A system for using a barbed tubular retainer in the treatment of mitral valve regurgitation by reshaping the mitral valve annulus using one or more plications of annular tissue each fixed by a retaining clip is described. The system includes four devices to achieve such percutaneous direct plication annuloplasty. The first is a crossing catheter. Second, a deflecting guide catheter is used to provide a means for guiding the plication device into proper position at the subvalvular region of the mitral valve annulus. Third, the plication device is then used to make plications in the subvalvular region of the mitral valve annulus. Fourth, a barbed tubular retainer deployed by the plication device in order to retain the plicated tissue in the plicated form. Alternatively, the fourth device is a retainer delivery catheter that enables delivery of a barbed tubular retainer that is attached to its distal end over the outside of the plication device.
**Fig. 1A**

1. **START Procedure**

2. **Femoral access**: Place 14F CSI

3. **Insert Crossing Catheter (CC) and Deflecting Guide (DG) stack up through CSI**

4. **Cross aortic valve (AV) with CC and advance into LV**

5. **Traverse aorta retrograde**

6. **Deflect DG moderately as advancing toward mitral valve**

7. **Advance DG over CC Cross AV and into LV**

8. **Seat deflecting region(s) of DG towards LV apex**

9. **Position tip of DG up posterior wall of LV under the mitral valve in subvalvular groove**

10. **Confirm plicator orientation and position using imaging**

11. **Slowly advance plicator jaws out of DG and into position under MV annulus**

12. **Determine orientation of plicator jaws using imaging**

13. **Insert loaded plicator into DG and advance to tip of DG**

14. **Confirm DG location and position using imaging**
FIG. 3

Aortic valve

Left coronary sinus

Noncoronary sinus

Aortic mitral curtain

Anterior commissure

Posterior commissure

Anterior leaflet

A1

A2

A3

P1

P2

P3

Posterior leaflet
PUSH-IN RETAINER SYSTEM FOR USE IN THE DIRECT PLICATION ANNULOPLASTY TREATMENT OF MITRAL VALVE REGURGITATION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 60/981,303 filed Oct. 19, 2007 which is hereby incorporated by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to a device and method for treating the vasculature and internal organs of a patient. Particularly, the present invention is directed to a system and method for treating mitral valve regurgitation in the heart of a patient using a plication device to plicate tissue and retain the plication using an internally or externally deliverable push-in retainer, preferably a barbed tubular retainer.

BACKGROUND OF THE INVENTION

[0003] Catheter based devices are used to treat a variety of medical problems in a minimally invasive manner. Catheters are used to place and expand angioplasty balloons used to widen veins and arteries narrowed by plaque. Small scaffolds called stents have been introduced into the vasculature using catheter-based systems in order to prevent the restenosis of such vessels. One of the problems that a catheter based device and system could be used to treat in a minimally invasive manner is mitral valve regurgitation, however, no commercially successful device for the treatment of mitral valve regurgitation in such a manner currently exists.

[0004] Mitral valve regurgitation is the backflow of blood from the left ventricle into the left atrium due to an improper alignment of the leaflets of the mitral valve thereby causing an imperfect closure of the valve. A gap between the anterior leaflet and posterior leaflet of the mitral valve is created by the improper closure providing a conduit for blood to flow through the mitral valve in a retrograde manner from the left ventricle to the left atrium. This gap may be a congenital defect or may be caused by disease, i.e., ischemic or idiopathic cardiomyopathy and/or intrinsic degenerative disease of components of the mitral valve apparatus. One type of condition, congestive heart failure (CHF), causes the heart to enlarge. In an enlarged heart the walls of the left ventricle are expanded or dilated which causes the papillary muscles to be displaced downward and/or outward resulting in a tethering of the chordae tendineae and subsequent tethers/pulling on the leaflets. Also, with CHF, the mitral annulus is dilated. The combination of the dilated annulus and the tethering on the leaflets prevents the leaflets from closing properly, thereby causing the problematic gap in the mitral valve. The resultant backflow through the mitral valve reduces the efficiency of the heart resulting in a need for the heart to beat faster and/or more forcefully in order to produce the same amount of blood flow. Mitral valve regurgitation may be asymptomatic in some patients but in other patients the reduction in blood flow and the resultant strain on the heart could result in arrhythmia, heart attack and possibly death.

[0005] The preferred current treatments for mitral valve regurgitation require open-heart surgery and/or the use of endoscopic techniques that are difficult for the surgeon and potentially dangerous for the patient. In one method of treatment, porcine heart valves or mechanical heart valves are used to replace the damaged or defective mitral valve. Such treatments require the use of open-heart surgery to accomplish the implantation. Such heterologous valves may be used in humans but often wear-out prematurely and additional open-heart surgery is required to replace such valves with additional heterologous or mechanical valves. Mechanical valves have been developed which may also be used as a replacement for a defective mitral valve, however, the implantation of a mechanical valve usually indicates long-term anticoagulant therapy to prevent clots from developing around the valve that could lead to a dangerous embolism. Long-term anticoagulant treatment causes other problems such as unwanted internal and external bleeding and possibly strokes.

[0006] Another open-heart surgical procedure for treating functional mitral valve regurgitation is annuloplasty. In an annuloplasty procedure, a generally "D" shaped annuloplasty ring is implanted on the mitral valve annulus to reduce the size of the stretched mitral valve annulus, most importantly, the septal-laterial dimension and improve closing (or coaptation) of the valve thereby reducing regurgitation. The surgeon surgically attaches, i.e., sews, the annuloplasty ring to the mitral valve on the atrial side of the mitral valve. The annuloplasty ring is sewn to the annulus on a top portion (i.e., the atrial side) of the mitral valve. Once implanted, tissue generally grows over the annuloplasty ring, and a line of contact between the annuloplasty ring and the mitral valve will essentially enable the mitral valve to appear and function as a normal mitral valve by reestablishing coaptation of the mitral valve leaflets but the durability of the effect is variable and may decline within six months after the procedure. Although a patient who receives the annuloplasty ring 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 the annuloplasty ring.

[0007] A second open-heart surgical procedure used in the treatment of degenerative mitral valve regurgitation is the Alfieri stitch procedure which the uses an edge-to-edge suture in the mitral valve. An edge-to-edge stitch is used to stitch together an area at approximately the center of a gap defined between the anterior and posterior leaflets of the mitral valve. Once the stitch is in place, the stitch is pulled in to form a suture that holds the anterior leaflet against the posterior leaflet. By reducing the size of the gap between the anterior leaflet and the posterior leaflet, the amount of leakage through the mitral valve may be substantially reduced. Durability has been a concern for Alfieri procedures done without the addition of an annuloplasty ring. In addition, use of the edge-to-edge procedure is only indicated in certain degenerative pathologies where the primary abnormality or gap between the leaflets is centrally located.

