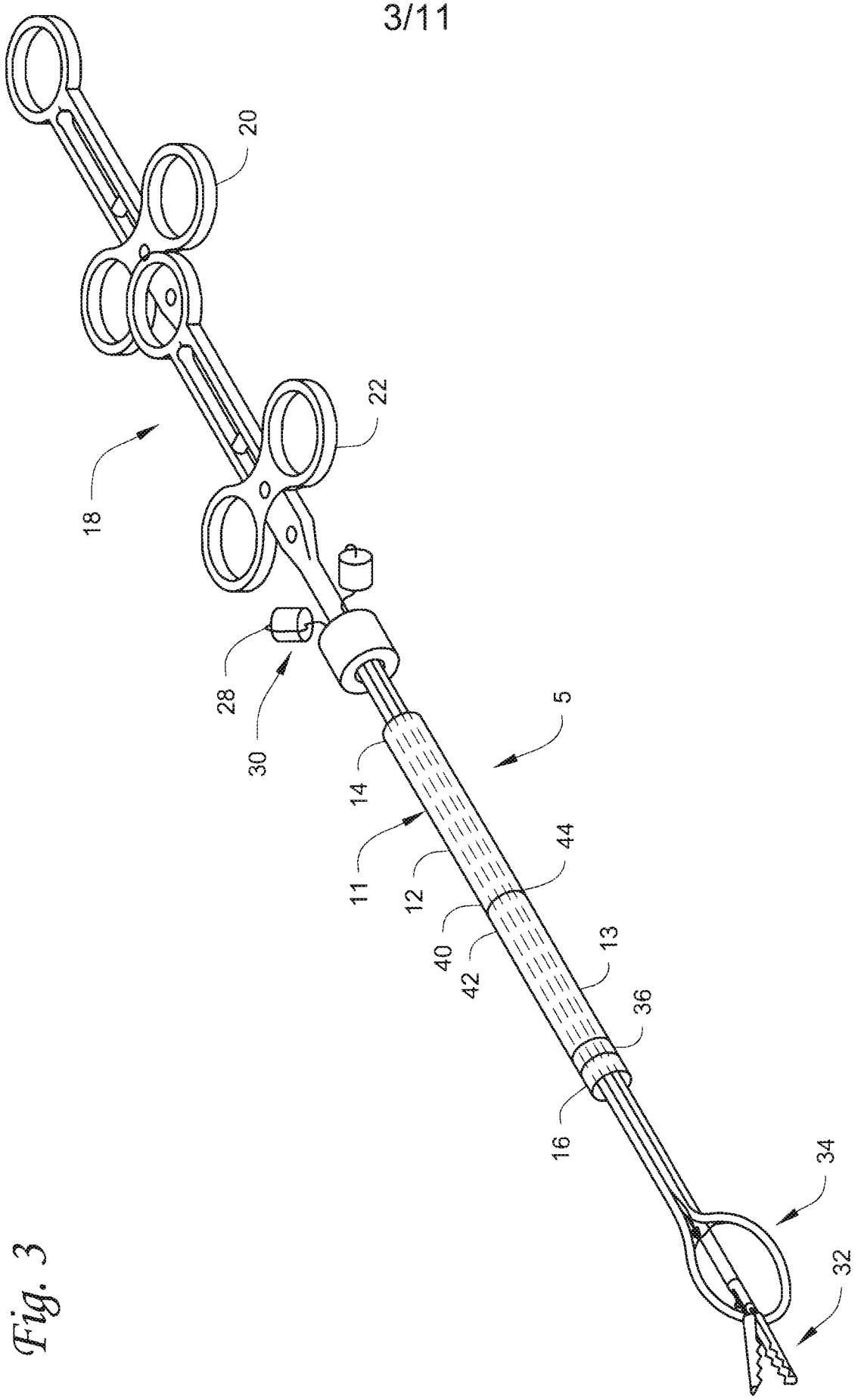


Fig. 3

