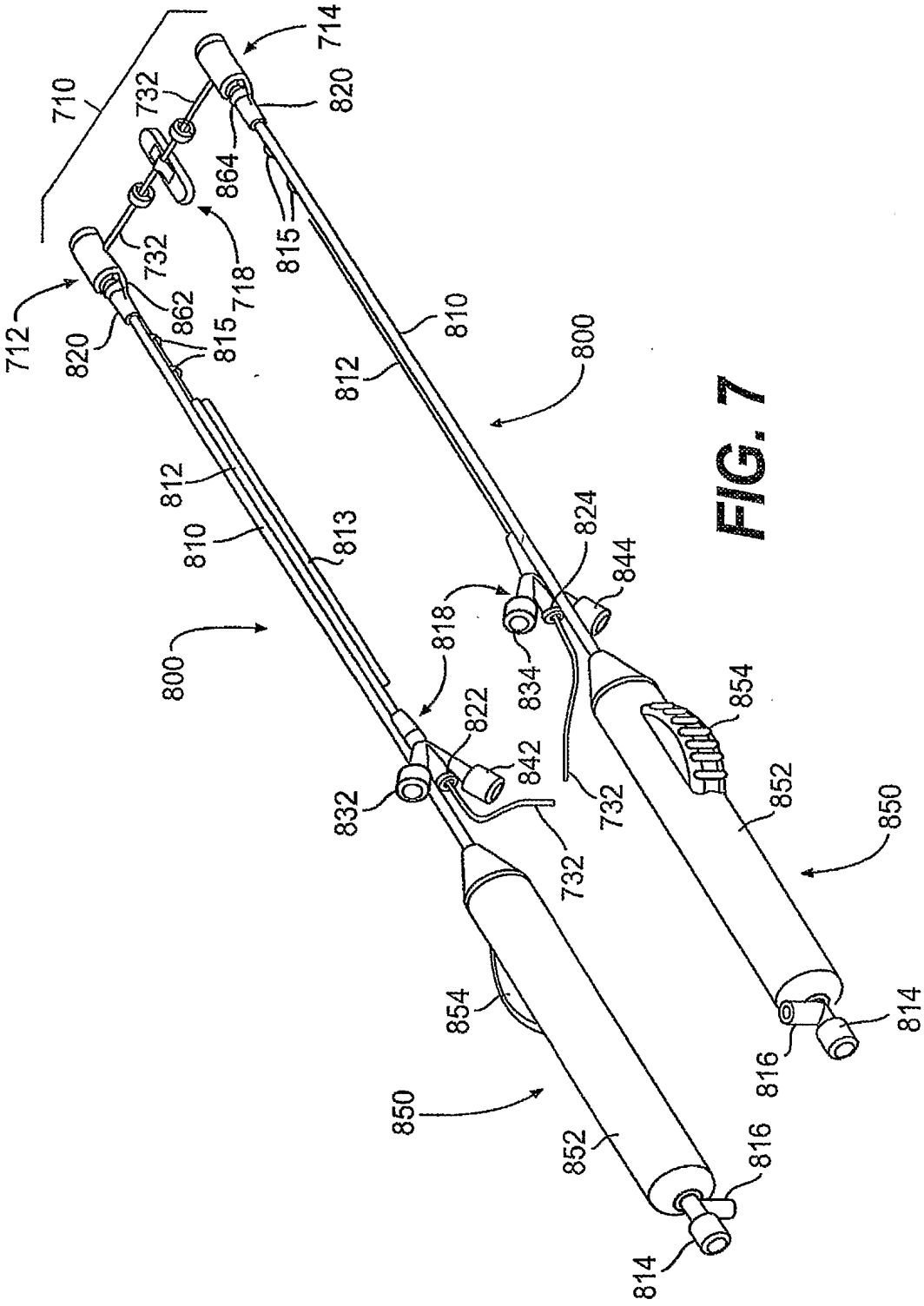

FIG. 7

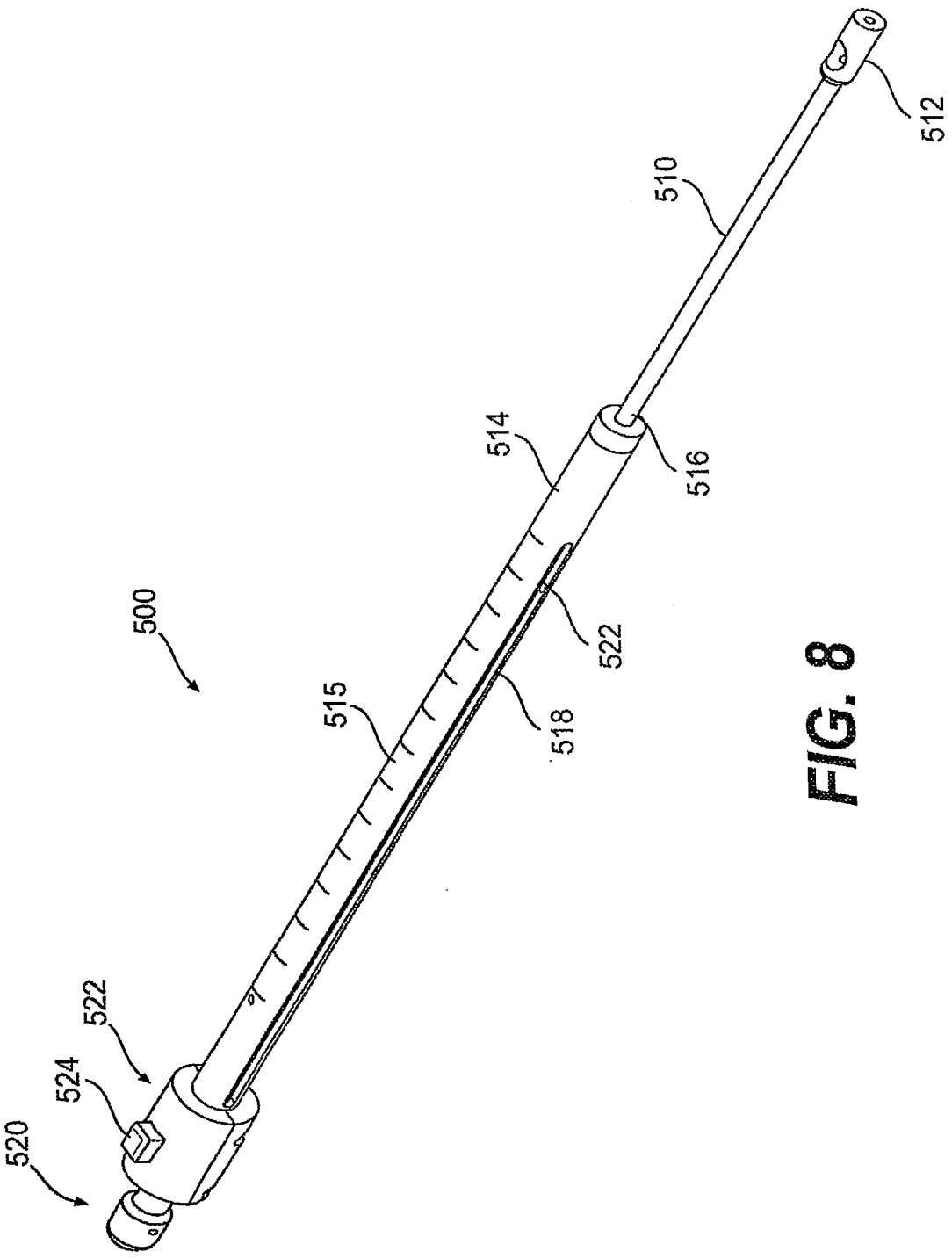

FIG. 8

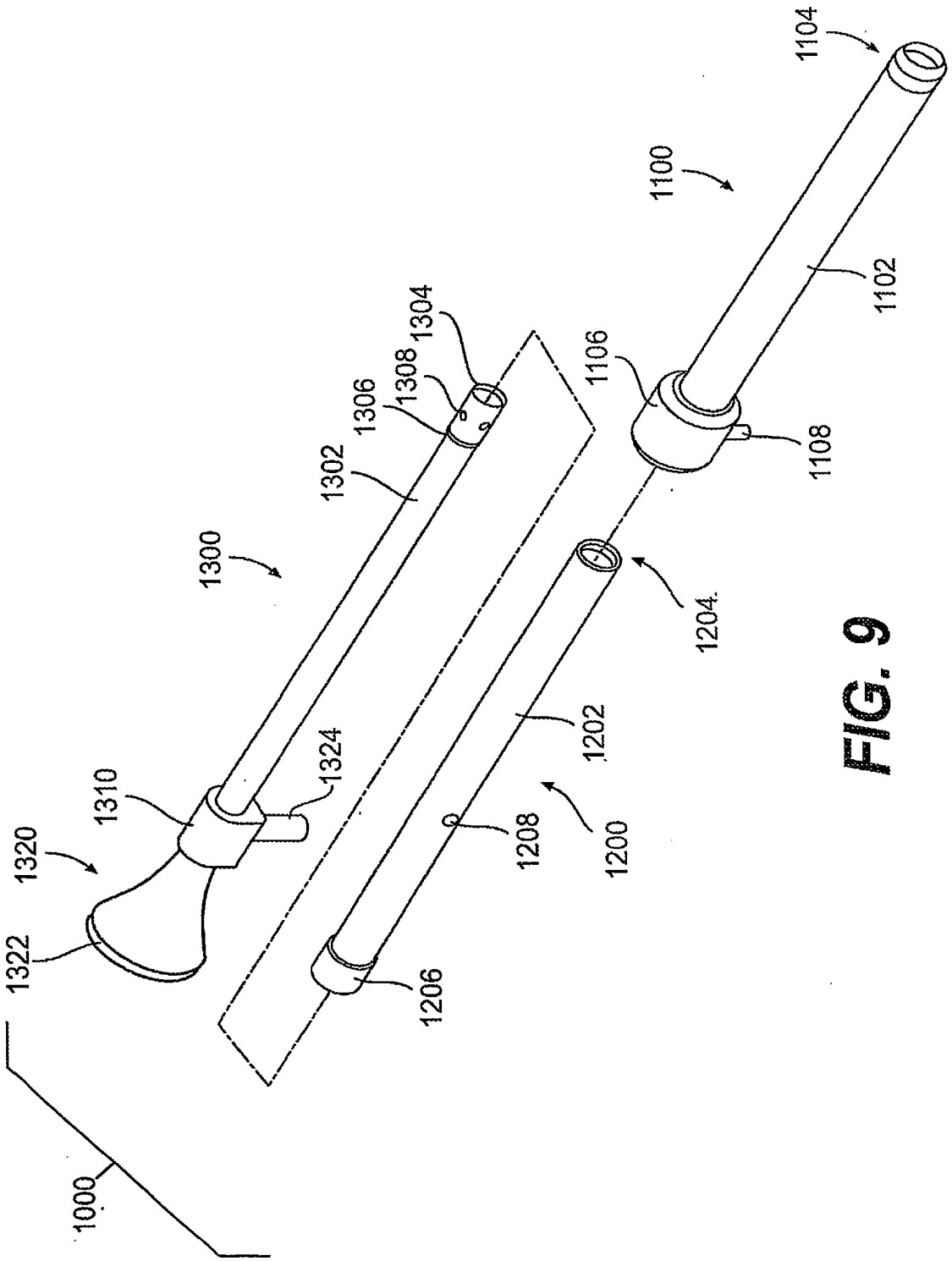

FIG. 9

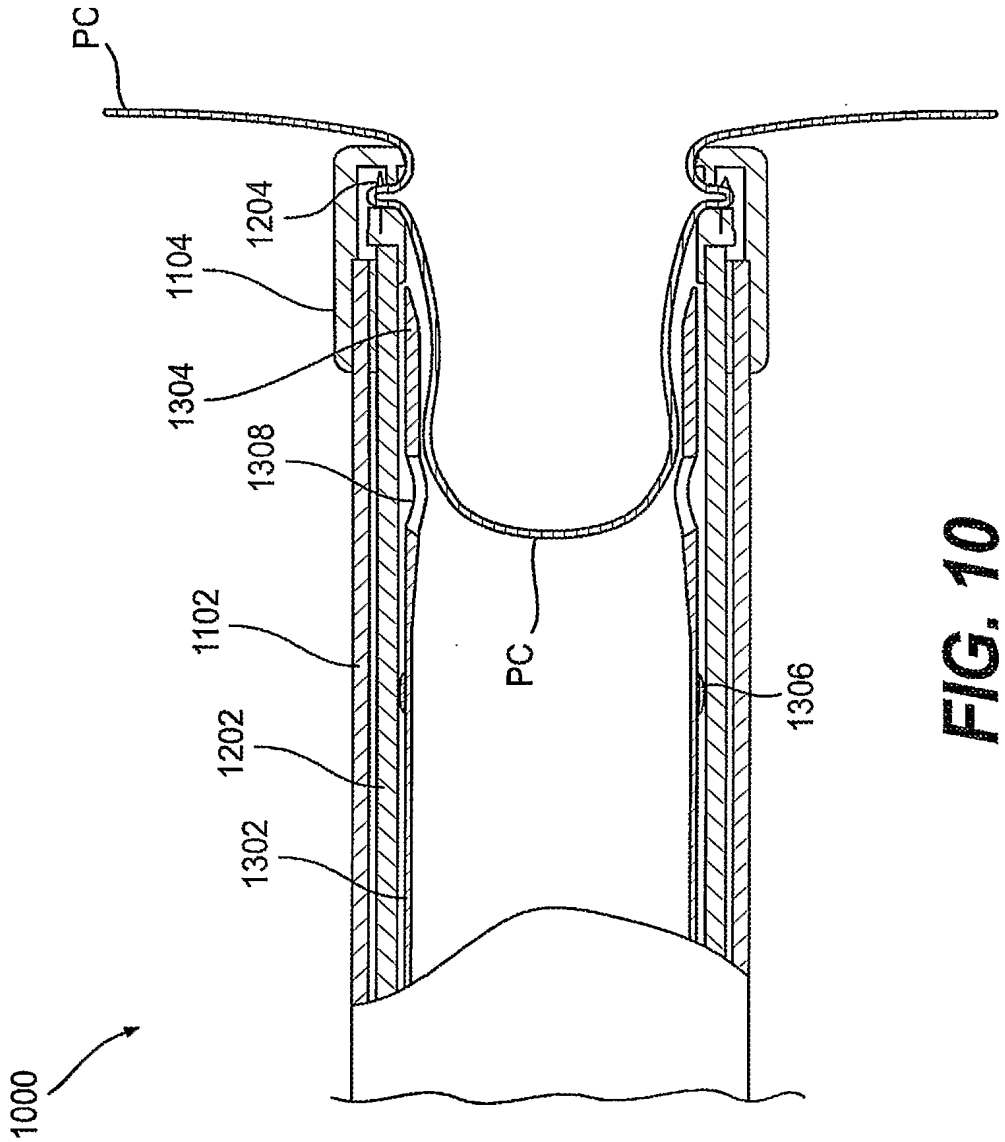

FIG. 10

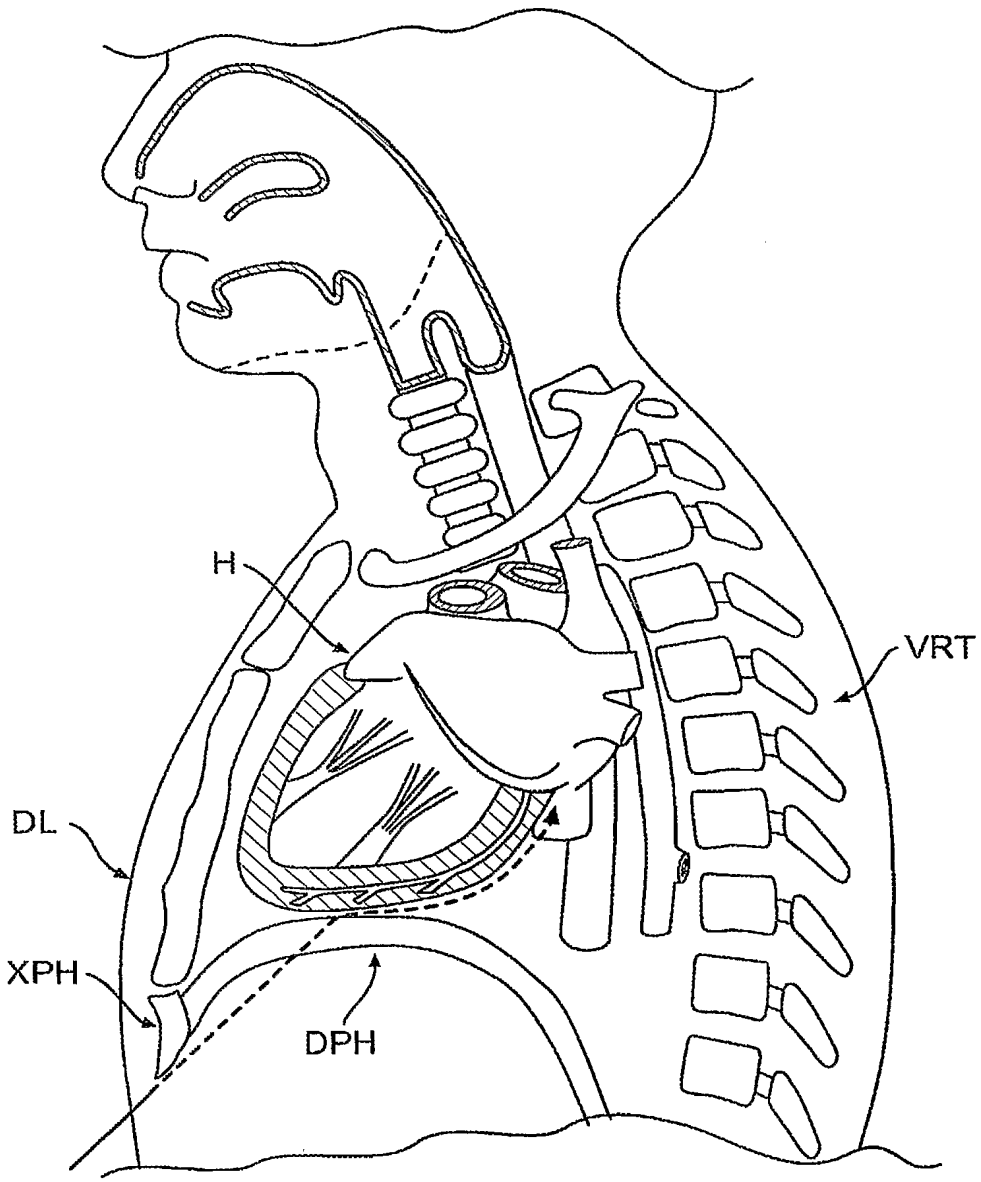

FIG. 11

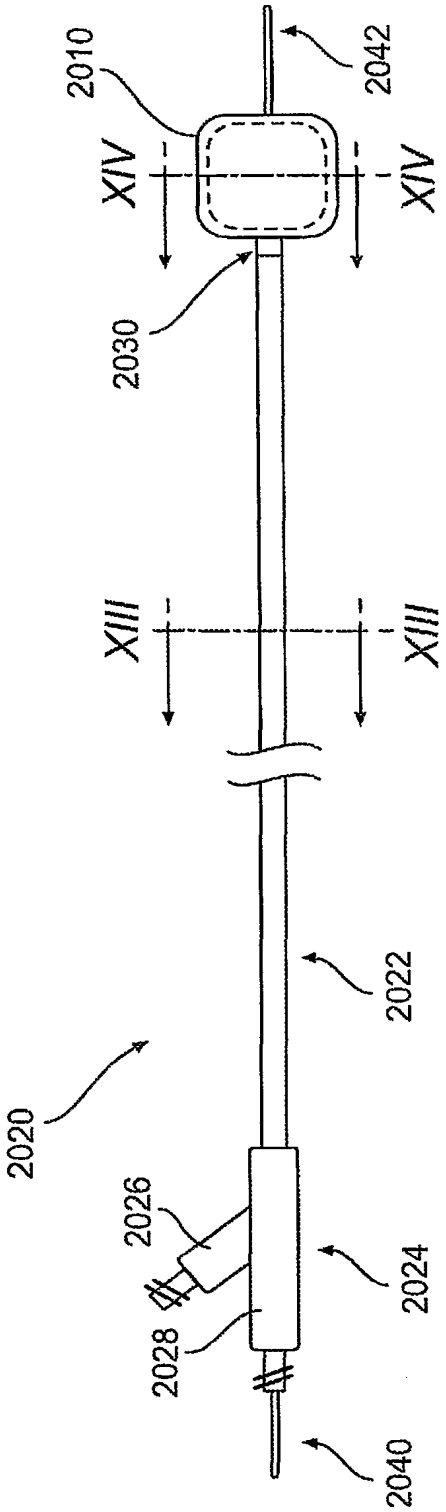

FIG. 12

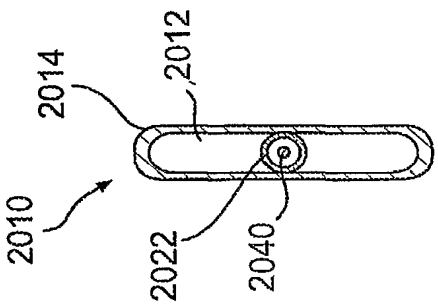

FIG. 14

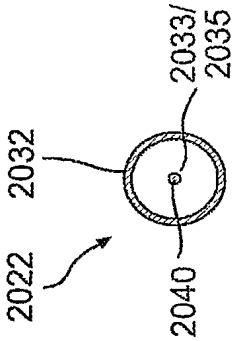

FIG. 13B

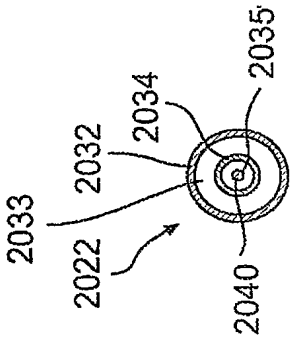

FIG. 13A

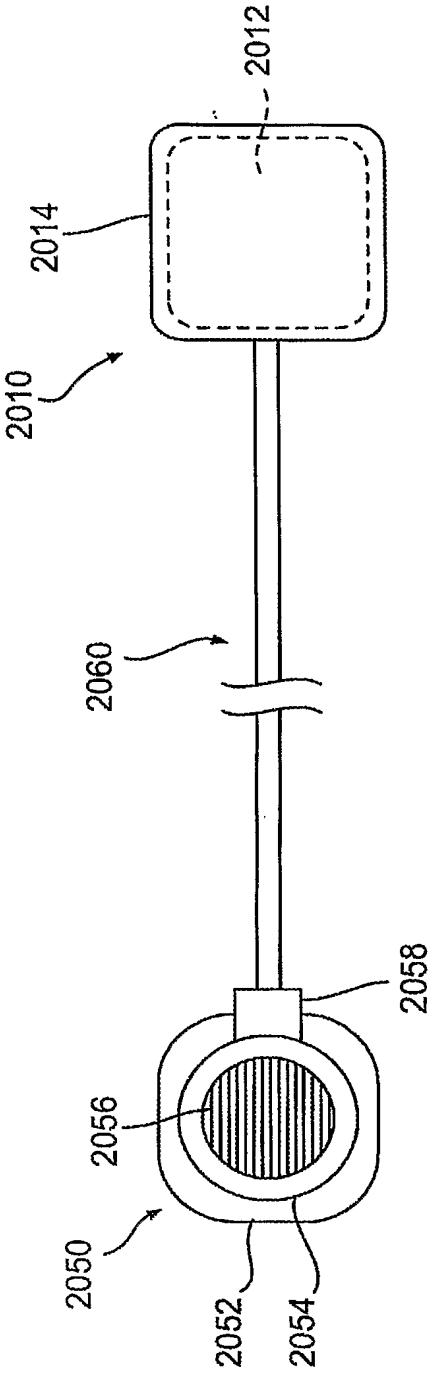

FIG. 15A

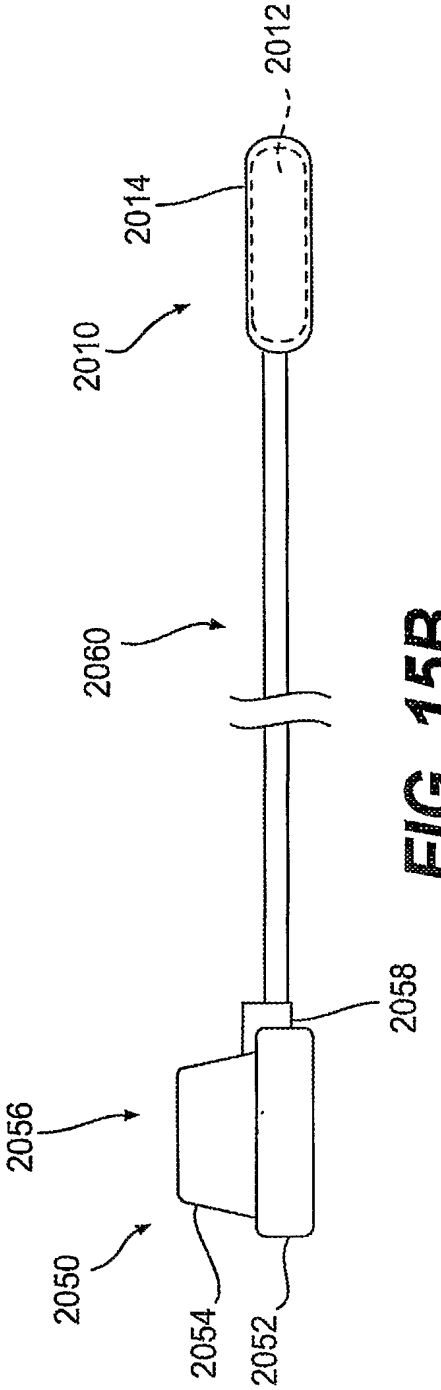

FIG. 15B

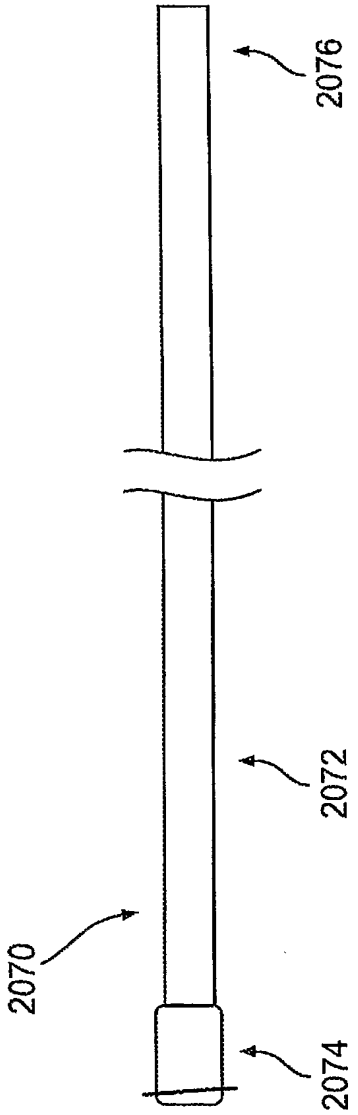

FIG. 16

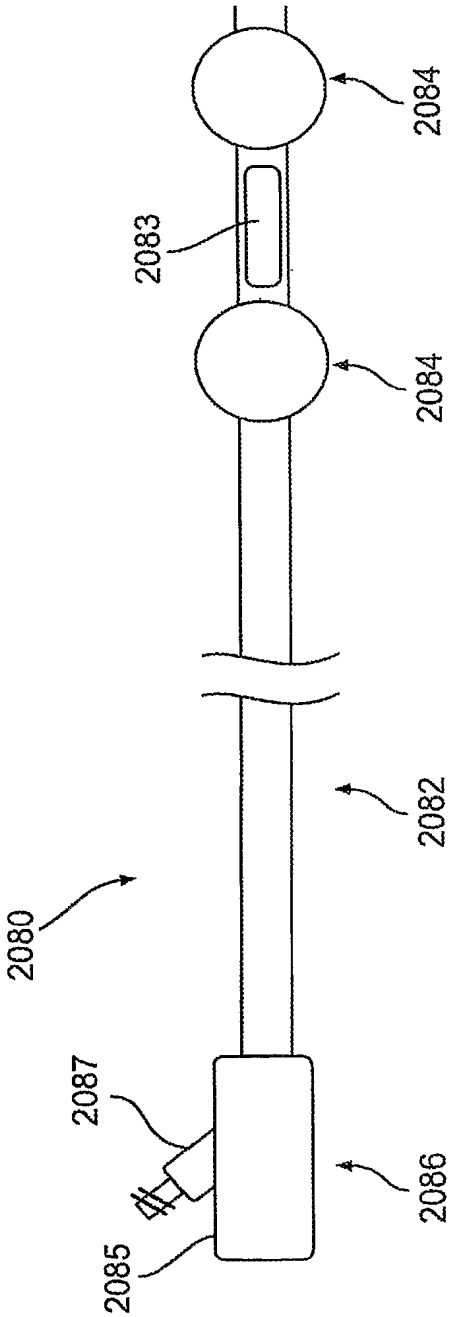

FIG. 17

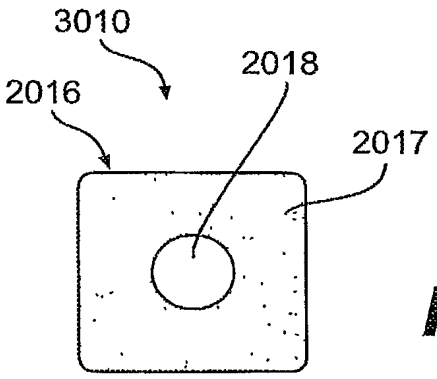

FIG. 18A

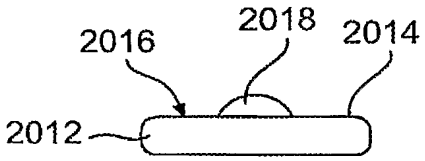

FIG. 18B

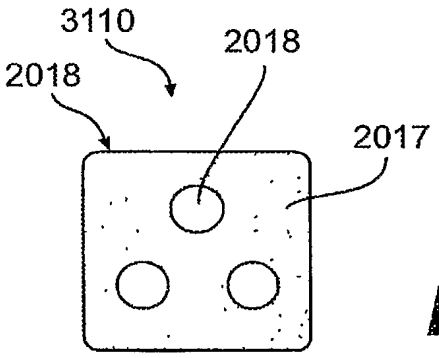

FIG. 19A

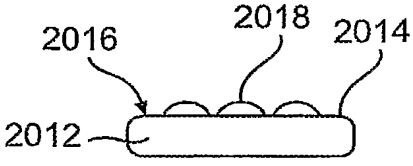

FIG. 19B

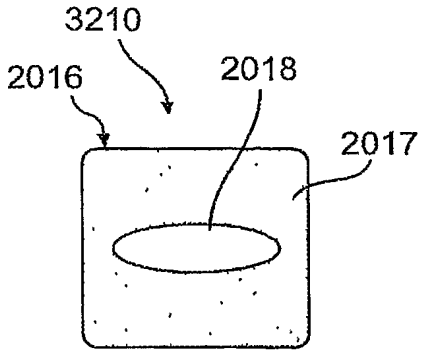

FIG. 20A

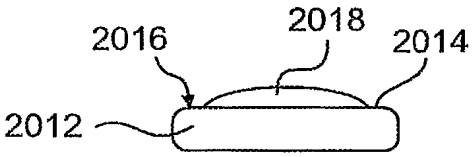

FIG. 20B

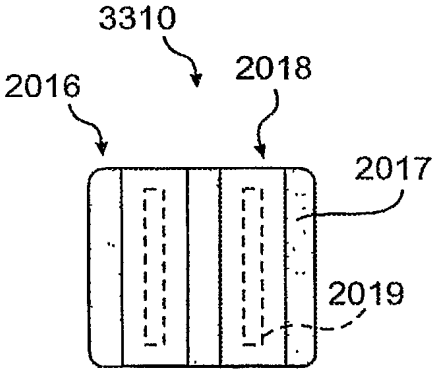

FIG. 21A

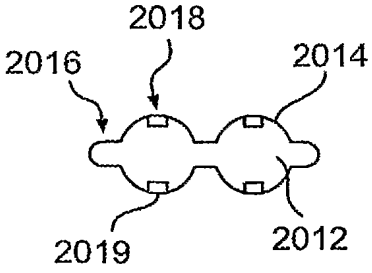

FIG. 21B

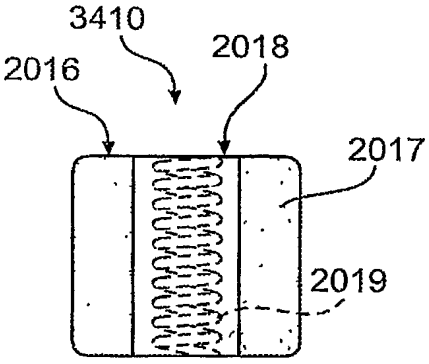

FIG. 22A

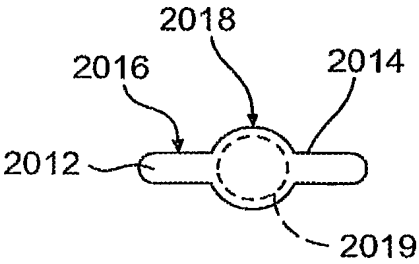

FIG. 22B

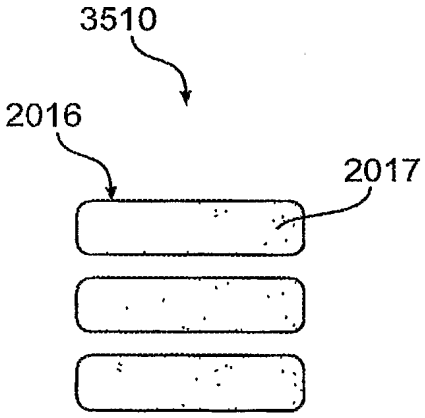

FIG. 23A

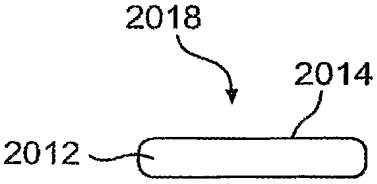

FIG. 23B

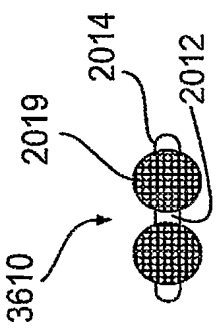

FIG. 24C

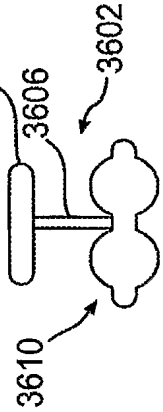

FIG. 24F

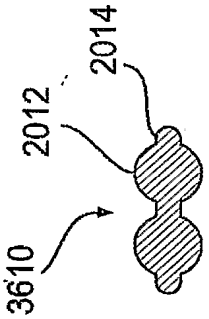

FIG. 24B

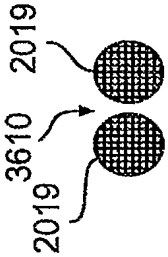

FIG. 24E

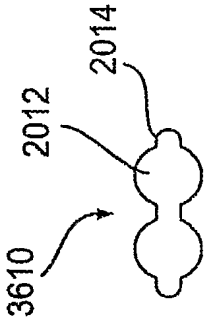

FIG. 24A

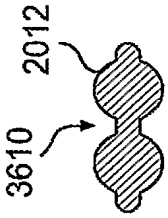

FIG. 24D

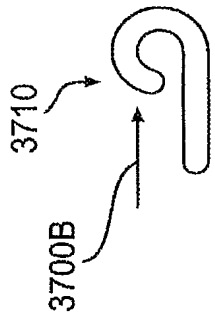

FIG. 25B

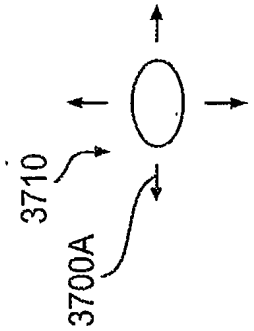

FIG. 25A

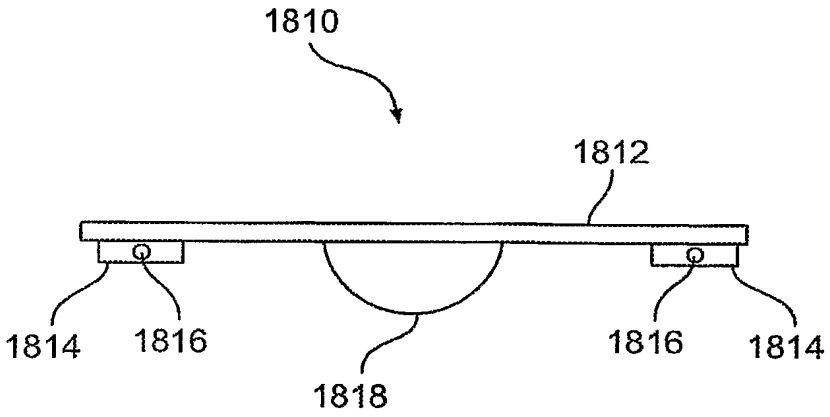

FIG. 26A

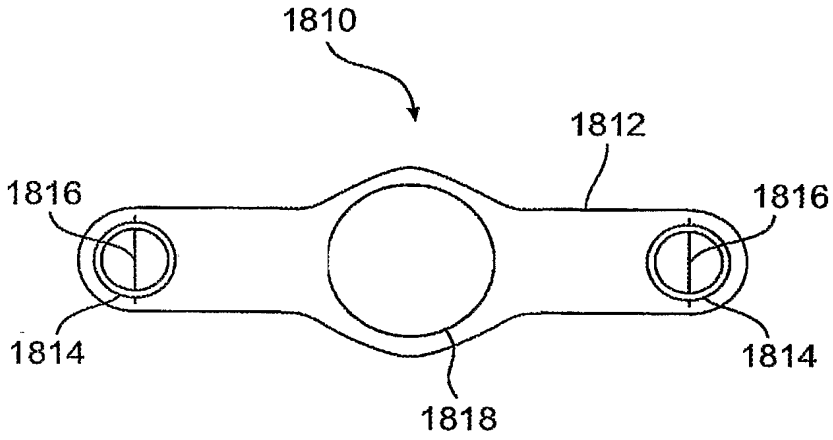

FIG. 26B

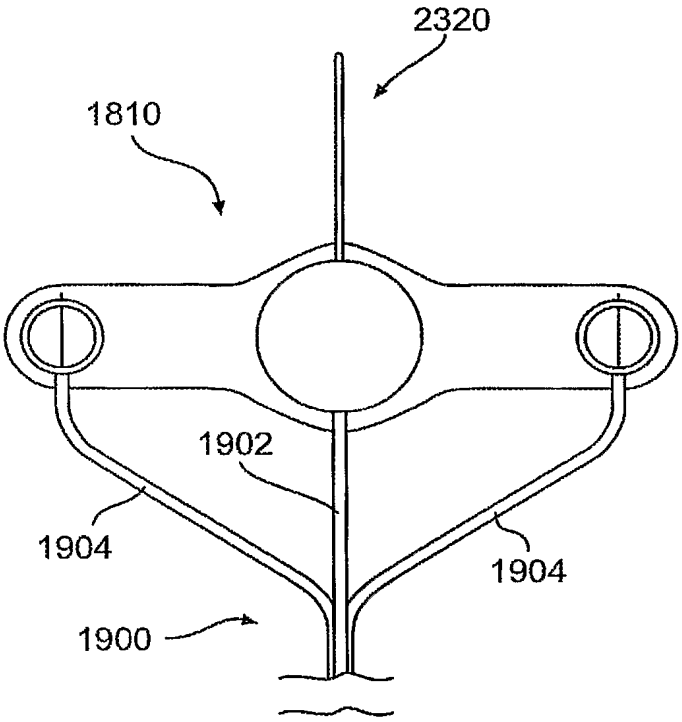

FIG. 27

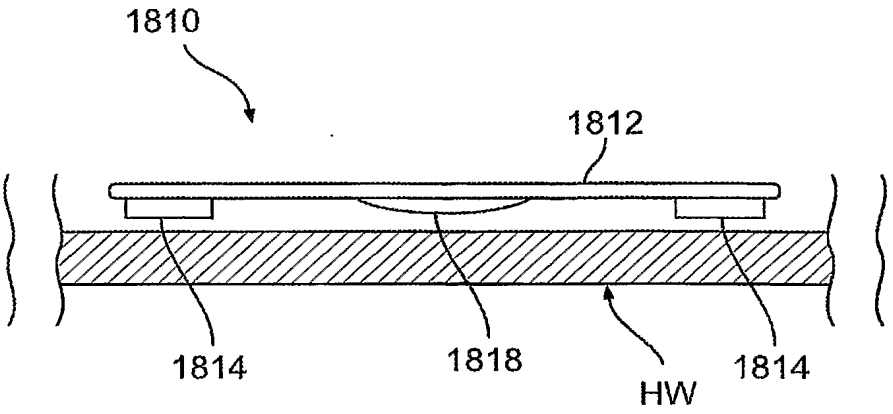

FIG. 28A

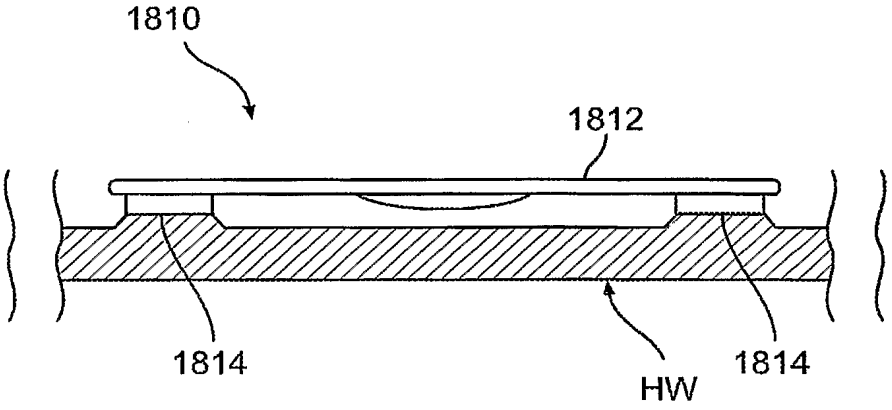

FIG. 28B

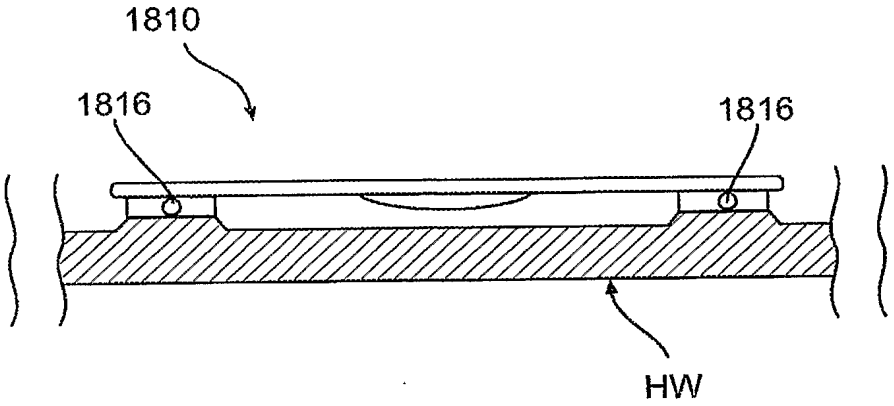

FIG. 28C

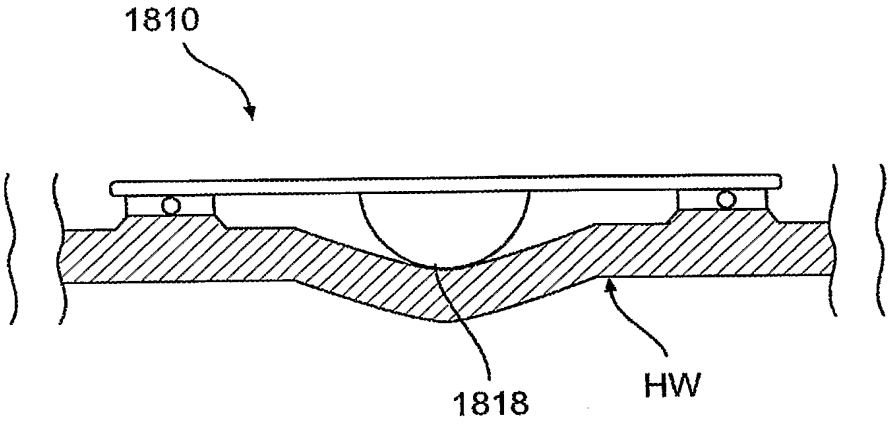

FIG. 28D

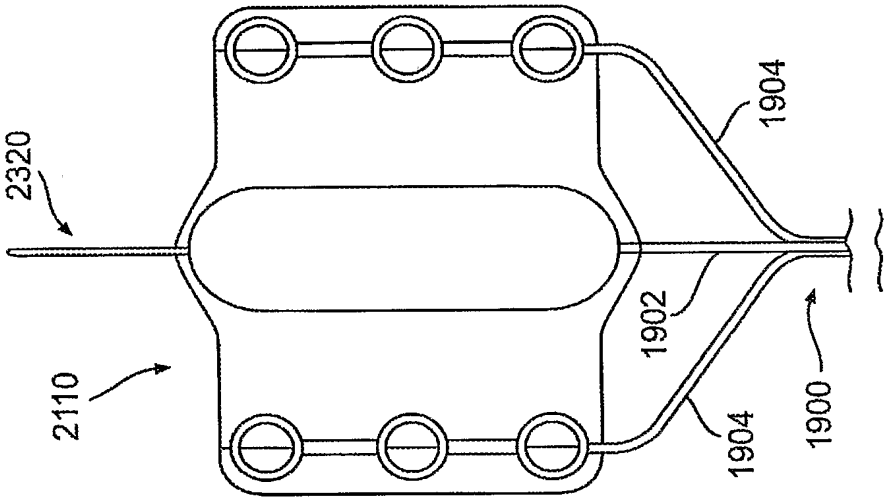

FIG. 29B

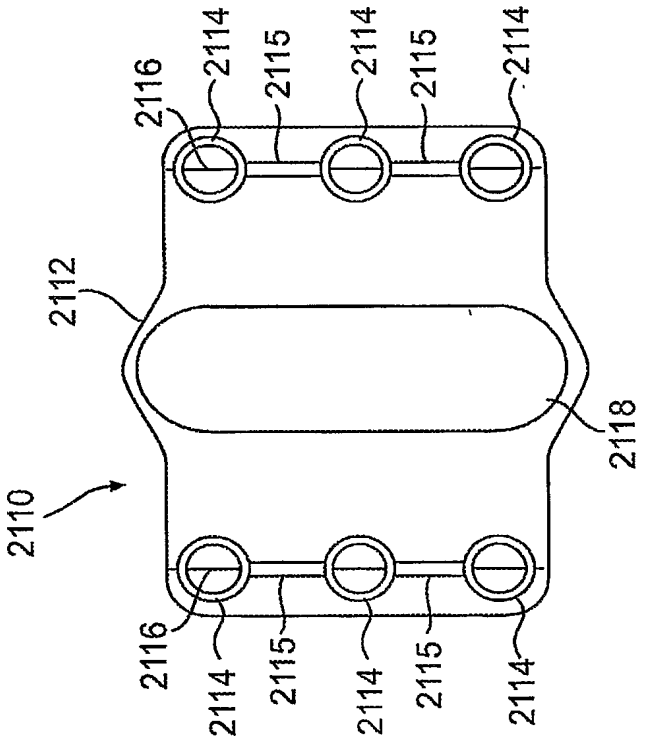

FIG. 29A

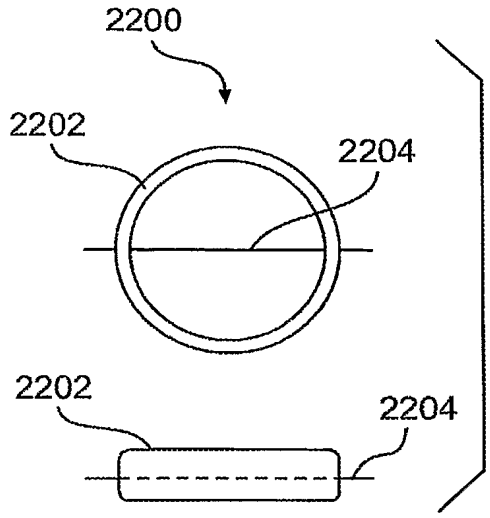

FIG. 30A

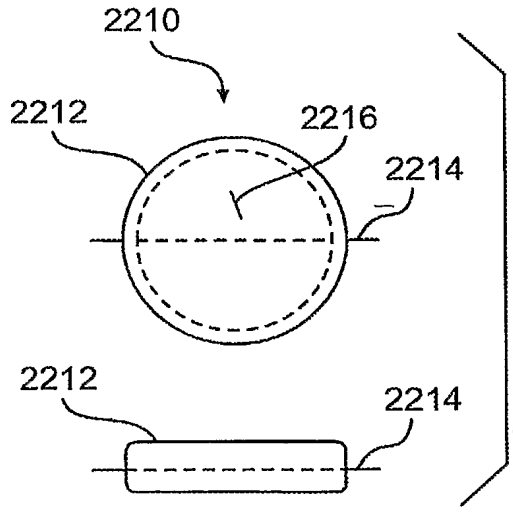

FIG. 30B

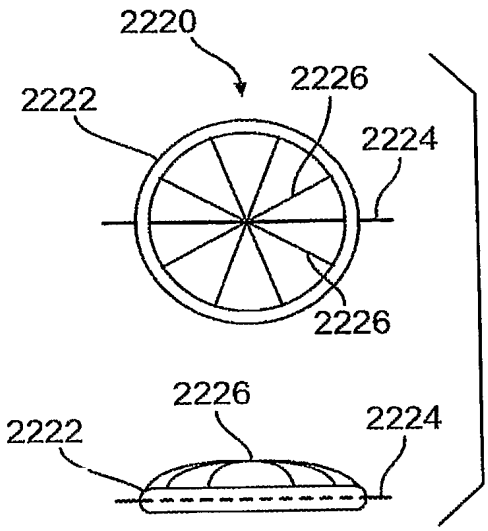

FIG. 30C

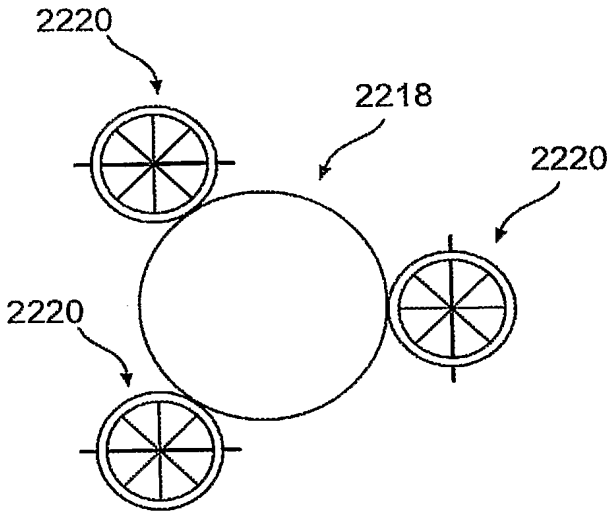

FIG. 30D

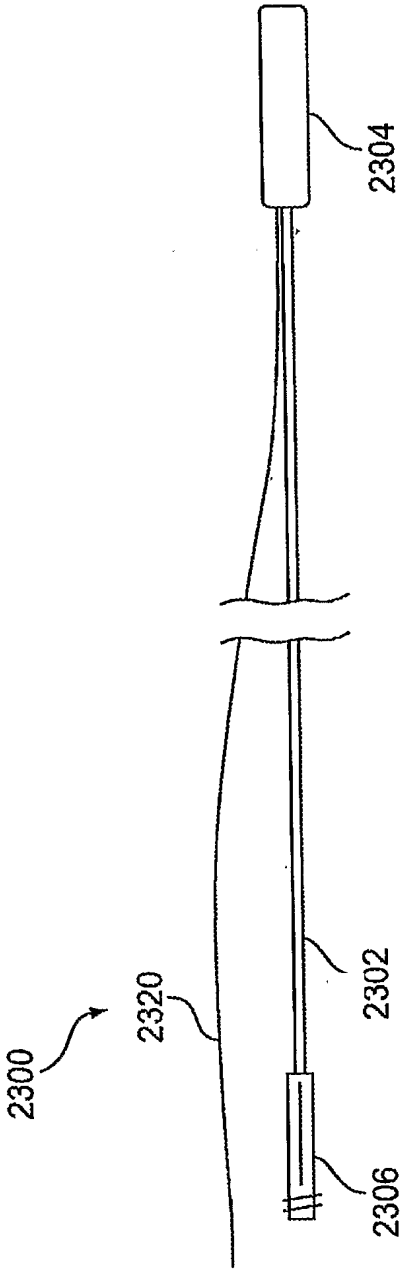

FIG. 31A

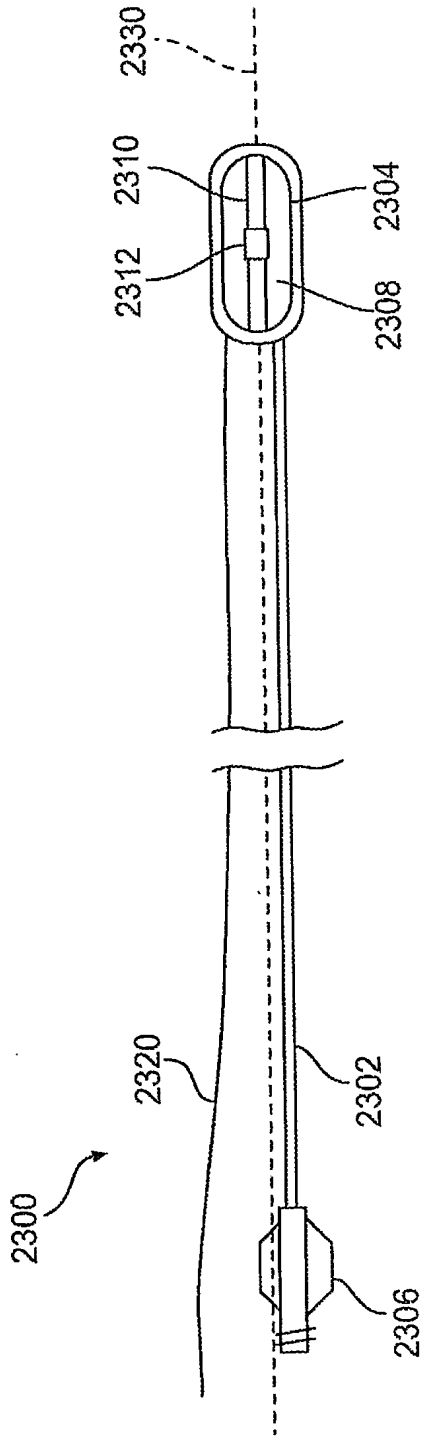

FIG. 31B

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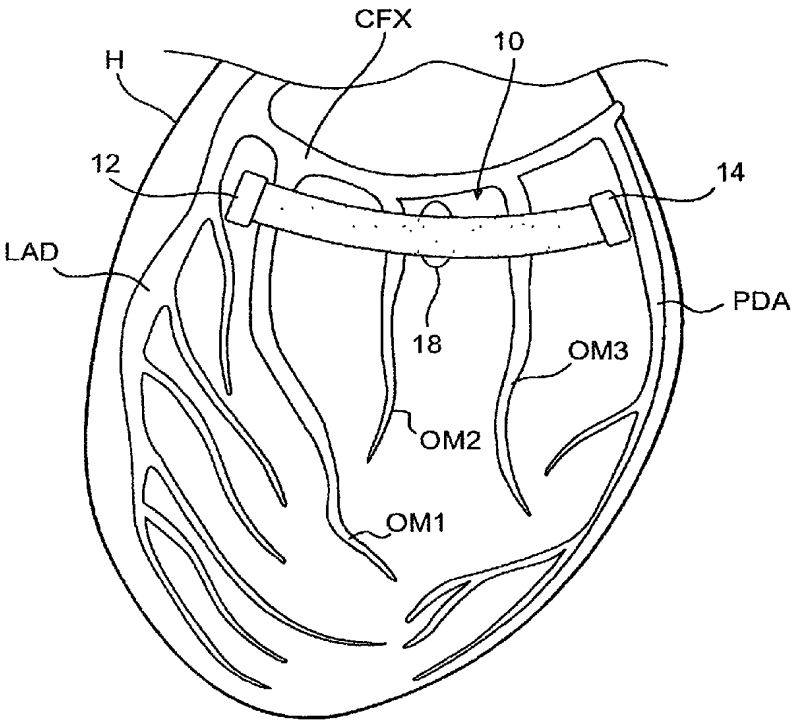
(74) Agents: **GARRETT, Arthur, S.** et al.; Finnegan, Henderson, Farabow, Garrett, & Dunner, L.L.P., 1300 I Street, NW, Washington, DC 20005-3315 (US).

[Continued on next page]

(54) Title: DEVICES AND METHODS FOR HEART VALVE TREATMENT



(57) Abstract: Devices and methods for improving the function of a valve (e.g., mitral valve) by positioning an implantable device outside and adjacent the heart wall such that the device alters the shape of the heart wall acting on the valve. The implantable device may alter the shape of the heart wall acting on the valve by applying an inward force and/or by circumferential shortening (cinching). The shape change of the heart wall acting on the valve is sufficient to change the function of the valve, and may increase coaptation of the leaflets, for example, to reduce regurgitation.

WO 2004/043265 A3

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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International Application No
PCT/US 03/35037

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/00 A61B17/04

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)
IPC 7 A61B

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)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/30292 A (SCHROEDER RICHARD F ;SCHWEICH CYRIL J JR (US); MORTIER TODD J (US)) 18 April 2002 (2002-04-18)	1-8, 10-30, 35,38, 39,42, 47-58, 71-73, 90,92-97
A	page 19, line 18 - page 21, line 21 figures 5A,5B	9,31-34, 37,59, 74-85

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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

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"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

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 March 2004	.12 JUL 2004

Name and mailing address of the ISA	Authorized officer
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	Compos, F

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/35037

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 406 420 B1 (SCHWEICH JR CYRIL J ET AL) 18 June 2002 (2002-06-18)	1-8, 10-30, 35,38, 39,42, 47-58, 71-73, 90,92-97
A	column 24, line 47 - line 65 column 26, line 4 - line 27 figures 45,48A,48B	9,31-34, 37,59, 74-85
X	US 2002/161275 A1 (MORTIER TODD J ET AL) 31 October 2002 (2002-10-31)	1-8, 10-30, 35,38, 39,42, 47-58, 71-73, 90,92-97
A	page 6, paragraph 83 - paragraph 85 page 6, paragraph 92 - paragraph 93 page 8, paragraph 113 - paragraph 114 figures 10,11,16,17,33,34	9,31-34, 37,59, 74-85
A	US 6 183 411 B1 (SCHWEICH JR CYRIL J ET AL) 6 February 2001 (2001-02-06) column 6, line 65 - column 7, line 52 figures 11-16	1-35, 37-39, 42, 47-59, 71-85, 90-97

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Form PCT/ISA/210 (continuation of second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/35037

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-35,37-39,42,47-59,71-85,90-97

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-35,37-39,42,47-59,71-85,90-97

   Device to be placed on the outer wall of the heart to alter heart valve function, the device having a first and second anchor, said anchors being linked by an interconnecting member, said interconnecting member having a protrusion to exert an inward force on the heart wall. The protrusion being expandable so that the amount of inward force applied can be varied.

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2. claims: 23,36,40,41,71,86-89

   Device to be placed on the outer wall of the heart to alter heart valve function, the device having a first and second anchor, said anchors being linked by an interconnecting member, said interconnecting member having a plurality of protrusions to exert an inward force on the heart wall. The number of protrusions being changeable and the protrusions being movable so that the force can be applied at several previce locations on the heart wall.

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3. claims: 23,43-46

   Device to be placed on the outer wall of the heart to alter heart valve function, the device having a first and second anchor, said anchors being linked by an interconnecting member, said interconnecting member having a protrusion to exert an inward force on the heart wall. The protrusion being rotatable from a low profile configuration to a larger profile deployed configuration so that the device can be easily delivery by catheter.

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4. claims: 60-62

   Pin with an associated multifilament material, said pin being barbed such that it cannot be withdrawn once inserted in tissue.

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5. claims: 63-66,114,115

   Delivery catheter for delivering an implant into the body.

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6. claim: 67

   Tensioning device to tension an elongated member.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

7. claims: 68-70

Device for accessing the pericardial space.

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8. claims: 98-101,116,117

Device to exert inward force on the external wall of the heart.

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9. claims: 102-113,118

Device comprising an elongated member with means to anchor said elongated member to the wall of the heart.

INTERNATIONAL SEARCH REPORT

ion on patent family members

International Application No
PCT/US 03/35037

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 03/35037

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(71) Applicant *(for all designated States except US)*: **EDWARDS LIFESCIENCES AG** [CH/CH]; Chemin Du Glapin 6, ch-1162 St. Prex (CH).

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(74) Agent: **SAUNDERS & DOLLEYMORE**; 9 Rickmansworth Road, Watford, Hertfordshire WD18 0JU (GB).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, 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, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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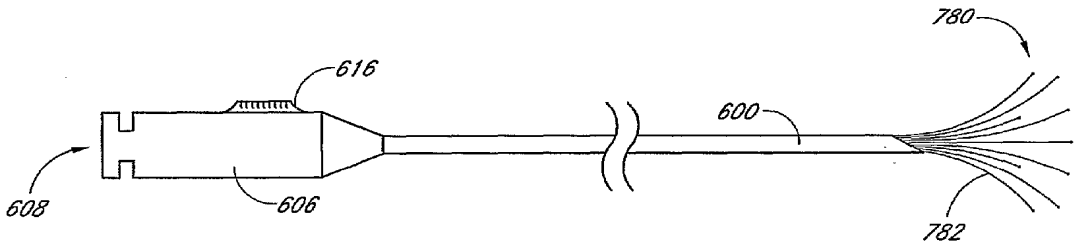
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: HEART VALVE LEAFLET LOCATOR



(57) Abstract: Disclosed are methods and devices for determining valve leaflet orientation. A catheter is provided with a conformable, radiopaque target. The target is deployed within a valve, such as the mitral valve. The conformable target conforms to the coaptation axis in response to closing of the valve leaflets. That coaptation axis may then be visualized, and utilized to determine information about valve operation, or to assist in placement of devices in the vicinity of the valve.

WO 2005/039428 A2

HEART VALVE LEAFLET LOCATOR

Background of the Invention

Field of the Invention

[0001] The present invention relates to methods and intravascular apparatus for determining information about a valve, including the orientation of the coaptation axis of a valve, between corresponding valve leaflets.

Description of the Related Art

[0002] A wide variety of transvascular procedures are known, for evaluating and treating a variety of relatively static conditions within the vasculature, such as aneurysms and partial or total occlusions. More recently, transvascular procedures have been developed, which call for evaluation and treatment of dynamic structures such as fully or partially operating valves. The present applicants believe that certain of these therapies can be optimized if it were possible to determine dynamic information about the valve, such as the coaptation axis and related leaflet orientation. The applicants believe that by determining the orientation of certain particular heart valve leaflets, the diagnosis and therapy of certain congestive heart failure patients may be improved.

[0003] Dilated cardiomyopathy occurs as a consequence of many different disease processes that impair myocardial function, such as coronary artery disease and hypertension. The left ventricle enlarges and the ejection fraction is reduced. The resulting increase in pulmonary venous pressure and reduction in cardiac output cause congestive heart failure. Enlargement of the mitral annulus and left ventricular cavity produce mitral valvular insufficiency. This in turn, causes volume overload that exacerbates the myopathy, leading to a vicious cycle of progressive enlargement and worsening mitral regurgitation.

[0004] According to recent estimates, more than 79,000 patients are diagnosed with aortic and mitral valve disease in U.S. hospitals each year. More than 49,000 mitral valve or aortic valve replacement procedures are performed annually in the U.S., along with a significant number of heart valve repair procedures.

[0005] Various surgical techniques have been developed to repair a diseased or damaged valve. One repair technique which has been shown to be effective in treating incompetence, particularly of the mitral and tricuspid valves, is annuloplasty, in which the effective size of the valve annulus is contracted by attaching a prosthetic annuloplasty ring to the endocardial surface of the heart around the valve annulus. The annuloplasty ring comprises an inner substrate of a metal such as stainless steel or titanium, or a flexible material such as silicone rubber or Dacron cordage, covered with a biocompatible fabric or cloth to allow the ring to be sutured to the heart tissue. The annuloplasty ring may be stiff or flexible, may be split or continuous, and may have a variety of shapes, including circular, D-shaped, C-shaped, or kidney-shaped. Examples are seen in U.S. Pat. Nos. 4,917,698, 5,061,277, 5,290,300, 5,350,420, 5,104,407, 5,064,431, 5,201,880, and 5,041,130, which are incorporated herein by reference.

[0006] Annuloplasty rings may also be utilized in combination with other repair techniques such as resection, in which a portion of a valve leaflet is excised, the remaining portions of the leaflet are sewn back together, and a prosthetic annuloplasty ring is then attached to the valve annulus to maintain the contracted size of the valve. Other valve repair techniques in current use include commissurotomy (cutting the valve commissures to separate fused valve leaflets), shortening mitral or tricuspid valve chordae tendonae, reattachment of severed mitral or tricuspid valve chordae tendonae or papillary muscle tissue, and decalcification of the valve leaflets or annulus. Annuloplasty rings may be used in conjunction with any repair procedures where contracting or stabilizing the valve annulus might be desirable.

[0007] Although mitral valve repair and replacement can successfully treat many patients with mitral valvular insufficiency, techniques currently in use are attended by significant morbidity and mortality. Most valve repair and replacement procedures require a thoracotomy, usually in the form of a median sternotomy, to gain access into the patient's thoracic cavity. A saw or

other cutting instrument is used to cut the sternum longitudinally, allowing the two opposing halves of the anterior or ventral portion of the rib cage to be spread apart. A large opening into the thoracic cavity is thus created, through which the surgical team may directly visualize and operate upon the heart and other thoracic contents. Alternatively, a thoracotomy may be performed on a lateral side of the chest, wherein a large incision is made generally parallel to the ribs, and the ribs are spread apart and/or removed in the region of the incision to create a large enough opening to facilitate the surgery.

[0008] Surgical intervention within the heart generally requires isolation of the heart and coronary blood vessels from the remainder of the arterial system, and arrest of cardiac function. Usually, the heart is isolated from the arterial system by introducing an external aortic cross-clamp through a sternotomy and applying it to the aorta to occlude the aortic lumen between the brachiocephalic artery and the coronary ostia. Cardioplegic fluid is then injected into the coronary arteries, either directly into the coronary ostia or through a puncture in the ascending aorta, to arrest cardiac function. The patient is placed on extracorporeal cardiopulmonary bypass to maintain peripheral circulation of oxygenated blood.

[0009] Of particular interest in the present application are techniques for the repair and replacement of the mitral valve. The mitral valve, located between the left atrium and left ventricle of the heart, is most easily reached through the wall of the left atrium, which normally resides on the posterior side of the heart, opposite the side of the heart that is exposed by a median sternotomy. Therefore, to access the mitral valve via a sternotomy, the heart is rotated to bring the left atrium into an anterior position. An opening, or atriotomy, is then made in the right side of the left atrium, anterior to the right pulmonary veins. The atriotomy is retracted by means of sutures or a retraction device, exposing the mitral valve adjacent to the atriotomy. One of the previously identified techniques may then be used to repair or replace the valve.

[0010] An alternative technique for mitral valve access has been used when a median sternotomy and/or rotational manipulation of the heart are inappropriate. In this technique, a thoracotomy is made in the right lateral side of the chest, usually in the region of the fourth or fifth intercostal space. One or more ribs may be removed from the patient, and other ribs near the incision are retracted outward to create a large opening into the thoracic cavity. The left atrium is then exposed on the posterior side of the heart, and an atriotomy is formed in the wall of the left atrium, through which the mitral valve may be accessed for repair or replacement.

[0011] Using such open-chest techniques, the large opening provided by a median sternotomy or right thoracotomy enables the surgeon to see the mitral valve directly through the left atriotomy, and to position his or her hands within the thoracic cavity in close proximity to the exterior of the heart for cannulation of the aorta and/or coronary arteries to induce cardioplegia, manipulation of surgical instruments, removal of excised tissue, and introduction of an annuloplasty ring or a replacement valve through atriotomy for attachment within the heart.

[0012] Mitral valve surgery, including mitral annuloplasty, is usually applied to patients with intrinsic disease of the mitral apparatus. As described, above, these patients may have scarring, retraction, tears or fusion of valve leaflets as well as disorders of the subvalvular apparatus. Definitive repair requires direct visualization of the valve.

[0013] Patients who develop mitral regurgitation as a result of dilated cardiomyopathy do not always have intrinsic mitral valve disease. Regurgitation occurs as the result of the leaflets being moved back from each other by the dilated annulus. The ventricle enlarges and becomes spherical, pulling the papillary muscles and chordae away from the plane of the valve and further enlarging the regurgitant orifice. In these patients, correction of the regurgitation does not require repair of the valve leaflets themselves, but simply a reduction in the size of the annulus and the sphericity of the left ventricle.

[0014] Mitral annuloplasty without repair of the leaflets or chordae has been shown to be effective in patients with dilated cardiomyopathy who are refractory to conventional medical therapy. Dr. Steve Bolling, at The University of Michigan and coworkers have operated on a cohort of such patients with New York Heart Association Class III and IV symptoms. Average symptom severity decreased from 3.9 preoperatively to 2.0 after surgery. Hemodynamics and ejection fraction improved significantly. Other investigators have achieved similar results as well. However, the morbidity, risks and expense of surgical annuloplasty are very high in patients with cardiomyopathy and congestive heart failure. Thus, a variety of new techniques for the treatment of congestive heart failure are being explored as adjuncts to drug therapy.

[0015] Several cardiac restraint devices have been described. U.S. Patent No. 5,702,343 to Alferness discloses a cardiac reinforcement device that is applied as a jacket over the epicardium in order to limit diastolic expansion. However, this requires an open chest operation to implant and does not directly affect the diameter of the mitral annulus. Another approach is disclosed in U.S. Patent No. 5,961,440 to Schweich, et al., in which tension members are placed through opposite walls of the heart such that they span the ventricle. Less invasive and "minimally" invasive techniques for valve repair and replacement continue to evolve, both on a stopped heart and on a beating heart. These techniques may provide some benefits over open chest procedures, but they are still attended by significant morbidity and mortality risks.

[0016] A need therefore remains for improved methods and devices for treating valvular disease and malformation, such as mitral valvular insufficiency, which are attended by significantly lower morbidity and mortality rates than are the current techniques, and therefore would be well suited to treat patients with dilated cardiomyopathy. Optimally, the procedure can be accomplished through a percutaneous, transluminal approach.

Summary of the Invention

[0017] There is provided in accordance with one aspect of the present invention, a method of determining the coaptation axis of a valve. The method comprises the steps of positioning a device within the valve, the device being movable in response to opening and closing of the valve. The device is observed when the valve is closed, to determine the orientation of the coaptation axis.

[0018] The positioning step may comprise transluminally positioning, such as through the aortic valve and into the mitral valve. Alternatively, the positioning step may comprise transluminally advancing the device into the right atrium and across the atrial septum into the mitral valve.

[0019] The device may comprise a plurality of radiopaque markers, and the positioning step comprises positioning the plurality of radiopaque markers within the valve such that the markers will align with the coaptation axis upon closing of the valve.

[0020] In accordance with another aspect of the present invention, there is provided a method of positioning an implant within the coronary sinus. The method comprises the steps of positioning a radiopaque device within the mitral valve. The radiopaque device is visualized, to determine a coaptation axis of the mitral valve. The implant is thereafter positioned within the coronary sinus, in a preselected relationship relative to the coaptation axis.

[0021] Preferably, the radiopaque device is movable in response to closing of the mitral valve. The device may comprise a plurality of radiopaque markers, which align in response to closing of the valve to conform to the coaptive edges of the valve leaflets. In one implementation of the invention, the positioning an implant step comprises positioning the implant such that it applies pressure on the P2 leaflet of mitral valve.

[0022] In accordance with another aspect of the present invention, there is provided a method of determining the coaptation axis of the mitral valve. The method comprises the steps of advancing the distal end of a catheter through the left ventricle to a position adjacent the mitral valve. A radiopaque

target is deployed from the distal end of the catheter, and the alignment of the radiopaque target in response to closing of the mitral valve is observed. The radiopaque target may comprise a plurality of radiopaque markers, such as a plurality of wires. The wires may be in the form of a collapsible basket.

[0023] In accordance with another aspect of the present invention, there is provided a leaflet orientation device, for determining the coaptive axis of a valve. The device comprises an elongate flexible tubular body, having a proximal end and a distal end. A conformable radiopaque target is carried by the distal end. The target is conformable in response to closing of the valve, to align with the coaptive edges of valve leaflets.

[0024] The conformable target may comprise a plurality of wires. In one embodiment, each of the plurality of wires is connected at a first end to the device, and are free at a second end. In another implementation, both the first ends and second ends of the wires are attached to the device. The conformable target may alternatively comprise a pig-tail support, or a membrane such as a wall of a collapsible balloon, each carrying at least one radiopaque marker.

[0025] The conformable target may be movable between a retracted position within the catheter, for transluminal navigation, and an extended position for determining valve leaflet orientation.

[0026] Further features and advantages of the present invention will become apparent to those of skill in the art in view of the detailed description of the preferred embodiments, which follows, when considered together with the attached drawings and claims.

Brief Description of the Drawings

[0027] Figure 1 is a schematic illustration of the heart, showing one embodiment of the mitral annuloplasty device of the present invention deployed within the coronary venous system.

[0028] Figures 2A and 2B are schematic illustrations of the mitral annuloplasty device shown in Figure 1, in second and first configurations.

[0029] Figure 3 is a side elevational view of an implant and deployment catheter according to the invention.

[0030] Figure 4 is a segmented view of the assembly shown in Figure 3, and shows an enlarged fragmentary view of an implant attachment region of the assembly.

[0031] Figure 5 shows a transverse cross-sectional view taken along line 5-5 in Figure 4.

[0032] Figure 6 shows a perspective view of a proximal region of an implant according to the invention.

[0033] Figure 7 shows a partially cross-sectioned side view of a region of a device assembly similar to that shown in Figure 6.

[0034] Figure 8A shows a partially cross-sectioned side view of an implant, in a first configuration during a first mode of use.

[0035] Figure 8B shows a similar view as that shown in Figure 8A, with the implant in a second configuration during a second mode of use.

[0036] Figures 9A-B show side elevational schematic views of a distal end portion of a delivery assembly coupled to an elongate body, and show the elongate body during two modes of operation, respectively.

[0037] Figure 9C shows a side elevational view of a portion of the implant shown in Figure 9A.

[0038] Figure 9D shows a cross sectional view taken along line 9D-9D in Figure 9C, showing an interlocking transverse slot pattern.

[0039] Figure 9E shows a cross-sectional view through the line 9E-9E of Figure 9D.

[0040] Figure 9F is a fragmentary cross sectional view of a connection between a forming or deflection element and an elongate body.

[0041] Figure 9G shows a fragmentary schematic view of two interlocking segments according to one specific mode for the elongate body shown in Figures 9A-F.

[0042] Figure 10 is a bottom plan view of an alternative medical device including a delivery assembly, comprising a handle assembly and a shaft, and an implant configured for remodeling a mitral valve.

[0043] Figure 11 is a cross section of the shaft of the medical device of Figure 10 taken along the view line 11-11 of Figure 10.

[0044] Figure 12 is an enlarged view of a portion of the medical device of Figure 10, including the implant and a connection assembly for removably connecting the implant to the delivery assembly.

[0045] Figure 13 is an enlarged view of the connection assembly of the medical device of Figure 12.

[0046] Figure 13A is a cross section view of the male connector of Figure 13.

[0047] Figure 13B is a cross section view taken along view line 13B-13B of Figure 13.

[0048] Figure 13C is a partial cross section view taken along view line 13C-13C of Figure 13A.

[0049] Figure 13D is a cross section view taken along view line 13D-13D of Figure 13.

[0050] Figure 14 is a plan view of a rotational driver of the delivery assembly of the medical device of Figure 10, viewed apart from the medical device.

[0051] Figure 15 is an end elevational view of a hex-shaped distal end of the driver of Figure 14, taken along the view line 15-15 of Figure 14.

[0052] Figure 16 is a cross section view of a handle assembly of the medical device of Figure 10.

[0053] Figure 17 is a cross sectional view taken along the view line 17-17 of Figure 16.

[0054] Figure 18 is a plan view of a portion of the handle assembly of Figure 16 taken along the line 18-18 of Figure 16.

[0055] Figure 19 is a plan view of a slot pattern for an implant such as that of Figure 10.

[0056] Figure 20 is an enlarged view of the slot arrangement of Figure 19.

[0057] Figure 21 is a cross sectional view of another implant in accordance with the present invention.

[0058] Figure 22 is a side elevational view of the device of Figure 21, in an actuated orientation.

[0059] Figure 23 is a side elevational view of an implant similar to that shown in Figure 22, in the implanted configuration, having an expandable basket thereon for securement in a vessel.

[0060] Figure 24 is a side elevational fragmentary view of an implant, illustrating a plurality of axial foreshortening voids.

[0061] Figure 25 is a side elevational view of an implant in accordance with the present invention, having a plurality of compression elements and/or securement members thereon.

[0062] Figure 26 is a side elevational view of an implant in accordance with the present invention, having an alternate compression element thereon.

[0063] Figure 27 is a side elevational view of an alternative implant in accordance with the present invention.

[0064] Figure 28 is an enlarged fragmentary cross sectional view of a portion of the implant illustrated in Figure 27.

[0065] Figure 29 is a cross sectional fragmentary view of a distal anchor assembly in accordance with the present invention.

[0066] Figures 30A and B are schematic views of an alternate implant in accordance with the present invention.

[0067] Figure 31A is a side elevational view of an alternative implant in accordance with the present invention.

[0068] Figure 31B is a cross-sectional view taken along line 31B-31B of Figure 31A.

[0069] Figure 31C is a plan view of a ratchet strip for use with the implant of Figures 31A and 31B.

[0070] Figure 31D is a plan view of a disconnect sub-assembly for use with the ratchet strip of Figures 31A-C.

[0071] Figure 31E is a cross-sectional view taken along line 31E-31E in Figure 31D.

[0072] Figure 31F is a plan view showing the catheter coupling of the implant of Figures 31A-B

[0073] Figure 32A is a cross-sectional view of a proximal deployment handpiece.

[0074] Figure 32B is a partial cross-sectional view of the proximal deployment handpiece of Figure 32A rotated 90 degrees.

[0075] Figure 33 is a side elevational view of an alternative implant in accordance with the present invention.

[0076] Figure 34 is a side elevational close-up view of the distal end of the implant of Figure 33.

[0077] Figure 35 is a side elevational close-up view of the proximal end of the implant of Figure 33.

[0078] Figure 36 is a side elevational cutaway view of an alternative implant in accordance with the present invention.

[0079] Figure 37 is a close-up view of the proximal end of the implant of Figure 36.

[0080] Figure 38 is a partial cross sectional view of the heart illustrating an aortic approach to the mitral valve.

[0081] Figure 38A is the mitral valve of Figure 38 in a closed position, as viewed from the left atrium, also known as the "short axis" view.

[0082] Figure 38B is the tricuspid valve of Figure 38 in a closed position, as viewed from the right atrium.

[0083] Figure 38C is the aortic valve of Figure 38 in a closed position, as viewed from the aorta.

[0084] Figure 38D is a cross sectional view of the mitral valve (also known as the "long axis" view) of Figure 38A taken along cut line 38D-38D.

[0085] Figure 38E is the mitral valve of Figure 38 in an opened position, as viewed from the left atrium.

[0086] Figure 38F is a cross sectional view of the mitral valve of Figure 38E taken along cut line 38F-38F.

[0087] Figure 39 is a partial cross sectional view of the heart and a deployed leaflet locator in accordance with one embodiment of the present invention.

[0088] Figures 40A through 40E illustrate deployment catheters for deploying a conformable target within a valve.

[0089] Figure 41A is a close-up schematic cross sectional view of the mitral valve during diastole and deployed leaflet locator of Figure 39.

[0090] Figure 41B is a close-up view of the mitral valve during diastole and another embodiment of a deployed leaflet locator.

[0091] Figure 42 is a view of the mitral valve during systole and leaflet locator of Figure 41A taken along view line 42-42.

[0092] Figure 42A is a partial cross sectional view of the heart illustrating the mitral valve and a prosthesis inserted into the coronary sinus aligned with respect to the transverse pressure axis of the mitral valve.

[0093] Figure 42B is another partial cross sectional view of the heart illustrating the mitral valve and a prosthesis inserted into the coronary sinus aligned with respect to the transverse pressure axis of the mitral valve.

[0094] Figure 42C is another partial cross sectional view of the heart illustrating the mitral valve and a prosthesis inserted into the coronary sinus aligned with respect to the coaptation axis of the mitral valve.

[0095] Figure 43 is a partial cross sectional view of the heart illustrating a transeptal approach to the mitral valve.

[0096] Figure 44 is a partial cross sectional view of the mitral valve and another embodiment of a leaflet locator, prior to deployment into the mitral valve.

[0097] Figure 44A is the mitral valve and leaflet locator of Figure 44 positioned within the mitral valve, taken along view line 44A-44A.

[0098] Figure 45 is a partial cross sectional view of the mitral valve and another embodiment of a leaflet locator.

[0099] Figure 46 is a perspective view of a leaflet locator in a delivery configuration in accordance with another embodiment of the present invention.

[0100] Figure 47 is a perspective view of the leaflet locator of Figure 46, shown in a deployed configuration.

[0101] Figure 48 is a cross sectional view of the leaflet locator of Figure 47.

[0102] Figure 48A is a cross sectional view of the leaflet locator of Figure 48 taken along cut line 48A-48A.

[0103] Figure 48B is a perspective view of another embodiment of a leaflet locator in accordance with the present invention.

[0104] Figure 48C is a close-up view of a locating wing of the leaflet locator of Figure 48B taken along view line 48C-48C.

[0105] Figures 49A-E are side views of another embodiment of a leaflet locator shown at different stages of deployment in accordance with the present invention.

[0106] Figure 50 is the mitral valve in a closed position and the leaflet locator of Figure 49E, as viewed from the left atrium.

Detailed Description of the Preferred Embodiment

[0107] Preferred embodiments of the present invention include a method and apparatus for performing mitral annuloplasty and remodeling of the left ventricle using a device that may be introduced percutaneously, and placed

within the coronary venous system of the heart. The device exerts compressive force on the mitral annulus and left ventricle, reducing the severity of mitral regurgitation and the size of the left ventricular cavity. The device thus enables reduction of the mitral annulus and constraint of the diastolic expansion of the left ventricle yet without the morbidity and other risks associated with open chest surgery. Additional details are disclosed in the parent application, Serial No. 10/066,302, filed on January 30, 2002, the disclosure of which is incorporated in its entirety herein by reference.

[0108] The present inventors have determined that the coronary sinus and veins provide an ideal conduit for the positioning of an intravascular prosthesis, or implant, for remodeling the mitral annulus, since they are positioned adjacent the mitral annulus and interventricular septum. As used herein, the term "implant" is a broad term, and should not be limited to a permanently introduced structure or device, but could additionally be a temporarily introduced device. The coronary sinus is contained within the atrioventricular groove, and is in close proximity to the posterior, lateral and anterior aspects of the mitral annulus. The coronary sinus and coronary veins are cannulated currently during any of a variety of percutaneous transvenous diagnostic and therapeutic procedures. Permanent placement of pacemaker and defibrillator leads within the coronary sinus and veins is both safe and well tolerated.

[0109] The annuloplasty system consists of several components. Desirably, there is a delivery system intended to be introduced percutaneously into a central vein such as the internal jugular, subclavian or femoral veins and to cannulate the coronary sinus. The implant of the present invention is deployed from the delivery system, preferably a delivery catheter, into the coronary venous system or into a position within or adjacent the myocardium, to influence the annulus of the mitral valve. Additional tools may be placed through or along the delivery catheter to position the device, apply elements in

place, and to control and/or cut tensioning elements (if provided) from the delivery system, as will be discussed in detail below.

[0110] Referring to **Figure 1**, there is illustrated a schematic view of the heart 10, having a preferred embodiment of a mitral annuloplasty and cardiac reinforcement device 40 positioned therein. The heart 10 generally comprises a right atrium 12, in communication with the superior vena cava 14 and inferior vena cava 16. The left ventricle 18 is positioned below the left atrial appendage 20. Relevant portions of the coronary vasculature include the coronary sinus 22, which extends from the ostium 24 to the junction 26 of the coronary sinus and the great cardiac vein 28. There may be anastomotic connections 29 between the great cardiac vein 28 and the middle cardiac vein 30, as is well understood in the art.

[0111] One embodiment of a mitral annuloplasty and cardiac reinforcement device 40 is illustrated generally in the coronary sinus 22. In particular, the device 40 extends from a proximal end 42 to a distal end 44. The proximal end 42 lies against the posterior aspect of the interatrial septum 46. The midportion 48 of the device 40 is positioned within the coronary sinus 22. The transitional section 50 of the device 40 lies at the junction 26 of the coronary sinus 22 and the great cardiac vein 28. The distal end 44 of the device 40 is lodged in the great cardiac vein 28.

[0112] The transitional region 50 is designed to reside in the proximal portion of the great cardiac vein 28. By deflecting out of a plane defined by the coronary sinus 22, it serves as an anchor 52 and prevents the device 40 from slipping out of the coronary sinus 22 when tension is applied. This embodiment of an anchor 52 is, preferably, very flaccid and flexible, thereby minimizing the risk of erosion of the device 40 through the wall of the great cardiac vein or other aspect of the coronary venous system. The proximal end 42 of the device 40 lies outside the ostium 24 of the coronary sinus 22 and is desirably curved upward so as to anchor against the posterior aspect of the interatrial septum 46. Advantageously, the proximal end 42 of the illustrated

device 40 is semicircular in shape and elliptical in profile so that no edges will promote erosion of adjacent tissue.

[0113] As an alternative anchor 52 to the distal extension of the device 40, any of a variety of structures may be provided. In general, the deployed device 40 will contact the wall of the coronary sinus 22 along the inside radius of its arcuate path. Thus, a tissue contacting surface 54 on the concave side of the deployed device 40 may be provided with any of a variety of friction enhancing surface structures, such as a plurality of transverse ridges, teeth or other projections, or modified surface textures to enhance friction. Alternatively, tissue engaging or piercing structures such as barbs may be provided on the surface 54 to engage the wall of the coronary sinus 22 to resist movement of the device 40, as will be discussed.

[0114] While use of such structures as anchors may provide some benefit in certain applications, embodiments herein shown and described are believed to be particularly useful in one aspect specifically because they operate without the need for such aggressive tissue engagement. It will be apparent to one of ordinary skill based upon this disclosure that the present embodiments provide independent device manipulation and shape control that allow for sufficient forces to be applied to the mitral valve without requiring the possibly harmful effects of puncturing and grabbing tissue within the sinus for the remodeling process. In one regard, the independent action of a barbless design allows for adjustment in both the tightening and loosening directions with reduced risk of significant tissue damage or erosion. In another regard, devices 40 according to at least certain embodiments beneficially maintains its length throughout its modified range of shapes while the sinus and adjacent valve annulus reduce their dimensions under the force of remodeling. In still a further regard, the independent action and lack of tissue piercing and grabbing anchors allow for the device to be removed from the patient after initial implantation within the sinus, such as for example in the event of complications or in applications intended to be temporary remedial measures, such as for bridging a

patient to surgery. Further to this regard, various shapes and sizes of devices may be required in a given patient before the appropriate one is found according to the observed *in vivo* response to implantation.

[0115] The specific dimensions, construction details and materials for the mitral annuloplasty and cardiac reinforcement device 40 can be varied widely, as will be appreciated by those of skill in the art in view of the disclosure herein. For example, dimensional adjustments may be made to accommodate different anatomical sizes and configurations. Materials and construction details can be varied to accommodate different tensioning mechanisms and other considerations.

[0116] In general, the device 40 defines an overall length from proximal end 42 to distal end 44. Preferably, the length is within the range of from about 2 cm to about 10 cm in an embodiment such as that illustrated in Figure 2A in which the anchor 52 comprises a distal extension of the body 66 for lodging within the great cardiac vein 28. One embodiment of the device 40 includes an elongate flexible body 66 about eight centimeters in length. In such an embodiment, the body 66 may be elliptical in cross section so that it will bend in a single plane when force is applied to the tensioning element within it, as will be discussed below. Distally the device 40 tapers and transitions to a round cross-section.

[0117] Referring to **Figures 2A-B**, there is illustrated an embodiment of the device 40 having a forming element 56, such as a wire, therein. Manipulation of the forming element 56 allows the device to be moved from a flexible orientation to enable percutaneous insertion into the vascular system and navigation into the coronary sinus (Figure 2B), to an arcuate configuration for compressing at least a portion of the mitral annulus (Figure 2A). The device 40 may be advanced from the first, flexible configuration to the second, arcuate configuration by either axial proximal retraction or distal advancement of the forming element 56 with respect to the body 66, depending upon the particular design.

[0118] In general, the device 40 comprises an elongate flexible support 58, extending from a proximal end 42 at least as far as a point of attachment 60. The support 58 may be a portion of the body 66 or may be a distinct component as will be discussed. The support 58 has a fixed length, and is substantially axially non-compressible and non-expandable. Thus, proximal axial retraction of the forming element 56 relative to the proximal end of the support 58 will desirably cause the support 58 to deflect in a first direction, tending to bend the body 66 about an axis transverse to the longitudinal axis of the body 66. Distal axial advancement of the forming element 56 with respect to the support 58 will cause lateral deflection of the support 58 in a second direction, tending to permit the body 66 to straighten due to the inherent resiliency of the support 58. This basic steering configuration can be embodied in many forms, which can be optimized by those of skill in the art to suit a particular construction for the body 66 depending upon the desired dimensions and clinical performance.

[0119] The forming element 56 extends from the proximal end 42 through the device 40 to the point of attachment 60. At the point of attachment 60, the forming element 56 is mechanically coupled, and preferably, directly coupled to the support 58. Alternatively, other suitable methods of attachment may be used. A proximal extension 64 of the forming element 56 extends from the proximal end 42 of the device 40, such as through an aperture 62. Proximal retraction of the forming element 56 through the aperture 62 causes the device 40 to bend from an implantation, or delivery orientation, for navigating the coronary vasculature during implantation, to a formed, or remodeling orientation for compression and constraint of the coronary sinus 22 and adjacent structures.

[0120] In the formed, remodeling orientation, the device 40 preferably provides a compressive force against the mitral annulus as has been discussed. This is desirably accomplished by forming the device into an arcuate configuration. Generally, the best fit curve of constant radius to which the

formed device conforms has a radius within the range of from about 1.0 cm to about 2.0 cm. The forming element may comprise any of a variety of materials and constructions, such as a polymeric or metal wire or strand, a multi-filament braided or woven line, a metal or polymeric ribbon, or other structure capable of retaining the device 40 under tension in the coronary sinus 22.

[0121] The device 40 further comprises a support 58, which may be the body 66 of the device 40 or a separate element positioned therein. In an embodiment in which the support 58 is a separate element contained within the device 40, support 58 may comprise any of a variety of generally axially non-compressible elements such as a metal or polymeric wire or column, ribbon, or "bottomed out" (e.g., fully compressed) spring which facilitates lateral bending but inhibits axial compression upon proximal retraction of forming element 56. A metal ribbon comprising stainless steel, nitinol, or other known materials may be desired in certain embodiments, due to its ability to influence the plane of curvature of the device 40 when in the formed orientation.

[0122] In the presently illustrated embodiment, the proximal extension 64 of the forming element 56 extends proximally throughout the length of a deployment catheter, to a control or free end which remains outside of the patient during the deployment procedure. Following placement of the device 40 in the coronary sinus, proximal traction on the proximal extension 64 will reconfigure the device 40 into the formed orientation within the coronary sinus, as will be discussed in connection with the method of use of preferred embodiments. After a sufficient tension has been placed on the coronary sinus 22, the forming element 56 is preferably locked in a fixed axial position with respect to the device 40, to resist distal movement of the forming element 56 through aperture 62. Any of a variety of suitable lock arrangements may be provided. Preferably, the lock 70 is provided on or near the proximal end 42, and, in particular, at or about the aperture 62. The lock may comprise any of a variety of structures, such as a suture knot, locking clamp or ring, an interference fit, ratchet and pawl structures, threaded engagement, an adhesive

bond, or a compression fit, as will be apparent to those of skill in the art in view of the disclosure herein.

[0123] The lock 70 (on any of the embodiments herein) may be initially disengaged, so that the forming element 56 may be retracted or advanced freely through the aperture 62 while the physician adjusts the tension on the device 40. After the desired tension is achieved, the lock 70 is activated to engage the forming element in a manner which will depend upon the lock design. Alternatively, the lock 70 may be biased into an engaged configuration, such as with ratchet or cam structures, so that the forming element can only be retracted proximally. Preferably, however, the lock will allow the forming element to be released so that the physician can release tension on the device 40 in the event of momentary over tightening.

[0124] The forming element 56 and support 58, with or without the tubular body discussed below, may be surrounded by a tubular jacket of ePTFE or a polyester fabric such as DACRON, or other material which is wrapped or stitched onto the forming element 56 to produce the final device 40. As a further alternative, the subassembly which includes the forming element 56, and, if present, support 58 may be positioned within a suitable length of tubing formed such as by extrusion. The tubing may be drawn down to a reduced diameter at the distal end 44. Additional post extrusion steps may be used to produce the desired cross-sectional configuration. Manufacturing techniques for the present invention will be apparent to those of skill in the art in view of the disclosure herein.

[0125] Any of a variety of additional features may be added to the device 40, depending upon the desired clinical performance. For example, the outside surface of the body 66 may be provided with any of a variety of coatings, such as poly-paraxylene, sold under the trademark PARALENE, PTFE or others to improve lubricity; heparin or other antithrombogenic agents; elastomers such as silicone, neoprene, latex or others to soften the surface and reduce the risk of trauma to the vascular intima, and the like. Adhesion

enhancing surfaces may be provided, such as ePTFE patches or jackets, to promote cellular ingrowth for long term anchoring. In addition, depending upon the deployment system design, the body 66 may be provided with a guidewire lumen extending axially therethrough, to allow the body 66 to be advanced distally over a guidewire during placement at the treatment site.

[0126] The device 40 may be implanted within the coronary sinus 22 either through direct surgical (e.g., thoracotomy, with or without sternotomy) access, such as in combination with another surgical procedure, via port access, or remotely by way of a percutaneous or surgical cut down access to the venous system. Preferably, the device 40 is implanted in a transluminal procedure, such as by way of a percutaneous access at one of the internal jugular, subclavian, or femoral veins.

[0127] **Figures 3-8B** illustrate an exemplary device assembly 200. In general, **Figure 3** is an overall view of assembly 200 that includes a delivery assembly 210 engaged to a prosthesis, or implant 250. According to similar overall delivery systems and methods elsewhere herein described, prosthesis 250 is adapted to be delivered in a first condition and shape into a vessel at least in part by manipulation of delivery assembly 210. Once in the desired region of the target vessel, prosthesis 250 is adapted to be adjusted to a second condition and shape within the vessel in order to influence an adjacent tissue structure. As also elsewhere herein described, a particularly beneficial mode of such operation places the prosthesis 250 within a coronary sinus for the purpose of influencing a mitral valve annulus, more specifically in order to influence the shape of the annulus in order to reduce mitral valve regurgitation.

[0128] **Figures 4-7** show the proximal aspects of device assembly 200, and in particular various details for delivery assembly 210 that includes an outer member 215 that is preferably tubular with an inner lumen 216 that is preferably sized to house an inner member 225. Inner member 225 in the variation shown is generally tubular and is substantially free to rotate within lumen 216, preferably by providing rotational force to inner member 225

proximally outside of the patient's body. According to the example shown, this rotational force is applied to inner member 225 via a thumbwheel 205 that is provided on proximal hub assembly 201 coupled to proximal end portion 211 of delivery assembly 210. Thumbwheel 205 is rotationally coupled to inner member 225 within hub assembly 201, which rotational coupling may be achieved according to a number of adaptations as would be apparent to one of ordinary skill.

[0129] Rotation of inner member 225 is transmitted into rotation of a rotational coupler 280 that is engaged within a proximal end portion 252 of prosthesis 250 as follows. Inner member 225 has an aperture 228 on its distal end portion that provides a female counterpart of a mated key interface between the inner member 225 and a male counterpart, desirably provided by a shaped proximal end 281 of a rotational coupler 280 that is also rotationally engaged within a proximal end portion 252 of prosthesis 250. The keyed fitting between inner member 225 and rotational coupler 280 allows for transmission of rotational forces to rotational coupler 280. In order to maintain releasable axial engagement of this keyed coupling, a flexible member such as a filament 240 is looped through an aperture 283 through proximal end 281 of rotational coupler 280 with both filament ends 242 and 244 extending proximally through inner member 225 to a location in the proximal end of the catheter. The filament 240 is generally held in sufficient tension to keep the distal keyed fitting engaged, though it is further contemplated that the mere presence of the filament may provide an interference against uncoupling if there is a sufficiently tight tolerance in the male/female interface of the keyed fitting.

[0130] Rotational coupler 280 is rotationally engaged within proximal end portion 252 of prosthesis 250 through a proximal port, or aperture 251, such that the rotational coupler 280 is adapted to rotate within and relative to the prosthesis 250. This relative rotation is converted to force a deflection of prosthesis 250 into the desired shape of the second configuration in situ as follows.

[0131] According to one aspect of the rotational coupling, the prosthesis 250 is preferably held to resist rotation while rotational coupler 280 is rotated within the prosthesis 250. This may be achieved simply by frictional forces of surrounding tissue after the prosthesis 250 has been delivered into the desired vessel such as the coronary sinus. According to another example, this may be achieved by providing a releasable interface such as a friction fit 218 between outer member 215 and proximal end portion 252 of prosthesis 250 wherein the frictional engagement of outer member 215 and prosthesis 250 are held in a relatively fixed position while inner member 225 and rotational coupler 280 are rotated. This embodiment is shown in **Figure 4**. In addition, or in the alternative to the friction fit interface, a keyed interface may be employed as shown in **Figures 6-7**. According to this mode, a shaped proximal fitting 253 including a flat surface 253' on the proximal end 252 of prosthesis 250 is adapted to mate as a male counterpart into a shaped aperture or fitting on the distal end 212 of outer member 215. This keyed interface allows for rotational coupling between the members in a similar manner as just described for the inner member 225 and rotational coupler 280, and may allow for a more releasable coupling with reduced friction upon axial detachment of the members.

[0132] The rotational forces from rotational coupler 280 may be converted to deflection forces on the prosthesis 250 according to one example as illustrated in **Figures 8A-B**. Prosthesis 250 includes a generally tubular wall or body 260 that has an inner lumen 262 and extends from the proximal end portion 252 to the distal end portion 254 of prosthesis 250. Secured along proximal end portion 252 is a nut fitting 263 that has a grooved inner bore 264 which communicates with inner lumen 262. Further to this specific embodiment, rotational coupler 280 is a screw member with outer helical threads 285 engaged within the mating threads of an inner surface (not shown) of a bore lumen such that a distal portion of screw threads 285 extends distally within lumen 262 and terminates at a second key fitting 287 similar to the

shaped proximal end portion 282 and also having an aperture 288. Similar to the proximal end of rotational coupler 280, another flexible member or filament 290 is looped through aperture 288 such that two arms 292, 294 extend distally therefrom to an attachment point along distal end portion 254 of prosthesis 250. Because nut fitting 263 is fixed in relation to outer tubular body 260, and because that tubular body is held in a relatively fixed position as provided above, rotation of rotational coupler 280 moves coupler 280 proximally relative to body 260. This proximal axial translation of rotational coupler 280 puts tension on filament 290, which puts tension on the body 260 due to the distal attachment. This tension on outer body 260 forces a deflection of the body 260. Therefore, rotational force is converted into a tensile force which, in turn, causes radial deflection of the body 260 relative to the longitudinal axis L of the device 250. In other words, the body 260 is deflected about an axis that is transverse to the longitudinal axis L. See Figure 8B.

[0133] The forced deflection described immediately above may be controlled in a particular plane by providing a composite structure within prosthesis 250 that is engineered to respond, e.g., yield, to these forces in a prescribed way. In the specific embodiment shown, a relatively noncompressible column support or spine member 270 is provided within lumen 262 of outer tubular body 260. This spine member 270 is more rigid and more resistant to axial forces, especially tensile forces, than the material of outer tubular body 260 alone. Therefore, providing spine member 270 along only one radial position along the circumference of the prosthesis 250 creates a bias on the device 250 to deflect away from the spine 270 toward a more compressive region of the device 250. Such composite design may further include a laminate structure, a composite structure - such as an imbedded wire reinforced wall structure, or may be achieved by engineering material variations in the device, such as for example by thinning, thickening, hardening, or softening the material at one location along the outer tubular body 260 relative to another region to urge the body 260 to deflect at a desired location.

[0134] As may be achieved by other controllable embodiments elsewhere herein described, deflection according to the present embodiment may be adjusted according to a healthcare provider's desires, and is adjustable in either direction – by either tightening the radius of curvature R or opening it. See Figure 8B. According to this specific embodiment however, the adjustability of and choice between tightening and loosening of the deflection depends upon the direction and extent of rotation placed upon the rotational force transmission system.

[0135] Once the desired deflection is achieved and desired therapeutic results are observed, the prosthesis 250 may be detached from the delivery assembly 210 by severing the torque or rotational force transmission system at the keyed fitting between the inner member 225 and the rotational coupler 280. This is accomplished by first releasing at least one arm 242, 244 of the proximal filament 240 while withdrawing the other arm, thereby threading the filament 240 through aperture 283 (as shown in bold arrows in Figure 8B) until it is unthreaded completely from the aperture 283. This allows inner member 225 to be withdrawn proximally from rotational coupler 280 to detach and thereby implant the prosthesis 250.

[0136] Alternatively, as with other adjustable deflection systems herein described, the prosthesis may be held in its therapeutic condition for a temporary period of time (which may nevertheless be prolonged during a hospital stay), during which time mitral valve regurgitation may be minimized, such as for example for the purpose of bridging the patient in a temporarily improved condition until other treatments may be performed, e.g. annuloplasty, valve surgery, heart transplant, etc. In this alternative temporary setting, at the appropriate time the deflected, contracted prosthesis may be adjusted back open from its cinched position around the valve, and then withdrawn without implantation by withdrawing the entire system, delivery assembly still engaged to the prosthesis. Moreover, it is further contemplated that such a temporary

prosthesis may be modified to remove the detachment mechanisms herein described, which may provide for a simpler and lower cost device.

[0137] Device assembly 200 is also shown in Figures 3 and 8A-B to include a distal guidewire tracking member with a guidewire lumen 265 which is adapted to slideably engage a guidewire 230 in order to be placed in a percutaneous transluminal procedure into the desired vessel location, such as within the coronary sinus 22. The particular guidewire lumen shown is integral within the distal aspects of prosthesis 250 as a "rapid exchange" or "monorail" design that allows for relatively independent movement of the guidewire and catheter in vivo. Moreover, this design removes the need for the guidewire to ride coaxial through the entire device assembly 200, as would be the case for example in an "over the wire" type system. The type shown beneficially allows for detachable engagement of prosthesis 250, which is preferably achieved after withdrawing the optional guidewire 230 from the distal lumen 265.

[0138] In each of the foregoing implantation methods, the physician preferably monitors the degree of regurgitation during the step of tightening the implant. Although any reduction in mitral regurgitation may be desirable, regurgitation is preferably reduced to something less than moderate (less than 2+). In any event, at least a one grade reduction is preferably achieved. On the other hand, reconfiguration of the implant 250 is desirably not accomplished to an extent sufficient to produce mitral stenosis, or any flow limitation of hemodynamic significance.

[0139] Thus, the method of implantation preferably further comprises the steps of monitoring the degree of mitral regurgitation during, and preferably also before and following the implantation and/or reconfiguration steps. The degree of mitral regurgitation may be monitored such as by transesophageal echo cardiography, intracardiac echo cardiography, fluoroscopy using radiocontrast in the left ventricle (LVgram), or left atrial or pulmonary capillary wedge pressure tracings, as are understood in the art, during the incremental restriction of the mitral annulus and/or left ventricle step. Once a

sufficient reduction in regurgitation has been achieved for a particular patient in the physician's judgement, the device 250 may be locked and the delivery assembly 210 detached from the device 250 and removed from the patient.

[0140] The method may additionally comprise the step of measuring the coronary sinus 22 and/or other coronary vein, and selecting an appropriately sized implant 250 from an array of implants of varying sizes. Such parameters may include diameter, length, or radius of curvature of the arc of the sinus. The appropriately sized implant 250 is thereafter positioned within the target vein. The implant 250 is thus preferably provided in a graduated array of sizes, so that the optimal size can be selected for each patient. The size of the coronary sinus 22 or other vein can be measured using any of a variety of techniques, such as echo cardiogram, MRI, CT Scan, or angiography as is understood in the art. Moreover, as is apparent to one of ordinary skill, measuring a parameter of the coronary sinus 22 generally provides indicia of certain parameters of the mitral valve and its annulus, such as for example mitral valve diameter, in which case either the coronary sinus parameter or the mitral valve parameter may provide the requisite information for choosing an appropriately dimensioned device 250 from the kit.

[0141] It follows that such mitral valve parameters may further be measured directly, such as by various of the methods just described, in order to generate the values used for choosing the appropriate device 250. Once a parameter for an anatomical feature is measured as herein described, its value is generally estimated according to the accuracy of the respective measuring tool – it is contemplated that persons without specialized medical skills or training can choose the appropriate medical device 250 from the kit once armed with this estimated value. For example, packaging for each device 250 of the kit may indicate the respective dimensions that are unique to that device 250 with respect to other devices of the kit, and the estimated value of the measured anatomical parameter may simply be compared.

[0142] It is contemplated and apparent that various of the embodiments herein described are adapted to accomplish manipulation of the coronary sinus 22 for mitral annulus reduction without substantially altering the length of the device 250 within the sinus 22. This may provide a benefit by increasing the useful purchase of the device 250 along the coronary sinus 22 and circumferentially around the mitral annulus as the sinus length and/or annulus diameter may be reduced during remodeling from the radial deflection of the prosthetic device 250. This may also mean that the dimension of the device 250 in a kit of devices may not directly correspond to the estimated value of the anatomical parameter that is measured. For example, the compared value of the measured device parameter may be shorter than an estimated coronary sinus 22 length due to a possible shortening of the sinus 22 during device 250 treatment. Or, the anatomical parameter may be estimated from an initial value based upon an anticipated or desired final result from treatment and such procedurally related value be used for choosing the appropriate device (*e.g.* comparing an estimated final length of the sinus or mitral valve diameter with a known dimension of the device in the remodeling configuration when used *in situ*).

[0143] As a further aspect to the present invention, the implant 250 is preferably combined with an appropriate drug therapy for treating congestive heart failure. Residual regurgitation and other hemodynamic functions are preferably measured following implantation of the implant of the present invention. Heart medications are preferably adjusted to take into account the reduction in regurgitation and/or reduction in left ventricle volume in formulating an ongoing drug therapy for the patient.

[0144] Still further, the present invention contemplates temporary use in the sinus 22 for mitral valve remodeling as a bridging regime in combination with other permanent treatments such as more conventional annuloplasty or valve replacement via surgery. Such combined systems of devices 250 and respective methods of use, which may further be combined with the pharmaceutical drug regimes, provide an overall treatment regime that

can provide a highly beneficial result for management of patients with harmful mitral valve regurgitation.

[0145] Any of the embodiments discussed herein may additionally be provided with one or more externally facing electrically conductive axially extending strips or annular bands, to enable the device 40 to function additionally as a cardiac pacing or other diagnostic or therapeutic cardiac electrode. The electrically conductive band or bands are placed in electrical communication with a pacing source or diagnostic instrument by way of one or more electrical conductors extending away from the device 40. The conductors may be electrically connected to any of a wide variety of electronic cardiac rhythm management devices, which are well known in the art.

[0146] As shown in one embodiment in **Figures 9A and 9B**, once in the coronary sinus the elongate body 320 is adapted to be adjusted from the first implantation (flexible) configuration to a second (relatively rigid) remodeling configuration that has a shape that is adapted to remodel the mitral valve annulus. According to the embodiment shown in Figure 9B, this shape is generally adapted to provide an external force onto the annulus in order to reduce its diameter along at least one transverse axis, such as according to the arcuate shape shown that at least in part grips down onto a portion of the circumference of the valve to provide a diameter reducing force. As is also shown in phantom, the arcuate shape may take different forms in terms of degree, and in a further highly beneficial application is controllable and selectable between various or through a continuous range of degrees. Such controllability according to the embodiment shown is also selective between intermediate deflectable portions 360, 370, 380, as is shown in Figure 9B and will be further developed below.

[0147] Elongate body 320 is constructed from tubular wall 325 that extends continuously along the length of the deflectable portions 360, 370, 380 of the elongate body 320. An array or plurality of distinct, discontinuous slots or voids 330 are formed within the wall 325, each void 330 having an elongated

shape that is transverse to the longitudinal axis. Voids 330 permit axial shortening of one side of the tubular wall 325, enabling the curvature illustrated in Figure 9B.

[0148] By further reference to the specific embodiment of **Figures 9A-F**, transverse voids 330 have a central groove-shaped region with two adjoining portions 332, 334 that converge at an apex 333 along the longitudinal axis. Such a shaped void 330 is defined at least in part by two opposing complementary shaped surfaces of two adjacent, longitudinally opposing portions 340, 350 of the wall of the elongate body 320. One of these portions 340 desirably assumes a convex shape in an axial, distal direction, and the other portion 350 is desirably concave in an axial, proximal direction around the apex 333. These shaped surfaces 340, 350 are preferably in a nested configuration with the convex portion 340 positioned within the concave portion 350. In this arrangement, lateral (rotational) movement of one of the adjacent wall portions 340, 350 relative to the other portion 340, 350 is substantially prevented by a mechanical interference with the other adjacent portion 340, 350. The relative nesting of adjacent portions 340, 350 of the elongate body 320 provides a mechanical interference to radial deflection along a first plane and substantially isolates deflection of the elongate body 320 along a second plane upon application of axial bending forces.

[0149] **Figure 9D** shows grooved voids 330 in plan view for the purpose of simplifying the illustration for better understanding. However, as depicted in Figure 9C and by reference to Figure 9E, these transverse voids 330 (and the generally the entire V-shaped portion herein described in detail) span across at least about 180 degrees of the circumference of the elongate body 320. Preferably, the transverse voids 330 span across more than about 300 degrees of the circumference of the elongate body 320, and still more preferably the voids span across between about 300 degrees and about 315 degrees of the circumference. By arranging such grooved voids in a similar alignment around the circumference of the wall 325, an integral and continuous backbone or spine

327 is formed along wall 325 that runs axially along the length of the elongate body 320. This overall arrangement of voids 330 and spine 327 has been observed to provide a desirable combination of bendability, due to the voided pattern, and axial integrity, due to the remaining wall structure.

[0150] The elongate body 320 of the implant 300 shown in **Figures 9A-F** generally has three deflectable portions 360, 370, 380, and one non-deflectable portion 310 along the longitudinal axis. Each deflectable portion 360, 370, 380 has a group of voids 330 as just described in order to be individually deflectable between the first and second configurations with an applied force from outside of the patient's body while the elongate body 320 is positioned within the coronary sinus. More specifically, three forming elements 365, 375, 385 may be coupled to the three deflectable portions 360, 370, 380, respectively, in order to apply a deflection force to that portion to reshape that portion between the first and second configurations. Each forming element 365, 375, 385 is preferably adapted to extend externally from the patient's body when the elongate body 320 is positioned within the coronary sinus in order to be manually manipulated to apply the deflection force to the respectively coupled deflectable portion 360, 370, 380. Deflection of each of these portions combined provides for the overall shape for the elongate body 320 in the second configuration.

[0151] Forming elements 365, 375, 385 are attached to elongate body 320 at unique, longitudinally spaced points of attachment 361, 371, 381, respectively, that are each at or distal to the distal end of each respectively coupled deflectable portion 360, 370, 380. One beneficial application is shown for the attachment of the forming members 365, 375, 385 to the body 320, wherein each point of attachment 361, 371, 381 has two axially spaced apertures, which are shown as proximal and distal apertures 362, 363 for point of attachment 361, proximal and distal apertures 372, 373 for attachment point 371, and proximal and distal apertures 382, 383 for point of attachment 381. As illustrated for point of attachment 371 in Figure 9F, a shaped distal end 377 for

forming element 375 is sized to be seated within distal aperture 373 where it is secured by a securing agent 374 which may be an adhesive, melt bond, or solder, for example. Any or all of the respective forming elements 365, 375, 385 may also be welded through the apertures to the wall. Forming element 375 extends proximally from distal aperture 373 and is further secured to wall 325 by additional securing agent 374 introduced through proximal aperture 372. The securing agent 374 may be applied in one operation from outside in through both apertures 372, 373. In addition, distal end 377 may also be shaped to provide a mechanical securement means for attachment during proximal axial forces, such as is shown in phantom in Figure 9F.

[0152] According to one specific embodiment that has been observed to be useful, the apertures for this attachment embodiment are generally between about 0.020 inches and about 0.022 inches in diameter with similar longitudinal spacing, and the distal end for the seated forming elements are between about 0.012 and about 0.014 inches in diameter. Further to that embodiment, wall 325 is generally constructed from a tubular, stainless steel wall or hypotube with a plurality of grooved voids 330 formed therein according to a pattern similar to that shown and described by reference to Figure 9D or elsewhere herein. The respective forming elements are soldered to the respective attachment points using gold/tin solder. Further to this embodiment, grooves such as shown and described by reference to Figure 9D were formed in the underlying stainless tube by laser cutting, though other well known techniques such as hand grinding, mechanical cutting, photo-lithography, etc. may alternatively be used.

[0153] As previously described herein, the applied force from the forming elements 365, 375, 385 are generally an axial force between the attachment points 361, 371, 381 to the elongate body 320 and a proximal location (not shown) along the elongate body 320 that is proximal to that deflectable portion. According to the specific embodiments shown this force is generally between the attachment points 361, 371, 381 and the proximal end

portion of the elongate body 320. The elongate body 320 may generally be held during forced deflection by means of a holding device (not shown) in order to substantially fix the proximal end portion of the elongate body 320 relative to the deflectable portion so that the axial force may be applied between those portions in situ. While the proximal manipulation of the forming elements 320 in order to apply the deflection force to the deflectable portions 360, 370, 380 may be axial as just described, it may in another regard be rotational.

[0154] Each deflectable portion 360, 370, 380 is substantially axially rigid and non-compressible relative to the longitudinal axis L, and therefore the overall axial length of elongate body 320 remains substantially constant between the first and second configurations. However, each deflectable portion is relatively flexible along a radial axis transverse to the longitudinal axis such that the deflectable portion is adapted to bend radially upon application of an axial force between a distal location on the elongate body at or distal to a distal end of the deflectable portion and a proximal location along the elongate body 320 proximal to that deflectable portion. In one regard, the elongate body 320 may be generally axially non-compressible or non-expandable between each deflectable portion 360, 370, 380 and the proximal end portion of the elongate body 320, such that each deflectable portion 360, 370, 380 is adapted to bend radially upon application of a compressive or tensile axial force, respectively, on the elongate body 320 between the distal location and a proximal location that is at the proximal end portion of the elongate body 320.

[0155] In still a further regard, other constructions for elongate body 320 may also provide for the combination of an integral and continuous wall 325 from the proximal end portion to the distal end portion of the body and a controlled radial bending response to axially compressive or tensile forces. In addition or in the alternative to the continuous integral wall incorporating the formed voids 330, the wall 325 may also include an engineered composite support structure with engineered support elements that are arranged to control

the spatial strain response to the stress of the applied forces. Other suitable shapes for voids 330 may also be acceptable.

[0156] One particular variation of the patterned voids according to the nested V-pattern (or U-pattern) embodiment shown in Figures 9A-F is shown in **Figure 9G**, wherein the nested adjoining portions 340, 350 include interfacing surfaces 342, 352 that have interlocking teeth 344, 354 which are adapted to be locked in a radially deflected pattern in the second configuration. More specifically, the interfacing pattern of teeth 344, 354 are adapted to perform like a ratchet mechanism. By positioning this region along an inner radius of curvature during the bending of forced deflection, compressive forces bring the convexly shaped tooth region 340 deeper into the fitted well formed by the concave receiving region 350. This motion provides an interference between teeth 344, 354 that deflects portion 340 until further motion toward portion 350 clears tooth 354 and recovery locks tooth 344 behind 354. This interactive motion of adjacent portions in voided regions is further represented by bold arrows in Figure 9G.

[0157] **Figure 10** illustrates an additional construction of a medical device 400 adapted to position an implant 402, or prosthesis, into the coronary sinus or other treatment site. Similar to the embodiments described above, medial device 400 includes a handle assembly 404 at a proximal end, while the implant 402 is located at a distal end. The handle assembly 404 and implant 402 are connected by an elongate, flexible catheter body 406. Desirably, the body 406 is or includes an extrusion of a material having sufficient column strength, that is, it resists compression in an axial direction, while permitting the body 406 to bend in a radial direction. Any of a variety of polymers well known in the transluminal catheter arts, such as HDPE or PEBAX, is used to form the body 406. However, other suitable materials may also be used. In one embodiment, the body 406 has an outside diameter of approximately 0.094 inches.

[0158] With reference to **Figure 11**, a plurality of lumens or passages extend in an axial direction along the length of the catheter body 406. The illustrated extrusion includes three small lumen 408, 410, 412 and one larger lumen 414. The small lumen 408, 410, 412 may be disposed substantially within one half of the circular cross section of the body 406 and each has an inside diameter of approximately 0.024 inches. The larger lumen 414 is desirably positioned substantially within a half of the circular cross section of the body 406 opposite the small lumen 408, 410, 412 and may have a diameter of approximately 0.044 inches. Collectively, the lumen 408, 410 and 412 allow control components (e.g., forming elements 365, 375, 385 of Figures 9A and 9B) of the medical device 400 to extend from the handle assembly 404 to the implant 402 while being protected within the shaft 406. Alternatively, only a single pull wire lumen or two pull wire lumen may be provided as needed, depending upon the desired number of pull wires. As will be described in detail below, the control components convert operational movements of the handle assembly 404 into desired resultant movement of the implant 402. The larger lumen 414 may be used to rotatably receive a driver 436 as will be discussed. Additionally, one or more of the lumen may be used to permit irrigation to the coronary sinus, infusion of drugs or contrast media, or other desired purposes.

[0159] With reference to **Figures 12 and 13**, the implant 402 is shown in greater detail. Figure 13 is an enlarged view of a portion of Figure 12 illustrating the releasable connection between the delivery assembly 401 and the implant 402. As described above, the implant 402 is removably connected to the delivery assembly 401 such that the delivery assembly 401 and implant 402 may be disconnected once the implant 402 has been properly positioned and tensioned within the coronary sinus or other body lumen or hollow organ.

[0160] The implant 402 defines a body portion 416, which is preferably tubular in shape with at least one central lumen extending therethrough. The overall length of the implant 402 can be varied, depending upon the intended treatment site and desired clinical performance. In one

application, in which the device is intended to be positioned within the coronary sinus to reduce the diameter of the mitral valve annulus across a predetermined plane, the implant 402 is generally within the range of from about 5 cm to about 15 cm in length. For most adult patients, axial lengths within the range of from about 6 cm to about 12 cm may be used. In one embodiment, the implant 402 is approximately 9 centimeters long, and may have a cross-sectional area of no more than approximately 15mm^2. Preferably, the implant 402 has a cross-sectional area of no more than about 10 mm^2.

[0161] The implant may be constructed from a similar material as those embodiments described above, such as any of a variety of stainless steels, Nitinol or other known materials suitable for implantation. An atraumatic distal tip 418 is provided on the distal end of the body portion 416. A leading end of the tip 418 may be rounded such that the atraumatic tip 418 will not cause significant tissue damage as it is advanced through the vasculature of the patient.

[0162] A nut 422 or other structure having a threaded aperture therein is provided at the proximal end of the body portion 416. Desirably, the nut 422 is axially and rotationally fixed relative to the body portion 416. For example, in the illustrated embodiment (see Fig. 13B) the outer edge of the nut 422 is circular with flat 464 on one side to provide keyway 481 for pullwire 458 and is sized to fit within the body portion 416. Nut 422 may be welded to body portion 416. Of course, other suitable arrangements for preventing relative rotation between the nut 422 and body 416 may be used, such as other mechanical interference arrangements, fasteners, solder or adhesives, for example.

[0163] The implant 402 additionally includes a screw 428 having a shaft portion 430 and a head portion 432. The shaft portion 430 includes external threads which mate with internal threads on the nut 422. Thus, rotation of the screw 428 relative to the body portion 416 results in the screw 428 translating axially with respect the body portion 416. This relative movement

may be utilized to move the body portion 416 of the implant 402 from an implantation configuration to a remodeling configuration through any suitable construction, such as through the use of a pull wire or other forming element as is described above, for example.

[0164] The head portion 432 of the screw 428 includes a rotational coupling such as a cavity 434 extending axially from a proximal end of head portion 432. Desirably, the cavity 434 is shaped to receive a control component of the medical device 400 such as driver 436. In the illustrated embodiment, the cavity 434 is hex shaped in cross section and sized to receive a hex-shaped distal end portion 438 of the driver 436 (Figure 14).

[0165] A male connector 440 contains the head portion 432 of the screw 428. See Fig. 13A. The male connector 440 includes a shaft portion 442 and a head portion 444. The head portion 444 of the male connector 440 has a larger outside diameter than the shaft portion 442. A passage 446 desirably extends axially through the male connector 440 and defines a first portion 448 and a second portion 450. The first portion 448 of the passage 446 is located proximate the head portion 444 of the male connector 440 and has a larger inside diameter than that of the second portion 450, which is located proximate the shaft portion 442 of the male connector 440. A transition between the first portion 448 and the second portion 450 defines a shoulder surface 452 which extends generally transverse to the longitudinal axis of the male connector 440. The first portion 448 of the passage 446 is preferably sized and shaped to receive the head portion 432 of the screw 428. Desirably, the head portion 432 of the screw 428 abuts the shoulder 452 of the passage 446.

[0166] An annular collar 454 secures the head portion 432 of the screw 428 within the passage 446. Desirably, the outer diameter of the collar 454 is approximately the same as the outer diameter of the head portion 444 of the male connector 440. The collar 454 includes an inner flange portion 456 which is sized and shaped to fit within the first portion 448 of the passage 446 of the male connector 440 in a press fit configuration.

[0167] In a similar manner to the embodiments described above, the implant 402 desirably includes a wire 458 which is operational for moving the implant 402 from a first, delivery configuration to a second, remodeling configuration. The wire 458 is desirably anchored to a distal end of the implant 402 by welding or any of the methods described above, or any other suitable method as may be determined by one of skill in the art. Desirably, the proximal end of the wire 458 is anchored to the male connector 440 and collar 454 and, preferably, is welded or otherwise bonded to the male connector 440 and collar 454. However, other suitable methods of attachment may also be used, such as an adhesive or mechanical fastener, for instance. Preferably, the male connector 440, and collar 454 have slots 460 and 462 to fit the proximal end of pull wire 458 to allow the wire 458 to lay flat and not increase the outside diameter of collar 454 or connector 440. See Fig. 13C. Nut 422 includes flat 464 on one side which is sized and shaped to permit clearance for the wire to pass therethrough. See Fig. 13B.

[0168] As described above, the delivery assembly 401 is preferably capable of being releasably coupled to the implant 402. For this purpose, a female connector 466 is desirably coupled, such as by thermal welding, to the connector wire 487 at the distal end of the shaft 406. The female connector 466 is preferably hollow and substantially cylindrical in shape. The distal end of the female connector 466 includes a plurality of prongs, or finger portions 468, which are able to flex radially outward to permit the female connector 466 to engage the shaft portion 442 of the male connector 440. Desirably, the resiliency of the material from which the female connector 466 is constructed enables the female connector 466 to firmly grip the male connector 440. Desirably, an inner surface of the finger portions 468 defines an annular projection 470 which corresponds with an annular groove 472 (see Fig. 13A) of the male connector 440. When the female connector 466 is engaged with the male connector 440, the annular projection 470 desirably rests in the annular

groove 472 to assist and inhibiting undesired relative axial movement between the delivery assembly 401 and the implant 402.

[0169] The delivery assembly 401 additionally includes a cover 474 that is coupled at the distal end of the shaft 406. The cover 474 is axially movable from a first position in which the finger portions 468 of the female connector 466 are uncovered to a second position where the cover 474 overlaps at least a substantial portion of the finger portions 468. In its second position, the cover 474 inhibits undesired flexing of the finger portions 468 to assist in maintaining a connection between the female connector 466 and the male connector 440.

[0170] To prevent rotational movement between the delivery system (including shaft 406 and female connector 466) and implant body portion 416, one of finger portions 468 is removed or omitted from female connector 466 to create space or keyway 483 that fits into key 485 that is thermally welded to shaft portion 442 of male connector 440.

[0171] **Figure 14** is an enlarged view of the driver 436 apart from the medical device 400. The driver 436 is desirably an elongate shaft and extends from a proximal end 480 to a distal end 482. The driver 436 may be constructed from a NiTi material, however, other suitable materials may also be used. The proximal end 480 of the driver 436 is desirably coupled for rotation with respect to the handle assembly 404, which will be described in greater detail below. The distal end 482 is preferably non circular such as hex-shaped in cross-section and is sized to engage the corresponding hex-shaped cavity 434 of the screw 428. Thus, rotation of the driver 436 results in corresponding rotation of the screw 428. Other suitable arrangements to permit rotational coupling of the driver 436 and screw 428 may also be used, such as using complementary polygonal or other non-round cross-sectional shapes for the mating components.

[0172] The driver 436 may include a shoulder 484 disposed on a proximal side of the hex-shaped distal end 482. Preferably, the diameter of the

shoulder 484 is larger than a width W (**Figure 15**) of the hex-shaped distal end 482. In one preferred embodiment, the diameter of the shoulder 484 is approximately 0.032-0.040 inches and the width W is approximately 0.027 inches. Thus, the shoulder 484 effectively functions as a stop when the hex-shaped distal end 482 of the driver is inserted into the cavity 434 of the screw 428. As illustrated, the shoulder 484 and the cavity 434 desirably include complementary chamfers 486, 488 (as shown on Fig. 13), respectively, to permit easier entry of the hex-shaped distal end 482 into the cavity 434.

[0173] The illustrated driver 436 may include one or more reduced-diameter portions 490 on a proximal side of the shoulder 484. The diameter of portion 490 may be smaller than both the width of the shoulder 484 and a diameter of a main portion 492 of the driver 436, which desirably extends from the proximal end of distal portion 490 to the proximal end 480. Preferably, the main portion 492 of the driver 436 has a diameter of approximately 0.04 inches. The reduced-diameter portion 490 may have a length of approximately 0.5 inches or more and a diameter of approximately 0.027 inches. However, other suitable dimensions may also be employed. Desirably, each of the transition between the reduced-diameter portion 490 and the main portion 492 of the driver 436 and the transition between the reduced-diameter portion 490 and the shoulder 484 define a chamfer 494, 495, respectively to advantageously reduce stress concentrations.

[0174] **Figure 16** is an enlarged cross-section of the handle assembly 404, which is primarily comprised of a proximal handle 500 and a distal handle 502. The distal handle 502 is configured to be held stationary during use of the medical device 400 and the proximal handle 500 is configured to be rotatable with respect to the distal handle 502, thus rotating the driver 436 to selectively move the implant 402 between a delivery position and a remodeling position.

[0175] The distal handle 502 is generally cylindrical in shape and defines an internal cavity 504. A threaded aperture 506 extends from the cavity 504 through the distal end of the distal handle 502 and is substantially

concentric with a longitudinal axis of the handle assembly 404. A proximal connector 508 is desirably retained by a threaded connection with the threaded aperture 506 and extends axially from a distal end of the distal handle 502. Desirably, the distal handle 502 additionally includes a threaded aperture 510 situated substantially transverse to the longitudinal axis and intersecting the threaded aperture 506. A set screw is advantageously in threaded connection with the threaded aperture 506 and may be tightened against the proximal connector 508 to inhibit undesired axial movement of the proximal connector 508 with respect to the distal handle 502.

[0176] The proximal connector 508 includes a central aperture 514 passing axially therethrough. The central aperture 514 is desirably substantially concentric with the longitudinal axis of the handle assembly 404 and receives the catheter shaft 406 in a fixed axial position with respect to the distal handle 502. The shaft 406 may be fixed to the proximal connector 508 in any suitable manner, such as by adhesives or thermal welding, for example.

[0177] In the illustrated embodiment, the cavity 504 opens through the proximal end of the distal handle 502 to receive a handle connector 516, preferably through a threaded connection therebetween. In addition, a set screw arrangement 517, similar to that described above in relation to the proximal connector 508, is desirably provided to inhibit undesired movement of the handle connector 516. The handle connector 516 is configured to connect the proximal handle 500 and the distal handle 502, while allowing relative rotation therebetween. The handle connector 516 desirably includes a shaft portion 518 extending proximally away from the distal handle 502. A cylindrical passage 520 extends axially through the proximal handle 500 and is sized to be rotatably mounted on the shaft portion 518 of the handle connector 516.

[0178] Preferably, the proximal handle 500 includes a handle release assembly 522 that permits releasable engagement to the distal handle 502. The release assembly desirably comprises an annular release collar 524 surrounding the proximal handle 500. The release collar 524 is sized to allow axial

movement with respect to the proximal handle 500. A plurality of wire retainers 526 (two shown) releasably engage the shaft portion 518 of the handle connector 516 to selectively secure the proximal handle 500 in a fixed axial position with respect to the distal handle 502. Each of the wire retainers 526 include a short leg 527, which is circular in cross-section and terminates in a ball end 528, and a long leg 529, which is preferably rectangular in cross-section. Desirably, the short leg 527 and the long leg 529 define an angle of approximately 75° between them when the wire retainer 526 is in a relaxed position. Preferably, each wire retainer 526 is constructed from any of a variety of known stainless steel alloys and a total of two, or four, or more wire retainers 526 are employed.

[0179] In the illustrated embodiment, the long leg 529 of the retainer 526 is held between an outer surface of the proximal handle 500 and an inner surface of the release collar 524 and, preferably, within a groove 530 defined by the proximal handle 500. A plurality of apertures 532 extend radially through the proximal handle 500 near its distal end. The outer surface of the proximal handle 500 defines a shoulder 534 between the grooves 530 and the apertures 532. The shoulder 534 mechanically deflects the wire retainer 526, when secured by the release collar 524, such that the angle between the short leg 527 and long leg 529 is increased from the relaxed position of the wire retainer 526. The inner surface of the release collar 524 defines an annular groove 536, which desirably straddles the shoulder 534, at least when the release collar 524 is in a relaxed position. The short leg 527 of the wire retainer 526 extends through the aperture 532. The groove 536 preferably engages a bend 538 defined by the transition between the short leg 527 and the long leg 529 of the wire retainer 526 to hold the ball end 528 within an annular groove 540 defined by the shaft portion 518 of the handle connector 516.

[0180] In Figure 16, the release collar 524 is in a first, or engaged position such that the ball end 528 is held within the annular groove 540 to inhibit removal of the proximal handle 500 from the distal handle 502. The

release collar 524 is movable toward the proximal end of the proximal handle 500 into a second, or release position to selectively permit the proximal handle 500 to be removed from the distal handle 502. When the release collar 524 is moved toward the release position, an edge of the groove 536 engages the wire retainer 526 to deflect the short leg 527 and move the ball end 528 out of the groove 540 of the handle connector 516, thereby releasing the proximal handle 500 from the distal handle 502.

[0181] A driver holder 525 is positioned within the proximal end of the passage 520 to fix the driver 436 for rotation with the proximal handle 500. Thus, the driver holder 525 is fixed for rotation with the proximal handle 500, preferably by having a flat 531 which is engaged by a flat portion 539 of the proximal end of the passage 520 (**Figure 17**). A set screw arrangement, similar to those described above, may be used to secure the driver holder 525 axially with respect to the proximal handle 500. A pair of set screws 535, 537 secure the driver 436 axially and rotationally with respect to the proximal handle 500. Thus, rotation of the proximal handle 500 results in rotation of the driver 436. Desirably, an end cap 541 is press fit over the proximal end of the proximal handle 500 to further secure the driver holder 525. The end cap 541 may include an aperture 540 extending axially therethrough. Desirably, the aperture 540 is substantially aligned with the driver 436.

[0182] With reference to **Figures 16 and 18**, the distal handle 502 includes a detach arrangement 542 which allows the delivery assembly 401 to be detached from the implant 402 once it has been properly positioned and moved from its delivery position into its remodeling position. The detach arrangement 542 includes an annular detach collar 544 surrounding the distal handle 502. The detach collar 544 is desirably concentric with the distal handle 502 and capable of sliding axially thereon. A handle pin 546 is positioned concentrically within the cavity 504 of the distal handle 502. A fastener, such as a screw 548, passes through a slot 550 in the distal handle 502 to connect the handle pin 546 to the detach collar 544. Preferably, external threads of the

fastener 548 mate with internal threads of apertures 552, 554 of the detach collar 544 and handle pin 546, respectively, to provide a secure connection therebetween.

[0183] The handle pin 546 is desirably substantially cylindrical in shape and defines an internal cavity 557 extending from an open proximal end to a closed distal end of the handle pin 546. The closed distal end of the handle pin 546 includes a pair of apertures 558, 560 extending axially therethrough, opening into the cavity 557. The aperture 558 is sized and positioned to permit the driver 436 to pass there through. The aperture 560 is sized to receive a proximal end of a detach wire 562. The detach wire 562 extends from the handle pin 546 to the cover 474 (Figure 13) through one of the lumen 408, 410, 412 of the shaft 406. The detach wire 562 is secured to the cover 474 by any suitable method, such as thermal welding, adhesives, or mechanical fasteners, for example. A set screw arrangement 564, similar to those described above, is utilized to secure the detach wire 562 within the aperture 560 for axial movement with the handle pin 546. Thus, when the detach collar 544 is moved toward the proximal end of the handle assembly 404, the detach wire 562 pulls the cover 474 to uncover the finger portions 468 of the female connector 466. When the cover 474 is in this position, the female connector 466 is able to be disconnected from the male connector 440 and, thus, the delivery assembly 401 is able to be disconnected from the implant 402, as described above.

[0184] The handle assembly 404 also desirably includes a detach collar lock arrangement 566 to substantially prevent undesired movement of the detach collar 544. The lock arrangement 566 preferably includes a threaded aperture 568 passing radially through the distal handle 502. A lock screw 570 is provided for threaded engagement with the threaded aperture 568. The lock screw 570 includes a head portion 572, which interferes with movement of the detach collar 544 toward a proximal end of the handle assembly 404 when the lock screw 570 is screwed substantially fully into the aperture 568. The lock screw 570 may be backed partially, or fully, out of the aperture 568 to permit

desired movement of the detach collar 544 toward the proximal end of the handle assembly 404.

[0185] Operation of the medical device 400 is substantially similar to the embodiments described above. Preferably, before the procedure is initiated, the lock screw 570 is positioned to prevent undesired movement of the detach collar 544, which could result in premature detachment of the delivery assembly 401 from the implant 402. Once the implant 402 has been desirably positioned within the coronary sinus by a suitable method, such as described above, the proximal handle 500 is rotated with respect to the distal handle 502 to cause rotation of the driver 436. Rotation of the driver 436 results in corresponding rotation of the screw 426 which, in turn, causes the implant 402 to move from a delivery configuration to a remodeling configuration, as described in detail above. The direction of rotation of the proximal handle 500 will vary depending on the orientation of the threaded connection between the screw 428 and the nut 422. However, if a right hand thread orientation is used, the proximal handle 500 will be rotated counter-clockwise to move the implant 402 from a delivery configuration to a remodeling configuration.

[0186] When the implant 402 has achieved a desired remodeling configuration, the lock screw 570 is backed off from its locked position to permit movement of the detach collar 544. The detach collar 544 may then be moved toward the proximal end of the handle assembly 404, thereby retracting the cover 474 and exposing the finger portions 468 of the female connector 466. The handle assembly 404 may then be pulled with a sufficient force to cause the finger portions 468 of the female connector 466 to deflect radially outwardly such that the female connector 466 may be disconnected from the male connector 440, thus disconnecting the delivery assembly 401 from the implant 402. The delivery assembly 401 is then removed from the patient, leaving the implant 402 in place.

[0187] Although a specific proximal hand piece has been disclosed in detail herein, any of a variety of alternative hand pieces can be readily

designed and constructed, as will be apparent of those of skill in the art, to enable practicing the present invention. In general, the proximal hand piece is provided with a tensioning control, for tightening and untightening the implant, and a release actuator for deploying the implant from the deployment catheter. The tensioning control may take any of a variety of forms, such as rotatable knobs or wheels, slidable levers, switches, buttons, knobs or other electrical control for controlling a motor drive on the rotatable driver, or others as will be apparent in view of the disclosure herein. Similarly, the release actuator may take any of a variety of forms, depending upon the construction of the release mechanism. In general, any of a variety of axially movable sliders, switches, levers, or rotatable collars, wheels or knobs may be utilized to control the release actuator. As a safety feature, any of a variety of locks may be provided, to prevent premature release of the implant.

[0188] In addition, the proximal control may be provided with any of a variety of auxiliary ports, such as a proximal guide wire port in an over the wire construction, and infusion ports for the infusion of medications, contrast media or other materials depending upon the intended functionality of the device.

[0189] Figures 19 and 20 illustrate the slot pattern on an alternative implant 600, similar to those described above, incorporating a plurality of voids 602 to influence the movement of the implant 600 from a delivery configuration to a remodeling configuration. **Figure 19** illustrates a plan view of a preferred void 602 arrangement, wherein 57 individual voids 602 are provided. In general, a first side of the implant is generally non-compressible, such as is achieved by the use of a tubular wall. The first side of the implant is radially opposite a second side of the implant, which is provided with the plurality of voids 602. The voids permit the second side of the implant to be axially expanded or contracted, thereby curving the implant as will be apparent to those of skill in the art. The number and configuration of the voids 602 will influence the bending characteristics of the implant. In general, voids which are

transverse to the longitudinal axis of the implant can assist in plane bending of the implant. For most implants intended for positioning within the coronary sinus, and therefore having an axial length of within the range of from about 5 to about 16 cm, at least about 10 and often at least about 20 voids are provided. Thirty or forty or more voids may also be provided, depending upon the desired finished curvature of the implanted device as well as the dimensions of the voids and intervening solid wall material.

[0190] **Figure 20** is an enlarged view of a series of adjacent voids 602. As in the embodiments described above, a plurality of voids 602 are arranged axially along the implant 600 and are positioned substantially transverse to the longitudinal axis of the implant 600. Desirably, the voids 602 extend around at least about 180° of the circumference of the implant 600 and, preferably, around at least approximately 300° of the circumference. In some embodiments, the voids 602 extend around between approximately 300° and 315° of the circumference of the implant 600. Alternatively, the tubular body of the implant may comprise a spring coil in which adjacent windings are slightly spaced apart. Axial column strength on the first side of the implant is provided by an axially extending support such as a flexible ribbon or core wire which may be soldered or otherwise attached to the spring coil to inhibit axial compression along the side which carries the support. The opposing side of the coil may be compressed or expanded, to impart a curve. The coil may be provided with an outer polymeric sleeve.

[0191] Desirably, both ends of each void 602 terminate in a curved void portion such as circular void end portion 603. Advantageously, the end portions 603 of the void 602 reduce stress concentrations at the ends of the voids 602 that result from bending of the implant 600 from a delivery configuration to a remodeling configuration. In one implementation, the end portions 603 have a diameter of approximately 0.018 inches and a circumferential distance between the centers of the two opposing circular portions 603 of a single void 602 is approximately 0.068 inches. This feature

decreases the likelihood of cracks originating in the material of the implant 600 at the ends of the voids 602.

[0192] Each void 602 is defined as a space between two opposing edge surfaces 604, 606 of the body of the implant 600. Surface 604 includes an axially extending projection such as substantially "U-shaped" projection 608 positioned within a complementary, substantially "U-shaped" recess 610 of surface 606. Alternative complementary configurations such as a chevron may also be used. An axis A_V of both the projection 608 and the complementary recess 610 is substantially parallel to the longitudinal axis of the implant 402.

[0193] An axial distance between the substantially transverse edges 604, 606 defines a width W_V of the void 602. The W_V of the void 602 may be varied, depending upon the desired performance. In general, widths within the range of from about 0.010 to about 0.040 inches are often used. In the illustrated embodiment, the width W_V is approximately 0.012 inches. Desirably, a distance between at least a portion of both sides of the projection 608 and recess 610 is less than the void width W_V and defines a pair of interference portions 612 between the surface 604 and the surface 606.

[0194] The interference portions 612 inhibit the implant 600 from moving out of a plane defined by the longitudinal axis of the implant 600 as it moves from a delivery configuration to a remodeling configuration. Advantageously, the surfaces 604, 606 contact one another in the interference portions 612 of the void 602 in response to a force urging the implant 600 to curve out of plane. Thus, with the illustrated arrangement, the implant 600 is maintained within the desired plane while moving from a delivery configuration to a remodeling configuration. Alternatively, the void 602 may be configured to permit a predetermined out of plane movement of the implant 600 if such is desirable, as will be appreciated by one of skill in the art. For example, only one interference portion 612 may be provided to impart a controlled rotational bend, or the distance between the surfaces 604, 606 may be increased or decreased in the interference portion 612.

[0195] Any of a variety of alternative implant body structures may be utilized, as will be apparent to those of skill in the art in view of the disclosure herein. In general, the body is transformable from a flexible, implantation orientation to a curved, implanted orientation. The specific void pattern or other structure for facilitating curvature may be varied, depending upon the desired manufacturing techniques and clinical performance. In addition, any of a variety of alignment structures may be utilized, to influence the shape of the implant in the implanted orientation. Although slot patterns have been described above which facilitate in plane bending of the implant, the same structures may be repositioned along the length of the implant in a manner that produces compound curvatures or other out-of-plane bending as the implant is changed to the implanted orientation.

[0196] Referring to **Figures 21 and 22**, there is illustrated an implant 100 in accordance with another aspect of the present invention. The implant 100 is adapted for positioning within or adjacent the coronary sinus, and for maintaining a compressive force on an aspect of the mitral valve annulus. The implant 100 comprises an elongate flexible body 102 having a proximal end 104 and a distal end 106. The body 102 may be constructed in any of a variety of manners, utilizing structures, materials and dimensions previously disclosed herein. In general, the body 102 is flexible such that it may be transluminally navigated to a deployment site such as within the coronary sinus. Alternatively, the implant may be advanced through tissue to a position outside of the coronary sinus such as within the wall of the heart or adjacent an exterior surface of the heart. The body 102 may thereafter be manipulated such that it imparts a compressive force on at least a portion of the mitral valve annulus, and the body 102 may be locked or restrained in the second configuration.

[0197] As illustrated in Figure 22, the body 102 may be considered to comprise a proximal segment 108, a central segment 110 and a distal segment 112. In the implanted orientation, as illustrated, the proximal segment 108 and the distal segment 112 are concave in a first direction, and the central segment

110 is concave in a second direction. This configuration additionally comprises at least a first transition 114 between the proximal segment 108 and central segment 110, and a second transition 116 in between the central segment 110 and the distal segment 112.

[0198] In the illustrated embodiment, the curvature of the proximal segment, central segment and distal segment reside in a single plane. However, the central segment 110 may reside in a plane which is rotationally offset from the plane which contains the proximal segment 108 and distal segment 112, depending upon the desired clinical performance and deployment site.

[0199] The implant 100 preferably additionally comprises one or more anchors, for retaining the body 102 at a deployment site. In the illustrated embodiment, at least one and, in some embodiments two or four or more proximal anchors 118 are carried by the proximal segment 108. In addition, at least one, and, in certain embodiments at least two or four or more distal anchors 120 are carried by the distal segment 112. In the illustrated embodiment, first and second proximal anchors 118 and first and second distal anchors 120 are provided.

[0200] The proximal anchors 118 and distal anchors 120 are provided on a first side of the body 102, which is the same side as the convex side of the central segment 110 when in the implanted orientation. In this orientation, the first side of the implant 100 is configured to reside against the wall of the inside radius of curvature of the coronary sinus. The proximal anchor 118 and distal anchor 120 engage the vessel wall on the mitral valve side of the coronary sinus, allowing advancement of the central segment 110 from the first side laterally to apply a compressive force to at least a portion of the mitral valve annulus.

[0201] Any of a variety of engagement structures such as proximal anchor 118 and distal anchor 120 may be utilized to retain the implant 100 against the wall of the coronary sinus. Alternatively, the implant 100 may be configured to "push off" of the opposing wall of the coronary sinus, to support

advancement of central segment 110 in the direction of the mitral valve. For example, the proximal segment 108 and distal segment 112 may be configured to extend all the way across the diameter of the coronary sinus, to contact the opposing wall. This may be accomplished by remodeling the device such that the amplitude equals or exceeds the diameter of the coronary sinus. Alternatively, the proximal and distal anchors 118, 120 may take the form of a tubular structure such as a self-expanding stent, or a stent which is expanded by a dilatation balloon or other expansion structure. The tubular anchor will then restrain the implant 100 in a desired orientation within the coronary sinus. As a further alternative, the proximal and distal ends of the implant may be extended through the wall of the coronary sinus, or stitched to or otherwise adhered to the wall of the coronary sinus, to permit the remodeling described herein. Additional alternative anchor configurations will be disclosed below.