[0008] Another method of treating mitral valve regurgitation is the implantation of a ventricular assist device. Such devices are expensive and difficult to implant and require the patient to use anti-coagulant therapy indefinitely. Long-term use of anti-coagulant therapy may result in unnecessary bleeding and strokes. Such ventricular assist devices are, therefore, indicated for use only in patients that would likely not survive without their use and are used to keep patients alive who are candidates for heart transplant surgery. Left ventricular assist devices are a “bridge” therapy rather than a final therapy.

[0009] While such invasive surgical procedures have under certain circumstances been shown to be effective in the treat-
ment 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.

[0010] Some minimally invasive procedures have been developed to treat mitral valve regurgitation but, to date, none have become commercially successful standard procedures. U.S. Pat. No. 6,619,291 to Hvalaka et al. discloses a minimally invasive method of performing annuloplasty including 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 order to substantially reduce an arc length associated with the mitral valve.

[0011] In U.S. Pat. Nos. 6,718,985 and 7,037,334 to Hvalaka et al. a series of plications near the mitral valve are created by T-bars that are threaded together to reshape the mitral valve. In U.S. Pat. No. 7,166,127 a catheter based system for treatment of mitral valve regurgitation uses a retainers adapted to be secured to the annulus of the mitral valve with flexible tensile members coupled to the retainers. A crimping device deployable through the catheter compresses a crimp onto the flexible tensile members after they are pulled toward one another to reduce the circumferential length of the annulus. In this system the number of permanent implants required in order to achieve an initial effect, and commitment to these implants before success of effect is able to be determined are serious drawbacks.

[0012] In United States Patent Application No. 2007/0093857, Rogers et al. describes a device and method for the treatment of mitral valve regurgitation using a minimally invasive procedure in which plications are made proximate the mitral valve of the patient and aretainer is placed to hold the plication.


[0014] United States Patent Application No. 2007/0025737 to Messerly et al. discloses a surgical retainer having a generally helical shape and a device having jaws for gripping tissue into which the helical retainer may be driven.


[0016] The need remains for a device and method for treating mitral valve regurgitation that can be used efficiently and effectively in a minimally invasive procedure and that provides the physician with the ability to know that the procedure has resulted in the desired effect prior to removing the device from the patient thereby reducing the need for and expense of repeat procedures. Such a procedure should provide the physician with the ability to changes the effect on the mitral valve during the procedure before taking an irreversible action.

SUMMARY OF THE INVENTION

[0017] The present invention provides a system and method for the treatment of mitral valve regurgitation. The method preferably uses a femoral retrograde approach of crossing the aortic valve. Access to the left ventricle is achieved through the aortic valve using the standard retrograde femoral artery approach utilizing a rounded crossing catheter (CC) preferably with a "J" or pigtail configuration. A deflecting guide catheter is then sent over the crossing catheter into the left ventricle. When the distal end of the deflectable catheter is in the left ventricle the crossing catheter is removed. The deflectable guide is preferably, but need not be, positioned between the papillary muscles with the distal segment lying along the posterior wall of the left ventricle and its tip is pointing towards the underside of the posterior mitral valve annulus. A plication device is then introduced through the deflectable catheter and is advanced out of the distal end of the deflectable catheter and is directed at the underside of the mitral valve, more preferably into the subvalvular groove and positioned so as to be able to grasp and plicate the tissue of the mitral valve at or near the annulus.

[0018] A test plication of the mitral valve annulus is created and the appropriateness of the plication is examined using imaging means such as TEE, ICE, TTE or fluoroscopy with or without contrast injection. If the plication is determined to be appropriate then a retainer is applied to the plication to retain the tissue in the plicated state. If the plication is not satisfactory then a retainer is not applied and the jaws of the plication device are released and the plicator is repositioned to plicate a different tissue target at or near the annulus of the mitral valve. Such "test" plications may be repeated a number of times prior to deploying the retainer.

[0019] If a single plication and retainer do not sufficiently reshape the mitral valve to correct the regurgitation then the original deflectable guide is repositioned and a second plicator with a retainer is introduced into the delivery guide and positioned and used in the same manner. Alternatively, a multi-retainer plicator can be used to provide the second or third retainers as necessary during the procedure without requiring the removal and reintroduction of the plication device. Once satisfactory changes in the annular geometry of the mitral valve and concomitant reduction in mitral valve regurgitation is achieved then the plication device and the deflectable guide are fully withdrawn and the femoral access site is closed using conventional closing techniques.

[0020] Four components comprise the system for percutaneous direct plication annuloplasty. The first is a prolapsable or curved tip crossing catheter preferably having a "J" or pigtail configuration. This may be used with or without a guidewire. In either case the crossing catheter is inserted in a stack or telescoped configuration with the second component, a deflecting guide catheter within which the crossing catheter is initially telescoped or stacked. The deflecting guide catheter is used to provide a means for guiding the plication device into proper position on the underside of the mitral valve preferably at the subvalvular region of the mitral valve at or near the annulus. The third component of the system is a plication device that has an end effector having opposing members at least one of which can be manipulated to open. The plication device is used to grasp tissue and also contains at least one retainer to retain the tissue in the plicated form if desired. A barbed tubular "crown-shaped" implant is intended for use in tissue to act as a retaining member for the plications made in the tissue by the end effector of the plication device. In an alternative embodiment, the barbed tubular retainer is delivered percutaneously to the tissue of the heart by attachment to the end of a retainer delivery catheter that is placed over the plication device and has a release mechanism. Using the external delivery mechanism enables a larger barbed tubular retainer that will retain more tissue than retainers that are delivered internally through the jaws of the plication device.
The present invention is a system for the treatment of mitral valve regurgitation through direct plication annuloplasty of a patient that includes a deflecting guide catheter having an elongate body with lumen therethrough ending in a distal opening for insertion through the aortic valve into the left ventricle of the patient and a plication device having a set of opposing jaws operable to plicate tissue in the mitral valve of the patient, wherein the plication device comprises at least one barbed tubular retainer for retaining plications in tissue created by the opposing jaws. The system may also include a crossing catheter for insertion through the aortic valve into the left ventricle of the patient and a guidewire for use in guiding the crossing catheter and the deflecting guide catheter through the vasculature of the patient and into the left ventricle. The plication device further includes a pusher adapted to engage the proximal end of the barbed tubular retainer wherein the plication device further includes a firing knob connected to a firing control wire adapted to rotate upon rotation of the firing knob in a first direction causing the pusher to move longitudinally and push the barbed tubular retainer into the plicated tissue.

Another embodiment the system for the treatment of mitral valve regurgitation through direct plication annuloplasty of a patient includes a deflecting guide catheter having an elongate body with lumen therethrough ending in a distal opening for insertion through the aortic valve into the left ventricle of the patient, a plication device having a set of opposing jaws operable to plicate tissue in the mitral valve of the patient and a retainer delivery catheter having a proximal end and a distal end and having a barbed tubular retainer disposed on the distal end for retaining plications in tissue created by the set of opposing jaws of the plication device. This embodiment may also include a crossing catheter having a distal end for insertion through the aortic valve into the left ventricle of the patient. The retainer delivery catheter further includes an adaptor adapted to releasably engage a mated adapter at the proximal end of the helical retainer. The on the retainer delivery catheter disengages the adapter on the barbed tubular retainer when the retainer delivery catheter is rotated in a first direction.

