US 20040019378A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2004/0019378 A1

Hlavka et al. (43) Pub. Date: Jan. 29, 2004

(54) METHOD AND APPARATUS FOR PERFORMING CATHETER-BASED ANNULOPLASTY

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(21) Appl. No.: **10/622,207**

(22) Filed: **Jul. 18, 2003**

Related U.S. Application Data

(62) Division of application No. 09/841,968, filed on Apr. 24, 2001, now Pat. No. 6,619,291.

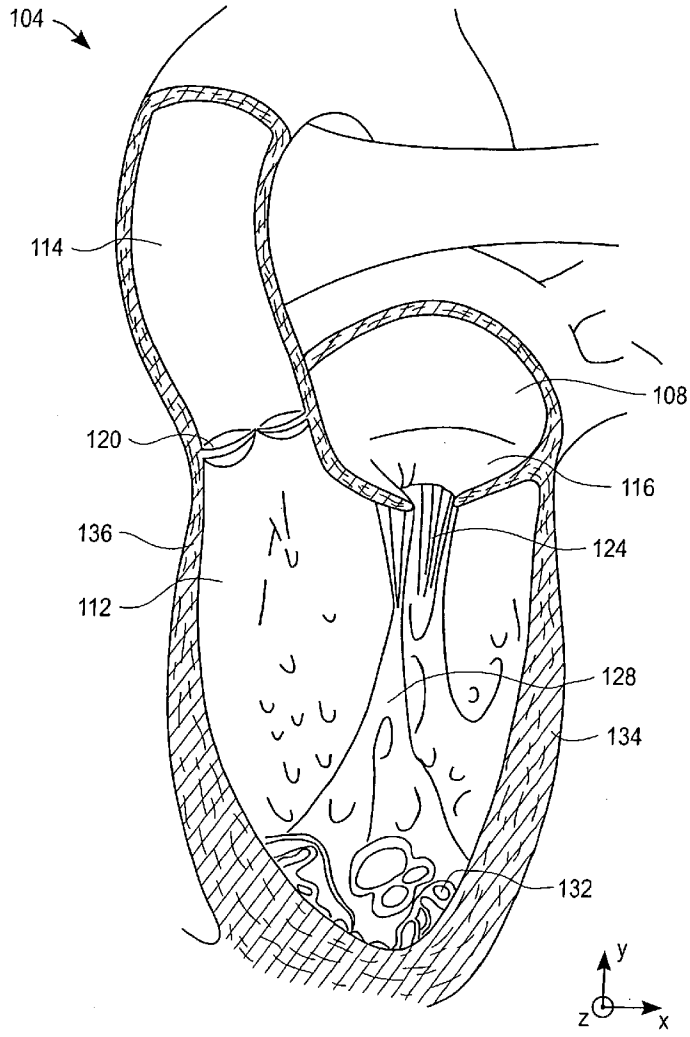
Publication Classification

(51) **Int. Cl.**[7] **A61F 2/24**

(52) **U.S. Cl.** **623/2.11**

(57) **ABSTRACT**

The present invention relates to a minimally invasive method of performing annuloplasty. According to one aspect of the present invention, a method for performing a procedure on a mitral valve of a heart includes inserting an implant into a left ventricle and orienting the implant in the left ventricle substantially below the mitral valve. The implant and tissue around the mitral valve are connected and tension is provided to the implant, in one embodiment, in order to substantially reduce an arc length associated with the mitral valve. In another embodiment, the implant is inserted into the left ventricle through the aorta and the aortic valve.



