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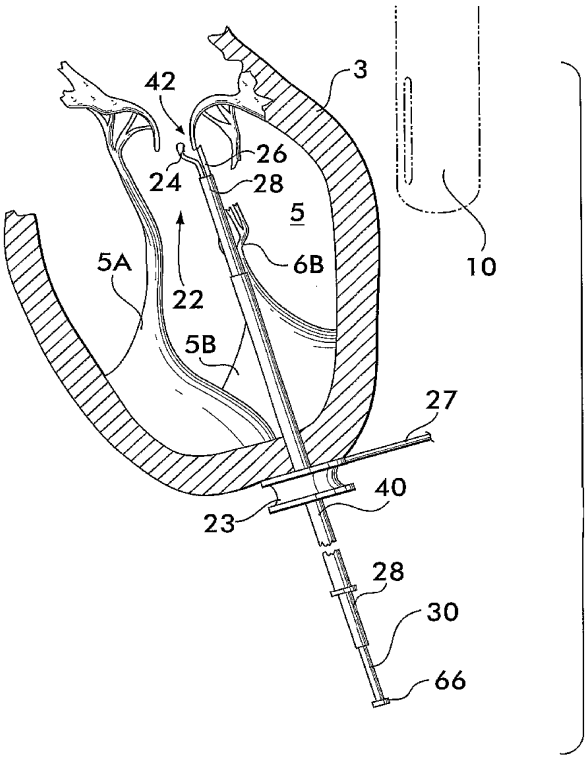

(57) Abstract: A method and apparatus for repairing the heart's mitral valve by using anatomic restoration without the need to stop the heart, use a heart-lung machine or making incisions on the heart. The method involves inserting a leaflet clamp through the heart's papillary muscle from which the leaflet has been disconnected, clamping the leaflet's free end and then puncturing the leaflet. One end of a suture is then passed through the hollow portion of the clamp, while the other end of the suture is maintained external to the heart. The clamp is then removed and the suture's two ends are fastened together with a securement ring/locking cap assembly to the heart wall exterior, thereby reconnecting the leaflet to the corresponding papillary muscle. The introduction of the clamp, puncturing of the leaflet, passage of the suture therethrough and removal of the clamp can be conducted a plurality of times before each suture's two ends are fastened to the securement ring/locking cap assembly.

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APPARATUS AND METHOD FOR MITRAL VALVE REPAIR WITHOUT CARDIOPULMONARY BYPASS, INCLUDING TRANSMURAL TECHNIQUES

SPECIFICATION

CROSS-REFERENCE TO RELATED APPLICATIONS

This utility application claims the benefit under 35 U.S.C. §119(e) of Provisional Application Serial No. 60/712,879 filed on August 30, 2005 entitled APPROACH TO AND DEVICE FOR MITRAL VALVE REPAIR WITHOUT CARDIOPULMONARY BYPASS AND EVENTUALLY WITHOUT AN INCISION WITH THORACOSCOPIC TECHNIQUES and whose entire disclosure is incorporated by reference herein.

BACKGROUND OF THE INVENTION

1. FIELD OF INVENTION

This invention relates to the mitral valve of the heart and more particularly, to methods and apparatus for repairing flail mitral valve leaflets.

2. DESCRIPTION OF RELATED ART

As shown most clearly in Fig. 1, the mitral valve 2 of the heart 3 comprises leaflets 4A and 4B that are attached to corresponding papillary muscles 5A and 5B through respective chordae tendinae 6A and 6B; thus, the chordae tendineae tether the mitral leaflet. Fig. 1 depicts a damaged mitral valve 2 in that one of leaflets 4B has flailed, e.g., the chordae tendineae 6B have ruptured, thereby separating the leaflet 4B from the papillary muscle 5B. This causes the now unsupported leaflet 4B to flail and the mitral valve 2 to leak and is referred to as "flail mitral valve" or just "flail."

The majority of routine mitral valve repairs presented in common clinical practice in the United States involves a flail mitral valve leaflet, typically, the P2 scallop of the posterior leaflet but it should be understood that other leaflet segments may be involved as well. Conventional surgical repair techniques have evolved from the work of Dr. Alan Carpentier, and typically involve resecting the unsupported or flail portion of the leaflet, which then requires reducing the size of the mitral annulus with a plication or suture shortening, leaflet repair with either primary or sliding plasty and implantation of a re-enforcing annulus ring. Previous approaches all involved connecting the patient to the heart lung machine to be able to safely stop the heart and approach the mitral valve by making an atrial incision. Recently, equivalent success rate and long term durability has been achieved with implantation of artificial chordae typically using 4-0

or 5-0 Gortex suture that has achieved equivalent success and long term durability measures. Some authors have reported finite element stress measurements on the repaired leaflet and note that conventional techniques flatten the leaflet or reduce its saddle shape creating more leaflet stress. They predict better durability with chordal replacement than conventional leaflet resection. However, both of these techniques require open visualization of the mitral valve with an arrested heart.

In addition, the devices being used in this type of mitral valve repair must minimize the use of small components, including fasteners, that can accidentally dislodge from the device or instrument or completed repair, and cause an embolism.

Thus, there remains a need for a new method and apparatus for supporting the leading edge of the flail leaflet segment with artificial chordae to the corresponding papillary muscle tip (e.g., posterior papillary muscle tip) that can be accomplished by a trained cardiothoracic surgeon monitoring the beating heart without cardiopulmonary bypass and, ideally, without an incision, e.g., using thoracoscopic techniques.

All references cited herein are incorporated herein by reference in their entireties.

BRIEF SUMMARY OF THE INVENTION

A method for repairing the mitral valve of a heart wherein at least one leaflet has suffered a defect with respect to its papillary muscle (e.g., a flail leaflet has partially detached, suffered chordal rupture or chordal defect such as but not limited to, elongated chordal defect). The method comprises: introducing a clamp transmurally into the beating heart and through the papillary muscle; grasping a portion of the leaflet with the clamp; piercing a hole in the leaflet; inserting a suture, having a first end, through the clamp and through the hole, and wherein the first end is displaced through the clamp instrument to emerge from a proximal end of the clamp; removing the clamp from the beating heart; and securing the first end, and a second end, of the suture against an exterior wall of the beating heart.

A method for repairing the mitral valve of a heart wherein at least one leaflet has suffered a defect with respect to its papillary muscle (e.g., a flail leaflet has partially detached, suffered chordal rupture or chordal defect such as but not limited to, elongated chordal defect). The method comprises: (a) introducing a clamp transmurally into the beating heart and through the papillary muscle; (b) grasping a portion of the leaflet with said clamp; (c) piercing a hole in the leaflet; (d) inserting a suture, having a first end, through said clamp and through said hole, said first end being displaced through said clamp to emerge from a proximal end of said clamp; (e) maintaining a second end of said suture external to the beating heart; (f) removing said

clamp from the beating heart; (g) repeating steps (a) – (f) to establish a plurality of first ends that emerge from a proximal end of said clamp and a plurality of second ends that are maintained external to beating heart; and (h) securing the plurality of first ends and the plurality of second ends against an exterior wall of the beating heart.

An apparatus for repairing the mitral valve of a heart wherein at least one leaflet has suffered a defect with respect to its papillary muscle (e.g., a flail leaflet has partially detached, suffered chordal rupture or chordal defect such as but not limited to, elongated chordal defect). The apparatus comprises: a clamp comprising first and second elongated members having respective first and second distal ends for clamping the leaflet; an external cylinder in which the clamp is slidable; a hollow piercing member, having a leading edge that can pierce tissue, that slides within the clamp; a suture driver device that couples to one end of the hollow piercing member, and wherein movement of the external cylinder acts on the first and second members to open or close the clamp to grasp or release the leaflet, and wherein the displacement of the hollow piercing member punctures the leaflet to form a hole therein and wherein the suture driver device drives a suture through the hollow piercing member for permitting said suture to pass through the leaflet and through the clamp for supporting mitral valve repair by connecting the leaflet to the papillary muscle.

An apparatus for stabilizing a portion of the heart wall of a beating heart to permit the transmural introduction of surgical instruments through the heart. The apparatus comprises a housing having: a first support surface that contacts the heart wall of the beating heart and provides a stable target for transmural penetration; a central passageway for permitting coupling of an epivascular ultrasound probe, for the passage of instruments used for the Seldinger technique, and for the passage of an introducer therethrough; and an extension formed with the first support surface for coupling to an externally fixed object.

A suture driver device for driving a suture through a surgical device that has penetrated some portion of a living being and wherein the surgical device provides a path for delivery of the suture. The suture driver device comprises: a syringe having a port that can couple to the surgical device, wherein the syringe comprises a chamber filled with a biocompatible fluid and with the suture, and wherein the suture comprises a weighted end that is initially disposed at the port such that when said syringe is activated, the weighted end is driven through the surgical device.

A suture driver device for driving a suture through a surgical device that has penetrated some portion of a living being and wherein the surgical device provides a path for

delivery of the suture. The suture driver device comprises a syringe having: a first port that can couple to a proximal end of the surgical device; a second port, in fluid communication with the first port; a chamber in fluid communication with the first and second ports and filled with a biocompatible fluid; and wherein, before the suture driver device is activated, the suture is passed through the first port and through the second port so that a first end of the suture is located externally of the suture driver device and a first weighted end of the suture is positioned at the first port.

An apparatus for securing the free ends of a suture that have passed through an internal body part of a living being. The apparatus comprises: a ring having an inner surface with a plurality of channels, wherein each of the channels comprises teeth; a corresponding plug that fits snuggly within an opening of the ring; wherein the free ends of the suture are passed through the opening in the ring and each one of the free ends are positioned in respective ones of the plurality of channels and wherein the plug is then positioned snuggly within the opening and wherein the ring and plug are positioned against the internal body part.

A strain gauge device for detecting the tension applied to the free ends of a suture that has passed through the body part of a living being. The strain gauge device comprises a housing that can be coupled to the free ends of the suture and wherein the housing comprises: a strain gauge or load cell for detecting the strain or load applied to the suture; a display, coupled to the strain gauge or load cell, for displaying tension values; a stepper motor, coupled to the display, for increasing or decreasing applied tension to the suture; and control keys coupled to the display and to the stepper motor for permitting a user to control the tension applied to the suture.

BRIEF DESCRIPTION OF SEVERAL VIEWS OF THE DRAWINGS

The invention will be described in conjunction with the following drawings in which like reference numerals designate like elements and wherein:

Fig. 1 is a partial cross-sectional view of a human heart depicting a failed mitral valve wherein the chordae tendineae have torn and the leaflet portion of the valve is disconnected from the papillary muscle and wherein a stabilizer, of the method of the present invention, has been releasably secured to the outer wall of the heart at the base of the papillary muscle;

Fig. 2 is a partial cross-sectional view of the heart of Fig. 1 showing a portion of the method and apparatus of the present invention whereby an introducer is passed through the stabilizer and heart wall and up through the papillary muscle of the failed mitral valve;

Fig. 3 is a partial cross-sectional view of the heart of Fig. 2 showing a portion of the method and apparatus of the present invention whereby a leaflet clamp has been fed through the introducer and is positioned just prior to clamping the free end of the leaflet;

Fig. 4 is a partial cross-sectional view of the heart of Fig. 3 showing a suture driver device of the method and apparatus of the present invention being coupled to the proximal end of the clamp after the flail leaflet has been clamped;

Fig. 5 is a partial cross-sectional view of the heart of Fig. 4 showing a suture of the method and apparatus of the present invention that has been passed through the free end of the leaflet, with the clamp already removed from the introducer, and whereby the ends of the suture are available through the introducer;

Fig. 6 is a partial cross-sectional view of the heart of Fig. 5 showing the mitral valve repaired using the method and apparatus of the present invention whereby the free ends of the suture have been passed through a securement ring that is positioned against the exterior side of the heart; and wherein the free ends of the suture are momentarily coupled to a strain gauge;

Fig. 6A is an enlarged isometric view of the securement ring of Fig. 6, showing internal channels with teeth for securing the free ends of the suture at a desired tension level, as well as a corresponding locking cap that fits snuggly within the securement ring;

Fig. 6B is an enlarged cross-sectional view of the securement ring and locking cap of Fig. 6A taken along line 6B-6B of Fig. 6A;

Fig. 7 is an enlarged partial cross-sectional view of the working end of the clamp of the method and apparatus of the present invention with the free end of the leaflet positioned between the clamp members;

Fig. 7A is an enlarged cross-sectional view of the working end of the clamp of the method and apparatus of the present invention showing the first member of the clamp displacing the free end of the leaflet toward the second member of the clamp;

Fig. 8 is an enlarged cross-sectional view of the working end of the clamp of the method and apparatus of the present invention showing the leaflet being clamped between the two clamp members;

Fig. 9 is an enlarged cross-sectional view of the working end of the clamp of the method and apparatus of the present invention showing the free end of the leaflet being punctured by a puncturing member;

Fig. 10 is an enlarged cross-sectional view of the working end of the clamp and whereby the suture is driven through one of the clamp members, through the hole in the free end of the leaflet and down through the other clamp member;

Fig. 11 is an enlarged cross-sectional view of the working end of the clamp and whereby the puncturing member has been withdrawn;

Fig. 12 is an enlarged cross-sectional view of the working end of the clamp and whereby the clamp members are drawn apart, thereby allowing these members to be displaced separately through the introducer without snagging the suture that has passed through the leaflet;

Fig. 13 is an enlarged cross-sectional view of the first member of the clamp and the suture passing through the leaflet after the second member of the clamp has already been withdrawn from the introducer (not shown);

Fig. 14 is a partial cross-sectional view of the overall invention depicting how the suture driver device couples to the clamp in order to drive the suture through one member of the clamp, through the aperture in the leaflet and back through the other member of the clamp; and

Fig. 14A is an enlarged partial cross-sectional view of an alternative port design of the suture driver device.

DETAILED DESCRIPTION OF THE INVENTION

The method and apparatus of the present invention are directed to repairing a mitral valve by securing the leading edge of a flail leaflet segment with artificial chordae to the corresponding papillary muscle tip. This is accomplished without cardiopulmonary bypass and, ideally, without an incision, e.g., using thoracoscopic techniques. Thus, the present invention provides a new method for mitral valve repair for the pathology of flail mitral leaflet using proven techniques but utilizing a novel approach and new instrumentation. This allows for anatomic restoration without the need to stop the heart, use the heart-lung machine or making incisions on the heart. The method is a cardiac surgical procedure that involves transmural techniques. The term "transmural" is used in its broadest sense and includes, but is not limited to, transventricular procedures. Thus, the method of the present invention can be adapted to thoracoscopic techniques and may obviate the need for open incision.

The apparatus 20 used to accomplish the method of the present invention is shown in Fig. 14. The apparatus 20 comprises a leaflet clamp 22 (comprising a first member 24 and a second member 26), a sleeve or external cylinder 28, a hollow piercing member 30 (e.g., a needle) and a suture driver device 32 (e.g., a syringe 34 comprising a suture 36 and a

biocompatible fluid 38, e.g., saline solution). As will be discussed in detail later, the method of the present invention basically involves:

-positioning the working end of the leaflet clamp 22, using an introducer or sheath 40, within the heart 3 through the papillary muscle from which the flail leaflet has partially detached, suffered chordal rupture or chordal defect (e.g., elongated chordal defect); see Fig. 3;

-grasping the free end of the flail leaflet with the clamp 22; see Fig. 4;

-piercing the clamped leaflet with the piercing member 30; see Fig. 9;

-passing a suture through the clamp 22/piercing member 30 using the suture driver device 32; see Fig. 5;

-removing the clamp 22, thereby leaving a suture that passes through the flail leaflet and its corresponding papillary muscle; see Fig. 6; and

-securing the ends of the suture against the exterior heart wall using a securement ring/lock cap such that the leaflet is connected to its corresponding papillary muscle (see Figs. 6-6B).

In describing the method and apparatus of the present invention, failure of the posterior leaflet is depicted by way of example only and it should be understood that other leaflet segments may be involved as well and that the method and apparatus are not limited, in any way, to the posterior leaflet. Moreover, the term "flail leaflet" is used in its broadest sense to mean any type of damage involving the leaflet, not just chordal rupture, e.g., partial chordal detachment, chordal rupture or some chordal defect (e.g., elongated chordal defect).

To begin the method of the present invention, the heart is exposed via sternotomy, left anterior thoracotomy or thorascopy (not shown) and the pericardium is opened. A transesophogeal ultrasound probe 10 (Figs. 2-3) is used by the surgeon to view the interior of the heart 3, including the mitral valve 2. Next, the entry point on the heart wall corresponding to the base of the papillary muscle 5B needs to be determined, hereinafter, "the base location 21." This is accomplished using a short focal length color Doppler epivascular ultrasound probe (not shown) which includes a needle guide channel (not shown). Once the base location 21 is determined, the surgeon then couples the epivascular ultrasound probe to a suction stabilizer 23 (Figs. 1-5) which is then applied to the base location 21. The stabilizer 23 stabilizes the base location 21 of the heart wall for supporting the epivascular ultrasound probe and entry of the introducer 40 and clamp 22, as will be discussed later. As can be seen from Fig. 2, the stabilizer 23 comprises a housing having a first support surface 23A that contacts the heart wall,

a second support surface 23B, a central passageway 23C positioned between these surfaces and an arm or extension 27 integrally formed with the first support surface 23A; the central passageway 23C may contain an access seal (not shown).

The surgeon then applies the suction stabilizer 23, along with the epivascular ultrasound probe, to the base location 21. The direction of the longitudinal axis (25, see Fig. 1) of the papillary muscle must be determined next using 2-D echo imaging with the epivascular ultrasound probe. Important epicardial, intramural and papillary blood vessels are identified with Doppler interrogation and avoided. Determination of the direction of the longitudinal axis (hereinafter "the direction 25") of the papillary muscle 5B permits defining the passage through the papillary muscle's apex.

With the base location 21 and the direction 25 determined and with the stabilizer 23 applied to the heart wall, the stabilizer 23 suction is activated and the stabilizer arm or extension 27 is made rigid (e.g., securing or anchoring the arm/extension 27 to a fixed object), thereby fixing the heart 3 and apparatus in preparation for the Seldinger technique insertion of a finder needle and guidewire, such as described in U.S. Patent Nos. 7,077,801 (Haverich) or 7,063,679 (Maguire, et al.), by way of example only, and both of which are incorporated by reference herein. In the Seldinger technique, a needle and subsequent guidewire (neither of which are shown) pass through the epivascular ultrasound probe, the stabilizer 23, the ventricular wall and central axis 25 of the papillary muscle 5B and emerge from the tip of the papillary muscle 5B into the ventricular chamber. The epivascular ultrasound probe and needle are removed; dilators (not shown) and the specialized introducer 40 are inserted over the guidewire. The guidewire is then removed and the introducer 40 is locked into the stabilizer 23, as shown in Fig. 2, providing a stable access platform for subsequent intracardiac instrumentation.

Under conditions of systemic heparinization and by continuously flushing the devices with heparinized saline, trans-ventricular, trans-papillary introduction of the short freestanding introducer 40 with a water-tight, as well as air-tight, access seal, affixed to the stabilizer 23, is accomplished. Similar introducers or sheaths of anti-thrombotic plastic are currently in use in the cath lab (i.e., a specialized radiologic suite where cardiac catheterization is performed) for arterial access, but this introducer 40 is considerably shorter and the seal is designed to withstand the greater pulse pressure differential and unbuffered dP/dT that exists in the left ventricle.

With the introducer 40 in place, the surgeon now inserts the clamp 22 through the introducer 40 as shown in Fig. 3 and using the transesophogeal ultrasound probe 10 positions a

working end 42 of the clamp 22 so that the flail leaflet 4B is located between the first and second members 24 and 26. A discussion of the working end 42 of the clamp 22 follows.

As can be seen most clearly in Fig. 7, the working end 42 of the clamp 22 comprises the first member 24 having a curved distal end 44 with an opening 46 having teeth or serrations 48 along its periphery. The first member 24 comprises a channel 50 for permitting passage of the suture 36, as will be discussed later. The working end 42 of the clamp 22 also comprises the second member 26 having a straight distal end 52 with an opening 54 also having teeth or serrations 56 along its periphery. The second member 26 (e.g., a substantially straight structure) also comprises a channel 58 for permitting passage of the hollow piercing member 30. It should be understood that the channels 50 and 58 are continuous through the members 24 and 26 and include entry or exit apertures at their respective proximal ends (not shown) thereof to allow the surgeon to introduce or remove instruments (e.g., the hollow piercing needle 30, suture 36, etc.) therefrom. The first and second members 24/26 may comprise a spring steel material; as a result, with the distal end 44 of the first member 24 having a curved configuration (including bend 59), the displacement of the external cylinder 28 in the direction 62 (Figs. 7-7B) causes its upper end 60 to ride along the outside surface of the first member 24. Contact of the upper end 60 with the bend 59 causes the distal end 44 to contact the leaflet 4B and move it towards the second member 26, as shown in Fig. 7A; as shown by the gap 67, Fig. 7A depicts a "light control" of the leaflet 4B just prior to clamping it. Further displacement of the sleeve 28 in the direction 62 causes the respective distal ends 44 and 52 to clamp the leaflet 4B therebetween, as shown in Fig. 8. Thus, in view of the previous discussion, and following the progression of Figs. 7 -8, the surgeon initially manipulates the proximal ends (not shown) of the clamp members 24 and 26 to position the free end 7 of the flail leaflet 4B between the first and second members 24/26 as shown in Figs. 3 and 7; the surgeon views this location using the transesophogeal ultrasound probe 10. Once the surgeon has properly positioned the free or leading edge 7 of the flail leaflet 4B between the two clamp members 24 and 26 (see Fig. 7), the surgeon gently grasps the free end 7 of the flail leaflet 4B in diastole (Fig. 7A) by partially advancing the external cylinder 28 in the direction of arrow 62. When the correct position is confirmed by echo images, clamping the leaflet free end 7 is completed by further advancement of the external cylinder 28 (in the direction of arrow 62, see Fig. 8), which also assures alignment of the respective distal ends 44 and 52 and the respective channels 50 and 58 in preparation for leaflet 4B puncturing and suture 36 advancement.

The hollow piercing member 30, if not already positioned inside the second clamp member 26, is then passed through the channel 58. The hollow piercing member 30 (e.g., a needle) comprises a sharp tapered edge 64. With the free end 7 of the flail leaflet 4B secured between the teeth/serrations 48/56, the surgeon applies pressure to the proximal end 66 (Fig. 3) of the hollow piercing member 30 in the direction of arrow 68 as shown in Fig. 9, thereby piercing the free end 7 of the flail leaflet 4B.

At this point, the suture driver device 32 is then coupled to proximal end 66 of the hollow piercing member 30, as shown in Fig. 4. Fig. 14 provides a more detailed view of an exemplary suture driver device 32. In particular, the device 32 comprises a syringe 34 and piston 70 and an integral stem 72. A driving side 74 of the piston 70 forms a movable wall of a chamber 76 in the syringe 34 that contains the suture 36 (e.g., 5-0 Goretex suture) and is filled with the biocompatible fluid 38. One end 78 of the suture 36 is weighted and is initially positioned at the delivery port 80 of the syringe 34; the weight acts to initially block the opening 82 in the port 80 (e.g., see Fig. 14A; alternatively, the weighted end 78 may be arranged to be internal of the port 80, in which case, the opening 82 is sized to permit passage of the weighted end 78). During insertion, the weighted end 78 and delivery port 80 are inserted into the open end 81 of the hollow piercing member 30. When the suture driver device 32 is activated by compressing the stem 72 into the syringe 34, the piston 70 compresses the fluid 38, thereby displacing the weighted end 78 by a fluid 38 stream up through the hollow piercing member 30 (see arrow 83 in Fig. 10) out of the tapered end 64 and through the channel 50 (shown by the arrow 84 in Fig. 10) in the first member 24. The fluid stream from the suture driver device 32 causes the weighted end 78 of the suture 36 to travel completely through the channel 50 so that the weighted end 78 emerges from an opening 86 (Fig. 14) in the proximal end 88 of the first member 24.

To prevent clogging the port 80 by the suture 36 as the suture driver device 32 is activated, the suture 36 is coiled (see Fig. 14) and treated with an adhesive (e.g., bonewax) when initially disposed in the chamber 76 against the piston 70. Thus, because of the applied bonewax, when fluid 38 is drawn into the chamber 76, and the coiled suture 36 is immersed in the fluid 38, the suture 36 remains coiled and only the pulling force of the weighted end 78 of the suture 36 (when the suture driver device 32 is activated) causes the coiled suture portions to separate and thereby avoid fouling or clogging the port opening 82.

At this point of the method of the present invention, a suture 36 has been effectively passed through the free end 7 of the leaflet 4B. Before the ends of the suture 36 can be tied off,

or otherwise secured, at this point, it only remains to remove the leaflet clamp 22 from the heart 3. Figs. 11-13 show the sequence of performing this removal. In particular, the hollow piercing member 30 is removed (Fig. 11) from the second clamp member 26 by sliding it out. This can be accomplished by displacing the suture driver device 32 away from the second member 26; alternatively, the suture driver device 32 can first be disengaged from the open end 81 of the hollow piercing member 30 and then the hollow piercing member 30 removed from the second member 26. In either case, removal of these items from the second member 26, is accomplished while leaving the suture 36 in place by not snagging it within the clamp 22 components during their removal. As shown in Fig. 12, with the hollow piercing member 30 removed, the clamp 22 is opened by displacing the sleeve 28 in the direction of arrow 63, which permits the first member 24 to swing away from the second member 26, thereby releasing the free end 7of the leaflet 4B. The second clamp member 26 is then displaced in the direction of arrow 63, thereby being retracted within the external cylinder 28 and removed therefrom. This leaves the first clamp member 24 and the suture 36 protruding out of the sleeve 28 (Fig. 12, the external cylinder 28 has been slid in the direction of the arrow 63 and is therefore no longer visible in Fig. 13) and the surgeon now needs to retract the first member 24 therein.

As can be seen most clearly in Fig. 13, the suture 36 rides along the tip of the distal end 44. An indentation or groove 89 (Figs.7-11 and 13) is provided in the tip of the distal end 44 to maintain the suture 36 at the tip of the distal end 44 during removal of the first clamp member 24. This prevents the suture 36 from becoming snagged or caught in the teeth/serrations 48, especially when the first clamp member 24 is being retracted within the sleeve 28, as discussed next.

The first clamp member 24 is retracted within the external cylinder 28 (as mentioned earlier, the contact of the protuberance 59 with the top edge (not shown) of the external cylinder 28 causes the first member 24 to displace to the right, with reference to Fig. 13). Once retracted within the external cylinder 28, the cylinder 28 is removed from the introducer 40. Thus, with the clamp 22 withdrawn, the result is a single suture 36 now is looped through the free end 7 of the leaflet and the ends 90 (Fig. 5) of the suture 36 protrude out of the proximal end of the introducer 40. More particularly, with the length of the suture 36 passing through the introducer/sheath 40, the ends 90 of the suture 36 are brought to the exterior of the heart 3 (and the patient) where the ends 90 are temporarily secured to the surgical drapes (not shown). Additional sutures can be established by re-introduction of the clamp 22 into the introducer/sheath 40 beside the previous sutures, and the above-described method is repeated

with the clamp 22 and suture driver device 32. Typically, three to eight sutures might be required to completely support the flail leaflet 4B, depending on the extent of pathology. After implantation of all of the sutures 36, with the pairs of ends all exterior to the heart 3, the sheath 40 is removed (Fig. 5), and the sutures 36 are individually adjusted to the appropriate length with real time echocardiographic guidance for optimal line of leaflet co-aptation. Furthermore, if no more sutures are to be passed through the leaflet 4B, the stabilizer 23 is also removed.

To complete the mitral valve repair, as shown in Fig. 6, a securement ring 92 and corresponding locking cap 94 (Figs. 6A-6B) are provided. In particular, the securement ring 92 comprises a plurality of channels having locking teeth therein. By way of example only, four such channels 96A-96D are shown in Fig. 6A, located 90 degrees from each other, and two of which, channels 96A and 96B, are depicted with the suture 36 disposed therein. The locking teeth 98 in each channel prevent the suture 36 portions from pulling out once they are positioned in these channels. Once each suture 36 portion is positioned within a respective channel, the locking cap 94 is secured inside the securement ring 92 as shown in Figs. 6A-6B, thereby locking the suture portions against the exterior heart wall. Besides securing the free ends 90 of the suture 36 against the ring 92, an integral rim 95 of the locking cap 94 also provides a surface for grasping the cap 94 should it ever be necessary to obtain access to the sutures 36 in the future during surgery. The ring 92/cap 94 assembly is designed to both complete hemostasis and distribute the tension on the new suture chordae in systole; both the ring 92 and cap 94 comprise biocompatible material. The end result is that the leaflet 4B is now coupled to its corresponding papillary muscle 5B.