The barbed tubular retainers of the present invention comprise a tubular base member having at least one barbed prong disposed on said tubular base member for engaging with the plicated tissue. The base member of the barbed tubular retainer may include a plurality of holes adapted to receive a suture. The barbed tubular retainer is releasably attached to the distal end of the retainer delivery catheter with a suture that runs from the proximal end of the retainer delivery catheter to the distal end of the retainer delivery catheter through the plurality of holes in the base member of the barbed tubular retainer. The barbed tubular retainer is released from the distal end of the retainer delivery catheter by removal of the suture from the patient. The barbed tubular retainer may be fabricated from one piece of material or the base member and the barbed prongs may be fabricated separately and joined together after the distal end of the base member is sharpened.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1A and 1B are a flow diagram describing the method of treating mitral valve regurgitation in accordance with the present invention.

FIGS. 2A-H depict the stages of the various steps of the method of treating mitral valve regurgitation in accordance with the present invention.

FIG. 3 depicts the plication regions in the method of treating mitral valve regurgitation in accordance with the present invention.

FIG. 4 is a perspective view of a crossing catheter for use in treating mitral valve regurgitation in accordance with the present invention.

FIG. 5 is a cutaway view of a portion of the body of the crossing catheter of FIG. 4.

FIG. 6 is an elevational view of a deflecting guide catheter for use in treating mitral valve regurgitation in accordance with the present invention.

FIGS. 7A and 7B are an exploded view and a perspective view respectively of the components of a handle for the deflecting guide catheter of FIG. 6.

FIG. 8 is an elevational view of the body portion of the deflecting guide catheter of FIG. 6.

FIGS. 9A and 9B are cross-sectional views of the body portion of the deflecting guide catheter of FIG. 8 taken through lines A and B respectively.

FIGS. 10A-10C are perspective views of the body portion of other embodiments of a deflecting guide catheter for use in treating mitral valve regurgitation.

FIG. 11 is an exploded perspective view of another embodiment of the handle and internal components used in a deflecting guide catheter in accordance with the present invention.

FIG. 12 is an elevational view of a plication device for use in treating mitral valve regurgitation in accordance with the present invention.

FIG. 13 is an elevational view of the plication device of FIG. 12 with a portion removed to expose the internal components.

FIG. 14A is an elevational view of the plication device of FIGS. 12 and 13 from the shuttle assembly to the distal end.

FIG. 14B is a cross sectional view of the portion of the plication device of FIG. 14A taken through line A-A.

FIG. 14C is an enlarged view of proximal end section D of the cross-sectional view of the portion of the plication device of FIG. 14B.

FIG. 14D is an enlarged view of distal section C of the cross-sectional view of the portion of the plication device of FIG. 14B.

FIG. 14E is an enlarged view of the distal tip section B of the cross-sectional view of the portion of the plication device of FIG. 14B.

FIG. 14F is an enlarged planar view of the distal tip of the plication device of FIG. 14A.

FIG. 14G is a detailed perspective view depicting the coupling of the end-effector control wire to the distal puller wires.

FIG. 14H is a detailed perspective view depicting the coupling of the end-effector control wire to the distal puller wires in an embodiment of the plication device having passive articulation.

FIG. 14I is a perspective view of the distal tip of the plication device of FIG. 14A in the open position with the barbed tubular retainer partially deployed.

FIG. 14J is a perspective view of the distal tip of the plication device of FIG. 14A in the closed position with the barbed tubular retainer partially deployed.
FIG. 15A is a perspective view of a barbed tubular retainer for use in a plication device for use in the treatment of mitral valve regurgitation in accordance with the present invention.

FIGS. 15B-D are planar views of the cut patterns used to create a barbed tubular retainer for use in a plication device in accordance with the present invention.

FIGS. 16A-16D are elevational views of the distal end of various embodiments of a plication device in accordance with the present invention.

FIG. 17 is an elevational view of a retainer delivery catheter for use in the method and system of the present invention.

FIG. 18 is an elevational view of the distal end of the retainer delivery catheter of FIG. 17.

FIG. 19 is an elevational view of the barbed tubular retainer with proximal adapter.

FIG. 20 is an elevational view of the barbed tubular retainer with proximal adapter and the retainer delivery catheter with mated adapter.

DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 is a flow diagram depicting a method of providing direct plication annuloplasty to the mitral valve in a heart such as that depicted in FIG. 2A in accordance with the present invention. At step 100 the procedure begins with a puncture for access to the femoral artery using standard techniques. At step 102 the physician or other practitioner places a catheter sheath introducer (CSI) into the femoral access point using standard techniques. Any known CSI may be used in the procedure with the preferable size being approximately 14 French. At step 104 a crossing catheter, preferably prolapsable or having a curved tip, and a deflecting guide catheter are inserted together in a "stack" formation through the CSI. Alternatively, the deflecting guide catheter is inserted through the CSI without a crossing catheter although the use of a crossing catheter is the preferred method. The crossing catheter is described herein in greater detail with respect to FIGS. 4 and 5 below and the deflecting guide catheter is described herein in greater detail with respect to FIGS. 6 to 11.

The stacked crossing catheter and deflecting guide catheter are advanced through the arterial system of the patient traversing the aorta of the patient in a retrograde manner at step 106. At step 108 the aortic valve (AV) is crossed with the crossing catheter and the crossing catheter is advanced into the left ventricle (LV) as depicted in FIG. 2B. At step 110 the deflecting guide catheter is advanced over the crossing catheter through the aortic valve and into the left ventricle as depicted in FIG. 2C. The deflecting guide catheter is deflected in a somewhat retroflexed manner as it is advanced approximately toward the mitral valve at step 112 as depicted in FIG. 2D and the crossing catheter is withdrawn at step 114.

FIGS. 15A-15D are planar views of the cut patterns used to create a barbed tubular retainer for use in a plication device in accordance with the present invention.

Whether or not a guidewire has been used, the procedure continues with step 116 where a region of the deflecting guide catheter is seated toward the mitral valve in the apex of the left ventricle as in FIG. 2E. At step 118, the tip of the deflecting guide catheter is advanced up the posterior wall of the left ventricle to a position under the mitral valve, preferably initially placed in the subvalvular groove in the P2 region of the as shown in FIG. 3. The term "annulus" is meant to include regions at or near the annulus. At step 120 the position of the tip of the deflecting guide catheter is confirmed by using an imaging method such as fluoroscopy. If fluoroscopy is used it may be used but it is preferable in most cases to use two views to confirm proper placement of the deflecting guide catheter in the P2 region of the mitral valve annulus. P2 is the likely target region for a first retainer although depending on the geometry of the mitral valve the first retainer may be placed in region P1 or region P3. Additional retainers may need to be placed in the same or other regions.