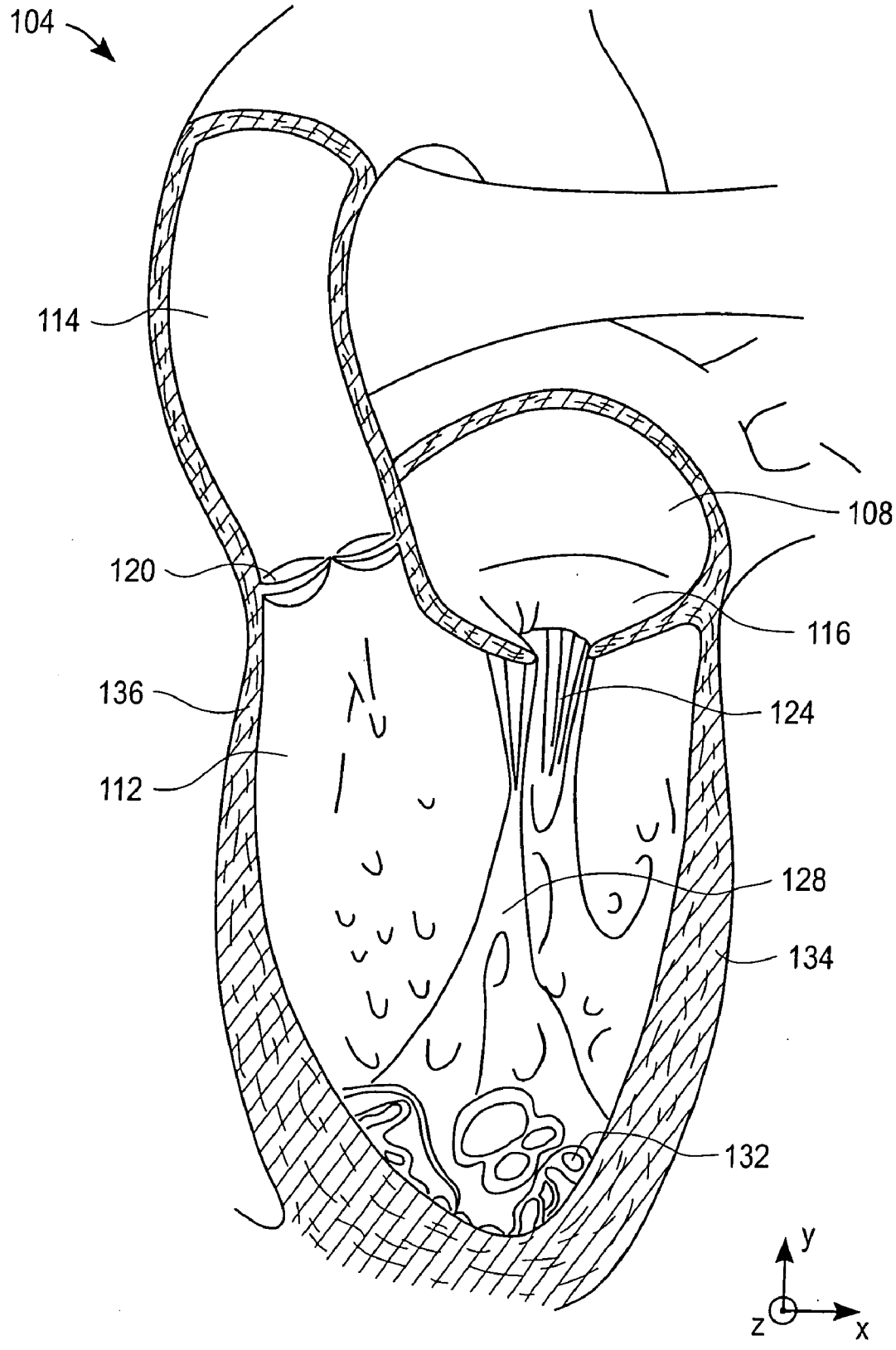


FIG. 1

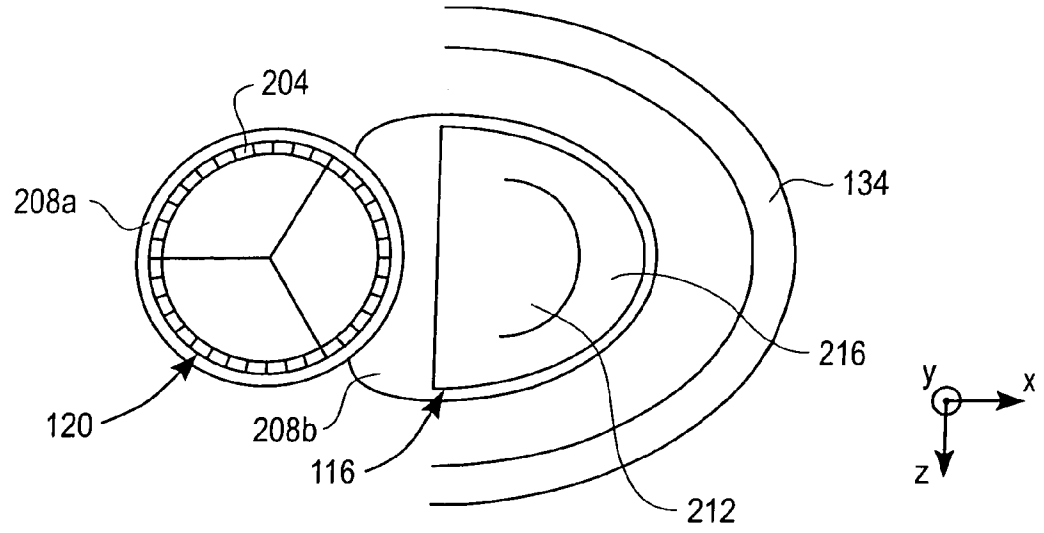

204
208a
134
216
120
208b
116
212
y
x
z

FIG. 2a

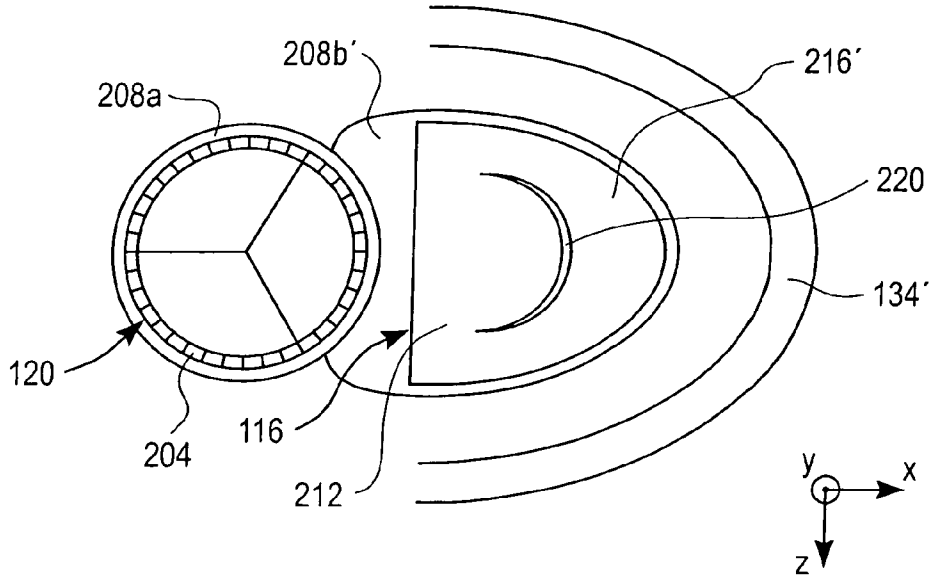

208b'
216'
208a
220
134'
120
204
116
212
y
x
z

FIG. 2b

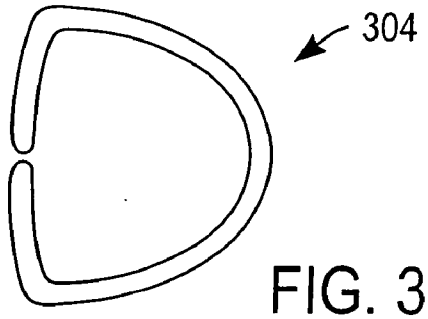


FIG. 3

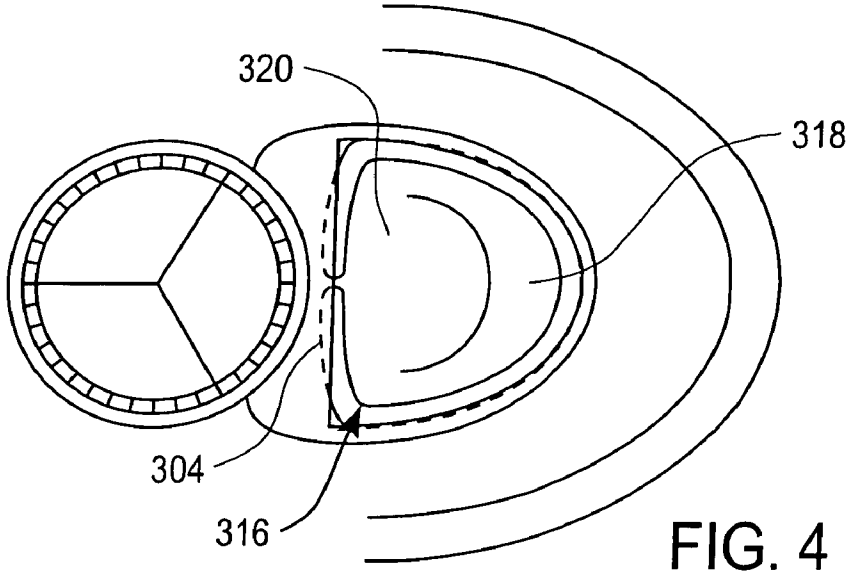


FIG. 4

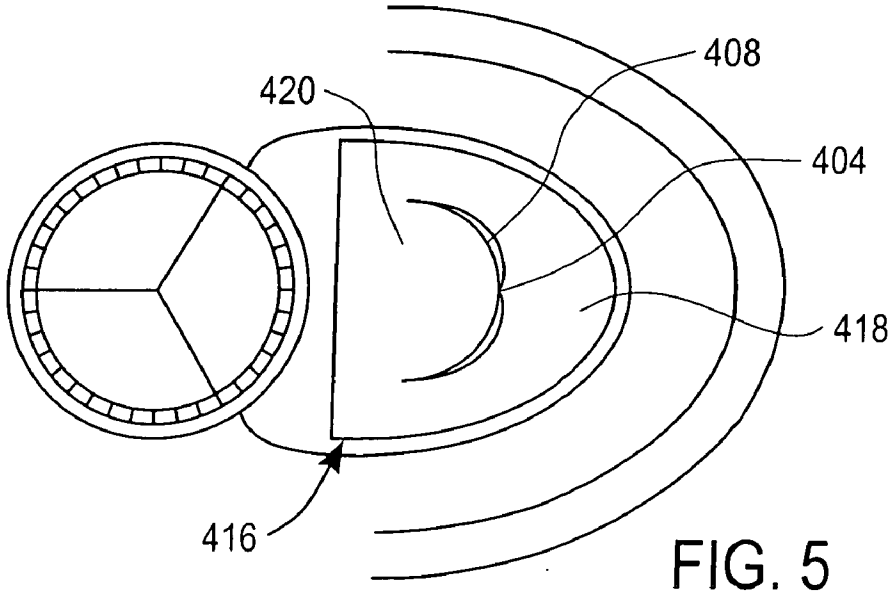


FIG. 5

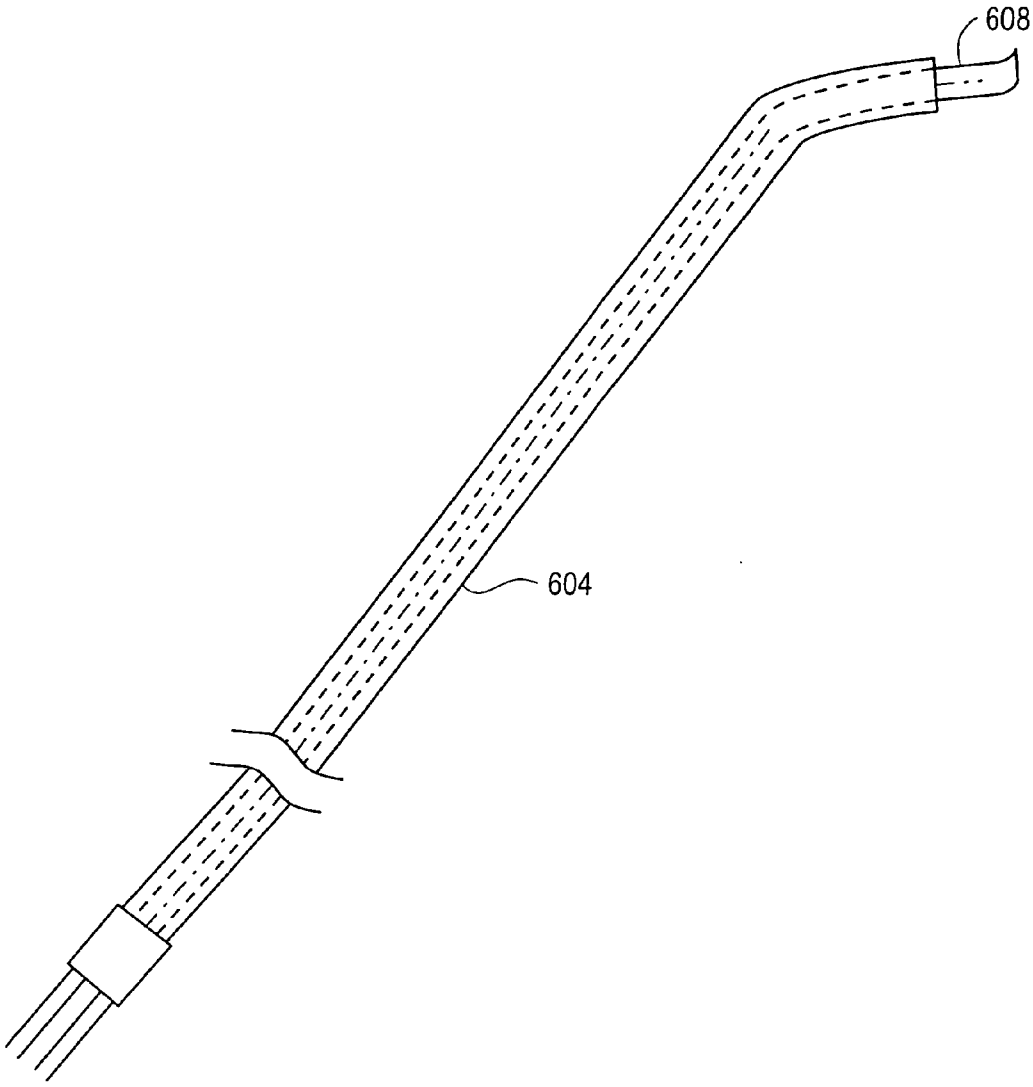


FIG. 6a

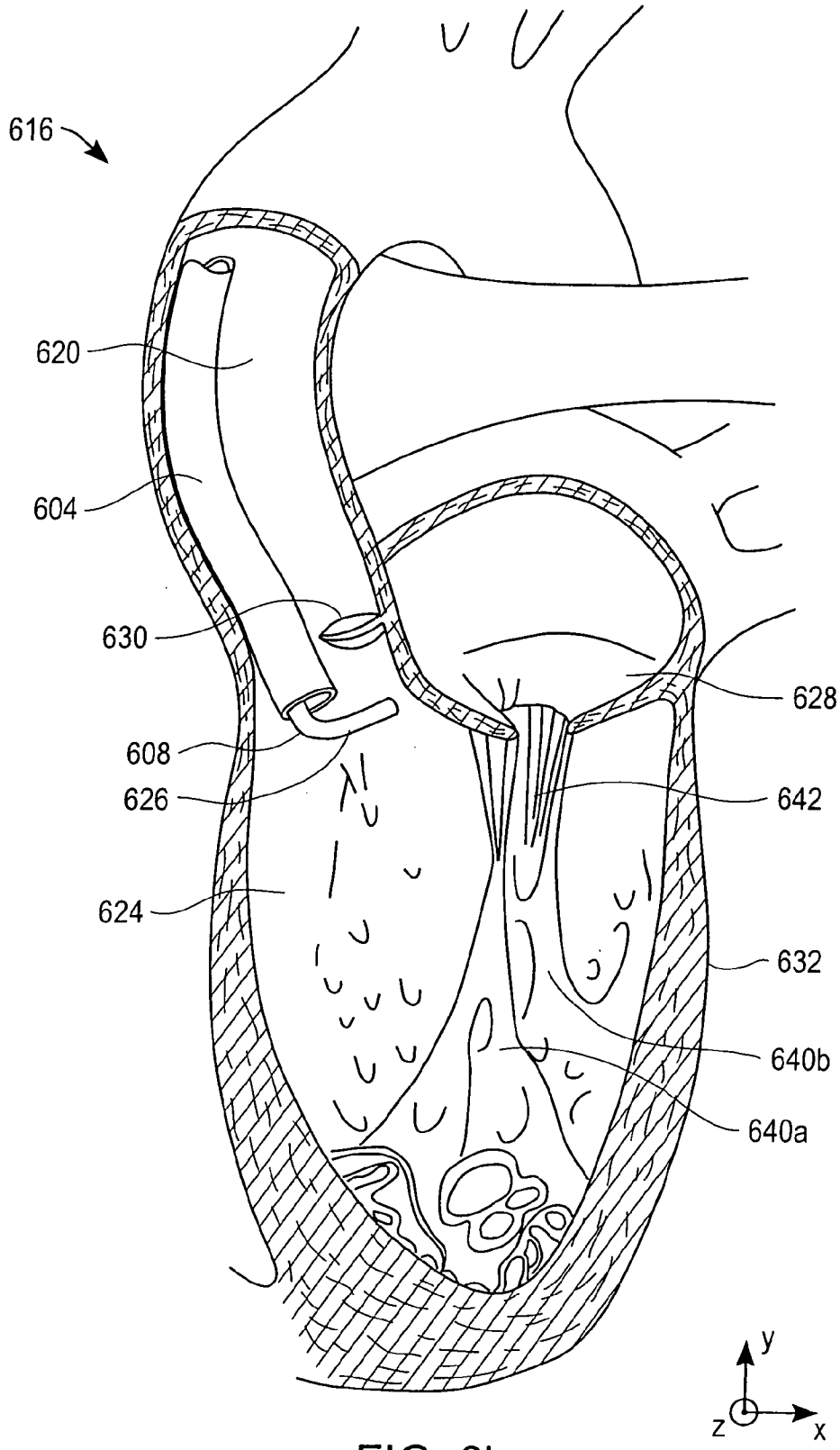


FIG. 6b

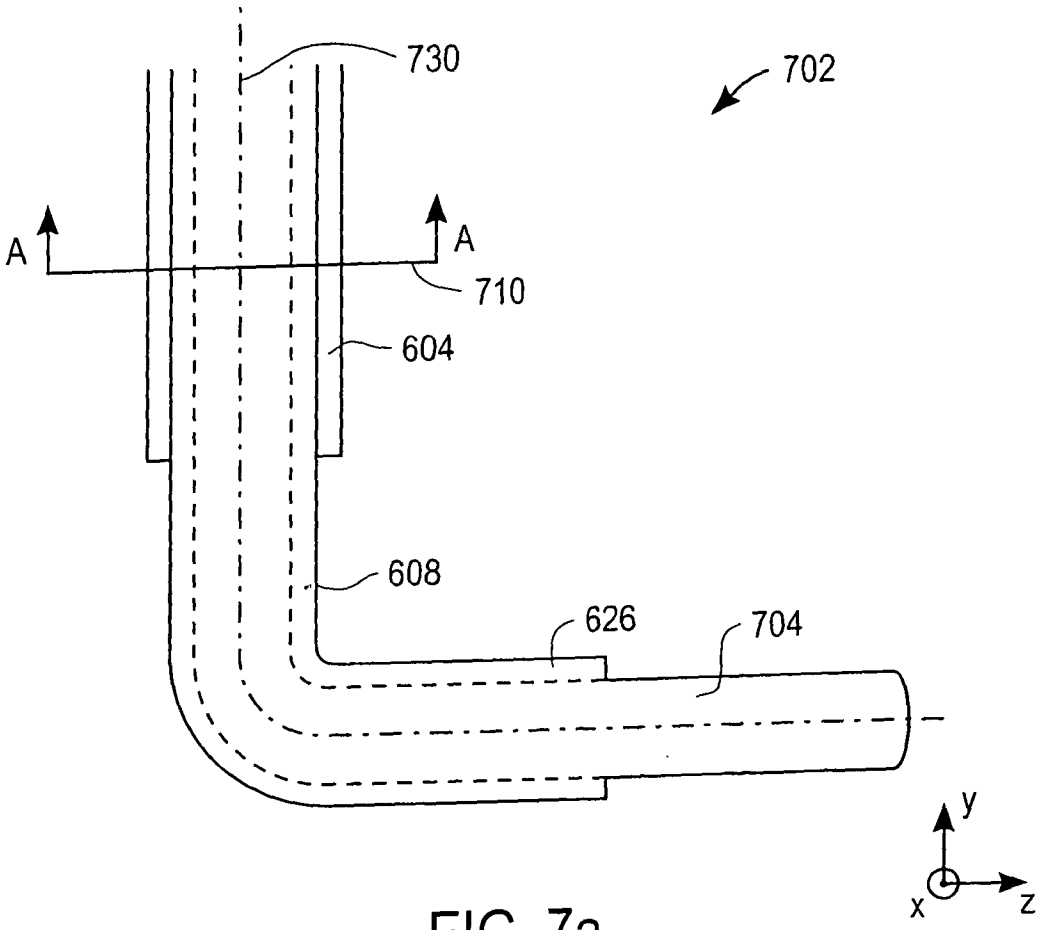


FIG. 7a

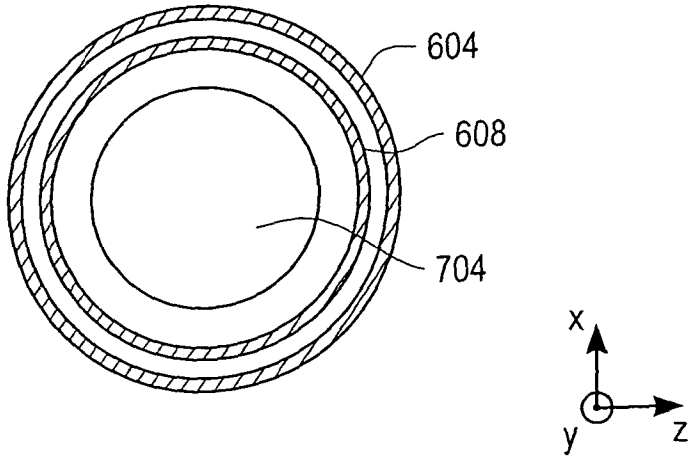


FIG. 7b

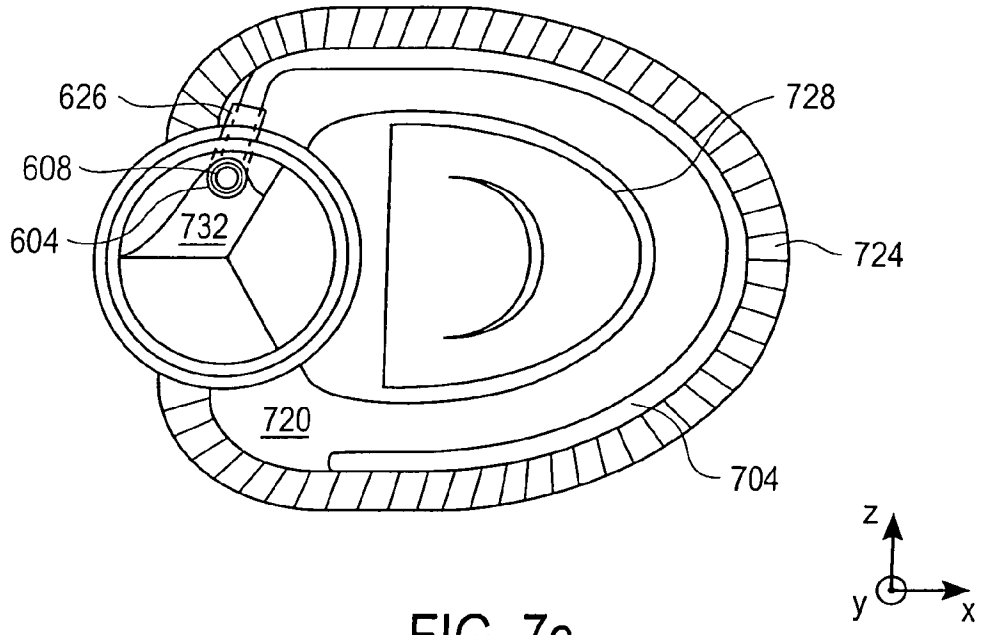


FIG. 7c

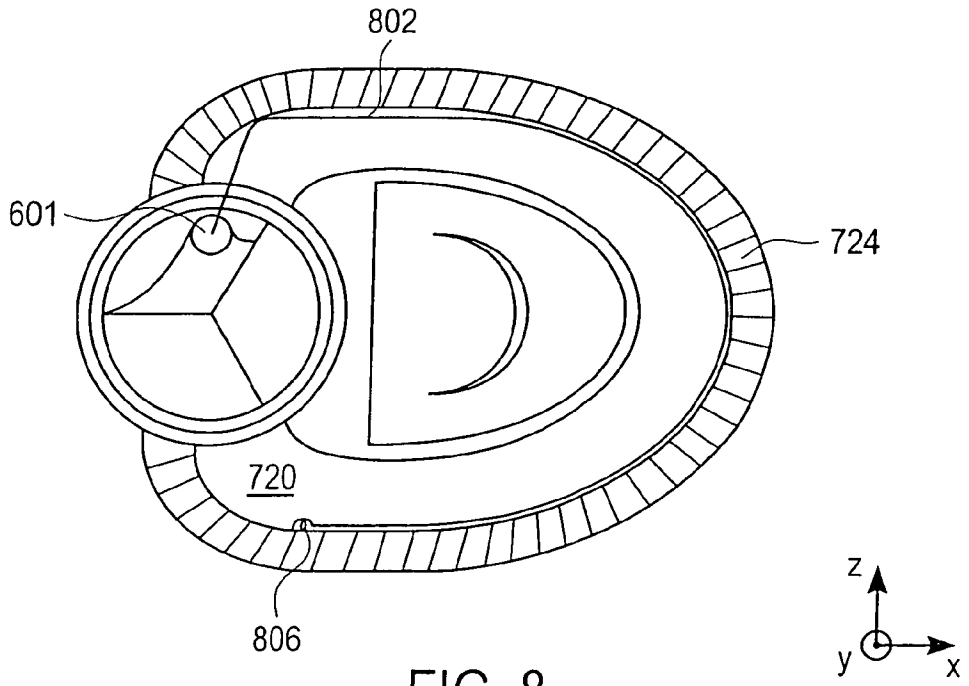


FIG. 8

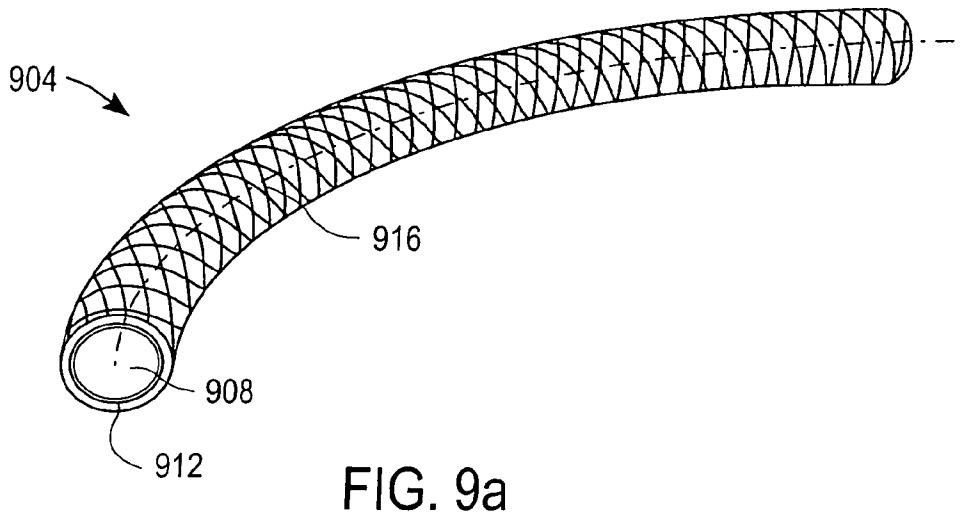


FIG. 9a