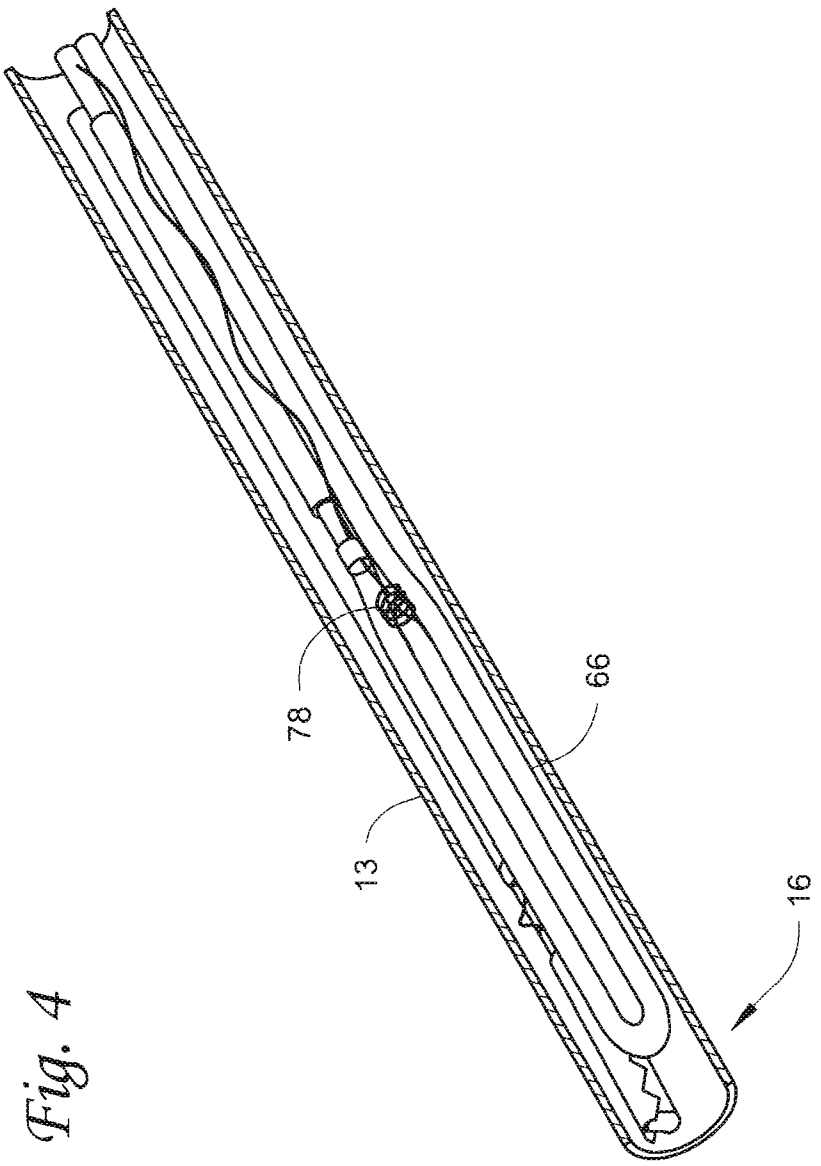


Fig. 4