It should be understood that prior to inserting the suture portions into the securement ring 92 channels, as shown in Fig. 6, the suture portions are first coupled to a strain gauge device 200. The strain gauge device 200 permits the surgeon to measure the tension applied to the suture 36, and adjust it accordingly, before locking the suture portions into the securement ring 92 channels. In particular, the free ends 90 of the suture 36 are passed through the securement ring 92. Next, the free ends 90 are coupled to the strain gauge device 200. The surgeon measures the tension being applied to the free ends 90 and can adjust that tension accordingly. Once the surgeon is satisfied with the tension on the suture portions 36, the surgeon positions the suture portions in respective securement ring channels (e.g., 96A-96D), thereby locking the suture within the securement ring 92 at the desired tension level. These tension measurements are important because it may not be ideal to apply the same tension to the repaired leaflet chordae as are applied to the undamaged chordae of the other leaflet. In fact,

such higher "tension" may have led to the flail leaflet in the first place. Thus, by using strain gauges/load cells as part of the method of the present invention, the surgeon can further assess repair physiology and thereby provide the most effective repair.

By way of example only, the strain gauge device 200 may comprise a strain gauge or load cell, such as the S251 miniature platform load cell by Strain Measurement Devices of Meriden, CT. The strain gauge device 200 may also comprise a display 202 for displaying the tension values. The device 200 may also comprise a stepper motor for applying incremental, increasing or decreasing, steps of tension for more precise control of the tension. Corresponding keys 204 provide such control to the surgeon.

It should be appreciated that by using the structure of the apparatus 20, there are no small components (e.g., known clamps and/or cutters that have articulating, hinged, journaled, etc,. components that utilize screws or other fasteners that can also dislodge) which enter the heart that can dislodge and form an embolism; rather, the components of the apparatus 20 form continuous members with no hinged or articulating parts that could break off.

The overall diameter of the clamp 22 must allow easy passage through the introducer 40 (e.g., an 8 to 10 french sheath or approximately 2.7 mm). This allows multiple subsequent passes of the external cylinder 28 within the sheath 40 along-side previously placed sutures 36. As mentioned earlier, the clamp members 24 and 26 may comprise spring steel such that they open when the clamp 22 is withdrawn (e.g., sliding a control ring (not shown) on the body of the device back). The respective distal ends 44 and 52 of the clamp members 24/26 close gently with partial advancement of the external cylinder 28, and firmly with complete advancement, which also aligns the respective channels 50 and 58. The channels 50 and 58 may contain heparinized saline flush and are capped (not shown) at their proximal ends until the leaflet 4B is grasped. The cap is removed for hollow piercing member 30/suture 36 passage, and can be replaced after completed suture placement, clamp 22 withdrawal and channel flushing for subsequent passes.

It should be noted that, although not shown, the preferred inner surface of the external cylinder 28 is oval or elliptical. This preferred shape prevents the first and second members 24 and 26 from passing each other during displacement of the external cylinder 28 (in the direction 62) which could cause misalignment of the distal ends 44 and 52 which could tear the leaflet 4B during clamping and could also cause misalignment of the respective channels 50 and 58.

An alternative port 80' design is shown in Fig. 14B. In this port 80', a suture port 100 is provided to permit passage of the suture 36 externally of the suture driver device 32. This

eliminates the need to stow the suture 36 within the suture driver device 32, as well as treat the suture with an adhesive, prior to use. In this embodiment, the free end (not shown) of the suture 36 is first passed through the port opening 82 and then through the suture port 100 until the weighted end 78 of the suture 36 comes to rest against the port opening 82, as shown in Fig. 14A. Because of the angled design of the suture port 100, when the suture driver device 32 is activated (as discussed with regard to Fig. 14), the fluid 38 drives the weighted end 78 up the hollow piercing member 30 (in the direction of the arrow 102), with minimal loss of fluid 38 through the suture port 100.

Another alternative embodiment (not shown) also permits passage of the suture externally of the suture driver device 32 but without the need for a suture port. In this alternative embodiment, a channel or groove on the outside surface of the port 80 is provided. With the weighted end 78 of the suture 36 disposed on the port opening 82 (as shown in Fig. 14A), once the suture driver device 32 is activated, the suture 36 is also drawn upward into the hollow piercing member 30 by the fluid stream and the suture 36 feeds upward through the channel or groove. Using this embodiment, it also eliminates the need to stow the suture 36 within the suture driver device 32, as well as treat the suture with an adhesive, prior to use.

As mentioned earlier, three to eight sutures may be required to completely support the flail leaflet 4B. Thus, as a result, the securement ring 92 may include sixteen locking channels since each suture looped through the leaflet 4B has two portions. Again, the number of locking channels is by way of example only and is not limited to those shown or discussed.

Although less preferred, an alternative to the suture driver device 32 is to have the suture 36 comprise a sharp-tipped wire (not shown) swedged to one end of the suture 36. "Swedging" is the same technology that attaches sutures to needles in open surgery. Thus, the sharp-tipped wire is manually displaced through the leaflet clamp 22, while towing the suture 36. Once the wire portion emerges from the proximal end 88 of the first member 24, the wire portion can be severed from the suture 36. A funnel enlargement of the tip opening 46 of the channel 50 directs transfer of the point of the wire into the first member channel 50 after it pierces the leaflet 4B.

Systemic heparin is reversed. The transpapillary muscle tract of the apparatus 20 and subsequent sutures are extrinsically compressed by ventricular pressure in systole. This compression and the tract length should minimize bleeding. Systemic beta blockade and avoiding early post-op hypertension are sensible precautions.

Performing the maneuvers of this method should be well tolerated by the beating heart

because they do not worsen, but rather progressively improve the severe valvular regurgitation as the operation progresses before ultimately eliminating the leak at completion. Planned evolution of this operation after initial development and testing is via a standard median sternotomy to allow conversion to standard operation, then as experience is gained and with minimally modified instrumentation, through a small anterior left thoracotomy incision to gain access to the off-apex base of the papillary muscle. Ultimately, it is desirable to develop the instruments and techniques to refine this repair into a minimally invasive left-sided thoracoscopic procedure without surgical incision.

Successful application of this technique would result in a natural appearing mitral valve resulting from restoration of normal anatomy. This is in contrast to other proposed off pump techniques derived from the Alfieri stitch. Failure of this technique should not result in embolization, worsening of baseline pathology or preclude subsequent cardiac surgeries including subsequent mitral valve operations. This technique might also be of value in other situations such as repair of leaking prosthetic valves or patches, tacking down of mobile intra-luminal or intra-chamber flaps or implants or leads, or whenever external suture support of other intra-cardiac structures or prostheses is required.

While the invention has been described in detail and with reference to specific examples thereof, it will be apparent to one skilled in the art that various changes and modifications can be made therein without departing from the spirit and scope thereof.

CLAIMS

WHAT IS CLAIMED IS:

1. A method for repairing the mitral valve of a heart wherein at least one leaflet has suffered a defect with respect to its papillary muscle, said method comprising:

introducing a clamp transmurally into the beating heart and through the papillary muscle;

grasping a portion of the leaflet with said clamp;

piercing a hole in the leaflet;

inserting a suture, having a first end, through said clamp and through said hole, said first end being displaced through said clamp instrument to emerge from a proximal end of said clamp;

removing said clamp from the beating heart; and

securing said first end, and a second end, of said suture against an exterior wall of the beating heart.

2. The method of Claim 1 wherein said step of introducing a clamp transmurally comprises:

using a probe to select an entry spot on a heart wall corresponding to the base of the papillary muscle; and

using said probe to select a direction for inserting said introducer along a center or longitudinal axis of the papillary muscle.

3. The method of Claim 2 wherein said step of using said probe to select a direction comprises:

coupling said probe to a stabilizer;

applying said stabilizer to the heart wall at said selected entry spot; and

selecting said direction using said probe.

4. The method of Claim 3 further comprising :

activating said stabilizer to stabilize a vicinity around said entry spot;

using the Seldinger technique to pass a needle and guidewire through said stabilizer and probe at said selected entry spot along said selected direction to emerge from a tip of the papillary muscle into the heart's ventricular chamber;

removing said needle and probe;

inserting said introducer over said guidewire;

removing said guidewire; and

locking said introducer to said stabilizer.

5. The method of Claim 1 wherein said probe comprises an epivascular ultrasound probe.

6. The method of Claim 1 wherein said step of piercing a hole in the leaflet comprises inserting a hollow piercing member through said clamp, said hollow piercing member having a leading edge that punctures the leaflet.

7. The method of Claim 6 wherein said step of inserting a suture through said clamp comprises using a fluid stream to drive a suture having a weight at its first end through said hollow piercing member while maintaining said second end of said suture at said proximal end of said clamp.

8. The method of Claim 7 wherein said step of using a fluid stream to drive a suture comprises disposing said suture in a syringe having a port that can couple to a proximal end of said hollow piercing member, said syringe comprising a chamber filled with a biocompatible fluid and with said suture, said first end being initially disposed at said port such that when said syringe is activated, said weight is driven through said clamp.

9. The method of Claim 7 wherein said step of using a fluid stream to drive a suture comprises:

providing a syringe having a first port that can couple to a proximal end of said hollow piercing member and having a second port, in fluid communication with said first port, said syringe comprising a chamber filled with a biocompatible fluid; and

passing said second end through said first port and through said second port until said first end is disposed at said first port such that when said syringe is activated, said weight is driven away from said first port while pulling said suture through said second port and through said first port and through said clamp.

10. The method of Claim 1 wherein said step of introducing a clamp comprises introducing first and second members that cooperate to form a clamp, said first member comprising a first opening at a first distal end that is communication with a first channel that runs the length of said first member, and wherein said second member comprises a second opening at a second distal end that is communication with a second channel that runs the length of said second member, said first and second openings being aligned when said first and second distal ends grasp the leaflet.

11. The method of Claim 10 wherein said step of piercing a hole in the leaflet comprises inserting a hollow piercing member through said second channel, said hollow piercing member having a leading edge that punctures the leaflet and enters said first opening.

12. The method of Claim 11 wherein said step of inserting a suture through said clamp comprises using a fluid stream to drive a suture having a weight at its first end through said hollow piercing member and through said first channel while maintaining said second end of said suture at said proximal end of said clamp.

13. The method of Claim 12 wherein said step of using a fluid stream to drive a suture comprises disposing said suture in a syringe having a port that can couple to a proximal end of said hollow piercing member, said syringe comprising a chamber filled with a biocompatible fluid and with said suture, said first end being initially disposed at said port such that when said syringe is activated, said weight is driven through said clamp.

14. The method of Claim 12 wherein said step of using a fluid stream to drive a suture comprises:

providing a syringe having a first port that can couple to a proximal end of said hollow piercing member and having a second port, in fluid communication with said first port, said syringe comprising a chamber filled with a biocompatible fluid; and

passing said second end through said first port and through said second port until said first end is disposed at said first port such that when said syringe is activated, said weight is driven away from said first port while pulling said suture through said second port and through said first port and through said clamp.

15. The method of Claim 1 wherein said step of securing said first end and a second end of said suture against an exterior wall of the beating heart comprises:

passing said first and second ends through a biocompatible ring having a plurality of channels within an inner surface thereof;

positioning said ring against the exterior wall of the beating heart;

inserting first and second portions of said suture in respective ones of said plurality of channels; and

inserting a cap within said ring to lock said first and second ends between said inner surface and said cap.

16. The method of Claim 15 wherein said step of passing said first and second ends through a biocompatible ring further comprises:

coupling said first and second ends to a strain gauge to determine any tension applied through said suture;

adjusting the tension of said suture until a desired tension is achieved; and

de-coupling said first and second ends from said strain gauge.

17. A method for repairing the mitral valve of a heart wherein at least one leaflet has suffered a defect with respect to its papillary muscle, said method comprising:

(a) introducing a clamp transmurally into the beating heart and through the papillary muscle;

(b) grasping a portion of the leaflet with said clamp;

(c) piercing a hole in the leaflet;

(d) inserting a suture, having a first end, through said clamp and through said hole, said first end being displaced through said clamp to emerge from a proximal end of said clamp;

(e) maintaining a second end of said suture external to the beating heart;

(f) removing said clamp from the beating heart;

(g) repeating steps (a) – (f) to establish a plurality of first ends that emerge from a proximal end of said clamp and a plurality of second ends that are maintained external to beating heart; and

(h) securing said plurality of first ends and said plurality of second ends against an exterior wall of the beating heart.

18. An apparatus for repairing the mitral valve of a heart wherein at least one leaflet has suffered a defect with respect to its papillary muscle, said apparatus comprising:

a clamp comprising first and second elongated members having respective first and second distal ends for clamping the leaflet;

an external cylinder in which said clamp is slidable;

a hollow piercing member, having a leading edge that can pierce tissue, that slides within said clamp;

a suture driver device that couples to one end of said hollow piercing member, and

wherein movement of said external cylinder acts on said first and second members to open or close said clamp to grasp or release the leaflet, wherein said displacement of said hollow piercing member punctures said leaflet to form a hole therein and wherein said suture driver device drives a suture through said hollow piercing member for permitting said suture to pass through the leaflet and through said clamp for supporting mitral valve repair by connecting the leaflet to the papillary muscle.

19. The apparatus of Claim 18 wherein said first member comprising a first opening at said first distal end that is communication with said first channel that runs the length of said first member, and wherein said second member comprises a second opening at said second distal end that is communication with a second channel that runs the length of said second member, said first and second openings being aligned when said first and second distal ends grasp the leaflet.

20. The apparatus of Claim 19 wherein said first distal end is curved and wherein said first opening is located at a first tip of said first distal end.

21. The apparatus of Claim 20 wherein said second member comprises a substantially straight structure and wherein said second opening is located at a second tip of said second distal end.

22. The apparatus of Claim 18 wherein said suture driver device comprises a syringe having a port that can couple to a proximal end of said hollow piercing member, said syringe comprising a chamber filled with a biocompatible fluid and with said suture, said suture comprising a weighted end that is initially disposed at said port such that when said syringe is activated, said weighted end is driven through said clamp.

23. The apparatus of Claim 22 wherein said suture is coiled and an adhesive applied thereto for maintaining said suture in a coiled state even when said coiled suture is immersed in said biocompatible fluid.

24. The apparatus of Claim 23 wherein said adhesive comprises bonewax.

25. The apparatus of Claim 18 wherein said suture driver device comprises a syringe having:

a first port that can couple to a proximal end of said hollow piercing member;

a second port, in fluid communication with said first port;

a chamber in fluid communication with said first and second ports and filled with a biocompatible fluid; and

wherein, before said suture driver device is activated, said suture is passed through said first port and through said second port so that a second end of said suture is located externally of said suture driver device and said weighted end of said suture is positioned at said first port.

26. The apparatus of Claim 25 wherein said second port is angled with respect to said first port such that said passage of said biocompatible fluid through said second port is minimized when said suture driver device is activated.

27. The apparatus of Claim 23 wherein said hollow piercing member is positioned within said second member.

28. The apparatus of Claim 21 wherein said hollow piercing member is a needle.

29. The apparatus of Claim 20 wherein said first member comprises spring steel.

30. The apparatus of Claim 21 wherein said second member comprises spring steel.

31. The apparatus of Claim 18 further comprising a securement ring, said securement ring being positioned against an exterior wall of said heart and comprising a plurality of channels within an inner surface of said ring for receiving respective portions of sutures that have passed through the leaflet, each of one of said plurality of channels comprising a plurality of teeth for capturing a respective portion of said suture.

32. The apparatus of Claim 31 further comprising a locking cap, said locking cap cooperating with said securement ring for locking said portions of said suture within said plurality of channels.

33. An apparatus for stabilizing a portion of the heart wall of a beating heart to permit the transmural introduction of surgical instruments through the heart, said apparatus comprises a housing having:

a first support surface that contacts the heart wall of the beating heart and provides a stable target for transmural penetration;

a central passageway for permitting coupling of an epivascular ultrasound probe, for the passage of instruments used for the Seldinger technique, and for the passage of an introducer therethrough; and

an extension formed with said first support surface for coupling to an externally fixed object.

34. A suture driver device for driving a suture through a surgical device that has penetrated some portion of a living being and wherein the surgical device provides a path for delivery of the suture, said suture driver device comprising a syringe having a port that can

couple to the surgical device, said syringe comprising a chamber filled with a biocompatible fluid and with said suture, said suture comprising a weighted end that is initially disposed at said port such that when said syringe is activated, said weighted end is driven through said surgical device.

35. The apparatus of Claim 34 wherein said suture is coiled and an adhesive applied thereto for maintaining said suture in a coiled state even when said coiled suture is immersed in said biocompatible fluid.

36. The apparatus of Claim 35 wherein said adhesive comprises bonewax.

37. A suture driver device for driving a suture through a surgical device that has penetrated some portion of a living being and wherein the surgical device provides a path for delivery of the suture, said suture driver device comprising a syringe having:

a first port that can couple to a proximal end of the surgical device;

a second port, in fluid communication with said first port;

a chamber in fluid communication with said first and second ports and filled with a biocompatible fluid; and

wherein, before said suture driver device is activated, said suture is passed through said first port and through said second port so that a first end of said suture is located externally of said suture driver device and a second weighted end of said suture is positioned at said first port.

38. The apparatus of Claim 37 wherein said second port is angled with respect to said first port such that said passage of said biocompatible fluid through said second port is minimized when said suture driver device is activated.

39. An apparatus for securing the free ends of a suture that have passed through an internal body part of a living being, said apparatus comprising:

a ring having an inner surface with a plurality of channels, each of said channels comprising teeth;

a corresponding plug that fits snuggly within an opening of said ring;

wherein the free ends of the suture are passed through said opening in said ring and each one of said free ends are positioned in respective ones of said plurality of channels and wherein said plug is then positioned snuggly within said opening and wherein said ring and plug are positioned against said internal body part.

40. A strain gauge device for detecting the tension applied to the free ends of a suture that has passed through the body part of a living being, said strain gauge device comprising a housing that can be coupled to the free ends of the suture, said housing comprising:

a strain gauge or load cell for detecting the strain or load applied to the suture;

a display, coupled to said strain gauge or load cell, for displaying tension values;

a stepper motor, coupled to said display, for increasing or decreasing applied tension to the suture; and

control keys coupled to said display and to said stepper motor for permitting a user to control the tension applied to the suture.