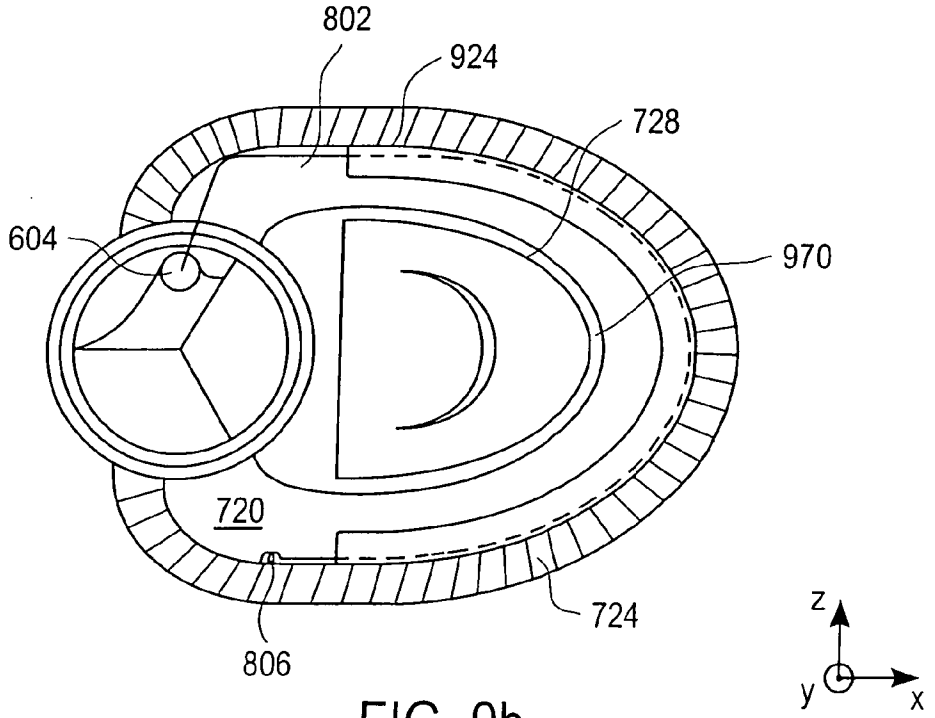


FIG. 9b

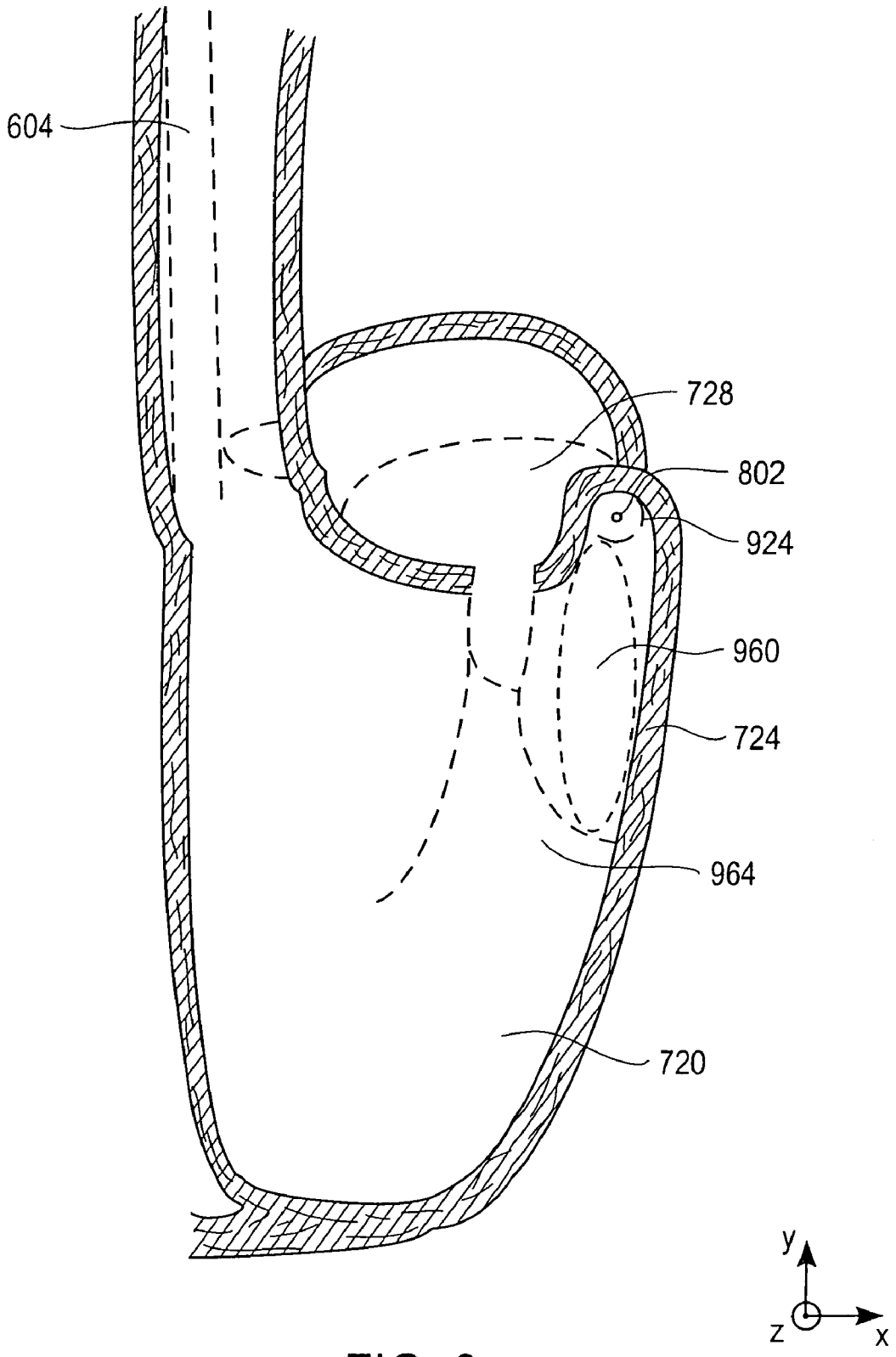


FIG. 9c

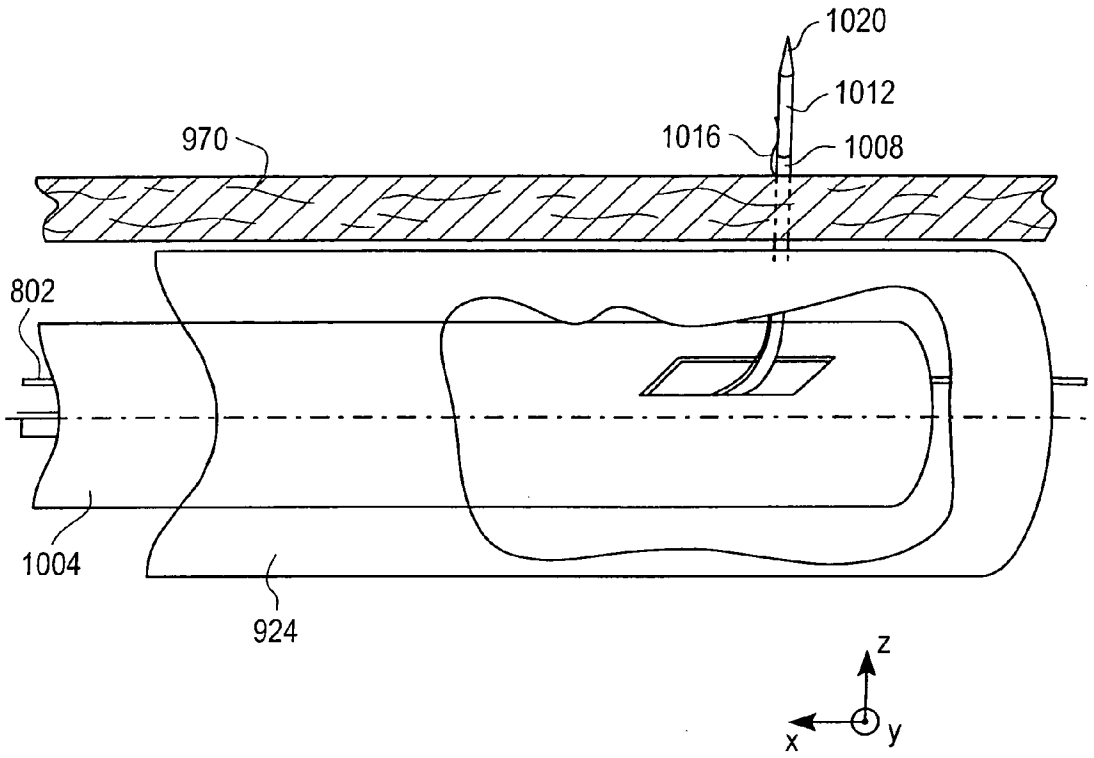


FIG. 10

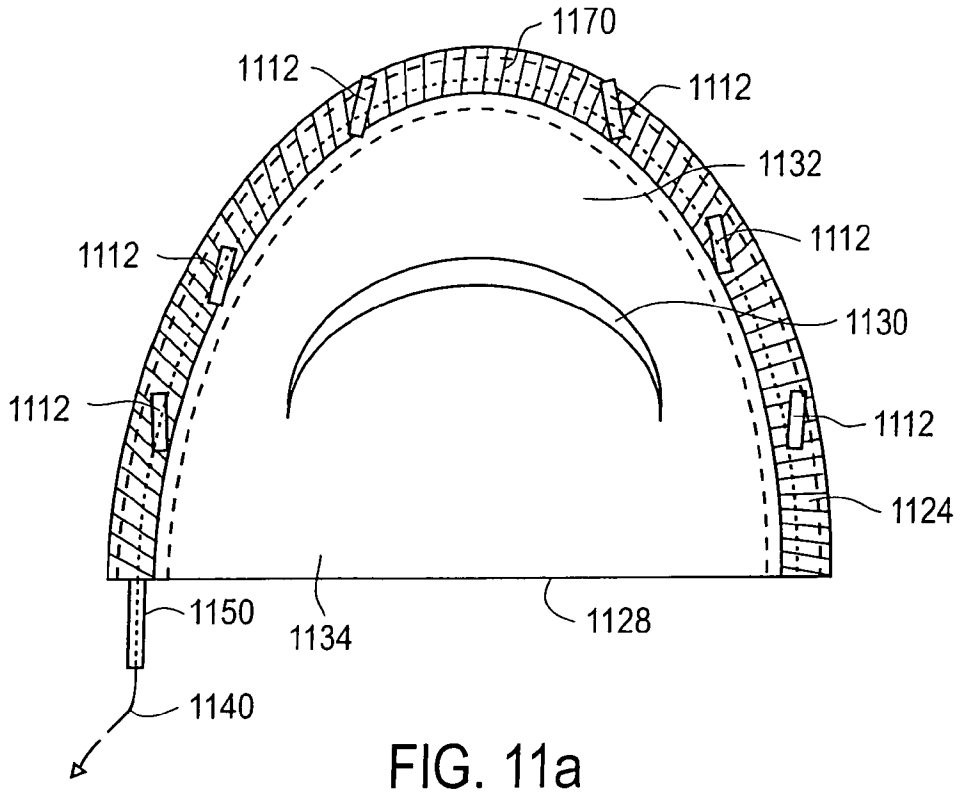


FIG. 11a

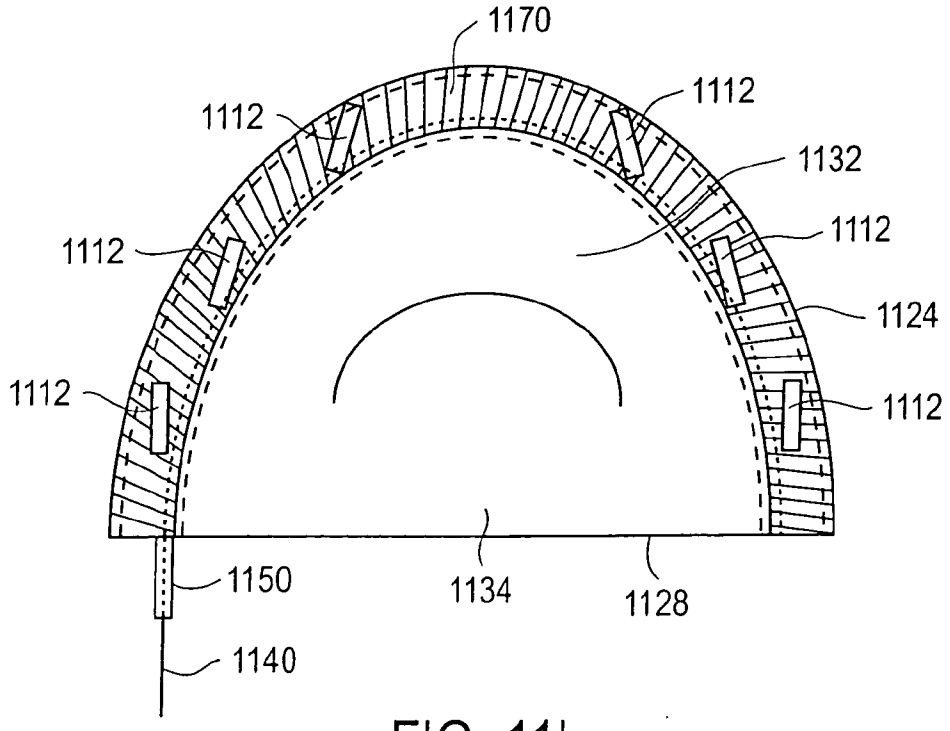


FIG. 11b

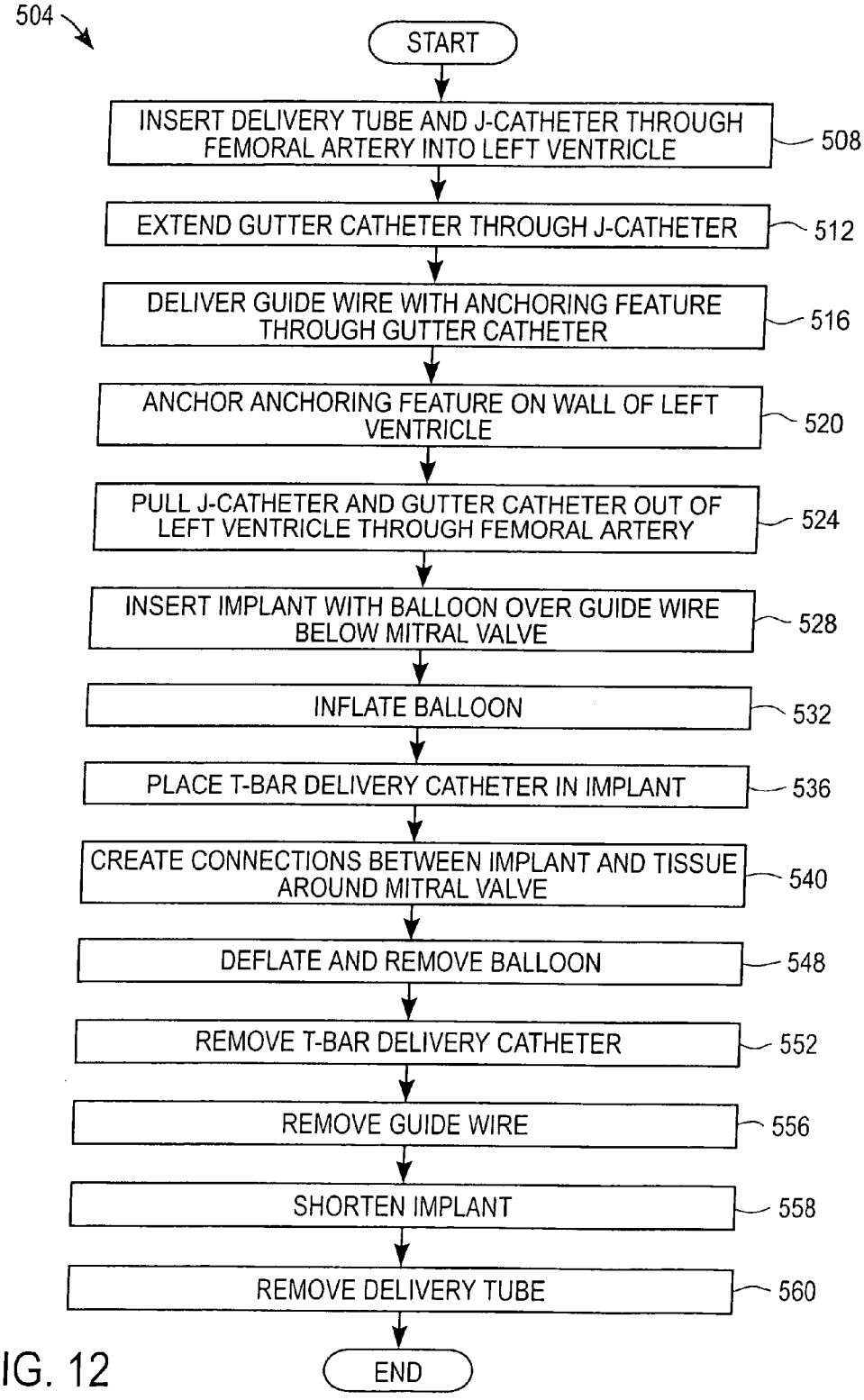

504
START
INSERT DELIVERY TUBE AND J-CATHETER THROUGH FEMORAL ARTERY INTO LEFT VENTRICLE
508
EXTEND GUTTER CATHETER THROUGH J-CATHETER
512
DELIVER GUIDE WIRE WITH ANCHORING FEATURE THROUGH GUTTER CATHETER
516
ANCHOR ANCHORING FEATURE ON WALL OF LEFT VENTRICLE
520
PULL J-CATHETER AND GUTTER CATHETER OUT OF LEFT VENTRICLE THROUGH FEMORAL ARTERY
524
INSERT IMPLANT WITH BALLOON OVER GUIDE WIRE BELOW MITRAL VALVE
528
INFLATE BALLOON
532
PLACE T-BAR DELIVERY CATHETER IN IMPLANT
536