[0202] Any of a variety of self expanding or mechanically expandable structures may be provided on the tubular body 102, to assist in anchoring and positioning the implant. For example, referring to **Figure 23**, the proximal end 104 of the tubular body 102 is provided with a radially expandable support 140. In general, support 140 comprises a plurality of axially extending ribs or elements 142, each of which may be additionally provided with one or more barbs 144. Additional structural details of suitable support structures may be found by reference to U.S. Patent Application having Serial No. 10/033,371 filed on October 19, 2001 and entitled "Adjustable Left Atrial Appendage Occlusion Device," published on August 15, 2002 as Publication No. US 2002/0111647A1, the disclosure of which is incorporated in its entirety herein by reference.

[0203] Referring to Figures 21 and 22, the implant 100 comprises an elongate forming element 122 which has been described in various forms previously. The forming element 122 extends between a distal point of attachment 124 to the body 102 and a proximal point of attachment 126 to a threaded collar or other axially moveable structure. Proximal movement of the

proximal point of attachment 126 with respect to the body 102 induces a curvature in the implant 100 as has been discussed.

[0204] In the illustrated configuration, the forming element 122 is attached at the proximal point of attachment to a threaded structure such as a nut 128. Alternatively, threads may be provided directly on a proximal portion of the forming element. Nut 128 is axially movably carried by a rotatable screw 130, using well understood complementary threaded engagement surfaces. Rotation of the screw 130 will cause relative axial movement of the nut 128 as will be understood by those of skill in the art.

[0205] The screw 130 is provided with one or more axial retention structures to permit rotation but inhibit axial movement thereof. In the illustrated embodiment, the screw 130 is provided with one or more radially outwardly extending projections such as flange 132, which is captured between a first bushing 134 and a second bushing 136 to prevent axial movement. Screw 130 may be retained against axial motion while permitting rotation using any of a variety of alternative structures, such as radially inwardly extending tabs or flanges from the inside surface of the body 102, which are slideably received by one or more radially inwardly extending annular grooves in the screw 130.

[0206] The proximal end of the screw 130 is provided with a rotational coupling 138. Coupling 138 is adapted to removably receive a rotatable driver carried by the deployment catheter such that rotation of the driver within the deployment catheter will produce axial movement of the nut 128. In one implementation, the coupling 138 comprises a recess having a non-round cross-sectional configuration, such as a hexagonal wall. This cooperates with the hexagonal distal end on the driver (disclosed previously herein) to produce a removable rotational coupling.

[0207] In the embodiment illustrated by Figure 22, the forming element 122 extends through the inside of the body 102 in each of the proximal segment 108 and distal segment 112, and extends along the outside of the body 102 along the central segment 110. See also Figure 21. This configuration, in

which the forming element 122 extends through a first aperture 140 in or near the proximal transition 114, and a second aperture 142 in or near the distal transition 116, has been found to be convenient in an implant adapted to assume a "w" implanted configuration as shown in Figure 21. Alternatively, the forming element 122 may extend along the inside of the body 102 throughout its length. The forming element 122 may extend along the outside of the body 102 throughout its length, or extend partially inside and partially outside of the body 102 depending upon the desired performance characteristics of the implant.

[0208] In connection with any of the preceding embodiments, it may be desirable for the implant to change in axial length as it is advanced from the first, flexible configuration for transluminal delivery, to the second configuration for remodeling the mitral valve annulus. This may be accomplished in a variety of ways, such as configuring two or more sections of the tubular body in a telescoping fashion, such that a first portion of the body is axially moveably positioned within a second portion of the body. This enables the axial length of the body to be controllably altered, during or apart from the transformation of the device to its implanted configuration. In certain applications, it may be desirable for the axial length of the implant to shorten as the implant is converted to its implanted orientation. Foreshortening of the implant by a distance within the range of from about 10% to about 95% of the maximum implant axial length is presently contemplated.

[0209] In one embodiment, controlled foreshortening may be accomplished by providing a plurality of foreshortening slots or chevrons in the outer wall of the tubular body. Referring to **Figure 24,** there is illustrated a fragmentary view of a portion of an elongate body 320. The configuration of Figure 24 can be applied to any of the previously disclosed embodiments, as will be apparent to those of skill in the art in view of the disclosure herein.

[0210] The elongate body 320 includes a plurality of transverse voids 330 as has been discussed. Axial compression of the elongate body 320 causes the voids 330 to axially close, thereby deflecting the elongate body 320

out of plane. In some of the previously disclosed devices, the voids 330 are aligned on a first side of the elongate body 320, and they oppose a second side of the elongate body 320 which is comparatively non collapsible and thereby acts as a spine for the device.

[0211] In accordance with the present, foreshortening feature, a first plurality of foreshortening voids 331 is provided on the elongate body 320. The foreshortening voids 331 are positioned on the elongate body 320 such that they permit axial compression of the body, upon application of the axially compressive force utilized to deflect the body out of plane. In the illustrated embodiment, the first plurality of foreshortening void 331 is axially aligned along the "backbone" or support side of the device, opposite to the voids 330.

[0212] A second plurality of foreshortening voids 333 may also be provided, spaced circumferentially apart from the first plurality of foreshortening voids 331. In the illustrated embodiment, the first and second foreshortening voids 331 and 333 are aligned along first and second longitudinal axes, which are spaced approximately 180° apart from each other around the circumference of the elongate body 320.

[0213] In general, foreshortening within the range of from about 1% to about 20% of the maximum length of the device is presently contemplated. The specific number and dimensions of the foreshortening voids may be optimized by those of skill in the art in view of the disclosure herein, taking into account the desired clinical performance.

[0214] Referring to **Figure 25**, there is illustrated an alternate construction of the implant 100 in accordance with the present invention, for accomplishing the radial inward compression previously discussed in connection with Figure 22. The implant 100 extends between a proximal end 104 and a distal end 106. The implant may be considered to be divided into two or more distinct zones, such as a central segment 110 and proximal and distal segments 108 and 112. At least one segment on the implant 100 includes a compression element 140, configured to generate radial compression such as

against the posterior leaflet of the mitral valve. In the illustrated design, the compression element 140 comprises a flexible ribbon 142. The flexible ribbon 142 is configured to project radially inwardly from the concave side of the implanted device 100, as the device 100 is transformed from its implantation configuration to its implanted configuration. In one embodiment, the ribbon 142 comprises a flat wire having a cross section of about 0.005 inches by about 0.020 inches, and having an axial length of from about 3 to about 4 cm.

[0215] Ribbon 142 may be configured to provide a radially outwardly directed compressive force using any of a variety of mechanisms. In one implementation, the ribbon 142 has a fixed length and is attached at first and second points spaced apart along the length of the implant 100. As the concave side of the implant 100 axially shortens, the fixed axial length of the ribbon 142 causes a preset bend to progress laterally outwardly in response to the bending of the implant. Alternatively, the compression element 140 may be activated in response to an active control, such as rotation of a threaded screw or movement of an axially moveable control.

[0216] In addition to a central compression element 140, additional compression elements may be provided. In the embodiment illustrated in Figure 25, a proximal compression element 139 and a distal compression element 143 are also provided. The desirability of two or three or more compression elements 140 spaced axially apart along the implant depends upon the desired clinical performance of the device.

[0217] In addition to the compression element 140, the implant 100 illustrated in Figure 25 additionally carries one or two or more proximal tissue anchors 118 and distal tissue anchors 120. Preferably, the proximal anchors 118 and the distal anchors 120 are positioned fully within the tubular body of the implant 100 during transluminal navigation. The proximal anchors 118 and distal anchors 120 are extended radially outwardly from the implant 100 in an inclined orientation to engage tissue at the time of deployment, such as simultaneously with the transformation of the implant 100 from the

implantation orientation to the implanted orientation. Additional details of particular anchor configurations and deployment sequences will be discussed below.

[0218] Referring to **Figure 26**, there is illustrated an alternate construction for the compression element 140. In this construction, the compression element 140 comprises a basket or other structure which extends radially outwardly in response to axially compressive movement. The basket 144 comprises a plurality of axially extending ribs 146 connected to the implant at a proximal hub 148 and distal hub 150. During tightening of the implant to compress the mitral valve annulus, the distal hub 150 and the proximal hub 148 are advanced towards each other, thereby axially shortening and radially expanding the wire basket 144. The basket may comprises two or three or more, and, preferably, at least about 6 axial ribbons 146. In one embodiment, the basket 144 is formed by providing a plurality of axially extending slots around the circumference of a metal tube. Any of a variety of medically compatible metals may be used, such as stainless steel, or nickel titanium alloys such as nitinol. The radially expandable support structure illustrated in Figure 23 may also be positioned on the implant in a central segment, to function as a compression element 140.

[0219] Referring to **Figures 27 and 28**, there is illustrated a further variation of the present invention. In this construction, the implant 100 comprises a proximal section 152 and a distal section 154. The bending mechanism has been relocated to the center of the device, and is illustrated as including a rotatable screw 156. The screw is rotated in response to rotation of a component 157 on a deployment device which is removably connectable to the rotatable screw. The component 157 on the deployment device is coupled to a rotatable driver positioned within the implant 100 and further rotatably coupled to the screw 156. Thus, a rotational force on the component 157 is translated to the rotatable driver 159 within the deployment device which causes the rotatable screw 156 to advance the proximal section 152 and the distal section 154 into

the implanted configuration, as illustrated in Figure 27. As the implant 100 is advanced toward the implanted configuration, one or more proximal anchors 118 and one or more distal anchors 120 are also deployed from the device 100, to engage tissue as has been discussed elsewhere herein.

[0220] An alternate tensioning assembly which may be used in a device like that illustrated in Figure 27 is shown in an enlarged fragmentary view in Figure 28. In general, the device 110 includes a rotatable screw 156. The rotatable screw 156 includes a proximal coupling 158, having a recess 160 or other releasable connector as has been discussed elsewhere herein. In one convenient construction, the recess 160 is provided with a polygonal cross section, such as to accommodate a hex coupling on the distal end of the deployment device (not shown). Any of a variety of complementary surface structures between the proximal coupling 158 and the deployment device may be utilized as has been discussed.

[0221] The proximal coupling 158 is connected to the threaded shaft 162. Threaded shaft 162 extends through an aperture 166 in a proximal block 168. Block 168 is attached to a proximal pull wire 170.

[0222] The threaded shaft 162 is threadably engaged within a threaded aperture 172 in a nut 174. The nut 174 is connected to a distal pull wire 176, which extends through the distal section of the implant 100. The proximal pull wire 170 extends proximally though the device to a point of attachment with respect to the tubular body, and the distal pull wire 176 extends distally to a point of attachment with respect to the tubular body.

[0223] As will be appreciated in view of the previous disclosure herein, rotation of the proximal coupling 158 will cause the threaded shaft 162 to rotate freely with respect to the aperture 166 in the proximal block 168, and to axially advance the nut 174 within the implant 110. Preferably, the aperture 166 in the proximal block 168 and the inner threads of the nut 174 are oppositely threaded with respect to one another such that the effect of rotation of the proximal coupling 158 in a first direction is to decrease the distance between

the proximal block 168 and the nut 174. Of course, the threaded shaft 162 is appropriately configured with cooperating threads as will be apparent to one of ordinary skill in the art. This will have the effect of bending both the proximal section 152 and distal section 154 into the curved orientation illustrated in Figure 27. In the illustrated construction, axial advancement of the proximal block 168 and the nut 174 towards each other will also deploy the proximal tissue anchors 118 and distal anchors 120. Preferably, the length of the threaded shaft 162 is configured such that a previously selected maximum number of rotations in a first direction cause the proximal block 168 and nut 174 to contact each other and interfere with further rotation of the screw 156. Thus, the maximum displacement of the proximal pull wire 170 and distal pull wire 176 can be selectively controlled thereby limiting the deflection of the proximal section 152 and the distal section 154 to a final desired shape.

[0224] Rotation of the proximal coupling 158 in a second, opposite direction will allow the implant to straighten out and become flexible again, such as to permit repositioning, retensioning , or removal. The rotational limit of the screw 156 in a second direction can be controlled by the interference of the proximal block 168 against the proximal coupling 158. As the screw 156 is rotated in a second direction and reaches its maximum rotation, the proximal block 168 contacts the proximal coupling and thereby inhibits any further screw rotation in the second direction.

[0225] The operation of the tissue anchors may be accomplished in any of a variety of ways, as will be apparent to those of skill in the art in view of the disclosure herein. One construction may be understood by reference to **Figure 29**. In this construction, the distal anchors 120 are automatically deployed in response to proximal retraction of the distal pull wire 176.

[0226] Referring the Figure 29, the distal pull wire 176 is provided with at least a first tissue barb 180 and optimally a second tissue barb 182. Additional barbs may be provided as desired. Tissue barbs 180 and 182 are inclined laterally in the proximal direction, and are aligned with openings 184

and 186, respectively, in the side wall of the implant 100. Proximal retraction of the distal pull wire 176 causes the tissue barbs 180 and 182 to advance laterally through the openings 184 and 186, at an angle which is inclined in the proximal direction, to engage tissue. Each of the tissue barbs 180 and 182 may be provided with a sharpened distal end, to facilitate penetrating tissue.

[0227] The distal pull wire 176 may extend proximally to the nut 174 as discussed in connection with Figure 28. Alternatively, the distal pull wire 176 may extend all the way to the proximal end of the implant 110, depending upon the design of the tightening mechanism.

[0228] In the embodiment illustrated in Figure 29, the distal pull wire 176 exits the tubular body at an aperture 188, and extends along the outside surface of the implant 100 on the concave side of the device when in the implanted orientation. Alternatively, the distal pull wire 176 may extend within the implant 100 throughout the length of the distal pull wire 176. The proximal anchor 118 may be constructed in a similar manner, as will be apparent to those of skill in the art.

[0229] When fully deployed, each of the tissue barbs 180 and 182 extend outwardly from the side of the implant for a distance within the range of from about 1 mm to about 5 mm. By adjusting the angle between the longitudinal axis of the barb 180 and the longitudinal axis of the implant, the length of the barb 180 can be adjusted while maintaining the lateral distance that the barb 180 may travel within the desired range.

[0230] In certain applications of the invention, it may be desirable to control the sequence by which the distal anchors and/or proximal anchors deploy, relative to the transformation of the implant from the implantation orientation to the implanted orientation. For example, it may be desirable for the distal anchors 120 to deploy into the wall of the coronary sinus prior to the implant placing any substantial compressive pressure on the mitral valve annulus. Following compression of the annulus, the proximal anchors may desirably be deployed. Alternatively, it may be desirable to deploy both the

proximal and distal anchors at the beginning of the compression cycle, to be followed by the application of pressure by the implant on the mitral valve annulus. Additionally, the proximal and/or distal anchors can be deployed before compression of the annulus. This sequence can be controlled in any of a variety of ways, such as by providing a mismatch between the angle of the barbs 180 and 182 within the implant, and the apertures 184 and 186 through which the barbs will travel. Providing friction to the deployment of the barbs will tend to delay deployment of the barbs until a sufficient tension force has been applied to the distal pull wire 176. Alternatively, by configuring the pull wire 176 and barbs 180 and 182 for minimal deployment friction, the barbs will tend to deploy prior to the application of significant compressive force on the mitral valve annulus. The sequence may be optimized by those of skill in the art in view of the desired clinical performance.

[0231] Although the foregoing embodiments have been described primarily in terms of a structure having a tubular housing with various components therein, the invention may be accomplished using a nontubular structure such as a pair of adjacent axial elements. In general, the lateral bending and compression functions of the invention can be accomplished as long as a first elongate flexible structure provides column strength, and a second forming element is attached near a distal end of the column strength element. Proximal axial retraction of the forming element will cause a lateral deflection of the column strength element, provided proximal movement of the column strength element is inhibited. Similarly, axial distal advancement of the forming element, if it is selected such that it has a sufficient column strength, will cause a lateral deflection of the column strength element in an opposite direction. The column strength element may be in the form of a ribbon, wire, bottomed out spring, or other element which will resist collapse under tension. In the foregoing embodiments, one side wall of the tubular body provides column strength, and the forming element operates as a pull wire such that proximal

retraction of the pull wire causes a lateral deflection of the column strength element.

[0232] A further implementation of the invention may be understood by reference to **Figures 30A and 30B**. In this construction, a distal section 154 has one or more tissue anchors 120, and a proximal section 152 has one or more proximal tissue anchors 118. The distal tissue anchor 120 and/or the proximal tissue anchors 118 may either be passive (as illustrated) or active, such that the anchors are pivotably or angularly adjustably carried by the implant. Active tissue anchors may either incline in response to positioning or tightening of the device, or be controlled by a separate rotatable or axially moveable control element. The proximal tissue anchors 118 and distal tissue anchors 120 need not both be active or passive. For example, the distal tissue anchor may be actively engageable with the adjacent tissue such as by manipulation of a tissue engagement control. The proximal tissue anchor may be passively engageable with the adjacent tissue. The reverse may also be accomplished, where the distal tissue anchor is passively engageable with adjacent tissue and the proximal tissue anchor is controllably engageable utilizing a control on the deployment catheter. The foregoing discussion concerning the active or passive tissue anchors applies to all of the embodiments herein, as will be apparent to those of skill in the art in view of the disclosure herein.

[0233] A tensioning element 190 is provided at about a junction between the distal segment 154 and the proximal segment 152. The tensioning element 190 is adapted to apply tension between the proximal anchors 118 and the distal anchors 120.

[0234] In one construction, at least one of the proximal section 152 and distal section 154 comprises a plurality of transverse engagement structures such as slots. See Figure 30B. The tensioning element 190 includes a rotatable threaded shaft (not shown), oriented such that the threads engage the transverse slots on the proximal or distal section. Rotation of the threaded shaft using any of a variety of rotatable engagement configurations disclosed elsewhere herein

will cause axial movement of the corresponding proximal or distal section 152, 154, as will be understood by those of skill in the art.

[0235] In one particular embodiment, the proximal section 152 is secured to the tensioning element 190. The distal section 154 is axially moveably engaged with the tensioning structure 190 by engagement of one or more rotatable threads within the tensioning structure 190, in a plurality of transverse slots on the distal section 154. Rotation of a rotatable driver in a first direction will draw the distal anchor 120 in a proximal direction, thereby decreasing the distance between the proximal anchor 118 and the distal anchor 120. Alternatively, the distal section 154 may be fixed with respect to the tensioning element 190, and the proximal section 152 may be axially advanced or retracted based upon the rotation of a rotatable driver. In a further alternative, each of the proximal section 152 and the distal section 154 may engage a threaded shaft in the tensioning element 190, to enable the axial distance between the proximal anchor 118 and the distal anchor 120 to be adjusted.

[0236] Each of the proximal anchors 118 and distal anchors 120 may be either actively deployed such as has been described previously herein, or may be fixed with respect to their corresponding section 152, 154. In an embodiment in which the anchor is fixed with respect to its corresponding support section, the anchors are retracted within a deployment sleeve for transluminal navigation. The deployment sleeve is advanced distally through the coronary sinus to the distal point of attachment of distal anchor 120. Proximal retraction of the outer sleeve with respect to the implant will release the distal anchor 120, which may incline radially outwardly in the proximal direction due to its own internal bias. Proximal traction on the distal anchor 120 will cause the distal anchor to engage tissue at the distal attachment site. The outer tubular sleeve may be further proximally retracted to release the proximal anchor 118. Rotation of the rotatable driver following engagement of the anchors will apply compressive force to the mitral valve annulus. Any of a variety of lateral engagement structures, such as have been previously disclosed

herein, may be adapted for use with the present embodiment, to focus pressure on a specific anatomical site such as the posterior leaflet of the mitral valve. See, for example, the compression element 140 illustrated in Figure 25, and corresponding text.

[0237] For example, a compression element 140 may be formed from an elongate flexible ribbon extending along the concave side of at least one of the distal section 154 and proximal section 152. A proximal end of the compression element 140 may be secured with respect to the proximal section 152, and a distal end of the compression element 140 may be secured with respect to the distal section 154. Upon manipulation of the tensioning element 190 to reduce the axial length of the implant, the compression element 140 will extend radially inwardly from the concave side of the device.

[0238] In the foregoing embodiment, deployment of the compression element is responsive to shortening or tensioning of the device. In an alternate implementation of the invention, the lateral advance of the compression element 140 may be controlled independently of tensioning the tensioning element 190. In this embodiment, the tensioning element 190 may be adjusted to seat the proximal anchors 118 and distal anchors 120, and to apply a degree of tension on the mitral valve annulus. During or following the tensioning step, the compression element 140 may be laterally deployed. Lateral deployment may be accomplished by rotating a rotatable driver or axially moving an axial driver within the deployment catheter, inflating a laterally expandable balloon by way of an inflation lumen in the deployment catheter, or through any of a variety of structures which will become apparent to those of skill in the art in view of the disclosure herein.

[0239] There is provided in **Figures 31A-C** a partially cross-sectioned side elevational view of an alternate construction of an implant 900, similar to that illustrated in Figure 30A. The implant 900 includes a proximal section 152, a distal section 154, and a tensioning element 190. The tensioning

element 190 couples the proximal section 152 to the distal section 154, and is used to apply and release tension therebetween.

[0240] As illustrated in Figure 31A, the proximal section 152 includes a proximal tissue anchor 118, and a proximal ribbon 902. The proximal tissue anchor 118 may be laser cut from stainless steel tube, and has an arcuate cross-sectional shape (not shown). Alternatively, any of a variety of tissue anchor designs and materials may be employed, as have been described in greater detail above, and as are known to those of skill in the art. In one embodiment, the proximal tissue anchor 118 includes a penetrating point 904, and two barbs 906 to hold the proximal tissue anchor 118 securely in place once deployed. A variety of penetrating points 904 and barbs 906 may be used to achieve desired clinical results, and the particular proximal tissue anchor 118 design may vary depending upon the particular clinical requirements.

[0241] The proximal tissue anchor 118 preferably includes two holes 908 that are used to partially rotatably couple the proximal tissue anchor 118 with a pivot 910 that is coupled to the proximal ribbon 902. One embodiment of such pivot 910 is shown in greater detail on Figure 31C. The pivot 910 may be integral to the material of the proximal ribbon 902, or may include a pin, or other device coupled to the proximal ribbon 902. The proximal section 152 also includes a spring 912, used to bias the proximal tissue anchor 118 so that its penetrating point 904 rotates away from the proximal ribbon 902 and towards tissue when deployed. In one embodiment, the spring 912 is cut from the same tubing used to form the proximal tissue anchor 118, and is integral thereto. In another embodiment, the spring 912 has a torsional design, as is well known to those of skill in the art.

[0242] The overall length of the proximal tissue anchor 118 preferably is about 6 mm, although the actual length will be selected based upon the particular requirements of the clinical setting. In one embodiment, the length of the proximal tissue anchor 118 will be selected such that it does not penetrate all the way through the wall of the coronary sinus when deployed. In

general, the length of the proximal tissue anchor 118 is in the range between about 1 mm and about 15 mm.

[0243] Distal section 154 preferably includes a distal tissue anchor 120, a distal ribbon 914, and a spring 912, as shown in Figure 31A. Distal tissue anchor 120 is similar to proximal tissue anchor 118, and has similar characteristics and dimensions as described in greater detail above. Distal ribbon 914 preferably includes multiple slots 916 to interface with the tensioning element 190, as described in greater detail below. The slot 916 pitch, or center-to-center spacing of the slots 916, partially defines the resolution of the adjustability of the tension applicable between the proximal and distal tissue anchors 118, 120. In one embodiment, the slot pitch is about 1 mm. Alternatively, the slot pitch is between 0.1 mm and 3 mm. In another embodiment, the slot pitch is not constant along the length of the distal ribbon 914. The distal ribbon 914 may be designed to have a greater pitch, or slot width towards the proximal end of the distal ribbon 914, and a smaller pitch or slot width towards the distal end of the distal ribbon 914. Alternatively, the distal ribbon 914 may have no slots such that continuous instead of stepped movement of the distal ribbon 914 is used to apply tension between the proximal and distal tissue anchors 118, 120. The method of applying tension between the proximal and distal tissue anchors 118, 120 is described in greater detail below. The distal ribbon 914 also preferably includes a pull-wire disconnect 918 for removable coupling to a tab pull-wire 944, as described in greater detail below with reference to Figures 31E-F.

[0244] As shown in Figures 31A and 31B, the implant 900 also includes a tensioning element 190. In one embodiment, the tensioning element 190 includes a housing 920, latch 922, spacer 924, and insert 926. In one embodiment, the housing 920 is made from a section of stainless steel tubing, although housings 920 of other shapes and materials may be used. In one embodiment, the housing 920 is made from nickel titanium tubing. The proximal ribbon 902 preferably is attached to the inside lumen of the housing

920 using any of a variety of methods, including welding, bonding, or by using any of a variety of fasteners, as is well known to those of skill in the art. In one embodiment, the proximal ribbon 902 is attached to the housing 920 such that the axial position of the proximal tissue anchor 118 is fixed with respect to the housing 920.

[0245] The housing 920 also includes a latch 922 that preferably is attached to a spacer 924 at the latch's 922 distal end. The latch 922 includes a tang 928 that bends towards the distal ribbon 914 at an angle relative to the distal ribbon 914. The tang 928 is designed to travel through an opening 930 in the spacer 924, and engage a slot 916 in the distal ribbon 914. By engaging the slot 916 in the distal ribbon 914, the latch 922 prevents axial movement of the distal ribbon 914, and distal tissue anchor 120, in the distal direction. The opening 930 in the spacer 924 is of sufficient dimension to allow the tang 928 of the latch 922 to flex enough to disengage the slot 916 in the distal ribbon 914 when the distal ribbon 914 is moved in the proximal direction. The interface between the latch 922 of the tensioning element 190 and the slot 916 of the distal ribbon 914 functions as a ratcheting mechanism. The ratcheting mechanism allows stepped movement of the distal ribbon 914 as it is moved in the proximal direction (as described in greater detail below), yet prevents the distal ribbon 914 from moving in the distal direction. The amount of movement of each ratcheting step is related to the pitch between the distal ribbon 914 slots 916, as described above.

[0246] In another embodiment, as mentioned above, the distal ribbon 914 does not contain slots. In such embodiment, friction between the tang 928 of the latch 922 and the distal ribbon 914 is sufficient to allow continuous, e.g., non-stepped, or infinitely adjustable, movement of the distal ribbon 914 in the proximal direction, yet prevent movement of the distal ribbon 914 in the distal direction. In another embodiment, shallow depressions, ribs or other texture, or partial thickness slots are added to the surface of distal ribbon 914 to provide enhanced friction against tang 928. In one embodiment,

movement of the distal ribbon 914 in the proximal direction may be achieved by releasing, or disengaging the tang 928 of the latch 922 from the distal ribbon 914.

[0247] In one embodiment, the housing 920 also includes a latch release ribbon 932 that preferably is disposed between the spacer 924 and the distal ribbon 914, as illustrated in Figure 31A. The latch release ribbon 932 is also axially moveable with respect to the housing 920 and the distal ribbon 914. In one embodiment, as the latch release ribbon 932 is moved proximally, the tang 928 of the latch 922 is lifted such that it disengages the slot 916 of the distal ribbon 914. While disengaged from the latch 922, the distal ribbon 914 may be moved in the distal direction, thereby increasing the distance between the proximal and distal anchors 118, 120.

[0248] In one embodiment, portions of the lumen of the housing 920 may be filled with an insert 926, as illustrated in **Figure 31B.** As shown, insert 926 fills the spaces between the spacer 924 and the housing 920 of the tensioning element 190. In one embodiment, the portion of the lumen between the distal ribbon 914 and the housing 920 does not contain an insert 926, although in other embodiments it does. In one embodiment, it is advantageous to omit an insert 926 between the distal ribbon 914 and the housing 920 so as to reduce friction on the distal ribbon 914 when moving the distal ribbon 914 with respect to the housing 920.

[0249] **Figure 31C** illustrates one embodiment of the distal ribbon 914, as described in greater detail above. The illustrated distal ribbon 914 is about 9 cm long, although the length of the distal ribbon 914 may be selected for the clinical requirements of the particular treatment. In general, the length of the distal ribbon 914 is in the range between about 2 cm and about 20 cm. The length of the proximal ribbon 902 has similar dimensions, such that the overall length of the implant 900 is in the range between about 2 cm and about 20 cm, preferably in the range between about 5 cm and about 15 cm, and more

preferably in the range between about 7 cm and about 10 cm. In one embodiment, the overall length of the implant 900 is about 9 cm.

[0250] In the illustrated construction, the crossing profile of the implant 900 is determined by the diameter of the housing 920, as illustrated in Figure 31B. In one embodiment, the diameter of the housing 920 is selected so that the implant 900 may be delivered inside of a catheter having an lumen with a diameter in the range between 6 French (approximately 0.079 inches) and 20 French (approximately 0.262 inches). In one embodiment, the length of the housing 920, as shown in Figure 31A is in the range between about 3 mm and about 10 mm, preferably in the range between about 5 mm and about 8 mm, and more preferably in the range between about 6 mm and about 7 mm.

[0251] Referring to **Figure 31D**, there is illustrated a disconnect subassembly 936, in accordance with one embodiment of the present invention. The disconnect subassembly 936 illustrates one mechanism by which the implant 900 is decoupled from a delivery catheter and handpiece, as described in greater detail below. Disconnect subassembly 936 includes the distal ribbon 914, a cover 938, a cover pull-wire 940, a tab 942, and a tab pull-wire 944. The pull-wire disconnect 918 of the distal ribbon 914 is engaged by a flange 946 protruding from the tab 942, as shown in greater detail in **Figure 31E**. A tab pull-wire 944 is coupled to the tab 942 such that proximal movement of the tab pull-wire 944 with respect to a catheter 948 (as shown in **Figure 31F** and described in greater detail below) translates into proximal movement of the distal ribbon 914, and distal tissue anchor 120 with respect to the proximal tissue anchor 118.

[0252] A cover 938, may comprise a stainless steel tube, is slid over the tab pull-wire 944 and distal ribbon 914. The cover 938 keeps the flange 946 of the tab 942 engaged with the pull-wire disconnect 918 of the distal ribbon 914 as the tab pull-wire 944 is moved in the proximal direction. The cover 938 is coupled to a cover pull-wire 940 such that movement of the cover pull-wire 940 in the proximal direction moves the cover 938 proximally, thereby releasing

the tab 942 from the pull-wire disconnect 918 of the distal ribbon 914. In one embodiment, the cover pull-wire 940 is a stainless steel hyptotube, and the tab pull-wire 944 is a stainless steel hypotube or wire of a smaller diameter than the lumen of the cover pull-wire 940. In one embodiment, the cover pull-wire 940 and tab pull-wire 944 are substantially concentrically aligned, such that the tab pull-wire 944 travels within the cover pull-wire 940 from the disconnect subassembly 936 to the handpiece 958 (as shown in Figure 32A).

[0253] A catheter 948, as shown in **Figure 31F** may be removably coupled to the housing 920 of the implant 900 with a catheter coupling 950. In one embodiment, the catheter coupling 950 includes a slot 952, and two fingers 954, which extend into the slot 952. The fingers 954 are attached to the catheter 948, such that axial and rotational movement of the catheter 948 translates into axial and rotational movement of the housing 920 and implant 900. The slot 952 may be located on the housing 920, and in one embodiment, is shaped so as to create a bayonet type coupling between the housing 920 and catheter 948, as is known to those of skill in the art. In other embodiments, more or less than two fingers 954 are used to removably couple the housing 920 to the catheter 948. In one embodiment, a circular ring, tabs, hooks or other devices well known to those of skill in the art, are used instead of fingers 954.

[0254] In one embodiment, the fingers 954 are coupled to a release wire 956 such that proximal movement of the release wire 956 causes the fingers 954 to flex inward, and disengage from the slot 952 of the housing 920. When disengaged, the catheter 948 may be rotated and moved proximally with respect to the housing 920 so as to decouple the catheter 948 from the implant 900. In one embodiment, the release wire 956 is also coupled to the latch release ribbon 932 (shown in Figure 31A). In one embodiment, proximal movement of the release wire 956 over a release distance causes the latch release ribbon 932 to disengage the latch 922 from the distal ribbon 914. In addition, proximal movement of the release wire 956 over the release distance

does not cause the fingers 954 to flex sufficiently to disengage from the slot 952 of the housing 920, as described above.

[0255] In one embodiment, the release wire 956 comprises a hypotube with a lumen of sufficient diameter to contain the cover pull-wire 940 and tab pull-wire 944. In one embodiment, the release wire 956, cover pull-wire 940 and tab pull-wire 944 are all substantially coaxially aligned, and arranged such that the cover pull-wire 940 is at least partially within the release wire 956, and the tab pull-wire 944 is at least partially within the cover pull-wire 940 as they travel proximally from the catheter coupling 950 and disconnect subassembly 936 to the handpiece, as described in greater detail below.

[0256] Referring now to **Figure 32A**, there is illustrated a handpiece 958, in accordance with another aspect of the present invention. Handpiece 958 includes a strain relief 960, body 962, distal actuator 964, interlock 966, and proximal actuator 968. The release wire 956, cover pull-wire 940, and tab pull-wire 944 enter the handpiece 958 via a lumen of the strain relief 960. The release wire 956 is coupled to a distal slider 970, the cover pull-wire 940 is coupled to a center slider 972, and the tab pull-wire 944 is coupled to a proximal slider 974. The body 962 may be formed from two or more pieces that are, for example, machined from metal or plastic, and joined together. Alternatively, the body 962 may be formed from one piece of material, for example, plastic that is formed by injection molding.

[0257] In one embodiment, the distal actuator 964 is threadingly engaged with the body 962 such that rotation of the distal actuator 964 results in axial movement of the distal actuator 964 with respect to the body 962. The distal actuator 964 is coupled to the distal slider 970 by at least one pin 976 (as shown in **Figure 32B**) that is free to travel within an axial slot 978 in the body 962. The distal slider 970 is coupled to the release wire 956 by welding, bonding, adhesion, crimping, or other method as is known to those of skill in the art. The catheter 948 extends from the handpiece 958 to the implant 900, and is coupled to the implant 900 as described above, thereby fixing the axial position

of the handpiece 958 with respect to the implant 900. As a result of the multiple couplings as described, rotation of the distal actuator 964 is translated into axial movement of the release wire 956 with respect to the handpiece 958, catheter 948, and implant 900. Proximal movement of the distal actuator 964 over the release distance, therefore causes the latch release ribbon 932 to move proximally sufficient to decouple the latch 922 from the distal ribbon 914, as described in greater detail above. Furthermore, additional proximal movement of the distal actuator 964 causes the fingers 954 of the catheter coupling 950 to disengage from the slot 952 of the housing 920, as described in greater detail above and below.

[0258] In one embodiment, the proximal actuator 968 is coupled to a threaded rod 980 such that rotation of the proximal actuator 968 causes the threaded rod 980 to rotate in the same direction. The threads of the threaded rod 980 engage threads located on an inside lumen of the center slider 972, through which the threaded rod 980 extends. The inside lumen of the proximal slider 974, through which the threaded rod 980 also extends, does not contain threads. The interlock 966 includes two pins 976 which engage both the center slider 972 and the proximal slider 974, and is free to move axially within a second axial slot 982 in the body 962. The interlock 966 causes the center slider 972 and the proximal slider 974 to remain fixed with respect to one another. Therefore, as the center slider 972 is moved proximally with respect to the body 962 from rotation of the proximal actuator 968, the proximal slider 974 move proximally with respect to the body 962 as well.

[0259] The interlock 966 may be removed from the handpiece 958 such that the center slider 972 and proximal slider 974 are no longer axially coupled. By removing the interlock 966, the center slider 972 is able to be moved proximally with respect to the proximal slider 974. Such adjustability is advantageous when manipulating the implant 900, and catheter 948, and during decoupling of the implant 900 from the catheter 948, as described in greater detail below.

[0260] In one embodiment, the center slider 972 is coupled to the cover pull-wire 940, such that proximal movement of the center slider 972 with respect to the body 962 results in proximal movement of the cover pull-wire 940 with respect to the catheter 948. In one embodiment, the proximal slider 974 is coupled to the tab pull-wire 944, such that proximal movement of the proximal slider 974 with respect to the body 962 results in proximal movement of the tab pull-wire 944 with respect to the catheter 948.

[0261] In one embodiment, the implant 900 is transluminally delivered to and deployed inside of the coronary sinus of a medical patient according to the following procedure. An outer sheath (not shown) is transluminally delivered to a distal region of the coronary sinus by using methods well known to those of skill in the art. The exact location within the coronary sinus is determined by the medical practitioner according to the clinical requirements of the particular case. The outer sheath contains a lumen of sufficient diameter to receive the implant 900. The implant 900 is coupled to the catheter 948, which is coupled to the handpiece 958, as described in greater detail above.

[0262] The implant 900 is advance distally to the distal tip of the outer tube by moving the handpiece 958 in the distal direction. The position of the implant 900 with respect to the outer tube and coronary sinus may be determined using fluoroscopic techniques, as are well known to those of skill in the art. When the implant 900 is properly positioned within the outer tube, within the coronary sinus, the outer tube is moved proximally, thereby exposing the distal tissue anchor 120. As described above, the distal tissue anchor 120 is biased to rotate to engage the medial wall of the coronary sinus under the force of the distal tissue anchor 120 spring 912. The handpiece 958 is then moved proximally to force the penetrating point 904 of the distal tissue anchor 120 into the heart tissue of the coronary sinus.

[0263] Once the distal tissue anchor 120 has adequately engaged the inside wall of the coronary sinus, the outer sheath is moved proximally, thereby

exposing the proximal tissue anchor 118. The shape of the proximal ribbon 902 allow proximal tissue anchor 118 to engage tissue.

[0264] The implant 900 is adjusted so that the distance between the proximal tissue anchor 118 and the distal tissue anchor 120 is reduced, and the shape of the mitral valve annulus is modified to improve clinical performance, as described in greater detail herein. The handpiece 958 is held and the proximal actuator 968 is rotated. Rotating the proximal actuator 968 causes the tab pull-wire 944 and cover pull-wire 940 to move proximally, as described above. Proximal movement of the tab pull-wire 944 and cover pull-wire 940 is translated into proximal movement of the distal ribbon 914, as described above. The housing 920 of the tensioning element 190 is coupled to the catheter 948 at the catheter coupling 950, and the catheter 948 is coupled to the handpiece 958. Therefore, proximal movement of the cover pull-wire 940 and tab pull-wire 944 with respect to the handpiece 958 causes the distal ribbon 914 and distal tissue anchor 120 to move proximally with respect to the housing 920 and proximal tissue anchor 118.

[0265] In one embodiment, the medical practitioner verifies the position and shape of the implant 900 and mitral valve annulus using visualization techniques as are well known to those of skill in the art, including fluoroscopy. If the medical practitioner determines that the distal tissue anchor 120 needs to be moved distally, in one embodiment, the following procedure is followed. The distal actuator 964 is rotated with respect to the handpiece 958 until the distal actuator 964 moves proximally a distance equal to the release distance, as described in greater detail above. By doing so, the release wire 956 is moved proximally a distance equal to the release distance, which causes the opening 930 in the latch release ribbon 932 to move proximally a distance equal to the release distance as well. Such movement lifts the tang 928 of the latch 922 out of the slot 916 of the distal ribbon 914, so that the distal ribbon 914 may thereafter be moved distally by rotating the proximal actuator 968 in the opposite direction as rotated above.

[0266] When the implant 900 is properly positioned, and the distance between the proximal tissue anchor 118 and the distal tissue anchor 120 has been adjusted to the appropriate dimension, the medical practitioner may then conclude the medical treatment by removing the catheter from the medical patient. To do so, in one embodiment, the catheter 948 is decoupled from the housing 920 of the implant 900, and the cover pull-wire 940 and tab pull-wire 944 are decoupled from the distal ribbon 914.

[0267] To decouple the cover pull-wire 940 and tab pull-wire 944 from the distal ribbon 914, the interlock 966 is removed from the handpiece 958, and the proximal actuator 968 is rotated with respect to the handpiece 958. As the proximal actuator 968 is rotated with the interlock 966 removed, the center slider 972 moves proximally with respect to the proximal slider 974, which causes the cover pull-wire 940 to move proximally with respect to the tab pull-wire 944. Proximal movement of the cover pull-wire 940 causes the cover 938 to move proximally with respect to the tab 942, thereby allowing the tab 942 to disengage from the pull-wire disconnect 918 of the distal ribbon 914. The tab 942 may disengage from the pull-wire disconnect 918 under its own bias, or may be removed therefrom by rotating the handpiece 958, as described below.

[0268] To decouple the catheter 948 from the housing 920 of the implant 900, the distal actuator 964 is rotated until it moves proximally with respect to the handpiece 958 over a distance sufficiently greater than the release distance. In one embodiment, the distal actuator 964 is rotated until its proximal movement is limited by interference between the pin 976 and the proximal edge of the axial slot 978. Such movement causes the fingers 954 attached to the distal end of the catheter 948 flex inward a distance sufficient to clear the slot 952 in the housing 920, and latch release ribbon 932 is fully withdrawn, as described above. The handpiece 958 is then rotated and moved proximally, which causes the fingers 954 of the catheter 948 to rotate and move out of the housing 920 slot 952. In one embodiment, the rotation and proximal movement

of the handpiece 958 also causes the flange 946 of the tab 942 to disengage from the pull-wire disconnect 918 of the distal ribbon 914. The catheter 948 is then removed from the patient's body by pulling it proximally out of the outer tube.

[0269] Referring to **Figure 33**, there is illustrated a side elevational view of an implant in accordance with the present invention. The implant includes a distal anchor, 120 which is shown in additional detail in **Figure 34**. The distal anchor 120 comprises a sharpened proximal end 702 for penetrating tissue. The distal end 704 is pivotally attached to the implant wall, such as by one or more pins 706 rotatably received within an aperture in the tubular wall. The distal anchor is moveable between a first position in which it extends parallel to the longitudinal axis of the implant, to provide a low crossing profile, and a second position as illustrated in Figure 34 when the tissue anchor is inclined radially outwardly from the longitudinal axis of the implant to engage tissue. Additional details of the distal anchor mechanism are illustrated in Figure 36.

[0270] The proximal end of the implant 710 is illustrated in **Figure 35**. The implant includes a proximal tissue anchor 712, which inclines radially outwardly away from the implant in the distal direction, on the mitral valve side of the device, for engaging the wall of the coronary sinus. Any of a variety of deployment mechanisms may be utilized for the proximal tissue anchor 712.

[0271] One or more of the proximal and distal anchors may be provided with a lateral alignment or biasing element for advancing the device laterally within the vessel so that the mitral valve side of the device is positioned against the coronary sinus wall. This will allow deployment of the proximal and distal anchors to fully engage the adjacent tissue. The lateral alignment structure illustrated in Figure 35 is in the form of a flexible wire, strip, or loop 714 which, when released from the deployment catheter and/or advanced out of the implant, will reside within the coronary sinus and provide a lateral spring bias against the implant. In the illustrated embodiment, the loop 714 is in the form of a biased wire, such as nitinol. Any of a variety of structures may be

utilized for maintaining the implant off center within the vessel, to optimize engagement of the tissue anchors with the vessel wall. For example, an inflatable side balloon on either the distal end of the deployment catheter or on the implant may be inflated during the tissue engaging step. Any of a variety of expandable wire cages may be mounted off center on either the implant or the distal end of the deployment catheter, for laterally moving the implant off center within the vessel.

[0272] Referring to **Figure 36**, there is illustrated a side elevational schematic view of the implant illustrated in Figures 33 through 35. As seen therein, the distal anchor 120 may be activated by axial proximal tension on the pull wire 720. The pull wire 720 is pivotally connected to the distal anchor 120, at a position which is offset laterally from an axis of rotation. The axis of rotation is concentric with one or more pins 706 which pivotally retain the distal anchor 120 in position at the distal end 722 of the implant. In the illustrated embodiment, proximal axial advancement of the pull wire 720 will cause the distal anchor 120 to incline radially outwardly with respect to the longitudinal axis of the implant.

[0273] A spine support 722 is illustrated at the central segment of the implant. Spine support 722 may comprise any of a variety of elements, such as a flexible ribbon of stainless steel, nitinol or other material, for enhancing the column strength of the implant in this region.

[0274] The proximal end 710 of the implant is illustrated in greater detail in **Figure 37**. As seen therein, the anchor hoop 714 is schematically illustrated. Anchor hoop 714 may comprise any of a variety of structures, such as a loop as illustrated in Figure 35 or other resilient element which may be biased radially outwardly from the longitudinal axis of the implant to contact the opposing side of the vessel wall and bias the proximal anchor hook 712 in the direction of the mitral valve side of the vessel wall.

[0275] In any of the embodiments disclosed herein, in which a tubular body is provided, the space within the tubular body may be utilized to

carry any of a wide variety of drug delivery vehicles. For example, microporous beads, filaments or other structures may be carried within the tubular body. Any of a variety of dissolvable or absorbable gels or other carriers may be utilized, for carrying one or more active agents, for delivery from the implant into the vessel or vessel wall. The active agent may be released from the carrier using any of a variety of known drug delivery techniques, such as by erosion of the carrier, migration of the active agent through a microporous structure, or other as is known in the drug delivery arts.

[0276] The active agent carrier carried within the implant may be provided with any of a variety of active agents. These agents include anticoagulants, anti-inflammatory agents, drugs to inhibit smooth muscle cell proliferation or other responses to injury, antibiotics, drugs to enhance endothelial growth, or others known in the art.

[0277] Although the preceding discussion has been primarily in the context of devices for encircling or positioning adjacent the mitral valve annulus, the valve leaflet orientation locator described below may be used in a wider variety of anatomies. In human pathology, the proper functioning of both cardiac and venous valves is of paramount importance. Disorders of cardiac valves causes significant morbidity and mortality. These disorders effect persons of all ages and can result from congenital or degenerative conditions, as well as from sequelae of infections. Stenosis and insufficiency of the aortic or mitral valves have a greater incidence than stenosis and insufficiency of the tricuspid and pulmonary valves. However, various interventional therapies, including surgical procedures and implants may desirably be utilized in connection with each of these valves. In addition, venous insufficiency is believed to contribute to various maladies, including edema, varicose veins, aching leg pain while standing, lipodermatosclerosis, and ulcerations. Venous insufficiency is essentially caused by venous hypertension and chronic venous stasis due to valvular incompetence both of an idiopathic nature and of a secondary nature following past illnesses of the venous systems. For many

transluminal therapies and potential therapies for any of these valves, the orientation of the valvular leaflets during both the "open" and "closed" configurations may be important information for the clinician. Thus, although the discussion below will be primarily in the context of the mitral valve, it is to be understood that the leaflet orientation locator of the present invention may be more broadly applicable to any valve, sphincter, or other dynamic portion of a lumen or hollow organ in the body.

[0278] Referring to **Figure 38**, there is provided a partial cross sectional view of a heart 750, illustrating an aortic approach to the mitral valve in accordance with one embodiment of the present invention. The heart 750 includes four chambers, known as the right atrium 752, right ventricle 754, left atrium 756, and left ventricle 758. The heart 750 also includes four valves, known as the mitral valve 760, tricuspid valve 762, aortic valve 764, and pulmonary valve 765. A septum 766 extends along a longitudinal axis of the heart 750, and separates the right atrium 752 and right ventricle 754 from the left atrium 756 and left ventricle 758.

[0279] Deoxygenated blood enters the right atrium 752 of the heart 750 from the upper extremities via the superior vena cava 768 and from the lower extremities via the inferior vena cava 770. As the heart 750 beats, deoxygenated blood is pumped from the right atrium 752 through the tricuspid valve 762 and into the right ventricle 754. From the right ventricle 754 the deoxygenated blood is pumped through the pulmonary valve 765 to the lungs. After the lungs oxygenate the blood, it returns to the left atrium 756 of the heart 750 via the pulmonary veins 773. As the heart 750 beats, the oxygenated blood is pumped from the left atrium 756 through the mitral valve 760 and into the left ventricle 758. From the left ventricle 758, the oxygenated blood is pumped through the aortic valve 764 to the aorta 774, where it is distributed throughout the rest of the body.

[0280] As illustrated in **Figures 38A-C**, the mitral valve 760, tricuspid valve 762, aortic valve 764, and pulmonary valve 765 (not shown)

include two or more opposing coaptive leaflets 776, which function to control the flow of blood through the valves. Proper coaptation of the leaflets 776 allows the mitral valve 760, tricuspid valve 762, aortic valve 764, and pulmonary valve 765 to limit the flow of blood to only one direction.

[0281] For example, during the portion of the heart beat known as diastole, blood accumulating in the left atrium 756 is passed through the mitral valve 760, and into the left ventricle 758. The mitral valve 760 in diastole is illustrated in **Figure 38E**. During diastole, the mitral valve 760 leaflets 776 open, as shown in greater detail in **Figure 38F**, so that blood may flow through. During systole, the heart 750 contracts, pressurizing the blood accumulated in the left ventricle 758. The pressurized blood causes the leaflets 776 of the mitral valve 760 to come together, as illustrated in **Figures 38A and 38D**, thereby preventing blood flow back into the left atrium 756. The pressurized blood is instead pumped through the aortic valve 764 to the aorta 774.

[0282] As is discussed further in connection with Figure 42, coaptive edges of adjacent valve leaflets lie generally along a plane which is parallel to blood flow through the valve and which lies between the two leaflets. A transverse coaptation axis 788 (see figure 38A) lies on the plane of coaptation.

[0283] In accordance with the leaflet orientation aspect of the present invention, a conformable device is positioned across the valve under evaluation. The device is sufficiently conformable that it will reconfigure in response to pressure exerted by the closing valve leaflets, such that it can provide an indication of the spacial orientation of the coaptation axis 788. In certain embodiments, in addition to allowing determination of the orientation of the coaptation axis, the orientation device of the present invention will also allow evaluation of the axial length of the coaptive edges, lying in the plane of the coaptation axis. This will allow, for example, orientation of other catheters or devices at a position which is both spaced apart from the coaptive axis and

centered on or otherwise positioned with respect to a transverse axis which crosses through the center of the valve as will be discussed below.

[0284] In one embodiment, as illustrated in Figure 38, a delivery catheter 778 is inserted into the aorta 774, and advanced through the aortic valve 764 into the left ventricle 758 of the heart 750. The distal end of the delivery catheter 778 is oriented so that it faces the mitral valve 760.

[0285] Referring to **Figure 39**, a conformable target or leaflet locator 780 for conforming to the closed leaflets is deployed from the delivery catheter 778 such that the leaflet locator 780 spans or at least partially enters the mitral valve 760. The leaflet locator 780 may also be used to image aortic, tricuspid, and pulmonary valve coaptation. A conformable target 780 can be used in a variety of anatomical environments in which it may be desireable to determine the orientation and shape of the surrounding tissue structure. In embodiments of the present invention described herein, the conformable target 780 may be used primarily as a leaflet locator 780.

[0286] The leaflet locator may comprise any of a variety of structures, such as wires, baskets, or membranes which are sufficiently conformable that they will be compressed by the surrounding tissue, including closing leaflets to conform to the surrounding tissue's coaptive edges. The leaflet locator is preferably also radiopaque, or carries a radiopaque coating or markers, to allow visualization of the primary coaptation axis.

[0287] As shown in greater detail in **Figure 41A**, one leaflet locator 780 includes at least one, two or three or more locating elements or fingers 782 that are at least partially positioned between the leaflets 776 of the mitral valve 760. The locating fingers 782 may be made from a radiopaque material, such as nickel-titanium, tantalum, or gold wires. Although other dimensions may also be used, the locating fingers may each comprise a wire having a diameter within the range of from about 0.001" to about 0.015", and a length within the range of from about 5 mm to about 80 mm.

[0288] In one embodiment, the locating fingers 782 each include a radiopaque marker 784 that may be located on the distal end of the locating finger 782, or positioned elsewhere thereon. The marker 784 may include plating, such as gold plating, or a mechanically attached marker, such as a crimped gold or tantalum band. Many other materials and methods of attachment as known to those of skill in the art may be used instead, or in addition to those described above.

[0289] A device for determining valve leaflet orientation, which can be readily adapted to carry any of a variety of leaflet locator structures, is illustrated schematically in Figures 40A through 40E. Referring to **Figure 40A**, there is illustrated a side elevational schematic view of a catheter 778 having an elongate flexible tubular body 600 extending between a proximal end 602 and a distal end 604. The tubular body 600 may be manufactured in accordance with any of a variety of techniques well understood in the intravascular catheter arts, such as extrusion from any of a variety of materials including PEEK, PEBAX, various densities of polyethylene, nylon, and others known in the art. The dimensions of the tubular body will be selected based upon the desired percutaneous access site as well as the target valve. For example, in an embodiment of the catheter 778 intended for a femoral access, for placement within the mitral valve, the tubular body 600 may have a length within the range of from about 110 cm to about 140 cm. The outside diameter of the tubular body will generally be no greater than about 0.131" (10 French).

[0290] In one embodiment, the catheter distal end 604 is pre-shaped or pre-curved, so that it is properly oriented when approaching the valve. For example, the cathether distal end 604 may be pre-shaped such that the longitudinal axis of the catheter's distal end 604 is substantially directed towards the center of the mitral valve annulus as the catheter 778 is placed into the left atrium or left ventricle of the heart. Techniques for pre-shaping and pre-curving catheters are well known in the art. For example, such techniques are well known for shaping guide cathethers.

[0291] The proximal end 602 of the tubular body 600 is provided with a manifold 606 as is known in the art. Manifold 606 may be injection molded or otherwise formed in accordance with known techniques. In the illustrated embodiment, manifold 606 is provided with a guidewire access port 608. Guidewire access port 608 is provided in an embodiment of the catheter 778 intended for advancement over the wire. For this purpose, guidewire access port 608 is in communication with a guidewire lumen 610, and a distal guidewire port 612 as is understood in the art. Alternatively, the catheter 778 may be configured for rapid exchange, in which case the proximal guidewire access port 608 will be positioned along the side wall of the tubular body 600 within about 5 or 50 cm from the distal end 604.

[0292] As a further alternative, the guidewire lumen 610 and associated access ports may be omitted. This may be desirable, for example, in an embodiment in which the catheter 778 is intended to be advanced transluminally through a tubular guide catheter.

[0293] The manifold 606 may additionally be provided with a control 614. The illustrated control 614 is in the form of a slider switch 616. However, any of a variety of controls 614 may be utilized, such as rotatable knobs, compressible grips, triggers, buttons, slider rings, or others depending upon the desired performance characteristics.

[0294] Control 614 is mechanically coupled to a control wire 789, which extends axially throughout the length of the tubular body 600 to a point of connection with the conformable target 780. For this purpose, the tubular body 600 is provided with a control wire lumen 618, as illustrated in **Figure 40B**.

[0295] The control wire 789 has sufficient pushability that, upon distal advance of the slider 616, the conformable target 780 is deployed from the distal end 604 (as shown in Figure 40A) of the catheter 778. See Figure 40D. Proximal retraction of the slider 616 will draw the conformable target 780

proximally within the tubular body 600, such as following observation of the coaptation axis.

[0296] As illustrated in **Figure 40C**, the distal end 604 of the tubular body 600 may be provided with a cavity 620 which may be in communication with or an enlargement of the control wire lumen 618. Cavity 620 provides a housing for the proximally retracted conformable target 780.

[0297] In the foregoing construction of catheter 778, distally advancing the control 614 causes the conformable target 780 to advance distally from the distal end 604 of the catheter 778. In an alternative configuration, the conformable target 780 is deployed without axial advance, such as by proximal retraction of an outer restraint. One implementation of this construction is illustrated schematically in Figure 40E.

[0298] Referring to **Figure 40E**, the catheter 778 comprises a proximal tubular body segment 624 which may extend from the manifold 606 distally to within about 5 or 10 cm from the distal end 604. The proximal tubular segment 624 terminates at a distal end 626. A distal tubular segment 628 extends concentrically within the proximal tubular segment 624, and beyond the distal end 626. Distal tubular segment 628 is axially moveably carried with respect to proximal tubular segment 624.

[0299] A control wire 630 is attached such as by adhesive bonding or other known technique to the distal tubular segment 628. Control wire 630 extends proximally to a control 614 on the manifold 606 as has been discussed. Proximal retraction of the control wire 630 will cause the distal tubular segment 628 to retract proximally concentrically within the proximal tubular segment 624.

[0300] An inner tube 632 extends throughout the length of the catheter 778. Inner tube 632 may be provided with a central lumen 610 such as a guidewire lumen, as has been discussed. Otherwise, the inner tube 632 may be utilized to inject radiopaque dye and/or medications during the procedure.

[0301] A conformable target 780 is attached to the inner tube 632. In this configuration, the distal tubular segment 628 is moveable between a first, distal orientation in which the conformable target 780 is contained within the distal tubular segment 628, and a second, proximal orientation in which the conformable target 780 is exposed beyond the distal end of the distal tubular segment 628. Manipulation of the control 614 will allow the distal tubular segment 628 to be extended or retracted, without axial movement of the conformable target 780, for positioning advantages that will be understood by those of skill in the art. In one embodiment, conformable target 780 does not substantially advance during deployment. This allows conformable target 780 to be positioned at the desired axial location and coaptation to be determined without repositioning the catheter 778. Coaptation may be determined simply by sliding distal tubular segment 628 to expose the conformable target 780.

[0302] The conformable target 780 may be attached to the inner tube 632 in any of a variety of ways, depending upon the nature of the conformable target. In the illustrated embodiment, the conformable target 780 comprises a plurality of distally extending radiopaque elements 782. Elements 782 may be bonded to the inner tube 632 using any of a variety of known techniques, such as adhesives. In addition or as an alternative, an attachment band 781 may be heat shrunk, crimped, or otherwise attached to the distal end of the inner tube 632 to entrap the proximal ends of the flexible element 782. In an embodiment not intended to preserve the use of the central lumen 610, the proximal end of the conformable target can be potted within the distal opening of lumen 610.

[0303] The locating fingers 782 may be unbound at their distal ends, as illustrated in Figures 40E and 41A, or may be bound at one or more ends. **Figure 41B** illustrates another embodiment where the locating fingers 782 are bound at both their proximal and distal ends to form a basket 786. The basket 786 includes axially extending locating fingers 782 as well as optional circumferentially spanning supports 787. The basket 786 may include one or more markers 784, such as described in greater detail above.

[0304] In different implementations of the invention, the leaflet locator 780 includes at least about three, four, eight, sixteen, or 24 locating fingers 782. In another construction, the leaflet locator 780 includes at least three locating fingers 782. In general, the leaflet locator 780 includes between about one and about 24 locating fingers 782, often between about three and about twenty locating fingers 782.

[0305] The locating fingers 782 extend an extension distance measured from the distal end of the delivery catheter 778 to the distal end of at least one locating finger 782. In different constructions, the extension distance is at least about 10, 20, 40, or 80 mm depending upon the valve under evaluation. In general, the extension distance is in the range between about 5 and 60 mm, often between about 10 and about 40 mm.

[0306] The basket 786 may be axially movable with respect to the delivery catheter 778 by use of an axially movable control wire 789. Control wire 789 may comprise wire having sufficient pushability that force applied to the basket 786 with the wire 789 does not cause the wire 789 to bend or kink under compression. Once delivered, the basket 786 assumes an expanded shape, such as, for example, a lemon-like shape as illustrated in Figure 41B. The basket 786 assumes the expanded shape under its own bias, such as for example, when the locating fingers 782 are made from shape memory metals, or spring wire. Alternatively, the basket 786 assumes the expanded shape under force of an expander, such as axial compression structures or a balloon (not shown), by using balloon expansion techniques well known to those of skill in the art.

[0307] Referring to **Figure 42**, as the heart 750 pumps and the leaflets 776 of the mitral valve 760 close, the locating fingers 782 of the leaflet locator 780 are brought into alignment with respect to a coaptation axis 788 of the mitral valve 760. As described in greater detail above, the leaflets 776 of the mitral valve 760 of a patient suffering from mitral valve regurgitation do not properly coapt during systole, and a gap 790 remains between them. When

there is a gap 790 between the mitral valve 760 leaflets 776, the locating fingers 782 of the leaflet locator 780 may become oriented as illustrated in Figure 42. Thus, as used herein, the term "coaptation axis" shall refer to a primary axis such as the major diameter on an ellipse, since the radiopaque elements within the closed valve may not line up in a perfectly linear fashion.

[0308] Using imaging techniques well known to those of skill in the art, such as fluoroscopy or transesophageal echocardiography (TEE), the practitioner is able to observe the orientation of the locating fingers 782 within the mitral valve 760. By observing the orientation of the locating fingers 782, the medical practitioner may assess the functionality of the mitral valve 760, and determine the orientation of the coaptation axis 788 extending therethrough. In addition, the practitioner may also determine the orientation of other axes with respect to the coaptation axis 788, such as an axis transverse to the coaptation axis, including a transverse pressure axis 791. In one embodiment, a transverse pressure axis 791 is an axis which substantially bisects a leaflet 776 of the mitral valve 760, and is perpendicular to the coaptation axis 788. In another embodiment, the transverse pressure axis 791 is an axis laterally offset from and parallel to an axis which substantially bisects a leaflet 776 of the mitral valve 760, and which is perpendicular to the coaptation axis 788. In yet another embodiment, the transverse pressure axis 791 extends at an angle with respect to an axis which substantially bisects a leaflet 776 of the mitral valve 760 and which is perpendicular to the coaptation axis 788, and the transverse pressure axis 791 is within the plane defined by the coaptation axis 788 and an axis which substantially bisects a leaflet 776 of the mitral valve 760.

[0309] In one embodiment, the practitioner positions an implant or prosthesis within the coronary sinus, such as described in any of the embodiments described with respect to Figures 1-37 above. The practitioner positions the implant or prosthesis with respect to the coaptation axis 788, or other axis as described above, such as the transverse pressure axis 791. In one embodiment, as illustrated in **Figure 42A** an implant is designed to assume a

"W" shape when deployed, such as implant 710 described in greater detail above with respect to Figures 33-37. The peak 822 at the center of the "W" shaped implant 710 is oriented with respect to the transverse pressure axis 791 in one embodiment, so as to control placement of pressure upon a portion of the inside wall of the coronary sinus 824. The peak 822 is positioned in contact with a portion of the inside wall of the coronary sinus 824 that is substantially intersected by the transverse pressure axis 791 of the mitral valve 760. In another embodiment, the peak 822 is positioned in contact with a portion of the inside wall of the coronary sinus 824 that is an offset distance (not shown) from the portion of the inside wall of the coronary sinus 824 that is substantially intersected by the transverse pressure axis 791 of the mitral valve 760. In addition, the proximal and distal anchors 712, 120 may be positioned within the coronary sinus 824 with respect to the coaptation axis 788 or transverse pressure axis 791 so as to control the placement of pressure applied to the mitral valve 760.

[0310] In another embodiment, as illustrated in **Figure 42B** an implant is designed to assume a "C" shape when deployed, such as implant 711, or any "C" shaped implant described in Figures 1-37 above. A peak 822 at one end of the "C" shaped implant 711 is oriented with respect to the transverse pressure axis 791 in one embodiment, so as to control placement of pressure upon a portion of the inside wall of the coronary sinus 824. The peak 822 is positioned in contact with a portion of the inside wall of the coronary sinus 824 that is substantially intersected by the transverse pressure axis 791 of the mitral valve 760. In another embodiment, the peak 822 is positioned in contact with a portion of the inside wall of the coronary sinus 824 that is an offset distance (not shown) from the portion of the inside wall of the coronary sinus 824 that is substantially intersected by the transverse pressure axis 791 of the mitral valve 760. In addition, the proximal and distal anchors 712, 120 may be positioned within the coronary sinus 824 with respect to the coaptation axis 788 or

transverse pressure axis 791 so as to control the placement of pressure applied to the mitral valve 760.

[0311] For example, as illustrated in **Figure 42C**, an implant 900, such as that described above with respect to Figures 31A-F, is placed within the coronary sinus to apply pressure to the mitral valve 760. In one embodiment, the distal anchor 120 is positioned with respect to the coaptation axis 788 or transverse pressure axis 791 so as to control the placement of pressure upon a portion of the inside wall of the coronary sinus 824. The distal anchor 120 is positioned in contact with a portion of the inside wall of the coronary sinus 824 that is an offset distance 826 from the portion of the inside wall of the coronary sinus 824 that is substantially intersected by the coaptation axis 788 or transverse pressure axis 791 of the mitral valve 760. In another embodiment, the proximal anchor 118 of the implant 900 is positioned in contact with a portion of the inside wall of the coronary sinus 824 that is an offset distance 826 from the portion of the inside wall of the coronary sinus 824 that is substantially intersected by the coaptation axis 788 or transverse pressure axis 791 of the mitral valve 760.

[0312] It is well understood by those of skill in the art that any implant or prosthesis able to apply pressure to the heart 750, including any of the implants or prostheses described above with respect to Figures 1-37, may be utilized. Remotely activated implants, such as those disclosed in Provisional Application Serial No. 60/488,334, filed July 18, 2003, titled "REMOTELY ACTUATED MITRAL ANNULOPLASTY SYSTEM AND METHODS," hereby incorporated by reference in its entirety, may be utilized as well. In addition, although the embodiments described position a portion of an implant with respect to the coaptation axis 788 or transverse pressure axis 791 of the mitral valve 760, the implant portions may be positioned with respect to other axes visualized or determined upon visualization of the leaflet locator 780 locating fingers 782.

[0313] In another embodiment, the peaks 822 or anchors 118, 120, 712 of Figures 42A-C or any other suitable implant or prosthesis as described above, are positioned in contact with a portion of the inside wall of the coronary sinus 824 located within a contact zone (not shown). The contact zone may be defined by the transverse pressure axis 791 and an offset distance. In another embodiment, the contact zone is defined by first and second axes extending at first and second angles with respect to the transverse pressure axis 791, and intersecting the coronary sinus 824. In one embodiment, the first and second axes intersect the point defined by the intersection of the transverse pressure axis 791 and coaptation axis 788.

[0314] Referring to **Figure 43**, there is provided a partial cross sectional view of a heart 750 illustrating a transeptal approach embodiment of a method of the present invention. A delivery catheter 778 is inserted into the right atrium 752 via the inferior vena cava 770, where it is pushed through the septum 766 of the heart 750, and into the left atrium 756. The distal end of the delivery catheter 778 is oriented so that it faces the mitral valve 760, as shown. The leaflet locator 780 is deployed from the delivery catheter 778 such that the locating fingers 782 extend in the direction from the left atrium 756 to the left ventricle 758, and at least one of the locating fingers 782 is at least partially between the leaflets 776 (not shown) of the mitral valve 760. It will be understood by those of skill in the art that other approaches to the mitral valve 760 may be utilized, including a transeptal approach where the delivery catheter 778 enters the heart 750 via the superior vena cava 768.

[0315] Referring to **Figure 44**, there is illustrated another embodiment of a leaflet locator 780, including a pigtail catheter 792 and markers 784. The pigtail catheter 792 includes a curved portion 793 and a substantially straight portion 795. Markers 784 are disposed along the curved portion 793, as shown in the embodiment of Figure 44. Markers 784 may be any material able to be visualized under visualization techniques well known to

those of skill in the art, including fluoroscopy and TEE, as described in greater detail above.

[0316] In one embodiment, pigtail catheter 792 includes four markers 784. In another embodiment, pigtail catheter 792 includes at least three markers 784. In another embodiment, the pigtail catheter 792 includes only one marker 784. At least a substantial portion of the curved portion 793 of the pigtail catheter 792 may be plated, loaded, or coextruded with a visualizable marker 784 such that it may be identified using any of the visualization techniques described in greater detail above.

[0317] The pigtail catheter 792 is inserted between the leaflets 776 of the mitral valve 760 such that the leaflets 776 are in at least partial contact with the curved portion 793 of the pigtail catheter 792. As the leaflets 776 come together, the curved portion 793 of the pigtail catheter 792 is rotated by the closing leaflets at least partially about an axis defined by the substantially straight portion 795 of the pigtail catheter 792. Once rotated, the curved portion 793 of the pigtail catheter 792 is aligned with respect to the coaptation axis 788 of the mitral valve 760, as illustrated in **Figure 44A**.

[0318] Referring to **Figure 45**, there is provided a leaflet locator 780 in accordance with another embodiment of the present invention. The leaflet locator 780 includes a pigtail catheter 792, wire 789, and basket 786. The pigtail catheter 792 and basket 786 are similar to those described in greater detail above. However, the pigtail catheter 792 includes a skive 794 located adjacent the portion of the pigtail catheter 792 where the curved portion 793 of the pigtail catheter 792 meets the substantially straight portion 795 of the pigtail catheter 792. A wire 789 is coupled to the basket 786, and both are initially disposed within a central lumen (not shown) of the pigtail catheter 792. As the pigtail catheter 792 is positioned at the delivery site, for example within the left ventricle 758, the wire 789 is slid longitudinally with respect to the substantially straight portion 795 of the pigtail catheter 792. As the wire 789 is so slid, the basket 786 and wire 789 exit the pigtail catheter 792 at the skive 794, moving in

the direction of the mitral valve 760. The wire 789 is moved until at least a portion of the basket 786 is positioned at least partially between the leaflets 776 of the mitral valve 760. Furthermore, locating fingers 782 may be thermally fused to inner tube 800.

[0319] **Figure 46** illustrates another leaflet locator 780 in accordance with yet another embodiment of the present invention. A leaflet locator 780 includes an outer tube 798, an inner tube 800, and locating fingers 782 spanning therebetween. An atraumatic tip 802 is disposed on one end of the inner tube 800. The locating fingers 782 are attached to the outer tube 798 at attachment windows 804. Locating fingers 782 may be bonded to the outer tube 798 using adhesives well known to those of skill in the art, such as polymer materials, or cyanoacrylate. Alternatively, a mechanical attachment, such as a pin, plug, band, ring, knot, anchor, or other structure suitable for such attachment, as is well know to those of skill in the art, may be used to attach locating fingers 782 to outer tube 798.

[0320] The outer tube 798 includes a central lumen extending at least partially therethrough, inside of which is placed at least a portion of inner tube 800. Inner tube 800 includes a central lumen extending at least partially therethrough, so that the leaflet locator 780 may be delivered to the deployment site (such as, for example, the left ventricle 758) via a guidewire (not shown), in either an over-the-wire or rapid exchange mode.

[0321] The inner tube 800 includes an atraumatic tip 802 so that as the leaflet locator 780 is advanced over the guidewire, the tissues surrounding the guidewire are not traumatized by the distal end of the inner tube 800. In addition, the atraumatic tip 802 may serve as an anchor to secure the distal ends of the locating fingers 782. Alternatively, any of the attachments described above may be used to attach locating fingers 782 directly to the inner tube 800, such as at the distal end of the inner tube 800, or to the atraumatic tip 802.

[0322] As the inner tube 800 is moved longitudinally with respect to the outer tube 798, the locating fingers 782 bend to form locating wings 808,

such as illustrated in **Figure 47**. The angle of bend 809 as well as the wing span 812 may be controlled by controlling the distance the inner tube 800 is moved with respect to the outer tube 798. The angle of bend 809 will generally decrease and the wing span 812 will generally increase as the atraumatic tip 802 is moved closer to the distal end of the outer tube 798, as illustrated in **Figures 48-48A.**

[0323] The locating fingers 782 may comprise a radiopaque material to enable visualization. Visualization may be enhanced by including coiled radiopaque wires 783 wound around the locating fingers 782, as illustrated in Figure 48C. As the inner tube 800 is moved longitudinally with respect to the outer tube 798, the locating fingers 782 bend to form locating wings 808 of locating fingers 782 carrying multiple loops 810 of radiopaque wires 783, such as illustrated in **Figures 48B and C.**

[0324] Radiopaque wires 783 allow visualization of the locating wings 808 according to the methods described in greater detail above. By adjusting or selecting various properties of the radiopaque wires 783, quality of visualization and flexibility of the locating wings 808 may be controlled. For example, quality of visualization and flexibility of the locating wings 808 can be affected by the diameter, cross sectional shape, and winding density (typically specified in windings per unit length) of the radiopaque wires 783. In one embodiment, the diameter of the radiopaque wires 783 is in the range of about 0.001" to about 0.015", in the range of about 0.002" to about 0.010", or about 0.005". In one embodiment, the cross sectional shape of the radiopaque wires 783 is circular, elliptical, square, rectangular, pentagonal, hexagonal, or octagonal. Other cross sectional shapes, or combinations thereof, may be selected, as is known to those of skill in the art. Different portions of a radiopaque wire 783 may have different cross sectional shapes, or different radiopaque wires 783 may have different cross sectional shapes. In one embodiment, the radiopaque wires 783 have a winding density in the range of about 1000 windings/in to about 67 windings/in, about 500 windings/in to about

100 windings/in, or about about 300 windings/in to about 200 windings/in. In one embodiment, the radiopaque wires 783 have a winding density of about 200 windings/in.

[0325] Quality of visualization and flexibility of the locating wings 808 may additionally be controlled by controlling the diameter of the loop 810 formed from the radiopaque wires 783. In one embodiment, the inside diameter of the loop 810 is approximately equal to the outside diameter of the locating finger 782. Alternatively, the inside diameter of the loop 810 formed from the radiopaque wires 783 is in the range of about 0.001" to about 0.015", in the range of about 0.002" to about 0.010", or about 0.005". In another embodiment, the diameter of the loop 810 formed from the radiopaque wires 783 is in the range of about 0.015" to about 0.025", or in the range of about 0.025" to about 0.035".

[0326] Referring to **Figures 49A-E**, there is provided another leaflet locator 780 in accordance with yet another embodiment of the present invention. Leaflet locator 780 includes an outer tube 798, an inner tube 800, and locating fingers 782 in the form of loops 810 extending from the distal end of the outer tube 798 to the distal end of the inner tube 800. As the inner tube 800 is moved longitudinally with respect to the outer tube 798, the locating finger 782 loops 810 are pushed out of the central lumen of the outer tube 798 to form a whisk-like shape. When fully deployed, the leaflet locator 780 of the present embodiment assumes the form illustrated in Figure 49E, with locating wings 808 extending radially with respect to the inner tube 800.

[0327] The leaflet locator 780 of any of Figures 46-49F is inserted between the leaflets 776 of the mitral valve 760 such that the leaflets 776 are in at least partial contact with the locating wings 808 or loops 810 of the leaflet locator 780, as illustrated in **Figure 50**. As the leaflets 776 come together, the locating wings 808 or loops 810 of the leaflet locator 780 are rotated at least partially about the inner tube 800. Once rotated, the locating wings 808 or loops

810 will become substantially aligned with respect to the coaptation axis 788 of the mitral valve 760, such that they may be visualized as illustrated in Figure 50.

[0328] Although the present invention has been described in terms of certain preferred embodiments, it may be incorporated into other embodiments or performed through other steps by persons of skill in the art in view of the disclosure herein. In addition, features from any one of the embodiments disclosed herein may be incorporated into other embodiments as will be apparent to those of skill in the art. The scope of the invention is therefore not intended to be limited by the specific embodiments disclosed herein, but is intended to be defined by the full scope of the following claims.

WHAT IS CLAIMED IS:

1. A method of determining the coaptation axis of a valve, comprising the steps of:

positioning a device within the valve, the device moveable in response to opening and closing of the valve; and

observing the device when the valve is closed, to determine the orientation of the coaptation axis.

2. A method of determining the coaptation axis of a valve as in Claim 1, wherein the positioning step comprises transluminally positioning.

3. A method of determining the coaptation axis of a valve as in Claim 2, comprising the steps of transluminally advancing the device through the aortic valve and into the mitral valve.

4. A method of determining the coaptation axis of a valve as in Claim 2, comprising the steps of transluminally advancing the device into the right atrium and across the atrial septum into the mitral valve.

5. A method of determining the coaptation axis of a valve as in Claim 1, wherein the positioning step comprises positioning a plurality of radiopaque markers within the valve.

6. A method of positioning an implant within the coronary sinus, comprising the steps of:

positioning a radiopaque device within the mitral valve;

visualizing the radiopaque device; and

positioning the implant within the coronary sinus in a preselected relationship to the radiopaque device.

7. A method of positioning an implant as in Claim 6, wherein the radiopaque device is movable in response to closing of the mitral valve.

8. A method of positioning an implant as in Claim 7, wherein the radiopaque device comprises a plurality of radiopaque markers which align in

response to closing of the valve to conform to the coaptive edges of the valve leaflets.

9. A method of positioning an implant as in Claim 6, wherein the positioning step comprises positioning the implant such that it applies pressure on the P2 leaflet of the mitral valve.

10. A method of determining the coaptation axis of the mitral valve, comprising the steps of:

advancing the distal end of a catheter through the left ventricle to a position adjacent the mitral valve;

deploying a radiopaque target from the distal end; and

observing the alignment of the radiopaque target in response to closing of the mitral valve.

11. A method as in Claim 10, wherein the deploying step comprises deploying a plurality of radiopaque markers.

12. A method as in Claim 11, wherein the deploying step comprises deploying a plurality of wires.

13. A method as in Claim 11, wherein the deploying step comprises deploying an expandable basket.

14. A leaflet orientation device, for determining the coaptive axis of a valve, comprising:

an elongate, flexible tubular body, having a proximal end and a distal end; and

a conformable radiopaque target carried by the distal end;

wherein the target is conformable in response to closing of the valve to align with the coaptive edges of valve leaflets.

15. A leaflet orientation device as in Claim 14, wherein the conformable target comprises a plurality of wires.

16. A leaflet orientation device as in Claim 14, wherein the conformable target comprises a pig tail support.

17. A leaflet orientation device as in Claim 14, wherein the conformable target comprises a collapsible basket.

18. A leaflet orientation device as in Claim 14, wherein the conformable target is axially movable with respect to the tubular body.

19. A leaflet orientation device as in Claim 14, wherein the conformable target comprises a balloon.

20. A leaflet orientation device as in Claim 14, wherein the conformable target is movable between a retracted position within the catheter for transluminal advance and an extended position for determining valve leaflet orientation.

21. A method of determining the coaptation configuration of a valve, comprising the steps of:

providing a conformable target, having a primary axis;

positioning the conformable target in the path of a valve leaflet; and

visualizing the target along a viewing axis which is transverse to the primary axis, in the vicinity of the valve leaflet.

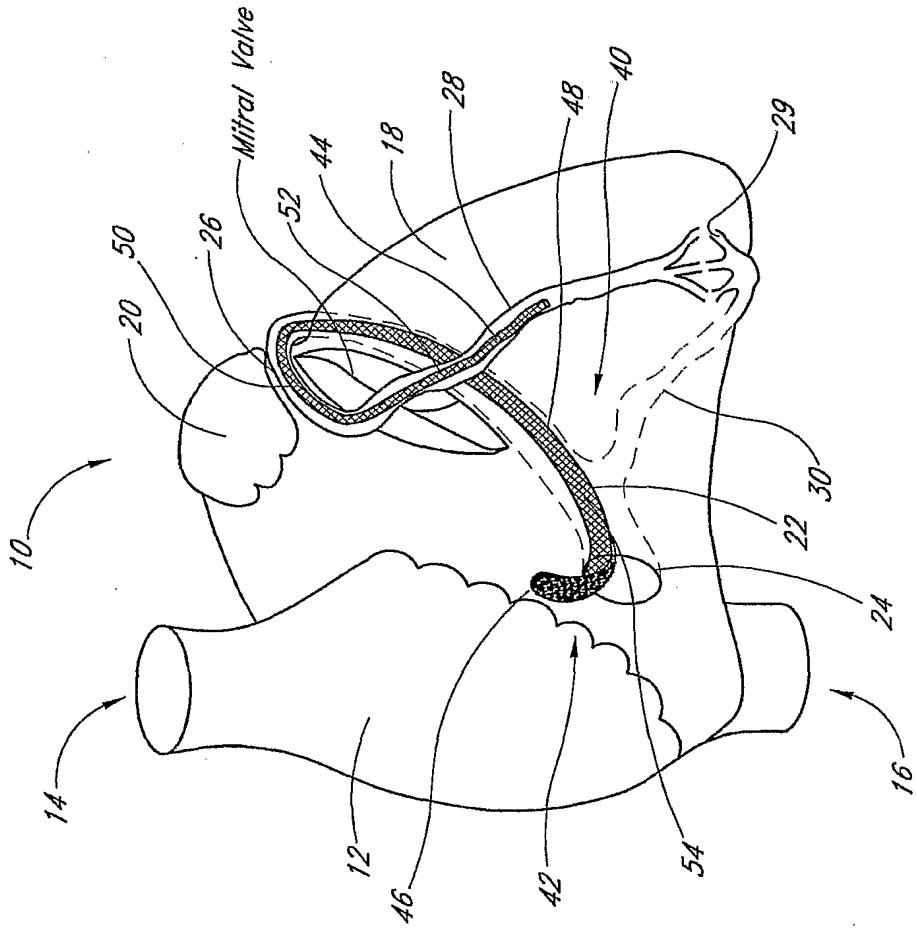

Mitral Valve
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FIG. 1

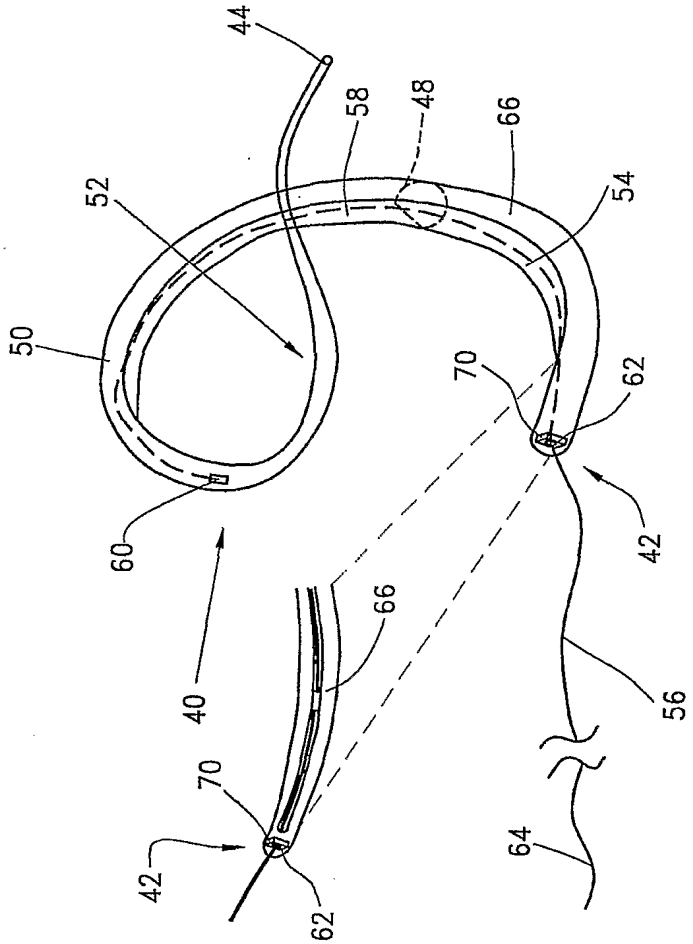

FIG. 2A

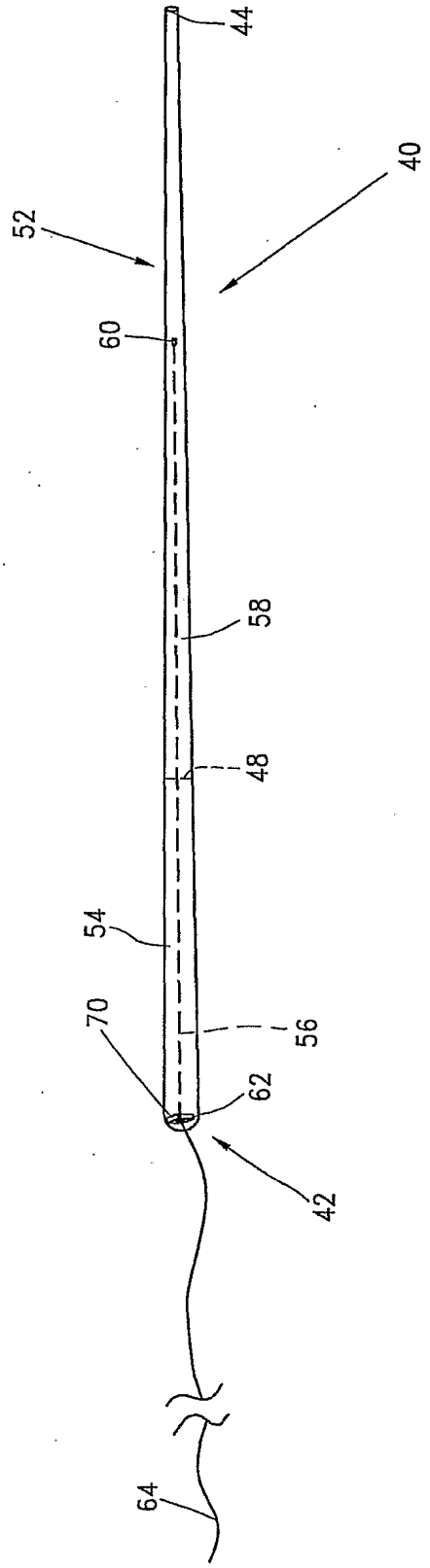

FIG. 2B

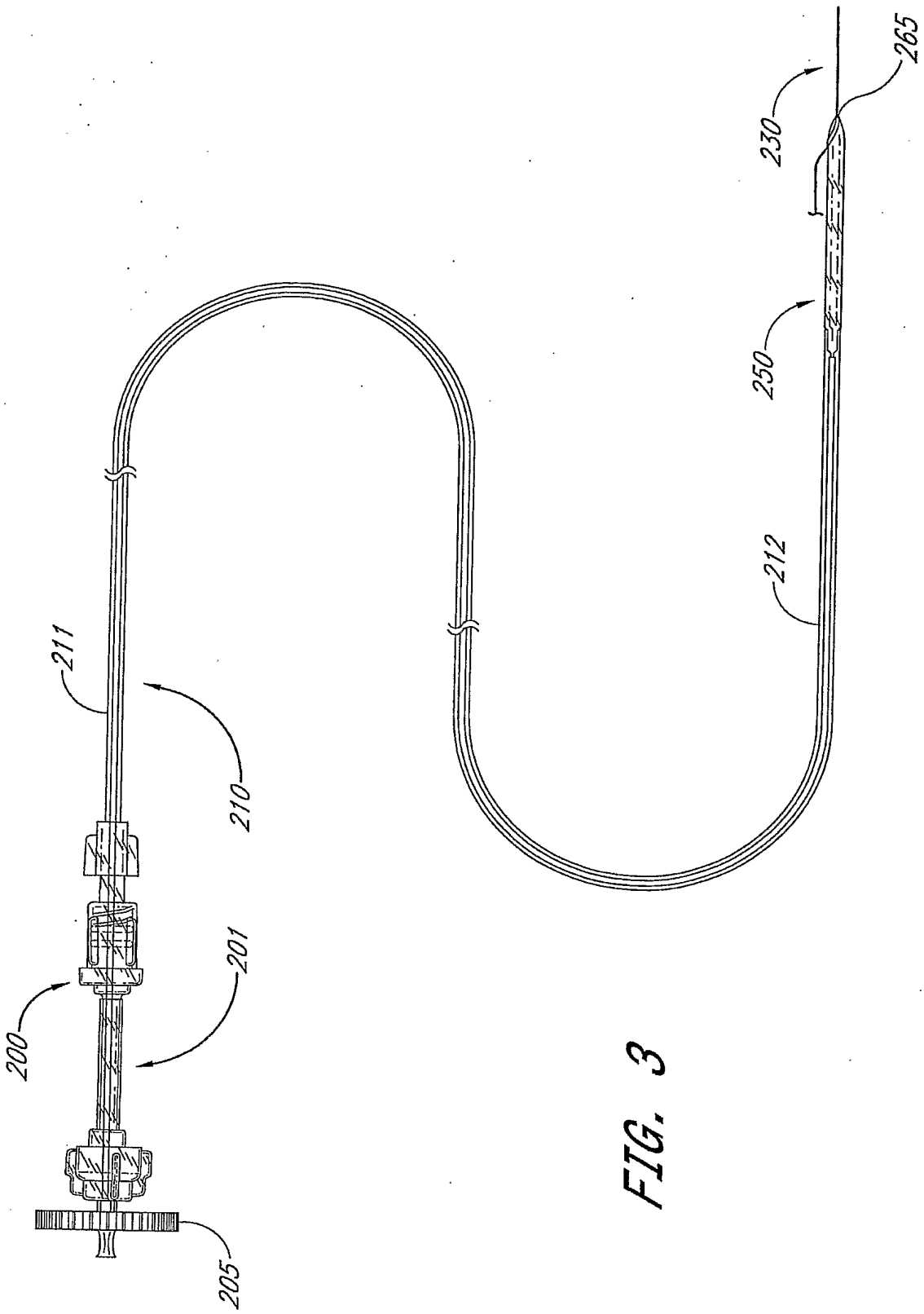

FIG. 3

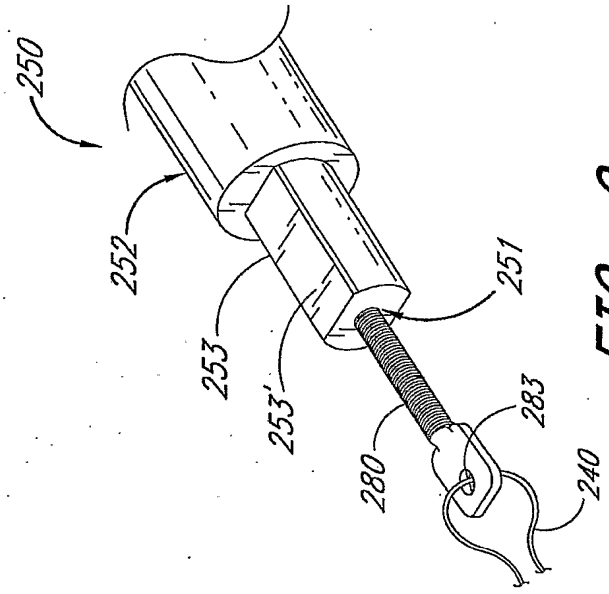

FIG. 6

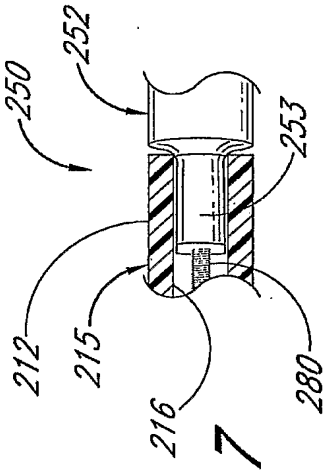

FIG. 7

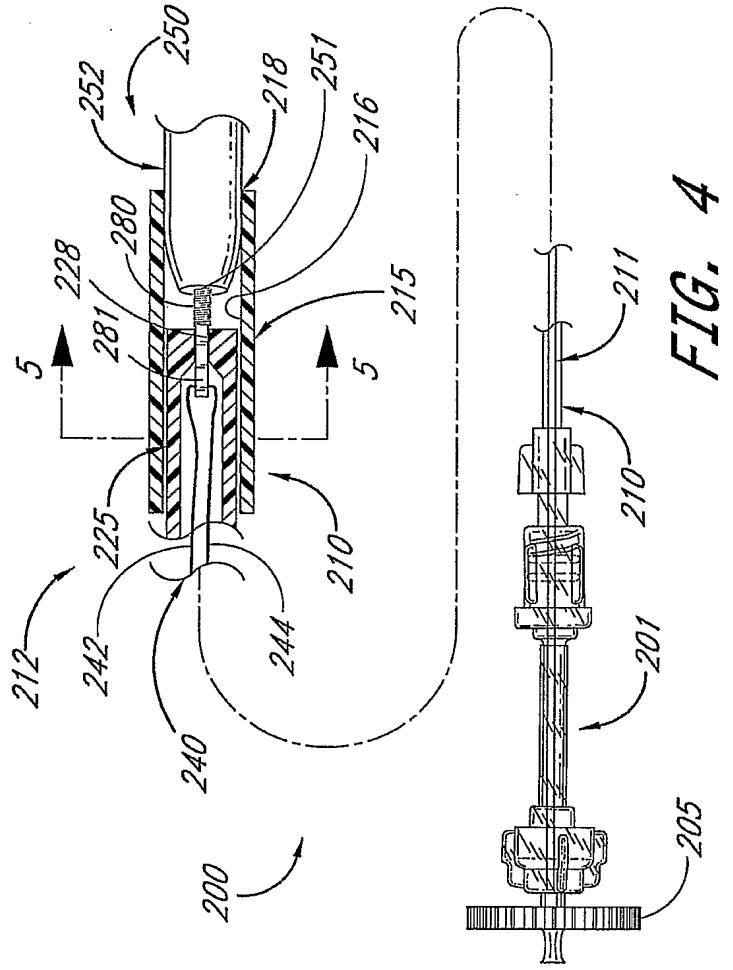

FIG. 4

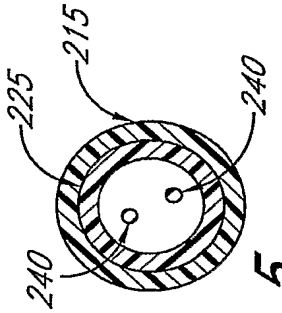

FIG. 5

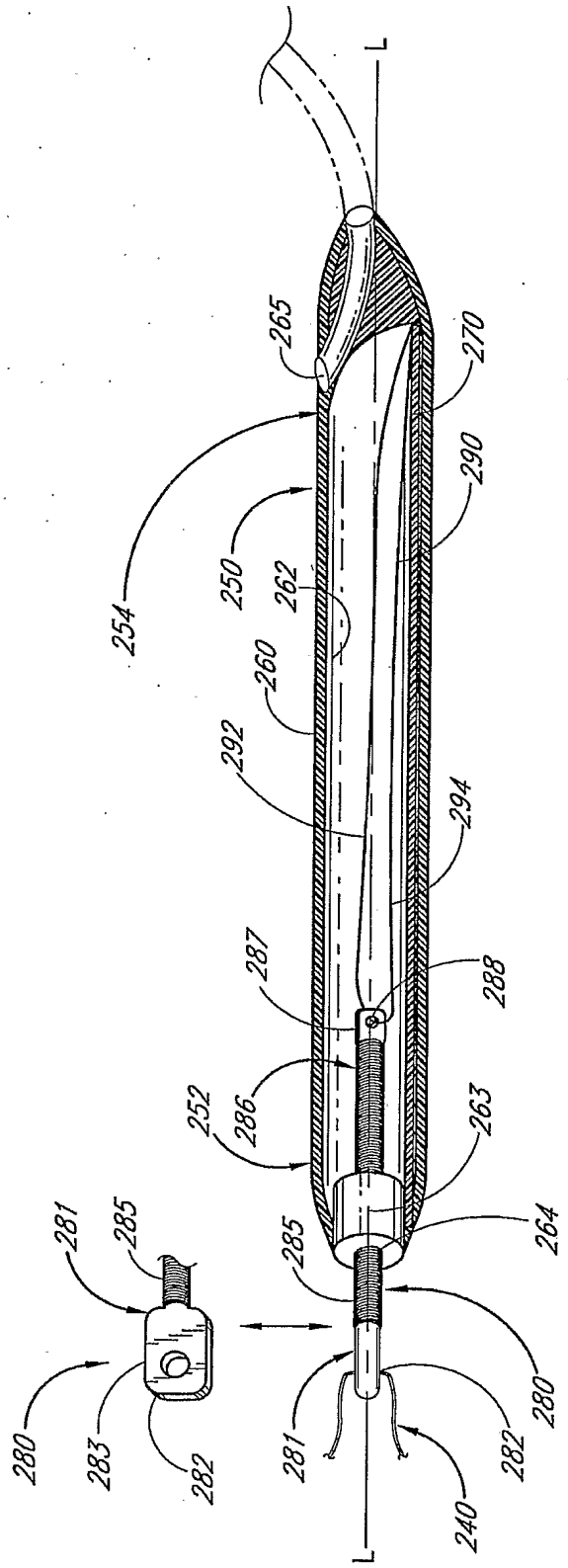
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FIG. 8A

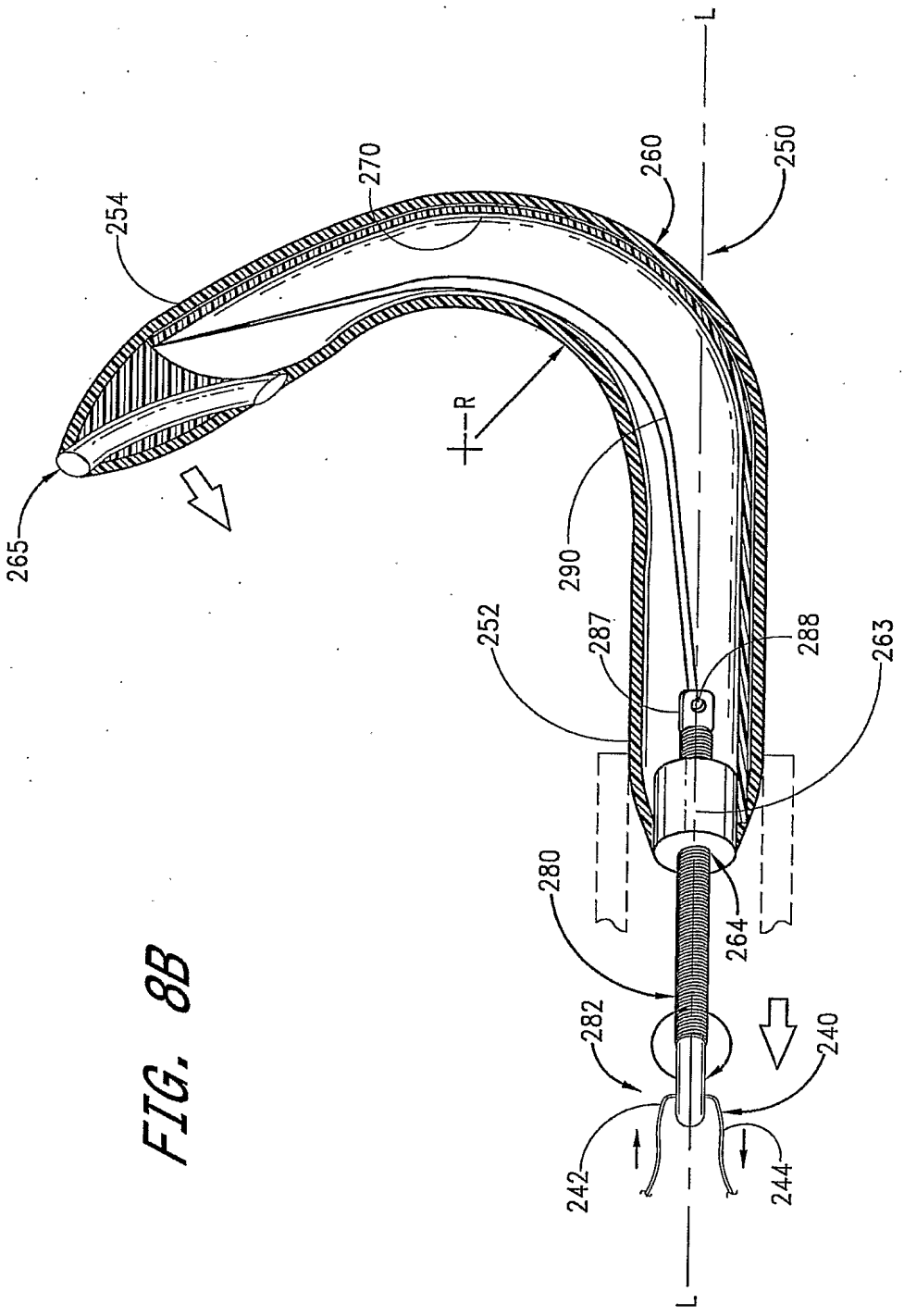
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FIG. 8B

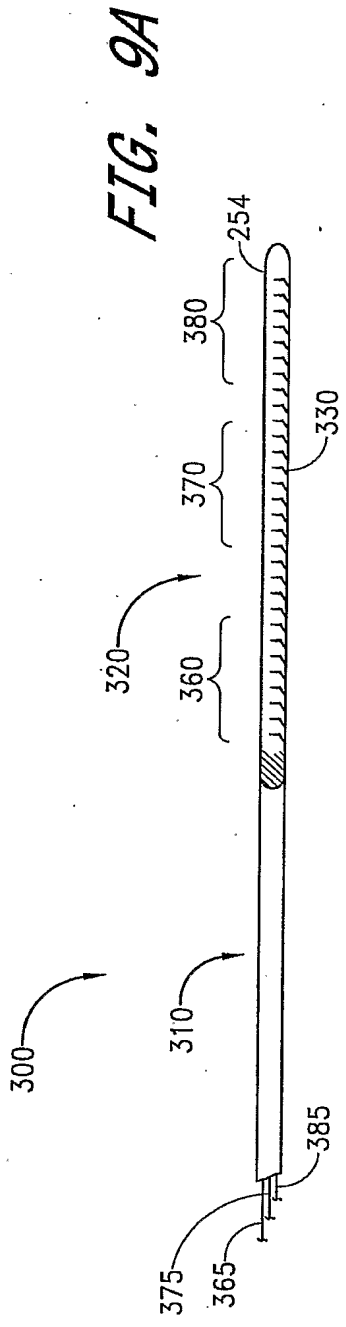
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FIG. 9A

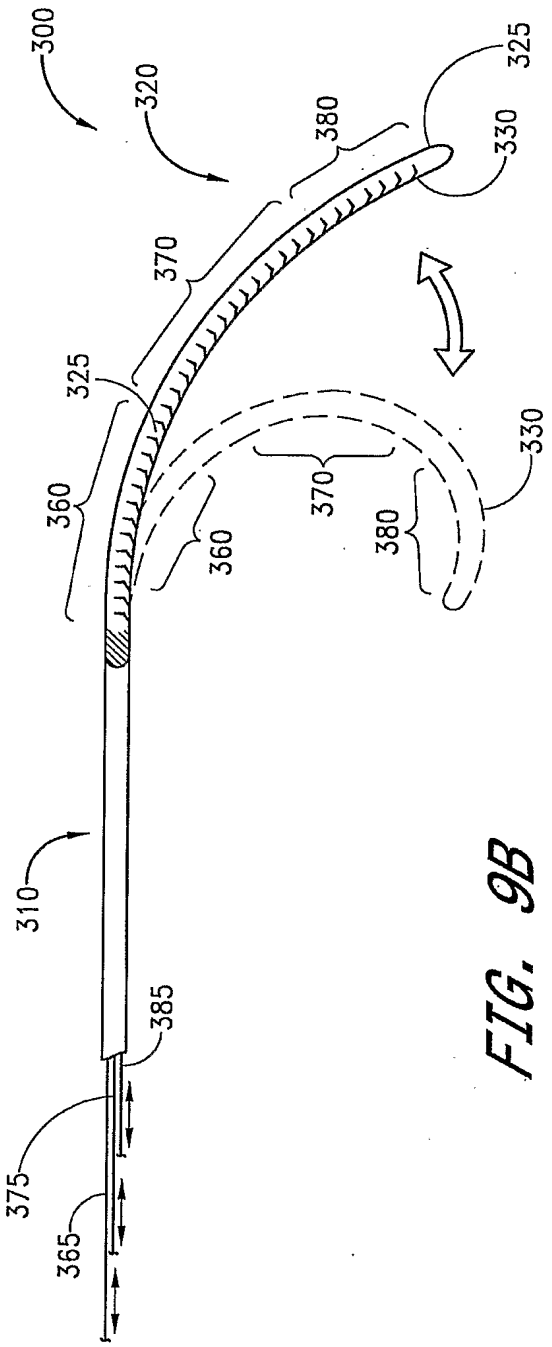
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FIG. 9B

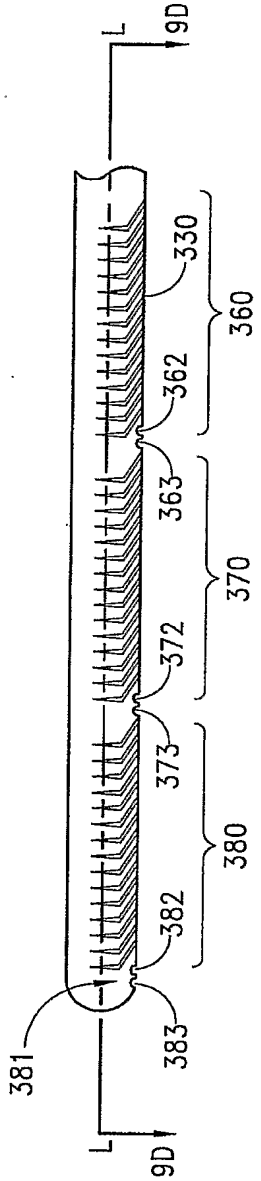

FIG. 9C

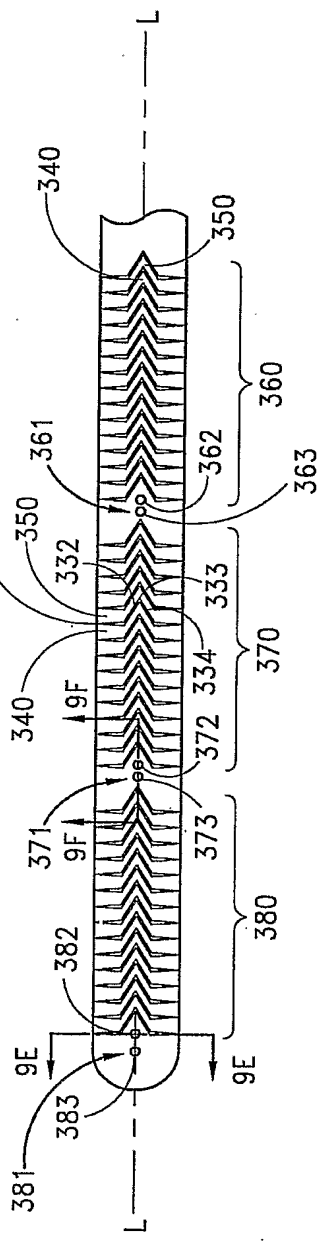

FIG. 9D

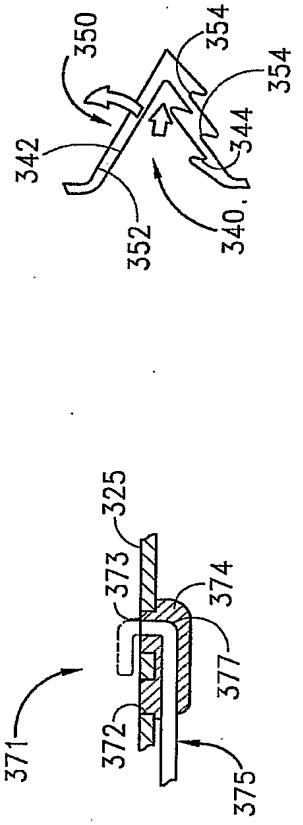

FIG. 9G

FIG. 9F

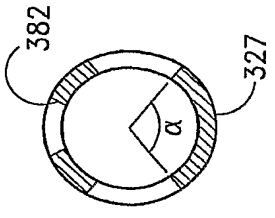

FIG. 9E

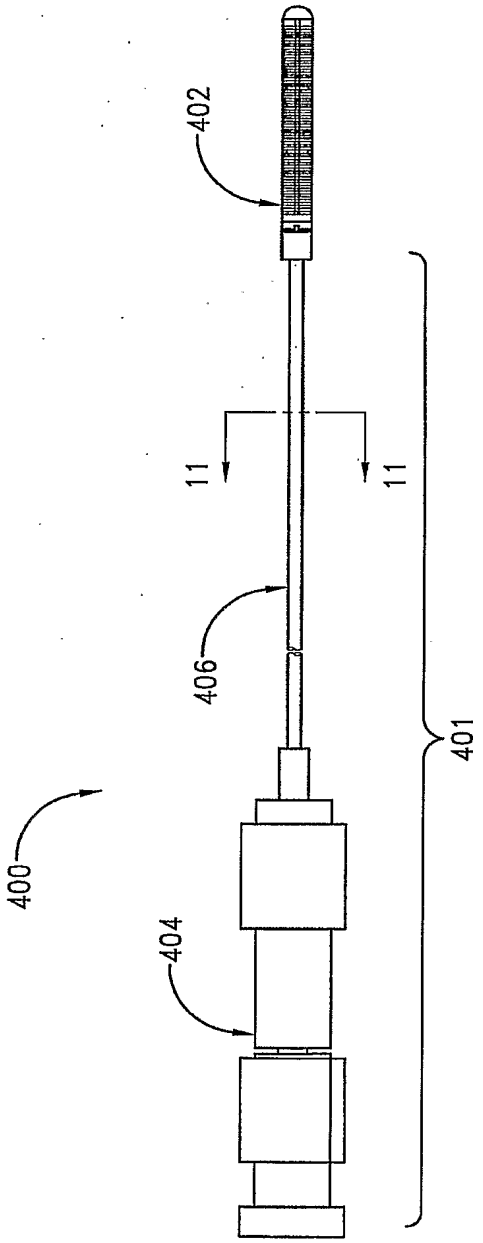

FIG. 10

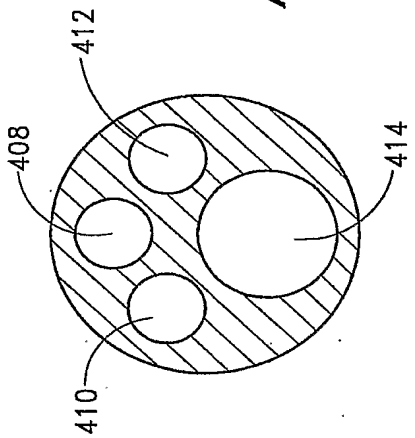

FIG. 11

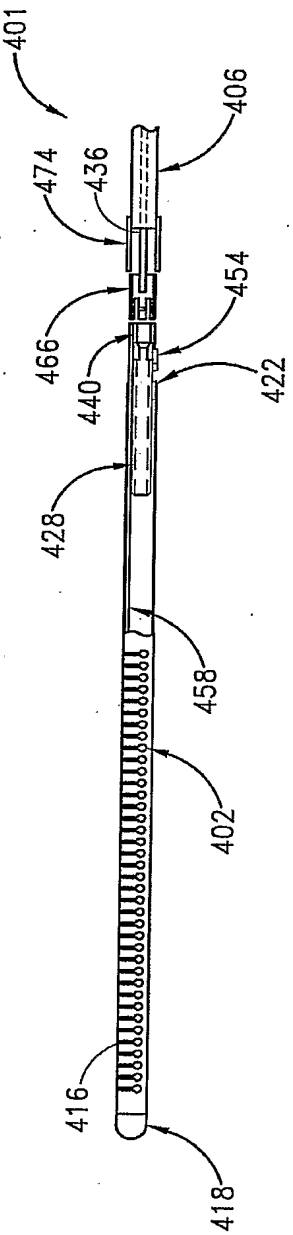
401
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FIG. 12

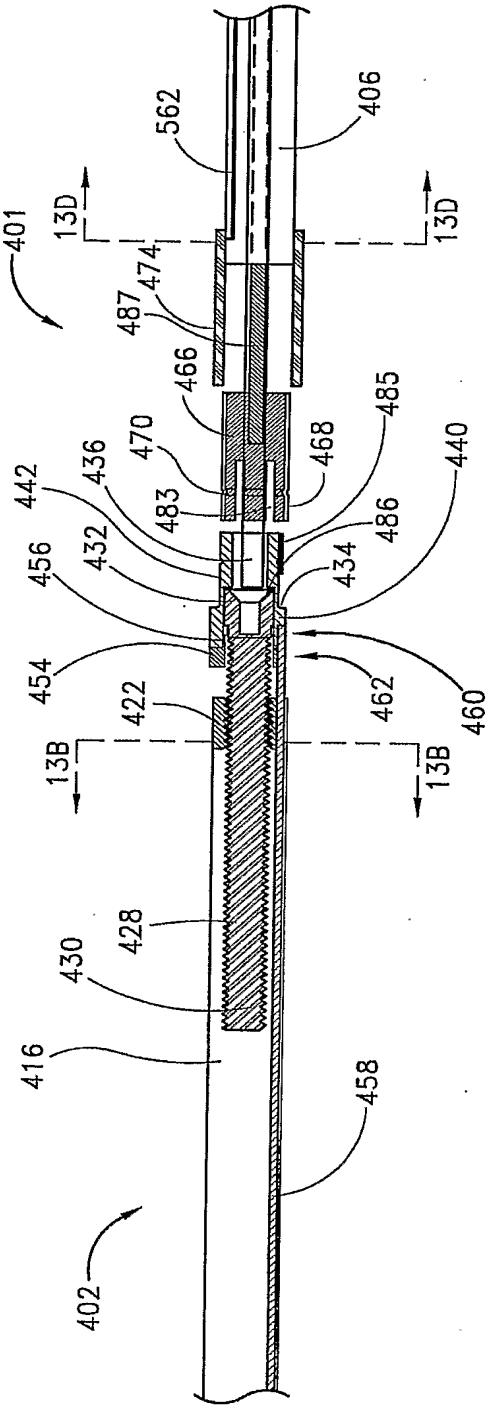
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FIG. 13

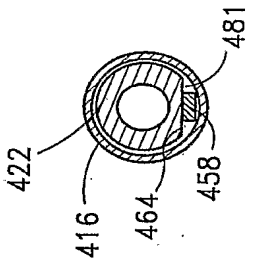

FIG. 13B

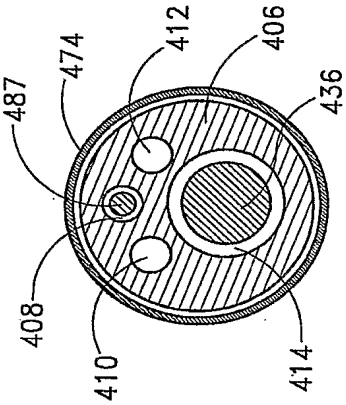

FIG. 13D

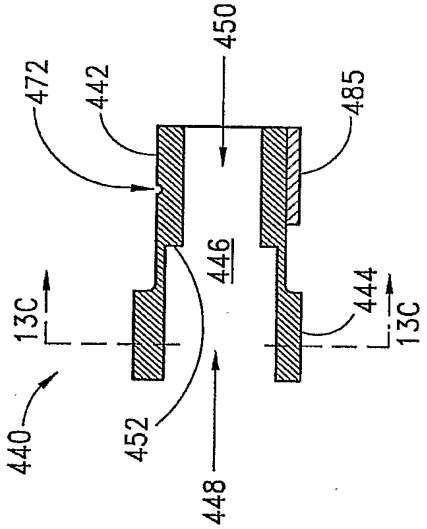

FIG. 13A

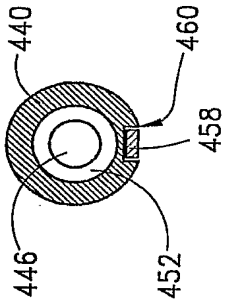

FIG. 13C

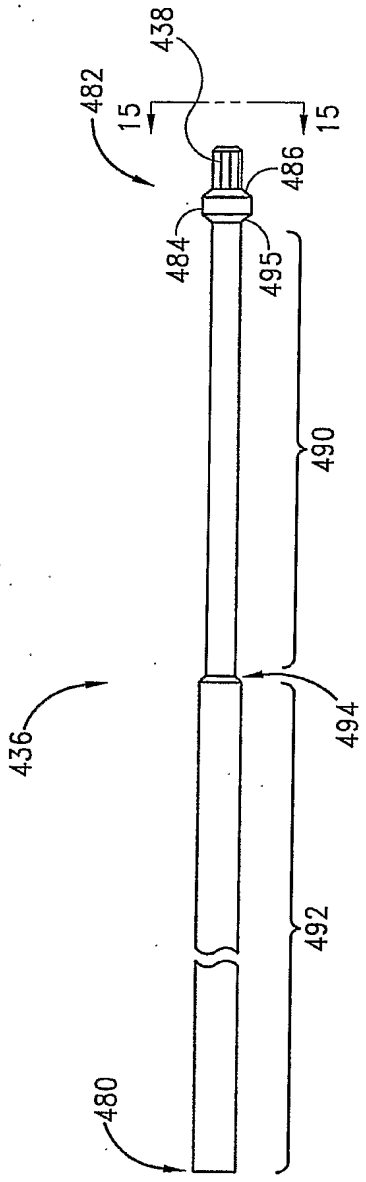

FIG. 14

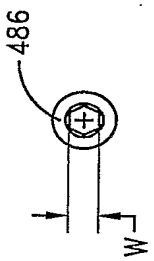

FIG. 15

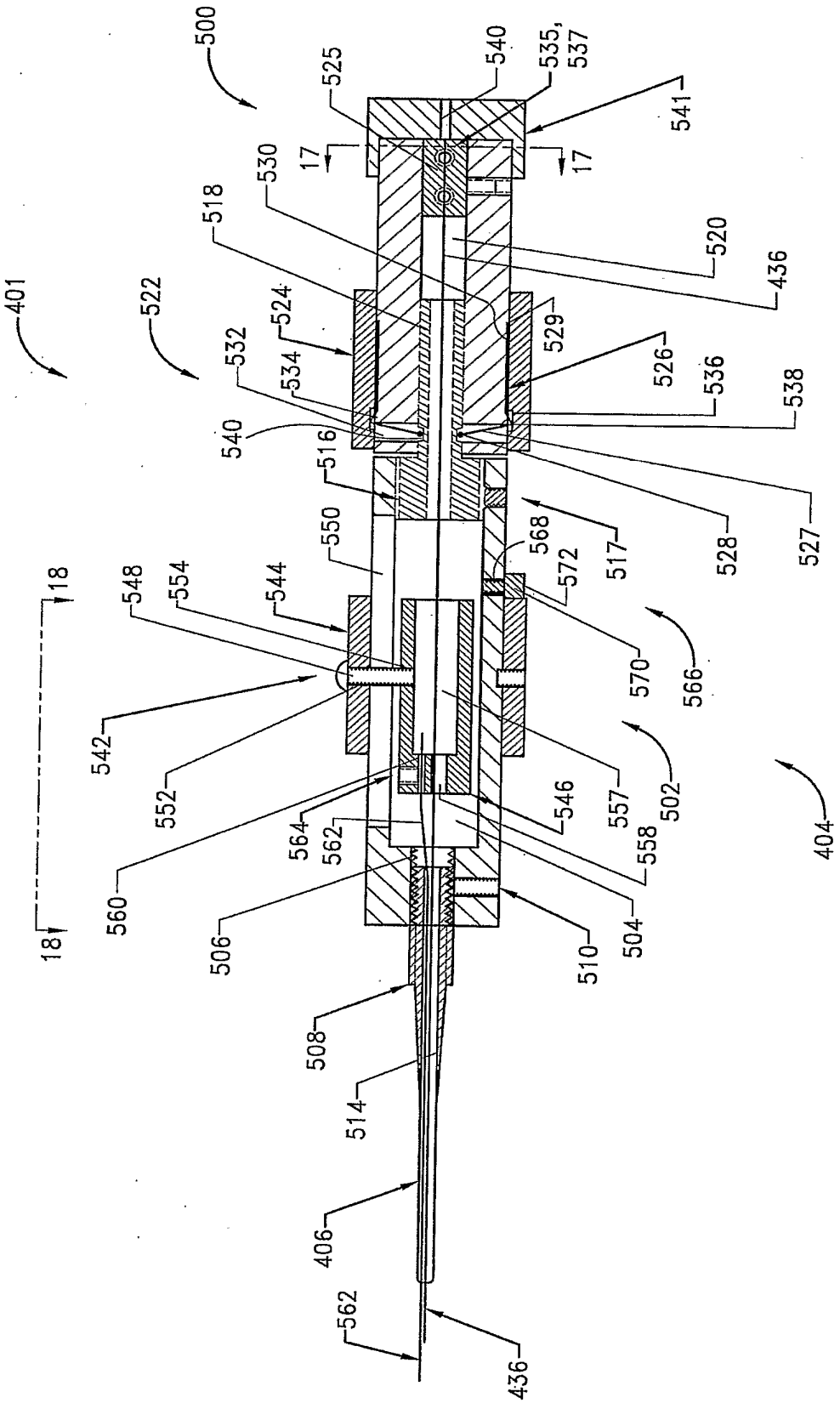
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FIG. 16

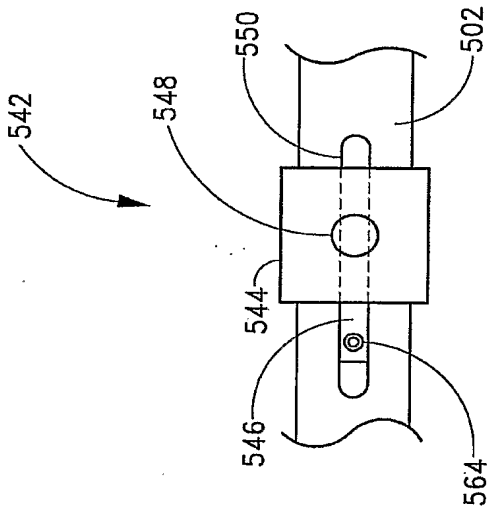


FIG. 18

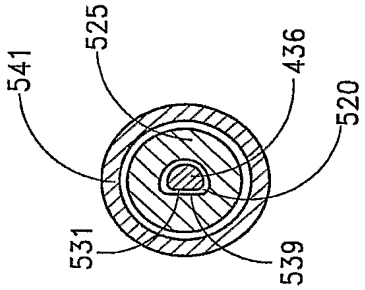


FIG. 17

FIG. 19

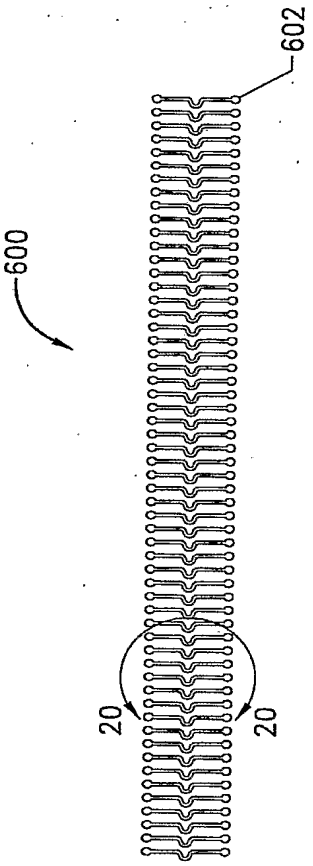
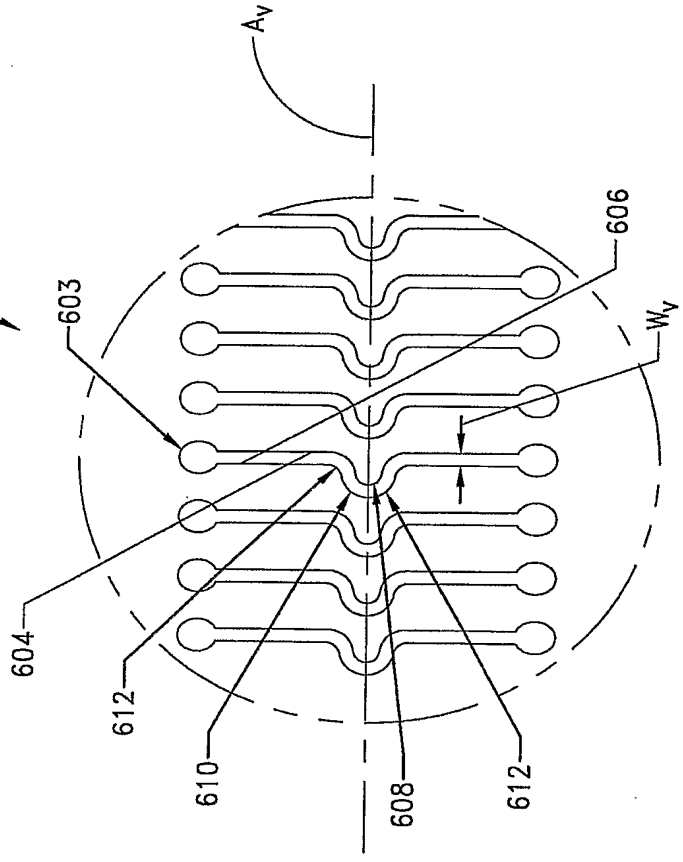


FIG. 20



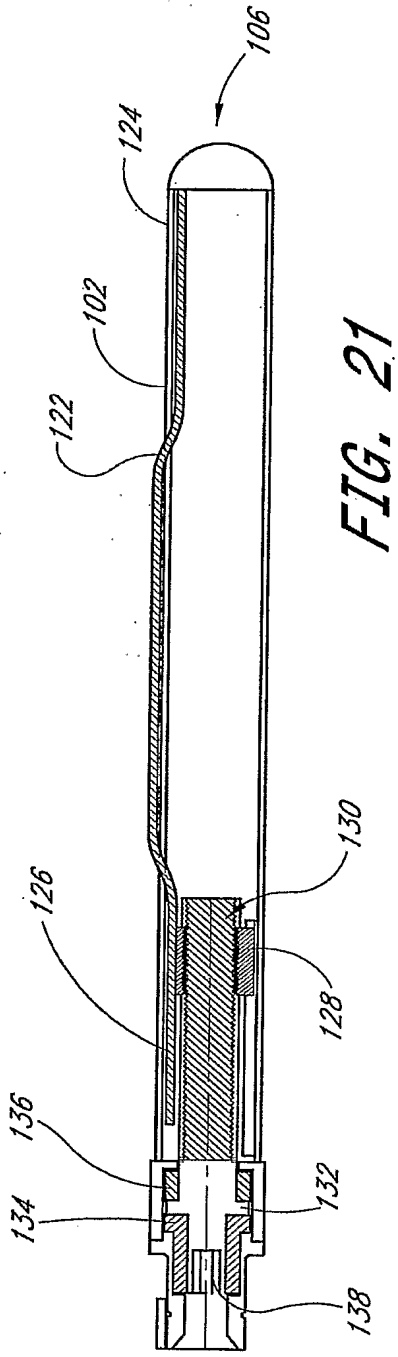

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FIG. 21

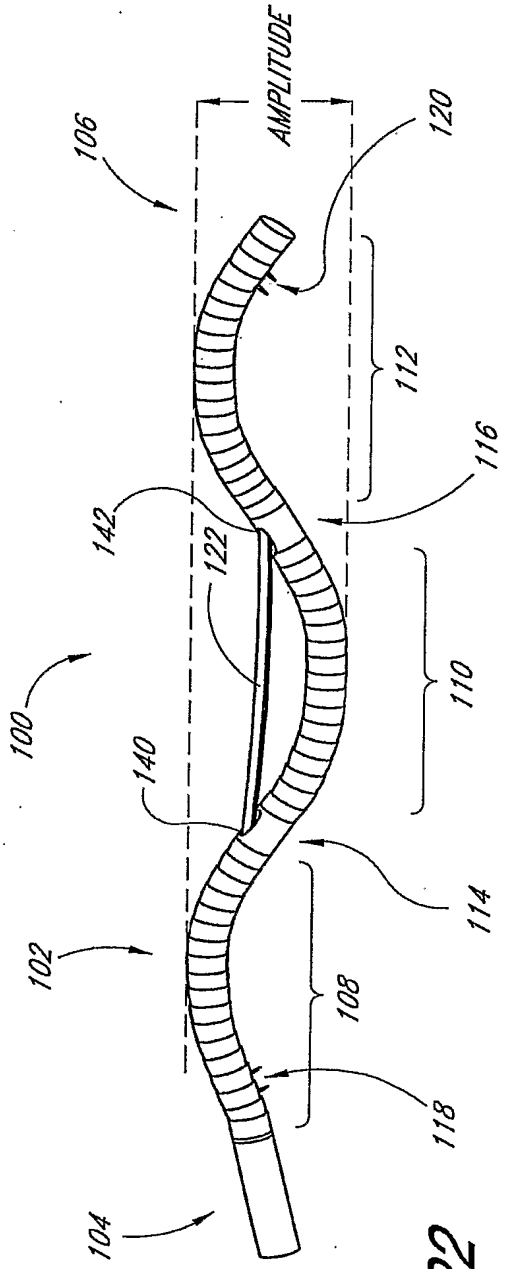
AMPLITUDE
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FIG. 22