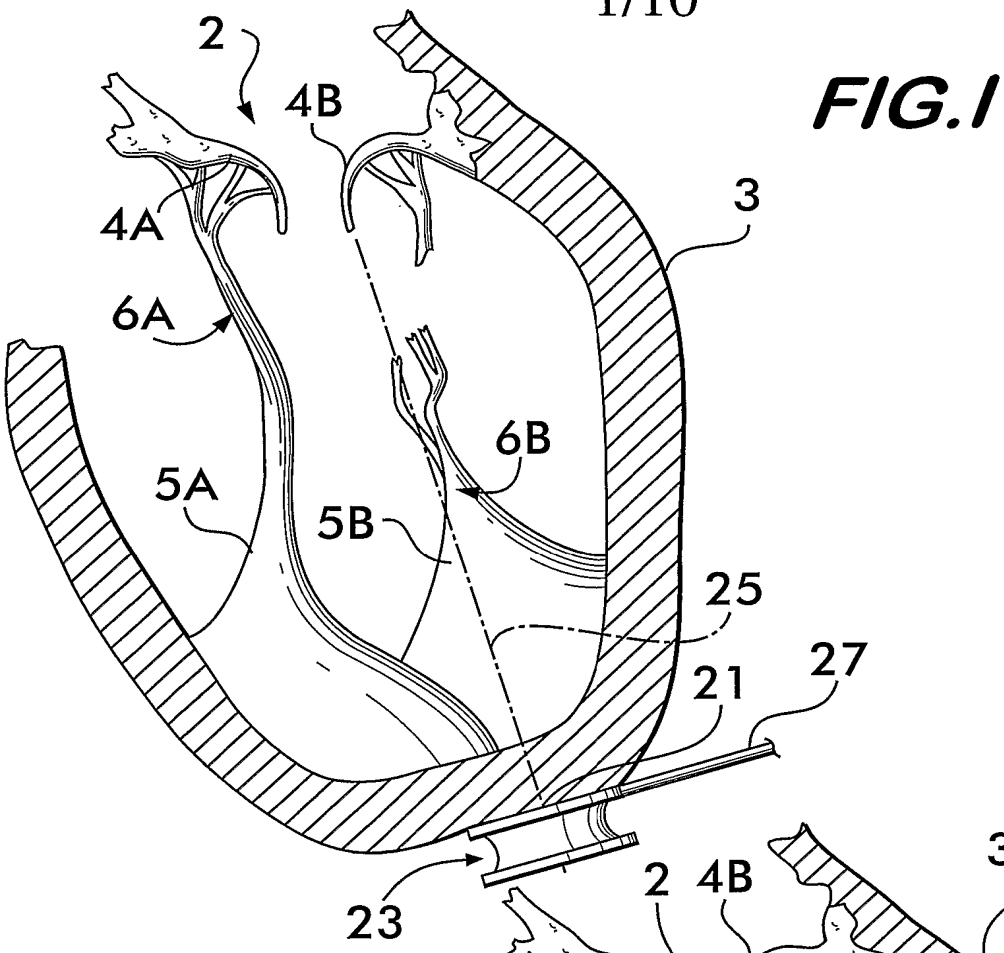

2
4B
3
4A
6A
6B
5A
5B
25
21
27
23

FIG.1

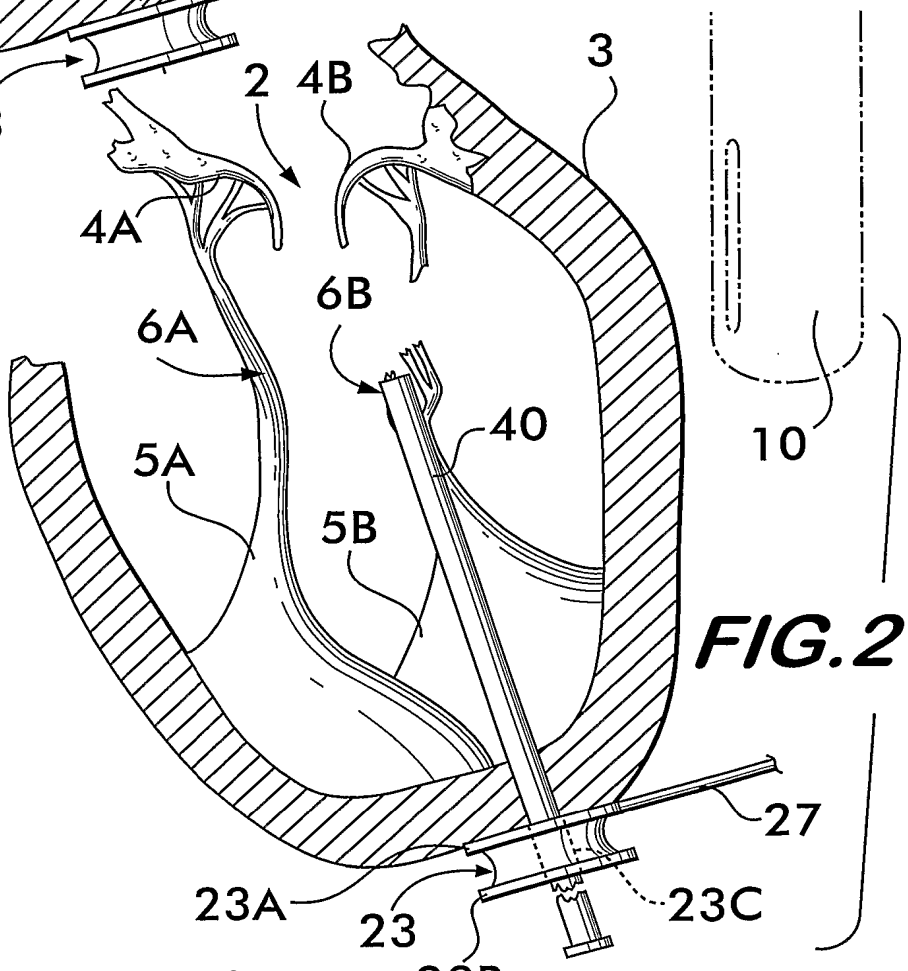

3
2
4B
4A
6B
6A
40
10
5A
5B
27
23A
23C
23
23B

FIG.2

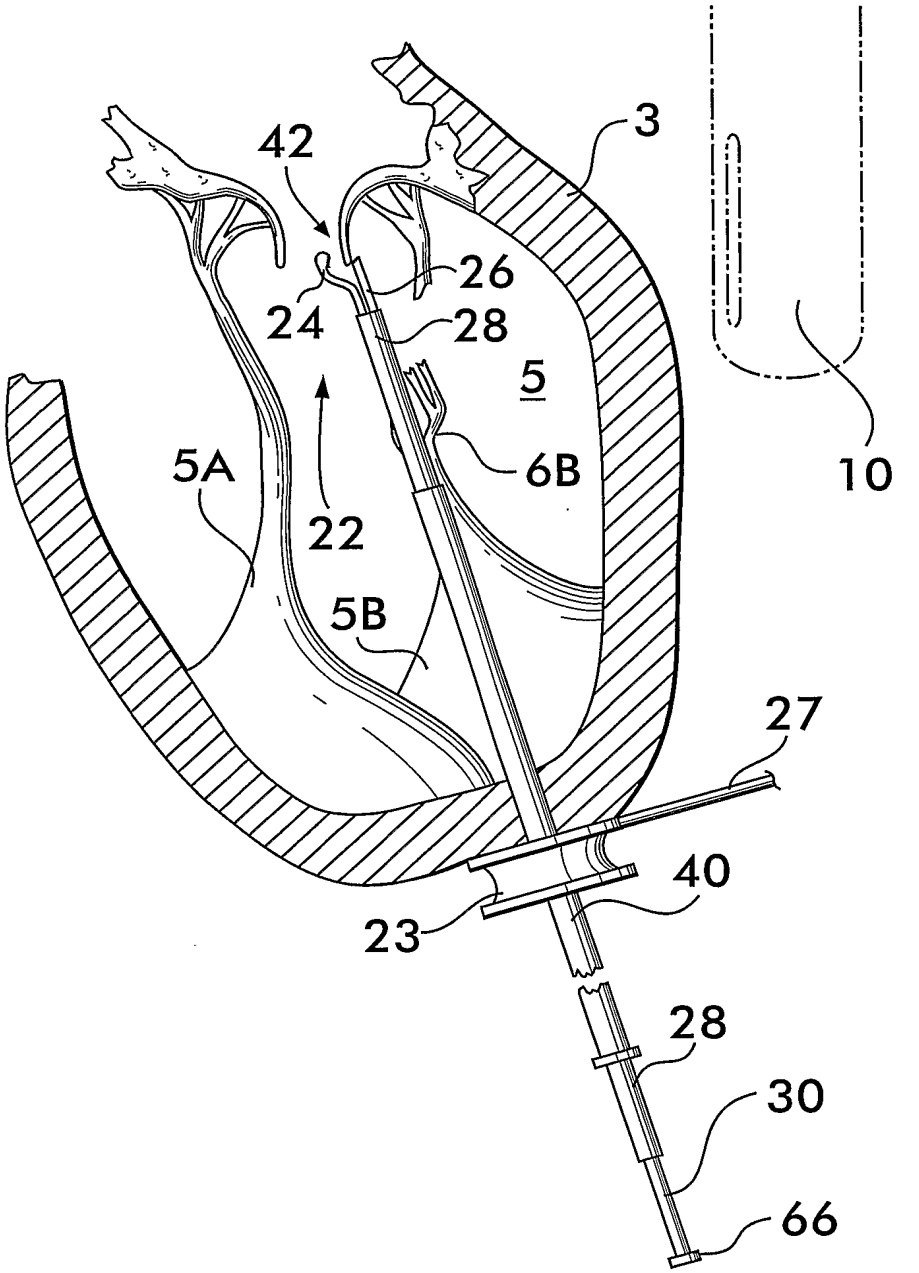


FIG.3

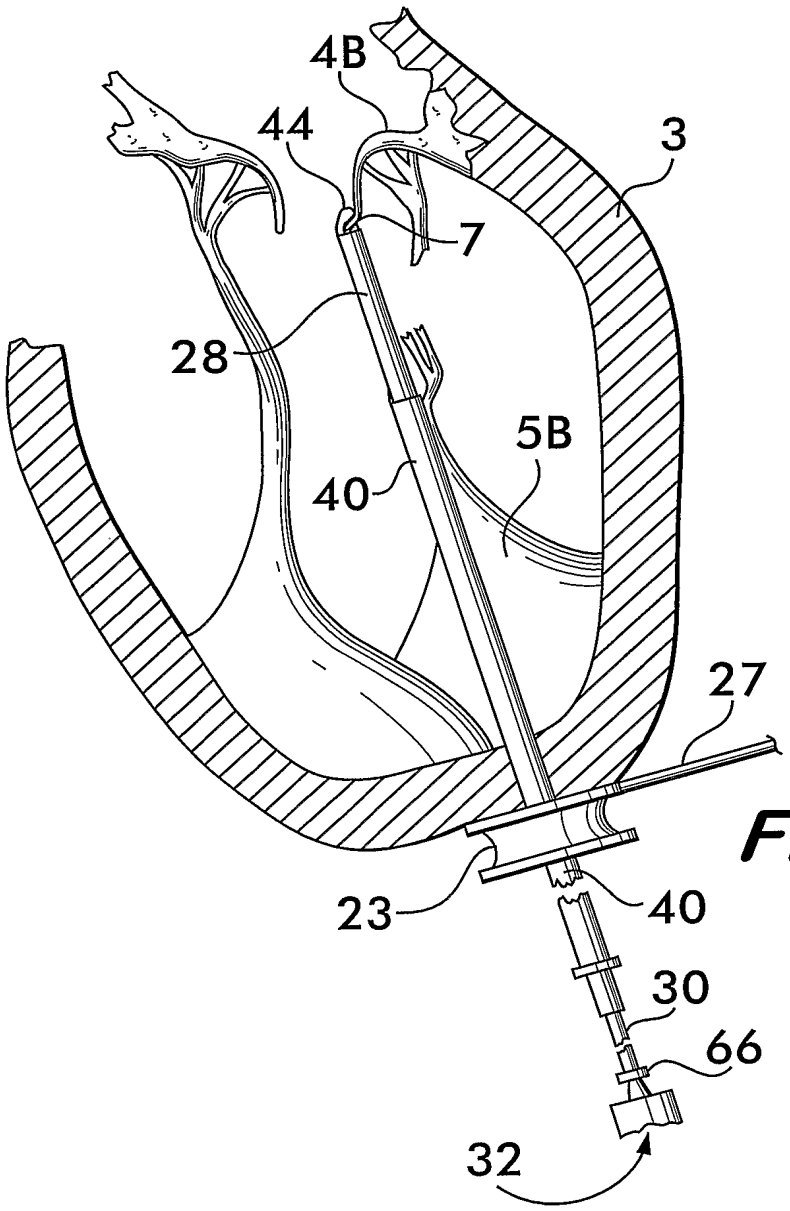


FIG.4

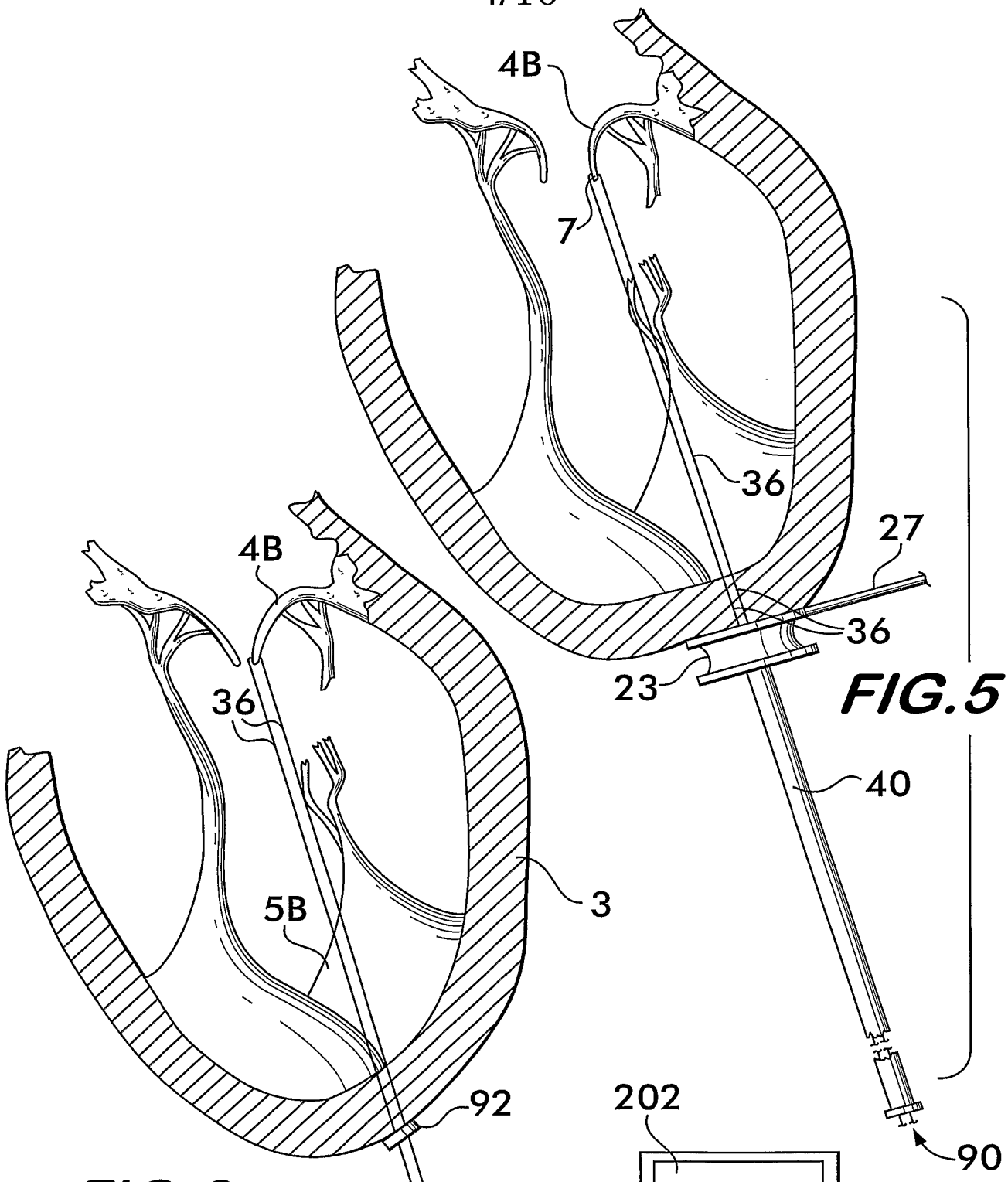

4B
7
36
27
36
23
40
90
4B
36
5B
3
92
202
Display
200
Activate
Reverse
Power
204
200

FIG.5

FIG.6

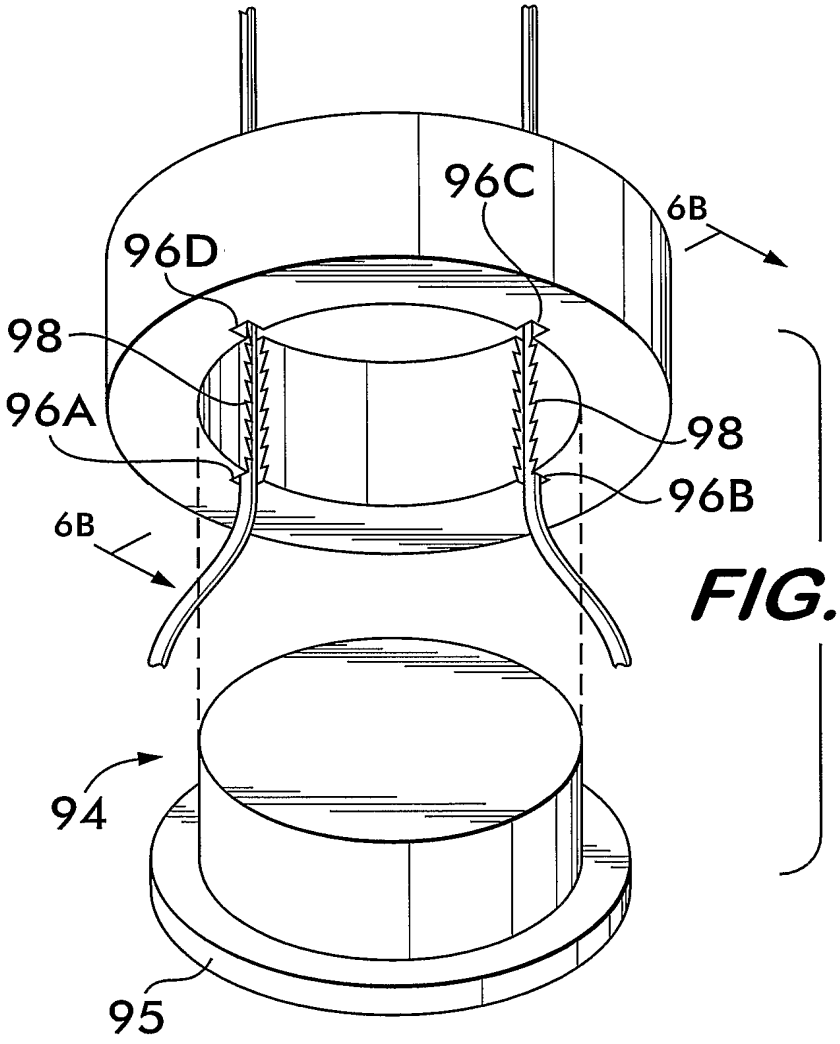


FIG. 6A

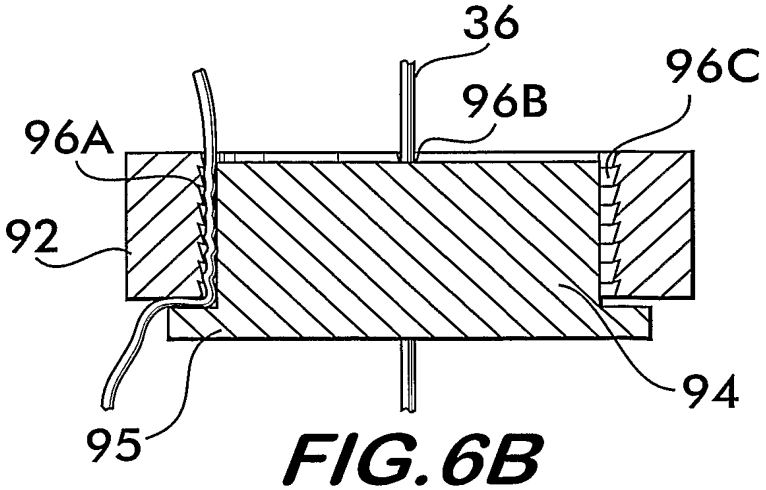
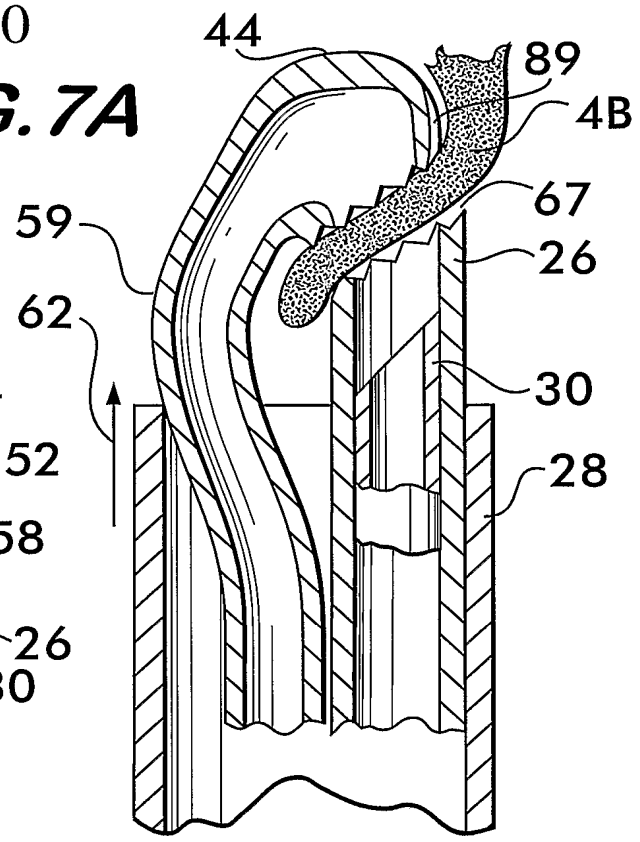


FIG. 6B

FIG. 7A



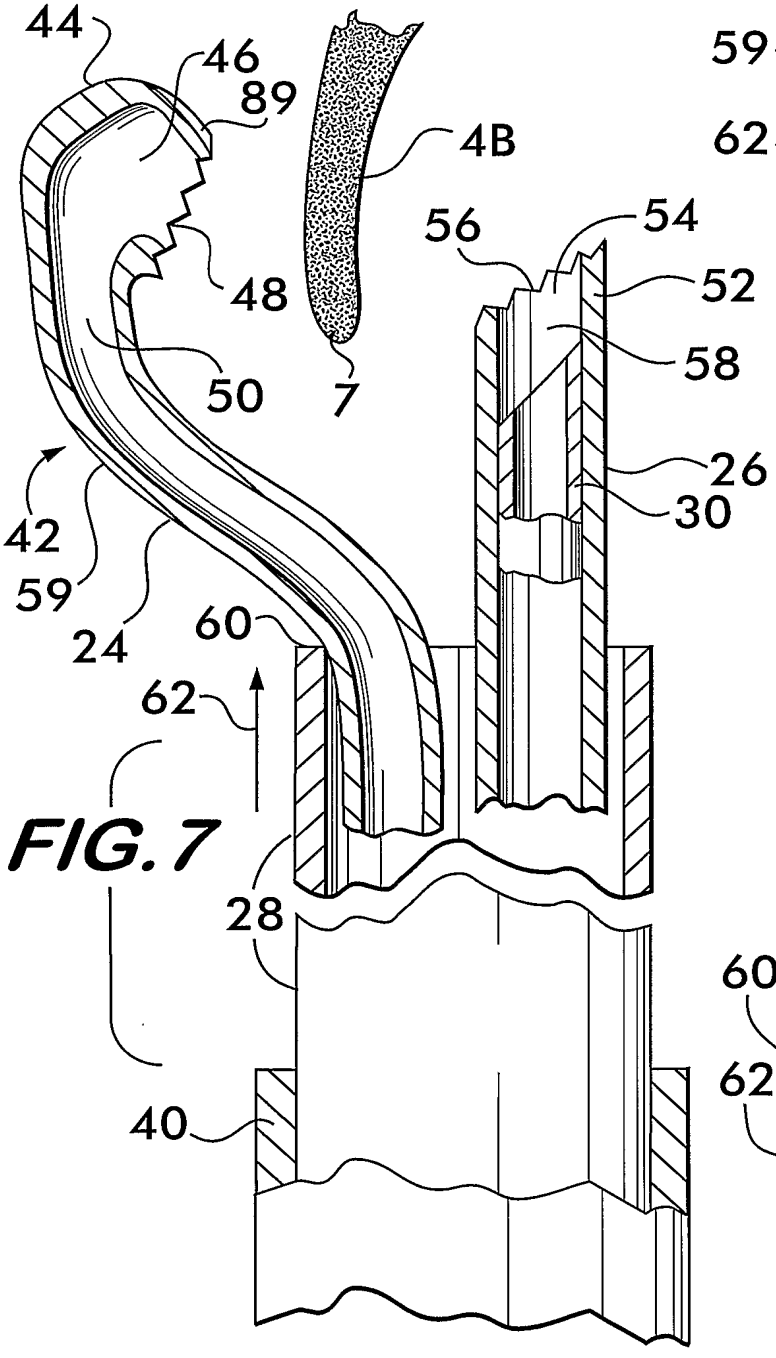


FIG. 7

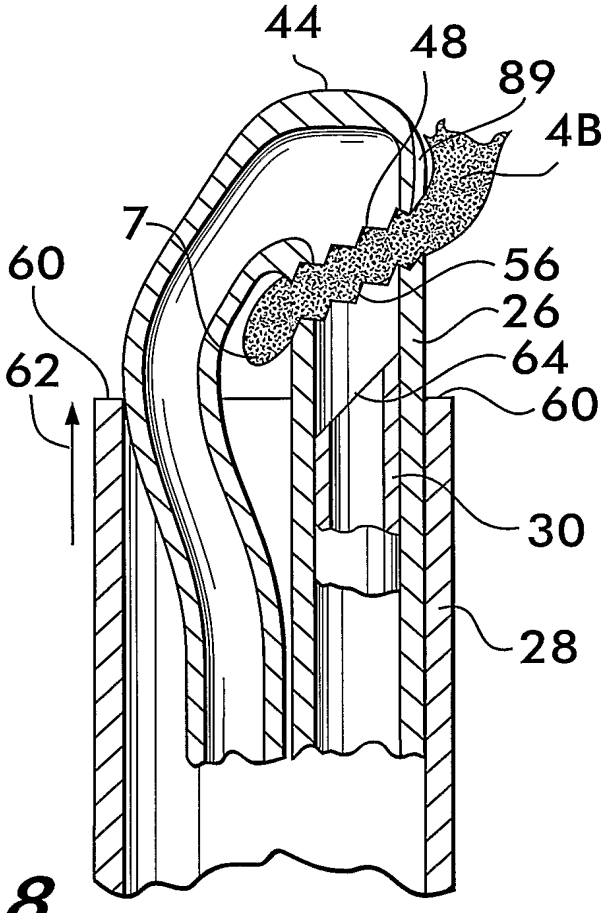


FIG. 8

FIG.9

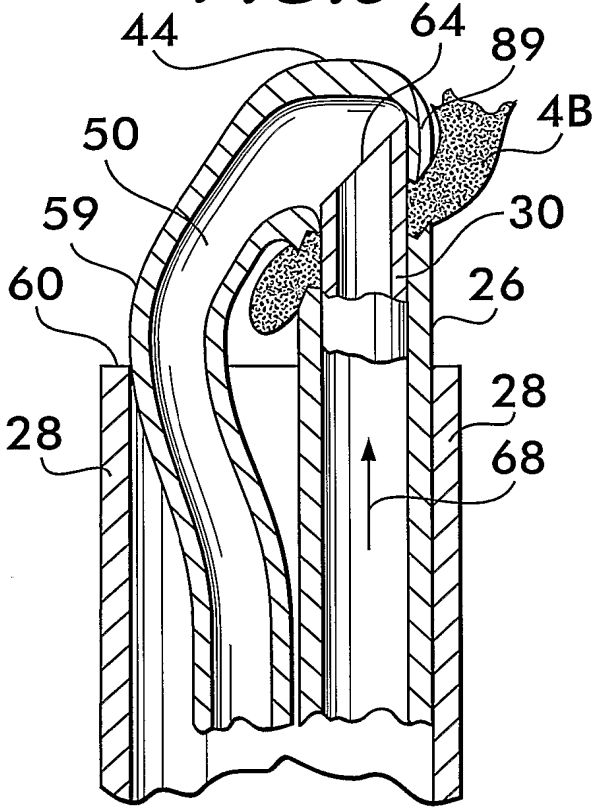
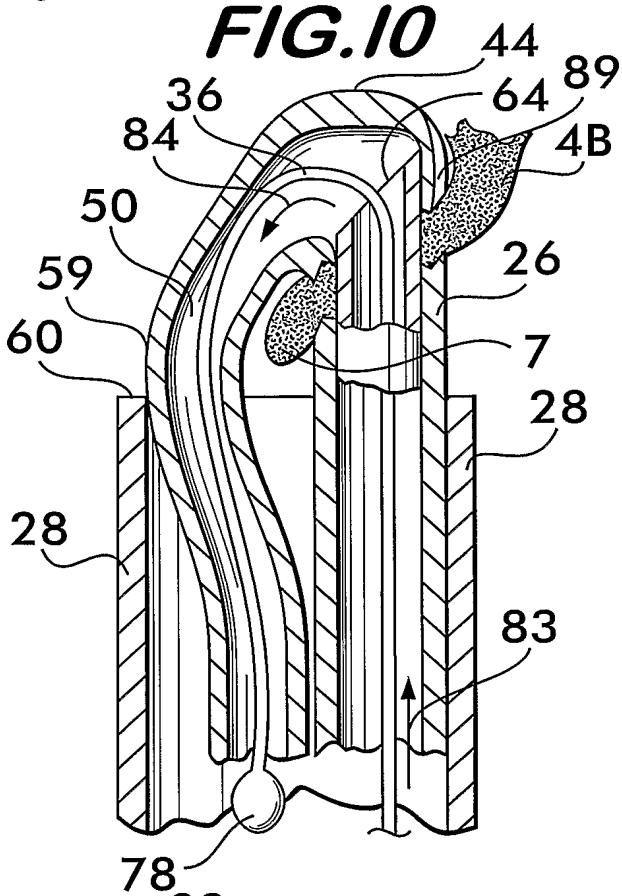