CREATE CONNECTIONS BETWEEN IMPLANT AND TISSUE AROUND MITRAL VALVE
540
DEFLATE AND REMOVE BALLOON
548
REMOVE T-BAR DELIVERY CATHETER
552
REMOVE GUIDE WIRE
556
SHORTEN IMPLANT
558
REMOVE DELIVERY TUBE
560
END

FIG. 12

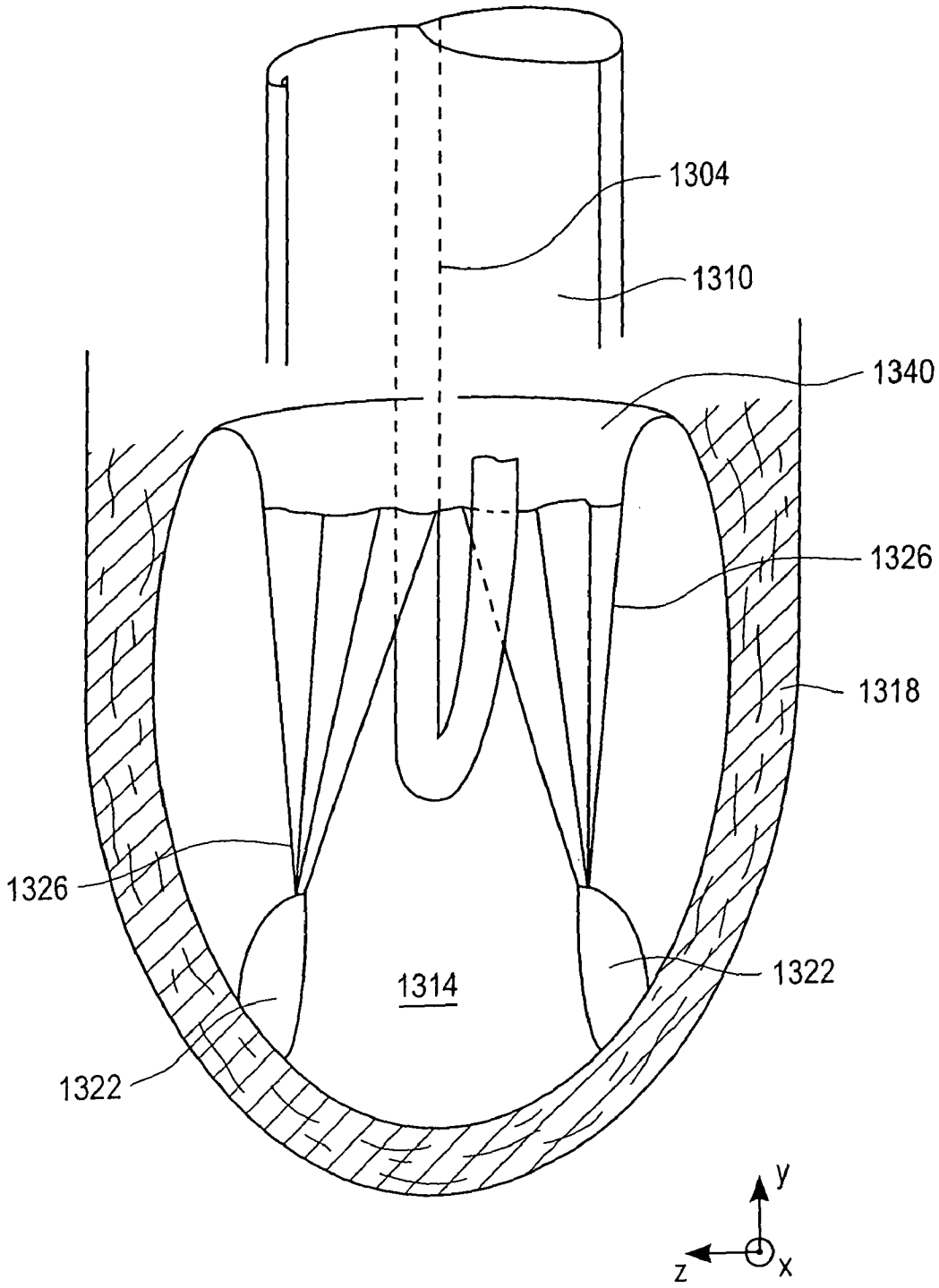


FIG. 13a

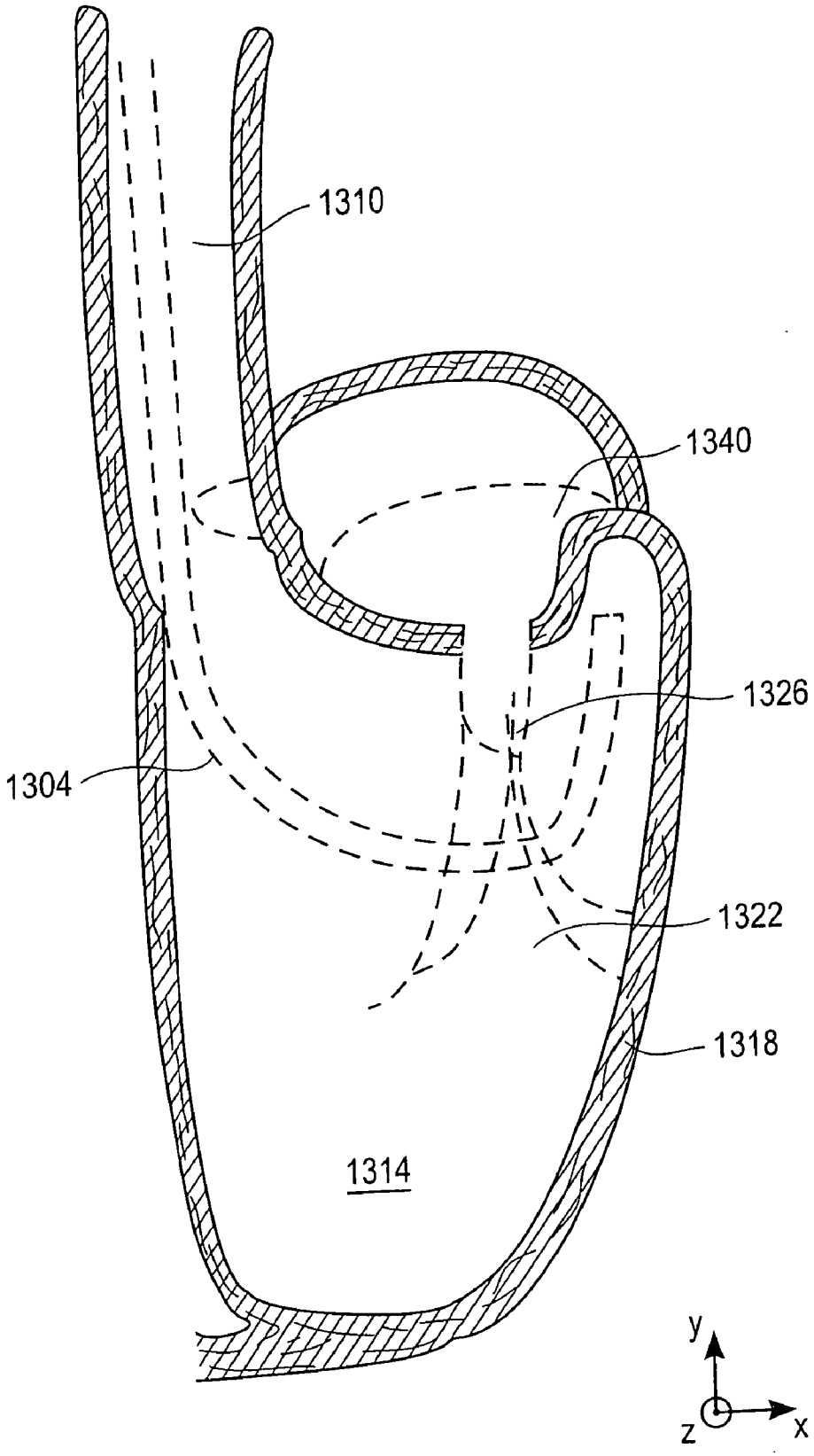


FIG. 13b

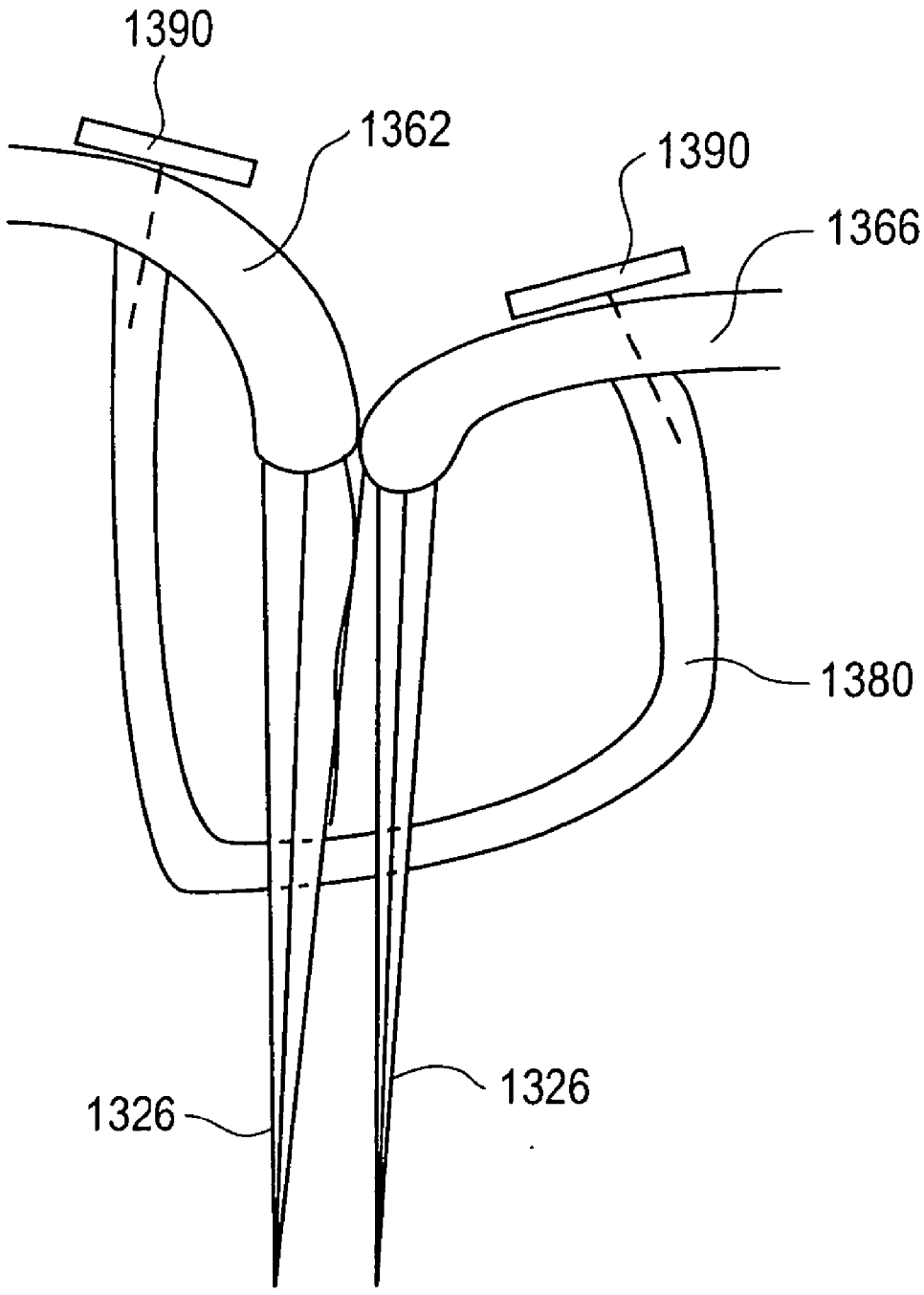


FIG. 13c

METHOD AND APPARATUS FOR PERFORMING CATHETER-BASED ANNULOPLASTY

BACKGROUND OF THE INVENTION

[0001] 1. Field of Invention

[0002] The present invention relates generally to techniques for treating mitral valve insufficiencies such as mitral valve leakage. More particularly, the present invention relates to systems and methods for treating a leaking mitral valve in a minimally invasive manner.