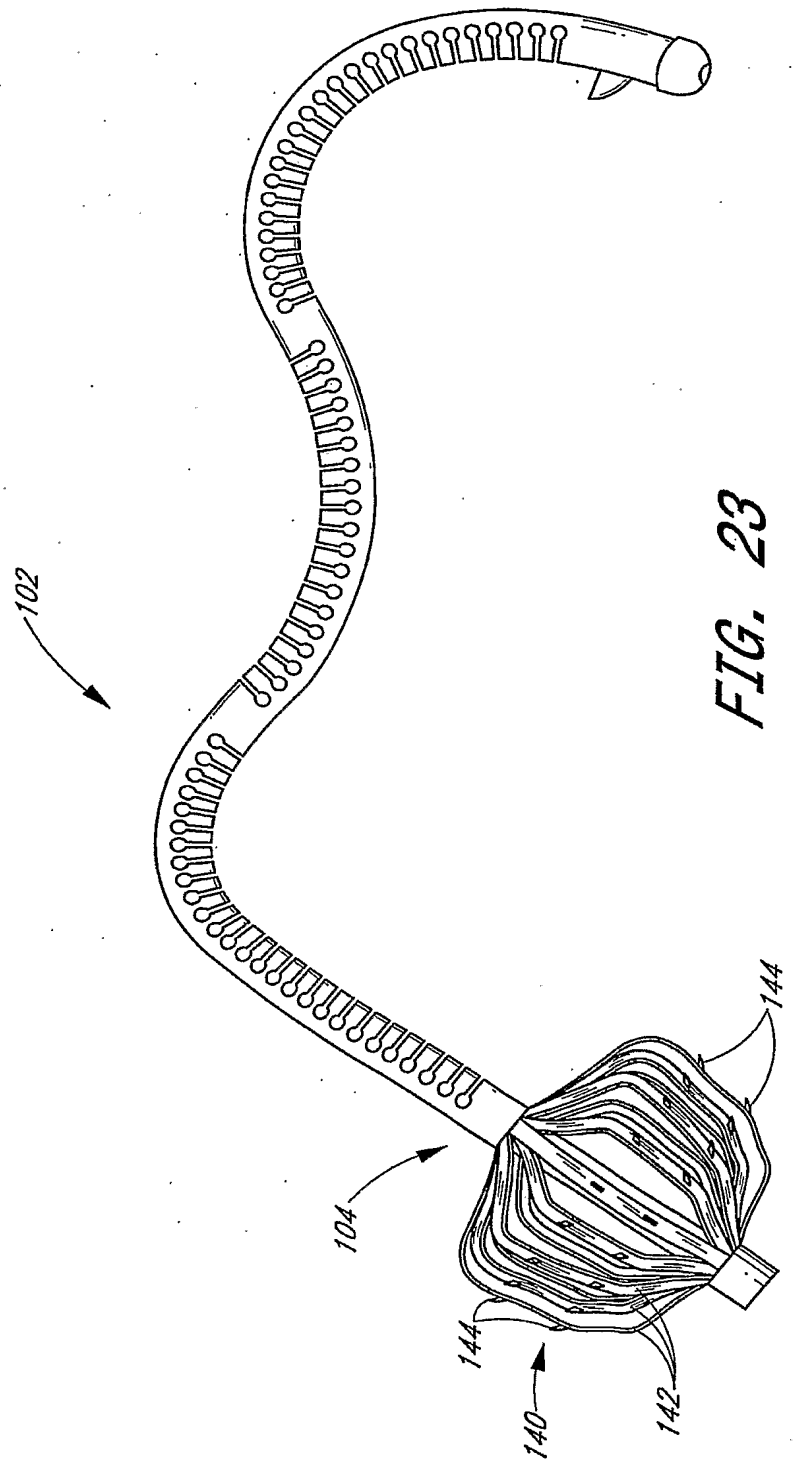

FIG. 23

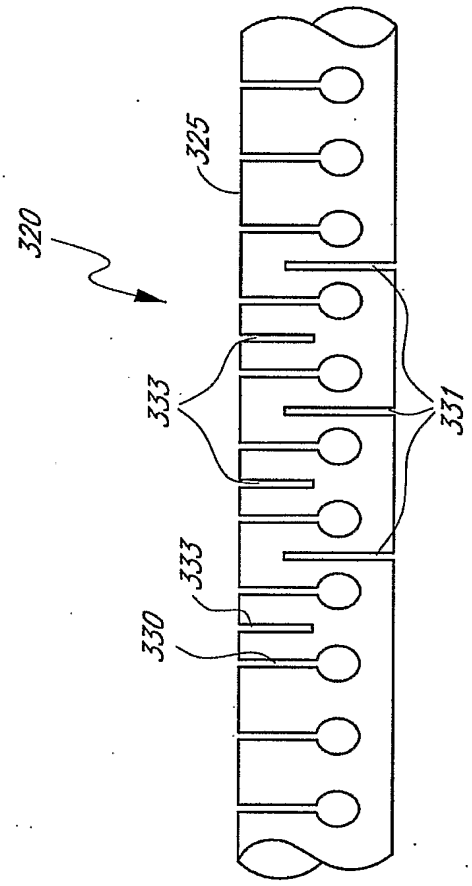

FIG. 24

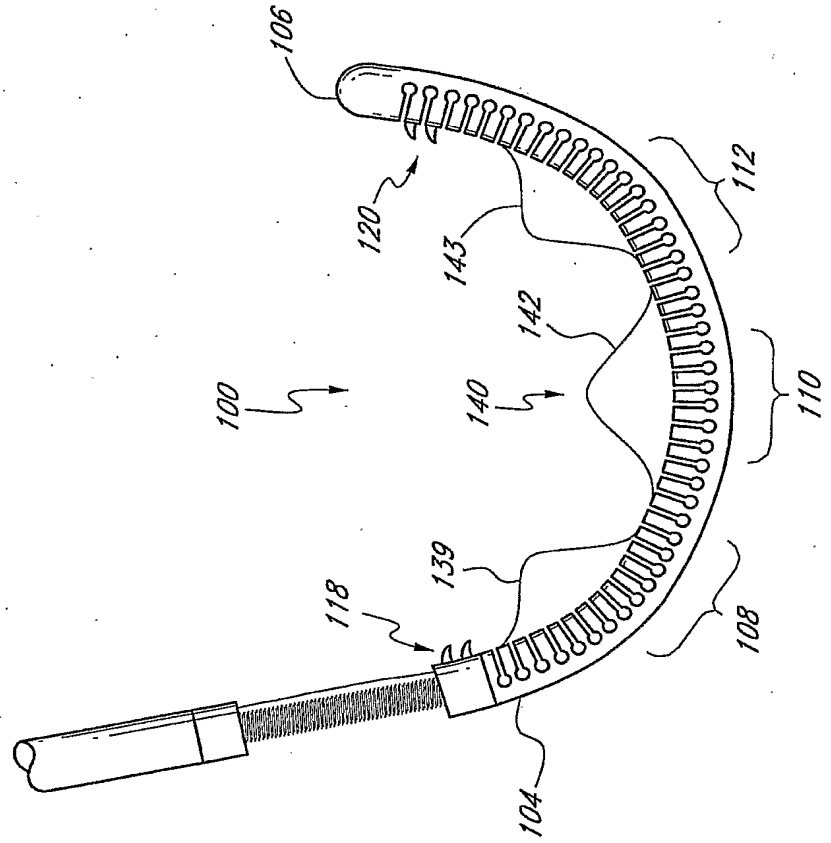

FIG. 25

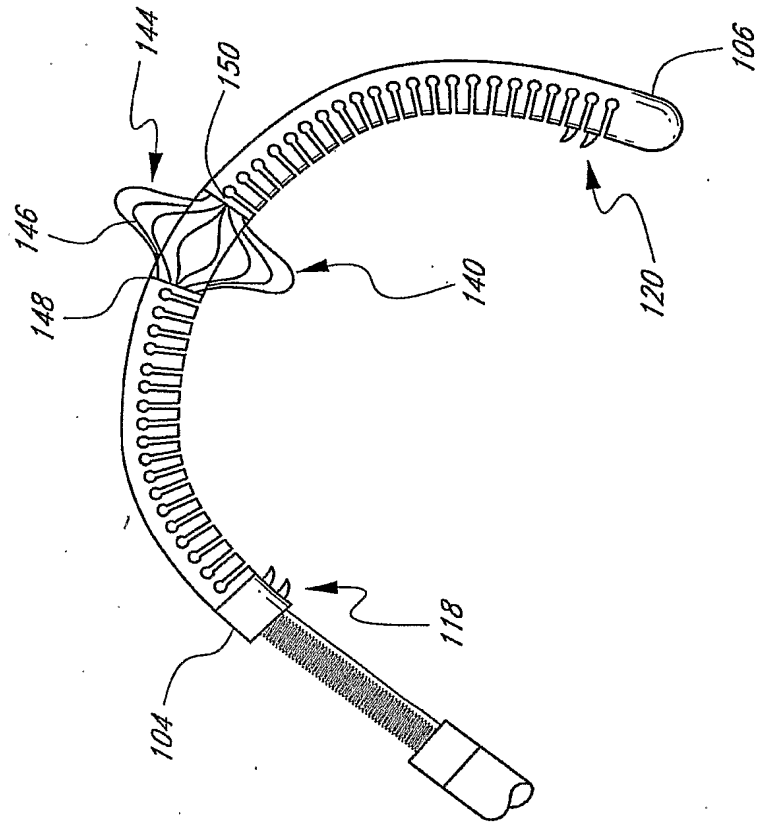

FIG. 26

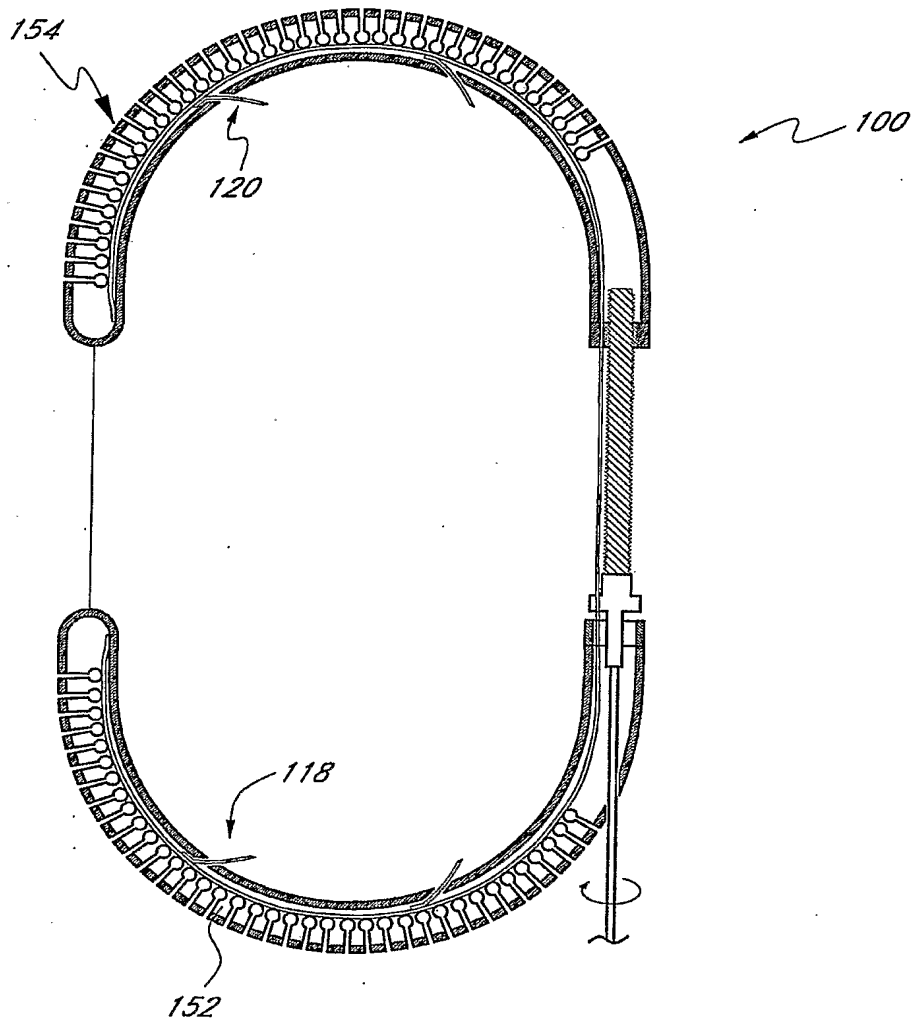

FIG. 27

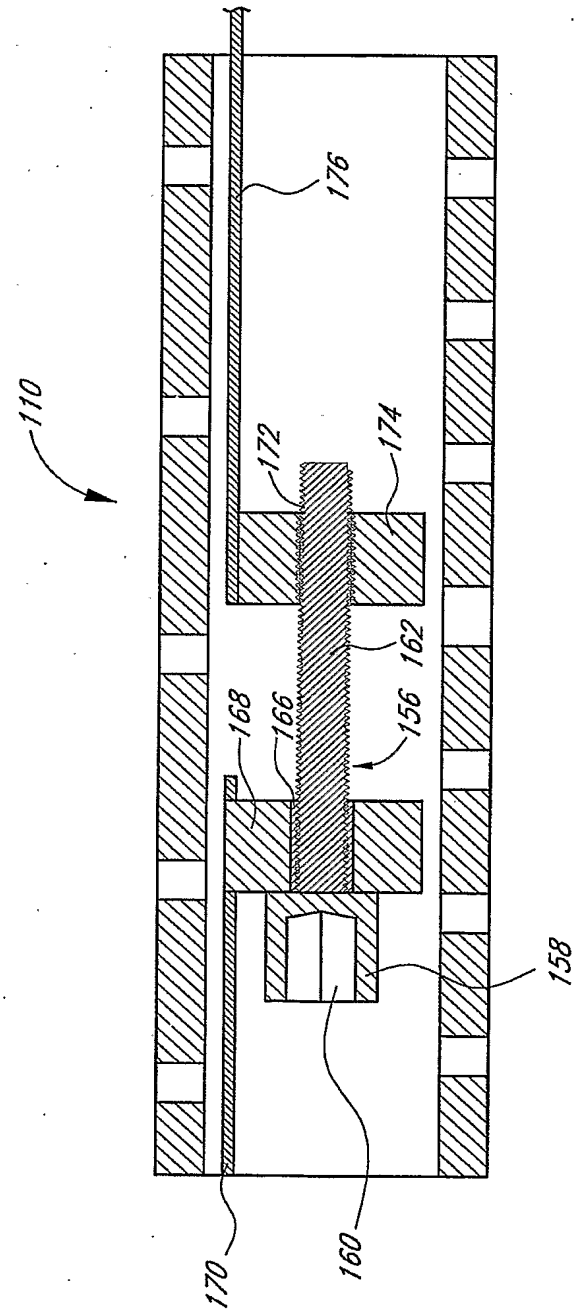

FIG. 28

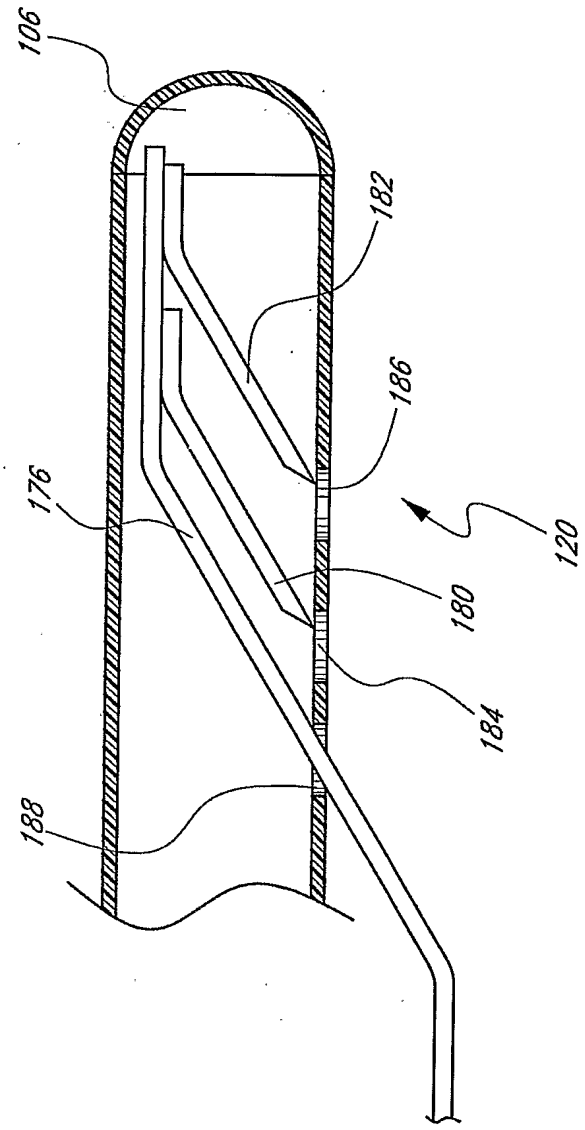

FIG. 29

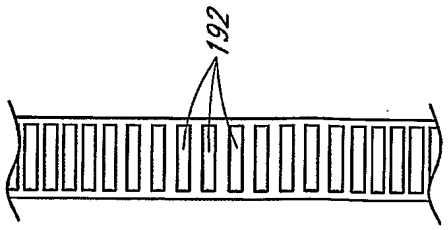

FIG. 30B

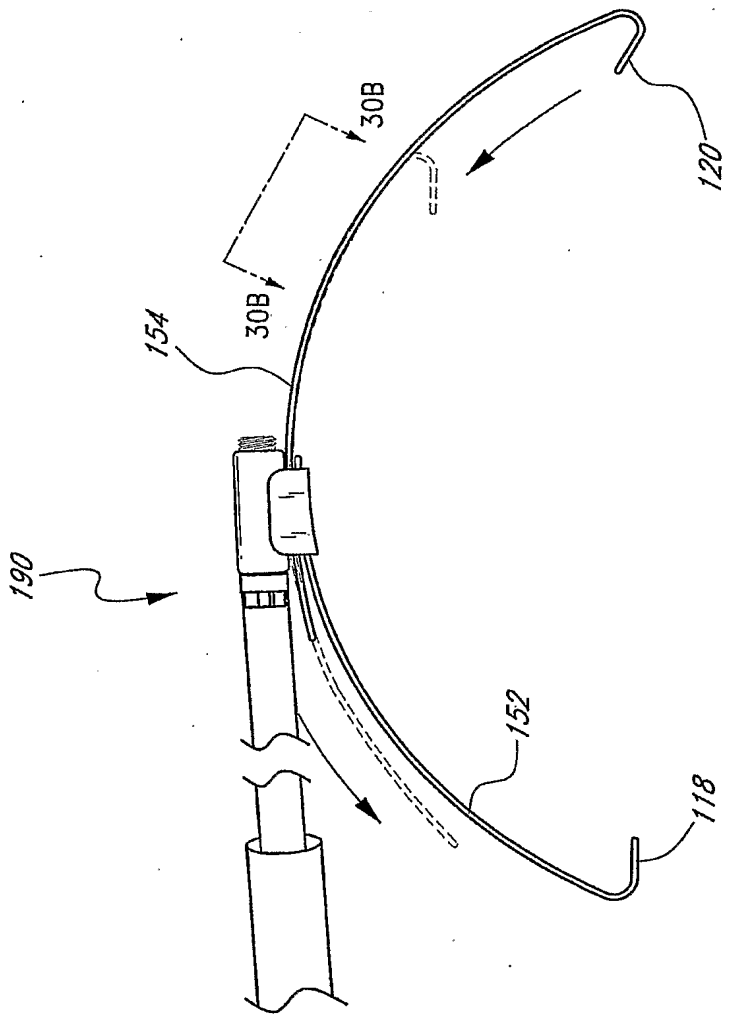

FIG. 30A

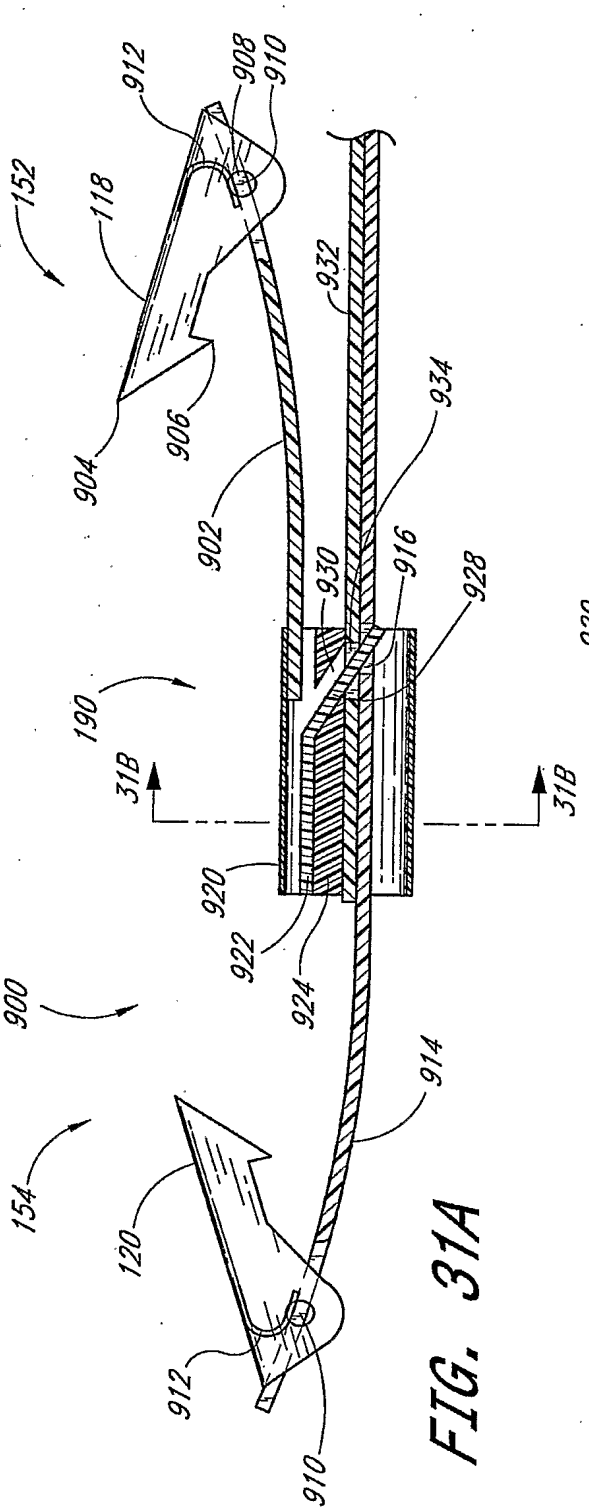

FIG. 31A

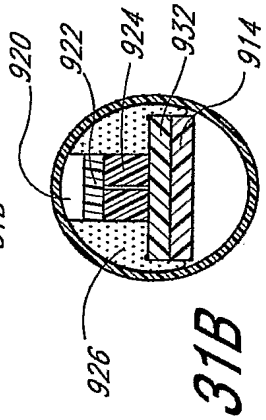

FIG. 31B

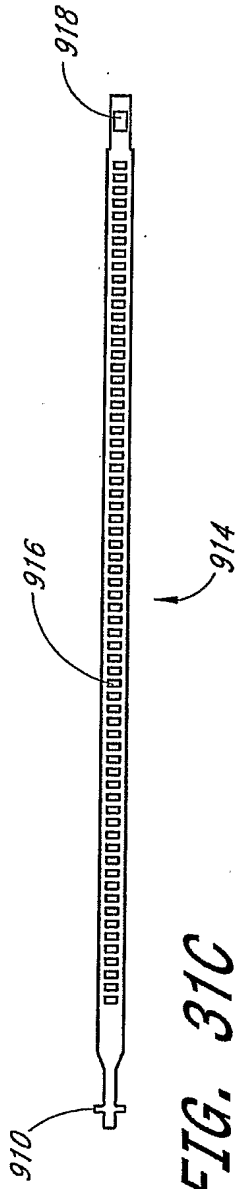

FIG. 31C

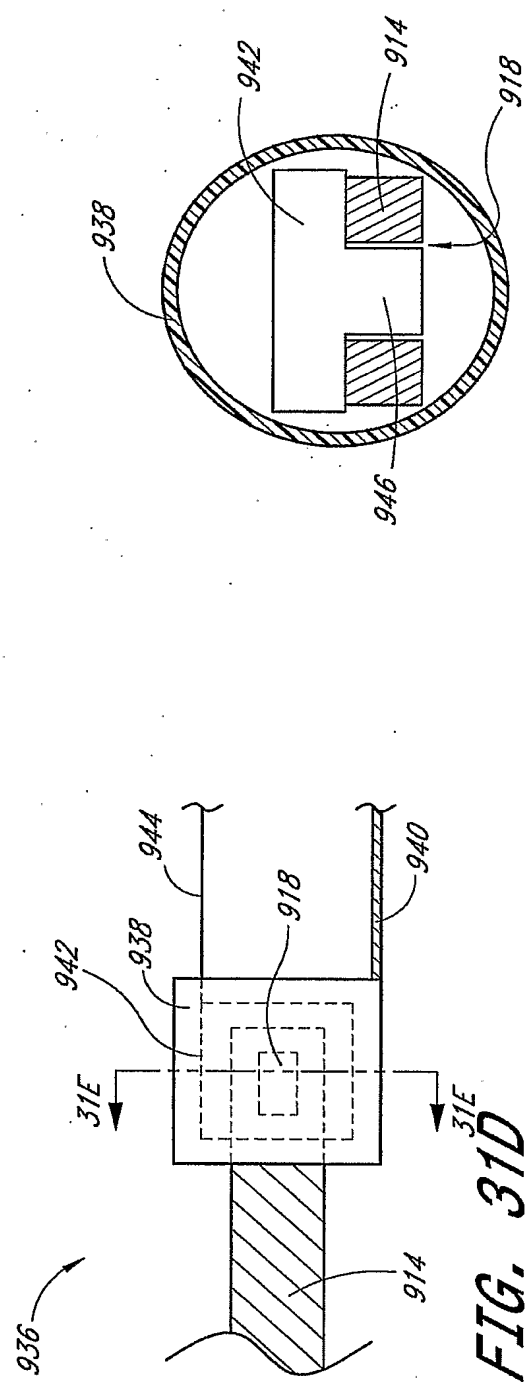

FIG. 31D

FIG. 31E

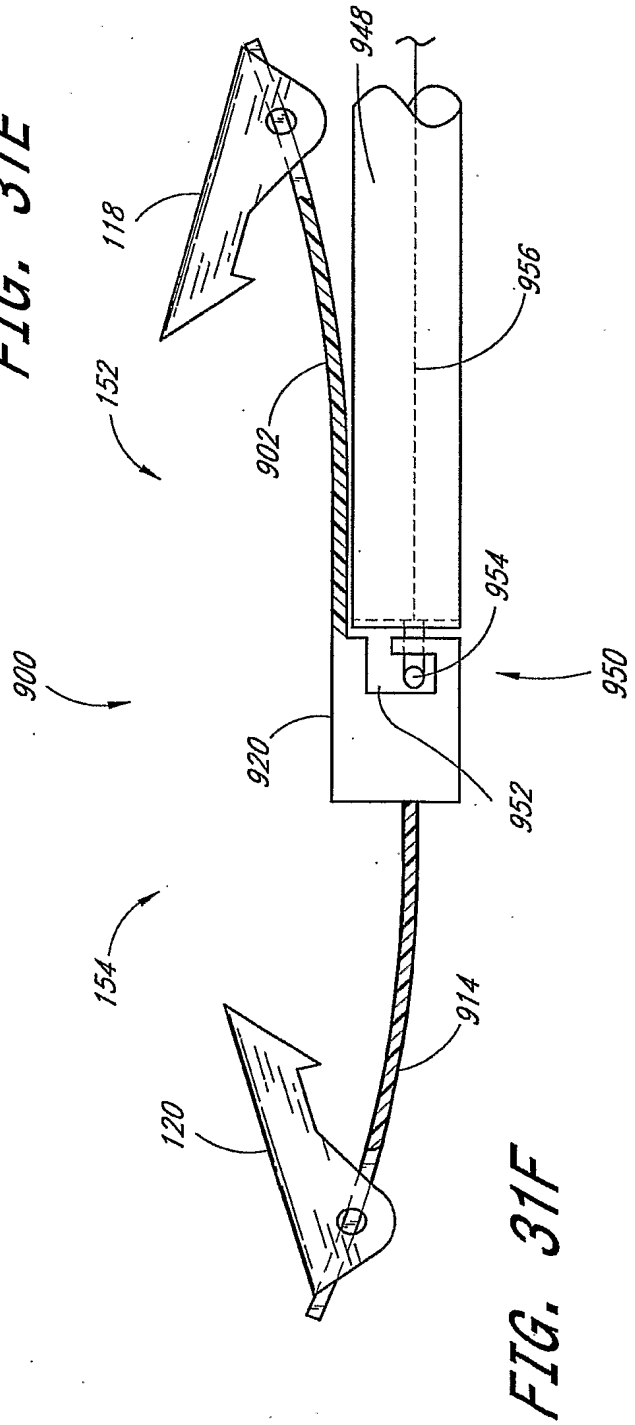

FIG. 31F

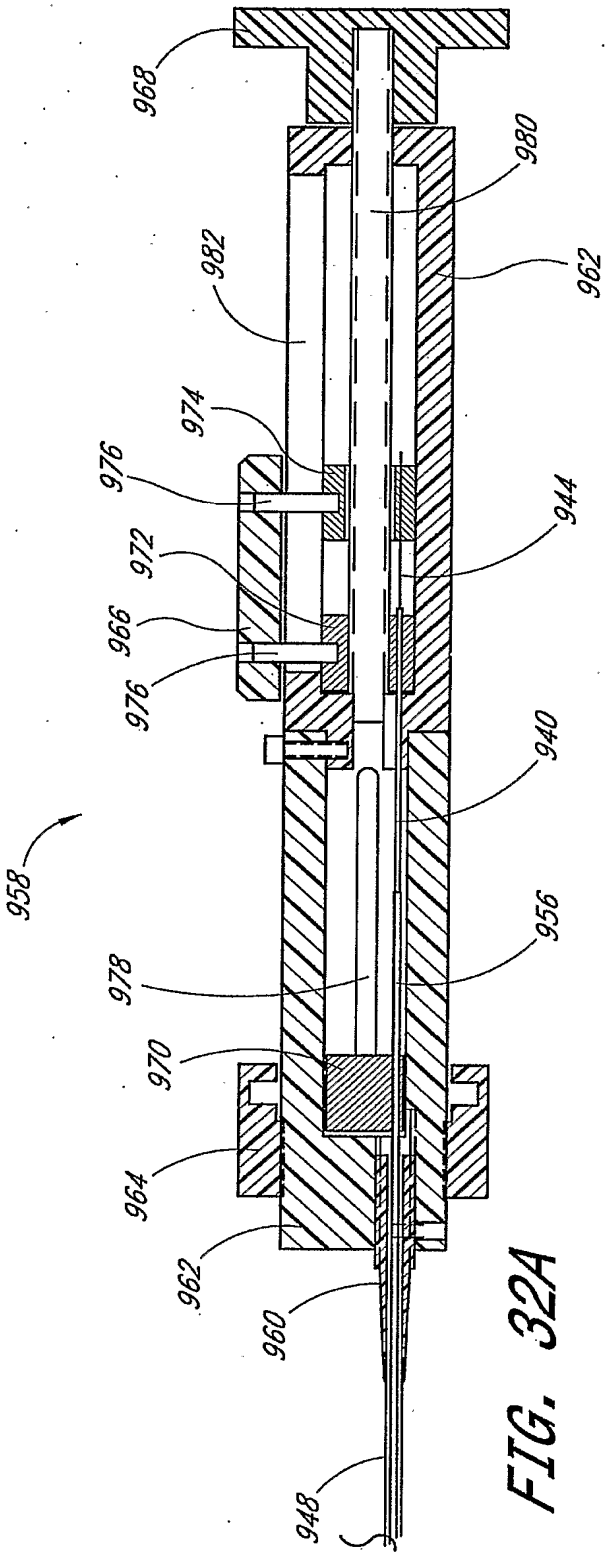

FIG. 32A

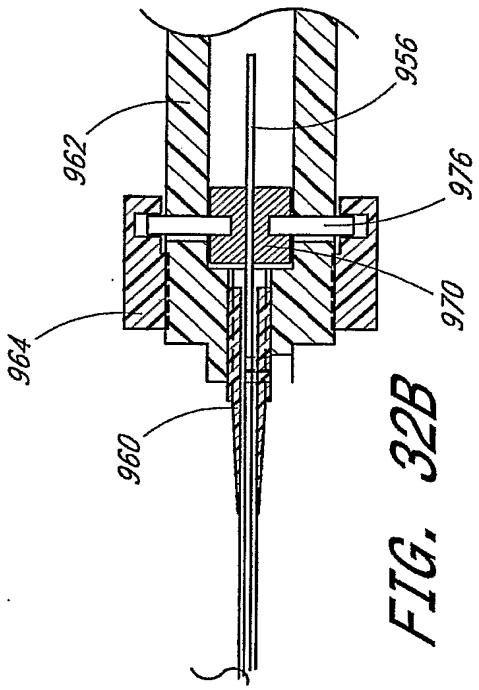

FIG. 32B

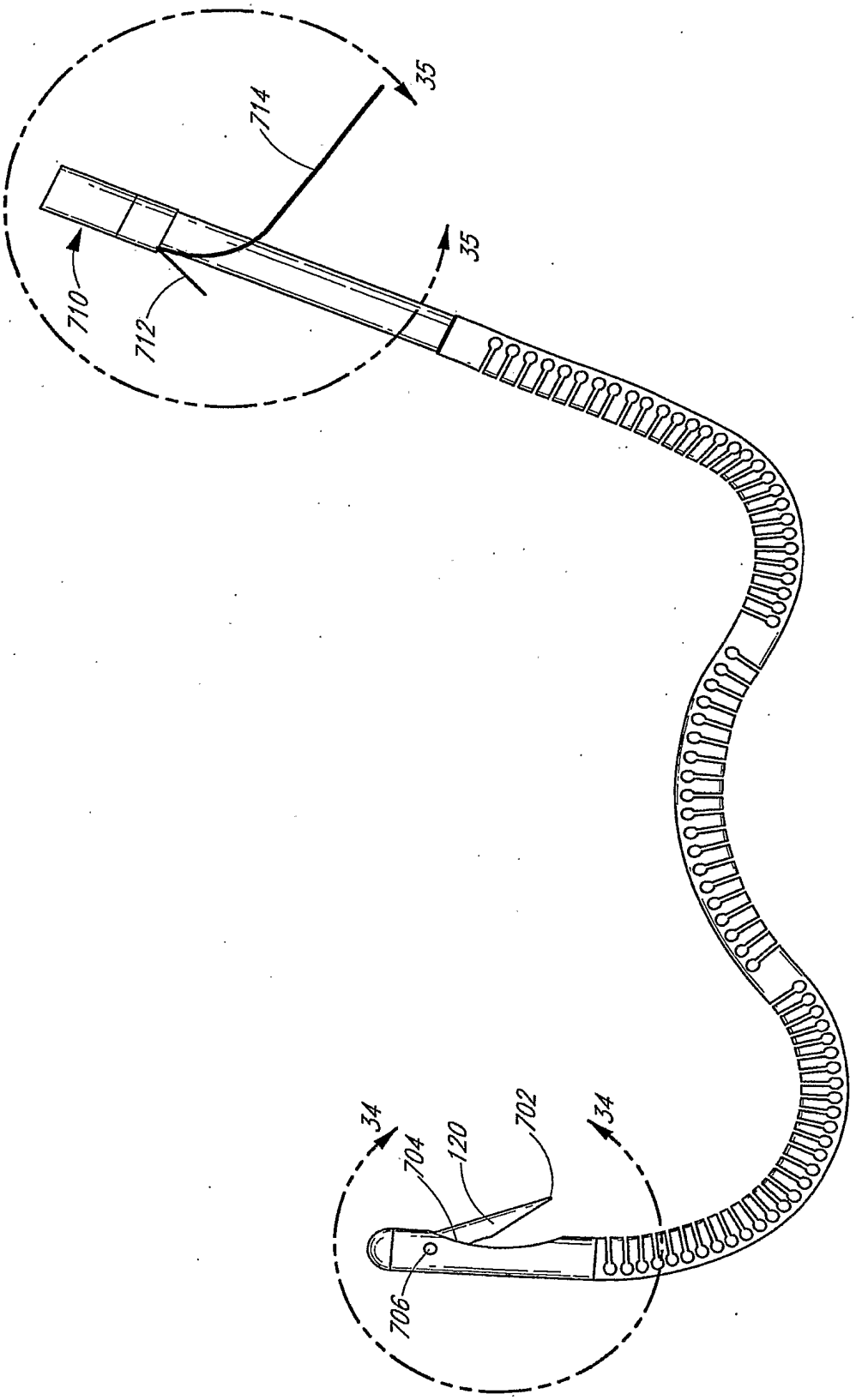

FIG. 33

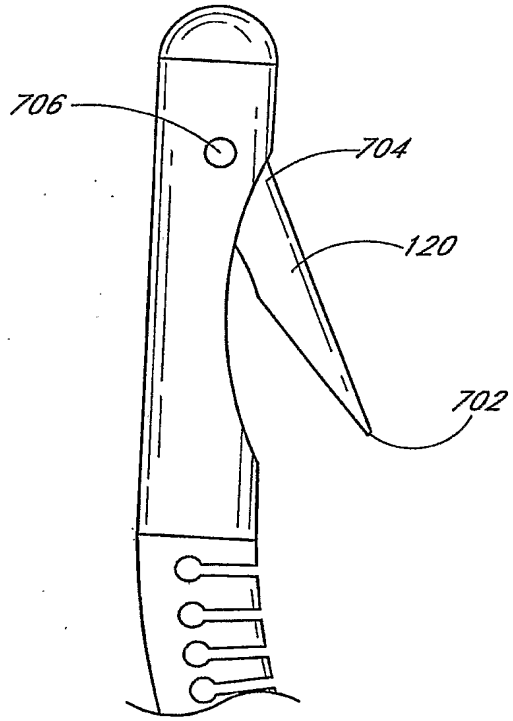

FIG. 34

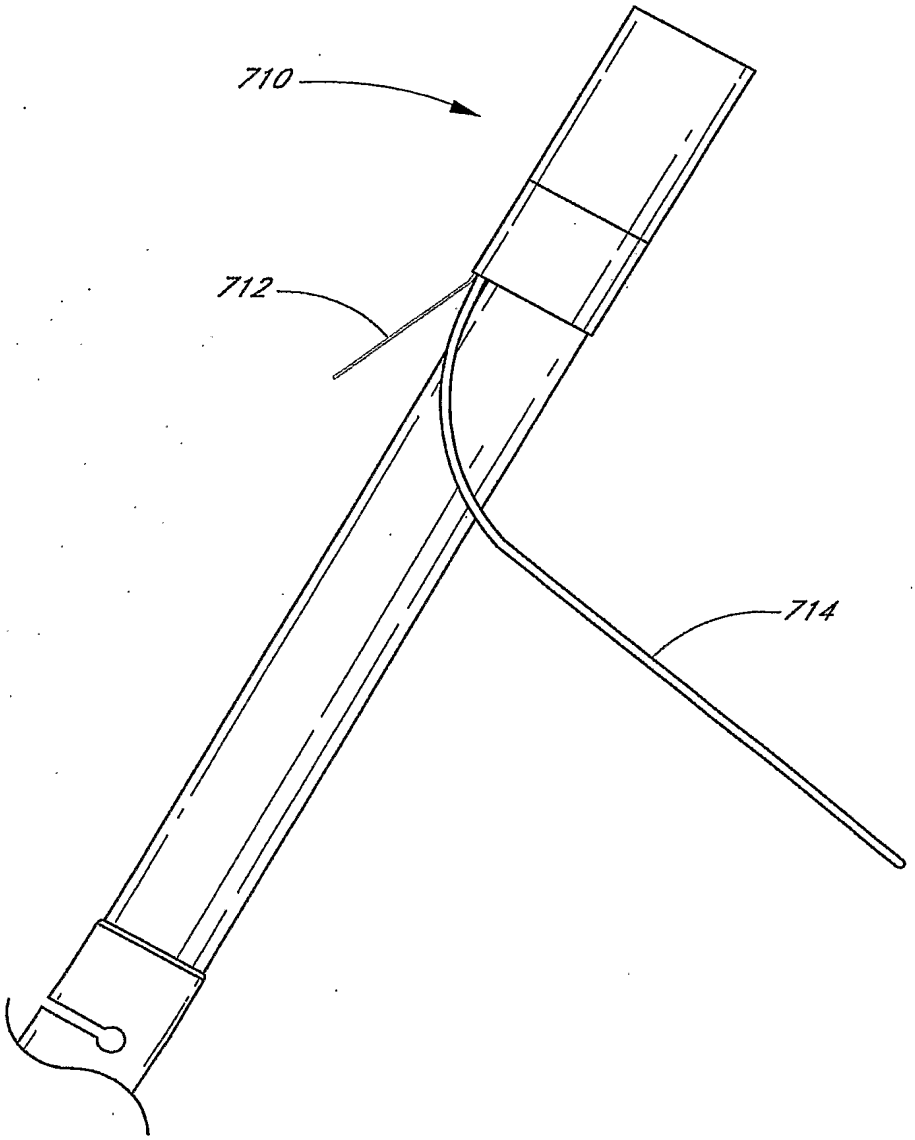

FIG. 35

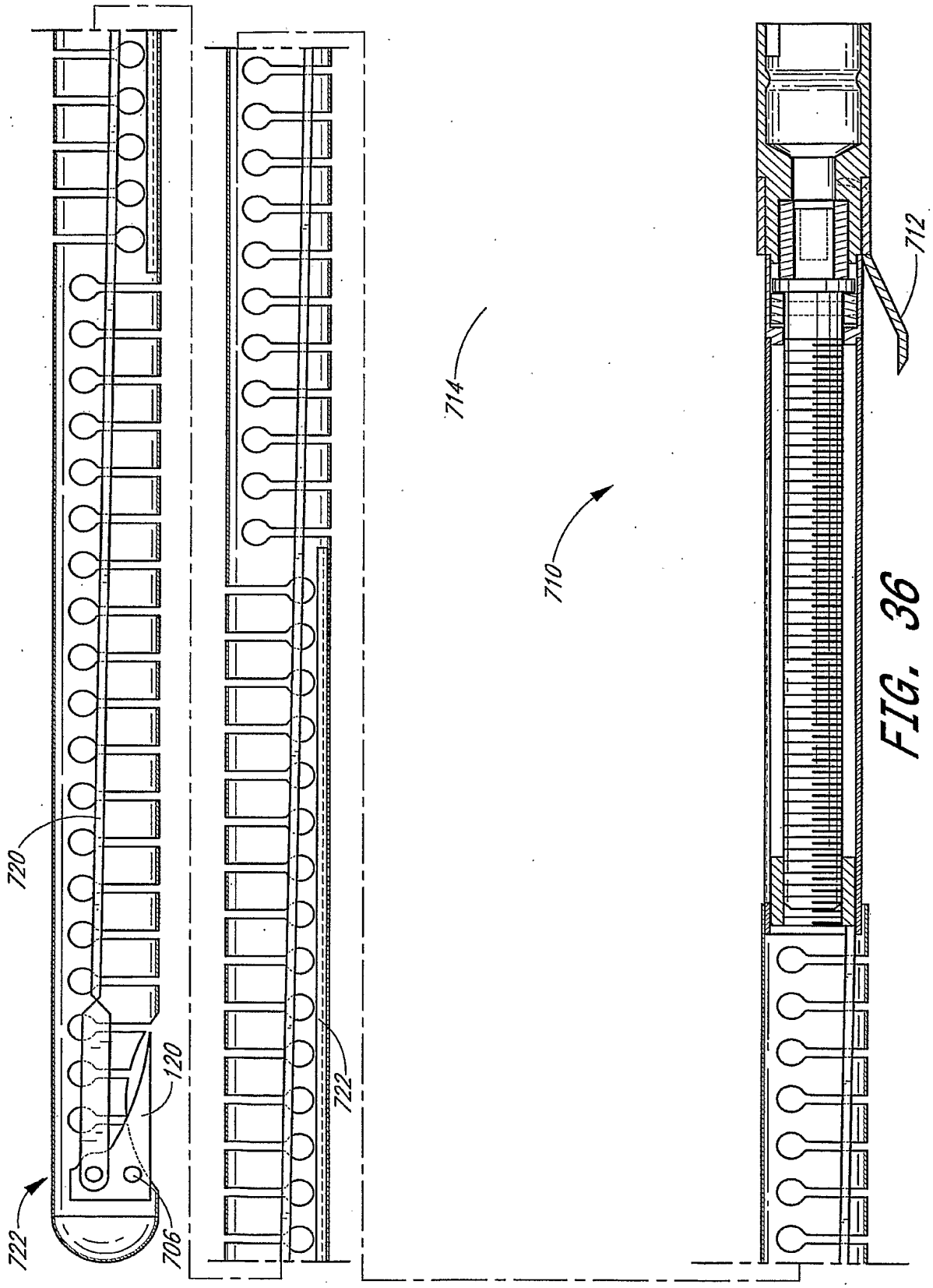

FIG. 36

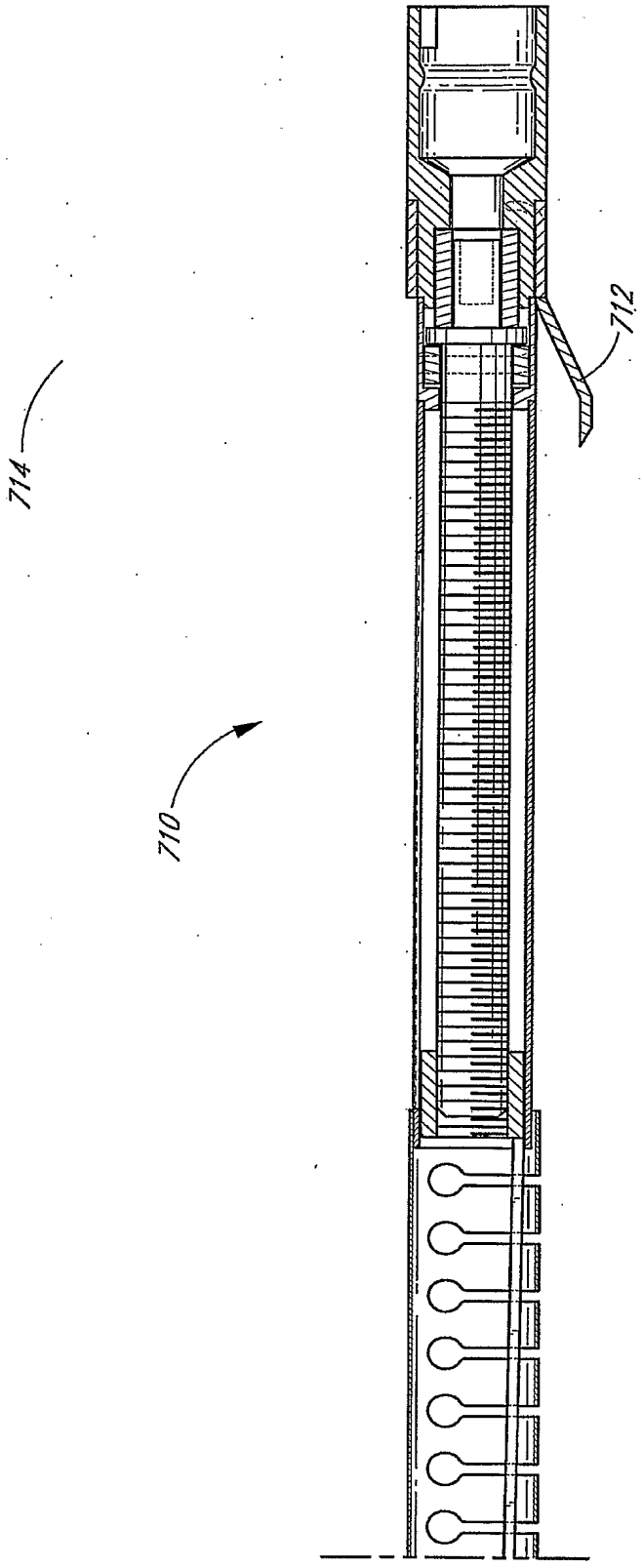

FIG. 37

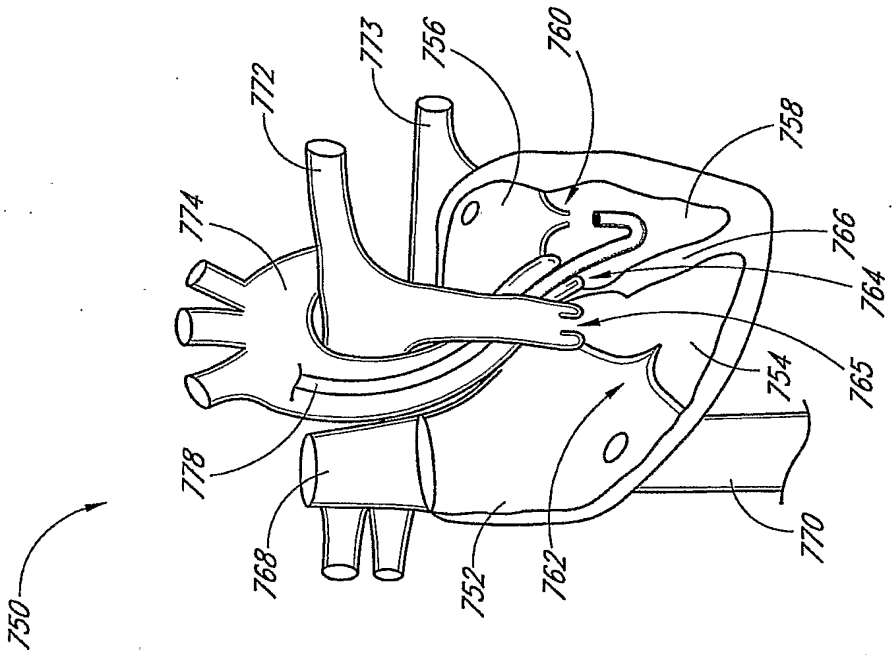

FIG. 38

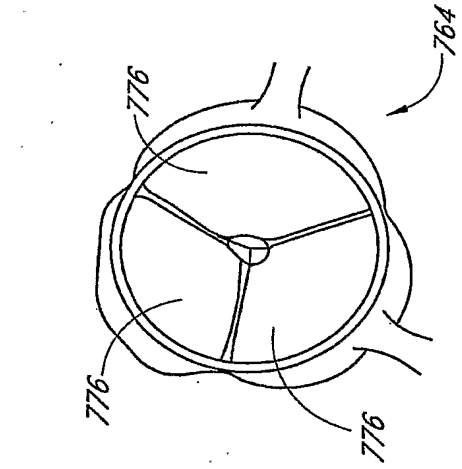

FIG. 38C

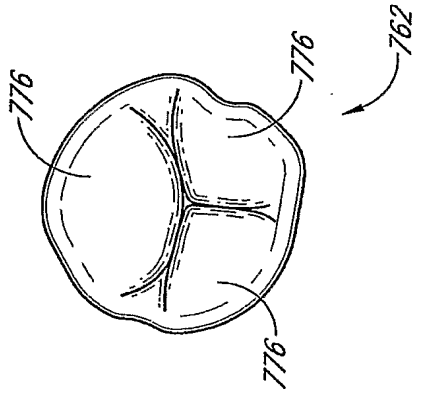

FIG. 38B

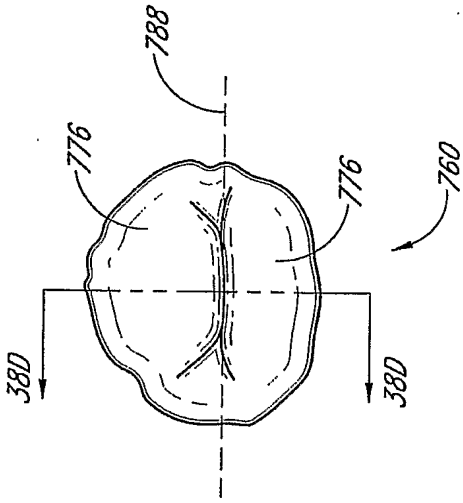

FIG. 38A

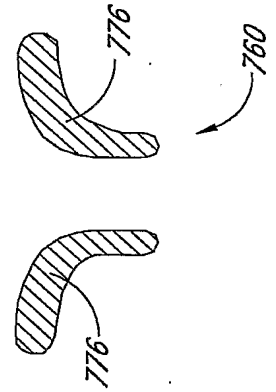

FIG. 38F

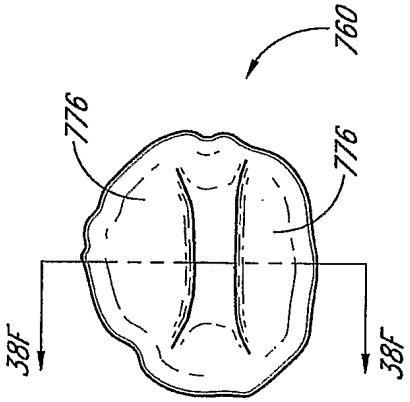

FIG. 38E

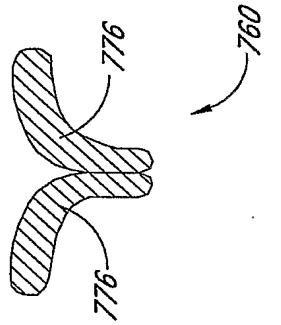

FIG. 38D

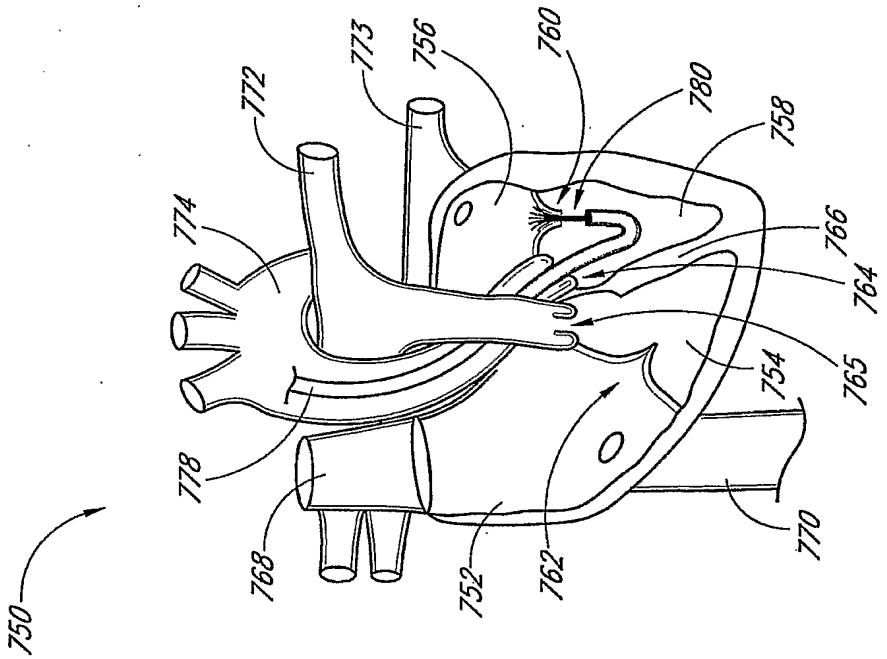
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FIG. 39

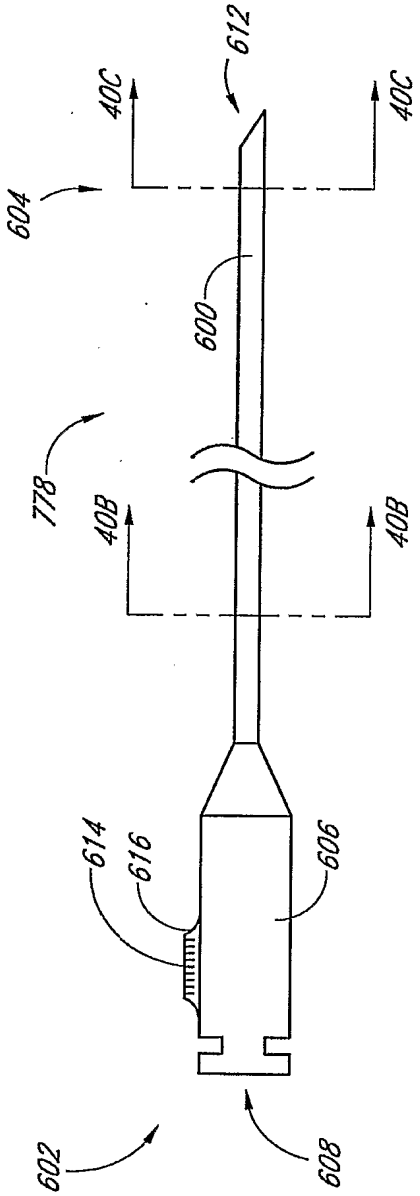

FIG. 40A

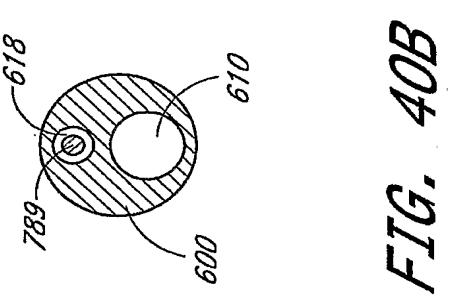

FIG. 40B

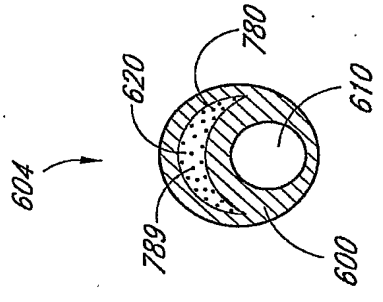

FIG. 40C

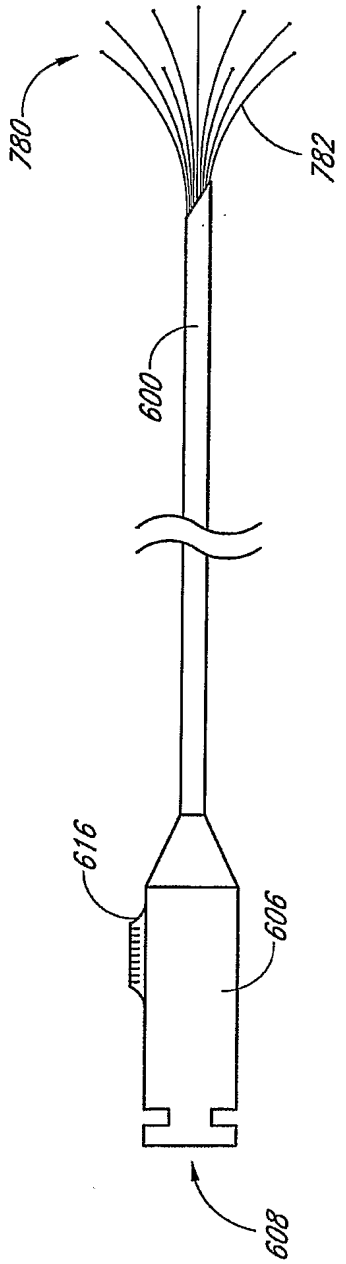

FIG. 40D

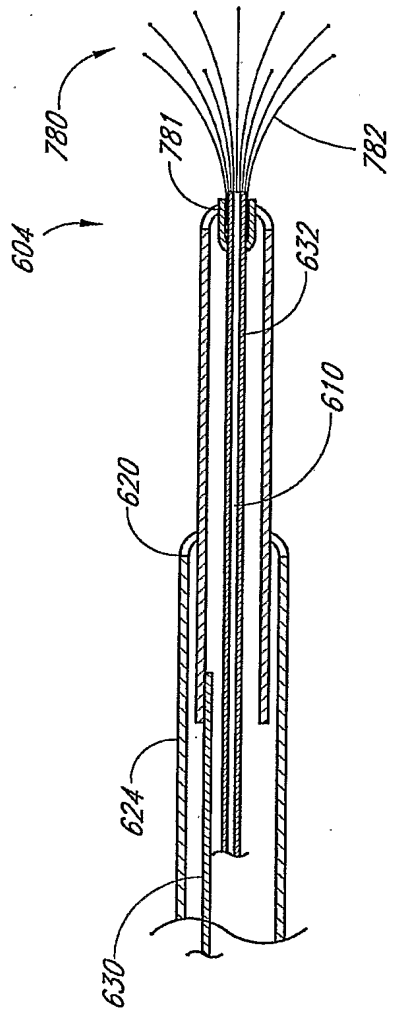

FIG. 40E

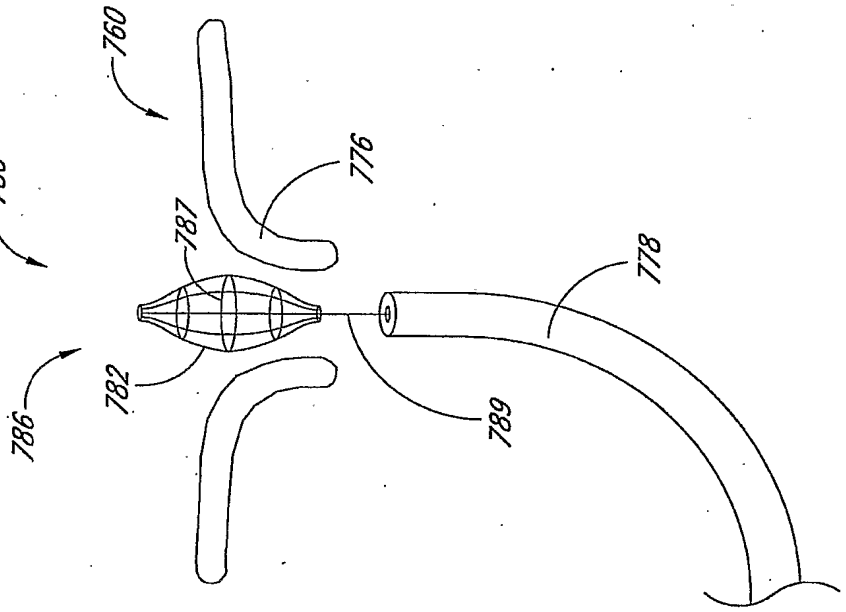

FIG. 41B

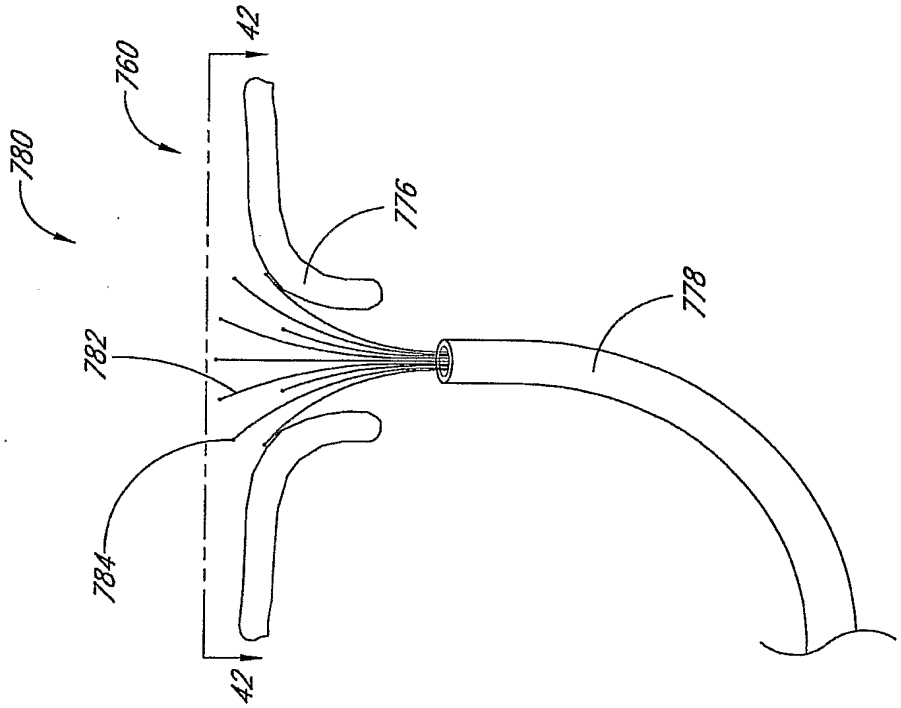

FIG. 41A

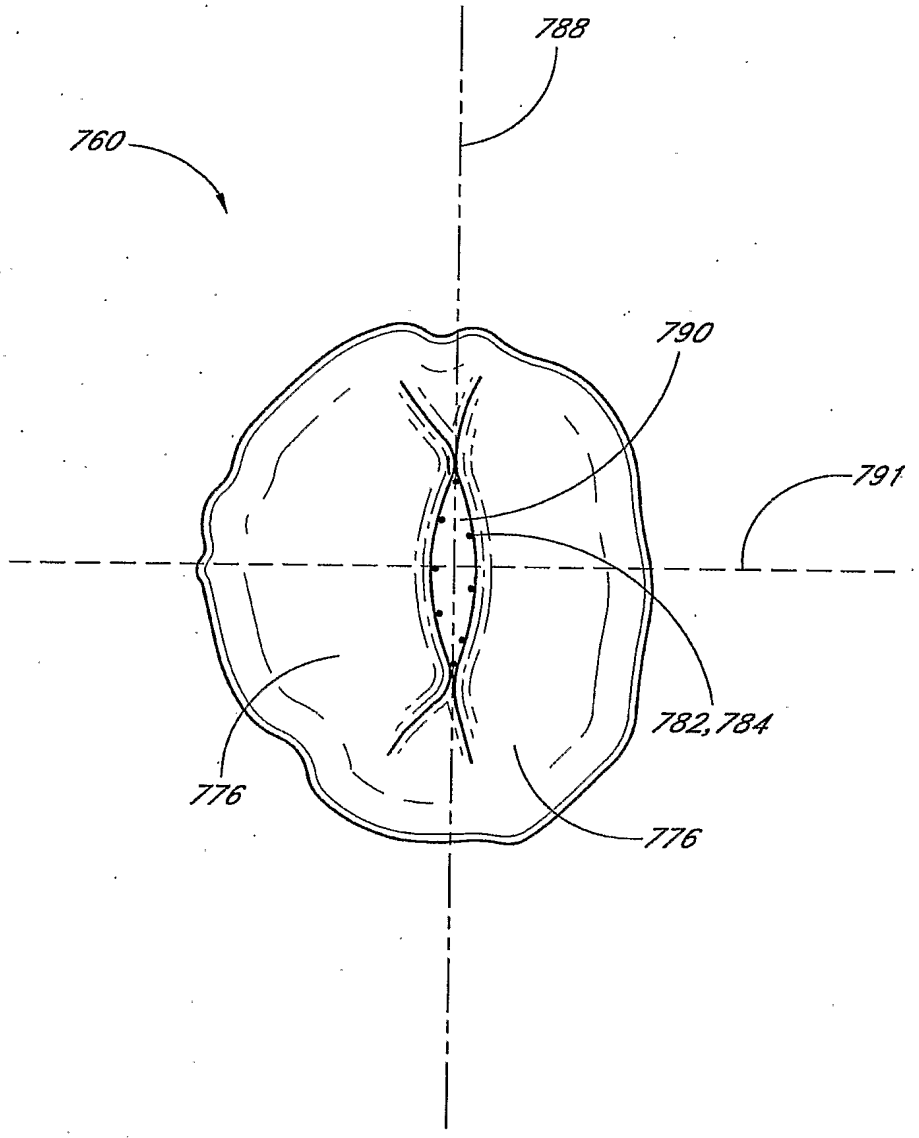

FIG. 42

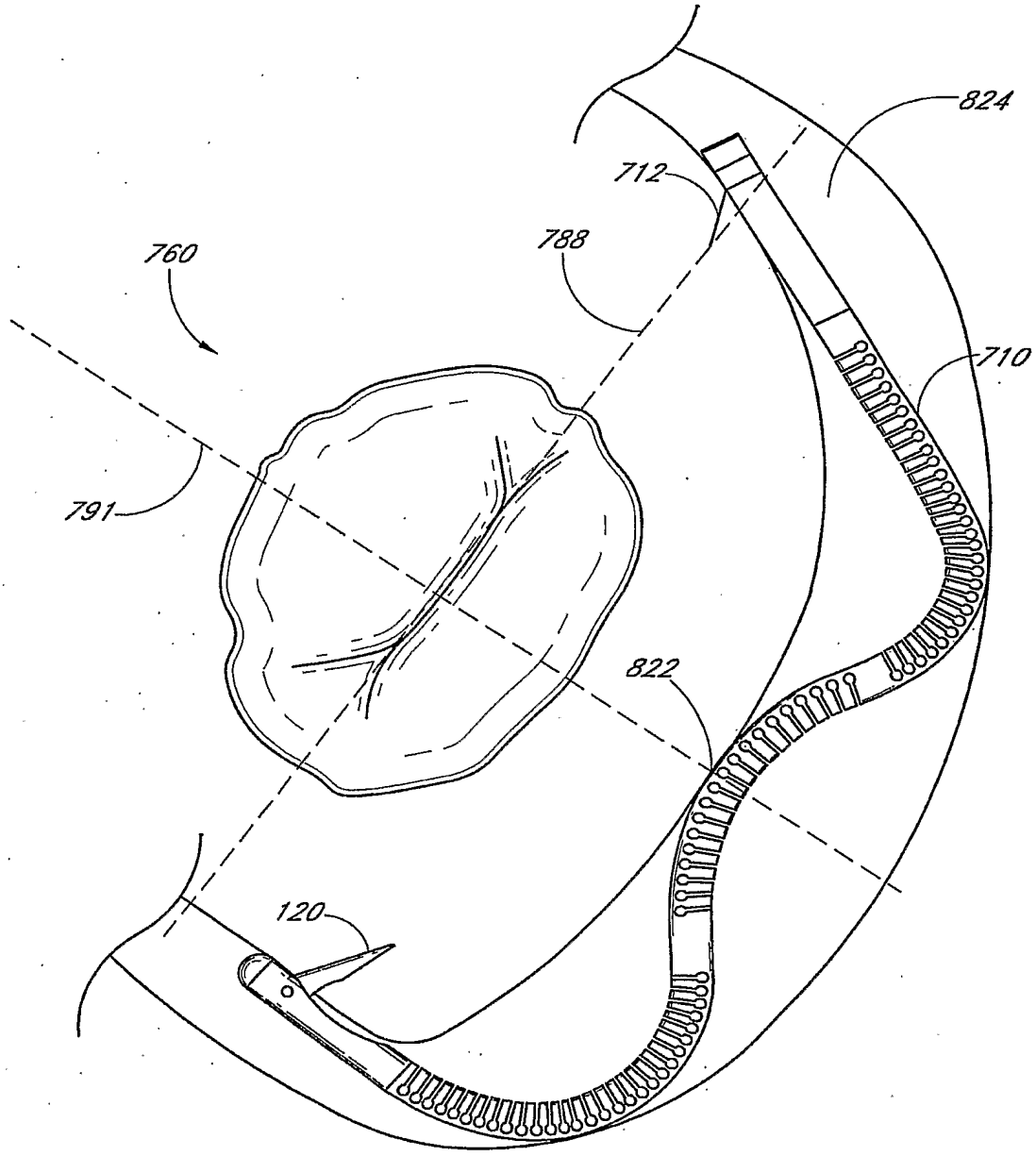

FIG. 42A

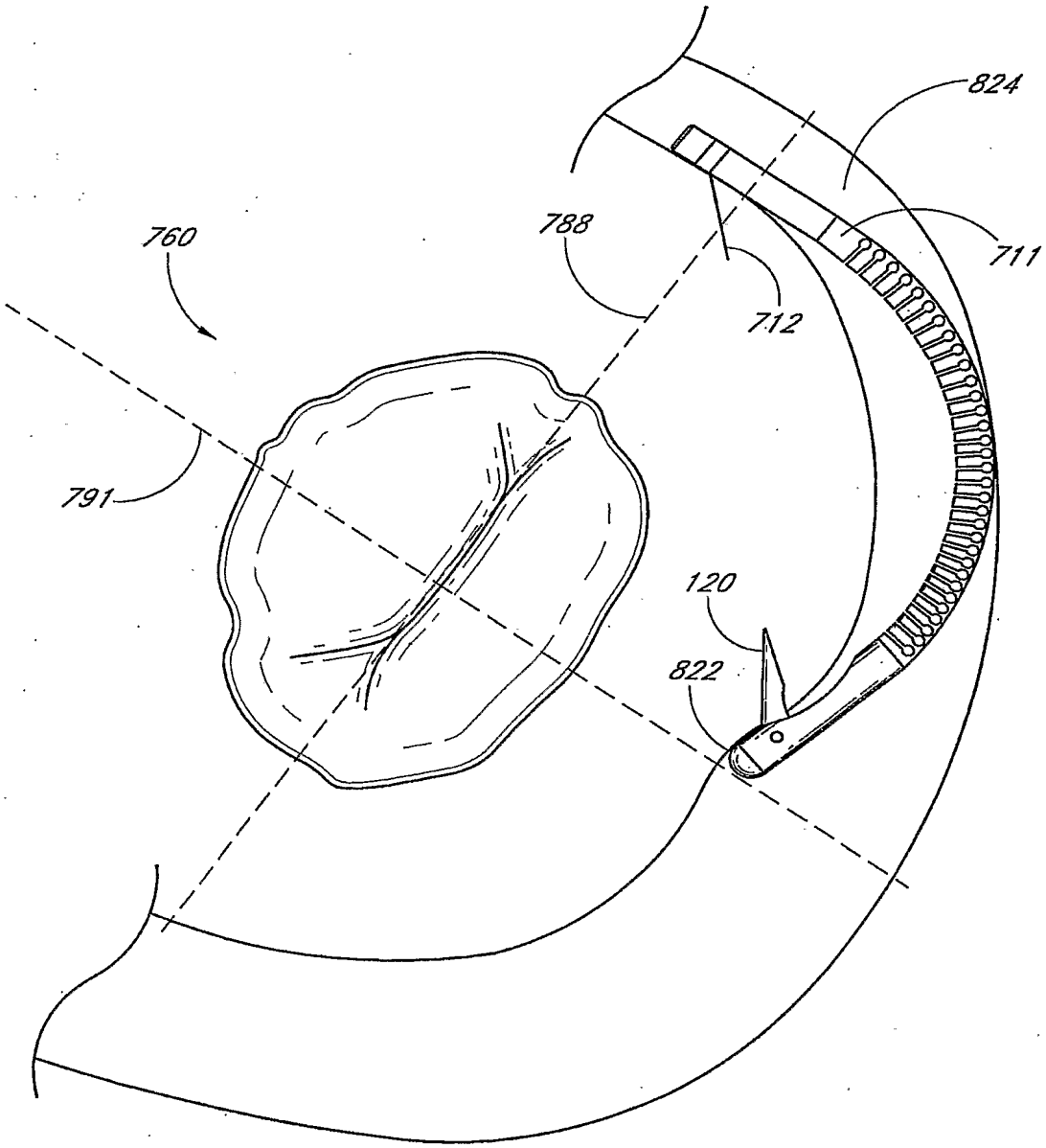

FIG. 42B

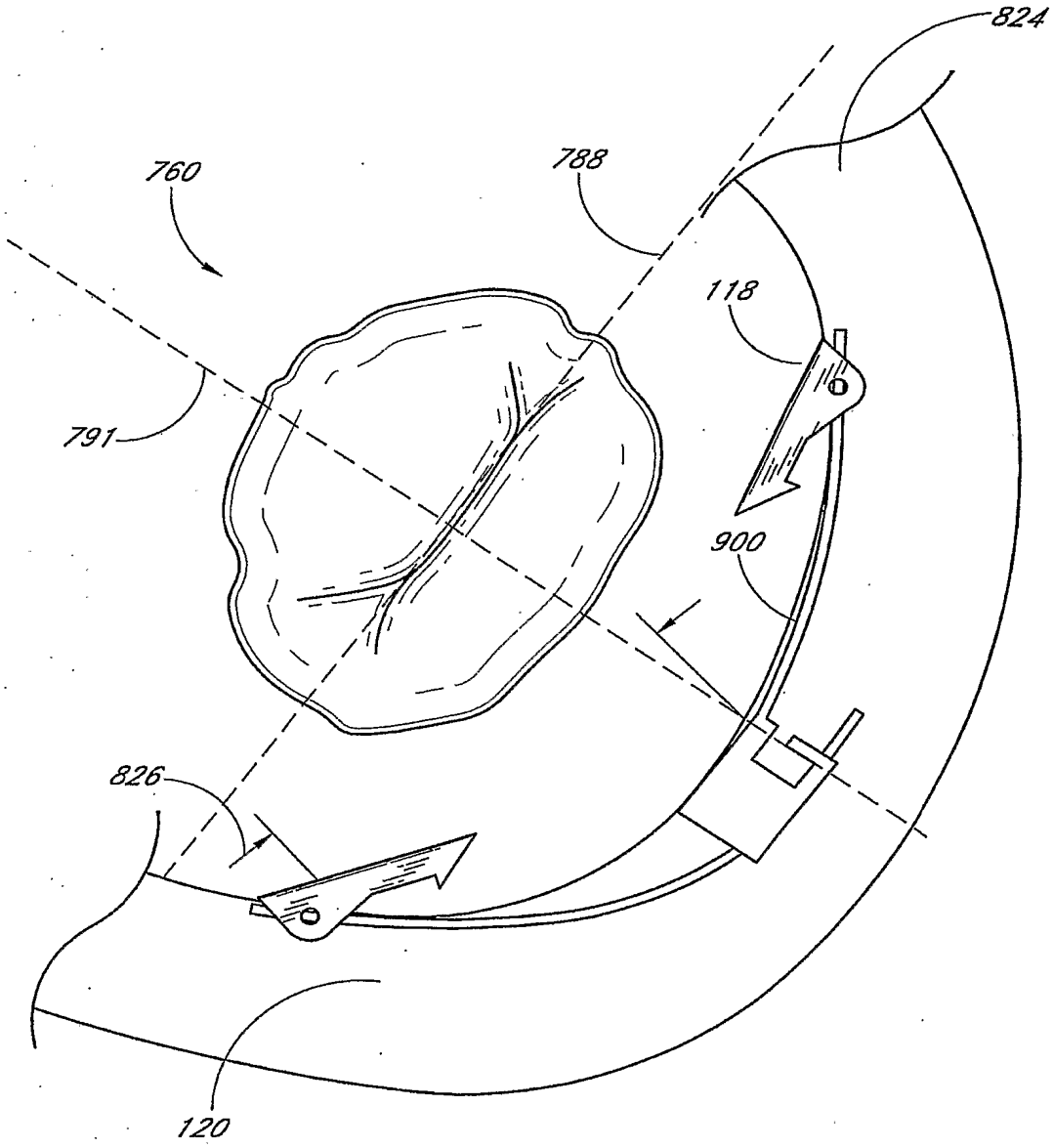

FIG. 42C

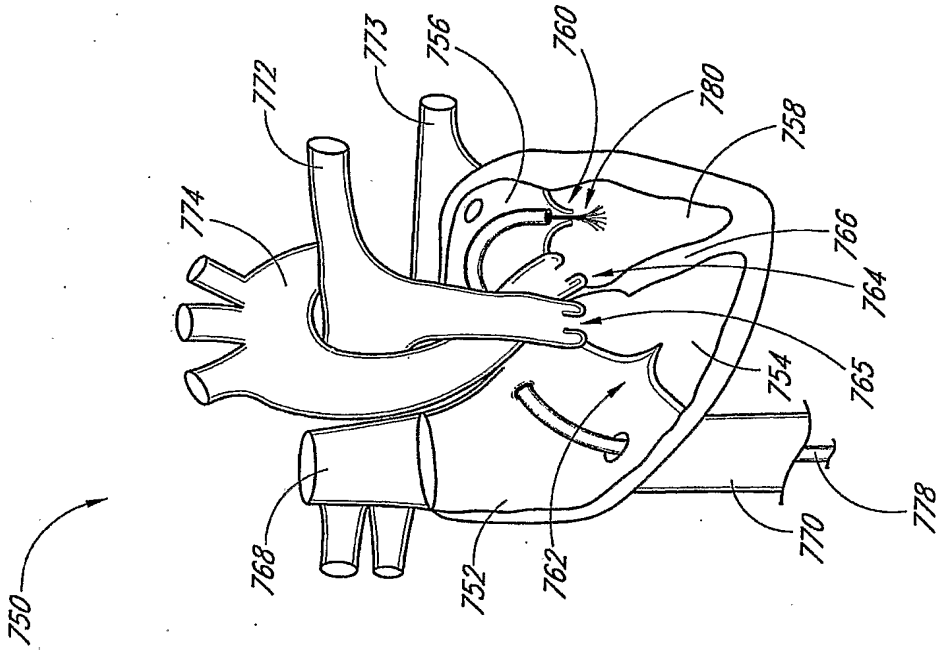
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FIG. 43

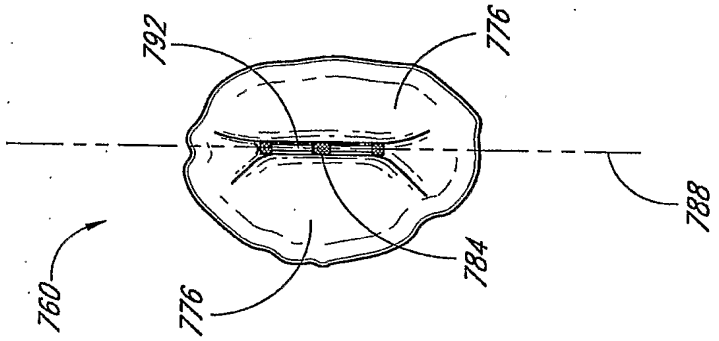
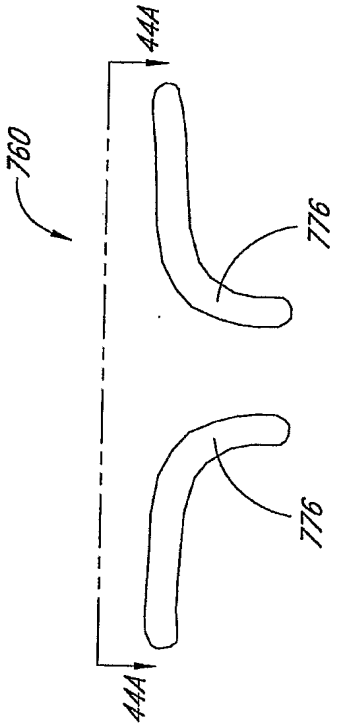


FIG. 44A



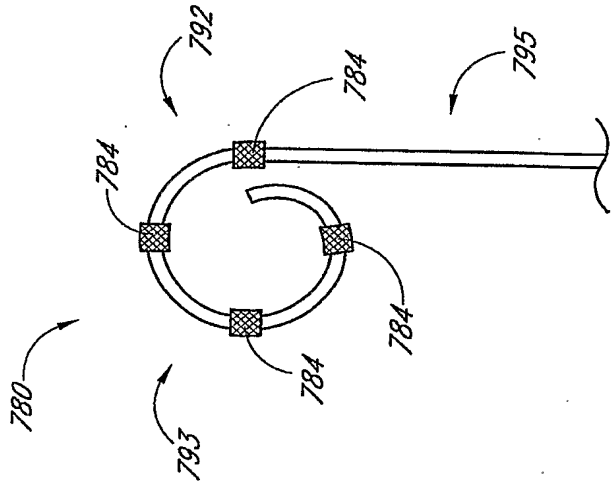


FIG. 44

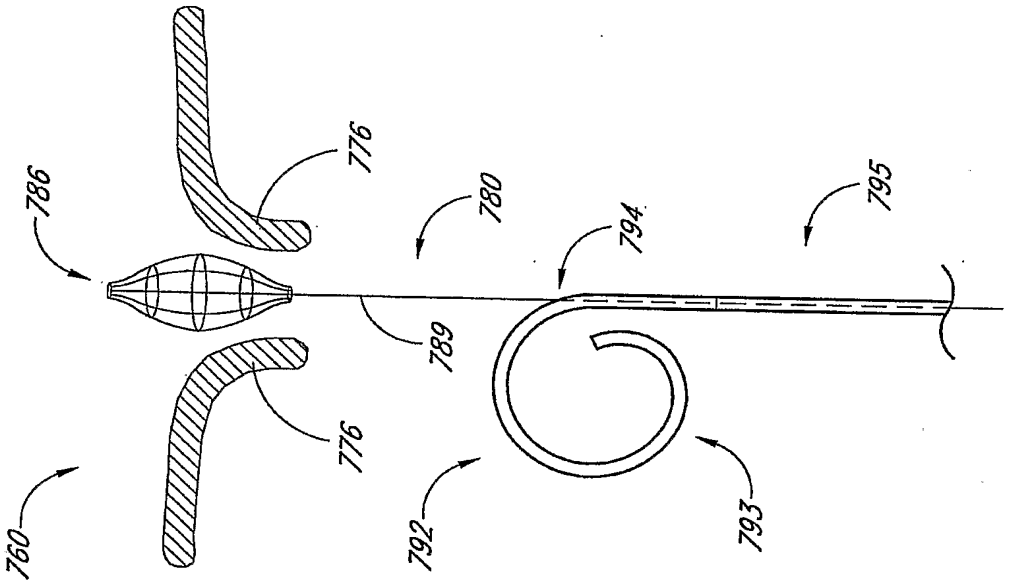


FIG. 45

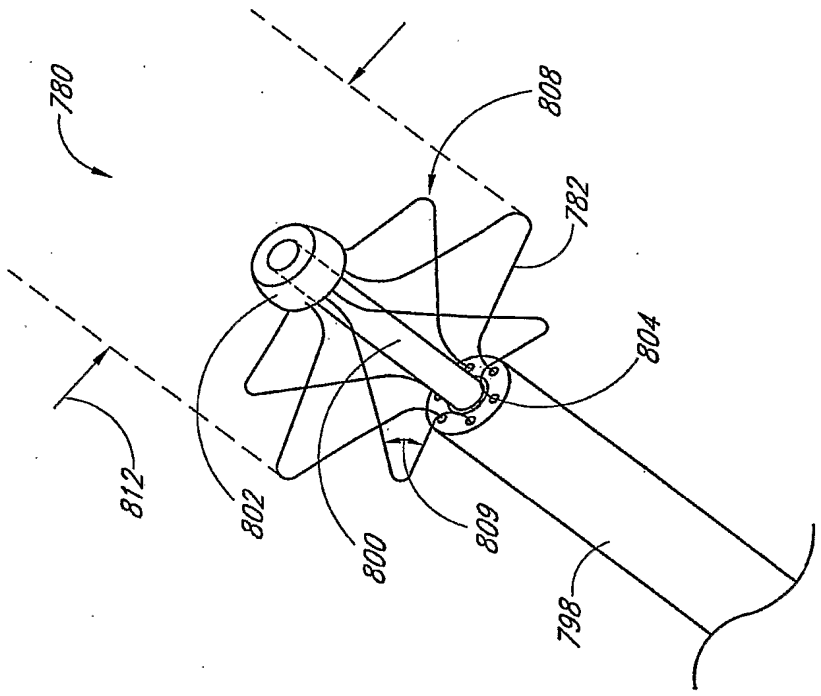


FIG. 47

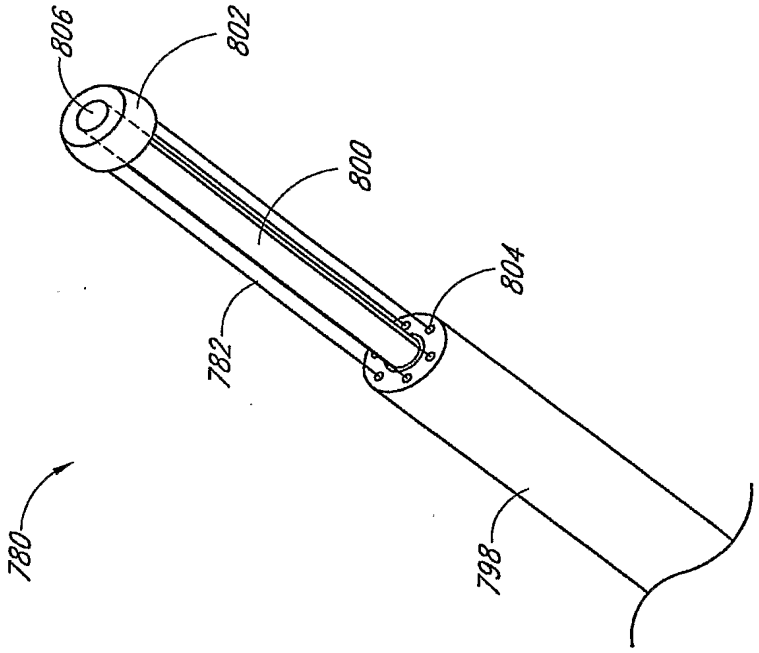


FIG. 46

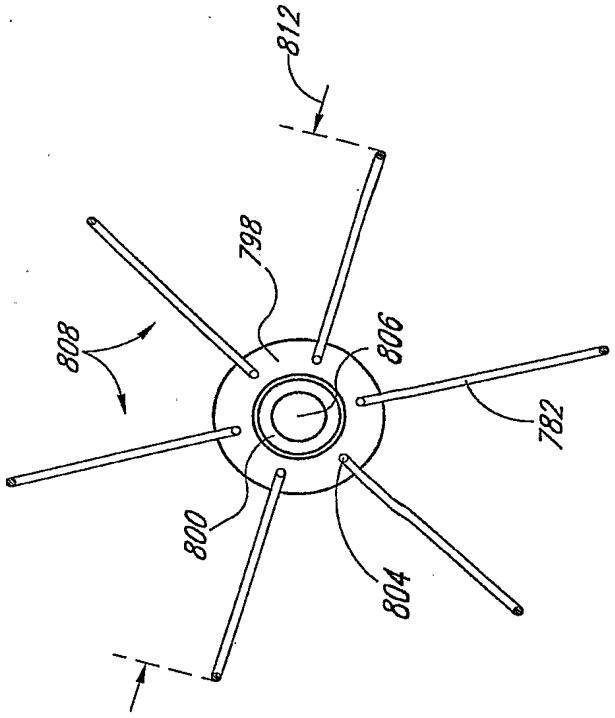


FIG. 48A

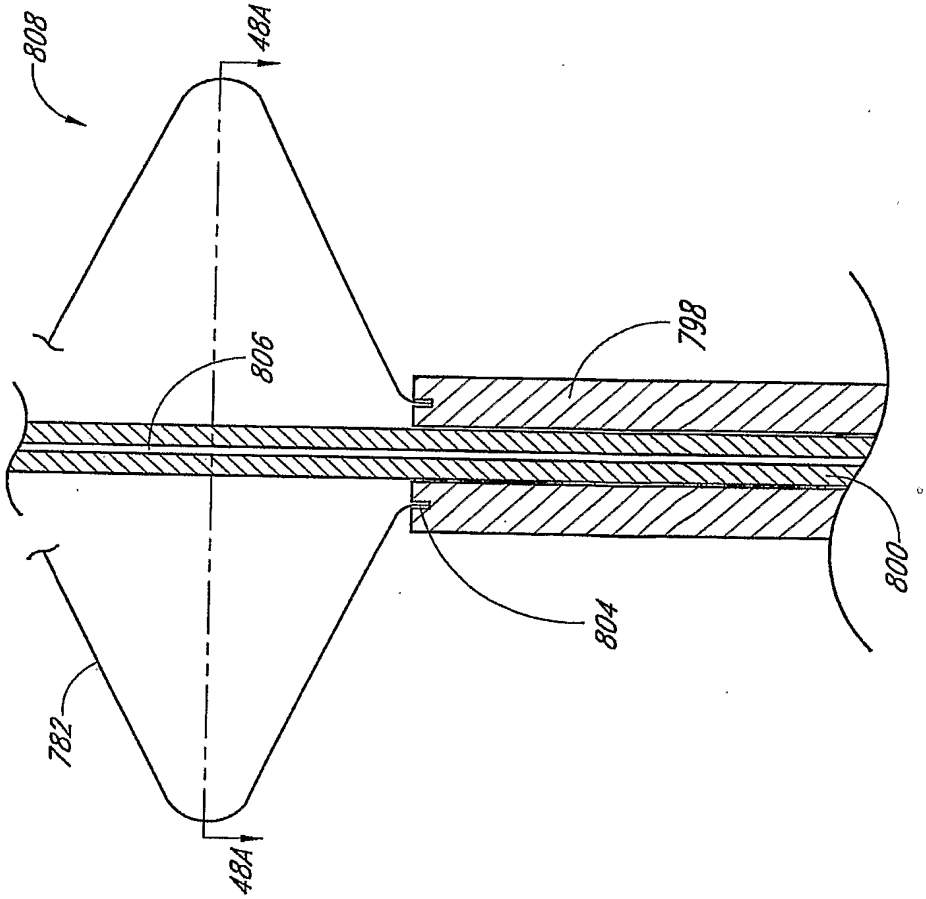


FIG. 48

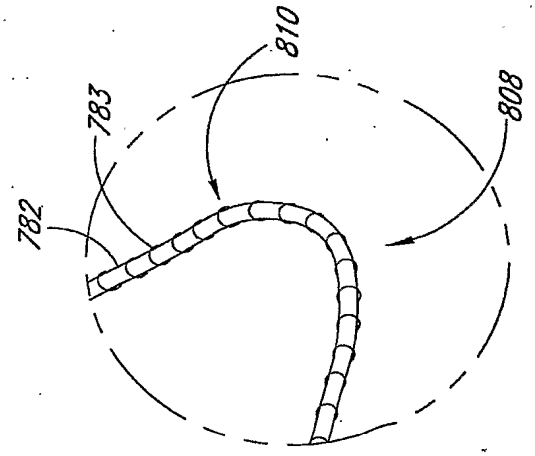


FIG. 48C

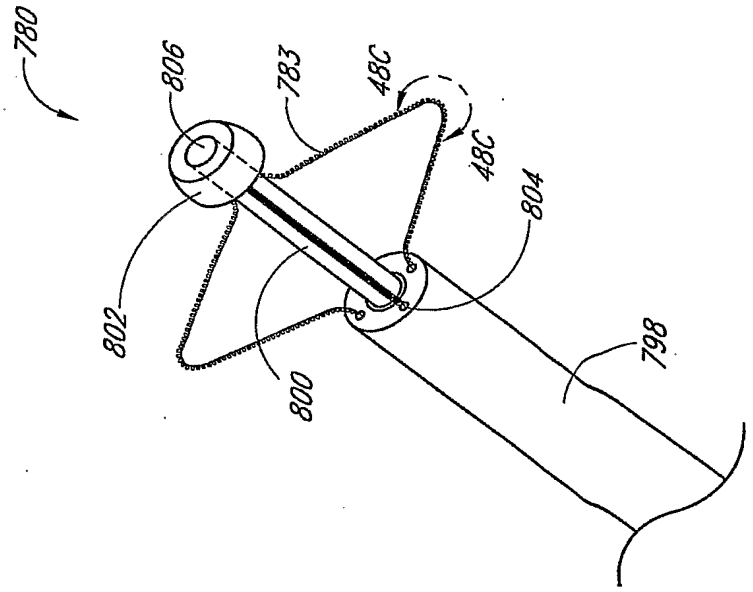


FIG. 48B

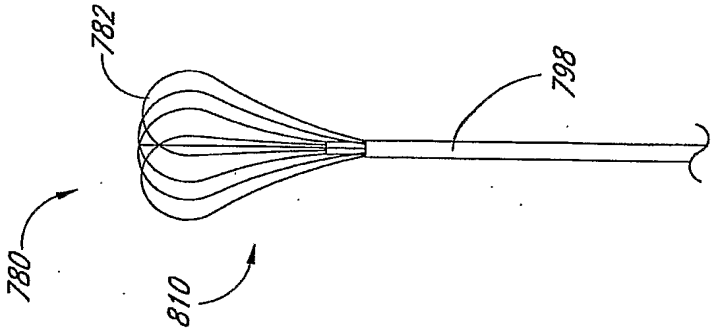


FIG. 49C

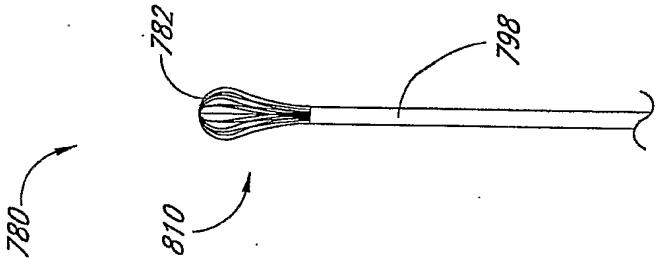


FIG. 49B

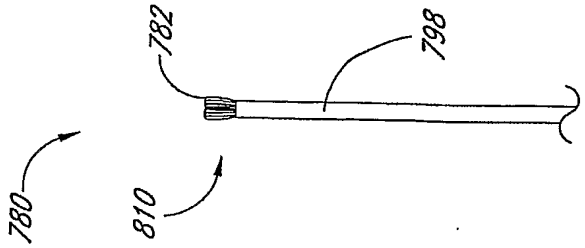


FIG. 49A

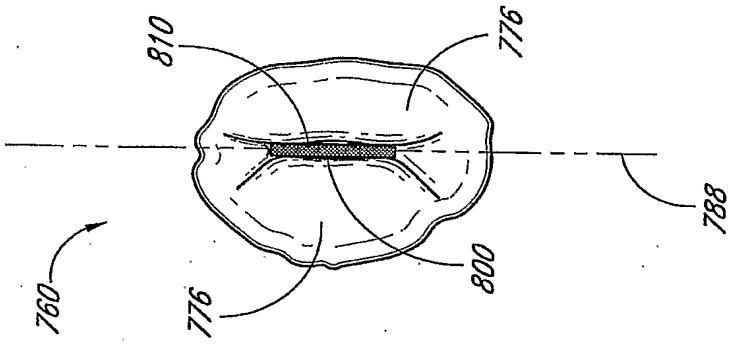


FIG. 50

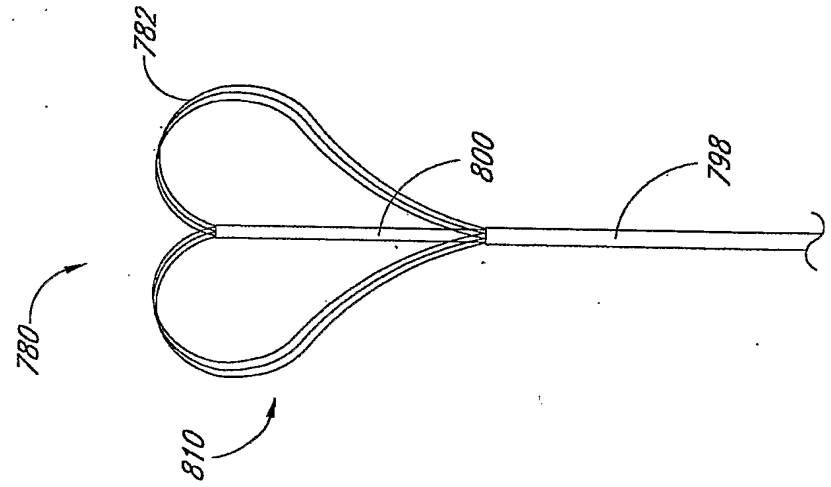


FIG. 49E

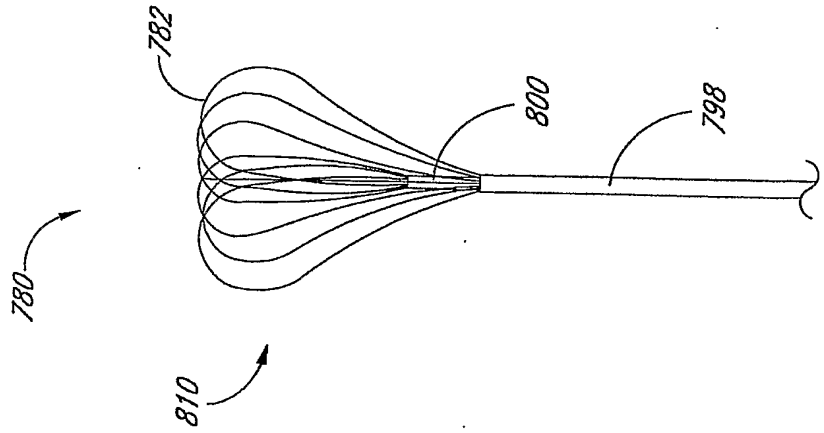


FIG. 49D

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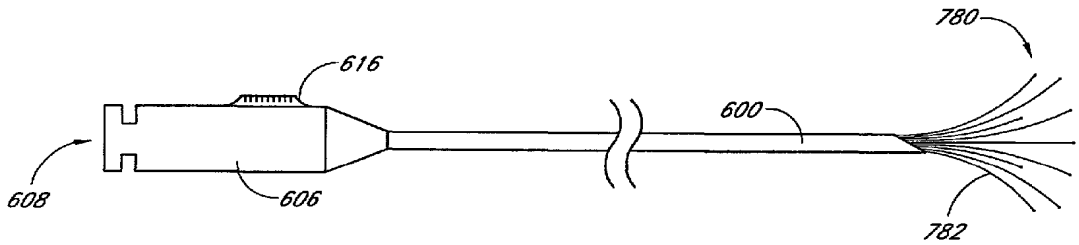
(54) Title: HEART VALVE LEAFLET LOCATOR



(57) Abstract: Disclosed are methods and devices for determining valve leaflet orientation. A catheter (778) is provided with a conformable, radiopaque target (780). The target is deployed within a valve, such as the mitral valve. The conformable target conforms to the coaptation axis (788) in response to closing of the valve leaflets (776). That coaptation axis may then be visualized, and utilized to determine information about valve operation, or to assist in placement of devices in the vicinity of the valve.

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP2004/011828

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B19/00

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)
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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)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 629 534 B1 (ST. GOAR FREDERICK G ET AL) 7 October 2003 (2003-10-07) paragraph '0142! - paragraph '0144! figures 18-20	14

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in 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	Date of mailing of the international search report
31 March 2005	11/04/2005

Name and mailing address of the ISA	Authorized officer
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	Amaro, H

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2004/011828

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-13,21
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internal Application No
PCT/EP2004/011828

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6629534 B1	07-10-2003	US 2004092962 A1	13-05-2004
		US 2004049207 A1	11-03-2004
		US 2004087975 A1	06-05-2004
		US 2004044350 A1	04-03-2004
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		US 2004030382 A1	12-02-2004
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		EP 1176913 A2	06-02-2002
		JP 2002540878 T	03-12-2002
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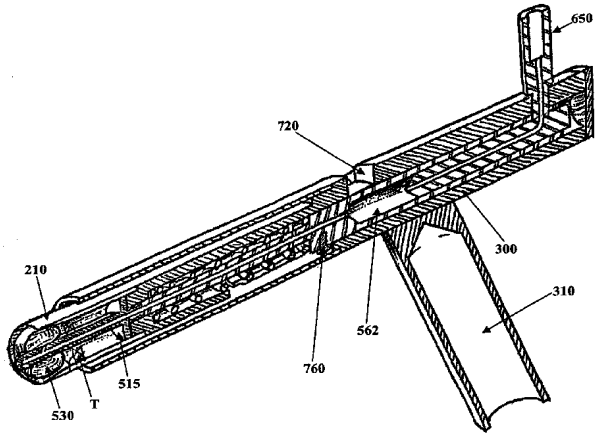
[Continued on next page]

(54) **Title:** APPARATUS AND METHOD FOR CONNECTING A CONDUIT TO A HOLLOW ORGAN



(57) **Abstract:** An apparatus and method for connecting a first conduit to the heart without the need for cardiopulmonary bypass. The first conduit may then be attached to a second conduit that has a prosthetic device interposed. The second conduit may then be connected to the aorta. The prosthetic device may be a prosthetic valve or a pump, for example. The apparatus of the present invention includes an implantable connector with first conduit component, a retractor expansion component, a coring component, and a pushing component. The retractor expansion component is slide-ably coupled to the coring component. The retractor expansion component serves to seat against and separate the inside apical wall of the left ventricle so that the coring component may cut cleanly through the myocardium to form a tissue plug without leaving any hanging attachments to the inside walls. By remaining seated against the inside wall, the retractor expansion component follows the tissue plug into the coring component. The surgeon applies force and rotary motion to the pushing component sufficient to cut the tissue plug and implant the prosthetic component.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

APPARATUS AND METHOD FOR CONNECTING A CONDUIT TO A HOLLOW ORGAN

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present invention relates to an apparatus and method for connecting a conduit to a hollow organ, and more particularly, to a surgical device connectable to the apex of a heart.

Description of the Related Art

[0002] As the average age of the United States population increases, so do the instances of aortic stenosis. An alternative approach to the conventional surgical replacement of the stenotic aortic valve involves the use of an apicoaortic conduit. In this approach, the native aortic valve is not removed, and a prosthetic valve is implanted in a parallel flow arrangement. A connection conduit (or tube) connects the apex of the heart to the descending aorta. Somewhere along this conduit, the prosthetic valve is interposed. Thus, blood leaves the heart through the apex and travels through the conduit (with valve) to the descending aorta.

[0003] Until recently, surgical procedures to implant an apicoaortic conduit have included a single, long incision, such as in the 6^{th} intercostal space, to expose the heart and allow retraction of the lungs to expose the descending aorta. Recognizing the potential for broader scale use of the apicoaortic conduit for aortic valve replacement, some surgeons are now attempting to use smaller incisions and are requesting development of surgical tools for a minimally invasive procedure. As an initial attempt to make the procedure less invasive, some surgeons have recently performed the following procedure.

[0004] The patient is placed on the table in the supine position. Anesthesia is induced, and the patient is intubated with a double-lumen endotracheal tube, this facilitates one-lung ventilation and allows the surgeon to work within the left chest. The patient is positioned with the left side up (90 degrees). The pelvis is rotated about 45 degrees, such that

the femoral vessels are accessible. An incision is made over the femoral vessels, and the common femoral artery and vein are dissected out. Heparin is administered. Pursestring sutures are placed in the femoral artery and vein. The artery is cannulated first, needle is inserted into the artery, and a guidewire is then inserted. Transesophageal echo is used to ascertain that the wire is in the descending aorta. Once this is confirmed, a Biomedicus arterial cannula is inserted over the wire, into the artery (Seldinger technique). The arterial cannula is typically 19 or 21 French. Once inserted, the pursestring sutures are snugged down over tourniquets. A similar procedure is followed for the femoral vein. The venous cannula is usually a few French larger than the arterial cannula. Once both vein and artery are cannulated, the cannulae are connected to the cardiopulmonary bypass, and the capability to initiate cardiopulmonary bypass at any time is present.

[0005] A 1 cm incision is made in approximately the 7^{th} interspace in the posterior axillary line; the videoscope (10 mm diameter) is inserted, and the left chest contents viewed. The location of the apex of the heart is determined, and the light from the scope used to transilluminate the chest wall; this allows precise localization of the incision. The incision is then performed; it is essentially an anterior thoracotomy, typically in the 6^{th} interspace. Recent incisions have been about 10 cm long, but are expected to become smaller and smaller with time. A retractor is inserted and the wound opened gently. A lung retractor is used to move the (deflated) left lung cephalad. The descending aorta is dissected free from surrounding soft tissue to prepare for the distal anastomosis. This dissection includes division of the inferior pulmonary ligament. A pledgeted suture is placed on the dome of the diaphragm and positioned to pull the diaphragm toward the feet (out of the way). The pericardium is incised about the apex of the heart, and the apex is freed up and clearly identified.

[0006] On the back table, the apicoaortic conduit is prepared: a 21 freestyle valve is sutured to an 18 mm Medtronic apical connector. The valve is also sutured to a 20 mm Hemashield graft. The Dacron associated with the apical connector is pre-clotted with thrombin and cryoprecipitate. The assembly is brought to the field, and a measurement made from the apex of the heart to the descending aorta. The assembly is trimmed appropriately. A partial-occluding clamp is then placed on the descending aorta, and the aorta opened with a knife and scissors. The conduit (the end with the 20 mm hemashield graft) is then sutured to the descending aorta using 4-0 prolene suture, in a running fashion. Once this is complete,

the clamp is removed and the anastomosis checked for hemostasis. Blood is contained by the presence of the freestyle aortic valve. The apical connector is placed on the apex, and a marker is used to trace the circular outline of the connector on the apex, in the planned location of insertion. Four large pledgeted sutures (mattress sutures) of 2-0 prolene are placed; one in each quadrant surrounding the marked circle. The sutures are then brought through the sewing ring of the apical connector. A stab wound is made in the apex in the center of the circle, and a tonsil clamp is used to poke a hole into the ventricle. To date, bypass has been initiated at this point, but doing so may not be necessary. A Foley catheter is inserted into the ventricle, and the balloon expanded. A cork borer is then used to cut out a plug from the apex. The connector is then parachuted down into position. A rotary motion is necessary to get the connector to seat in the hole. The four quadrant sutures are tied, and hemostasis is checked. If there is a concern regarding hemostasis, additional sutures are placed. The retractor is removed, chest tubes are placed, and the wound is closed.

[0007] Surgical tools developed specifically to implant the apicoaortic conduit are expected to provide the means for a much less invasive procedure. The procedure is expected to be performed with a series of smaller thoracotomy incisions between the ribs, such as immediately over the apex of the heart. In addition to avoiding the median sternotomy, development of appropriate surgical tools is expected to avoid the need for cardiopulmonary bypass, so that the procedure can be performed on a beating heart. The diseased aortic valve does not need to be exposed or excised. The stenotic aortic valve is left in place and continues to function at whatever level it remains capable of, and the apicoaortic conduit accommodates the balance of aortic output.

[0008] The major obstacle to widespread adoption of this superior technique is the nearly complete lack of efficient devices to perform the procedure. Surgeons wishing to adapt the procedure must gather a collection of instruments from a variety of manufacturers. Often these instruments were created for quite different purposes, and the surgeon is forced to adapt them as required and manually manipulate them during a procedure.

[0009] U. S. Published Patent Application 2003/0130668 A1 (Nieman) describes a method and apparatus for remotely cannulating a body part, such as a heart. The method and apparatus are endoscopic, i.e the instruments are mounted on the end of a long flexible member and inserted into the body through a trocar, i.e., a sharply pointed surgical instrument contained in a cannula. The endoscopic procedure is complicated. After the device is placed at or near the apex of the heart, the surgeon or some other controller performs at least 13

separate steps to secure the cannula in the heart wall. An attachment ring (which includes an apical ring and a locking stem) is sutured to the heart wall, and subsequently the cannula is connected to the attachment ring as a separate step. Because the procedure is endoscopic, imaging means (e.g., fluoroscopy) is used to place a balloon at the correct depth within the ventricle to provide occlusion.

[0010] The complex endoscopic procedure disclosed in Nieman appears to require that the cut tissue core be removed from the body prior to advancing the cannula to the heart wall. Further, Nieman appears to provide two mechanisms for placing the cannula in the heart wall. One such mechanism is to create a hole that is large enough to easily slide the cannula into the hole. This does not provide a tight fit between the cannula and cored heart wall to prevent blood loss from the cored heart wall and from the ventricle and relies entirely upon the sutured attachment ring to achieve hemostasis thus providing a period of time during which there could be great losses of blood. The second mechanism is to achieve a tight (interference) fit between the cannula and cored hole. However, such a tight fit requires substantial axial and torsional forces to be applied to the cannula. The flexible endoscopic instrument disclosed in Nieman cannot provide such forces to be transmitted

[0011] U. S. Patent Publication No. 2004/0162608 (Haverich) discloses a method and apparatus for implanting a conduit into the wall of a heart. As illustrated in FIG. 8A, Haverich shows a conduit on a cutter that has a "corkscrew driver" with a coil. The corkscrew is rotated to cause the cutter to penetrate through the myocardium. However, substantial axial force is required to cleanly penetrate the myocardium, and such force is not easily applied by a corkscrew. Further, the pointed tip of the corkscrew can damage other areas of the heart wall (e.g., the septum) while applying axial force and rotation. Haverich discloses a balloon used for hemostasis. However, the balloon is a separate instrument that cannot be combined with the corkscrew.

[0012] U. S. Patent Publication No. 2002/0045846 (Kaplon) discloses a device similar to Haverich except that a trocar is used to penetrate the organ wall instead of a cutter with corkscrew. No tissue plug is formed with a trocar. Use of a trocar makes it difficult to achieve hemostasis during a procedure on a beating heart. To addess this, rigid conduit 18 is inserted through the connector 16 after the connector is implanted with the trocar and sewn into place. Connector 16 does not appear to penetrate the heart wall. Connector 16 has a built-in valve to prevent blood loss after the trocar is removed and until conduit 18 is inserted

SUMMARY OF THE INVENTION

[0013] A connector conduit according to the preferred embodiment includes a rigid apical connector portion which will serve to provide egress from the left ventricle (such as from the apex or lateral wall), a flexible conduit portion which will carry blood from the connector to the arterial system (such as to the descending thoracic aorta or the ascending thoracic aorta), and the aortic valve itself, which will be situated somewhere within the conduit. The present invention primarily addresses implantation of an apical connector with an attached length of conduit, referred to herein as the connector conduit (or connector). The connector conduit is implanted using an applicator. Although this discussion focuses primarily on the apex of the left ventricle, it is understood that the present invention can be used to implant a connector conduit to any wall of the left ventricle or other hollow organ.

[0014] As described earlier, the surgeon conventionally uses a cork borer to cut a tissue plug from the ventricle wall. Once the tissue plug is removed, the surgeon must attempt to occlude the resulting hole, such as with a finger, a balloon or some other occlusion means, until the connector conduit is inserted. Despite attempts to occlude the resulting hole, substantial blood loss is inevitable. Cardiopulmonary bypass is used to reduce blood loss.

[0015] An object of the present invention is to integrate the cork borer and connector conduit to form a system in which the connector conduit is inserted into the ventricle wall as the tissue plug is being created, thereby eliminating the need for a separate occlusion means and greatly reducing blood loss. Such integration may be achieved by mounting the connector conduit directly onto the outer diameter of a coring element or integrating the cutter and the connector conduit, which cuts the tissue plug and occludes blood flow through the inner diameter. In this way, the cross sectional area for blood loss is reduced to the gap between the coring element and connector conduit.

[0016] Another object of the present invention is to combine the coring element with other features to form a complete applicator for securing the connector conduit into the ventricle wall. These features may include a mounting element and a handle element. The mounting element is an extension to the coring element that serves to add axial length to the coring element onto which the full length of the connector conduit may be mounted. The mounting element may be of the same diameter as the coring element. The handle element provides a grip to facilitate the necessary positioning, twisting and pushing force necessary to

cut the tissue plug and to insert the connector into the ventricle wall. The handle could have a pistol handle shape, for example.

[0017] Another object of the present invention is to provide the option for additional features for the complete applicator system for securing the connector conduit into the ventricle wall, particularly at the apex. These additional features may include a retractor element and a quick connect coupling element.

[0018] The refractor element may have an expanding element for: 1) shaping the apex of the ventricle into a preferred shape for cutting the tissue plug, 2) providing a backing surface for the coring element in order to sandwich the heart wall between the coring element and expanding element, 3) pulling the tissue plug to within the coring element, and/or 4) ensuring that the tissue plug remains inside the coring element. The expanding element could be a liquid-inflated balloon sponge, or a mechanically-operated umbrella, as examples.

[0019] The expanding element is mounted onto the retractor element, and the retractor element is slide-ably mounted within the coring element. A coupling element, such as a compression spring, provides the force to move the retractor element relative to the coring element. The retractor element may be designed to prevent relative rotation between the expanding element and coring element, thereby reducing the likelihood of damage to the expanding element. The retractor element may also include a section of increased diameter that abuts the outer heart wall to prevent premature or undesired cutting of the ventricle wall by preventing contact between the coring element and ventricle.

[0020] Another object of the present invention is to provide an expanding element that has a similar look and feel as the conventional procedure. For example, the expanding element may be a balloon. A syringe element may expand the expanding element to a predetermined level by inflation with a liquid. To minimize the space required for the syringe, the balloon may be designed specifically to require minimal inflation volume while still performing the necessary functions of the expanding element. In addition, a filling element of the applicator may provide the means to fill the syringe element and balloon from an external liquid source and to provide the means to purge air from the expanding element.

[0021] Another object of the present invention is to provide a connector conduit that has many of the features of the conventional apical connector (e.g., Medtronic™ apical connector) and includes additional features to make it compatible with the applicator and the surgical procedure. Additional features to make the connector conduit compatible with the

applicator include 1) an ability to straighten the connector conduit from a bent configuration so that it will slide onto a straight mounting element, 2) a modified leading edge on the connector to ease insertion into the heart wall, and 3) a clamping element that includes portions of both the connector conduit and the applicator which serves to lock the connector conduit to the applicator in a predetermined position and to facilitate applying the twisting and pushing force necessary to insert the connector.

[0022] An additional feature of the connector conduit to make it compatible with the surgical procedure is a quick connect coupler to expedite attachment of the connector conduit to the remainder of the prosthesis, which includes the prosthetic valve. The quick connect coupler is necessary to prevent a long time delay between implanting the connector conduit into the ventricle and achieving blood flow through the complete prosthesis. Such quick connect coupler may consist of a first part that is attached to the connector conduit and a second part that is attached to the remainder of the prosthesis, which includes the prosthetic valve.

[0023] An additional feature of the connector conduit to make it compatible with the surgical procedure is to provide a length of conduit that may be collapsed, such as with an occlusion clamp, to prevent blood flow through the connector conduit before the quick connect coupler is connected and the surgeon is ready to allow blood flow through the complete prosthesis.

[0024] In one configuration of the invention, expansion of the expanding element and the position of the retractor element are controlled independently by the surgeon. For example, if the expanding element is a balloon connected to a syringe, the volume of liquid in the balloon is controlled by the position of the plunger inside the syringe. Similarly, a bolt may be used to control the position of the retractor element relative to the coring element. In this configuration, the surgeon must independently control the positions of the syringe plunger and the retractor element bolt.

[0025] Another configuration of the present invention provides a sequencing element (such as a cam mechanism) that ensures that critical steps of the procedure are performed in the proper sequence. The sequencing element synchronizes expansion of the expanding element with position of the retractor element. The sequencing element includes a sequencing bolt. The surgeon uses one hand to hold the applicator handle and the other hand to slide the sequencing bolt. In this way, independent control of the expanding and retractor

elements is eliminated. Independent positions of these components are not user driven; rather, positions of these components are synchronized by the sequencing element. One example of a sequencing element is described next; however, it is understood that a sequencing element may be used to control fewer steps or additional steps of securing the connector conduit into the ventricle wall.

[0026] The system is set up with the connector conduit mounted onto the applicator and with the retractor fully extended. The procedure begins by making a small knife wound in the apex and pushing the retractor element (with fully-deflated expanding element) through the heart wall and into the ventricle. The surgeon slides the sequencing bolt from a first position to a second position. Once the sequencing bolt is in the second position, the surgeon may release the sequencing bolt. The sequencing element ensures that this sliding motion serves to first expand the expanding element and, after the expanding element is fully expanded, to release the retractor element so that the retractor element can move the expanding element relative to the coring element. The surgeon may now use the handle to apply twisting and pushing force to place the connector conduit into the ventricle wall. During this time, the sequencing element simultaneously coordinates:

a. application of compressive force between the expanding element and the coring element, thereby sandwiching and shaping the heart wall for cutting the tissue plug,

b. the coring element to cut a hole in the ventricle wall, thereby creating a tissue plug,

c. insertion of the connector conduit into the hole, and

d. the retractor element to retract the tissue plug from the hole into the coring element.

[0027] Once the tissue plug is created, the sequencing element partially reduces the diameter of the expanding element so that the expanding element can enter the inner diameter of the coring element while remaining of large enough diameter to prevent the tissue plug from sliding off of the retractor element. This change in diameter of the expanding element occurs automatically to a pre-set intermediate diameter without attention from the surgeon. Once the surgeon has placed the connector conduit at the desired position within the ventricle wall, the applicator may be removed.

[0028] In a preferred configuration, the connector conduit is a fabric (e.g., Dacron) covered device that is specifically designed for insertion into the wall of the left ventricle, such as at the apex. It contains a structural frame, a sewing flange (or suture ring) for attachment to the heart, and a standard fabric (e.g., Dacron) flexible vascular graft that extends through the lumen of the entire length of the structural frame and for some additional length beyond. An outer fabric may also cover the outside of the structural frame. The components of the connector conduit are interconnected, such as with polyester thread. The fabric may include orientation marks, such as a line along the length of the conduit. In addition, a quick connect coupling may be used to attach the connector conduit to the remainder of the prosthesis, which includes the prosthetic valve or ventricular assist device, as examples.

[0029] A function of the structural frame is to provide mechanical integrity, i.e., rigidity, for the connector conduit. The structural frame may include a leading edge, a cage, a bend, and a holder. The leading edge is the first portion of the structural frame to be pushed through the heart wall. To minimize effort needed to push the connector through the heart wall, such leading edge may be tapered and/or beveled, for example. The cage is the portion of the structural frame that resides within the heart wall. The bend is the portion of the structural frame that holds the conduit in a preferred shape to direct blood flow from the left ventricle to the aorta, as described next in more detail. The holder is the portion of the structural frame that provides a means of mechanical connection between the connector conduit and applicator.

[0030] The bend in the structural frame may be any appropriate angle (such as 90 degrees) to properly direct the conduit from the ventricle to the portion of the aorta where the conduit is to be connected. For example, the bend in the structural frame may be around 90 degrees if the conduit is to be connected to the descending thoracic aorta, or a larger angle bend may be used if the conduit is to be connected to the ascending thoracic aorta, for example. As described next, such bend may be flexible or rigid.

[0031] In one embodiment, the bend of the structural frame may be flexible. For example, a set of equally-spaced circular rings mounted perpendicularly on a spine could form a bend that can flex to a range of angles. The circular rings provide radial support to prevent collapse of the conduit due to external forces. The spine may be at the outer radius of the bend or at the inner radius of the bend, as examples. In this embodiment, the bend can be straightened out from a preferred angle such that a mounting element of the applicator may

be inserted straight through the lumen of the connector. Upon removal of the mounting element, if the bend is constructed of a material with a relatively high modulus of elasticity (e.g., PEEK), the connector returns to its bent configuration. If the bend is constructed of a material with a relatively low modulus of elasticity (e.g., polypropylene, polyethylene), the connector forms the bent configuration only when an external force is applied, such as by a bending means. Such bending means could involve pulling on threads that are weaved through the circular rings so that the bend is formed when the threads are pulled, for example. When the bend is at the preferred angle, the user may tie or crimp the threads together, for example, thereby preventing straightening of the bend. Such bending means allows the user to select any one of a plurality of possible bend angles as the preferred angle. Such bending means may also be used with a bend constructed of a material with a relatively high modulus of elasticity, such as to prevent straightening beyond the preferred angle.

[0032] In another embodiment, the bend of the structural frame may be rigid. In this embodiment, since the bend cannot be straightened out, the bend must include a port such that the mounting element of the applicator may be inserted through such port and through the lumen of the cage. In this embodiment, the conduit must include a branch of additional conduit to form a Y. Such additional branch of conduit is coaxial with the cage for mounting the connector conduit onto the applicator. Once the connector conduit is implanted into the heart wall and the applicator is removed, the branch of conduit is occluded, such as by sewing or stapling the conduit closed, for example. The branch is then removed, such as by cutting with scissors.

[0033] In another embodiment of the connector conduit, a quick connect coupler may be used to attach the connector conduit to the remainder of the prosthesis, which includes the prosthetic valve. The complete prosthesis may be divided into two parts: a first part that includes the prosthetic valve with lengths of conduit attached to both the upstream and downstream sides of the prosthetic valve and a second part that includes the connector conduit. The quick connect coupler allows the surgeon to rapidly connect said first part to said second part. In this way, the surgical procedure may be performed by first attaching said first part of the complete prosthesis to the aorta. Then, after the connector conduit is secured into the ventricle wall, the quick connect coupler allows rapid completion of the flow circuit to minimize the time between insulting the heart by cutting the hole and reducing the work load on the heart by allowing blood flow through the prosthesis.

[0034] An applicator is used to implant the connector conduit into the ventricle wall. In a preferred embodiment, the applicator provides mechanical support on the surfaces of both the inner diameter and the outer diameter for some portion of the fabric-covered structural frame. Such support may be necessary to avoid unwanted distortion or movement of the structural frame while the connector conduit is being implanted through the heart wall. For example, the mounting element of the applicator, which is inserted straight through the lumen of the connector, may provide mechanical support (such as radial support) on the inner-diameter surface to reduce distortion of the structural frame during implantation. On the outer-diameter surface, the applicator may include a concentric tubular structure, referred to as the pushing element. The pushing element provides mechanical support (such as radial support) on the outer-diameter surface of the structural frame to reduce distortion during implantation. In a preferred embodiment, the mounting element and the pushing element are rigidly connected.

[0035] In a related embodiment, an indexing means provides an interface between the pushing element and connector conduit that may prevent or greatly reduce rotation and/or axial movement of the connector conduit relative to the pushing element. As such, rotary or axial force applied to the pushing element is transmitted to the connector conduit through the locking means. An effective locking means may incorporate portions of the pushing element, mounting element and connector conduit. For example, the indexing means may include a slot-and-key arrangement that 1) positions the connector conduit at a preferred angle relative to the pushing element thereby orienting the bend in the structural frame, 2) prevents axial and rotary motion of the connector conduit relative to the pushing element, and 3) allows the connector conduit to be easy mounted onto and released from the applicator. Such indexing means may include a pushing element with an adjustable diameter that allows both rigid mounting and unhindered release of the connector conduit. Such indexing means may also include a connector conduit with a holder that locks to the pushing element, such as with a slot-and-key arrangement and/or with a tight friction fit, as examples. Such holder may be sandwiched firmly between the mounting element and pushing element.

[0036] In a preferred configuration, the mounting element extends from a coring element that shares the same axis and has the same outer diameter as the mounting element. The coring element is used to cut a hole into the heart wall. Such coring element could consist of a thin-walled tube, the leading edge of which has been sharpened or serrated. The inner diameter of the connector conduit could fit snugly on the outer diameter of the coring

element and mounting element. In use, the coring element could produce a hole in the heart wall that is smaller than the outer diameter of the connector conduit, thereby producing a snug fit.

[0037] In a related embodiment, a handle may be rigidly attached to the pushing element. The handle may be at a substantially right angle after the manner of a pistol grip, for example. Such a handle attachment provides a more effective method of applying the insertion force and back-and-forth rotation needed to implant the connector conduit.

[0038] In a preferred configuration, located concentrically within the mounting element is a retractor element consisting of a generally tubular structure having a pointed end that is inserted through the left ventricle wall. The tubular structure could be rigid. In a preferred embodiment, the pointed end of the retractor element could be a blunted point. In this way, after a small knife wound is made in the epicardium (outer surface of the heart), the blunted point could enter the knife wound and divide muscle fibers to penetrate the myocardium and left ventricle chamber. A purpose of the blunted point is to reduce the likelihood of damage should the point unintentionally contact other areas of the inner wall during use. In an alternative embodiment, the retractor element could include a very sharp pointed end being capable of producing its own entrance hole into the wall of the heart. Alternately, it could have a blunted point that would simply follow a previously created hole through the entire thickness of the ventricle wall. If so desired, the tubular structure of the retractor allows use of a guide-wire to follow a previously created hole.

[0039] Near the pointed end of the retractor element is an expanding element, such as an inflatable balloon, an unfolding umbrella-like construction, an expandable collar, or similar structure. Once inside the ventricle, the expanding element is expanded from an initial diameter that may approximate the outer diameter of the retractor element to a second diameter. In a preferred configuration, the expanding element expands to a second diameter that is larger than the outer diameter of the coring element. The expanding element expanded to its second diameter seats snugly against the inside wall of the ventricle. Functions of the expanding element may include 1) expanding symmetrically to shape the inner wall of the ventricle into a preferred shape for cutting the tissue plug, and 2) fully retracting to within the coring element while remaining at least partially expanded.

[0040] A first function of the expanding element is symmetric expansion, which provides at least two benefits. The first benefit is related to the variable, cone-shaped

geometry of the left ventricular chamber near the apex. Symmetric expansion of the expanding element to a diameter that is larger than the outer diameter of the coring element effectively flattens out the ventricle wall in the vicinity of the apex so that the ventricle wall is more perpendicular to the sharpened leading edge of the coring element, thereby allowing the coring element to cut through the entire thickness of the ventricle wall. The tubular structure of the retractor element must resist the radial reaction forces from the ventricle walls. The second benefit of symmetric expansion is to ensure contact between the expanding element and the leading edge of the coring element along its entire circumference as the tissue plug is formed. Asymmetric expansion of the expanding element can result in formation of a plug with hanging attachments to the left ventricle wall.

[0041] A second function of the expanding element is to fully retract and retain the plug within the coring element after the plug is cut. Such full retraction ensures that the applicator will slide out of the connector conduit (after the connector is implanted) without the plug and expanding element coming into contact with the inner diameter of the connector conduit. Such contact could increase the force required to remove the applicator from the connector conduit and could possibly result in debris from the removed plug being deposited on the inner diameter of the connector conduit. In addition, the expanding element must remain at a large-enough diameter after being retracted to within the coring element to ensure that the plug cannot slide off the end of the retractor element.

[0042] In a related embodiment, this second function could include a coupling element that forces the retractor element to retract within the mounting element. In a preferred configuration, the coupling element could be a compression spring, for example. In this configuration, the retractor element could be slide-ably connected to the mounting element by means of the compression spring. The force produced by the compression spring tends to pull the expanding element snugly against the inside wall of the ventricle and to pull the tissue plug into the coring element after the tissue plug is detached from the ventricle. Alternatively, the user could manually provide the necessary force to retract the retractor element to within the coring element.

[0043] In a preferred embodiment, the expanding element can be: 1) initially at a first diameter that approximates the outer diameter of the retractor element, 2) expanded to a second diameter that is larger than the outside diameter of the coring element, and 3) then reduced to a third diameter that is smaller than the inside diameter of the coring element but larger than the outer diameter of the retractor element. Inflation to the second diameter

accommodates the first function of the expanding element (described above), and reducing to the third diameter accommodates the second function of the expanding element (described above).

[0044] In a preferred embodiment, the expanding element is a balloon. The balloon may be inflated using an access means, such as a plunger in cylinder configuration (like a syringe) connected to the balloon by a flow passage, such as a channel integrated into the retractor element. An appropriate fluid to inflate the balloon could be saline, for example. The balloon material should be selected to best perform the functions of the expanding element. Polyurethane is a preferred material. Polyurethane is an elastic material that allows a balloon to be expanded symmetrically to as much as twice the original volume using a hand-held syringe. Such balloons are strong, abrasion resistant, and durable. Use of latex, another elastic material, is less desirable. Latex balloons typically expand asymmetrically, so use of a latex balloon as the expanding element could necessitate a means integrated into the balloon to ensure symmetric expansion. In the present invention, a latex balloon could be inflated to a symmetric diameter as determined by tension rods or sutures, for example, attached to the balloon and the retractor element. Once the tissue plug is formed, the plunger could be displaced to reduce the size of the balloon to allow retraction into the coring element. A means to prevent damage to the latex balloon by the coring element may be used. Alternatively, the balloon may be constructed of polyethylene terephthalate (PET; trade names include Dacron and Mylar), which is a non-elastic material. Balloons made of PET may be symmetrically inflated to higher pressures without appreciable change in the balloon volume.

[0045] In one configuration of the present invention, expansion of the expanding element and the position of the retractor element are controlled independently by the surgeon. Consider the example of using a balloon as the expanding element. Inflation of such balloon could be fully controlled by the surgeon, such as by using a finger to displace a plunger inside a cylinder. In such case, the surgeon could inflate the balloon to any volume up to the maximum volume of the plunger/cylinder. Also in this configuration, the position of the slide-able retractor element relative to the coring element may be independently controlled by means of a bolt attached to the retractor element that passes through an indexed slot in the mounting element. In a preferred embodiment with the mounting element rigidly connected to a pushing element, the indexed slot could be in such pushing element. As the bolt is moved from one indexed position in the slot to another, the retractor is advanced or retracted

relative to the coring element. In a preferred configuration with compression spring coupling between the retractor element and coring element, an indexed slot with the retractor element fully advanced (ready for insertion into the left ventricle wall) could be used. The bolt could then be manually released from the indexed slot after inflating a balloon on the retractor element. The compression spring would then pull the balloon firmly against the inner heart wall, thereby sandwiching the heart wall between the balloon and coring element.

[0046] Independent control of the expanding element and retractor element could require increased surgeon training to ensure operation of these elements in the proper sequence. Alternatively, various latching or locking means could be used. For example, once the balloon has been inflated to a preset maximum volume, a latching means could lock the plunger into place, thereby preventing unintentional deflation of the balloon. If necessary, deflation to an appropriate volume for retraction into the coring element could be automatically triggered when the retractor element reaches a preset position during retraction. Alternatively, inflation and deflation of such balloon to preset maximum and reduced volumes could occur automatically, such sequence being initiated by pressing a spring-loaded trigger that displaces the plunger, for example. In addition, a safety latch or other means could prevent manual release of the bolt until the expanding element is fully expanded. These separate latching or locking means could result in a complicated mechanical configuration.

[0047] In a preferred configuration of the present invention, a sequencing element, such as a cam mechanism, is used to coordinate expansion of the expanding element with position of the retractor element. Control of the expanding element and control of the retractor element position are coordinated so that the surgeon need only move a single sequencing bolt to control both the expanding element and the retractor element. The specific actions of the expansion element and retractor element that are controlled by the sequencing element may be chosen by the device designer to best accommodate the degree of control preferred by surgeons.

[0048] In one embodiment of a preferred configuration that includes a sequencing element, the cylinder used to inflate/deflate the balloon (the syringe cylinder) may be integrated into the retractor element. Thus, the syringe cylinder, retractor element, balloon, and flow passage connecting the syringe cylinder to the balloon are integrated into a single component, referred to as the retractor assembly. The plunger used to inflate/deflate the balloon (the syringe plunger) may include a sequencing bolt extending radially from the

plunger axis. Such sequencing bolt also extends radially through a slot in the syringe cylinder. As such, the slot in the syringe cylinder limits axial movement of the plunger in the syringe cylinder. By having a plurality of circumferentially interconnected slots of various axial lengths in the syringe cylinder, the degree of balloon inflation may be controlled by moving the sequencing bolt to a preferred axial slot. Synchronization of balloon inflation/deflation with motion of the retractor assembly relative to the pushing element (which is rigidly connected to the mounting element) may be achieved with two cam slots in the pushing element, for example. The first cam slot controls motion of a cam follower rigidly attached to the retractor assembly, thereby controlling the position of the retractor assembly relative to the pushing element. The second cam slot synchronizes inflation/deflation of the balloon relative to the position of the retractor assembly within the pushing element. The sequencing bolt serves as the cam follower in the second cam slot. Safety features may be integrated into the design of the cam mechanism. For example, the cam and follower can be designed to prevent movement of the retractor assembly relative to the pushing element (which is rigidly connected to the coring element) until the balloon is fully inflated.

[0049] Various other features may be included to ensure safety and proper use of the connector conduit with applicator. For example, a port with a two-way valve may be integrated into the plunger/cylinder with balloon system to allow for filling with fluid and removal of air. As another example, a mounting tool may be used to mount the connector conduit over the coring element without damage to the fabric. As another example, a folding tool may be used to squeeze fluid from the balloon and to fold the balloon for use. As another example, the mounting tool and folding tool may be integrated into a single tool.

[0050] The invention facilitates procedures using an integral device in which the various steps are preformed in a coordinated, i.e. sequenced manner. This renders the procedure simple and safe and reduces the likelihood of tissue damage or other complications. Other features and advantages of the invention will be apparent from the detailed description and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0051] FIG. 1 illustrates an apicoaortic conduit.

[0052] FIG. 2A is a perspective view of the structural frame of one embodiment of a connector shown in a bent configuration.

[0053] FIG. 2B is a perspective view of the structural frame of the connector of FIG. 2A shown in a straight configuration.

[0054] FIG. 3A is a cross-sectional view another embodiment of the structural frame of the connector, covered in fabric, with an incorporated sewing flange and shown in the bent configuration.

[0055] FIG. 3B is a cross-sectional view of the structural frame of the connector of FIG. 3A shown in a straight configuration.

[0056] FIG. 3C is a cross-sectional view of the connector of FIG. 3A shown in the straight configuration, and with a fabric conduit in place.

[0057] FIG. 4 is a cross-sectional view of an embodiment of the device showing the coring element and the retractor element in place within the straightened connector.

[0058] FIG. 5 is a cross-sectional view of a cylinder plug tool that slides over the retractor element and into the coring element, which is used to load the connector-conduit onto the coring element.

[0059] FIG. 6 is a cross-sectional view of an embodiment of the device showing the placement of a compression spring between the retractor element and the coring element.

[0060] FIG. 7 is a cross-sectional view of another embodiment of the device showing the placement of a pushing element.

[0061] FIG. 8A is a cross-sectional view of yet another embodiment of the device showing the attachment of a handle to the pushing element with an access means for the expandable element integrated into the pushing element, wherein the expandable element is shown contracted.

[0062] FIG. 8B shows the embodiment of FIG. 8A with the expandable element expanded.

[0063] FIG. 9 is a cross-sectional view of an embodiment of the device showing the inclusion of a sliding bolt on the retractor element and related indexed slots on the pushing device.

[0064] FIG. 10 is a partial view the pushing element of FIG. 9 showing the indexed slots on the pushing device.

[0065] FIG. 11A is a perspective view of a flexible structural frame of another embodiment of the connector conduit shown in a straight configuration.

[0066] FIG. 11B is a perspective view of the structural frame of FIG. 11A shown in a bent configuration.

[0067] FIG. 11C is a perspective view of the structural frame of FIG. 11B shown with a beveled and tapered leading edge.

[0068] FIG. 12 is a perspective view of an alternative embodiment of FIG. 10B.

[0069] FIG. 13A is a perspective view of the flexible structural frame of FIG. 11B shown in the straightened configuration and incorporating a bending means.

[0070] FIG. 13B is a perspective view of the structural frame of FIG. 13A after activating the bending means.

[0071] FIG. 14 is a perspective view of a non-bendable structural frame of a connector conduit.

[0072] FIG. 15 is a cross-sectional view of a connector conduit shown in a bent configuration.

[0073] FIG. 16 is a cross-sectional view of a non-bendable connector conduit.

[0074] FIG. 17A is a cross-sectional view of a mounting element (including a coring element) and a pushing element of the applicator with a loaded connector conduit.

[0075] FIG. 17B is a cross-sectional view FIG. 17A without the connector conduit**[0076]** FIG. 18A is a perspective view of a squeeze ring for a locking means to secure the connector conduit within the applicator.

[0077] FIG. 18B is a perspective view of a locking means shown in the locked position.

[0078] FIG. 18C is a perspective view of a locking means shown in the unlocked position.

[0079] FIG. 19 is a cross-sectional view of the device of FIG. 17B including a retractor element.

[0080] FIG. 20 is a cross-sectional view of a folding and mounting tool.

[0081] FIG. 21 is a cross-sectional view of an assembly including an applicator having a syringe.

[0082] FIG. 22A is a cross-sectional view of a sequencing belt.

[0083] FIG. 22B is a cross-sectional view of the retractor body and expanding element.

[0084] FIG. 22C is a cross-sectional view of the positioning mans and coring element

[0085] FIGS. 23A - 23C the sequencing can mechanism in various states.

[0086] FIGS. 24A - 24E illustrate the applicator in various states.

[0087] FIG 25 is a perspective view of an integrated connector conduit and cutting elements.

[0088] FIG 26 is the device of FIG 25 with the cutting element withdrawn.

[0089] FIG 27A – 27D illustrate components of a retractor having an expandable umbrella element.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0090] FIG. 1 is an illustration of an apicoaortic conduit, which extends from the apex of the left ventricle to the descending aorta with a prosthetic valve positioned within the conduit. The preferred embodiment of the present invention includes aspects of the connector conduit and an applicator used to implant the connector conduit.

[0091] The connector-conduit with applicator of the present invention is best described as consisting of five major parts: a connector-conduit, a retractor, hole forming device such as a coring element, a pushing component, and a handle. A fabric material pleated conduit of a type common and well known in the field is permanently fixed to the inner surface of a rigid connector to form the connector-conduit. The conduit extends from the forward edge of the connector and continues beyond the connector, as a flexible portion, for some distance.

[0092] The connector-conduit includes a rigid portion defined by an internal support structure made of a suitably flexible material that is preferentially biased to assume a bent configuration (such as a right angle) upon removal of restraining forces. In one embodiment, the connector internal support structure is covered with fabric, such as knitted or woven Dacron, for example. A suturing ring is integrated into the covering fabric and provides a suitable flange for suturing the connector to the surface of the heart. The leading edge of the connector is tapered to facilitate insertion of the connector-conduit component. The "rigid" portion is rigid enough to facilitate insertion as described below and to maintain the hole in an open position. However, the rigid portion can be flexible. Accordingly, the term "rigid" as defined herein means relatively rigid and can include flexibility.

[0093] As shown in FIG. 2A, the structural frame 10 of the connector-conduit is a series of circular rings 14 joined to a curved spine 18. During implantation, the curved spine 18 is straightened, as shown in FIG. 2B, resulting in a straight pathway for the passage of instruments. As an alternative, the connector-conduit could include circular rings 14 without curved spine 18. As such, the circular rings would prevent collapse of the conduit, but the curved conduit would be formed manually after implantation, rather than by being formed by the curved spine 18. As another alternative, a modified coil spring in the shape of a curve could be used instead of circular rings 14 and curved spine 18. Properties of the coil spring would be chosen to prevent radial collapse and to provide appropriate stiffness of the curved position.

[0094] The leading edge of structural frame 10 is a taper 20 which allows for easy insertion of the connector through the ventricle wall. The material of the structural frame 10 could be a shape memory alloy (e.g., Nitinol), plastic, or other similar biocompatible material.

[0095] FIG. 3A illustrates a fabric covering 24 over the outside surface of structural frame 10. Because connector surface 22 is in contact with the myocardial hole after implantation, a suturing ring or flange 26 is incorporated into the fabric covering 24 to provide an attachment site for sutures to anchor the connector to the heart. The fabric covered suture ring 26 could be made of a biocompatible foam or rubber.

[0096] FIG. 3B shows the fabric covered structural frame 10 and suturing flange 26 in a straightened position. The straightened position can be achieved by, for example, inserting a straight instrument through the lumen of the frame. Alternately, the structure can

be held in the open position through the use of stay stitches 28, or the like, placed such that the circular rings 14 are held in close proximity.

[0097] FIG. 3C is a view similar to FIG. 3B, showing the structural frame in the straightened position with a pleated fabric conduit 30. Conduit 30 extends from taper 20 of the structural frame 10, through the length of the structural frame 10, and for some additional length beyond the structural frame 10 to define a flexible portion of the connector conduit. An orientation marker (not shown) on connector surface 22, for example, is used to identify the direction that conduit 30 will be oriented once implanted into the heart. The orientation marker is visible at all times to assist the surgeon while placing the connector-conduit 32 into the connector-conduit applicator and to facilitate implantation at an appropriate angle into the heart. Also, a radiopaque marker(s) (not shown) may be integrated into the entire length of fabric covering 24 and conduit 30 to facilitate identification and location of the structure by X-ray or other means.

[0098] Referring to FIG. 4, in accordance with another embodiment of the present invention, a hole forming device such as coring element 40, is placed concentrically within the lumen of the connector-conduit 32. The coring element 40 preferably consists of a tubular structure, which could be made entirely of metal (such as stainless steel) or primarily of a plastic material with a metal insert for the leading edge 42. In a preferred configuration, the leading edge 42 of coring element 40 may be suitably sharpened such that it cuts a plug of tissue of approximately the same diameter as the outer diameter of the coring element 40. Note that the hole forming device can be any known mechanism for forming a hole, such as a laser cutter, a thermal ablation device, a chemical ablation device, or the like.

[0100] An interference fit between connector surface 22 and the hole created by the coring element 40 is necessary to reduce bleeding from the cut myocardial surface and to reduce blood leakage from the left ventricle. The amount of such interference fit is the difference between the diameters of the hole created by the coring element 40 and the outer surface of the connector 22.

[0101] In a preferred embodiment of the device, the coring element 40 has an outer diameter that closely matches the inner diameter of the connector-conduit 32. Such construction allows removal of the coring element 40 through the connector-conduit 32 while presenting only a small blood pathway between these two elements. Such construction is

intended to minimize blood loss from the left ventricle when the coring element 40 has completed its cut.

[0102] FIG. 4 further illustrates the concentric placement of the retractor element 50 within the coring element 40. Retractor element 50 includes a blunt tip 52, a tubular body 54, an expanding element 56, such as a balloon, and an access means 58 for engageably expanding element 56. Access means 58 can be a plunger 58a in a cylinder 58b configuration, whereby displacement of the plunger expands or contracts expanding element 56. A centering plug 60 is shown concentrically positioned within and rigidly attached to coring element 40. The centering plug 60 concentrically positions retractor element 50, which slideably moves within the centering plug 60. The centering plug 60 also presents a barrier to the flow of blood through coring element 40, once the tissue plug is formed. Proper placement of centering plug 60 within coring element 40 should consider tradeoffs between two different parameters. First, centering plug 60 should be placed at a position within coring element 40, which allows ample space for the expanding element 56 and the tissue plug. Second, since radial force from the heart wall tends to deflect the expanding element 56, retractor element 50 must have a sufficient stiffness to substantially resist such deflection. Such deflection may also be reduced by limiting the axial distance between the expanding element 56 and centering plug 60.

[0103] FIG. 5 shows a cylinder plug tool 45 for insertion into coring element 40 prior to loading connector-conduit 32 onto coring element 40. Cylinder plug tool 45 facilitates loading connector-conduit 32 without damage from leading edge 42 of coring element 40. Once the connector-conduit 32 is loaded, cylinder plug tool 45 is removed and placed aside. As a safety measure, cylinder plug tool 45 has an extended length with a tapered blunted end 45a, which extends to cover retractor element 50, preventing insertion of the retractor element 50 into the left ventricle before cylinder plug 45 is removed.

[0104] Referring to FIG. 6, another embodiment of the present invention shows a compression spring 70 placed around the retractor element 50. One end of the compression spring 70 seats on the centering plug 60, and the other end seats on a sliding plug 72. Sliding plug 72 is rigidly connected to retractor element 50. Spring 70 ensures that expanding element 56 seats snugly against the inside wall of the ventricle to symmetrically displace the ventricle wall from the path of the coring element. Once the tissue plug is cut from the ventricle by coring element 40, spring 70 also pulls the tissue plug fully within the coring element 40.

[0105] FIG. 7 illustrates a further embodiment, wherein a cylinder-shaped pushing element 80 is positioned concentrically outside the connector-conduit element 32. Pushing element 80 is used to apply force to the coring element 40 and connector-conduit element 32. This force is required for the coring element 40 to cut the hole in the myocardium and for pushing the connector-conduit element 32 into the hole. The end of the pushing element 80 that is in contact with the suture ring 26 has a roughened surface 82 intended to prevent relative rotary motion between the suture ring 26 and pushing element 80. As such, the pushing element 80 allows both a force and a back-and-forth rotary motion to simultaneously be applied to the coring element 40 and connector-conduit element 32, as required to fully seat the suture ring 26 flush with the surface of the heart. Pushing element 80 could be made of metal, plastic or other suitable material.

[0106] Referring to FIGS. 8A and 8B, a handle 90 is rigidly attached to pushing element 80. As shown, handle 90 is configured similar to a pistol grip, for example, handle 90 having an angle of about 70 degrees, with the pushing element 80. Handle 90 provides a user-friendly interface for the surgeon to hold with one hand, to position the coring element 40, to apply axial force to the connector-conduit element and to provide a back-and-forth rotational motion of around 90 degrees. Of course, many alternatives exist for the user interface. For example, the pushing element 80 itself could be used as the handle. As another example, a handle could form a "T" shape on the end of the pushing element 80.

[0107] Also shown in FIG. 8A, an access means 58 is used to expand or contract expanding element 56. Access means 58, for example, can be a trigger-type mechanism integrated into handle 90. As such, the user can use a finger to pull plunger 58a into the cylinder 58b, thereby displacing the fluid (such as saline) inside the cylinder 58b into the balloon 56. FIG. 8B shows the inflation of the balloon 56. As a safety feature, the plunger can have a latching device (not shown) that latches the plunger 58a with the balloon fully inflated, thereby preventing deflation of the balloon before intended.

[0108] FIGS. 9 and 10 show a mechanism for controlling deployment of the retractor element 50. A slot 84 is cut into pushing element 80. Slot 84 has an index 84a to lock retractor element 50 at full extension and an index 84b to lock retractor element 50 at full retraction. Bolt 72a is rigidly attached to sliding plug 72. Bolt 72a can be manually displaced within slot 84 to position the retractor element 50. In operation, bolt 72a is positioned in index 84a until the retractor element 50 is fully inserted into the left ventricle and the expanding element 56 is at full expansion. At that time, bolt 72a is manually released

from index 84a, which allows compression spring 70 to retract retractor element 50 until expanding element 56 contacts the inside wall of the left ventricle. A damping means (not shown) may be included to prevent sudden retraction of the retractor element upon release from index 84a. Also not shown is a safety latch or other means to prevent manual release of the bolt 72a until the expanding element 56 is fully expanded.

[0109] As the surgeon applies force and rotation using handle 90, compression spring 70 continues to displace retractor element 50. When retractor element 50 is fully retracted, the surgeon can rotate bolt 72a into index 84b to lock the retractor element 50 in place. Moreover, when retractor element 50 is fully retracted, the expanding element 56 is also fully retracted into coring element 40, indicating that the tissue plug has been successfully removed from the left ventricle and is within the coring element 40.

[0110] Referring to the embodiment of FIGS. 11A - 11C, the connector conduit has a structural frame 101 defining a rigid portion, which may be constructed from a single material or a combination of materials. The structural frame 101 includes a tapered leading edge 110 designed to reduce the effort needed to push the connector through the heart wall located at one end of a cage section 120 and a bend portion 140 that is normally biased into a bent configuration. As shown in FIG. 11C, a tapered and beveled leading edge 150 may further reduce the required effort. During use, cage 120 resides primarily within the heart wall, so it must be constructed so as to be rigid enough to not collapse due to radial forces exerted by the heart wall. The cage 120 may include cage slots 121. The cage slots 121 allow the passage of thread to secure the conduit or the sewing flange.

[0111] A holder 130 is formed at one end of cage 120 and may be used to grasp the connector during implantation. As will be described further herein, holder 130 can have a slot-and-key configuration with the applicator. As such, the holder 130 utilizes holder slots 431 or a holder button 430 (FIG. 12). Holder button 430 may be a separate part that is anchored (e.g., by thread or glue) to structural frame 101. If desired, the holder slots 431 or holder button 430 may be designed to place the flexible bend 140 or rigid bend 145 (FIG .14) at a preferred angle relative to the applicator. Alternatively, the holder 130 may rely upon a tight friction fit with the applicator. In a preferred configuration, the holder 130 relies upon both a slot-and-key and a tight friction fit to lock the holder 130 relative to the applicator.

[0112] Referring again to FIGS. 11A and 11B, bend portion 140 includes circular rings 141 and a curved spine 142. The circular rings 141 prevent radial collapse of the

conduit, and the curved spine 142 holds the conduit in a preferred shape to direct blood flow from the heart to the aorta. The curved spine 142 may be at the outer radius of bend portion 140 (as shown) or at the inner radius of the flexible bend. As an alternative, flexible bend 140 may include two curved spines at the mean radius. As another alternative, the structural frame 101 could include circular rings 141 without curved spine 142. As another alternative, a modified coil spring in the shape of a preferred bend could be used instead of circular rings 141 and curved spine 142. Properties of the coil spring would be chosen to prevent radial collapse and to provide appropriate stiffness of the curved position.

[0113] The structural frame of FIGS. 11A - 12 is intended for mounting onto the outer diameter of a straight mounting element. As such, the bend portion 140 must be constructed to allow straightening of the curved spine 142. If curved spine 142 is made of a material or combination of materials with higher modulus of elasticity (e.g., PEEK, metal), the flexible bend 140 is stiffer. As such, the flexible bend 140 may be biased to resume a preferred shape (e.g., a 90° bend) when removed from the mounting element. If the curved spine 142 is made of a material with a lower modulus of elasticity (e.g., polypropylene, polyethylene), the bend portion 140 is less stiff. As such, the bend portion 140 may be biased relatively straight when removed from the straight mounting element. In such case, some bending means may be needed to position the bend portion 140 into the preferred shape.

[0114] One embodiment of a bending means is shown in FIGS. 13A and 13B, which illustrate use of threads 143 that are secured to the holder 130 (for example) and weaved through circular rings 141. When threads 143 are pulled, the bend portion 140 changes from the normally biased, straight configuration of FIG. 13A to the bent configuration of FIG. 13B. When the flexible bend 140 reaches the preferred shape, the threads may be tied to form a knot or crimped. If desired, the bending means can be used with a curved spine 142 constructed of a high modulus of elasticity material to prevent straightening beyond the preferred angle.

[0115] As discussed previously, structural frame 101 may be constructed with a fixed bend 145, as shown in FIG. 14. A port 146 allows the mounting of structural frame 101 with a fixed bend 145 onto a straight mounting element.

[0116] FIG. 15 is a cross-section of a connector conduit 100 that includes a rigid portion defined by structural frame 101 with bend portion 140, and a flexible portion defined by conduit 160. The rigid portion also includes outer fabric 161, and sewing flange 170.

Orientation marks (not shown) may be included on the conduit 160 or outer fabric 161. Conduit 160 may be a pleated vascular graft constructed of woven Dacron. Outer fabric 161 could be a knitted Dacron fabric material that stretches to accommodate contours of the structural frame 101. Sewing flange 170 could be constructed of a soft silicone rubber, for example, to allow easy passage of a needle when fastening sewing flange (or sewing ring) 170 to the outer surface of the heart. To allow visualization on x-ray, for example, the sewing flange could be made radiopaque, such as by mixing barium sulfate into the silicone rubber. The sewing flange may have a cloth covering such as that used for outer fabric 161. Alternatively, the sewing flange 170 may consist entirely of folded cloth. The components of the connector conduit 100 may be fastened together as needed, such as with thread.

[0117] Referring to FIG. 16, a cross-section of a connector conduit 100 is similar to that shown in FIG. 15, except that the structural frame 101 is constructed with fixed bend 145. A conduit branch 162 intersects with conduit 160 through port 146 of rigid bend 145 to allow passage of a straight mounting element through the connector conduit 100. Once the connector conduit 100 is implanted into the ventricle, branch 162 may be occluded at the intersection with conduit 160. Branch 162 may then be cut off.

[0118] FIG. 15 and FIG. 16 further illustrate a quick connect coupler 180 for expediting attachment of the connector conduit 100 to the remainder of the prosthesis, which may include a prosthetic valve or ventricular assist device, as examples. As shown, the male end of quick connect coupler 180 is a continuation of or is attached to vascular graft 160. The male end of quick connect coupler 180 includes rigid connector frame 181, which may be constructed of a biocompatible plastic or metal. Vascular graft 160 covers the inner diameter of connector frame 181, and an outer fabric 165 covers the outer diameter of connector frame 181. Outer fabric 165 may be continuous with vascular graft 160. Outer fabric 165 is not of a pleated construction, such as is typical of vascular graft 160. The cloth-covered connector frame 181 provides a rigid surface onto which the female end of quick connect coupler 180 may be mounted. The female end of quick connect coupler 180 includes vascular graft 186 and pull ring 185. Vascular graft 186 attaches on its downstream end to the remainder of the prosthesis, which may include a prosthetic valve or ventricular assist device, as examples. Vascular graft 186 may be a pleated vascular graft constructed of woven Dacron, for example. Graft extension 186a is a continuation portion of or is attached to vascular graft 186. A rigid pull ring 185 (which may be constructed of a biocompatible plastic or metal) is attached to graft extension 186a. The male end of quick connect coupler

180 has a larger outer diameter than vascular graft 186. This construction provides a stop so that the male end of quick connect coupler 180 reaches an abrupt change to a smaller diameter provided by vascular graft 186. In this way, the surgeon knows when the male end is fully inserted into the female end of quick connect coupler 180. In use, the surgeon may grasp pull ring 185 with one hand and connector frame segment 181a of connector frame 181 with the other hand. Pull ring 185 is pulled over outer fabric 165 until the male end of quick connect coupler 180 contacts the smaller diameter vascular graft 186. A large suture or umbilical tape 187 may then be tied around graft extension 186a to reduce blood loss by occluding the annular gap between the outer diameter of outer fabric 165 and the inner diameter of graft extension 186a. Stay sutures may also be used to connect outer fabric 165 to graft extension 186a, thereby preventing separation of the male and female ends of quick connect coupler 180.

[0119] FIG. 15 and FIG. 16 further illustrate a collapsible portion 160a between connector conduit 100 and quick connect coupler 180. Such collapsible portion 160a allows use of a cross clamp, for example, to fully collapse portion 160a to occlude flow after the applicator is removed beyond collapsible portion 160a. Collapsible portion 160a can be made of the same material as the rest of the flexible portion, or can be made of a different material.

[0120] In use, the applicator of the present invention is used to implant the connector conduit 100 into the ventricle wall or other organ wall. FIG. 17A shows a cross-section of the connector conduit 100 (FIG. 15) loaded onto a mounting element 200. For clarity, the applicator is shown without the connector conduit 100 in FIG. 17B. Mounting element 200 includes a cylindrical coring element 210, serving as a hole forming element, that is concentric with and has the same diameter as the mounting element 200. The mounting element 200 and coring element 210 are placed concentrically within the lumen of the connector conduit 100. Coring element 210 includes a thin-walled tube and a sharpened cutting edge 210a, which may be tapered on the inner diameter, for example, to form the sharpened cutting edge 210a. The coring element 210 is used to cut a cylindrical-shaped core (or hole) in the heart wall, producing a plug from the heart wall that resides within the coring element 210. The mounting element 200 could be constructed of plastic (e.g., ABS), and the coring element 210 could be constructed of metal (e.g., stainless steel). In a preferred embodiment, the mounting element 200 and coring element 210 have an outer diameter that closely matches the inner diameter of the connector conduit 100. One purpose of such a

construction is to minimize blood loss from the left ventricular chamber when the coring element 210 has completed its cut. Also in order to reduce blood loss from the left ventricular chamber and from the cut myocardial surface and to yield a snug fit of the connector conduit within the ventricular myocardium, the cutting diameter of the coring element 210 is chosen to produce a core that is smaller in diameter than the outer surface 163 of the of the connector conduit 100.

[0121] FIGS. 17A and FIG. 17B further illustrate a cylinder-shaped pushing element 300 positioned concentrically outside the connector conduit 100. In a preferred embodiment, the pushing element 300 transmits pushing force and rotation to the connector conduit 100. In further accordance with a preferred embodiment, the pushing element 300 is rigidly attached to mounting element 200, such that pushing element 300 transmits pushing force and rotation to the mounting element 200 and coring element 210. Pushing element 300 may be constructed of plastic (e.g., ABS) or metal (e.g., stainless steel). However, it should be appreciated that the present invention contemplates the use of other materials.

[0122] In further accordance with a preferred embodiment, a locking means provides an interface that prevents movement of the connector conduit 100 relative to the pushing element 300. Such locking means may include components that are integral with the pushing element 300, connector conduit 100, mounting element 200, and coring element 210. FIGS. 18A to 18C illustrate one embodiment of such a locking means. This embodiment combines a slot-and-key arrangement with a friction enhancing arrangement. The slot-and-key arrangement includes notch 421 (the slot) of pushing element 300 and holder button 430 (the key) of structural frame 101. Positioning holder button 430 into notch 421 prevents rotation of connector conduit 100 relative to pushing element 300 and prevents axial motion in one direction. Axial motion allowing removal of the connector conduit 100 from the applicator is not prevented in this embodiment. Rather, this axial motion is reduced by providing a friction enhancing arrangement consisting of squeeze ring 410 (which includes two groove pins 411) and squeeze arms 425a and 425b that cantilever from pushing element 300 to form wide groove 420a and narrow groove 420b. Alternatively, notch 421 could fit tightly around the circumference of holder button 430 to prevent movement of the connector conduit 100 relative to the pushing element 300 in both rotational and axial directions. As shown, notch 421 is divided, with one half cut from squeeze arm 425a and the other half from squeeze arm 425b. Alternatively, notch 421 could reside entirely within either squeeze arm. Alternatively, several notches 421 could be used.

[0123] When squeeze ring 410 is positioned at or near notch 421 as shown in FIG. 18B, squeeze ring 410 holds squeeze arms 425a and 425b tightly against connector conduit 100, creating a tight friction fit. In this position, groove pins 411 within wide groove 420a do not tend to separate squeeze arms 425a and 425b. When squeeze ring 410 is positioned as shown in FIG. 18C, groove pins 411 within narrow groove 420b tend to separate squeeze arm 425a and 425b to allow the connector conduit to be easily moved into position or removed. In a similar embodiment (not shown), the slot-and-key arrangement could include teeth (keys) that extend radially inwards from the inner diameter of squeeze arms 425a and 425b to fit into holder slots 431 of holder 130 of structural frame 101 (see FIG. 11A). In this embodiment, a squeeze ring (with groove pins) and squeeze arms similar to those shown in FIGS. 18A to 18C would be used to engage and disengage the teeth from holder slots 431, rather than to provide a tight friction fit.

[0124] In accordance with a further embodiment of the present invention, a retractor component/element 500 with a generally tubular structure is located concentrically within the mounting element 200, as shown in FIG. 19. The retractor element 500 can slide axially relative to the mounting element 200. The retractor element 500 consists of a blunt tip 510, a tubular body 520, and an expanding element 530 that includes an access passage 531. The expanding element 530 is shown as a balloon in FIG. 19, which may be inflated and deflated with fluid (e.g., saline) through access passage 531 using a plunger and cylinder arrangement.

[0125] Retractor element 500 is held concentric within the mounting element 200 by centering plug 220 and sliding plug 521. Centering plug 220 is rigidly attached to mounting element 200, and sliding plug 521 is rigidly attached to tubular body 520. Since radial force from the heart wall tends to deflect the expanding element 530, tubular body 520 must have a sufficient stiffness to substantially resist such deflection. Such deflection may also be reduced by limiting the axial distance between the expanding element 530 and centering plug 220.

[0126] A coupling element, such as compression spring 540, slideably couples retractor element 500 to mounting element 200. Compression spring 540 biases refractor element proximally to ensure that expanding element 530 seats snugly against the inside wall of the ventricle to shape and partially flatten the ventricle wall (particularly at the apex) so that coring element 210 may cut perpendicular to the ventricle wall. Once the tissue plug is cut from the ventricle by coring element 210, spring 540 pulls the tissue plug fully within the

coring element 210. In the preferred embodiment, expanding element 530 is a balloon in the shape of a circular torrid.