FIG.10



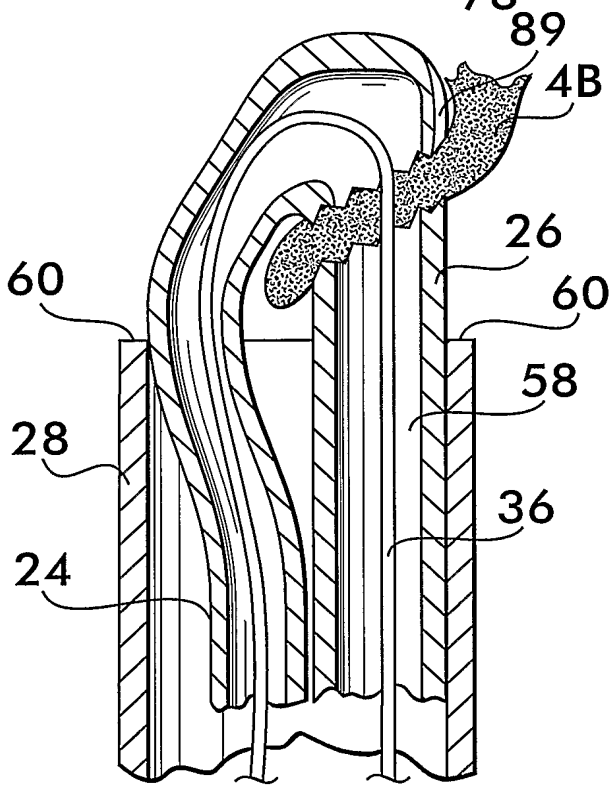


FIG.11

FIG.12

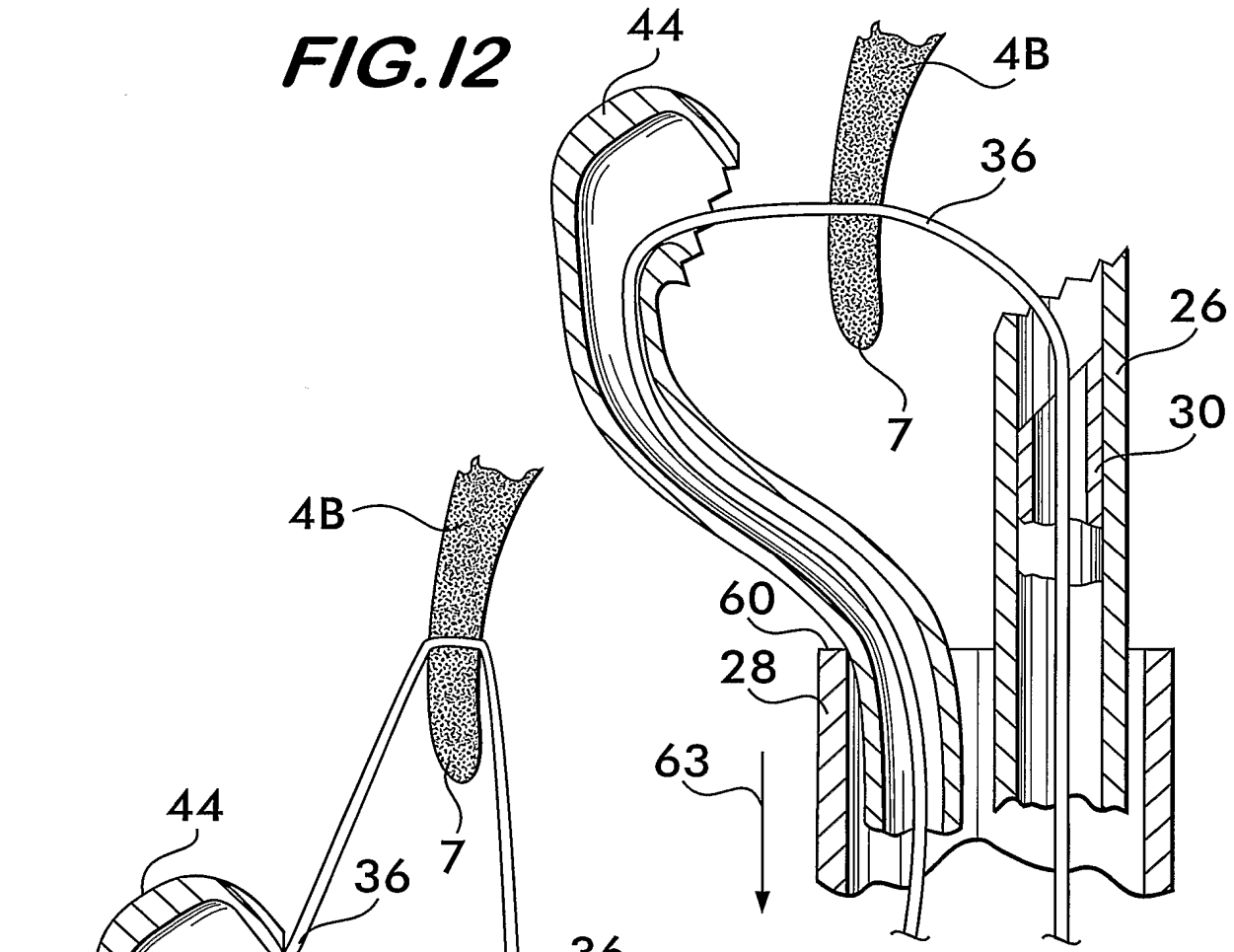


FIG.13

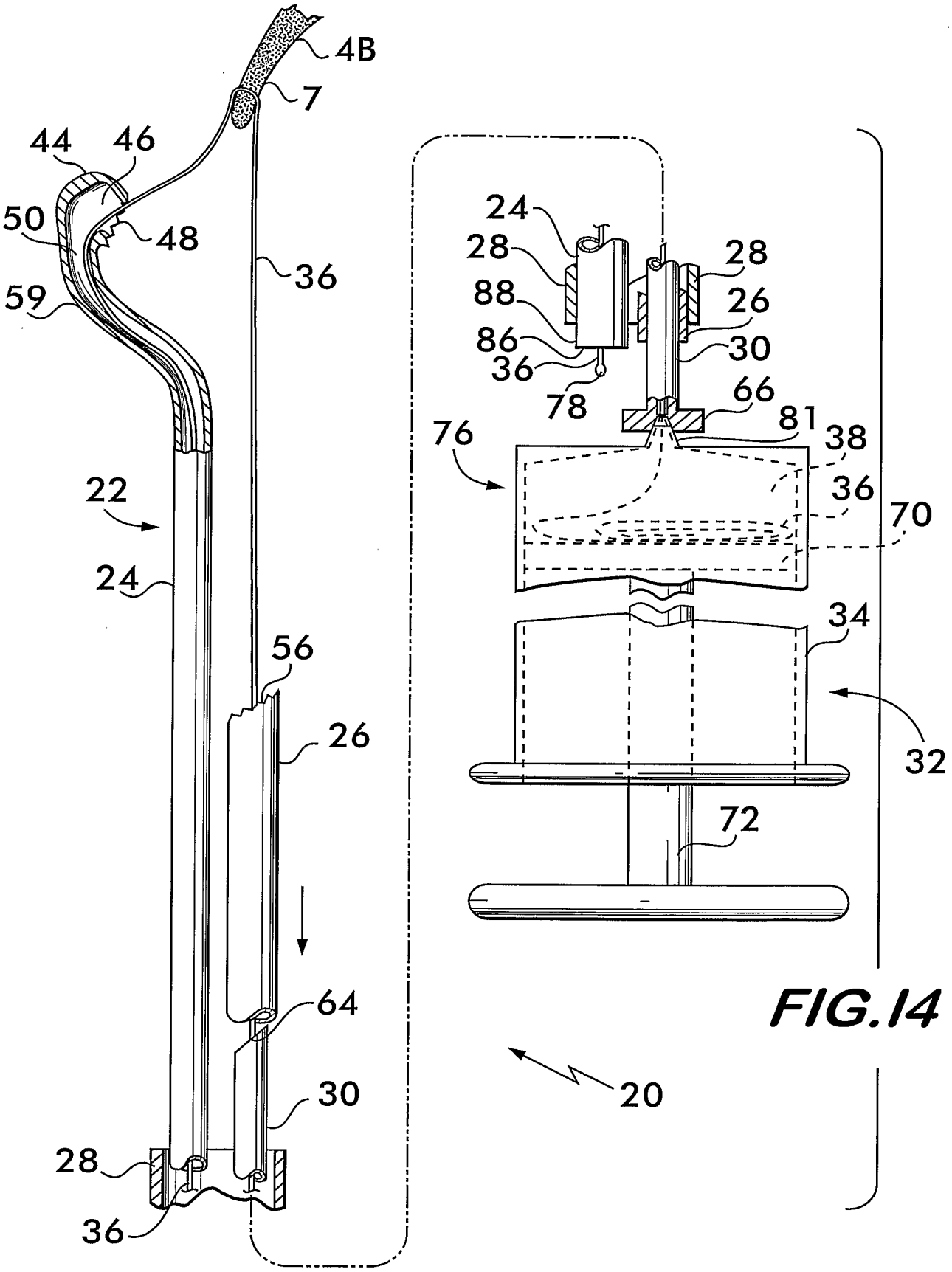

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FIG.14

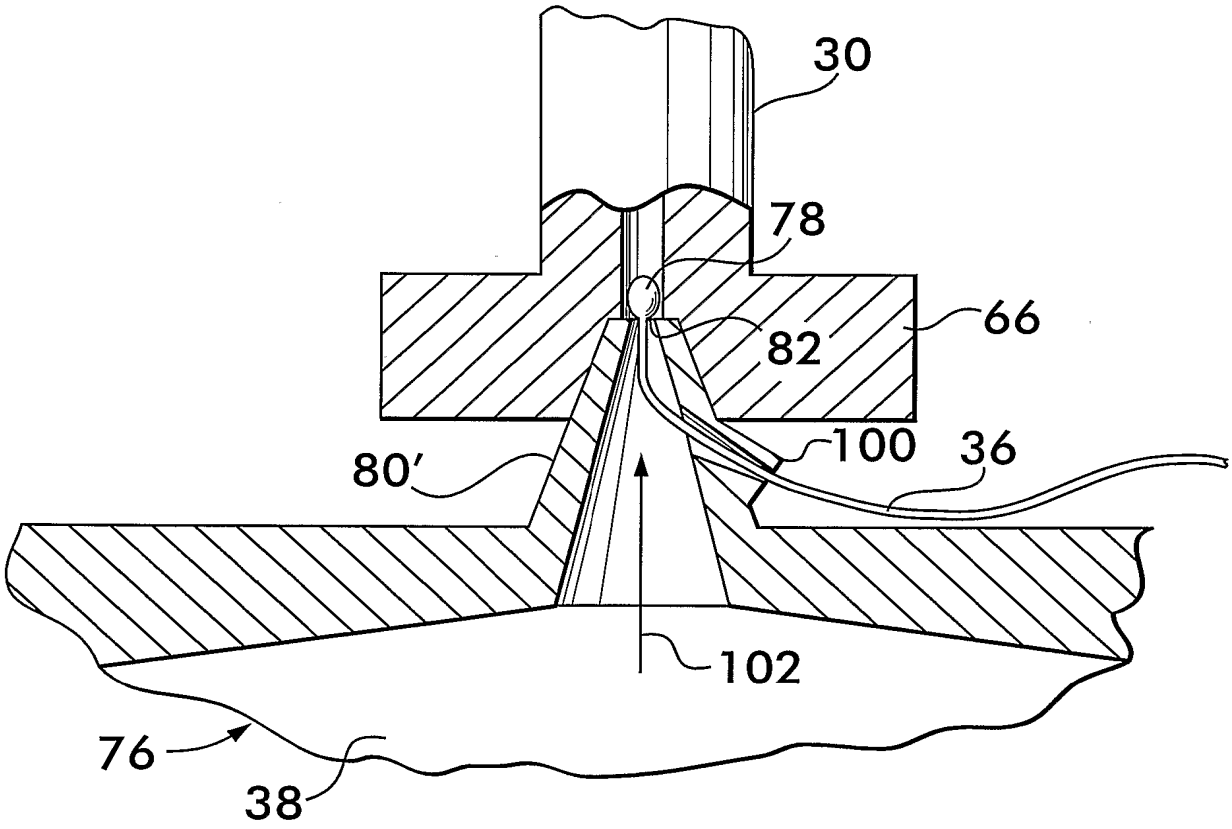

FIG. 14A

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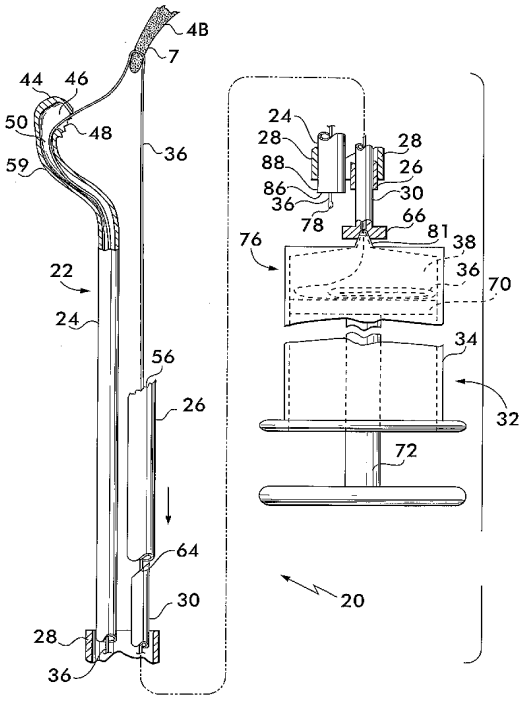
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ,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

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

Published:
— *with international search report*

[Continued on next page]

(54) Title: APPARATUS AND METHOD FOR MITRAL VALVE REPAIR WITHOUT CARDIOPULMONARY BYPASS, INCLUDING TRANSMURAL TECHNIQUES



(57) Abstract: A method and apparatus for repairing the heart's mitral valve by using anatomic restoration without the need to stop the heart, use a heart-lung machine or making incisions on the heart. The method involves inserting a leaflet clamp through the heart's papillary muscle from which the leaflet has been disconnected, clamping the leaflet's free end and then puncturing the leaflet. One end of a suture is then passed through the hollow portion of the clamp, while the other end of the suture is maintained external to the heart. The clamp is then removed and the suture's two ends are fastened together with a securement ring/locking cap assembly to the heart wall exterior, thereby reconnecting the leaflet to the corresponding papillary muscle. The introduction of the clamp, puncturing of the leaflet, passage of the suture therethrough and removal of the clamp can be conducted a plurality of times before each suture's two ends are fastened to the securement ring/locking cap assembly.

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— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(88) Date of publication of the international search report:
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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/032308

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/04

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/107531 A1 (SCHRECK STEFAN G [US] ET AL) 8 August 2002 (2002-08-08) paragraph [0064]; figures 4a-4c paragraph [0070]; figures 6a-6c figure 5b	18
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A	US 2004/167573 A1 (WILLIAMSON WARREN P [US] ET AL) 26 August 2004 (2004-08-26) paragraph [0115]; figures 2-5	18
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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
9 May 2007	18/05/2007

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Ducreau, Francis

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/032308

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98/48704 A (BETH ISRAEL HOSPITAL [US]; COHN WILLIAM [US]) 5 November 1998 (1998-11-05) page 7, line 2 - line 11; figure 1 page 8, line 20 - line 24; figure 4	33
X	DE 198 28 099 A1 (RUDOLF GMBH MEDIZINTECHNIK [DE]) 30 December 1999 (1999-12-30) abstract; figure 1	33
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A	EP 1 016 377 A2 (DEPUY ORTHOPAEDICS INC [US] ETHICON INC [US]) 5 July 2000 (2000-07-05) paragraph [0017]; figures 5,6	39
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A	WO 99/04699 A (INNOVASIVE DEVICES INC [US]) 4 February 1999 (1999-02-04) figures 9,10	39

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/032308

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

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

1. [X] Claims Nos.: 1-17
because they relate to subject matter not required to be searched by this Authority, namely:

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

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

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

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

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

see additional sheet

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

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

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

18-33,39

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

Remark on Protest

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

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

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 18-32

   Apparatus for repairing the mitral valve of a heart wherein at least one leaflet has suffered a defect with respect to its papillary muscle, said apparatus comprising a clamp, an external cylinder, a hollow piercing member and a suture driver device.

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2. claim: 33

   Apparatus for stabilizing a portion of the heart wall of a beating heart to permit the transmural introduction of surgical instruments through the heart, said apparatus comprises a housing having a first support surface, a central passageway and an extension formed with said first support surface.

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3. claims: 34-36

   A suture driver device comprising a syringe, a chamber filled with a biocompatible fluid and with a suture.

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4. claims: 37,38

   A suture driver comprising a syringe, a first port, a second port and a chamber filled with a biocompatible fluid and with a suture.

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5. claim: 39

   Apparatus for securing the free ends of a suture that have passed through an internal body part of a living being, said apparatus comprising a ring and a corresponding plug.

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6. claim: 40

   A strain gauge device comprising a housing that can be coupled to the free ends of the suture, said housing comprising a strain gauge or load cell, a display, a stepper motor and control keys.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2006/032308

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2006/032308

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9904699 A		US 5902321 A	11-05-1999

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31 May 2007 (31.05.2007)

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PCT/US2006/045217

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22 November 2006 (22.11.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
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(71) Applicant and
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(74) Agent: **REESER, Robert, B.**; One Metropolitan Square, Suite 2600, St. Louis, MO 63102 (US).

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

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

Published:
— *without international search report and to be republished upon receipt of that report*

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

(54) Title: METHODS AND APPARATUS FOR ATRIOVENTRICULAR VALVE REPAIR

(57) Abstract: Methods and apparatus for use in repairing an atrioventricular valve in a patient are provided. The methods comprise accessing the patient's atrioventricular valve percutaneously, securing a fastening mechanism to a valve leaflet, and coupling the valve leaflet, while the patient's heart remains beating, to at least one of a ventricular wall adjacent the atrioventricular valve, a papillary muscle, at least one valve chordae, and a valve annulus to facilitate reducing leakage through the valve.

WO 2007/062128 A2

METHODS AND APPARATUS FOR ATRIOVENTRICULAR VALVE REPAIR

BACKGROUND OF THE INVENTION

[0001] This invention relates generally to medical methods and apparatus, and more particularly, to methods and apparatus for the endovascular or minimally invasive surgical repair of atrioventricular valves of the heart, including the mitral valve and the tricuspid valve.

[0002] The heart includes four valves that direct blood through the two sides of the heart. The mitral valve lies between the left atrium and the left ventricle and controls the flow of blood into the left side of the heart. The valve includes two leaflets, an anterior leaflet and a posterior leaflet, that close during systole. The leaflets are passive in that they open and close in response to pressure induced to the leaflets by the pumping of the heart. More specifically, during a normal cycle of heart contraction (systole), the mitral valve functions as a check valve to prevent the flow of oxygenated blood back into the left atrium. In this manner, oxygenated blood is pumped into the aorta through the aortic valve.

[0003] Occasionally, the mitral valve is formed abnormally through a congenital condition. More often, however, the mitral valve degenerates with age. Among the problems that can develop is mitral valve regurgitation in which the mitral valve leaflets become unable to close properly during systole, thus enabling leakage to flow through the mitral valve during systole. Over time, regurgitation of the mitral valve can adversely affect cardiac function and may compromise a patient's quality of life and/or life-span.

[0004] Mitral valve regurgitation can result from a number of different mechanical defects in the mitral valve. For example, the valve leaflets, the valve chordae which connect the leaflets to the papillary muscles, or the papillary muscles themselves may become damaged or otherwise dysfunctional. Moreover, the

valve annulus may become damaged or weakened and may limit the ability of the mitral valve to close adequately during systole.

[0005] Known treatments for mitral valve regurgitation commonly rely on valve replacement or annuloplasty, or strengthening of the mitral valve through surgical repairs and/or implanting a mechanical structure within the mitral valve. For example, the most prevalent and widely accepted known techniques to correct mitral valve regurgitation, repair the mitral valve via open heart surgery. During such an invasive surgical procedure, it is known to suture adjacent segments of the opposed valve leaflets together in a procedure known as a "bow-tie" or "edge-to-edge" surgical technique. Although each of the afore-mentioned treatments can be effective, generally known treatments rely on open heart surgery wherein the patient's chest is opened and the patient's heart is stopped while the patient is place on a cardiopulmonary bypass. The need to open the patient's chest and to place the patient on a cardiopulmonary bypass creates inherent risks that may be traumatic to the patient.

[0006] Percutaneously treatments are less invasive than the treatments mentioned above, but such treatments may be less effective and more difficult to effect repair because of the limited amount of space in and around the mitral valve in which to maneuver a repair device or devices. For example, U.S. Patent No. 6,875,224 to Grimes describes a percutaneous mitral valve repair method in which the opposed leaflets are each immobilized to enable the two leaflets to be fastened together. Furthermore, U.S. Patent No. 6,6290,534 to St. Goar et al. describes a plurality of embodiments for use in endovascular repair of cardiac valves in which, in each embodiment, both leaflets are grasped and held firmly in position prior to permanent treatment. However, grasping both leaflets while the patient's heart is beating may be a time-consuming and laborious task that demands a coordinated effort on the part of the surgical team. Moreover, to facilitate grasping both leaflets percutaneously may require that the patient's heart be temporarily stopped or slowed by drugs or other techniques. Slowing and/or stopping the patient's heart during surgery may increase the risks to the patient.

BRIEF DESCRIPTION OF THE INVENTION

[0007] In one aspect, a method of repairing an atrioventricular valve in a patient is provided. The method comprises accessing the patient's atrioventricular valve percutaneously, securing a fastening mechanism to a valve leaflet, and coupling the valve leaflet, while the patient's heart remains beating, to at least one of a ventricular wall adjacent the atrioventricular valve, a papillary muscle, at least one valve chordae, and a valve annulus to facilitate reducing leakage through the valve.

[0008] In another aspect, a method of repairing a mitral valve in the heart of a patient is provided. The method comprises accessing the patient's mitral valve percutaneously, securing a first end of a fastening mechanism to a valve leaflet of the mitral valve, and coupling a second end of the fastening mechanism to a cardiac structure other than a mitral valve leaflet to facilitate reducing leakage through the patient's mitral valve during ventricular systole.

[0009] In a further aspect, a method of enhancing operation of a patient's heart valve is provided. The method comprises inserting a guide catheter along the venous system of the patient to approach the mitral valve, guiding a fastening mechanism towards one of a mitral valve and a tricuspid valve within the patient's heart, and securing a first end of the fastening mechanism to one of the mitral valve and the tricuspid valve using one of fusing, gluing, stapling, clipping, riveting, anchoring, and suturing. The method also comprises securing a second end of the fastening mechanism to a cardiac structure other than a valve leaflet to facilitate enhancing operation of the valve during ventricular systole.

[0010] In an additional aspect, a medical kit for use in repairing a mitral valve is provided. The kit includes a guide catheter and a fastening mechanism. The guide catheter is configured for insertion along the venous system of the patient to approach the mitral valve. The fastening mechanism is positionable percutaneously within the patient using the guide catheter. The fastening mechanism includes a first end and an opposite second end. The first end is configured to couple

to the mitral valve using one of fusing, gluing, stapling, clipping, riveting, anchoring, and suturing. The second end is configured to only couple to a cardiac structure other than a valve leaflet to facilitate enhancing operation of the valve during ventricular systole.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Figure 1 is a cross-sectional view of the left and right ventricles of a human heart in diastole;

[0012] Figure 2 is an another cross-sectional view of the heart shown in Figure 1 during systole;

[0013] Figure 3 is an exemplary schematic illustration of a fastening mechanism that may be used to facilitate repair of a cardiac valve within the heart shown in Figures 1 and 2;

[0014] Figure 4 is an enlarged view of a portion of the fastening mechanism shown in Figure 2 and coupled to a papillary muscle in the heart shown in Figures 1 and 2;

[0015] Figure 5 is a schematic view of an alternative embodiment of a portion of a fastening mechanism that may be used to facilitate repair of a cardiac valve within the heart shown in Figures 1 and 2;

[0016] Figure 6 is a schematic view of an another alternative embodiment of a portion of a fastening mechanism that may be used to facilitate repair of a cardiac valve within the heart shown in Figures 1 and 2;

[0017] Figure 7 is a schematic view of a further alternative embodiment of a portion of a fastening mechanism that may be used to facilitate repair of a cardiac valve within the heart shown in Figures 1 and 2; and

[0018] Figure 8 is a flowchart illustrating an exemplary method for the endovascular repair of a cardiac valve.

DETAILED DESCRIPTION OF THE INVENTION

[0019] Figure 1 is a cross-sectional view of the left and right ventricles 10 and 12, respectively, of a human heart 14 during diastole. Ventricles 10 and 12 are separated by an interatrial septum 15. Figure 2 is a cross-sectional view of heart 14 during systole. The present invention provides methods and apparatus for the endovascular repair of cardiac valves, particularly atrioventricular valves 16, which inhibit back-flow of blood from a heart ventricle during contraction (systole). In particular, the present invention may be used in repairing, but is not limited to repairing, mitral valves 20.

[0020] As used herein, the term "endovascular," refers to procedure(s) of the present invention that are performed with interventional tools and supporting catheters and other equipment introduced to the heart chambers from the patient's arterial or venous vasculature remote from the heart. The interventional tools and other equipment may be introduced percutaneously, i.e., through an access sheath, or may be introduced via a surgical cut down, and then advanced from the remote access site through the vasculature until they reach heart 14. As such, the methods and apparatus described herein generally do not require penetrations made directly through an exterior heart muscle, i.e., myocardium, although there may be some instances where penetrations will be made interior to the heart, e.g., through the interatrial septum to provide for a desired access route. Moreover, as will be appreciated by one of ordinary skill in the art, the methods and apparatus described herein are not limited to use with percutaneous and intravascular techniques, but rather the present invention may be used with open surgical procedures as well.

[0021] The atrioventricular valves 16 are each located at a junction of the atria and their respective ventricles. The atrioventricular valve 16 extending between the right atrium 30 and the right ventricle 12 has three valve leaflets (cusps) and is referred to as the tricuspid or right atrioventricular valve 31. The atrioventricular valve 16 between the left atrium 32 and the left ventricle 10 is a

bicuspid valve having only two leaflets or cusps 34 and is generally referred to as the mitral valve 20.

[0022] During operation of the heart 14, the valve leaflets 34 open during diastole when the heart atria fill with blood, allowing the blood to pass into the ventricle. During systole, however, the valve leaflets 34 are pushed together such that the free edges 36 of the leaflets 34 are closed against each other along a line of coaptation to prevent the back-flow of blood into the atria. Back flow of blood or "regurgitation" through the mitral valve 20 is facilitated to be prevented when the leaflets 34 are closed, such that the mitral valve 20 functions as a "check valve" which prevents back-flow when pressure in the left ventricle 10 is higher than that in the left atrium 32.

[0023] The mitral valve leaflets 34 are attached to the surrounding heart structure along an annular region referred to as the valve annulus 40. The free edges 36 of the leaflets 34 are secured to the lower portions of the left ventricle 10 through tendon-like tissue structures, known as chordae tendineae or chordae 42. The chordae 42 are attached to the papillary muscles 44 which extend upwardly from the lower portions of the left ventricle and interventricular septum 46.

[0024] A number of structural defects in the heart can cause mitral valve regurgitation. For example, ruptured chordae 42 may cause a valve leaflet 34 to prolapse if inadequate tension is induced to the leaflet 34 through the remaining unruptured chordae 42. Moreover, and for example, regurgitation may also occur in patients suffering from cardiomyopathy, wherein the heart 14 is dilated and the increased size prevents the valve leaflet edges 36 from contacting each other properly, or in patients who have suffered ischemic heart disease wherein the functioning of the papillary muscles 44 may be impaired. Generally during regurgitation the free edges 36 of the anterior and posterior leaflets 34 do not contact sufficiently along the line of coaptation, but rather leakage may occur through a gap defined between the leaflets 34.

[0025] Figure 3 is an exemplary schematic illustration of a fastening mechanism 50 that may be used to facilitate repair of an atrioventricular valve 16 within heart 14 (shown in Figures 1 and 2). Figure 4 is an enlarged view of a portion of the fastening mechanism shown in Figure 3 and coupled to a papillary muscle 44. Fastening mechanism 50 includes a first attachment end 60 and a second attachment end 62. In the exemplary embodiment, first attachment end 60 includes a generally deformable clip portion 64 that is sized and shaped to couple to a free edge 36 (shown in Figures 1 and 2) of a leaflet 34 (shown in Figures 1 and 2). In alternative embodiments, first attachment end 60 is coupled to leaflet 34 without using clip portion 64.

[0026] Overall dimensions of, and material properties used in fabricating, clip portion 64 are variably selected based on the leaflet 34 being repaired. In the exemplary embodiment, portion 64 is pinched or crimped against a leaflet free edge 36 to facilitate repair of the valve as described in more detail below. More specifically, in this embodiment, fastening mechanism 50 is coupled to valve 16 such that an outer surface of leaflet free edge 36 is grasped without mechanism 50 penetrating the leaflet tissue. Specifically, in the exemplary embodiment, the leaflet free edge 36 is crimped between opposing sides 66 and 68 of portion 64. In another embodiment, portion 64 is coupled to a free edge 36 using any suitable means that enables portion 64 to remain coupled to leaflet free edge 36, such as, but not limited to, with gluing, stapling, suturing, fusing, riveting, external clips, or any combination thereof.

[0027] Alternatively, first attachment end 60 may be secured to leaflet 34 through atraumatic partial, or full penetration, or piercing of leaflet 34. For example, first attachment end 60 and/or portion 64 may include attachment prongs that extend from clip portion 64 and that are configured to pinch, partially penetrate, or pierce the leaflet 34. In one alternative embodiment, first attachment end 60 may be inserted from a first side of the leaflet 34, through leaflet 34, and outward from an opposite second side of the leaflet 34. In such an embodiment, in use first attachment end 60 is coupled to, and secured against the second side of the leaflet. In another

alternative embodiment, first attachment end is inserted only partially through the leaflet 34, and thus is secured to leaflet tissue intermediate the first and second sides of the leaflet.

[0028] In another alternative embodiment, first attachment end 60 is attached to leaflet 34 using any suitable means that will enable fastening mechanism 50 to function as described herein, such as, but not limited to, an adhesive process, a riveting process, a suturing process, a stapling process, or any combination thereof. In a further alternative embodiment, a threaded locking member or any other suitable mechanical coupling, may be used to secure first attachment end 60 to the leaflet. In another alternative embodiment, attachment end 60 may be fused directly to the leaflet 34 using a known fusion process in which laser, RF, microwave or ultrasonic energy, for example, is applied at specified coaptation points.

[0029] In the exemplary embodiment, clip portion 64 is fabricated from a formable material that is coated in a protective cloth-like material. Clip portion 64 may be fabricated from any suitable biocompatible material that enables fastening mechanism 50 to function as described herein, such as, but not limited to, titanium alloys, platinum alloys, stainless steel, or any combination thereof. In the exemplary embodiment, clip portion 64 is coated with a fabric material such as, but not limited to, a DACRON® material, a TEFLON® material, a GORE-TEX®, or any material or combination thereof that enables clip portion 64 to function as described herein. In one embodiment, clip portion 64 is covered by a material that encourages tissue in-growth.

[0030] In the exemplary embodiment, a tensioning member 70 extends from clip portion 64 to second attachment end 62. The overall size, shape, and material used in member 70 is variably selected depending on the application. For example, in one embodiment, member 70 is fabricated from a mesh material. The relative location of member 70 with respect to clip portion 64 is variably selected based on the amount of tension to be induced, the desired locations for the tension to be induced, and based on the leaflet 34 being repaired.

[0031] In the exemplary embodiment, tensioning member 70 includes an attachment pad 74. The overall size, shape, thickness, and material used in fabricating pad 74, as well as the number and location of pad 74, are variably selected based on the intended use of fastening mechanism 50. Alternatively, fastening mechanism 50 includes more than one tensioning member 70. In another alternative embodiment, fastening mechanism 50 may include a single tensioning member 70 that includes a forked or bifurcated end that includes two pads 74. In yet another alternative embodiment, fastening tensioning member 70 does not include pad 74. In a further alternative embodiment, fastening mechanism 50 includes at least one tensioning member that is formed with a looped end that is sized to circumscribe the cardiac structure to which it is attached, and is cinchable to facilitate securing fastening mechanism 50 to the papillary muscle 44. Tensioning member 70 facilitates inducing tension to the leaflet 34 being repaired, and pad 74 facilitates distributing loading across the papillary muscle 44. Moreover, pad 74 is sized for placement along an external surface of papillary muscle 44 when fastening mechanism 50 is coupled to the papillary muscle 44.

[0032] In the exemplary embodiment, tensioning member 70 and pad 74 are formed integrally together. Alternatively, pad 74 may be securely coupled to member 70 using any of a plurality of known coupling means. In the exemplary embodiment, member 70 is coupled to papillary muscle 44 using a fastener (not shown) that is inserted at least partially through papillary muscle 44. In one embodiment, the fastener has a tack-like configuration. In another embodiment, the fastener is mechanically coupled to the papillary muscle 44 using, for example, a suitable threaded coupling. In a further embodiment, at least one of a pair of interlocking fasteners is inserted through a pad 74 prior to insertion through the papillary muscle 44 and prior to the two fasteners being interlocked. In another embodiment, pad 74 is coupled in position against the papillary muscle 44 by a cinch-type fastener that circumscribes the papillary muscle 44 when securely cinched. In another alternative embodiment, pad 74 is coupled directly to the papillary muscle 44 using any suitable means that will enable fastening mechanism 50 to function as

described herein, such as, but not limited to, an adhesive process, a riveting process, a suturing process, a coil or corkscrew device, a stapling process, external clips, or any combination thereof. In a further alternative embodiment, a threaded locking member and a self-locking or spin-lock ratcheting fastener may be used to secure member 70 to the papillary muscle 44. In yet a further alternative embodiment, pad 74, and/or tensioning member 70 is coupled to the papillary muscle 44 using a flat ribbon that has been heat-set in the shape of double loops.

[0033] Pad 74 and member 70 may be fabricated from any material that enables pad 74 and member 70 to function as described herein. For example, pad 74 and member 70 may be fabricated from, but are not limited to being fabricated from, a DACRON® material, a TEFLON® material, a GORE-TEX®, or any material or combination. In addition, depending on the application, pad 74 and member 70 may be fabricated from, but are not limited to being fabricated from a superelastic material or a shaped memory alloy (SMA) material, such as, but not limited, to Nitinol®, stainless steel, plastic, or any of several known shaped memory alloys (SMA) that have properties that develop a shaped memory effect (SME). In one embodiment, pad 74 is fabricated from a material that encourages tissue in-growth.

[0034] During use, to repair a mitral valve 20 using fastening mechanism 50, first attachment end 60 is coupled securely to mitral valve 20 and second attachment end 62 is coupled to a cardiac structure, such as the papillary muscle 44. Alternatively, second attachment end 62 may be coupled to any cardiac structure other than a mitral valve leaflet 34 such as, but not limited to, a ventricular wall 46 adjacent the atrioventricular valve 30, a valve chordae 42, either intact or ruptured, a valve annulus 36, an interatrial septum 15 or any combination thereof. In the exemplary embodiment, second attachment end 62 is coupled to the papillary muscle 44. More specifically, when end 62 is firmly secured to the papillary muscle 44, pad 74 is retained tightly against the exterior surface of the papillary muscle 44. As such, loading induced to the papillary muscle from fastening mechanism 50 is distributed across pad 74.

[0035] In the exemplary embodiment, overall dimensions and material properties of member 70 are variably selected to facilitate inducing a desired tension to leaflet 34 and to facilitate improving the ability of the atrioventricular valve 16 to close against the elevated pressures within the ventricle during systole. More specifically, member 70 is variably selected to facilitate modifying operation of the leaflet 34 such that the free ends 36 of the opposed leaflets 34 again contact each other during systole along the line of coaptation to prevent the back-flow or regurgitation of blood through the mitral valve 20 into the atria.

[0036] Figure 5 is a schematic view of an alternative embodiment of a portion of a fastening mechanism 100 that may be used to facilitate repair of a cardiac valve 16 (shown in Figures 1 and 2). Fastening mechanism 100 is substantially similar to fastening mechanism 50 (shown in Figures 3 and 4) and, components of fastening mechanism 100 that are identical to components of fastening mechanism 50 are identified in Figure 5 using the same reference numerals used in Figures 3 and 4. Accordingly, fastening mechanism 100 includes first attachment end 60, second attachment end 62 (shown in Figures 3 and 4), and at least one tensioning member 110 extending therebetween. In the exemplary embodiment, tensioning member 110 includes an anchor member 112. It should be noted that although attachment end 60 is illustrated, the anchor member 112 may also be included at attachment end 62 and/or end 60, or at any suitable location between ends 60 and 62 depending on the application.