[0003] 2. Description of the Related Art

[0004] Congestive heart failure (CHF), which is often associated with an enlargement of the heart, is a leading cause of death. As a result, the market for the treatment of CHF is becoming increasingly prevalent. For instance, the treatment of CHF is a leading expenditure of Medicare and Medicaid dollars in the United States of America. Typically, the treatment of CHF enables many who suffer from CHF to enjoy an improved quality of life.

[0005] Referring initially to **FIG. 1**, the anatomy of a heart, specifically the left side of a heart, will be described. The left side of a heart **104** includes a left atrium **108** and a left ventricle **112**. An aorta **114** receives blood from left ventricle **112** through an aortic valve **120**, which serves to prevent regurgitation of blood back into left ventricle **112**. A mitral valve **116** is disposed between left atrium **108** and left ventricle **112**, and effectively controls the flow of blood between left atrium **108** and left ventricle **112**.

[0006] Mitral valve **116**, which will be described below in more detail with respect to **FIG. 2***a*, includes an anterior leaflet and a posterior leaflet that are coupled to cordae tendonae **124** which serve as "tension members" that prevent the leaflets of mitral valve **116** from opening indiscriminately. When left ventricle **112** contracts, cordae tendonae **124** allow the anterior leaflet to open upwards until limited in motion by cordae tendonae **124**. Normally, the upward limit of opening corresponds to a meeting of the anterior and posterior leaflets and the prevention of backflow. Cordae tendonae **124** arise from a columnae carnae **128** or, more specifically, a musculi papillares of columnae carnae **128**.

[0007] Left ventricle **112** includes trabeculae **132** which are fibrous cords of connective tissue that are attached to wall **134** of left ventricle **112**. Trabeculae **132** are also attached to an interventricular septum **136** which separates left ventricle **112** from a right ventricle (not shown) of heart **104**. Trabeculae **132** are generally located in left ventricle **112** below columnae carnae **128**.

[0008] **FIG. 2***a* is a cut-away top-view representation of mitral valve **116** and aortic valve **120**. Aortic valve **120** has a valve wall **204** that is surrounded by a skeleton **208***a* of fibrous material. Skeleton **208***a* may generally be considered to be a fibrous structure that effectively forms a ring around aortic valve **120**. A fibrous ring **208***b*, which is substantially the same type of structure as skeleton **208***a*, extends around mitral valve **116**. Mitral valve **116** includes an anterior leaflet **212** and a posterior leaflet **216**, as discussed above. Anterior leaflet **212** and posterior leaflet **216** are generally thin, flexible membranes. When mitral valve **116** is closed (as shown in **FIG. 2***a*), anterior leaflet **212** and posterior leaflet **216** are generally aligned and contact one another to create a seal. Alternatively, when mitral valve **116** is opened, blood may flow through an opening created between anterior leaflet **212** and posterior leaflet **216**.

[0009] Many problems relating to mitral valve **116** may occur and these insufficiencies may cause many types of ailments. Such problems include, but are not limited to, mitral regurgitation. Mitral regurgitation, or leakage, is the backflow of blood from left ventricle **112** into the left atrium **108** due to an imperfect closure of mitral valve **116**. That is, leakage often occurs when a gap is created between anterior leaflet **212** and posterior leaflet **216**.

[0010] In general, a relatively significant gap may exist between anterior leaflet **212** and posterior leaflet **216** (as shown in **FIG. 2***b*) for a variety of different reasons. For example, a gap may exist due to congenital malformations, because of ischemic disease, or because a heart has been damaged by a previous heart attack. A gap may also be created when congestive heart failure, e.g., cardiomyopathy, or some other type of distress causes a heart to be enlarged. When a heart is enlarged, the walls of the heart, e.g., wall **134** of a left ventricle, may stretch or dilate, causing posterior leaflet **216** to stretch. It should be appreciated that anterior leaflet **212** generally does not stretch. As shown in **FIG. 2***b*, a gap **220** between anterior leaflet **212** and stretched posterior leaflet **216'** is created when wall **134'** stretches. Hence, due to the existence of gap **220**, mitral valve **116** is unable to close properly, and may begin to leak.

[0011] Leakage through mitral valve **116** generally causes a heart to operate less efficiently, as the heart must work harder to maintain a proper amount of blood flow therethrough. Leakage through mitral valve **116**, or general mitral insufficiency, is often considered to be a precursor to CHF. There are generally different levels of symptoms associated with heart failure. Such levels are classified by the New York Heart Association (NYHA) functional classification system. The levels range from a Class 1 level which is associated with an asymptomatic patient who has substantially no physical limitations to a Class 4 level which is associated with a patient who is unable to carry out any physical activity without discomfort, and has symptoms of cardiac insufficiency even at rest. In general, correcting for mitral valve leakage may be successful in allowing the NYHA classification grade of a patient to be reduced. For instance, a patient with a Class 4 classification may have his classification reduced to Class 3 and, hence, be relatively comfortable at rest.

[0012] Treatments used to correct for mitral valve leakage or, more generally, CHF, are typically highly invasive, open-heart surgical procedures. Ventricular assist devices such as artificial hearts may be implanted in a patient whose own heart is failing. The implantation of a ventricular assist device is often expensive, and a patient with a ventricular assist device must be placed on extended anti-coagulant therapy. As will be appreciated by those skilled in the art, anti-coagulant therapy reduces the risk of blood clots being formed, as for example, within the ventricular assist device. While reducing the risks of blood clots associated with the ventricular assist device is desirable, anti-coagulant therapies may increase the risk of uncontrollable bleeding in a patient, e.g., as a result of a fall, which is not desirable.

[0013] Rather than implanting a ventricular assist device, bi-ventricular pacing devices similar to pace makers may be

implanted in some cases, e.g., cases in which a heart beats inefficiently in a particular asynchronous manner. While the implantation of a bi-ventricular pacing device may be effective, not all heart patients are suitable for receiving a bi-ventricular pacing device. Further, the implantation of a bi-ventricular pacing device is expensive.

[0014] Open-heart surgical procedures which are intended to correct for mitral valve leakage, specifically, involve the implantation of replacement valves. Valves from animals, e.g., pigs, may be used to replace a mitral valve **116** in a human. While the use of a pig valve may relatively successfully replace a mitral valve, such valves generally wear out, thereby requiring additional open surgery at a later date. Mechanical valves, which are less likely to wear out, may also be used to replace a leaking mitral valve. However, when a mechanical valve is implanted, there is an increased risk of thromboembolism, and a patient is generally required to undergo extended anti-coagulant therapies.

[0015] A less invasive surgical procedure involves heart bypass surgery associated with a port access procedure. For a port access procedure, the heart may be accessed by cutting a few ribs, as opposed to opening the entire chest of a patient. In other words, a few ribs may be cut in a port access procedure, rather than opening a patient's sternum.

[0016] One open-heart surgical procedure that is particularly successful in correcting for mitral valve leakage and, in addition, mitral regurgitation, is an annuloplasty procedure. During an annuloplasty procedure, an annuloplasty ring may be implanted on the mitral valve to cause the size of a stretched mitral valve **116** to be reduced to a relatively normal size. **FIG. 3** is a schematic representation of an annuloplasty ring. An annuloplasty ring **304** is shaped approximately like the contour of a normal mitral valve. That is, annuloplasty ring **304** is shaped substantially like the letter "D." Typically, annuloplasty ring **304** may be formed from a rod or tube of biocompatible material, e.g., plastic, that has a DACRON mesh covering.

[0017] In order for annuloplasty ring **304** to be implanted, a surgeon surgically attaches annuloplasty ring **304** to the mitral valve on the atrial side of the mitral valve. Conventional methods for installing ring **304** require open-heart surgery which involve opening a patient's sternum and placing the patient on a heart bypass machine. As shown in **FIG. 4**, annuloplasty ring **304** is sewn to a posterior leaflet **318** and an anterior leaflet **320** of a top portion of mitral valve **316**. In sewing annuloplasty ring **304** onto mitral valve **316**, a surgeon generally alternately acquires a relatively large amount of tissue from mitral tissue, e.g., a one-eighth inch bite of tissue, using a needle and thread, followed by a smaller bite from annuloplasty ring **304**. Once a thread has loosely coupled annuloplasty ring **304** to mitral valve tissue, annuloplasty ring **304** is slid onto mitral valve **316** such that tissue that was previously stretched out, e.g., due to an enlarged heart, is effectively pulled in using tension applied by annuloplasty ring **304** and the thread which binds annuloplasty ring **304** to the mitral valve tissue. As a result, a gap, such as gap **220** of **FIG. 2***b*, between anterior leaflet **320** and posterior leaflet **318** may be substantially closed off. After the mitral valve is shaped by ring **304**, the anterior and posterior leaflets **320**, **318** will reform to create a new contact line and will enable mitral valve **318** to appear and to function as a normal mitral valve.

[0018] Once implanted, tissue generally grows over annuloplasty ring **304**, and a line of contact between annuloplasty ring **304** and mitral valve **316** will essentially enable mitral valve **316** to appear and function as a normal mitral valve. Although a patient who receives annuloplasty ring **304** may be subjected to anti-coagulant therapies, the therapies are not extensive, as a patient is only subjected to the therapies for a matter of weeks, e.g., until tissue grows over annuloplasty ring **304**.

[0019] A second surgical procedure which is generally effective in reducing mitral valve leakage involves placing an edge-to-edge suture in the mitral valve. With reference to **FIG. 5**, such a surgical procedure, e.g., an Alfieri stitch procedure or a bow-tie repair procedure, will be described. An edge-to-edge stitch **404** is used to stitch together an area at approximately the center of a gap **408** defined between an anterior leaflet **420** and a posterior leaflet **418** of a mitral valve **416**. Once stitch **404** is in place, stitch **404** is pulled in to form a suture which holds anterior leaflet **420** against posterior leaflet **418**, as shown. By reducing the size of gap **408**, the amount of leakage through mitral valve **416** may be substantially reduced.

[0020] Although the placement of edge-to-edge stitch **404** is generally successful in reducing the amount of mitral valve leakage through gap **408**, edge-to-edge stitch **404** is conventionally made through open-heart surgery. In addition, the use of edge-to-edge stitch **404** is generally not suitable for a patient with an enlarged, dilated heart, as blood pressure causes the heart to dilate outward, and may put a relatively large amount of stress on edge-to-edge stitch **404**. For instance, blood pressure of approximately 120/80 or higher is typically sufficient to cause the heart to dilate outward to the extent that edge-to-edge stitch **404** may become undone, or tear mitral valve tissue.

[0021] While invasive surgical procedures have proven to be effective in the treatment of mitral valve leakage, invasive surgical procedures often have significant drawbacks. Any time a patient undergoes open-heart surgery, there is a risk of infection. Opening the sternum and using a cardiopulmonary bypass machine has also been shown to result in a significant incidence of both short and long term neurological deficits. Further, given the complexity of open-heart surgery, and the significant associated recovery time, people who are not greatly inconvenienced by CHF symptoms, e.g., people at a Class 1 classification, may choose not to have corrective surgery. In addition, people who most need open heart surgery, e.g., people at a Class 4 classification, may either be too frail or too weak to undergo the surgery. Hence, many people who may benefit from a surgically repaired mitral valve may not undergo surgery.

[0022] Therefore, what is needed is a minimally invasive treatment for mitral valve leakage. Specifically, what is desired is a method for reducing leakage between an anterior leaflet and a posterior leaflet of a mitral valve that does not require conventional surgical intervention.

SUMMARY OF THE INVENTION

[0023] The present invention relates to a non-invasive method of performing annuloplasty. According to one aspect of the present invention, a method for performing a procedure on a mitral valve of a heart includes inserting an implant into a left ventricle and orienting the implant in the

left ventricle substantially below the mitral valve. The implant may be attached to tissue near the mitral valve. In one embodiment, the implant is shortened in order to substantially reduce an arc length associated with the mitral valve. In another embodiment, the implant is inserted to the left ventricle through the aorta and the aortic valve.

[0024] In still another embodiment, connecting the implant and the tissue includes introducing a catheter into the left ventricle using a guide element as a track. The catheter includes at least one pointed wire which carries a coupling element and has a tip section that may be substantially pushed through the implant and the tissue to substantially couple the implant with the tissue. In such an embodiment, the coupling element may be a T-bar.

[0025] Performing an annuloplasty on a mitral valve by accessing the left ventricle of the heart using a catheter enables complicated surgical procedures to be avoided when treating mitral valve leakage. Avoiding surgical procedures generally makes annuloplasty more accessible to patients who may benefit from annuloplasty. As mitral valve leakage is often considered to be an early indicator of congestive heart failure, a non-invasive annuloplasty procedure which corrects for leakage problems may greatly improve the quality of life of many patients who might not be suitable for invasive annuloplasty procedures.

[0026] According to another aspect of the present invention, a method for accessing the left ventricle of a heart includes introducing an elongated body into the aorta, and passing at least a portion of the elongated body through the aortic valve. Once the portion is passed through the aortic valve, the portion is located, or positioned, in the left ventricle. In one embodiment, locating the portion in the left ventricle involves positioning the portion in the space between a plane associated with the mitral valve and a plane associated with the papillary muscles of the left ventricle. In such an embodiment, the elongated body may be an implant, and locating the portion in the left ventricle may further involve positioning the implant substantially against tissue near the mitral valve.

[0027] In accordance with still another aspect of the present invention, a method for performing annuloplasty includes accessing the left ventricle to provide an implant such as a tensionable arrangement to the left ventricle. Once the left ventricle is accessed, the tensionable arrangement is coupled to fibrous tissue around a mitral valve of the heart. The tensionable arrangement is coupled to a ventricular side of the mitral valve. Finally, the tensionable arrangement is tensioned such that it substantially reduces an arc length associated with the mitral valve. In one embodiment, the tensionable arrangement is an implant, and tensioning the tensionable arrangement involves substantially collapsing the implant.