[0127] FIG. 20 illustrates a mounting and folding tool 900, which includes coring element taper 910, balloon taper 920, conduit taper 930, and retractor element port 940. Tool 900's outer diameter may be equal to or slightly larger than coring element 210's outer diameter to prevent damage to fabrics of the vascular graft 160 and outer fabric 161, when the connector conduit 100 is being mounted onto or demounted from mounting element 200. As an alternative, a thin-walled tube, such as a plastic shrink tube, may be positioned over outer diameters of tool 900 and coring element 210 to further prevent damage to fabrics slid past the sharpened edge 210a of the coring element. Coring element taper 910 fits snugly within coring element 210 to ensure a concentric fit between tool 900 and coring element 210, thereby further reducing the likelihood of damage to vascular graft 160 and outer fabric 161. Conduit taper 930 eases placement of vascular graft 160 onto tool 900. Tool 900 may be used to deflate and fold expanding element 530 by placing tool 900 onto retractor element 500 and by pushing and rotating (in one direction) tool 900 until coring element taper 910 contacts coring element 210. Balloon taper 920 provides a surface for controlled deflation and folding of the expanding element 530. Once the balloon is deflated and folded and the connector conduit 100 is fully mounted onto the applicator, tool 900 may be removed.

[0128] FIG. 21 illustrates an embodiment of an applicator assembly (connector conduit 100 not shown). In this assembly, the surgeon has independent control of the position of retractor element 500 and the volume of expanding element 530. Handle 310, which extends from pushing element 300 to form a pistol grip, provides a means for the surgeon to apply axial force and back-and-forth rotary motion while implanting connector conduit 100. The position of retractor element 500 is controlled by the position of retractor bolt 522 in slot 320 of pushing element 300. Retractor bolt 522 is rigidly attached to sliding plug 521 of retractor element 500. Slot 320 is extended circumferentially to form index 321, which may be used to hold the retractor element 500 fully extended (i.e., with expanding element 530 at maximum distance from coring element 210). Expanding element 530 is connected to cylinder 562 by access passage 531 and flexible tube 550. Expanding element 530 volume is controlled by the position of plunger 600 in cylinder 562. Cylinder 562 is oriented in handle 310 so that plunger 600 with trigger 563 forms a pistol handle with trigger arrangement. Expanding element 530 can be inflated with saline, when trigger 563 is squeezed. Plunger spring 565 may be used to deflate expanding element 530 when the

trigger is released. Alternatively, trigger 563 could be replaced with a finger ring so that the user must apply force to control both inflation and deflation of expanding element 530, thereby eliminating the need for plunger spring 565. As a safety feature, the plunger 600 may include a latching device (not shown) that latches the plunger 600 with the balloon fully inflated, thereby preventing premature deflation of the balloon. A related safety feature may include another latching device (not shown) that latches plunger 600 with the balloon partially inflated, such as to prevent the tissue plug from coming off of retractor element 500. As one of many alternatives to handle 310, the handle could form a "T" with pushing element 300.

[0129] In operation, retractor bolt 522 is positioned in index 321 until the retractor element 500 is fully inserted into the ventricle and expanding element 530 is fully inflated. At that time, retractor bolt 522 is manually released from index 321, which allows compression spring 540 to retract retractor element 500 until expanding element 530 contacts the inside wall of the ventricle. A damping means (not shown) may be included to prevent sudden retraction of the retractor element 500 upon release from index 321. Also not shown is a safety latch or other means to prevent manual release of the retractor bolt 522 until the expanding element 530 is fully expanded. As the surgeon applies force and rotation using handle 310, compression spring 540 continues to displace retractor element 500. When retractor element 500 is fully retracted, expanding element 530 is also fully retracted to within coring element 210, indicating that the tissue plug has been successfully removed from the left ventricle and is within the coring element 210.

[0130] FIG. 22A to FIG. 22C are components of a preferred embodiment shown in FIGS. 24A-24E, that uses a sequencing element to coordinate the position of retractor element 500 with the expansion of expanding element 530 (FIG. 22B). In this embodiment, the sequencing element is a cam mechanism. The cam mechanism helps to ensure proper use of the applicator during implantation of connector conduit 100 (not shown). As shown in FIG. 22B, retractor element 500, referred to as the retractor assembly, includes cylinder portion 562 integrated therein. The retractor assembly is positioned concentrically within pushing element 300 during use. The retractor assembly contains elements of the cam mechanism formal therein, including cylinder cam slot 710, which is a slot cut completely through the cylinder 562 wall, and a retractor cam follower 760, which may be a pin or screw in cylinder 562 (as shown) or may be an integral part of cylinder 562. Retractor element 500 may include a section of increased diameter such as stopper disk 515 to prevent cutter

element 210 from cutting the heart when retractor element 500 is initially inserted. FIG. 22A illustrates plunger 600 (in the form of a sequencing bolt as described below), which is positioned concentrically within cylinder 562 during use. Plunger 600 contains elements of the cam mechanism, including bolt portion 650 with plunger cam follower 750. Plunger cam follower 750 moves within cylinder cam slot 710 and pusher cam slot 720. Plunger 600 includes passage 610 and purge/fill valve 630 (valve body not shown). Valve 630 can be opened to allow fluid flow into and out of passage 610. When closed, valve 630 allows no fluid flow in either direction. Valve 630 may be connected (such as with a catheter) to a reservoir of saline, for example, to purge the expanding element 530, access passage 531 and any other volume in the flow circuit of air before filling these volumes with fluid (such as saline). O-ring groove 620 of plunger 600 contains an o-ring (not shown) to prevent loss of fluid.

[0131] FIG. 22C illustrates a positioning assembly, which is made up of rigidly connected components including pushing element 300, cutting element 210, and handle 310. The pusher assembly contains elements of the cam mechanism, including pusher cam slot 720 and retractor cam slot 730. The pusher cam slot 720 is a slot cut completely through the pushing element 300 wall to accommodate plunger cam follower 750.

[0132] FIG. 23A to FIG. 23C illustrate operation of the cam mechanism. FIG. 23A illustrates cylinder cam slot 710 cut into cylinder 562 of FIG. 22B. Cylinder cam slot 710 contains three interconnected axial cam slots at angles Θ_1, Θ_2 and Θ_3 around the circumference of cylinder 562, as further illustrated in FIG. 23C. The axial cam slot at each angle corresponds to a range of allowable axial positions of plunger 600 within cylinder 562. At angle Θ_1, the axial length of the cam slot corresponds to the maximum stroke of plunger 600 within cylinder 562. This maximum stroke allows filling the expanding element 530 from minimum volume to maximum volume. At angle Θ_2, the axial cam slot allows plunger 600 movement to provide expanding element 530 volumes ranging from maximum volume to an intermediate volume (at an intermediate stroke) that is greater than minimum volume but less than maximum volume. At angle Θ_3, the axial cam slot retains plunger 600 at the position of maximum volume of the expanding element 530. FIG. 23A also illustrates positions A, B, C, D and E of plunger cam follower 750 within cylinder cam slot 710 during the steps of operation.

[0133] FIG. 23B illustrates pusher cam slot 720 and retractor cam slot 730 cut into the pusher assembly of FIG. 22C. FIG. 23B also illustrates positions A, B, C, D and E of

plunger cam follower 750 within pusher cam slot 720 and retractor cam follower 760 within retractor cam slot 730 during the steps of operation. FIG. 23C illustrates angles Θ_1 to Θ_6 for cylinder 562 and the pusher assembly. For purposes of description, the value of the angles increases from Θ_1 to Θ_6. Pusher cam slot 720 includes angles Θ_1 and Θ_3, which may correspond with angles Θ_1 and Θ_3 of cylinder 562 (see FIG. 23A). Pusher cam slot 720 includes angle Θ_4, which is larger than Θ_3. The axial length of pusher cam slot 720 from position A to position B corresponds to the maximum stroke of the plunger 600, as described above. The axial length of pusher cam slot 720 from position C to position E corresponds to the intermediate stroke (as described above) plus the axial distance traversed by retractor cam follower 760 from position C to position E in retractor cam slot 730. Retractor cam slot 730 includes angles Θ_5 and Θ_6. Positions A and B at angle Θ_5 prevent compression spring 540 from displacing cylinder 562 within the pusher assembly.

[0134] In operation, retractor cam slot 730 controls the motion of cylinder 562 within the pusher assembly. As shown in FIG. 23A and FIG. 23B, when plunger cam follower 750 (of sequencing bolt 600) is moved circumferentially from position B to position C in both cylinder cam slot 710 and pusher cam slot 720, retractor cam follower 760 is forced from position B to position C in retractor cam slot 730, which allows compression spring 540 (see FIG. 19) to push cylinder 562 axially within the pusher assembly. Retractor cam follower 760 within retractor cam slot 730 holds cylinder 562 at a constant angular position relative to the pusher assembly during movement from position C to positions D and E; therefore, movement of plunger cam follower 750 from position C to position D within pusher cam slot 720 forces cam follower 750 into the axial slot corresponding to angle Θ_2 of cylinder 562.

[0135] Referring to FIGS. 24A to 24E, the applicator of the present invention is shown at various steps during use. Note that these figures do not include details of the locking means to securely hold the connector conduit 100. FIG. 24A to FIG. 24E correspond to positions A to E, respectively, which are described in FIG. 23A to FIG. 23C. Recognizing that individual surgeons may find alternative steps to properly use the invention, a representative sequence of steps for use of the applicator to implant a connector conduit is described. These steps include first preparing the applicator with the connector conduit. With the retractor assembly in the fully extended position as shown in FIG. 24A, a mounting and folding tool 900 is positioned into the coring element 210, as shown in FIG. 20. The connector conduit 100 of FIG. 15 is then loaded into the applicator by sliding connector

conduit 100 over the folding tool 900 until sewing flange 170 contacts notch 421 (see FIG. 18). The connector conduit is then locked into place using the locking means. Tool 900 is then removed. A catheter is attached to purge/fill valve 630 and to a reservoir of saline. Valve 630 is opened. Sequencing bolt 600 is then moved back and forth from position A to position B several times to purge the fluid system of air and to fill the system with fluid, such as saline. Once the air is purged, sequencing bolt 600 is placed at position A, and tool 900 is again positioned into the coring element 210 – this time to squeeze fluid from the balloon and to fold the balloon. When tool 900 is in place, valve 630 is closed, and the catheter is removed. Tool 900 is removed. The applicator with connector conduit is now ready for use, as shown in FIG. 24A.

[0136] Before implanting the connector conduit 100 into the ventricle wall, the portion of the prosthesis that includes the prosthetic valve or ventricular assist device, as examples, is connected to the aorta. This portion of the prosthesis also includes the female end of quick connect coupler 180. By implanting this portion of the prosthesis first, the time between insulting the heart by cutting a hole and beginning blood flow through the complete prosthesis is minimized.

[0137] A template with similar dimensions as connector conduit 100 is placed on the apex of the heart, and a marker is used to trace the circular outline of the connector onto the apex, in the planned location of insertion. Multiple (8 to 12) large pledgeted sutures (mattress sutures) of for example, 2-0 prolene, are placed in the apex surrounding the marked circle. With the connector conduit 100 loaded in the applicator of FIG. 24A, the sutures are brought through sewing flange 170 of the connector conduit 100. A knife is used to make a stab wound in the apex at the center of the circle. With the applicator in the position shown in FIG. 24A, blunt tip 510 of retractor element 500 is inserted into the stab wound and pushed through the apex into the left ventricle chamber until stopper disk 515 contacts the epicardium (outside surface of the heart). Sequencing bolt 600 is moved from position A to position B to inflate the balloon behind tissue T of the heart wall (see FIG. 24B). The surgeon moves sequencing bolt 600 from position B to position C (see FIG. 24C) and then releases sequencing bolt 650. Beginning at position C of FIG. 24C, compression spring 540 pushes the retractor assembly from position C to position D (see FIG. 24D). When the retractor assembly moves from position C to position D, tissue T of the heart wall is first sandwiched between the balloon and the sharpened edge of the coring element 210a. By the surgeon using handle 310 to apply axial force and back-and-forth rotary motion, the

sharpened edge of the coring element 210a cuts though the heart wall to form a plug of tissue T that resides in the coring element 210. At position D, the retractor assembly has been retracted until the balloon is in contact with coring element 210 and the tissue plug is fully within coring element 210. Also at position D, cylinder cam slot 710 has forced plunger cam follower 750 circumferentially to angle Θ_2, thereby allowing deflation of the balloon to begin. Between position D (FIG. 24D) and position E (FIG. 24E), the balloon deflates to the intermediate volume (described earlier), and the retractor assembly retracts to its final position. If necessary, the surgeon may pull sequencing bolt 600 to its final position E.

[0138] Connector conduit 100 is now fully implanted. The sutures are tied, and hemostasis is checked. Additional sutures may be placed if needed. The locking means (not shown) holding the connector conduit in the applicator is released, and the applicator is partially removed to a position where a clamp can be placed directly on collapsible graft 160a to prevent blood flow through the conduit 160. Once the clamp is in place, the applicator may be completely removed from connector conduit 100. The male and female ends of quick connect coupler 180 may now be connected. Umbilical tape 187 may be tied around graft extension 186a to reduce any blood leakage, and stay sutures may be used to secure graft extension 186a to outer fabric 165. Once the flow passage of the prosthesis is purged of air, the clamp may be released to allow blood flow through the prosthesis. Flexible bend 140 is formed by pulling threads 143 and tying a knot. The connector conduit 100 is now fully implanted.

[0139] As illustrated in FIG. 27, an alternative embodiment, can use a connector conduit having and integral hole forming element. Hole forming element 21' is integrally formed, i.e. formed as a single component, with respect to connector conduit 100'. Connector conduit 100' can be loaded on an applicator (not having a separate hole forming element) in a manner similar to that disclosed above. After forming the hole and inserting the connector conduit into the hole, hole forming element 210' can be withdrawn into a distal end of connector conduit 100', as illustrated in FIG. 26, to reduce the possibility of unintended tissue damage. Such withdrawal can be accomplished by the sequencing means, a manual mechanism on the applicator, or with a separate instrument.

[0140] In the preferred embodiment described above, the expansion element is a balloon. However, an alternative expansion element, in the form of an umbrella mechanism, is illustrated in FIGs. 27A-27D. Retractor 500' includes cylinder 810 (shown in cross section), and piston element 820 slideably disposed in cylinder 810. Bolt 650 having

follower 750 is formed on cylinder 810. Shaft 830 extends from piston element 820 and has umbrella mechanism 850 formed on an end thereof. Umbrella mechanism 85 included plural bendable leaf elements 852 that are fixed to shaft 830 at the end of shaft 830. Leaf elements 852 are fixed to ring 854 at the other end thereof. Rign 854 is slideably disposed on shaft 830. Accordingly, movement of shaft 830 to te right in the FIGS. causes ring 854 to be pushed toward the end of shaft 830 as ring 854 abuts an end of cylinder 810, as shown in FIG. 27 D. Slot 710 guides follower 750, ad bolt 650 cooperates with remaining elements in the sequencing mechanism in the manner described above, to coordinate the expansion state of expansion element 850.

[0141] Although the present invention has been described in relation to particular embodiments thereof, many other variations and modifications and other uses will become apparent to those skilled in the art. It is preferred therefore, that the present invention be limited not by the specific disclosure herein, but only by the appended claims.

WHAT IS CLAIMED IS:

1. An applicator for forming a hole in a wall of a hollow organ and for inserting a connector conduit into the hole to facilitate connection of the connector conduit to the hollow organ, said applicator comprising:

a hole forming element for forming a hole in the wall of the organ, said hole forming element having a cutting element on a distal end thereof and being adapted for coupling with the connector conduit, with a distal end of said connector conduit being adjacent said cutting element during a procedure for implanting the connector conduit within the organ wall;

positioning means coupled to said hole forming element for positioning said hole forming element;

a retractor element operatively coupled to said positioning means; and

sequencing means for coordinating the relative movement of said retractor element with respect to said hole forming element in a sequential manner to thereby carry out a procedure for forming a hole in the wall of the hollow organ and inserting the connector conduit in the hole.

2. The applicator of claim 1, wherein said cutting element is a cutting blade defined on a distal end of said hole forming element.

3. The applicator of claim 1, further comprising occluding means for providing substantial hemostasis throughout a procedure for implanting the connector conduit within the organ wall while the organ remains at substantially normal physiological pressures.

4. The applicator of claim 3, wherein the organ is a heart.

5. The applicator of claim 1, further comprising a connector conduit coupled to said hole forming element, said cutting element extending from said connector conduit such that said connector conduit can be inserted into the organ wall substantially at the same time as the hole is being formed by said hole forming element.

6. The applicator of claim 1, further comprising a connector conduit coupled to said hole forming element, said cutting element extending from said connector conduit such that the

hole can be cut and said connector conduit can be inserted into the organ wall as a result of the same motion imparted to said positioning means.

7. The applicator of claim 1, further comprising a connector conduit coupled to said hole forming element, such that said connector conduit is fixed with respect to said positioning means.

8. The applicator of claim 1, wherein a distal end thereof, as a whole, defines a blunt tip.

9. The applicator of claim 1, further comprising a connector conduit coupled to said hole forming element.

10. The applicator of claim 9, wherein the connector conduit is integrally formed with said hole forming element.

11. The applicator of claim 9, wherein said connector conduit is disposed on a mounting portion defined on an outer surface of said hole forming element.

12. The applicator of claim 11, wherein said outer surface of said hole forming element has a diameter that is substantially equal to an inner diameter of said connector conduit.

13. The applicator of claim 9, wherein said hole forming element and said connector conduit are fixed relative to one another during a hole forming and conduit insertion procedure.

14. The applicator of claim 1, wherein said retractor element includes a protective stopper element disposed distally of said cutting element when said retractor element is in a distal position with respect to said cutting element to thereby protect tissue from being damaged by said cutting element during insertion of the retractor element into the organ.

15. The applicator of claim 1, wherein said retractor element is disposed at least in part within said hole forming element.

16. The applicator of claim 15, wherein said retractor element is disposed at least in part within said hole forming element, and wherein said occluding means is defined by an outer diameter of at least a portion of said retractor element and an inner diameter of at least a portion of said positioning means.

17. The applicator of claim 1, wherein said retractor element comprises a retractor body movably disposed within said hole forming element and an expansion element disposed on a distal end of said retractor body, said expansion element being expandable.

18. The applicator of claim 17, wherein said expansion element is expandable from an unexpanded state to fully expanded state and to a partially expanded state.

19. The applicator of claim 17, wherein said expansion element is a balloon.

20. The applicator of claim 19, wherein said balloon is in the shape of a circular toroid.

21. The applicator of claim 17, wherein said expansion element is an expandable sponge.

22. The applicator of claim 17, wherein said expansion element is an umbrella mechanism.

23. The applicator of claim 18, further comprising means for expanding said expansion element from the unexpanded state, to the fully expanded state, and to the partially expanded state in a sequential manner, said means for expanding being coupled to said sequencing means..

24. The applicator of claim 23, wherein said expansion element is a balloon and said means for expanding comprises a syringe in fluid communication with said balloon.

25. The applicator of claim 23, wherein said expansion element is a sponge and said means for expanding comprises a syringe in fluid communication with said sponge.

26. The applicator of claim 23, wherein said expansion element is an umbrella device and said means for expanding comprises a cylinder having a piston slideable therein and coupled to said umbrella device.

27. The applicator of claim 17, further comprising means for moving said retractor element relative to said hole forming element whereby said expansion element is moved from a position distally outside of said hole forming element to a position within said hole forming element.

28. The applicator of claim 9, wherein said positioning means is operative to transmit axial and torsional force applied by a surgeon to the hole forming element and the connector conduit whereby the surgeon can cut the hole and insert the connector conduit into the organ with the same motion.

29. The applicator of claim 18, wherein said sequencing means further comprises means for coordinating the expansion state of said expansion element with respect to the relative movement of said retractor element and said hole forming element.

30. The applicator of claim 29, wherein said sequencing means comprises a cam mechanism.

31. The applicator of claim 29, wherein said sequencing means comprises a gear mechanism.

32. The applicator of claim 29, wherein said sequencing means comprises at least one servo mechanism operatively coupled to the positioning means and a controller operatively coupled to said at least one servo mechanism.

33. The applicator of claim 32, wherein said controller mechanism comprises a microprocessor based device.

34. The applicator of claim 33, further comprising a button operatively coupled to said sequencing means for activating said sequencing means upon depression of the button to

thereby accomplish steps of a procedure for implanting the connector conduit within the organ wall.

35. The applicator of claim 24, wherein said retractor body comprises a cylinder portion and a retractor mounting portion extending from a distal end of said cylinder portion, said expansion element being disposed on said retractor mounting portion, and wherein said syringe comprises a sequencing bolt slidably disposed within said cylinder portion, said sequencing bolt being coupled to said sequencing means.

36. The applicator of claim 35, wherein said positioning means further comprises a pushing element for transmitting force to the connector conduit, said sequencing means comprising a first slot formed in said pushing element, said sequencing bolt extending through said first slot and being movable in said first slot.

37. The applicator of claim 36, wherein said sequencing means comprises a second slot formed in said pushing element and wherein said retractor element includes a retractor follower formed on said retractor body and movably disposed in said second slot.

38. The applicator of claim 37, wherein said sequencing means comprises a cam slot formed in said retractor body, said sequencing bolt extending through said cam slot and being movable within said cam slot.

39. The applicator of claim 38, wherein said sequencing bolt is movable between a first and second position in said first slot to move said sequencing bolt in said cylinder portion and expand said expansion element to the fully expanded state while said retractor follower in said second slot remains locked with said retractor element in a fully extended position relative to said hole forming element.

40. The applicator of claim 39, wherein said sequencing bolt is movable between the second position and a third position in said first slot and in said cam slot to lock said expansion element in the fully expanded state.

41. The applicator of claim 40, wherein said sequencing bolt is movable between the third position and a fourth position in said first slot, such that when said sequencing bolt is moved

to the fourth position said retractor cam follower is simultaneously moved within said second slot to enable said retractor element to move with respect to said hole forming element.

42. The applicator as recited in claim 41, wherein movement of said sequencing bolt from the first position to the fourth position can be accomplished manually in a substantially continuous manner.

43. The applicator of claim 41, wherein said sequencing bolt is movable between the fourth position and a fifth position in said first slot, such that said retractor element is simultaneously moved with respect to said hole forming element to position the organ wall between said expansion element and said cutting element, whereby upon manipulation of said positioning means a hole in the tissue is cut by said hole forming element and the connector conduit is moved into the hole.

44. The applicator of claim 43, further comprising means for automatically accomplishing movement of said sequencing bolt between said fourth position and said fifth position.

45. The applicator of claim 43, wherein said sequencing bolt is movable between the fifth position and a sixth position in said first slot and said cam slot, wherein at said sixth position said sequencing bolt is moved with respect to said cylinder portion whereby said expansion element is in the partially expanded state and said retractor element moves in a proximal direction with respect to said hole forming element until said expansion element is at least partially disposed within said hole forming element.

46. The applicator of claim 45, further comprising means for automatically accomplishing movement of said sequencing bolt between said fifth position and said sixth position.

47. The applicator of claim 45, further comprising a biasing element coupled to said retractor element and said pushing element to bias said retractor element in a proximal direction with respect to said pushing element and thereby automatically move said sequencing bolt from said fourth position to said fifth position and from said fifth position to said sixth position.

48. The applicator as recited in claim 47, wherein said biasing element is a spring.

49. The applicator of claim 9, wherein said connector conduit includes a rigid portion having first and second ends and a tapered leading edge on the first end of said rigid portion to ease insertion into the organ wall.

50. The applicator of claim 49, wherein said connector conduit further includes a flexible portion extending from the second end of said rigid portion.

51. The applicator of claim 50, wherein said rigid portion includes a bendable portion at said second end.

52. The applicator of claim 51, wherein said bendable portion is normally biased to form said conduit into a bent configuration.

53. The applicator of claim 51, wherein said bendable portion is normally biased to form said conduit into a straight configuration.

54. The applicator of claim 53, further comprising means for bending said bendable portion into a bent configuration.

55. The applicator of claim 54, wherein said means for bending comprises threads that can be tightened against the biasing force of said bendable portion.

56. The applicator of claim 52, further comprising means for straightening said connector conduit from a bent configuration to load the connector conduit on the applicator.

57. The applicator of claim 50, wherein said connector conduit comprises a quick connect coupler disposed on one end of said flexible portion.

58. The applicator of claim 50, wherein at least a part of said flexible portion is made of a collapsible material to permit clamping of said portion to occlude blood flow through said connector conduit when said connector conduit is removed from said applicator.

59. The applicator of claim 35, wherein, in said partially expanded state, said expansion element has a diameter that is larger than a diameter of said retractor mounting portion.

60. The applicator of claim 35, wherein, in said fully expanded state, said expansion element has an outer diameter larger than an outer diameter of said hole forming element to thereby facilitate positioning of the organ wall as said expansion element is biased toward said hole forming element.

61. The applicator of claim 35, wherein, in said partially expanded state, said expansion element has an outer diameter that is less than an inner diameter of said hole forming element and greater than an outer diameter of said retractor mounting portion to thereby position a tissue plug within said hole forming element.

62. The applicator of claim 35, wherein said syringe is in fluid communication with said expansion element via an axial passageway defined in said retractor mounting portion.

63. The applicator of claim 62, wherein said sequencing bolt has a passage formed therethrough that is in fluid communication with said syringe to facilitate purging and filling of said balloon.

64. The applicator of claim 11, wherein said positioning means includes a pushing element disposed at one end of said mounting portion for transmitting axial and torsional force from said positioning means to said hole forming element and the connector conduit.

65. The applicator of claim 64, wherein said positioning means further includes a handle attached to said pushing element for facilitating application of axial and torsional forces necessary to cut the tissue and position the connector conduit in the wall of the hollow organ.

66. The applicator as recited in claim 9, further comprising an indexing element formed on said connector conduit and a mating element formed on said positioning means to maintain the connector conduit in a predetermined position with respect to said hole forming element during cutting of the tissue and insertion of the connector conduit in the wall of the hollow organ.

67. The applicator as recited in claim 50 wherein said rigid portion has a bend defined therein, a hole being formed in said rigid portion at said bend to facilitate insertion of an applicator into said rigid portion.

68. The applicator as recited in claim 50, wherein said flexible portion extends through said rigid portion.

69. The applicator as recited in claim 50, wherein said connector conduit further includes a sewing ring to facilitate attaching said connector conduit to tissue with sutures.

70. A connector conduit adapted to be connected to a hollow organ by having a portion thereof inserted into a hole formed in a wall of the hollow organ, said connector conduit comprising:

a substantially rigid portion defining a first end and having a tapered leading edge to facilitate insertion through a wall of an organ;

a flexible portion defining a second end, said flexible portion being collapsible to permit clamping to occlude blood flow through said connector conduit during a procedure.

71. A connector conduit as recited in claim 70, wherein said rigid portion includes a bendable portion that is normally biased into a bent configuration.

72. A connector conduit as recited in claim 70, wherein said rigid portion includes a bendable portion that is normally biased into a straight configuration.

73. A connector conduit as recited in claim 70, further comprising an indexing element that is adapted to engage a mating element on an applicator to maintain the connector conduit in a predetermined position with respect to the applicator during insertion of the connector conduit in a hole.

74. A connector conduit as recited in claim 72, further comprising means for bending said bendable portion into a bent configuration.

75. The applicator of claim 74, wherein said means for bending comprises threads that can be tightened against the biasing force of said bendable portion.

76. The connector conduit of claim 70, wherein said flexible portion extends through said rigid portion.

77. The connector conduit of claim 70, further comprising a cover disposed over said rigid portion.

78. The connector conduit of claim 70, further comprising a quick connect coupler element disposed on one end of said flexible portion.

79. The connector conduit as recited in claim 78, wherein said quick connect coupler element comprises a rigid connector frame and serves as a male coupler.

80. The connector conduit as recited in claim 79 wherein said flexible portion is made of a fabric material and wherein said flexible portion extends through said rigid connector frame so that an internal surface of said rigid connector frame is covered with said fabric material.

81. The connector conduit as recited in claim 80, wherein an outer surface of said rigid connector frame is covered with said fabric material, said fabric material being continuous with fabric material on the internal surface of the connector frame.

82. The connector conduit of claim 81, further comprising a mating conduit element having a mating female quick connect coupler element to thereby permit coupling said mating conduit element to said flexible portion of said conduit after said connector conduit has been connected to the hollow organ with an applicator.

83. The connector conduit as recited in claim 82, wherein the female coupler comprises a flexible, fabric tube having an inner diameter that is substantially the same as the outer diameter of the rigid connector frame.

84. The connector conduit as recited in claim 83, wherein the female coupler further comprises a continuation portion of the fabric material having a larger diameter than the fabric material.

85. The connector conduit as recited in claim 84, wherein the outer diameter of the male connector is larger than the inner diameter of the fabric tube.

86. The connector conduit as recited in claim 85, wherein an outer surface of the rigid connector frame provides a surface onto which the female coupler may be mounted.

87. The connector conduit as recited in claim 86, wherein the female coupler includes a rigid pull ring mounted on the outer diameter of the continuation portion to facilitate pulling of the flexible fabric onto the male coupler.

88. The connector conduit of claim 70, wherein said rigid portion has a bend defined therein, a hole being formed in said rigid portion at said bend to facilitate insertion of an applicator into said rigid portion.

89. The connector conduit of claim 88, wherein said flexible portion is defined by a conduit element that extends through said rigid portion, said flexible portion being bifurcated at said bend portion.

90. The connector conduit as recited in claim 70, further comprising a sewing ring to facilitate attaching said connector conduit to tissue with sutures.

91. The applicator as recited in claim 1, further comprising a removable protection element disposed adjacent said cutting element to facilitate loading of a connector conduit on said outer surface prior to a procedure.

92. The applicator as recited in claim 1, further comprising a compression tool removable and slidably disposed over said balloon to purge fluid from said balloon.

93. The applicator as recited in claim 17, wherein said sequencing means comprises means for causing the elements to assume the following states in seriatim;

a) a first state where the retractor element is locked in a fully extended position relative to the hole forming element with the expansion element in the unexpanded state;

b) a second state in which the expansion element is in the fully expanded state and the expansion element moves toward the hole forming element;

c) a third state in which the hole has been formed; and

d) a fourth state in which the expansion element is in the partially expanded state and the expansion element is moved to be at least partially disposed in the hole forming element.

94. The applicator as recited in claim 38, wherein said sequencing means comprises means for causing the elements to assume the following states in seriatim;

a) a first state in which the sequencing bolt is moved in the first slot and the cam slot to expand the expansion element while the retractor element is locked in a fully extended position relative to the hole forming element;

b) a second state in which the sequencing bolt is moved in the first slot and the cam slot to retain the expansion element as fully expanded;

c) a third state in which the sequencing bolt moves in the first slot and the retractor follower moves in the second slot to release the retractor element and permit the spring to move the retractor element toward the hole forming element; and

d) a fourth state in which the sequencing bolt moves in the first slot while being locked in the cam slot and the retractor follower moves in the second slot to complete forming of the hole and allow insertion of the connector conduit into the hole; and

e) a fifth state in which the sequencing bolt moves in the first slot and in the cam slot to release the sequencing bolt from a locked position in the cam slot to allow the expansion element to assume the partially expanded state while the expansion element is moved to be at least partially disposed in the hole forming element.

95. The applicator as recited in claim 1, wherein the relative rotational position of the expansion element and the hole forming element are fixed.

96. The applicator as recited in claim 1, further comprising means for damping relative motion of the retractor element with respect to the hole forming element.

97. A method for using an applicator to form a hole in a wall of a hollow organ and insert a connector conduit into the hole, said applicator comprising a hole forming element having a cutting element on a distal end thereof and being coupled to the connector conduit with a distal end of said connector conduit being adjacent said cutting element, a retractor element having an expansion element, and sequencing means for coordinating the relative movement of said retractor element with respect to said hole forming element, said method comprising:

a) inserting a distal end of the retractor element through a slit formed in the wall of the organ while the retractor element is locked in a fully extended position relative to the hole forming element and the expansion element is in an unexpanded state

b) expanding the expansion element to a fully expanded state and moving the expansion element toward the hole forming element;

c) forming the whole with the cutting element and inserting the connector conduit into the hole by manipulating the hole forming element while the expansion element presses the tissue toward the cutting element;

d) decreasing the size of the expansion element to a partially expanded state and moving the expansion element to be at least partially disposed in the hole forming element; and

e) decoupling the applicator from the connector conduit to remove the applicator while the connector conduit remains in the hole.

98. The method of claim 97, wherein said cutting element is a cutting blade formed on a distal portion of said hole forming element and wherein said forming step comprises pressing a cutting blade into the tissue and applying torsional force to the cutting blade.

99. The method of claim 97, further comprising occluding blood flow through the applicator to create substantial hemostasis throughout a procedure for implanting the connector conduit within the organ wall while the organ remains at substantially normal physiological pressures.

100. The method of claim 97, wherein said hole forming element and said connector conduit are fixed relative to one another said forming step.

101. The method of claim 97, wherein said expansion element is a balloon.

102. The method of claim 101, wherein said balloon is in the shape of a circular toroid.

103. The method of claim 97, wherein said expansion element is an expandable sponge.

104. The method of claim 97, wherein said expansion element is an umbrella mechanism.

105. The method of claim 97, wherein said sequencing means comprises a cam mechanism.

106. The method of claim 97, wherein said sequencing means comprises a gear mechanism.

107. The method of claim 97, wherein said sequencing means comprises at least one servo mechanism operatively coupled to the positioning means and a controller operatively coupled to said at least one servo mechanism.

108. The method of claim 108, wherein said controller mechanism comprises a microprocessor based device.

109. The method of claim 109, further comprising a button operatively coupled to said sequencing means for activating said sequencing means upon depression of the button to thereby accomplish steps of a procedure for implanting the connector conduit within the organ wall.

FIG. 1

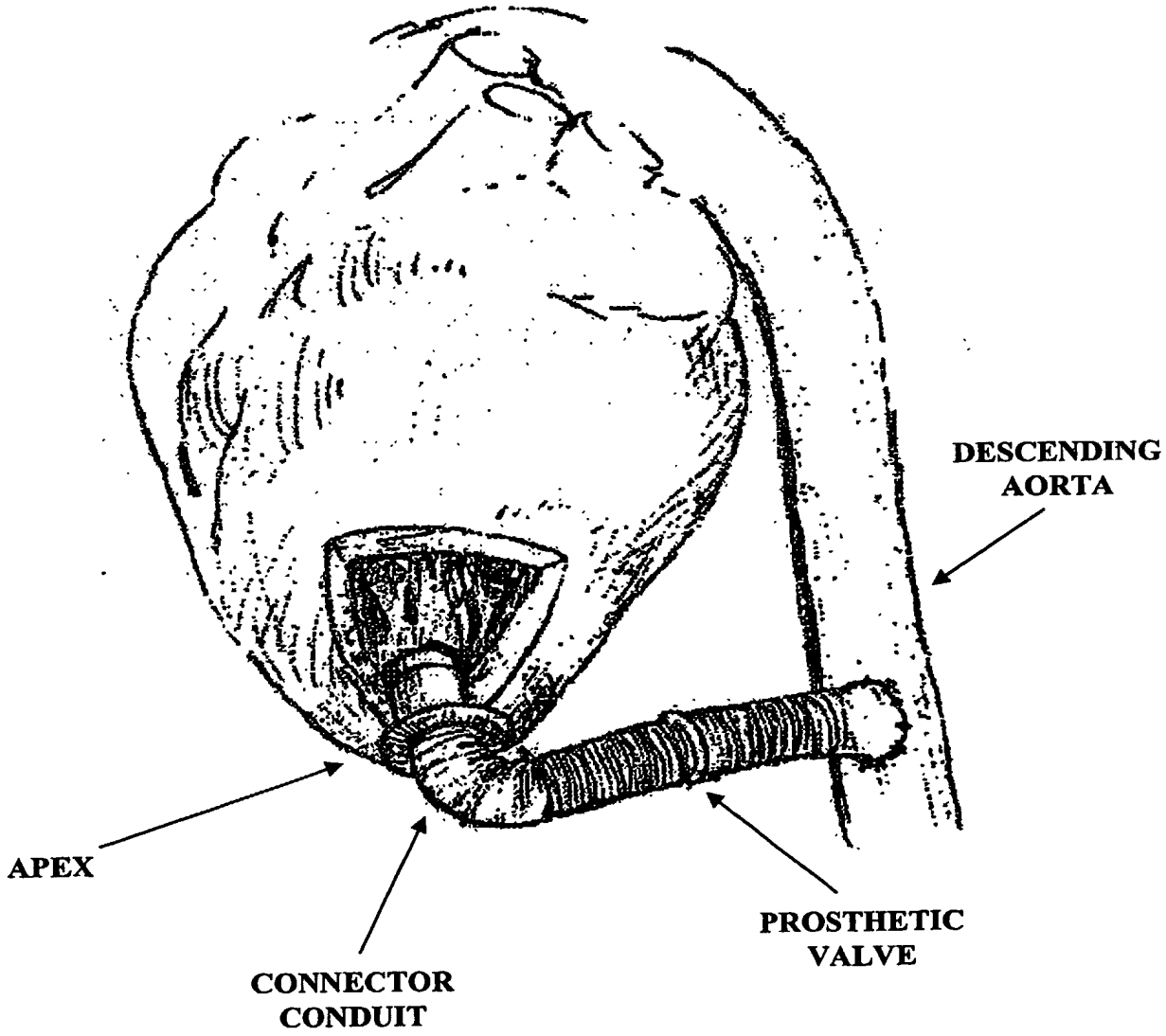


FIG. 2A

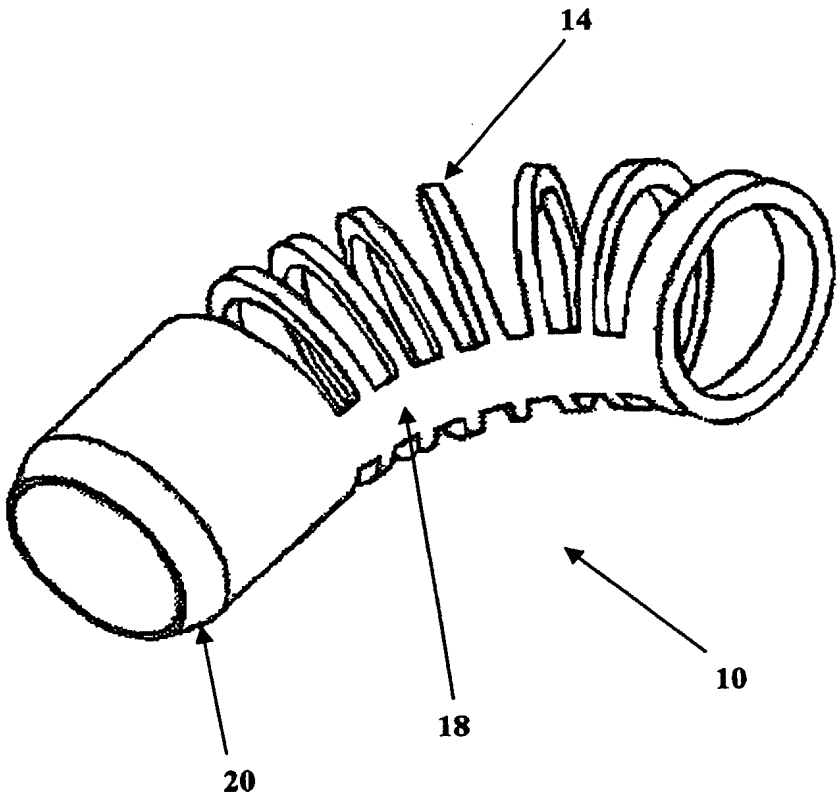
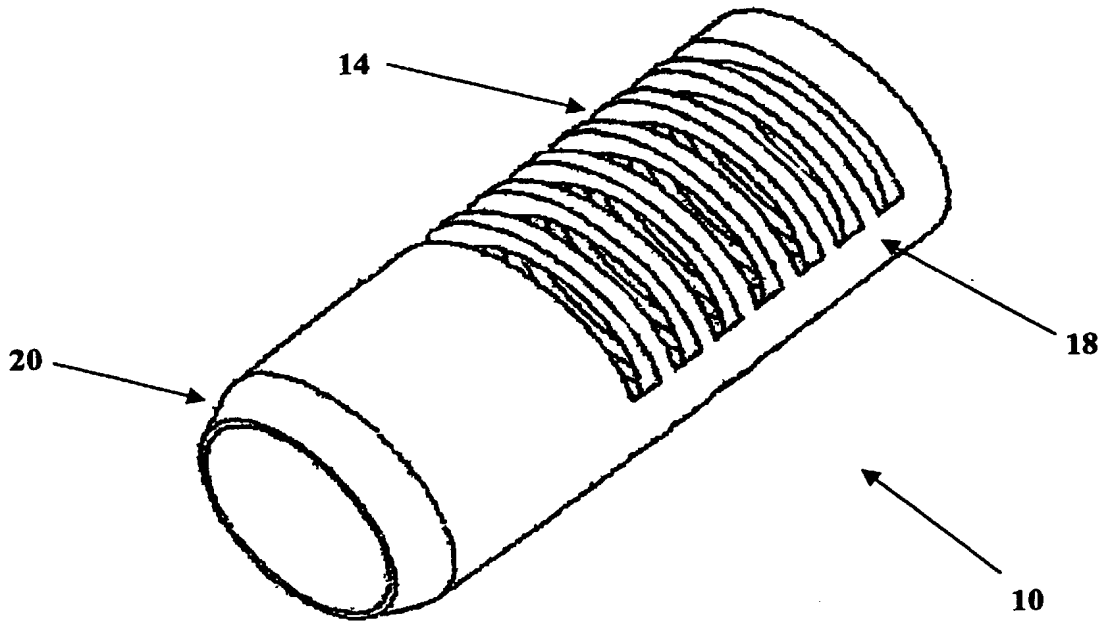


FIG. 2B



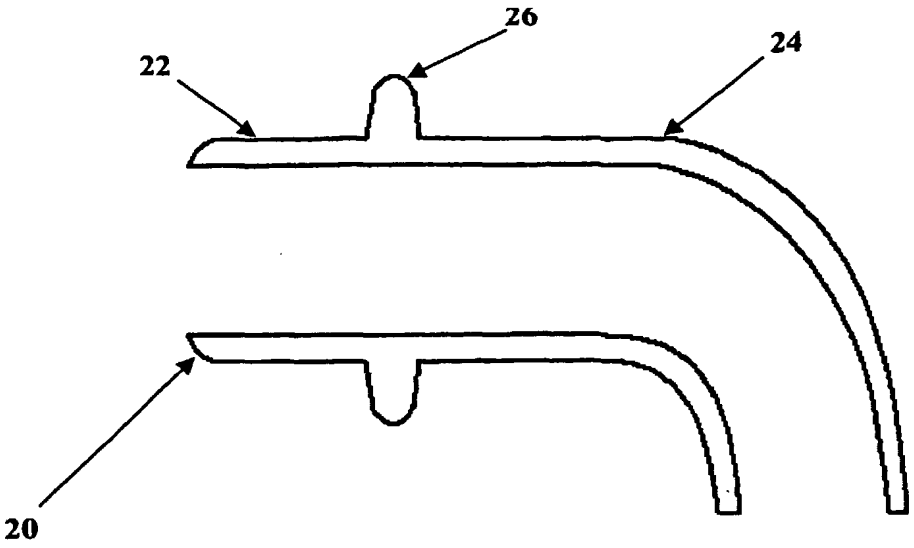


FIG. 3A

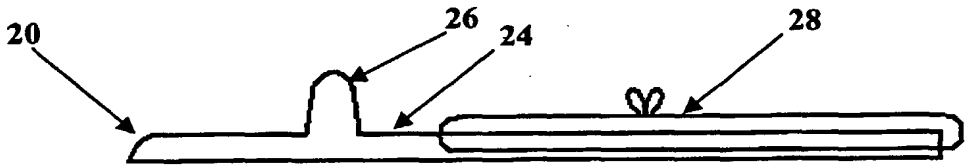


FIG. 3B

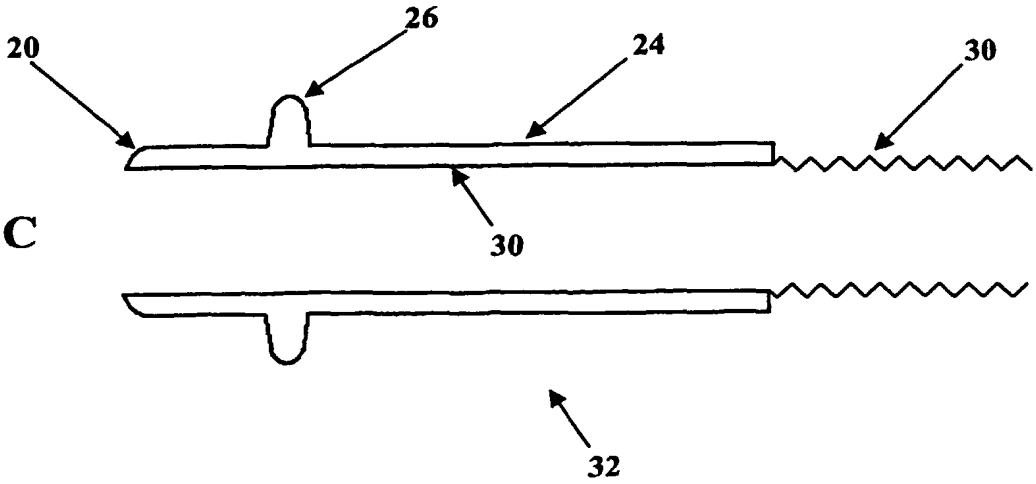


FIG. 3C

FIG. 4

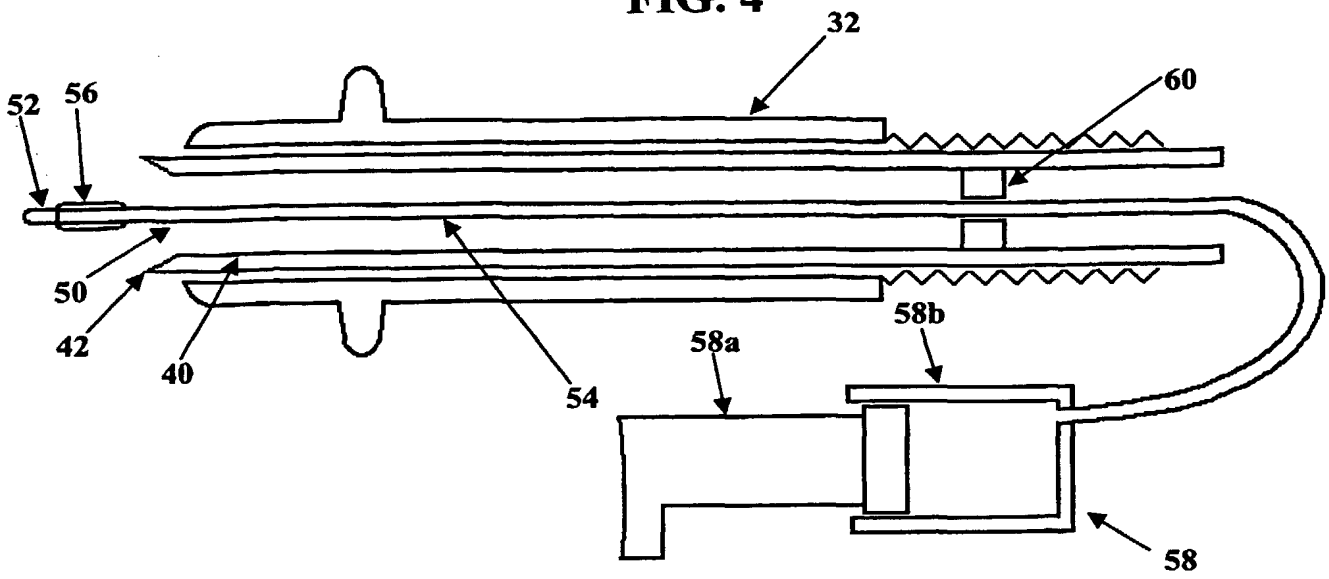


FIG. 6

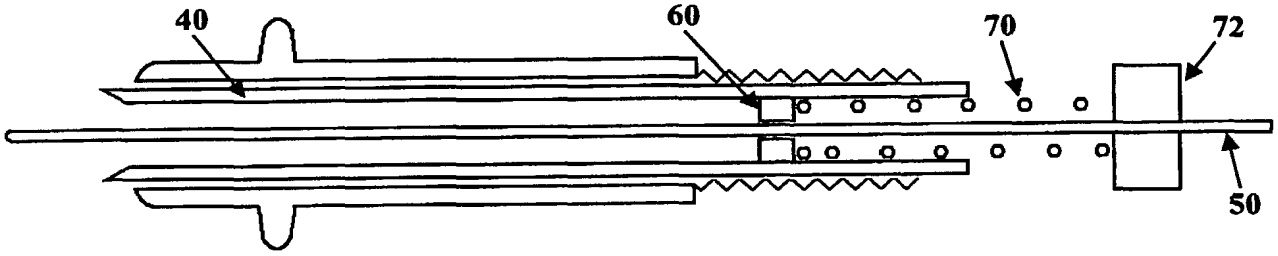


FIG. 7

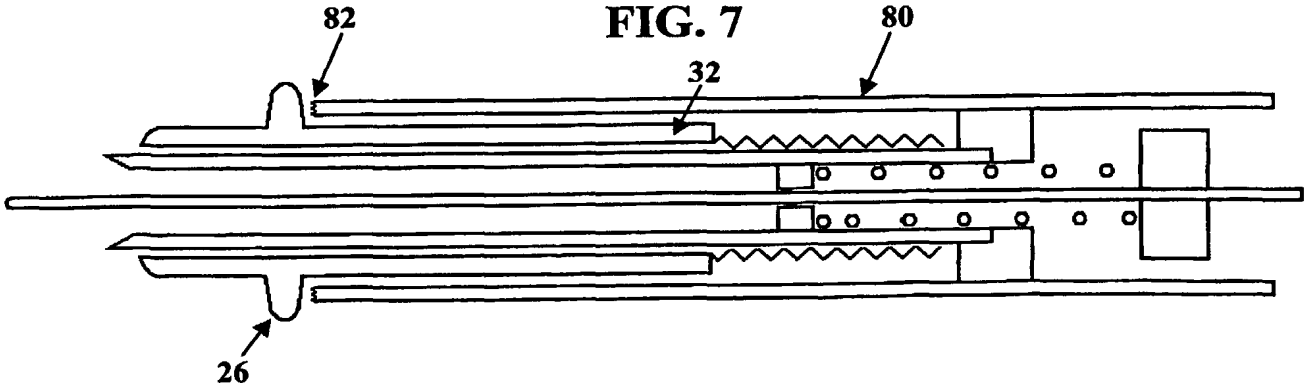


FIG. 5

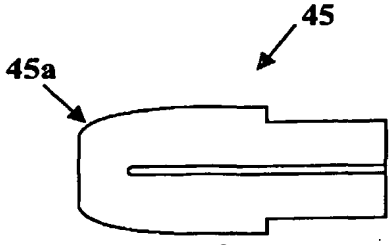


FIG. 8A

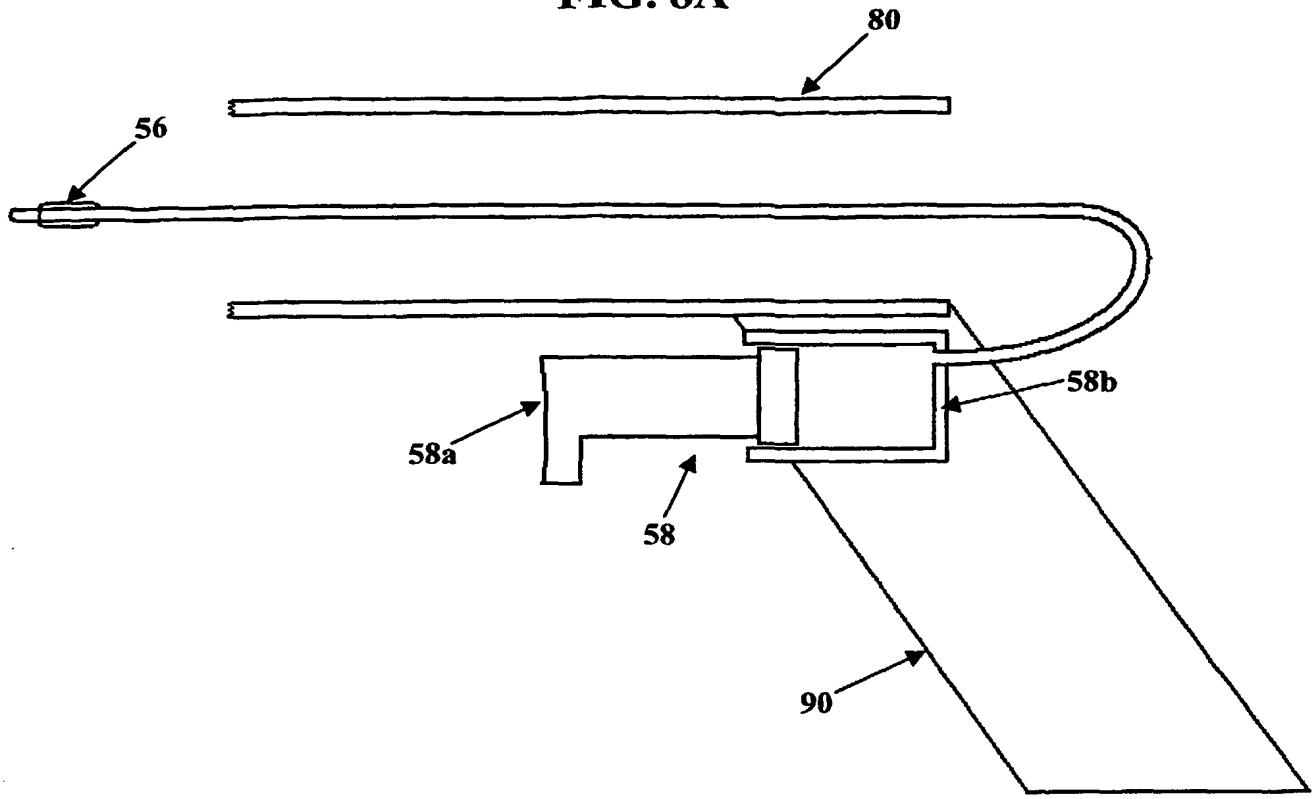


FIG. 8B

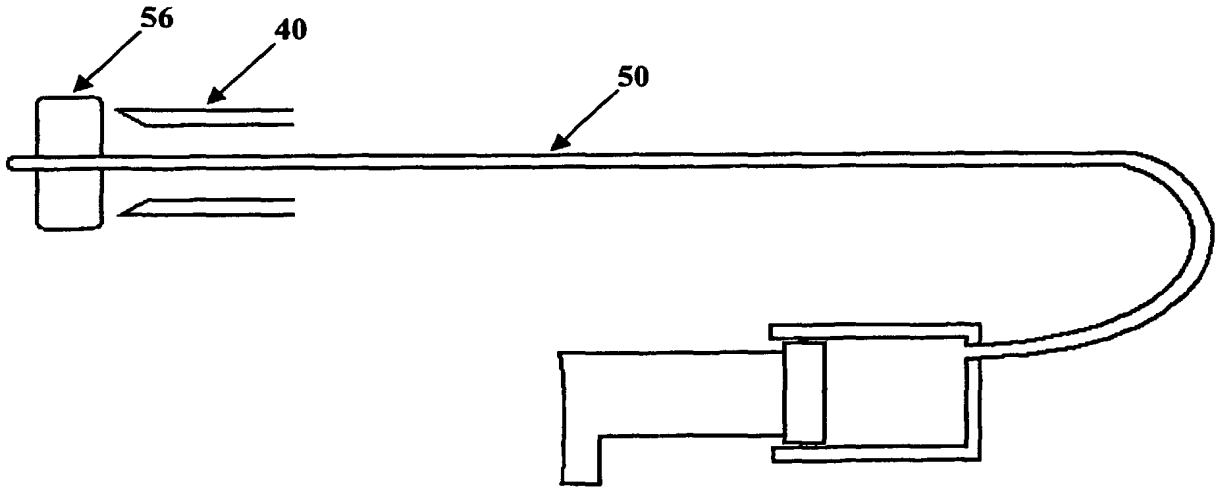


FIG. 9

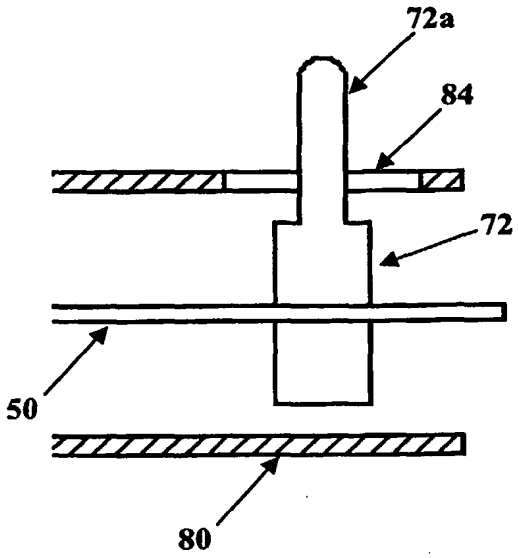


FIG. 10

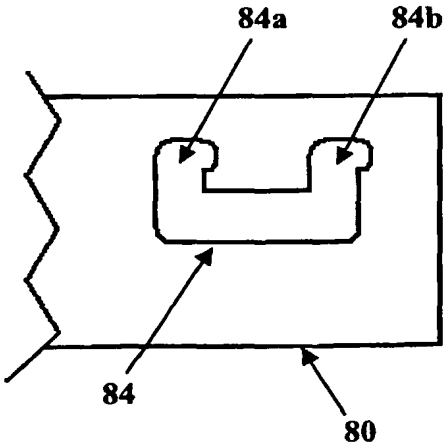


FIG. 11A

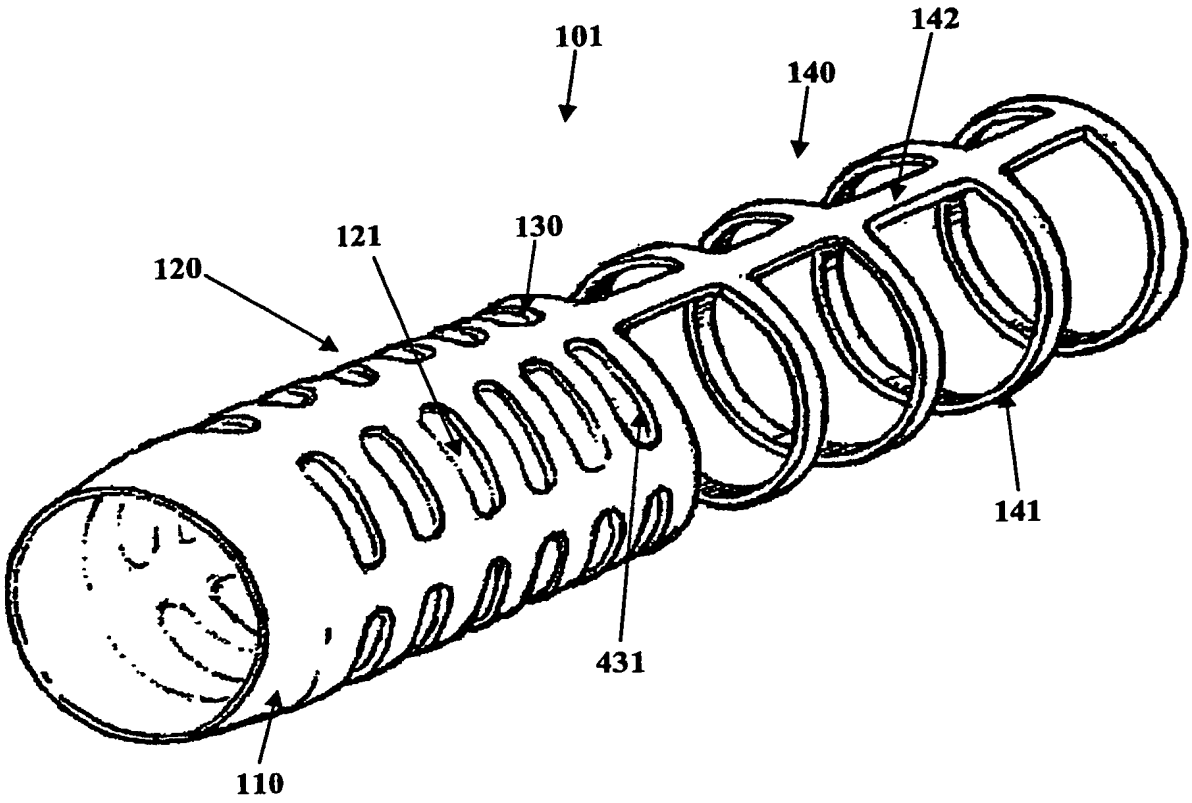


FIG. 11B

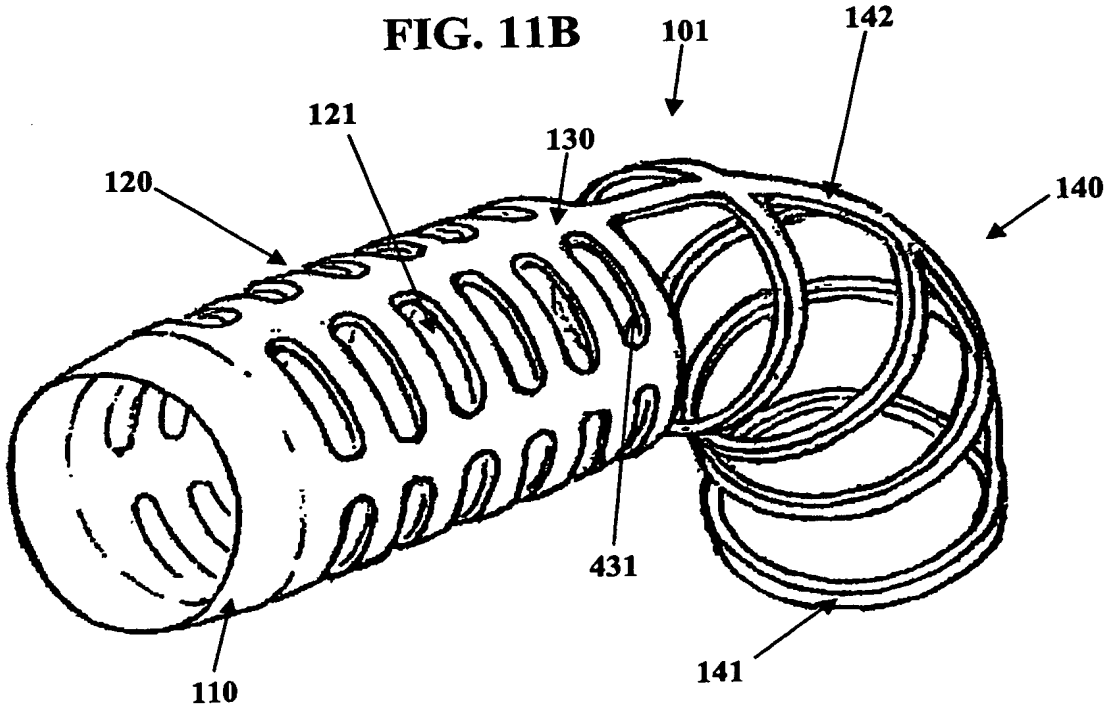


FIG. 11C

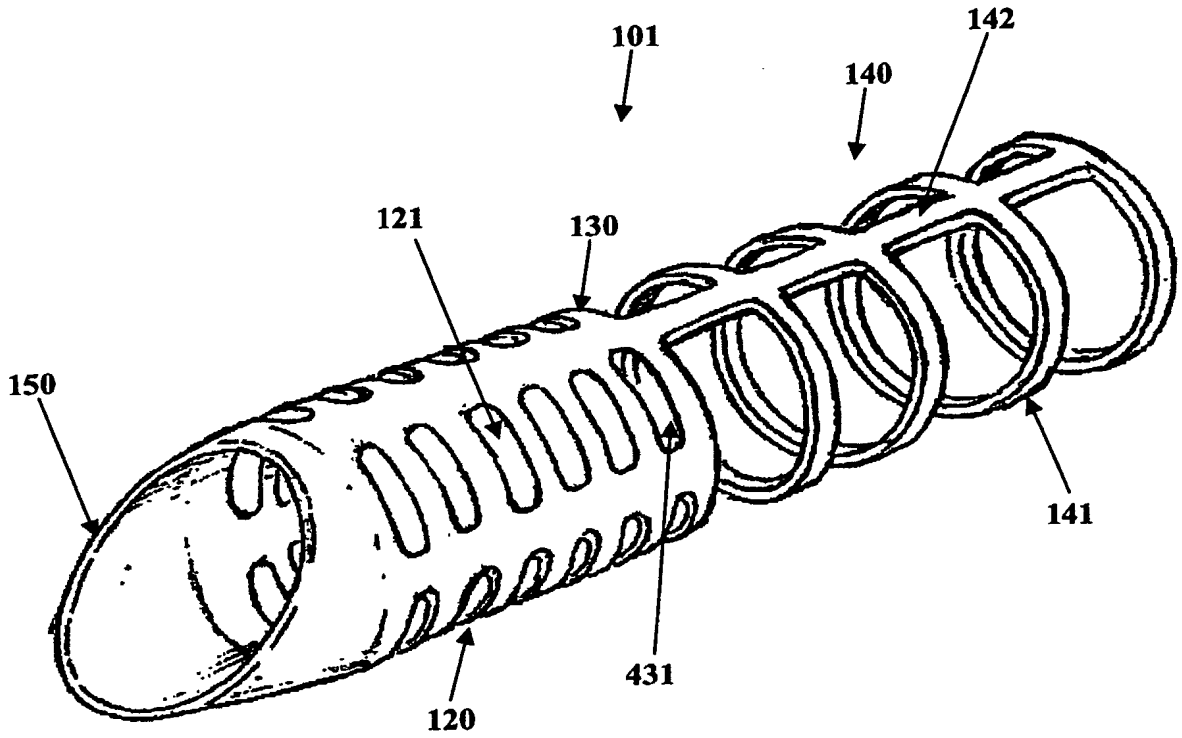


FIG. 12

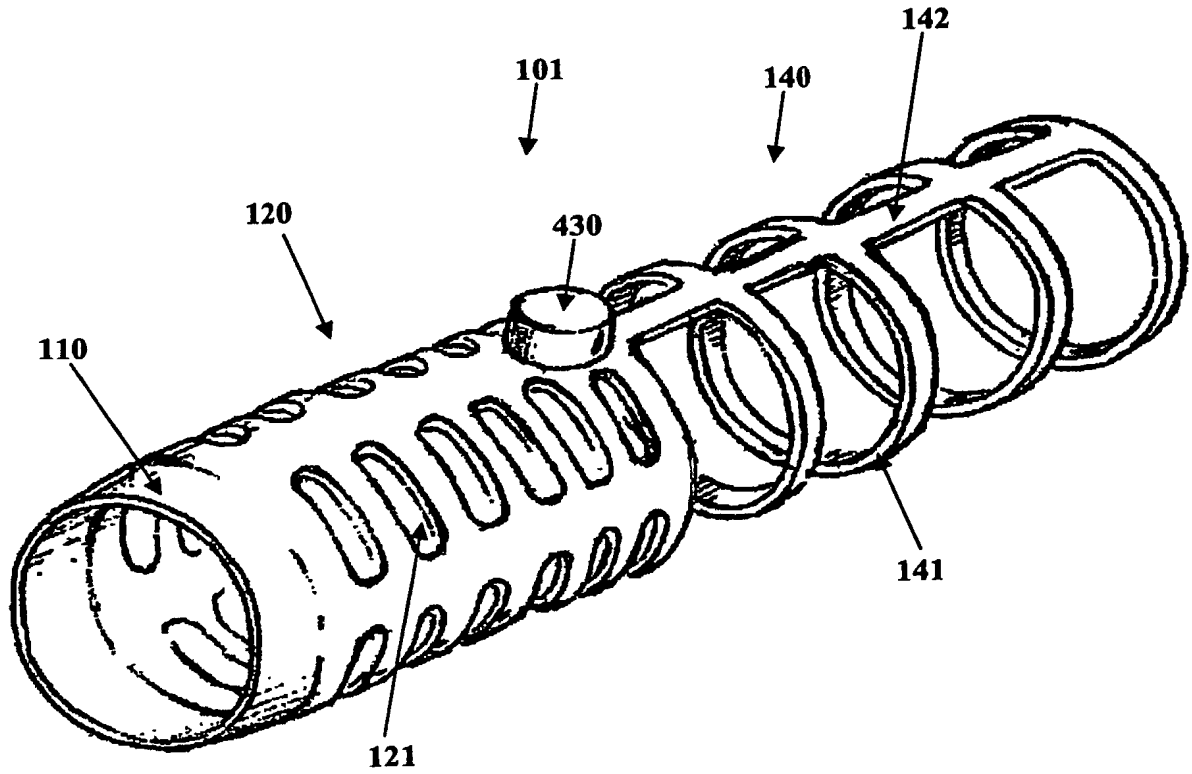


FIG. 13A

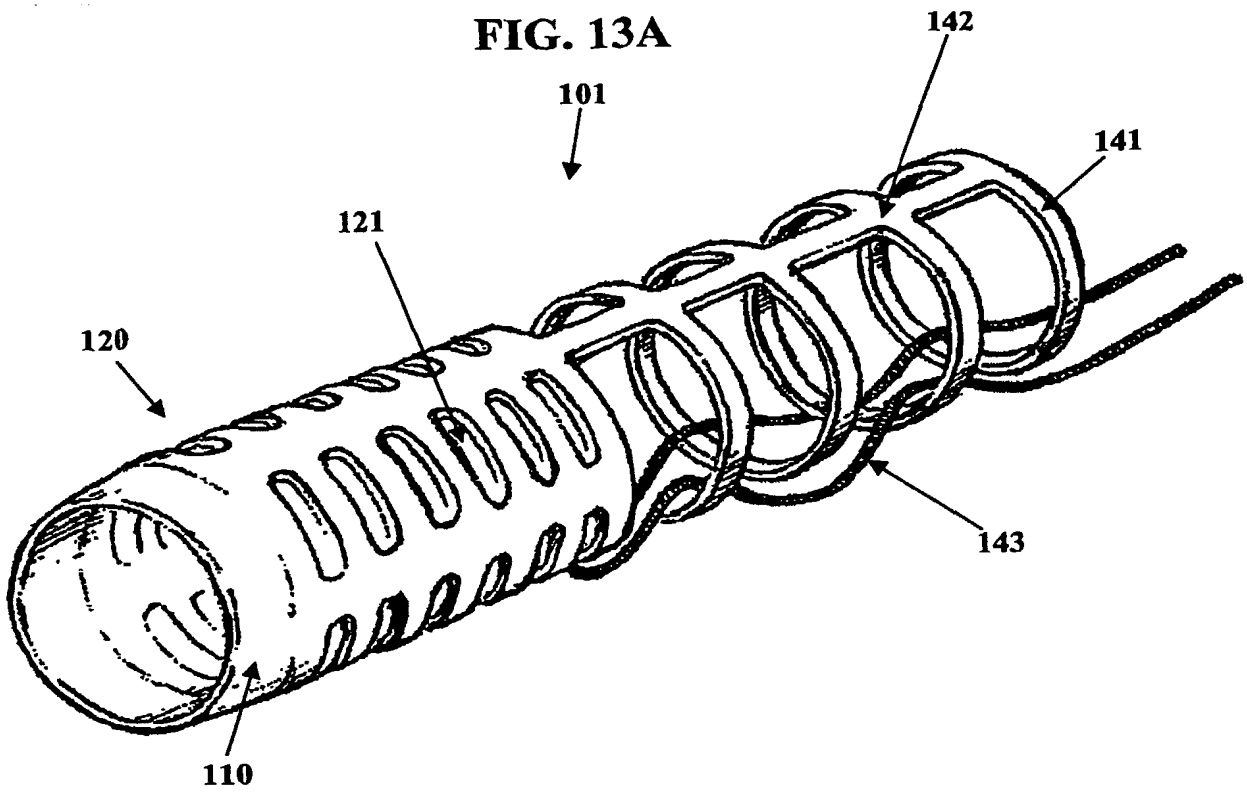


FIG. 13B

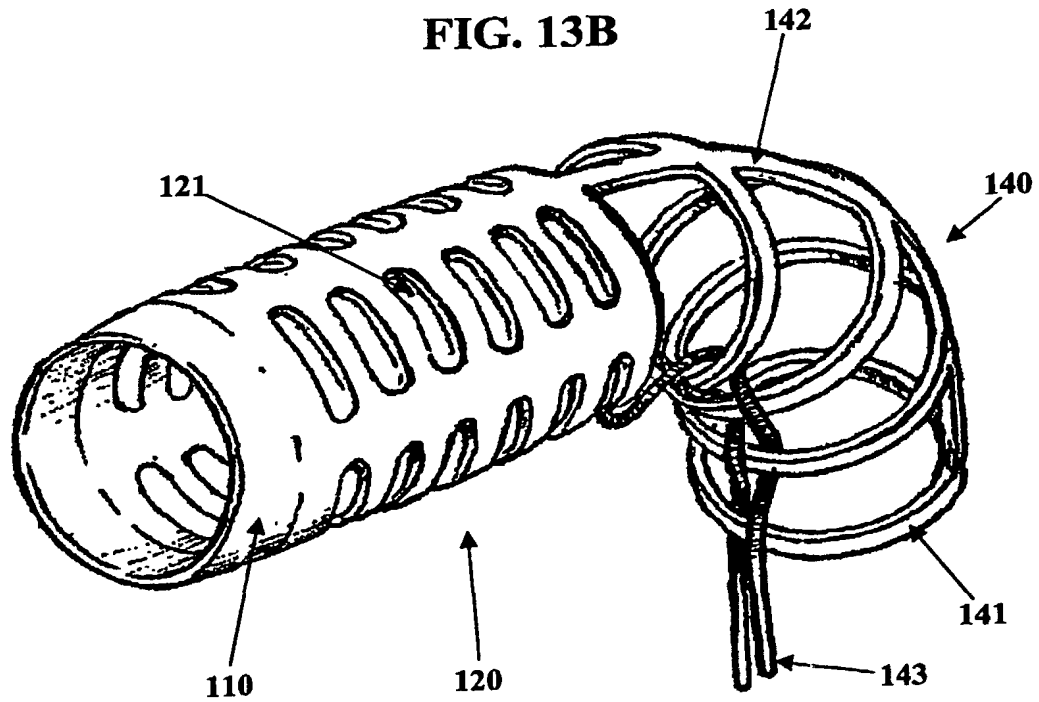


FIG. 14

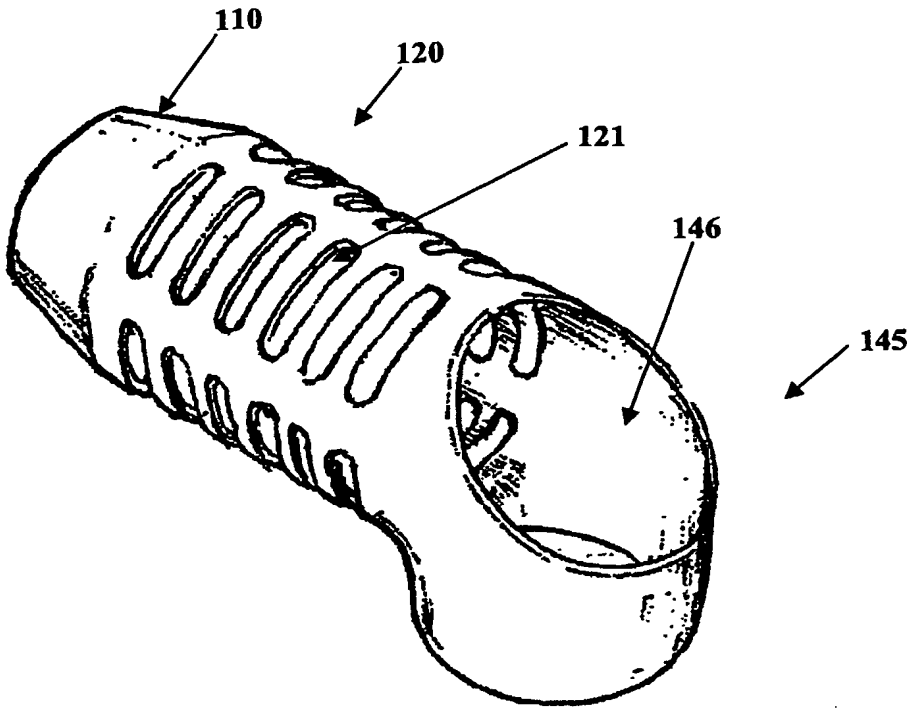


FIG. 15

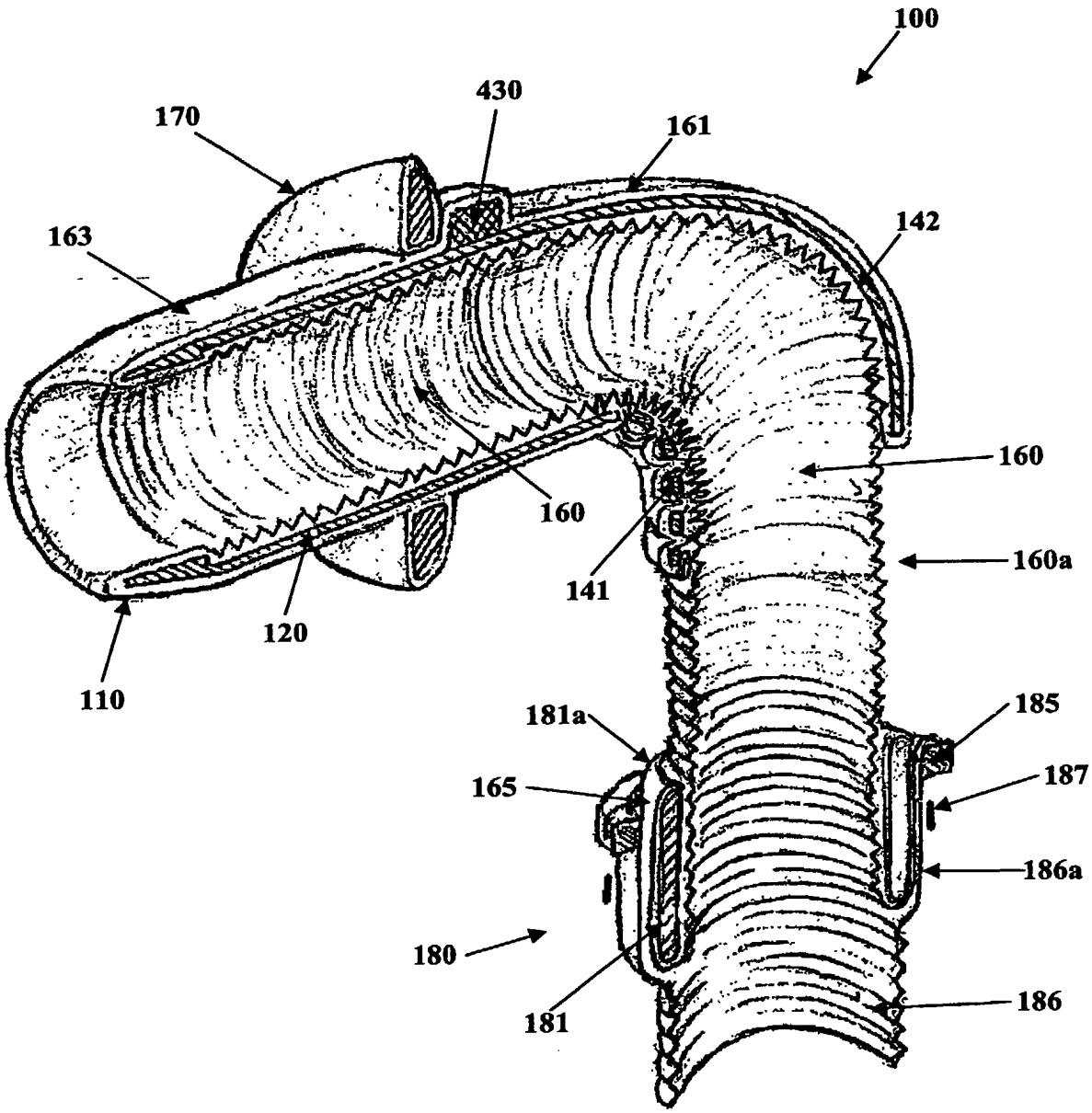


FIG. 16

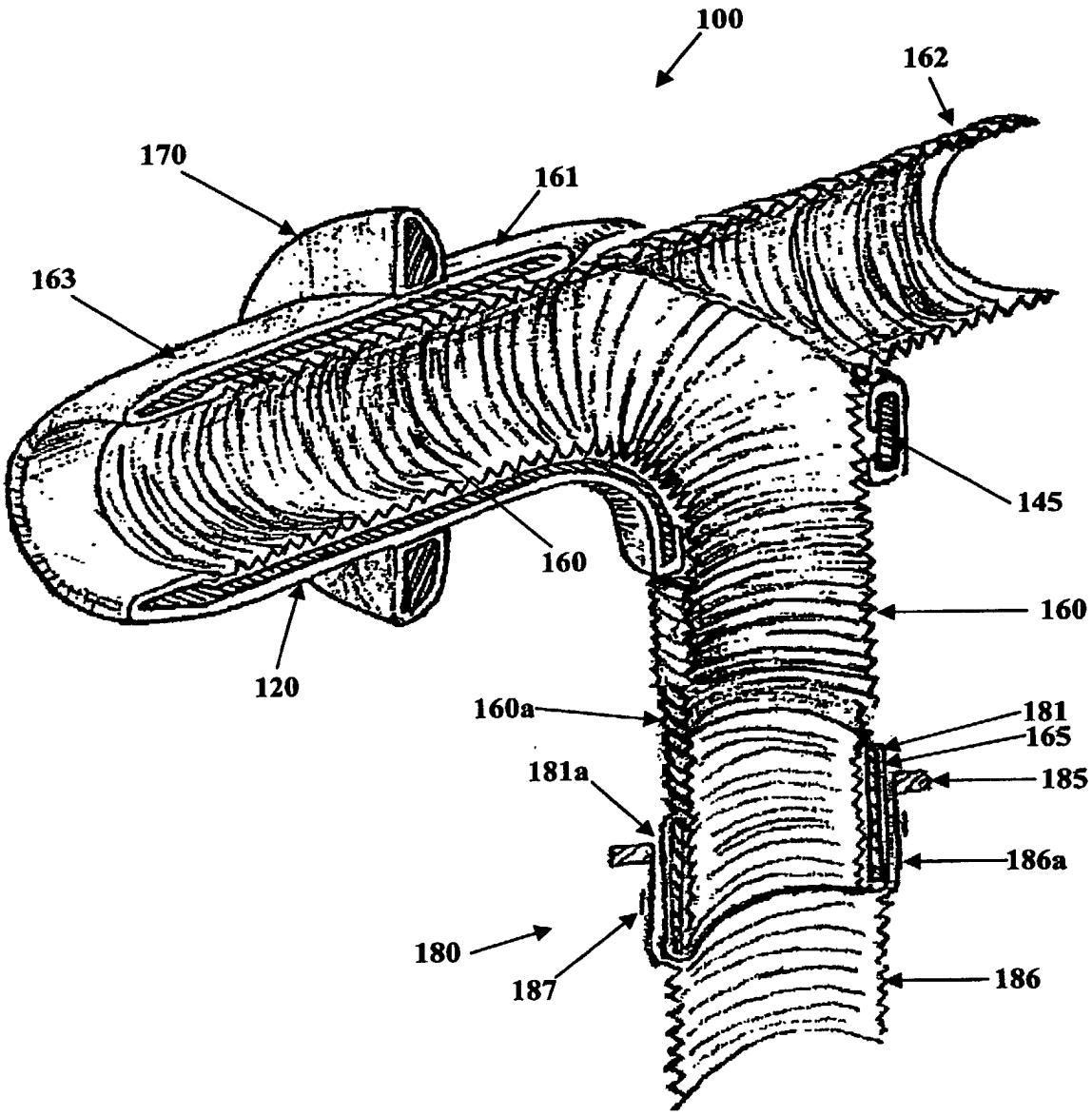


FIG. 17A

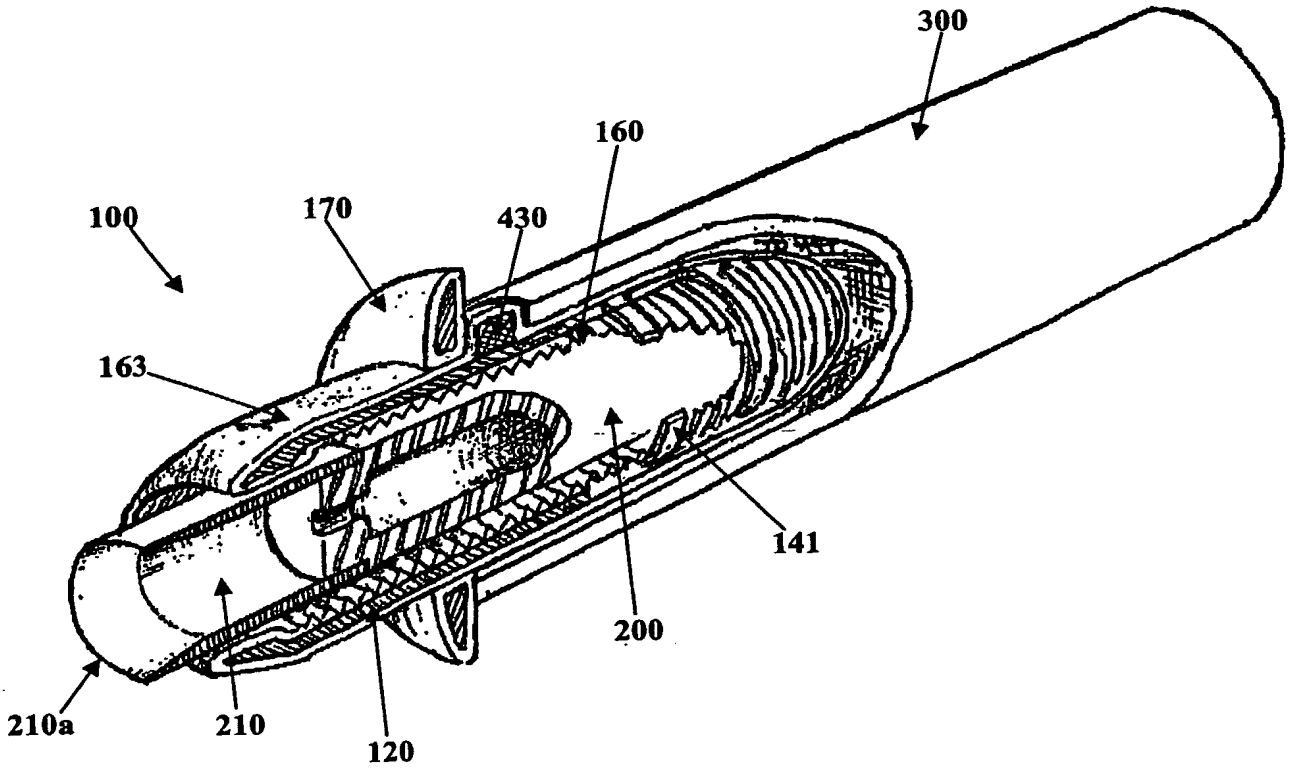


FIG. 17B

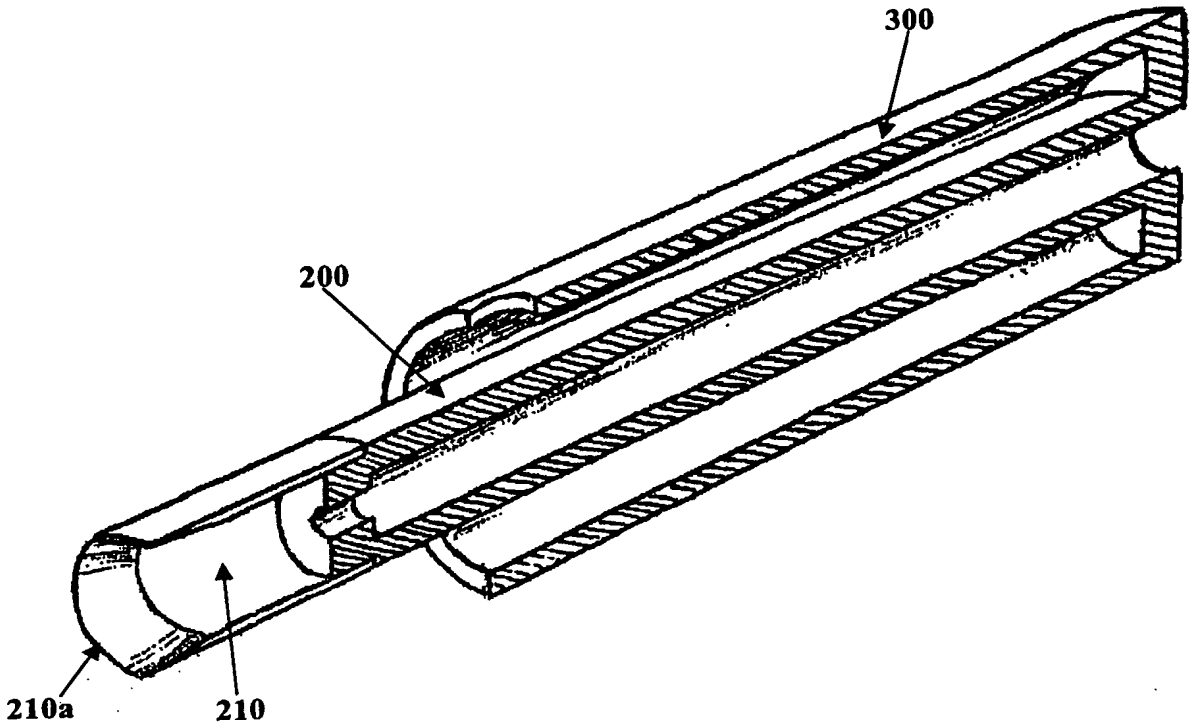


FIG. 18A

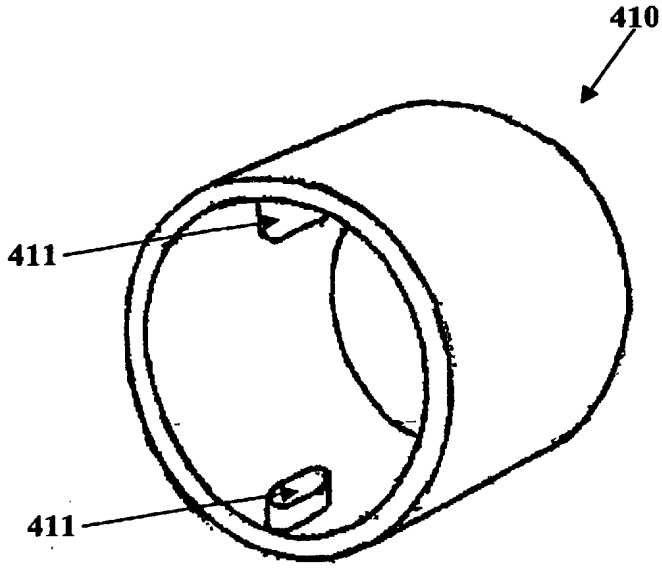


FIG. 18B

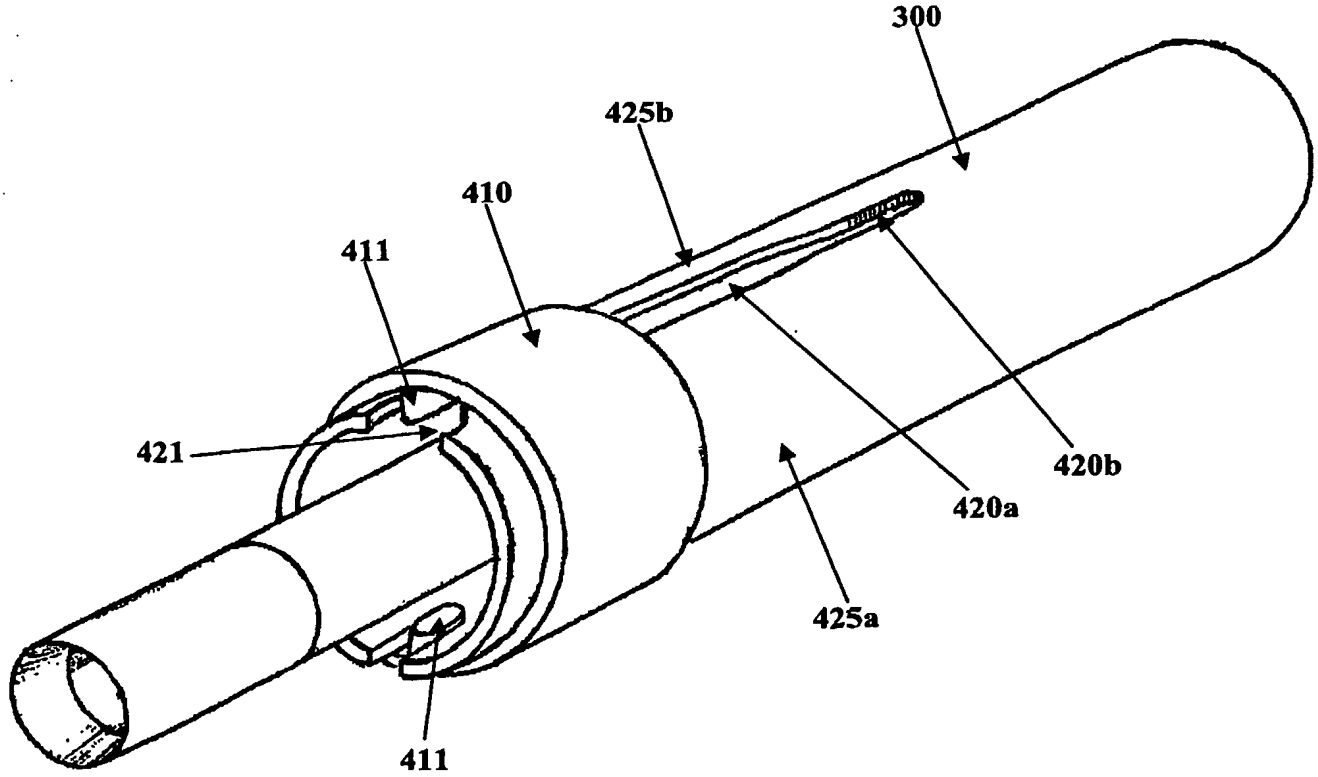


FIG. 18C

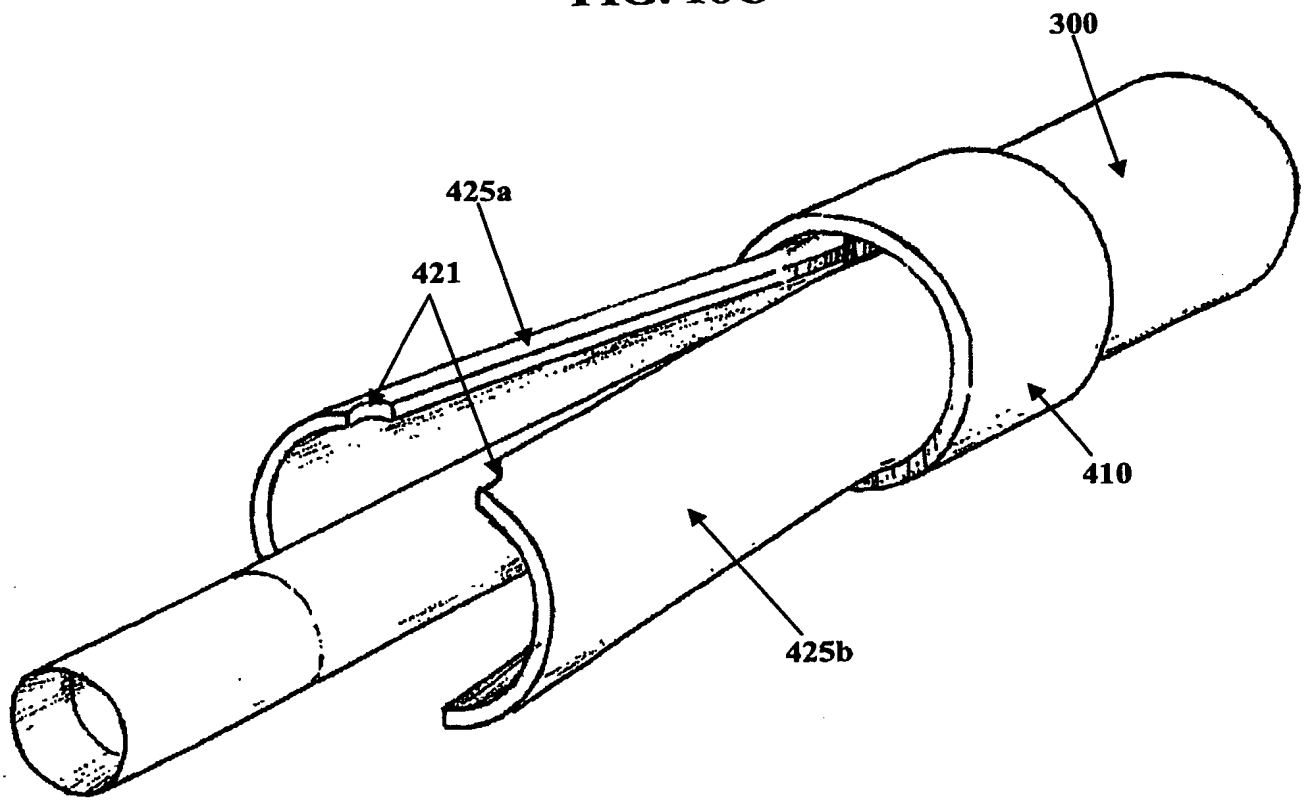


FIG. 19

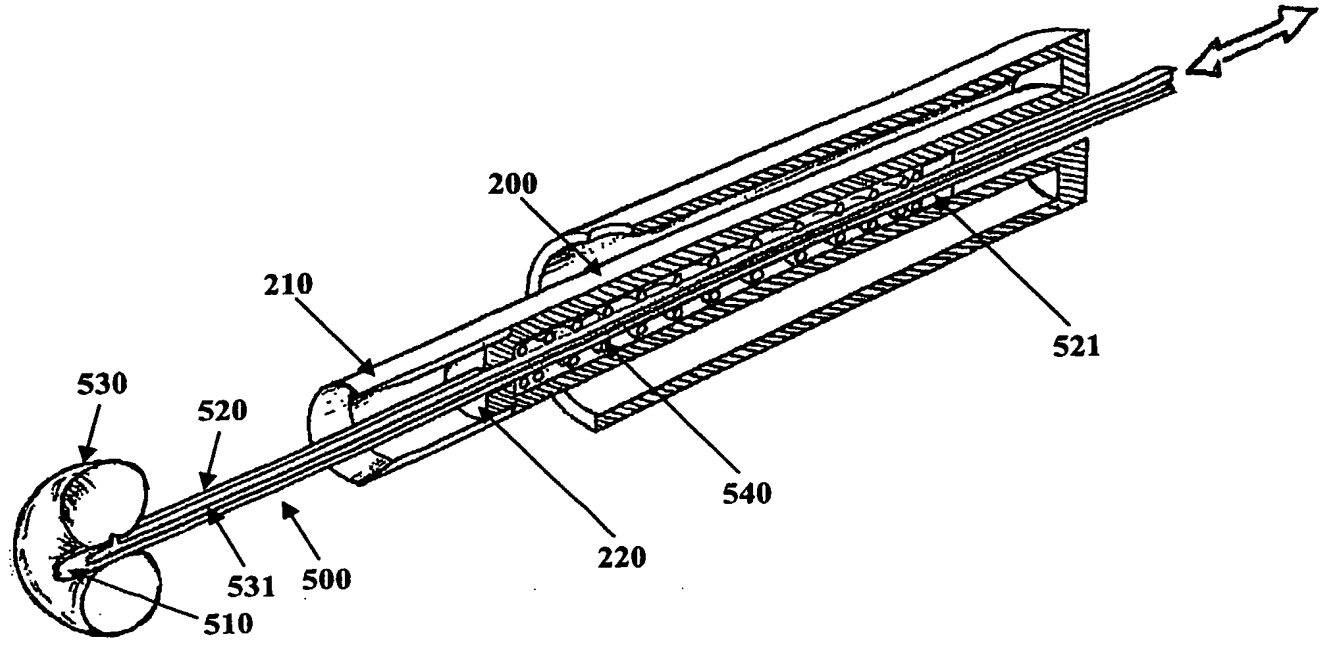


FIG. 20

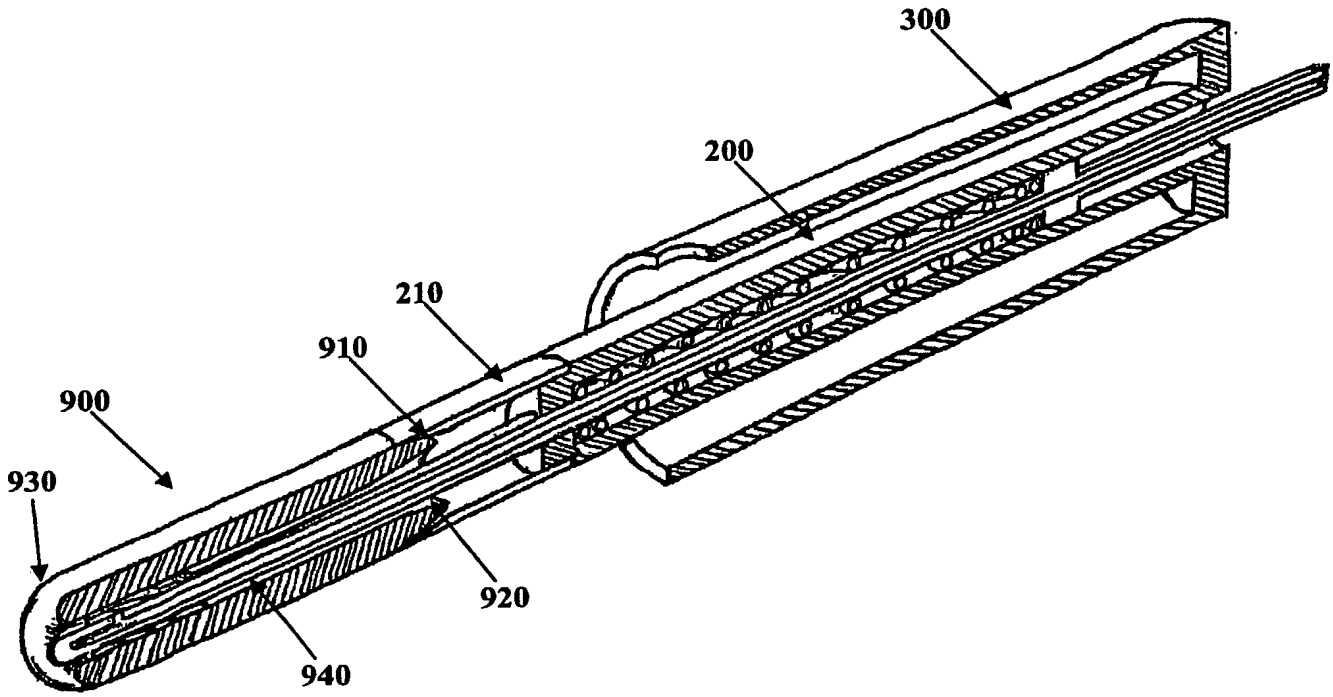


FIG. 21

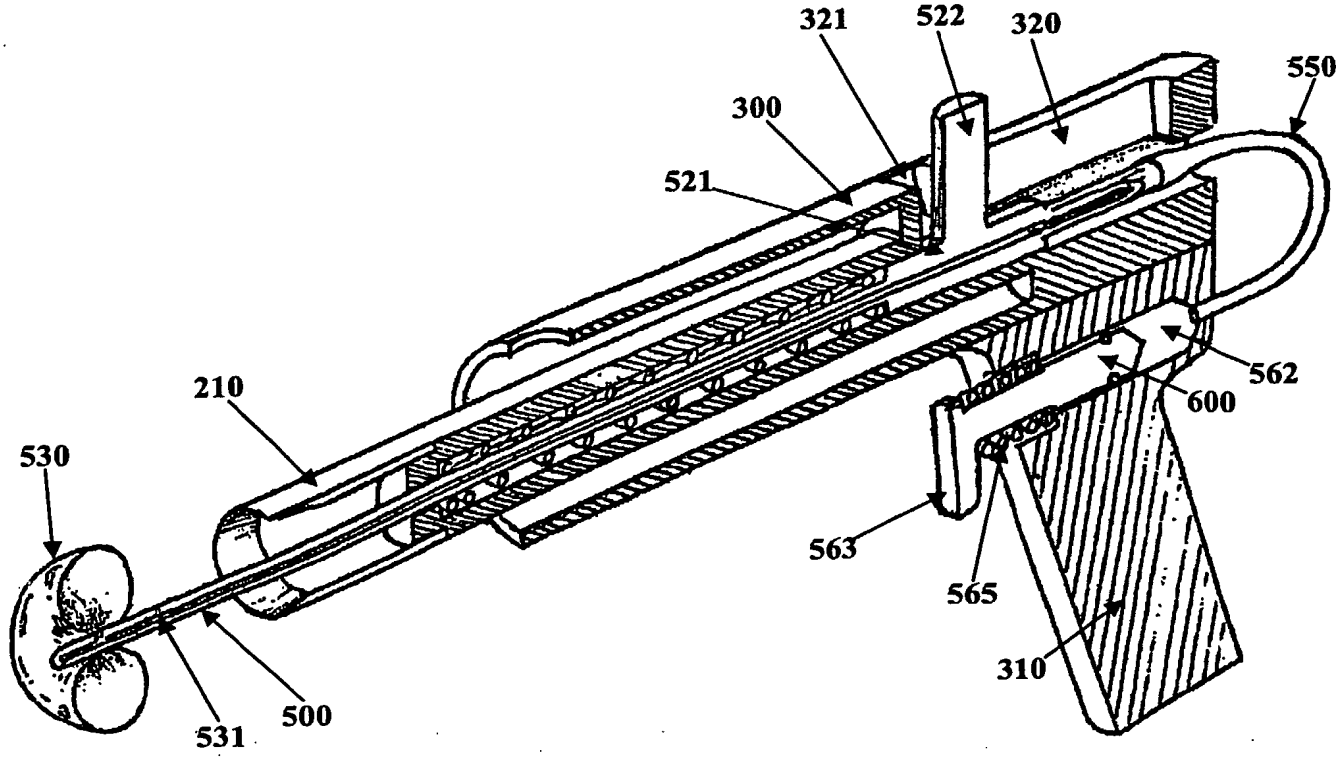


FIG. 22A

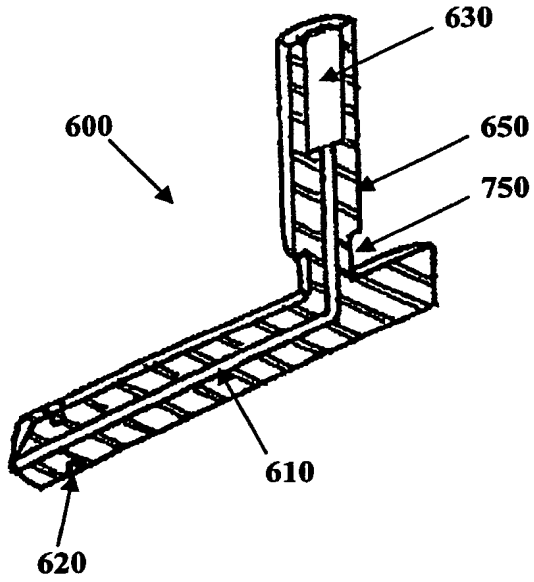


FIG. 22B

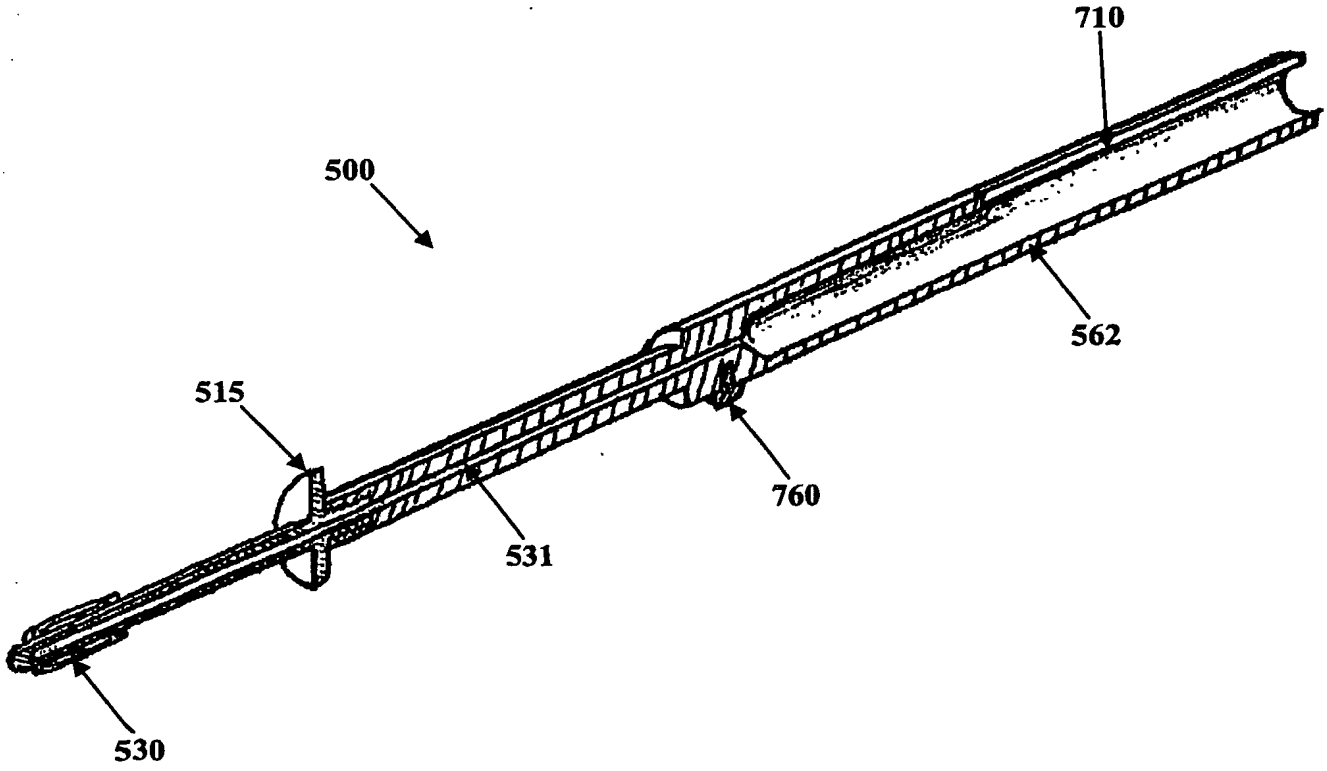


FIG. 22C

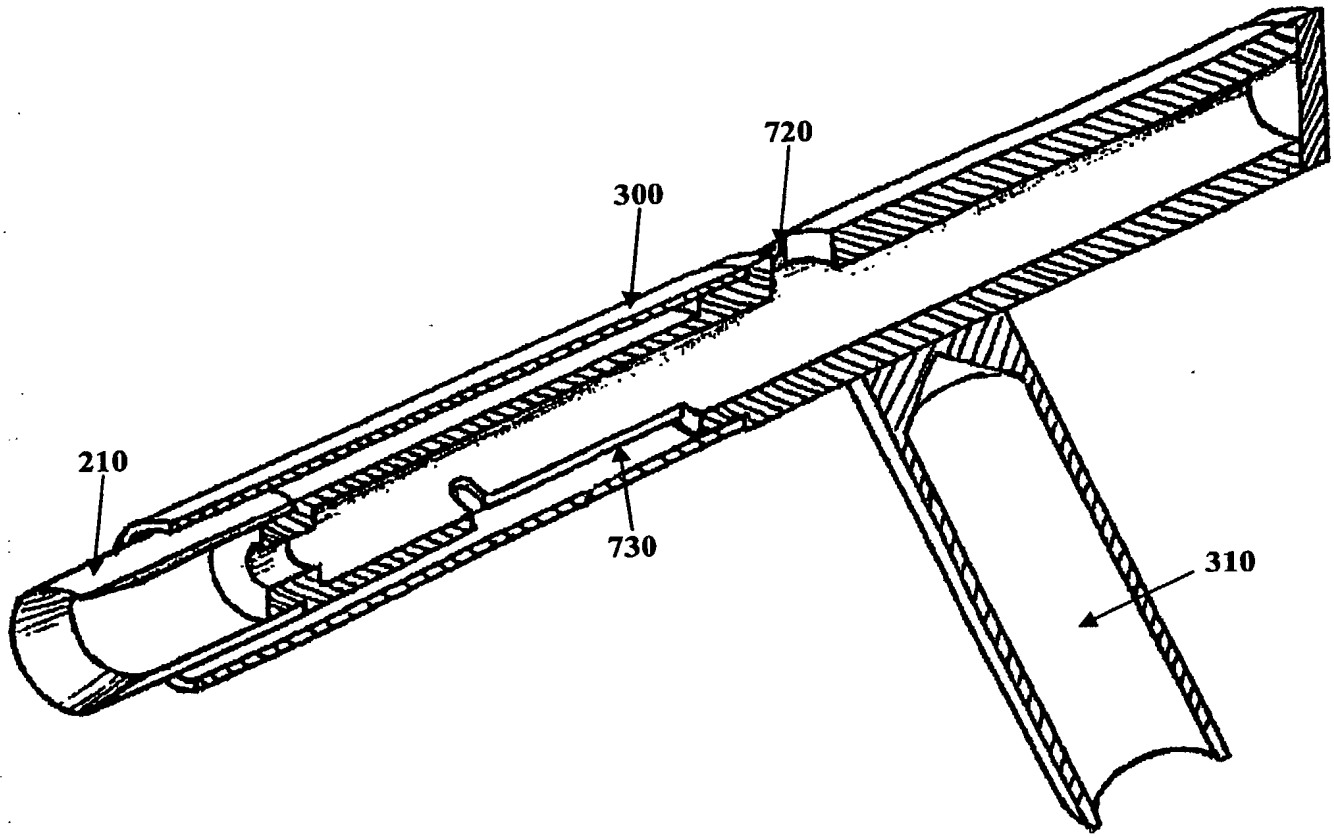


FIG. 23A

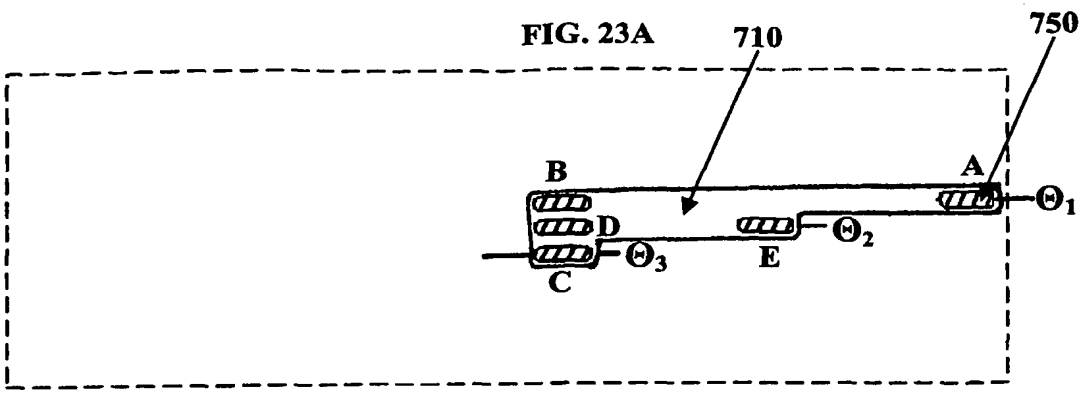


FIG. 23B

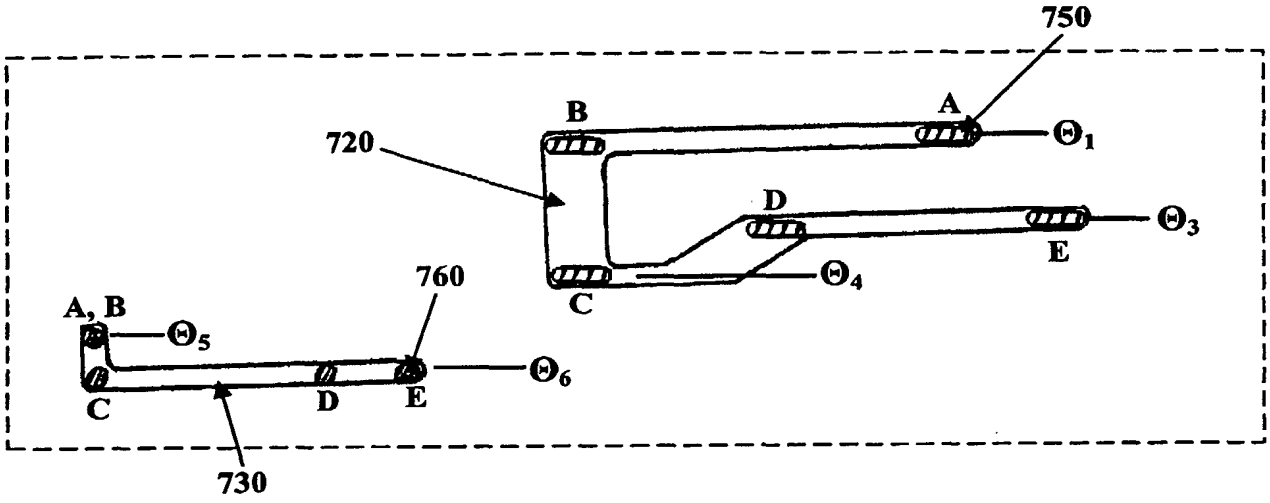
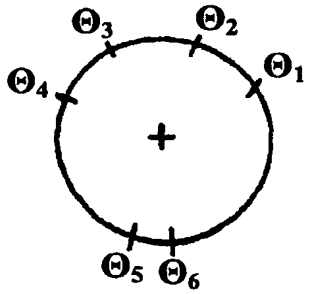


FIG. 23C



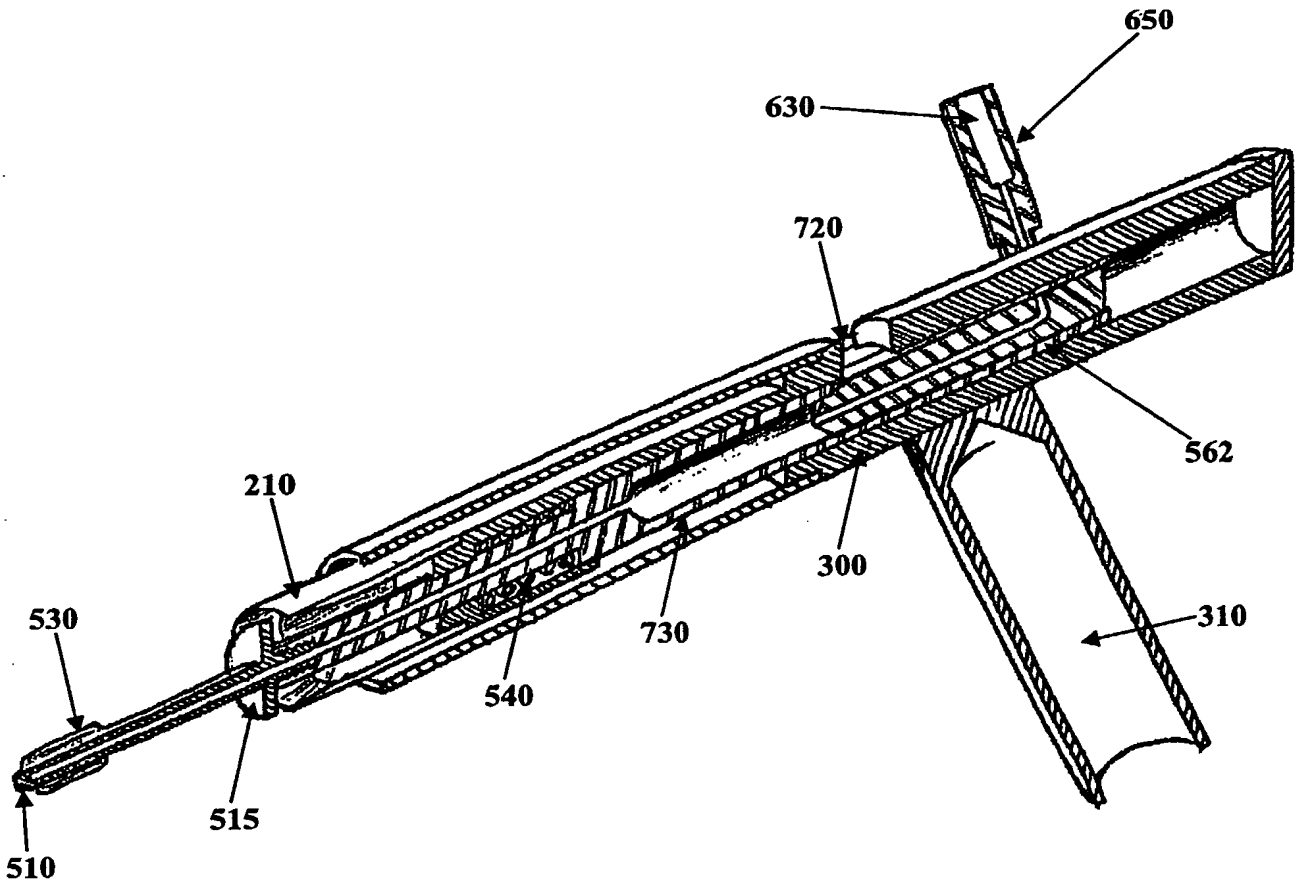
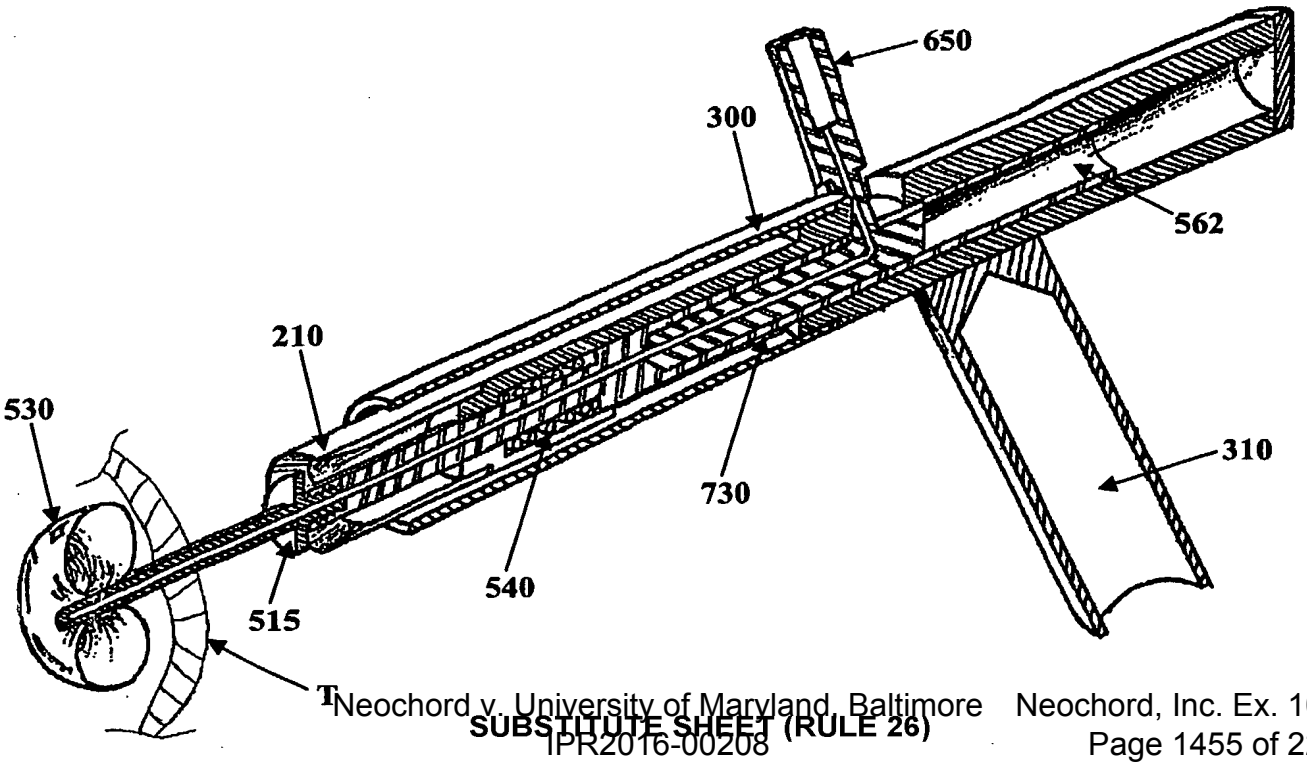


FIG. 24B



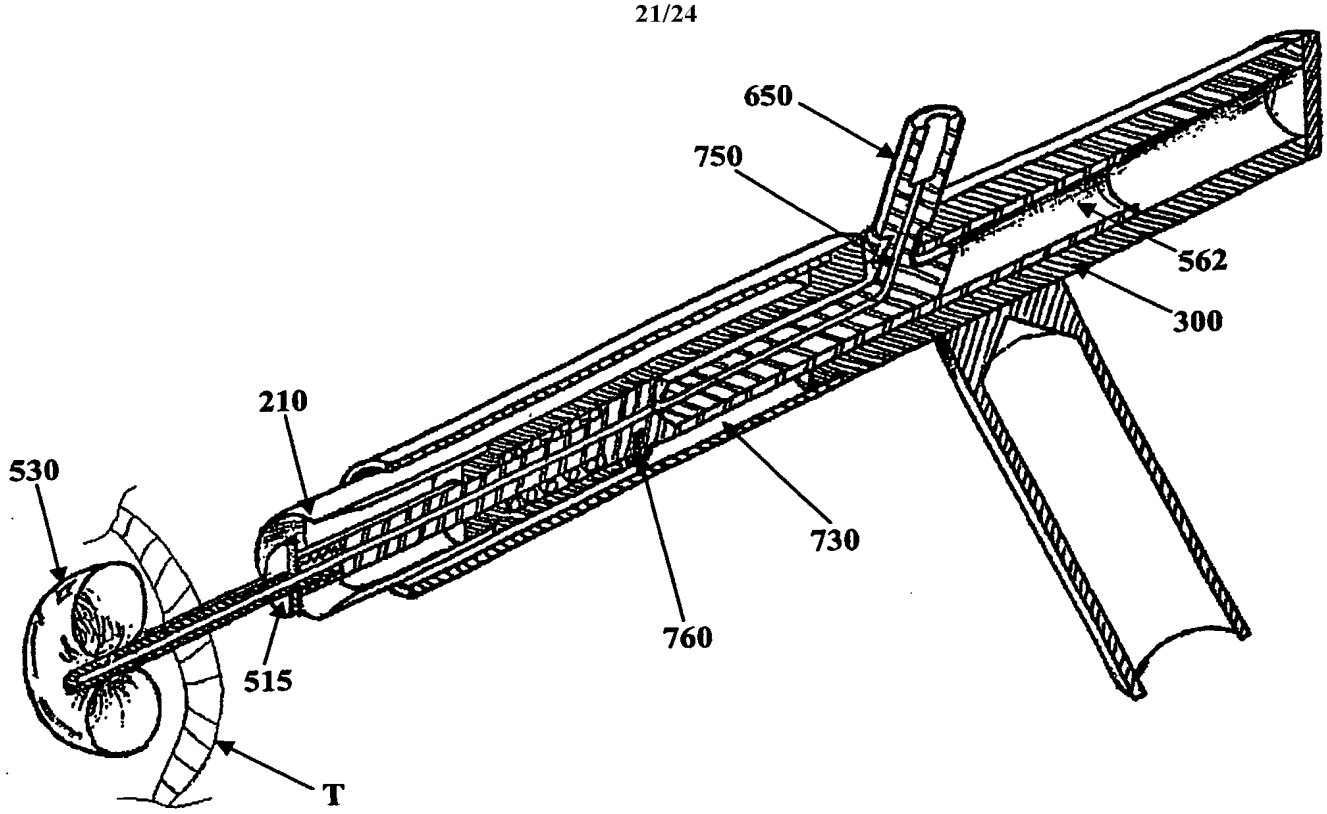


FIG. 24D

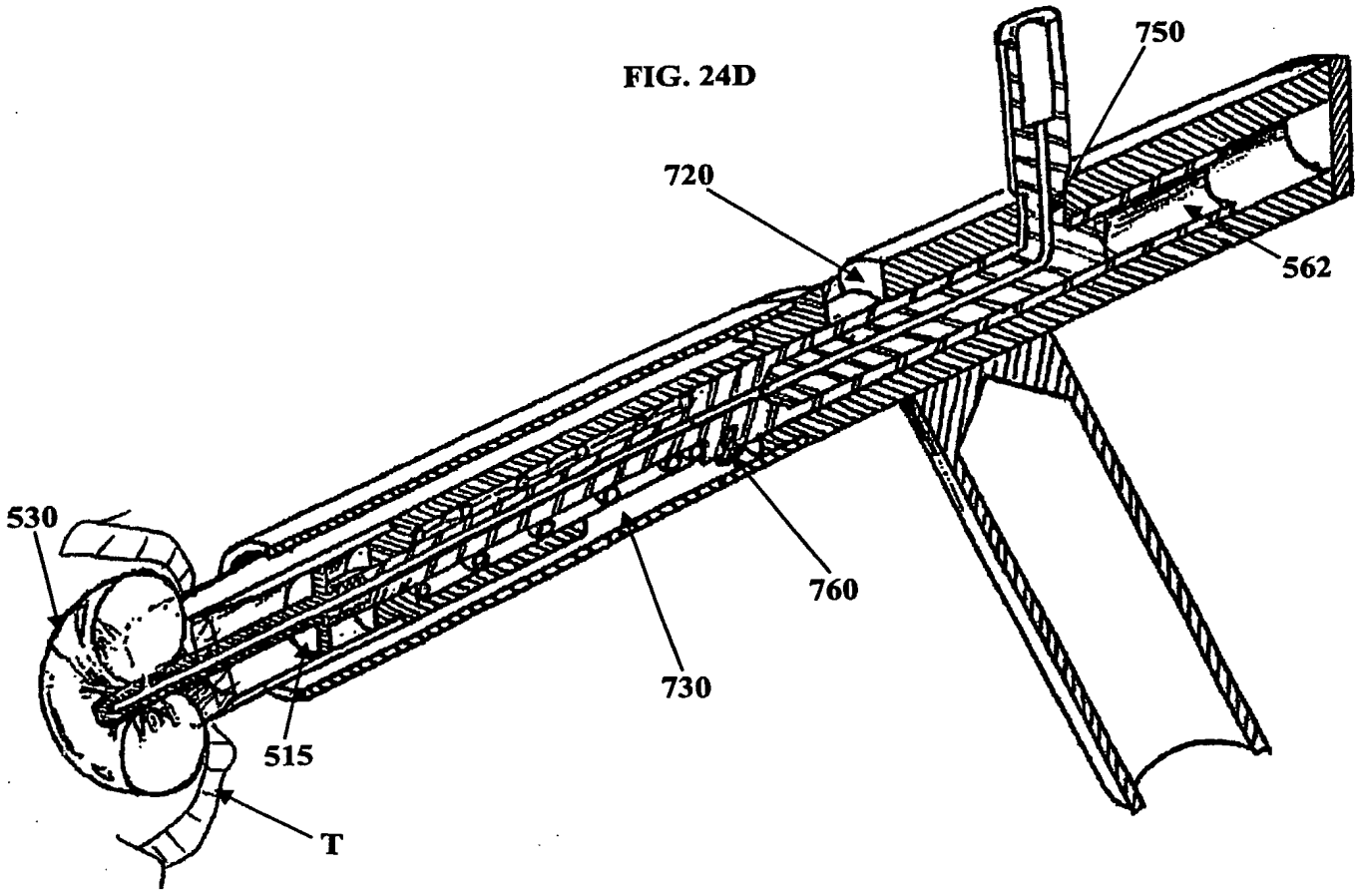


FIG. 24E

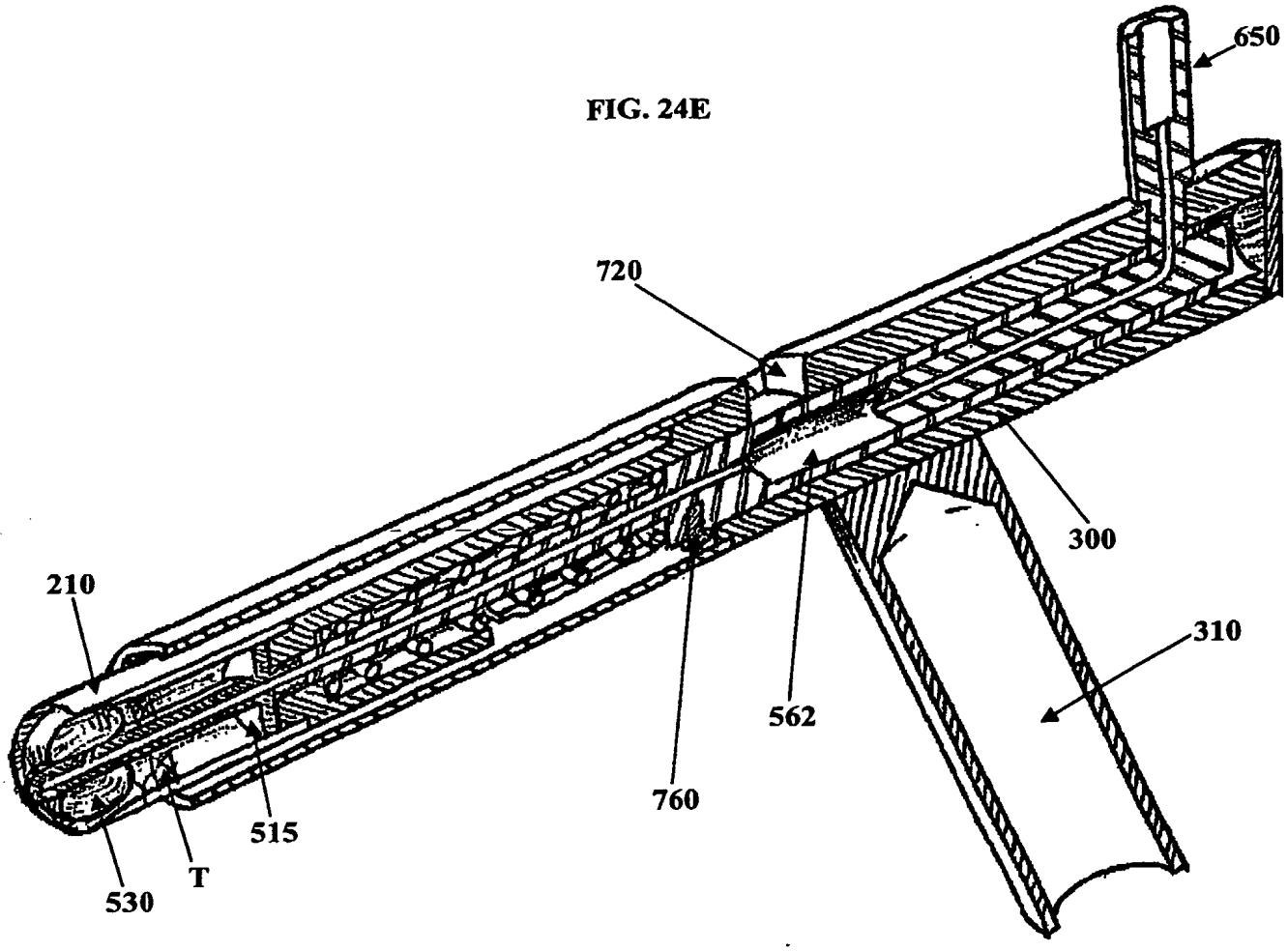


FIG. 27D

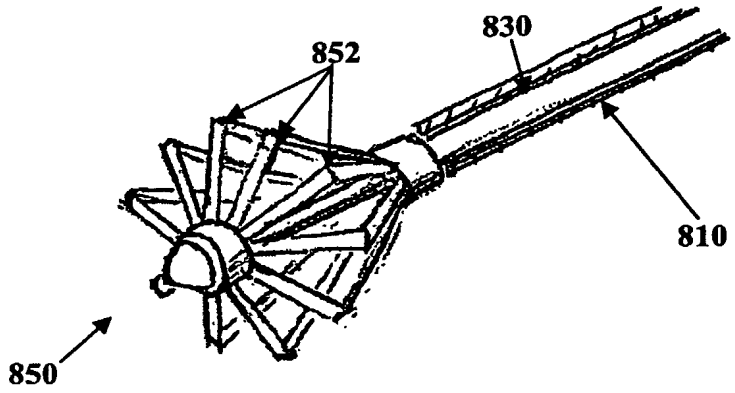


FIG. 25

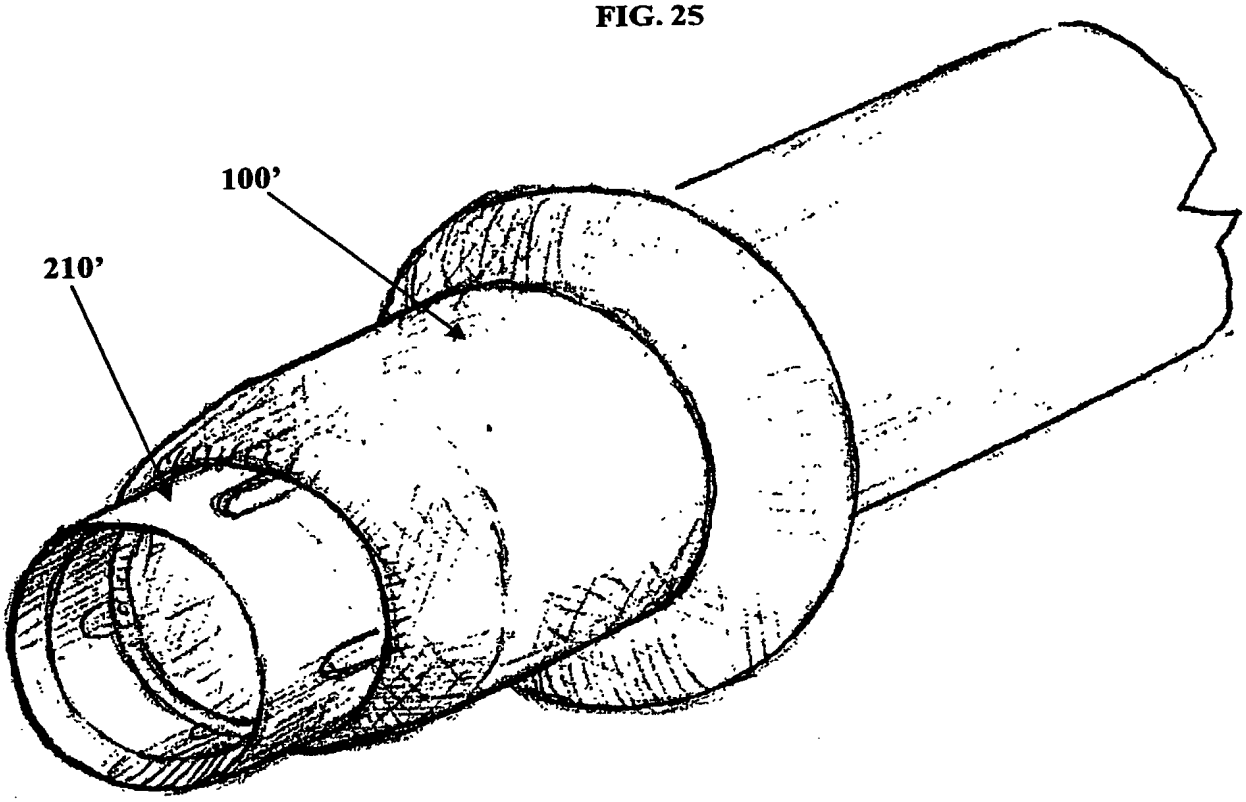


FIG. 26

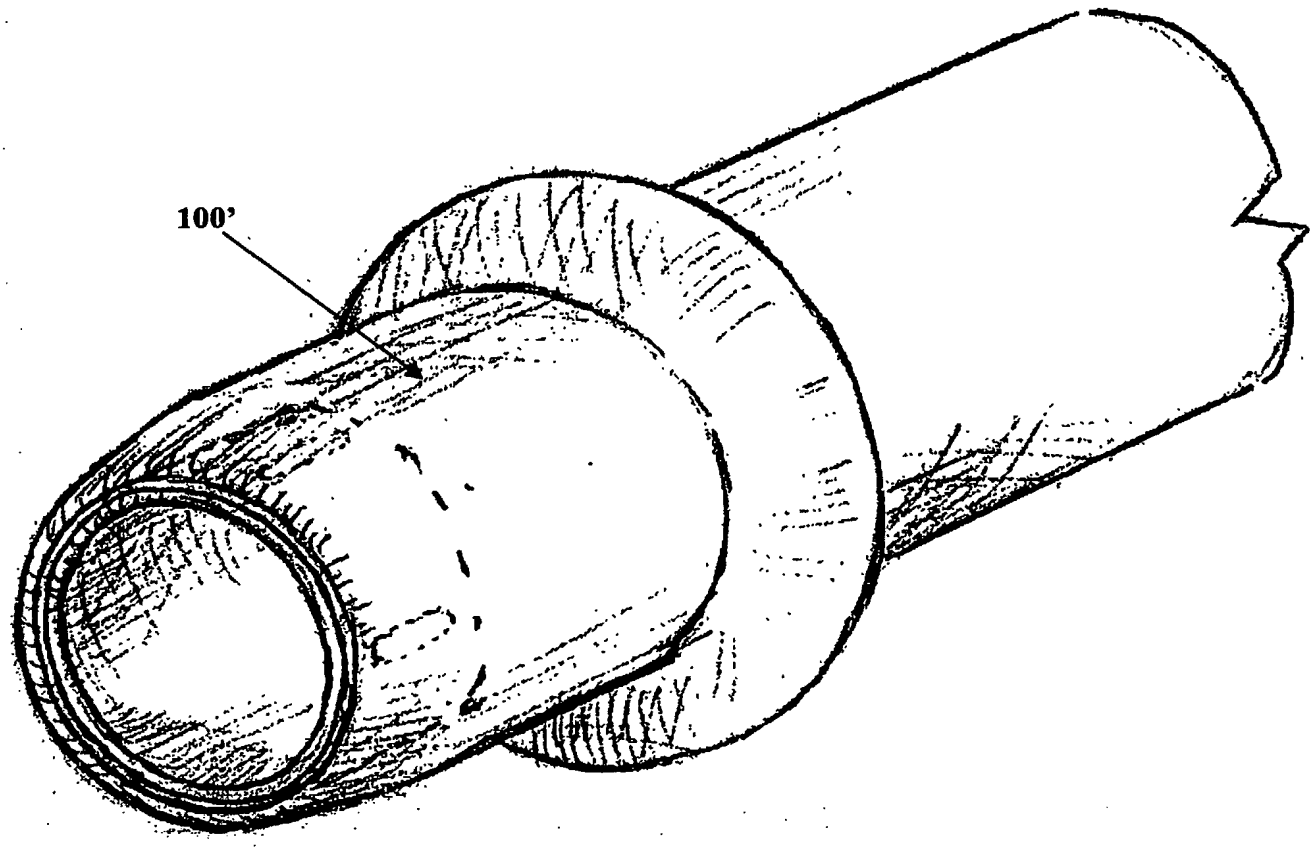


FIG. 27A

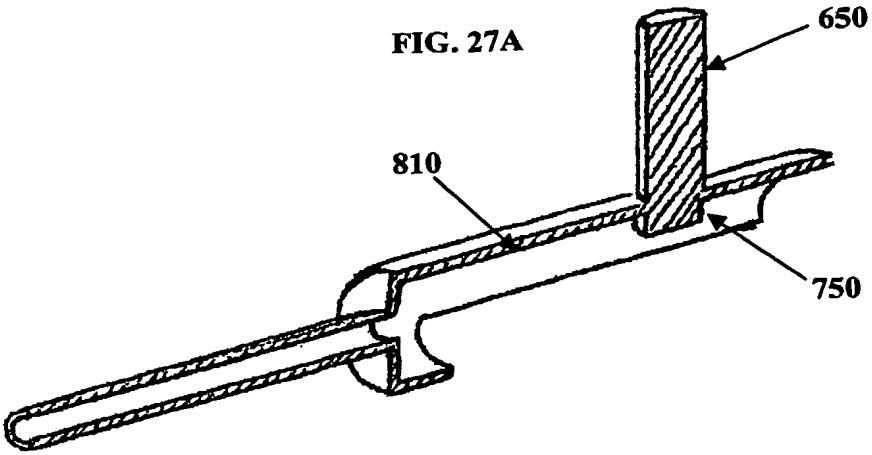


FIG. 27B

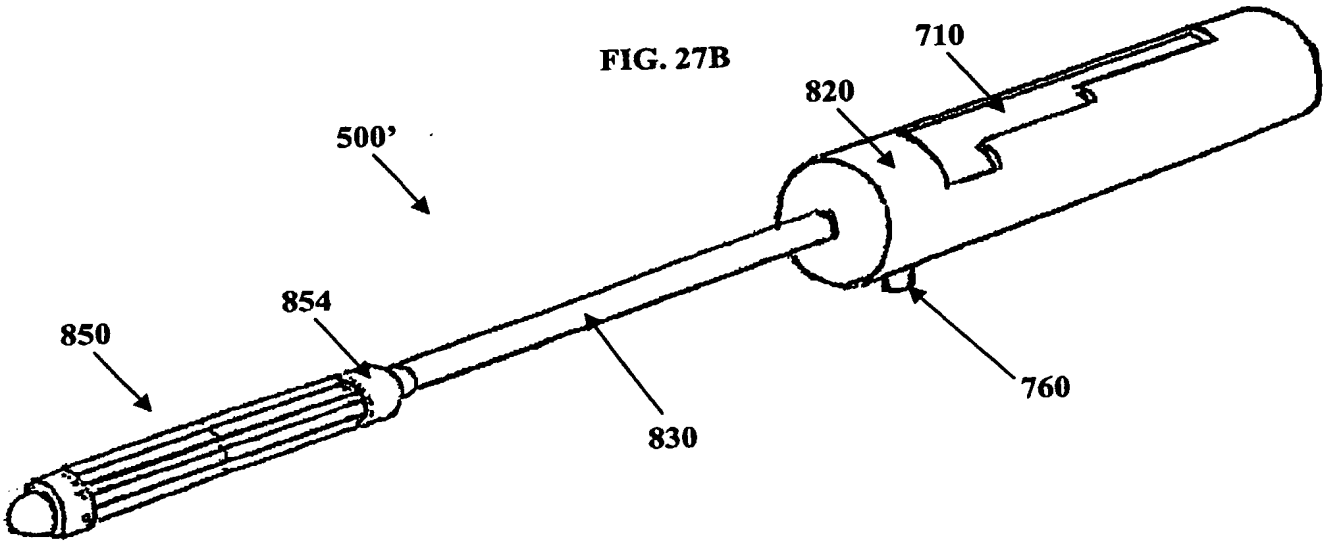
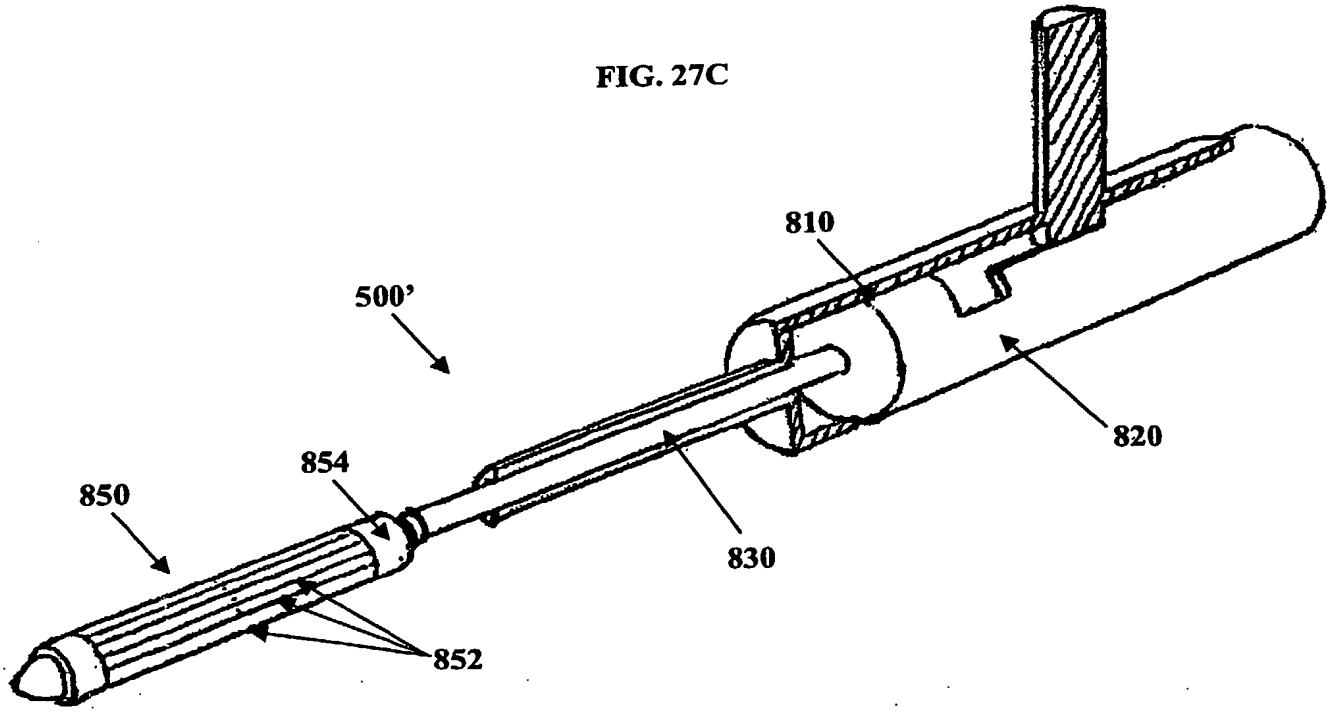


FIG. 27C



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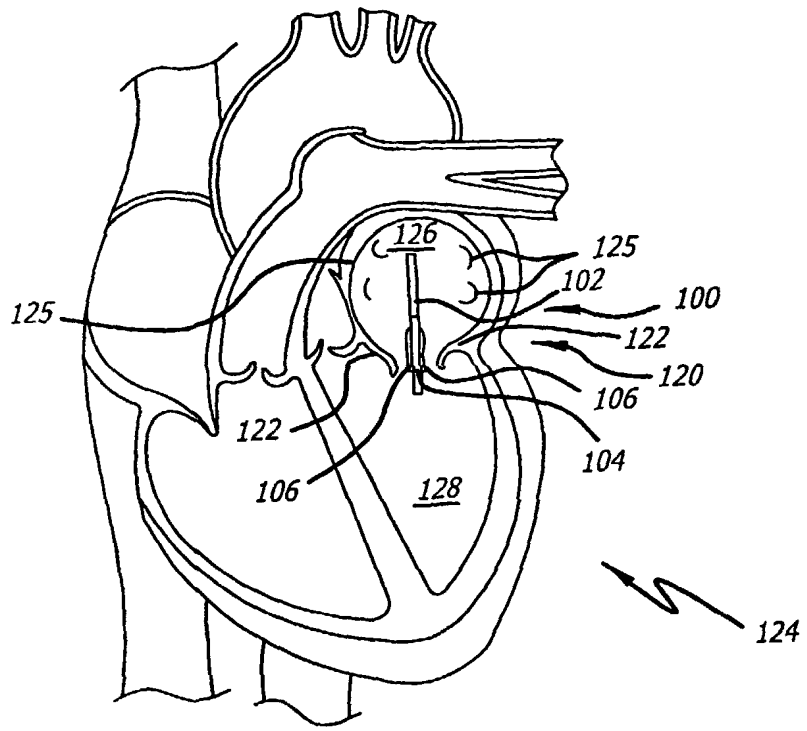
(54) **Title:** DEVICE AND METHOD FOR TREATMENT OF HEART VALVE REGURGITATION



(57) **Abstract:** In one embodiment, the present invention provides a prosthesis that can be implanted within a heart to at least partially block gaps that may be present between the two mitral valve leaflets. In one preferred embodiment, the prosthesis includes an anchoring ring that expands within the left atrium to anchor the prosthesis and a pocket member fixed to the anchoring ring. The pocket member is positioned within the mitral valve, between the leaflets so that an open end of the pocket member is positioned within the left ventricle. When the mitral valve is open, blood flows past the pocket member, maintaining the pocket member in a collapsed state. When the mitral valve closes, the backpressure of the blood pushes into the pocket member, expanding the pocket member to an inflated shape. The mitral valve leaflets contact the expanded pocket member, allowing the prosthesis to block at least a portion of the openings between the leaflets, thereby minimizing regurgitated blood flow into the left atrium.