[0037] Tensioning member 110 is substantially similar to tensioning member 70 and as such, facilitates inducing tension to the leaflet 34 (shown in Figures 1 and 2) being repaired. In the exemplary embodiment, tensioning member 110 and anchor member 112 are formed integrally together. Alternatively, anchor member 112 may be securely coupled to tensioning member 110 using any of a plurality of known coupling means. In the exemplary embodiment, member 110 is coupled to leaflet 34 using anchor member 112, or any other cardiac structure other than a mitral valve leaflet 34, such as, but not limited to, a ventricular wall 46 (shown in Figures 1 and 2) adjacent the atrioventricular valve 30 (shown in Figures 1 and 2),

a valve chordae 42 (shown in Figures 1 and 2), either intact or ruptured, a valve annulus 36 (shown in Figures 1 and 2), an interatrial septum 15 (shown in Figures 1 and 2), a papillary muscle 44 (shown in Figures 1, 2, and 4), or any combination thereof.

[0038] In the exemplary embodiment, anchor member 112 has a distal end 114 that is pointed and is self-piercing that facilitates transmural attachment to a ventricular wall. Accordingly, the anchor member distal end 114 may be fabricated of any material having sufficient rigidity to pierce, and/or at least partially penetrate, through a portion of the cardiac component to which it is intended to be attached. For example, the distal end 114 may be fabricated from, but is not limited to being fabricated from, stainless steel, titanium, various shaped memory or superelastic materials, metal alloys, various polymers, and combinations thereof. Moreover, the geometries, tip sharpness, and dimensions of anchor member 112 are variably selected to ensure a desired amount of piercing, if any, occurs. In an alternative embodiment, the anchor member distal end 114 does not actually pierce the cardiac structure, but rather is positioned in a desired position by a surgical instrument, such as, but not limited to a piercing catheter or a needle.

[0039] In the exemplary embodiment, anchor member 112 includes a plurality of anchoring arms 120 that are biased outwardly from tensioning member 110. Alternatively, anchor member 112 may include, but is not limited to including, a plurality of penetrating and/or non-penetrating petals, wings, propellers, coils, arms, ribbons, tubes, loops, grappling hooks, barbs, or clips, that are extend outwardly from tensioning member 110 to enable fastening mechanism 100 to function as described herein. Moreover, in other embodiments, anchor member 112 may include expandable arms that expand outwardly from a compressed state. For example, in one embodiment, the arms 120 function similarly to an umbrella and include a pleated, supported material member that is biased outwardly, as described herein. Furthermore, the cross-sectional shape of arms 120 is illustrated as exemplary only. Rather, anchor member 112, arms 120, and tensioning member 110 may be fabricated

with any cross-sectional shape that enables fastening mechanism 100 to function as described herein.

[0040] In the exemplary embodiment, arms 120 are biased outwardly such as is possible using pre-shaped, resilient metallic rods, for example. Alternatively, the arms 120 may be fabricated from any suitable material and in any suitable manner that enables arms 120 to function as described herein. For example, arms 120 may be fabricated from, but are not limited to being fabricated from Nitinol®, stainless steel, plastic, superelastic alloys, polymers, or any of several known shaped memory alloys (SMA) that have properties that develop a shaped memory effect (SME). Moreover, arms 120 may be fabricated from, but are not limited to being fabricated from, a DACRON® material, a TEFLON® material, a GORE-TEX®, or any material or combination. In one embodiment, arms 120 are fabricated from a material that encourages tissue in-growth.

[0041] During installation, after distal end 114 has penetrated at least partially through the cardiac component to which it is being attached, arms 120 are advanced through the penetration or opening and are displaced outwardly. More specifically, as tensioning member 100 is withdrawn or retracted from the opening in an opposite direction to that of insertion within the opening, because arms 120 are biased outwardly from tensioning member 100. More specifically, the biasing of the arms 120 causes the arms 120 to contact the surface of the cardiac component radially outward from the opening, such that the arms 120 are not retractable through the opening as tensioning member 100 is withdrawn from the opening. Rather, as tensioning member 100 is withdrawn from the opening, anchor member 112 is secured against a tissue surface of the cardiac component.

[0042] Figure 6 is a schematic view of an alternative embodiment of a portion of a fastening mechanism 150 that may be used to facilitate repair of a cardiac valve 16 (shown in Figures 1 and 2). Fastening mechanism 150 is substantially similar to fastening mechanisms 50 and 100 (shown in Figures 3 and 4, and 5, respectively) and, components of fastening mechanism 150 that are identical to

components of fastening mechanism 50 and 100 are identified in Figure 6 using the same reference numerals used in Figures 3-5. Accordingly, fastening mechanism 150 includes first attachment end 60 (shown in Figures 3-5), second attachment end 62 (shown in Figures 3 and 4), and at least one tensioning member 152 extending therebetween. In the exemplary embodiment, tensioning member 152 includes an anchor member 156. It should be noted that although attachment end 62 is illustrated, the anchor member 156 may also be included at attachment end 60 and/or end 62, or at any suitable location between ends 60 and 62 depending on the application.

[0043] Tensioning member 152 is substantially similar to tensioning member 70, and/or tensioning member 110, and as such, facilitates inducing tension to the leaflet 34 (shown in Figures 1 and 2) being repaired. In the exemplary embodiment, tensioning member 152 and anchor member 156 are formed integrally together. Alternatively, anchor member 156 may be securely coupled to tensioning member 152 using any of a plurality of known coupling means. In the exemplary embodiment, member 152 is coupled to leaflet 34 using anchor member 156, or any other cardiac structure other than a mitral valve leaflet 34, such as, but not limited to, a ventricular wall 46 (shown in Figures 1 and 2) adjacent the atrioventricular valve 30 (shown in Figures 1 and 2), a valve chordae 42 (shown in Figures 1 and 2), either intact or ruptured, a valve annulus 36 (shown in Figures 1 and 2), an interatrial septum 15 (shown in Figures 1 and 2), a papillary muscle 44 (shown in Figures 1, 2, and 4), or any combination thereof.

[0044] In the exemplary embodiment, anchor member 156 is formed with a cork-screw or coil configuration and has a distal end 160 that is pointed and is self-piercing. Accordingly, the anchor member 156 may be fabricated of any material having sufficient rigidity to pierce, and/or at least partially penetrate, through a portion of the cardiac component to which it is intended to be attached. For example, the distal end 156 may be fabricated from, but is not limited to being fabricated from, stainless steel, titanium, various shape memory or superelastic materials, metal alloys, various polymers, and combinations thereof. In an alternative embodiment, the anchor member 156 is not self-tapping, but rather is threadably coupled within a

starter hole formed a surgical instrument, such as, but not limited to a piercing catheter or a needle.

[0045] In one embodiment, anchor member 156 may be formed from a shape memory wire that is annealed or heat-set in a straight configuration and then coiled. In such an embodiment, anchor member 156 may be processed to have different properties by varying the diameter and tension therein along its length. For example, when anchor member 156 is heated to a pre-determined temperature, such as with RF energy, a designated portion of anchor member 156 will become a randomly oriented mass of material having self-locking struts to prevent disentanglement. When the anchor member 156 is heated to a different pre-determined temperature, a full entanglement of occurs such that anchor member 156 is compressed together.

[0046] In an alternative embodiment, anchor member 156 includes a plurality of tines or arms that are biased outwardly from member 156, and more particularly from tip 160. In such an embodiment, the arms facilitate securing the anchor member 156 in position within the cardiac structure to which it is embedded. Moreover, in other embodiments, anchor member 156 may include expandable arms that expand outwardly from a compressed state. Alternatively, anchor member 156 may include other self-locking struts that facilitate preventing member 156 from backing out of the cardiac structure to which it is threadalby coupled. Furthermore, the cross-sectional shape of anchor member 156 is illustrated as exemplary only. Rather, anchor member 156 and tensioning member 152 may be fabricated with any cross-sectional shape, dimensions, or material that enables fastening mechanism 150 to function as described herein. For example, anchor member 156 may be formed with, but is not limited to being formed with, a self-tapping screw configuration, a mesh configuration, or with a helical configuration.

[0047] Moreover, in another embodiment, anchor member 156 is formed with a coiled configuration having a helical filament that includes a secondary helical structure that includes, for example, a plurality of loops. In such an embodiment, anchor member 156 may include an inner element fabricated from a

shaped memory material and an outer element that is substantially concentrically aligned with respect to the inner element, and is fabricated from a second material, such as a radiopaque material or a heat-activated material. Furthermore, in other embodiments, to facilitate endovascular orientation, the coil may be fabricated with a stacked coil configuration in which no space is defined between adjacent windings of the coil, but rather, the coil assumes a coil configuration when heated to a pre-determined temperature as it is deployed.

[0048] Figure 7 is a schematic view of an alternative embodiment of a portion of a tensioning member 200 that may be used to facilitate repair of a cardiac valve 16 (shown in Figures 1 and 2). Tensioning member 200 extends between first and second attachment ends 60 and 62 (shown in Figure 3 and 4) and in the exemplary embodiment, includes at least two anchoring loops 202 and 204, and an adjustment mechanism 206 extending between loops 202 and 204. In the exemplary embodiment, loops 202 and 204 are each formed integrally with respective attachment ends 60 and 62. In another embodiment, loops 202 and 204 are coupled to ends 60 and 62 using any suitable coupling means.

[0049] In the exemplary embodiment, adjustment mechanism 206 enables each attachment end 60 and 62 to be coupled to a leaflet 34 (shown in Figures 1 and 2) and to any other cardiac structure other than a mitral valve leaflet 34, without tension being induced to either end 60 or 62. Moreover, once ends 60 and 62 are coupled to the leaflet 34 and the cardiac structure, adjustment mechanism 206 enables a pre-determined tension to be induced between the leaflet 34 and the cardiac structure.

[0050] In the exemplary embodiment, adjustment mechanism 206 functions similarly to a drawstring and includes a locking mechanism 220 that facilitates maintaining a desired tension between the leaflet 34 and the cardiac structure. More specifically, after ends 60 and 62 have each been securely coupled to the leaflet and the cardiac structure, as adjustment loop 222 is pulled away from ends 60 and 62, adjustment mechanism 206 is drawn radially inward between ends 60 and

62, inducing tension between the leaflet 34 and the cardiac structure, and locking mechanism 220 is coupled to adjustment loop 222 to facilitate ensuring that ends 60 and 62 are maintained in their relative position such that the tension induced between ends 60 and 62 is maintained. In an alternative embodiment, adjustment mechanism 206 does not include locking mechanism 222, but rather any suitable method of maintaining the tension between ends 60 and 62 may be utilized, such as, but not limited to, self-locking twist fastener devices or swivel fasteners. Moreover, in a further embodiment, adjustment mechanism 206 does not include locking mechanism 220, but rather the tension induced by the placement of loop 222 is maintained by a knot tied in position adjacent loop 222.

[0051] In alternative embodiments, other adjustment mechanisms other than mechanism 206 may be used, such as, but not limited to, the installation of a spreader bar mechanism within at least one loop of a daisy chained tension member, the use of a turnbuckle-type mechanism, and/or the use of tensioning member that is shortened as it is twisted, such as would be possible with a tourniquet-type attachment. Moreover, in further alternative embodiments, at least a portion of adjustment mechanism 206 is fabricated from a shaped metal alloy that is formed into a component that when coupled within a fastener assembly either constricts or bows outwardly to induce tension between the ends 60 and 62.

[0052] Figure 8 is a flowchart illustrating an exemplary method for the endovascular repair of a cardiac valve. Initially, the mitral valve, or other atrioventricular valve being repaired is accessed percutaneously 300. Depending on the point of vascular access, the approach to the mitral valve may be "antegrade" and require entry into the left atrium by crossing the interatrial septum. Alternatively, approach to the mitral valve can be "retrograde" wherein the left ventricle is entered through the aortic valve. Once access 300 is achieved, the interventional tools and supporting catheter(s) will be positioned 302 endovascularly adjacent the valve being repaired. As will be appreciated by one of ordinary skill in the art, the present invention may be used with open surgical techniques wherein the heart is stopped and the heart valve accessed through the myocardial tissue.

[0053] The interventional tools used for performing the valve repairs may be specifically designed for use with the present invention, or existing tools may be modified to accommodate the present invention. For example, in one embodiment, a 1° catheter is used to position or guide a plurality of smaller catheters in which the 1° catheter is used to accomplish general positioning of the device relative to the valve being repaired, and the smaller catheters facilitate the more precise positioning necessary to repair the valve in accordance with the present invention. In other embodiments, a guide catheter, a needle bearing catheter, an introducer, or a similar device may be used.

[0054] Once positioned 302, the leaflet to be repaired is captured 310 and the first attachment end of the fastening mechanism is securely coupled to the leaflet 312. Specifically, as described above, the fastening mechanism may be coupled to the leaflet in a plurality of manners, but in each case, the first attachment end of the mechanism is securely coupled to the valve leaflet in need of repair. The leaflet may be captured 310 using any of a plurality of known methods, including, but not limited to using grasping pins, articulated graspers, vacuum-assisted graspers, or any other suitable method.

[0055] The second attachment end of the fastening mechanism is then securely coupled 330 to a cardiac structure other than a mitral valve leaflet. The tension induced 332 to the mitral valve leaflet is selected to substantially simulate the same tension, operation, and functionality of a natural chordae member coupled to the leaflet. In at least some embodiments, tension induced to the mitral valve leaflet is adjustable via adjustments of the tensioning member.

[0056] After repairing the valve leaflet, flow through the valve can be observed by conventional cardiac imaging techniques, such as trans-esophegeal echocardiography (TEE), intracardiac echocardiography (ICE) or other ultrasonic imaging technique, fluoroscopy, angioscopy, catheter based magnetic resonance imaging (MRI), computed tomography (CT) and the like. By observing the flow through the repaired valves, it can be determined whether or not back flow or

regurgitation has ceased, or whether the tension induced to the leaflet requires adjustment.

[0057] Exemplary embodiments of methods and fastener mechanisms for use in repairing atrioventricular valves are described above in detail. Although the methods are herein described and illustrated in association with the above-described atrioventricular valve, it should be understood that the present invention may be used with any atrioventricular valve. More specifically, the fastener mechanisms and methods of repair are not limited to the specific embodiments described herein, but rather, aspects of each fastener mechanism and/or method of repair may be utilized independently and separately from other fastener mechanisms and/or repair methods.

[0058] While the invention has been described in terms of various specific embodiments, those skilled in the art will recognize that the invention can be practiced with modification within the spirit and scope of the claims.

WHAT IS CLAIMED IS:

1. A method of repairing an atrioventricular valve in a patient, said method comprising:

accessing the patient's atrioventricular valve percutaneously;

securing a fastening mechanism to a valve leaflet; and

coupling the valve leaflet, while the patient's heart remains beating, to at least one of a ventricular wall adjacent the atrioventricular valve, a papillary muscle, and at least one valve chordae, and a valve annulus to facilitate reducing leakage through the valve.

2. A method in accordance with Claim 1 wherein securing a fastening mechanism to a valve leaflet further comprises securing the fastening mechanism to an edge of the valve leaflet.

3. A method in accordance with Claim 1 wherein securing a fastening mechanism to a valve leaflet further comprises:

forming an opening extending at least partially through the valve leaflet; and

inserting the fastening mechanism through the opening defined in the valve leaflet prior to coupling the fastening mechanism to the valve leaflet.

4. A method in accordance with Claim 1 wherein securing a fastening mechanism to a valve leaflet further comprises securing the fastening mechanism to the valve leaflet using at least one of a staple, a rivet, an adhesive material, and a suture.

5. A method in accordance with Claim 1 wherein securing a fastening mechanism to a valve leaflet further comprises securing the fastening mechanism to the valve leaflet of one of a tricuspid valve and a mitral valve.

6. A method in accordance with Claim 1 wherein coupling the valve leaflet further comprises inserting a portion of the fastening mechanism at least partially through a portion of at least one papillary muscle.

7. A method in accordance with Claim 1 wherein coupling the valve leaflet further comprises securing the fastening mechanism substantially circumferentially around a portion of one of a papillary muscle and a chordae.

8. A method in accordance with Claim 1 wherein coupling the valve leaflet further comprises:

forming an opening extending at least partially through at least one of the ventricular wall adjacent the atrioventricular valve, the at least one valve chordae, the papillary muscle, and the valve annulus; and

securing the fastening mechanism to the at least one of the at least one valve chordae, and the valve annulus.

9. A method in accordance with Claim 1 wherein coupling the valve leaflet further comprises securing the fastening mechanism to at least one of the ventricular wall adjacent the atrioventricular valve, the papillary muscle, the at least one valve chordae, and the valve annulus using at least one of a staple, a rivet, an adhesive material, and a suture.

10. A method in accordance with Claim 1 wherein coupling the valve leaflet further comprises threadably coupling the fastening mechanism to at least one of the ventricular wall adjacent the atrioventricular valve, the papillary muscle, the at least one valve chordae, and the valve annulus.

11. A method in accordance with Claim 1 wherein securing a fastening mechanism to a valve leaflet comprises securing a fastening mechanism fabricated from at least one of a superelastic material, and a shaped memory alloy material.

12. A method of repairing a mitral valve in the heart of a patient wherein the mitral valve is connected to at least one natural chordae, said method comprising:

accessing the patient's mitral valve endovascularly;

securing a first end of a fastening mechanism to a valve leaflet of the mitral valve; and

coupling a second end of the fastening mechanism to a cardiac structure other than a mitral valve leaflet to facilitate simulating the function of a natural chordae.

13. A method in accordance with Claim 12 wherein securing a first end of a fastening mechanism to a valve leaflet further comprises securing the first and second ends of the fastening mechanism within the patient while the patient's heart is non-arrested.

14. A method in accordance with Claim 12 wherein securing a first end of the fastening mechanism to a valve leaflet further comprises securing the fastening mechanism first end to an edge of the mitral valve leaflet to facilitate reducing leakage through the patient's mitral valve.

15. A method in accordance with Claim 12 wherein securing a first end of the fastening mechanism to a valve leaflet further comprises inserting the first end of the fastening mechanism through an opening extending at least partially through the mitral valve leaflet.

16. A method in accordance with Claim 12 wherein securing a first end of the fastening mechanism to a valve leaflet further comprises fusing the first end of the fastening mechanism to the mitral valve leaflet.

17. A method in accordance with Claim 12 wherein securing a first end of the fastening mechanism to a valve leaflet further comprises:

inserting the fastening mechanism from a first side of the mitral valve leaflet through an opening extending through the mitral valve leaflet; and

securing the fastening mechanism to the second side of the mitral valve leaflet.

18. A method in accordance with Claim 12 wherein securing a first end of the fastening mechanism to a valve leaflet further comprises securing the first end of the fastening mechanism to the mitral valve leaflet using at least one of stapling, riveting, fusing, gluing, and suturing.

19. A method in accordance with Claim 12 wherein coupling a second end of the fastening mechanism to a cardiac structure other than a mitral valve leaflet further comprises securing the second end of the fastening mechanism through an opening formed in a papillary muscle.

20. A method in accordance with Claim 12 wherein coupling a second end of the fastening mechanism to a cardiac structure other than a mitral valve leaflet further comprises extending the second end of the fastening mechanism substantially circumferentially around a papillary muscle.

21. A method in accordance with Claim 12 wherein coupling a second end of the fastening mechanism to a cardiac structure other than a mitral valve leaflet further comprises securing the second end of the fastening mechanism substantially circumferentially around a portion of a mitral valve chordae.

22. A method in accordance with Claim 12 wherein coupling a second end of the fastening mechanism to a cardiac structure other than a mitral valve leaflet further comprises inserting the second end of the fastening mechanism into an opening extending at least partially through at least one of a ventricular wall adjacent the atrioventricular valve, a valve chordae, a papillary muscle, and a valve annulus.

23. A method in accordance with Claim 12 wherein coupling a second end of the fastening mechanism to a cardiac structure other than a mitral valve leaflet

further comprises coupling the second end of the fastening mechanism to the cardiac structure using at least one of stapling, riveting, fusing, gluing, and suturing.

24. A method in accordance with Claim 12 wherein coupling a second end of the fastening mechanism to a cardiac structure other than a mitral valve leaflet further comprises fusing the second end of the fastening mechanism to the cardiac structure.

25. A method in accordance with Claim 12 wherein coupling a second end of the fastening mechanism to a cardiac structure other than a mitral valve leaflet further comprises threadably coupling the second end of the fastening mechanism to the cardiac structure.

26. A method of enhancing operation of a patient's heart valve, said method comprises:

inserting a guide catheter along the venous system of the patient to approach the mitral valve;

guiding a fastening mechanism towards one of a mitral valve and a tricuspid valve within the patient's heart;

securing a first end of the fastening mechanism to one of the mitral valve and the tricuspid valve using one of fusing, gluing, stapling, clipping, riveting, anchoring, and suturing; and

securing a second end of the fastening mechanism to a cardiac structure other than a valve leaflet to facilitate enhancing operation of the valve.

27. A method in accordance with Claim 26 wherein securing a second end of the fastening mechanism further comprises securing the second end to the cardiac structure using one of fusing, gluing, stapling, clipping, riveting, and suturing.

28. A method in accordance with Claim 26 further comprising deploying a shaped memory fastener to effect securing the fastening mechanism to the valve.

29. A method in accordance with Claim 26 wherein securing a second end of the fastening mechanism to a cardiac structure further comprises securing the second end of the fastening mechanism through an opening defined in the cardiac structure to which the second end is secured.

30. A method in accordance with Claim 26 wherein securing a second end of the fastening mechanism to a cardiac structure further comprises extending the fastening mechanism second end substantially circumferentially around the cardiac structure.

31. A method in accordance with Claim 26 wherein securing a second end of the fastening mechanism to a cardiac structure comprises threadably coupling the fastening mechanism second end to the cardiac structure.

32. A medical kit for use in repairing a mitral valve, said kit comprising:

a guide catheter configured for insertion along the arterial system of the patient to approach the mitral valve; and

a fastening mechanism positionable endovascularly within the patient using said guide catheter, said fastening mechanism comprising a first end and an opposite second end, said first end configured to couple to the mitral valve using one of fusing, gluing, stapling, clipping, riveting, anchoring, and suturing, said second end configured to only couple to a cardiac structure other than a valve leaflet to facilitate enhancing operation of the valve during ventricular systole.

33. A medical kit in accordance with Claim 32 wherein at least one of said fastening mechanism first and second ends comprises an anchor member comprising at least two arms.

34. A medical kit in accordance with Claim 32 wherein at least a portion of said fastening mechanism is braided.

35. A medical kit in accordance with Claim 32 wherein said fastening mechanism comprises at least one loop.

36. A medical kit in accordance with Claim 32 wherein one of said fastening mechanism first end and said fastening mechanism second end comprises a helical coil.

37. A medical kit in accordance with Claim 32 wherein said guide catheter comprises one of a mitral leaflet catheter, a cinching device, and a papillary muscle catheter.

38. A surgical kit in accordance with Claim 32 wherein said fastening mechanism is fabricated from at least one of a superelastic material, and a shaped memory alloy material.

39. A medical kit in accordance with Claim 32 wherein one end of said fastening mechanism comprises a clip configured to couple to an edge of the mitral valve.

40. A medical kit in accordance with Claim 32 wherein one end of said fastening mechanism comprises at least one adjustable loop.