[0028] According to yet another aspect of the present invention, a device which is suitable for use in an annuloplasty procedure includes a structure, a mesh, and a tensioning element. The structure is a spring-like element that is configured to be compressed onto itself when tension is applied. The mesh is a woven mesh that is arranged over the structure, and the tensioning element is arranged to apply tension to the structure. The device is such that when the device is coupled to fibrous tissue in proximity to the mitral valve of a heart, the tensioning element causes the device to reduce an arc length associated with the mitral valve. In one embodiment, device is suitable for being coupled to a ventricular side of the mitral valve. In another embodiment, the device includes a coupler which extends through the structure and the mesh to couple the device to the fibrous tissue. In such an embodiment, the coupler may take the form of a T-bar.

[0029] In accordance with still another aspect of the present invention, a device for use in an annuloplasty procedure includes a compressible member and a shortening device. The compressible member is movable between an open uncompressed position for insertion into a left ventricle through a catheter and a closed position. The shortening device is operable to move the compressible member between the open uncompressed position and the closed position. In general, the device is positioned to reduce an opening of a mitral valve. In one embodiment, the device also includes mesh covering that extends over at least a portion of the compressible member.

[0030] These and other advantages of the present invention will become apparent upon reading the following detailed descriptions and studying the various figures of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0031] The invention may best be understood by reference to the following description taken in conjunction with the accompanying drawings in which:

[0032] **FIG. 1** is a cross-sectional front-view representation of the left side of a human heart.

[0033] **FIG. 2***a* is a cut-away top-view representation of the mitral valve and the aortic valve of **FIG. 1**.

[0034] **FIG. 2***b* is a cut-away representation of a stretched mitral valve and an aortic valve.

[0035] **FIG. 3** is a representation of an annular ring that is suitable for use in performing a conventional annuloplasty procedure.

[0036] **FIG. 4** is a representation of a mitral valve and an aortic valve after the annular ring of **FIG. 3** has been implanted.

[0037] **FIG. 5** is a representation of a mitral valve and an aortic valve after a single edge-to-edge suture has been applied to reduce mitral regurgitation.

[0038] **FIG. 6***a* is a representation of a delivery tube and a J-catheter in accordance with an embodiment of the present invention.

[0039] **FIG. 6***b* is a cut-away front view of the left side of a heart in which the delivery tube and the J-catheter of **FIG. 6***a* have been inserted in accordance with an embodiment of the present invention.

[0040] **FIG. 7***a* is a representation of a catheter assembly in accordance with an embodiment of the present invention.

[0041] **FIG. 7***b* is a cross-sectional representation of the catheter assembly of **FIG. 7***a* in accordance with an embodiment of the present invention.

[0042] **FIG. 7***c* is a cut-away top-view representation of a left ventricle in which the gutter catheter of **FIGS. 7***a* and **7***b* has been positioned in accordance with an embodiment of the present invention.

[0043] **FIG. 8** is a cut-away top-view representation of a left ventricle in which a guide wire has been positioned in accordance with an embodiment of the present invention.

[0044] **FIG. 9***a* is a representation of a portion of an implant in accordance with an embodiment of the present invention.

[0045] **FIG. 9***b* is a cut-away top-view representation of a left ventricle in which an implant has been positioned in accordance with an embodiment of the present invention.

[0046] **FIG. 9***c* is a cross-sectional front-view representation of a left ventricle in which the implant of **FIG. 9***b* and a balloon have been inserted in accordance with an embodiment of the present invention.

[0047] **FIG. 10** is a representation of a T-bar delivery catheter in accordance with an embodiment of the present invention.

[0048] **FIG. 11***a* illustrates an implant that is coupled to fibrous tissue around a mitral valve before tension has been applied to the implant in accordance with an embodiment of the present invention.

[0049] **FIG. 11***b* illustrates the implant of **FIG. 1 a** after tension has been applied to the implant in accordance with an embodiment of the present invention.

[0050] **FIG. 12** is a process flow diagram which illustrates the steps associated with one method of performing annuloplasty using a catheter in accordance with an embodiment of the present invention.

[0051] **FIG. 13***a* is a cut-away representation of a left ventricle in which a catheter has been inserted in accordance with a second embodiment of the present invention.

[0052] **FIG. 13***b* is a cross-sectional representation of a left ventricle in which the catheter of **FIG. 13***a* has been inserted in accordance with the second embodiment of the present invention.

[0053] **FIG. 13***c* is a representation of a clip which is coupled to an anterior leaflet and a posterior leaflet in accordance with the second embodiment of the present invention.

DETAILED DESCRIPTION OF THE EMBODIMENTS

[0054] Invasive, open-heart surgical procedures are generally effective in the treatment of mitral valve leakage. However, open-heart surgical procedures may be particularly hazardous to some patients, e.g., frail patients or patients who are considered as being very ill, and undesirable to other patients, e.g., patients who are asymptomatic and do not wish to undergo a surgical procedure. As such, open-heart surgical procedures to correct mitral valve leakage or, more generally, mitral valve insufficiency, are not suitable for many patients who would likely benefit from reducing or eliminating the mitral valve leakage.

[0055] A catheter-based annuloplasty procedure enables annuloplasty to be performed on a patient without requiring that the patient undergo open-heart surgery, or be placed on cardiopulmonary bypass. Catheters may be introduced into the left ventricle of a heart through the aorta to position a guide wire and an implant on the ventricular side of a mitral valve, i.e., under a mitral valve. Catheters may also be used to couple the implant to fibrous tissue associated with the skeleton of the heart around the mitral valve, and to reduce leakage between an anterior leaflet of the mitral valve and a posterior leaflet of the mitral valve by applying tension to the implant.

[0056] The use of catheters to perform an annuloplasty procedure enables the annuloplasty procedure to be performed without open-heart surgery, and without a bypass procedure. Recovery time associated with the annuloplasty, as well as the risks associated with annuloplasty, may be substantially minimized. As a result, annuloplasty becomes a more accessible procedure, since many patients who might previously not have received treatment for mitral valve leakage, e.g., frail patients and asymptomatic patients, may choose to undergo catheter-based annuloplasty.

[0057] To begin a catheter-based annuloplasty procedure, a delivery tube and a J-catheter may be inserted into a left ventricle of the heart through the aorta. Inserting the delivery tube and the J-catheter through the aorta enables the left ventricle of the heart to be reached substantially without coming into contact with trabeculae or the cordae tendonae in the left ventricle. **FIG. 6***a* is a diagrammatic representation of a delivery tube and a J-catheter in accordance with an embodiment of the present invention. Delivery tube **604** has a substantially circular cross section, and is configured to receive a J-catheter **608**. J-catheter **608** is arranged to move longitudinally through and opening in delivery tube **604** as needed.

[0058] In general, delivery tube **604** is an elongated body which may be formed from a flexible, durable, biocompatible material such as nylon, urethane, or a blend of nylon and urethane, e.g., PEBAX®. Likewise, J-catheter **608**, which is also an elongated body, may also be formed from a biocompatible material. A material used to form J-catheter **608** is typically also relatively flexible. In the described embodiment, a tip of J-catheter **608** is rigid enough to allow the tip of J-catheter **608** to maintain a relatively curved shape, e.g., a "J" shape. The curve in J-catheter **608** is configured to facilitate the positioning of a gutter catheter, as will be described below with respect to **FIGS. 7***a-c*.

[0059] **FIG. 6***b* is a schematic representation of delivery tube **604** and J-catheter **608** positioned within a heart in accordance with an embodiment of the present invention. As shown, after delivery tube **604** and J-catheter **608** are effectively "snaked" or inserted through a femoral artery, portions of delivery tube **604** and of J-catheter **608** are positioned within an aorta **620** of a heart **616**. A tip **626** of J-catheter **608**, which is substantially oriented at a right angle from the body of J-catheter **608**, and an end of delivery tube **604** are oriented such that they pass through an aortic valve **630**. Hence, an end of delivery tube **604** and tip **626** are positioned at a top portion of left ventricle **624**, where wall **632** of left ventricle **624** is relatively smooth. The relative smoothness of the top portion of left ventricle **624** enables a catheter to be properly positioned within left ventricle **624** by guiding the tip of the catheter along wall **632**. In one embodiment, tip **626** is oriented such that it is positioned approximately just below a mitral valve **628** on the ventricular side of mitral valve **628**.

[0060] Once positioned within left ventricle **624**, J-catheter **608** may be rotated within delivery tube **604** such that

tip **626** is may enable a gutter catheter fed therethrough to run along the contour of wall **632**. Typically, the gutter catheter runs along the contour of wall **632** in an area that is effectively defined between a plane associated with papillary muscles **640**, a plane associated with the posterior leaflet of mitral valve **628**, cordae tendonae **642**, and wall **632**. A "gutter" is located in such an area or region and, more specifically, is positioned substantially right under mitral valve **628** where there is a relatively insignificant amount of trabeculae.

[**0061**] With reference to **FIGS. 7***a*-**7***c*, a gutter catheter will be described in accordance with an embodiment of the present invention. A gutter catheter **704**, which is part of a catheter assembly **702** as shown in **FIG. 7***a*, is arranged to be extended through J-catheter **626** such that gutter catheter **704** may be steered within a left ventricle just beneath a mitral valve. Gutter catheter **704**, which may include a balloon tip (not shown), is typically formed from a flexible material such as nylon, urethane, or PEBAX®. In one embodiment, gutter catheter **704**, which is steerable, may be formed using a shape memory material.

[**0062**] As shown in **FIGS. 7***a* and **FIG. 7***b*, which represents a cross section of catheter assembly **702** taken at a location **710**, gutter catheter **704** is at least partially positioned within J-catheter **608** which, in turn, is at least partially positioned within delivery tube **604**. Gutter catheter **704** may be free to rotate within and extend through J-catheter **608**, while J-catheter **608** may be free to rotate within and extend through delivery tube **604**.

[**0063**] Referring next to **FIG. 7***c*, the positioning of gutter catheter **704** within a left ventricle of the heart will be described in accordance with an embodiment of the present invention. It should be appreciated that the representation of gutter catheter **704** within a left ventricle **720** has not been drawn to scale, for ease of illustration and ease of discussion. For instance, the distance between a wall **724** of left ventricle **720** and a mitral valve **728** has been exaggerated. In addition, it should also be appreciated that the positioning of delivery tube **604** and, hence, J-catheter **608** and gutter catheter **704** within aortic valve **732** may vary.

[**0064**] Gutter catheter **704** protrudes through tip **626** of J-catheter **608**, and, through steering, essentially forms an arc shape similar to that of mitral valve **728** along the contour of a wall **724** of left ventricle **720** just beneath mitral valve **728**, i.e., along the gutter of left ventricle **720**. Wall **724** of left ventricle **720** is relatively smooth just beneath mitral valve **728**, i.e., generally does not include trabeculae. Hence, inserting catheter assembly **702** through an aortic valve **732** into an upper portion left ventricle **720** allows gutter catheter **704** to be navigated within left ventricle **720** along wall **724** substantially without being obstructed by trabeculae or cordae tendonae.

[**0065**] Gutter catheter **704** generally includes an opening or lumen (not shown) that is sized to accommodate a guide wire through which a guide wire may be inserted. The opening may be located along the central axis of gutter catheter **704**, i.e., central axis **730** as shown in **FIG. 7***a*. Delivering a guide wire through gutter catheter **704** enables the guide wire to effectively follow the contour of wall **724**. In general, the guide wire may include an anchoring tip which enables the guide wire to be substantially anchored against wall **724**. **FIG. 8** is a diagrammatic top-view cut-away representation of a left side of a heart in which a guide wire has been positioned in accordance with an embodiment of the present invention. It should be appreciated that the representation of the left side of a heart in **FIG. 8** has not been drawn to scale, and that various features have been exaggerated for ease of discussion. A guide wire **802** is positioned along wall **724** of left ventricle **720**. Once guide wire **802** is inserted through gutter catheter **704** of **FIGS. 7***a*-**7***c*, and anchored against wall **724** using an anchoring tip **806**, gutter catheter **704**, along with J-catheter **708**, are withdrawn from the body of the patient. It should be appreciated that delivery tube **604** typically remains positioned within the aorta after guide wire **802** is anchored to wall **724**.

[**0066**] Guide wire **802**, which may be formed from a material such as stainless steel or a shape memory material, is generally anchored such that guide wire **802** effectively passes along a large portion of wall **724**. Typically, guide wire **802** serves as a track over which an implant may be positioned. With reference to **FIG. 9***a*, one embodiment of an implant will be described in accordance the present invention. A section **904** of an implant includes an opening **908** therethrough which is arranged to fit over a guide wire, i.e., guide wire **802** of **FIG. 8**. In general, an implant is sized to be inserted through a femoral artery, an aorta, and an aortic valve. Section **904** includes a biocompatible structure **912** over which a biocompatible woven mesh **916** is placed. Mesh **916** enables mitral valve tissue regrowth to occur in and around mesh **916** once the implant is positioned under the mitral valve. While structure **912** may take a variety of different forms, in one embodiment, structure may be formed as an open spring element which may effectively be shortened or collapsed onto itself, e.g., when tension is applied to an overall implant as will be described below with respect to **FIGS. 11***a* and **11***b*.

[**0067**] **FIG. 9***b* is a cut-away top-view representation of a left side of a heart in which an implant has been inserted over a guide wire in accordance with an embodiment of the present invention. It should be understood that the relative dimensions of features of the portion of the heart shown in **FIG. 9***b* are not to scale, and some dimensions have been exaggerated for purposes of discussion. An implant **924** is positioned over guide wire **802** such that implant **924** substantially follows the curved contour of mitral valve **728** and, hence, fibrous tissue **970** around mitral valve **728**. That is, implant **924** is shaped approximately like a horseshoe. Guide wire **802** effectively supports implant **924** to position implant **924** substantially below mitral valve **728** in left ventricle **720**.

[**0068**] As discussed above with respect to **FIG. 5**, implant **924** may be coupled to a balloon or balloons which may be inflated to effectively push implant **924** up against a bottom side of mitral valve **728**. With reference to **FIG. 9***c*, the positioning of implant **924** against the bottom side of mitral valve **728** will be described in accordance with an embodiment of the present invention. **FIG. 9***c* is a diagrammatic cross-sectional side view representation of a left side of a heart. A balloon **960**, which is generally coupled to implant **924**, may be inflated once implant **924** is positioned over guide wire **802**. Balloon **960**, once inflated, substantially fills space in left ventricle **720** between mitral valve **728** and a papillary muscle **964**. Inflating balloon **960** enables the pressure within balloon **960** to effectively force implant **924**

against fibrous tissue **970** of the fibrous ring around mitral valve **728**. In one embodiment, balloon **960** is formed from an elastomeric material.

[**0069**] Once implant **924** is suitably positioned, a T-bar delivery catheter may be inserted through implant **924**, as mentioned above with respect to **FIG. 5**. Although a T-bar delivery catheter is described as providing T-bars which are suitable for coupling implant **924** to fibrous tissue **970** associated with the fibrous ring around mitral valve **728**, it should be understood that other methods may be used to couple implant **924** to tissue. Substantially any mechanism or device which may reliably hold tissue may be used. Suitable devices include, but are not limited to, anvil arrangements, staples, clips, barbs, and sutures.