WO 2006/032051 A2

DEVICE AND METHOD FOR TREATMENT OF HEART VALVE REGURGITATION

RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application Serial No. 60/609,345 filed September 14, 2004 entitled Device and Method for Reducing Mitral Valve Regurgitation; and U.S. Provisional Application Serial No. 60/657,919 filed March 3, 2005 entitled Device and Method for Reducing Mitral Valve Regurgitation; both of which are hereby incorporated by reference.

BACKGROUND OF THE INVENTION

[0002] The mitral valve is one of the most crucial of the four valves of the human heart, preventing the regurgitation of blood from the left ventricle into the left atrium during contraction of the heart. Located between the left atrium and the left ventricle, the mitral valve includes two leaflets positioned to block blood flow in a closed state while allowing blood flow in an opened state.

[0003] The mitral valve is opened and closed by a pressure differential between the left atrium and left ventricle and by a complex network of collagenous cord-like structures called chordae tendineae that extend from the free edges of the mitral valve leaflets to the papillary muscles on the ventricular wall of the heart. As the papillary muscles contract, they pull on the leaflets and thereby open the mitral valve, allowing blood to flow into the left ventricle. As the papillary muscles relax, the pull on the leaflets is reduced, causing the mitral valve to close and thereby block blood flow into the left ventricle.

[0004] Normal operation of the mitral valve can be impaired when the valve leaflets fail to coapt or fully close, allowing regurgitated blood to flow back into the left atrium. This mitral valve regurgitation is often caused by a congenital valve defect or by changes to the heart geometry due to disease. For example, an infection may cause the mitral valve annulus to enlarge and thereby change the position and orientation of the valve leaflets. In

another example, a mitral valve defect may cause prolapse or a mismatch of the leaflets, allowing blood flow to regurgitate back into the left atrium.

[0005] One early approach to treatment of an insufficient mitral valve involved surgical replacement with an artificial valve. In these procedures, open-heart surgery was typically performed on the patient to replace the faulty valve with either a mechanical or biologically derived valve. While this treatment procedure has been improved with time, significant limitations still exist. For example, the removal and replacement of a mitral valve is highly invasive and therefore greatly increases the risk of serious complications such as infection or rejection.

[0006] Other surgical techniques have been developed to reduce the amount of heart remodeling necessary with valve replacement. One such technique is known as bowtie repair, in which a center region of each mitral valve leaflet is sutured together. Another technique involves creating a placation around the valve annulus, thereby reducing the cross-sectional area of the valve annulus. While these techniques require less remodeling than valve replacement, a substantial amount of remodeling is still required. Further, it can be difficult to evaluate the efficacy of the surgical procedure before the conclusion of the surgery.

[0007] In yet another technique, an annuloplasty ring is sewn within the annulus of the mitral valve. Since the diameter of the annuloplasty ring is smaller than the diameter of the mitral valve annulus, the leaflets of the valve are moved together, increasing coaptation. In addition to also being highly invasive, annuloplasty rings generally distort the natural curved shape of the mitral valve and can further limit the contractility of the annulus.

[0008] While the techniques described above have been used with some success for the treatment of mitral valve deficiencies, additional treatment procedures are needed that require little or no remodeling of the heart. Further, additional treatments are needed that can be performed with minimal invasiveness and yet can more effectively reduce or eliminate mitral valve regurgitation.

OBJECTS AND SUMMARY OF THE INVENTION

[0009] It is an object of the present invention to overcome the limitations of the prior art.

[0010] It is an object of the present invention to provide an improved method and device for treating mitral valve regurgitation.

[0011] It is another object of the present invention to provide a prosthesis device that reduces regurgitation of blood into the left atrium.

[0012] It is yet another object of the present invention to provide a prosthesis device that can be delivered and deployed percutaneously within a patient.

[0013] It is another object of the present invention to provide a prosthesis device that can dynamically fill gaps between mitral valve leaflets.

[0014] It is another object of the present invention to provide a prosthesis device that can reduce most pathologies of mitral valve regurgitation.

[0015] The present invention seeks to achieve these objects, as well as others not specifically enumerated here, by providing a prosthesis that can be implanted within a heart to at least partially block gaps that may be present between the two mitral valve leaflets. In one preferred embodiment, the prosthesis includes an anchoring ring that expands within the left atrium to anchor the prosthesis and a pocket member fixed to the anchoring ring. The pocket member is positioned within the mitral valve, between the leaflets so that an open side of the pocket member is positioned within the left ventricle. When the mitral valve is open, blood flows past the pocket member, maintaining the pocket member in a collapsed state. When the mitral valve closes, the backpressure of the blood pushes into the pocket member, expanding the pocket member to an inflated shape. The mitral valve leaflets contact the expanded pocket member, allowing the prosthesis to block at least a portion of the openings between the leaflets, thereby minimizing regurgitated blood flow into the left atrium.

[0016] Another preferred embodiment of the present invention provides device for treating valve regurgitation comprising:

a coaptation member sized for placement at least partially between leaflets of a valve, said coaptation member having an expanded state and a deflated state and having a length substantially equal to a commissure of said leaflets; and

an anchoring structure connected to said coaptation member, said anchoring structure having a compressed state sized to fit within a delivery catheter and an expanded state sized for fixation on at least a portion of a wall of a chamber adjacent said valve.

[0017] Another preferred embodiment of the present invention provides a method of treating valve regurgitation comprising:

loading a prosthesis within a delivery catheter, said prosthesis including an anchoring portion and a coaptation portion;

advancing said delivery catheter to a chamber of a heart;

deploying said coaptation portion within a valve;

expanding said anchoring portion to contact a wall of said chamber; and

supporting said coaptation portion within a commisure of said valve.

[0018] Another preferred embodiment of the present invention provides a device for substantially blocking blood flow in a valve during systole comprising:

a flexible member having a lateral dimension;

a support member coupled to said flexible member and shaped to position said lateral dimension of said flexible member along a commissural length of a leaflet of said valve;

an anchoring member coupled to said support member, said anchoring member including a compressed configuration and an expanded configuration;

wherein said expanded configuration of said anchoring member is shaped to position said support member at least partially within said valve.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] Figure 1A illustrates a front view of a prosthesis according to one preferred embodiment of the present invention;

[0020] Figure 1B illustrates a perspective view of the prosthesis of Figure 1A;

[0021] Figure 1C illustrates a profile view of the prosthesis of Figure 1A in an expanded configuration;

[0022] Figure 1D illustrates a profile view of the prosthesis of Figure 1A in an deflated configuration;

[0023] Figure 2A illustrates a bottom view of the prosthesis of Figure 1A in a deflated configuration within a mitral valve;

[0024] Figure 2B illustrates a bottom view of the prosthesis of Figure 1A in an expanded configuration within a mitral valve;

[0025] Figure 3A illustrates a profile view of the prosthesis of Figure 1A in a deflated configuration within a mitral valve;

[0026] Figure 3B illustrates a profile view of the prosthesis of Figure 1A in an expanded configuration within a mitral valve;

[0027] Figure 4 illustrates a front view of the prosthesis of Figure 1A in a delivery catheter;

[0028] Figure 5A illustrates a front view of a prosthesis according to another preferred embodiment of the present invention;

[0029] Figure 5B illustrates a side view of the prosthesis of Figure 5A;

[0030] Figure 5C illustrates a perspective view of the prosthesis of Figure 5A;

[0031] Figure 5D illustrates a perspective view of the prosthesis of Figure 5A;

[0032] Figure 6 illustrates a side view of the prosthesis of Figure 5A within a heart;

[0033] Figures 7A and 7B illustrate a side view of the prosthesis of Figure 5A within a delivery catheter;

[0034] Figures 8A and 8B illustrate a side view of the prosthesis of Figure 5A with a retrieval thread;

[0035] Figure 9A illustrates a front view of a prosthesis according to another preferred embodiment of the present invention;

[0036] Figure 9B illustrates a side view of the prosthesis of Figure 9A;

[0037] Figure 9C illustrates a perspective view of the prosthesis of Figure 9A;

[0038] Figure 9D illustrates a perspective view of the prosthesis of Figure 9A;

[0039] Figure 9E illustrates an enlarged view of area 9E in Figure 9D;

[0040] Figure 10A illustrates a front view of a prosthesis according to another preferred embodiment of the present invention;

[0041] Figures 10B-10D illustrate various perspective views of the prosthesis of Figure 10A;

[0042] Figure 11 illustrates a side view of the prosthesis of Figure 10A during deployment from a delivery catheter;

[0043] Figure 12A illustrates a front view of a prosthesis according to another preferred embodiment of the present invention;

[0044] Figure 12B illustrates a side view of the prosthesis of Figure 12A;

[0045] Figures 12C-12E illustrate various perspective views of the prosthesis of Figure 12A;

[0046] Figure 13 illustrates a side view of the prosthesis of Figure 12A within a heart;

[0047] Figure 14A illustrates a front view of a prosthesis according to another preferred embodiment of the present invention;

[0048] Figure 14B illustrates a side view of the prosthesis of Figure 14A;

[0049] Figure 14C illustrates a top view of the prosthesis of Figure 14A;

[0050] Figures 14D and 14E illustrate various perspective views of the prosthesis of Figure 14A;

[0051] Figure 15 illustrates a side view of the prosthesis of Figure 14A within a heart;

[0052] Figures 16A and 16B illustrate side views of the prosthesis of Figure 14A within a delivery catheter;

[0053] Figure 17A illustrates a front view of a prosthesis according to another preferred embodiment of the present invention;

[0054] Figure 17B illustrates a top view of the prosthesis of Figure 17A;

[0055] Figures 17C and 17D illustrate perspective views of the prosthesis of Figure 17A;

[0056] Figure 18A illustrates a front view of a prosthesis according to another preferred embodiment of the present invention;

[0057] Figures 18B and 18C illustrate various perspective views of the prosthesis of Figure 18A;

[0058] Figure 18D illustrates an enlarged view or area 18D in Figures 18B;

[0059] Figure 19A illustrates a front view of a prosthesis according to another preferred embodiment of the present invention;

[0060] Figures 19B and 19C illustrate various perspective views of the prosthesis of Figure 19A;

[0061] Figure 19D illustrates an enlarged view or area 19D in Figures 19B;

[0062] Figure 20A illustrates a front view of a prosthesis according to another preferred embodiment of the present invention;

[0063] Figures 20B and 20C illustrate various perspective views of the prosthesis of Figure 20A;

[0064] Figure 21A illustrates a side view of the prosthesis of Figure 20A in a partially deployed configuration;

[0065] Figure 21B illustrates an enlarged view of area 21B in Figure 21A;

[0066] Figure 22A illustrates a front view of a prosthesis according to another preferred embodiment of the present invention;

[0067] Figures 22B and 22C illustrate various perspective views of the prosthesis of Figure 22A;

[0068] Figure 23A illustrates a front view of a prosthesis according to another preferred embodiment of the present invention;

[0069] Figure 23B illustrates a top view of the prosthesis of Figure 23A;

[0070] Figures 23C and 23D illustrate various perspective views of the prosthesis of Figure 20A;

[0071] Figure 24A illustrates a front view of a prosthesis according to another preferred embodiment of the present invention;

[0072] Figure 24B illustrates a side view of the prosthesis of Figure 23A;

[0073] Figures 24C and 24D illustrate various perspective views of the prosthesis of Figure 20A;

[0074] Figure 24E illustrates an enlarged view of area 24E in Figure 24D;

[0075] Figure 25 illustrates a side view of a prosthesis within a heart according to another preferred embodiment of the present invention;

[0076] Figure 26A illustrates a side view of a prosthesis within a heart according to another preferred embodiment of the present invention; and

[0077] Figure 26B illustrates a cross-sectional view of the prosthesis of Figure 26A.

DETAILED DESCRIPTION OF THE INVENTION

[0078] The present invention seeks to reduce the amount of blood that flows into the left atrium from the left ventricle during the systole phase of heart contraction. Most instances of this mitral valve regurgitation are caused by poor coaptation of the mitral valve leaflets that create openings between these leaflets when the mitral valve is closed. The present invention decreases the size of these opening between the mitral valve leaflets, and in some cases completely eliminates the openings, allowing the mitral valve to function with little or no regurgitation. This is achieved in at least some of the example embodiments described in this specification by positioning a member between the two mitral valve leaflets to close or fill up the openings between the leaflets when closed.

[0079] Figures 1A-4

[0080] One such design can be seen in Figures 1A-4 which illustrates a preferred embodiment of a prosthesis 100 according to the present invention. The prosthesis 100 includes a pocket 106 formed from flexible material 104 disposed on a ring 102. As best seen in Figure 1B, the pocket 106 includes a lower open end 106A that, when properly oriented within a mitral valve 120 of a heart 124, expands as the mitral valve 120 closes,

blocking any openings between the mitral valve leaflets 122. Further, the pocket 106 contracts or deflates as the mitral valve 120 opens, maximizing blood flow from a left atrium 126 to a left ventricle 128. In this sense, the pocket 106 can more generally be described as an expandable occluding member or a coaptation member.

[0081] The pocket 106 is preferably created by gluing, stitching, or otherwise adhering at least two layers of the flexible material 104 at or around line 108. These layers can be achieved with two distinct pieces of material, or a single piece of material folded against itself. Preferably, the flexible material 104 is made from pericardial tissue or other biological or artificial materials with similar flexibilities, such as bovine tissue, polyurethane, or as described in U.S. Patent No. 6,764,510, the contents of which are herein incorporated by reference. The shape of the pocket 106 and the flexibility of the flexible fabric 108 allow the pocket 106 to achieve a deflated position, as best seen in Figures 1D, 2A and 3A and an expanded position as best seen in Figures 1C, 2B and 3B.

[0082] While the pocket 106 can be shaped in a variety of different configurations, pocket shapes that facilitate entry and escape of blood from the pocket 106, such as the rounded arch-shape of pocket 106, are preferred. Configurations of the pocket 106 that include sharp corners or rough seams are less preferred due to their disruptive effect on blood flow into and out of the pocket 106. Preferably, the pocket 106 also includes an overall length similar to that of the mitral valve 120 and more preferably substantially the length of the mitral valve commissure, allowing the pocket 106 to fill any openings that may be present along the length of leaflets 122, as seen best in Figure 2B. While a single pocket 106 is preferred, additional pockets or partitions within the pocket can also be included in the present invention.

[0083] The ring 102 is preferably made from an elastic, shape-memory material such as Nitinol which allows the prosthesis 100 to be compressed or loaded into a delivery catheter 110, as seen in Figure 4, then expanded to a predetermined shape within the left atrium 126, as seen in Figures 3A and 3B. The ring 102 is sized to press against the walls of the left atrium 126 of the heart 124, and in some configurations within the commissure of the mitral valve 120, thereby anchoring the position of the prosthesis 100, while positioning the

pocket 106 at least partially through a mitral valve 120. Additionally, the lower open end 106A of the pocket 106 is positioned near or within the left ventricle 128. In this sense, the ring 102 can more generally be described as an anchoring framework or an anchoring structure.

[0084] Once positioned within the heart 124, the prosthesis 100 functions in a similar manner to a heart valve, opening during diastole and closing during systole. More specifically, as blood enters the left atrium from the pulmonary veins 125 near the top of the left atrium 126, the blood flow moves downward towards the mitral valve 120. As the blood flow reaches the mitral valve 120, it pushes against the mitral valve leaflets 122 as the mitral valve 120 is opened by the papillary muscles. The blood flow also pushes against the pocket 106 of the prosthesis 100, forcing out any blood that may be within the pocket 106 and causing the pocket 106 to assume a substantially deflated or compressed position, as seen in Figure 3A. This compressed configuration of the pocket 106 provides a streamline profile that minimizes blood flow resistance and other disruptive effects that a device within the left atrium might otherwise cause. In this respect, the blood flow during diastole passes into the left atrium 126, through the mitral valve 120 and past the prosthesis 100 to allow passage of the blood flow into the left ventricle 128.

[0085] During systole, backpressure from the blood in the left ventricle 128 presses against the mitral valve leaflets 122, as the papillary muscles move these leaflets 122 to a closed position. Additionally, this backpressure of blood in the left ventricle 128 enters the pocket 106 of the prosthesis 100, causing the pocket 106 to achieve an expanded shape, as seen in Figure 3B. The mitral valve leaflets 124 coapt against the expanded pocket 106, as best seen in Figure 2B, minimizing or even eliminating gaps that would otherwise be present between the two leaflets 122. Thus, blood flow during systole expands the prosthesis 100 to reduce or eliminate any openings that would otherwise be present between the leaflets 122, ultimately reducing or preventing regurgitation of blood into the left atrium 126.

[0086] Due in part to the dynamic, flexible nature of the pocket 106, the prosthesis 100 can expand to fill a wide range of opening sizes between the leaflets 122 without the need

for an equally wide range of pocket sizes. In other words, the same size pocket 106 can expand to fill a relatively small opening or a relatively large opening between the mitral valve leaflets 122. Thus, the same size prosthesis 100 may be appropriate for a patient with relatively severe mitral valve regurgitation as well as relatively mild mitral valve regurgitation. Different sizes of prosthesis 100 may be appropriate, however, for different size mitral valves 120, since it is preferred that the pocket 106 extends along the length of the commissure of the mitral valve or the length of the "meeting line" between the two leaflets.

[0087] The prosthesis 100 is preferably delivered to the left atrium 126 percutaneously by a catheter 110, as seen in Figure 4. For example, the delivery catheter 110 may be fed through the femoral vein, into the right atrium and passed through a pre-made puncture in the atrial septum 125. In another example, the delivery catheter 110 can be passed through the femoral artery into the aorta, through the aortic valve and into the left ventricle.

[0088] Alternately, the prosthesis 100 can be inserted into the left atrium 126 through an opening in the atrial wall of the heart 125 during open-heart surgery. Although the prosthesis 100 can be seen and positioned more easily during open-heart procedures, percutaneous delivery is less invasive and therefore includes a substantially lower risk of complications.

[0089] Figures 5A-8B

[0090] Another preferred embodiment of a prosthesis 200 according to the present invention can be seen in Figures 5A-7B. While generally similar to the prosthesis 100, the prosthesis 200 also includes four anchoring loops 202 that expand to anchor the prosthesis 200 within the left atrium 126 and position a pocket 206 between the mitral valve leaflets 122, along the length of the mitral valve commissure. In this respect, the anchoring loops 202 can more generally be described as an anchoring framework or an anchoring structure.

[0091] The pocket 206 is supported by support arms 204 and bottom support 208 which provide a support framework for the pocket 206. Preferably the side arms 204 and the

bottom support 208 are a single, unitary wire that connect to the anchoring loops 202, however multiple segments of wire can be connected together, for example by welding or soldering, as well. As with the previously described embodiment of the prosthesis 100, the support arms 204 and the bottom support 208 are preferably composed of an elastic, memory-shape material, such as Nitinol, which allows the prosthesis 200 to be compressed and loaded into a catheter 110, as seen in Figures 7A and 7B, then deployed to the predetermined shape seen in Figures 5A-6. Preferably, the wires used for the support arms 204 and the bottom support 208 are sized and shaped to cause minimal deformation of the free edges of the leaflets 122, and therefore minimize distortion of the mitral valve geometry. In this respect, the pocket support arms 204 can alternatively be described as a framework, a support structure, or a positioning frame.

[0092] The pocket 206 is similar to the pocket 106 of the previous embodiment, preferably being composed of a flexible biological or artificial material that is sized and shaped to form a pocket-shape with an opening directed opposite to the anchoring loops 202. The pocket 206 can be directly stitched, glued, or adhered to the outer support arms 204 for support. Alternately, the flexible fabric of the pocket 206 can be stitched to form an elongated passage for the support arms 204 on the outer surface of the pocket 206.

[0093] As best seen in Figure 6, the pocket 206 is positioned at least partially within the mitral valve 120 so that the open end of the pocket 206 is faced toward the left ventricle 128. In this configuration, the pocket 206 is deflated during diastole, minimizing blood flow blockage in the mitral valve 120, and expanded during systole, at least partially filling any openings between the mitral valve leaflets 122 and thereby minimizing blood flow regurgitation into the left atrium 126.

[0094] The prosthesis 200 is preferably delivered to the left atrium 126 by a percutaneous delivery catheter 110 but can also be implanted during open-heart surgery, as described in regards to the prosthesis 100. Since the pocket 206 has a horizontally elongated shape that requires a specific orientation within the mitral valve 120, percutaneous delivery of the prosthesis 200 to the proper position may be more difficult than delivery during open-heart surgery. Accordingly, the delivery catheter 110 may

include a retrieval thread 210 and a push rod 212 as seen in Figures 8A and 8b to retrieve the prosthesis 200 back into the catheter 110 and redeploy the prosthesis 200 at a new position within the left atrium 126.

[0095] Preferably, the retrieval thread 210 is composed of a thin but strong material such as metal, silk, or polypropylene, and is a single segment. Both free ends of the retrieval thread 210 are positioned at a proximal end of the delivery catheter 110, while the body of the thread 210 extends through the deliver catheter 110, through each anchoring loop 202 and back through the catheter 110.

[0096] Depending on the configuration of the prosthesis 200 in an expanded state, the retrieval thread 210 alone may not provide the necessary force to fully recompress and recapture the prosthesis 200. In such situations, the pusher rod 212 may be used in conjunction with the retrieval thread 210 to manipulate the prosthesis 200 into a shape acceptable for recapture within the delivery catheter 110. For example, the operator of the delivery catheter 110 may pull on the retrieval thread 210 while pushing on the anchoring loops 202 with the pusher rod 212. The simultaneous pushing and pulling deform the anchoring loops 202 into an elongated shape that can more easily be recaptured by the delivery catheter 110, allow the user to reposition the distal end of the delivery catheter 110 and redeploy the prosthesis 200.

[0097] Figures 9A-9E

[0098] Figures 9A-9E illustrate another preferred embodiment of a prosthesis 250 that is mostly similar to the prosthesis 200 previously shown in Figures 5A-8B, having anchoring loops 252 fixed to support arms 258 and a pocket 254 disposed between the support arms 256. However, as best seen in Figure 9E, the support arms 258 of the present prosthesis 250 are positioned and attached within the pocket 254 instead of on the outer surface of the pocket 254, creating a more uniform outer surface shape compared with the prosthesis 200. Additionally, the bottom support 256 includes a loop 256A that is configured to exert force against the support arms 258 to maintain the pocket 254 in a fully expanded position.

[0099] Figures 10A-11

[00100] Figures 10A-11 illustrate yet another embodiment of a prosthesis 300 according to the present invention that is generally similar to the previously described embodiments of this specification, having support arms 304 that support a pocket 306 made from flexible material.

[00101] Unlike the embodiments previously described in this specification, the prosthesis 300 includes an anchoring cage 302 that is unitary with the support arms 304. Preferably, both the anchoring cage 302 and the support arms 304 are cut from a single metal tube, such as by laser cutting the desired pattern into the tube or by other techniques used to manufacture stents. The metal of the tube is preferably composed a shape memory material, such as those commonly used for stents such as Nitinol. In this regard, the anchoring cage 302 can more generally be described as an anchoring framework or an anchoring structure.

[00102] Once expanded within the left atrium 126, the anchoring cage 302 contacts the tissue of the left atrium 126 in more positions that embodiments previously described in this specification and therefore more uniformly distributes the anchoring force within the left atrium 126. Additionally, the expanded shape of the anchoring cage 302 can be shaped to better conform to the geometry of the left atrium 126 and therefore more precisely position the pocket 306 at a desired location.

[00103] As with the previously described embodiments of this specification, the prosthesis 300 is preferably delivered percutaneously with a delivery catheter 110 as seen in Figure 11, but may alternately be deployed during open-heart surgery. In the case of percutaneous deployment, the prosthesis 300 compresses to a relatively small pre-deployed state, as seen in Figure 11.

[00104] Figures 12A-13

[00105] Figures 12A-13 illustrate another preferred embodiment of a prosthesis 400 according to the present invention, which is generally similar to the previously described

embodiments, such as the prosthesis 200 shown in Figures 5A-8B. More specifically, the similarities of the prosthesis 400 include anchoring loops 402 that anchor and position a pocket 406 via support arms 404. The pocket 406 is similarly positioned within the mitral valve 120 so as to expand into any openings between the mitral valve leaflets 122 when the mitral valve 120 is closed.

[00106] In contrast to the previously described embodiments, the prosthesis 400 includes multiple anchoring loops 402 that form a spherical, lemon shape having a terminating region 408. The overall shape of the anchoring loops 402 expand to apply pressure against the left atrium 126 at different angles which better maintains the position of the prosthesis 400. Additionally, the terminating region 408 can press against the tissue of the left atrium 126 or can alternatively be positioned within an incision within the wall of the left atrium 126 (e.g. a percutaneous access incision within the atrium septum) to provide further anchoring support.

[00107] The body of the prosthesis 400 includes wires 402A-402E that are shaped to form the anchoring loops 402, as well as two pocket supports 404. Wires 402B, 402C, and 402D are shaped to have a generally circular shape with each of the free ends captured by terminating region 408. In this respect, each wire 402B, 402C, and 402D forms a single loop of the prosthesis 400.

[00108] One end of wire 402A is fixed within terminating region 408 while the other end extends down to form a pocket support 404, including an arch-shape in between the two ends having a similar shape to those formed by wires 402B, 402C, and 402D. The second pocket support 404 is formed from wire 404E which is similarly fixed within terminating region 408. As with the previously described embodiments described in this specification, the pocket 406 is fixed to the pocket supports 404, thereby maintaining the pocket 406 at a desired location within the mitral valve 120, as best seen in Figure 13. In this regard, the anchoring loops 402 can more generally be described as an anchoring framework or an anchoring structure.

[00109] Figures 14A-16B

[00110] In another preferred embodiment illustrated in Figures 14A-16B, a prosthesis 500 is shown according to the present invention. Similar to previous embodiments discussed within this specification, the prosthesis 500 includes a pocket 506 that is supported and positioned by an anchoring wire 502. While the present prosthesis 500 includes curved anchoring regions 502A, similar to the curved anchoring wires of previously discussed embodiments, these anchoring regions 502A are composed of a single anchoring wire 502. By using a single anchoring wire 502, the prosthesis 500 minimizes the possible sharp ends or edges that may otherwise be present. In this sense, the anchoring wire 502 can more generally be described as an anchoring framework or an anchoring structure.

[00111] As seen in Figures 16A and 16B, one possible delivery method of the prosthesis 500 includes compressing or loading the prosthesis 500 within the percutaneous delivery catheter 110 and delivering the prosthesis 500 to the left atrium 126. Once within the left atrium 126, the prosthesis 500 expands to the predefined shape seen in Figure 15. Thus, the prosthesis 500 maintains the position of the pocket 506 within the mitral valve 120, similar to previously discussed embodiments, reducing regurgitation.

[00112] Figures 17A-17D

[00113] Figures 17A-17D illustrate yet another preferred embodiment of a prosthesis 600 according to the present invention that reduces mitral valve regurgitation similar to the embodiments previously described in this specification by anchoring a pocket 606 within the mitral valve 120.

[00114] In contrast, present prosthesis 600 includes anchoring wires 602 shaped to have an asymmetrical egg structure that more closely resembles the asymmetrical interior of the left atrium 126. Since the asymmetry of the anchoring wires 602 matches the natural asymmetry of the left atrium 126, the prosthesis 600 expands and orients itself in a predetermined position, providing stable anchoring and consistent alignment of the pocket 606 with the mitral valve 120. Further, this asymmetrical design facilitates delivery and

deployment from the position of an incision through the atrial septum, since the prosthesis 600 expands to firmly engage the geometry of the left atrium 126. In this regard, the anchoring wires 602 can more generally be described as an anchoring framework or an anchoring structure.

[00115] The pocket 606 also includes a radial or cylinder shape when fully expanded, and can more generally be described as an expandable occluding member or a coaptation member. The radial shape imparts a uniform hydraulic function that is similar, regardless of the rotationally orientation of the pocket 606 relative to the mitral valve leaflets 122 (i.e. the commissure of the mitral valve 120). In this respect, the prosthesis 600 can be deployed to a greater number of orientations without adversely affecting the reduction of regurgitation.

[00116] Figures 18A-18D

[00117] Figures 18A-18D show another preferred embodiment of a prosthesis 700 according to the present invention that is much like the previously described prosthesis 600, having anchoring wires 702 forming an asymmetrical shape similar to the geometry of the left atrium 126. However, the present prosthesis 700 includes a pocket 706 with an elongated, non-radial shape that is coupled to the anchoring wires 702 by a rotating swivel 710. The swivel 710 allows rotation between the pocket 706 and the anchoring wires 702, allowing the pocket 706 to achieve a desired rotational orientation within the mitral valve 120, regardless of the orientation of the anchoring wires 702. In this respect, the anchoring wires 702 can more generally be described as an anchoring framework or an anchoring structure.

[00118] As best seen in Figure 18D, the swivel 710 is composed of wire loop 708 that extends from an unseen wire support of the pocket 706. The anchoring wires 702 include a wire coil 704 that encircles and thereby engages the wire loop 708, allowing the anchoring wires 702 to rotate in relation to the pocket 706. In this respect, the surgeon can more easily deploy the prosthesis 700 percutaneously by first positioning the pocket 706 at a desired position within the mitral valve 120, then deploying the anchoring wires 702 without the need to adjust the overall rotational orientation of the prosthesis 700. Additionally, the

ability of the prosthesis 700 to rotate allows the pocket 706 to self align so that each mitral valve leaflet 122 contacts against an elongated side of the pocket 706.

[00119] Figures 19A-19D

[00120] Figures 19A-19D illustrate a preferred embodiment of a prosthesis 800 that is similar to the embodiments previously described in this specification, especially the prosthesis 700 shown in Figures 18A-18D. More specifically, the prosthesis 800 includes anchoring wires 802 which expand to an asymmetrical shape, similar to the geometry of the left atrium 126. Additionally, the prosthesis 800 includes an elongated pocket 806 coupled to the anchoring wires 802 by a rotating joint 810. In this regard, the anchoring wires 802 can more generally be described as an anchoring framework or an anchoring structure.

[00121] In contrast to the previously described prosthesis 700, the prosthesis 800 includes a pocket support wire 804 that not only supports the structure of the pocket 806, as described in other embodiments in this specification, but also wraps around a cylinder 808, then branches radially outward into loop shapes 804A, as best seen in Figure 19D. The ends of anchoring wires 802 are coupled within the cylinder 808 so as to allow the anchoring wires 806 rotate freely from the pocket 806.

[00122] The looped regions 804A of the pocket support wire 804 assist the freely rotating pocket 806 in orienting itself to a desired position within the mitral valve 120. Additionally, these outer looped regions 804A can be sized and shaped to provide support to the pocket 806 by resting on the annulus of the mitral valve 120.

[00123] Alternately, the looped regions of the pocket support wire 804 can be shaped to at least partially interlock with a portion of the anchoring wires 802 to allow the anchoring wires 802 to freely rotate within a range, determined and therefore restricted by the length of the loops of the pocket support wire 804. Such a rotational restriction may better assist the surgeon in delivering and deploying by allowing at least some degree of rotational control over the pocket 806 in a deployed configuration.

[00124] Figures 20A-21B

[00125] Figures 20A-21B illustrate yet another preferred embodiment of a prosthesis 900 according to the present invention which is generally similar to the previously discussed embodiments of this specification, such as prosthesis 600 of Figures 17A-17D. For example, the prosthesis 900 includes a pocket 906 having a radial shape and pocket support wires 908, as well as anchoring wires 902 fixed to the pocket 906 and having an asymmetrical shape generally matching the inner geometry of the left atrium 126.

[00126] However, the prosthesis 900 includes two separately deployable support structures: the previously mentioned anchoring wires 902 and inner support wires 904. The inner support wires 904 include elongated region 904A and anchoring region 904B which continues within the pocket 906 as support wires 908. The anchoring wires 902 and inner support wires 904 can more generally be described as an an anchoring framework or an anchoring structure.

[00127] As best seen in Figures 21A and 21B, the support structures 902 and 904 can be deployed separately during a percutaneous deliver with the deliver catheter 110. As the prosthesis 900 is pushed out of the delivery catheter 110, the inner support wire 904, including elongated region 904A and anchoring region 904B, expand first while the anchoring wires 902 remain relatively compressed.

[00128] The expanded shape of the anchoring region 904B is preferably sized and shaped to engage at least a portion of the annulus of the mitral valve 120. In this respect, the user can direct the pocket 906 to a desired position within the mitral valve 120 while the anchoring region 904B expands to at least partially anchor the pocket 906 in place. Once the user has achieved a desired position for the pocket 906, the remaining anchoring wires 902 can be deployed from the delivery catheter 110, allowing them to expand to press against the left ventricle 126, thereby further anchoring the prosthesis 900 in place.

[00129] Figures 22A-22C

[00130] Figures 22A-22C illustrate yet another preferred embodiment of a prosthesis 1000 according to the present invention. Generally, this prosthesis 1000 is similar to the embodiments previously described in this specification, such as prosthesis 600 of Figures 17A-17D, including anchoring wires 1002, pocket support wires 1004, and pocket 10006 having a radial shape.

[00131] In addition to these similarities, the prosthesis 1000 includes region 1002A of anchoring wires 1002 that curve towards the open end of the pocket 1006. When expanded within the left atrium 126, the region 1002A of the present invention at least partially contacts the annulus of the mitral valve 120. This annulus support prevents the pocket 1006 from being pushed past the mitral valve 120 into the left ventricle 128, maintaining the overall vertical position of the prosthesis within the left atrium 120. In this respect, the anchoring wires 1002 can more generally be described as an anchoring framework or an anchoring structure.

[00132] Figures 23A-23D

[00133] Turning now to Figures 23A-23D, yet another preferred embodiment of a prosthesis 1100 according to the present invention is shown. Again, this prosthesis is generally similar to the previous embodiments described in this specification, including a pocket 1106 having an elongated shape, anchoring wires 1102, and lower loops 1104 that partially support the pocket 1106 and extent out from a top portion of the pocket 1106.

[00134] However, the free ends of the anchoring wires 1102 are wound around lower loops 1104, allowing the loops of anchoring wire 1102 to pivot on the lower loops 1104 to achieve more complex anchoring configurations. By achieve more complex anchoring configurations, the prosthesis 1100 can provide better support and therefore more constant positioning of the pocket 1106 over time. In this regard, the anchoring wires 1102 can more generally be described as an anchoring framework or an anchoring structure.

[00135] Figures 24A-24E

[00136] Figures 24A-24E illustrate another preferred embodiment of a prosthesis 1200 according to the present invention, having a pocket 1206 with an elongated shape, a pivot loop 1204 that is part of an unseen pocket support wire within the pocket 1206, and an anchoring wire 1202 having a region 1210 wound around the pivot loop 1204 to form a freely rotating pivot 1212.

[00137] To achieve additional complexity with the design of the anchoring wire 1202, portions of the anchoring wire fixed to each other with knitting 1208, as best seen in Figure 24E. By achieving additional complexity and looping structures, the prosthesis 1200 may be better able to anchor and therefore secure itself within the left atrium 126. Further, the knitting 1208 allows the bound regions of the anchoring wire 1202 to hinge relative to each other, which can allow more efficient packing within a delivery catheter 110 or more complex deployment strategies within the left ventricle 126. In this respect, the anchoring wire 1202 can more generally be described as an anchoring framework or an anchoring structure.

[00138] Figure 25

[00139] Turning to Figure 25, yet another preferred embodiment of a prosthesis 1300 is illustrated according to the present invention. Specifically, prosthesis 1300 demonstrates a pocket 1306 having pocket supports 1304, generally similar to the embodiments previously described in this specification, and further including a stent anchor 1302 coupled to the pocket supports 1304. In this respect, the stent anchor 1302 can more generally be described as an anchoring framework or an anchoring structure.

[00140] The stent anchor 1302 can be composed of a variety of different materials and structures as is known in the art. For example, some stent techniques can be seen in U.S. Patent No. 6,936,067; 6,929,658; 6,926,743; 6,923,828; and 6,902,575; the contents of each are herein incorporated by reference.

[00141] Figures 26A-26B

[00142] Turning to Figures 26A and 26B, yet another preferred embodiment of a prosthesis 1400 is illustrated according to the present invention, which includes an alternative anchoring and positioning system for a pocket 1406. Specifically, a positioning arm 1402 anchors within the atrial septum 125, having multiple septum attachment arms 1402 that extend from the base of the positioning arm 1402 and press against both the right and left sides of the atrial septum 125. Preferably, the septum attachment arms 1402 are similar in size and shape to those in atrial septal closure devices known in the art. To this end, the positioning arm 1402 can more generally be described as an anchoring framework or an anchoring structure.

[00143] In this respect, the prosthesis 1400 can be delivered via an incision in the atrial septum 125, first positioning the pocket 1406 within the mitral valve 120, then extending the septum attachment arms 1404 against both the left and right sides of the atrial septum 125 for anchoring support. The positioning arm 1402 substantially occludes the incision within the atrial septum 125, while the septum attachment arms 1402 retain the septal tissue around the positioning arm 1402, preventing blood from passing between through the septum 125.

[00144] While the preferred embodiments disclosed in this specification include expandable pockets, it should be understood that other designs can be used with the anchoring designs contemplated by the present invention. For example, a solid and preferably flexible plate member can alternatively be used, having a similar shape and size as described in regards to the pockets of the embodiments of this specification.

[00145] Preferably, the solid member is relatively soft, having a flexibility that allows some compression, especially when contacted by mitral valve leaflets. More preferably, the solid member could be created by adhering two pieces of pericardial tissue together and providing supporting members or wires similar to those described in regards to the pocket in the previous embodiments. In place of supporting members, Nitinol string may be attached to both the solid member and the left ventricle 128, preventing the solid member

from moving into the left atrium 126. Alternatively, the solid member can be composed of a resilient, biocompatible polymer material such as polyurethane.

[00146] Preferably, the embodiments of this specification may also include flexible polymeric sheets, such as polyurethane, that connect the anchoring loops or anchoring wire that contact the left atrium 126. In this respect, the flexible sheets further decreases stress on the left atrium walls by more evenly distributing anchoring force.

[00147] It should be understood different elements of the embodiments of this application can be combine to form additional design contemplated by the present invention. For example, the septal anchoring prosthesis 1400 shown in Figures 26A and 26B may be combine with the anchoring structures shown with the prosthesis 900 of Figures 20A-20C.

[00148] While the embodiments disclosed in the present invention have been specifically described as used with the mitral valve of the heart, it is also contemplated that these embodiments may be adapted for use with other heart valves. For example, the anchoring structures can be modified to press against a different geometry within the heart and the pocket can be adapted to a different shaped valve, such as a tricuspid valve.

[00149] Although the invention has been described in terms of particular embodiments and applications, one of ordinary skill in the art, in light of this teaching, can generate additional embodiments and modifications without departing from the spirit of or exceeding the scope of the claimed invention. Accordingly, it is to be understood that the drawings and descriptions herein are proffered by way of example to facilitate comprehension of the invention and should not be construed to limit the scope thereof.

What is claimed is:

1. A device for treating valve regurgitation comprising:

a coaptation member sized for placement at least partially between leaflets of a valve, said coaptation member having an expanded state and a deflated state and having a length substantially equal to a commissure of said leaflets; and

an anchoring structure connected to said coaptation member, said anchoring structure having a compressed state sized to fit within a delivery catheter and an expanded state sized for fixation on at least a portion of a wall of a chamber adjacent said valve.

2. The device of claim 1, wherein said coaptation member includes a flexible pocket, said flexible pocket comprised of flexible material disposed on a support structure wherein said support structure is sized to urge said flexible material along a length of said commissure.

3. The device of claim 2, wherein said flexible material is pericardial tissue.

4 The device of claim 1, wherein said anchoring structure is comprised of an anchoring wire.

5. The device of claim 4, wherein said anchoring wire is shaped for fixation against a wall of a left atrium.

6. The device of claim 4, wherein said anchoring wire is shaped to contact a mitral valve annulus.

7. The device of claim 1, wherein said anchoring structure is sized to conform substantially to a portion of a left atrium.

8. The device of claim 1, wherein said anchoring structure is rotatably connected to said coaptation member.

9. The device of claim 1, wherein said anchoring structure is size for fixation on an atrial septum.

10. The device of claim 1, wherein said anchoring structure is comprised of a stent portion.

11. The device of claim 1, wherein said anchoring structure includes a ring.

12. The device of claim 1, wherein said anchoring structure includes a plurality of loops.

13. The device of claim 1, wherein said anchoring structure includes a wire having a plurality of curved portions.

14. The device of claim 1, wherein said anchoring structure includes an anchoring cage.

15. The device of claim 1, wherein said anchoring structure includes a first anchoring member having an expanded shape sized for fixation against said portion of a wall of a chamber adjacent to said valve, and a second anchoring member having an expanded shape sized for fixation against a valve annulus.

16. A method of treating valve regurgitation comprising:

loading a prosthesis within a delivery catheter, said prosthesis including an anchoring portion and a coaptation portion;

advancing said delivery catheter to a chamber of a heart;

deploying said coaptation portion within a valve;

expanding said anchoring portion to contact a wall of said chamber; and

supporting said coaptation portion within a commisure of said valve.

17. A method of claim 16, further comprising:

expanding said coaptation portion during systole; and

deflating said coaptation portion during diastole.

18. A method of claim 16, wherein the deploying of said coaptation within a valve includes deploying said coaptation portion within a mitral valve.

19. The method of claim 16, wherein said deploying said coaptation portion within said valve includes aligning a length of said coaptation portion along a commissure of said valve.

20. The method of claim 17, wherein said expanding said coaptation portion during systole includes filling said coaptation portion with blood.

21. The method of claim 17, wherein said deflating said coaptation portion during diastole includes removing blood from said coaptation portion.

22. The method of claim 17, wherein said expanding said coaptation portion during systole includes substantially blocking blood flow along a length of a mitral valve leaflet.

23. The method of claim 16, wherein said expanding said anchoring portion to contact a wall of said chamber further includes expanding said anchoring portion to contact a valve annulus.

24. The method of claim 16, wherein said expanding said anchoring portion to contact a wall of said chamber includes expanding a first region of said anchoring portion to contact a first location within said chamber and expanding a second region of said anchoring portion to contact a second location within said chamber.

25. A device for substantially blocking blood flow in a valve during systole comprising:

a flexible member having a lateral dimension;

a support member coupled to said flexible member and shaped to position said lateral dimension of said flexible member along a commissural length of a leaflet of said valve;

an anchoring member coupled to said support member, said anchoring member including a compressed configuration and an expanded configuration;

wherein said expanded configuration of said anchoring member is shaped to position said support member at least partially within said valve.

26. The device of claim 25, wherein said flexible member includes an expanded state and a deflated state.

27. The device of claim 26, wherein said flexible member is a solid and flexible plate member.

28. The device of claim 27, wherein said flexible member is comprised of pericardial tissue.

29. The device of claim 25, wherein said flexible member includes a cavity.

30. The device of claim 29, wherein said cavity includes an opening positioned towards a left ventricle.

31. The device of claim 25, wherein said flexible member comprises pericardial tissue.

32. The device of claim 25, wherein said support member is comprised of a wire.

33. The device of claim 25, wherein said anchoring member is comprised of an anchoring wire.

34. The device of claim 33, wherein said anchoring wire is shaped for fixation against a wall of a left atrium.

35. The device of claim 33, wherein said anchoring wire is shaped to contact a mitral valve annulus.

36. The device of claim 25, wherein said anchoring member is sized to conform substantially to a portion of a left atrium.

37. The device of claim 25, wherein said anchoring member is rotatable connected to said flexible member.

38. The device of claim 25, wherein said anchoring member is comprised of a stent portion.

39. The device of claim 25, wherein said anchoring member includes a ring.

40. The device of claim 25, wherein said anchoring member includes a plurality of loops.

41. The device of claim 25, wherein said anchoring member includes a wire having a plurality of curved portions.

42. The device of claim 25, wherein said anchoring member comprises an anchoring cage.

43. The device of claim 25, wherein said anchoring member includes a first anchoring member having an expanded shape sized for fixation against a portion of a wall of a chamber adjacent to said valve, and a second anchoring member having an expanded shape sized for fixation against a valve annulus.

44. The device of claim 25, wherein said anchoring member is configured to be at least partially anchored within an atrial septum.

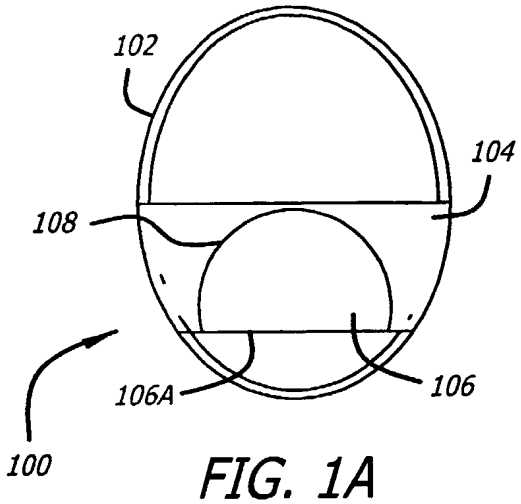


FIG. 1A

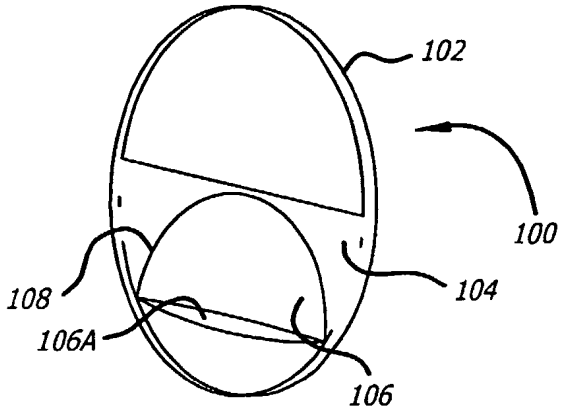


FIG. 1B

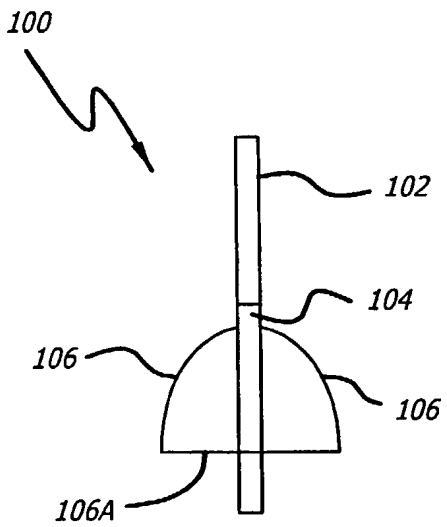


FIG. 1C

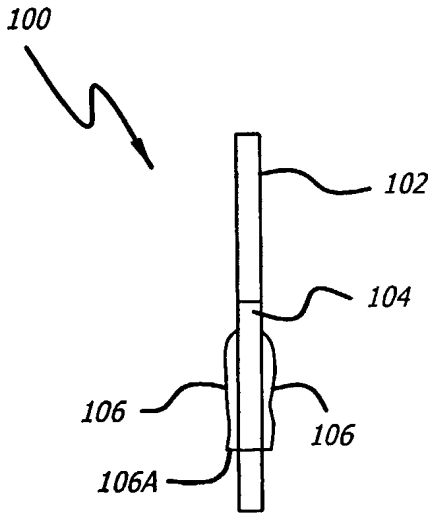
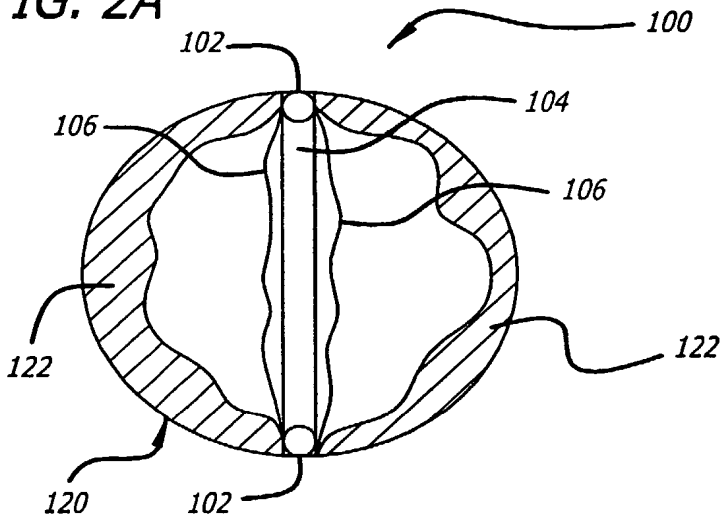


FIG. 1D

FIG. 2A



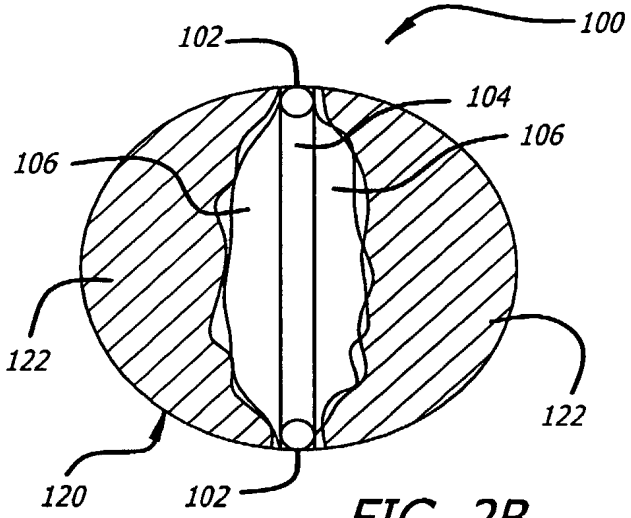


FIG. 2B

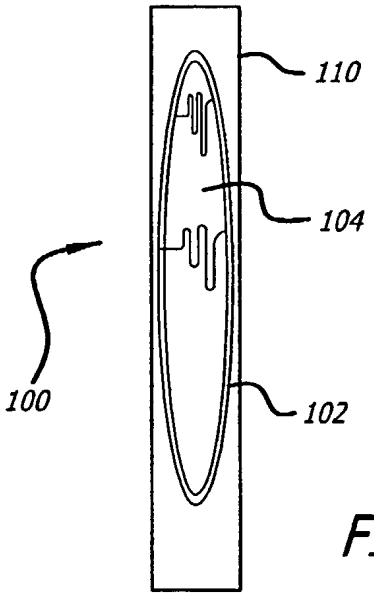
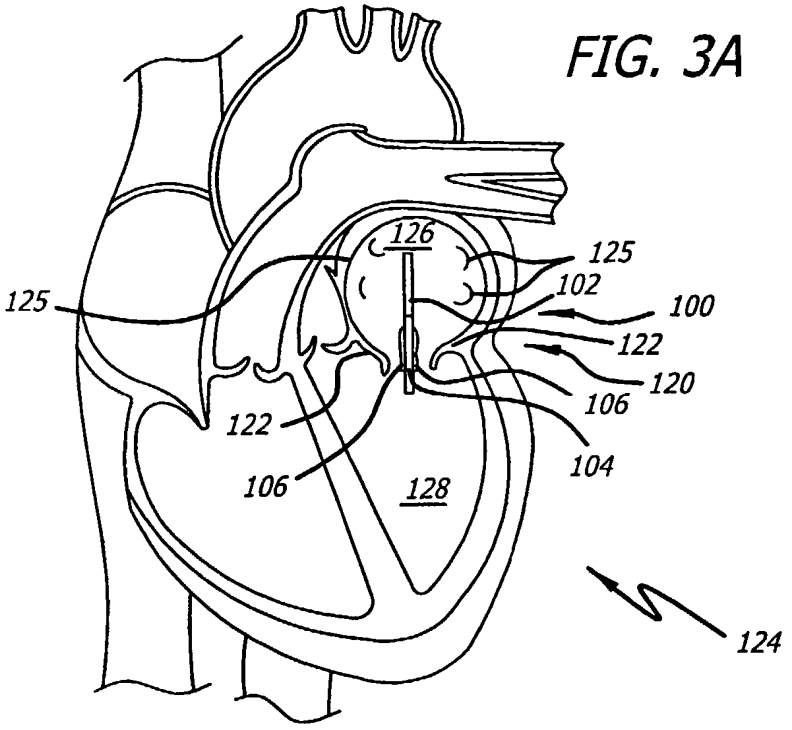


FIG. 4

FIG. 3A



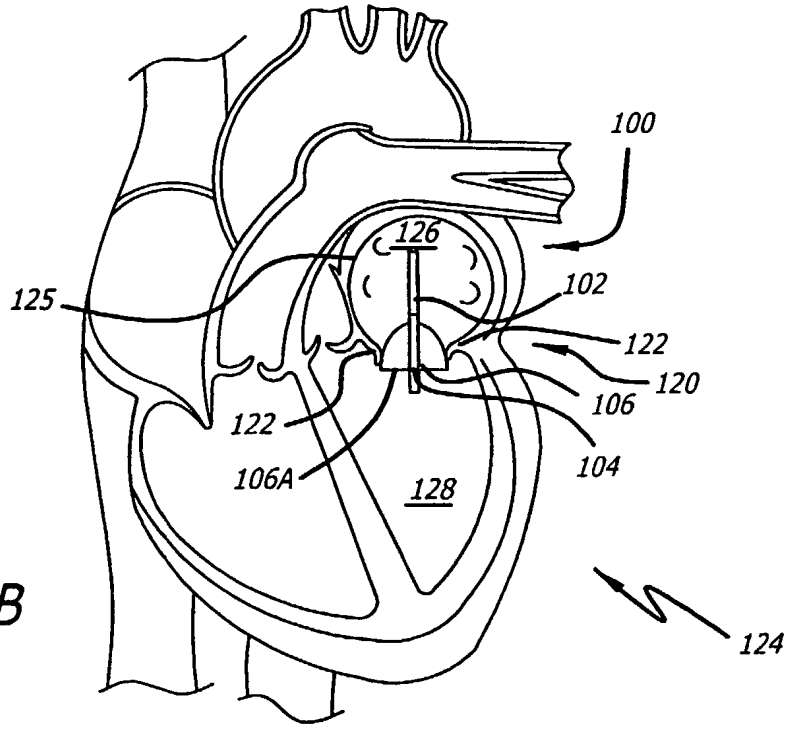


FIG. 3B

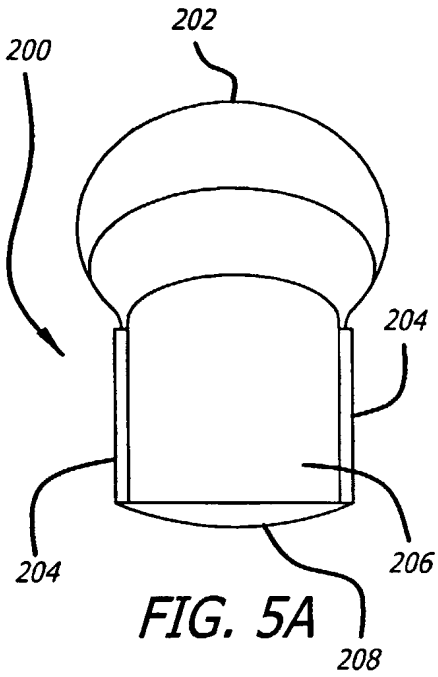


FIG. 5A

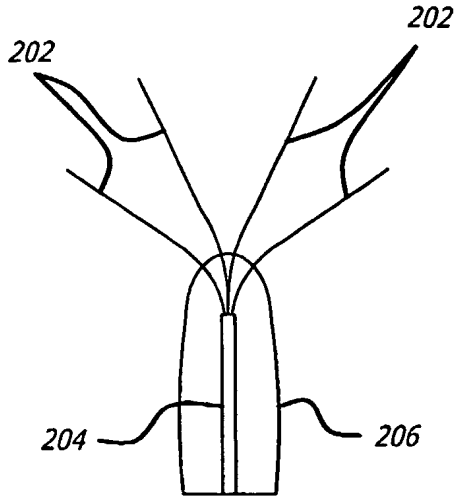


FIG. 5B

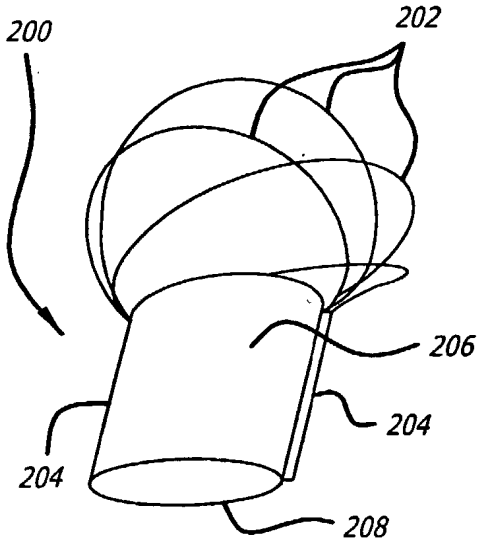


FIG. 5C

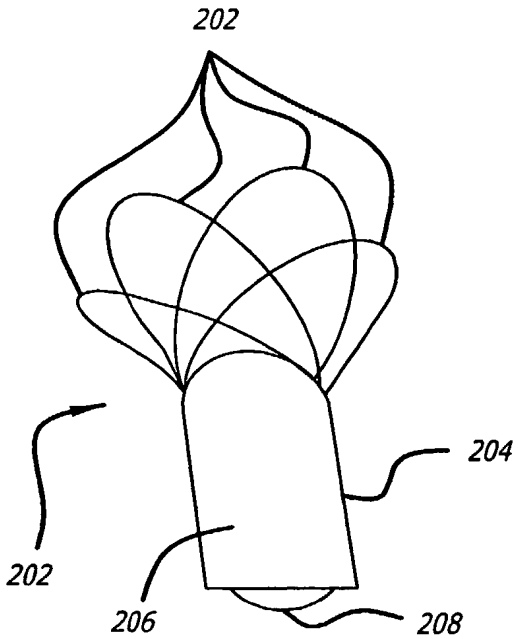


FIG. 5D

FIG. 6

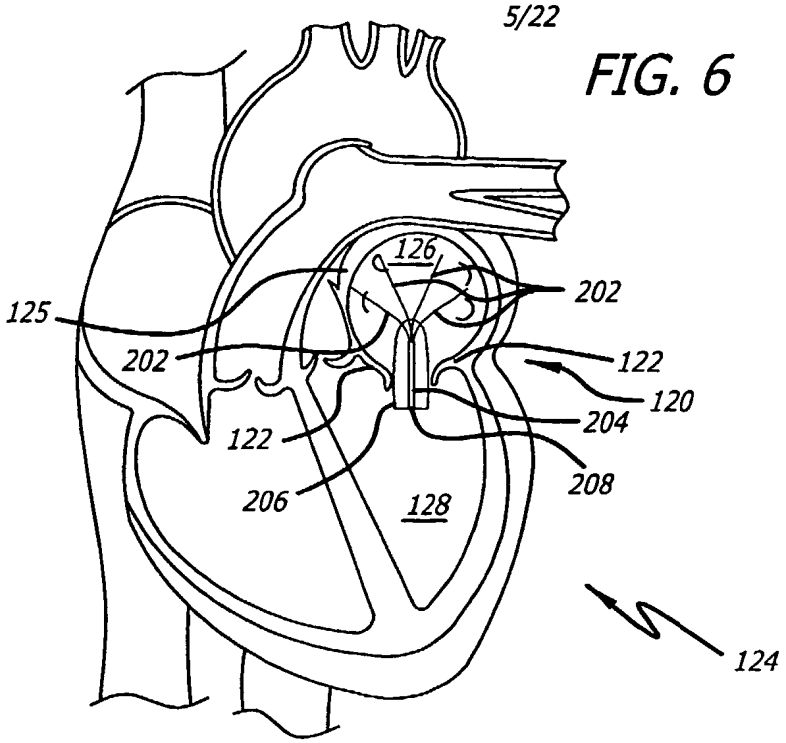
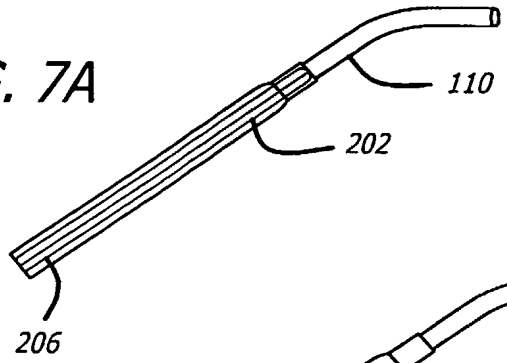


FIG. 7A



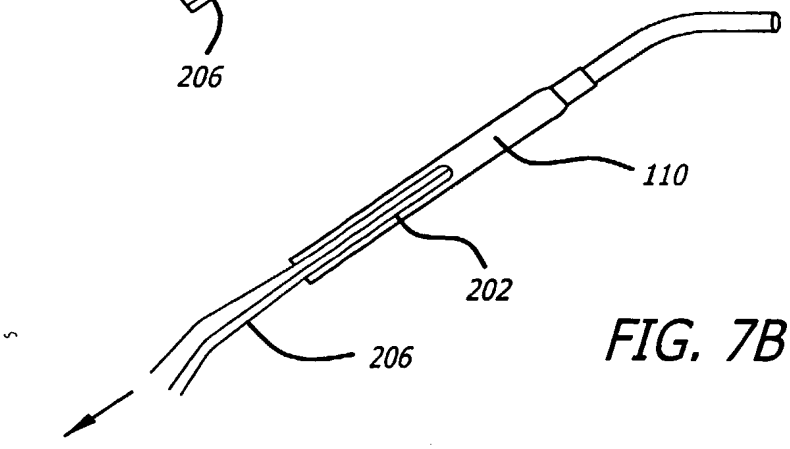


FIG. 7B

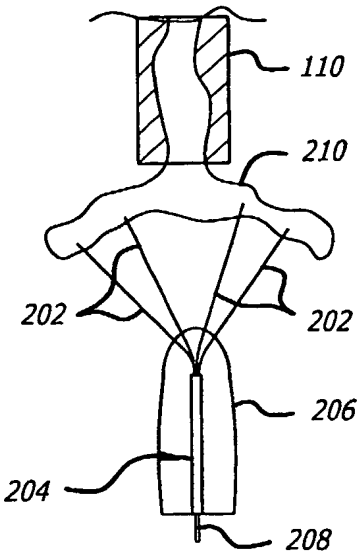


FIG. 8A

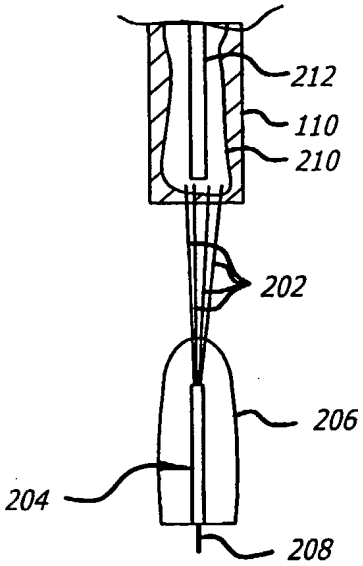


FIG. 8B

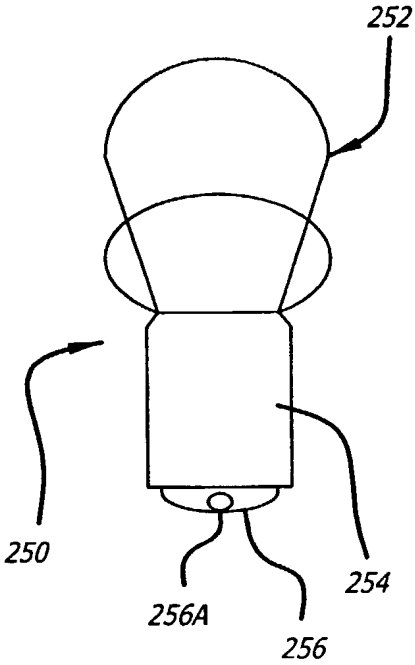


FIG. 9A

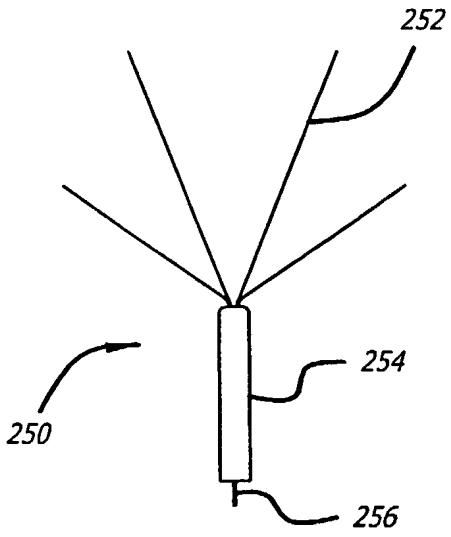


FIG. 9B

FIG. 9C

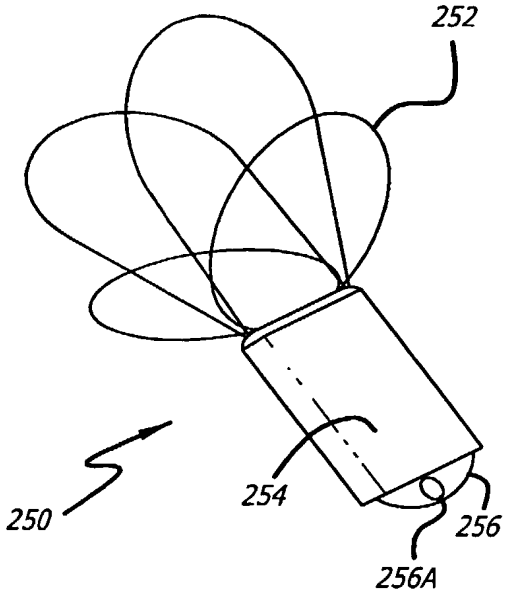
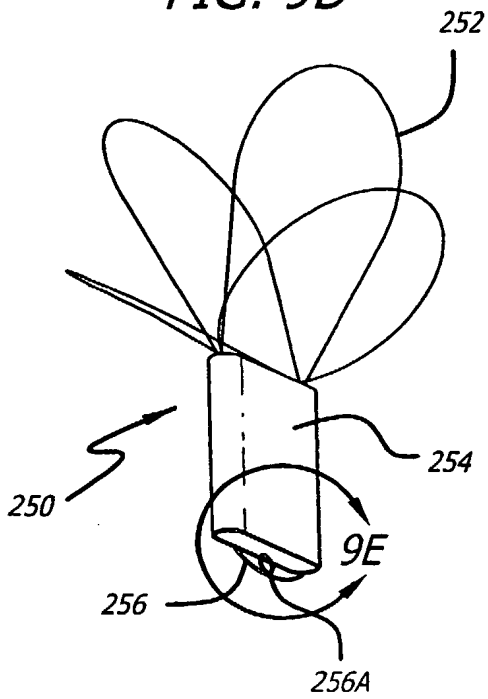


FIG. 9D



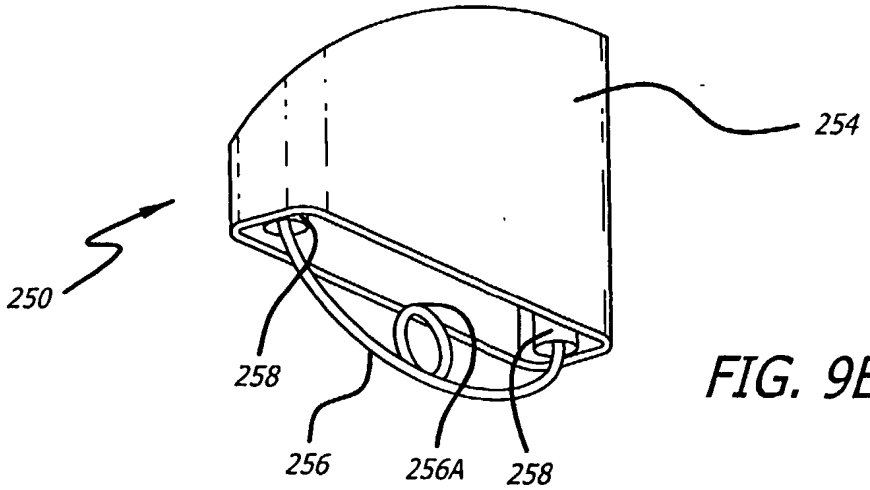


FIG. 9E

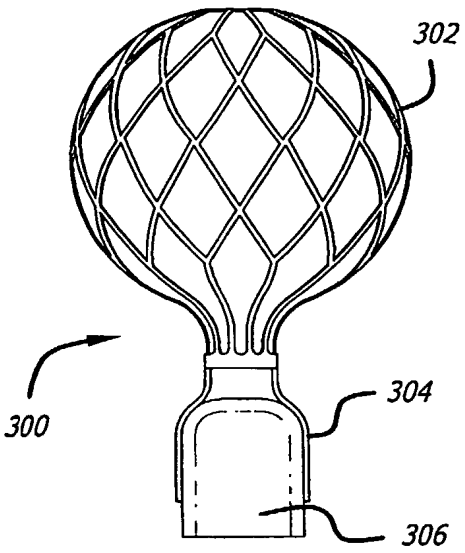


FIG. 10A

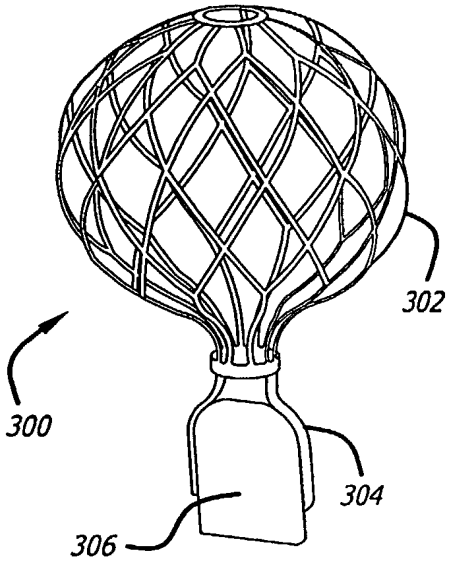


FIG. 10B

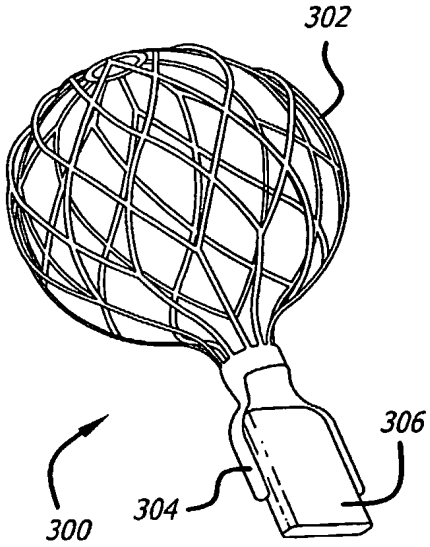


FIG. 10C

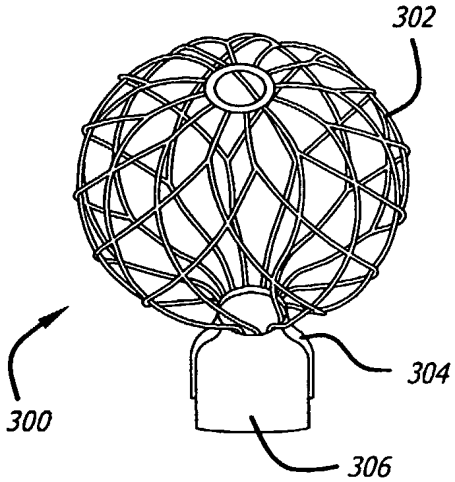


FIG. 10D

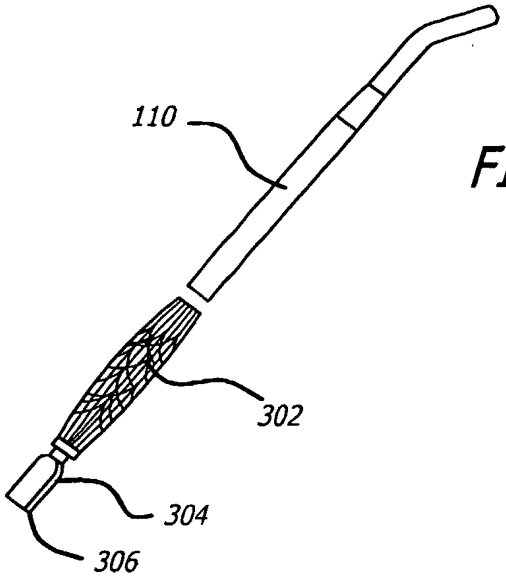
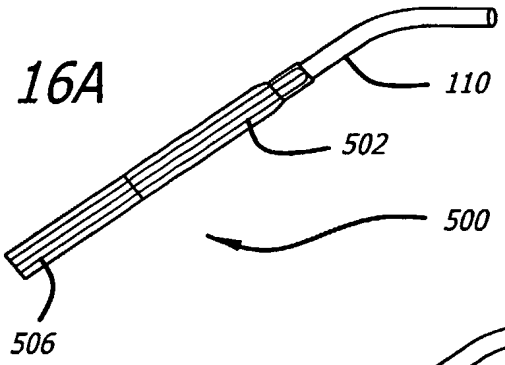


FIG. 11

FIG. 16A



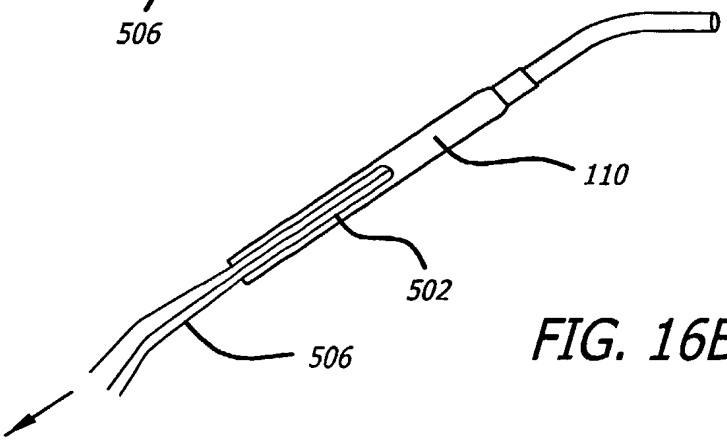


FIG. 16B

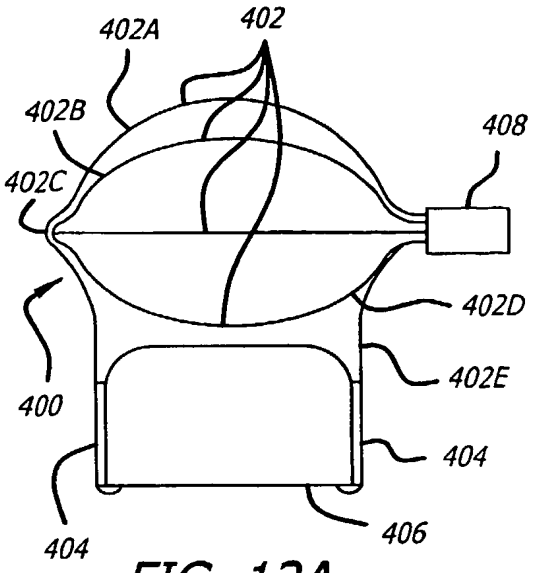


FIG. 12A

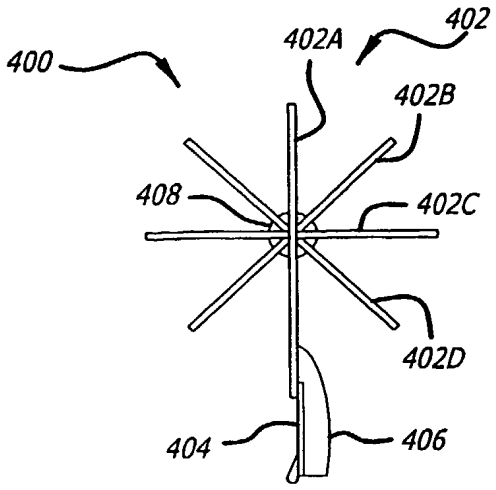


FIG. 12B

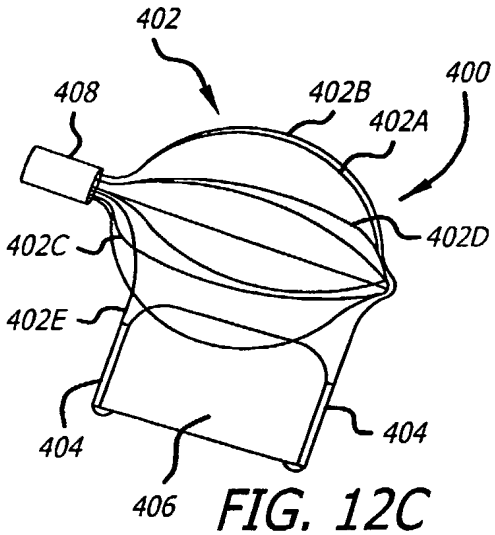


FIG. 12C

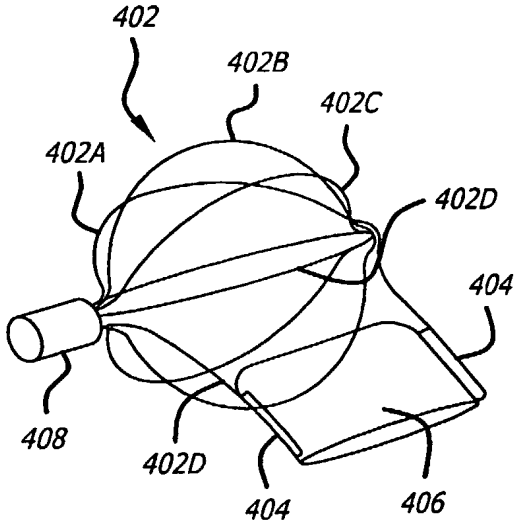


FIG. 12D

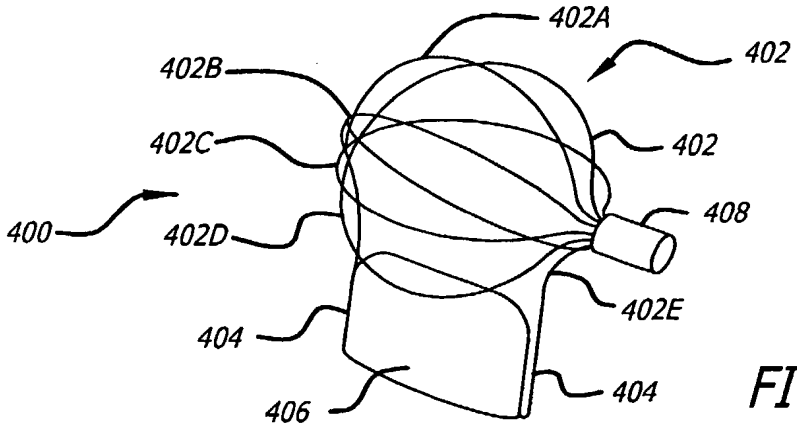
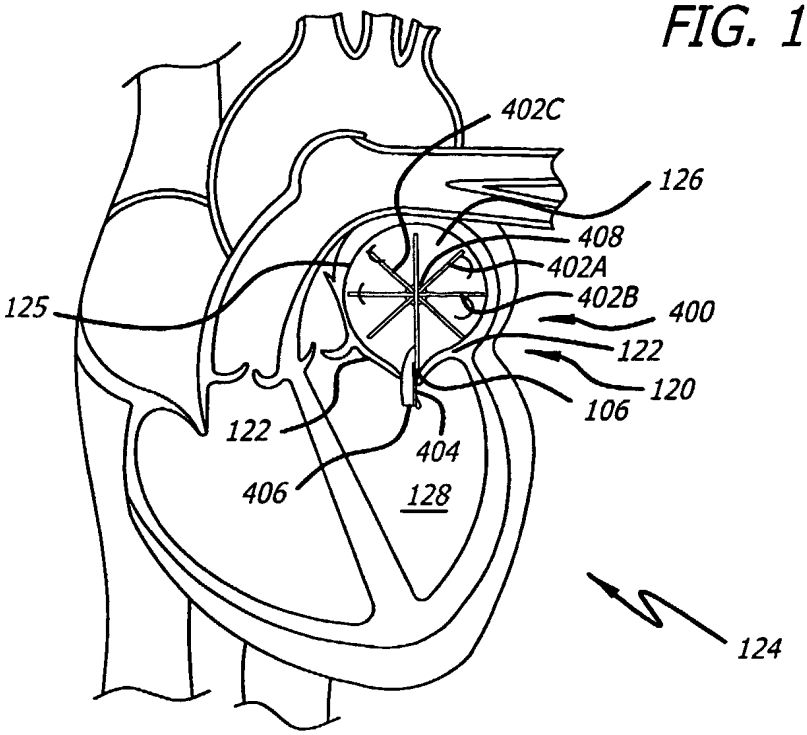


FIG. 12E

FIG. 13



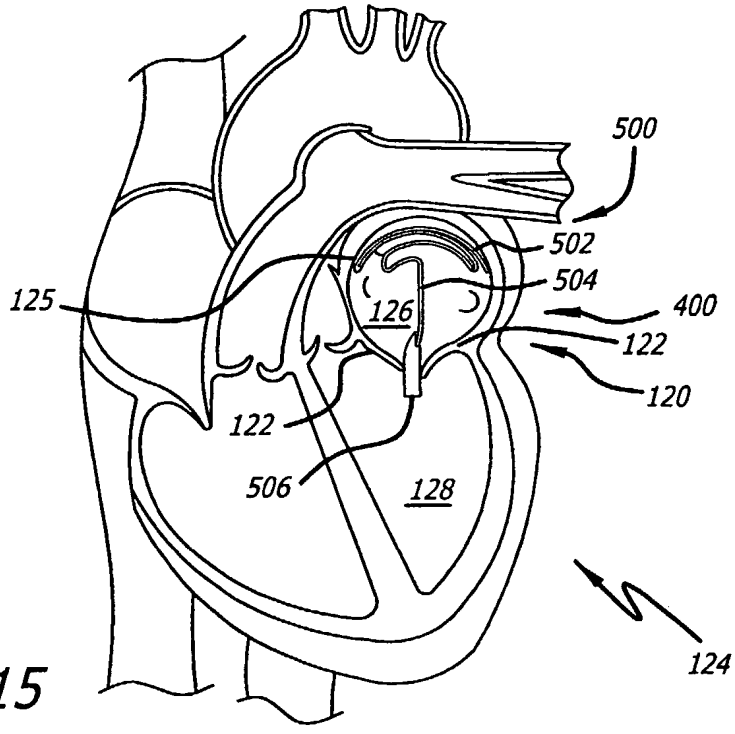


FIG. 15

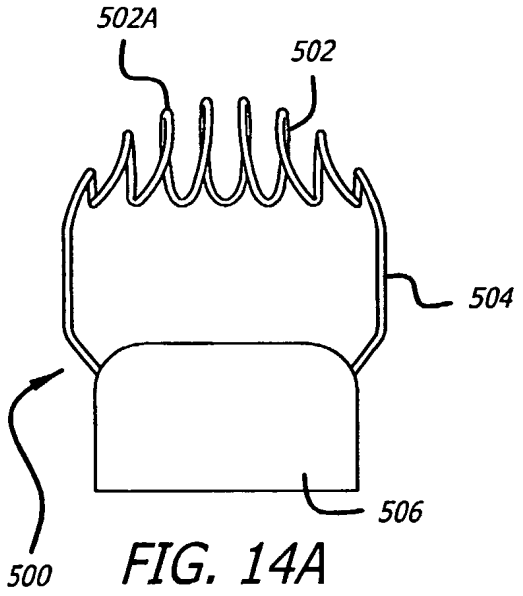


FIG. 14A

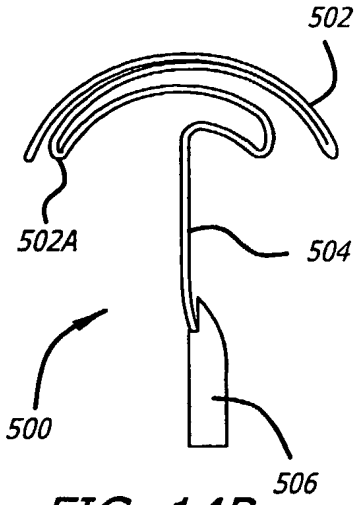


FIG. 14B

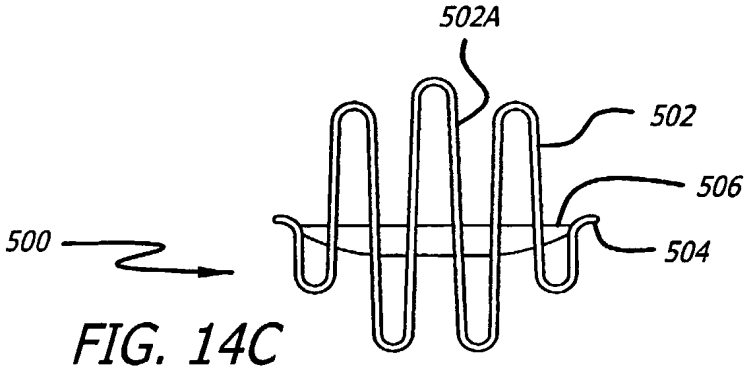


FIG. 14C

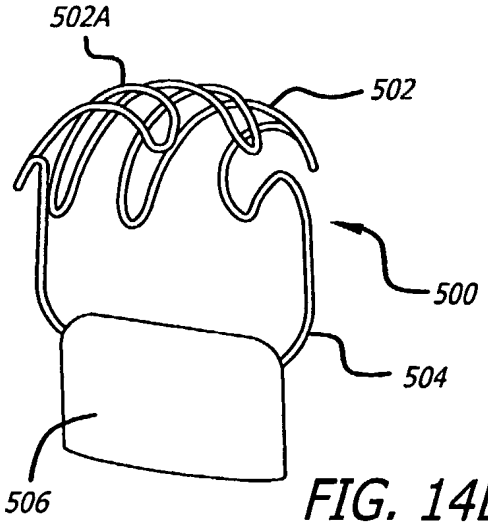


FIG. 14D

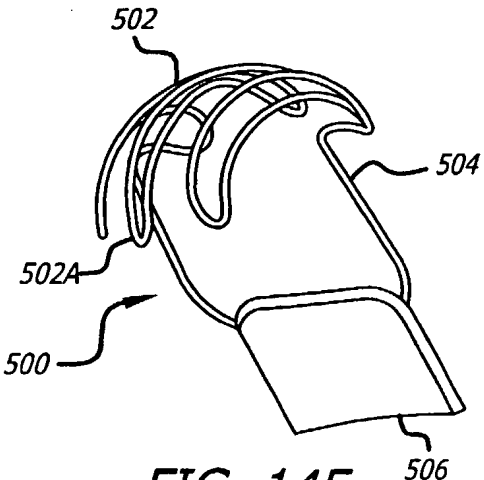


FIG. 14E

FIG. 17A

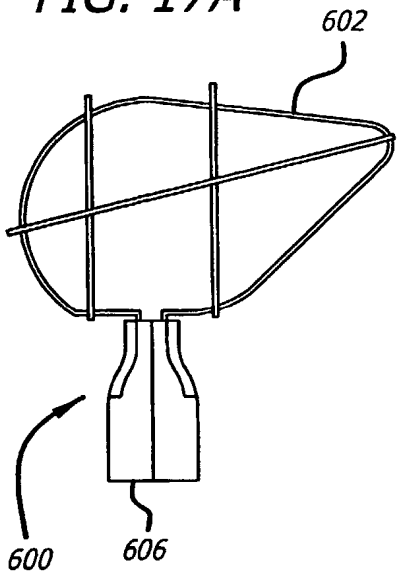
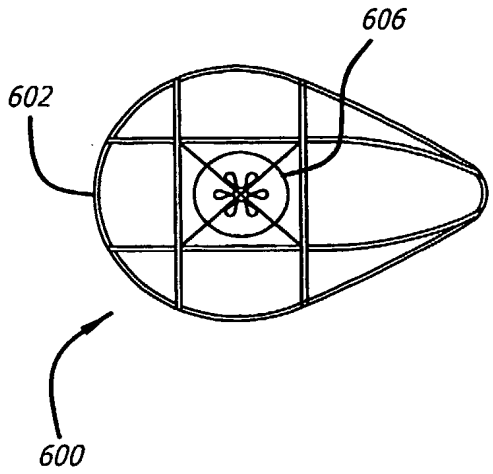


FIG. 17B



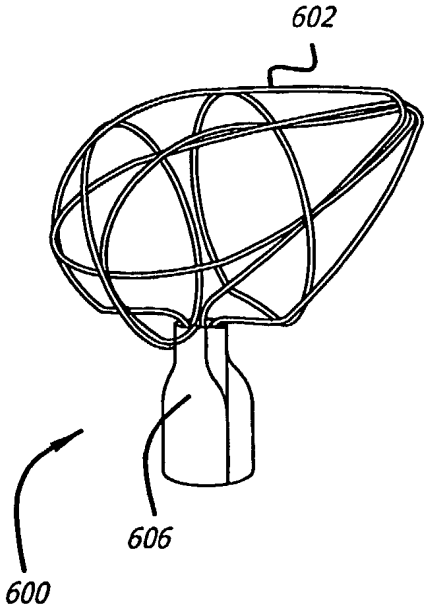


FIG. 17C

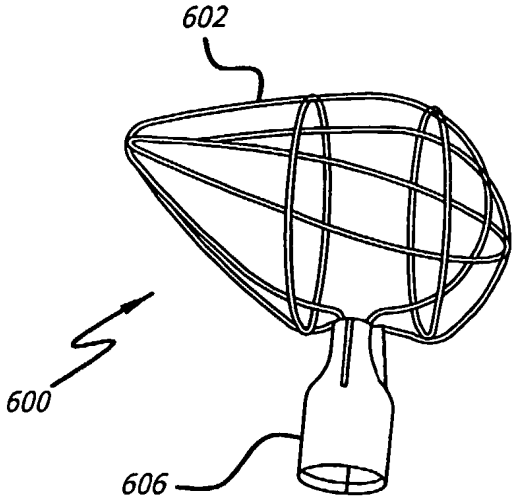


FIG. 17D

FIG. 18A

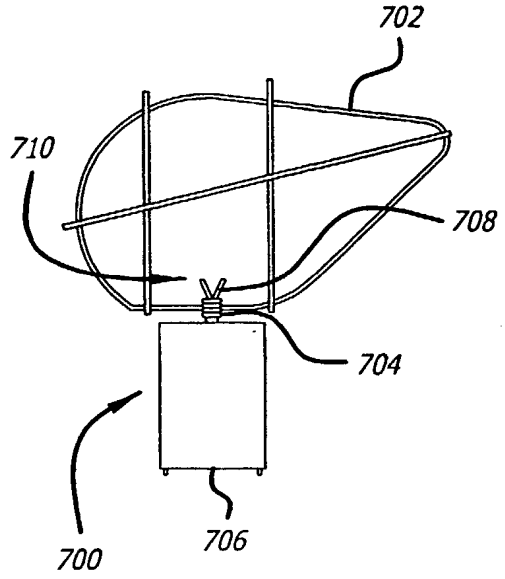
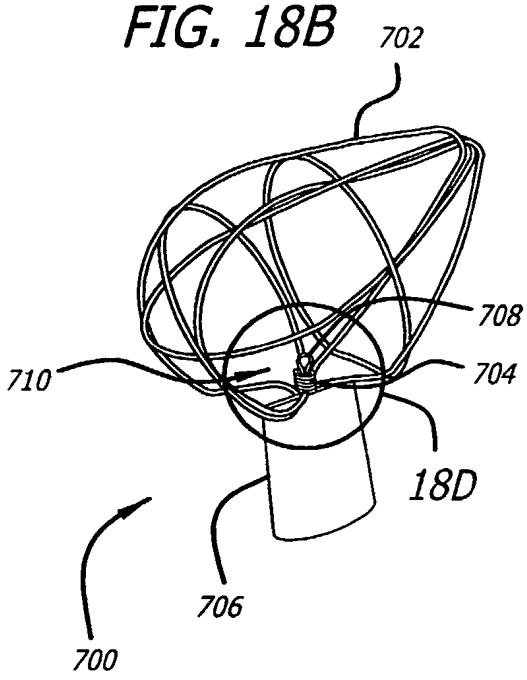


FIG. 18B



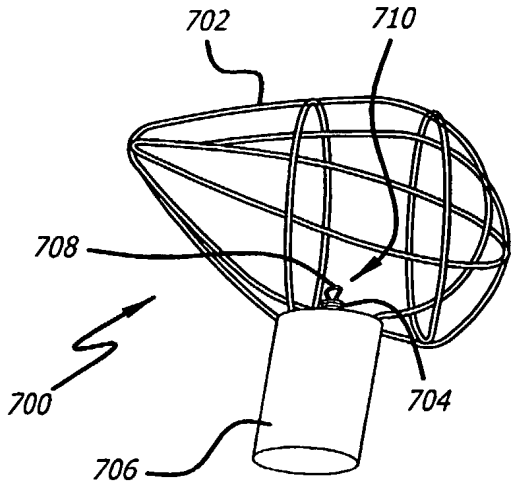


FIG. 18C

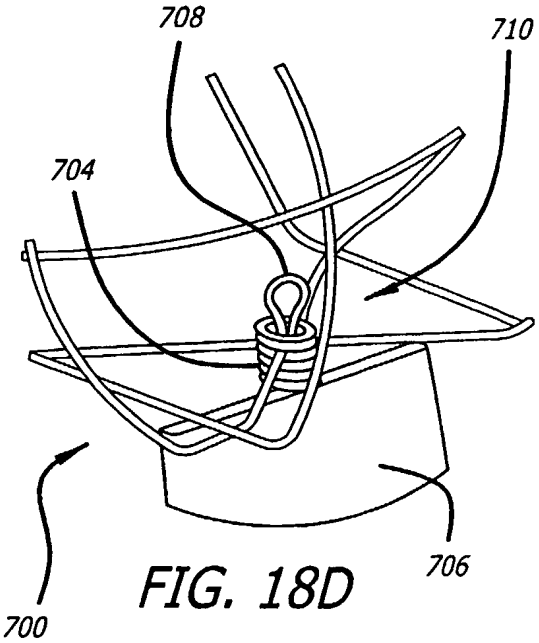


FIG. 18D

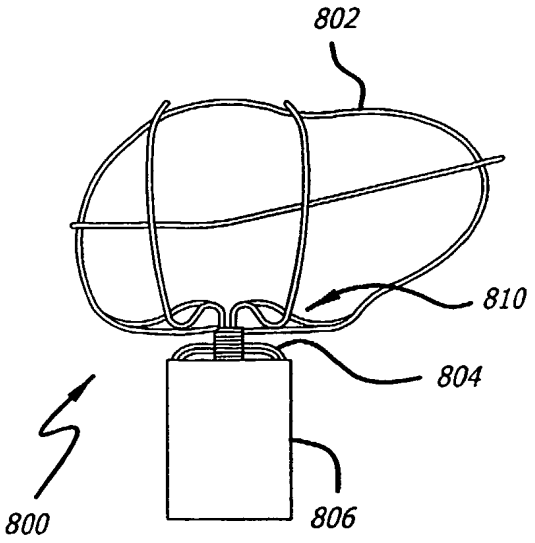


FIG. 19A

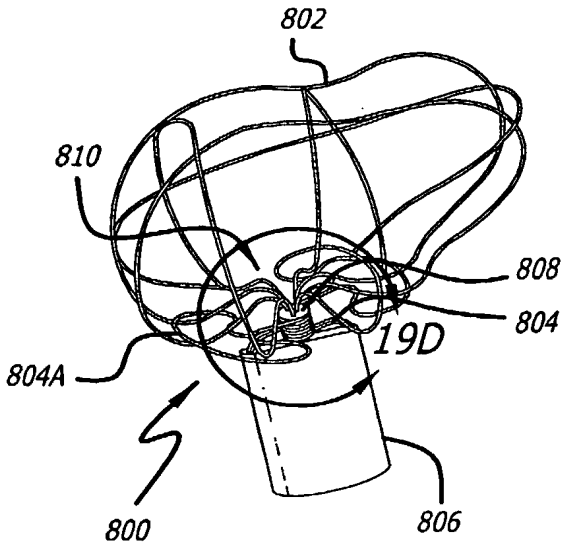


FIG. 19B

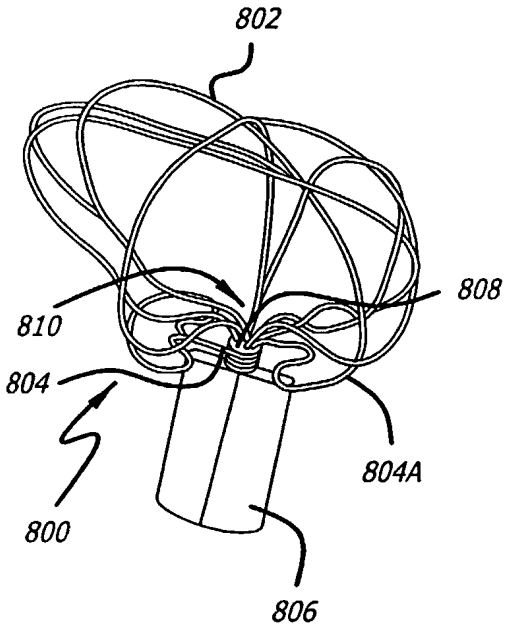


FIG. 19C

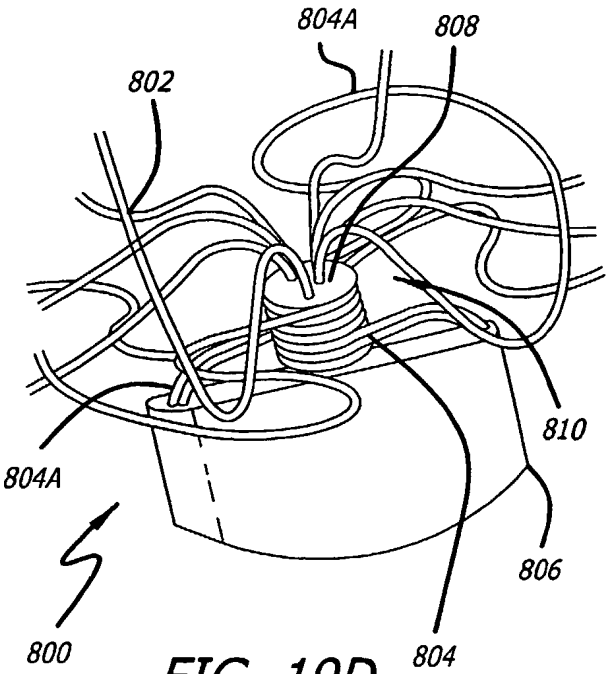


FIG. 19D

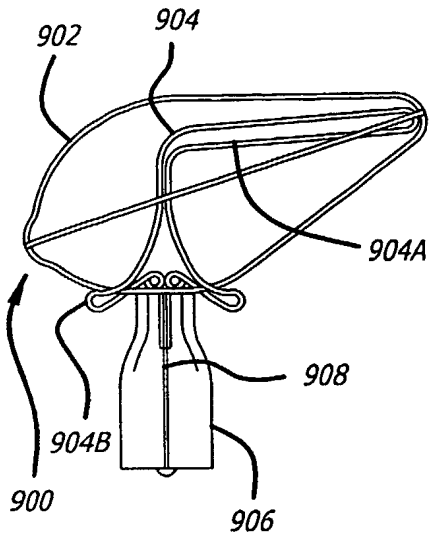


FIG. 20A

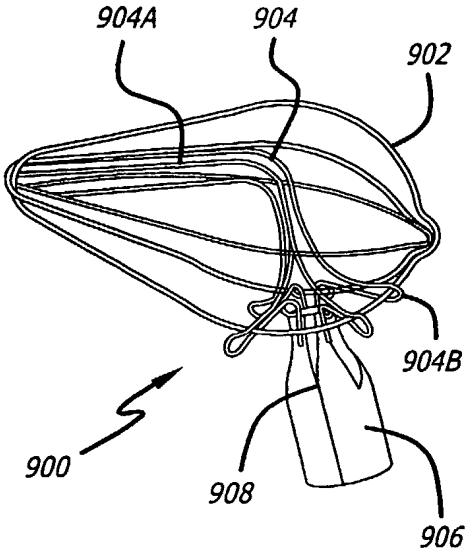


FIG. 20B

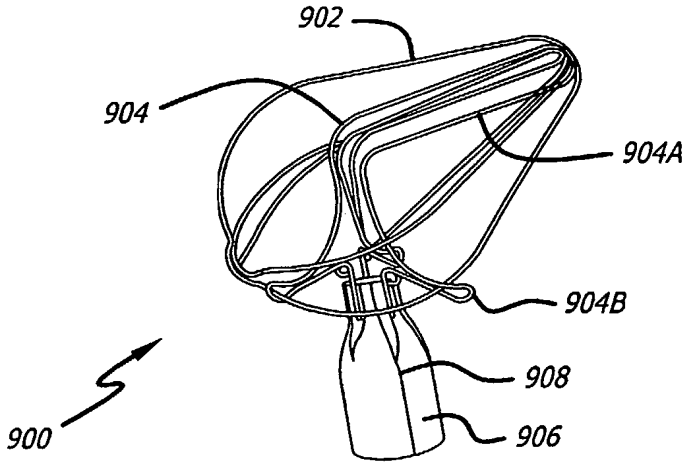
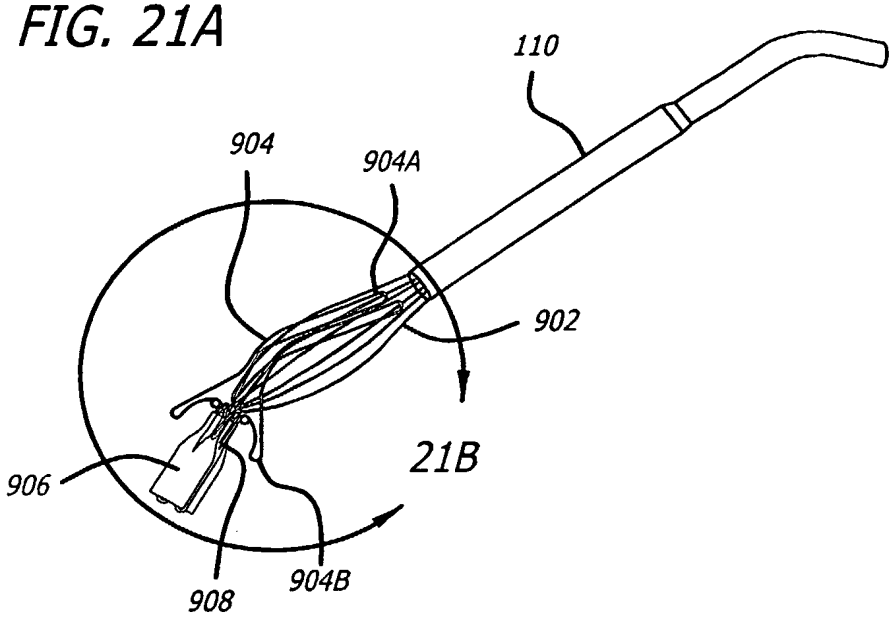


FIG. 20C

FIG. 21A



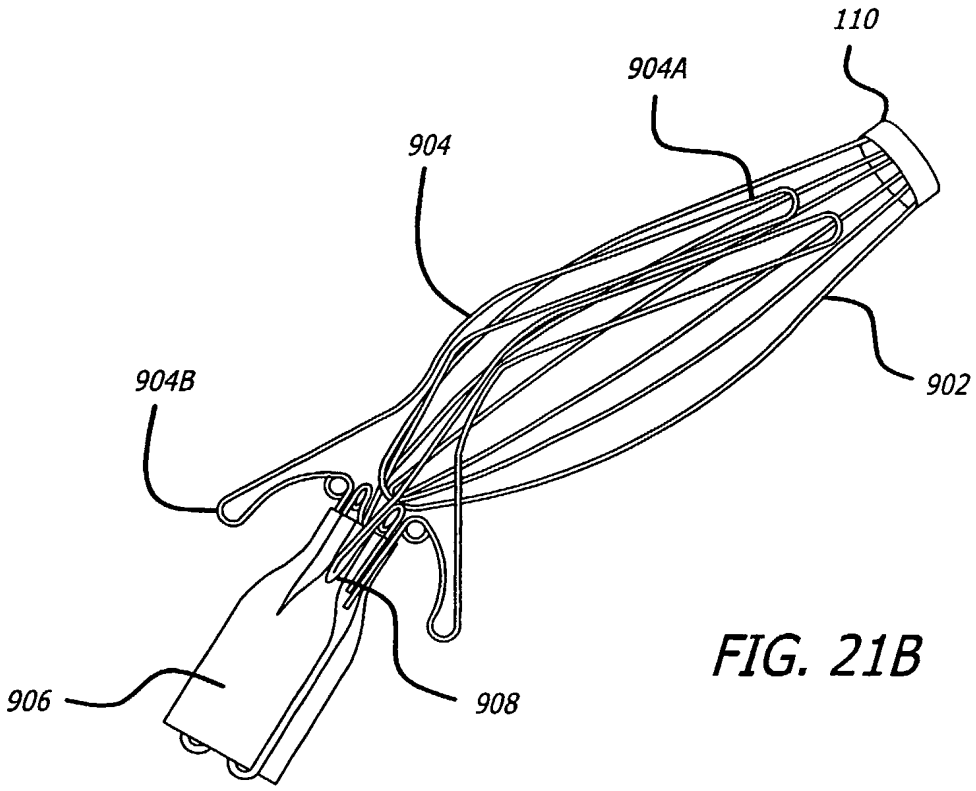


FIG. 21B

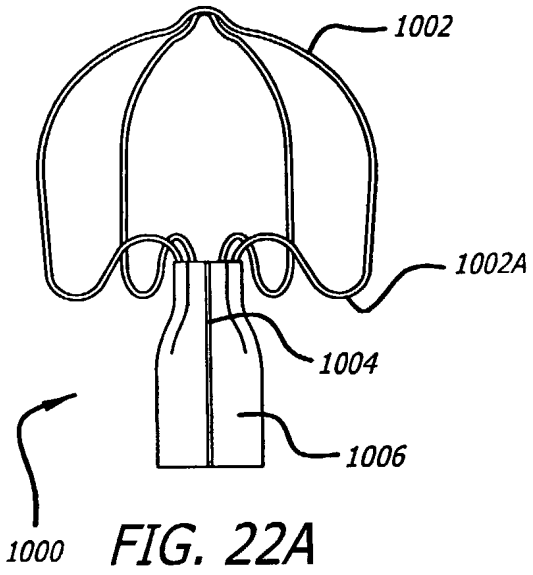


FIG. 22A

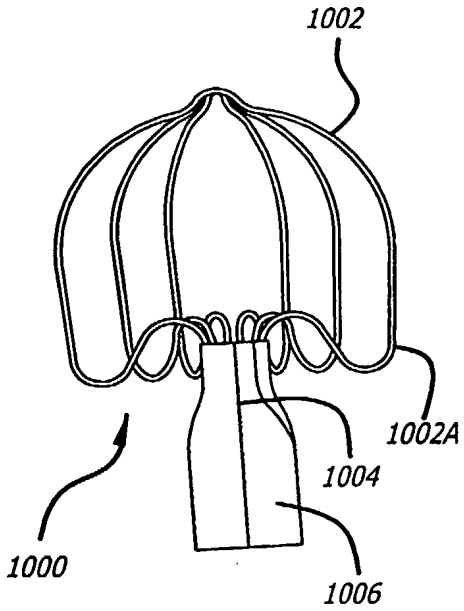


FIG. 22B

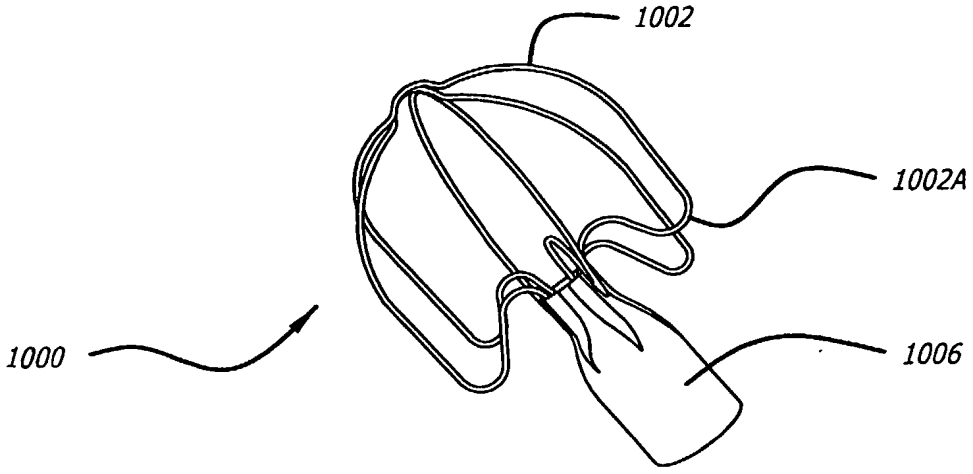


FIG. 22C

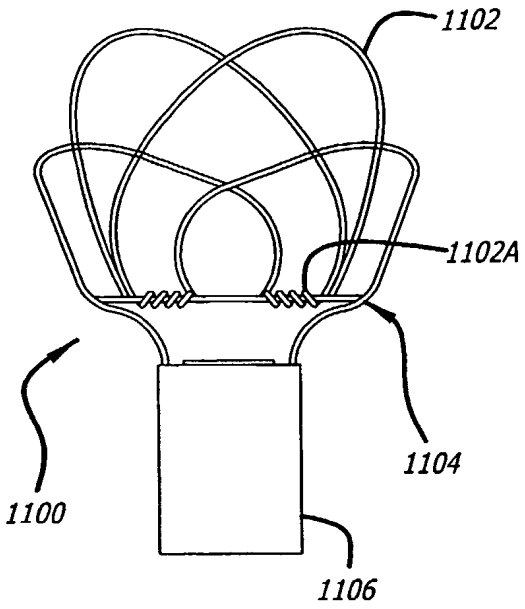


FIG. 23A

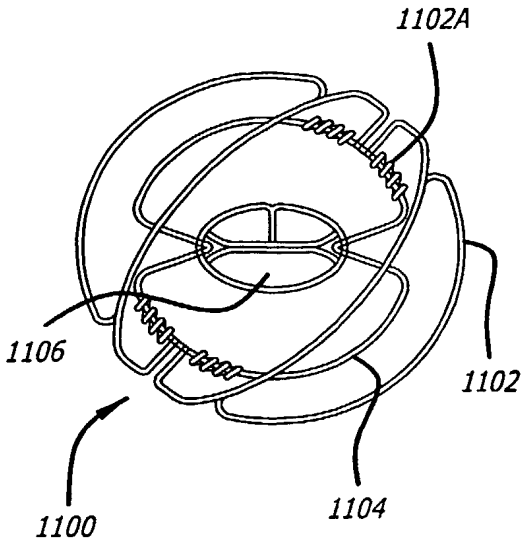


FIG. 23B

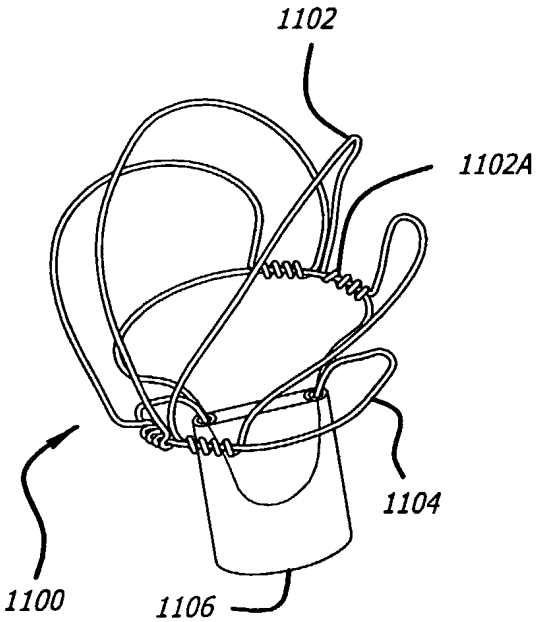


FIG. 23C

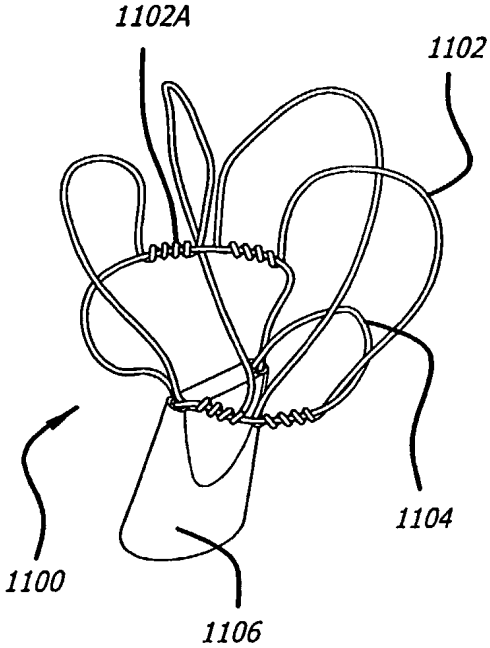


FIG. 23D

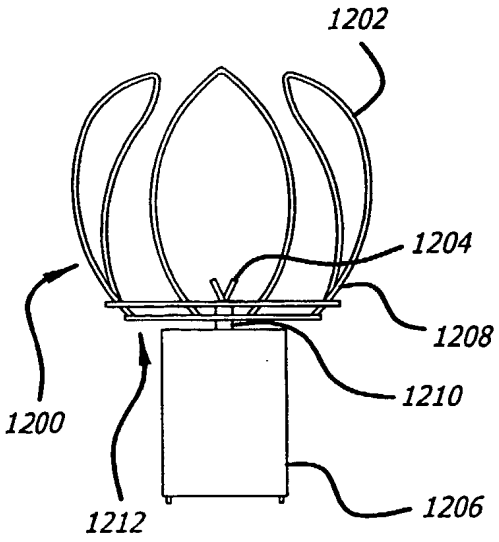


FIG. 24A

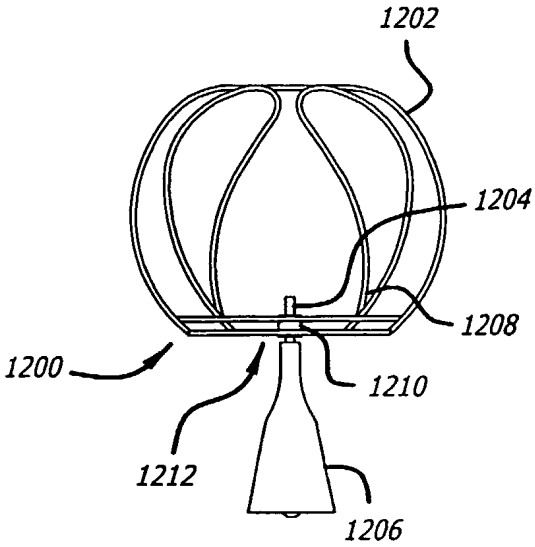


FIG. 24B

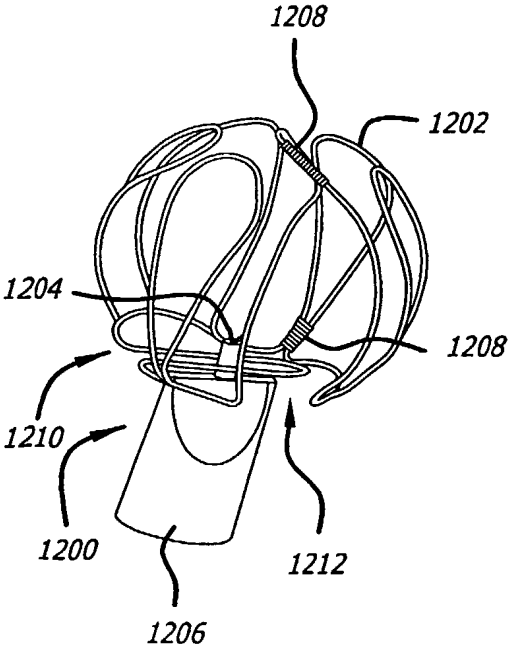


FIG. 24C

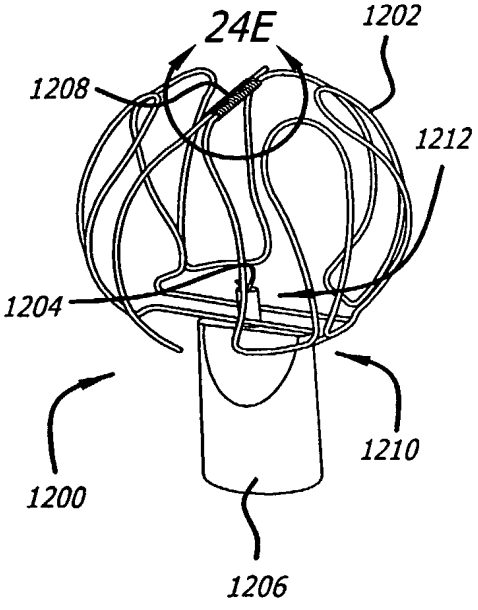
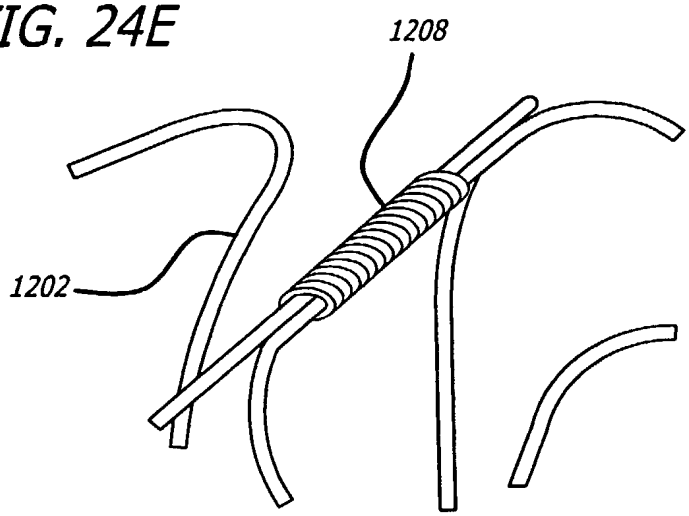


FIG. 24D

FIG. 24E



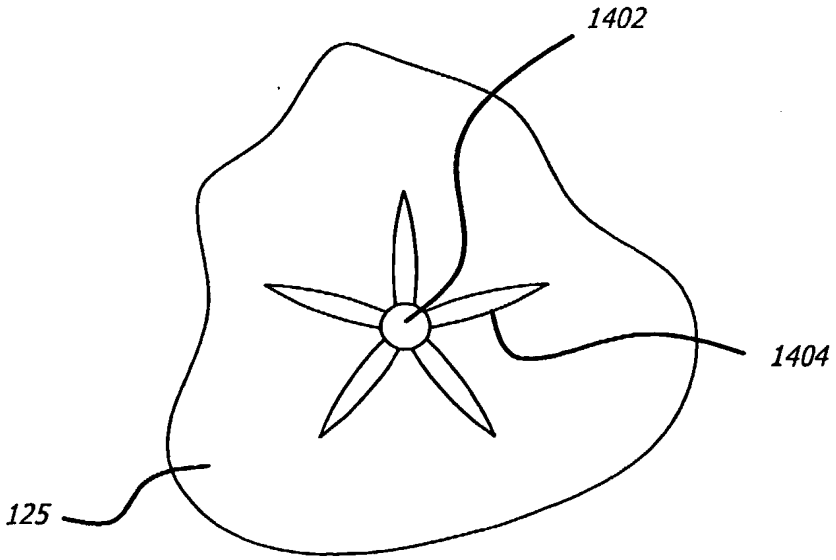
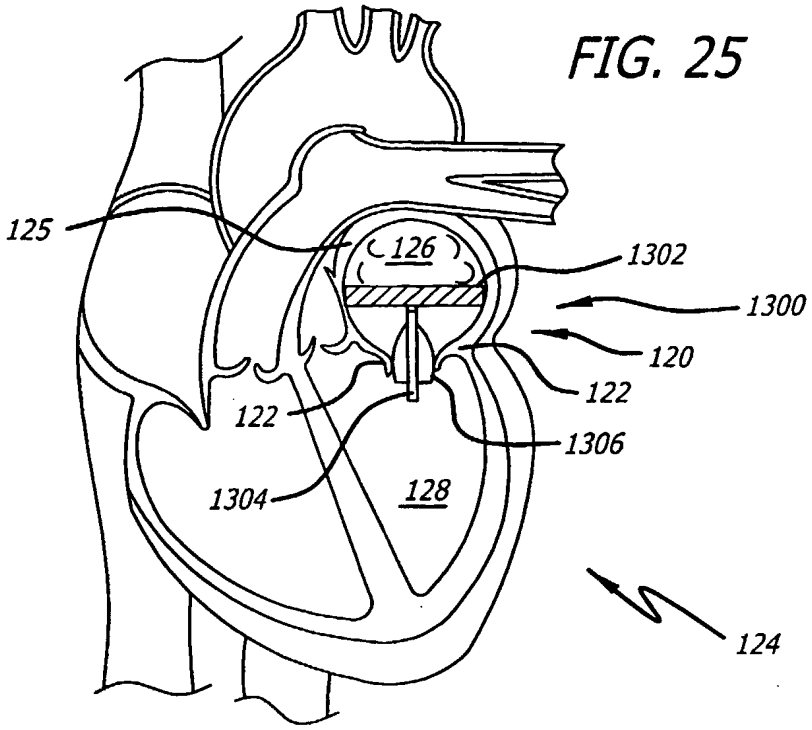


FIG. 26B

FIG. 25



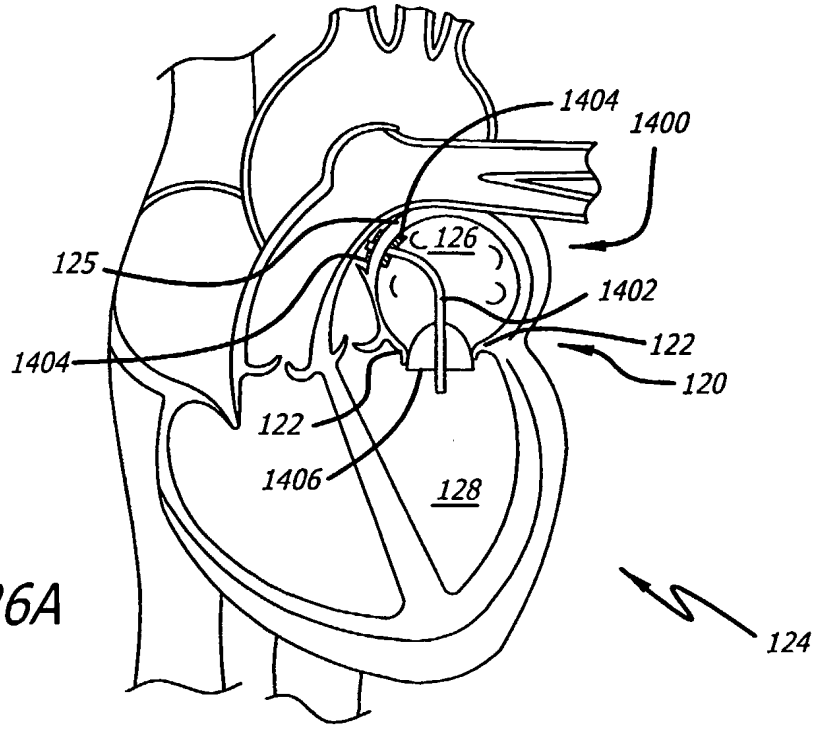


FIG. 26A

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60/657,919 3 March 2005 (03.03.2005) US

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(74) Agent: **HAUSER, David, L.**; Edwards Lifesciences, LLC, Legal Dept., One Edwards Way, Irvine, CA 92614 (US).

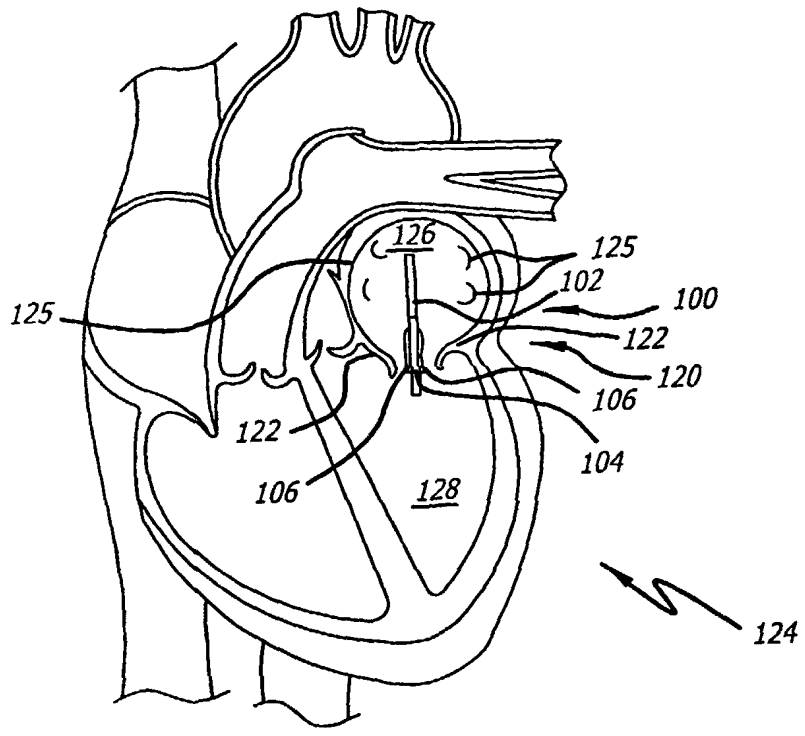
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK,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

[Continued on next page]

(54) **Title:** DEVICE AND METHOD FOR TREATMENT OF HEART VALVE REGURGITATION



(57) **Abstract:** The prosthesis (100) includes a pocket (106) formed from flexible material (104) disposed on a ring (102). When properly oriented in a mitral valve (120) of a heart (124), the pocket (106) expands as the mitral valve closes, blocking any openings between the mitral valve leaflets (122). During systole, backpressure from the blood in the left ventricle (128) presses against the mitral valve leaflets (122), as the papillary muscles move these leaflets (122) to a closed position. The mitral valve leaflets (124) coapt against the expanded pocket (106), minimizing or even eliminating gaps that would otherwise be present between the two leaflets (122).

WO 2006/032051 A3

(88) Date of publication of the international search report:
25 January 2007

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/33381

A. CLASSIFICATION OF SUBJECT MATTER
IPC: **A61F 2/24**(2006.01)

USPC: 623/2.1
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)
U.S. : 623/2.1, 2.36

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 practicable, search terms used)
EAST BRS search terms: "coapt$5 with leaflet".

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,332,402 A (TEITELBAUM) 26 July 1994 (26.07.1994), see the figures and column 1, line 65 to column 2, line 39 and column 4, line 25 to column 6, line 64.	1, 2, 4-7, and 9 --- 3
Y	US 2003/0199975 A1 (GABBAY) 23 October 2003 (23.10.2003), see paragraph [0053].	3
X	US 5,397,351 A (PAVCNIK et al) 14 March 1995 (14.03.1995), see the entire document.	1, 4-7, and 9
X	US 2001/0021872 A1 (BAILEY et al) 13 September 2001 (13.09.2001); see the entire document.	1, 2, 4-7 and 9
A, P	US 2005/0038508 A1 (GABBAY) 17 February 2005 (17.02.2005), see the abstract and figures.	1-7 and 9

☐ 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 application or patent 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
03 October 2006 (03.10.2006)

Date of mailing of the international search report
01 DEC 2006

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Facsimile No. (571) 273-3201

Authorized officer
Paul B. Prebilic

Telephone No. (571)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/33381

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of any additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-7 and 9

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/33381

BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-15, drawn to a device for treating valve regurgitation.

Group II, claim(s) 16-24, drawn to a method of treating valve regurgitation.

Group III, claim(s) 25-43, drawn to a device for substantially blocking blood flow during systole.

The inventions listed as Groups I to III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: US Patent Publication 2003/0083742 provides evidence (see the figures) that the claimed common technical feature of a coaptation member with an anchoring structure was known to the prior art.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

A. Figures 1A to 4 (Claim 11)
B. Figures 5A to 8B (Claim 12)
C. Figures 9A to 9F
D. Figures 10A to 11 (Claim 14)
E. Figure 12A to 13
F. Figures 14A to 16B (Claim 13)
G. Figures 17A to 17D
H. Figures 18A to 18D (Claim 8)
I. Figures 19A to 19D (Claim 15)
J. Figures 20A to 21B
K. Figures 22A to 22C
L. Figures 23A to 23D
M. Figures 24A to 24E.
N. Figure 25 (Claim 10)
O. Figures 26A and 26B.

The claims are deemed to correspond to the species listed above in the following manner:

See the claim numbers adjacent to the Species list above

The following claim(s) are generic: 1-7 and 9.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the species has a different mode of operation and function differently. For this reason, they are considered patentably distinct and do not constitute a single general inventive concept.

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(54) **Title:** APPARATUS AND METHOD FOR CONNECTING A CONDUIT TO A HOLLOW VESSEL

(57) **Abstract:** The present invention provides a system and method for forming a side branch on a hollow vessel, such as the aorta. The side branch is preferably adapted to be connected to a connector conduit, but any other suitable use is also acceptable. The system comprises a graft including a side branch portion, and an applicator comprising a hole forming element adapted to form a hole in the wall of the vessel and an insertion element adapted to be inserted through the wall of the vessel, the insertion element comprising a retraction element adapted to enter into engagement with the graft. The hole forming element may comprise a cutting element adapted to cut a hole in the wall of the vessel, and a positioning element adapted to hold the position of the applicator relative to the vessel. The system further comprises a graft protection element adapted to prevent the graft from being damaged by the cutting element. In this case, the clamping element and the graft protection element may be the same element, for example, an expansion element, which may be expandable from an unexpanded state to fully expanded state and to a partially expanded state. The expansion element may be a balloon, which may be in the shape of a circular toroid, and may include a tension member that restricts the dimensions of the balloon. In addition, the expansion element may be an umbrella mechanism.

WO 2006/065966 A2

APPARATUS AND METHOD FOR CONNECTING A CONDUIT TO A HOLLOW VESSEL

FIELD OF THE INVENTION

[0001] The present invention relates to an apparatus and method for connecting a conduit to a hollow vessel, and more particularly, to a surgical device connectable to the aorta to bypass the aortic valve.

BACKGROUND

[0002] As the average age of the United States population increases, so do the instances of aortic stenosis. An alternative approach to the conventional surgical replacement of the stenotic aortic valve involves the use of an apicoaortic conduit. In this approach, the native aortic valve is not removed, and a prosthetic valve is implanted in a parallel flow arrangement. A connection conduit (or tube) connects the apex of the heart to the descending aorta. Somewhere along this conduit, the prosthetic valve is interposed. Thus, blood leaves the heart through the apex and travels through the conduit (with valve) to the descending aorta.

[0003] Until recently, surgical procedures to implant an apicoaortic conduit have included a single, long incision, such as in the 6^{th} intercostal space, to expose the heart and allow retraction of the lungs to expose the descending aorta. Recognizing the potential for broader scale use of the apicoaortic conduit for aortic valve replacement, some surgeons are now attempting to use smaller incisions and are requesting development of surgical tools for a minimally invasive procedure. As an initial attempt to make the procedure less invasive, some surgeons have recently performed the following procedure.

[0004] The patient is placed on the table in the supine position. Anesthesia is induced, and the patient is intubated with a double-lumen endotracheal tube, this facilitates one-lung ventilation and allows the surgeon to work within the left chest. The patient is positioned with the left side up (90 degrees). The pelvis is rotated about 45 degrees, such that the femoral vessels are accessible. An incision is made over the femoral vessels, and the common femoral artery and vein are dissected out. Heparin is administered. Pursestring sutures are placed in the femoral artery and vein. The artery is cannulated first, needle is inserted into the artery, and a guidewire is then inserted. Transesophageal echo is used to ascertain that the wire is in the descending aorta. Once this is confirmed, a Biomedicus arterial cannula is inserted over the wire, into the artery (Seldinger technique). The arterial

cannula is typically 19 or 21 French. Once inserted, the pursestring sutures are snugged down over tourniquets. A similar procedure is followed for the femoral vein. The venous cannula is usually a few French larger than the arterial cannula. Once both vein and artery are cannulated, the cannulae are connected to the cardiopulmonary bypass, and the capability to initiate cardiopulmonary bypass at any time is present.

[0005] A 1 cm incision is made in approximately the 7th interspace in the posterior auxillary line; the videoscope (10 mm diameter) is inserted, and the left chest contents viewed. The location of the apex of the heart is determined, and the light from the scope used to transilluminate the chest wall; this allows precise localization of the incision. The incision is then performed; it is essentially an anterior thoracotomy, typically in the 6th interspace. Recent incisions have been about 10 cm long, but are expected to become smaller and smaller with time. A retractor is inserted and the wound opened gently. A lung retractor is used to move the (deflated) left lung cephalad. The descending aorta is dissected free from surrounding soft tissue to prepare for the distal anastomosis. This dissection includes division of the inferior pulmonary ligament. A pledgeted suture is placed on the dome of the diaphragm and positioned to pull the diaphragm toward the feet (out of the way). The pericardium is incised about the apex of the heart, and the apex is freed up and clearly identified.

[0006] On the back table, the apicoaortic conduit is prepared: a 21 freestyle valve is sutured to an 18 mm Medtronic apical connector. The valve is also sutured to a 20 mm Hemashield graft. The Dacron associated with the apical connector is pre-clotted with thrombin and cryoprecipitate. The assembly is brought to the field, and a measurement made from the apex of the heart to the descending aorta. The assembly is trimmed appropriately. A partial-occluding clamp is then placed on the descending aorta, and the aorta opened with a knife and scissors. The conduit (the end with the 20 mm hemashield graft) is then sutured to the descending aorta using 4-0 prolene suture, in a running fashion. Once this is complete, the clamp is removed and the anastomosis checked for hemostasis. Blood is contained by the presence of the freestyle aortic valve. The apical connector is placed on the apex, and a marker is used to trace the circular outline of the connector on the apex, in the planned location of insertion. Four large pledgeted sutures (mattress sutures) of 2-0 prolene are placed; one in each quadrant surrounding the marked circle. The sutures are then brought through the sewing ring of the apical connector. A stab wound is made in the apex in the center of the circle, and a tonsil clamp is used to poke a hole into the ventricle. To date, bypass has been initiated at this point, but doing so may not be necessary. A Foley catheter is

inserted into the ventricle, and the balloon expanded. A cork borer is then used to cut out a plug from the apex. The connector is then parachuted down into position. A rotary motion is necessary to get the connector to seat in the hole. The four quadrant sutures are tied, and hemostasis is checked. If there is a concern regarding hemostasis, additional sutures are placed. The retractor is removed, chest tubes are placed, and the wound is closed.

[0007] Surgical tools developed specifically to implant the apicoaortic conduit are expected to provide the means for a much less invasive procedure. The procedure is expected to be performed with a series of smaller thoracotomy incisions between the ribs, such as immediately over the apex of the heart. In addition to avoiding the median sternotomy, development of appropriate surgical tools is expected to avoid the need for cardiopulmonary bypass, so that the procedure can be performed on a beating heart. The diseased aortic valve does not need to be exposed or excised. The stenotic aortic valve is left in place and continues to function at whatever level it remains capable of, and the apicoaortic conduit accommodates the balance of aortic output.

[0008] The major obstacle to widespread adoption of this superior technique is the nearly complete lack of efficient devices to perform the procedure. Surgeons wishing to adapt the procedure must gather a collection of instruments from a variety of manufacturers. Often these instruments were created for quite different purposes, and the surgeon is forced to adapt them as required and manually manipulate them during a procedure.

[0009] A less invasive means to implant the apical connector is described in U.S. Patent Application Serial No. 11/086,577, which is hereby incorporated by reference in its entirety. A customized apical connector with an insertion tool referred to as an applicator is described therein. Also described is a quick connect coupler, which may be employed by the invention described herein. The apical connector invention allows the apical connector to be implanted without use of cardiopulmonary bypass and with a negligible amount of blood loss. Although this prior invention provides a key enabling technology that will allow mainstream use of the apicoaortic procedure, additional surgical tools and prostheses are needed to make the procedure even less invasive.

SUMMARY OF THE INVENTION

[0010] An object of the present invention is to provide the necessary surgical tools and prostheses to enable combined percutaneous and minimally invasive surgical techniques to implant the aortic connector of the apicoaortic conduit with minimal blood loss.

[0011] Another object of the present invention is to allow the surgeon to precisely select the site for anastomosis by inserting the distal end of an applicator into the aorta at the selected site.

[0012] Another object of the present invention is to provide an applicator that includes a cutter that cuts a hole in the aorta with negligible blood loss. Embodiments of the applicator may use a balloon or a cutter guard to protect the prosthesis from the cutter.

[0013] Another object of the present invention is to mechanically coordinate movement of some of the components of the applicator to provide safety and ease of use for the surgeon.

[0014] Another object of the present invention is to provide an aortic connector that establishes an anastomosis between the descending aorta and the portion of the apicoaortic conduit prosthesis not included in the aortic connector. The aortic connector includes an aortic graft that is deployed within the aorta and a side branch that will extend through the aorta wall at the site selected by the surgeon. The side branch is folded inside the aortic graft until after the aortic branch is expanded. The side branch may include a quick connect coupler and an occlusion means. The occlusion means may be a sewn seam or a prosthetic valve, as examples.

[0015] Thus, the present invention provides an applicator for forming a hole in a wall of a hollow vessel, such as the aorta, and engaging a graft. The applicator comprises a hole forming element adapted to form a hole in the wall of the vessel and an insertion element adapted to be inserted through the wall of the vessel. The hole forming element comprises a cutting element adapted to cut a hole in the wall of the vessel and a positioning element adapted to hold the position of the applicator relative to the vessel, and the insertion element comprises a retraction element adapted to enter into engagement with a graft. The applicator may further comprise a graft protection element adapted to prevent the graft from being damaged by the cutting element.

[0016] The positioning element may further comprise a reaction element adapted to be positioned on the outside of the wall of the vessel, and a clamping element adapted to be positioned on the inside of the wall of the vessel, wherein the wall of the vessel may be held between the reaction element and the clamping element, thereby holding the position of the applicator relative to the vessel. In addition, the cutting element may be a cutting blade, and may be cylindrically shaped.

[0017] The clamping element may be formed of any suitable material. For example, the clamping element may be an expansion element, such as a balloon, or may be made of a rigid material, such as a clamp pad. In addition, it is preferred that the clamping element be adapted to prevent a tissue plug from entering the vessel, the tissue plug comprising the portion of the wall removed when the hole is formed in the vessel.