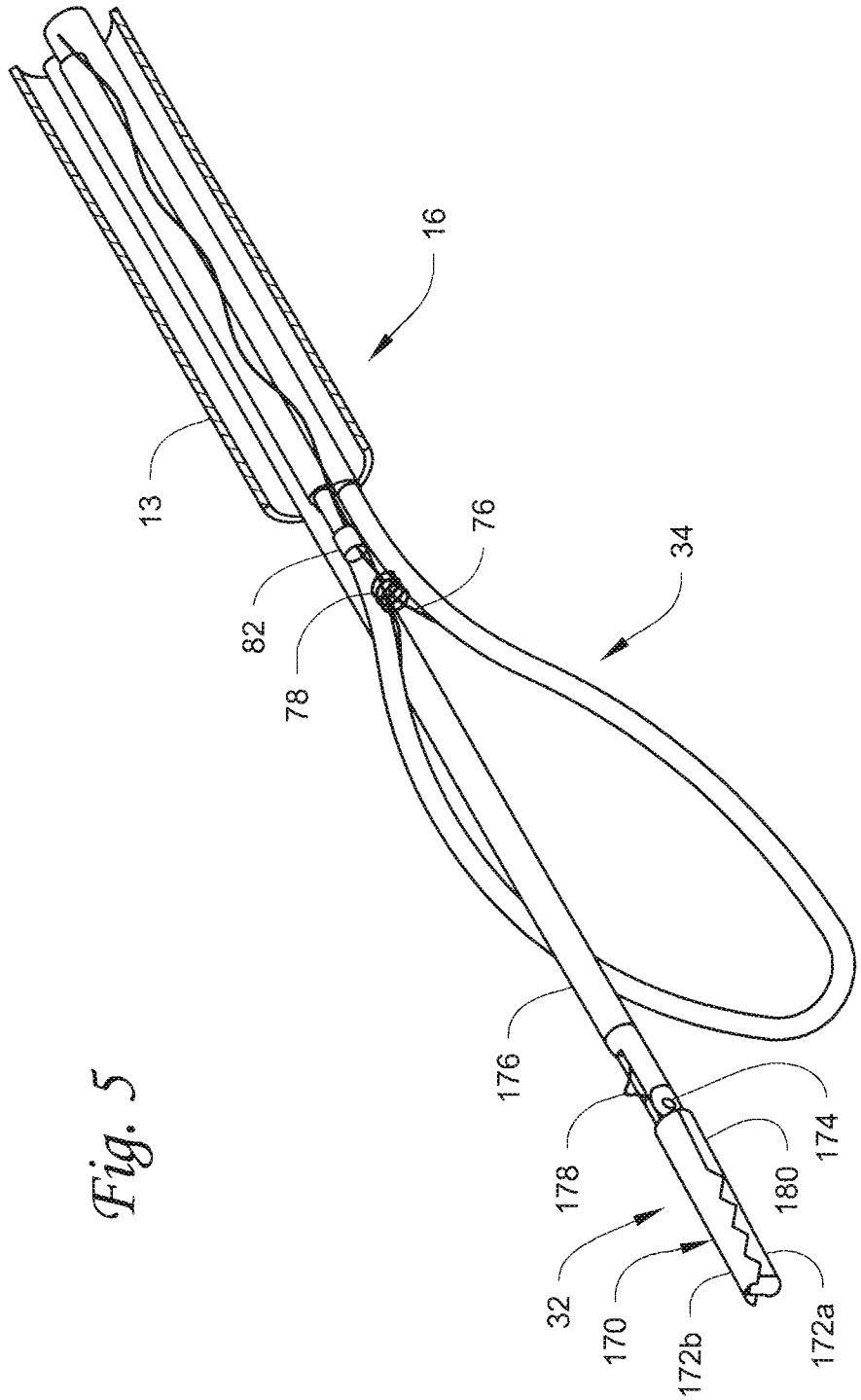


Fig. 5

Fig. 6

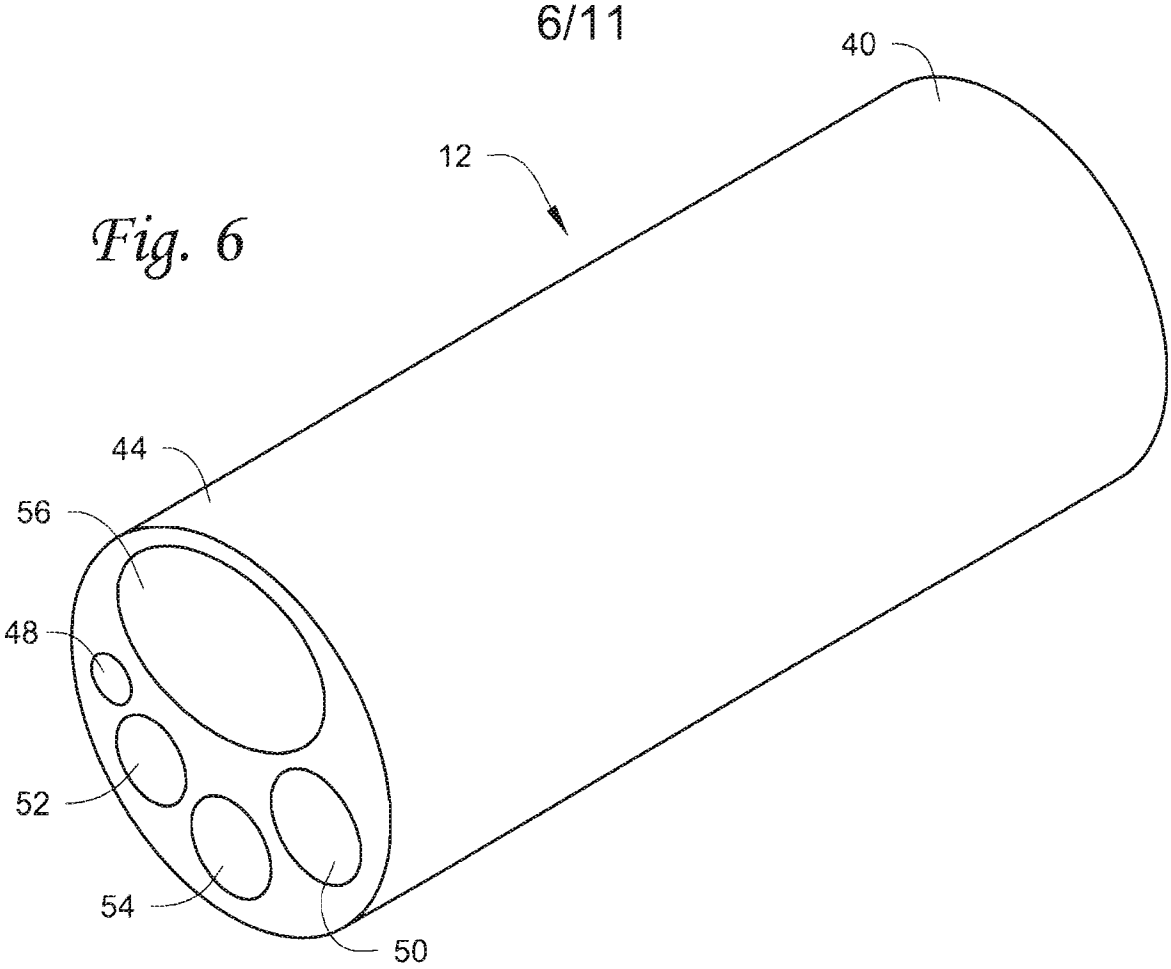