At step 122 a plication device 400 is loaded with one or more retainers is inserted into the deflecting guide catheter and advanced to the tip of the deflecting guide catheter. A plication device for use in this method is described in greater detail herein with respect to FIGS. 12 through 14H. At step 124 the rotational orientation of the jaws of the plication device is determined using an imaging method and the jaws are placed in the correct orientation. The preferable rotational orientation for the jaws of the plication device is such that both tips of the jaws once opened would represent a "chord" of the arc defined by the mitral valve annulus when pushed into contact with the annulus. Next, at step 126 the plication device is advanced out of the end of the deflecting guide catheter into position under the annulus of the mitral valve as depicted in FIG. 2E. The orientation and position of the plication device is confirmed at step 128 using an imaging method. Again, if fluoroscopy is used as the imaging method, at least one and preferably two views are be used to confirm orientation and placement of the jaws of the plication device. An injection of a known contrast agent either using a separate contrast catheter or through the deflecting guide catheter may be used to help define the line of the annulus as viewed under fluoroscopy. At step 130 a decision is made by the physician whether or not the jaws of the plication device are properly positioned. If the plication device is not properly positioned then at step 134 an attempt is made to reposition the jaws of the plication device. At step 136 the position of the plication device is evaluated again using an imaging method as described previously and in more detail below. If the plication device is positioned correctly then step 132 and onward are performed as discussed below. If the plication device is not positioned properly after at least one attempt at repositioning the plication device is performed to achieve a desired position and the plication device is withdrawn from the patient at step 150.

If the jaws are properly positioned, a diagnostic clamp or plication is performed at step 132. As part of the diagnostic clamping (or plication), the jaws of the plication device are opened as depicted in FIG. 2F; the plication device is advanced onto the tissue of the annulus of the mitral valve and the jaws are closed as depicted in FIG. 2G. The diagnostic plication is evaluated at steps 140, 142 and 144. If diagnostic plication results in an acceptable change in the mitral valve annulus and/or an acceptable reduction in mitral valve...
regurgitation then a retainer is applied using the plication device at step 140 and the plication device is released as depicted in FIG. 2H. Embodiments of a retainer that may be applied to the tissue are described in greater detail herein with respect to FIG. 15. At step 142, if the diagnostic plication results in an unacceptable change to the mitral valve then the procedure is abandoned and both the plication device and the deflectable guide catheter are withdrawn from the patient at step 150. At step 144, if the diagnostic plication results in an insufficient or inadequate reduction in mitral valve regurgitation (MR) and/or insufficient or inadequate change in the mitral valve then the diagnostic plication is released and an attempt to reposition the jaws of the plication device is performed at step 134.

[0059] If the change to the mitral valve is acceptable and a retainer has been applied, then at step 145 a determination regarding the impact of the plication on the regurgitation of the mitral valve is made using a method of imaging the flow of blood through the valve such as Doppler echocardiography. At steps 146, 147 and 148 various decisions are made regarding the procedure and continuation of the procedure. At step 146, if the determination is made that there has been an acceptable total reduction in mitral valve regurgitation and/or acceptable change in the mitral valve then the procedure branches to step 150 with the retrieval of the plication device and the deflecting guide catheter. If the total change to mitral valve regurgitation is inadequate or insufficient and/or change to the mitral valve is inadequate or insufficient (step 147) then the plication device currently in use is withdrawn if it is a single retainer device and an additional plication device is inserted and the procedure continues from step 122. If the plication device is a multi-retainer device then the procedure continues from step 124 without withdrawal of the plication device. If the determination regarding the impact of the plication on mitral valve regurgitation results in a finding of an adverse result at step 148 then the procedure will likely be abandoned and both the plication device and deflecting guide catheter are removed from the patient at step 150. After removal of the plication device and the deflecting guide catheter, the catheter sheath introducer is removed and the access site is closed at step 152 using known methods.

[0060] In an alternative embodiment the retainer is releasably attached to a retainer delivery catheter 600 as depicted in FIGS. 17 and 18. The retainer delivery catheter can be inserted together with the plication device at step 122. The primary difference with the use of the retainer delivery catheter is the advancement of the retainer delivery catheter at step 140 if it is determined that the plication has resulted in an acceptable change in the mitral valve. At step 140, the Tuohy valve of the retainer delivery catheter 600 would be opened and the retainer delivery catheter would be advanced over the jaws at the distal end of the plication device into contact with the tissue. The retainer delivery catheter 600 would be advanced forward with a application of sufficient distal pressure in order to drive the barbed tubular retainer into and around the plicated tissue until the proximal edge of the barbed tubular fastener clears the distal tip of the jaws of the plication device as seen in an imaging modality such as fluoroscopy. This indicates to the physician that the barbed tubular fastener has been fully implemented. Removal of the retainer delivery catheter 600 is accomplished by rotating the shaft clockwise until disengagement of the distal end from the barbed tubular retainer is observed in the fluoror or other image. Alternatively, if sutures are used to keep the barbed tubular retainer attached to the retainer delivery catheter as shown in FIG. 19, then the end of the suture is pulled by the user thereby releasing the barbed tubular retainer. The retainer delivery catheter is moved slightly proximally to allow the jaws of the plication device to be opened and then both the plication device and the retainer delivery catheter may then be removed from the patient. In a system in which a retainer delivery catheter is used the deflecting guide catheter would need to be sized to accommodate both the plication device and the retainer delivery catheter.

[0061] In the above method various imaging modalities may be used to determine proper placement of the plication device under the mitral valve annulus. Fluoroscopy is one real-time imaging modality that is useful, preferably, where images are taken in at least two planes. Radiopaque markers placed on the distal end of the plication device will aid in determining proper placement. A three-dimensional profile of the plication device can be created using x-ray images acquired in at least two planar projections in real-time. Alternatively, rotational angiographic imaging may be used. Additionally, registering pre-acquired CT or MRI image data with the fluoroscopic image will provide additional anatomic data to the physician to aid proper placement of the plication device and retainer or retainer. Similarly, a three-dimensional real-time ultrasound image acquired in real-time may be registered with the fluoroscopic image.

[0062] Another imaging modality useful for this purpose is intracardiac echocardiography (ICE) used to produce an ICE image. The ICE image may be produced by an ICE catheter placed inside one of the chambers of the heart such as the right ventricle, left ventricle, left atrium or the right atrium. Alternatively, the ICE catheter could be placed inside on of the great vessels of the heart of the patient. The ICE catheter may also be placed on the epicardial or pericardial sack surfaces of the heart via a minimally invasive approach such as a subxiphoid approach. No matter the modality used, the images of the mitral valve should be taken synchronized to the cardiac cycle.