[0018] The retraction element may comprise a graft attachment tool, which is preferably radiopaque. In addition, the retraction element may be further adapted to be withdrawn from the hole formed in the wall of the vessel after entering into engagement with the graft, thereby withdrawing a portion of the graft. In this case, the portion of the graft withdrawn by the retraction element forms a side branch to the vessel. The insertion element may also comprise a trocar.

[0019] The present invention also provides a method for forming a hole in a wall of a hollow vessel, such as the aorta, and engaging a graft. The method comprises inserting an insertion element through the wall of the vessel until at least a portion of a retraction element of the insertion element may be positioned within the vessel, positioning the wall of the vessel relative to the applicator with a positioning element, engaging the graft with the retraction element, and forming the hole in the wall of the vessel with the cutting element.

[0020] The cutting element may be a cutting blade, and the forming step may comprise pressing the cutting blade into the wall of the vessel and applying torsional force to the cutting blade. Also, the insertion element may further comprise a trocar.

[0021] The positioning step may comprise biasing, or positioning, a reaction element on the outside of the wall of the vessel, biasing, or positioning, a clamping element on the inside of the wall of the vessel, and holding the wall of the vessel between the reaction element and the clamping element. The clamping element may be a balloon, or may be made of a rigid material, such as a clamp pad. In addition, the clamping element may be adapted to prevent a tissue plug from entering the vessel, the tissue plug comprising the portion of the wall removed when the hole may be formed in the vessel.

[0022] The method may also comprise positioning a graft protection element between the graft and the cutting element prior to the forming step, and the graft may be predisposed within the vessel. Also, the retraction element may comprise a graft attachment tool, which is preferably radiopaque. The method may further comprise of withdrawing the retraction element from the hole formed in the wall of the vessel after the steps of engaging and forming, thereby withdrawing a portion of the graft, which preferably forms a side branch to the vessel.

[0023] The present invention also provides a system for forming a side branch on a hollow vessel, such as the aorta. The side branch is preferably adapted to be connected to a connector conduit, such as the remainder of an apical aortic prothesis, but any other suitable use is also acceptable. The system further comprises a graft including a main vessel portion and a side branch portion, and an applicator comprising a hole forming element adapted to form a hole in the wall of the vessel and an insertion element adapted to be inserted through the wall of the vessel, the insertion element comprising a retraction element adapted to enter into engagement with the graft. The side branch portion of the graft is preferably maintained in a compressed state prior to the formation of the side branch. In addition, the insertion element may include a trocar.

[0024] The hole forming element may comprise a cutting element adapted to cut a hole in the wall of the vessel, and a positioning element adapted to hold the position of the applicator relative to the vessel. The positioning element comprises a reaction element adapted to be positioned on the outside of the wall of the vessel, and a clamping element adapted to be positioned on the inside of the wall of the vessel, wherein the wall of the vessel may be held between the reaction element and the clamping element, thereby holding the position of the applicator relative to the vessel. The cutting element may be a cutting blade, and preferably has a cylindrical shape.

[0025] The clamping element may be an expansion element, such as a balloon, or may be formed of rigid materials, such as a clamp pad. The clamping element may also be adapted to prevent a tissue plug from entering the vessel, the tissue plug comprising the portion of the wall removed when the hole may be formed in the vessel. In this regard, if the clamping element is a balloon, it is preferred that the balloon have a diameter smaller than that of the cutting element, and that the balloon not be deflated after being used as the clamping element.

[0026] The system further comprises a graft protection element adapted to prevent the graft from being damaged by the cutting element. In this case, the clamping element and the graft protection element may be the same element, for example, an expansion element, which may be expandable from an unexpanded state to fully expanded state and to a partially expanded state. The expansion element may be a balloon, which may be in the shape of a circular toroid, and may include a tension member that restricts the dimensions of the balloon. In addition, the expansion element may be an umbrella mechanism.

[0027] The retraction element may comprise a graft attachment tool, which is preferably radiopaque. The retraction element may be further adapted to be withdrawn from the hole formed in the wall of the vessel after entering into engagement with the graft, thereby withdrawing a portion of the graft. The portion of the graft withdrawn by the retraction element is preferably the side branch portion.

[0028] The invention also relates to a graft device adapted to be used in the formation of a side branch in a hollow vessel. The graft device comprises a graft containment element, which is adapted to contain the graft in a compressed state, a graft element including a main vessel portion and a side branch portion, the graft element being adapted to be contained with the graft containment element in a compressed state, and a graft attachment element, which is adapted to enter into engagement with a corresponding attachment element. The graft containment element may comprise a sheath, a chain stitch, or the like. As used herein, a chain stitch comprises a series of loops or slipknots that are looped through one another such that one slipknot in the stitch prevents the next slipknot from releasing. The graft attachment element may comprise a loop, and is preferably radiopaque. The graft device may also comprise a graft protection element. Furthermore, the side branch of the graft may be occluded, and the graft device may further comprise a means for opening the occlusion in the side branch portion. Moreover, the compressed state of the graft may comprise a folded configuration, a partial inside-out configuration, or the like. When the graft containment element is removed from the graft, the graft element expands from a compressed state to an expanded state. In addition, the graft device may comprise separate graft containment elements for each of the main vessel and side branch portions of the graft device, thereby allowing each portion to expand from its compressed state separately.

[0029] It should be noted that the clamping element and the graft protection element may be combined into a single element. For example, the functionality of the clamping element and the graft protection element may be obtained using a single expansion element. Such an expansion element may be expandable from an unexpanded state to fully expanded state and to a partially expanded state. Examples of expansion elements include balloons and umbrella mechanisms. If the expansion element is a balloon, it is preferred that the balloon be in the shape of a circular toroid. Optionally, a tension member may be included that restricts the dimensions of the balloon.

[0030] The present invention also provides a means for expanding the expansion element from the unexpanded state, to the fully expanded state, and to the partially expanded state in a sequential manner. In the fully expanded state, the expansion element preferably

has an outer diameter larger than an outer diameter of the cutting element. In the partially expanded state, the expansion element preferably has an outer diameter that is less than an inner diameter of the hole forming element and greater than an outer diameter of the retraction element to thereby position a tissue plug within the hole forming element. Also, if the expansion element is a balloon, the means for expanding may comprise a syringe in fluid communication with the balloon. If the expansion element is an umbrella device, the means for expanding may comprise a cylinder having a piston slideable therein and coupled to the umbrella device.

[0031] Furthermore, the present invention provides a sequencing means for coordinating at least one of holding the position of the applicator relative to the vessel with the positioning element, cutting a hole in the wall of the vessel with the cutting element, inserting the an insertion element through the wall of the vessel, entering the retraction element into engagement with the graft, and withdrawing the retraction element from the hole formed in the wall of the vessel. The sequencing means may comprise a cam mechanism, a gear mechanism, at least one servo mechanism operatively coupled to the applicator and a controller operatively coupled to the at least one servo mechanism, and the like. The controller may comprise a microprocessor based device. In addition, a button may be operatively coupled to the sequencing means for activating the sequencing means upon depression of the button to thereby accomplish steps of a procedure for forming the hole in the vessel. Furthermore, the sequencing means may coordinate the expansion state of the expansion element with respect to the relative movement of the cutting element and the clamping element.

BRIEF DESCRIPTION OF THE DRAWINGS

[0032] FIG. 1 is a schematic of a conventional apicoaortic conduit.

[0033] FIGS. 2A to 2E are schematics of the retractor with trocar tool and attachment tool.

[0034] FIGS. 3A to 3I illustrate operation of an applicator to deploy the aortic connector.

[0035] FIGS. 4A to 4H illustrate operation of an alternative embodiment of an applicator to deploy the aortic connector

DETAILED DESCRIPTION OF THE INVENTION

[0036] The present invention addresses the anastomosis between the apicoaortic prosthesis and the descending aorta. Primarily because of the difficulty reaching this anastomosis, this portion of the procedure remains highly invasive, time consuming and technically challenging. Also, it is well recognized that the partial occlusion clamp used in the conventional apicoaortic procedure can harm the aorta walls and can dislodge debris from the inner aortic wall.

[0037] More and more, operating rooms are incorporating fluoroscopy to allow combined efforts of surgeons and interventional radiologists during a single procedure. This trend is expected to continue. As such, the present invention combines a percutaneous (or endovascular) approach with a minimally invasive surgical approach. The goals of the present invention are to provide surgical and interventional tools and prostheses to enable the descending aorta anastomosis to be less time consuming, less technically challenging, and to be performed with minimal blood loss. Moreover, use of a partial occlusion clamp is eliminated.

[0038] The present invention makes use of advances in percutaneous repair of abdominal and thoracic aortic aneurysms. Several companies now offer vascular grafts that are percutaneously delivered and implanted at the aneurysm site. Examples of related inventions are described in U.S. Patent Nos. 6,551,350, 6,843,803, and 6,827,735. Some inventions have presented side branches from the main vascular graft for deployment at the renal arteries or at the aortic arch, for example; however, none of these inventions have provided the necessary surgical tools and modifications to the aortic graft for a side branch to serve as the anastomosis between the apicoaortic prosthesis and the descending aorta.

[0039] The present invention also enables an alternative use of prosthetic valves that are currently under development for percutaneous aortic valve replacement, such as described in U.S. patent number 6,893,460 by Spenser, et al. Although these valves are typically intended for percutaneous delivery and deployment at the native aortic valve location, these valves could be delivered percutaneously for use in the apicoaortic conduit.

[0040] Thus, the present invention provides a system comprising the complete apicoaortic prosthesis according to the preferred embodiment includes a rigid apical connector portion which will serve to provide egress from the left ventricle (such as from the apex or lateral wall), a flexible conduit portion which will carry blood from the connector to the arterial system (such as to the descending thoracic aorta), and the aortic valve itself, which will be situated somewhere within the conduit. The present invention primarily

addresses attachment of a flexible conduit portion to the arterial system. The present invention includes an implantable aortic connector and the necessary instruments to position, deploy and secure the device.

[0041] In addition, the present invention allows the surgeon to precisely select a site along the descending aorta where an anastomosis between an aortic connector and descending aorta will be formed. The site selection may be based upon imaging performed prior to bringing the patient to the surgical suite, such as computer aided tomography imaging. Site selection may also include minimally invasive ultrasound imaging and visual inspection. After selecting the anastomosis site, the surgeon introduces a placement instrument or applicator through a small incision between the ribs that requires little or no rib spreading. The distal end of the applicator is then inserted through the aortic wall at the selected site. The interventional radiologist or cardiologist (the interventionalist) then delivers an unexpanded aortic connector to the selected site and attaches the aortic connector to the applicator, thereby precisely placing the aortic connector at the selected anastomosis site. The aortic connector can then be deployed by expanding an aortic graft inside the aorta. Then a side branch can be pulled from within the aortic graft to be attached to the remainder of the apicoaortic prosthesis. The side branch may include a quick connect coupler. Some occlusion means is needed to prevent blood loss until the aortic connector is attached to the remainder of the apicoaortic prosthesis and the surgeon is ready to begin blood flow. This occlusion means may be a sewn seam that is removed to allow blood flow. Alternatively, the occlusion means could be a prosthetic valve, which is an integral part of the apicoaortic conduit. The prosthetic valve serves as a check valve, eliminating the need for a separate occlusion means, such as a sewn seam.

[0042] Referring now to the figures, FIG. 1 is an illustration of an apicoaortic conduit, which extends from the apex of the left ventricle to the descending aorta with a prosthetic valve positioned within the conduit. The present invention includes an aortic connector that serves to create an effective aortic anastomosis. The preferred embodiment of the present invention includes aspects of the aortic connector and an applicator used to implant the aortic connector.

[0043] FIGS. 2A to 2E illustrate an embodiment of the distal end of a retractor 10 which will be inserted through the aorta wall. The retractor 10 includes a hollow retractor housing 11. In use, the retractor housing 11 extends from inside the descending aorta to outside the chest wall. In one embodiment, a balloon 12 is mounted onto the distal end of the retractor housing 11. The balloon 12 may be made of polyurethane, for example. A flow

passage 15 extends from a syringe, for example, located outside the chest wall through an opening 16 in the retractor housing 11 and to the interior of the balloon 12. In use, the balloon 12 may be inflated with saline. Applying a pulling force to the retractor housing 11 pulls the inflated balloon snugly against the inside wall of the aorta. To reduce the volume of balloon 12 and to decrease the flow resistance resulting from the presence of balloon 12 in the aorta, balloon 12 may include joints, or tension members, 12a in the form of point or line connections, as shown in FIG. 2C. The balloon joints 12a must include small separations 12b to allow for fluid entry and exit to all portions of the balloon 12. The balloon joints 12a serve as tension members that limit expansion of balloon 12.

[0044] FIG. 2D illustrates a trocar tool 13 mounted inside the retractor housing 11. The trocar tool 13 may be inserted and removed from the retractor housing 11. The trocar 13 is used to make a hole in the aorta wall through which the distal end of the retractor 10 is inserted. The trocar 13 may be spring loaded with a mechanism to allow quick retraction of the trocar 13 into the retractor housing 11 after the hole is made in the aorta wall, thereby preventing accidental damage to the aorta wall. FIG. 2E illustrates a radiopaque attachment tool 14, shown as a simple hook. The attachment tool 14 may be inserted and removed from the retractor housing 11. In use, the attachment tool 14 is used to position folded aortic connector 50 precisely with respect to the applicator. Attachment tool 14 may also be a guidewire (separate from guidewire 55) inserted through retractor housing 11 and extending to a distal site, such as to a percutaneous entry site through the femoral artery at the groin. The hollow retractor housing 11 includes a check valve that prevents blood loss from the aorta when the trocar tool 13 or attachment tool 14 is not inserted. This check valve allows insertion of the trocar tool 13 and attachment tool 14 without damage to the check valve.

[0045] In addition to the retractor 10, the applicator includes a reaction tube 30 and a cutter tube 20, both located concentrically with the retractor 10, as illustrated in FIGS. 3A to 3I. Cutter tube 20 includes a sharp edge 20a. A description of how the applicator is used to implant the aortic connector 50 will be used to further describe these components.

[0046] The applicator shown in FIG. 3A used to position the aortic connector 50 consists of a retractor 10, a reaction tube 30, and a cutter tube 20. Movements and actions of these elements and components of these elements may be coordinated manually or by mechanisms which reside primarily outside the chest wall. These mechanisms may be controlled independently or in a coordinated manner, such as by using a cam mechanism similar to those described in U.S. Patent Application Serial No. 11/086,577.

[0047] Both percutaneous and minimally invasive surgical techniques are used to implant the aortic connector 50 (FIG. 3I). A fluoroscope is required for the percutaneous aspects of the procedure. The aortic connector is percutaneously delivered from the femoral artery in the groin to its final position in the descending aorta. The aortic connector 50 may be folded to a diameter of 19 Fr (6 mm), for example, for percutaneous delivery. Visualization of the surgical aspects of the procedure may be achieved with a 10-mm diameter videoscope, for example. Three to five small incisions between the ribs are needed for the videoscope and for minimally invasive surgical tools, including the applicator described herein.

[0048] The surgical portion of the procedure includes dissection of the descending aorta from the surrounding soft tissue in the area where the side branch portion 52 (FIG. 3I) of the aortic connector 50 will pass through the aortic wall. Computerized tomography may be performed prior to the surgery to identify an acceptable region of the descending aorta for the side branch 52 to pass through the aortic wall. In the operating room, ultrasound may be used to confirm the desired location for the aortic connector 50. Such ultrasound device may be of a wand configuration to penetrate a small incision between the ribs to precisely locate any calcium islands or other diseased areas of the aorta that should be avoided. Once the precise location where the side branch portion 52 of the aortic connector will pass through the aorta wall is chosen, the surgeon is ready to use the applicator, as described next.

[0049] A first embodiment of the present invention is shown in FIGS. 3A to 3I. FIG. 3A illustrates the distal end of the applicator with retractor 10, cutter tube 20, and reaction tube 30. The applicator is shown outside the aorta 70 with balloon 12 deflated. The trocar tool 13 is inserted into the retractor housing 11. (Details of retractor housing 11 and flow passage 15 are shown in FIG. 2D.) Once the desired location where the side branch portion 52 of the aortic connector 50 will pass through the aorta is chosen, the retractor 10 with trocar tube 13 is inserted through the aorta wall and progressed until reaction tube 30 is pressed against the outer wall of the aorta, as shown in FIG. 3B. Then, balloon 12 is inflated. Then, retractor 10 is moved axially with respect to the reaction tube 30 and cutter tube 20 until the aorta 70 is firmly sandwiched between the balloon 12 and reaction tube 30. A spring may be used to move the retractor 10 relative to the reaction tube 30 and to provide the compressive force to sandwich the aorta wall. Alternatively, this compressive force may be provided by the inflation of balloon 12 so that no axial movement of retractor 10 is needed to firmly sandwich, or clamp, the aorta wall between the reaction tube and the balloon.

[0050] FIG. 3C illustrates percutaneous introduction of aortic connector 50 along guidewire 55. The aortic connector 50 is shown in a folded configuration to reduce its diameter to allow percutaneous introduction. The side branch portion 52 is stored within aortic graft portion 51 in a partial inside-out configuration shown more clearly in FIG. 3E to FIG. 3G. The folded configuration may be achieved by putting aortic connector 50 into a sheath which is removed to allow stent expansion of the aortic graft 51 to its final position. A separate sheath could allow stent expansion of quick connect coupler 53 of the side branch 52. Alternatively, the aortic connector 50 could be held in its folded configuration by a restraining member such as a chain stitch that is released by pulling a thread on one end of the stitch, as described in U.S. patent 6,551,350 by Thornton, et al. Such restraining member holds the aortic graft 51, which has an integrated stent, in a folded configuration until the restraining member is released. Whether held in a folded configuration by a sheath or other restraining member, unfolding or expansion of the aortic connector 50 propagates from the middle of the aortic graft 51 towards both ends, as described later and shown in FIG. 3D to FIG. 3F. At this middle position along the aortic graft 51 is a radiopaque attachment hook or loop 54 which the interventionalist connects to radiopaque attachment tool 14. Attachment loop 54 may be connected to the end of side branch portion 52, as shown in FIG. 3H, for example. In use, once the folded aortic connector 50 is percutaneously delivered to the vicinity of where the retractor 10 has been inserted into aorta 70, the attachment tool 14 and attachment loop 54 are manipulated by the interventionalist until they are joined, as shown in FIG. 3C. Fluoroscopy may be used to facilitate this attachment. Once the aortic connector 50 is attached to the applicator, attachment tool 14 may be partially retracted into retractor housing 11 to closely position the end of side branch portion 52 where it will pass through the aortic wall, as illustrated in FIG. 3D.

[0051] FIG. 3E and FIG. 3F illustrate deployment of the aortic graft portion 51 of aortic connector 50. Deployment of aortic graft 51 is arranged to position the side branch 52 at the precise location of where side branch 52 will pass through the aortic wall. Such deployment is achieved by allowing the stent to expand the aortic graft from the middle outwards, as shown in FIG. 3E and FIG. 3F. Such expansion may be achieved by removing sheaths from both ends of the aortic graft 51 or by a restraining member that propagates expansion from the middle of the graft outwards.

[0052] The aortic graft 51 is shown fully deployed in FIG. 3F. Also shown in FIG. 3F is the side branch portion 52 of aortic connector 50. Side branch portion 52 is shown with about half of its length in a folded configuration 52a with the rest in an unfolded

configuration 52b (see FIG. 3H and FIG. 3I). In a preferred embodiment, the folded portion 52a of side branch 52 serves as the female quick connect coupler 53. The folded portion 52a may be held in this configuration by a sheath or other restraining member, similar to the means to fold the aortic graft 51. Both the folded portion 52a and the unfolded portion 52b of the side branch are shown substantially inside the aortic graft 51. Furthermore, unfolded portion 52b is shown in an inside out configuration.

[0053] FIG. 3G illustrates deployment of cutter tube 20 to remove a round tissue plug 71 (see FIG. 3H) from the aorta wall. The cutter tube 20 is moved axially with respect to the reaction tube 30 and retractor 10 by a mechanism which may reside outside the chest wall. Such mechanism may be operated independently or in a coordinated manner, such as by using a cam mechanism. Once the cutter tube 20 is deployed, the surgeon applies rotary motion to the cutter tube 20. The retractor 10 rotates with the cutter tube 20 to substantially prevent relative rotary motion between the balloon 12 and cutter tube 20. The reaction tube 30 may rotate with the cutter tube 20 and retractor 10, or, alternatively, the reaction tube 30 may not rotate. Relative rotation means must be provided to allow rotation of retractor 10 without excessive rotation of side branch 52 relative to aortic graft 51. In one embodiment, the relative rotation means is provided by preventing rotation of the attachment tool 14 relative to the side branch 52. In another embodiment, the attachment tool 14 includes a rotating joint, such as a twistable cord, between the distal hook and the main body of the attachment tool 14.

[0054] Axial motion of the retractor 10 relative to the cutter tube 20 may be controlled in a similar fashion as is described in U.S. Patent Application Serial No. 11/086,577 filed March 23, 2005, and in U.S. Provisional Patent Application Nos. 60/726,223 and 60/726,222, both of which were filed October 14, 2005. As such, once the cutter tube 20 has removed a tissue plug 71 from the aorta 70, the balloon 12 is partially deflated, thereby assuring that the tissue plug 71 remains on the retractor 10. Also, axial motion of the retractor 10 relative to cutter tube 20 continues until the balloon is partially or totally retracted to inside the cutter tube 20. In one embodiment, the balloon 12 partially deflates automatically, after the retractor 10 reaches a predetermined axial position relative to cutter tube 20. A cam mechanism may be used to provide the automatic partial deflation. In another embodiment, the balloon 12 does not partially deflate without a deliberate action by the surgeon, such as by releasing a safety latch, which may be done by pressing a button or turning a knob.

[0055] As a safety feature, simultaneously with or after the balloon 12 is partially deflated and partially retracted inside cutter tube 20, the cutter tube 20 moves axially relative to the reaction tube 30 until the sharp edge 20a of cutter tube 20 is retracted to within reaction tube 30, thereby preventing the sharp edge 20a from accidentally cutting other tissue, as shown in FIG. 3H. Such motion may be achieved independently or in a coordinated manner, such as with a cam mechanism.

[0056] Once the balloon 12 is partially deflated and partially retracted inside the cutter tube 20, movement of the applicator relative to the aorta 70 serves to remove the side branch portion 52 from within the aortic graft portion 51 of aortic connector 50, as shown in FIG. 3H. The folded portion 52a of side branch 52 remains folded until released, such as by removing a sheath or by releasing a restraining member. Release of the restraining member may occur simultaneously with releasing of attachment tool 14 from attachment loop 54. Also shown in FIG. 3H is aortic graft stent 57, which was not shown in prior figures for clarity. Details of the stent 57 are well known to those in the art.

[0057] The aortic connector 50 shown in FIG. 3I consists of an aortic graft portion 51 with a side branch portion 52. The aortic graft portion 51 includes a stent component 57 to provide expansion of the graft once deployed to its final position in the aorta. The aortic graft portion 51 resides inside the aorta. The side branch portion 52 extends from the aortic graft portion 51 through the aorta wall and connects to the remainder of the prosthesis illustrated in FIG. 1. The side branch portion 52 may include an occluding means 56 to prevent blood flow through the side branch 52 until the occluding means 56 is removed. The side branch portion 52 may also include the female or male half of a quick connect coupler 53, as described in U.S. Patent Application Serial No. 11/086,577. Such quick connect coupler 53 may include a stent component 58 that is compressed to a small diameter for percutaneous delivery and expands to its final diameter for use as the female or male portion of the quick connect coupler 53. The side branch portion 52 may also include a folded valve (not shown) that may serve as the prosthetic valve shown in FIG. 1. The prosthetic valve serves as a check valve in the side branch portion 52, thereby eliminating the need for a separate occluding means 56, such as a sewn seam.

[0058] The deployed aortic connector is illustrated in FIG. 3I. Side branch stent 58 has been released, either by removing a sheath or by releasing a restraining member. This stented portion of side branch 52 may serve as the female quick connect coupler 53 for attaching to the remainder of the prosthesis, as shown in FIG. 1. Occlusion means 56 can be a sewn joint that prevents blood flow through the side branch 52 until the aortic connector 50

is connected to the remainder of the prosthesis, as shown in FIG. 1, air is removed from the flow channel, and the surgeon is ready to begin blood flow through the prosthesis. In one embodiment, pulling cord 56a from the graft removes the occluding means. In another embodiment, the occluding means could be a valve that serves as the prosthetic valve in FIG. 1.

[0059] A second embodiment of the present invention is shown in FIGS. 4A to 4H. This embodiment replaces the balloon 12 with a solid clamp pad 17, which is rigidly attached to the distal end of retractor housing 11'. In the alternative, clamp pad 17 itself may be an expansion element, such as a balloon, which a smaller diameter than the cutting element, thereby only allowing it to function as a clamping element. Clamp pad 17 may also include spikes or hooks that penetrate the aortic wall to help prevent movement of the aortic wall relative to the clamp pad 17 after the aortic wall is firmly sandwiched between the clamp pad 17 and reaction tube 30'. Also, the reaction tube 30' in this embodiment is located concentrically between the cutter tube 20' and retractor 10'. A description of how the applicator is used to implant the aortic connector 50 will be used to further describe the components of this embodiment.

[0060] FIG. 4A illustrates the applicator with trocar tool 13' penetrating aorta 70. The trocar 13' is shaped to cut a small slit in the aortic wall of sufficient length to provide a tight or interference fit between the clamp pad 17 and the slit, with the slit being just large enough to allow clamp pad 17 to penetrate the slit. Once the slit is formed, the surgeon manipulates the clamp pad 17 to force the clamp pad 17 through the aorta wall. Manipulation of the clamp pad 17 is achieved by moving the proximal end of the retractor housing 11', which is located outside the chest wall. Once the clamp pad 17 enters the aorta 70, retractor 10' is moved axially relative to reaction tube 30' to sandwich the aorta between clamp pad 17 and reaction tube 30', as shown in FIG. 4B. A spring may be used to move the retractor 10' relative to reaction tube 30' and to provide the compressive force to sandwich the aorta wall. Alternatively, a squeeze mechanism with a mechanical ratchet may be used to clamp the aortic wall between the clamp pad 17 and reaction tube 30'. FIG. 4B also shows the trocar tool 13' removed from the retractor 10'. Check valve 18 prevents blood loss through the retractor housing 11'.

[0061] FIG. 4C illustrates introduction of attachment tool 14' into retractor 10'. The applicator with attachment tool 14' is now ready for attachment to aortic connector 50. Note that attachment tool 14' could be a guidewire (separate from guidewire 55) that is introduced

from outside the chest wall through the retractor housing 11' and to a distal location, such as the percutaneous introduction site for the aortic connector 50.

[0062] FIG. 4D illustrates percutaneous introduction of aortic connector 50 along guidewire 55. Deployment of the aortic connector 50 and details of the aortic connector 50 itself may be assumed to be the same as that described in FIGS. 3C to 3I, except for differences specifically described herein. One addition to the aortic connector 50 is a cutter guard 19 which protects the aortic connector fabric from the sharp cutter tube 20' when the tissue plug is cut, as described more fully with FIG. 4F.

[0063] The state depicted in FIG. 4D is comparable to that of FIG. 3C. Once the aortic connector 50 is attached to the applicator, attachment tool 14' may be partially retracted into retractor housing 11' to closely position the end of side branch portion 52 where it will pass through the aortic wall. The aortic graft portion 51 of aortic connector 50 may then be expanded, as shown in FIG. 4E. Similar to FIG. 3E and FIG. 3F, deployment of aortic graft 51 is achieved by expanding the aortic graft 51 from the middle outwards. FIG. 4E also illustrates cutter tube 20'.

[0064] FIG. 4F illustrates deployment of the cutter tube 20' with sharp edge 20a shown partially penetrating the aortic wall. The cutter tube 20' is moved axially with respect to reaction tube 30' by a mechanism which may reside outside the chest wall. Such mechanism may use a spring to apply the axial force needed for the cutter tube 20' to cut the aortic wall. Such mechanism may be operated independently or in a coordinated manner, such as by using a cam mechanism. Once the cutter tube 20' is deployed, the surgeon applies rotary motion, if necessary, to the cutter tube 20' to create tissue plug 71. As depicted in FIG. 4F, the surgeon may also apply a slight pulling force to the applicator, thereby slightly distorting the aorta. In this way, the surgeon will readily recognize when the tissue plug 71 has been fully cut from the aortic wall.

[0065] Also shown in FIG. 4F is cutter guard 19, which resides external to aortic graft portion 51 and is rigidly connected to attachment loop 54'. (Cutter guard 19 was not shown in prior figures for clarity.) Cutter guard 19 replaces balloon 12 to protect the aortic connector 50 from the sharp cutter tool 20'. FIG. 4F shows one embodiment of a cutter guard 19, which may include a wire (e.g., nitinol) frame 19a embedded within polyurethane sheet 19b, for example. When aortic graft portion 51 is expanded, such as by removing a sheath or by releasing a restraining member, cutter guard 19 is simultaneously released. The diameter of cutter guard 19 is slightly larger than the cutter tube 20' diameter, so that the cutter guard 19 protects aortic connector 50 from sharp edge 20a.

[0066] Once the tissue plug 71 is retracted to inside cutter tube 20', movement of the applicator relative to the aorta 70 serves to remove the side branch portion 52 from within the aortic graft portion 51, as shown in FIG. 4G. Cutter guard 19 is pulled against the sharp edge 20a of cutter tube 20'.

[0067] The deployed aortic connector 50 is illustrated in FIG. 4H. Side branch stent 58 has been released, either by removing a sheath or by releasing a restraining member. As an example, releasing a restraining member to expand side branch stent 58 could provide for separation from disconnect means 59, so that attachment loop 54' with cutter guard 19 and disconnect means 59 remains attached to attachment tool 14'. Prior to releasing the restraining member, disconnect means 59 is held securely within side branch stent 58. Also shown in FIG. 4H are axial stiffeners 60, which serve to maintain separation between aortic graft stents on each end of aortic graft portion 51. Axial stiffeners 60 are also shown in figures 3H and 3I.

[0068] While the invention has been described with particular reference to the preferred embodiments, it will be understood by those skilled in the art that various changes may be made and equivalents substituted for elements of the preferred embodiment without departing from the invention. In addition, many modifications may be made to adapt a particular situation and material to a teaching of the present invention without departing from the essential teachings of the present invention.

[0069] As is evident from the foregoing discussion, certain aspects of the invention are not limited to the particular details of the examples illustrated, and it is therefore contemplated that other modifications and applications will occur to those skilled in the art. It is accordingly intended that the claims shall cover all modifications and applications as do not depart from the spirit and scope of the invention.

What Is Claimed Is:

1. An applicator for forming a hole in a wall of a hollow vessel and engaging a graft, the applicator comprising:

a hole forming element adapted to form a hole in the wall of the vessel, the hole forming element comprising a cutting element adapted to cut a hole in the wall of the vessel and a positioning element adapted to hold the position of the applicator relative to the vessel; and

an insertion element adapted to be inserted through the wall of the vessel, the insertion element comprising a retraction element adapted to enter into engagement with a graft.

2. The applicator of claim 1, wherein the positioning element comprises:

a reaction element adapted to be positioned on the outside of the wall of the vessel; and

a clamping element adapted to be positioned on the inside of the wall of the vessel,

wherein the wall of the vessel is held between the reaction element and the clamping element, thereby holding the position of the applicator relative to the vessel.

3. The applicator of claim 2, wherein the clamping element is a balloon.

4. The applicator of claim 2, wherein the clamping element is made of a rigid material.

5. The applicator of claim 2, wherein the clamping element is adapted to prevent a tissue plug from entering the vessel, the tissue plug comprising the portion of the wall removed when the hole is formed in the vessel.

6. The applicator of claim 1, further comprising a graft protection element adapted to prevent the graft from being damaged by the cutting element.

7. The applicator of claim 1, wherein the graft is predisposed within the vessel.

8. The applicator of claim 1, wherein the retraction element comprises a graft attachment tool.

9. The applicator of claim 8, wherein the graft attachment tool is radiopaque.

10. The applicator of claim 1, wherein the retraction element is further adapted to be withdrawn from the hole formed in the wall of the vessel after entering into engagement with the graft, thereby withdrawing a portion of the graft.

11. The applicator of claim 10, wherein the portion of the graft withdrawn by the retraction element forms a side branch to the vessel.

12. The applicator of claim 6, wherein the clamping element and the graft protection element are the same element.

13. The applicator of claim 12, wherein the clamping element and the graft protection element is an expansion element.

14. The applicator of claim 13, wherein the expansion element is expandable from an unexpanded state to fully expanded state and to a partially expanded state.

15. The applicator of claim 13, wherein the expansion element is a balloon.

16. The applicator of claim 15, wherein the balloon is in the shape of a circular toroid.

17. The applicator of claim 15, wherein one or more tension members restrict the dimensions of the balloon.

18. The applicator of claim 13, wherein the expansion element is an umbrella mechanism.

19. The applicator of claim 14, further comprising means for expanding the expansion element from the unexpanded state, to the fully expanded state, and to the partially expanded state in a sequential manner.

20. The applicator of claim 19, wherein the expansion element is a balloon and the means for expanding comprises a syringe in fluid communication with the balloon.

21. The applicator of claim 19, wherein the expansion element is an umbrella device and the means for expanding comprises a cylinder having a piston slideable therein and coupled to the umbrella device.

22. The applicator of claim 1, wherein the cutting element is a cutting blade.

23. The applicator of claim 22, where the cutting blade is cylindrically shaped.

24. The applicator of claim 1, wherein the vessel is the aorta.

25. The applicator of claim 1, wherein the insertion element further comprises a trocar.

26. The applicator of claim 1, further comprising a sequencing means for coordinating at least one of holding the position of the applicator relative to the vessel with the positioning element, cutting a hole in the wall of the vessel with the cutting element, inserting the insertion element through the wall of the vessel, entering the retraction element into engagement with the graft, and withdrawing the retraction element from the hole formed in the wall of the vessel.

27. The applicator of claim 26, wherein the sequencing means comprises a cam mechanism.

28. The applicator of claim 26, wherein the sequencing means comprises a gear mechanism.

29. The applicator of claim 26, wherein the sequencing means comprises at least one servo mechanism operatively coupled to the applicator and a controller operatively coupled to the at least one servo mechanism.

30. The applicator of claim 29, wherein the controller comprises a microprocessor based device.

31. The applicator of claim 26, further comprising a button operatively coupled to the sequencing means for activating the sequencing means upon depression of the button to thereby accomplish steps of a procedure for forming the hole in the vessel.

32. The applicator of claim 14, further comprising a sequencing means for coordinating the expansion state of the expansion element with respect to the relative movement of the cutting element and the clamping element.

33. The applicator of claim 14, wherein, in the fully expanded state, the expansion element has an outer diameter larger than an outer diameter of the cutting element.

34. The applicator of claim 14, wherein, in the partially expanded state, the expansion element has an outer diameter that is less than an inner diameter of the hole forming element and greater than an outer diameter of the retraction element to thereby position a tissue plug within the hole forming element.

35. The applicator of claim 26, wherein the sequencing means comprises means for causing the elements to assume the following states in seriatim;

a) a first state where the insertion element is positioned within the vessel;

b) a second state where the positioning element is holding the position of the applicator relative to the vessel; and

c) a third state in which the hole has been formed with the cutting element.

36. A method for forming a hole in a wall of a hollow vessel and engaging a graft, the method comprising:

inserting an insertion element through the wall of the vessel until at least a portion of a retraction element of the insertion element is positioned within the vessel;

positioning the wall of the vessel relative to the applicator with a positioning element;

engaging the graft with the retraction element; and

forming the hole in the wall of the vessel with the cutting element.

37. The method of claim 36, wherein the cutting element is a cutting blade.

38. The method of claim 37, wherein the forming step comprises pressing the cutting blade into the wall of the vessel and applying torsional force to the cutting blade.

39. The method of claim 36, wherein the positioning step comprises:

biasing a reaction element on the outside of the wall of the vessel;

biasing a clamping element on the inside of the wall of the vessel; and

holding the wall of the vessel between the reaction element and the clamping element.

40. The method of claim 39, wherein the clamping element is a balloon.

41. The method of claim 39, wherein the clamping element is made of a rigid material.

42. The method of claim 39, wherein the clamping element is adapted to prevent a tissue plug from entering the vessel, the tissue plug comprising the portion of the wall removed when the hole is formed in the vessel.

43. The method of claim 36, further comprising positioning a graft protection element between the graft and the cutting element prior to the forming step.

44. The method of claim 36, wherein the graft is predisposed within the vessel.

45. The method of claim 36, wherein the retraction element comprises a graft attachment tool.

46. The method of claim 45, wherein the graft attachment tool is radiopaque.

47. The method of claim 36, further comprising withdrawing the retraction element from the hole formed in the wall of the vessel after the steps of engaging and forming, thereby withdrawing a portion of the graft.

48. The method of claim 47, wherein the portion of the graft withdrawn by the retraction element forms a side branch to the vessel.

49. The method of claim 39, wherein the clamping element and the graft protection element are the same element.

50. The method of claim 49, wherein the clamping element and the graft protection element is an expansion element.

51. The method of claim 50, wherein the expansion element is expandable from an unexpanded state to fully expanded state and to a partially expanded state.

52. The method of claim 50, wherein the expansion element is a balloon.

53. The method of claim 52, wherein the balloon is in the shape of a circular toroid.

54. The method of claim 52, wherein one or more tension members restrict the dimensions of the balloon.

55. The method of claim 50, wherein the expansion element is an umbrella mechanism.

56. The method of claim 51, further comprising expanding the expansion element from the unexpanded state to the fully expanded state to the partially expanded state in a sequential manner.

57. The method of claim 56, wherein the expansion element is a balloon and the step of expanding is carried out with a syringe in fluid communication with the balloon.

58. The method of claim 56, wherein the expansion element is an umbrella device and step of expanding is carried out with a cylinder having a piston slideable therein and coupled to the umbrella device.

59. The method of claim 36, wherein the vessel is the aorta.

60. The method of claim 36, wherein the insertion element further comprises a trocar, thereby facilitating the inserting step.

61. The method of claim 36, further comprising a sequencing means for carrying out the method.

62. The method of claim 61, wherein the sequencing means comprises a cam mechanism.

63. The method of claim 61, wherein the sequencing means comprises a gear mechanism.

64. The method of claim 61, wherein the sequencing means comprises at least one servo mechanism and a controller operatively coupled to the at least one servo mechanism.

65. The method of claim 64, wherein the controller comprises a microprocessor based device.

66. The method of claim 61, further depressing a button operatively coupled to the sequencing means to activate the sequencing means.

67. The method of claim 56, further comprising a sequencing means for carrying out the expansion of the expansion element from the unexpanded state to the fully expanded state to the partially expanded state in a sequential manner.

68. The method of claim 51, wherein, in the fully expanded state, the expansion element has an outer diameter larger than an outer diameter of the cutting element.

69. The method of claim 51, wherein, in the partially expanded state, the expansion element has an outer diameter that is less than an inner diameter of the hole forming element and greater than an outer diameter of the retraction element to thereby position a tissue plug within the hole forming element.

70. The method of claim 61, wherein the sequencing means comprises means for causing the elements to assume the following states in seriatim;

a) a first state where the insertion element is positioned within the vessel;

b) a second state where the positioning element is holding the position of the applicator relative to the vessel; and

c) a third state in which the hole has been formed with the cutting element.

71. A system for forming a side branch on a hollow vessel, the system comprising:

a graft including a main vessel portion and a side branch portion, the graft being in a compressed state; and

an applicator comprising a hole forming element adapted to form a hole in the wall of the vessel and an insertion element adapted to be inserted through the wall of the vessel, the insertion element comprising a retraction element adapted to enter into engagement with the graft.

72. The system of claim 71, wherein the hole forming element comprises:

a cutting element adapted to cut a hole in the wall of the vessel; and

a positioning element adapted to hold the position of the applicator relative to the vessel.

73. The system of claim 72, wherein the positioning element comprises:

a reaction element adapted to be positioned on the outside of the wall of the vessel; and

a clamping element adapted to be positioned on the inside of the wall of the vessel,

wherein the wall of the vessel is held between the reaction element and the clamping element, thereby holding the position of the applicator relative to the vessel.

74. The system of claim 73, wherein the clamping element is a balloon.

75. The system of claim 73, wherein the clamping element is made of a rigid material.

76. The system of claim 73, wherein the clamping element is adapted to prevent a tissue plug from entering the vessel, the tissue plug comprising the portion of the wall removed when the hole is formed in the vessel.

77. The system of claim 71, further comprising a graft protection element adapted to prevent the graft from being damaged by the cutting element.

78. The system of claim 71, wherein the graft is predisposed within the vessel.

79. The system of claim 71, wherein the retraction element comprises a graft attachment tool.

80. The system of claim 79, wherein the graft attachment tool is radiopaque.

81. The system of claim 71, wherein the retraction element is further adapted to be withdrawn from the hole formed in the wall of the vessel after entering into engagement with the graft, thereby withdrawing a portion of the graft.

82. The system of claim 81, wherein the portion of the graft withdrawn by the retraction element is the side branch portion.

83. The system of claim 77, wherein the clamping element and the graft protection element are the same element.

84. The system of claim 83, wherein the clamping element and the graft protection element is an expansion element.

85. The system of claim 84, wherein the expansion element is expandable from an unexpanded state to fully expanded state and to a partially expanded state.

86. The system of claim 84, wherein the expansion element is a balloon.

87. The system of claim 86, wherein the balloon is in the shape of a circular toroid.

88. The system of claim 86, wherein one or more tension members restrict the dimensions of the balloon.

89. The system of claim 84, wherein the expansion element is an umbrella mechanism.

90. The system of claim 85, further comprising means for expanding the expansion element from the unexpanded state, to the fully expanded state, and to the partially expanded state in a sequential manner.

91. The system of claim 90, wherein the expansion element is a balloon and the means for expanding comprises a syringe in fluid communication with the balloon.

92. The system of claim 90, wherein the expansion element is an umbrella device and the means for expanding comprises a cylinder having a piston slideable therein and coupled to the umbrella device.

93. The system of claim 72, wherein the cutting element is a cutting blade.

94. The system of claim 93, wherein the cutting blade is cylindrically shaped.

95. The system of claim 71, wherein the vessel is the aorta.

96. The system of claim 71, wherein the insertion element further comprises a trocar.

97. The system of claim 71, further comprising a sequencing means for coordinating at least one of forming the hole in the wall of the vessel and inserting the insertion element through the wall of the vessel.

98. The system of claim 97, wherein the sequencing means comprises a cam mechanism.

99. The system of claim 97, wherein the sequencing means comprises a gear mechanism.

100. The system of claim 97, wherein the sequencing means comprises at least one servo mechanism operatively coupled to the applicator and a controller operatively coupled to the at least one servo mechanism.

101. The system of claim 100, wherein the controller comprises a microprocessor based device.

102. The system of claim 97, further comprising a button operatively coupled to the sequencing means for activating the sequencing means upon depression of the button to thereby accomplish steps of a procedure for forming the hole in the vessel.

103. The system of claim 85, further comprising a sequencing means for coordinating the expansion state of the expansion element with respect to the relative movement of the cutting element and the clamping element.

104. The system of claim 85, wherein, in the fully expanded state, the expansion element has an outer diameter larger than an outer diameter of the cutting element.

105. The system of claim 85, wherein, in the partially expanded state, the expansion element has an outer diameter that is less than an inner diameter of the hole forming element and greater than an outer diameter of the retraction element to thereby position a tissue plug within the hole forming element.

106. The system of claim 97, wherein the sequencing means comprises means for causing the elements to assume the following states in seriatim;

a) a first state where the insertion element is positioned within the vessel; and

b) a second state in which the hole has been formed with the cutting element.

107. A graft device adapted to be used in the formation of a side branch in a hollow vessel, the graft device comprising:

a graft containment element, the graft containment element being adapted to contain the graft in a compressed state;

a graft element including a main vessel portion and a side branch portion, the graft element being adapted to be contained with the graft containment element in a compressed state; and

a graft attachment element, the graft attachment element being adapted to enter into engagement with a corresponding attachment element.

108. The graft device of claim 107, wherein the graft containment element comprises a sheath.

109. The graft device of claim 107, wherein the graft containment element comprises chain stitch.

110. The graft device of claim 107, wherein the graft attachment element comprises a loop.

111. The graft device of claim 107, wherein the graft attachment element is radiopaque.

112. The graft device of claim 107, wherein, when the graft containment element is removed, the graft element expands from a compressed state to an expanded state.

113. The graft device of claim 107, wherein the compressed state comprises a folded configuration.

114. The graft device of claim 107, wherein the compressed state comprises a partial inside-out configuration.

115. The graft device of claim 107, wherein the side branch portion is occluded.

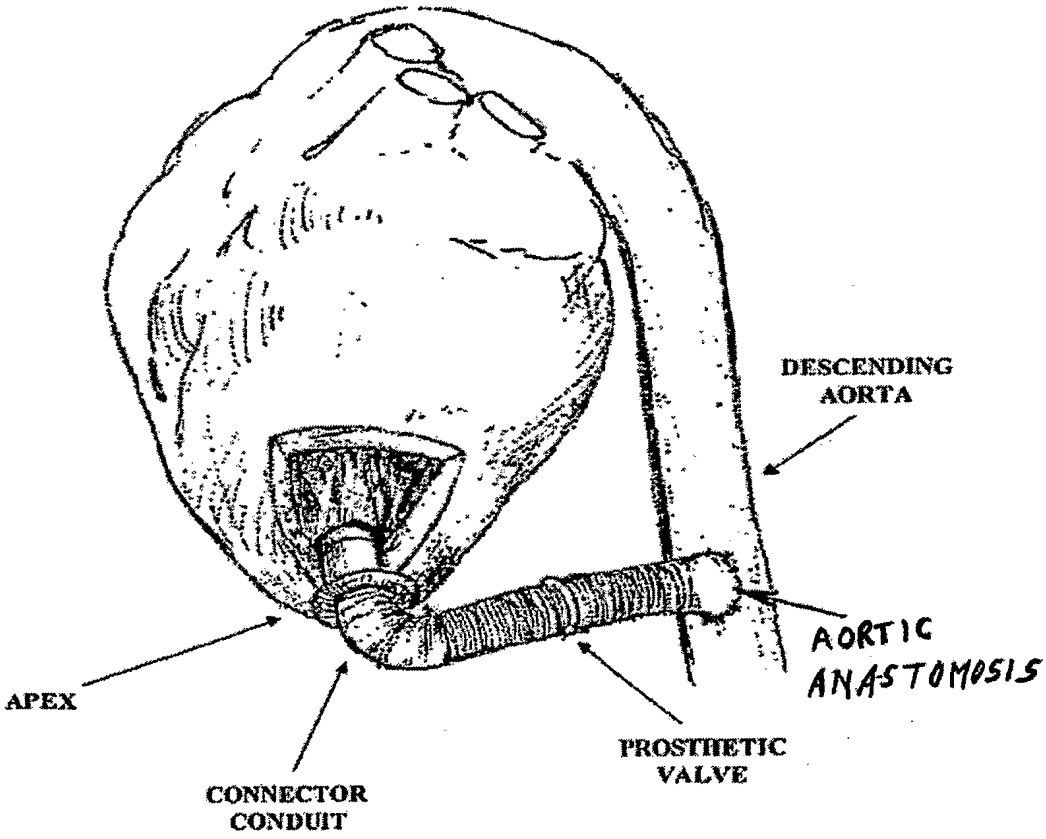
116. The graft device of claim 115, further comprising a means for opening the occlusion in the side branch portion.

117. The graft device of claim 107, further comprising a graft protection element.

118. The graft device of claim 107, wherein the side branch portion comprises a quick connect coupler.

119. The graft device of claim 118, wherein the quick connect coupler is compressible.

FIG. 1



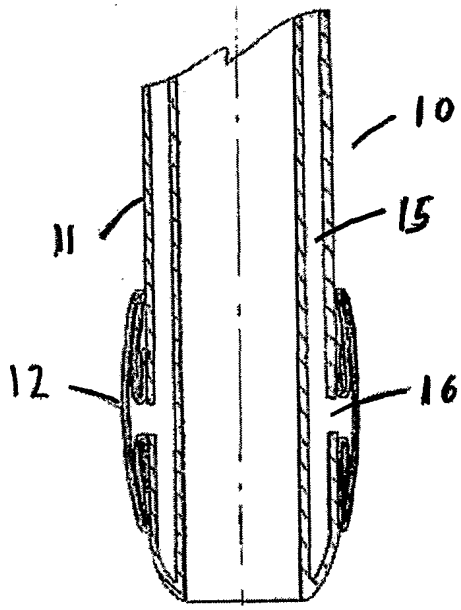


FIG. 2A

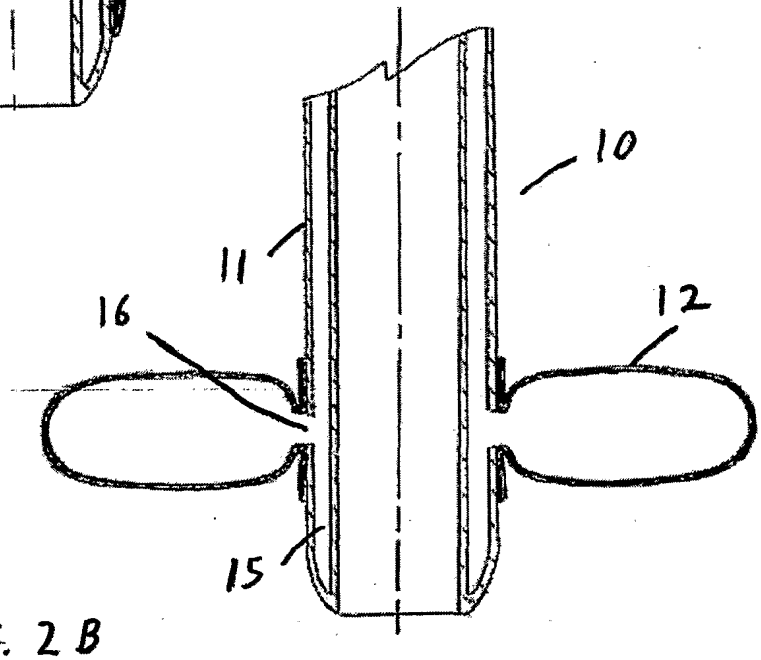


FIG. 2B

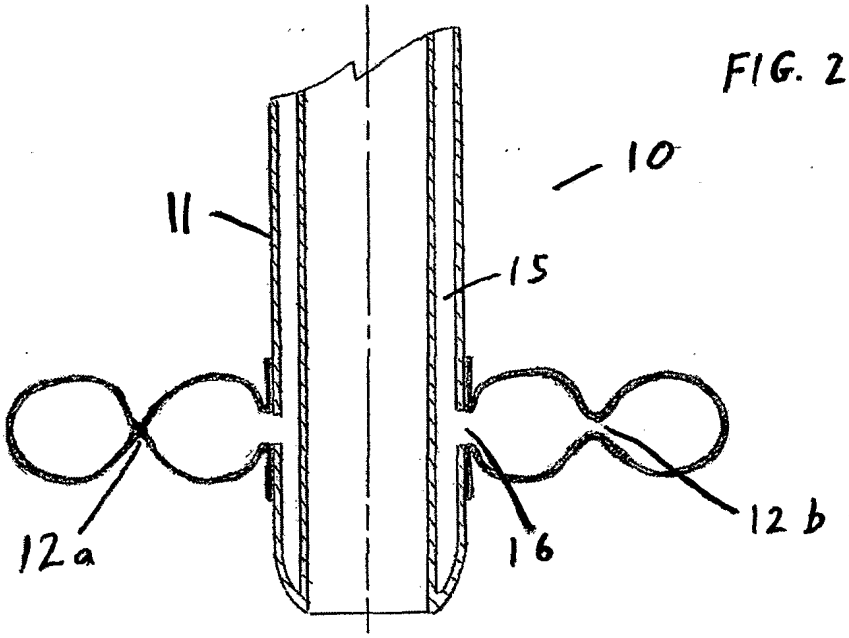


FIG. 2C

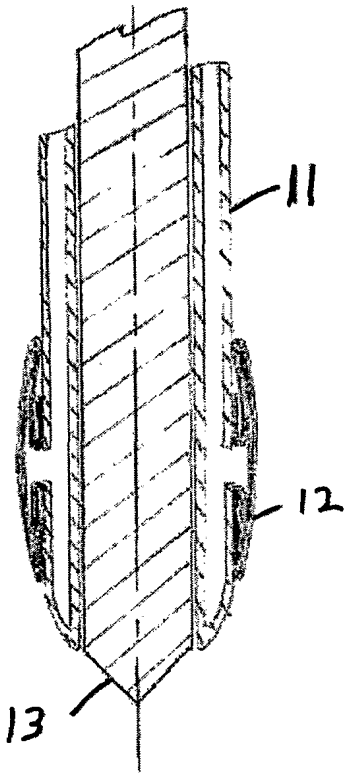


FIG. 2D

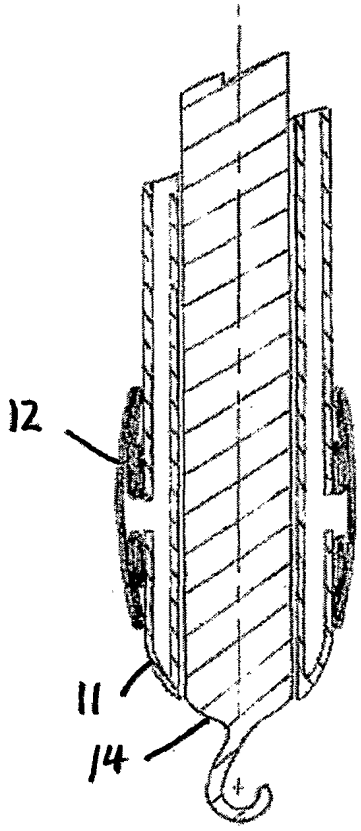


FIG. 2E

FIG. 3A

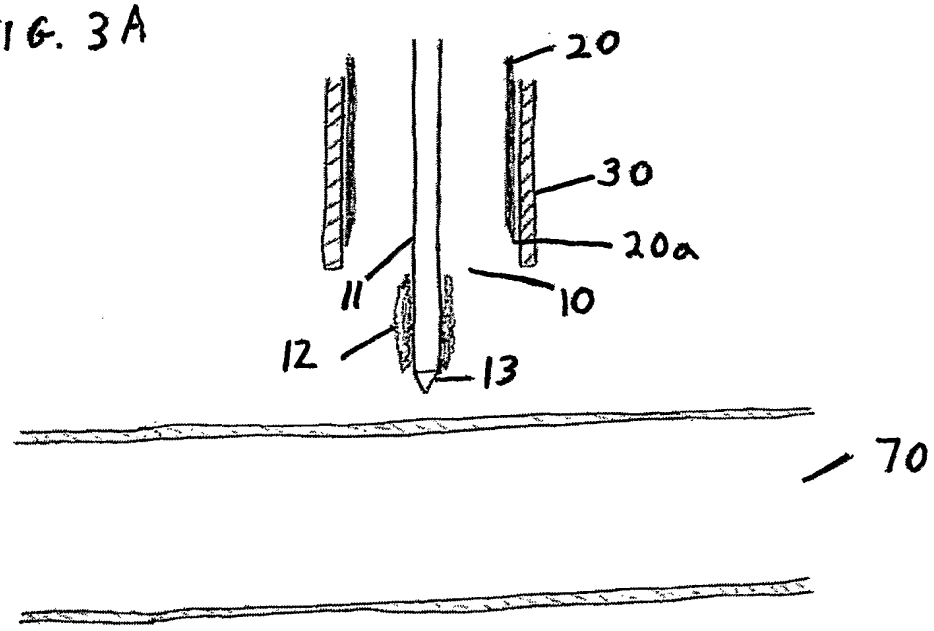


FIG. 3B

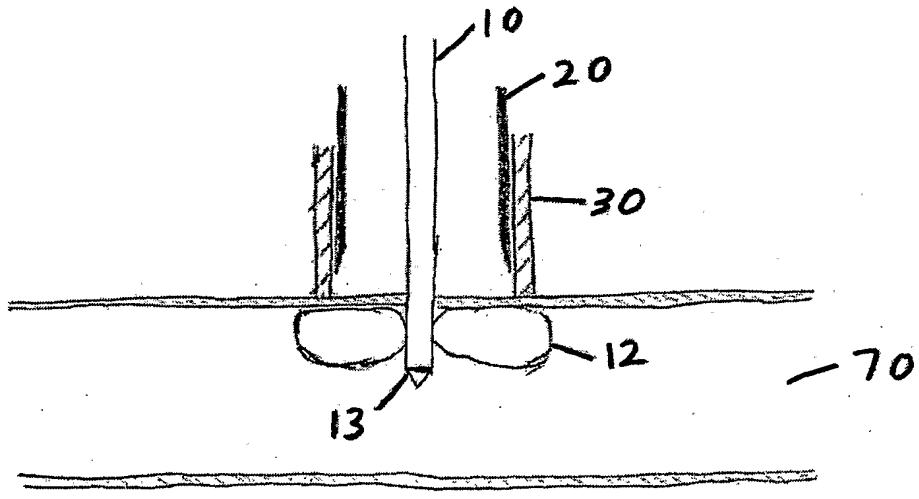


FIG. 3C

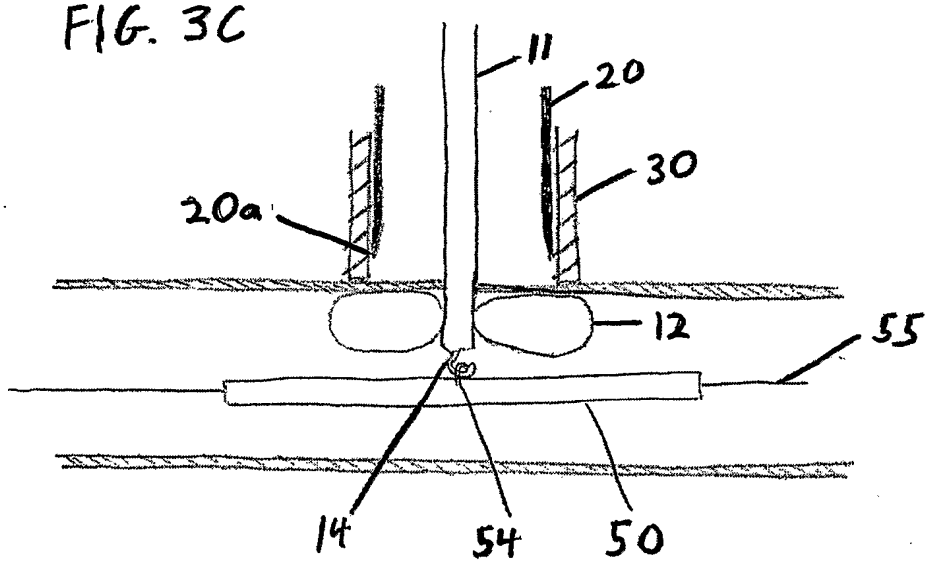


FIG. 3D

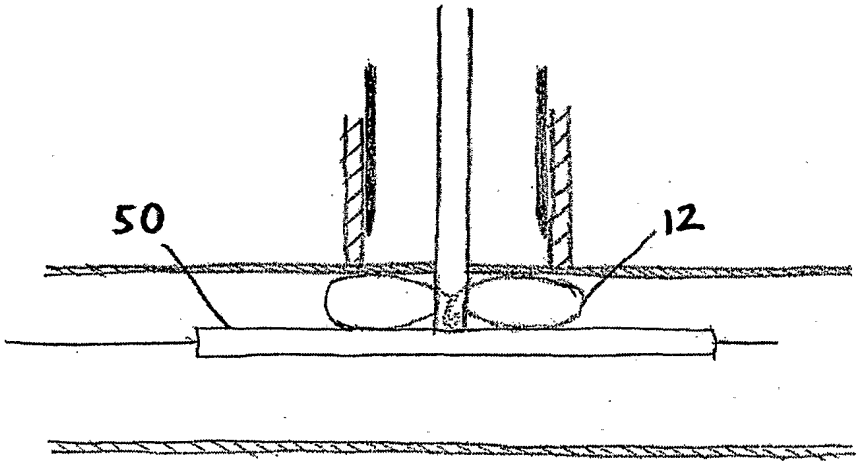


FIG. 3E

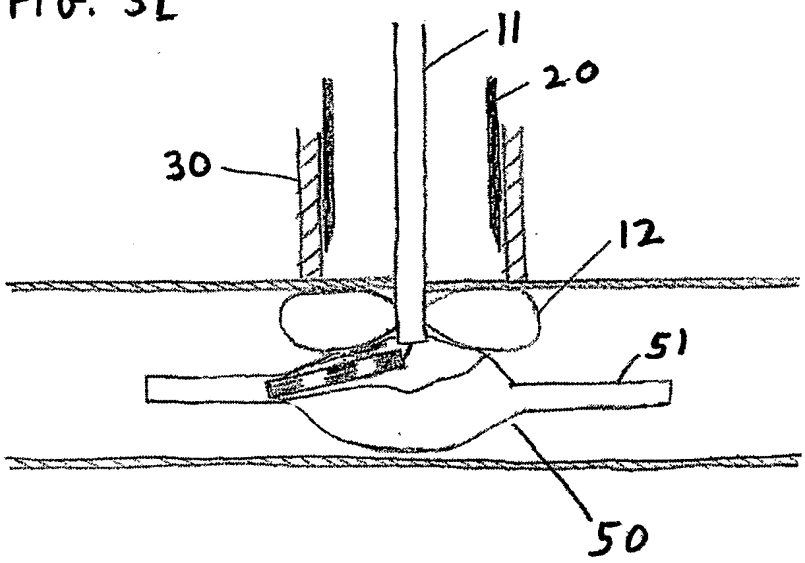


FIG. 3F

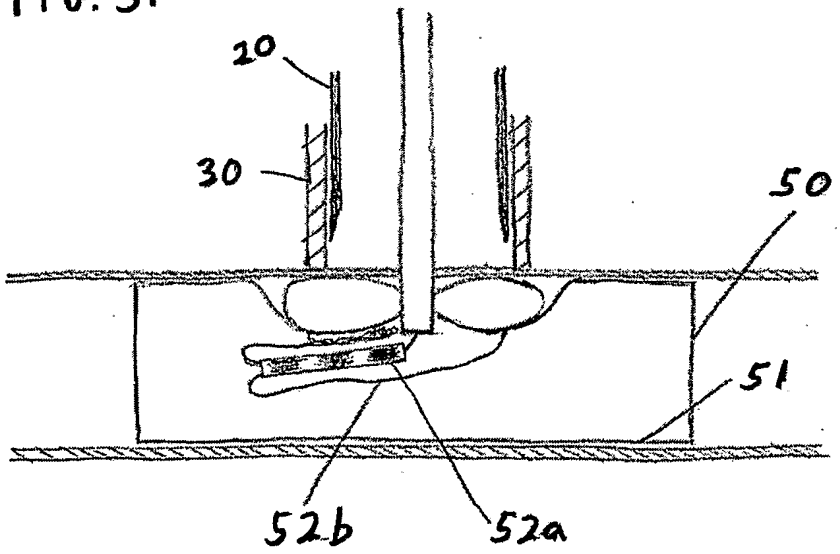


FIG. 3G

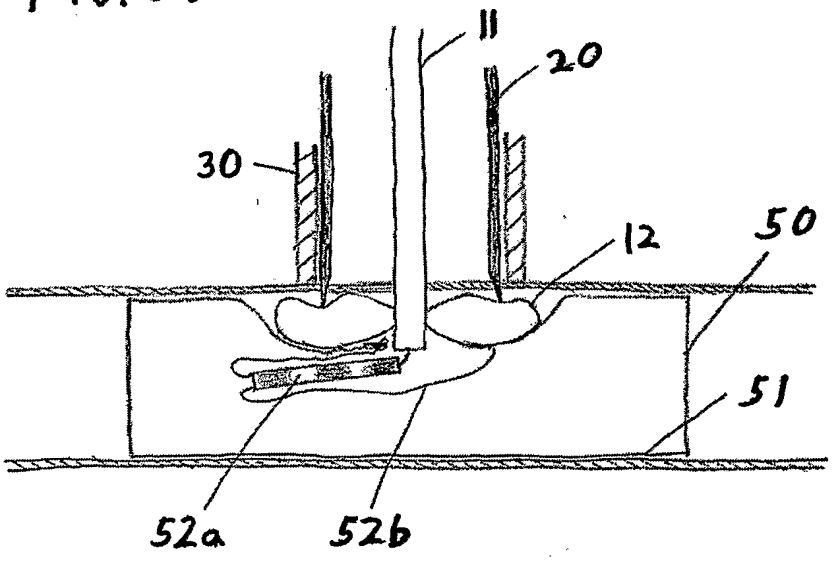


FIG. 3H

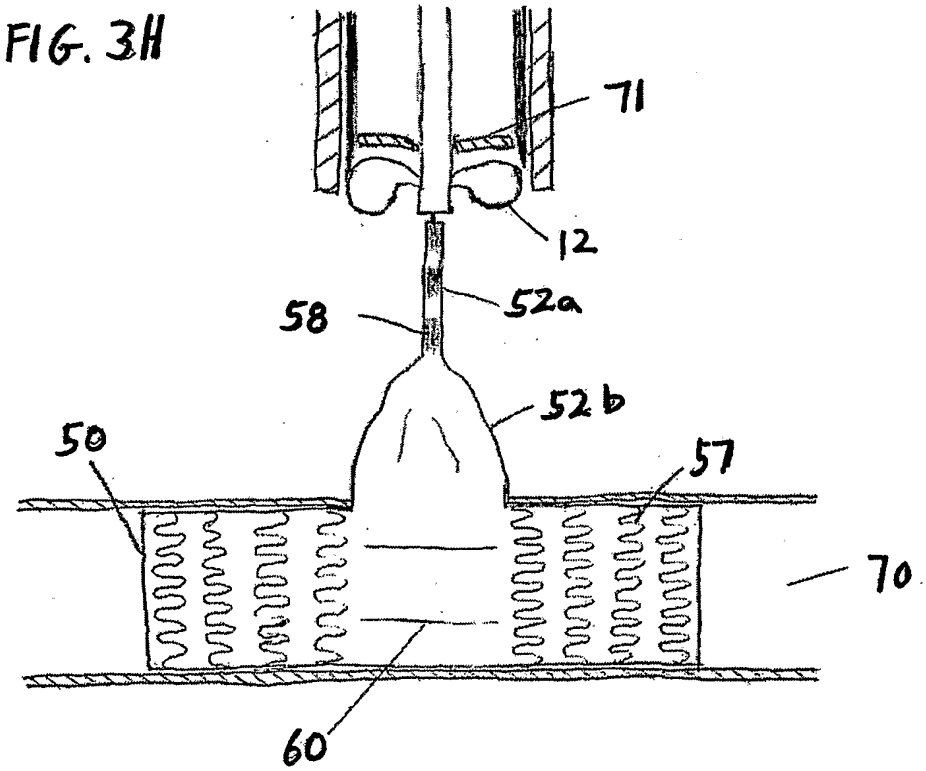


FIG. 3I

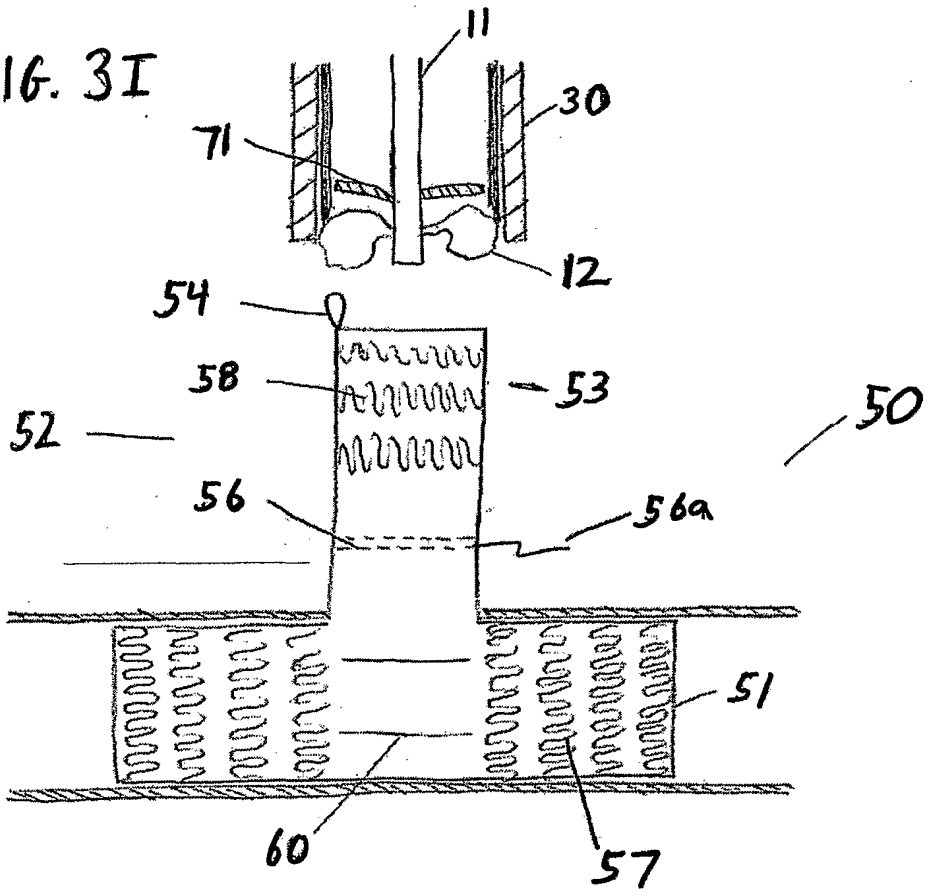


FIG. 4A

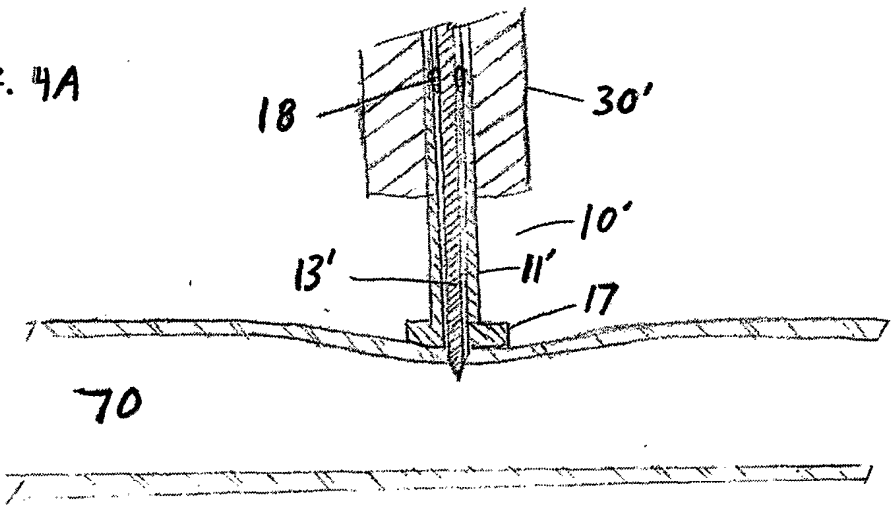


FIG. 4B

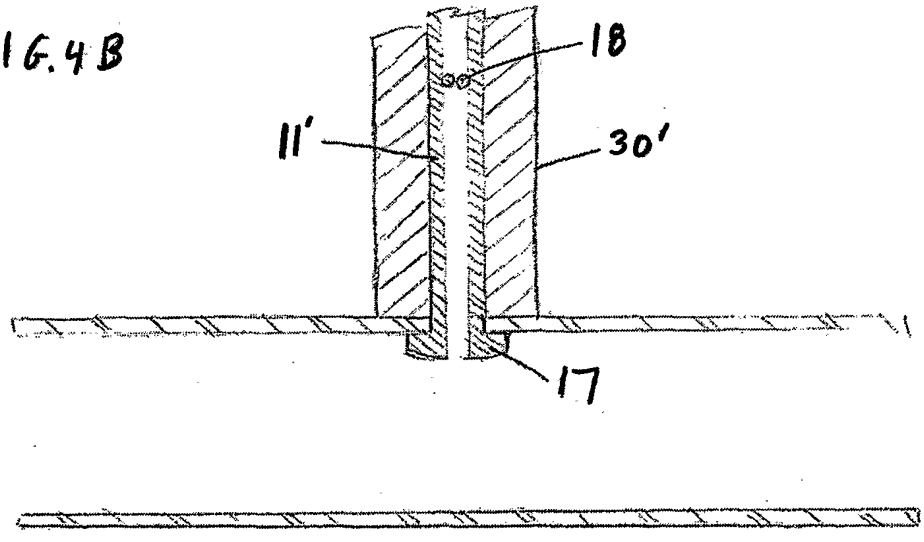


FIG. 4C

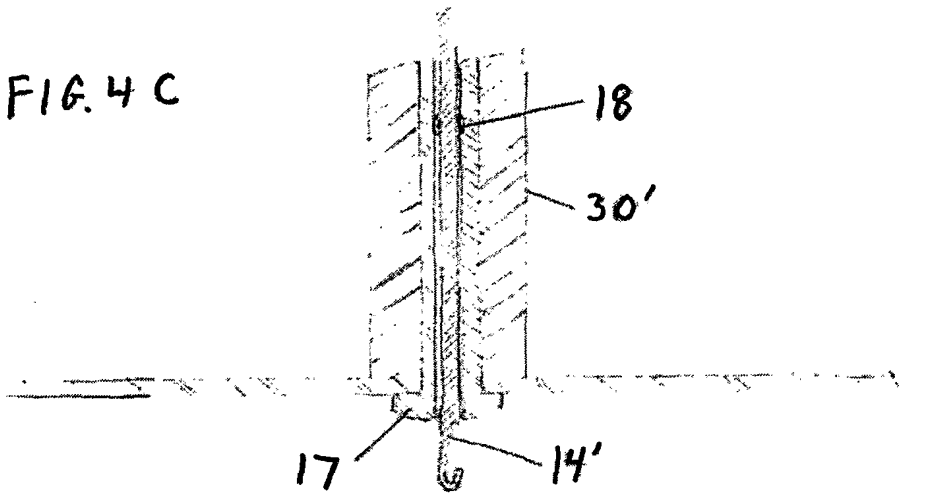


FIG. 4D

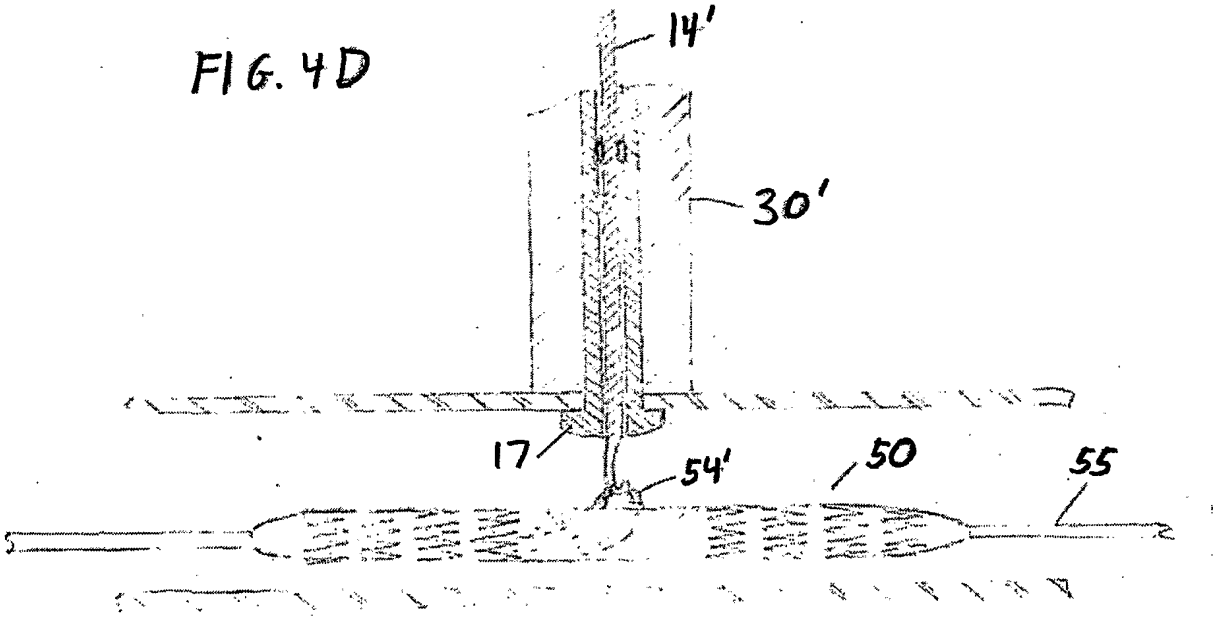


FIG.4E

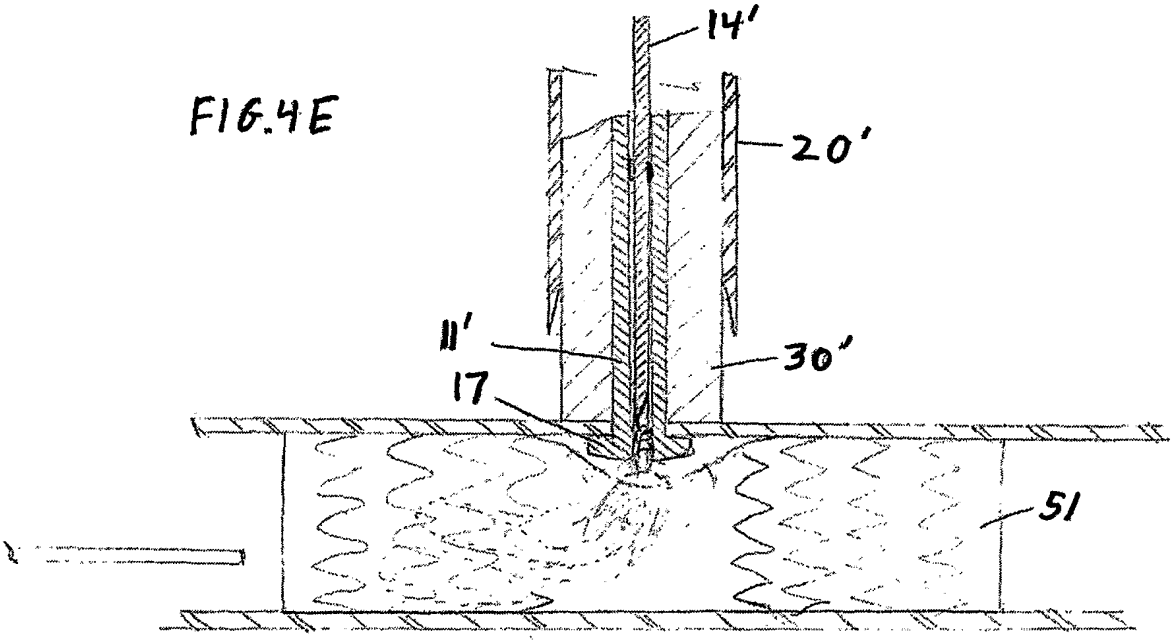
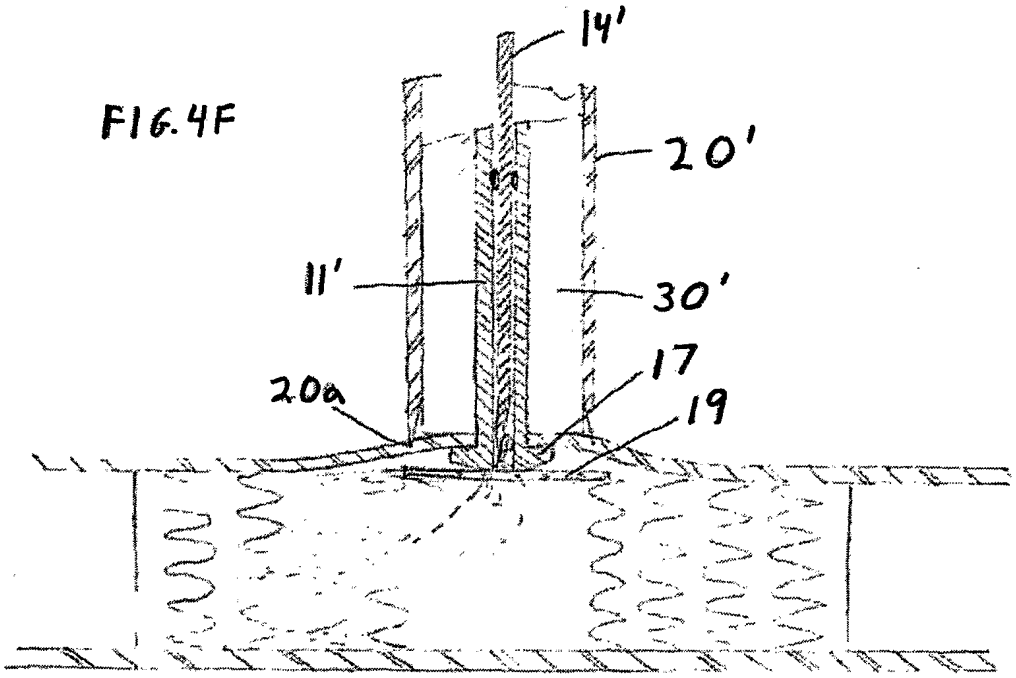


FIG. 4F



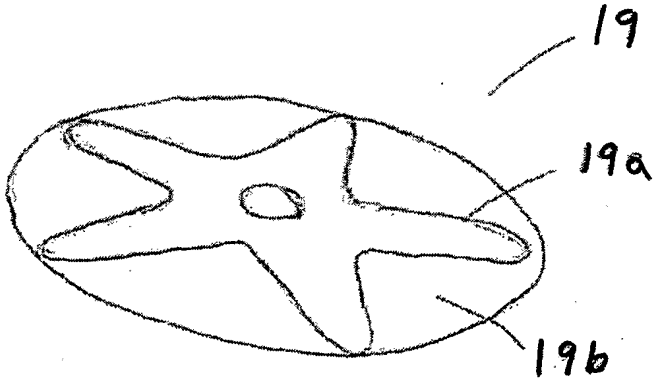


FIG. 4G

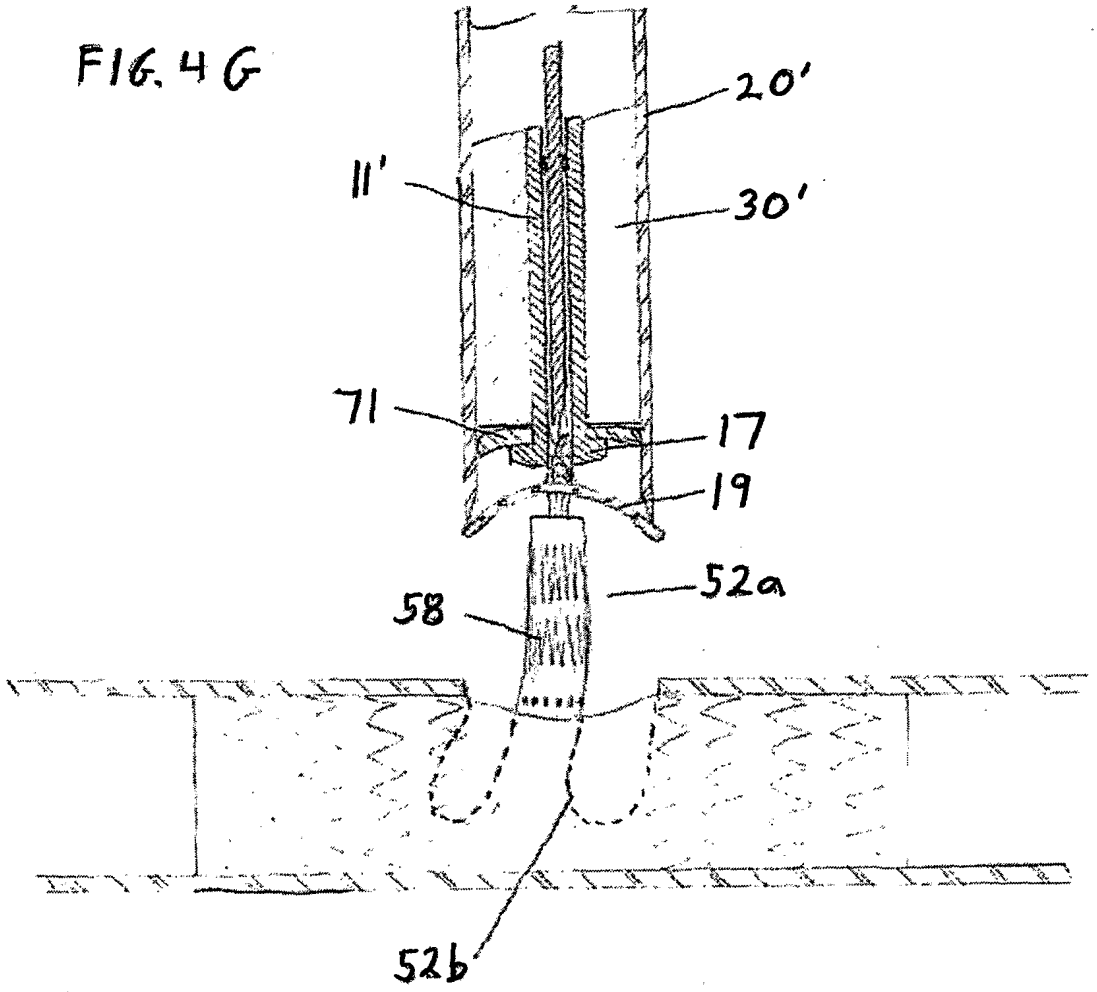
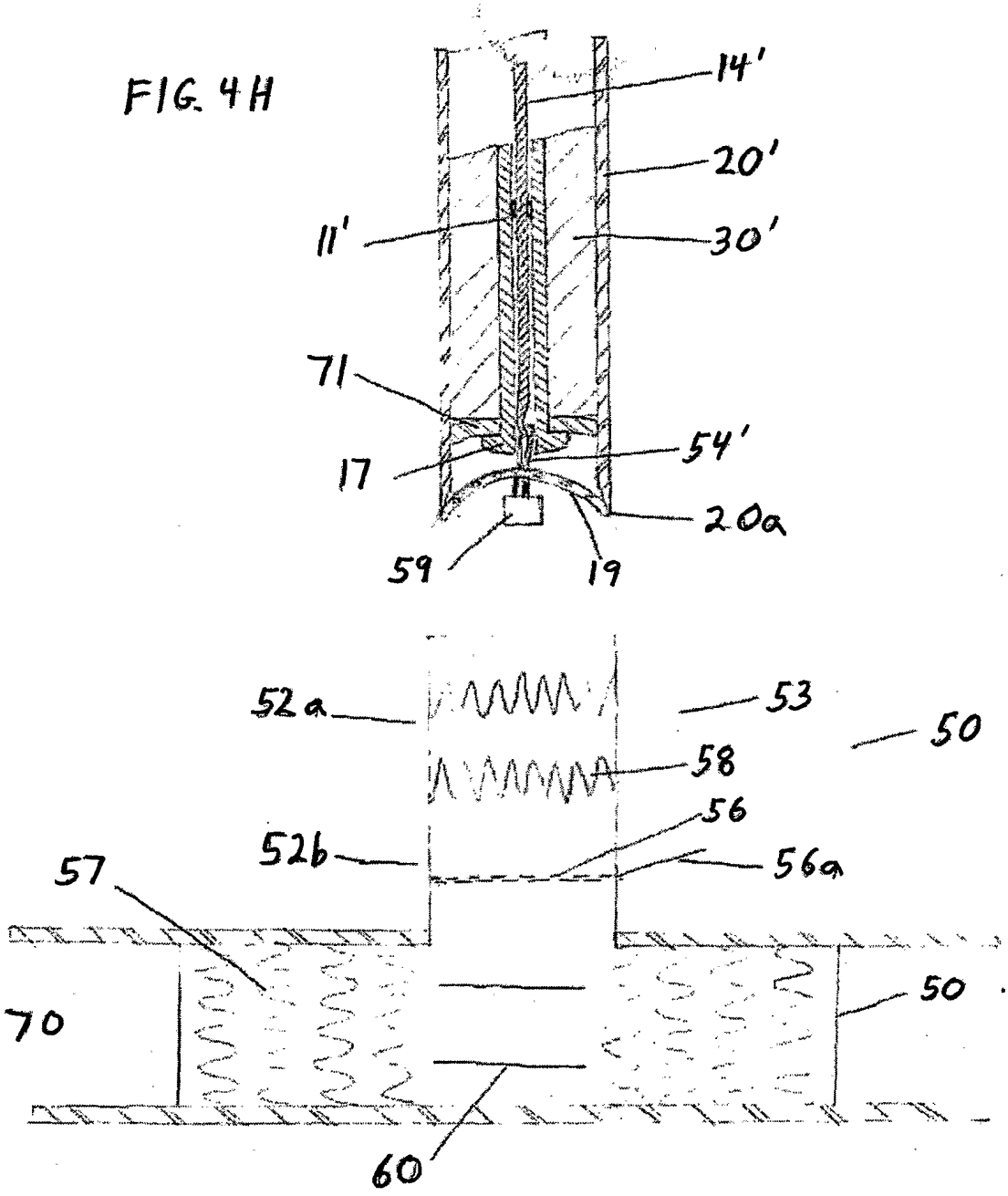


FIG. 4H



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(51) International Patent Classification:
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(21) International Application Number:
PCT/US2005/045373

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15 December 2005 (15.12.2005)

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11/086,577	23 March 2005 (23.03.2005)	US
60/726,223	14 October 2005 (14.10.2005)	US
60/726,222	14 October 2005 (14.10.2005)	US

(71) Applicant *(for all designated States except US)*: **CORREX, INC.** [US/US]; 46 Sunset Road, Weston, Massachusetts 02493 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **BEANE, Richard, M.** [US/US]; 52 Burr Road, Hingham, Massachusetts 02043 (US). **CRUNKLETON, James, A.** [US/US]; 46 Sunset Road, Weston, Massachusetts 02493 (US). **SMITH, Joseph, L., Jr.** [US/US]; 113 Oak Road, Concord, Massachusetts 01742 (US). **BROWN, John, A.** [US/US]; 7970 N. Illinois Street, Indianapolis, IN 46260 (US). **GAMMIE, James, S.** [US/US]; 2207 Wiltonwood Road, Stevenson, MD 21153 (US).

(74) Agent: **PANDISCIO, Mark, J.**; PANDISCIO & PANDISCIO, P.C., 470 Totten Pond Road, Waltham, MA 02451 (US).

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

[Continued on next page]

(54) Title: APPARATUS AND METHOD FOR CONNECTING A CONDUIT TO A HOLLOW VESSEL

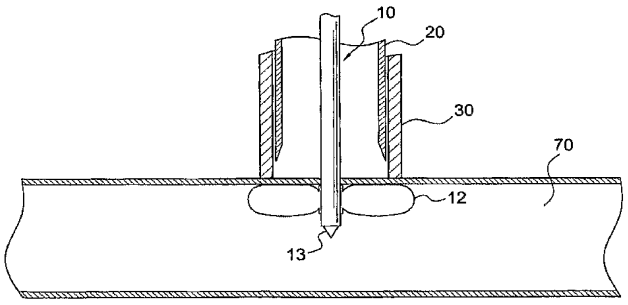

FIG. 3B

(57) Abstract: The present invention provides a system and method for forming a side branch on a hollow vessel, such as the aorta. The side branch is preferably adapted to be connected to a connector conduit, but any other suitable use is also acceptable. The system comprises a graft including a side branch portion, and an applicator comprising a hole forming element adapted to form a hole in the wall of the vessel and an insertion element adapted to be inserted through the wall of the vessel, the insertion element comprising a retraction element adapted to enter into engagement with the graft. The hole forming element may comprise a cutting element adapted to cut a hole in the wall of the vessel, and a positioning element adapted to hold the position of the applicator relative to the vessel. The system further comprises a graft protection element adapted to prevent the graft from being damaged by the cutting element. In this case, the clamping element and the graft protection element may be the same element, for example, an expansion element, which may be expandable from an unexpanded state to fully expanded state and to a partially expanded state. The expansion element may be a balloon, which may be in the shape of a circular toroid, and may include a tension member that restricts the dimensions of the balloon. In addition, the expansion element may be an umbrella mechanism.

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(88) Date of publication of the international search report:
7 May 2009

(15) Information about Correction:
Previous Correction:
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International application No.
PCT/US05/45373

A. CLASSIFICATION OF SUBJECT MATTER
IPC: **A61F 2/06**(2006.01);**A61B 17/32**(2006.01)

USPC: 606/184;623/1.23
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)
U.S. : 606/184;623/1.23

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 practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2002/0082614 A1 (LOGAN et al) 27 June 2002 (27.06.2002), figures 25-32.	1,2,4-8,10-14,18,19,21-27,32-39,41-45,47-51,55,56,58-62,67-73,75-79,81-85,89,90,92-98,103-110,112-119 --- 3,9,15-17,20,28-31,40,46,52-54,57,63-66,74,80,86-88,91,99-102,111
Y	US 2002/0183769 A1 (SWANSON et al) 05 December 2002 (05.12.2002), figure 9.	3,15-17,20,40,52-54,57,74,86-88,91

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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"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	Date of mailing of the international search report
07 May 2008 (07.05.2008)	20 MAY 2008
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Ryan Severson Telephone No. (571) 272-3142

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(51) International Patent Classification: Not classified

(21) International Application Number:
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60/645,677 21 January 2005 (21.01.2005) US

(71) Applicant *(for all designated States except US)*: **MAYO FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH** [US/US]; 200 First Street SE, Rochester, MN 55905 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **SPEZIALI, Giovanni** [US/US]; 130 Cheval Lane NE, Rochester, MN 55906 (US).

(74) Agent: **SAMMONS, Barry, E.**; QUARLES & BRADY LLP, 411 East Wisconsin Avenue, Milwaukee, WI 53202 (US).

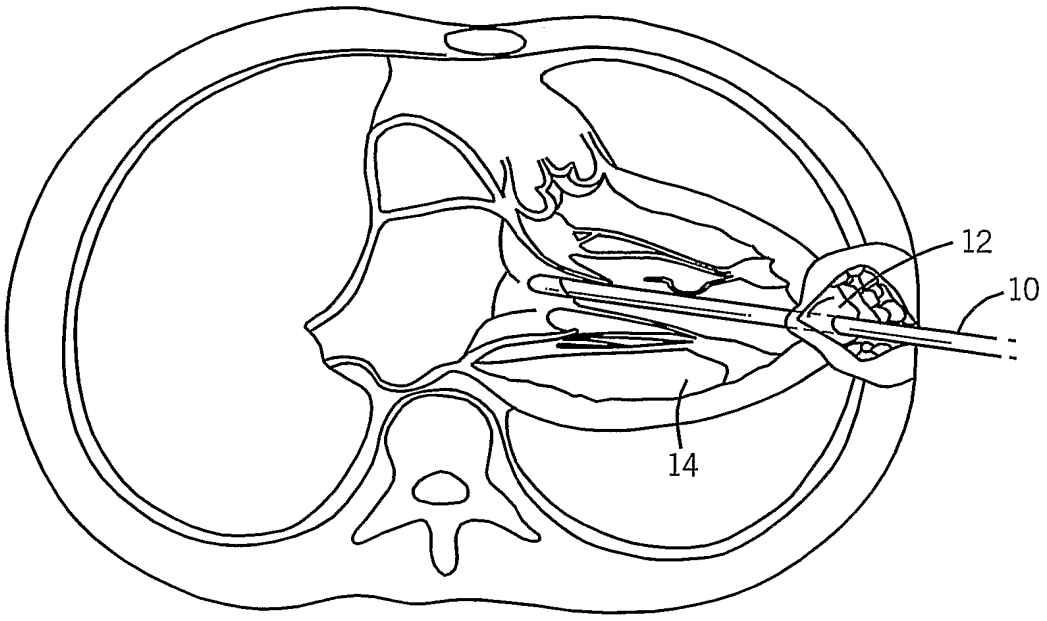
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, 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, HU, IE, IS, IT, LT, LU, LV, MC, NL, 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:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) **Title:** THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS



(57) **Abstract:** An instrument for performing thorascopic repair of heart valves includes a shaft for extending through the chest cavity and into a heart chamber providing access to a valve needing repair. A movable tip on the shaft is operable to capture a valve leaflet and a needle is operable to penetrate a capture valve leaflet and draw the suture therethrough. The suture is thus fastened to the valve leaflet and the instrument is withdrawn from the heart chamber transporting the suture outside the heart chamber. The suture is anchored to the heart wall with proper tension as determined by observing valve operation with an ultrasonic imaging system.

WO 2006/078694 A2

THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is based on U.S. Provisional Patent Application Serial No. 60/645,677 filed on January 21, 2005 and entitled "THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS."

BACKGROUND OF THE INVENTION

[0002] Various types of surgical procedures are currently performed to investigate, diagnose, and treat diseases of the heart and the great vessels of the thorax. Such procedures include repair and replacement of mitral, aortic, and other heart valves, repair of atrial and ventricular septal defects, pulmonary thrombectomy, treatment of aneurysms, electrophysiological mapping and ablation of the myocardium, and other procedures in which interventional devices are introduced into the interior of the heart or a great vessel.

[0003] Using current techniques, many of these procedures require a gross thoracotomy, usually in the form of a median sternotomy, to gain access into the patient's thoracic cavity. A saw or other cutting instrument is used to cut the sternum longitudinally, allowing two opposing halves of the anterior or ventral portion of the rib cage to be spread apart. A large opening into the thoracic cavity is thus created, through which the surgical team may directly visualize and operate upon the heart and other thoracic contents.

[0004] Surgical intervention within the heart generally requires isolation of the heart and coronary blood vessels from the remainder of the arterial system, and arrest of cardiac function. Usually, the heart is isolated from the arterial system by introducing an external aortic cross-clamp through a sternotomy and applying it to the aorta between the brachiocephalic artery and the coronary ostia. Cardioplegic fluid is then injected into the coronary arteries, either directly into the coronary ostia or through a puncture in the aortic root, so as to arrest cardiac function. In some cases, cardioplegic fluid is injected into the coronary sinus for retrograde perfusion of the myocardium. The patient is placed on cardiopulmonary bypass to maintain peripheral circulation of oxygenated blood.

[0005] Of particular interest to the present invention are intracardiac procedures for surgical treatment of heart valves, especially the mitral and aortic valves. According to recent estimates, more than 79,000 patients are diagnosed with aortic and mitral valve disease in U.S. hospitals each year. More than 49,000 mitral valve or aortic valve replacement procedures are performed annually in the U.S., along with a significant number of heart valve repair procedures.

[0006] Various surgical techniques may be used to repair a diseased or damaged valve, including annuloplasty (contracting the valve annulus), quadrangular resection (narrowing the valve leaflets), commissurotomy (cutting the valve commissures to separate the valve leaflets), shortening mitral or tricuspid valve chordae tendonae, reattachment of severed mitral or tricuspid valve chordae tendonae or papillary muscle tissue, and decalcification of valve and annulus tissue. Alternatively, the valve may be replaced, by excising the valve leaflets of the natural valve, and securing a replacement valve in the valve position, usually by suturing the replacement valve to the natural valve annulus. Various types of replacement valves are in current use, including mechanical and biological prostheses, homografts, and allografts, as described in Bodnar and Frater, Replacement Cardiac Valves 1-357 (1991), which is incorporated herein by reference. A comprehensive discussion of heart valve diseases and the surgical treatment thereof is found in Kirklin and Barratt-Boyes, Cardiac Surgery 323-459 (1986), the complete disclosure of which is incorporated herein by reference.

[0007] The mitral valve, located between the left atrium and left ventricle of the heart, is most easily reached through the wall of the left atrium, which normally resides on the posterior side of the heart, opposite the side of the heart that is exposed by a median sternotomy. Therefore, to access the mitral valve via a sternotomy, the heart is rotated to bring the left atrium into a position accessible through the sternotomy. An opening, or atriotomy, is then made in the left atrium, anterior to the right pulmonary veins. The atriotomy is retracted by means of sutures or a retraction device, exposing the mitral valve directly posterior to the atriotomy. One of the fore mentioned techniques may then be used to repair or replace the valve.

[0008] An alternative technique for mitral valve access may be used when a median sternotomy and/or rotational manipulation of the heart are undesirable. In this technique, a large incision is made in the right lateral side of the chest, usually in the region of the fifth intercostal space. One or more ribs may be removed from the patient, and other ribs near the incision are retracted outward to create a large opening into the thoracic cavity. The left atrium is then exposed on the posterior side of the heart, and an atriotomy is formed in the wall of the left atrium, through which the mitral valve may be accessed for repair or replacement.

[0009] Using such open-chest techniques, the large opening provided by a median sternotomy or right thoracotomy enables the surgeon to see the mitral valve directly through the left atriotomy, and to position his or her hands within the thoracic cavity in close proximity to the exterior of the heart for manipulation of surgical instruments, removal of excised tissue, and/or introduction of a replacement valve through the atriotomy for attachment within the heart. However, these invasive, open-chest procedures produce a high degree of trauma, a significant risk of complications, an extended hospital stay, and a painful recovery period for the patient. Moreover, while heart valve surgery produces beneficial results for many patients, numerous others who might benefit from such surgery are unable or unwilling to undergo the trauma and risks of current techniques.

[0010] The mitral and tricuspid valves inside the human heart include an orifice (annulus), two (for the mitral) or three (for the tricuspid) leaflets and a subvalvular apparatus. The subvalvular apparatus includes multiple chordae tendinae, which connect the mobile valve leaflets to muscular structures (papillary muscles) inside the ventricles. Rupture or elongation of the chordae tendinae result in partial or generalized leaflet prolapse, which causes mitral (or tricuspid) valve regurgitation. A commonly used technique to surgically correct mitral valve regurgitation is the implantation of artificial chordae (usually 4-0 or 5-0 Gore-Tex sutures) between the prolapsing segment of the valve and the papillary muscle. This operation is generally carried out through a median sternotomy and requires cardiopulmonary bypass with aortic cross-clamp and cardioplegic arrest of the heart.

SUMMARY OF THE INVENTION

[0011] The present invention is a method and apparatus for performing a minimally invasive thoracoscopic repair of heart valves while the heart is beating. More specifically the method includes inserting an instrument through the subject's chest wall and through the heart wall. The instrument carries on its distal end a movable element which is manipulated to grasp a valve leaflet and hold it while a needle mechanism punctures the valve leaflet and loops a suture around a portion of the valve leaflet. The instrument is withdrawn from the heart along with the suture and the suture is tied off at the apex of the heart after adjusting its tension for optimal valve operation as observed with an ultrasonic imaging system.

[0012] In addition to grasping and needle mechanisms, the instrument includes fiber optics which provide direct visual indication that the valve leaflet is properly grasped. A set of illuminating fibers terminate at the distal end of the instrument around the needle mechanism in close proximity to a set of sensor fibers. The sensor fibers convey light from the distal end of the instrument to produce an image for the operator. When a valve leaflet is properly grasped, light from the illuminating fibers is reflected off the leaflet surface back through the sensor fibers. On the other hand, if the valve leaflet is not properly grasped the sensor fibers see blood.

[0013] A general object of the invention is to provide an instrument and procedure which enables heart valves to be repaired without the need for open heart surgery. The instrument is inserted through an opening in the chest wall and into a heart chamber while the heart is beating. The instrument enables repair of a heart valve, after which it is withdrawn from the heart and the chest.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0014] Under general anesthesia and double-lumen ventilation, the patient is prepped and draped so as to allow ample surgical access to the right lateral, anterior and left lateral chest wall (from the posterior axillary line on one side to the posterior axillary line on the other side). As shown in Fig. 1, one or more thoracoscopic ports are inserted in the left chest through the intercostal spaces and an instrument 10 is inserted through one of these ports into the chest cavity. Alternatively, a small (3-5 cm) left thoracotomy is performed in the fifth or sixth intercostals space on the anterior axillary line. The patient is fully heparinized. After collapsing the left lung,

the pericardium overlying the apex 12 of the left ventricle 14 is opened and its edges are suspended to the skin incision line. This provides close access to the apex of the heart. Guidance of the intracardiac procedure is provided by a combination of transesophageal or intravascular echocardiography (not shown in the drawings) and with direct visualization through a fiber-optical system built into the instrument 10 as will be described in detail below. A double-pledgeted purse-string suture is placed on the apex of the left ventricle 12 and a stab incision is made at that location. The surgical instrument 10 is inserted through this incision, into the left ventricular chamber 14 of the beating heart.

[0015] Referring particularly to Fig. 2, the instrument 10 may be used to grasp a prolapsing segment of the mitral valve 16 and an artificial chorda 18 may be secured to its free edge. Accurate positioning of the implanted artificial chorda 18 is guaranteed by both echo and direct fiberoptic visualization as will be described in detail below. The instrument 10 is then withdrawn from the left ventricle chamber 14 pulling the unattached end of the neo-implanted chorda 18 with it. Hemostasis is achieved by tying the purse-string suture around the incision in the left ventricular apex 12 after the instrument 10 and chorda 18 are withdrawn. As shown in Fig. 3, the neo-implanted chorda 18 is appropriately tensioned under direct echo-Doppler visualization and secured outside the apex 12 of the heart. That is, a tension is placed on the neo-implanted chorda 18 and the operation of the repaired valve 16 is observed on the ultrasound image. The tension is adjusted until regurgitation is minimized.

[0016] While a single chorda 18 is implanted in the above description, additional chorda, or sutures, can be implanted and attached to the apex 12 of the heart wall with optimal tension. In this case the tensions in all the neo-implanted chorda 18 are adjusted until optimal valve operation is achieved.

[0017] As shown in Figs. 4 and 5, the instrument 10 used to perform the above procedure includes a rigid metal shaft 100 having a handle 120 at its extrathoracic (proximal) end which enables the instrument to be manipulated and guided into position. Actuating mechanisms for controlling the grasping mechanism and needle mechanism located at the distal end 140 of the instrument are also mounted near the handle 120. As will be described below, the grasping mechanism

is operated by squeezing the scissor-grip handle 120, and the needle mechanism is operated by moving an up-turned control shaft 122.

[0018] Located on the distal, intracardiac end 140 of the instrument 10 is a grasping mechanism which can be operated to hold a prolapsing valve leaflet. As shown in Figs. 6 and 7, in the preferred embodiment this mechanism is a tip 160 which is supported on the distal end of the shaft 100 by a set of rods 162. The rods 162 slide within the shaft 100 to move the tip 160 between an open position as shown in Figs. 6B and 7 and a closed position as shown in Fig. 6A when the scissor-grip handle 120 is operated. As will be explained below, a mitral valve leaflet is located in the gap between the open tip 160 and the distal end of shaft 100 and it is captured by closing the tip 160 to pinch the valve leaflet therebetween.

[0019] Disposed in a needle lumen 164 formed in the shaft 100 is a needle 180 which connects to the control shaft 122 at the proximal end of shaft 100. Needle mechanism 180 slides between a retracted position in which it is housed in the lumen 164 near the distal end of the shaft 100 and an extended position in which it extends into the sliding tip 160 when the tip is in its closed position. As a result, if a valve leaflet has been captured between the tip 160 and the distal end of shaft 100 the needle may be extended from the lumen 164 by moving control shaft 122 to puncture the captured leaflet and pass completely through it.

[0020] The distal end of the shaft 100 also contains an artificial chorda, or suture 18 that is to be deployed in the patient's heart. The suture 18 is typically a 4-0 or 5-0 suture manufactured by a company such as Gore-Tex. This suture 18 is deployed by the operation of the grasping mechanism and the needle mechanism 180 as described in more detail below.

[0021] The shaft 100 has a size and shape suitable to be inserted into the patient's chest and through the left ventricle cardiac wall and form a water-tight seal with the heart muscle. It has a circular or ellipsoidal cross-section and it houses the control links between the handle end and the intracardiac end of the instrument as well as a fiber optic visualization system described in more detail below.

[0022] As shown in Figs. 8A-8F, the preferred embodiment of the suture deployment system at the distal end of the instrument 10 is positioned around a valve leaflet 16 to be repaired as shown in Fig. 8A. The suture 18 is folded at the

middle to form a loop 19 that is positioned in the tip 160. Both ends of the suture 18 are disposed in a suture lumen 165 formed in the shaft 100 beneath the rods 162. As shown in Fig. 8B, the valve leaflet 16 is grasped by closing the tip 160, and the needle 180 is extended to puncture the leaflet 16 and extend into the tip 160. A notch 166 formed on one side of the needle 180 hooks the suture loop 19. The needle 180 is then retracted back through the leaflet 16 to pull the suture loop 19 through the puncture opening as shown in Fig. 8C. The leaflet 16 is then released and the instrument 10 is withdrawn from the heart as shown in Fig. 8D pulling both ends and the midpoint of the suture 18 with it. As shown in Fig. 8E, the suture 18 is released by the instrument 10 and the surgeon inserts the two suture ends 21 through the loop 19 at its midpoint. The ends 21 are then pulled and the loop 19 slides along the suture 18 back into the heart chamber 14 where it forms a Larks head around the edge of the valve leaflet as shown in Fig. 8F.

[0023] Multiple sutures 18 may be implanted in this manner until a satisfactory result is obtained. After deployment of the sutures 18, the heart wall incision is repaired by either a pre-positioned purse-string suture or by any kind of appropriate hemostatic device or technique. Hemostasis is checked, appropriate chest drainage tubes are positioned and secured, and all incisions are closed.

[0024] As shown in Figs. 9A-9D, a second embodiment of the suture deployment system at the distal end of the instrument 10 is positioned around a valve leaflet 16 to be repaired as shown in Fig. 9A. The suture 18 in this embodiment is a closed loop with one end of the loop disposed in the tip 160 and its other end disposed in the lumen 164 and wrapped around the needle 180. The needle 180 is extended through the grasped valve leaflet 16 into the instrument tip 160 where it hooks one end of the looped suture 18 in a notch 166 formed on one side of the needle as shown in Fig. 9B. The needle 180 is then retracted to pull the the looped suture 18 through the puncture opening in the leaflet 16. The leaflet is then released as shown in Fig. 9C by sliding the tip 160 to its open position. The instrument 10 is then withdrawn as shown in Fig. 9D to slide the unhooked end of the looped suture 18 along the length of the needle toward the leaflet 16 where it forms a Larks head around the leaflet edge.

[0025] The instrument 10 is then withdrawing from the heart chamber 14 pulling the hooked end of the suture 18 through the heart wall. The suture 18 is secured to the outside of the heart apex.

[0026] As shown in Figs. 10A-10D, a third embodiment of the suture deployment system at the distal end of the instrument 10 is positioned around a valve leaflet 16 to be repaired as shown in Fig. 10A. The midpoint 17 of the suture 18 is looped around the lumen 164 and its two loose ends 20 are coiled up in the tip 160. After the tip 160 is closed to capture the valve leaflet 16, the needle 180 is extended through the grasped valve leaflet 16 into the instrument tip 160. The free ends 20 of the suture 18 are positioned in the tip 160 to form a loop 19 and a notch 166 formed on one side of the needle extends through this loop 19 and "hooks" the free ends of the suture 18 as shown in Fig. 10B. The needle 180 is then retracted back into the lumen 164 to pull the hooked ends of the suture 18 through the puncture opening in the leaflet 16. The leaflet is then released as shown in Fig. 10C by sliding the tip 160 to its open position. The instrument 10 is then withdrawn from the heart as shown in Fig. 10D to pull the free ends 20 back through the valve leaflet 16 and a Larks head is formed around the leaflet edge by the midpoint 17 of the suture 18.

[0027] The instrument 10 is then withdrawn from the heart chamber 14 pulling the free ends 20 of the suture 18 through the heart wall. The free ends 20 of the suture 18 are secured to the outside of the heart apex.

[0028] Other suture deployment systems are possible where, for example, the needle may penetrate through the leaflet and link up with a snap fitting device that is attached to one end of the looped suture 18 in the instrument tip 160. The needle then withdraws pulling the device and looped suture back through the penetration opening in the leaflet as described above.

[0029] As shown in Fig. 7 to enhance visibility during this procedure, four fiberoptic channels 170 extend along the length of the instrument shaft 100 and terminate at its distal end. Each channel 170 contains at least one illuminating fiber which connects at its extrathoracic end to a white light source (not shown in the drawings). Each channel 170 also contains at least one sensor fiber which conveys reflected light from the distal end back to a visualization monitor (not shown in the

drawings) connected to its extrathoracic end. In the preferred embodiment each channel 170 includes two illuminating fibers and two sensor fibers.

[0030] The four fiberoptic channels 170 are disposed around the needle lumen 164 such that when a valve leaflet 16 is properly grasped, the valve leaflet tissue 16 rests against the distal end of all the fibers 170. As a result, light is reflected off the tissue back into the sensor fibers and four white circles are displayed on the visualization monitor. When the leaflet 16 is not properly pressed against the distal end of a channel 170, light is not reflected from the leaflet 16 and the visualization monitor displays the red color reflected from blood. When no valve tissue is captured, the monitor shows four red dots and when valve tissue is captured, the dots corresponding to the fiberoptic channels 170 contacting the tissue turn white. If the monitor shows all four dots as white, it means that the valve tissue capture is optimal. If only the upper two dots turn white and the bottom dots remain red, the "bite" on the valve leaflet 16 is too shallow for a proper attachment of the suture 18.

[0031] In addition to the fiberoptic visualization system that insures that a valve leaflet is properly captured, other real-time visualization systems are employed to help guide the instrument 10 to the valve leaflet 16. Preferably a transesophageal or intravascular color-Doppler echocardiography system is used for this purpose. As explained above, this imaging system is also used to determine the length of the neo-implanted artificial chordae in real-time by observing reduction or disappearance of regurgitation by transesophageal or intravascular color-Doppler echocardiography.

CLAIMS

1. A method for repairing a heart valve, the steps comprising:

a) inserting an instrument through the subject's chest wall and into the chest cavity;

b) inserting the distal end of the instrument through a heart wall and entering a heart chamber;

c) grasping a leaflet on the heart valve with a movable device on the distal end of the instrument;

d) puncturing the leaflet with a needle disposed on the distal end of the instrument and drawing a suture through the puncture to connect the suture thereto;

e) anchoring the suture to another structure in the heart;

f) withdrawing the instrument from the heart chamber; and

g) withdrawing the instrument from the chest cavity.

2. The method as recited in claim 1 in which step e) includes withdrawing the suture with the instrument from the heart chamber as recited in step f) and anchoring the suture to the outer surface of the heart wall.

3. The method as recited in claim 2 in which the tension on the suture is adjusted before anchoring by observing the operation of the heart valve using a medical imaging system.

4. The method as recited in claim 1 which includes placing a purse-string suture in the heart wall around the location of the instrument insertion.

5. The method as recited in claim 1 in which the distal end of the instrument is inserted in step b) through the apex of the heart.

6. The method as recited in claim 5 in which step e) includes withdrawing the suture with the instrument from the heart chamber as recited in step f) and anchoring the suture to the outer surface of the heart wall near the apex of the heart.

7. An instrument for repairing a heart valve the combination comprising:

a shaft for insertion through a chest wall and into a heart chamber;

a movable element mounted on the distal end of the shaft and being operable from the extrathoracic end of the shaft to capture and hold a valve leaflet against the distal end of the shaft;

a suture disposed in the distal end of the instrument; and

a needle mechanism mounted on the distal end of the shaft and being operable from the extrathoracic end of the shaft to penetrate through a captured valve leaflet and draw a suture back through the penetration.

8. The instrument as recited in claim 7 which includes:

an illumination fiberoptic that extends through the shaft and terminates at the distal end of the shaft; and

a sensor fiberoptic that extends through the shaft and terminates at the distal end of the shaft;

wherein the distal ends of the fiberoptics are positioned such that light is conveyed to the valve leaflet when the valve leaflet is captured and reflected back through the sensor fiberoptic.

9. The instrument as recited in claim 8 in which there are a plurality of illumination and sensor fiberoptics with their distal ends disposed around the needle mechanism.

10. The instrument as recited in claim 7 in which the movable element is a tip which is slidably mounted to the distal end of the shaft and slidable from an open position in which a space is created between the tip and the distal end of the shaft and a closed position in which the space is substantially reduced to grasp a valve leaflet therebetween.

11. The instrument as recited in claim 10 in which the needle mechanism is operable to extend outward from the distal and of the shaft, through a captured valve leaflet and into the tip.

12. The instrument as recited in claim 11 in which the suture is disposed in the tip and the needle mechanism includes means for attaching to the suture when extended into the tip.

13. The instrument as recited in claim 12 in which the means for attaching is a notch formed along one side of a needle that penetrates through the valve leaflet, the notch being positioned when the needle mechanism is extended into the tip to hook the suture.

14. The instrument as recited in claim 11 in which the suture is disposed in the shaft with a loop formed at its midpoint extending into the tip.

15. The instrument as recited in claim 14 in which the means for attaching is a notch formed along one side of a needle that penetrates through the valve leaflet, the notch being positioned when the needle mechanism is extended into the tip to hook the loop formed in the suture.

16. The instrument as recited in claim 11 in which the suture is a loop and the needle mechanism includes a notch formed along one side of the needle that penetrates through the valve leaflet, the notch being positioned when the needle mechanism is extended into the tip to hook one end of the suture loop disposed therein.

17. The instrument as recited in claim 16 in which another end of the suture loop wraps around the needle mechanism at a point proximal the valve leaflet.

FIG. 1

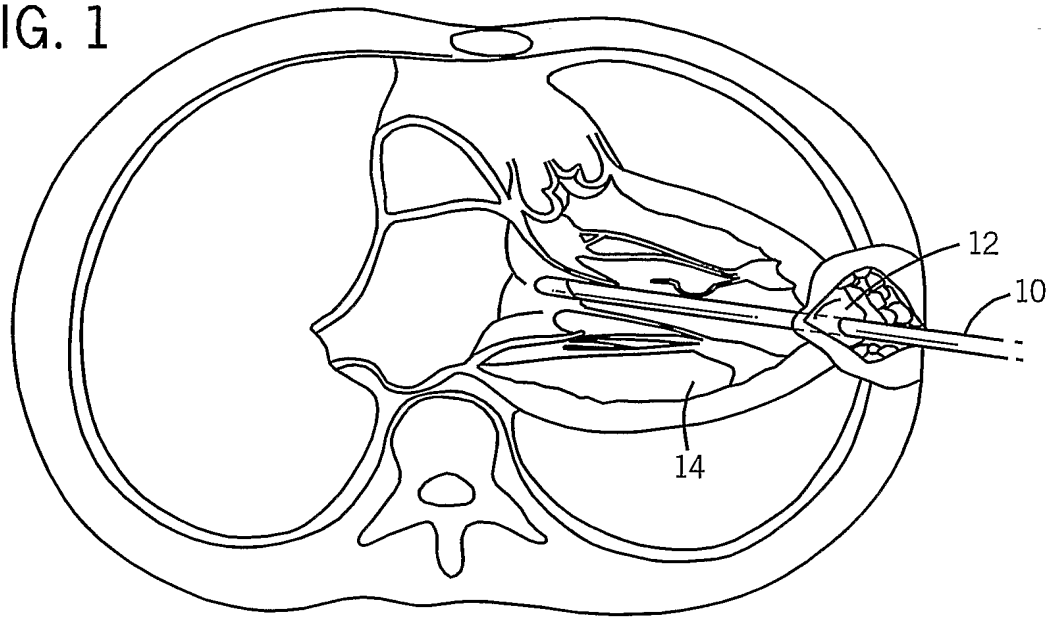


FIG. 2

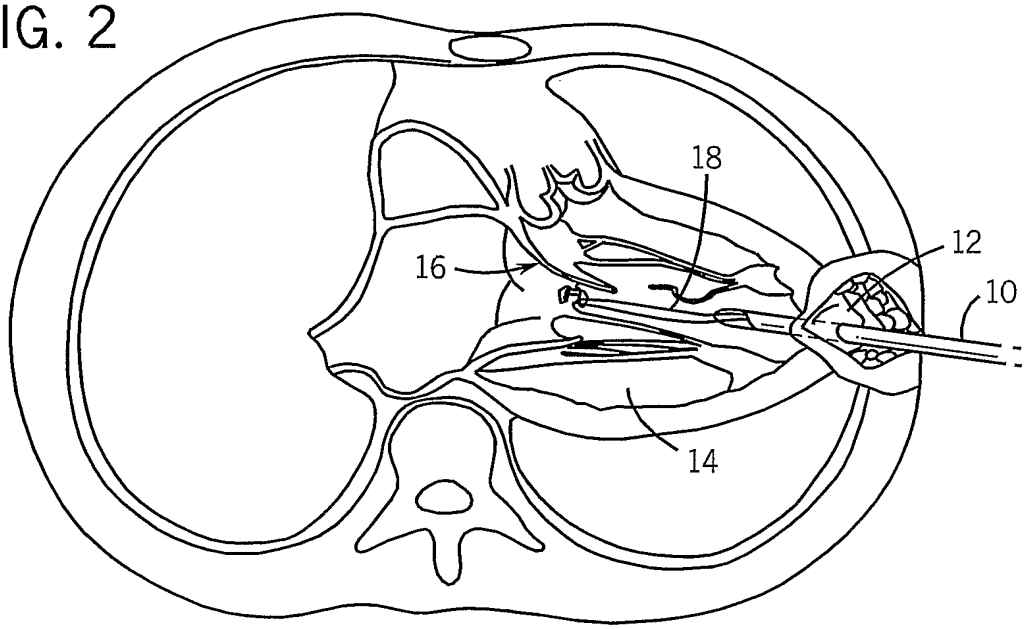


FIG. 3

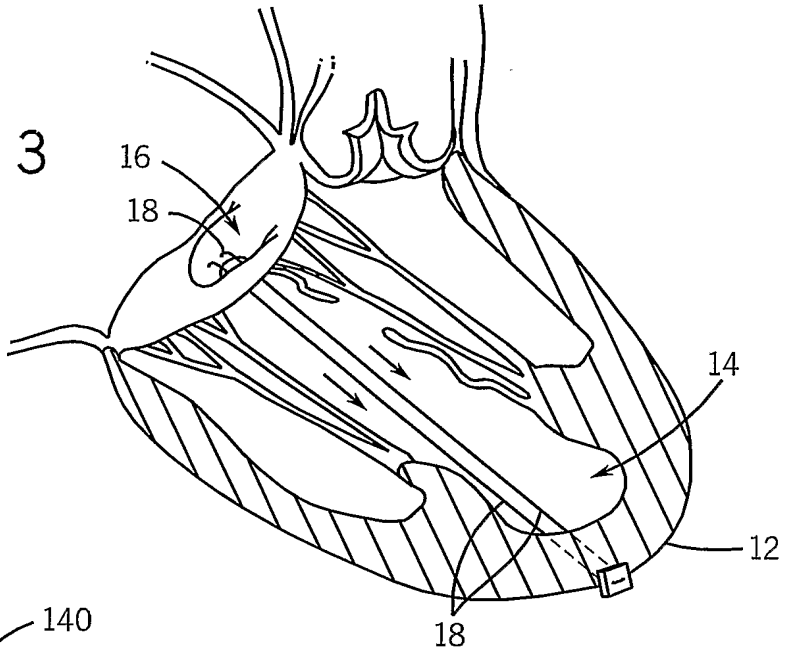


FIG. 4

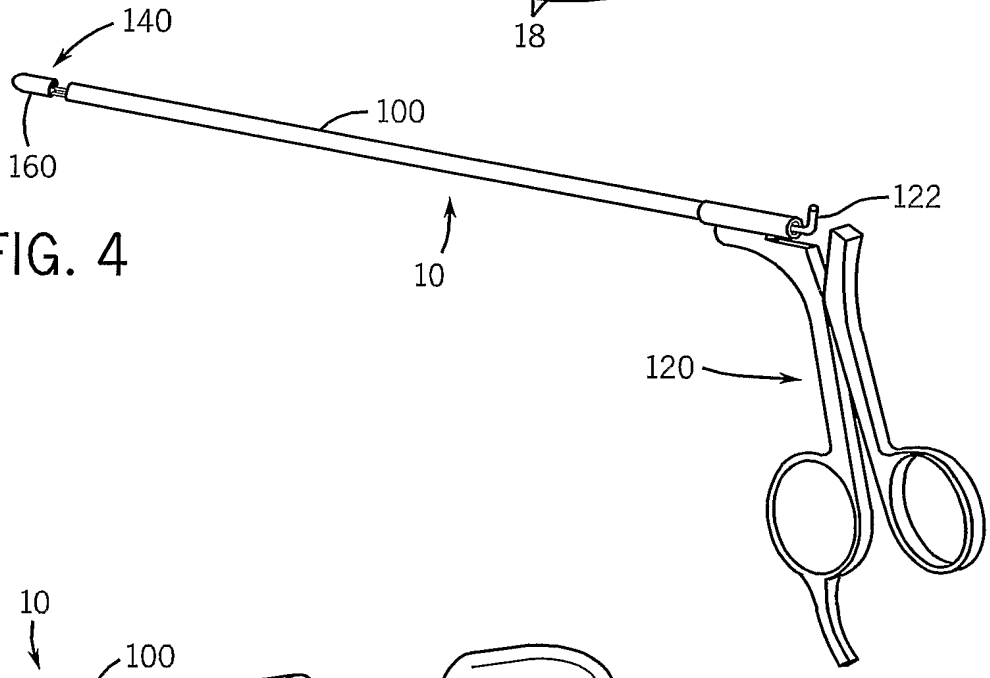


FIG. 5

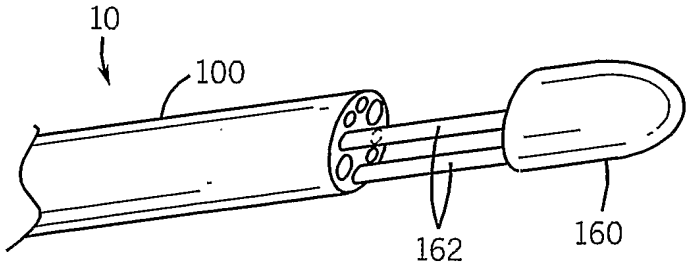


FIG. 6A

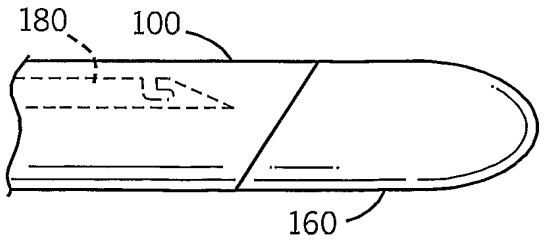
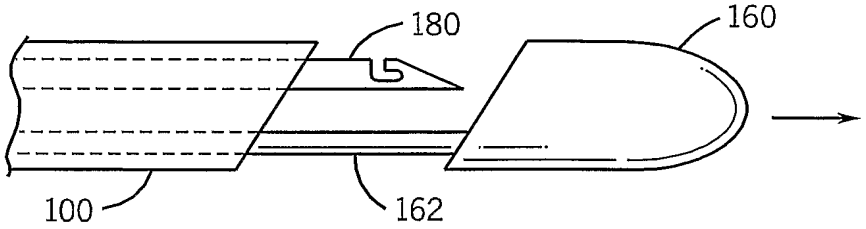


FIG. 6B



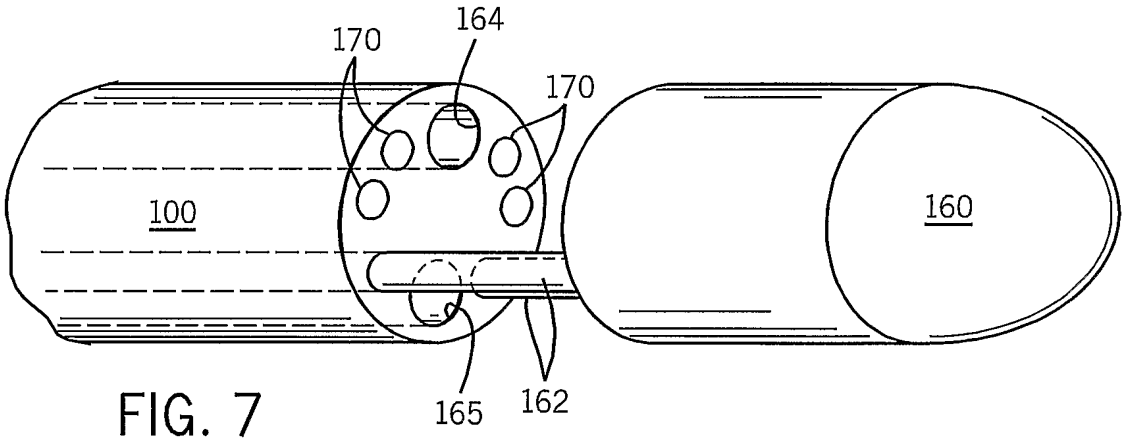


FIG. 7

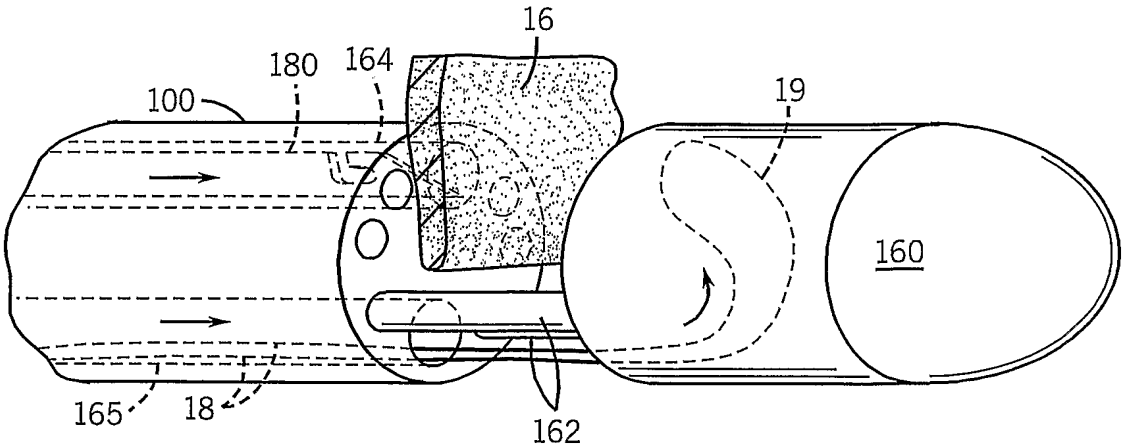


FIG. 8A

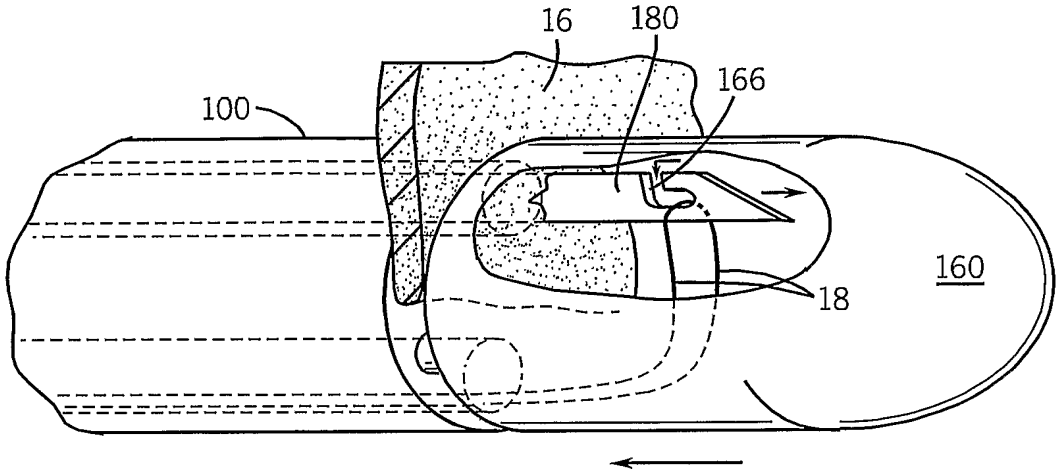


FIG. 8B

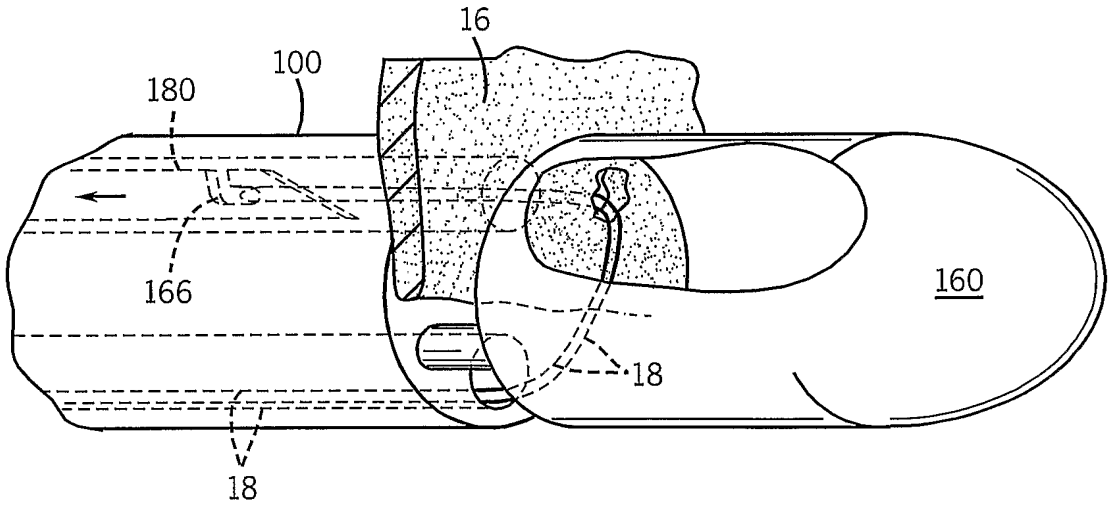


FIG. 8C

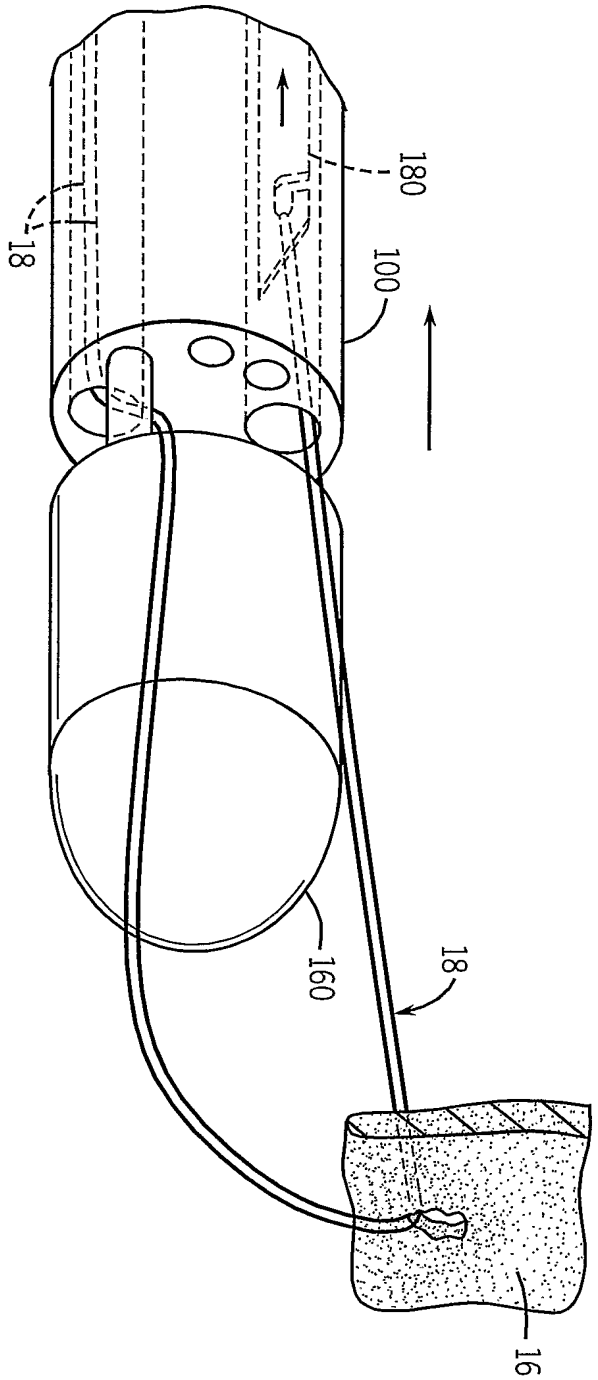


FIG. 8D

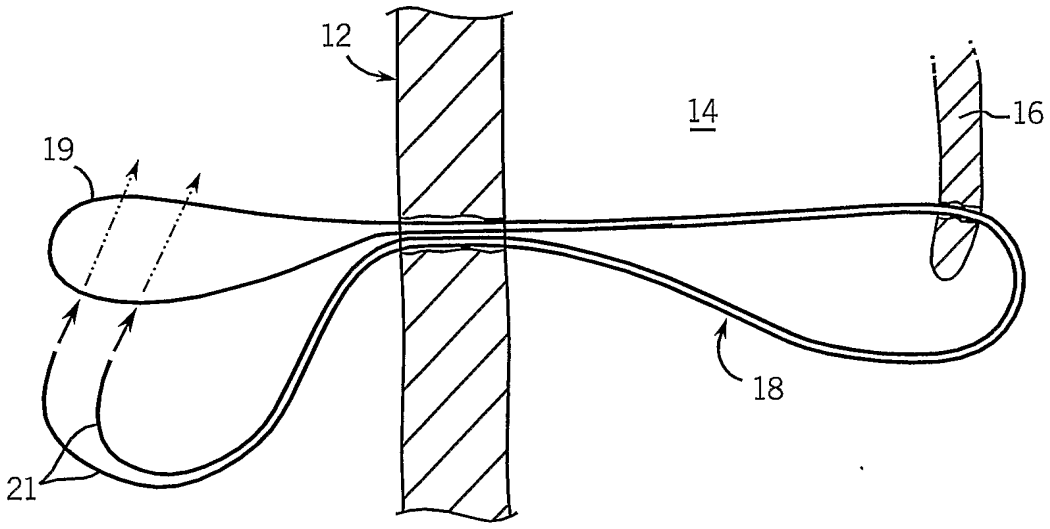


FIG. 8E

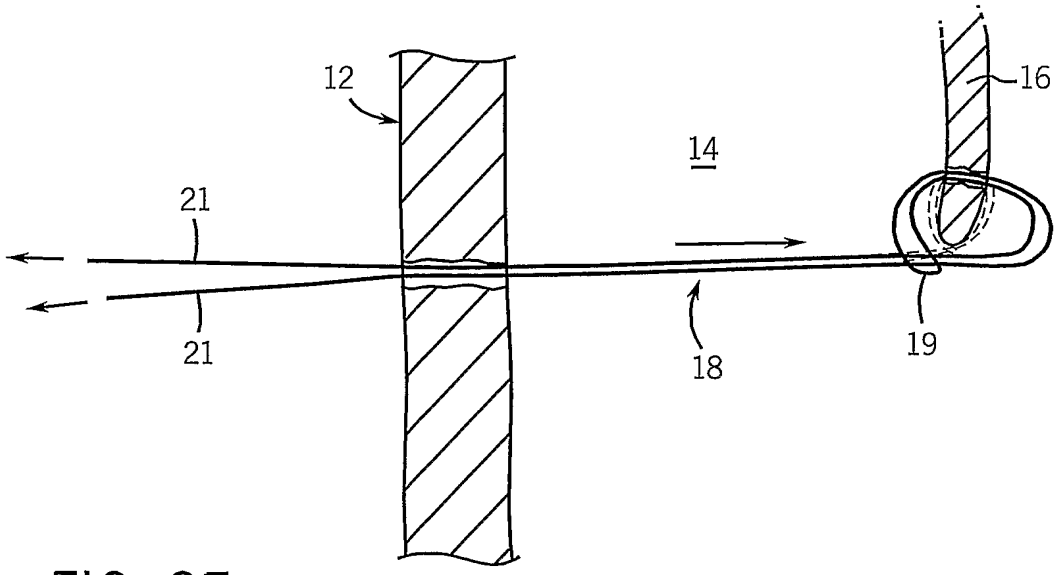


FIG. 8F

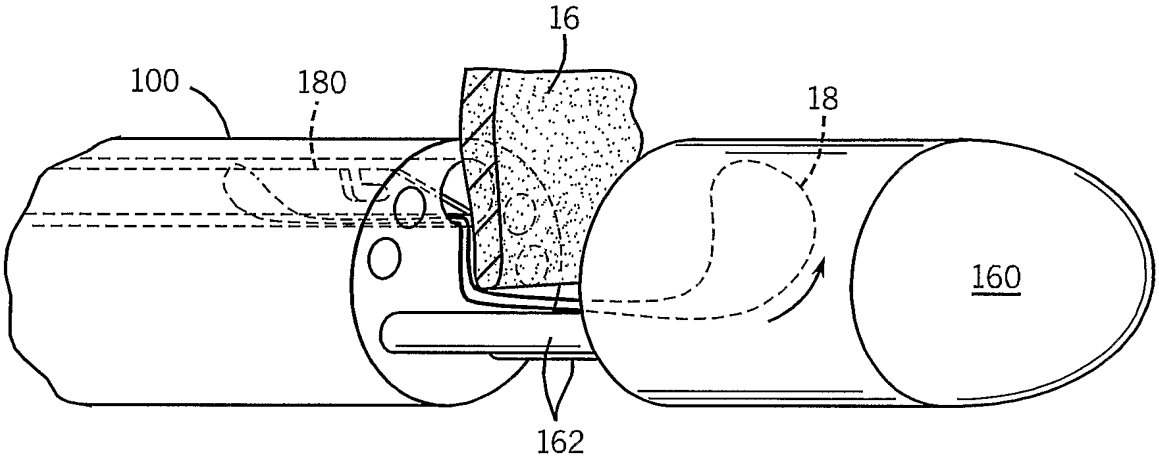


FIG. 9A

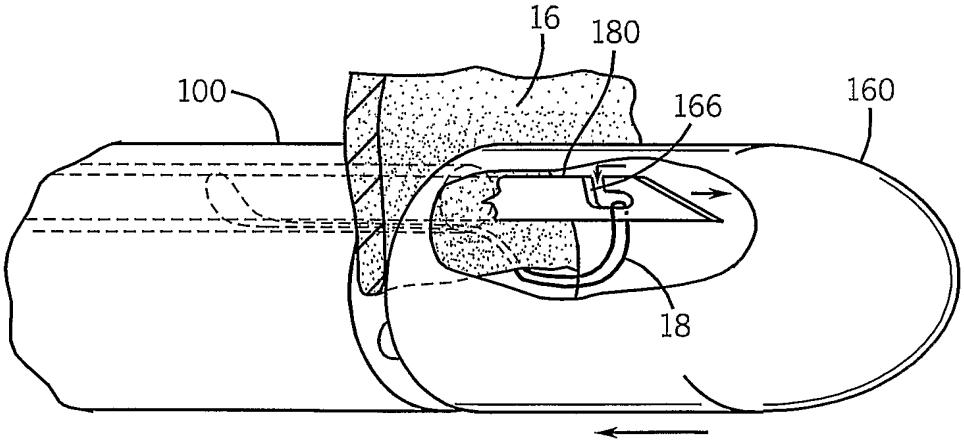


FIG. 9B

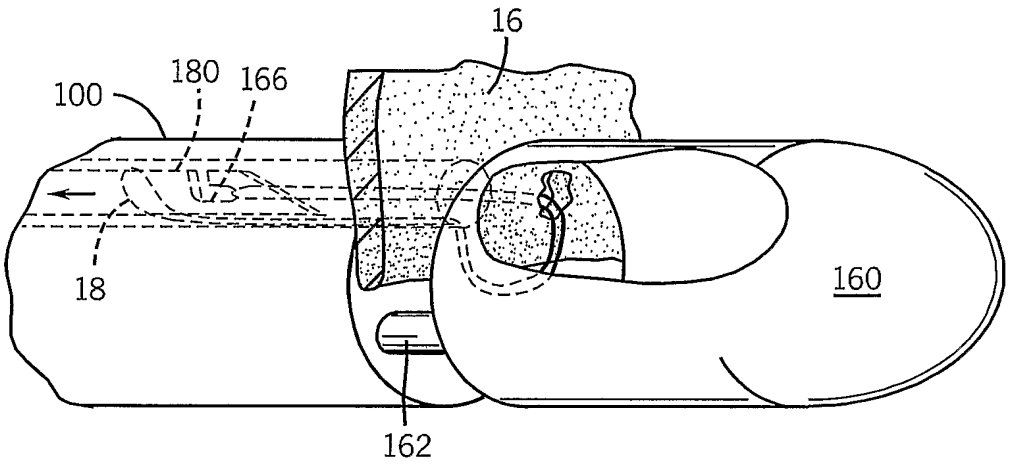


FIG. 9C

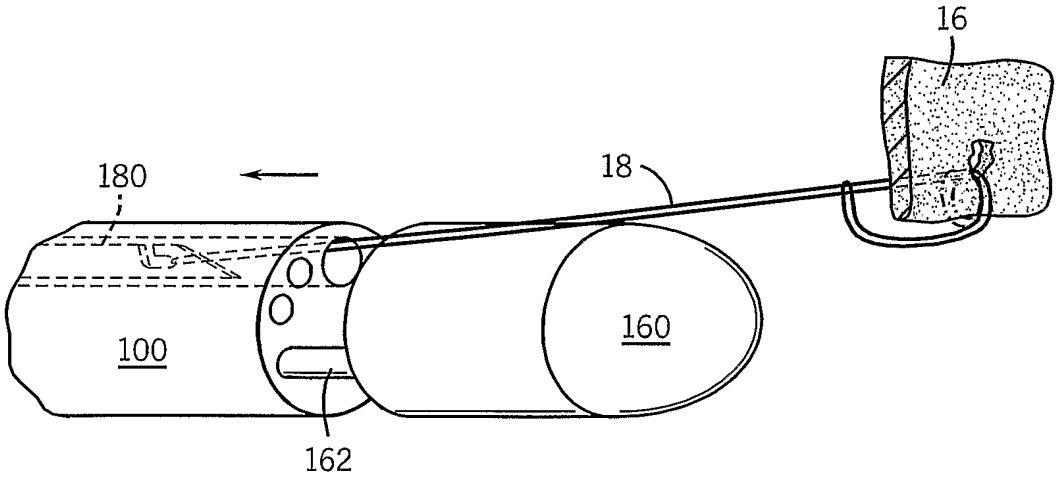


FIG. 9D

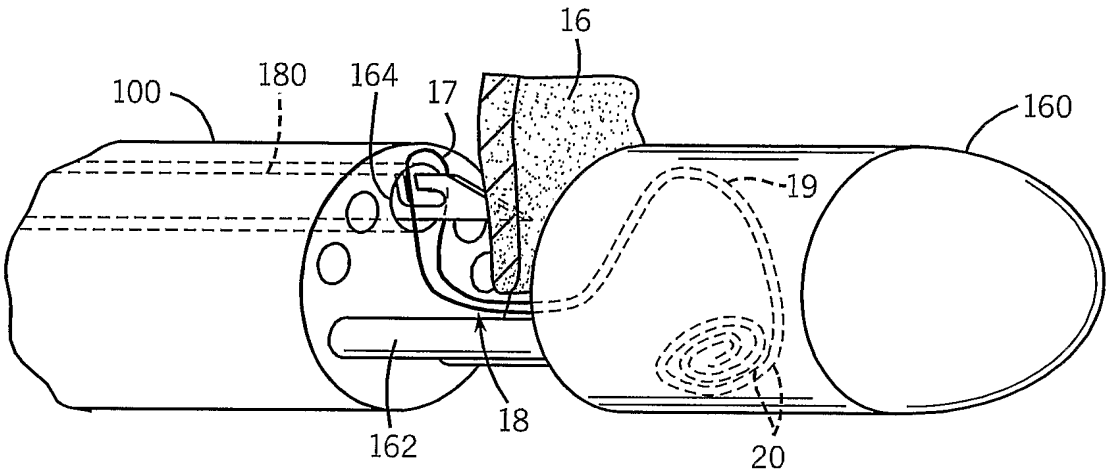


FIG. 10A

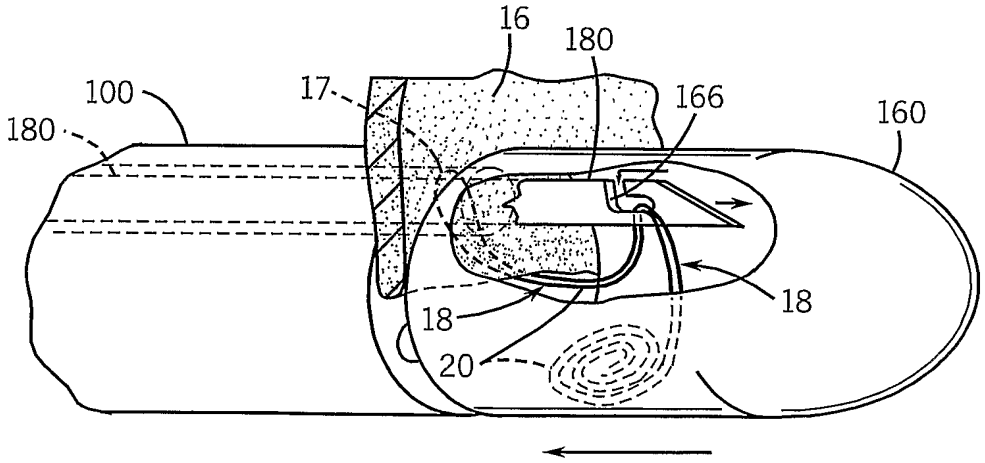


FIG. 10B

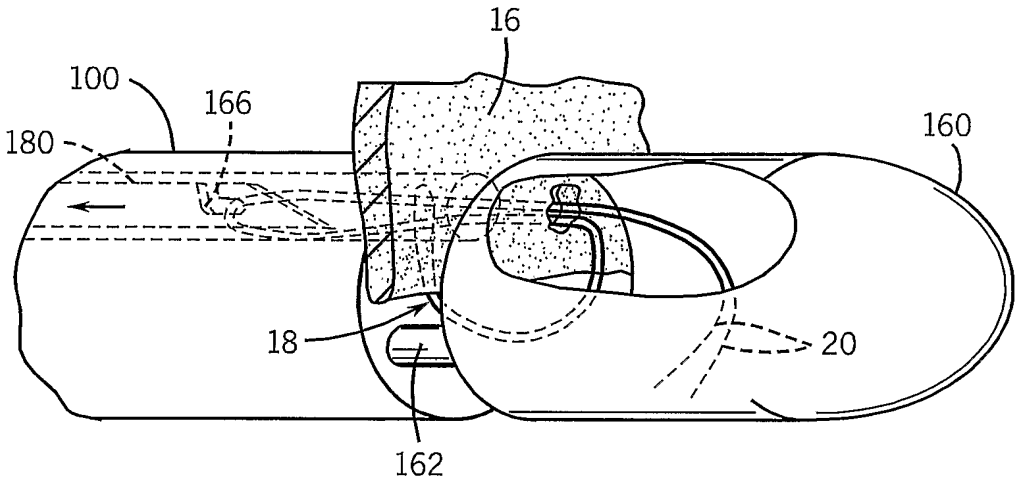


FIG. 10C

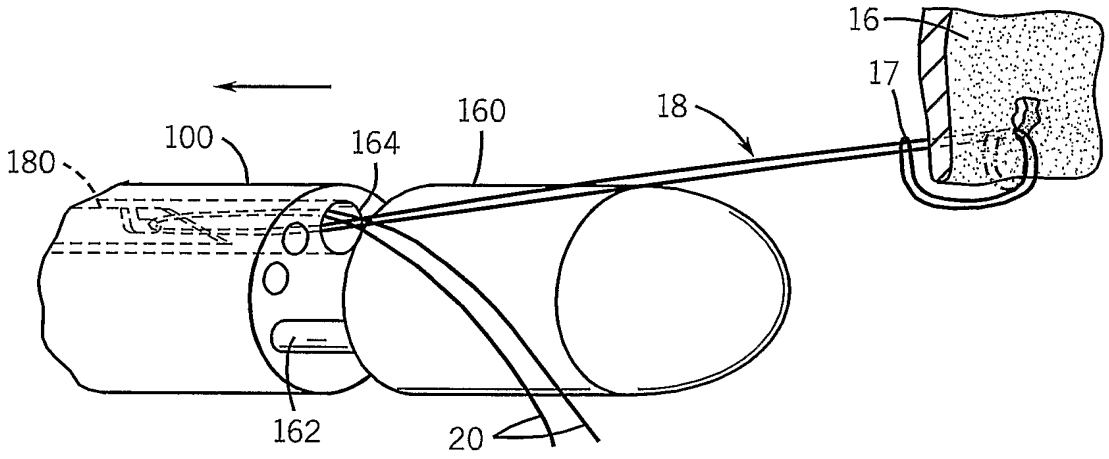


FIG. 10D

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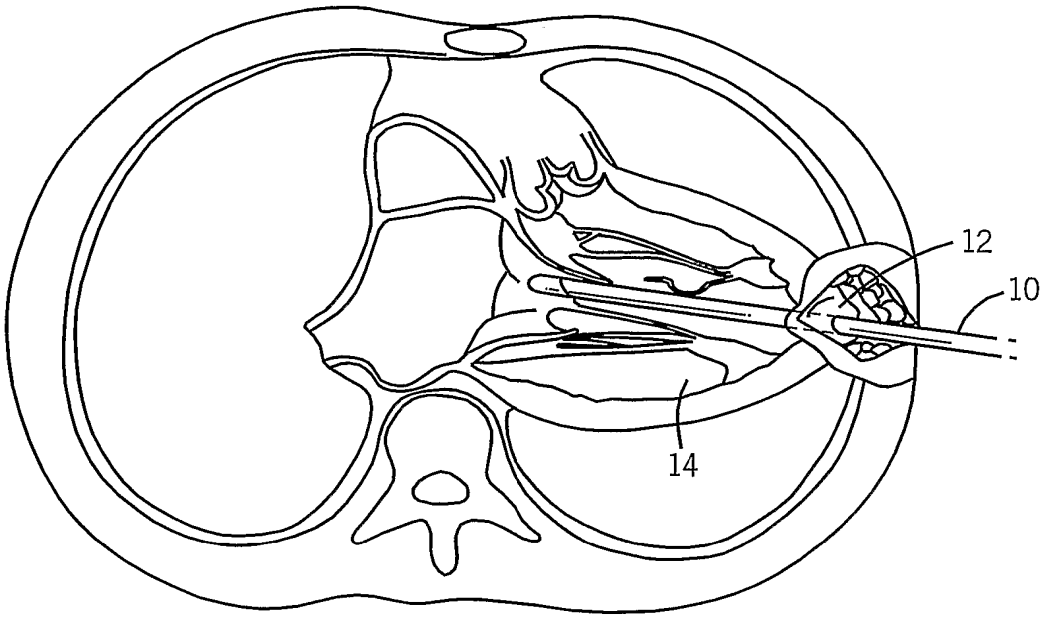
[Continued on next page]

(54) Title: THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS



(57) Abstract: An instrument for performing thorascopic repair of heart valves includes a shaft for extending through the chest cavity and into a heart chamber providing access to a valve needing repair. A movable tip on the shaft is operable to capture a valve leaflet and a needle is operable to penetrate a capture valve leaflet and draw the suture therethrough. The suture is thus fastened to the valve leaflet and the instrument is withdrawn from the heart chamber transporting the suture outside the heart chamber. The suture is anchored to the heart wall with proper tension as determined by observing valve operation with an ultrasonic imaging system.