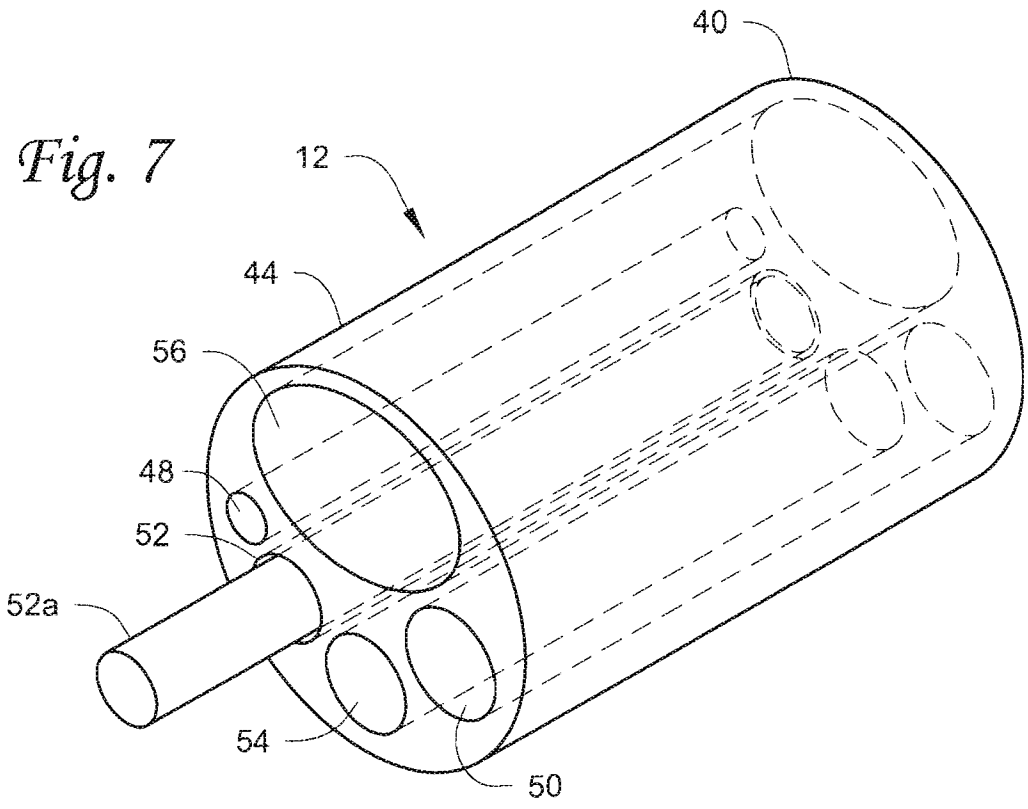