[0063] Various imaging modalities are also useful in determining whether the plication achieves the desired impact on the function of the mitral valve in real-time or near real-time prior to applying the retainer to the plication. Real-time means that the latency period is acceptable to perform the procedure and is preferably no more than 500 milliseconds. Color Doppler ultrasound imaging may be used for such a purpose with or without an ultrasound contrast agent being administered to the patient. Alternatively, x-ray fluoroscopy could be used in determining the impact of a plication on mitral valve regurgitation by using an x-ray contrast bolus injection into one of the chambers of the heart, preferably the left ventricle. Bi-planar angiographic imaging or intra-chamber optical imaging may also be used. If infra-chamber optical imaging is used it is preferable that the deflecting guide catheter further comprise an optical imaging system particularly one that operates in infrared wavelengths.

[0064] Determining a location for the first tissue plication may be based on an optimization plan generated using a three-dimensional functional numerical simulation based on imaging data generated by one or more of the aforementioned imaging method. For example, by analyzing the distribution of annular tissue relative to the location of the primary regurgitant flow through the valve, a primary target for initial plication therapy may be determined. It may be desirable to place the plication at the location of greatest distortion of the
annulus due to the pathology of the patient’s heart. The generation of the optimization plan may be performed prior to step of inserting the crossing catheter. The generation of the optimization plan may be performed after the step of applying a retainer to the first tissue plication in order to determine the preferred location for subsequent plication or plications.

Alternatively, the plications could be made on the atrial surface if a transseptal approach is used. This can be accomplished by accessing the right atrium using SVC or IVC venous approaches. Then access the left atrium is accomplished using a standard transseptal puncture/access kit such as a Brockenbrough transseptal needle kit. The deflecting guide catheter would then be introduced through the puncture and deflected such that the tip pointed towards the annulus of the mitral valve. The subsequent step of plication annuloplasty procedure would then be the substantially the same as set forth above except that the approach is from the atrial side of the mitral valve rather than the undersurface.

The above method is implemented using a multi-component system comprising a crossing catheter 200, a deflecting guide catheter 300, and a plication device 400 containing at least one plication retainer 500. FIG. 4 is a perspective view of a crossing catheter 200 for use in the procedure described in the present application. Crossing catheter 200 is comprised of a body portion 210 having a proximal end 210a and a distal end 210b. Connected to proximal end 210a are a female luer lock 216 and a Tuohy-Borst hemostasis valve 214. At the distal end 210b portion is an external tube which preferably is a pigtail 218 or has a “J” configuration (not shown). Pigtail 218 is approximately 2.0 centimeters or less in diameter. In FIG. 4, pigtail 218 is attached to body portion 210 at a splice location that is approximately 4 centimeters from the distal end of the device. Pigtail 218 is attached to body portion 210 using heat bonding as the body portion 210 and pigtail 218 are made from the same or similar material. Pigtail 218 is comprised of a polymer, preferably, Pebax® polymer block amide having a durometer of approximately 55D if comprised of one layer or two layers having durometers of approximately 40D in the outer layer and 55D in the inner layer. Body portion 210 may be comprised of one layer having a durometer between 55D and 72D or may have two layers. If two layers are used the preferred durometers are 70D for the outside and 63D for the inside. The total length of the body portion and pigtail together is approximately 149 centimeters and should extend beyond the deflecting guide catheter when fully inserted into the deflecting guide catheter. The length of the crossing catheter may vary depending on the length of the deflecting guide catheter used. The location at which the pigtail may be attached to the body portion may also vary from 3 centimeters to approximately 44.5 centimeters from the distal tip of the crossing catheter 200. The crossing catheter may also be comprised of one material from the body portion through the pigtail. In such case the use of an outer material with a durometer of 55D and an inner material with a durometer of 40D is preferred. A flat wire braid 212 of flat wires of approximately 0.001" by 0.003" may be embedded in the polymer comprising the proximal portion of body portion 210 in order to provide extra stiffness and torqueability. An inner layer 211 of PTFE provides a lubricious inner coating and a separation between the polymer and the inner lumen. The stiffness of the pigtail portion of the crossing catheter is chosen so that a standard guidewire such as the Cordis Emerald 0.035" guidewire will open the pigtail yet will return to the pigtail shape when retracted. Such a guidewire is placed in the guidewire lumen defined by the inner layer 211 of the crossing catheter and should extend through the entire length of the crossing catheter.

Crossing catheter 200 may be used with or without a guidewire as described above and is preferably used in conjunction with the deflecting guide catheter depicted in FIGS. 6 through 10A-C. Deflecting guide catheter 300 is comprised of a handle 310 and a body portion 350. FIG. 7A is an exploded view of an embodiment of the handle 310 depicting the internal components of the handle and FIG. 7B is a perspective view of the internal components of handle 310 as assembled. Handle 310 is comprised of upper handle shell 312 and lower handle shell 314 which are made of a durable moldable polymeric material such as polycarbonate or other similar material and are designed to mate with one another in a snap fit arrangement. At the proximal end of handle 310 is a hemostasis valve 316 which is adapted to fit onto the proximal handle tip 318. Hemostasis valve 316 may be of any known design for such a valve such as a tuohy-borst type valve. Proximal actuator assembly 324 is comprised of a thumb actuator 324a that is adapted to be inserted through slot 313 in the upper handle shell 312. Optionally, a two-piece construction with a thumb cap 325 may be used to facilitate assembly if slot 313 is narrow. The thumb actuator 324a and optional thumb cap 325 are used to cause forward motion in the proximal direction of puller wire 327a. Such motion is retained as the prong or prongs 324e biased by spring 324d around pivot point aixel pin 324c engages the teeth 322a in proximal rack 322. Such proximal motion of the proximal actuator assembly 324 and the associated puller wire 327a causes the deflection of the distal end of the deflecting guide catheter 300. If the user desires to have distal motion of the proximal actuator assembly 324 then the user pushes release trigger 324b which counters the bias of spring 324a thereby releasing prong or prongs 324e from engagement with the teeth 322a of the proximal rack 322. Proximal hypotube 331a provides a passage way for puller wire 327a and prevents kinking of the wire. Distal hypotube 331b is designed to telescope inside hypotube 331a. At the end of puller wire 327a are fixedly attached crimp tube 344a and a floating crimp tube stop 334b that prevents the crimp tube from being embedded in the proximal end of the actuator assembly. The user may then move the actuator assembly distally thereby changing the deflection of the distal end of the deflecting guide catheter. Movement of the actuator assembly may be made by the physician using something other than his or her thumb and the terms “thumb actuator” and “thumb cap” are not meant to be limiting.

Handle 310 further comprises a distal actuator assembly 328 having a similar thumb actuator 328a, release trigger 324b, axel pin 324c, spring 328a and prong 328e. Optional thumb cap 329 is affixed over thumb actuator 328a. The distal actuator assembly 328 is connected to a second puller wire 327b (shown in FIG. 11) that enables the user to cause deflection of the distal end of the deflecting guide catheter. In a preferred embodiment the first and second puller wires are attached (through known methods and means such as welding, brazing or adhesives) to anchor bands 385a and 385b that are embedded in the distal region 360 of the body portion 350 of the deflecting guide. The puller wires and their respective anchor band connection points may also be arranged so that they are not next to one another (in an axial
manner) but so that each provides motion of the distal end in another plane or in the other direction within the same plane. Also, the second puller wire and actuator are not necessary if it is only necessary to provide one type of movement in the deflecting guide catheter. Correspondingly, if greater than two types of deflection are required, additional thumb actuators assemblies coupled to puller wires and anchor bands may be added in a similar manner to the catheter. The second distal actuator assembly has the same components as functions in the same manner as the proximal actuator assembly. The primary difference is that the distal actuator assembly 328 requires a passageway for passage of the first puller wire 327a through the distal assembly which passage is aided by hypotube 331b.