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Minimum documentation searched (classification system followed by classification symbols)
U.S. : 606/139,144,148

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 practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,908,428 A (SCIRICA et al) 01 June 1999 (01.06.1999), see entire document.	1-7 and 10-17
Y	US 6,149,660 A (LAUFER et al) 21 November 2000 (21.11.2000), see col. 14, lines 34-37.	8 and 9

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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"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

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) **Title:** DEVICES AND METHODS FOR PERICARDIAL ACCESS

(57) **Abstract:** Devices and methods for establishing pericardial access to facilitate therapeutic and/or diagnostic applications. Pericardial access is facilitated, in part, by a tissue grasping device that reliably holds pericardial tissue, even in the presence of fatty deposits. The tissue grasping portion may include a tissue penetrating tip, a tissue dilating distal section, a tissue retention neck, and a tissue stop. When advanced into the pericardium, the tip may serve to create an opening (e.g., pierce, cut, etc.) in the pericardium, the distal section may serve to dilate the opening, the neck may serve to hold the tissue upon recoil of the dilated opening, and the stop may serve to limit further penetration once tissue is retained in the neck.

WO 2006/116310 A2

DEVICES AND METHODS FOR PERICARDIAL ACCESS

CROSS REFERENCE TO RELATED APPLICATIONS

[001] This patent application claims the benefits of priority to U.S. Patent Application No. 11/115,408, filed on April 27, 2005, entitled DEVICES AND METHODS FOR PERICARDIAL ACCESS, the entirety of which is incorporated herein by reference.

FIELD OF THE INVENTION

[002] The present invention relates to devices and associated methods for less invasively accessing the heart. More particularly, the invention relates to devices and methods for accessing the pericardial space around the heart.

BACKGROUND OF THE INVENTION

[003] Access to the outside (epicardial) surface of the heart for various therapeutic and diagnostic purposes is typically achieved using a surgical technique. For example, placement of epicardial leads for electrophysiological applications has been historically performed surgically. However, surgically accessing the heart necessarily involves a certain amount of invasiveness and associated trauma, both of which are desirably minimized.

[004] A variety of less invasive techniques for accessing the epicardial surface of the heart have been proposed in the prior art. These techniques focus, at least in part, on methods of crossing the pericardium and accessing the pericardial space, which are (usually) necessary precursors to accessing the epicardial surface of the heart.

[005] For example, U.S. Patent No. 4,991,578 to Cohen describes a method and system for implanting self-anchoring epicardial defibrillation electrodes within the pericardial space. The system includes means for distending the pericardium from the heart by using suction or by injecting a small volume of fluid into the pericardium. A needle having a lumen therethrough is inserted from a subxyphoid or other percutaneous position into the body tissue until a tip thereof punctures the distended pericardium at a selected location. A guide wire is inserted into the pericardium through the lumen of the needle, and while the guide wire remains in the pericardial space, the needle is removed. A sheath is introduced over the guide wire, with the aid of a dilator, and inserted into the tissue until one end thereof is positioned within the pericardium. The defibrillation lead,

with its electrode in a retracted position, is inserted through the sheath until the electrode is likewise positioned within the pericardium, whereupon the electrode is deployed in order to make contact with a large area of tissue within the pericardium.

[006] Another example may be found in U.S. Patent No. 5,071,428 to Chin et al., which discloses a method and apparatus for providing intrapericardial access and inserting intrapericardial electrodes. Intrapericardial access is established by clamping the wall of the pericardium between elongate jaw elements carrying axially aligned tubular guides and passing a guide wire through the guides and the pericardial tissue therebetween. In the preferred embodiment, the jaw elements include interengageable ratchets for holding the elements in clamping engagement with the wall of the pericardium and aligned pointed extensions for piercing the pericardial tissue clamped between the elements. Further intrapericardial access is provided by an additional tubular guide carried by the jaw element intended to be disposed in the pericardium during placement of the guide wire.

[007] Yet another example may be found in U.S. Patent No. 6,231,518 to Grabek et al., which discloses devices and methods for diagnosis and treatment of cardiac conditions through the pericardial space that are particularly suited for performing minimally invasive procedures from the surface of the heart including electrophysiology mapping and ablation, drug delivery, restenosis prevention, stent placement, etc. Preferred pericardial access devices use suction or mechanical grasping during access of the pericardium. The preferred devices provide for separating the parietal pericardium from the epicardial surface of the heart to reduce the chance of trauma to the heart wall during access of the pericardial space. Once the pericardial space is accessed, a material transport tube can be placed into the pericardial space for administering or removing materials from the pericardial space.

[008] Each of the above-described prior art techniques relies, at least in part, on the use of grasping or suction means to hold the pericardium in order to pull it away from the epicardial surface of the heart and pass a guide or other device therethrough. However, the disclosed grasping and suction means are not highly effective on fatty deposits, which are commonly present on the outer surface of the pericardium. Fatty deposits typically have little structural integrity and are easily delaminated from the pericardium, and therefore do not serve as a reliable means for holding the pericardium.

Because fatty deposits are particularly common in older and/or overweight patients requiring cardiac therapy, these prior art techniques are not highly effective for a significant portion of the patient population.

SUMMARY OF THE INVENTION

[009] To address at least some of these needs, the present invention provides, in exemplary non-limiting embodiments, devices and methods that may more dependably and consistently hold pericardial tissue to facilitate pericardial access and cardiac therapy. In an exemplary embodiment, a tissue grasping device is provided that may reliably hold pericardial tissue, even in the presence of fatty deposits. The tissue grasping portion may include a tissue penetrating tip, a tissue dilating distal section, a tissue retention neck and a tissue stop. When advanced into the pericardium, the tip may serve to create an opening (e.g., pierce, cut, etc.) in the pericardium, the distal section may serve to dilate the opening, the neck may serve to hold the tissue upon recoil of the dilated opening, and the stop may serve to limit further penetration once tissue is retained in the neck. The tissue grasping device may be used to facilitate pericardial access for a variety of therapeutic and/or diagnostic applications as will be described in more detail hereinafter.

[010] According to an exemplary aspect, the invention may include a method for accessing the pericardial space of the heart. The method may comprise, from a remote location, inserting a portion of an access device through the pericardium such that the portion automatically is inserted to a predetermined depth beyond the pericardium. After inserting the portion through the pericardium, the method may further comprise separating the pericardium from the epicardium via the inserted portion of the access device.

[011] In yet another exemplary aspect, a method for separating a first tissue layer from a second tissue layer that is less fibrous than the first tissue layer, so as to provide access to the space between the tissue layers may comprise inserting a portion of an access device through the first tissue layer such that the portion automatically is inserted to a predetermined depth beyond the first tissue layer. The method further may comprise engaging the first tissue layer with the inserted portion of the device and separating the first tissue layer from the second tissue layer by moving the inserted portion in a proximal direction substantially opposite to the direction of insertion.

[012] Yet another exemplary aspect of the invention includes an apparatus for accessing a space between a first layer of tissue and a second, adjacent layer of tissue that is less fibrous than the first layer of tissue. The device may comprise a shaft having a distal portion, wherein the distal portion is configured to be inserted at least through the first tissue layer when the shaft is advanced in a first insertion direction. The distal portion may be further configured to engage with the first tissue layer and to separate the first tissue layer from the second tissue layer when the distal portion is moved in a second direction substantially opposite to the first direction.

[013] A further exemplary aspect includes an apparatus for accessing the pericardial space of the heart to perform a medical procedure. The apparatus may comprise a distal portion being configured to be automatically inserted through the pericardium to a predetermined depth beyond the pericardium and to separate the pericardium from the epicardium. The apparatus may further be configured to provide access to the pericardial space from a location remote from the pericardial space.

[014] According to another exemplary aspect, the invention includes an apparatus for delivering medical devices to the pericardial space of a heart. The apparatus may comprise a dilator shaft having a distal end, a proximal end, and a lumen configured to receive at least one medical device. The dilator shaft may have an expanded region proximate the distal end of the shaft, the expanded region being configured to be positioned in the pericardial space and to engage the pericardium while the at least one medical device is advanced through the lumen and into the pericardial space.

BRIEF DESCRIPTION OF THE DRAWINGS

[015] Aside from the structural and procedural arrangements set forth above, the invention could include a number of other arrangements, such as those explained hereinafter. It is to be understood that both the foregoing summary and the following detailed description are exemplary. The accompanying drawings are included to provide a further understanding of the invention and are incorporated in and constitute a part of this specification. Together with the following detailed description, the drawings illustrate exemplary embodiments and serve to explain certain principles. In the drawings,

[016] Figures 1A and 1B are schematic illustrations of pericardial access devices;

[017] Figures 2A – 2H are schematic illustrations showing the device of Figure 1A in use;

[018] Figures 3A – 3C show a pericardial access device similar to the device of Figure 1A but with more detail;

[019] Figure 3D shows a guide wire for use in the device of Figures 3A – 3C;

[020] Figure 4 is an anatomical illustration showing a sub-xyphoid approach for using a pericardial access device;

[021] Figure 5 is a block diagram showing how a pericardial access device may be used;

[022] Figure 6 is a block diagram showing in more detail how a pericardial access device may be used;

[023] Figures 7 – 13 are schematic illustrations of various alternative pericardial access devices; and

[024] Figures 14 – 15 are schematic illustrations of access supplementation devices.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

[025] The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention.

[026] The devices and methods described herein are discussed herein with reference to the human heart H, but may be equally applied to other animal hearts not specifically mentioned herein. For purposes of discussion and illustration, several anatomical features may be labeled as follows: dermal layer DL; sternum ST; xiphoid XPH; diaphragm DPH; heart wall HW; pericardium P; pericardial space PS; and fatty deposit F.

[027] With reference to Figures 1A and 1B, schematic embodiments of a pericardial access device 1000 are shown. Pericardial access device 1000 may be used to facilitate a variety of cardiac therapies and diagnostics as will be described in more detail hereinafter. Generally, the access device 1000 provides for less invasive surgical access from a point outside the patient's body, through a transthoracic port (e.g., subxyphoid or

intercostal) to the pericardial space around the patient's heart, as will be described in more detail hereinafter. Alternative access devices and approaches are described in U.S. Published Patent Application No. 2004/0148019 A1 to Vidlund et al., the disclosure of which is incorporated by reference herein, all of which may be utilized in one form or another to facilitate the therapeutic and diagnostic techniques described hereinafter.

[028] With continued reference to Figures 1A and 1B, pericardial access device 1000 includes a stylet member 1100 and a trocar member 1200. Stylet member 1100 is removably insertable into trocar member 1200. The trocar member 1200 includes an elongate shaft 1202 and a tissue grasping portion 1210 that, together with the tip of the stylet member 1100, assists in piercing and retaining the pericardial sac such that it may be pulled away from the heart to enlarge the pericardial space. In Figure 1A, the shaft 1202A includes a lumen (shown by dashed line) extending therethrough that is sized to accommodate the stylet 1100 and the guide wire 1300 (shown in subsequent Figures) in sequence. In Figure 1B, the shaft 1202B includes a lumen (shown by dashed line) extending therethrough that is sized to accommodate the stylet 1100 and the guide wire 1300 side-by-side. More specifically, in the embodiment of Figure 1B, the proximal portion of the lumen in the shaft 1202B may have a relatively larger size to slidably accommodate the stylet 1100 and the guide wire 1300 side-by-side, and the distal end of the lumen may have a relatively smaller size to accommodate the stylet 1100 and the guide wire 1300 individually.

[029] Once the pericardial sac is pierced and retained by the tissue grasping portion 1210, and the pericardial sac is pulled away from the heart to enlarge the pericardial space, the stylet member 1100 may be removed from (embodiment of Figure 1A) or retracted into (embodiment of Figure 1B) the trocar member 1200 and a guide wire 1300 may be advanced in its place. With the guide wire extending through the trocar member 1200 and into the pericardial space, the trocar member 1200 may be removed leaving the guide wire in place. The guide wire thus provides pericardial access from a remote site outside the patient's body and may be used to guide and advance other devices into the pericardial space as described herein.

[030] The tissue grasping portion 1210 includes a tissue penetrating tip 1104, a tissue dilating distal section 1212, a tissue retention neck 1214 and a tissue stop 1216.

When advanced into the pericardium, the tip 1104 may serve to create an opening (e.g., pierce, cut, etc.) in the pericardium, the distal section 1212 may serve to dilate the opening, the neck 1214 may serve to hold the tissue upon recoil of the dilated opening, and the stop 1216 may serve to limit further penetration once tissue is retained in the neck.

[031] To further illustrate the operation of the tissue grasping portion 1210, it is helpful to consider the environment in which it is particularly suited for use. The pericardial space PS is defined between the pericardium P (a.k.a., pericardial sac) and the outside (epicardial) surface of the heart HW. The pericardial sac is very close to (and often in intimate contact with) the epicardial surface of the heart. Therefore, it is helpful to separate the pericardium from the epicardium to provide ready and safe access to the pericardial space. Although separating the pericardium from the epicardium may be readily accomplished using open surgical techniques, it is far more difficult to do so using remote access techniques (e.g., endoscopic, transthorascopic, percutaneous, etc.). To delineate between the epicardial and pericardial layers, the tissue grasping portion 1210 selectively penetrates the pericardial tissue to a limited extent when advanced, and holds onto pericardial tissue when retracted.

[032] More specifically, the tissue grasping portion 1210 is configured to hold onto fibrous tissue such as the pericardium, while not holding onto other less fibrous tissues such as the heart wall (epicardium, myocardium, and endocardium) and surrounding fatty tissues. The tissue grasping portion 1210 is also configured to readily pass through fibrous tissue to a predetermined, limited depth. With this arrangement, the tissue grasping portion 1210 may be advanced to penetrate various layers of fibrous and less-fibrous tissue, stop at a predetermined depth when a fibrous tissue layer is penetrated, and upon retraction, grasp onto the fibrous tissue layer (and not the other less-fibrous layers) to pull the fibrous layer away from the adjacent less-fibrous layer. For example, the pericardial access device 1000 may be inserted from a point outside the cardiac space toward the heart, automatically stop when the pericardium is penetrated to a prescribed depth, and selectively hold onto the pericardium when retracted to pull the pericardium away from the epicardial surface, thereby increasing the pericardial space and providing ready access thereto.

[033] With reference to Figures 2A – 2H, the functional operation of the pericardial access device 1000, and in particular tissue grasping portion 1210, may be appreciated in more detail. The access device is advanced (e.g., from a sub-xyphoid or intercostal approach) toward the heart H until the distal end thereof is proximate or engages the pericardium P or fatty deposits F residing on the outside of the pericardium as shown in Figure 2A. The device 1000 is then advanced further such that the tip 1104 penetrates and creates an initial opening in the fatty deposit F and the pericardium P until it resides in the pericardial space PS as shown in Figure 2B. As the device 1000 is advanced further, the distal section 1212 (obstructed and thus not labeled in Figure 2B, but visible in Figures 1A and 1B) elastically dilates the pericardium P to increase the size of the initial opening created by the tip 1104. After the distal section 1212 passes through the pericardial layer, the pericardium elastically recoils about the neck 1214 (obstructed and thus not labeled in Figure 2C, but visible in Figures 1A and 1B) and is retained therein as shown in Figure 2C. The stop (or shoulder) 1216 abuts the recoiled pericardium and prevents further advancement of the device therethrough, and thereby limits excessive penetration or prevents penetration of the tip 1104 into the heart wall HW.

[034] With the pericardium P retained in the neck 1214 of the tissue grasping portion 1210, the stylet 1100 is removed proximally from the internal lumen of the trocar 1200 as indicated by arrow 1500 shown in Figure 2D. Before or after the stylet 1100 is removed, the trocar 1200 may be pulled proximally as indicated by arrow 1510 shown in Figure 2E. By pulling proximally on the trocar 1200 with the pericardium P retained in the neck 1214 of tissue grasping portion 1210, the pericardium P is pulled away from the heart wall HW to increase the space therebetween and allow safe passage into the pericardial space PS of devices subsequently advanced through the trocar 1200. For example, after the stylet 1100 has been removed from the trocar 1200, a guide wire 1300 may be advanced distally through the internal lumen of the trocar 1200 as indicated by arrow 1520 in Figure 2F. The guide wire 1300 is advanced through the trocar 1200 until the distal end portion 1310 thereof resides in the pericardial space.

[035] With the guide wire 1300 extending through the trocar 1200 and the distal end portion 1310 of the guide wire 1300 residing in the pericardial space, the guide wire 1300 may be further advanced into the pericardial space PS to avoid accidental

dislodgement therefrom as the trocar 1200 is removed, leaving the guide wire 1300 in place as shown in Figure 2G. With the guide wire 1300 defining a path from a remote site outside the patient's body to the pericardial space PS, subsequent devices such as dilator 1400 may be readily advanced thereover to supplement access (e.g., enlarge luminal size, retain pericardium, etc.) to the pericardial space PS as shown in Figure 2H. Once pericardial access is established, therapeutic and/or diagnostic devices may be inserted therein as will be described in more detail hereinafter.

[036] With reference to Figures 3A – 3C, a more detailed embodiment of an access device 2000 is shown. With specific reference to Figure 3A, the alternative access device 2000 includes a stylet member 2100 and a trocar member 2200. Stylet member 2100 is removably insertable into trocar member 2200 as shown in Figure 3B. The trocar member 2200 includes a tissue grasping portion 2210 that, together with the tip of the stylet member 2100, assists in piercing and retaining the pericardial sac such that it may be pulled away from the heart to enlarge the pericardial space. Once this is accomplished, the stylet member 2100 may be removed from the trocar member 2200 and a guide wire 2300, as shown in Figure 3D, may be inserted its place. With the guide wire 2300 extending through the trocar member 2200 and into the pericardial space, the trocar member 2200 may be removed leaving the guide wire 2300 in place. The guide wire 2300 thus provides pericardial access from a remote site and may be used to guide and advance delivery devices as described herein.

[037] Stylet member 2100 includes an elongate shaft 2102 having a tissue piercing distal tip 2104 and a proximal hub 2106. Trocar member 2200 includes an elongate hollow shaft 2202, a distally disposed tissue grasping portion 2210 and a proximally disposed hub 2206. The shaft 2202 may comprise a stainless steel hypotube with a lumen extending therethrough. The lumen in the trocar member 2200 may extend through the hub 2206, hollow shaft 2202 and distal tissue grasping portion 2210. The elongate shaft 2102 of the stylet member 2100 is insertable into the lumen extending through the trocar member 2200 such that the distal tip 2104 of the stylet device 2100 protrudes from the distal end of the tissue grasping portion 2210 when the proximal hub 2106 of the stylet member 2100 engages and locks with the proximal hub 2206 of the

trocar member 2200 as best seen in Figure 3B. When assembled, the tip 2104 functions integrally with the tissue grasping portion 2210 and may be considered a part thereof.

[038] The tip 2104 of the stylet member 2100 is configured to pierce tissue, particularly fibrous tissue such as the pericardium surrounding the heart, and less fibrous tissue such as the fatty tissues disposed on the exterior of the pericardium. The tip 2104 may be conical with a sharp apex, semi-conical with one or more sharpened edges, or any other geometry suitable for piercing fibrous tissue. Proximal of the apex, the shape of the tip 2104 may be configured to dilate fibrous tissue, such that once the apex pierces the fibrous layer, the tip serves to dilate (as opposed to cut) the hole initiated by the apex. For example, proximal of the apex, the tip 2104 may be circular in cross-section to minimize propagation of the hole initiated by the apex.

[039] A smooth transition may be provided between the tip 2104 of the stylet 2100 and the tissue dilating distal section 2212 of the tissue grasping portion 2210 such that the distal section 2212 continues to dilate the tissue pierced by the apex of the tip 2104. The distal section 2212 may be the same or similar geometry (e.g., conical with a circular cross-section) as the tip 2104 proximal of the apex. A neck 2214 may be provided proximal of the distal section 2212, the profile (e.g., diameter) of which may be selected to allow the fibrous tissue to elastically recoil and resist withdrawal. A shoulder or stop 2216 may be provided proximal of the neck 2214, the profile (e.g., diameter) of which may be selected to limit or stop penetration of the tip 2104 once the shoulder 2216 engages fibrous tissue. Thus, the tip 2104 and distal section 2212 may be configured to penetrate and dilate fibrous tissue, the neck 2214 may be configured to permit elastic recoil of the fibrous tissue and resist withdrawal therefrom, and the shoulder 2216 may be configured to stop penetration through fibrous tissue.

[040] Various sizes and geometries of the aforementioned components are contemplated consistent with the teachings herein. The size and geometry of the tip 2104, and in particular the apex of the tip 2104, may be selected to initially penetrate fibrous tissue (e.g., pericardial tissue) and less-fibrous tissue (e.g., fatty tissue, epicardial tissue, myocardial tissue, etc.). The size and geometry of the tip 2104 proximal of the apex, and the size and geometry of the distal section 2212 may be selected to elastically dilate (but not over-dilate) fibrous tissue initially penetrated by the apex of the tip 2104. The degree

of elastic dilation of the fibrous tissue may be sufficiently high to provide for elastic recoil around the neck 2214, but not so high as to cause plastic dilation or tearing of the fibrous tissue. The size and geometry of the neck 2214 may be selected such that the fibrous tissue elastically recoils sufficiently to create a relatively high withdrawal force permitting the fibrous tissue layer to be pulled away from adjacent less-fibrous layers without tearing the fibrous tissue layer. The size and geometry of the shoulder 2216 may be selected such that further penetration is prohibited once the shoulder 2216 engages fibrous tissue.

[041] Taking advantage of the fact that fibrous tissue is relatively tough, tends to elastically deform and tends not to tear, whereas less-fibrous or non-fibrous tissue is weaker and tends to plastically deform or tear, the combination of sizes and geometries of the tip 2104, distal portion 2212, neck 2214 and shoulder 2216 may be selected to advance and penetrate through both fibrous and less-fibrous tissue, stop penetration once fibrous tissue is encountered, and grasp the fibrous tissue (while releasing the less-fibrous tissue) upon retraction. As such, the size and geometry of the aforementioned elements may be selected as a function of the characteristics of the tissue layers being separated. In particular, the dimensions and geometries may be chosen to selectively secure (e.g., hold or grasp) tissue of a relatively higher degree of fibrousness or toughness, and release (e.g., not hold or grasp) tissue of a relatively lower degree of fibrousness or toughness.

[042] For selective securing of the pericardium, Figure 3C and the following Table 1 provides example working dimensions by way of illustration, not limitation. Those skilled in the art will recognize that depending on the tissue layers being separated, these dimensions may be modified according to the teachings herein.

Dimension	Example Range	Working Example #1	Working Example #2
A	0.063 – 0.125"	0.125"	0.063"
B	0.020 – 0.060"	0.040"	0.020"
C	0.011 – 0.020"	0.020"	0.011"
D	0.032 – 0.065"	0.032"	0.020"
E	0.032 – 0.065"	0.065"	0.032"
F	0.080 – 0.100"	0.090"	0.080"

Table 1

[043] With reference to Figure 3C and the working examples in Table 1, a number of general observations and statements may be made. For example, after the pericardium is initially pierced by the apex of tip 2104, dimensions A and E are important to achieve the desired amount of elastic pericardial dilation without tearing. Generally speaking, the more pericardial tearing that occurs, the less pericardial retention is achieved. Thus, the larger dimension E is, the longer dimension A may need to be to cause pericardial dilation and minimize tearing. Also, the greater dimension A is relative to E, the lower the force that is required to pierce the pericardium and subsequently dilate it, which may be desirable in some instances. After the pericardium is dilated to the desired degree, the difference between dimensions D and E are important to achieve the desired amount of pericardial retention. To this end, the step from the distal portion 2212 to the neck portion 2214 may be defined as dimension (E – D). Generally speaking, the more elastic pericardial dilation that occurs, the smaller step (E – D) may be to achieve adequate retention. Note also that the depth of tissue penetration is generally governed by the sum of dimensions A and B. While B must be sufficiently wide to accommodate the pericardial layer, dimension A may be adjusted to reduce penetration too far beyond the pericardial layer.

[044] From the foregoing, it is apparent that the tissue grasping portion 2210 together with the tip 2104 of the stylet member 2100 assist in piercing and retaining the pericardial sac such that it may be pulled away from the heart to enlarge the pericardial space. Once this is accomplished, the stylet member 2100 may be removed from the trocar member 2200 and a guide wire 2300, as shown in Figure 3D, may be inserted in its place. Alternatively, the proximal portion of the lumen in the shaft 2202 of the trocar member 2200 may have a relatively larger size to slidably accommodate the stylet 2100 and the guide wire 2300 side-by-side, and the distal end of the lumen may have a relatively smaller size to accommodate the stylet 2100 and the guide wire 2300 individually, thus allowing the stylet 2100 to be pulled proximally but not removed from the trocar 2200 and the guide wire 2300 to be advanced distally in its place. Although a wide variety of guide wire designs may be employed for this purpose, the guide wire design illustrated in Figure 3D has some advantages, particularly when used in combination with trocar member 2200.

[045] With continued reference to Figure 3D, a distal portion of the guide wire 2300 is shown in longitudinal cross-section. Guide wire 2300 includes an elongate shaft 2310 having a proximal end and a distal end. The flexibility of the shaft 2310 increases from its proximal end to its distal end, which may be accomplished by providing reduced diameter or changes in cross section along its length. In the illustrated embodiment, the shaft 2310 of the guide wire 2300 includes a relatively stiff proximal core portion 2312 having a circular cross section, a relatively flexible middle portion 2314 having a rectangular (ribbon-like) cross section, and a highly flexible distal end portion 2316 having a rectangular (ribbon-like) cross section. A radiopaque coil 2320 may be wound around the middle portion 2314 and distal portion 2316, with a proximal end connected to the distal end of the proximal core portion 2312, and a distal end terminating in a distal weld ball 2322 connected to the distal end portion 2316. The distal turns of the coil 2320 may be spaced apart to reduce column strength and increase flexibility as will be discussed in more detail hereinafter.

[046] The guide wire 2300 may be formed of conventional materials using conventional techniques, and may have conventional dimensions except as may be noted herein. The following dimensions are given by way of example, not limitation. The guide wire 2300 may have a diametric profile of about 0.018 inches, for example, or other dimension sized to fit through trocar 2200. In the illustrated embodiment, the proximal core portion 2312 may have a diameter of about 0.018 inches, and the outer profile of the coil 2320 may also have a diameter of about 0.018 inches. The middle portion 2314 may be about 0.010 x 0.002 inches in cross section, and the distal portion 2316 may be about 0.002 x 0.004 inches in cross section and about 1.0 inches in length. The guide wire 2300 may have an overall length of about 44.0 inches, for example, or other dimension sized to extend through and beyond the ends of the trocar 2200 and to provide sufficient length for subsequent devices (e.g., sheaths, dilators, balloon catheters, etc.) to be advanced over the wire 2300. The length of the highly flexible portion(s) of the guide wire 2300 may be selected to be longer than the trocar 2200 such that the guide wire 2300 buckles at the proximal end thereof at a lower force than is required to cause the distal end thereof to penetrate into the epicardial surface of the heart wall.

[047] The middle 2314 and distal 2316 portions of the guide wire 2300 form an atraumatic section. The middle portion 2314 is highly flexible due to its ribbon-like cross-section and relatively small dimensions. The distal portion 2316 has both high flexibility (due to its ribbon-like cross-section and relatively small dimensions) and low buckle strength (due to the spacing of coil turns). Thus, the middle 2314 and distal 2316 portions are rendered atraumatic. This is particularly true for the distal portion 2316 which is the first portion of the guide wire 2300 to extend beyond the distal end of the trocar 2200 when the guide wire is fully inserted therein. The combination of the loosely spaced coils 2320 and the highly flexible ribbon 2316 allows the distal end of the guide wire to deflect laterally when it extends out of the distal end of the trocar and engages the heart wall. Because the buckle strength of the highly flexible atraumatic distal portion is less than the force required to penetrate the heart wall (as may occur with stiffer conventional wires), the risk of the guide wire 2300 inadvertently penetrating into the heart wall when advanced through the distal end of the trocar 2200 is minimized.

[048] The pericardial access devices 1000, 2000 described hereinbefore are particularly suitable for a transthoracic anterior approach as shown in Figure 4 with a dashed line and a distal arrow. The approach utilized for devices 1000, 2000 may comprise a subxiphoid approach as shown. However, a lateral or posterior approach may utilize similar devices 1000, 2000 and techniques to access the pericardial space from the side or back between the ribs (intercostal space).

[049] A general method for using access devices 1000, 2000 is illustrated by block diagram in Figure 5. As indicated by block 10, the method includes the initial step of providing a suitable access device 1000, 2000 such as those described previously. As indicated by block 20, access to the pericardial space may then be established as generally described previously and as described in more detail hereinafter. As indicated by block 30, therapeutic and/or diagnostic device(s) may then be provided depending on the particular clinical application. A variety of clinical applications are enabled by this pericardial access method, non-limiting and non-exhaustive examples of which include: epicardial lead placement and pacing, cardiac repair, valve repair, left atrial appendage occlusion, pulmonary vein occlusion, cardiac ablation, drug delivery, cardiac tamponade relief, cardiac biopsy, and minimally invasive CABG. Each of the foregoing clinical

applications involves a particular set of therapeutic/diagnostic devices and associated delivery tools, non-limiting and non-exhaustive examples of which include: epicardial pacing leads, cardiac restraint devices, valve repair devices, left atrial appendage occlusion devices, pulmonary vein occlusion devices, cardiac ablation systems, drug delivery catheters, cardiac tamponade relief devices, biopsy devices, minimally invasive CABG devices, etc., together with their associated delivery tool(s). As indicated by block 40, the delivery device(s) and the associated therapeutic/diagnostic device(s) may be inserted over or through the access means (e.g., guide wire or sheath, depending on the application) and into the pericardial space PS. The therapeutic or diagnostic application may then be performed as indicated by block 50. After the therapeutic or diagnostic session is complete, the devices may be removed as indicated by blocks 60 and 70. Examples of suitable valve repair devices (e.g., devices for improving valve function) and their corresponding methods of use are disclosed in U.S. Patent Application No. _____, filed on a date even herewith, entitled DEVICES AND METHODS FOR HEART VALVE TREATMENT to Vidlund et al. (Attorney Docket No. 07528.0046), the entire disclosure of which is incorporated herein by reference.

[050] The method of establishing pericardial access as indicated by block 20 in Figure 5 may be broken down into more detail as illustrated in Figure 6. The breakdown shown in Figure 6 is given by way of example, not limitation, to better understand some of the functional aspects of the devices and methods described elsewhere herein. In the illustrated example, pericardial access includes the following sub-steps: dermal traversal 110; soft tissue traversal 120; pericardial engagement/approximation 130; pericardial traversal 140; pericardial retention 150; pericardial retraction 160; pericardial space access 170; access supplementation 180; and intra-pericardial space navigation 190. These steps may be taken alone or in a variety of combinations, divisions or repetitions, and the order may be modified as well.

[051] The sub-steps of percutaneous traversal 110, soft tissue traversal 120, and pericardial engagement/approximation 130 may be accomplished using conventional tools and techniques modified for this particular application. In a percutaneous method, a needle and wire, and/or blunt dilator and/or introducer may be used to pierce and dilate dermal and soft tissue layers. Alternatively, in a surgical method, a blade and/or coring

device and/or cautery device may be used to cut or bore through dermal and soft tissue layers. As a further alternative, a combination of theses tools and methods may be employed for a hybrid percutaneous/surgical methodology. For example, as generally shown in Figure 4, a small incision may be made in the dermal layers and sub-dermal soft tissue layers just below the xyphoid in the direction of the cardiac space just above the diaphragm (to avoid accessing the pleural space and thus eliminating the need for venting). An introducer sheath (e.g., 8F) and dilator may be inserted through the incised area in a direction toward the inferior-anterior side of the pericardial space, generally coplanar with the annulus of the mitral valve. The desired position of the distal end of the introducer (which may be radiopaque) may be confirmed and/or adjusted using fluoroscopic techniques, and once the introducer is in the desired position, the dilator may be removed therefrom. Thus, the introducer sheath extends across the dermal and soft tissue layers and the distal end thereof engages the pericardial sac or resides adjacent thereto.

[052] The sub-steps of pericardial traversal 140, pericardial retention 150, pericardial retraction 160, and pericardial space access 170 may be accomplished using the system described with reference to Figures 3A – 3D. For example, with the introducer sheath extending into the chest cavity and its distal end residing adjacent the pericardial sac, and with the dilator having been removed, the access device 2000 (stylet member 2100 and trocar member 2200 assembled) may be inserted into the introducer until the distal tip thereof engages the pericardium. The position of the distal end of the access device (which may be radiopaque) may be confirmed and/or adjusted using fluoroscopic techniques (e.g., AP and lateral views) to ensure the proper pericardial access point and avoid critical coronary structures (e.g., coronary arteries). To further ensure that critical coronary structures such as arteries, veins, etc. are not in the direct path of the access device 2000, fluoroscopic techniques may be employed to illuminate the coronary vasculature and visualize the anticipated path of the access device 2000 relative thereto.

[053] With tactile feedback and fluoroscopic visualization guiding the physician, the access device 2000 may be further advanced until the tip penetrates the pericardial sac and the shoulder engages the outside of the pericardium to stop further penetration. Once the pericardium is penetrated and the shoulder abuts the outside of the pericardial sac, the

pericardial layer resides within the neck recess of the access device and is retained therein. The stylet member 2100 may be removed from the trocar member 2200, and a guide wire 2300 may be inserted in its place. While applying gentle proximal traction to the trocar member 2200 to pull the pericardium away from the heart wall, the guide wire 2300 may be advanced until its distal atraumatic end extends beyond the distal end of the trocar 2200 and into the pericardial space. With the guide wire 2300 defining a path extending from a location outside the body, into and partially through the chest cavity, and into the pericardial space, the trocar 2200 and the introducer sheath may be removed therefrom.

[054] The sub-step of access supplementation 180 may be accomplished using additional guides, sheaths, dilators, guide wires and/or by a balloon catheter or mechanical dilator advanced over the guide wire. For example, the balloon catheter or dilator may be used to enlarge the size of the hole in the pericardium. A guide catheter (e.g., 6F) may then be advanced over the guide wire into the pericardial space, and the relatively small (0.018 inch diameter) guide wire may be replaced with a relative large (0.035 inch diameter) guide wire. A larger introducer sheath and dilator may then be advanced over the larger guide wire, and the dilator and guide wire may then be removed from the sheath. Thus, the relatively large bore introducer defines a path extending from a location outside the body, into and partially through the chest cavity, and into the pericardial space, thus providing a path for subsequent therapeutic/diagnostic devices.

[055] The sub-step of intra-pericardial space navigation 190 may be accomplished in part by curves provided in the introducer sheath and/or curves provided in the delivery system associated with the particular therapeutic/diagnostic device(s) utilized. However, the extent of intra-pericardial space navigation may be minimized by the appropriate access approach as shown in Figure 4. For example, a desirable access approach results in an introducer extending across the right ventricle and toward the left ventricle, with the curve of the introducer sheath directed toward the left ventricle, which is a common destination site for many therapeutic and diagnostic applications.

[056] With reference to Figure 7, an alternative pericardial access device 2400 is shown. Access device 2400 includes a different tissue grasping mechanism 2410, but may be used with the same stylet 2100 as described previously including tip 2404. Tissue grasping portion 2410 includes a tissue dilating distal section 2412 and a proximal stop or

shoulder 2416 serving the same or similar functions as described previously. Tissue grasping portion 2410 also includes one or more protrusions 2414 that may comprise barbs, ridges, tapered edges (as shown), etc., or may alternatively comprise indentations. The protrusions 2414 may be formed, for example, by partially slicing into the wall of a polymeric (e.g., PEEK) tube and bending the sliced portion outward. The protrusions 2414 may serve to further elastically dilate tissue and retain the tissue upon recoil, similar to the function of the neck described previously.

[057] With reference to Figure 8, an alternative pericardial access device 2500 is shown. Access device 2500 includes a different tissue grasping mechanism 2510, and may be used with the same stylet 2100 as described previously with a modified tip 2504. Tip 2504 includes one or more sharpened edges to reduce the force required to pierce through the pericardium (and other tissues). This may be advantageously employed to penetrate through the pericardium without pushing the pericardium against the heart wall, thus reducing the risk of piercing coronary vasculature. The remaining elements of the tissue grasping portion 2510 may be the same or similar as described previously, including tissue dilating distal section 2512, neck 2514 and stop or shoulder 2516.

[058] With reference to Figure 9, an alternative pericardial access device 2600 is shown. Access device 2600 includes a different tissue grasping mechanism 2610, but may be used with the same stylet 2100 as described previously including tip 2604. Tissue grasping portion 2610 includes a tissue piercing tip 2604, a tissue dilating distal section 2612, a neck 2614 and a proximal stop or shoulder 2616 serving the same or similar functions as described previously. In this embodiment, however, the shoulder 2616 is movable along the length of the distal section 2612 and neck 2614, and is biased in the distal direction by biasing member (e.g., spring) 2620. In operation, the shoulder 2616 slides back (proximal direction) as the tip 2604 and dilating distal section 2612 penetrate tissue. When the tip 2604 and dilating distal section 2612 penetrate through a fibrous tissue layer, the tissue elastically recoils around the neck 2614 and the shoulder 2616 slides forward (distal direction) to fold or plicate the fibrous tissue layer therebetween and thus provide additional retention force. When it is desired to remove the device 2600, the shoulder may be retracted back (proximal direction) to at least partially release the tissue layer therefrom.

[059] With reference to Figure 10, an alternative pericardial access device 3000 is shown schematically. Access device 3000 includes a tubular stylet 3100 arranged side-by-side with a trocar member 3200. Stylet 3100 and trocar member 3200 may be disposed in a sheath 3300 to retain their proximity and to facilitate delivery through dermal and soft tissue layers leading to the access site. As compared to the access devices 1000, 2000 described previously wherein a solid stylet is disposed in a hollow trocar, access device 3000 provides a hollow stylet 3100 disposed adjacent a solid trocar 3200. Whereas the lumen in the hollow trocar 1200, 2200 of access devices 1000, 2000 provided a pathway for the guide wire, the lumen in the hollow stylet 3100 of access device 3000 provides a pathway for the guide wire to be inserted from a remote site outside the patient's body and into the pericardial space.

[060] The hollow stylet 3100 may include an elongate shaft 3102, a distal tissue piercing tip 3104, and a proximally disposed handle 3106. The shaft 3102 and tip 3104 may comprise a metallic or rigid polymeric construction such as a stainless steel hypotube. The trocar 3200 may include an elongate shaft 3202 comprising a metallic or rigid polymeric construction and a proximally disposed handle 3206. The trocar 3200 also includes a tissue grasping portion 3210 having a tissue piercing tip 3204, a tissue dilating distal section 3212, a tissue retaining neck 3214, and a stop or shoulder portion 3216, each of which serve the same or similar function as described previously. However, in use, after the tissue grasping portion 3210 has penetrated and retained a fibrous tissue layer therein, the hollow stylet 3100 is advanced in a distal direction to pierce the tissue layer adjacent the tissue grasping portion 3210 to gain access to the pericardial space and provide a pathway thereto.

[061] With reference to Figures 11A and 11B, two versions (A & B) of an alternative pericardial access device 3400 is shown. Each access device 3400A, 3400B includes a different tissue grasping mechanism 3410A, 3410B but may be used with the same stylet 2100 as described previously including tip 3404. The tissue grasping portions 3410A and 3410B each include a tissue piercing tip 3404, a tissue dilating distal section 3412, a neck 3414 and a proximal stop or shoulder 3416 serving the same or similar functions as described previously. In the embodiment shown in Figure 11A, one or more (e.g., four as shown) wings 3420 extend radially from the distal end of the neck 3414 to

assist in retaining the pericardium. The wings 3420 may comprise a highly elastic or super elastic construction such as NiTi wire. In use, as the tissue grasping portion 3410A is advanced through the pericardium, the wings 3420 are elastically folded back onto the neck 3414 in their delivery configuration. When the distal end of the neck 3414 extends through the pericardium, the wings 3420 elastically expand to their deployed configuration (as shown) in the pericardial space to resist withdrawal therefrom. In the embodiment shown in Figure 11B, the wings 3420 are positioned at the distal end of the shoulder 3416 such that they expand between the pericardium and fatty deposits disposed thereon, or within such fatty deposits to assist in retaining the pericardium. In both embodiments, the wings 3420 provide an increase in surface area upon deployment to more securely retain the pericardium and/or its adjacent layers. It is contemplated that the wings 3420 may be disposed in either or both positions (e.g., distal of neck 3414 or distal of shoulder 3416) as shown in Figures 11A and 11B.

[062] With reference to Figure 12, an alternative pericardial access device 3500 is shown. Access device 3500 includes a different tissue grasping mechanism 3510, but may be used with the either stylet 2100 or hollow stylet 3100 (not shown) as described previously, which is insertable into lumen 3506 of the trocar shaft 3502. Tissue grasping portion 3510 includes a tissue piercing tip 3514 and a helical anchor 3512. In use, as the device 3500 is advanced toward the pericardium, the tip 3514 pierces the pericardium and fatty deposits disposed thereon, and the helical anchor 3512 may be screwed into the same by rotation of the shaft 3502. With the tissue grasping portion 3510 attached to the pericardium, the stylet 2100 or 3100 (not shown) may be advanced through lumen 3506, through the pericardium and into the pericardial space thus providing access thereto.

[063] With reference to Figure 13, an alternative pericardial access device 3600 is shown. Access device 3600 includes a different tissue grasping mechanism 3610, but may be used with the same stylet 2100 as described previously, including shaft 2102, tip 2104, and hub or handle 2106. Tissue grasping portion 3610 includes a tissue piercing tip 3604/2104, a tissue dilating distal section 3612, a neck 3614 and a proximal stop or shoulder 3616 serving the same or similar functions as described previously. In this embodiment, however, the tissue grasping portion 3610 also includes an inflatable balloon 3620 disposed about a distal portion of the neck 3614. An inflation port 3608 is provided

in the hub or manifold 3606 to facilitate inflation and deflation of the balloon 3620 via an inflation lumen extending through the trocar shaft 3602. In use, as the tissue grasping portion 3610 is advanced through the pericardium with the balloon 3620 in its deflated delivery configuration. When the neck 3614 extends through the pericardium, the balloon 3620 may be inflated (i.e., expanded) to its deployed configuration (as shown) in the pericardial space to resist withdrawal therefrom. After a guide wire is inserted into the pericardial space PS in place of the stylet 2100, the balloon 3620 may be deflated to facilitate removal of the device 3600.

[064] With reference to Figure 14, an access supplementation device 200 is shown in the form of a sheath with a distally disposed balloon 210. The device is similar to a conventional sheath and may be used, for example, in the sub-step of access supplementation 180 as described previously. Device 200 includes a multi-lumen tubular shaft 202 with a distally disposed balloon 210 and a proximally disposed manifold 208. Manifold 208 includes a thru port 204 for insertion of devices therethrough, and an inflation port 206 for selective inflation and deflation of balloon 210. Device 200 has the particular advantage of balloon 210 which may reside is the pericardial space and resist pull-out as other devices (e.g., guide wires, dilators, therapeutic devices, etc.) are inserted therethrough.

[065] With reference to Figure 15, another access supplementation device 300 is shown in the form of a dilator with a distally disposed collar 310. The device is similar to a conventional dilator and may be used, for example, in the sub-step of access supplementation 180 as described previously. Device 300 includes a tubular shaft 302 having a lumen extending therethrough, with a distally disposed collar 310 and a proximally disposed manifold 308. Manifold 308 includes a thru port 304 for insertion of devices therethrough, and an infusion port 306 for infusing fluids or flushing the shaft 302. The collar 310 has a proximal ridge that catches on the inside surface of the pericardium when the collar 310 is disposed in the pericardial space to resist pull-out as other devices (e.g., guide wires, dilators, therapeutic devices, etc.) are inserted therethrough or thereover.

[066] Suction may also be applied to device 300 through its internal lumen to cause evacuation of the pericardial space and/or to cause the pericardium to be urged

toward the heart wall. Urging the pericardium toward the heart wall aids in placing devices in intimate contact with the epicardial surface of the heart wall. Optionally, the device 300 may incorporate a steering mechanism known in the art to cause deflection of the tip and facilitate navigation in the pericardial space.

[067] From the foregoing, it will be apparent to those skilled in the art that the present invention provides, in exemplary non-limiting embodiments, devices and methods for establishing pericardial access to facilitate therapeutic and/or diagnostic applications. Further, those skilled in the art will recognize that the present invention may be manifested in a variety of forms other than the specific embodiments described and contemplated herein. Accordingly, departures in form and detail may be made without departing from the scope and spirit of the present invention as described in the appended claims.

WHAT IS CLAIMED IS:

1. A method for accessing the pericardial space of the heart, the method comprising:

from a remote location, inserting a portion of an access device through the pericardium such that the portion automatically is inserted to a predetermined depth beyond the pericardium; and

after inserting the portion through the pericardium, separating the pericardium from the epicardium via the inserted portion of the access device.

2. The method of claim 1, wherein the separating of the pericardium from the epicardium occurs without the use of suction.

3. The method of claim 1, wherein the separating of the pericardium from the epicardium occurs by engaging the portion with an inner surface of the pericardium.

4. The method of claim 1, wherein the inserting the portion of the access device includes inserting a distal portion of the access device, the distal portion comprising a dilation member and a region of reduced cross-section proximal the dilation member.

5. The method of claim 1, wherein the inserting the portion of the access device includes piercing the pericardium.

6. The method of claim 1, wherein the inserting the portion of the access device includes dilating the pericardium.

7. The method of claim 6, wherein dilating the pericardium includes elastically dilating the pericardium.

8. The method of claim 7, further comprising allowing the pericardium to elastically recoil around a region of reduced cross-section of the portion once the portion has been inserted to the predetermined depth.

9. The method of claim 7, wherein elastically dilating the pericardium includes elastically dilating the pericardium by an amount such that the pericardium can be separated from the epicardium without tearing the pericardium.

10. The method of claim 1, wherein the inserting of the portion of the access device such that the portion automatically is inserted to a predetermined depth includes inserting the portion until a region of enlarged cross-section of the portion abuts the pericardium, the region of enlarged cross-section being configured such that it cannot be inserted past the pericardium.

11. The method of claim 10, wherein the region of enlarged cross-section includes a shoulder.

12. The method of claim 1, wherein the separating of the pericardium from the epicardium includes retracting the portion in a proximal direction substantially opposite to the direction of insertion.

13. The method of claim 12, wherein retracting the portion includes releasing tissue less fibrous than the pericardium from the portion of the device.

14. The method of claim 13, wherein the less fibrous tissue includes at least one of epicardial tissue and myocardial tissue.

15. The method of claim 1, wherein the separating of the pericardium from the epicardium includes engaging the pericardium with a region of enlarged cross-section of the portion of the access device.

16. The method of claim 1, further comprising piercing the pericardium with a stylet.

17. The method of claim 1, wherein the access device includes a trocar and the method further comprises piercing the pericardium with a stylet received in a lumen of the trocar.

18. The method of claim 17, further comprising removing the stylet from the trocar after the pericardium is separated from the epicardium.

19. The method of claim 1, wherein the inserting of the portion of the access device through the pericardium includes inserting the portion through varying types of tissue layers making up the pericardium.

20. The method of claim 19, wherein inserting the portion through varying types of tissue layers includes inserting the portion through fibrous tissue and less-fibrous tissue.

21. The method of claim 20, wherein inserting the portion through the fibrous tissue includes inserting the portion through pericardial tissue.

22. The method of claim 21, wherein inserting the portion through less-fibrous tissue includes inserting the portion through fatty tissue.

23. The method of claim 22, wherein the fatty tissue is exterior to the pericardial tissue.

24. The method of claim 1, further comprising performing a medical procedure in the pericardial space.

25. The method of claim 24, wherein the medical procedure is chosen from a diagnostic or treatment procedure.

26. The method of claim 24, wherein the medical procedure is chosen from epicardial lead placement and pacing, cardiac repair, valve repair, left atrial appendge occlusion, pulmonary vein occlusion, cardiac ablation, drug delivery, cardiac tamponade relief, cardiac biopsy, and minimally invasive CABG.

27. The method of claim 24, further comprising delivering a medical device to the pericardial space.

28. The method of claim 27, wherein the delivering of the medical device includes delivering a medical device chosen from epicardial pacing leads, cardiac restraint devices, valve repair devices, left atrial appendage occlusion devices, pulmonary vein occlusion devices, cardiac ablation devices, drug delivery devices, cardiac tamponade relief devices, biopsy devices, and minimally invasive CABG devices.

29. The method of claim 24, further comprising inserting a medical tool into the pericardial space.

30. The method of claim 29, wherein the inserting of the medical tool includes inserting a medical tool chosen from at least one of catheters, sheaths, dilators, and guidewires into the pericardial space.

31. The method of claim 1, further comprising imaging the distal portion of the access device.

32. The method of claim 31, further comprising adjusting and/or confirming the position of the distal portion via the imaging.

33. The method of claim 1, further comprising advancing the access device toward the heart from one of a sub-xyphoid and intercostal approach.

34. The method of claim 1, further comprising traversing soft tissue and dermal layers with the access device prior to inserting the access device into the pericardium.

35. The method of claim 34, wherein the traversing the soft tissue and dermal layers includes percutaneously and/or surgically traversing the soft tissue and dermal layers.

36. A method for separating a first tissue layer from a second tissue layer that is less fibrous than the first tissue layer, so as to provide access to the space between the tissue layers, the method comprising:

inserting a portion of an access device through the first tissue layer such that the portion automatically is inserted to a predetermined depth beyond the first tissue layer;

engaging the first tissue layer with the inserted portion of the device; and

separating the first tissue layer from the second tissue layer by moving the inserted portion in a proximal direction substantially opposite to the direction of insertion.

37. The method of claim 36, wherein the separating of the first tissue layer from the second tissue layer occurs without the use of suction.

38. The method of claim 36, wherein the separating of the first tissue layer from the second tissue layer occurs without direct visualization of the layers.

39. The method of claim 36, wherein the moving of the portion to perform the separating step includes manipulating the portion from a location remote from the tissue layers.

40. The method of claim 36, further comprising dilating the first tissue layer.

41. The method of claim 40, wherein the dilating includes elastically dilating the first tissue layer.

42. The method of claim 40, wherein the dilating includes dilating tissue of the first tissue layer substantially without tearing the tissue.

43. The method of claim 40, wherein the dilating occurs during the inserting of the portion.

44. The method of claim 40, further comprising allowing the dilated tissue layer to recoil around a region of reduced cross-section of the portion.

45. The method of claim 36, further comprising inserting a medical instrument into the space between the separated tissue layers.

46. An apparatus for accessing a space between a first layer of tissue and a second, adjacent layer of tissue that is less fibrous than the first layer of tissue, the device comprising:

a shaft having a distal portion,

wherein the distal portion is configured to be inserted at least through the first tissue layer when the shaft is advanced in a first insertion direction, and

wherein the distal portion is further configured to engage with the first tissue layer and to separate the first tissue layer from the second tissue layer when the distal portion is moved in a second direction substantially opposite to the first direction.

47. The apparatus of claim 46, wherein the distal portion is configured to separate the first tissue layer from the second tissue layer without the use of suction.

48. The apparatus of claim 46, wherein the distal portion is configured to provide access to the space between the first and second tissue layers from a location remote from the tissue layers.

49. The apparatus of claim 46, wherein the distal portion is configured to be manipulated to separate the first and second tissue layers without direct visualization of the tissue layers.

50. The apparatus of claim 46, wherein the distal portion is configured to be imaged.

51. The apparatus of claim 46, wherein the distal portion is configured to be imaged via fluoroscopy.

52. The apparatus of claim 46, wherein the distal portion is configured to be automatically inserted to a predetermined depth.

53. The apparatus of claim 46, wherein the distal portion is configured to penetrate the first tissue layer and automatically be limited from further penetration at a predetermined depth of insertion.

54. The apparatus of claim 46, further comprising a penetration tip configured to penetrate the first tissue layer and second tissue layer during insertion of the distal portion.

55. The apparatus of claim 54, wherein the distal portion comprises a dilation member.

56. The apparatus of claim 55, wherein the dilation member is configured to dilate tissue of the first tissue layer substantially without tearing the tissue.

57. The apparatus of claim 56, wherein the dilation member is configured to elastically dilate tissue of the first tissue layer.

58. The apparatus of claim 56, wherein the dilation member is configured to elastically dilate tissue of the first tissue layer such that the dilated tissue is capable of recoiling.

59. The apparatus of claim 55, wherein the distal member further comprises a region of enlarged cross-section located proximal to the dilation member.

60. The apparatus of claim 59, wherein the region of enlarged cross-section is configured to engage the first tissue layer so as to automatically limit the depth of insertion of the distal portion.

61. The apparatus of claim 60, wherein the dilation member and the region of enlarged cross-section are configured so as to trap the first tissue layer therebetween so as to separate the first tissue layer from the second tissue layer upon moving the distal portion in the second direction.

62. The apparatus of claim 59, wherein the region of enlarged cross-section includes a shoulder.

63. The apparatus of claim 62, wherein the shoulder is moveable relative to the dilation member.

64. The apparatus of claim 63, wherein the shoulder is spring-biased in a direction toward the dilation member.

65. The apparatus of claim 54, wherein the distal portion further comprises a protrusion disposed proximal to the penetration tip.

66. The apparatus of claim 65, wherein the protrusion is configured to engage with the first tissue layer so as to separate the first tissue layer from the second tissue layer when the distal portion is moved in the second direction.

67. The apparatus of claim 65, wherein the protrusion is chosen from a barb, ridge, tapered edge, and partial slice in an exterior surface of the distal portion.

68. The apparatus of claim 54, wherein the penetration tip comprises at least one sharpened edge.

69. The apparatus of claim 54, wherein the penetration tip is on a stylet configured to be inserted through a lumen defined by the shaft.

70. The apparatus of claim 46, wherein the distal portion comprises at least one wing-like member configured to engage with the first tissue layer.

71. The apparatus of claim 70, wherein the wing-like member has a collapsed configuration and an expanded configuration.

72. The apparatus of claim 70, wherein the wing-like member is elastic.

73. The apparatus of claim 72, wherein the wing-like member is superelastic.

74. The apparatus of claim 70, wherein the wing-like member is configured to engage the first tissue layer at a surface between the first tissue layer and the second tissue layer.

75. The apparatus of claim 74, wherein the wing-like member is configured to be positioned on a side of the first tissue layer opposite to a side that is adjacent to the second tissue layer.

76. The apparatus of claim 70, wherein the wing-like member is configured to be positioned on a side of the first tissue layer opposite to a side that is adjacent to the second tissue layer.

77. The apparatus of claim 46, wherein the shaft defines a lumen.

78. The apparatus of claim 77, wherein the lumen is configured to receive a medical tool.

79. The apparatus of claim 78, wherein the medical tool is chosen from guidewires and stylets.

80. The apparatus of claim 46, wherein the shaft is solid.

81. The apparatus of claim 54, wherein the distal portion comprises a helical arrangement disposed proximal to the penetration tip.

82. The apparatus of claim 46, wherein the distal portion comprises an expandable member configured to engage the first tissue layer during separating of the first tissue layer from the second tissue layer.

83. The apparatus of claim 82, wherein the expandable member includes a balloon.

84. The apparatus of claim 82, wherein the expandable member is configured to be inserted past the first tissue layer in a collapsed configuration.

85. The apparatus of claim 82, wherein the expandable member is configured to be placed in an expanded configuration once it is inserted past the first tissue layer and to engage the first tissue layer when in the expanded configuration.

86. The apparatus of claim 46, wherein the distal portion is configured to separate the pericardium from the epicardium.

87. The apparatus of claim 46, further comprising a stylet.

88. The apparatus of claim 87, wherein the stylet is configured to be received in a lumen defined by the shaft.

89. The apparatus of claim 87, wherein the stylet and the shaft are configured to be advanced through a sleeve.

90. The apparatus of claim 89, wherein the stylet and the shaft are configured to be positioned side-by-side while advanced through the sleeve.

91. The apparatus of claim 46, wherein the distal portion comprises a penetration tip, a dilation member proximal the penetration tip, a region of reduced cross-section proximal the dilation member, and a region of enlarged cross-section proximal the region of reduced cross-section.

92. The apparatus of claim 91, wherein the distance from the penetration tip to the beginning of the region of reduced cross-section ranges from approximately 0.063 in. to approximately 0.125 in.

93. The apparatus of claim 91, wherein the region of reduced cross-section has a length ranging from approximately 0.020 in. to approximately 0.060 in.

94. The apparatus of claim 91, wherein the region of reduced cross-section has a diameter ranging from approximately 0.032 in. to approximately 0.065 in.

95. The apparatus of claim 91, wherein the region of enlarged cross-section has a diameter ranging from approximately 0.080 in. to approximately 0.1 in.

96. The apparatus of claim 91, wherein a diameter at the largest cross-section of the dilation member ranges from approximately 0.032 in. to approximately 0.065 in.

97. The apparatus of claim 96, wherein a combined length of the penetration tip and the dilation member ranges from approximately 0.063 in. to approximately 0.125 in.

98. The apparatus of claim 46, wherein the distal portion comprises a tissue grasping portion.

99. The apparatus of claim 98, wherein the distal portion comprises a penetration tip and the tissue grasping portion is disposed proximal to the penetration tip.

100. The apparatus of claim 98, wherein the tissue grasping portion is configured to grasp the first tissue layer to separate the first tissue layer from the second tissue layer when the distal portion is moved in the second direction.

101. The apparatus of claim 98, wherein the distal portion further comprises a dilation portion configured to elastically dilate tissue of the first tissue layer as it passes therethrough.

102. The apparatus of claim 101, wherein the tissue grasping portion is configured to engage tissue that has been dilated by the dilation portion and has recoiled from its dilated state.

103. The apparatus of claim 98, wherein the tissue grasping portion comprises at least one at least one protrusion.

104. The apparatus of claim 98, wherein the tissue grasping portion comprises a helical arrangement.

105. The apparatus of claim 98, wherein the tissue grasping portion comprises a region that transitions from a larger cross-sectional area to a smaller cross-sectional area along a proximal direction of the distal portion.

106. The apparatus of claim 98, wherein the tissue grasping portion comprises a region of reduced cross-section area between two regions having a larger cross-sectional area.

107. The apparatus of claim 98, wherein the tissue grasping portion comprises at least one expandable member.

108. The apparatus of claim 46, further comprising a guidewire configured to be received by a lumen defined by the shaft.

109. The apparatus of claim 108, wherein a flexibility of the guidewire increases from a proximal location of the guidewire to a distal location of the guidewire.

110. The apparatus of claim 109, wherein the guidewire has varying cross-sections along its length associated with varying regions of flexibility.

111. The apparatus of claim 108, wherein the guidewire includes a weld ball on a distal end of thereof.

112. The apparatus of claim 109, wherein a flexibility of the guidewire is the greatest along a first section from the distal end of the guidewire to a location along the length of the guidewire.

113. The apparatus of claim 112, wherein the guidewire includes a second section proximal to the first, the second section being less flexible than the first section.

114. The apparatus of claim 113, wherein the guidewire includes a third section proximal to the second section, the third second being less flexible then the second section.

115. An apparatus for accessing the pericardial space of the heart to perform a medical procedure, the apparatus comprising:

a distal portion being configured to be automatically inserted through the pericardium to a predetermined depth beyond the pericardium and to separate the pericardium from the epicardium,

wherein the apparatus is configured to provide access to the pericardial space from a location remote from the pericardial space.

116. The apparatus of claim 115, wherein the distal portion is configured to separate the pericardium from the epicardium without the use of suction.

117. The apparatus of claim 115, wherein the distal portion comprises a dilation member and a region of reduced cross-section proximal the dilation member.

118. The apparatus of claim 117, wherein the distal portion includes a region of enlarged cross-section proximal the region of reduced cross-section, the region of enlarged cross-section being configured to abut the pericardium such that it cannot be inserted past the pericardium.

119. The apparatus of claim 118, wherein the region of enlarged cross-section includes a shoulder.

120. The apparatus of claim 117, wherein the distal portion is configured such that once the dilation member is inserted past the pericardium, moving the distal portion in a proximal direction causes the dilation member to separate the pericardium from the epicardium.

121. The apparatus of claim 117, wherein the dilation member is configured to elastically dilate the pericardium.

122. The apparatus of claim 121, wherein the dilation member is configured to elastically dilate the pericardium by an amount such that the dilation member can separate

the pericardium from the epicardium without tearing the pericardium upon moving the distal portion in a proximal direction.

123. The apparatus of claim 117, wherein the dilation member is configured to dilate the pericardium during insertion by an amount such that the pericardium elastically recoils around the region of reduced cross-section.

124. The apparatus of claim 115, further comprising a penetration tip configured to pierce the pericardium.

125. An apparatus for delivering medical devices to the pericardial space of a heart, the apparatus comprising:

a dilator shaft having a distal end, a proximal end, and a lumen configured to receive at least one medical device,

the dilator shaft having an expanded region proximate the distal end of the shaft, the expanded region being configured to be positioned in the pericardial space and to engage the pericardium while the at least one medical device is advanced through the lumen and into the pericardial space.

126. The apparatus of claim 125, wherein the expanded region includes an inflatable member.

127. The apparatus of claim 126, wherein the inflatable member includes a balloon.

128. The apparatus of claim 125, wherein the expanded region includes a collar.

129. The apparatus of claim 128, wherein the collar includes a proximal ridge.

130. The apparatus of claim 125, further comprising a manifold in flow communication with the lumen.

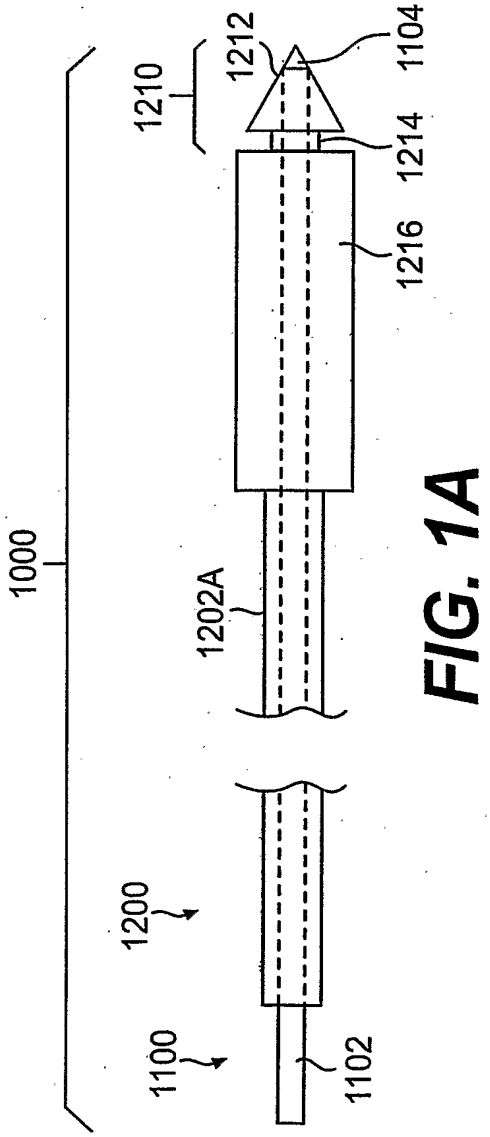
131. The apparatus of claim 130, wherein the manifold is disposed at the proximal end of the shaft.

132. The apparatus of claim 130, wherein the manifold includes a port leading to the lumen configured to receive the at least one medical device.

133. The apparatus of claim 130, wherein the shaft further comprises an inflation lumen and the manifold defines an inflation port in flow communication with the inflation lumen.

134. The apparatus of claim 133, wherein the expanded region includes an inflatable member in flow communication with the inflation lumen.

135. The apparatus of claim 130, wherein the manifold defines an infusion port in flow communication with the lumen.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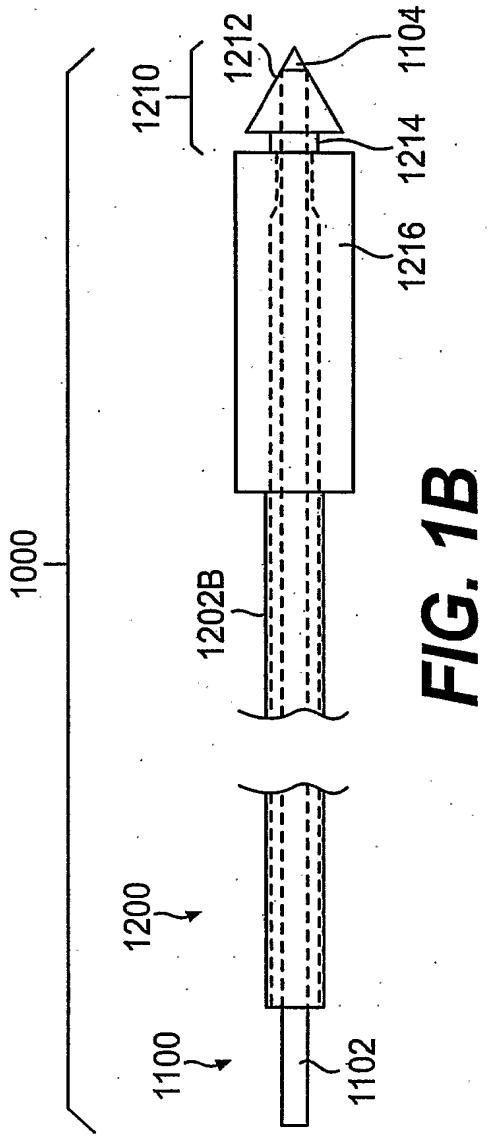
1210
1212
1104
1214
1216
1202A
1200
1100
1102

FIG. 1A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1210
1212
1104
1214
1216
1202B
1200
1100
1102

FIG. 1B

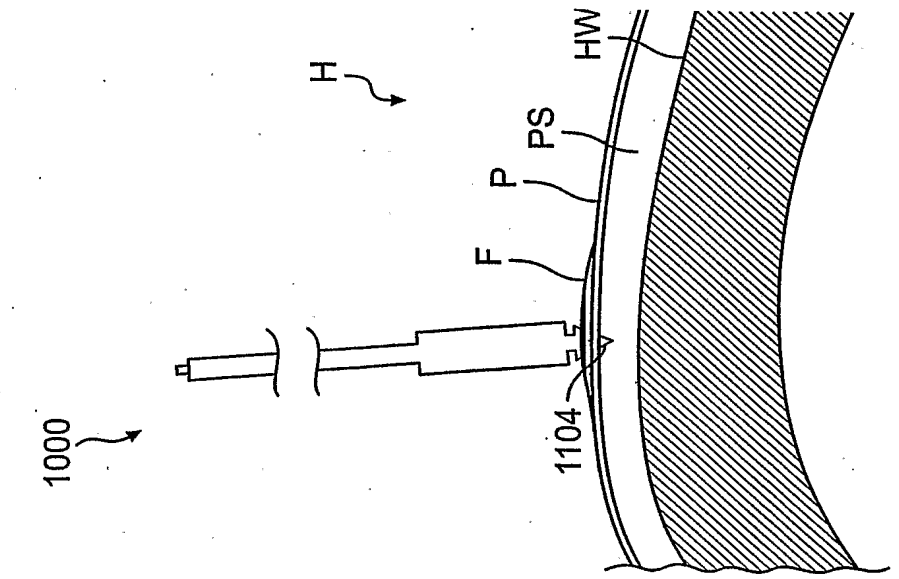


FIG. 2B

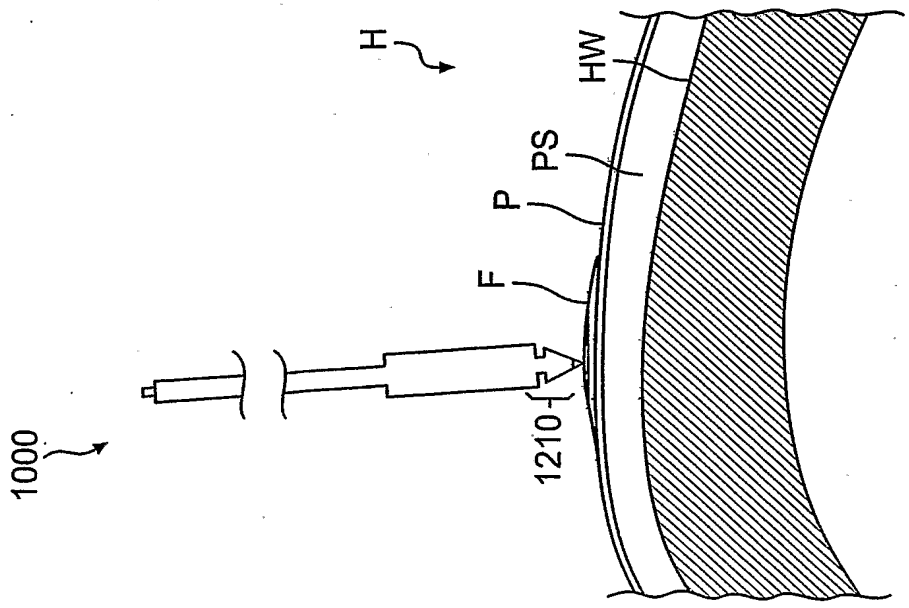


FIG. 2A

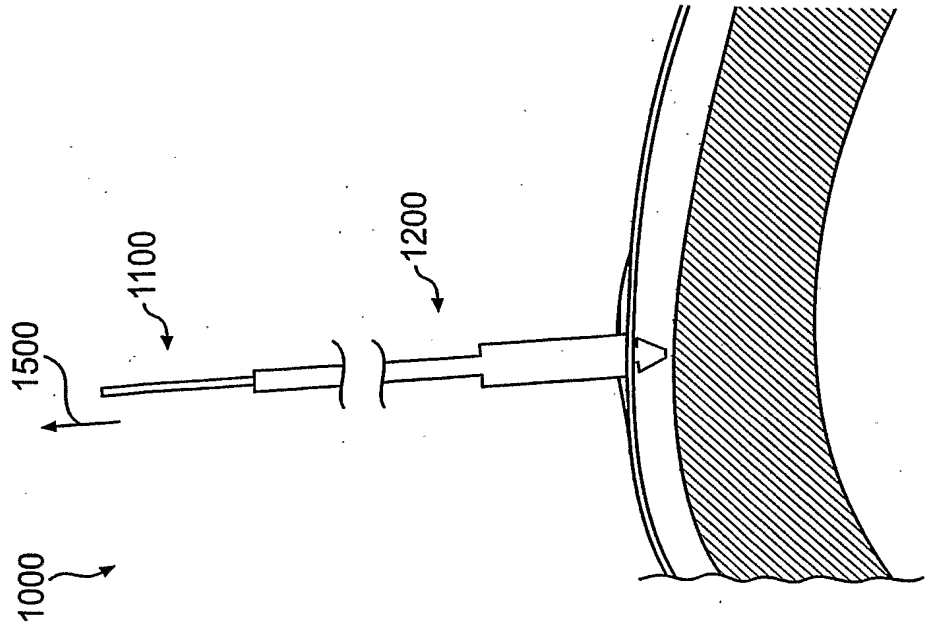


FIG. 2D

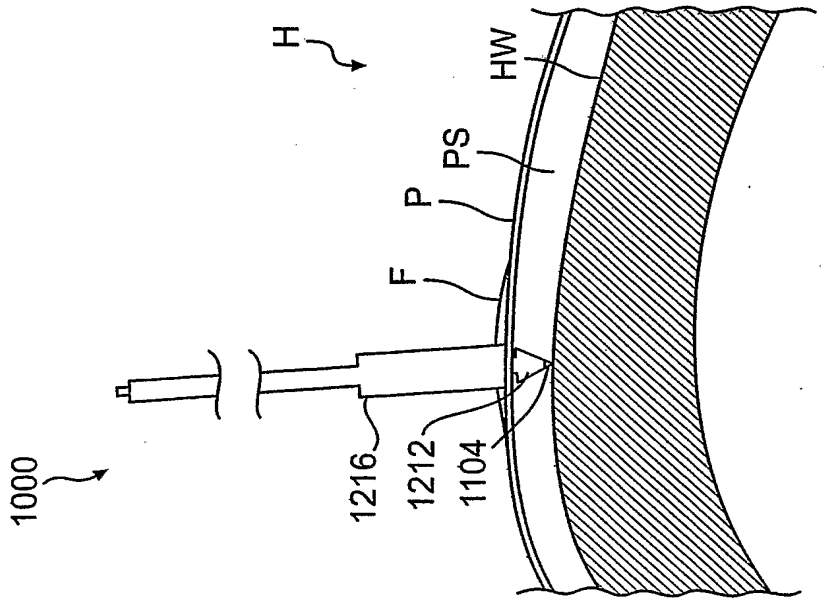


FIG. 2C

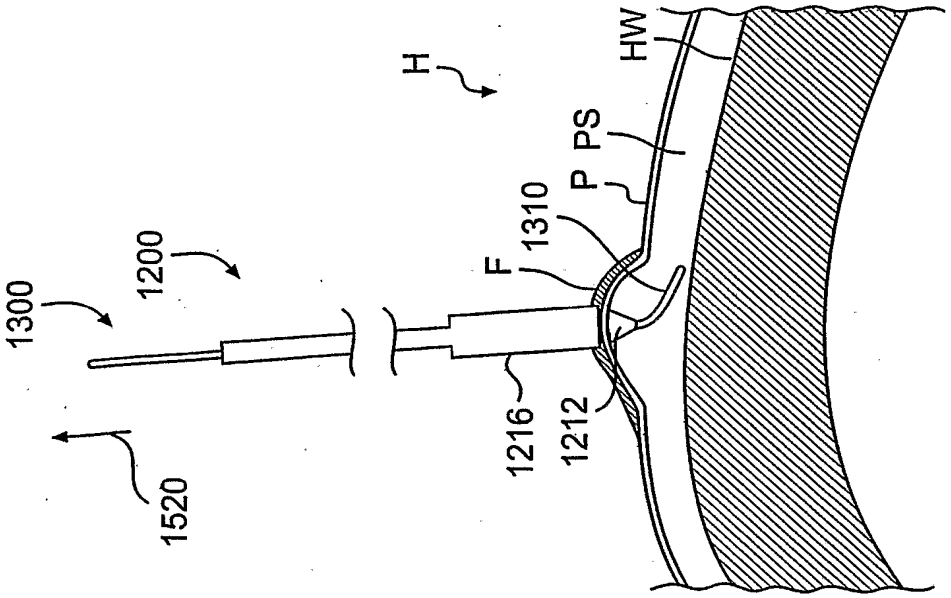
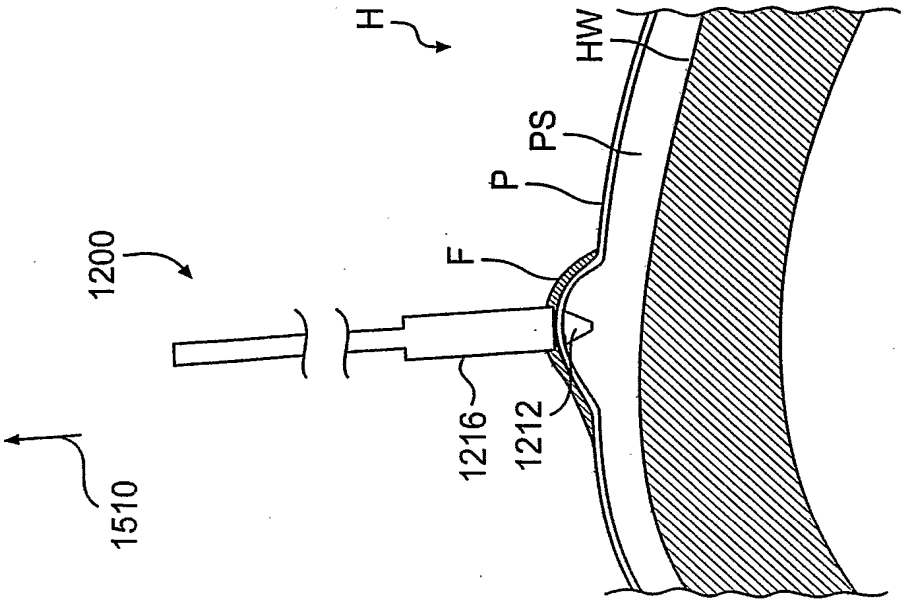

H
HW
PS
P
1310
F
1200
1300
1520
1216
1212

FIG. 2F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HW
PS
P
F
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1510
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1212

FIG. 2E

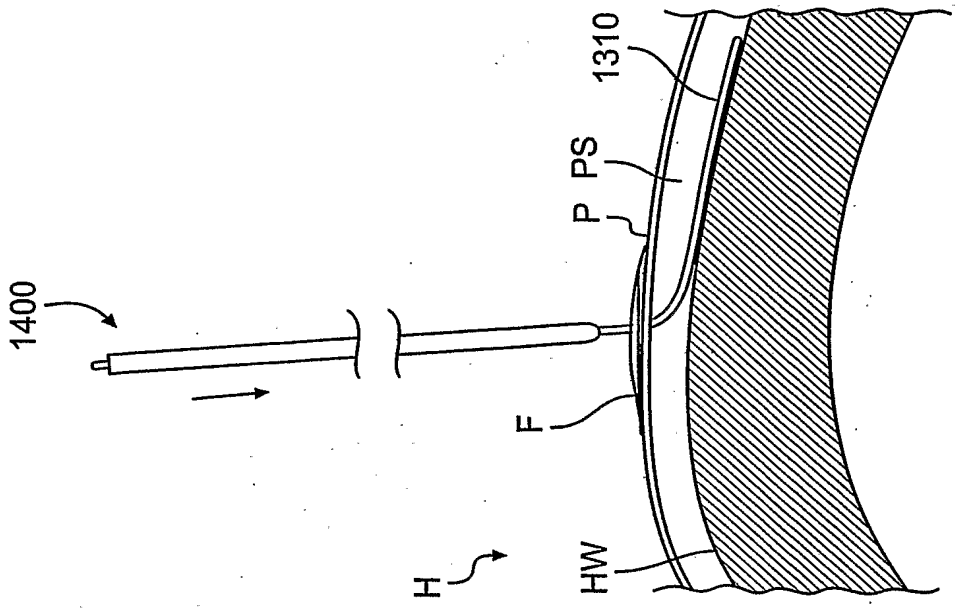

FIG. 2H

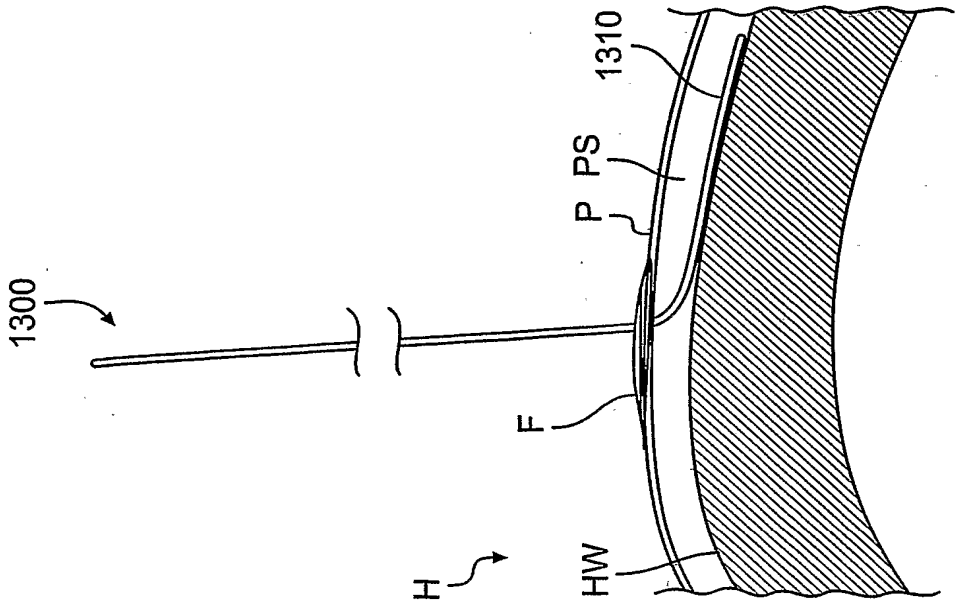

FIG. 2G

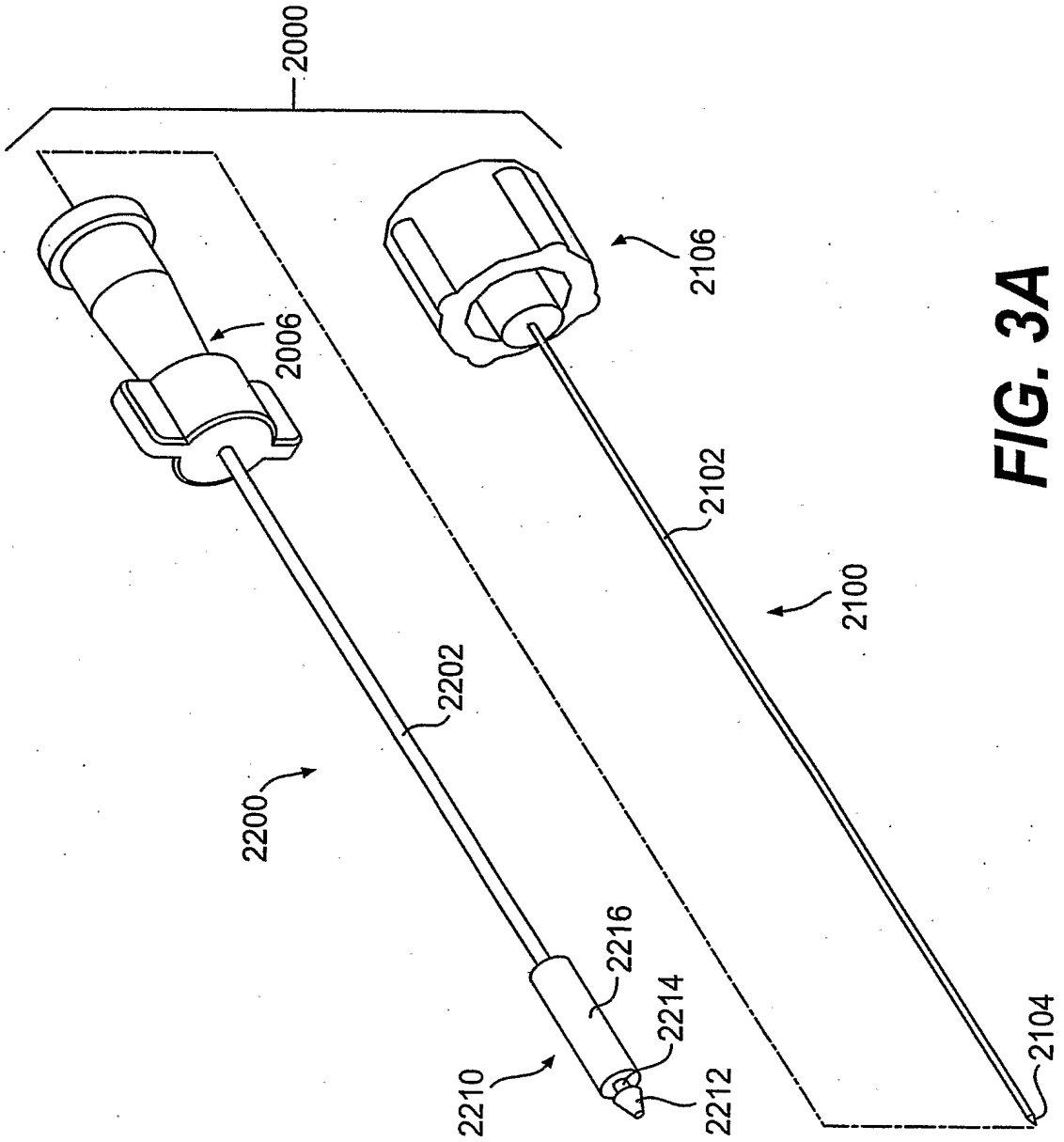

FIG. 3A

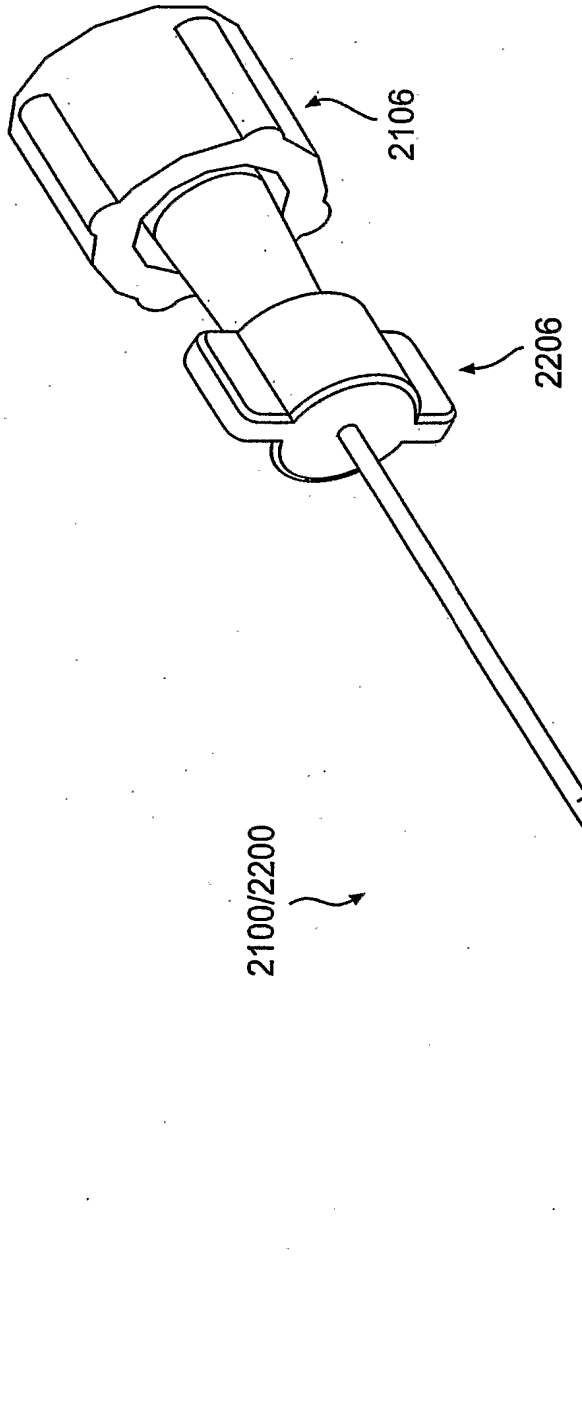

FIG. 3B

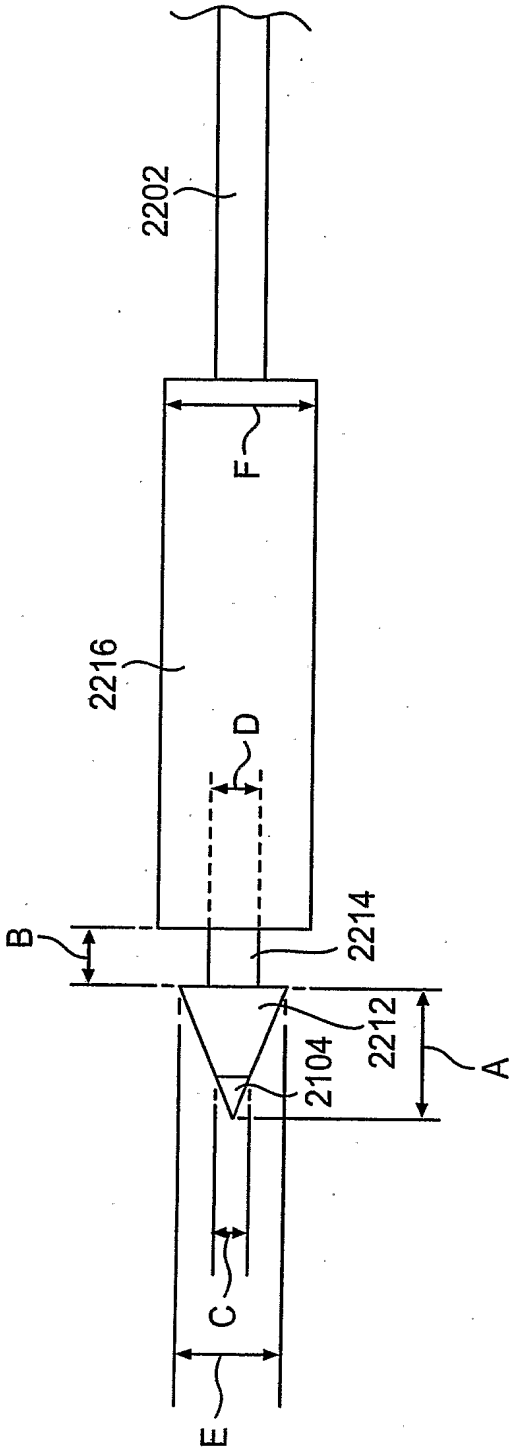

FIG. 3C

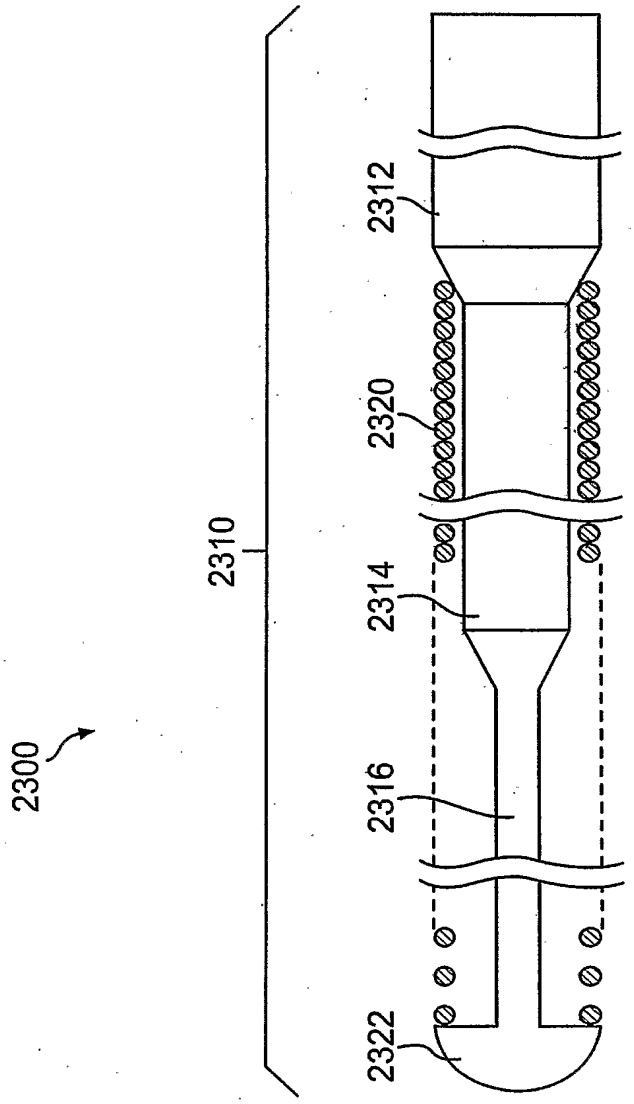

FIG. 3D

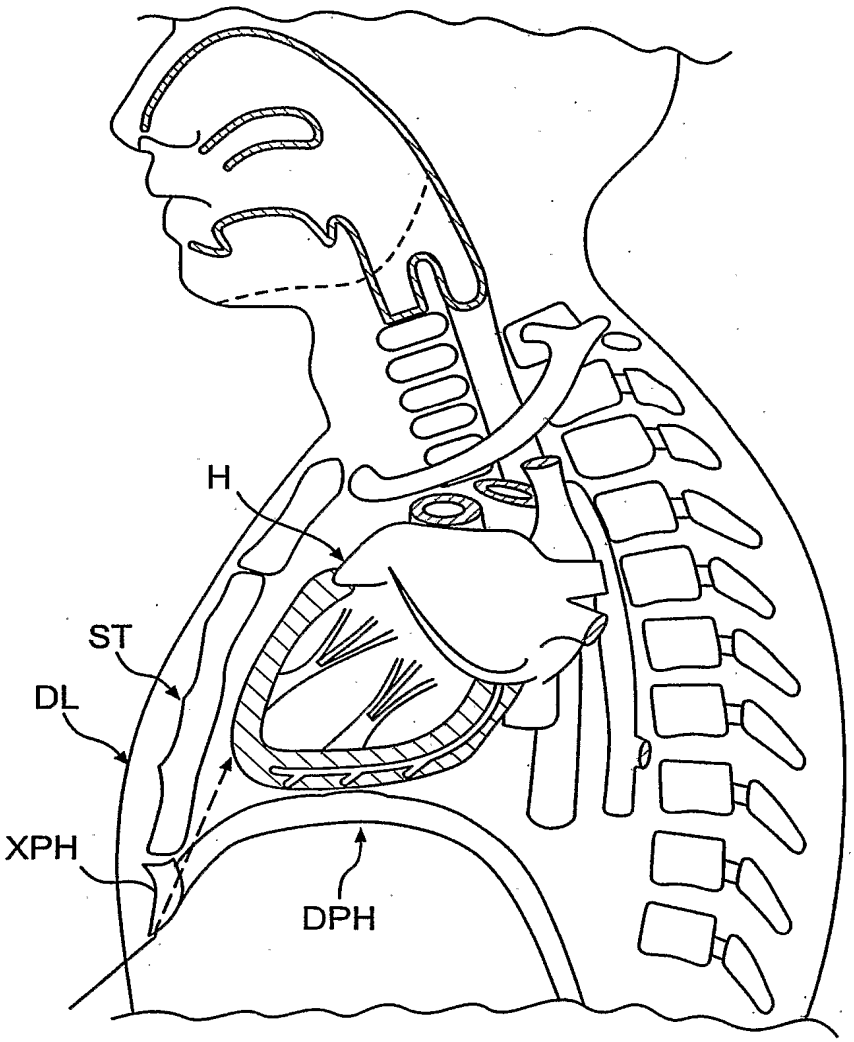

FIG. 4

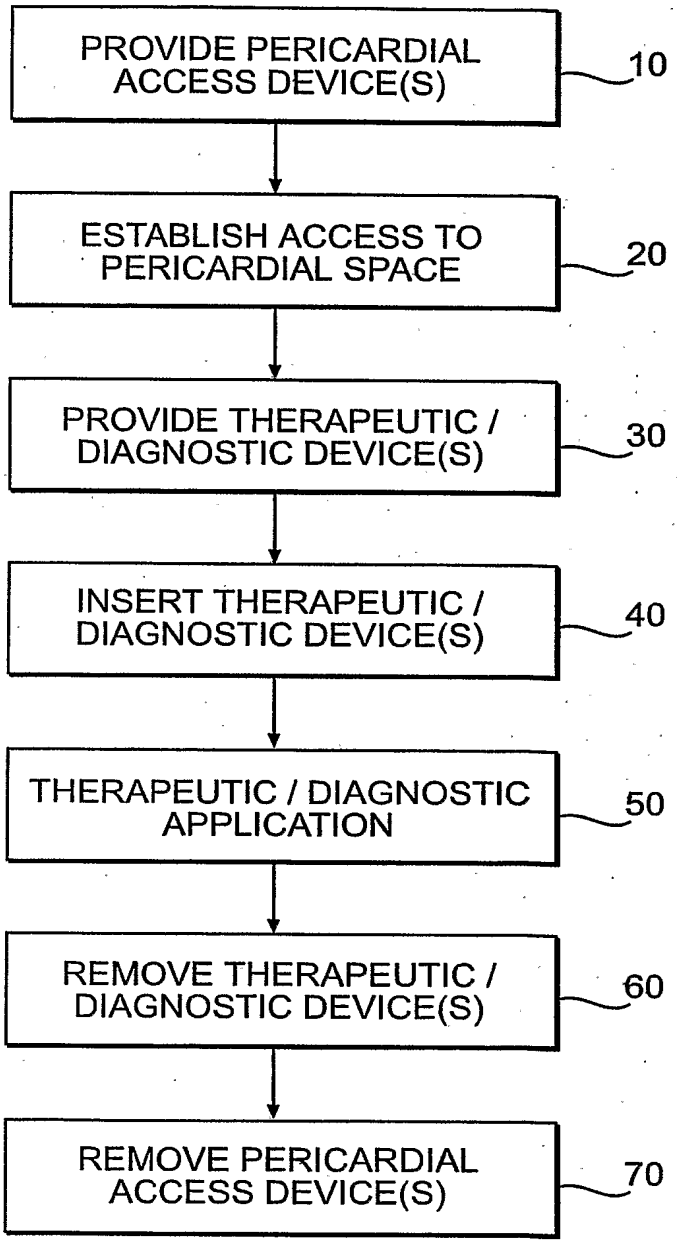
PROVIDE PERICARDIAL ACCESS DEVICE(S)
10
ESTABLISH ACCESS TO PERICARDIAL SPACE
20
PROVIDE THERAPEUTIC / DIAGNOSTIC DEVICE(S)
30
INSERT THERAPEUTIC / DIAGNOSTIC DEVICE(S)
40
THERAPEUTIC / DIAGNOSTIC APPLICATION
50
REMOVE THERAPEUTIC / DIAGNOSTIC DEVICE(S)
60
REMOVE PERICARDIAL ACCESS DEVICE(S)
70

FIG. 5

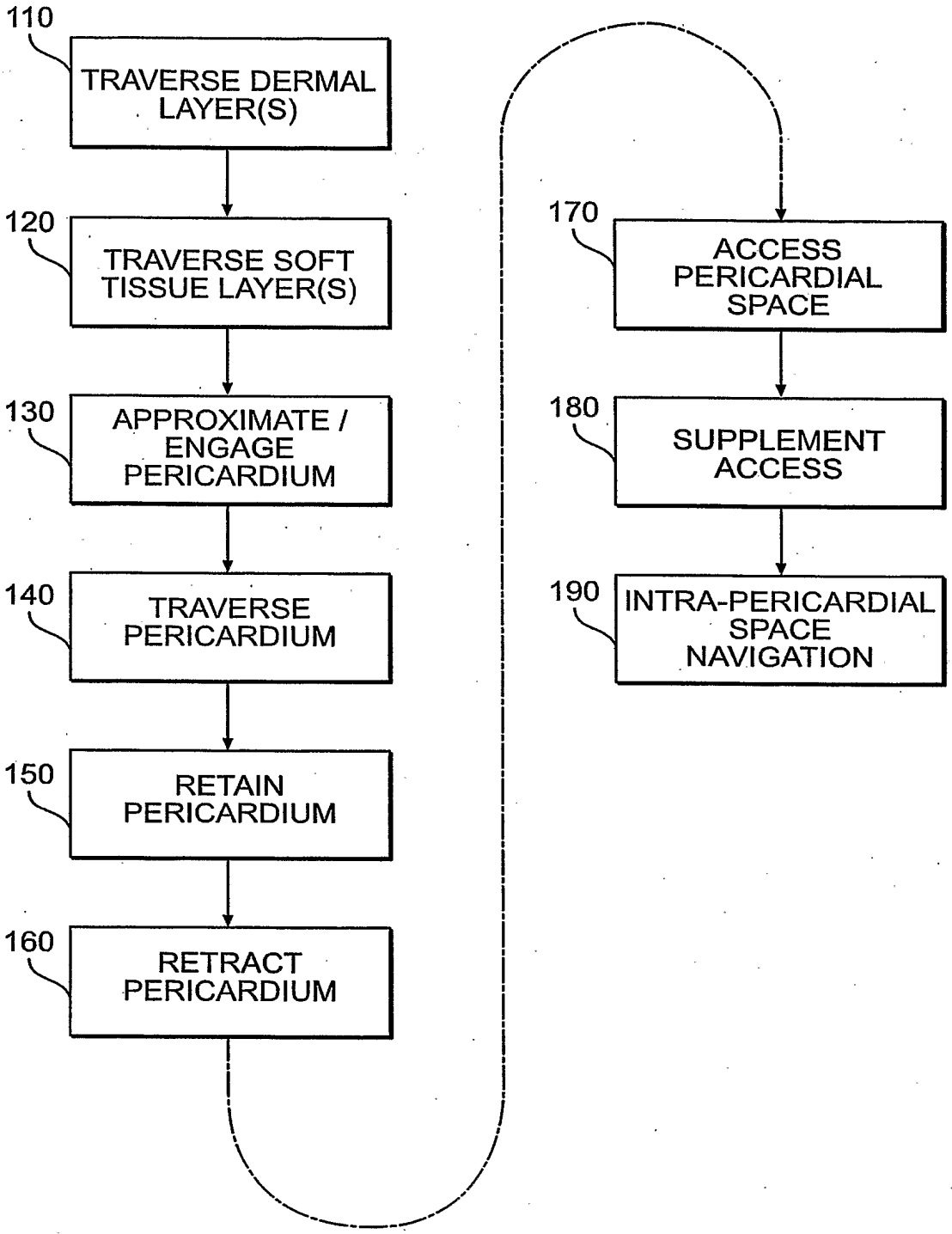
110
TRAVERSE DERMAL LAYER(S)
120
TRAVERSE SOFT TISSUE LAYER(S)
130
APPROXIMATE / ENGAGE PERICARDIUM
140
TRAVERSE PERICARDIUM
150
RETAIN PERICARDIUM
160
RETRACT PERICARDIUM
170
ACCESS PERICARDIAL SPACE
180
SUPPLEMENT ACCESS
190
INTRA-PERICARDIAL SPACE NAVIGATION

FIG. 6

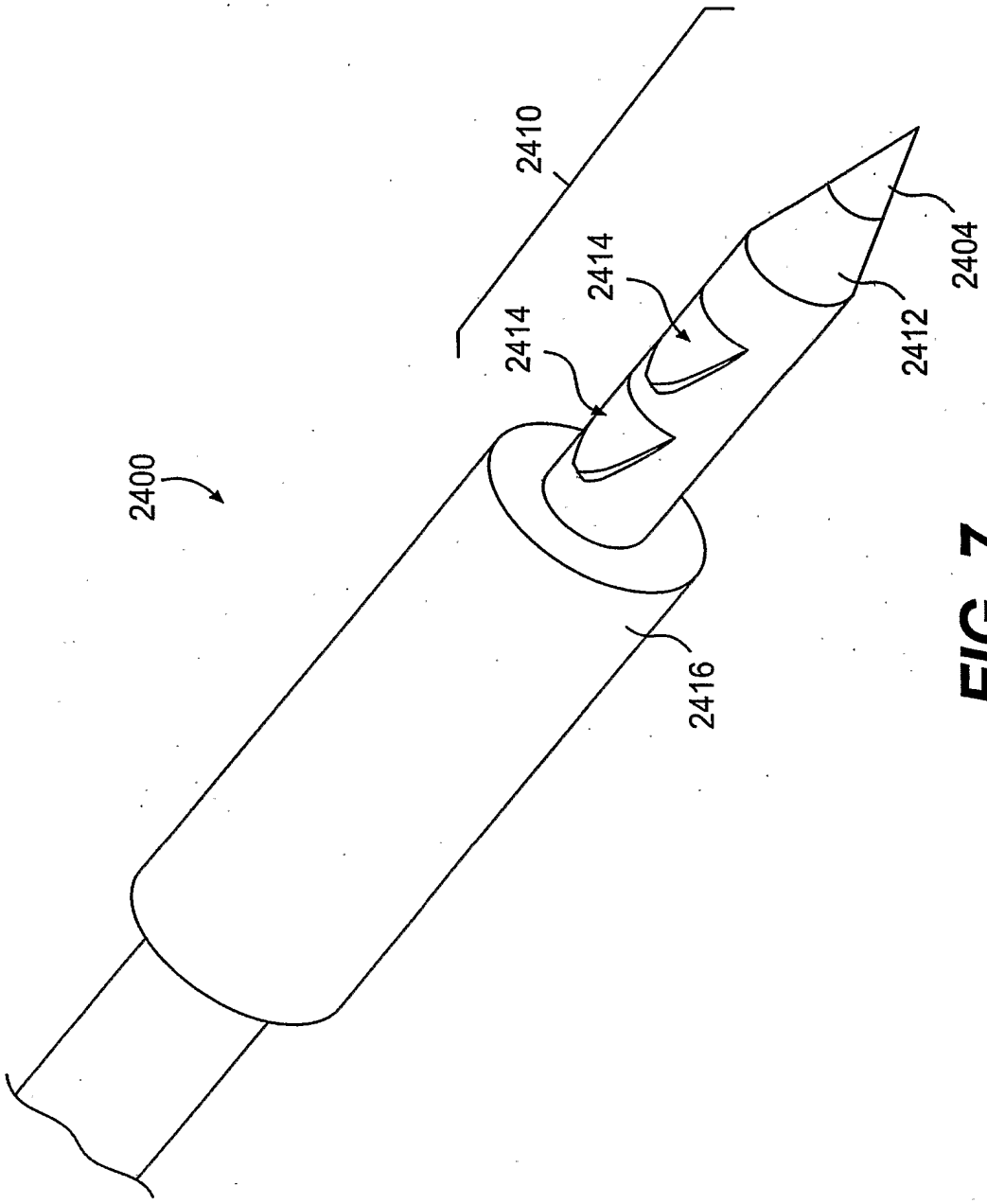

FIG. 7

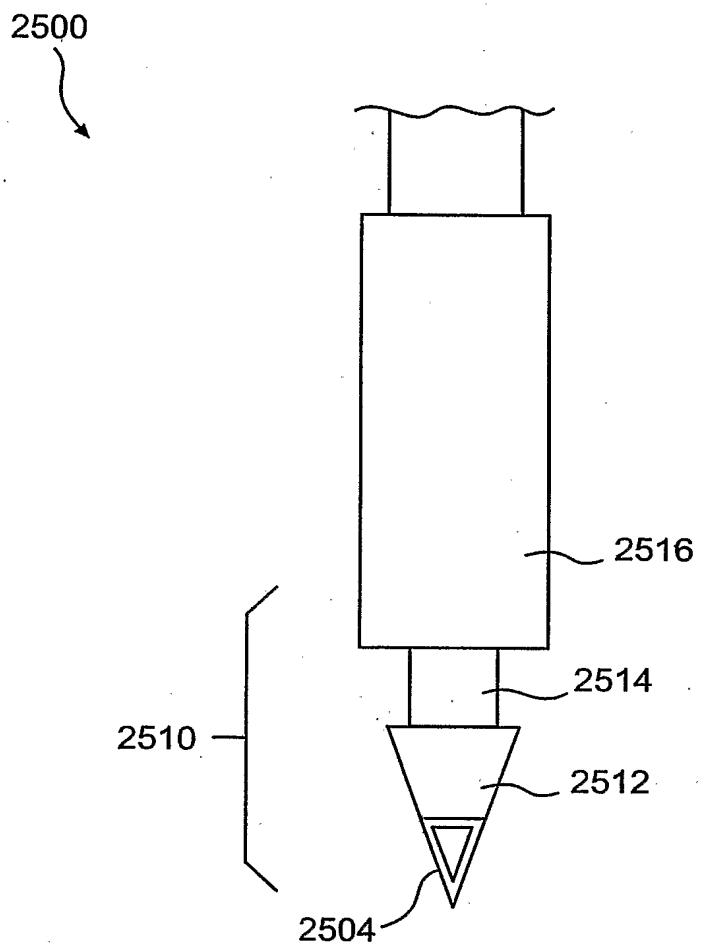

FIG. 8

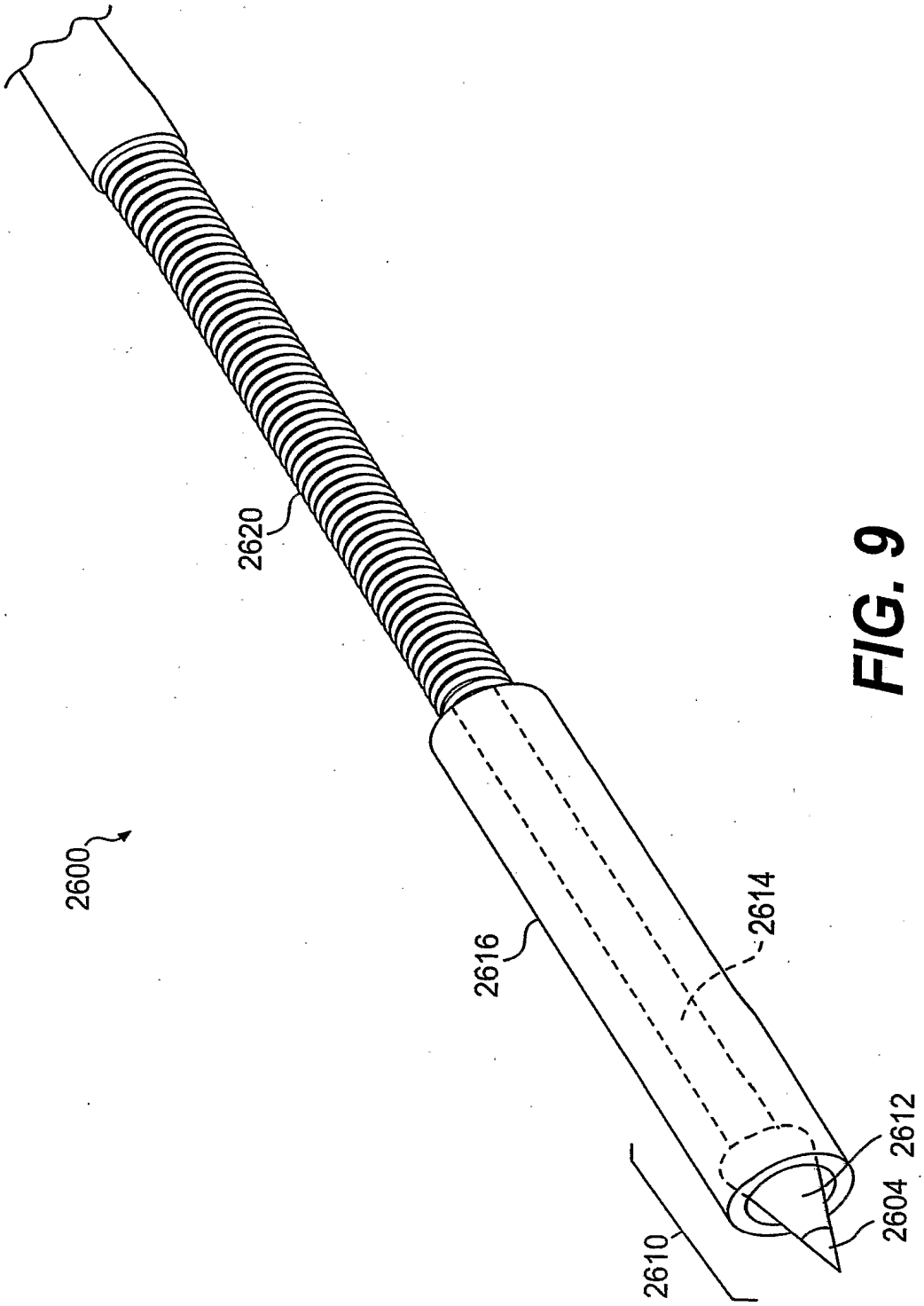

FIG. 9

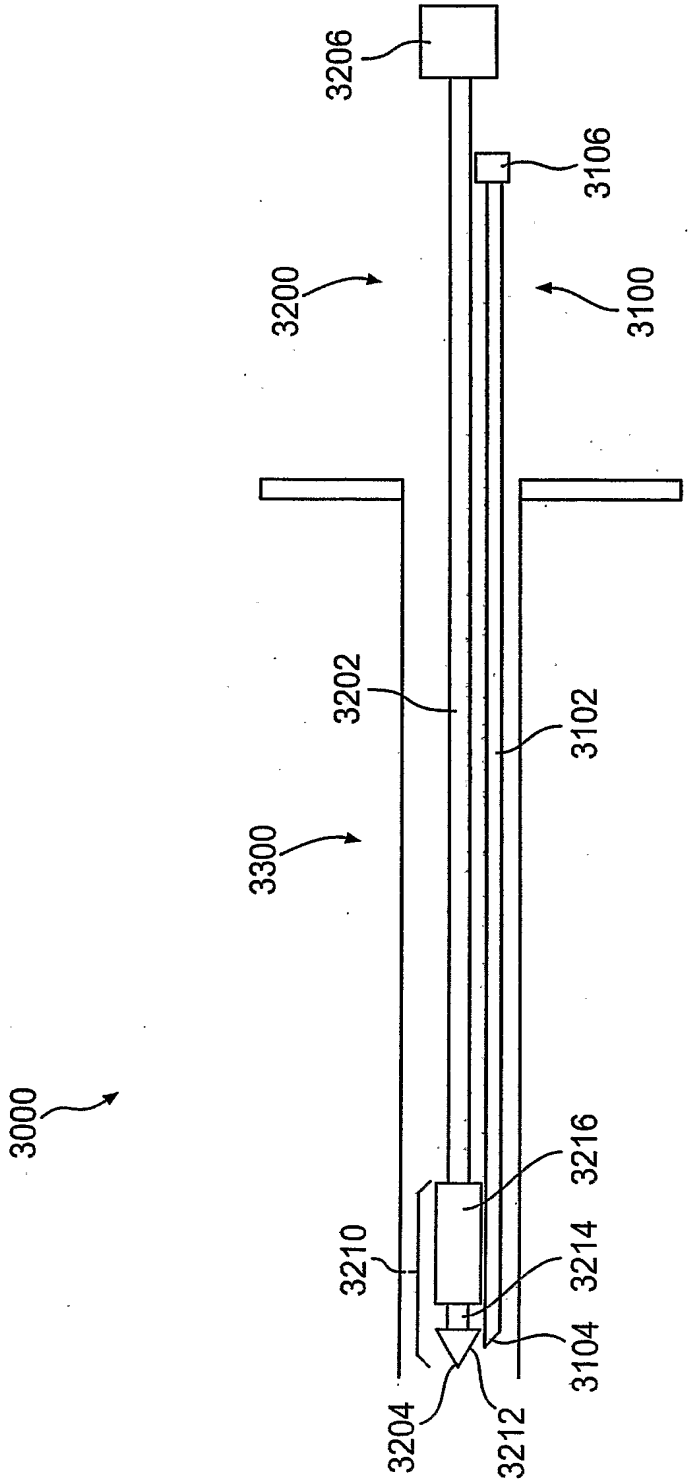
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FIG. 10

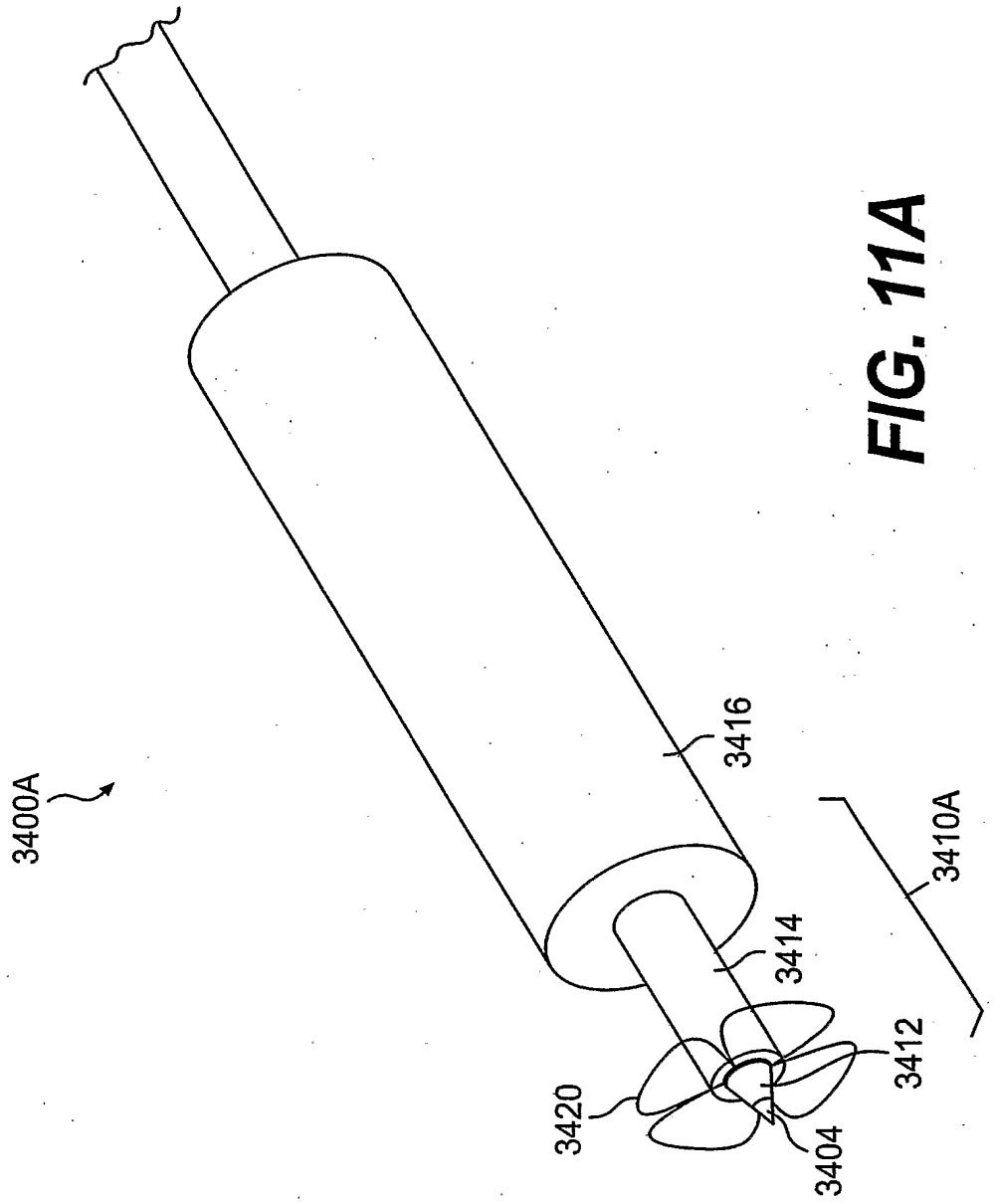

FIG. 11A

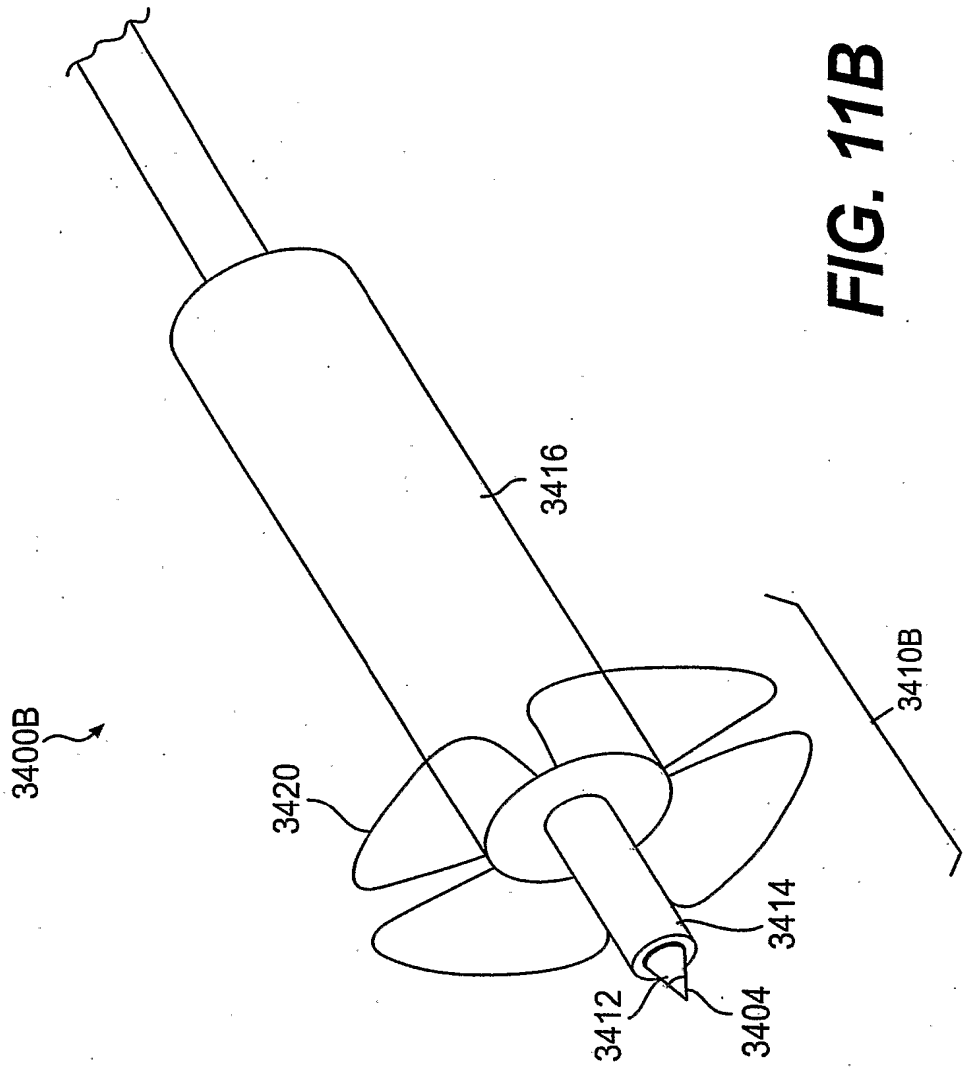

FIG. 11B

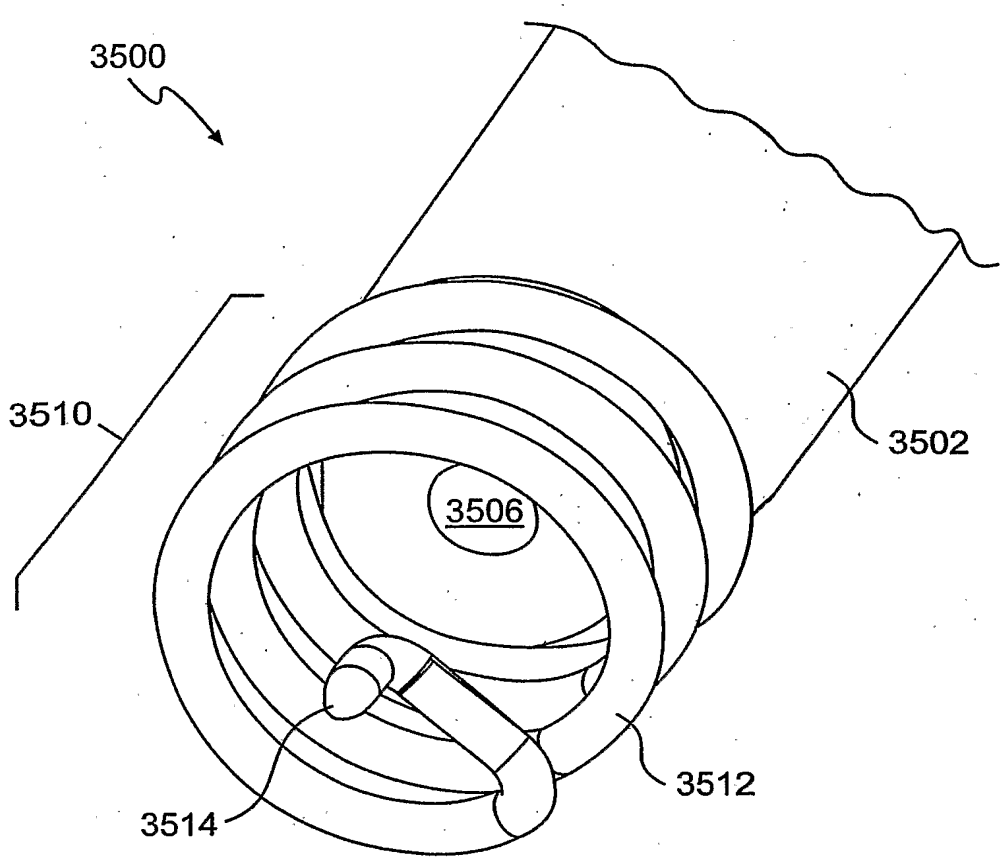

FIG. 12

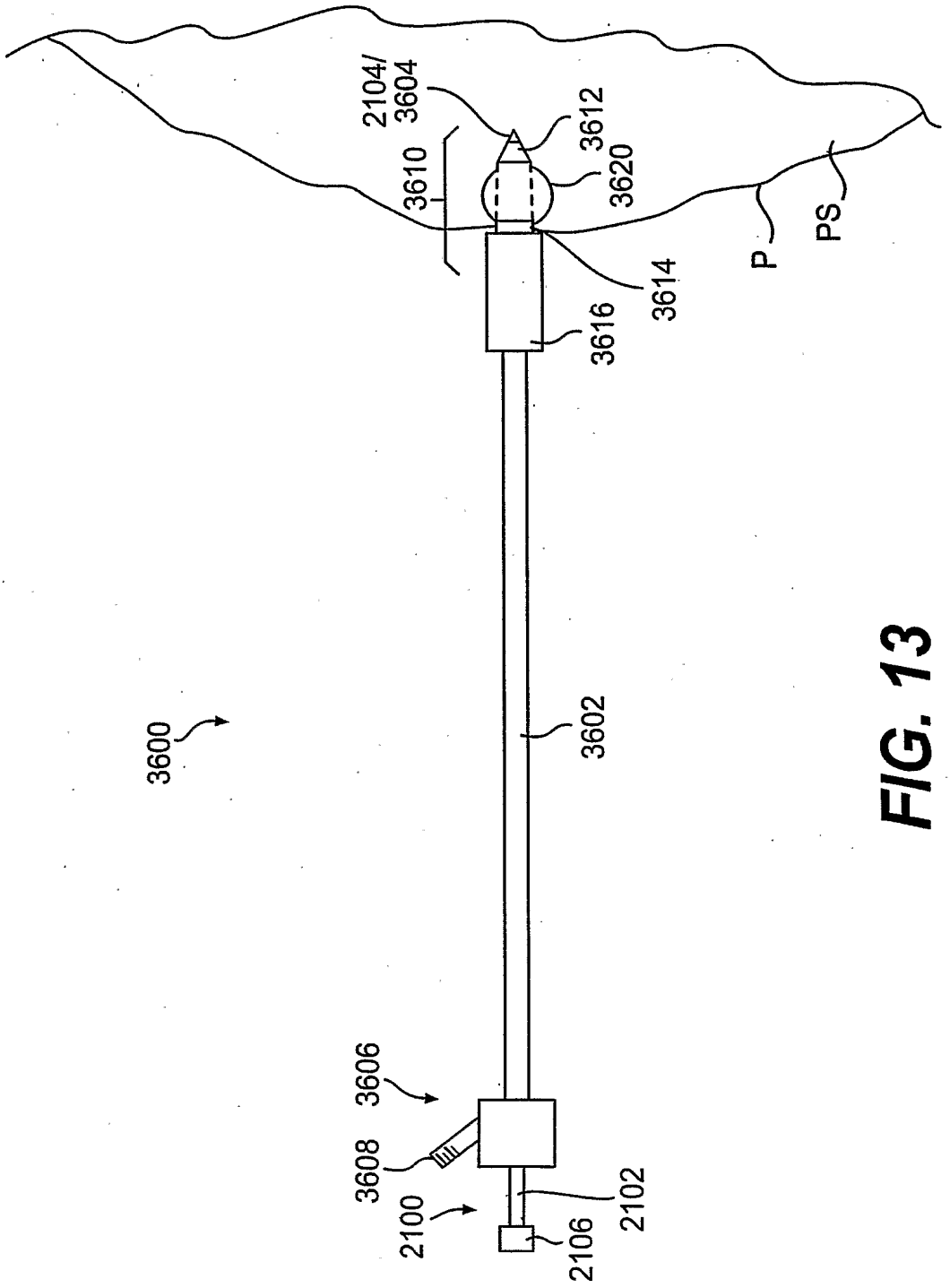
2104/
3604
3612
3610
3620
P
PS
3614
3616
3600
3602
3606
3608
2100
2102
2106

FIG. 13

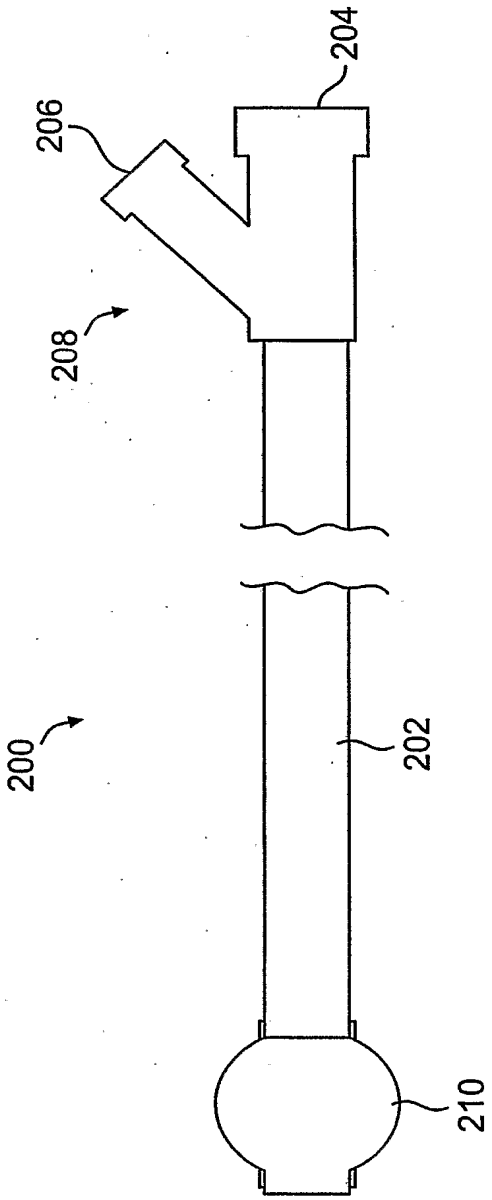

FIG. 14

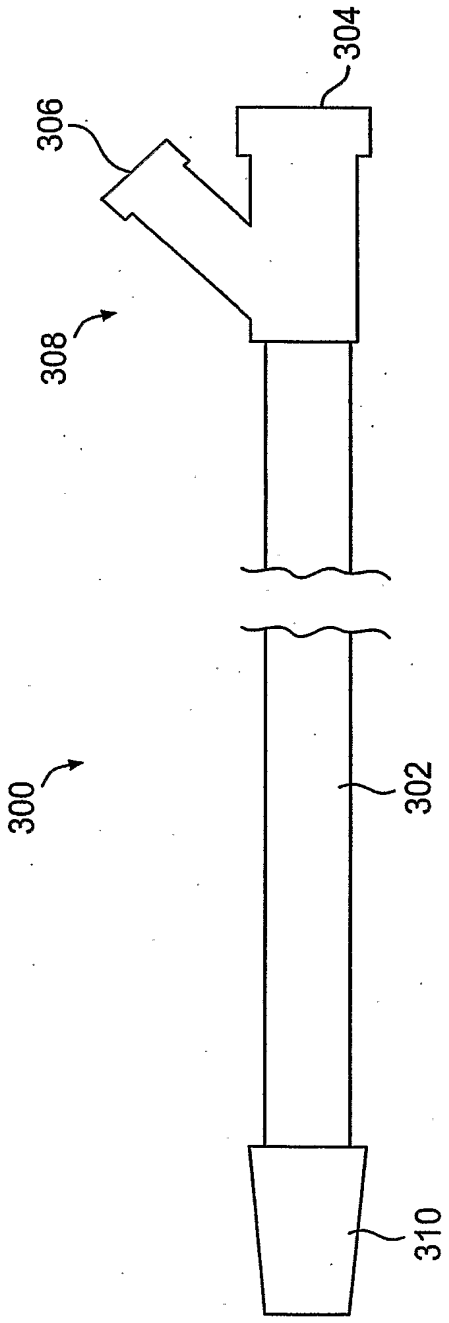

FIG. 15

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

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(22) International Filing Date: 25 April 2006 (25.04.2006)

(25) Filing Language: English

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(30) Priority Data:
11/115,408 27 April 2005 (27.04.2005) US

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

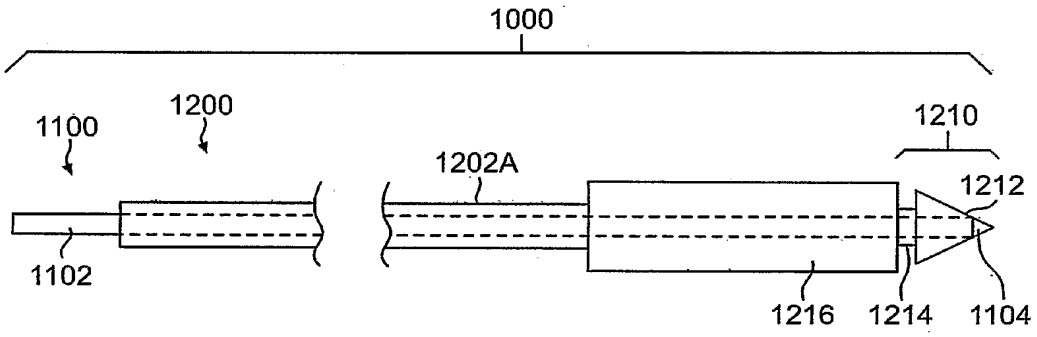
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, 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*

(88) Date of publication of the international search report:
3 May 2007

[Continued on next page]

(54) Title: DEVICES AND METHODS FOR PERICARDIAL ACCESS



(57) Abstract: Devices and methods for establishing pericardial access to facilitate therapeutic and/or diagnostic applications. Pericardial access is facilitated, in part, by a tissue grasping device that reliably holds pericardial tissue, even in the presence of fatty deposits. The tissue grasping portion may include a tissue penetrating tip, a tissue dilating distal section, a tissue retention neck, and a tissue stop. When advanced into the pericardium, the tip may serve to create an opening (e.g., pierce, cut, etc.) in the pericardium, the distal section may serve to dilate the opening, the neck may serve to hold the tissue upon recoil of the dilated opening, and the stop may serve to limit further penetration once tissue is retained in the neck.

WO 2006/116310 A3

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/015470

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/00

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

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)
EPO-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 2003/093104 A1 (BONNER MATTHEW D ET AL) 15 May 2003 (2003-05-15) paragraphs [0002], [0006], [0010], [0053], [0054], [0076]; figures 9,29,30,32	46
X	WO 03/066147 A (KAPLAN, AARON, V) 14 August 2003 (2003-08-14) page 3, line 6 - page 5, line 6; figures 1,5a-5f abstract	46
X	US 2002/026094 A1 (ROTH ALEX T) 28 February 2002 (2002-02-28) paragraphs [0085], [0086]; figures 2,3,2d,2e	46

-/--

[X] Further documents are listed in the continuation of Box C.

[X] 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	Date of mailing of the international search report
9 October 2006	29 01. 2007

Name and mailing address of the ISA/	Authorized officer
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	Béraud, Florent

4

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/015470

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 231 518 B1 (GRABEK JAMES R ET AL) 15 May 2001 (2001-05-15) cited in the application figure 7b -----	46

4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/015470

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-45
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [X] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

see annex

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 1-45

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

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Continuation of Box II.2

Claims Nos.:

Present claim 46 relate to an apparatus which has a given desired effect, namely to be inserted at least through the first tissue layer when the shaft is advanced in a first insertion direction, to engage with the first tissue layer and to separate the first tissue layer from the second tissue layer when the distal portion is moved in a second direction substantially opposite to the first direction. This result-to-be achieved type of definition does not allow the scope of the claim to be ascertained.

However, the description and the figures do provide support and disclosure in the sense of Article 6 and 5 PCT for such an apparatus having the said effect. This non-compliance with the substantive provisions is to such an extent, that the search was performed taking into consideration the non-compliance in determining the extent of the search of the claim (PCT Guidelines 9.19 and 9.20).

The search of claims 46 to 124 was consequently restricted to the specifically disclosed apparatus having the desired effect, see description [027] to [029] and fig.1a and fig.1b, and to the broad concept of an apparatus having the desired effect.