Fig. 7



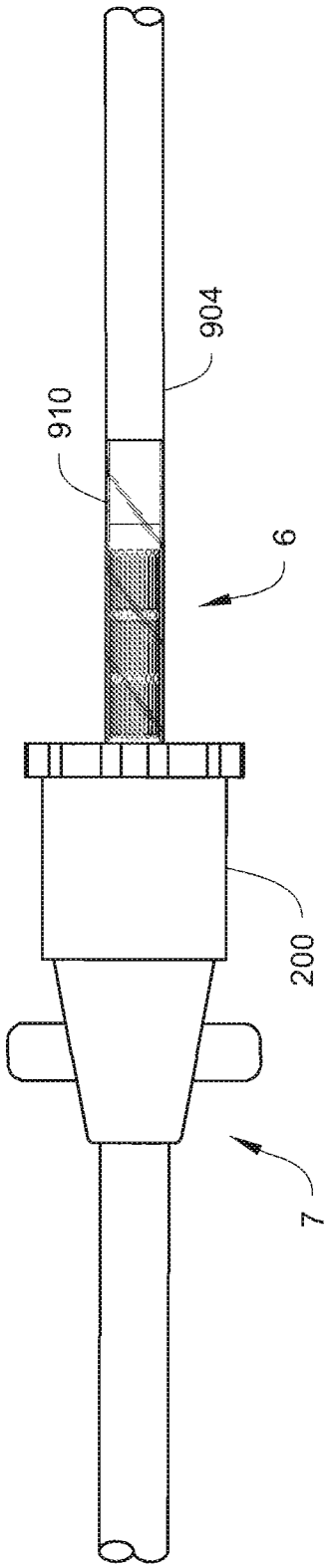


Fig. 8

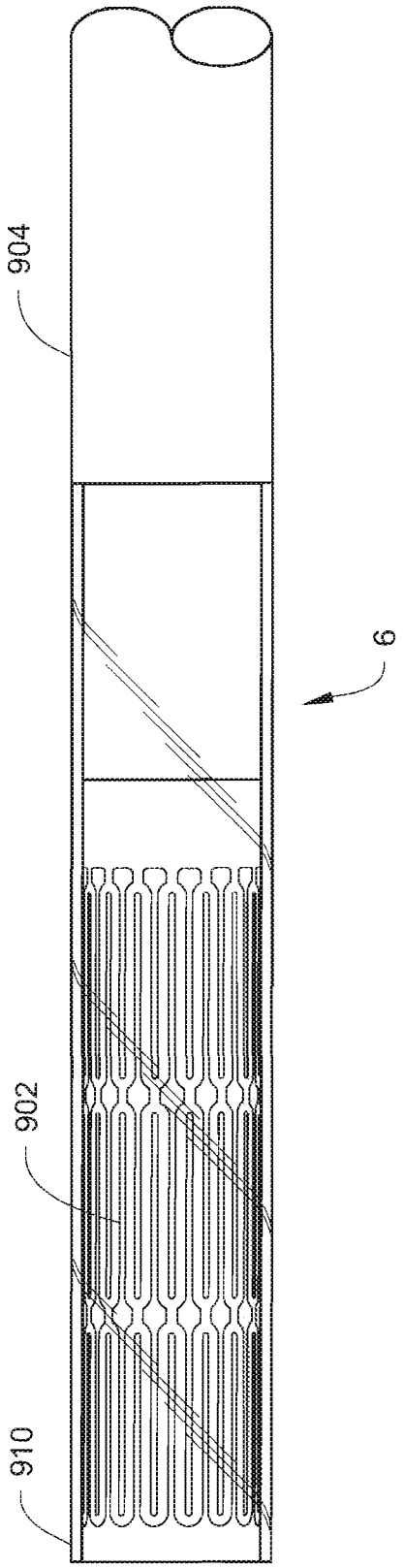


Fig. 9

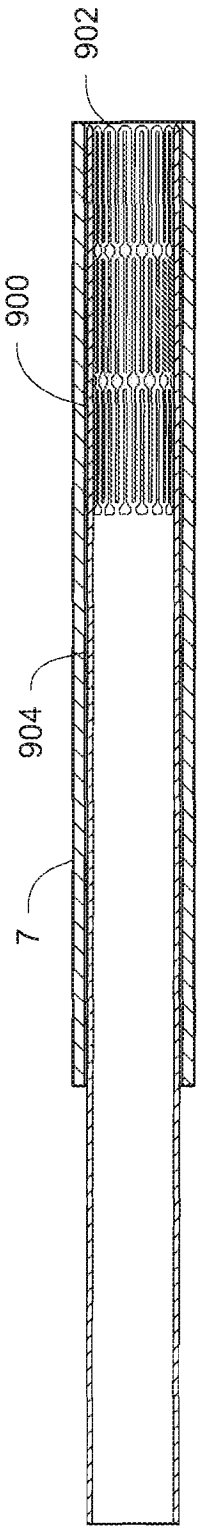