[**0070**] Referring next to **FIG. 10**, one embodiment of a T-bar delivery catheter will be described in accordance with an embodiment of the present invention. A T-bar delivery catheter **1004** may be positioned over guide wire **802** and within implant **924**. It should be appreciated that T-bar delivery catheter **1004** and implant **924** have not been drawn to scale. Within delivery catheter **1004** is a wire **1008** which carries a T-bar **1012**. T-bar **1012** is coupled to an extension **1016** which may be used to effectively tie off T-bar **1012** such that T-bar **1012** holds implant **924** against fibrous tissue **970** around the mitral valve. Typically, a pointed or sharpened end **1020** of wire **1008** penetrates both implant **924** and fibrous tissue **970**. Once end **1020** and T-bar **1012** are both located above fibrous tissue **970**, wire **1008** may be retracted, while T-bar **1012** remains above fibrous tissue **970**, i.e., on an atrial side of fibrous tissue **970**. Retracting wire **1008** and, in one embodiment, delivery catheter **1004**, entirely out of a patient enables an additional T-bar to be loaded onto wire **1008**. Once an additional T-bar is positioned on wire **1008**, wire **1008** may be reinserted into delivery catheter **1004**, and delivery catheter **1004** may be used to enable another location along implant **924** to be essentially attached to fibrous tissue **970**.

[**0071**] In general, the number of T-bars **1012** which may be used to create connections between implant **924** and fibrous tissue **970** may vary widely. By way of example, the use of approximately six or eight T-bars **1012** may be suitable, although fewer or more T-bars **1012** may be used as necessary. After all T-bars **1012** are in place with respect to implant **924**, T-bars **1012** may be tightened by tying off extensions **1016** associated with T-bars **1012**.

[**0072**] While T-bars **1012** create relatively intimate contact between implant **924** and fibrous tissue **970**, in order to effectively shorten implant **924**, i.e., to provide treatment or therapy using implant **924**, implant **924** is typically tensioned. That is, the size of mitral valve **728** may be reduced by tensioning implant **924**. With reference to **FIGS. 11***a* and **11***b*, one method of providing tension to an implant will be described in accordance with an embodiment of the present invention. An implant **1124** is positioned under a mitral valve **1128**, i.e., in a left ventricle of a heart, and is held against mitral valve **1128** using coupling devices **1112** that effectively attach implant **1124** to fibrous tissue **1170**. In the described embodiment, coupling devices **1112** are T-bars, although it should be understood that other coupling devices, e.g., staples or barbs, may be used in lieu of T-bars.

[**0073**] In order to reduce the size of mitral valve **1128**, which is stretched such that a gap **1130** is evident between a posterior leaflet **1132** and an anterior leaflet **1134**, a tensioning element **1140** which is inserted within implant **1124** may be tensioned to shorten an arc length of implant **1124**. Generally, tensioning element **1140** may be inserted within implant **1134** using a catheter after implant **1134** is inserted into the left ventricle. Alternatively, tensioning element **1140** may be preloaded in implant **1134**. As shown, tensioning element **1140** is a string which may be pulled and ultimately tied off to effectively reduce the arc length associated with the curved outer edge of mitral valve **1128**. Pulling on and tying off tensioning element **1140** may be achieved through the use of a catheter **1150** inserted within implant **1134**.

[**0074**] When tension element **1140** is tensioned, implant **1124** effectively collapses onto itself, or is shortened. As previously mentioned, implant **1124** may be formed from a spring-like structure that is covered by a mesh. The spring-like structure is an elongated body may be collapsed onto itself or shortened when tension is applied. Hence, as shown in **FIG. 11***b*, the arc length associated with mitral valve **1128** may be reduced, e.g., by a two-to-one ratio. Reducing the arc length associated with mitral valve **1128** allows gap **1130** to be greatly reduced. In one embodiment, gap **1130** effectively disappears such that there is no leakage of mitral valve **1128**.

[**0075**] In one embodiment, implant **1124** is arranged to bend and to collapse onto itself such that a radius of curvature associated with implant **1124** may vary. That is, applying tension to implant **1124** allows the radius of curvature of implant **1124** to be reduced. As implant **1124** is coupled to fibrous tissue **1170** in proximity to mitral valve **1134**, when the radius of curvature of implant **1124** is reduced, the size of mitral valve **1134** is also reduced.

[**0076**] It should be appreciated that the configuration of tensioning element **1140** be different than shown herein. While tensioning element **1140** may be a string or a similar element which may be tied off, tensioning element **1140** may also be substantially any element on which tension may be applied by pulling. Another particularly suitable tension element is a cable wrap or "zip tie," which is generally an element that may be looped onto itself and then tightened by pulling, e.g., through the use of a catheter such as catheter **1150** of **FIG. 11***a*. Releasing such an element after pulling generally does not significantly alter the tension associated with the element.

[**0077**] Tensioning element **1140**, in cooperation with an adjustable, or collapsible, implant **1124** allows implant **1124** to be continually adjusted as needed. By way of example, if a patient requires a readjustment of implant **1124** at some point after the initial catheter-based annuloplasty, the patient may undergo a relatively simple catheter-based procedure designed to alter the tension in implant **1124**. Further, the need to select an implant **1124** for use based upon the size of a particular implant **1124** may be reduced, as an implant **1124** of a single size may be adjusted when already implanted to properly reduce the size of a stretched mitral valve **1128**.

[**0078**] Once implant **1124** is properly adjusted, a patient may be placed on anticoagulant therapy until mitral tissue has begun to successfully grow around and into implant **1124**. When tissue growth has reached a desired level, the new tissue may then effectively support implant **1124**, and the patient may generally cease anticoagulant therapy. As

catheter-based annuloplasty is not an open surgery and is considered to be relatively non-invasive, the recovery time from catheter-based annuloplasty is relatively short when compared to the recovery time required by conventional surgical annuloplasty procedures.

[0079] With reference to **FIG. 12**, the performance of an annuloplasty procedure using a catheter-based system will be described in accordance with an embodiment of the present invention. Once a patient is prepared, e.g., sedated, an annuloplasty procedure **504** may begin with the insertion of a delivery tube and a J-catheter into the left ventricle of the heart of the patient. The delivery tube and the J-catheter may be inserted into the body of the patient through the femoral artery, and threaded through the femoral artery and the aorta into the left ventricle of the heart. Generally, the J-catheter is positioned within the delivery tube. One embodiment of the delivery tube and a J-catheter were described above with respect to **FIGS. 6***a* and **6***b*. As will be appreciated by those skilled in the art, the delivery tube and the J-catheter are typically each threaded through the aortic valve to reach the left ventricle.

[0080] Once the delivery tube and the J-catheter are positioned within the left ventricle, a gutter catheter may be extended through the J-catheter in step **512**. As was discussed above with reference to **FIGS. 7***a-c*, the gutter catheter is arranged to effectively run against a gutter of the wall of the left ventricle substantially immediately under the mitral valve. Specifically, the gutter catheter may be positioned in the space in the left ventricle between the mitral valve and the musculi papillares, or papillary muscles. The gutter catheter often has a tip that is steerable and flexible. In one embodiment, the tip of the gutter catheter may be coupled to an inflatable balloon. The J-catheter serves, among other purposes, the purpose of allowing the gutter catheter to be initially oriented in a proper direction such that the gutter catheter may be positioned along the wall of the left ventricle.

[0081] In step **516**, a guide wire with an anchoring feature may be delivered through the gutter catheter, e.g., through a lumen or opening in the gutter catheter. The guide wire is delivered through the gutter catheter such that it follows the contour of the gutter catheter against the wall of the left ventricle. After the guide wire is delivered, the anchoring feature of the guide wire is anchored on the wall of the left ventricle in step **520**. Anchoring the guide wire, or otherwise implanting the guide wire, on the wall of the left ventricle enables the guide wire to maintain its position within the left ventricle.

[0082] The J-catheter and the gutter catheter are pulled out of the left ventricle through the femoral artery in step **524**, leaving the guide wire anchored within the left ventricle, as was discussed above with respect to **FIG. 8**. Once the J-catheter and the gutter catheter are removed from the left ventricle, an implant which may be coupled to a substantially deflated balloon is inserted into the left ventricle using the guide wire as a guide track in step **528**. In other words, an implant that is intended to be coupled to the mitral valve is positioned in the left ventricle under the mitral valve, i.e., on a ventricular side of the mitral valve. One suitable implant was described above with respect to **FIG. 9***a*. In one embodiment, the implant may be inserted into the left ventricle using a catheter which may be retracted once the implant is positioned under the mitral valve in contact with the fibrous tissue around the mitral valve.

[0083] After the implant and the balloon are inserted in the left ventricle, the balloon is inflated in step **532**. Inflating the elastomeric balloon at a relatively modest pressure using, for example, an air supply coupled to the balloon through the implant, serves to cause the implant to be pressed up against the fibrous tissue around the mitral valve. Generally, the inflated balloon substantially occupies the space between the mitral valve and the papillary muscles. In one embodiment, more than one balloon may be used to position the implant against the fibrous tissue around the bottom of the mitral valve.

[0084] A T-bar delivery catheter is inserted through the implant in step **536**, once the balloon is inflated in step **532**. The T-bar delivery catheter effectively delivers T-bars, or similar mechanisms, which are arranged to attach or otherwise couple the implant to an annulus of the mitral valve, e.g., the fibrous tissue of the skeleton around the mitral valve. In step **540**, connections are created between the implant and substantially any suitable tissue near the mitral valve to effectively attach the implant to the tissue. The connections may be created by extending sharpened wires which carry elements such as T-bars through the implant and the tissue, then retracting the sharpened wires, and locking the T-bars in place, as discussed above with respect to **FIG. 10**.

[0085] Once a desired number of connections, e.g., six connections, are made between the implant and the tissue, then the balloon may be deflated and removed from the left ventricle in step **548**. It should be understood that since the implant is effectively connected to tissue around the mitral valve, deflating the balloon does not cause the position of the implant to be significantly moved. After the balloon is deflated, the T-bar delivery catheter is removed from the left ventricle in step **522**. In step **556**, the guide wire may be removed. The implant is then typically shortened in step **558**, as for example by providing tension to the implant. As will be appreciated by those skilled in the art, shortening the implant involves contracting the mitral valve or, more specifically, the posterior leaflet of the mitral valve. Although the implant may be shortened in substantially any suitable manner, in one embodiment, the implant may be shortened by tightening a string or a cord associated with the implant to effectively reduce the arc length associated with the implant, e.g., by a two-to-one ratio. Once the implant is successfully shortened, the delivery tube may be removed in step **560**. After the delivery tube is removed, the annuloplasty procedure is completed.

[0086] It should be appreciated that implanting an implant in tissue near the mitral valve, then shortening the implant, is just one method of treating mitral valve leakage in a minimally invasive manner using a catheter-based system. Another method, which will be described below with respect to **FIGS. 13***a* and **13***b*, involves accessing the mitral valve through the aorta and the left ventricle, and implanting a clip element which serves to effectively pinch together the anterior leaflet and the posterior leaflet of the mitral valve to reduce leakage. **FIG. 13***a* is a schematic cut-away representation of a left ventricle of the heart in which a catheter that is suitable for use in accessing a mitral valve in accordance with a second embodiment of the present inven-

tion is positioned. **FIG. 13***b* is a cross-sectional representation of the left ventricle and the catheter of **FIG. 13***a*. A catheter **1304** is inserted into a left ventricle **1314** through an aortic valve **1310**. Catheter **1304**, which may be steerable and flexible, has a curved orientation such that catheter **1304** may pass between cordae tendonae **1326** that are coupled to papillary muscles **1322** and mitral valve **1340**. That is, catheter **1304** is shaped to pass through a plane defined by papillary muscles **1322**, as well as cordae tendonae **1326**, to reach a posterior leaflet "side" of mitral valve **1340**.

[**0087**] As shown, catheter **1304** does not follow the contour of a wall **1318** of left ventricle **1314**, and is still positioned such that a portion of catheter **1304** is positioned in a region of left ventricle **1314** between mitral valve **1340**, cordae tendonae **1326**, papillary muscles **1322**, and wall **1318**. Hence, catheter **1304** is able to directly access a posterior leaflet of mitral valve **1340** substantially directly. A catheter **1304** which, in one embodiment, accesses a gutter portion of left ventricle **1314** may be easier to fabricate and to actively control than a catheter assembly which includes a J-catheter and a gutter catheter, e.g., J-catheter **608** and gutter catheter **704** of **FIG. 7***a*, as catheter **1304** generally does not need to be manipulated with many direction changes. Instead, catheter **1304** may be formed to include either a curved end portion, as shown in **FIG. 13***b*, or a v-shaped end portion which both enable an end portion of catheter **1304** to access the portion of left ventricle **1314** that is positioned substantially immediately under mitral valve **1340**.

[**0088**] A tip portion of catheter **1304** may be directed against mitral valve **1340**, thereby facilitating the ability to place a tissue anchor or clip element which may act to pinch an anterior leaflet against a posterior leaflet. **FIG. 13***c* is a schematic representation of a clip element positioned with respect to a posterior leaflet and an anterior leaflet of a mitral valve in accordance with a second embodiment of the present invention. It should be appreciated that the elements in **FIG. 13***c* have not be drawn to scale for purposes of discussion. A clip **1380**, which may be formed from a material such as steel, may be coupled to an anterior leaflet **1362** and a posterior leaflet **1366** of a mitral valve using catheter **1304** of **FIGS. 13***a* and **13***b*. Clip **1380**, which passes between cordae tendonae **1326** associated with anterior leaflet **1362** and cordae tendonae **1326** associated with posterior leaflet **1366**, may be coupled to anterior leaflet **1362** and posterior leaflet **1366** using, for example, T-bar arrangements **1390**.

[**0089**] By pinching together anterior leaflet **1362** and posterior leaflet **1366**, the leakage through a gap (not shown) between anterior leaflet **1362** and posterior leaflet **1366** may be reduced. While the presence of clip **1380** may result in a patient having to undergo anticoagulant therapies, the placement of clip **1380** in lieu of an implant such as implant **924** of **FIG. 9***b* may minimize the amount of time associated with a leakage correction process.

[**0090**] Although only a few embodiments of the present invention have been described, it should be understood that the present invention may be embodied in many other specific forms without departing from the spirit or the scope of the present invention. By way of example, methods of introducing an implant into the left ventricle to correct for mitral valve leakage, or mitral valve insufficiency, may be applied to introducing implants which correct for leakage in other valves. For instance, the above-described procedure may be adapted for use in repair a leaking valve associated with a right ventricle.

[**0091**] While connecting an implant to fibrous tissue associated with the mitral valve of the heart has generally been described, the implant may be connected to other types of tissue which are near, around, in proximity to, or include the mitral valve. Other tissues to which an implant may be connected include tissues associated with the myocardium, or tissues associated with the wall of the left ventricle. In one embodiment, the implant may be substantially directly connected to the leaflets of the mitral valve.

[**0092**] In general, methods of accessing a left ventricle through the aorta may be applied to procedures other than annuloplasty. The left ventricle may be accessed to perform mapping or ablation therapies, or to stabilize a patient suffering from an acute valve failure, e.g., by filling space in the left ventricle by inflating a balloon. Also, a balloon, either steady state or pulsatile, may be used to increase the ejection fraction associated with the left ventricle. The left ventricle may also be accessed in order to access the left atrium through the mitral valve. Specifically, the smooth portion of the left ventricle, e.g., the gutter, may be accessed en route to accessing the left atrium. It should be appreciated that accessing the gutter may be used in conjunction with access routes via other channels to the heart such as a coronary sinus and a transceptal approach to the left atrium.