It is to be noted that similar reasoning would apply to the independent claims 115 and 125.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 46-114

An apparatus for accessing a space between a first layer of tissue and a second, adjacent layer of tissue that is less fibrous than the first layer of tissue, the device comprising:
a shaft having a distal portion,
wherein the distal portion is configured to be inserted at least through the first tissue layer when the shaft is advanced in a first insertion direction, and
wherein the distal portion is further configured to engage with the first tissue layer and to separate the first tissue layer from the second tissue layer when the distal portion is moved in a second direction substantially opposite to the first direction.

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2. claims: 115-124

An apparatus for accessing the pericardial space of the heart to perform a medical procedure, the apparatus comprising:
a distal portion being configured to be automatically inserted through the pericardium to a predetermined depth beyond the pericardium and to separate the pericardium from the epicardium,
wherein the apparatus is configured to provide access to the pericardial space from a location remote from the pericardial space.

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3. claims: 125-135

An apparatus for delivering medical devices to the pericardial space of a heart, the apparatus comprising:
a dilator shaft having a distal end, a proximal end, and a lumen configured to receive at least one medical device,
the dilator shaft having an expanded region proximate the distal end of the shaft, the expanded region being configured to be positioned in the pericardial space and to engage the pericardium while the at least one medical device is advanced through the lumen and into the pericardial space.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2006/015470

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2003093104 A1	15-05-2003	US 6613062 B1	02-09-2003
		US 2004087938 A1	06-05-2004
		US 2004024435 A1	05-02-2004
WO 03066147 A	14-08-2003	AU 2002243789 A1	02-09-2003
US 2002026094 A1	28-02-2002	NONE	
US 6231518 B1	15-05-2001	NONE	

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(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
30 November 2006 (30.11.2006)

PCT

(10) International Publication Number
WO 2006/127509 A2

(51) International Patent Classification:
H04B 10/00 (2006.01)

(21) International Application Number:
PCT/US2006/019554

(22) International Filing Date: 22 May 2006 (22.05.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/683,089 20 May 2005 (20.05.2005) US

(71) Applicant *(for all designated States except US)*: **MAYO FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH** [US/US]; 200 First Street SW, Rochester, MN 55905 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **SPEZIALI, Giovanni** [US/US]; 130 Cheval Lane NE, Rochester, MN 55906 (US). **BRUCE, Charles** [ZA/US]; 413 Eagle Lane SW, Rochester, MN 55902 (US).

(74) Agent: **RAASCH, Kevin, W.**; MUETING, RAASCH & GEBHARDT, P.A., P.O. Box 581415, Minneapolis, MN 55458-1415 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, 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, HU, IE, IS, IT, LT, LU, LV, MC, NL, 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:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) **Title:** DEVICES AND METHODS FOR REDUCING CARDIAC VALVE REGURGITATION

(57) **Abstract:** Devices and methods that may be used to reduce valve regurgitation are disclosed by locating a body across the regurgitant valve. When the valve closes, the body obliterates/ameliorates the regurgitant orifice in the valve, thereby reducing or preventing valve regurgitation. The body may be expandable. The devices may be implantable such that they can remain in place within a subject for extended periods of time.

WO 2006/127509 A2

DEVICES AND METHODS FOR REDUCING CARDIAC VALVE REGURGITATION

RELATED APPLICATION

The present application claims the benefit under 35 U.S.C. § 119(e) of U.S. Provisional Patent Application No. 60/683,089, filed May 20, 2005 and titled DEVICES AND METHODS FOR REDUCING CARDIAC VALVE REGURGITATION, which is hereby incorporated by reference in its entirety.

The present invention relates to devices and methods for reducing cardiac valve regurgitation, more particularly, the present invention provides expandable devices designed to limit flow through a leaking cardiac valve and methods of using those devices.

There are four valves in the human heart. The mitral and tricuspid valves are situated between the left atrium and ventricle and between the right atrium and ventricle respectively. The aortic valve is between the left ventricle and the aorta, and the pulmonary valve is situated between the right ventricle and the pulmonary artery. Heart valves include a fibrous frame (or annulus) and moveable leaflets or cusps.

Valvular regurgitation can occur when the valve leaflets (for the tricuspid and mitral valve) or the valve cusps (for the aortic or pulmonary valve) do not coapt properly when the valve is closed. This can be caused by a variety of disease processes, including, e.g., leaflet or cusp retraction, annular dilatation (e.g., annuloaortic ectasia, mitral or tricuspid annular dilatation, etc.), etc. Also, the leaflets or cusps of a valve can prolapse (or fall back) as a result of stretching or rupture of their support system. What all these processes have in common is that an orifice (a regurgitant orifice) remains after valve closure through which blood can flow backwards (i.e., not in the intended direction), thus creating valve regurgitation.

In some instances, valve regurgitation may be beneficial as discussed in U.S. Patent No. 5,509,428 (Dunlop). In most instances, however, valve regurgitation is not desirable.

SUMMARY OF THE INVENTION

The present invention provides devices and methods that may be used to reduce valve regurgitation. The devices may preferably be implantable such that they can remain in place within a subject for extended periods of time.

The present invention preferably provides a device with an appropriately sized and shaped body that can be placed across a regurgitant valve so that, when the valve closes, the body obliterates/ameliorates the regurgitant orifice in the valve, thereby reducing or preventing valve regurgitation.

It may be preferred that the shape of the body be such that when the valve closes, the body itself provides support to the valve leaflets or cusps. It is anticipated that in some situations (particularly when regurgitation is functional due to annular dilatation) reverse remodeling of the volume overloaded chamber may occur such that the regurgitation may decrease over time as the annular dilatation recedes permitting reduction in body size or even removal of the body.

In some embodiments, the body may change shape in response to the direction of fluid flow to enhance the ability of the body to reduce or prevent regurgitant flow.

In one aspect, the present invention may provide a device for reducing regurgitant flow through a cardiac valve, wherein the device includes an expandable body, wherein the body has a collapsed profile adapted for percutaneous delivery of the body to an internal body location and an expanded profile larger than the collapsed profile, wherein the body is adapted to close a regurgitant orifice in a cardiac valve when in the expanded profile. The device also includes a tether attached to the body, wherein the tether has a proximal end attached to the body and a distal end distal from the body; and an anchor located at the distal end of the tether, wherein the anchor is adapted to fix the position of the distal end of the tether at a selected location.

In one variation, the devices may include, e.g., an expandable body in the form of an inflatable balloon and an inflation lumen in fluid communication with the inflatable balloon, wherein the inflatable balloon can be expanded to place the expandable body in the expanded profile by delivering an inflation fluid into the inflatable balloon through the inflation lumen. The inflation fluid may include a radio-opaque substance.

In another variation, the expandable body may include a supporting structure and a sheet material attached to the supporting structure. The sheet material may include a polymeric film.

The expandable bodies in devices of the present invention may be constructed of fluid-impermeable materials.

The expandable bodies in devices of the present invention may have a dynamic hemodynamic conformational shape that changes in response to fluid flow and/or pressure variations around the expandable body.

The location of the expandable body on the tether may be, in some embodiments, adjusted.

The cross-sectional profile of the expandable bodies in devices of the present invention may be selected from the group consisting of round, oval, flattened oval, triangular, fluted, and combinations of two or more thereof.

In another aspect, the present invention may provide a method of reducing regurgitant flow through a cardiac valve by providing a device that includes an expandable body, wherein the body has a collapsed profile adapted for percutaneous delivery of the body to an internal body location and an expanded profile larger than the collapsed profile, wherein the body is adapted to close a regurgitant orifice in a cardiac valve when in the expanded profile; a tether attached to the body, wherein the tether has a proximal end attached to the body and a distal end distal from the body; and an anchor located at the distal end of the tether. The method further includes delivering the device to an internal body location; attaching the anchor to tissue at a selected location, wherein the expandable body is located across a regurgitant cardiac valve; and expanding the expandable body from its collapsed profile to its expanded profile.

The methods of the present invention may optionally include expanding the expandable body by inflating a balloon located within the expandable body. The inflating may include delivering an inflation fluid to the expandable body, wherein the inflation fluid may include a radio-opaque substance.

The expandable body may include a supporting structure and a sheet material attached to the supporting structure, wherein expanding the expandable body may include expanding the supporting structure. The sheet material may include a polymeric film.

The expandable bodies used in the methods of the present invention may be constructed of fluid-impermeable materials.

The expandable bodies used in the methods of the present invention may have a dynamic hemodynamic conformational shape that changes in response to fluid flow and/or pressure variations around the expandable body.

The methods of the present invention may optionally include adjusting a location of the expandable body on the tether after attaching the anchor.

The cross-sectional profile of the expandable body used in a method of the present invention may be selected from the group consisting of round, oval, flattened oval, triangular, fluted, and combinations of two or more thereof.

The methods of the present invention may include selecting the expandable body to correlate with the shape of a regurgitant orifice in the regurgitant valve.

These and other features and advantages of the devices and methods of the present invention may be described below in connection with various exemplary embodiments of the invention.

BRIEF DESCRIPTIONS OF THE FIGURES

FIG. 1 depicts a competent tricuspid valve when closed.

FIG. 2 depicts a tricuspid valve with a regurgitant orifice.

FIG. 3 depicts one example of a device for reducing regurgitant flow through a tricuspid valve, the device being deployed within a right ventricle.

FIG. 4 is a side view of the device of FIG. 3 before deployment.

FIG. 5 is a cross-sectional view of the device of FIG. 4 taken along line 5-5 in FIG. 4.

FIG. 6 is a cross-sectional view of an alternative embodiment of an expandable body that may be used in devices according to the present invention.

FIGS. 7A & 7B depict one example of a body that may be used with a device of the present invention, the body being capable of dynamically changing shape in response to changes in the direction of fluid flow.

FIGS. 8 & 9 depict another example of a device for reducing regurgitant flow, the device assuming a smaller profile during flow in the intended direction (FIG. 8) and a larger profile in response to backward flow (FIG. 9).

DESCRIPTION OF EXEMPLARY EMBODIMENTS OF THE INVENTION

In the following detailed description of some exemplary embodiments of the invention, reference is made to the accompanying figures which form a part hereof, and in which are shown, by way of illustration, specific embodiments in which the invention may be practiced. It is to be understood that other embodiments may be utilized and structural changes may be made without departing from the scope of the present invention.

FIGS. 1 & 2 depict tricuspid valves, with the valve 10 in FIG. 1 being a competent valve in the closed position in which the valve 10 essentially prevents backflow with leaflets or cusps 14, 16 & 18 that act together to close the opening 12.

In contrast, FIG. 2 depicts a tricuspid valve 110 that includes a regurgitant orifice 112 that is not closed by the leaflets or cusps 114, 116 & 118. Backflow through the regurgitant orifice 112 in the valve 110 may, however, be reduced using the devices and methods of the present invention.

FIG. 3 depicts deployment of one exemplary device in a heart while FIG. 4 depicts the distal portion of the device 200 outside of the heart. The device 200 includes a body 220 that is positioned across a regurgitant valve 210. The body 220 is retained in place by a tether 230 that is connected to tissue using an anchor 240 attached to the wall of the right ventricle 211.

Although the device 200 is depicted as deployed within the right ventricle 211, it should be understood that the devices of the present could alternatively include a body positioned across an aortic valve and attached using a tether anchored within the left ventricle.

Deployment of the device may preferably be accomplished percutaneously, using a catheter 250 having a lumen 252 through which the device is delivered and deployed. After deployment, the catheter 250 may preferably be removed, leaving the body 220 in position across the regurgitant valve 210. The device 200 may preferably be inserted through a peripheral vein or artery using delivery catheter 250. Alternatively, the device 200 may be positioned through a surgical procedure directly through the heart muscle into the appropriate heart cavity. If the body 220 of the device 200 is in the form of an expandable body (e.g., inflatable balloon, etc.) that can be delivered in a smaller, unexpanded state, it may be more suited for delivery through a peripheral vein or artery.

It may be preferred that the body 220 placed across the valve 210 be liquid impermeable, i.e., that blood cannot flow through the body 220 itself. In some instances, limited permeability of the body 220 may be acceptable where the permeability is low enough such that the body 220 substantially closes the regurgitant orifice such that biologically insignificant amounts of blood pass therethrough when the valve 210 is closed with the body 220 in position across the valve 210.

The body 220 may preferably be retained in place across the valve 210 using, e.g., a temporarily or permanently implanted tether 230 whose extremities can be secured to the heart and/or to a blood vessel in such a way to prevent dislodgement or migration of the body 220 from the valve 210. The tether 230 may take any suitable form, e.g., the tether 230 may be a modified catheter, etc. The body 220, tether 230, anchor 240 are depicted in FIG. 4 as extending along a longitudinal axis 221. It may be preferred that the tether 230 hold the body in position under both tension and (at least to some extent) compression acting along the longitudinal axis 221.

The body 220 may be attached such that its position across the valve 210 may be adjusted after implantation. For example, it may be preferred that, if the body 220 is affixed using a tether 230 anchored within the subject, the body 220 may preferably be movable proximally or distally along the tether 230 to adjust its location across the valve 210.

One example of a potentially useful tether 230 may be in the form of a ventricular pacemaker lead to which the body 220 is attached. When in place across the valve 210, the body 220 can be used to treat tricuspid valve regurgitation. The distal end of the tether (lead) 230 may preferably be secured to the right ventricular endocardial surface using, e.g., a tissue anchor 240, such that the lead acts as a tether 230 to retain the body 220 in position across the valve 210.

The tether 230 may be attached by any suitable technique or techniques. Some potentially suitable attachment techniques may involve, e.g., screws or other structures commonly used in the field of cardiac pacemaker/defibrillation leads. See, e.g., U.S. Patent Nos. 5,350,419 (Bendel et al.). The structures used to deliver the body 220 may preferably be flexible, semi-flexible and/or steerable. Alternatively or in addition to the screws or other structures used in connection with pacemaker/defibrillation leads, the body 220 may be held in place by one or more sutures, strings, wires, etc. appropriately anchored to the subject's heart chambers and/or vessels.

It may be preferred that the body 220 be provided in the form an expandable structure such as, e.g., an expandable balloon. The expandable body 220 may be characterized as having a collapsed profile adapted for percutaneous delivery of the body 220 (through, e.g., catheter 250) to an internal body location and an expanded profile larger than the collapsed profile, wherein the expandable body 220 is adapted to close a regurgitant orifice in a cardiac valve when in the expanded profile.

If the body 220 is provided in the form of a balloon, it may be preferred that the balloon be manufactured of a soft, pliable material or polymer (e.g., polyethylene, polyurethane, etc.) and that can be inflated or deflated as needed to precisely obliterate the regurgitant orifice. Examples of some potentially suitable polymers found in other medical balloons/materials may be described in, e.g., U.S. Patent Nos. 4,422,447 (Schiff); 5,338,301 (Diaz); or 6,010,479 (Dimitri).

If the body 220 is in the form of an inflatable balloon, a catheter 260 (e.g., the same catheter used to deliver and/or secure the balloon in position or a different catheter), may be used to connect the body 220 to an inflation source 262. Using the catheter 262, inflation fluid may be delivered to the body 220 through a port such that balloon inflation can be adjusted as needed. Inflatable balloons used in connection with the present invention may be filled with any suitable gas, liquid, gel, etc. Examples of some potentially suitable materials may include, e.g., saline solution, CO_2, etc.

The body, tether, anchor, etc. and/or inflation fluid used to inflate the body (if any) may preferably include a radio-opaque substance or markers to check its correct positioning, continued inflation, leakage, etc.

In some embodiments, the inflation source 262 may remain connected to the body 220 (through, e.g., catheter 260 or another catheter). The inflation source 262 could then synchronize inflation and deflation of the body 220 to coincide with valve 210 closing and opening. The inflation source 262 may preferably inject a fluid to inflate and, e.g., remove the inflation fluid from the body 220 (partially or completely) during deflation via, e.g., a pump and reservoir contained in inflation source 220. In some instances, the entire system, e.g., body 220, catheter 260, and inflation source 262 may all be implantable within a subject.

The bodies used in connection with the present invention may have, e.g., a round cross-section. Body 220, as depicted in the cross-sectional view of FIG. 5, has a

round cross-sectional shape formed by wall 222 and internal volume 224. Also seen in FIG. 5 is a port 226 through which inflation fluid may be delivered and/or removed from the internal volume 224 of the body 220.

Although body 220 has a generally circular profile or cross-section as seen in FIG. 5, the bodies used to close regurgitant valve orifices in accordance with the present invention may have a cross-section that more closely conforms to the shape of the regurgitant orifice (e.g., oval, triangular, flattened oval, fluted, combinations or two or more thereof, etc.). FIG. 6 is a cross-sectional view of only one potential example of a body 320 that includes three flutes 326 extending radially outward from the longitudinal axis 321.

In some instances, the shape or profile of the body used to occupy a regurgitant orifice may preferably be selected from a variety of shapes and/or sizes (or even custom tailored to each application) by obtaining an image of the regurgitant orifice to use as a guide or template to select/build an appropriate-shaped body. The longitudinal section of the body (i.e., the shape along the longitudinal axis) may preferably be in the shape of a fusiform or other appropriate shape that reduces flow obstruction past the body when the valve is in the open position.

As discussed above, the bodies used in connection with the present invention may take a variety of cross-sectional shapes, e.g., round, oval, etc. If the body is in the form of an inflatable balloon, the balloon may preferably exhibit some compliance and flexibility that may help to more closely conform to the shape of the regurgitant orifice during closing. In some instances, the balloon may preferably include an internal rigid or semi-rigid structure (e.g., fine metal wire ribbing) to assist in maintaining a selected shape of the balloon. Such structures may also allow for fine-tuning of the balloon shape after implantation by deforming the structures with the body deployed in the valve.

Such structures in the body may also be used to expand the body to a usable cross-sectional profile in the absence of an inflation fluid (e.g., such structures could be manufactured of shape memory materials such as, e.g., nickel-titanium alloys, shape memory polymers, etc.).

Although some of the bodies used to close regurgitant orifices may be static, i.e., may have a fixed shape after deployment (and expansion, if required), other bodies used in devices of the present invention may alternatively change shape in response to

fluid flow past the body. Such changeable bodies may be characterized as having a dynamic hemodynamic conformational shape. Conformational change may allow the body to adopt an improved hemodynamic profile in diastole while increasing obstruction to regurgitant flow and leaflet support in systole.

FIGS. 7A & 7B depict an example of one such body 420 which, when subjected to fluid flow in the direction of arrow 428, the body 420 may take a shape in which the proximal and distal ends have a similar size (e.g., a more cylindrical or sausage-like shape) such that flow past the body 420 in the direction 428 is facilitated. In contrast, during reverse flow in the direction of arrow 429 in FIG. 7B, the body 420 may assume a shape that is more capable of restricting the regurgitant orifice. For example, the body 420 may assume a pear-like shape in which the cross-sectional size of the balloon is enlarged at the downstream end of the body 420 (e.g., due to increased ventricular pressure as compared with the lower atrial pressure). This dynamic hemodynamic conformational change may preferably increase the body diameter in relation to the regurgitant orifice and, in addition, the sides of the pear-shaped body may provide increased support for the leaflets of a valve traversed by the body 420.

Still another example of a device with a potentially suitable body that may be used in connection with the present invention to reduce regurgitant flow through a valve is depicted in FIGS. 8 & 9. The body 520 is preferably, like the devices described above, preferably connected to a tether 530 (only a portion of which is depicted) or otherwise attached such that the body 520 can be held in place relative to a regurgitant valve. The tether 530 and body 520 may preferably be delivered and attached in much the same manner with the other devices described herein.

In general, the body 520 may be described as having an umbrella-like or parachute-like shape. It may be preferred that the body 520 have a retained memory structure biased to hold the body 520 in its open shape (FIG. 9). To accomplish that, it may be preferred to manufacture the body 520 with arms or struts 522 constructed of, e.g., shape-memory material (e.g., nickel-titanium alloys, shape-memory polymers, etc.). Flow past the body 529 in the direction of arrow 529 in FIG. 9 may be restricted by suspending sheet material 524 between the arms 522. The sheet material 524 may be constructed of any suitable material, e.g., polymer films (e.g., polyethylene, etc.), meshes, fabrics, etc. may all be used if they provide a desired level of flow restriction.

During, e.g., diastole, the pressure of inflowing fluid would preferably collapse the arms 522 sufficiently to allow blood to flow past the body 520 in the direction of arrow 528 in FIG. 8. During, e.g., systole, the arms 522 would preferably regain their expanded shape to reduce regurgitation in the direction of the arrow 529 as seen in FIG. 9. As a result, the body 520 may also be characterized as having a dynamic hemodynamic conformational shape. It may be preferred that the valve leaflets of a valve with which the device is used contact the body 520 when it is in its expanded state as seen in FIG. 9, with the body potentially providing support to the leaflets.

Although not explicitly depicted in connection with any specific exemplary embodiments, the devices of the present invention may include pressure sensors or other sensors capable of transmitting hemodynamic or other information outside the subject. Such sensors may be located on or in the body, the tether, or any other selected location on or in the device.

As used herein and in the appended claims, the singular forms "a," "and," and "the" include plural referents unless explicitly limited to the singular form or the context clearly dictates otherwise.

All references and publications cited herein are expressly incorporated herein by reference in their entirety into this disclosure. Illustrative embodiments of this invention are discussed and reference has been made to possible variations within the scope of this invention. These and other variations and modifications in the invention will be apparent to those skilled in the art without departing from the scope of the invention, and it should be understood that this invention is not limited to the illustrative embodiments set forth herein. Accordingly, the invention is to be limited only by the claims provided below and equivalents thereof.

CLAIMS:

1. A device for reducing regurgitant flow through a cardiac valve, the device comprising:

an expandable body, wherein the body comprises a collapsed profile adapted for percutaneous delivery of the body to an internal body location and an expanded profile larger than the collapsed profile, wherein the body is adapted to close a regurgitant orifice in a cardiac valve when in the expanded profile;

a tether attached to the body, wherein the tether comprises a proximal end attached to the body and a distal end distal from the body; and

an anchor located at the distal end of the tether, wherein the anchor is adapted to fix the position of the distal end of the tether at a selected location.

2. A device according to claim 1, wherein the expandable body comprises an inflatable balloon, and wherein the device further comprises an inflation lumen in fluid communication with the inflatable balloon, wherein the inflatable balloon can be expanded to place the expandable body in the expanded profile by delivering an inflation fluid into the inflatable balloon through the inflation lumen.

3. A device according to claim 2, wherein the inflation fluid comprises a radio-opaque substance.

4. A device according to claim 1, wherein the expandable body comprises a supporting structure and a sheet material attached to the supporting structure.

5. A device according to claim 4, wherein the sheet material comprises a polymeric film.

6. A device according to any of claims 1-5, wherein the expandable body is constructed of fluid-impermeable materials.

7. A device according to any of claims 1-6, wherein the expandable body comprises a dynamic hemodynamic conformational shape that changes in response to fluid flow and/or pressure variations around the expandable body.

8. A device according to any of claims 1-7, wherein a location of the expandable body on the tether can be adjusted.

9. A device according to any of claims 1-8, wherein cross-sectional profile of the expandable body is selected from the group consisting of round, oval, flattened oval, triangular, fluted, and combinations of two or more thereof.

10. A method of reducing regurgitant flow through a cardiac valve, the method comprising:

providing a device comprising:

an expandable body, wherein the body comprises a collapsed profile adapted for percutaneous delivery of the body to an internal body location and an expanded profile larger than the collapsed profile, wherein the body is adapted to close a regurgitant orifice in a cardiac valve when in the expanded profile;

a tether attached to the body, wherein the tether comprises a proximal end attached to the body and a distal end distal from the body; and

an anchor located at the distal end of the tether;

delivering the device to an internal body location;

attaching the anchor to tissue at a selected location, wherein the expandable body is located across a regurgitant cardiac valve; and

expanding the expandable body from its collapsed profile to its expanded profile.

11. A method according to claim 10, wherein expanding the expandable body comprises inflating a balloon located within the expandable body.

12. A method according to claim 11, wherein the inflating comprises delivering an inflation fluid to the expandable body, wherein the inflation fluid comprises a radio-opaque substance.

13. A method according to claim 10, wherein the expandable body comprises a supporting structure and a sheet material attached to the supporting structure, wherein expanding the expandable body comprises expanding the supporting structure.

14. A method according to claim 13, wherein the sheet material comprises a polymeric film.

15. A method according to any of claims 10-14, wherein the expandable body is constructed of fluid-impermeable materials.

16. A method according to any of claims 10-15, wherein the expandable body comprises a dynamic hemodynamic conformational shape that changes in response to fluid flow and/or pressure variations around the expandable body.

17. A method according to any of claims 10-16, further comprising adjusting a location of the expandable body on the tether after attaching the anchor.

18. A method according to any of claims 10-17, wherein the cross-sectional profile of the expandable body is selected from the group consisting of round, oval, flattened oval, triangular, fluted, and combinations of two or more thereof.

19. A method according to any of claims 10-18, further comprising selecting the expandable body to correlate with the shape of a regurgitant orifice in the regurgitant valve.

Fig. 1
(PRIOR ART)

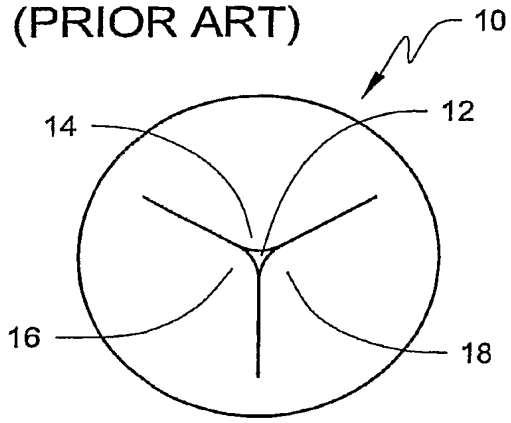


Fig. 2
(PRIOR ART)

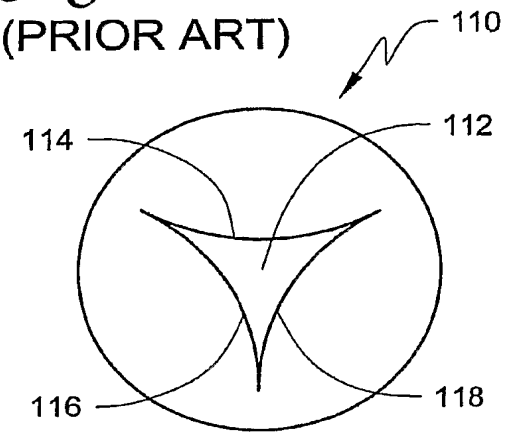


Fig. 3

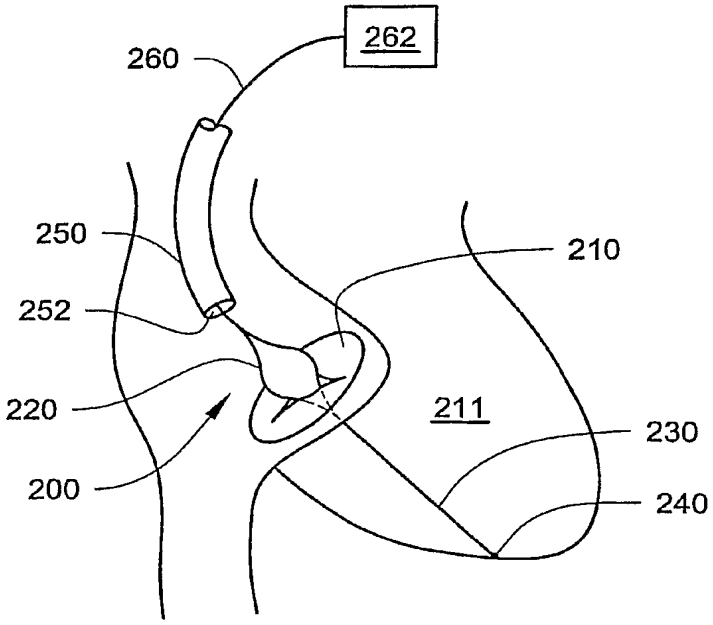


Fig. 4

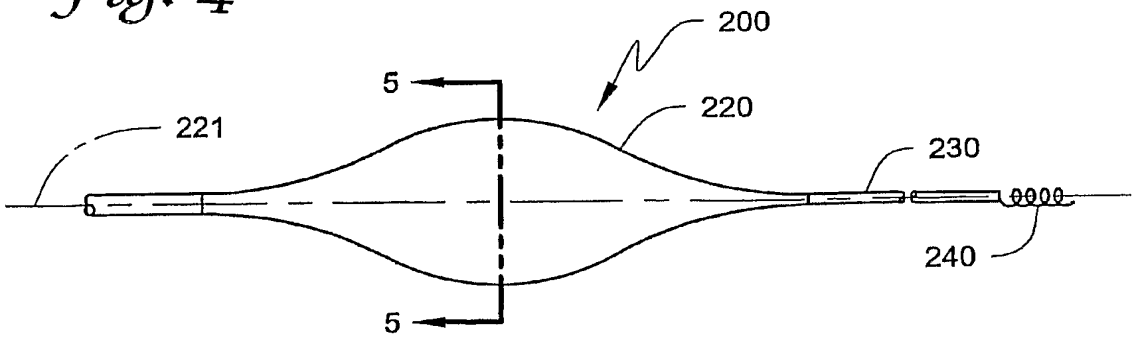


Fig. 5

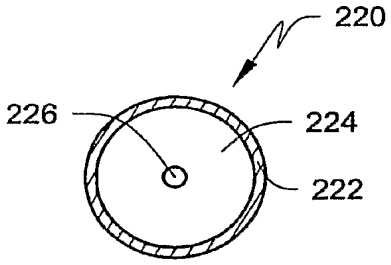


Fig. 6

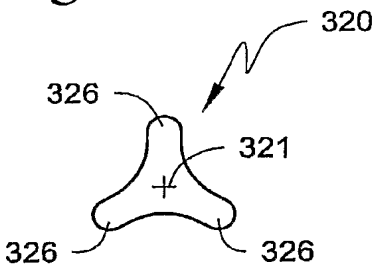


Fig. 7A

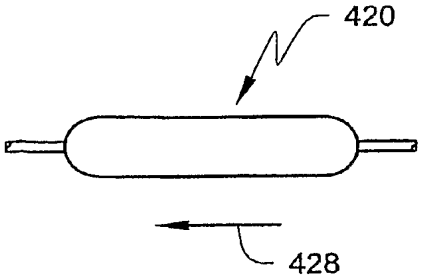


Fig. 7B

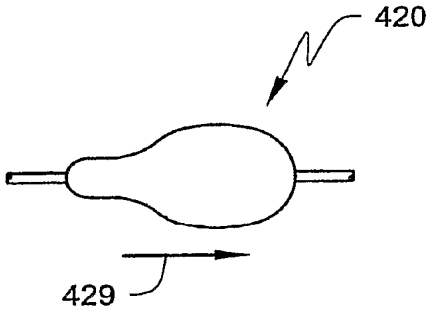


Fig. 8

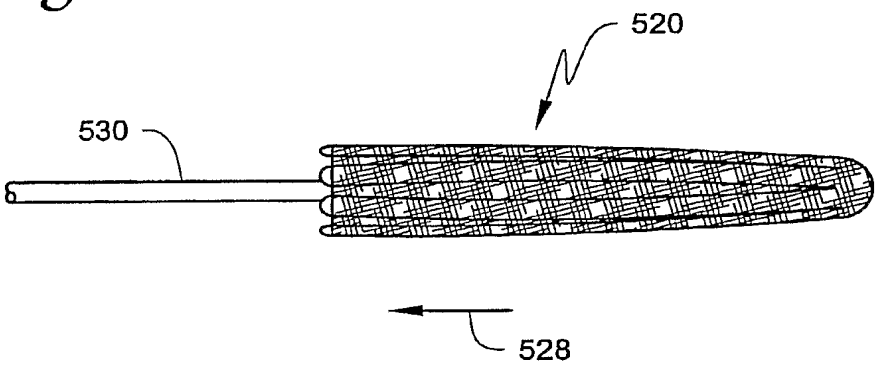
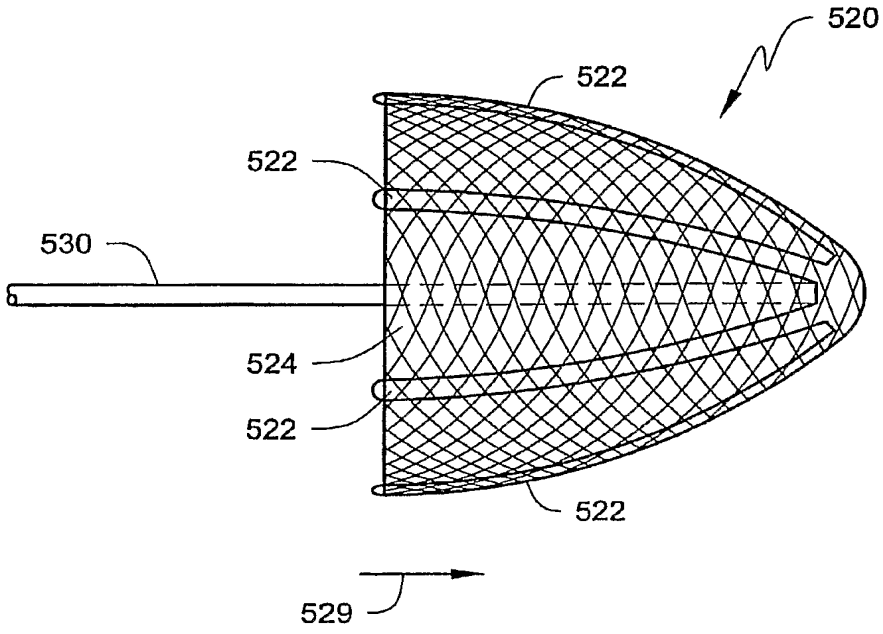


Fig. 9



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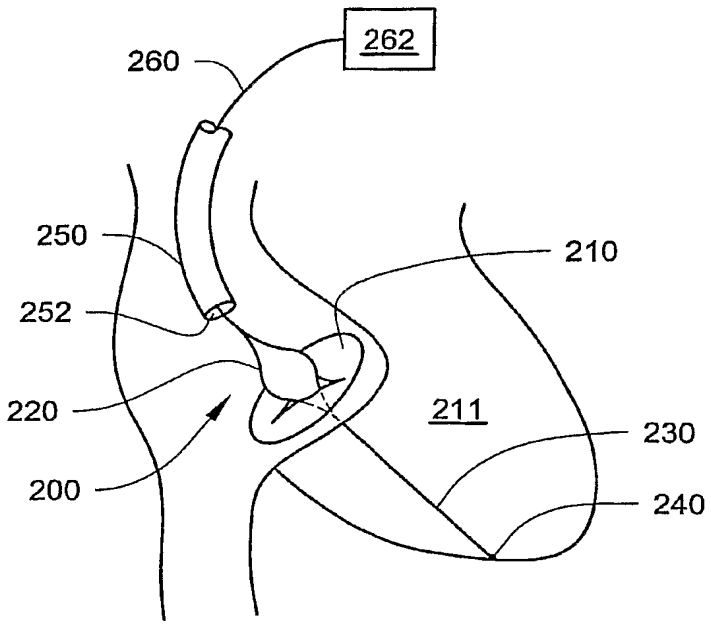
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: DEVICES AND METHODS FOR REDUCING CARDIAC VALVE REGURGITATION



(57) Abstract: Devices and methods that may be used to reduce valve regurgitation are disclosed by locating a body across the regurgitant valve. When the valve closes, the body obliterates/ameliorates the regurgitant orifice in the valve, thereby reducing or preventing valve regurgitation. The body may be expandable. The devices may be implantable such that they can remain in place within a subject for extended periods of time.

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US06/19554

A. CLASSIFICATION OF SUBJECT MATTER
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USPC: 623/2.34
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)
U.S. : 623/2.34, 2.1

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 practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,764,510 B2 (VIDLUND et al) 20 July 2004 (20.07.2004), see figures 11a-11m, 12, 18, 19 and respective portions of the document.	1-3, 6, 10-12, 15
X	US 6,482,28 B1 (NORRED) 19 November 2002 (19.11.2002), see entire document.	1, 4-6, 10, and 13-15

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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"&" document member of the same patent family

Date of the actual completion of the international search
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Date of mailing of the international search report
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Continuation of B. FIELDS SEARCHED Item 3:
East text search
search terms: cardiac, heart, valve, leaflet, regurgitant, regurgitation, balloon, tether, anchor

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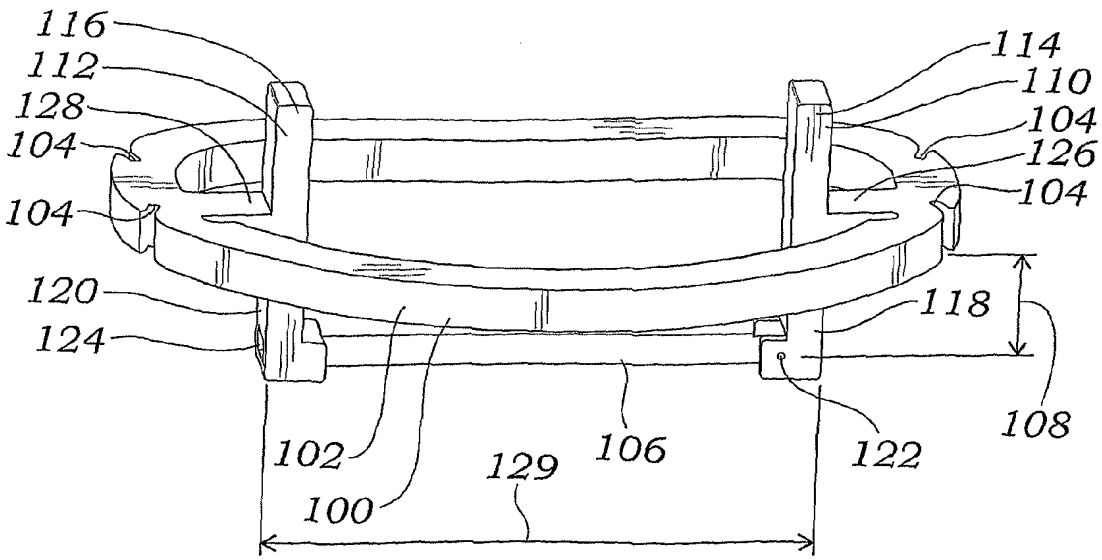
(54) **Title:** APPARATUS, SYSTEM, AND METHOD FOR TREATMENT OF POSTERIOR LEAFLET PROLAPSE



(57) **Abstract:** The invention is an apparatus, system, and method for repairing heart valves. A suture line is secured to a papillary muscle, and then passed through a portion of a heart valve leaflet. A reference element (106) is provided at a desired distance from a plane defined by the heart valve annulus (100) . The suture line is secured to the heart valve leaflet at a position adjacent the reference element. The reference element may part of a device configured for placement on or in a heart valve annulus . The reference element may be slidingly secured to the device so that the distance of the reference element from the main body of the device can be varied by a surgeon or other user. The reference element may be a line of suture, which may be pre-installed during manufacture of the device or may be installed by the surgeon or other user.

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APPARATUS, SYSTEM, AND METHOD FOR TREATMENT OF POSTERIOR LEAFLET PROLAPSE

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application claims priority to commonly assigned U.S. provisional patent application number 60/694,479 filed June 27, 2005, which is incorporated herein by reference in its entirety for all purposes.

FIELD OF THE INVENTION

[0002] The present invention relates generally to medical devices and particularly to repairing posterior leaflet prolapse in a mitral valve.

BACKGROUND OF THE INVENTION

[0003] In vertebrate animals, the heart is a hollow muscular organ having four pumping chambers: the left and right atria and the left and right ventricles, each provided with its own one-way valve. The natural heart valves are identified as the aortic, mitral (or bicuspid), tricuspid, and pulmonary, and are each mounted in an annulus comprising dense fibrous rings. The mitral and tricuspid valves have thread-like bands of fibrous tissue that attach to the valve at one end and to the papillary muscles at the other end.

[0004] Heart valve disease is a widespread condition in which one or more of the valves of the heart fails to function properly. Diseased heart valves may be categorized as either stenotic, wherein the valve does not open sufficiently to allow adequate forward flow of blood through the valve, and/or incompetent, wherein the valve does not close completely, causing excessive backward flow of blood through the valve when the valve is closed. Valve disease can be severely debilitating and even fatal if left untreated.

[0005] Various surgical techniques may be used to repair a diseased or damaged valve. One method for treating defective valves is through repair or reconstruction. One repair technique that has been shown to be effective in treating incompetence is annuloplasty, in which the effective size and/or shape of the valve annulus is modified by securing a repair segment, such as an annuloplasty ring, around the heart valve annulus. For example, the valve annulus may be contracted by attaching a prosthetic annuloplasty repair segment or ring to an interior wall of the heart around the valve annulus. The annuloplasty ring is designed to support the functional changes that occur during the cardiac cycle: maintaining coaptation and valve integrity to prevent reverse flow while permitting good hemodynamics during forward flow.

[0006] The annuloplasty ring typically comprises an inner substrate, often formed from a metal (such as stainless steel or titanium) or from a flexible material (such as silicone rubber or Dacron cordage), which is typically covered with a biocompatible fabric or cloth to allow the ring to be sutured to the heart tissue. Depending on a particular application, annuloplasty rings may be stiff or flexible, may be split or continuous, and may have a variety of shapes, including circular, D-shaped, C-shaped, saddle-shaped, and/or kidney-shaped. Examples are seen in U.S. Pat. Nos. 5,041,130, 5,104,407, 5,201,880, 5,258,021, 5,607,471, 6,187,040, and 6,805,710, the contents of which are incorporated herein by reference in their entirety. Many annuloplasty rings are formed in a plane, but some rings are generally non-planar. Such non-planar rings can be saddle-shaped, and/or bowed along various portions, such as being bowed along their anterior or straight side to conform to the desired shape of the annulus at that location.

[0007] In many diseased valves, the chordae tendineae are either ruptured, otherwise damaged, or of an improper length. When chordae

conform to the desired shape of the annulus at that location.

[0007] In many diseased valves, the chordae tendineae are either ruptured, otherwise damaged, or of an improper length. When chordae tendineae are too long, too short, or otherwise damaged, the corresponding tricuspid or mitral valve to which they are attached typically may fail to close properly. For example, chordae tendineae which are ruptured or are too long allow a valve to prolapse, wherein one or more valve leaflets swing backward past their proper closed position. This can lead to regurgitation, which is the unwanted backflow of blood from a ventricle to an atrium resulting from imperfections in the valve. When the valve allows such backward flow into an atrium, the corresponding ventricle must pump progressively harder to circulate blood throughout the body, which in turn promotes congestive heart failure.

[0008] Repairing and/or replacing dysfunctional chordae tendineae has been performed for some time. The techniques for such repair are often complicated due to the difficulties in accessing the surgical site, in identifying the dysfunctional chordae tendineae, and in determining the proper length for the repaired and/or replacement chordae tendineae.

[0009] Another approach to valve repair involves surgical excision of all or a portion of one or more of the valve leaflets of the particular heart valve. In such a procedure, a damaged portion of a valve leaflet is excised, with the remaining portions of the valve leaflet stitched together to repair the opening created by the removal of the damaged portion. This procedure tightens the valve leaflet, which can prevent valve prolapse and thereby improve valve function. An example of such a procedure is a segmental

resection of the mitral valve, wherein a prolapsing portion of a posterior leaflet is excised and the remaining portions sewed together to tighten the leaflet.

[0010] Quadrangular resection of the prolapsed area is a relatively common valve repair technique which has demonstrated excellent results. However, the technique is relatively complex and can require the surgeon to make numerous real-time decisions during the course of the procedure, including determining how large to make the resection, whether to perform an annulus plication to close the gap, etc.

[0011] The goal of mitral valve repair is to restore a good surface of coaptation to ensure satisfactory function of the valve. Because leaflet tissue is the primary component defining the surface of coaptation of the valve, it may be preferable to preserve as much as possible of the leaflet tissue, as opposed to resecting significant portions thereof. Preserving as much tissue as possible maintains anatomic and dynamic relationships, allowing for better distribution of forces and stresses on the valve components. However, in order to preserve the leaflet tissue, other aspects of the dysfunctional valve may have to be modified and/or treated, such as the shape of the valve annulus and any damaged chordae.

[0012] Accordingly, there has been a need for an improved apparatus, system, and method to repair dysfunctional heart valves, including mitral valves. The present invention satisfies one or more of these needs.

SUMMARY OF THE INVENTION

[0013] The present application is generally described with respect to its use in the repair of the mitral valve, which regulates blood flow from the left atrium (LA) to the left ventricle (LV). However, the invention could also be applied to repair of other valves, such as the tricuspid or aortic valve repairs.

[0014] The invention includes correction of mitral valve prolapse using replacement chordae, such as expanded neochordae suture (such as ploytetrafluroethylene (e-PTFE)) without leaflet resection, or with minimal leaflet resection, to resuspend the free edge of the posterior leaflet. One or more replacement chordae sutures can be passed through the papillary muscle and through the leaflet, adjusted to the proper length, and tied in position. The desired number and length of the replacement chordae depends on the needs of the particular patient, including characteristics of the valve annulus, the valve leaflets, and the existing chordae.

[0015] The invention can include application of a heart valve annuloplasty ring. The annuloplasty ring can reshape the heart valve annulus to a desired shape, and/or prevent the heart valve annulus from further and undesired deformation. The annuloplasty ring can also fix the valve annulus in the systolic position.

[0016] The invention can also include modifications to the valve leaflet itself. For example, the surgeon may suture the indentations on the valve leaflet, particularly where the indentations are relatively deep and where an annuloplasty ring is used to fix the valve annulus in the systolic position.

[0017] Various aspects of the invention can be used individually or in combination to repair a valve. The invention is applicable to various ways of

accessing the valve for repair, including an open surgical approach such as sternotomy, or a minimally-invasive approach such as percutaneous or intercostal. The standard atriotomy approach is often used for mitral valve repair procedures.

[0018] Other features and advantages of the present invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings which illustrate, by way of example, the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] Figure 1 depicts a top view of a mitral valve being exposed for viewing and analysis by the surgeon;

[0020] FIG. 2 depicts a top view of a mitral valve being analyzed by a surgeon;

[0021] FIG. 3 depicts a top view of a mitral valve under analysis of the prolapsed area of the mitral valve posterior leaflet;

[0022] FIG. 4. depicts a top view through a mitral valve with placement of artificial chordae suture through the papillary muscle;

[0023] FIG. 5A depicts a top view of a mitral valve with placement of artificial chordae suture through the free edge of the posterior leaflet;

[0024] FIG. 5B depicts a side view of a mitral valve with placement of artificial chordae suture through the free edge of the posterior leaflet;

[0025] FIG. 6A is a side view of a mitral valve and papillary muscle with placement and tying of artificial chordae suture where there is no significant excess of tissue;

[0026] FIG. 6B is a side view of a mitral valve and papillary muscle with placement and tying of artificial chordae suture where there is an excess of tissue;

[0027] FIG. 7 is a side view of a mitral valve and papillary muscle with tying of the artificial chordae suture;

[0028] FIG. 8 is a top view of a mitral valve with sutures applied to the posterior leaflet indentations;

[0029] FIG. 9 is top view of a mitral valve with an annuloplasty ring implanted and with a saline injector;

[0030] FIG. 10 is a top perspective view of a guide device according to an embodiment of the invention;

[0031] FIG. 11 is a side perspective view of the guide device of FIG. 10;

[0032] FIG. 12 is a top view of the guide device of FIGS. 10-11 positioned on or in a mitral valve annulus according to an embodiment of the invention;

[0033] FIG. 13 is a side perspective view, in partial cross-section, of the guide device of FIGS. 10-11 positioned on or in a mitral valve annulus according to an embodiment of the invention;

[0034] FIGS. 14A-14C are side views in partial cross section of a guide device according to an embodiment of the invention;

[0035] FIG. 15 is a side view in partial cross section of a guide device according to an embodiment of the invention;

[0036] FIGS. 16A and 16B are side views in partial cross section of a guide device according to an embodiment of the invention; and

[0037] FIGS. 17A and 17B are side views in partial cross section of a guide device according to an embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[0038] FIG. 1 depicts a heart 10 with an incision 12 in the left atrial wall 14 through which the mitral valve 16 is exposed for viewing during a surgical proceeding. The atrial wall incision 12 is held open with one or more retractors 18, giving the surgeon a full view for analysis of the mitral valve 16. Note that the viewing can be achieved directly a shown, as is typically the case for open chest and/or open heart surgical methods, or indirectly through an endoscope or other visualization devices, as may be used for minimally invasive procedures. In the exposure depicted in FIG. 1, a suture 20 (such as a

3-0 suture) is passed around and below the inferior vena cava 22, then makes a shallow pass through (i.e., takes a superficial bite of) the left atrial endothelium 24 at a position 26 about 1.5 cm behind the mitral valve annulus 28. Note that in the particular embodiment depicted, the suture is passed through the left atrial endothelium 18 at approximately the 5 o'clock position on the valve annulus 28, with noon being the middle 22 of the anterior leaflet A and 6 o-clock being the middle 24 of the posterior leaflet P), and then passes back behind and below the inferior vena cava 16. By applying a gentle tug on the suture 20, the desired exposure can be achieved.

[0039] Once the desired exposure and/or viewing of the mitral valve 16 are achieved, a thorough surgical analysis of the mitral valve structure can be performed. An alphanumeric code is often used to designate areas of the mitral valve 16, and this code is used in this application and its drawings. The letters P and A refer to the posterior leaflet P and anterior leaflet A, respectively. Each leaflet is also divided into three portions, with the antero-lateral portion of the leaflet designated with the number 1, the middle portion with the number 2, and the postero-medial portion with the number 3. The posterior leaflet portions are typically referred to as scallops due to their shapes, with the antero-lateral scallop designated as P1, the middle scallop designated as P2, and the postero-medial scallop designated as P3. Corresponding (i.e., opposing) portions of the anterior leaflet are designated as A1, A2, and A3, respectively.

[0040] Usually the antero-lateral scallop P1 of the posterior leaflet P is free from prolapse and can be used as a reference point with which to compare the other segments. With the help of one or more nerve hooks 34 or similar devices, as depicted in FIG. 2, the free edge of P1 is compared to free edges or other portions of A1, then to A2, P2, A3, and P3. Note that this order of

comparison is just one example, and the invention is not limited to this specific order. Using such a step-by-step exploration of essentially the entire mitral valve, it is possible to achieve a good three-dimensional understanding of the mitral valve. This analysis can determine and/or identify prolapse or other dysfunction in the valve. In the particular mitral valve 16 depicted in FIG. 2, the analysis reveals a prolapse 36 of the posterior leaflet P, located in P2 in which the free edge of the posterior leaflet middle scallop P2 overrides the free edge of the anterior leaflet middle portion A2 due to one or more ruptured chordae 38 (shown in FIG. 3). Note that the result of the surgical valve analysis can be compared to the intraoperative echo findings.

[0041] Once the prolapsed area (or areas) of the posterior leaflet P is identified, one or more stay sutures 40 (such as 2-0 stay sutures) are be passed around the normal chordae, and/or through the posterior leaflet P itself (as depicted in FIG. 3), on each side of the prolapsed area 36 of the posterior leaflet P to delineate the pathological zone. Gentle pressure on these stay sutures 40 will provide exposure of the prolapsed area 36 and ruptured chordae 38, as depicted in FIG. 3.

[0042] Analysis of the prolapsed area 36 is directed toward two main aspects of the tissue: the quality of the tissue, and the quantity/amount of tissue (which corresponds to the height of the posterior leaflet P in the prolapsed area). In considering the quality of the tissue, the presence and extent of mucoid degeneration should be assessed. The aim of the operation is to construct a vertical buttress in which the surface area is generally smooth and flat to ensure an even surface for coaptation. Mucoid degeneration may be too irregular, producing bulging pockets which make the surface of coaptation uneven and irregular. In such a case, a resection to remove such uneven areas may be necessary. Mucoid degeneration may also be too

excessive at the base of the posterior leaflet P, reducing the pliability of the junction between the mitral valve annulus 28 and posterior leaflet P. This can displace the surface of coaptation anteriorly, which may increase the risk of systolic anterior motion (SAM). SAM occurs when the anterior leaflet of the mitral valve is "pulled" into the outflow of the left ventricle during the systolic phase, which can cause leakage through the mitral valve into the left atrium.

[0043] In assessing the quantity of tissue, the surgeon will evaluate the height of the posterior leaflet P. An excess of tissue is considered to be present when the height of the posterior leaflet P exceeds 2cm. It is important to take note of such a situation, because it will affect the length of the artificial chordae to be implanted.

[0044] To provide a better view of and/or access to the area of the chordae 42 and the papillary muscles 44a, 44p, one or more anterior stay sutures 46, such as 2-0 stay sutures, are passed around the chordae 42 of the anterior leaflet A, as depicted in FIG. 4. Two such sutures 46 may be sufficient, depending on the particular application and patient. Gentle pulling on these anterior stay sutures 46, when combined with gentle pulling on the posterior stay sutures 40 and hence on the posterior leaflet P, provides good views and/or access into the left ventricular cavity and to the papillary muscles 44a, 44p. Using a forceps 48, it is then relatively convenient to grasp the anterior papillary muscle 44a to improve its exposure and stability. A chordae replacement suture 50a, such as mattress suture of 4-0 e-PTFE, is placed through the fibrotic part of the top 52a of the anterior papillary muscle 44a. In the embodiment depicted, the chordae replacement suture 50a is placed using a curved needle 54 and needle holder 56. It is often desirable that the exit point of the suture 50a be oriented towards the prolapsed area 36. The chordae replacement suture 50a is then tied down, which can involve three or

four knots, on the anterior papillary muscle 44a. The same maneuver may then be repeated for the posterior papillary muscle 44p, whereby chordae replacement suture 50p (depicted in FIG. 5A) is passed through the fibrotic part of the top 52p of the posterior papillary muscle 44p.

[0045] To respect and protect the structure of the subvalvular apparatus (e.g., chordae, etc.), it is often desirable that the chordae replacement sutures 50a, 50p be placed through the papillary muscle head(s) that anchors the diseased chordae being replaced and/or repaired. The actual placement of the chordae replacement sutures 50a, 50p depends on the particular application, including the particular patient and surgeon. The main principle is that the artificial chordae are securely anchored.

[0046] Prolapses are most typically localized, such as the localized prolapse 36 of the middle scallop P2 of the posterior leaflet P depicted. However, extensive lesions or other elements, which may include abnormalities in other portions of the leaflet(s), may complicate the repair. For example, if the prolapsed area 36 of the posterior leaflet P is greater than just the middle portion of middle scallop P2, or if other lesions and/or aspects are present, installation of additional artificial chordae may be needed to resuspend the prolapsed area 36.

[0047] With the chordae replacement sutures 50a, 50p passed through and tied via knots 58a (58p not shown) to the desired papillary muscle or muscles 44a, 44p, the chordae replacement sutures 50a, 50p are then brought up through the free margin(s) of the leaflet, which in the embodiment depicted is the posterior leaflet P. In bringing the chordae replacement sutures 50a, 50p up, care is taken to avoid entangling the chordae replacement sutures 50a, 50p in the native non-diseased chordae 42 or other subvalvular elements. In the

embodiment of FIGS. 5A and 5B, one suture 50a is placed between the middle of P2 and the indentation between P1-P2. (The other suture 50p will be placed between the middle of P2 and the indentation P2-P3, although this procedure is not depicted in FIGS. 5A and 5B.)

[0048] In the embodiment depicted more clearly in FIG. 5B, the double-armed suture 50a is passed through the auricular side 60 of the posterior leaflet P at and/or adjacent the free edge 62 where the natural chordae were/are attached, and then back through to the auricular side 60 about 4 to 5 mm away from the free edge 62. The distance between the two arms 64, 66 of suture 50a as they pass through the posterior leaflet P may be approximately 3mm to avoid plication and/or damage of the leaflet tissue which might impair the smoothness and regularity of the surface of coaptation.

[0049] Note that the procedure depicted in FIGS. 5A and 5B only shows the tying and connection of chordae replacement suture 50a to the posterior leaflet P and anterior papillary muscle 44a. Where desired, and depending on the particular application, the procedure may be repeated to connect chordae replacement suture 50p (where present) to the posterior leaflet P and posterior papillary muscle 44p, or to any leaflet and appropriate papillary muscle.

[0050] To ensure proper valve operation, the artificial chordae formed by the chordae replacement sutures 50a, 50p are tied off at a proper length. In the embodiment of FIGS. 6A and 6B, the stay sutures of the posterior leaflet P have been removed, so that the leaflet free edge 62 is freely mobilized.

[0051] Adjusting the length of the artificial chordae to the proper length should include consideration of the any excess leaflet tissue, which has

been identified as a risk factor for postoperative SAM. Anterior displacement of the surface of coaptation towards the ventricular outflow tract has also been identified as a risk factor for SAM. To reduce the risk of SAM, the degree of correction of the prolapse of the posterior leaflet P should be such that the surface of coaptation remains vertical and posterior, parallel to the posterior wall of the left ventricle and away from the left ventricular outflow tract. In other words, if the excess tissue is large then the artificial chordae should be made shorter.

[0052] Depending on the particular application, the goal may include not only correction of the prolapse, but also transformation of the posterior leaflet into a vertical buttress against which the anterior leaflet will come into apposition to create a proper seal and prevent valve leakage. To achieve this, it is important that the free edge of the posterior leaflet is prevented from moving anteriorly towards the outflow tract of the left ventricle.

[0053] The length of the artificial chordae is selected to compensate for any excess of tissue of the posterior leaflet P. If there is no excess of tissue, then the artificial chordae length is selected to bring the free edge 62 of the posterior leaflet P to the level of the plane 70 of the valve annulus 28, as shown in FIG. 6A. If there is excess tissue, then the artificial chordae length is selected to bring the free edge 62 of the posterior leaflet P to a lower level 72, as shown in FIG. 6B. The lower level 72 is typically at a depth 73 between 5mm and 8mm underneath the plane 70 of the valve annulus 28, depending on the particular application and factors such as the height of the posterior leaflet P. Once the posterior leaflet free edge 62 is brought to the desired level, the chordae replacement sutures 50a, 50p are gently tied using one or more knots 74 on the auricular side 60 of the posterior leaflet P. In one embodiment three

to four knots may be necessary, although other numbers of knots may also be used depending on the particular application.

[0054] Note that there may be variations on the particular manner in which the chordae replacement sutures are placed in and/or secured to the leaflets, depending on the particular application. For example, in the embodiments depicted in FIGS. 5B to 6B, the chordae replacement suture 50a passes from the auricular side 60 of the posterior leaflet P at or adjacent the free edge, then passes back through the posterior leaflet P at a distance of about 3mm from the free edge. The chordae replacement suture 50a is then depicted being tied using a standard square knotting method. These suturing positions and distances could be varied, however, depending on the particular application and characteristics such as the strength of the particular leaflet tissue. A key issue to address for suture placement and securing is that the chordae replacement suture(s) should hold.

[0055] FIG. 7 depicts the chordae replacement suture 50a being passed again through the posterior leaflet P, and then tied on the ventricular side 68 of the posterior leaflet P. Depending on the particular application and the suture involved (e.g., if the chordae replacement suture(s) are a relatively slippery material, such as e-PTFE), a total of 10 to 12 knots may be necessary to tie off the chordae replacement suture, which can leave a relatively prominent remnant. Tying the final knot or knots on the ventricular side 68 can prevent excessive irregularity on the surface of coaptation due to any prominent remnant from the final knot, and also avoids any motion of the leaflet P along the chordae replacement suture which may create unnecessary repeated tension or other stress on the leaflet P and/or replacement chordae suture.

[0056] Most mitral valves have a naturally-occurring crease or indentation between P1 and P2, and another indentation between P2 and P3. If one or both of the indentations between P1 and P2 and between P2 and P3 are relatively deep, they may interfere with the goal of transforming the posterior leaflet into a relatively smooth and regular vertical buttress. In a natural and untreated mitral valve, these indentations serve the physiological purpose of making it possible for the posterior leaflet to expand slightly to follow the diastolic dilatation of the annulus without tension. However, if the annulus is to be fixed into the systolic position by the implantation of an annuloplasty ring, the indentations will no longer serve their useful role, and may instead interfere with proper valve function. For example, the indentations may be the cause of residual leak attributed by an irregular surface of coaptation. Accordingly, when the indentations are relatively deep and/or an annuloplasty ring is to be implanted, it may be desirable to suture the indentations. FIG. 8 depicts a mitral valve 16 with chordae replacement sutures 50a, 50p installed to create replacement chordae. The mitral valve 16 has an indentation 74 between P1 and P2, and another indentation 76 between P2 and P3. The indentations 74, 76 have been closed with suture 78, 80, such as a 5-0 monofilament running suture.

[0057] With the artificial chordae in place (and the indentations sutured, if desired), an annuloplasty ring may be installed. In the embodiment of such an installation in a mitral valve 16 depicted in FIG. 9, ring-securing sutures 82 (such as 2-0 breaded sutures) are passed through the mitral valve annulus 28 and then into the annuloplasty ring 84. The ring-securing sutures 82 are placed in a way that respects the desired geometry of the native valve 16. In the embodiment shown, four sutures 82 are placed at the level of the anterior leaflet A between the two commissures 86, and the remaining sutures 82 are placed adjacent the posterior leaflet P. The middle 30 of the anterior

leaflet A corresponds to the middle 88 of the annuloplasty ring 84 to avoid any distortion of the mitral valve 16 from the desired geometry.

[0058] The role of the annuloplasty ring 16 is not only to reduce the size of the mitral valve annulus 28, but also to remodel the shape of the mitral valve 16, which is typically deformed as a consequence and/or cause of the mitral valve insufficiency. In fixing the mitral valve 16 in a systolic position, the annuloplasty ring 84 will prevent any further dilatation. The size of the annuloplasty ring 84 is selected according to various factors, such as the anterior leaflet surface area, the intertrigonal distance, etc.

[0059] After ring implantation, and before closure of the operational site, the result of the repair may be tested. In FIG. 9, the mitral valve 16 is tested by injecting saline 90 into the left ventricle using an injector 92. Two important goals are to confirm the absence of regurgitation and determine the aspect of the line of closure. The line of closure is typically preferred to be symmetrical, close to the ring, and parallel to the posterior aspect of the ring. A posterior line of closure indicates that the surface of coaptation is away from the ventricular outflow tract.

[0060] After closure of the left atrium and restoration of normal hemodynamic function, and echocardiographic analysis or other assessment of heart function can determine the quality of the result. The absence of regurgitation as well as a free (unobstructed) outflow tract signals a successful repair. Additionally, the height of the surface of coaptation can be measured, which is usually between 12mm and 18mm in a successful repair. For a successful treatment, the echocardiographic analysis typically will show a posterior leaflet with little or no mobility hanging vertically from the annulus and forming a buttress against which the anterior leaflet comes in apposition.

[0061] Referring again to FIGS. 6A and 6B, obtaining a desired length of the chordae replacement sutures 50a (50p not shown) is important in achieving a proper repair of the mitral valve 16. A guide that indicates the annular plane or other level at which to tie off the sutures could be helpful to a surgeon or other person installing the chordae replacement sutures. An embodiment of such a guide device 100 is depicted in FIGS. 10 and 11. The guide device 100 depicted includes a generally ring-shaped main body 102 which, in the embodiment depicted, is shaped similar to the annulus of the valve being treated. The guide device 100 is configured to be placed onto or into the mitral valve being treated. The guide device 100 includes one or more suture anchors 104, which are configured to receive suture to permit the guide device 100 to be temporarily sutured on or in the mitral valve annulus. The guide device 100 also includes a generally horizontal guide element in the form of a cross bar 106. In the particular embodiment depicted, the cross bar 106 is secured to the guide device 100 at a depth 107 of about 5mm below the generally ring-shaped main body 102, although other cross bar depths are also within the scope of the invention. The selection of cross bar depth depends on the particular application, including such factors as the height of the leaflet to which the replacement chordae are to be attached, etc. Depths of between 0 and 8mm are of specific interest to the invention.

[0062] The cross bar 106 is secured to the guide device 100 via a cross bar release mechanism which includes a first vertical bar 110 and a second vertical bar 112. The vertical bars 110, 112 each include a proximal portion 114, 116 that extends above the generally ring-shaped main body 102 of the guide device 100. Each of the vertical bars 110, 112 also includes a distal portion 118, 120 that is secured to the cross bar 106.

[0063] One vertical bar 110 is secured at its distal portion 118 to the cross bar 106 via a hinge in the form of a pin 122. The other vertical bar 112 includes a hole 124 configured to slidingly receive an end of the cross bar 106. Both of the vertical bars 110, 112 are secured to the generally ring-shaped main body 102 of the guide device 100 via at least partially flexible connections 126, 128. By pressing inwardly on the proximal portions 114, 116 of the vertical bars 110, 112 (i.e., by pressing the proximal portion of one vertical bar toward the proximal portion of the opposite vertical bar), the distal portions 118, 120 of the vertical bars 110, 112 are forced apart by the rotation of the vertical bars 110, 112 about the connections 126, 128. As the distal portions 118, 120 move apart, the cross bar 106 is pulled out of the hole 124, and is then free to rotate about pin 122 as depicted in FIG. 11.

[0064] In the embodiment of FIGS. 10 and 11, the "sub-valvular" assembly formed by the cross bar 106 and its supports (i.e., the vertical bar lower portions 118, 120) has a length 129 that is less than the maximum width 130 of the generally ring-shaped main body 102 of the guide device 100. The cross bar 106 is also held by the vertical bars 110, 112 at a position slightly inward from the periphery of the ring-shaped main body 102. The ring-shaped main body 102 is generally configured to match the shape of the annulus of the valve to be treated. As depicted in FIGS. 12-13, the "inward" positioning of the cross bar 106 and vertical element lower portions 118, 120 permits the cross bar 106 to be passed through the valve annulus 28 and between the valve leaflets A, P at a position that facilitates guiding the appropriate length at which to tie off replacement chordae sutures.

[0065] In the embodiment depicted in FIGS. 12 and 13, the guide device 100 is positioned on or in the valve annulus 28 prior to tying the chordae replacement suture(s) 50a, 50p to the valve posterior leaflet P.

Depending on the particular application, the guide device 100 can be placed onto or into the valve annulus 28 after the chordae replacement suture(s) 50a, 50p have been secured to the respective papillary muscle(s) 44a (44p not shown), but prior to the chordae replacement suture(s) 50a, 50p being firmly tied to the valve posterior leaflet P. The guide device 100 is placed onto the valve annulus 28 with distal portions 118, 120 of the vertical bars 110, 112 extending through the valve annulus 28 and into the subvalvular area. This positions the cross bar 106 extending down into the valve annulus 28 into the ventricle area at a desired depth 107, which can be anywhere from 0mm to 10mm below the plane 70 of the valve annulus 28, depending on the particular application and such issues as the extent of excess posterior leaflet tissue, etc. In the particular embodiment depicted, the guide device 100 is positioned on or in the valve annulus 28 so that the ring-shaped main body 102 is generally parallel to the plane 70 of the valve annulus 28. For the particular guide device 100 depicted, which has a cross bar 106 generally parallel to the ring-shaped main body 102, the cross bar 106 will thus be positioned generally parallel to the plane 70 of the valve annulus 28.

[0066] With the guide device 100 in the desired position, the surgeon or other user can temporarily secure the guide device main body 102 to the valve annulus 28 using one or more stay sutures 132 passing through the suture anchors 104.

[0067] With the chordae replacement suture(s) tied to the papillary muscle(s), the surgeon or other user will proceed to tie the chordae replacement sutures to the valve leaflet, as previously depicted in FIGS. 5A to 7. As depicted in FIGS. 12 and 13, the cross bar 106 of the guide device 100 serves as an indicator of the proper height at which to tie the chordae replacement suture(s) 50a, 50p to the valve leaflet. As depicted in FIG. 13, the

surgeon can pass the first arms 64a (64p not shown) and second arms 66a (66p not shown) of each replacement suture 50a (50p not shown) on either side of the cross bar 106, then tie one or more knots 58a (58p not shown) in the suture(s) so that the cross bar 106 is held between the suture knots 58a (58p not shown) and the posterior valve leaflet P. With the chordae replacement suture(s) 50a (50p not shown) thus secured to the posterior valve leaflet P at the desired length, the guide device 100 and cross bar 106 can be removed. In the device depicted in FIGS. 10-13, the user can squeeze together the proximal portions 114, 116 of the vertical bars 110, 112, thus releasing the cross bar 106 from one vertical bar 116 and permitting the cross bar 106 to be slid out from between the knots 58a (58p not shown) and the posterior valve leaflet P. The user can then tie additional finishing knots in the chordae replacement suture(s) 50a, 50p, as was previously depicted in FIGS. 7 and 8, to make the connection to the valve leaflet P more secure and/or permanent, and also to take in any slack in the chordae replacement sutures 50a, 50p that may have been created by the removal of the cross bar 106.

[0068] Depending on the particular application, the device could include a cross bar 106 having a depth 107 that is adjustable. For example, in the embodiment depicted in FIGS. 14A-14C, the vertical bars 110, 112 are secured to the main body 102 via connections 134 that permit the vertical bars 110, 112 to be raised and/or lowered with respect to the main body 102. One or more of the connections 134 may include a locking apparatus (not shown) for securing the vertical bars 110, 112 at the desired position once the vertical bars 110, 112 have been slid to that position(s). The locking mechanism could be one of many such devices and/or methods known in the art for locking a sliding element into position with respect to a fixed element. A user can thus select the desired depth at which to place the cross bar 106, slide one or both of the vertical bars 110, 112 up or down until the cross bar 106 is at the

desired position, lock the connections 134 to secure the vertical bars 110, 112 and cross bar 106 in the desired position, and proceed to use the guide device 100 to determine the proper length for chordae replacement suture(s). In FIG. 14A, the cross bar depth 108 is relatively small, while in FIG. 14B the cross bar depth 108 is increased. In FIGS. 14A and 14B, the cross bar 106 is depicted as being generally parallel to the ring-shaped main body 102. However, by sliding the vertical bars 110, 112 to different depths 108a, 108b, as depicted in FIG. 14C, an angled configuration of the cross bar 106 can be achieved. Such an angled cross bar configuration could be selected for situations where different replacement chordae required different lengths. A device 100 such as that depicted in FIG. 14C thus has a cross bar 106 that is generally non-parallel from the ring-shaped main body 102. Placing the device 100 of FIG. 14C with the ring-shaped main body 102 on or in a valve annulus and also parallel to the plane of the valve annulus (in similar fashion to the position depicted in FIGS. 12 and 13 for the "parallel bar" device of FIGS. 10 and 11) would result in the cross bar 106 being in generally non-parallel relation to the plane of the valve annulus.

[0069] The replacement chordae reference element, which in FIGS. 10-11 and FIGS. 14A-14C was a cross bar 106, could comprise a generally non-flexible member or a generally flexible member. In FIGS. 10-11 and 14A-14C, the cross bar 106 was a generally non-flexible bar. A flexible element, such as a flexible bar or flexible suture, could also be used. For example, in FIG. 15 a line of suture 136 is used as the cross bar reference element. The cross bar suture 136 is drawn relatively tightly between the vertical bars 110, 112, passing through to create a reference line positioned below and generally parallel with the guide device ring-shaped main body 102. in the particular embodiment depicted, the cross bar suture 136 is secured to the vertical bars 110, 112 by passing through suture holes 138 and

then being tied in knots 140. In use, once the replacement chordae suture(s) have been tied off and it is desired to remove the guide device and cross bar suture, the cross bar suture can simply be cut with a scalpel by the surgeon or other user, and then the guide device removed and the remaining ends of the cross bar suture pulled from between the chordae replacement suture knots and the posterior leaflet.

[0070] In another embodiment of the invention, multiple cross bars could be used, with the surgeon removing unwanted cross bars prior to employing the apparatus. For example, in the embodiment of FIGS. 16A and 16B, multiple lines of suture 136a, 136b, 136c are positioned at various depths on the vertical elements 110, 112. The guide device 100 includes depth markings 142a, 142b, 142c which indicate the depths of the respective suture bars 136a, 136b, 136c. The depth markings 142a, 142b, 142c depicted in FIGS. 16A and 16B are simple lines or notches, but other depth markings could alternatively or additionally be used, such as numbers, letters, or other markings, depending on the particular application. Prior to placing the guide device 100 on or into the valve annulus, the surgeon or other user can select the desired depth and remove those suture bars that are not at the desired depth, while retaining the suture bar that is at the desired depth. In FIG. 16B, the user has removed, via cutting or other means, the highest suture bar 136a and lowest suture bar 136c, thereby leaving middle suture bar 136b in place for use as the replacement chordae reference element. Note that the use of removable bar elements is not limited to suture bars, but could also use generally rigid bars, etc., configured to be selectively removed by a surgeon or other user.

[0071] FIGS. 17A-17B depict a further embodiment of the invention, wherein the user selects the desired depth and installs the cross bar or other

replacement chordae reference element at the desired depth. The device 100 of FIGS. 17A-17B includes two vertical bars 110, 112 each having several holes 138 or other suture-retaining elements along at least a part of the length of the vertical bars 110, 112. Depth markings 142 may also be included along the length of the vertical bars 110, 112 to indicate the "depth" of any cross bar suture that might be tied through a particular the hole (i.e., the distance of each hole from a plane passing through the guide device generally ring-like peripheral body and representing the plane of the valve annulus). A surgeon or other use can thus select the desired depth, determine which holes correspond to the desired depth, and then pass suture through a desired hole in one vertical bar to a desired hole in the second vertical bar. The surgeon or other user can thus tie off the suture line in knots 140 or via other retaining methods known in the art at a desired hole in each vertical bar 110, 112, thereby creating a device such as that depicted in FIG. 17B with a cross bar suture 136 extending between the vertical bars 110, 112 at the desired depth. The selected holes in each vertical element 110, 112, could be at the same level, as in FIG. 17B, thereby providing a cross bar suture 136 that is generally parallel to the ring-shaped main body 102. Alternatively, the selected holes from each vertical element could be at different levels, thereby providing a cross bar suture that is at angle from (i.e., non-parallel to) the ring-shaped main body 102. Such an embodiment would have similar characteristics, uses, and applications to that depicted in and discussed with respect to FIG. 14C.

[0072] In the embodiments discussed above, the discussion and figures have largely focused on replacing chordae for the posterior leaflet of the mitral valve. The invention could also be used, however, to replace other chordae, such as chordae of the mitral valve anterior leaflet or chordae of other valves.

[0073] Although the specific embodiment depicted and described involved an open surgical approach, the invention is also applicable to minimally invasive approaches, including percutaneous approaches (including accessing the treatment site through the circulatory system) and intercostal approaches (including accessing the treatment through the heart wall, including the apex of the heart).

[0074] While the invention can be performed without any valve leaflet resection, some resection may be desirable, depending on the condition of the heart valve leaflet. The invention can reduce the need and/or extent of any resection, but may need to be combined with some resection, particularly where a valve leaflet has a particularly large amount of excess tissue.

[0075] While the invention has been described with reference to particular embodiments, it will be understood that various changes and additional variations may be made and equivalents may be substituted for elements thereof without departing from the scope of the invention or the inventive concept thereof. For example, while the invention is specifically discussed in application with repair and/or replacement of chordae tendineae, it has applicability in other areas where it is desired to repair similar structures. In addition, many modifications may be made to adapt a particular situation or material to the teachings of the invention without departing from the essential scope thereof. Therefore, it is intended that the invention not be limited to the particular embodiments disclosed herein, but that the invention will include all embodiments falling within the scope of the appended claims.

WHAT IS CLAIMED IS:

1. An apparatus for repairing a heart valve, comprising:

a support body, the support body defining a reference plane therethrough and being configured for placement on or in a heart valve annulus;

a first reference element, the first reference element secured to the support body and positioned at a distance of 3mm to 15mm from the support body reference plane.

2. The apparatus of claim 1, wherein the first reference element comprises an elongated device having a first end and a second end, wherein the first end is secured to the support body at a first distance from the support body reference plane, and the second end is secured to the support body at a second distance from the support body reference plane.

3. The apparatus of claim 2, wherein the first distance is substantially equal to the second distance.

4. The apparatus of claim 3, wherein the first distance is greater than the second distance.

5. The apparatus of claim 2, wherein the first reference element is configured to fit between adjacent valve leaflets of a heart valve when the support body is placed on or in a heart valve annulus of the heart valve.

6. The apparatus of claim 2, wherein the first reference element comprises an elongated bar.

7. The apparatus of claim 2, wherein the first end is releasably secured to the support body.

8. The apparatus of claim 2, wherein the first end is connected to the support body via a sliding connection.

9. The apparatus of claim 8, wherein the sliding connection further comprises a locking mechanism.

10. The apparatus of claim 2, wherein the first reference element comprises a line of suture.

11. The apparatus of claim 2, wherein the apparatus is configured to provide variation in the first distance and in the second distance.

12. The apparatus of claim 2, further comprising:

a second reference element, the second reference element secured to the support body and positioned at a second reference distance of 3mm to 15mm from the support body reference plane, wherein the second reference distance is different from the first reference distance.

13. The apparatus of claim 12, further comprising:

a third reference element, the third reference element secured to the support body and positioned at a third reference distance of 3mm to 15mm from the support body reference plane, wherein the third reference distance is different from the second reference distance and from the first reference distance.

14. An apparatus for repairing a heart valve, comprising:

a support body, the support body defining a reference plane therethrough and being configured for placement on or in a heart valve annulus;

a first elongated member extending from the support body in a direction away from the support member reference plane to a first member length of at least 3mm; and

a second elongated member extending from the support body in a direction away from the support member reference plane to a second member length of at least 3mm.

15. The apparatus of claim 14, wherein the first elongated member comprises a plurality of first suture attachment points, the first suture attachment points positioned at different positions along the length of the first elongated member.

16. The apparatus of claim 15, further comprising:

indicia indicating the distance from one or more of the first suture attachment points to the support member reference plane.

17. The apparatus of claim 15, wherein the second elongated member comprises a plurality of second suture attachment points, the second suture attachment points positioned at different positions along the length of the second elongated member.

18. The apparatus of claim 17, further comprising:

indicia indicating the distance from one or more of the second suture attachment points to the support member reference plane.

19. The apparatus of claim 15, wherein each of the first suture attachment points comprises a hole passing through the first elongated member.

20. The apparatus of claim 17, further comprising:

a first suture line passing from a first of the first suture attachment points to a first of the second suture attachment points.

21. The apparatus of claim 20, further comprising:

A second suture line passing from a second of the first suture attachment points to a second of the second suture attachment points.

22. The apparatus of claim 21, further comprising:

A third suture line passing from a third of the first suture attachment points to a third of the second suture attachment points.

23. A method of repairing a heart valve having a heart valve annulus with corresponding annular plane, comprising:

securing a first suture line to a first papillary muscle at a first attachment point, wherein the first papillary muscle is positioned in a heart chamber adjacent the heart valve;

passing a portion of the first suture line through a first heart valve leaflet of the heart valve;

providing a chordae reference element;

positioning the chordae reference element within the heart chamber at a position at least 3mm from the annular plane of the heart valve annulus;

securing the first suture line to the first heart valve leaflet, wherein the first suture line is secured to the first heart valve at a position adjacent the chordae reference element.

24. The method of claim 23, wherein securing the first suture line to the first heart valve leaflet comprises passing the suture line around the chordae reference element and tying a knot in the first suture line such that the chordae reference element is positioned between the knot and the first heart valve leaflet.

25. The method of claim 23, wherein the heart valve comprises a mitral valve, the heart valve leaflet comprises a first portion, a second portion, and a middle portion positioned between the first and second portions, and the method further comprises:

suturing a first surface indentation between the first portion and the middle portion of the leaflet; and

suturing a second surface indentation between the second portion and the middle portion of the leaflet.

26. The method of claim 23, wherein providing the chordae reference element comprises:

providing a main support body configured to be placed on or in the heart valve annulus, the main support body defining a support body plane;

providing a reference element that is slidingly secured to the apparatus so that the distance from the reference element to the support body plane can be varied by sliding the reference element toward and/or away from the support body plane.

27. The method of claim 26, wherein providing the chordae reference elements comprises:

sliding the reference element to a desired position with respect to the support body plane.

28. The method of claim 23, wherein providing the chordae reference element comprises:

providing a main support body configured to be placed on or in the heart valve annulus, the main support body defining a support body plane;

providing a plurality of reference elements secured to the apparatus, each of the plurality of reference elements positioned at different distance from the support body plane.

29. The method of claim 28, wherein providing the chordae reference element comprises:

selecting the chordae reference element from among the plurality of reference elements; and

removing all of the reference elements except the chordae reference element.

30. The method of claim 23, wherein providing the chordae reference element comprises:

providing a main support body configured to be placed on or in the heart valve annulus, the main support body defining a support body plane;

providing a first element extending away from the main support body plane, the first element comprising a plurality of first suture attachment points;

providing a second element extending away from the main support body plane, the second element comprising a plurality of second suture attachment points;

securing a first end of a suture line to one of the first suture attachment points; and

securing a second end of the suture line to one of the second suture attachment points.

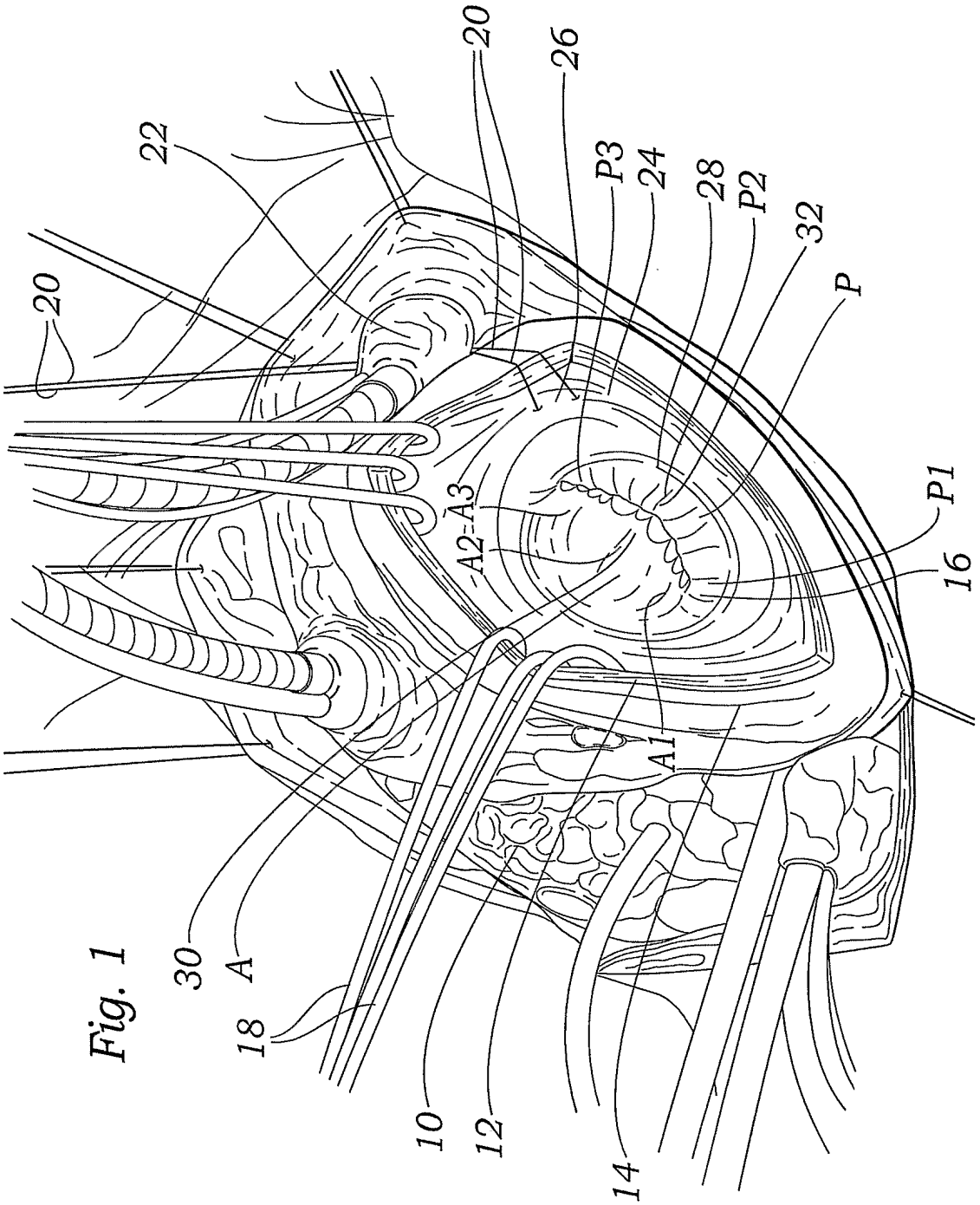


Fig. 1

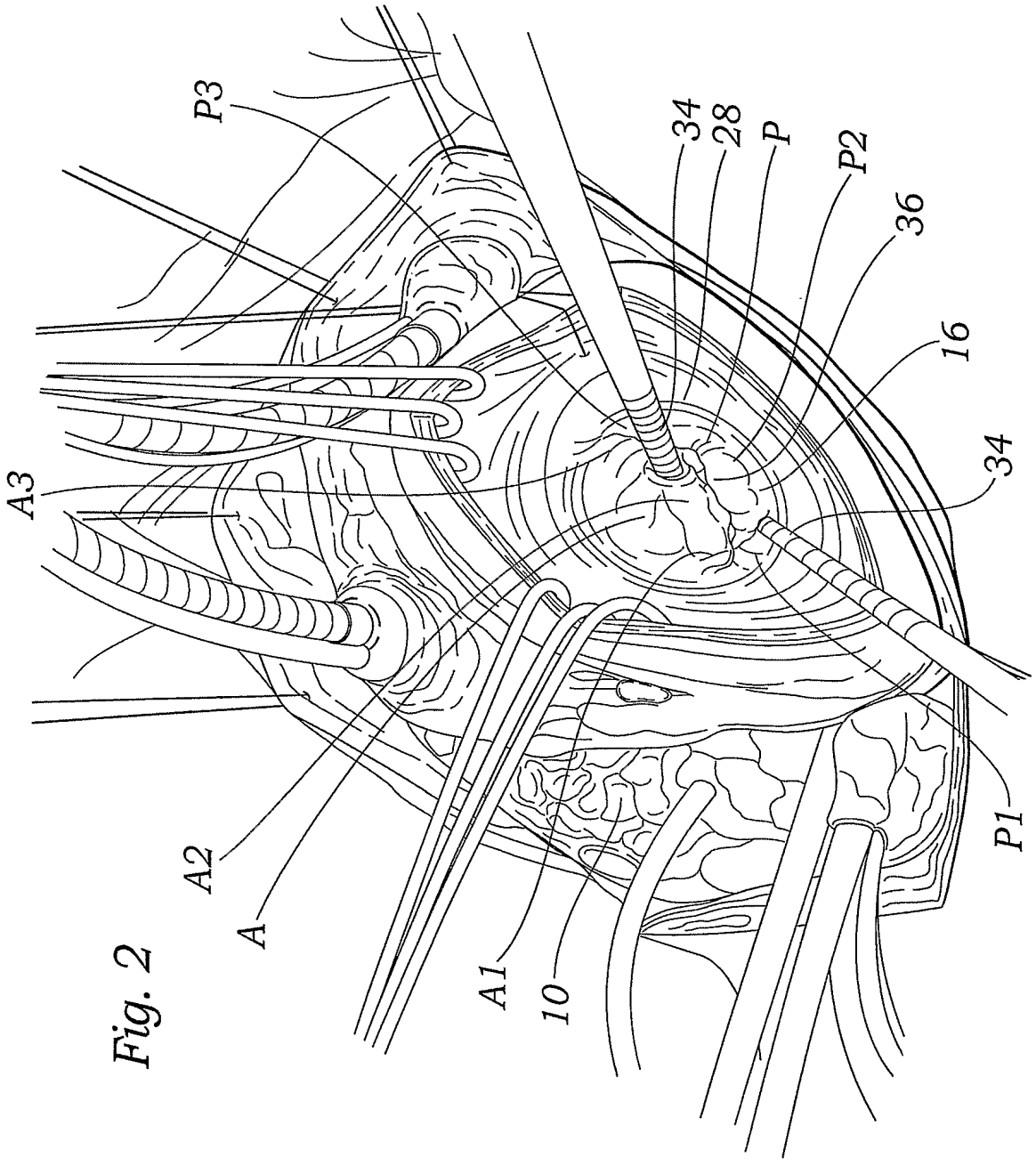


Fig. 2

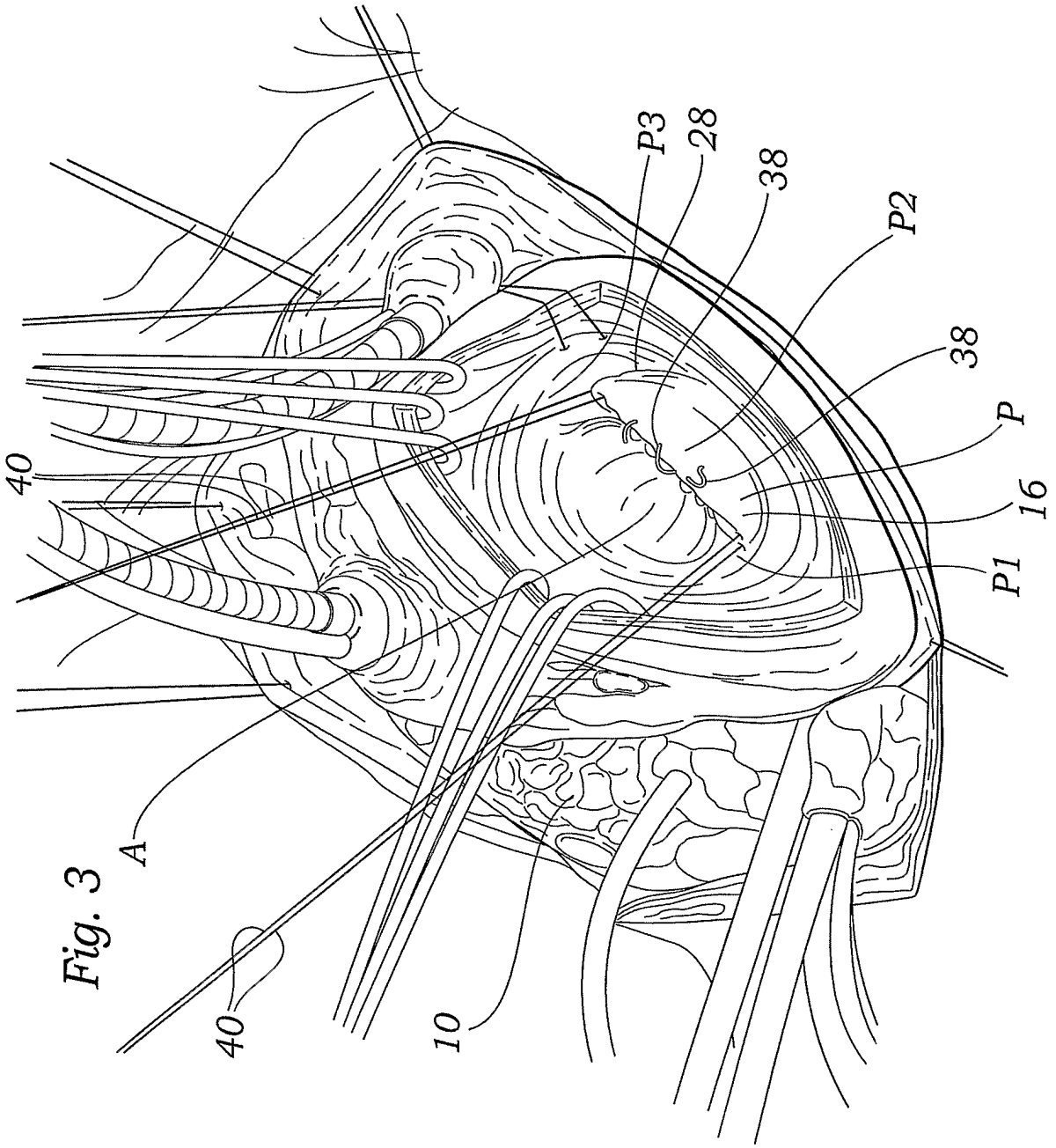


Fig. 3

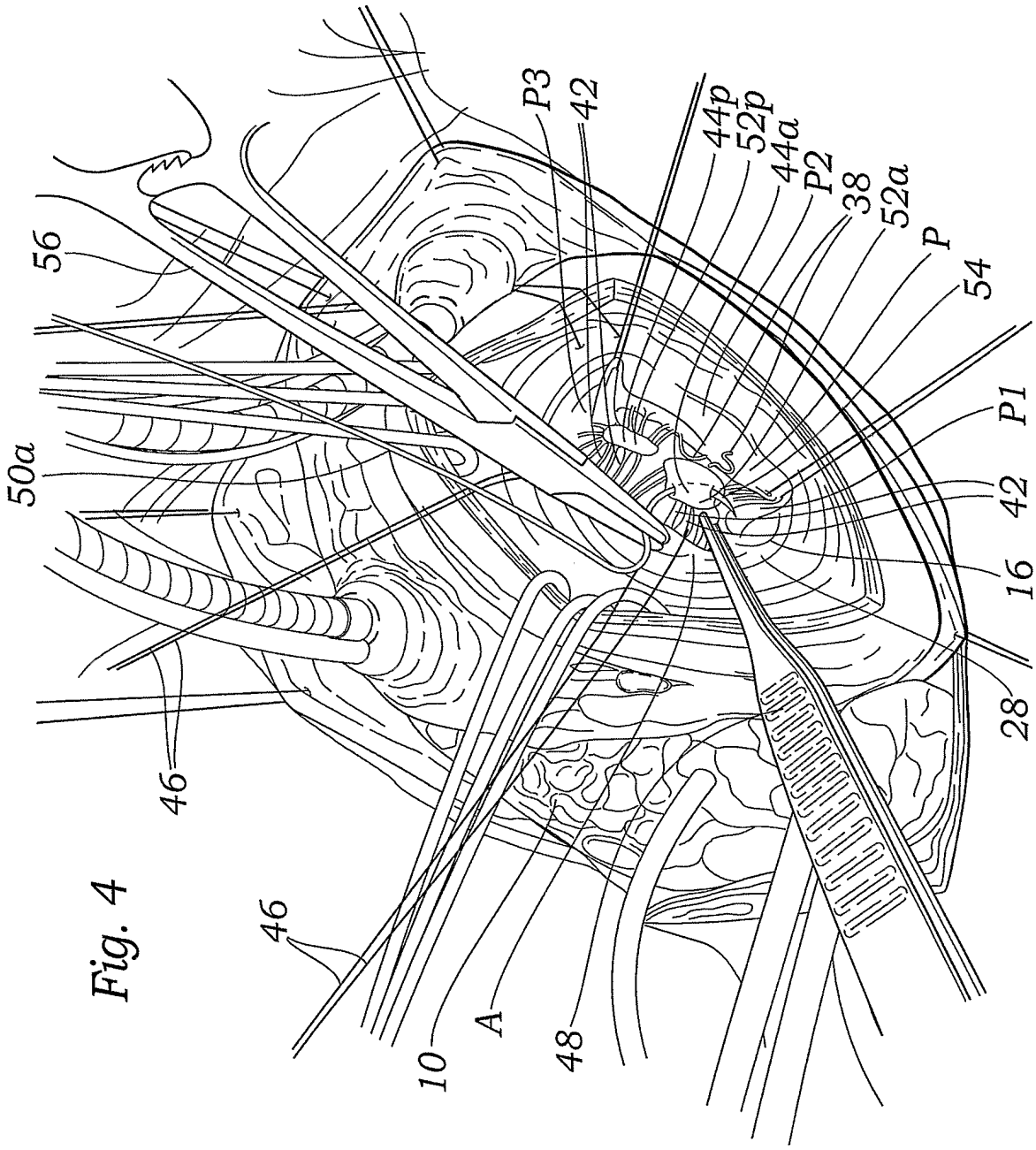


Fig. 4

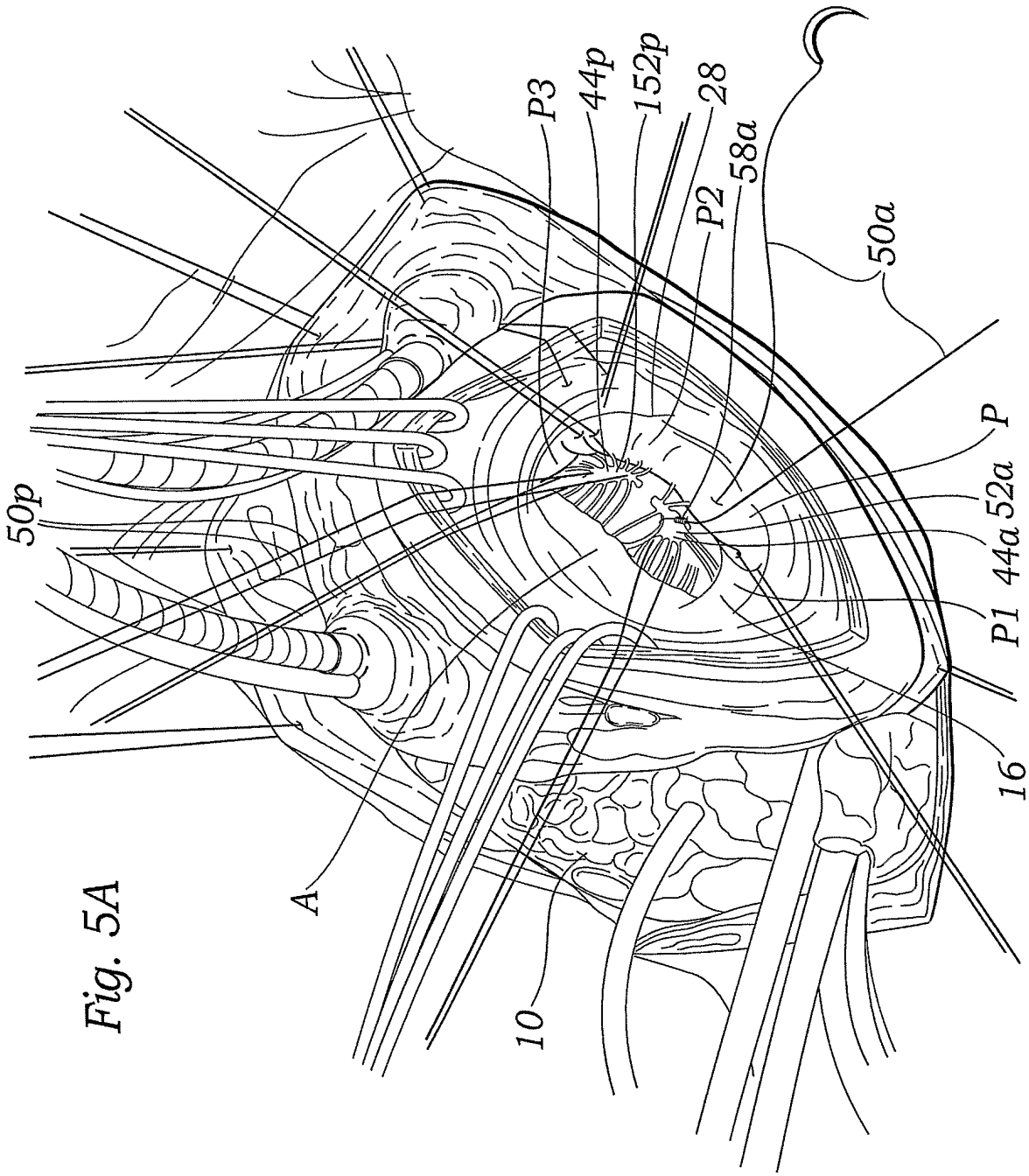


Fig. 5A

Fig. 5B

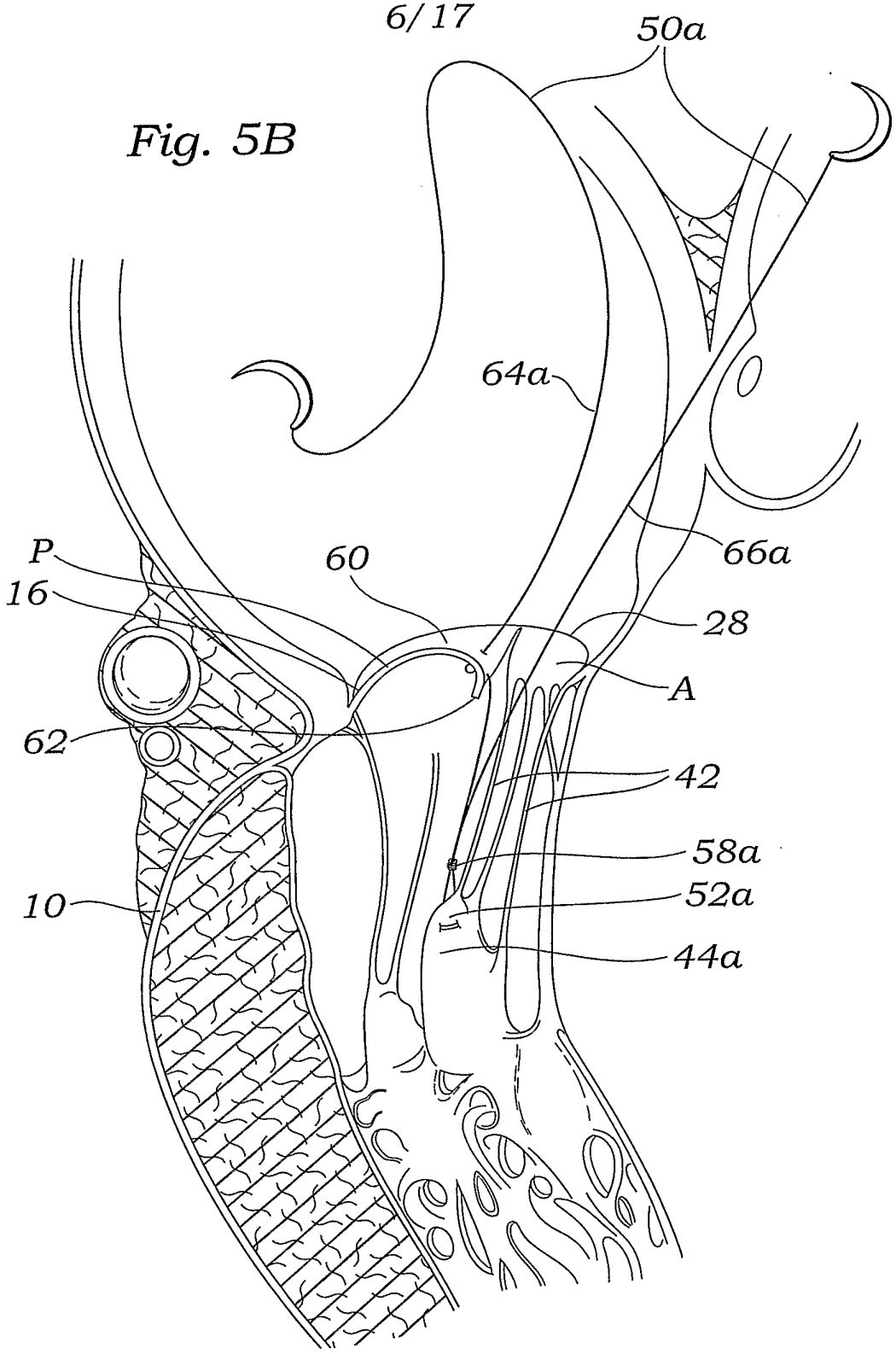


Fig. 6A

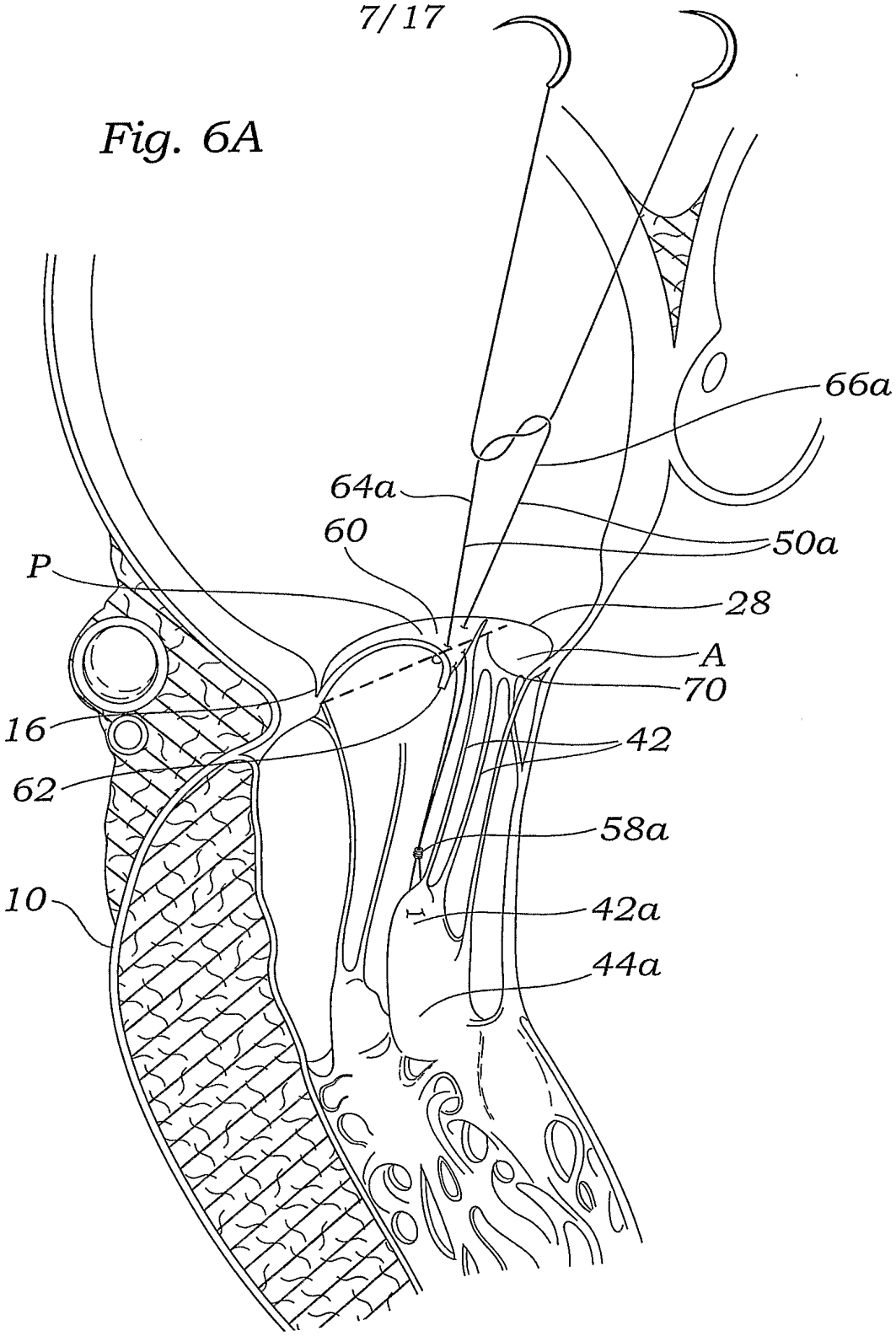


Fig. 6B

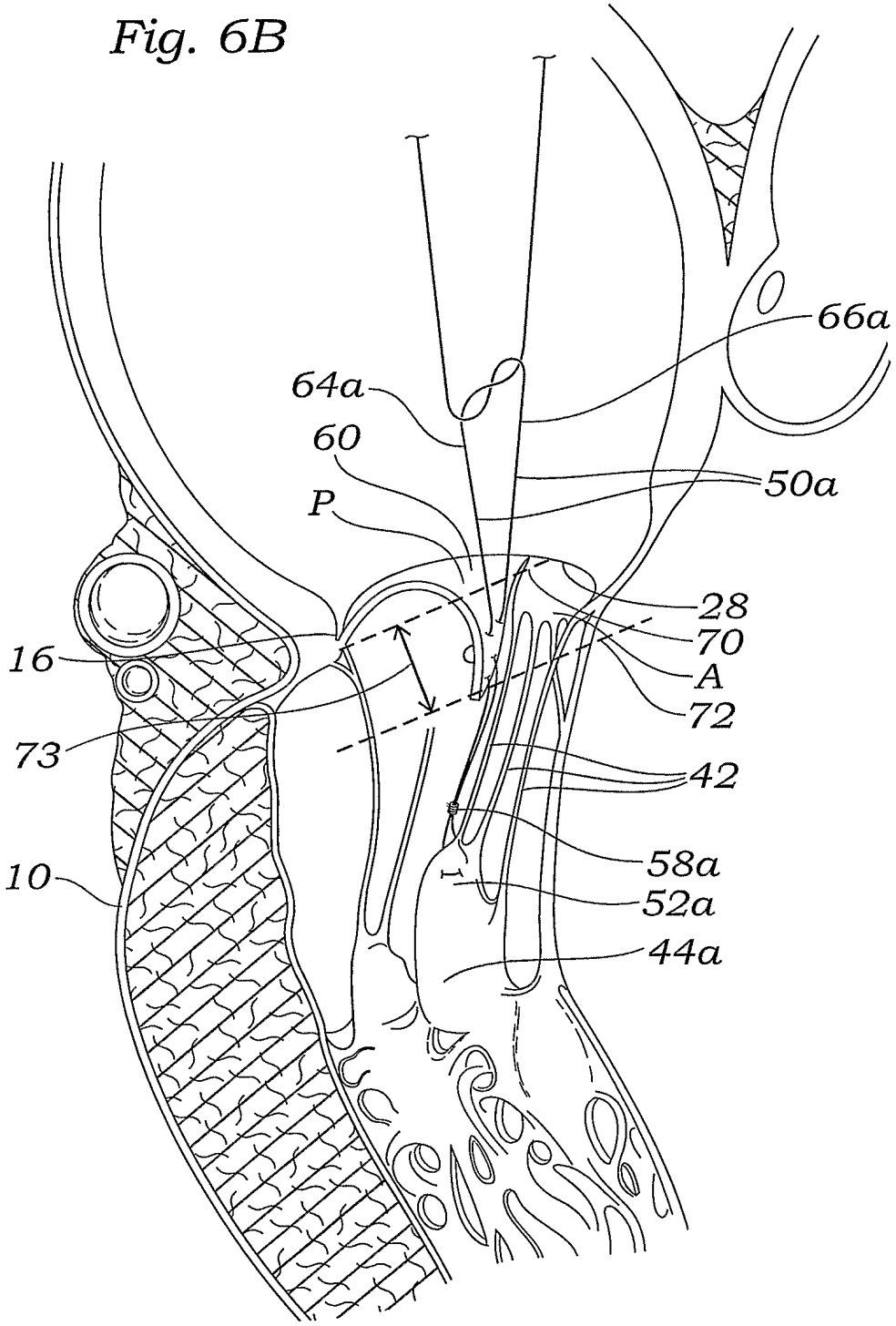
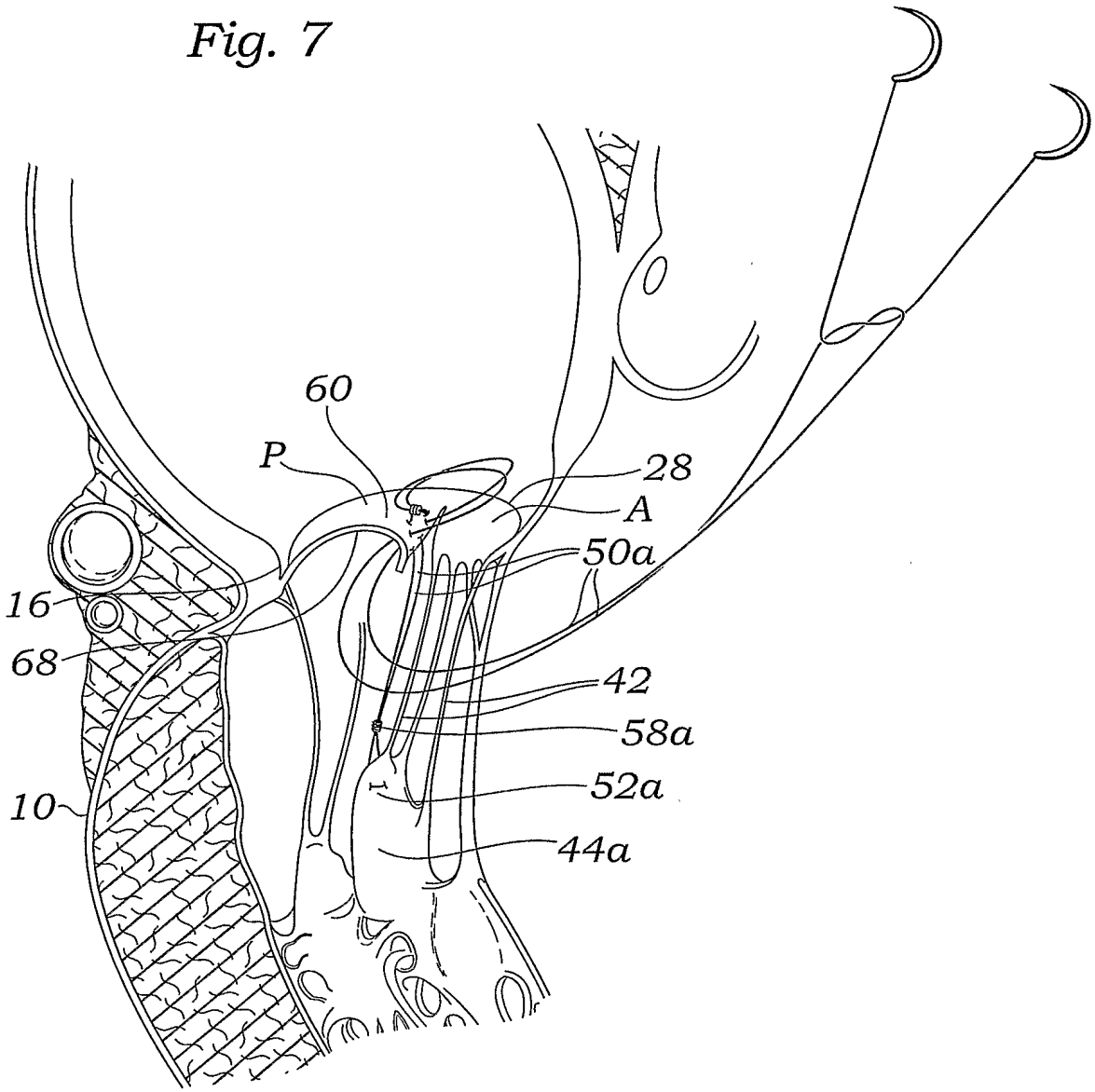


Fig. 7



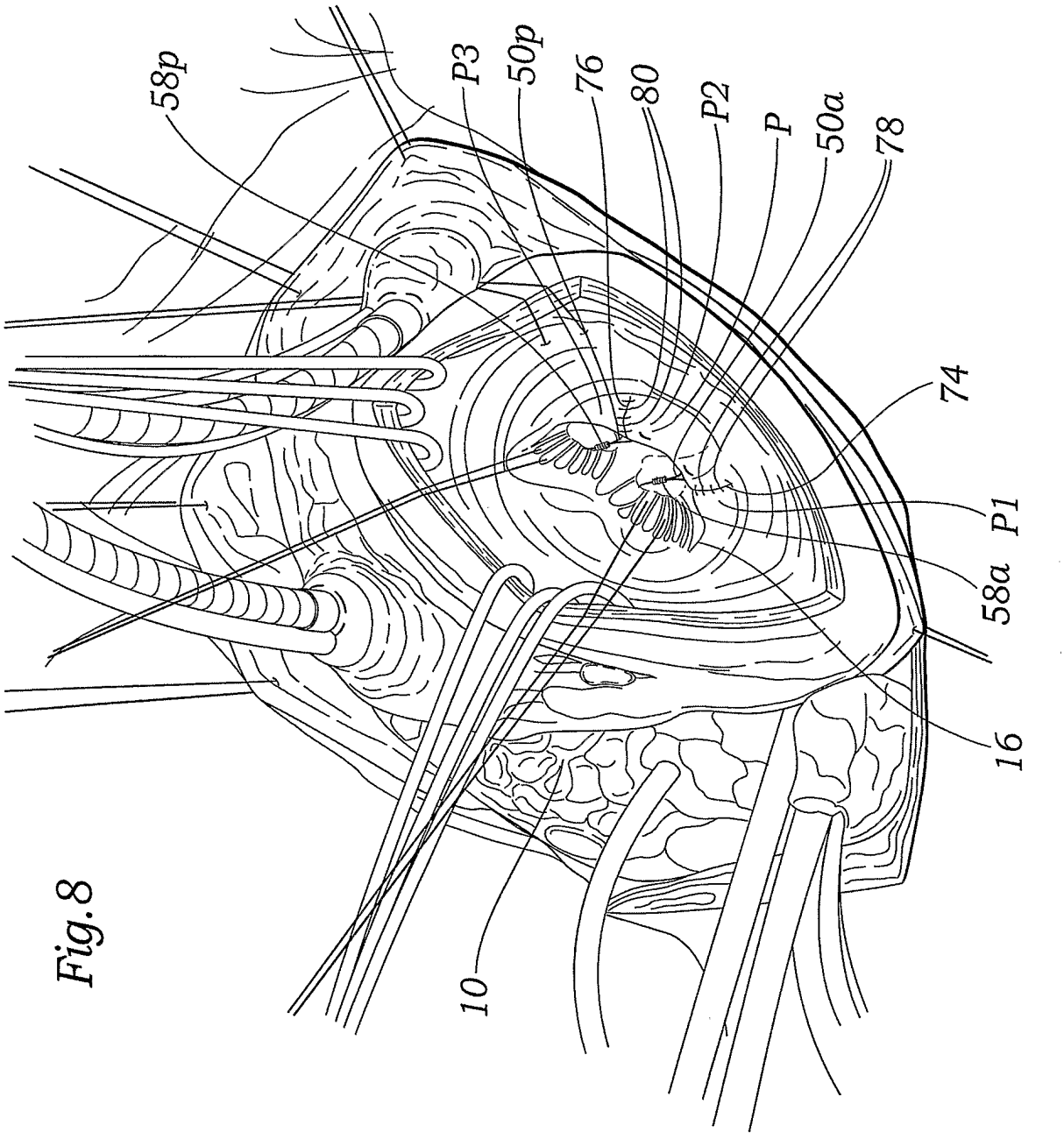


Fig.8

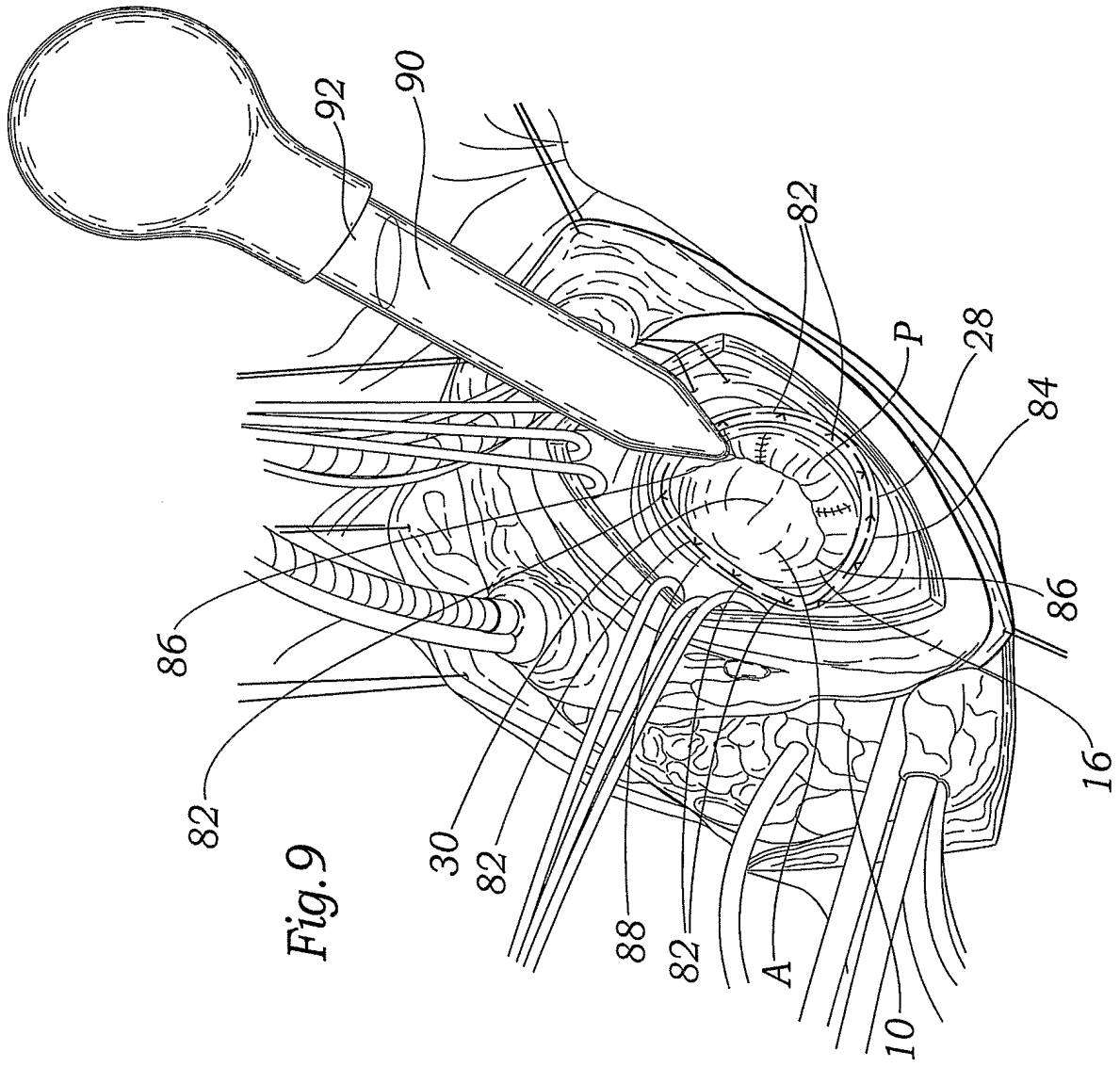
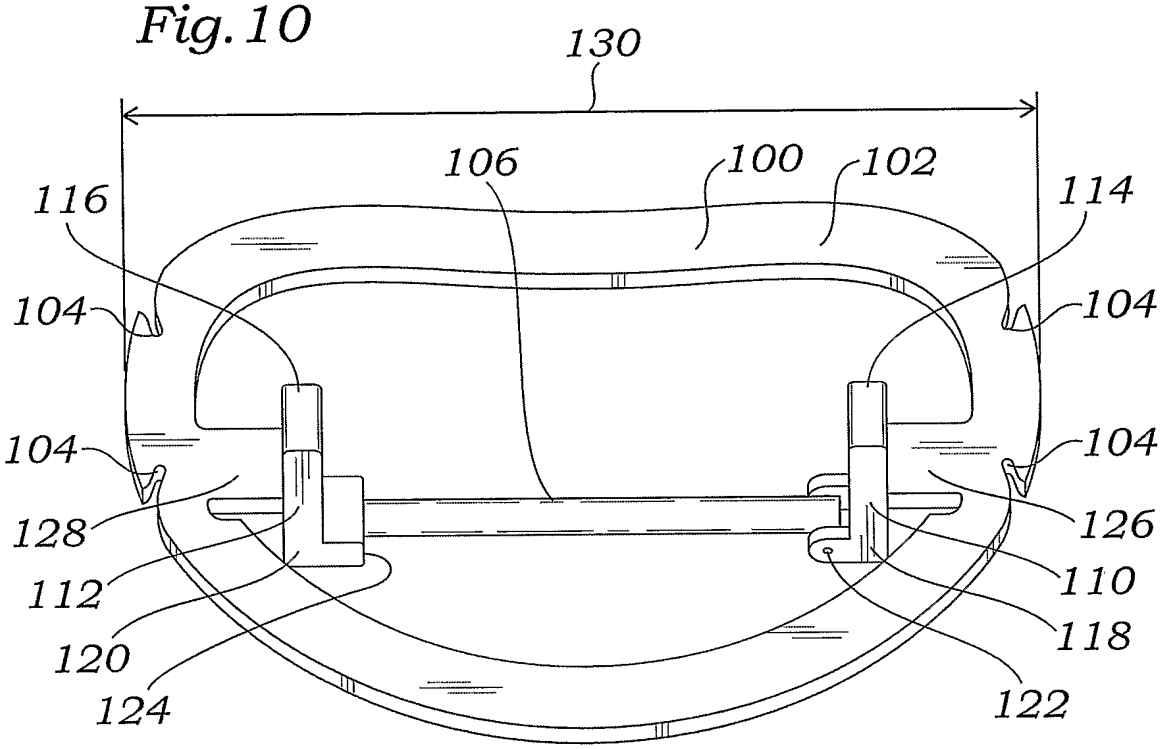


Fig.9

Fig. 10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116
114
104
104
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104
128
126
112
110
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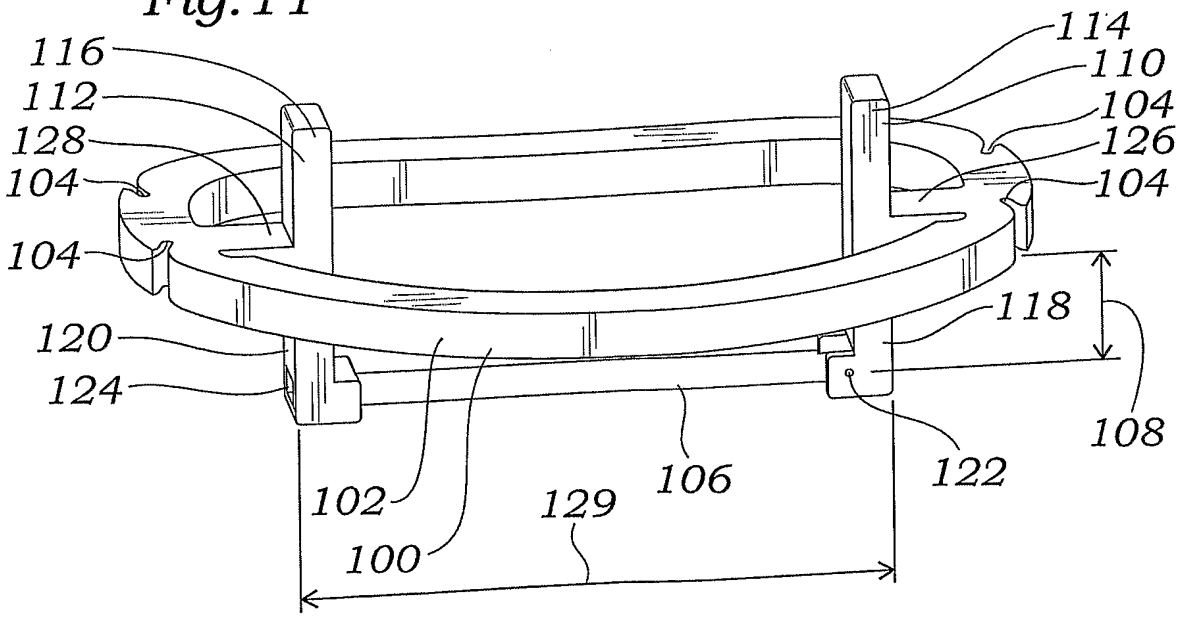
118
124
122

Fig. 11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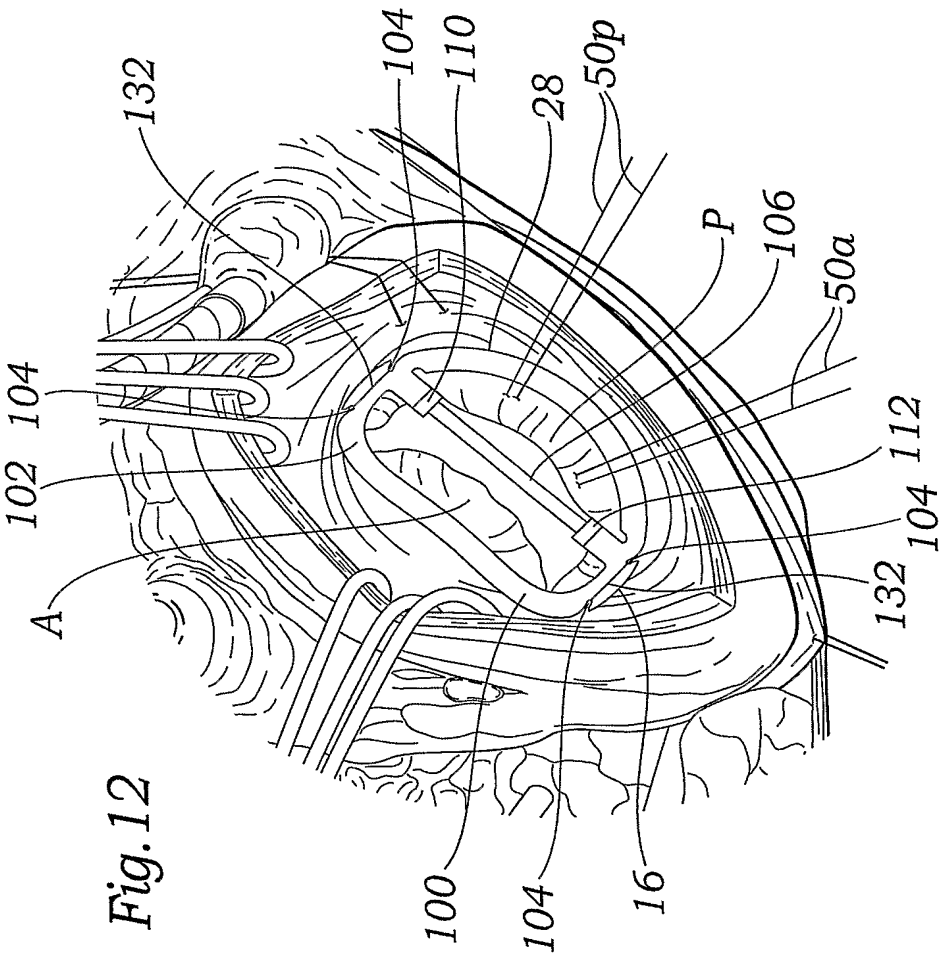
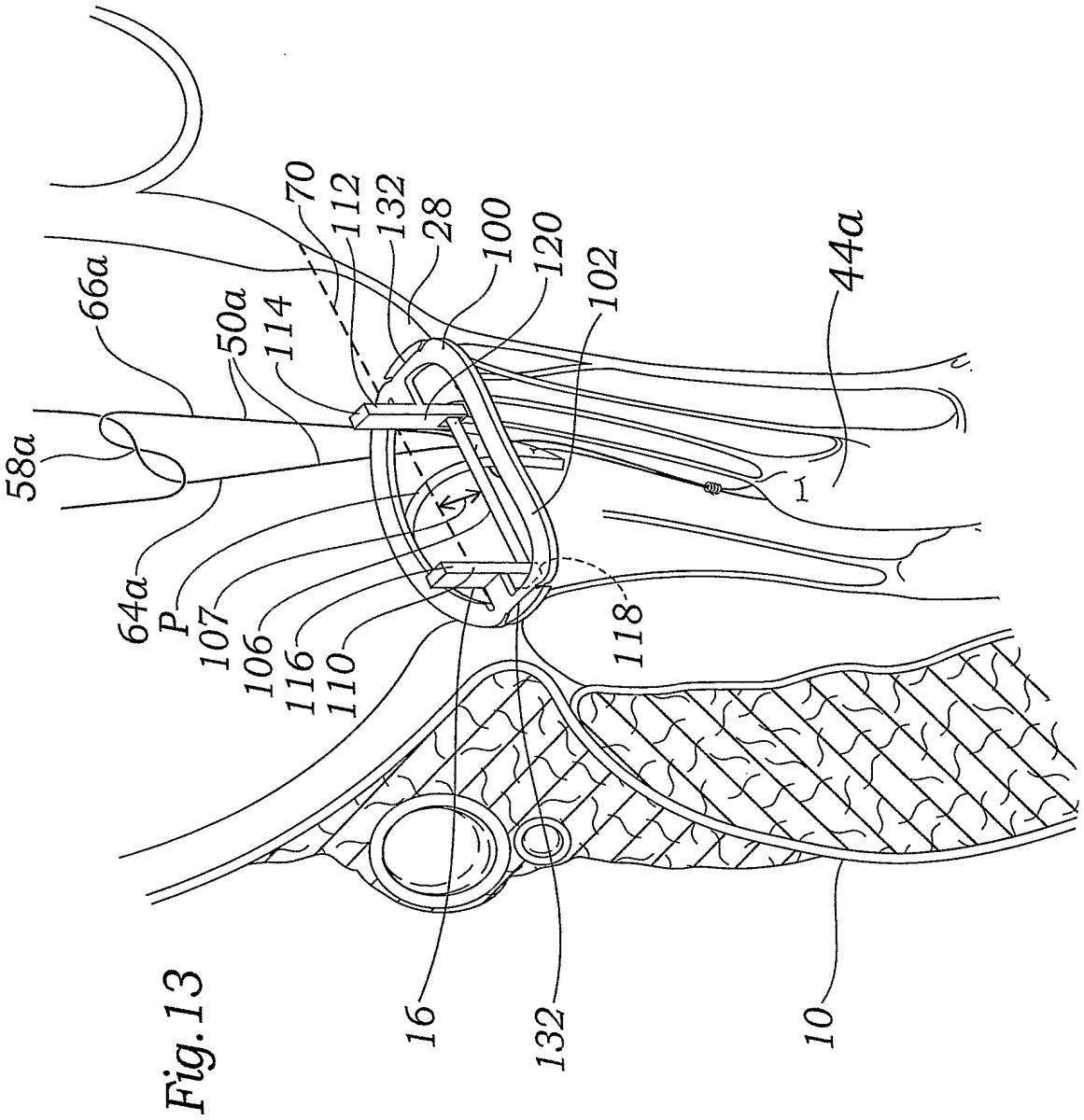


Fig.12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112
132
28
100
120
102
44a
66a
50a
114
58a
64a
P
107
106
116
110
118
1
16
132
10

Fig. 13

Fig. 14A

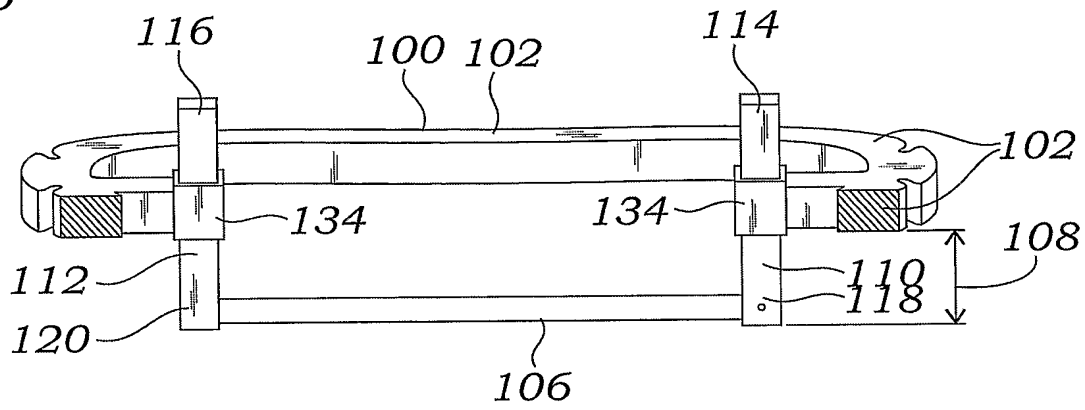


Fig. 14B

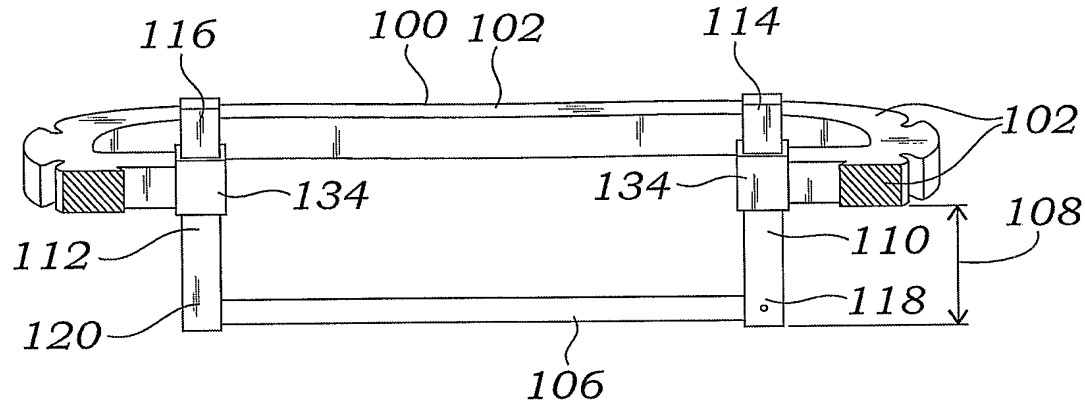


Fig. 14C

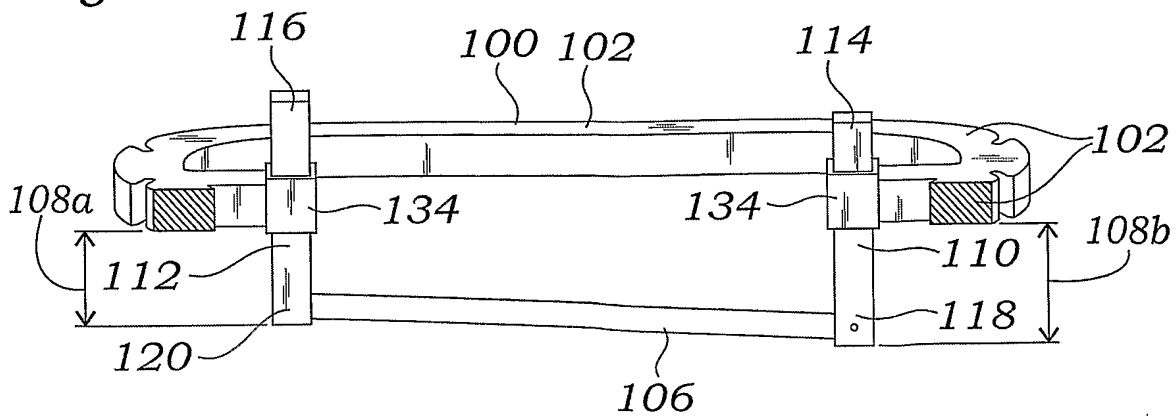


Fig. 15

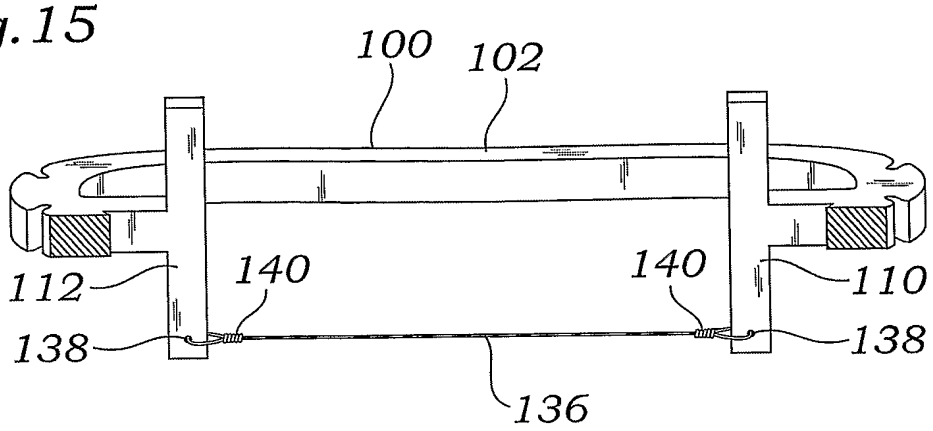


Fig. 16A

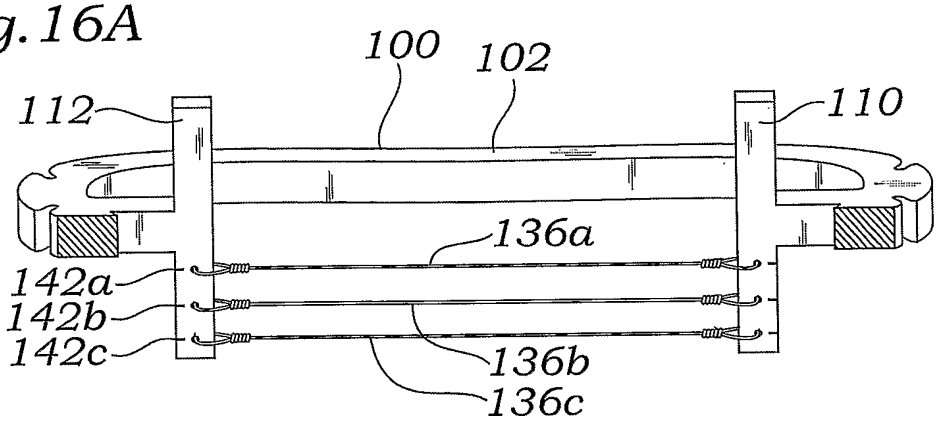


Fig. 16B

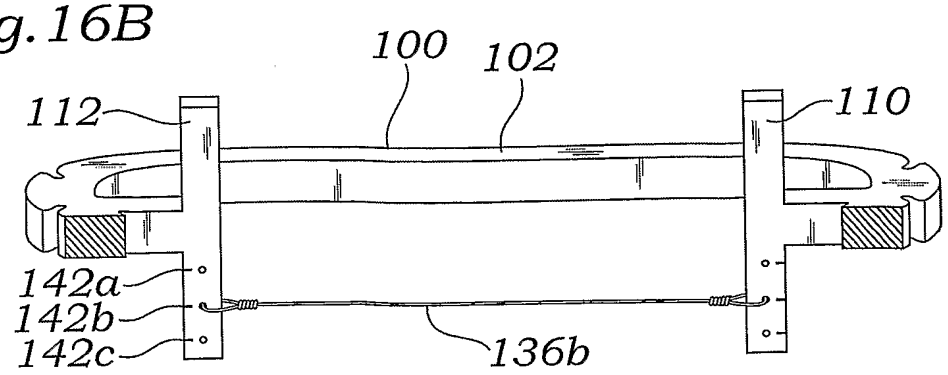


Fig. 17A

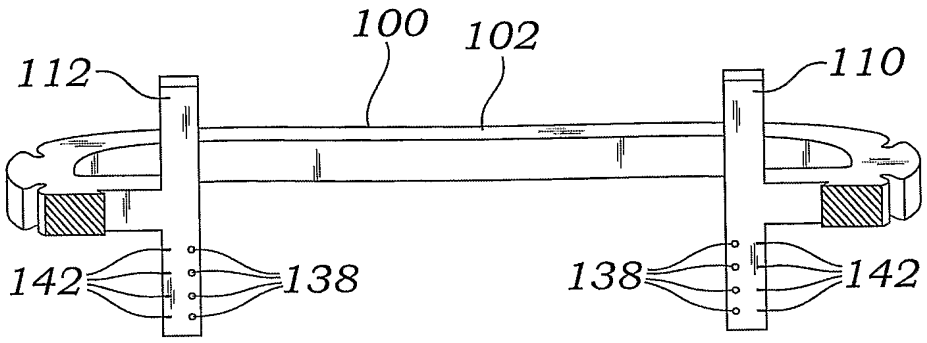
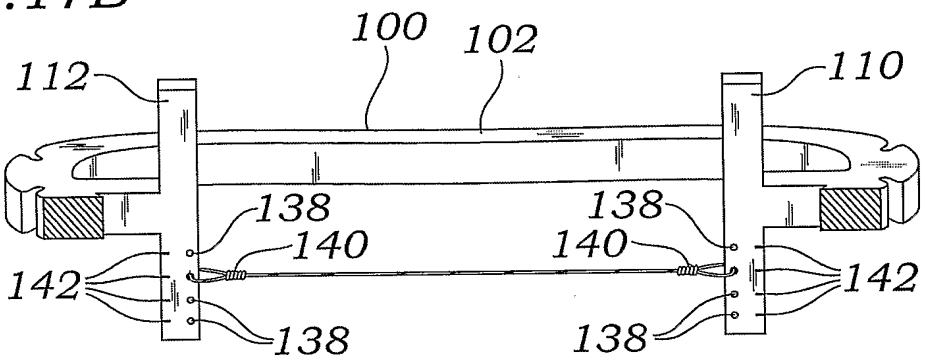


Fig. 17B



INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/024889

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/24

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)
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)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 2005/038508 A1 (GABBAY SHLOMO) 17 February 2005 (2005-02-17) paragraph [0036] - paragraph [0042]; figures 3,9	1,14 2-13, 15-22
X	US 2005/107871 A1 (REALYVASQUEZ FIDEL ET AL) 19 May 2005 (2005-05-19) paragraph [0037] - paragraph [0038]; figures 3a,3b	1,14
A	US 5 662 705 A (LOVE ET AL) 2 September 1997 (1997-09-02) the whole document	1-22
A	US 5 061 277 A (CARPENTIER ET AL) 29 October 1991 (1991-10-29) the whole document	1-22

☐ 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	Date of mailing of the international search report
27 September 2006	06/10/2006

Name and mailing address of the ISA/	Authorized officer
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	SERRA I VERDAGUER, J

1

Form PCT/ISA/210 (second sheet) (April 2005)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 23-30

The subject-matter of claims 23 to 30, discloses a method for repairing a heart valve. The method comprises the step of securing a first suture line to a first papillary muscle. The International preliminary searching authority is not required to search methods for treatment of the human body by surgery or therapy (Rule 39.1(iv)).

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/024889

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 23–30
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2006/024889

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2005038508 A1	17-02-2005	NONE	
US 2005107871 A1	19-05-2005	NONE	
US 5662705 A	02-09-1997	US 5584878 A	17-12-1996
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