Fig. 10A

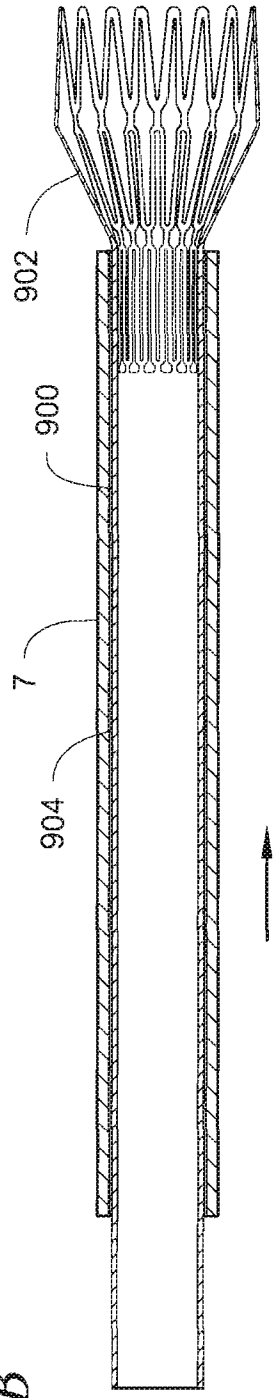


Fig. 10B

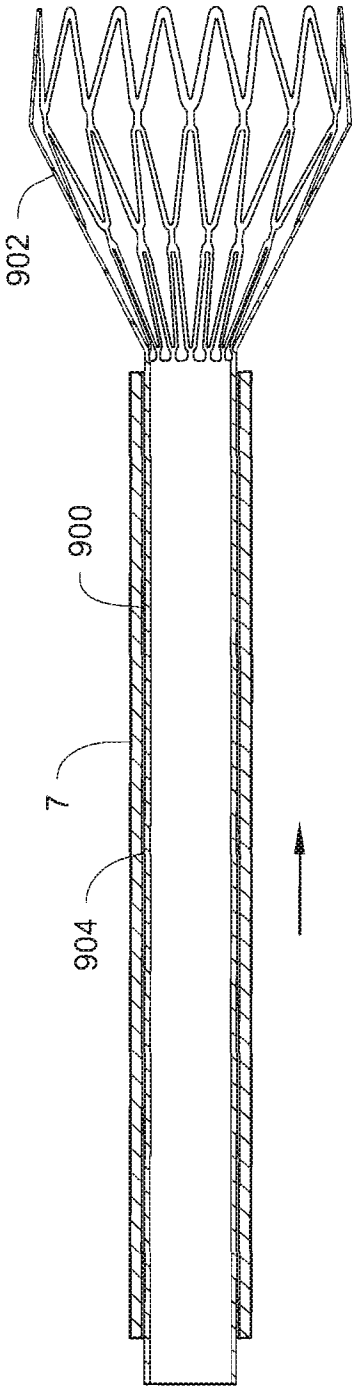
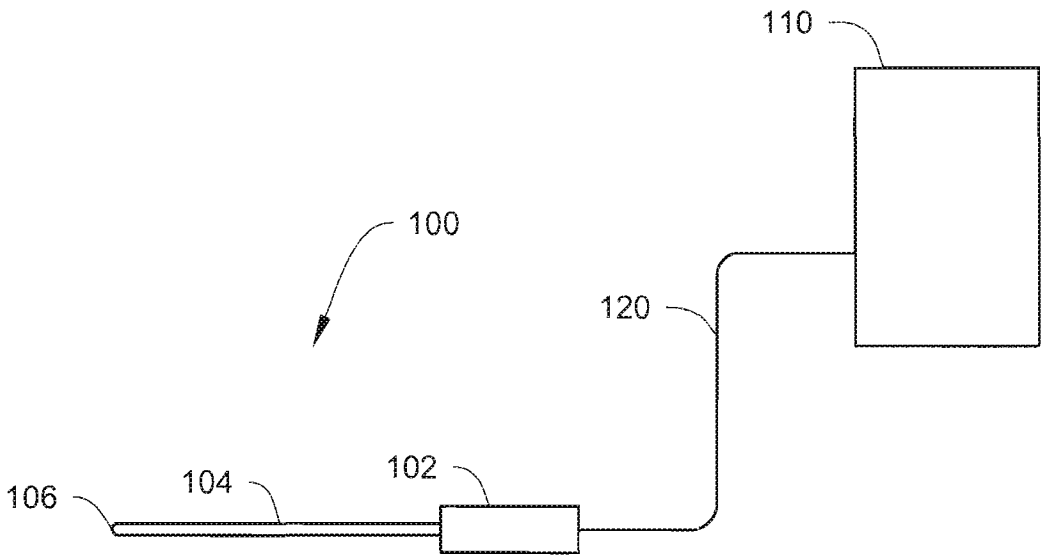