[0069] The second puller wire 327b ends at the distal end with a similar crimp tube 335a and crimp stop tube 335b. Nose cone 330 provides a transition between the handle shell 312/314 and the proximal region 390 of the body portion 350. Actuator assemblies 324 and 328 and racks 322 and 326 are comprised of a polymeric material such as polycarbonate. Such assemblies could be made of machined or molded metal, such as aluminum, although that would result in a lower cost and weight device. Racks 322 and 326 with teeth 322a and 326a may be separate components or may preferably be molded into the lower handle shell 314 as depicted in the alternative embodiment shown in FIG. 11. Handle insert 338 is used as a divider between the two racks 322 and 326 and provides a support for proximal hypotube 331a. Puller wires 327a and 327b are preferably high tensile strength 304 stainless steel (e.g. tensile strength greater than 300 ksi) but may also be made of other high strength materials such as MP35N, other stainless steel, or woven fibers such as Kevlar or Vectran.

[0070] Puller wires 327a and 327b are preferably a single, solid core high tensile strength 304 stainless steel wire (e.g. tensile strength greater than 300 ksi) of approximately 0.008" in diameter but may also be made of other high strength materials such as MP35N, other stainless steel, or woven fibers such as Kevlar or Vectran. At the distal end of each puller wire is an anchor band 385a or 385b that is embedded in the wall of the catheter body at the point of anchoring. Changing the location of the anchor band along the axial length of the catheter body will change the deflection profile of the deflectable guide catheter.

[0071] Body portion 350 of deflecting guide catheter 300 is depicted in FIG. 8 and FIGS. 9A and 9B. Body portion is separated into four regions: distal region 360, intermediate distal region 370, main intermediate region 380 and proximal region 390. Distal region 360 at the distal end is approximately 3.5 centimeters in length and is made of a polymeric material such as Pebax with a durometer of between 25D and 40D and preferably 35D. A radiopaque material such as bisphosphate carbonate is added to the material in distal region 360 to enable the distal region 360 of the deflecting guide catheter 300 appear in fluoroscopy and other imaging procedures. The wall thickness in the distal region 360 is between approximately 0.012 and 0.014 inches. The anchor band 385a for the first puller wire is embedded near the distal end of distal region 360 and the anchor band 385b for the second puller wire is embedded near the proximal end of distal region 360 or at the distal end of region 370. The anchor bands are preferably placed between the lubricious liner 365 and the braid 385 although it could be placed above the braid in an alternative embodiment. Each anchor band is made of 304 stainless steel and each puller wire is attached to its respective anchor band using welding or other means for joining metal that is known in the art. The internal diameter of distal region 360 as well as the entire body portion is defined by a lubricious liner 365 preferably PTFE that has an interior diameter of approximately 0.127 inches and is approximately 0.002 inches thick. The outer diameter of distal region 360 is approximately 0.172 inches between the anchor bands and approximately 0.176 inches at the location of the distal band. A braid 375 of wires having a diameter between 0.0025 and 0.003 inches in a 1 over 1, 1 over 2 under 2 or 2 over 2 pattern is embedded in the polymeric wall of the catheter from the proximal region 390 to the distal region 360. At the distal end of the distal region 360 of deflecting guide 300 is an extruded atrumatic tip 362 comprised of 33.5% 25D Pebax, 6.4% 55D Pebax and 60% bisnuth subcarbonate and having a slight taper toward its distal end. The atrumatic tip is optional although preferred in order to avoid tissue damage during insertion in the vessels of the patient.

[0072] Intermediate distal region 370 is comprised of the same type of polymeric material but has a higher durometer of between 35D and 55D to provide a stiffer region. Intermediate distal region 370 is between approximately 2.8 and 4.0 centimeters in length and contains the same lubricious liner 365 and wire braid 375 as the distal region. The wall thickness in the intermediate distal region is similarly between 0.012 and 0.014 inches and the outer diameter is approximately 0.172 inches. Main intermediate region 380 has a slightly smaller outer diameter at 0.166 inches but has the same lubricious liner and braid as the other regions. The main difference in this region is the higher durometer of between 55D and 63D for the polymeric material used in order to provide increasing stiffness. The main intermediate region is approximately 20 to 28 centimeters in length, preferably 20 centimeters. Proximal region 390 has a similar composition in that the outer diameter is the same as the immediately prior region. The durometer in this region is increased to approximately 72D providing even greater stiffness and the length of this region is approximately 73 to 88 centimeters, preferably 88 centimeters. The lubricious layer 365 and braid 375 are the same.

[0073] From the proximal region 390 through the body portion 350 until the position of first and second anchor bands 385a/385b run two wire or braid reinforced tubes 395a/395b of approximately 0.0088 inches in internal diameter which house the first and second puller wires respectively. Various modifications can be made to the deflecting guide catheter if different characteristics are desired. One puller wire, anchor band and reinforced tube could be used instead of two. The braid may be changed to a different size wire and braid type. The polymeric material of the outer body may be varied as depicted in FIGS. 10A-10C. In FIG. 10A materials having two different durometers are used in an alternating fashion. Material A is used in two circumferential portions opposite one another while material B is used in two other opposing circumferential portions. The durometer of material A may be greater than the durometer of material B or vice versa depending on the deflection characteristics desired. Use of two different durometer materials in such a way provides the benefit of balancing the ability or ease of the catheters to deflect in a particular direction with the requirement for lateral stiffness. In FIG. 10B two circumferential portions of material A and material B are used to provide a certain desired deflection characteristic. In FIG. 10C the use of two different durometer
The deflection guide catheter may further comprise a magnetic based location sensor such as those manufactured by Biosense Webster for sensing the location and orientation (six degrees of freedom) of the distal end of the deflecting guide catheter and for providing location information that may be registered with other preacquired or real-time images or otherwise used to depict the location of the distal end of the deflecting guide catheter on a real-time display map of the heart. Systems such as the Carto® system produced by Biosense Webster would be useful for this purpose.