[**0093**] While a balloon may be inflated within a left ventricle such that the balloon is effectively trapped under the posterior leaflet of a mitral valve to treat sudden heart failure. The balloon may remain positioned in the left ventricle until surgery is performed on the heart, at which time the balloon may be removed. In one embodiment, such a balloon may be arranged to be filled with blood that clots off, thereby enabling the balloon to become what is effectively a permanent structure in the left ventricle that reduces mitral regurgitation.

[**0094**] Access to the left ventricle may also facilitate the use of a camera within left ventricle. For example, a camera may be fed into the left ventricle on the tip of a catheter-like device to enable the interior of the left ventricle to be viewed to identify any anomalies which may be present in the left ventricle. It should be appreciated that such a camera may also be passed into the coronary sinus.

[**0095**] Rather than implanting an implant to correct for mitral valve insufficiency using a catheter-based approach, a series of local plications to the mitral valve may be used to achieve annuloplasty. By way of example, a catheter or other device that is suitable for creating local plications may be located along the wall of a left ventricle beneath the mitral valve. Local plications may be created by elements which engage fibrous tissue and close upon themselves such that tissue is engaged. Alternatively, a one-way tensioning device may be used to effectively pull in on the local plications, e.g., elements, such that the arc length of the mitral valve is effectively reduced.

[**0096**] Local plications may generally be created through the use of staple elements which engage each other once they penetrate the fibrous tissue, or hook-like elements. It should be appreciated, however, that in other embodiments, suture type materials may be used to create local plications.

[0097] While an implant which may effectively collapse onto itself, e.g., be shortened, when tension is applied is suitable for use in a catheter-based annuloplasty as described above, it should be appreciated that such an implant is suitable for use in a variety of different annuloplasty procedures. For instance, the implant may be used in a conventional, surgical annuloplasty procedure since its use may enable a surgeon to continuously adjust the amount by which the arc length of a mitral valve may be reduced.

[0098] An implant has generally been described as having a shape which is similar to that of a horseshoe ring. Implants of other shapes may generally be implanted within a heart to correct for mitral valve insufficiency. By way of example, an implant which has a curved shape that does not follow substantially the entire arc length of a mitral valve may be implanted without departing from the spirit or the scope of the present invention. Such an implant may generally cover a larger area than would be covered by a local plication.

[0099] It should be understood that although a guide wire has been described as including an anchoring tip to anchor the guide wire to a wall of the left ventricle, a guide wire may be anchored with respect to the left ventricle in substantially any suitable manner. By way of example, a guide wire may include an anchoring feature which is located away from the tip of the guide wire. In addition, a guide wire may more generally be any suitable guiding element which is configured to facilitate the positioning of an implant.

[0100] An elastomeric balloon has been described as being suitable for use in effectively forcing an implant against a surface to which the implant is to be connected. In lieu of an elastomeric balloon, substantially an expanding structure may be used to push the implant against a surface. By way of example, an expanding metal structure which is expandable from a closed position into an open position may be used to provide pressure or force on an implant.

[0101] While access to the gutter of the left ventricle has been described as being associated with a minimally invasive catheter annuloplasty procedure, it should be understood that the gutter of the left ventricle may also be accessed, e.g., for an annuloplasty procedure, as a part of a surgical procedure. For instance, the aorta of a heart may be accessed through an open chest surgical procedure before a catheter is inserted into the aorta to reach the left ventricle. Alternatively, an implant may be introduced on a ventricular side of a mitral valve through a ventricular wall which is accessed during an open chest surgical procedure.

[0102] The steps associated with performing a catheter-based annuloplasty may be widely varied. Steps may generally be added, removed, reordered, and altered without departing from the spirit or the scope of the present invention. Therefore, the present examples are to be considered as illustrative and not restrictive, and the invention is not to be limited to the details given herein, but may be modified within the scope of the appended claims.

What is claimed is:

1. A method for performing a procedure on a mitral valve of a heart, the method comprising:

inserting at least one implant into a left ventricle of the heart;

positioning the at least one implant with respect to the mitral valve, wherein positioning the implant includes orienting the implant in the left ventricle substantially below the mitral valve; and

attaching the implant to tissue located near the mitral valve.

2. A method as recited in claim 1 further including:

reducing an arc length of the implant, wherein reducing the arc length of the implant substantially reduces an arc length associated with the mitral valve.

3. A method as recited in claim 1 wherein inserting the implant into the left ventricle includes:

introducing the implant into an aorta; and

passing the implant through an aortic valve interposed between the aorta and the left ventricle.

4. A method as recited in claim 3 further including:

introducing a guide element into the left ventricle, the guide element being configured to be positioned in the left ventricle between a plane of the mitral valve and a plane associated with papillary muscles of the heart, wherein inserting the implant into the left ventricle includes positioning the implant such that the implant uses the guide element as a track.

5. A method as recited in claim 4 further including:

removing the guide element from the left ventricle after attaching the implant to the tissue.

6. A method as recited in claim 4 wherein introducing the guide element into the left ventricle includes:

introducing a first catheter assembly into the aorta, the first catheter assembly including an angled catheter, and a gutter catheter, wherein the angled catheter substantially carries the gutter catheter, the angled catheter being arranged to facilitate positioning of the gutter catheter;

positioning the gutter catheter beneath the mitral valve between the plane of the mitral valve and the plane associated with the papillary muscles, wherein positioning the gutter catheter includes positioning the gutter catheter along a wall of the left ventricle; and

inserting the guide element into a lumen of the gutter catheter.

7. A method as recited in claim 6 wherein introducing the guide element into the left ventricle further includes:

anchoring the guide element against the wall.

8. A method as recited in claim 4 wherein attaching the implant to the tissue includes:

introducing a catheter into the left ventricle using the guide element as a track, wherein the catheter includes at least one pointed wire, the pointed wire including a tip section, the pointed wire further being configured to carry a coupling element, the tip section being configured for insertion into the implant and the tissue;

pushing the tip section through the implant and the tissue, wherein pushing the tip section through the implant and the tissue positions at least a part of the coupling element on an atrial side of the tissue; and

retracting the tip section from the implant and the tissue, wherein retracting the tip section causes the coupling element to substantially couple the implant with the tissue.

9. A method as recited in claim 8 wherein the coupling element is a T-bar.

10. A method as recited in claim 3 further including:

introducing a guide element into the left ventricle, the guide element being configured to be positioned in the left ventricle in a region of the left ventricle substantially bounded by leaflets of the mitral valve, the papillary muscles of the heart, a ventricular wall, and cordae tendonae, wherein inserting the implant into the left ventricle includes positioning the implant such that the implant uses the guide element as a track.

11. A method as recited in claim 1 further including:

adjusting an arc length of the implant.

12. A method as recited in claim 1 wherein the tissue is fibrous tissue.

13. A method for performing annuloplasty on a mitral valve of a heart, the method comprising:

inserting a first catheter assembly into a left ventricle through an aorta of the heart and an aortic valve of the heart;

positioning a guide element along a wall of the left ventricle beneath the mitral valve using the first catheter assembly;

positioning at least one implant in the left ventricle beneath the mitral valve using the guide element as a guide; and

connecting the at least one implant to tissue near the mitral valve.

14. A method as recited in claim 13 wherein the implant includes a shortening means, and the method further includes:

shortening the implant using the shortening means, wherein shortening the implant substantially reduces an arc length of the mitral valve.

15. A method as recited in claim 13 wherein the first catheter assembly includes a first catheter and a second catheter, the second catheter being located at least partially within the first catheter, the first catheter being arranged to facilitate the positioning of the second catheter along the wall of the left ventricle, and wherein positioning the guide element along the wall includes:

inserting the guide element through the second catheter; and

anchoring the guide element against the wall.

16. A method as recited in claim 15 further including:

removing the first catheter and the second catheter from the left ventricle; and

inserting a third catheter into the left ventricle, the third catheter configured to carry the implant and to use the guide element as a guide.

17. A method as recited in claim 13 wherein connecting the implant to the tissue near the mitral valve includes:

inserting a fourth catheter into the left ventricle, the fourth catheter being configured to carry a first connection element; and

inserting the first connection element through the implant and the tissue such that the implant and the tissue are coupled by the first connection element.

18. A method as recited in claim 17 wherein the fourth catheter is further configured to carry a second connection element, the method further including:

inserting the second connection element through the implant and the tissue such that the implant and the tissue are coupled by the second connection element.

19. A method as recited in claim 17 wherein positioning the implant in the left ventricle beneath the mitral valve using the guide element further includes:

inserting at least one balloon into the left ventricle; and

inflating the balloon, wherein inflating the balloon positions the implant generally against the mitral valve.

20. A method as recited in claim 17 wherein positioning the implant in the left ventricle beneath the mitral valve using the guide element further includes:

inserting at least one expandable element into the left ventricle; and

expanding the expandable element, wherein expanding the expandable element positions the implant generally against the mitral valve.

21. A method for accessing a left ventricle of a heart, the method comprising:

introducing an elongated body into an aorta of the heart;

passing at least a portion of the elongated body through an aortic valve positioned between the aorta and the left ventricle; and

positioning the portion of the elongated body in the left ventricle.

22. A method as recited in claim 21 wherein locating the portion of the elongated body in the left ventricle includes positioning the portion of the elongated body between a plane associated with a mitral valve of the heart and a plane associated with papillary muscles of the left ventricle.

23. A method as recited in claim 22 wherein the elongated body is an implant, and locating the portion of the elongated body in the left ventricle further includes positioning the implant substantially against tissue near the mitral valve.

24. A method as recited in claim 22 wherein the elongated body is a catheter.

25. A method as recited in claim 24 wherein the catheter is arranged to provide at least one plication in the tissue near the mitral valve.

26. A method as recited in claim 21 wherein locating the portion of the elongated body in the left ventricle includes positioning the portion of the elongated body between a plane associated with a mitral valve of the heart, a plane associated with papillary muscles of the left ventricle, cordae tendonae of the left ventricle, and a wall of the left ventricle.

27. A method as recited in claim 26 wherein the elongated body is an implant, and locating the portion of the elongated body in the left ventricle further includes positioning the implant substantially against tissue near the mitral valve.

28. A method as recited in claim 26 wherein the elongated body is a catheter.

29. A method as recited in claim 28 wherein the catheter is arranged to provide at least one plication in the tissue near the mitral valve.

30. A method as recited in claim 21 further including:

introducing an expandable element into the aorta, wherein the expandable element is substantially unexpanded;

positioning the expandable element in the left ventricle; and

expanding the expandable element, wherein expanding the expandable element causes the portion of the elongated body to contact a target region of the heart.

31. A method as recited in claim 30 wherein the target region of the heart is tissue near the a mitral valve of the heart.

32. A method for performing annuloplasty, the method comprising:

accessing a left ventricle of a heart to provide an implant to the left ventricle; and

coupling the implant to tissue near a mitral valve of the heart, wherein the implant is coupled to a ventricular side of the mitral valve.

33. A method as recited in claim 32 further including:

shaping the implant, wherein shaping the implant substantially reduces an arc length associated with the mitral valve.

34. A method as recited in claim 33 wherein shaping the implant includes substantially reducing an arc length of the implant by providing tension to the implant.

35. A method as recited in claim 32 wherein accessing the left ventricle includes inserting an elongated body into the left ventricle through an aorta and an aortic valve of the heart.

36. A method as recited in claim 35 wherein providing the elongated body into the left ventricle includes inserting the elongated body into the left ventricle between a plane associated with the mitral valve and a plane associated with papillary muscles of the heart.

37. A method as recited in claim 35 wherein providing the elongated body into the left ventricle includes inserting the elongated body into a region of the left ventricle substantially defined between a plane associated with the mitral valve, a plane associated with papillary muscles of the heart, a wall of the left ventricle, and cordae tendonae of the heart.

38. A device for use in an annuloplasty procedure, the device comprising:

a member, the member being arranged to be substantially shortened with respect to itself when tension is applied to the member;

a mesh, the mesh being arranged over the member; and

a tensioning element, the tensioning element being configured to apply tension to the member, wherein when the device is coupled to tissue surrounding a mitral valve of a heart, the tensioning element is configured to cause the device to reduce an arc length associated with the mitral valve.

39. A device according to claim 38 wherein the device is suitable for being positioned on a ventricular side of the mitral valve.

40. A device according to claim 39 wherein the tensioning element is continuously adjustable to alter the tension applied to the member.

41. A device according to claim 39 wherein the tensioning element is at least partially located within the member.

42. A device according to claim 39 further including:

a coupler, the coupler being arranged to extend through the member and the mesh, the coupler further being arranged to couple the device to the tissue.

43. A device according to claim 42 wherein the coupler is a T-bar.

44. A device for use in an annuloplasty procedure, the device comprising:

a collapsible member, wherein the collapsible member is movable between an extended position for insertion into a left ventricle through a catheter and a short position; and

a shortening device, the shortening device being operable to move the compressible member between the extended position and the short position, wherein the device is positioned to reduce an opening of a mitral valve when the device is in the short position.

45. A device according to claim 44 further including:

a mesh covering, the mesh covering extending over at least a portion of the compressible member.

46. A device according to claim 44 wherein the device is suitable for being coupled to tissue near the mitral valve.

47. A device according to claim 46 further including:

a coupler, the coupler being configured to extend through the structure and the mesh, the coupler further being arranged to couple the device to the tissue.

48. A system for performing annuloplasty on a mitral valve of a heart, the system comprising:

a catheter assembly configured for insertion through an aorta of the heart into a left ventricle of the heart to reach a region of the left ventricle substantially below the mitral valve;

a guide element shaped for insertion into the catheter assembly, the guide element having an anchorable feature; and

an implant, the implant being shaped for insertion over the guide element into the left ventricle substantially below the mitral valve, wherein the implant is configured to be connected to tissue of the heart.

49. A system according to claim 48 wherein the catheter assembly includes a delivery tube and a gutter catheter, the gutter catheter being positioned at least partially within the delivery tube, wherein a portion of the gutter catheter is configured to be positioned substantially within a region of the left ventricle defined between a plane associated with the papillary muscles of the left ventricle and a plane associated with the mitral valve.

50. A system according to claim 49 wherein the guide element is shaped for insertion into a lumen of the gutter catheter.

51. A system according to claim 48 wherein the catheter assembly includes a delivery tube and a gutter catheter, the gutter catheter being positioned at least partially within the delivery tube, wherein a portion of the gutter catheter is configured to be positioned substantially within a region of

the left ventricle defined between a plane associated with the papillary muscles of the left ventricle, a plane associated with the mitral valve, cordae tendonae of the left ventricle, and a wall of the left ventricle.

52. A system according to claim 48 further including:

a delivery catheter, the connection catheter configured to provide a connection element, wherein the connection element is configured to connect the implant to the tissue.

53. A system according to claim 52 wherein the tissue is located near the mitral valve.

55. A system according to claim 53 wherein the tissue is fibrous tissue.

56. A system according to claim 51 wherein the implant includes a shortening element, the shortening element being arranged to shorten an arc length associated with the implant, wherein shortening the arc length associated with the implant reduces an arc length associated with a posterior leaflet of the mitral valve.

57. A system according to claim 51 wherein the implant is configured to have a shortened state and an unshortened state, wherein when the implant is inserted over the guide element, the implant is in the unshortened state, and wherein when the arc length associated with the implant is shortened, the implant is in the shortened state.

58. A system according to claim 48 wherein the guide element is formed from one of a stainless steel material and a shape memory material.

59. A system according to claim 48 wherein the catheter assembly is at least partially formed from at least one of a nylon material and a urethane material.

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