Fig. 10C

Fig. 11



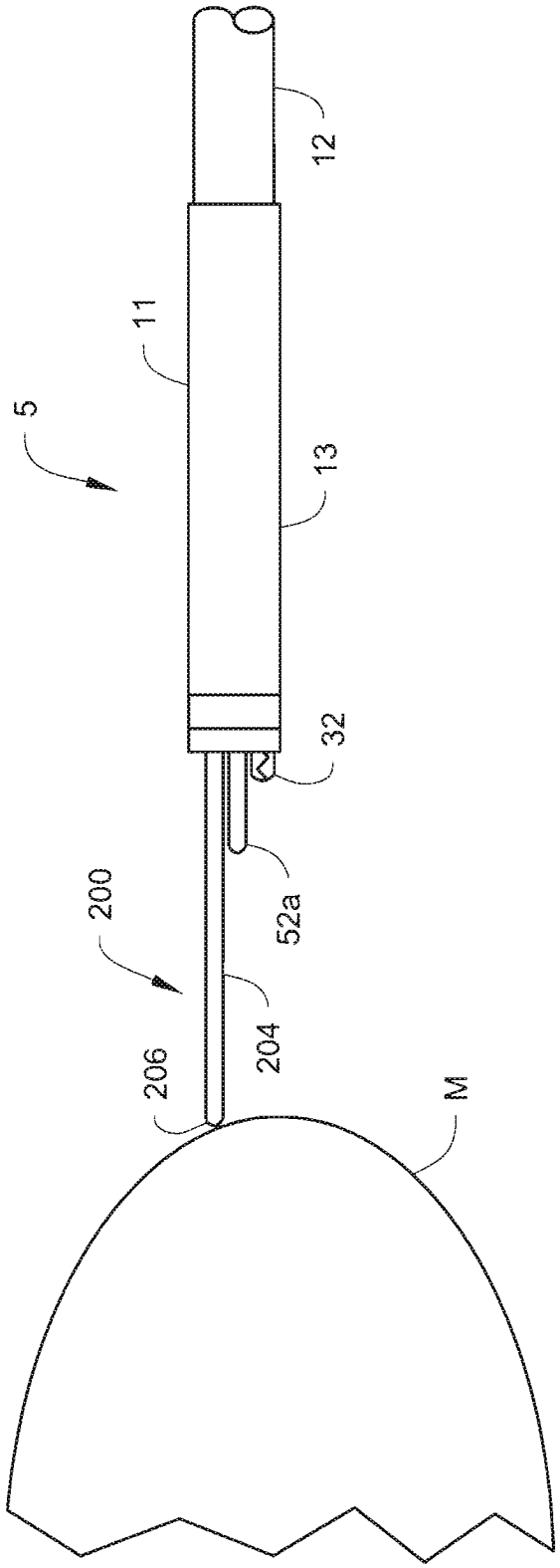