At the proximal end of the elongate shaft 452 is the coil connector 512 which is made of a metal, preferably brass, and is used as a means for connecting the proximal portion 452a of the elongate shaft 452 to the handle assembly. Dual lumen inner sheath 560 has lumens for end-effector control wire 510 and firing control wire 490. Filler tube connector 562 is used to connect the coil connector 512 to the elongate shaft 452 and is glued to coil connector 512 and elongate shaft 452 using an adhesive glue such as cyanoacrylate. Elongate shaft 452 is broken into proximal shaft section 452a and distal shaft section 452b. Proximal shaft section 452a is preferably nitinol and has a dovetail laser pattern. Distal shaft section 452b is preferably stainless steel and has a similar dovetail pattern cut through the wall of the shaft. Other patterns could also be used such as a helical cut as shown in FIG. 16A. FIG. 16B depicts another variation of the plication device where the proximal shaft section is similar to that above but the nut is placed significantly more distally and the stainless steel distal shaft section with a dovetail pattern is replaced with a helical cut creating a ribbon coil. FIG. 16C depicts the placement of the nut and the dovetail patterns of the proximal and distal shaft portions discussed with respect to FIGS. 14A-F above. FIG. 16D depicts the passively articulating jaws of the alternative embodiment discussed above.

The firing control wire 490 extends through the elongate shaft 452 and through a bore formed in the wire connector 542 and is threadably mated to a threaded bore in nut 550. The distal end of the firing control wire 490 extends into a retainer pusher 554 set in a retainer pusher sleeve 556, both of which are shown in FIG. 14E and which is described in more detail in US. Patent Publication No. 2005/0277954. In general, rotation of the firing knob 430 is effective to rotate the firing control wire 490. Since the firing control wire 490 is threadably mated to the nut 550, which is fixed between the
proximal and distal portions of the elongate shaft 452, the threaded bore in nut 550 will cause the firing control wire 490 to move distally through the elongate shaft 452, thereby advancing the retainer pusher 554 in a distal direction. The retainer pusher 554 is positioned proximal to the barbed helical retainer 500 stored within a garage 532 in the distal portion of the elongate shaft 452, and thus distal movement of the pusher 554 will advance the retainers 550 through the shift 452 to position the barbed tubular retainer 500 within the jaws 524a and 524b of the end effector 520. A person skilled in the art will appreciate that a variety of other techniques can be used to advance a plurality of retainers through the elongate shaft and to position a retainer within the jaws.

0079] FIGS. 14I and 14J are perspective views of the distal portion of the plication device having an internal barbed tubular retainer. FIG. 14I depicts the plication device with the jaws 524a and 524b in the open position after barbed tubular retainer 500 has been advanced into the tissue of the patient (the tissue is not shown). FIG. 14J depicts the plication device with the jaws 524a and 524b in the closed position with the barbed tubular retainer in a deployed position.

0080] FIG. 15A is a perspective view of a barbed tubular retainer 500 in accordance with the present invention. A preferred barbed tubular retainer 500 is comprised of a tubular base member 502 from which a plurality of barbed prongs 504 project. The number of barbed prongs 504 and the number of barbs on each can be modified as desired depending on the application and manufacturing constraints. A barbed prong 504 should have a minimum of one barb on its distal tip and a barbed tubular retainer should have at least one barbed prong 504 and preferably at least two. The length of a barbed tubular retainer 500 should be approximately 0.200 inches in length. The barbed tubular retainer should be comprised of stainless steel or other biocompatible material such as MP3N, platinum, nickel and cobalt chromium or alloys thereof but may also be made of a polymer material such as one made of poly lactic acid (PLA) or poly glycolic acid (PGA).

0081] FIG. 15B depicts a plan view of the material cut to form a barbed tubular retainer 500. The barbed prongs 504 and suture holes 506 may be cut by known means into a sheet of biocompatible material and then the material may be joined to form a tube. Alternatively the patterns depicted in FIG. 15B may be formed by known means such as laser cutting directly into a tubular form of the proper dimension. The distal side of tubular base member 502 as well as the edges of barbed prongs 504 should be sharpened in order to improve tissue penetration. A plurality of suture holes 506 may be formed in the tubular base member 502 in order to provide a means for attaching the barbed tubular retainer 500 to the distal end of a retainer delivery catheter 600 described in greater detail with respect to FIGS. 17 and 18.

0082] The radius of the barbed tubular retainer may vary depending on the amount of tissue it is desired to retain and whether it is used in the internal or external delivery mode. For the mitral valve application the diameter of the barbed tubular retainer should be between 0.030 inches and 0.100 inches and more preferably approximately 0.060 inches. The barbed tubular retainer may also contain or be covered with one or more radiopaque markers such as tantalum micro-coils to facilitate position and or viewing of the helical retainer fluoroscopically during procedures. Alternatively, the retainer may be made of a material that includes a radiopaque material such as gold, platinum, or tantalum as part of the alloy or composite.

0083] Preferably, the barbed tubular retainer is delivered at the distal end of a plication device described in this application. The barbed tubular retainer would be translated along the axis of the plication device after the jaws of the plication device have created a plication of the tissue at the mitral valve annulus.

0084] The barbed tubular retainer could be coated with one or more pharmacologically active agents such as heparin for the purpose of reducing thrombotic potential.

0085] FIGS. 15C and 15D depict other cut patterns for making a barbed tubular retainer 500 in accordance with the present invention. FIG. 15C depicts cut patterns for one-piece barbed tubular retainers and FIG. 15D depicts cut patterns for multi-piece barbed tubular retainers where the barbed prongs 504 are made separately form the base member 502 to permit the distal end of the base member to be more easily sharpened. Barbed prongs 504 are then attached to the base member using known means such as welding, brazing or the use of adhesives.

0086] FIG. 17 depicts the retainer delivery catheter 600 in conjunction with the plication device 400 and the barbed tubular retainer 500. Retainer delivery catheter 600 comprises a Tuohy-Borst type valve that is used to releasably affix the retainer delivery catheter to the elongate shaft 452. During use, the valve 610 is opened thereby permitting longitudinal translation of the retainer delivery catheter with respect to the plication device. The retainer delivery catheter further comprises a shaft 620 which is made of a braided polymer material but may also be made of nitinol, stainless steel or other biocompatible metal and which has a trapezoidal pattern cut into the wall of shaft 620 thereby provided flexibility and torqueability. In one embodiment shown in FIG. 18, at the distal end of retainer delivery catheter 620 the barbed tubular retainer 500 is releasably attached using a suture 602 designed to releasably engage the proximal end of the barbed tubular retainer 500. Suture 602 runs from the Tuohy-Borst valve 610 through the length of the retainer delivery catheter to the distal end through holes in the distal end of the retainer delivery catheter and through suture holes 506 in the barbed tubular retainer 500. Once the barbed tubular retainer 600 is pushed into the plicated tissue, the suture 602 may be pulled from one of its proximal ends to release the barbed tubular retainer 500 from the distal end of the retainer delivery catheter. The retainer delivery catheter is preferably 11 fronth but other sizes may be used depending on the size of the plication device 400 and the deflecting guide catheter 300 used.