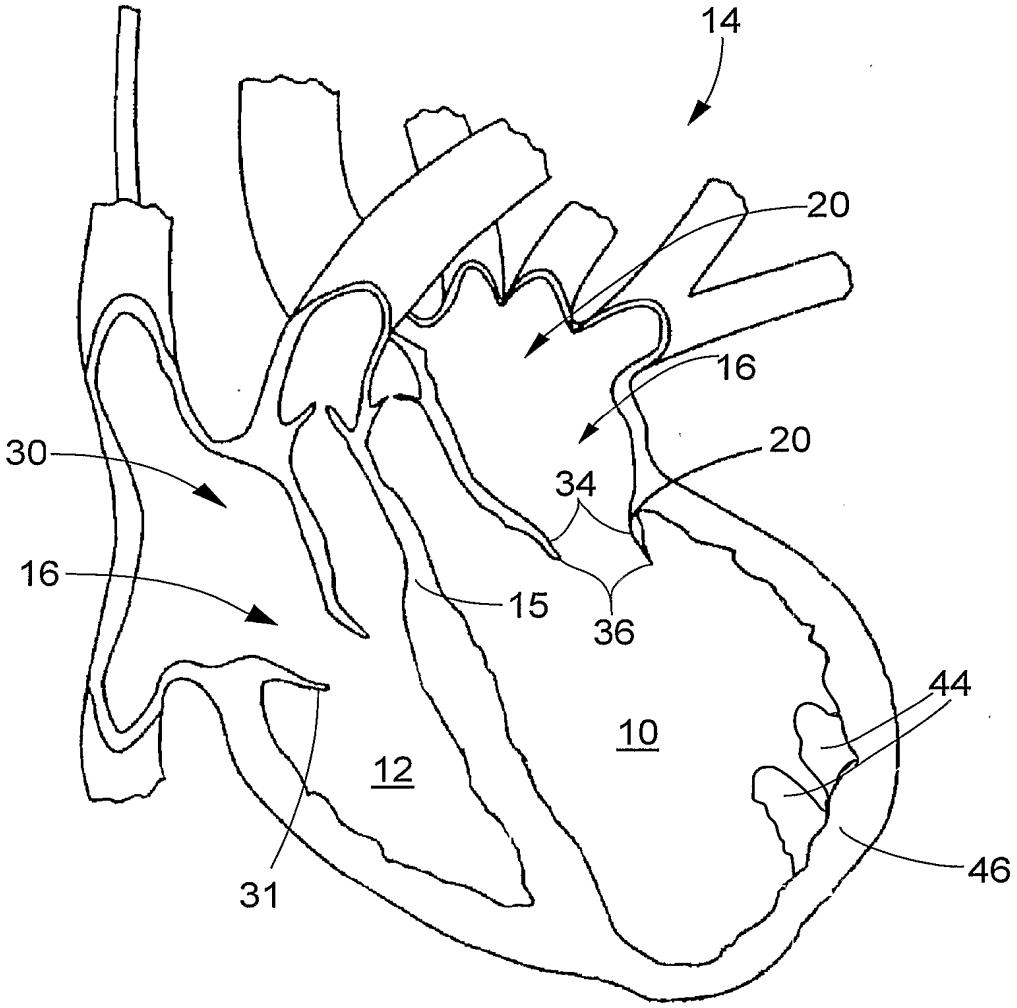

FIG. 1

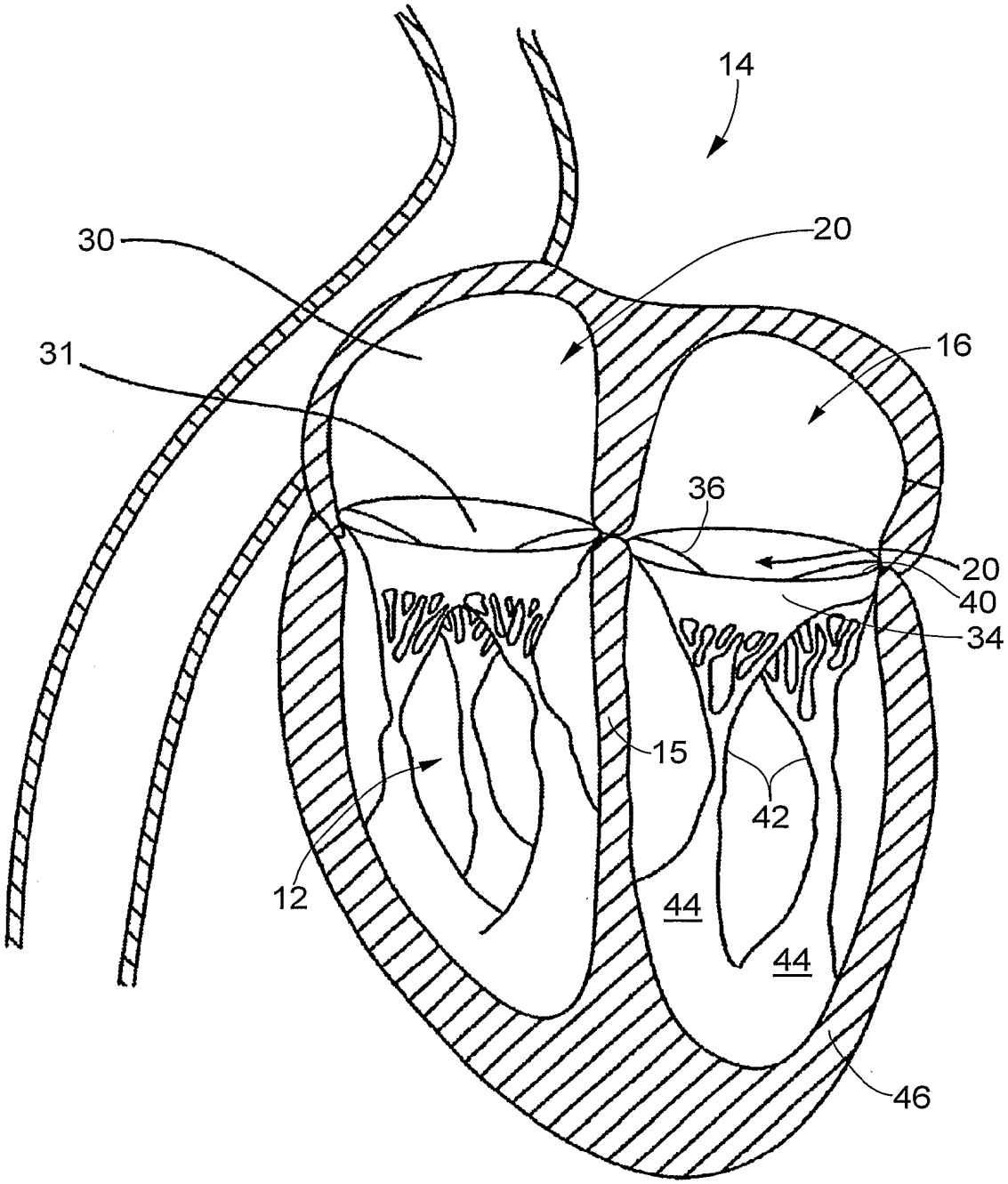

FIG. 2

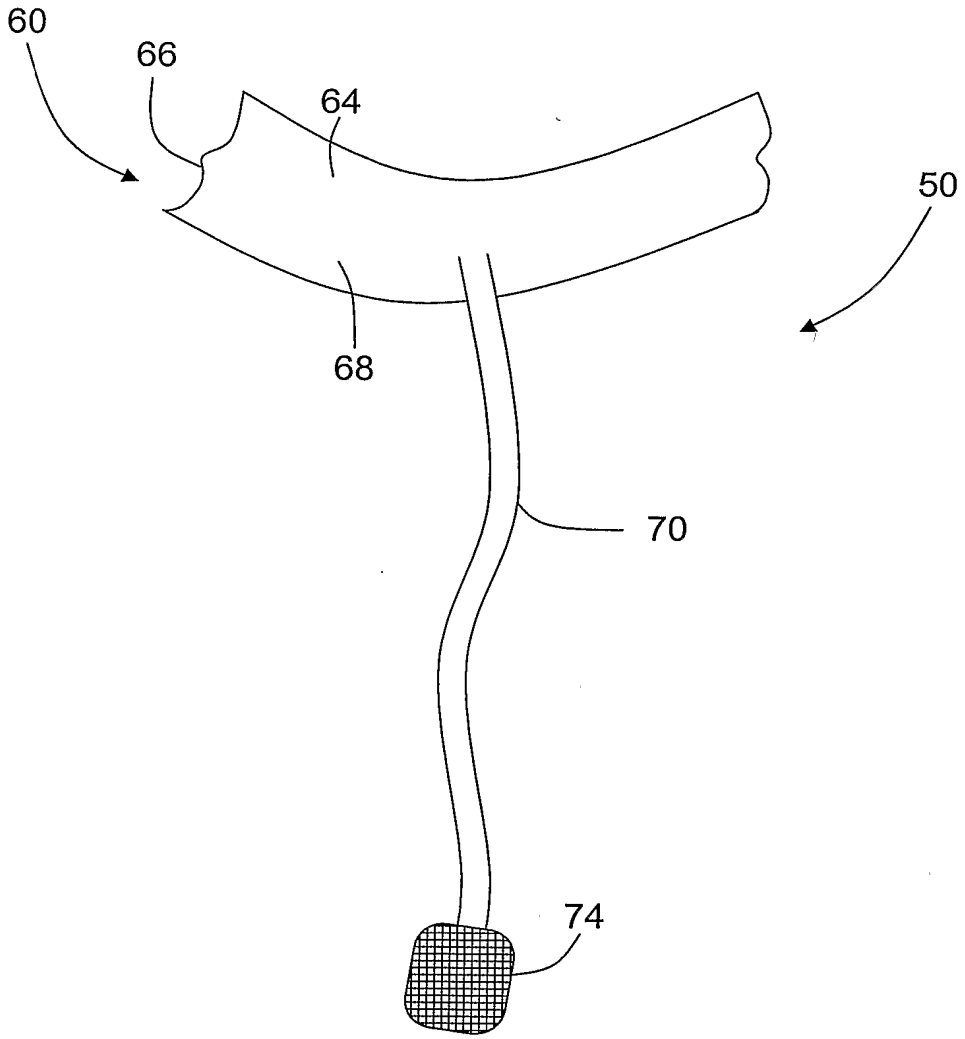

FIG. 3

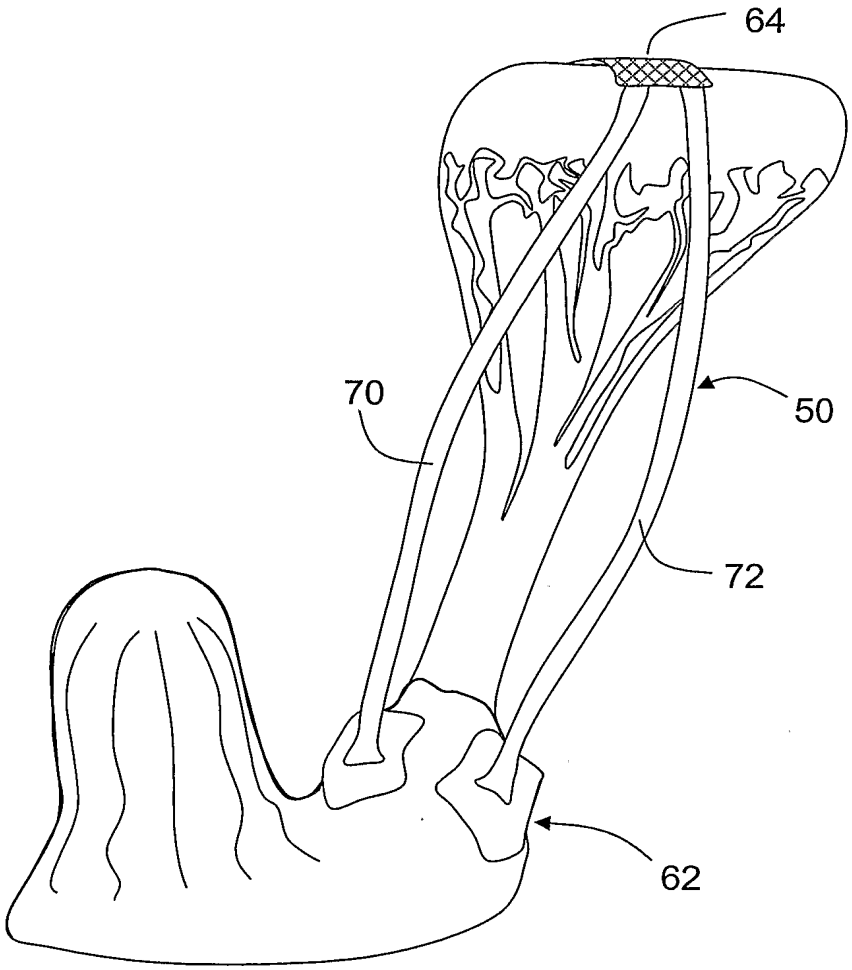

FIG. 4

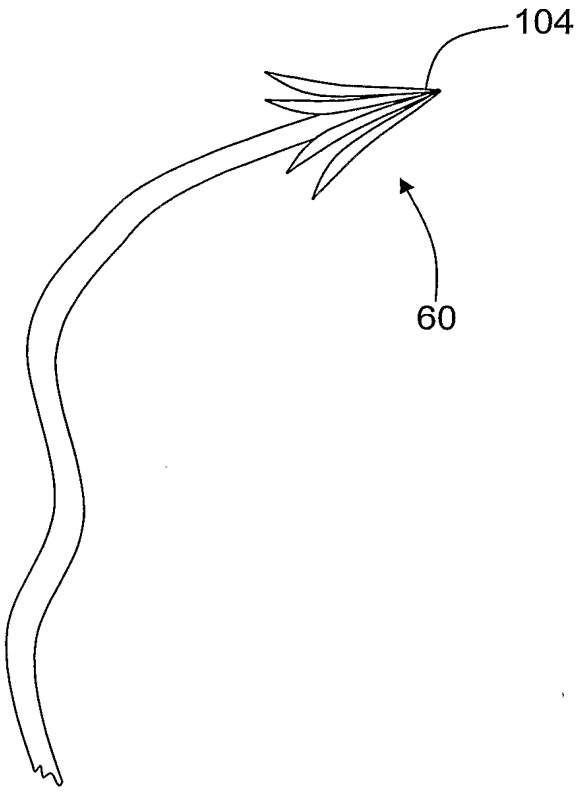

FIG. 5

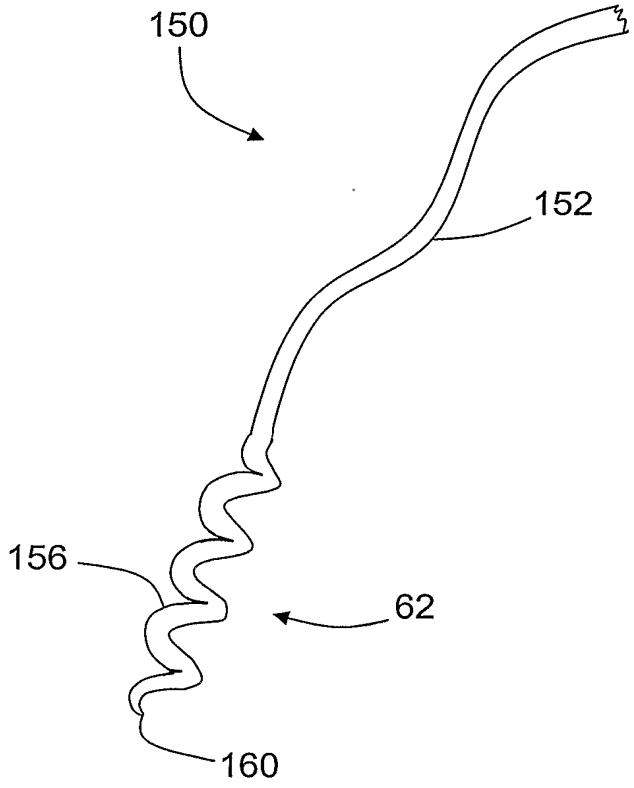

FIG. 6

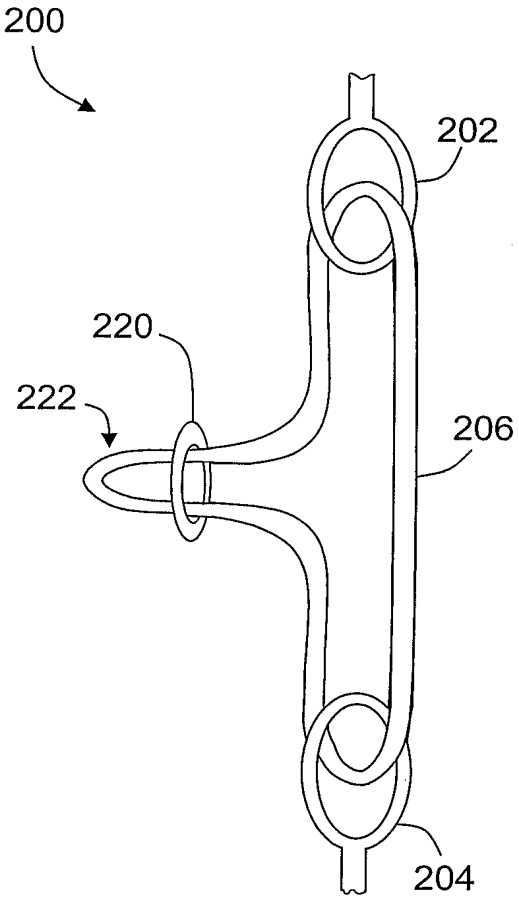

FIG. 7

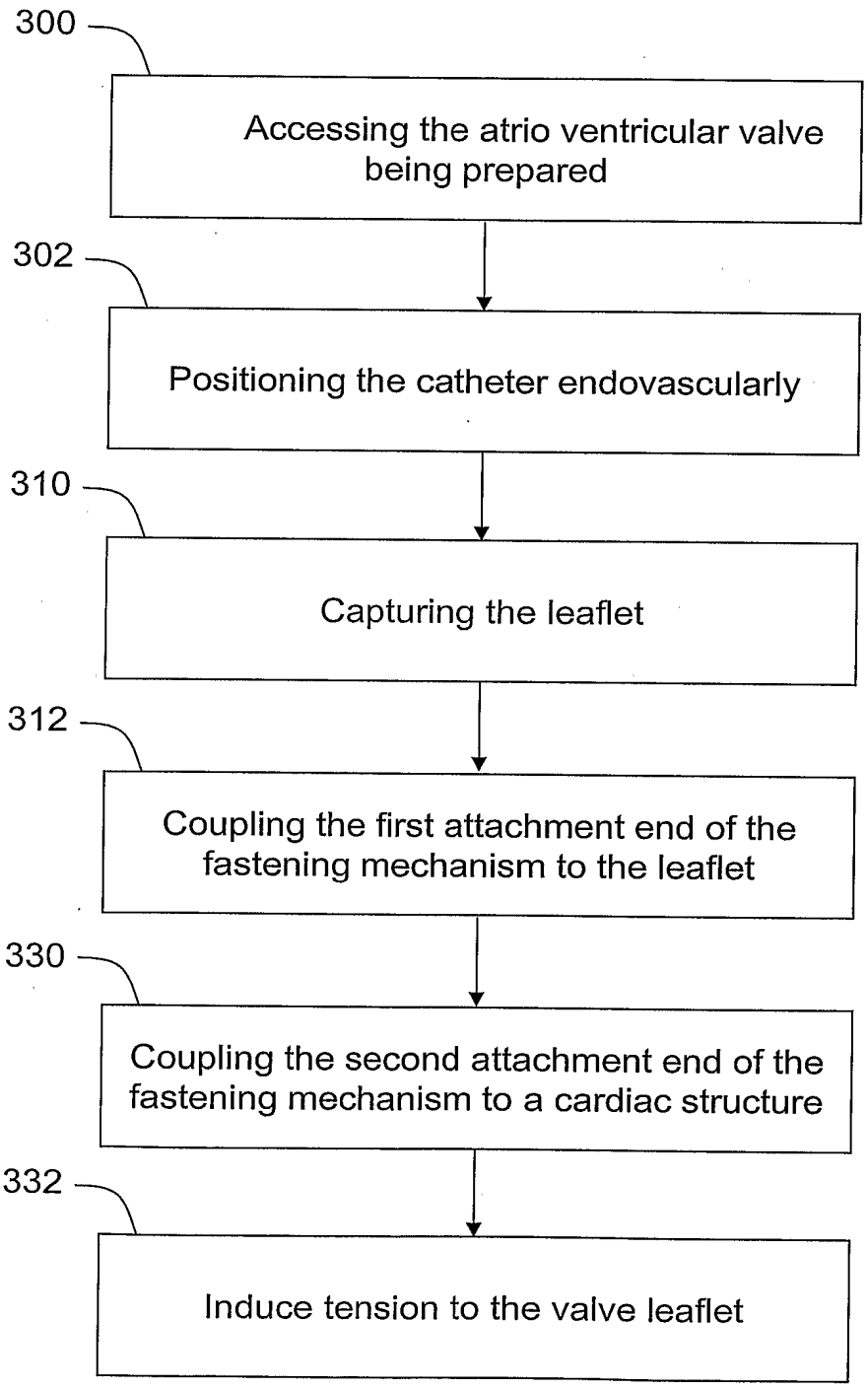
300
Accessing the atrio ventricular valve being prepared
302
Positioning the catheter endovascularly
310
Capturing the leaflet
312
Coupling the first attachment end of the fastening mechanism to the leaflet
330
Coupling the second attachment end of the fastening mechanism to a cardiac structure
332
Induce tension to the valve leaflet

FIG. 8

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(74) Agent: **REESER, Robert, B.**; One Metropolitan Square, Suite 2600, St. Louis, MO 63102 (US).

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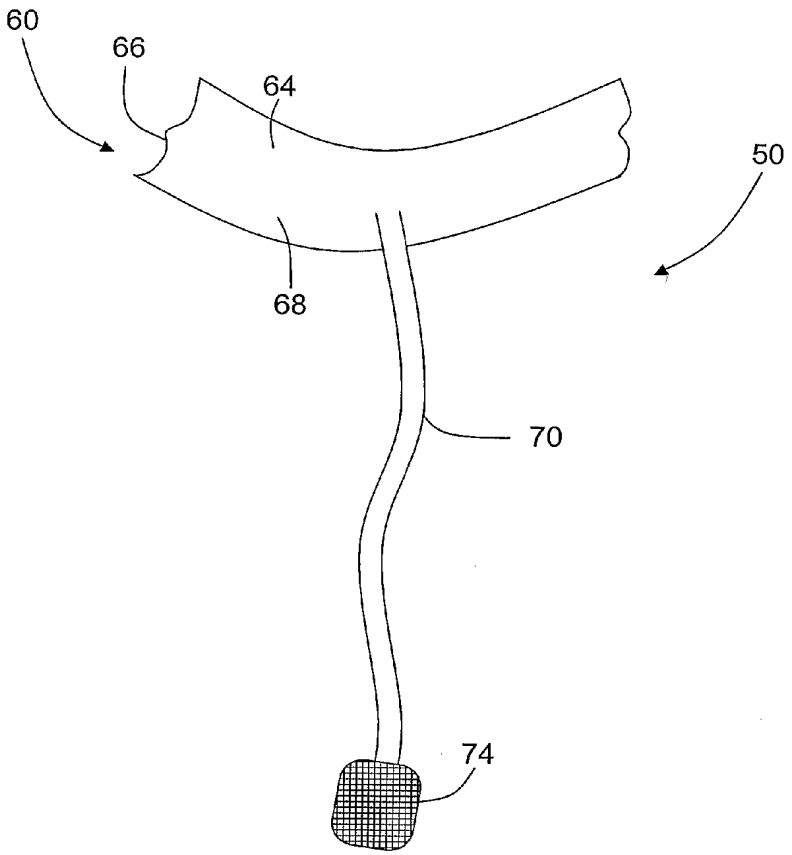
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT,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

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

[Continued on next page]

(54) **Title:** METHODS AND APPARATUS FOR ATRIOVENTRICULAR VALVE REPAIR



(57) **Abstract:** Methods and apparatus for use in repairing an atrioventricular valve in a patient are provided. The methods comprise accessing the patient's atrioventricular valve percutaneously, securing a fastening mechanism to a valve leaflet, and coupling the valve leaflet, while the patient's heart remains beating, to at least one of a ventricular wall adjacent the atrioventricular valve, a papillary muscle, at least one valve chordae, and a valve annulus to facilitate reducing leakage through the valve.

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International application No.
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A. CLASSIFICATION OF SUBJECT MATTER
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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
PubWEST (DB=USPT, PGPB, USOC, EPAB, JPAB) (see search terms below)

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

PubWest(PGPB,USPT,USOC,EPAB,JPAB); google
Search Terms Used: beat$, coupl$, fasten$, atrioventricular, papillary, chordae, annulus, leaflet, valve, heart,

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----- Y	US 2005/0240202 A1 (SHENNIB et al.) 27 October 2005 (27.10.2005), Entire document Especially para [0001], [0018]-[0023], [0048], [0071].	1-31 --------- 36,39
X ----- Y	US 2005/0125011 A1 (SPENCE et al.) 09 June 2005 (09.06.2005), Entire document Especially FIG. 3B, 3C and para [0023]-[0027], [0113]-[0114], [0144].	32-33,35,37-38,40 ---------- 34,36,39
Y	US 2005/0075727 A1 (WHEATLEY) 7 April 2005 (07.04.2005), para [0027].	34

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

* Special categories of cited documents:
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"E" earlier application or patent but published on or after the international filing date
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"P" document published prior to the international filing date but later than the priority date claimed
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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 April 2007 (12.04.2007)	06 AUG 2007
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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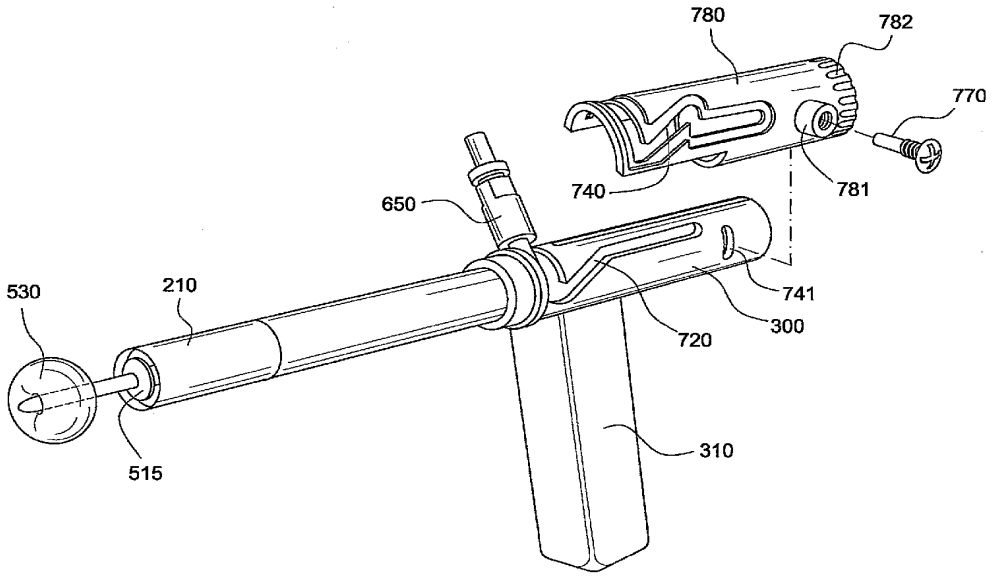
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR,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

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

Published:
— *with international search report*

[Continued on next page]

(54) **Title:** APPARATUS AND METHOD FOR FORMING A HOLE IN A HOLLOW ORGAN



(57) **Abstract:** The invention relates to an apparatus and method for forming a hole in a wall of a hollow organ. The applicator includes a hole forming element for forming a hole in the wall of the organ, a positioning means (300) for positioning the hole forming element, and a retractor element (500). In addition, the applicator includes a sequencing means (600) for coordinating the relative movement of the retractor element and the hole forming element in a sequential manner to thereby carry out a procedure for forming a hole in the wall of the hollow organ. The sequencing means may further include a safety latch element operatively coupled to the retracting means and the hole forming element. The safety latch of the invention prevents damage to the internal surface of the organ during the formation of the hole.

WO 2007/081418 A1

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

APPARATUS AND METHOD FOR FORMING A HOLE IN A HOLLOW ORGAN

FIELD OF THE INVENTION

[0001] The present invention relates to an apparatus and method for forming a hole in a hollow organ, and more particularly, to a surgical device and method for forming a hole in a heart.

BACKGROUND OF THE INVENTION

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

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

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

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

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

[0006] On the back table, the apicoaortic conduit is prepared, such as a 21 Freestyle valve sutured on the inflow opening to an 18-mm Medtronic apical connector and sutured on the outflow opening to a 20-mm Hemashield graft. The Dacron associated with the apical connector is pre-clotted with thrombin and cryoprecipitate. The assembly is brought to the field, and a measurement made from

the apex of the heart to the descending aorta. The assembly is trimmed appropriately. A partial-occluding clamp is then placed on the descending aorta, and the aorta opened with a knife and scissors. The conduit (the end with the 20 mm Hemashield graft) is then sutured to the descending aorta using 4-0 prolene suture, in a running fashion. Once this is complete, the clamp is removed and the anastomosis checked for hemostasis. Blood is contained by the presence of the Freestyle aortic valve. The apical connector is placed on the apex, and a marker is used to trace the circular outline of the connector on the apex, in the planned location of insertion. Four large pledgeted sutures (mattress sutures) of 2-0 prolene are placed; one in each quadrant surrounding the marked circle. The sutures are then brought through the sewing ring of the apical connector. A stab wound is made in the apex in the center of the circle, and a tonsil clamp is used to poke a hole into the ventricle. Bypass may be initiated at this point, but some surgeons have developed crude manual techniques to avoid bypass entirely. A Foley catheter is inserted into the ventricle, and the balloon expanded. A cork borer is then used to cut out a plug from the apex. The connector is then parachuted down into position. A rotary motion is necessary to get the connector to seat in the hole. The four quadrant sutures are tied, and hemostasis is checked. If there is a concern regarding hemostasis, additional sutures are placed. The retractor is removed, chest tubes are placed, and the wound is closed.

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

[0008] The major obstacle to widespread adoption of this superior configuration is the nearly complete lack of efficient devices to perform the procedure. Surgeons

wishing to adopt the procedure must gather a collection of instruments from a variety of manufacturers. Often these instruments were created for quite different purposes, and the surgeon is forced to adapt them as required and manually manipulate them during a procedure.

[0009] U. S. Published Patent Application 2005/0149093 A1 (Pokorney) describes a device for implanting an apicoaortic conduit between the apex of the heart and the descending aorta. The device for cannulating the apex uses a piercing and dilating approach to avoid cutting a tissue plug. Substantial force may be required to cut and dilate a hole to place the conduit to its final position. The force may significantly deform the heart to prevent placement of the conduit or even harm internal heart structures.

[0010] U. S. Published Patent Application 2003/0130668 A1 (Nieman) describes ideas for remotely cannulating a body part, such as a heart. The method and apparatus are endoscopic, i.e. the instruments are mounted on the end of a long flexible member and inserted into the body through a trocar, i.e., a sharply pointed surgical instrument contained in a cannula. The endoscopic procedure appears complicated. After the device is placed at or near the apex of the heart, the surgeon or some other controller performs at least 13 separate steps to secure the cannula in the heart wall. Coordination of these steps with a user-friendly interface may be challenging. An attachment ring (which includes an apical ring and a locking stem) is sutured to the heart wall, and subsequently the cannula is connected to the attachment ring as a separate step. Because the procedure is endoscopic, imaging means (e.g., fluoroscopy) is used to place a balloon at the correct depth within the ventricle to provide occlusion.

[0011] The complex endoscopic procedure disclosed in Nieman appears to require that the cut tissue core be removed from the body prior to advancing the cannula to the heart wall. Further, Nieman appears to provide two mechanisms for placing the cannula in the heart wall. One such mechanism is to create a hole that is large enough to easily slide the cannula into the hole. This does not provide a tight fit between the cannula and cored heart wall to prevent blood loss from the cored heart

wall and from the ventricle and relies entirely upon the sutured attachment ring to achieve hemostasis thus providing a period of time during which there could be great losses of blood. The second mechanism is to achieve a tight (interference) fit between the cannula and cored hole. However, such a tight fit requires substantial axial and torsional forces to be applied to the cannula. The flexible endoscopic instrument disclosed in Nieman may not provide such forces to be transmitted.

[0012] U.S. Patent No. 7,077,801 (Haverich) discloses various approaches for implanting a conduit into the wall of a heart. As illustrated in FIG. 8A, Haverich shows a conduit on a cutter that has a "corkscrew driver" with a coil. The corkscrew is rotated to cause the cutter to penetrate through the myocardium. However, substantial axial force is required to cleanly penetrate the myocardium, and such force is not easily applied by a corkscrew. Further, the pointed tip of the corkscrew can damage other areas of the heart wall (e.g., the septum) while applying axial force and rotation. Haverich discloses a balloon used for hemostasis. However, the balloon is a separate instrument that cannot be combined with the corkscrew.

[0013] U.S. Patent No. 6,726,648 (Kaplon) discloses a device similar to Haverich except that a trocar is used to penetrate the organ wall instead of a cutter with corkscrew. No tissue plug is formed with a trocar, but substantial force may be required. Use of a trocar makes it difficult to achieve hemostasis during a procedure on a beating heart. To address this, rigid conduit 18 is inserted through the connector 16 after the connector is implanted with the trocar and sewn into place. Connector 16 does not appear to penetrate the heart wall. Connector 16 has a built-in valve to prevent blood loss after the trocar is removed and until conduit 18 is inserted.

[0014] U.S. Patent No. 6,942,672 (Heilman) discloses another device for implanting a conduit to the heart wall that uses a sealed enclosure to eliminate air and to prevent blood loss.

SUMMARY OF THE INVENTION

[0015] The invention relates to an applicator for forming a hole in a wall of a hollow organ. The applicator includes a hole forming element for forming a hole in the wall of the organ, the hole forming element having a cutting element on a distal

end thereof. The applicator also includes a positioning means coupled to the hole forming element for positioning the hole forming element, a retractor element operatively coupled to the positioning means, and a sequencing means for coordinating the relative movement of the retractor element and the hole forming element in a sequential manner to thereby carry out a procedure for forming a hole in the wall of the hollow organ.