Fig. 12

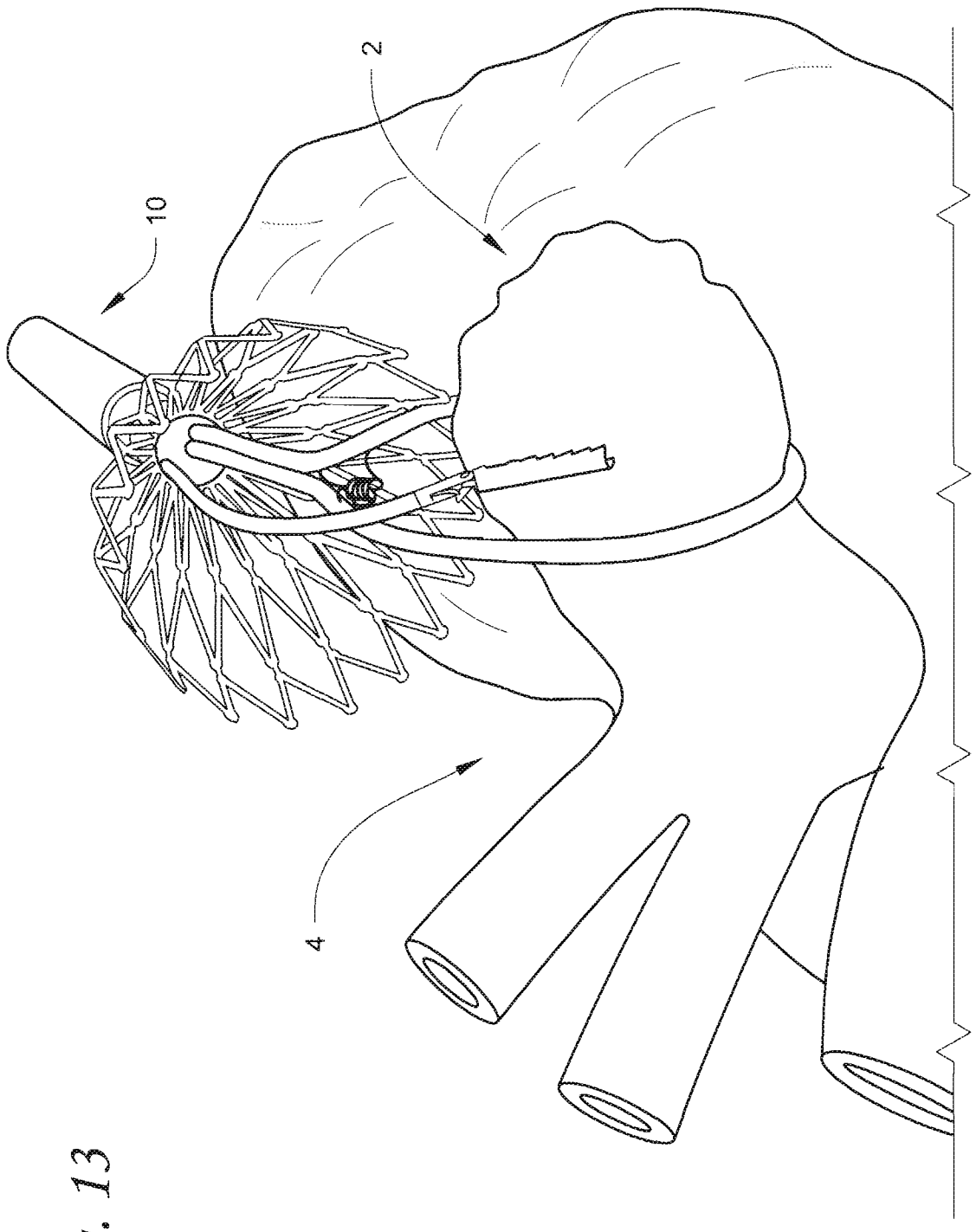


Fig. 13