0087] Alternatively an adapter 508 as depicted in FIG. 19 could be used to temporarily attach the barbed tubular retainer 500 to the distal end of the retainer delivery catheter 600. An adapter 508 is attached to or cut into the proximal end, i.e., the tubular base member 502 of the barbed tubular retainer which is adapted to be movably fastened to the distal end of the retainer delivery catheter 600. The adapter may be laser welded to the retainer or formed into the retainer. Another mating adapter 625 is fastened to the retainer delivery catheter as shown in FIG. 20 such that the two adapters may be releasably attached. Using a geometric cut in the adapters the barbed tubular retainer may be releasably attached to the retainer delivery catheter but still provide the ability to transmit rotational torque and/or axially directed forces. Alternatively the barbed tubular retainer may have a frangible tem-
porary tack weld in a place intended to be broken after implantation of the retainer into the intended tissue.

[0088] The devices disclosed herein can also be designed to be disposed of after a single use, or they can be designed to be used multiple times. In either case, however, the device can be reconditioned for reuse after at least one use. Reconditioning can include any combination of the steps of disassembly of the device, followed by cleaning or replacement of particular pieces, and subsequent reassembly. In particular, the device can be disassembled, and any number of the particular pieces or parts of the device can be selectively replaced or removed in any combination. Upon cleaning and/or replacement of particular parts, the device can be reassembled for subsequent use either at a reconditioning facility, or by a surgical team immediately prior to a surgical procedure. Those skilled in the art will appreciate that reconditioning of a device can utilize a variety of techniques for disassembly, cleaning and/or replacement, and reassembly. Use of such techniques, and the resulting reconditioned device, are all within the scope of the present application.

[0089] The preceding description has been presented with reference to presently preferred embodiments of the invention. Workers skilled in the art and technology to which this invention pertains will appreciate that alterations and changes in the described structure may be practiced without meaningfully departing from the principal, spirit and scope of this invention.

[0090] Accordingly, the foregoing description should not be read as pertaining only to the precise structures described and illustrated in the accompanying drawings, but rather should be read consistent with and as support to the following claims which are to have their fullest and fair scope.

What is claimed is:

1. A system for the treatment of mitral valve regurgitation through direct plication annuloplasty of a patient comprising: a deflecting guide catheter having an elongate body with lumen there through ending in a distal opening for insertion through the aortic valve into the left ventricle of the patient; a plication device having a set of opposing jaws operable to plicate tissue in the mitral valve of the patient; wherein the plication device comprises at least one barbed tubular retainer for retaining plications in tissue created by the opposing jaws.

2. The system of claim 1 further comprising a crossing catheter for insertion through the aortic valve into the left ventricle of the patient;

3. The system of claim 2 further comprising a guidewire for use in guiding the crossing catheter and the deflecting guide catheter through the vasculature of the patient and into the left ventricle.

4. The system of claim 1 wherein a proximal section of the elongate tubular body of the plication device is comprised of nitinol and a distal section of the elongate tubular body is comprised of stainless steel.

5. The system of claim 1 wherein the plication device further includes a pusher adapted to engage the proximal end of the barbed tubular retainer.

6. The system of claim 7 wherein the plication device further includes a firing knob connected to a firing control wire adapted to rotate upon rotation of the firing knob in a first direction causing the pusher to move longitudinally and push the barbed tubular retainer into the plicated tissue.

7. The system of claim 1 wherein the barbed tubular retainer comprises a tubular base member having at least one barbed prong disposed on said tubular base member for engaging with the plicated tissue.

8. The system of claim 7 wherein the barbed tubular comprises four barbed prongs disposed on said tubular base member.

9. The system of claim 1 wherein the barbed tubular retainer has at least one radiopaque marker disposed thereon.

10. The system of claim 9 wherein the radiopaque marker disposed on the barbed tubular retainer is a tantalum micro coil.

11. The system of claim 1 wherein the barbed tubular retainer is comprised of stainless steel, MP35N, nitinol, cobalt chromium or alloys thereof.

12. The system of claim 1 wherein the barbed tubular retainer is comprised of a polymeric material.

13. The system of claim 12 wherein the polymeric material is poly lactic acid (PLA) and/or poly glycolic acid (PGA).

14. A system for the treatment of mitral valve regurgitation through direct plication annuloplasty of a patient comprising: a deflecting guide catheter having an elongate body with lumen therethrough ending in a distal opening for insertion through the aortic valve into the left ventricle of the patient; a plication device having a set of opposing jaws operable to plicate tissue in the mitral valve of the patient; and, a retainer delivery catheter having a proximal end and a distal end and having a barbed tubular retainer disposed on the distal end for retaining plications in tissue created by the set of opposing jaws of the plication device.

15. The system of claim 14 further comprising a crossing catheter having a distal end for insertion through the aortic valve into the left ventricle of the patient.

16. The system of claim 14 wherein the retainer delivery catheter has an elongate tubular body comprised of a composite of a polymeric material and a braided wire mesh.

17. The system of claim 15 wherein the retainer delivery catheter has an elongate tubular body comprised of metal with a pattern cut through the metal along at least a portion of the elongate tubular body.

18. The system of claim 17 wherein the pattern is a trapezoidal pattern.

19. The system of claim 17 wherein the elongate tubular body of the retainer delivery catheter is comprised of nitinol or stainless steel.

20. The system of claim 14 wherein the retainer delivery catheter further includes an adaptor adapted to releasably engage a mating adapter at the proximal end of the helical retainer.

21. The system of claim 20 wherein the adaptor on the retainer delivery catheter disengages the adapter on the barbed tubular retainer when the retainer delivery catheter is rotated in a first direction.

22. The system of claim 14 wherein the barbed tubular retainer comprises a tubular base member having at least one barbed prong disposed on said tubular base member for engaging with the plicated tissue.

23. The system of claim 22 wherein the barbed tubular comprises four barbed prongs disposed on said tubular base member.

24. The system of claim 14 wherein the barbed tubular retainer has at least one radiopaque marker disposed thereon.
25. The system of claim 24 wherein the radiopaque marker disposed on the barbed tubular retainer is a tantalum micro-coil.

25. The system of claim 14 wherein the barbed tubular retainer is comprised of stainless steel, MP35N, platinum, nitinol, cobalt chromium or alloys thereof.

27. The system of claim 14 wherein the barbed tubular retainer is comprised of a polymeric material.

28. The system of claim 27 wherein the polymeric material is poly lactic acid (PLA) and/or poly glycolic acid (PGA).

29. The system of claim 23 wherein the base member of the barbed tubular retainer comprises a plurality of holes adapted to receive a suture.

30. The system of claim 29 wherein the barbed tubular retainer is releasably attached to the distal end of the retainer delivery catheter with a suture that runs from the proximal end of the retainer delivery catheter to the distal end of the retainer delivery catheter through the plurality of holes in the base member of the barbed tubular retainer.

31. The system of claim 30 wherein the barbed tubular retainer is released from the distal end of the retainer delivery catheter by removal of the suture from the patient.

32. The system of claim 22 wherein the base member and the barbed prongs are fabricated from one piece of material.

33. The system of claim 22 wherein the base member and the barbed prongs are fabricated separately and joined together after the distal end of the base member is sharpened.