[0016] The invention also relates to a method of forming a hole in a wall of a hollow organ. The method includes steps of forming a hole in the wall of the organ with a hole forming element, the hole forming element having a cutting element on a distal end thereof, positioning the hole forming element with a positioning means coupled to the hole forming element, the positioning means being operatively coupled to a retractor element, and coordinating the relative movement of the retractor element with respect to the hole forming element in a sequential manner with a sequencing means to thereby carry out a procedure for forming a hole in the wall of the hollow organ.

[0017] The retractor element may comprise a retractor body movably disposed within the hole forming element and an expansion element disposed on a distal end of the retractor body, and the expansion element may be expandable from an unexpanded state to fully expanded state and to a partially expanded state. The sequencing means may control the expansion of the expansion element from the unexpanded state, to the fully expanded state, and to the partially expanded state in a sequential manner. In addition, the sequencing means may include a safety latch element operatively coupled to the retracting means and the hole forming element, and may further include a sequencing bolt that extends through a cylinder cam slot formed in the retractor element, a pusher cam slot formed in a pusher element, and a safety latch cam slot formed in the safety latch element.

[0018] In this case, the sequencing means comprises a means for causing the elements to assume the following states in seriatim:

[0019] a) a first state in which the sequencing bolt moves from a first position to a second position in each of the cylinder cam slot, the pusher cam slot, and the

safety latch cam slot, thereby expanding the expansion element to a fully expanded state while retaining the retractor element in a fully extended position relative to the hole forming element;

[0020] b) a second state in which the sequencing bolt moves from the second position to a third position in the cylinder cam slot, the pusher cam slot, and the safety latch cam slot, thereby retaining the expansion element in the fully expanded state and the retractor element in the fully extended position;

[0021] c) a third state in which the sequencing bolt moves from the third position to a fourth position in the cylinder cam slot, the pusher cam slot, and the safety latch cam slot, thereby permitting the retractor element to move towards the hole forming element while retaining the expansion element in the fully expanded state;

[0022] d) a fourth state in which the sequencing bolt is locked in a fourth position in the safety latch cam slot, the cylinder cam slot, and the pusher cam slot, thereby retaining the expansion element in the fully expanded state;

[0023] e) a fifth state in which the safety latch element is moved relative to the retractor element such that the sequencing bolt is repositioned from the fourth position to a fifth position in the safety latch cam slot while remaining in the fourth position in the cylinder cam slot and the pusher cam slot, thereby releasing the expansion element in the fully expanded state; and

[0024] f) a sixth state in which the sequencing bolt moves from the fifth position to a sixth position in the safety latch cam slot, and simultaneously, from the fourth position to a fifth position in the cylinder cam slot and the pusher cam slot, to allow the expansion element to assume the partially expanded state.

[0025] Accordingly, the invention provides a safety latch that keeps the expansion element in a fully expanded state (i.e. the fourth state) covering the sharp edge of the cutting element to protect the inner surfaces of the hollow organ (i.e. the heart) until the safety latch is released by a deliberate action of the surgeon. In this

way, the surgeon can push and rotate the hole forming element while positioning the connector conduit in the apex wall without damaging the inner surfaces of the heart.

[0026] In addition, the invention provides a safety latch that the surgeon cannot deliberately or inadvertently release before the sequencing bolt is at the proper position. Furthermore, the invention provides relief to the requirement that the expansion element be moved to be at least partially disposed in the hole forming element, thereby preventing sticking of the cam mechanism during reloading. Also, the invention provides an applicator that cuts a hole in the heart wall without simultaneously implanting a connector conduit in the heart wall.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] Fig. 1 illustrates an exemplary apicoaortic conduit.

[0028] Figs. 2A - 2C illustrate are cross-sectional views of a sequencing bolt, retractor body, expanding element, positioning means, and cutting element described in U.S. Patent Application Publication No. 2005-0251187.

[0029] Figs. 3A - 3C illustrate the sequencing can mechanism disclosed in U.S. Patent Application Publication No. 2005-0251187 in various states.

[0030] Figs. 4A - 4E illustrate a cross-sectional view of the applicator disclosed in U.S. Patent Application Publication No. 2005-0251187 in various states.

[0031] Fig. 5 is an exploded view of the applicator and safety latch of the invention.

[0032] Figs. 6A - 6D illustrate the sequencing cam mechanism of the invention with a safety latch in various states.

[0033] Figs. 7A - 7D illustrate the applicator of the invention with a safety latch in various states.

DETAILED DESCRIPTION OF THE INVENTION

[0034] Referring now to the figures, related U.S. Patent Application Publication No. 2005-0251187 to Beane, et al., which is incorporated herein by reference in its

entirety, describes use of a sequencing element (such as a cam mechanism) that helps to ensure that critical steps of implanting a connector conduit into the apex of the left ventricle are performed in the proper sequence. (See Fig. 1). Once a tissue plug is created, the sequencing element partially reduces the diameter of the expanding element so that the expanding element can enter the inner diameter of the cutting element while remaining of large enough diameter to prevent the tissue plug from sliding off of the retractor element.

[0035] For example, the '187 patent application publication relates to an applicator for forming a hole in a wall of a hollow organ and for inserting a connector conduit into the hole to facilitate connection of the connector conduit to the hollow organ. The applicator includes a hole forming element for forming a hole in the wall of the organ, a positioning means coupled to the hole forming element for positioning the hole forming element, a retractor element operatively coupled to the positioning means, and a sequencing means for coordinating the relative movement of the retractor element with respect to the hole forming element in a sequential manner to thereby carry out a procedure for forming a hole in the wall of the hollow organ and inserting the connector conduit in the hole.

[0036] The hole forming element has a cutting element on a distal end thereof and is adapted for coupling with the connector conduit, with a distal end of the connector conduit being adjacent to the cutting element during a procedure for implanting the connector conduit within the organ wall. The retractor element preferably includes a retractor body movably disposed within said hole forming element and an expansion element disposed on a distal end of said retractor body, the expansion element being expandable.

[0037] Figs. 2A-2C illustrate components of a preferred embodiment of U.S. Patent Application Publication No. 2005-0251187, which is shown in Figs. 4A-4E. This embodiment uses a sequencing element to coordinate the position of retractor element 500 with the expansion of expanding element 530 (Fig. 2). In this embodiment, the sequencing element is a cam mechanism. The cam mechanism helps to ensure proper use of the applicator during implantation of connector conduit 100

(See Fig. 1). As shown in Fig. 2B, retractor element 500, referred to as the retractor assembly, includes cylinder portion 562 integrated therein. The retractor assembly is positioned concentrically within pushing element 300 during use. The retractor assembly contains elements of the cam mechanism formal therein, including cylinder cam slot 710, which is a slot cut completely through the cylinder 562 wall, and a retractor cam follower 760, which may be a pin or screw in cylinder 562 (as shown) or may be an integral part of cylinder 562. Retractor element 500 may include a section of increased diameter such as stopper disk 515 to prevent cutter element 210 from cutting the heart when retractor element 500 is initially inserted. Fig. 2A illustrates plunger 600 (in the form of a sequencing bolt as described below), which is positioned concentrically within cylinder 562 during use. Plunger 600 contains elements of the cam mechanism, including bolt portion 650 with plunger cam follower 750. Plunger cam follower 750 moves within cylinder cam slot 710 and pusher cam slot 720. Plunger 600 includes passage 610 and purge/fill valve 630 (valve body not shown). Valve 630 can be opened to allow fluid flow into and out of passage 610. When closed, valve 630 allows no fluid flow in either direction. Valve 630 may be connected (such as with a catheter) to a reservoir of saline, for example, to purge the expanding element 530, access passage 531 and any other volume in the flow circuit of air before filling these volumes with fluid (such as saline). O-ring groove 620 of plunger 600 contains an o-ring (not shown) to prevent loss of fluid.

[0038] Fig. 2C illustrates a positioning assembly, which is made up of rigidly connected components including pushing element 300, cutting element 210, and handle 310. The pusher element contains elements of the cam mechanism, including pusher cam slot 720 and retractor cam slot 730. The pusher cam slot 720 is a slot cut completely through the pushing element 300 wall to accommodate plunger cam follower 750.

[0039] In addition, the '187 patent application publication discloses that the expansion element may be expandable from an unexpanded state to fully expanded state and to a partially expanded state. In this case, the sequencing means may also include a means for causing the elements to assume the following states in seriatim.

The first state is a state in which the sequencing bolt is moved in the first slot and the cam slot to expand the expansion element while the retractor element is locked in a fully extended position relative to the hole forming element. The second state is a state in which the sequencing bolt is moved in the first slot and the cam slot to retain the expansion element as fully expanded. The third state is a state in which the sequencing bolt moves in the first slot and the retractor follower moves in the second slot to release the retractor element and permit the spring to move the retractor element toward the hole forming element. The fourth state is a state in which the sequencing bolt moves in the first slot while being locked in the cam slot and the retractor follower moves in the second slot to complete forming of the hole and allow insertion of the connector conduit into the hole. The fifth state is a state in which the sequencing bolt moves in the first slot and in the cam slot to release the sequencing bolt from a locked position in the cam slot to allow the expansion element to assume the partially expanded state while the expansion element is moved to be at least partially disposed in the hole forming element.

[0040] Figs. 3A - 3C illustrate operation of the cam mechanism disclosed in U.S. Patent Application Publication No. 2005-0251187. Fig. 3A illustrates cylinder cam slot 710 cut into cylinder 562 of Fig. 2B. Cylinder cam slot 710 contains three interconnected axial cam slots at angles Θ_1, Θ_2 and Θ_3 around the circumference of cylinder 562, as further illustrated in Fig. 3C. The axial cam slot at each angle corresponds to a range of allowable axial positions of plunger 600 within cylinder 562. At angle Θ_1, the axial length of the cam slot corresponds to the maximum stroke of plunger 600 within cylinder 562. This maximum stroke allows filling the expanding element 530 from minimum volume to maximum volume. At angle Θ_2, the axial cam slot allows plunger 600 movement to provide expanding element 530 volumes ranging from maximum volume to an intermediate volume (at an intermediate stroke) that is greater than minimum volume but less than maximum volume. At angle Θ_3, the axial cam slot retains plunger 600 at the position of maximum volume of the expanding element 530. Fig. 3A also illustrates positions A,

B, C, D and E of plunger cam follower 750 within cylinder cam slot 710 during the steps of operation.

[0041] Fig. 3B illustrates pusher cam slot 720 and retractor cam slot 730 cut into the pusher element of Fig. 2C. Fig. 3B also illustrates positions A, B, C, D and E of plunger cam follower 750 within pusher cam slot 720 and retractor cam follower 760 within retractor cam slot 730 during the steps of operation. Fig. 3C illustrates angles Θ_1 to Θ_6 for cylinder 562 and the pusher element. For purposes of description, the value of the angles increases from Θ_1 to Θ_6. Pusher cam slot 720 includes angles Θ_1 and Θ_3, which may correspond with angles Θ_1 and Θ_3 of cylinder 562 (see Fig. 3A). Pusher cam slot 720 includes angle Θ_4, which is larger than Θ_3. The axial length of pusher cam slot 720 from position A to position B corresponds to the maximum stroke of the plunger 600, as described above. The axial length of pusher cam slot 720 from position C to position E corresponds to the intermediate stroke plus the axial distance traversed by retractor cam follower 760 from position C to position E in retractor cam slot 730. Retractor cam slot 730 includes angles Θ_5 and Θ_6. Positions A and B at angle Θ_5 prevent compression spring 540 from displacing cylinder 562 within the pusher element.

[0042] In operation, retractor cam slot 730 controls the motion of cylinder 562 within the pusher element. As shown in Fig. 3A and Fig. 3B, when plunger cam follower 750 (of sequencing bolt 600) is moved circumferentially from position B to position C in both cylinder cam slot 710 and pusher cam slot 720, retractor cam follower 760 is forced from position B to position C in retractor cam slot 730, which allows compression spring 540 (see Fig. 18) to push cylinder 562 axially within the pusher element. Retractor cam follower 760 within retractor cam slot 730 holds cylinder 562 at a constant angular position relative to the pusher element during movement from position C to positions D and E; therefore, movement of plunger cam follower 750 from position C to position D within pusher cam slot 720 forces cam follower 750 into the axial slot corresponding to angle Θ_2 of cylinder 562.

[0043] Referring to Figs. 4A - 4E, the applicator of U.S. Patent Application Publication No. 2005-0251187 is shown at various steps during use. Fig. 4A to Fig.

4E correspond to positions A to E, respectively, which are described in Fig. 3A to Fig. 3C. Recognizing that individual surgeons may find alternative steps to properly use the invention, a representative sequence of steps for use of the applicator to implant a connector conduit is described. Sequencing bolt 600 is moved from position A to position B to inflate the balloon behind tissue T of the heart wall (see Fig. 4B). The surgeon moves sequencing bolt 600 from position B to position C (see Fig. 4C) and then releases sequencing bolt 650. Beginning at position C of Fig. 4C, compression spring 540 pushes the retractor assembly from position C to position D (see Fig. 4D). When the retractor assembly moves from position C to position D, tissue T of the heart wall is first sandwiched between the balloon and the sharpened edge of the cutting element 210a. By the surgeon using handle 310 to apply axial force and back-and-forth rotary motion, the sharpened edge of the cutting element 210a cuts though the heart wall to form a plug of tissue T that resides in the cutting element 210. At position D, the retractor assembly has been retracted until the balloon is in contact with cutting element 210 and the tissue plug is fully within cutting element 210. Also at position D, cylinder cam slot 710 has forced plunger cam follower 750 circumferentially to angle Θ_2, thereby allowing deflation of the balloon to begin. Between position D (Fig. 4D) and position E (Fig. 4E), the balloon deflates to the intermediate volume (described earlier), and the retractor assembly retracts to its final position. If necessary, the surgeon may pull sequencing bolt 600 to its final position E.

[0044] To prevent possible injury to the inner surfaces of the heart (e.g., ventricle wall, chordae tendinae), the expansion element should remain in the fully expanded state (i.e. at position D, or the fourth state, in Fig. 3B) until the connector conduit has been fully inserted and placed into its final position within the apex wall. If the connector conduit is only partially inserted at the fourth state and the expansion element is allowed to assume the partially expanded state before the connector conduit is completely inserted to its final position, the sharp edge of the hole forming element may be exposed to the inner surfaces of the heart (e.g., endocardium, chordae tendinae) during twisting and pushing motion to place the connector conduit to its final position within the apex wall, which can result in damage to the inner surfaces of

the heart. In this way, the fully expanded expansion element covers the sharp edge of the hole forming element while the connector conduit is being maneuvered to its final position, thereby preventing damage to the inner surfaces of the heart.

[0045] Accordingly, the invention reduces the likelihood of damage to the inner surfaces of the heart by improving on the applicator described above by providing a safety latch that prevents proceeding from the fourth state to the fifth state described above until the safety latch is released by a deliberate action of the surgeon. In this way, the surgeon can place the connector conduit into its final position within the apex before deliberately releasing the safety latch to allow the expansion element to assume the partially expanded state.

[0046] Fig. 5 illustrates an exploded view of an exemplary applicator and safety latch of the invention. The basic components shown in Fig. 5, and their reference numerals, are identical to those disclosed in U.S. Patent Application Publication No. 2005-0251187. For example, the applicator shown in Fig. 5 includes a handle 310, an expanding element 530, a stopper disk 515, a cutter element 210, a bolt portion 650 (i.e. a sequencing bolt), and a pusher element 300. Pusher element 300 also includes a pusher cam slot 720 and a pusher latch cam slot 741. Fig. 5 further includes the safety latch element of the invention. The safety latch element of the invention includes a latch cylinder 780, which includes a safety latch cam slot 740, a lever 781, a grooved surface 782, and a spring element (not shown).

[0047] During operation, latch cylinder 780 fits concentrically over pushing element 300 such that safety latch cam slot 740 is positioned generally over pusher cam slot 720. In this configuration, sequencing bolt 650 may extend through both pusher cam slot 720 and safety latch cam slot 740. In addition, a spring element (not shown) is positioned within latch cylinder 780 such that when latch cylinder 780 is installed over pushing element 300, the spring element rotationally biases latch cylinder 780 relative to pushing element 300.

[0048] The safety latch element further includes a safety latch cam follower 770, which is, for example, a threaded pin that fits snugly in a lever 781 and extends

through latch cylinder 780 into pusher latch cam slot 741. Thus, when latch cylinder 780 is rotated relative to pusher element 300, the tip of safety latch cam follower 770 moves within pusher latch cam slot 741 (shown). In addition, there is a further optional cam slot (i.e. retractor latch cam slot 742) which may be positioned in the retractor element (see Fig. 6A), which is concentrically located within pusher element 300. According to the preferred embodiment, the tip of safety latch cam follower 770 further extends through pusher latch cam slot 741 into retractor latch cam slot 742, to thereby restrict rotational movement of latch cylinder 780 with respect to both pusher element 300 and the retractor element, and vice versa. Thus, safety latch cam follow 770 with pusher latch cam slot 741 and retractor latch cam slot 742 constrain movement of latch cylinder 780 relative to pushing element 300 and the retractor element to allow only limited rotary motion. This rotary motion is facilitated with lever 781 and grooved surface 782.

[0049] Figs. 3 and 4 illustrate the orientations and relative positioning of the slots in the retractor assembly (Fig. 3A) and the pusher element (Fig. 3B) as disclosed in the '187 patent application publication. The slots are illustrated such that, during operation, the slots in Fig. 3B would be overlaid above the slots in Fig. 3A. These figures further describe the relative movement of the retractor element and the pusher element when sequencing bolt 650 is moved through cylinder cam slot 710 of the retractor assembly and, simultaneously, pusher cam slot 720 of the pusher assembly. When plunger cam follower 750 (of sequencing bolt 650) is moved to position C in pusher cam slot 720, a compression spring 540 pushes cylinder 562 axially within the pusher element from position C to position E. (See Fig. 4).

[0050] In addition, with respect to Figs. 3 and 4, after the sequencing bolt completes the move from position C to position E, the user may wish to reload the device by reversing the movement of the cam mechanism from position E to position C. During movement from position E to position C, the force applied to sequencing bolt 650 serves to fully inflate expanding element 530 and to compress compression spring 540. When position D is reached during reloading, if the force applied to sequencing bolt 650 to inflate expanding element 530 exceeds the force required to

compress spring 540, cylinder 562 can move relative to pushing element 300, thereby misaligning the cam slots and resulting in undesired binding of the sequencing bolt 650 in the cam slots. This binding can be avoided by reducing movement of the retractor element 500 by reducing the length of the retractor cam slot 730 to stop at position D. (See Fig. 3B). As a result, expansion element 530 does not fully retract into cutting element 210. Fig. 6B illustrates an exemplary retractor cam slot 730 that has been shortened as is described above. As is clear in Fig. 6B, positions D, E, and F in retractor cam slot 730 are all in the same position.

[0051] Referring back to Figs. 3 and 4, as plunger cam follower 750 passes position D, the hole is formed in the organ and the expansion state of the expansion element changes from a fully expanded state to a partially expanded state. When this occurs, it is possible for the expansion element to assume the partially expanded state prior to completely cutting through the wall of the organ. In addition, while the surgeon is twisting and pushing the applicator to form the hole and position the connector conduit, if used, the premature deflation of the expansion element to the partially expanded state can result in exposure of the sharp cutting edge of the hole forming element to the inner surfaces of the hollow organ (e.g., endocardium, chordae tendinae). This exposure can result in damage to the inner surfaces of the organ, possibly resulting in injury or death to the patient.

[0052] In contrast, the present invention provides a safety latch element that prevents exposure of the sharp cutting edge to the inner surfaces of the hollow organ. In particular, as is shown in Figs. 6A – 6D, which shows the planar orientations and relative positioning of the slots of the invention in the retractor assembly (Fig. 6A), the pusher element (Fig. 6B), and the safety latch (Fig. 6C), the invention includes a safety latch feature in a safety latch cam slot that stops the movement of sequencing bolt 650 at position D, and prevents proceeding from position D until the safety latch is released by a deliberate action of the surgeon. This feature is embodied in the safety latch cam slot at position D, which is located, in Fig. 6C, in a corner portion of safety cam slot 740. As mentioned above, the safety latch element also includes an internal spring element which rotationally biases the safety latch relative to the pusher

assembly. In this arrangement, the spring rotationally biases the safety latch assembly in a downward direction in Fig. 6C, thereby biasing the sequencing bolt into position D of the safety latch cam slot and preventing inadvertent rotation of the safety latch cam slot relative to the pusher assembly into position E.

[0053] Fig. 6A is a planar representation of cylinder 562 (i.e. the retractor assembly), and illustrates the positioning of cylinder cam slot 710 and retractor latch cam slot 742 on cylinder 562. In addition, Fig. 6A illustrates the positioning of retractor cam follower 760, which is rigidly attached to cylinder 562. During operation, safety latch cam follower 770, which is inserted through latch 781 (Fig. 5) and pusher latch cam slot 741 (Fig. 6B), enters optional retractor latch cam slot 742 as the expanding element 530 approaches the sharp edge of the cutting element 210. Latch cylinder 780 can then be rotated to move safety latch cam follower 770 from position D to position E in retractor latch cam slot 742 to operationally lock cylinder 562 and the retractor assembly axially relative to the pushing element 300. This axial locking reduces movement of cylinder 562 within the pushing element 300 when sequencing bolt 650 is moved from position F to position C, such as when reloading the applicator for reuse. It should be noted that optional retractor latch cam slot 742 can be used in conjunction with, or as an alternative to, a shortened retractor cam slot 730 as a means to prevent undesired binding of the sequencing bolt in the cam slots.

[0054] Similarly, Fig. 6B is a planar representation of pushing element 300. Pushing element 300 preferably includes three slots: a retractor cam slot 730, a pusher cam slot 720, and a pusher latch cam slot 741. It should be noted that retractor cam slot 730 as described with reference to the present invention, is of a length suitable to bring the expansion element into contact with the tip of the cutting element, but is preferably not of sufficient length to cause the expansion element to withdraw into the hole forming element prior to extraction of the applicator. As is noted above, safety latch cam follower 770 is positioned within pusher latch cam slot 741. Thus, safety latch cam follower 770 is capable of movement within the limits of pusher latch cam slot 741. As can be seen in Fig. 6B, safety latch cam follower 770 can rotate within the limits of pusher latch cam slot 741. In addition, the relative positioning of the

pusher assembly relative to the retractor assembly is controlled by the interactions between retractor cam follower 760 and the retractor cam slot 730. Pusher cam slot 720 is the primary slot in pushing element 300 for controlling movement of components within the applicator, such as the expansion element. Plunger cam follower 750 (of sequencing bolt 650), which also passes through safety latch cam slot 740 and cylinder cam slot 710, is positioned within pusher cam slot 720.

[0055] Fig. 6C is a planar representation of the safety latch element of the invention, including latch cylinder 780. Latch cylinder 780 includes a safety latch cam slot 740, through which plunger cam follower 750 passes, and latch 781, through which safety latch cam follower 770 passes. Safety latch cam follower 770 is preferably rigidly attached to latch cylinder 780. In addition, it should be noted that portions of safety latch cam slot 740 may not be fully enclosed, provided such open portions do not interfere with the functionality of the safety latch element and the movement of the sequencing bolt.

[0056] Fig. 6D illustrates angles of rotation Θ_1 to Θ_4, α_1 to α_2, and β_1 to β_2 for cylinder 562, pushing element 300 and latch cylinder 780. In addition, positions A, B, C, D, E and F illustrate positions of plunger cam follower 750, retractor cam follower 760 and safety latch cam follower 760 within cam slots. Each of these positions represents a state point. In the design described in Figs. 6A – 6D, cylinder 562 moves axially relative to pushing element 300 only when sequencing bolt 650 moves from position C to position D. The extent of relative movement is defined by the length of retractor cam slot 730 between position C and position D. Cylinder 562 does not move axially while expanding element 530 assumes the partial expansion state when sequencing bolt 650 moves from position E to position F.

[0057] Figs. 7A – 7D represent the applicator at several state points. Fig. 7A corresponds to position A, as described in Fig. 6A – 6D. Fig. 7B corresponds to position B, as described in Fig. 6A – 6D. Fig. 7C corresponds to position D, as described in Fig. 6A - 6D. Fig. 7D corresponds to position F, as described in Fig. 6A – 6D.

[0058] Thus, during operation, the sequencing means causes the elements to assume a plurality of distinct states. After the initial setup, each element will be in position A, with the expansion element being in a deflated state, and the retractor element being in a fully extended position. (See Fig. 7A). In this initial position, the trocar of the retractor element has already been pushed through the wall of the organ to be cut, and the deflated expansion element is positioned within the organ.

[0059] When the surgeon is ready to begin the sequencing procedure, sequencing bolt 650 is moved from position A (Fig. 7A) to position B (Fig. 7B). This movement causes plunger cam follower 750 (of sequencing bolt 650) to move from a first position (A) to a second position (B) in each of the cylinder cam slot, the pusher cam slot, and the safety latch cam slot. This movement causes the expansion element to expand to a fully expanded state while retaining the retractor element in a fully extended position relative to the hole forming element. Thus, at this point, the expansion element is in a fully expanded state within the organ. (See Fig. 7B).

[0060] Sequencing bolt 650 is then rotated from position B to position C in the cylinder cam slot, the pusher cam slot, and the safety latch cam slot, thereby retaining the expansion element in the fully expanded state and the retractor element in the fully extended position. This is a rotational step which places retractor cam follower 760 in position C in retractor cam slot 730 while retaining safety latch cam follower 770 in position C in pusher latch cam slot 741.

[0061] When sequencing bolt 650 reaches position C, compression spring 540 biases the retractor assembly, and expansion element 530, towards position D. This movement affects many of the components. For example, as sequencing bolt 650 moves from position C to position D, expansion element 530 is biased towards cutter element 210, thereby causing cutter element 210 to come into contact with the wall of the organ. The surgeon then pushes and rotates cutter element 210 to cause cutter element 210 to cut into and through the wall of the organ, thereby creating the tissue plug. When sequencing bolt 650 reaches position D, cutting element 210 comes into contact with fully expanded expansion element 530, thereby completing the cutting

process of the wall of the organ. In addition, as sequencing bolt 650 moves from position C to position D, retractor cam follower 760 moves from position C to position D in retractor cam slot 730 and safety latch cam follower 770 is retained in position D in retractor latch cam slot 742. Thus, the net effect of the movement from position C to position D is to move the retractor element towards the hole forming element, thereby forming the hole with cutting element 210, while retaining the expansion element in the fully expanded state throughout the process. Fig. 7C illustrates the state of the applicator when sequencing bolt 650 is in position D.

[0062] The fourth state is a state in which sequencing bolt 650 is locked in position D. This state is made possible through the use of the safety latch of the invention. As is shown in Fig. 7C, sequencing bolt 650 is positioned in an angled portion of safety latch cam slot 740 at position D, and is in axial abutment with a side of safety latch cam slot 740, thereby preventing further axial movement of sequencing bolt 650 relative to the safety latch. Thus, in this position, the expansion element is retained in the fully expanded state. In addition, at position D, expanding element 530 is in contact with the sharp edge of cutting element 210. At position D, the expanding element 530 has sufficient stiffness and is of sufficiently larger diameter than cutting element 210 to prevent the sharp edge of cutting element 210 from contacting the inside surface of the organ, which, in the case of a heart, is the ventricle. Protecting the inner surface of the organ from the sharp edge allows the surgeon to twist and push the connector conduit to its final position, if a connector conduit is used.

[0063] When the user is ready to extract the applicator from the organ (i.e. when the connector conduit, if used, is installed in its final position), the user may use lever 781 or grooved surface 782 to deliberately rotate the safety latch element relative to sequencing bolt 650. This movement repositions sequencing bolt 650 from position D to position E in safety latch cam slot 740. The position of sequencing bolt 650 does not change relative to pusher cam slot 720 or cylinder cam slot 710 during this repositioning.

[0064] As soon as the safety latch element is rotated relative to sequencing bolt 650, thereby causing sequencing bolt 650 to be repositioned in position E in safety latch cam slot 740, the sequencing bolt exits the axial abutment it had with the side of safety latch cam slot 740, and the pressure from the compression of expansion element 530 axially biases sequencing bolt 650 towards position F. As sequencing bolt 650 approaches position F, expansion element 530 collapses from a fully expanded state to a partially expanded state. As is shown in Fig. 7D, when sequencing bolt 650 reaches position F, partially expanded expansion element 530 is pressed against cutting element 210, which is ideal for extraction of the applicator from the organ and connector conduit, if used.

[0065] The design of the safety latch ensures that rotation of latch cylinder 780 relative to pushing element 300 results in partial deflation of the expanding element 530 only when the sequencing bolt 650 is at position D before rotation. This design provides a safety latch that the surgeon cannot deliberately or inadvertently release before the sequencing bolt 650 is at position D.

[0066] Thus, through the use of the safety latch element, the expansion element remains in its fully expanded state at position D, and is prevented from changing from the fully expanded state to the partially expanded state until the surgeon deliberately chooses to do so. By retaining the expansion element in the fully expanded state, the safety latch enables the sharp edge of the hole forming element to be completely covered by the fully expanded expansion element, thereby preventing exposure of the inner surfaces of the organ to the sharp edge of the hole forming element, and the possibility of resulting damage to the inner surfaces of the organ.

[0067] Furthermore, in some circumstances, surgeons may wish to cut a hole in the wall of a hollow organ, such as the heart, without simultaneously inserting a connector conduit into the hole. Accordingly, the present invention may be used solely to cut a hole in the heart wall, and does not require simultaneous insertion of a conduit connector or other device. The connector conduit could be implanted in the hole as a separate step.

What is claimed is:

1. An applicator for forming a hole in a wall of a hollow organ comprising:

a hole forming element for forming a hole in the wall of the organ, the hole forming element having a cutting element on a distal end thereof;

a positioning means coupled to the hole forming element for positioning the hole forming element;

retractor element operatively coupled to the positioning means; and

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

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

3. The applicator of claim 2, wherein the expansion element is expandable from an unexpanded state to fully expanded state and to a partially expanded state.

4. The applicator of claim 3, wherein the sequencing means controls the expansion of the expansion element from the unexpanded state, to the fully expanded state, and to the partially expanded state in a sequential manner.

5. The applicator of claim 4, wherein the sequencing means further comprises a safety latch element operatively coupled to the retracting means and the hole forming element.

6. The applicator of claim 5, wherein the sequencing means further comprises a sequencing bolt that extends through a cylinder cam slot formed in the

retractor element, a pusher cam slot formed in a pusher element, and a safety latch cam slot formed in the safety latch element.

7. The applicator of claim 6, wherein the sequencing means comprises a means for causing the elements to assume the following states in seriatim:

a) a first state in which the sequencing bolt moves from a first position to a second position in each of the cylinder cam slot, the pusher cam slot, and the safety latch cam slot, thereby expanding the expansion element to a fully expanded state while retaining the retractor element in a fully extended position relative to the hole forming element;

b) a second state in which the sequencing bolt moves from the second position to a third position in the cylinder cam slot, the pusher cam slot, and the safety latch cam slot, thereby retaining the expansion element in the fully expanded state and the retractor element in the fully extended position;

c) a third state in which the sequencing bolt moves from the third position to a fourth position in the cylinder cam slot, the pusher cam slot, and the safety latch cam slot, thereby permitting the retractor element to move towards the hole forming element while retaining the expansion element in the fully expanded state;

d) a fourth state in which the sequencing bolt is locked in a fourth position in the safety latch cam slot, the cylinder cam slot, and the pusher cam slot, thereby retaining the expansion element in the fully expanded state;

e) a fifth state in which the safety latch element is moved relative to the retractor element such that the sequencing bolt is repositioned from the fourth position to a fifth position in the safety latch cam slot while remaining in the fourth position in the cylinder cam slot and the pusher cam slot, thereby releasing the expansion element from the fully expanded state; and

f) a sixth state in which the sequencing bolt moves from the fifth position to a sixth position in the safety latch cam slot, and simultaneously, from the fourth position to a fifth position in the cylinder cam slot and the pusher cam slot, to allow the expansion element to assume the partially expanded state.

8. The applicator of claim 1, wherein the organ is a heart.

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

10. The applicator of claim 2, wherein the expansion element is a balloon.

11. The applicator of claim 2, wherein the expansion element is an expandable sponge.

12. The applicator of claim 2, wherein the expansion element is an umbrella mechanism.

13. The applicator of claim 1, wherein the sequencing means comprises a cam mechanism.

14. The applicator of claim 1, wherein the sequencing means comprises a gear mechanism.

15. The applicator of claim 1, wherein the sequencing means comprises at least one servo mechanism operatively coupled to the positioning means and a controller operatively coupled to the at least one servo mechanism.

16. The applicator of claim 15, further comprising a button operatively coupled to the sequencing means for activating the sequencing means upon depression of the button to thereby accomplish steps of a procedure for implanting the connector conduit within the organ wall.

17. A method of forming a hole in a wall of a hollow organ comprising:

forming a hole in the wall of the organ with a hole forming element, the hole forming element having a cutting element on a distal end thereof;

positioning the hole forming element with a positioning means coupled to the hole forming element, the positioning means being operatively coupled to a retractor element; and

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

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

19. The method of claim 18, wherein the expansion element is expandable from an unexpanded state to fully expanded state and to a partially expanded state.

20. The method of claim 19, wherein the sequencing means controls the expansion of the expansion element from the unexpanded state, to the fully expanded state, and to the partially expanded state in a sequential manner.

21. The method of claim 20, wherein the sequencing means further comprises a safety latch element operatively coupled to the retracting means and the hole forming element.

22. The method of claim 21, wherein the sequencing means comprises a sequencing bolt that extends through a cylinder cam slot formed in the retractor element, a pusher cam slot formed in a pusher element, and a safety latch cam slot formed in the safety latch element.

23. The method of claim 22, wherein the sequencing means comprises a means for causing the elements to assume the following states in seriatim:

a) a first state in which the sequencing bolt moves from a first position to a second position in each of the cylinder cam slot, the pusher cam slot, and the safety latch cam slot, thereby expanding the expansion element to a fully expanded state while retaining the retractor element in a fully extended position relative to the hole forming element;

b) a second state in which the sequencing bolt moves from the second position to a third position in the cylinder cam slot, the pusher cam slot, and the safety latch cam slot, thereby retaining the expansion element in the fully expanded state and the retractor element in the fully extended position;

c) a third state in which the sequencing bolt moves from the third position to a fourth position in the cylinder cam slot, the pusher cam slot, and the safety latch cam slot, thereby permitting the retractor element to move towards the hole forming element while retaining the expansion element in the fully expanded state;

d) a fourth state in which the sequencing bolt is locked in a fourth position in the safety latch cam slot, the cylinder cam slot, and the pusher cam slot, thereby retaining the expansion element in the fully expanded state;

e) a fifth state in which the safety latch element is moved relative to the retractor element such that the sequencing bolt is repositioned from the fourth position to a fifth position in the safety latch cam slot while remaining in the fourth position in the cylinder cam slot and the pusher cam slot, thereby releasing the expansion element from the fully expanded state; and

f) a sixth state in which the sequencing bolt moves from the fifth position to a sixth position in the safety latch cam slot, and simultaneously, from the fourth position to a fifth position in the cylinder cam slot and the pusher cam slot, to allow the expansion element to assume the partially expanded state.

24. The method of claim 17, wherein the organ is a heart.

25. The method of claim 17, wherein a connector conduit is coupled to the hole forming element.

26. The method of claim 18, wherein the expansion element is a balloon.

27. The method of claim 18, wherein the expansion element is an expandable sponge.

28. The method of claim 18, wherein the expansion element is an umbrella mechanism.

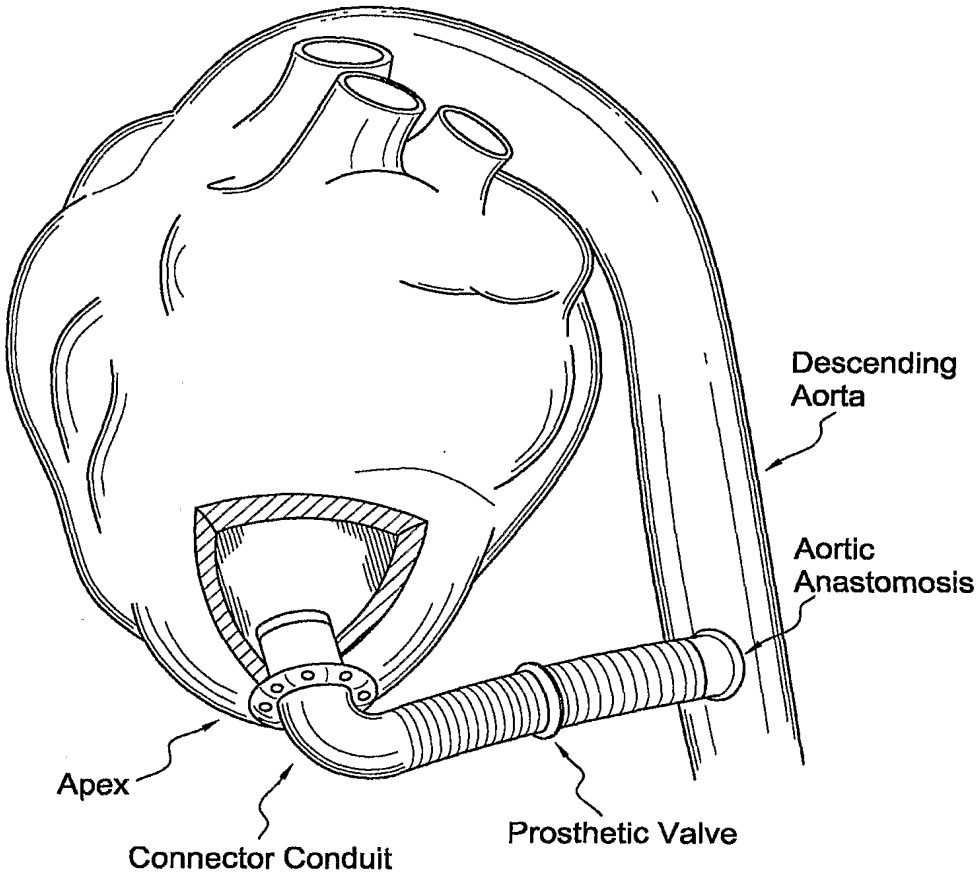
29. The method of claim 17, wherein the sequencing means comprises a cam mechanism.

30. The method of claim 17, wherein the sequencing means comprises a gear mechanism.

31. The method of claim 17, wherein the sequencing means comprises at least one servo mechanism operatively coupled to the positioning means and a controller operatively coupled to the at least one servo mechanism.

32. The method of claim 31, further comprising a button operatively coupled to the sequencing means for activating the sequencing means upon depression of the button to thereby accomplish steps of a procedure for implanting the connector conduit within the organ wall.

FIG. 1



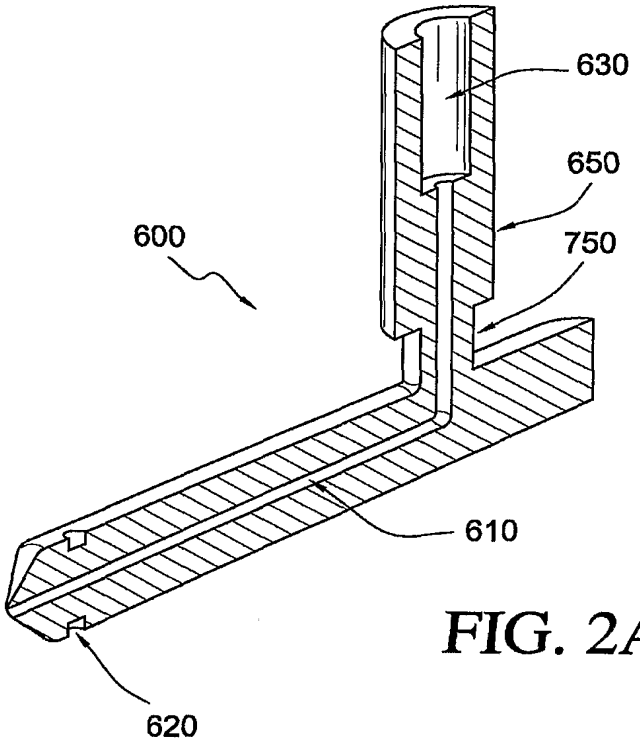


FIG. 2A

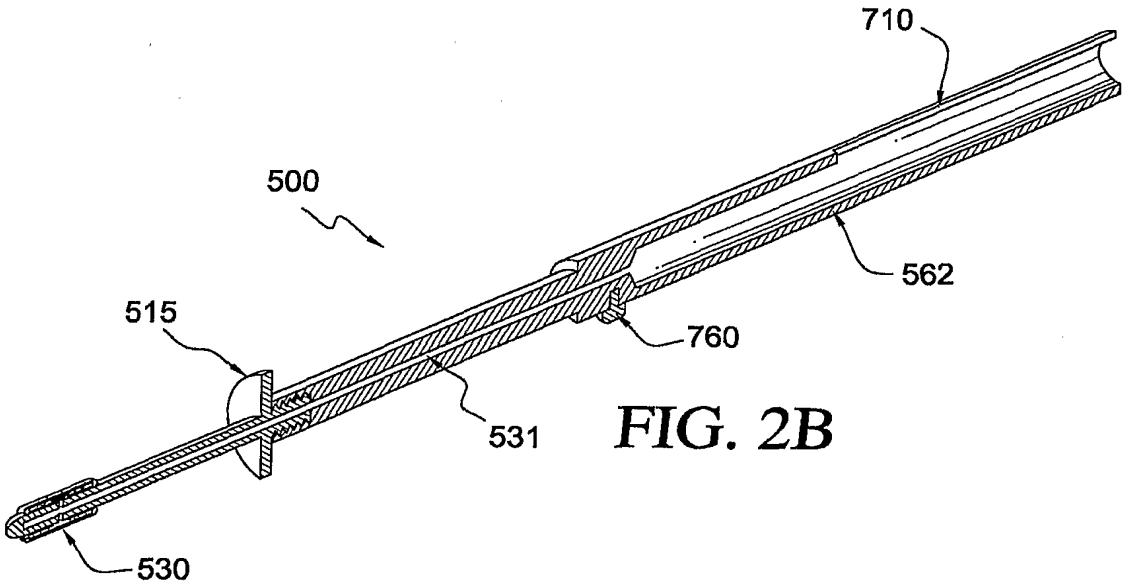


FIG. 2B

FIG. 2C

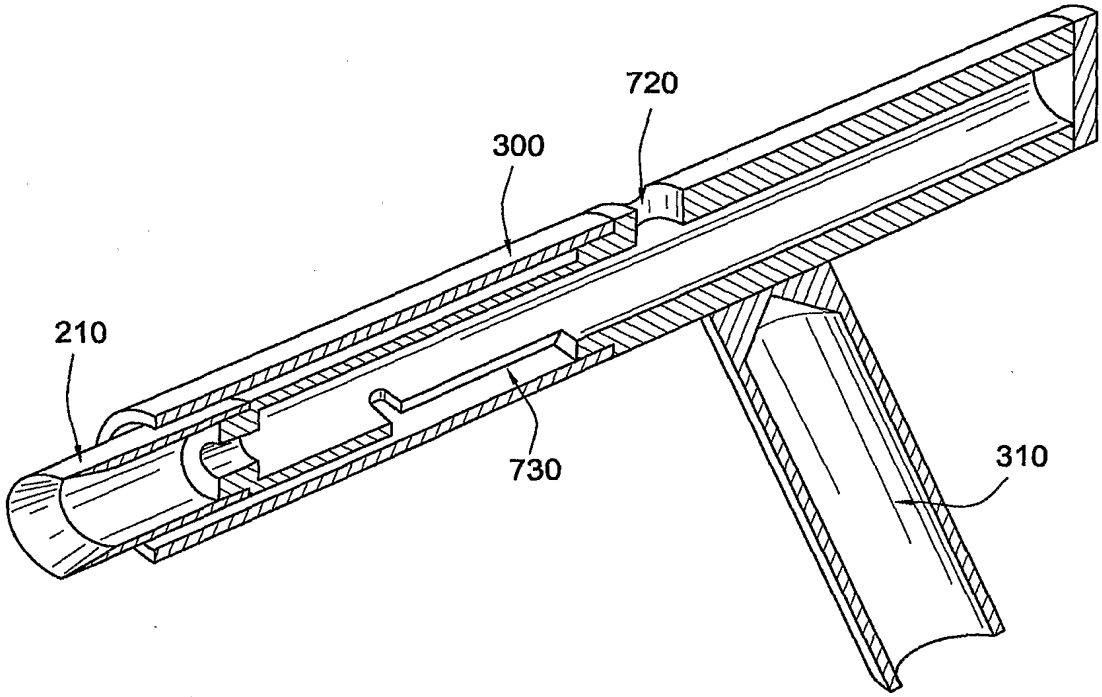


FIG. 3A

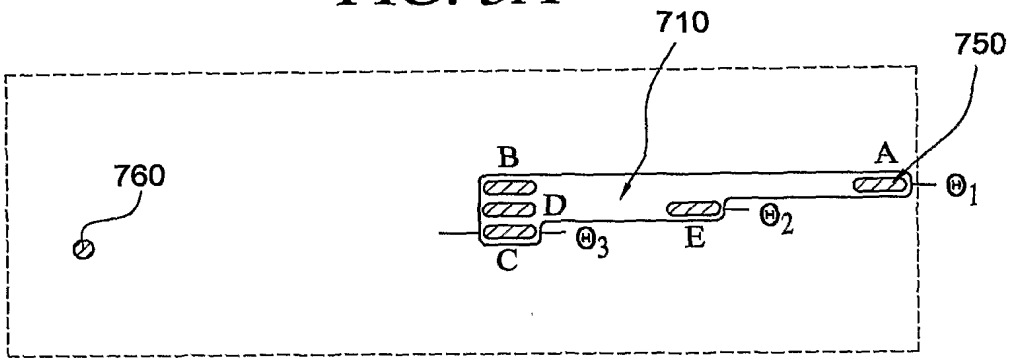


FIG. 3B

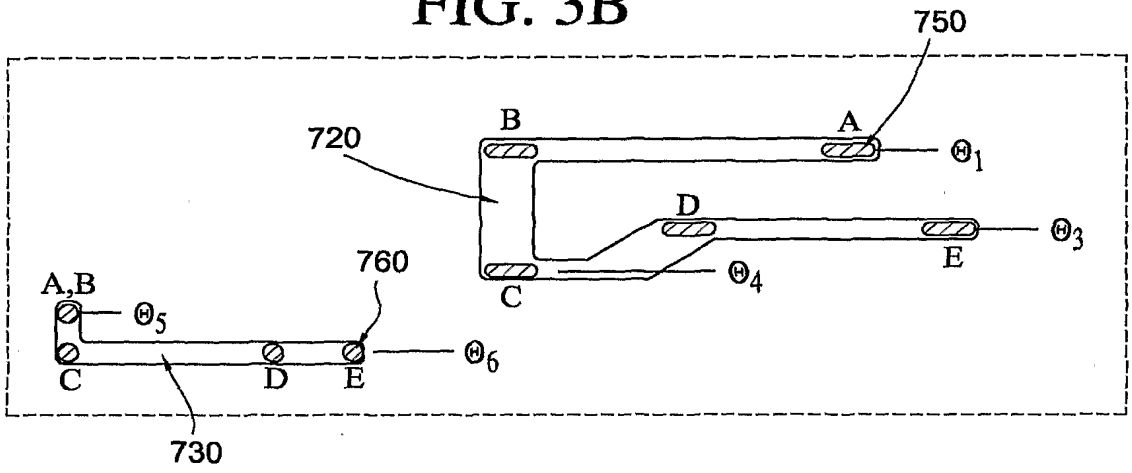


FIG. 3C

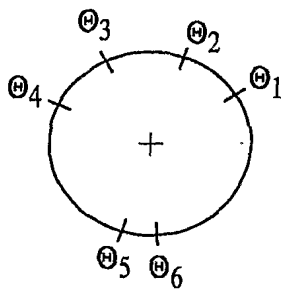


FIG. 4A

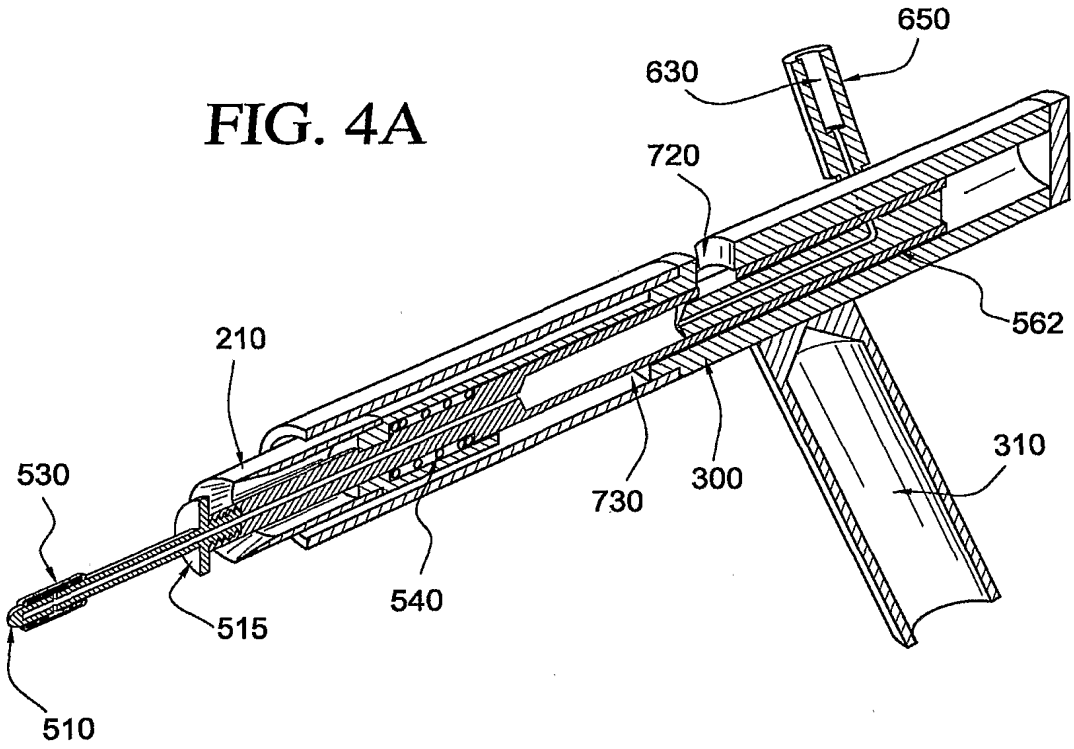


FIG. 4B

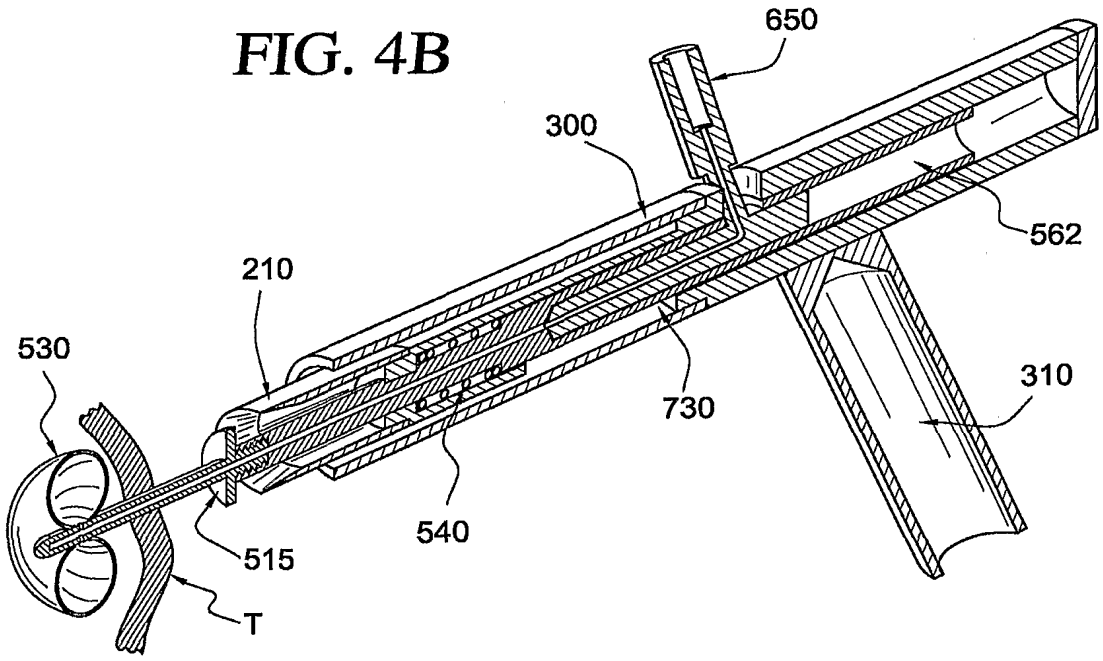


FIG. 4C

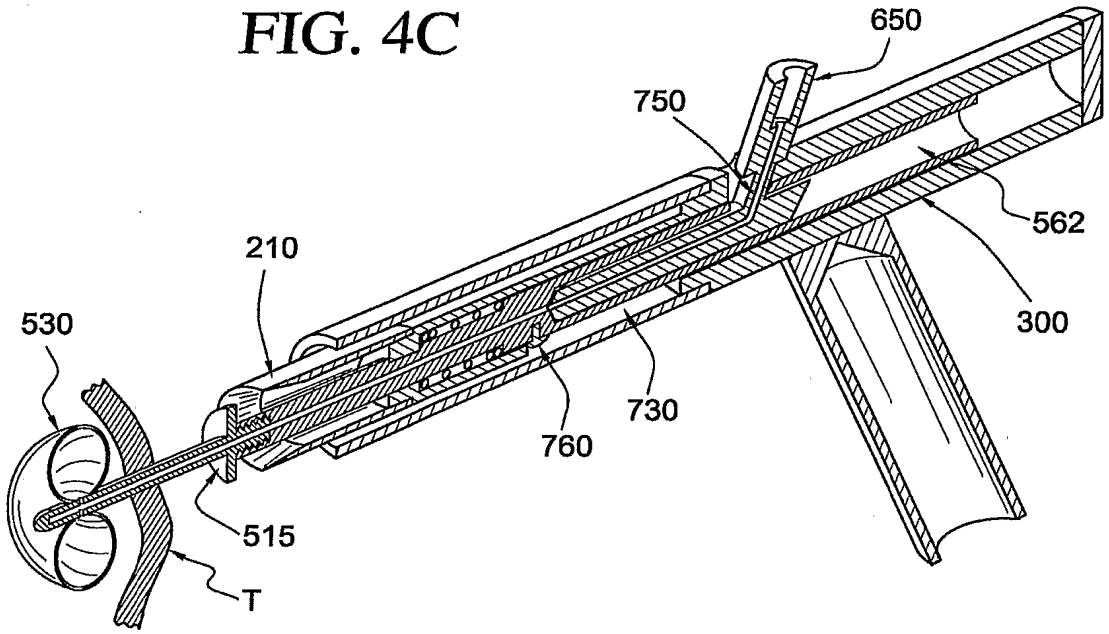


FIG. 4D

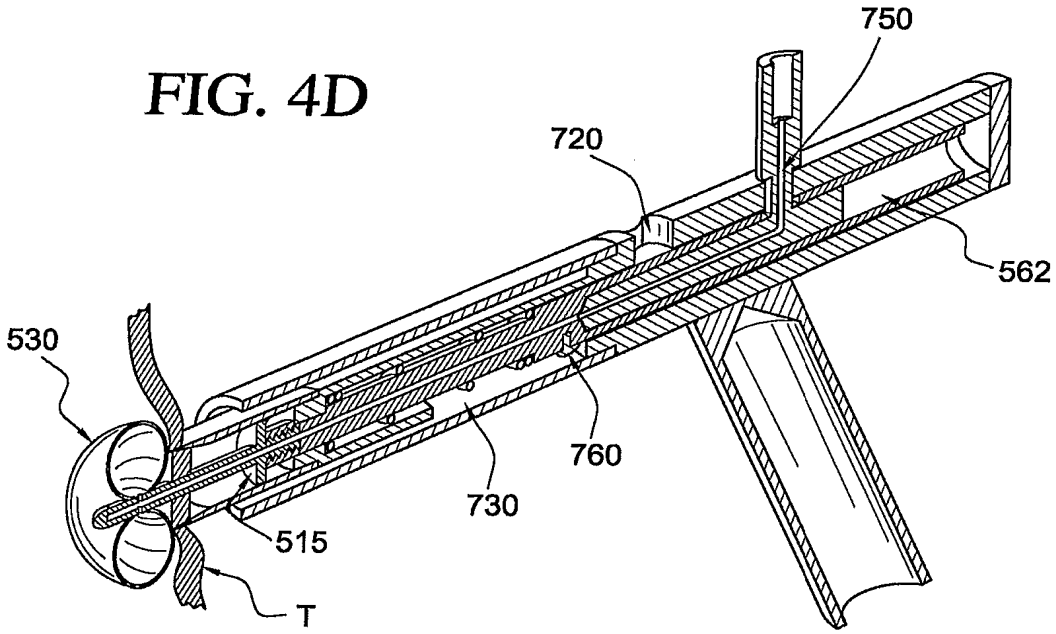
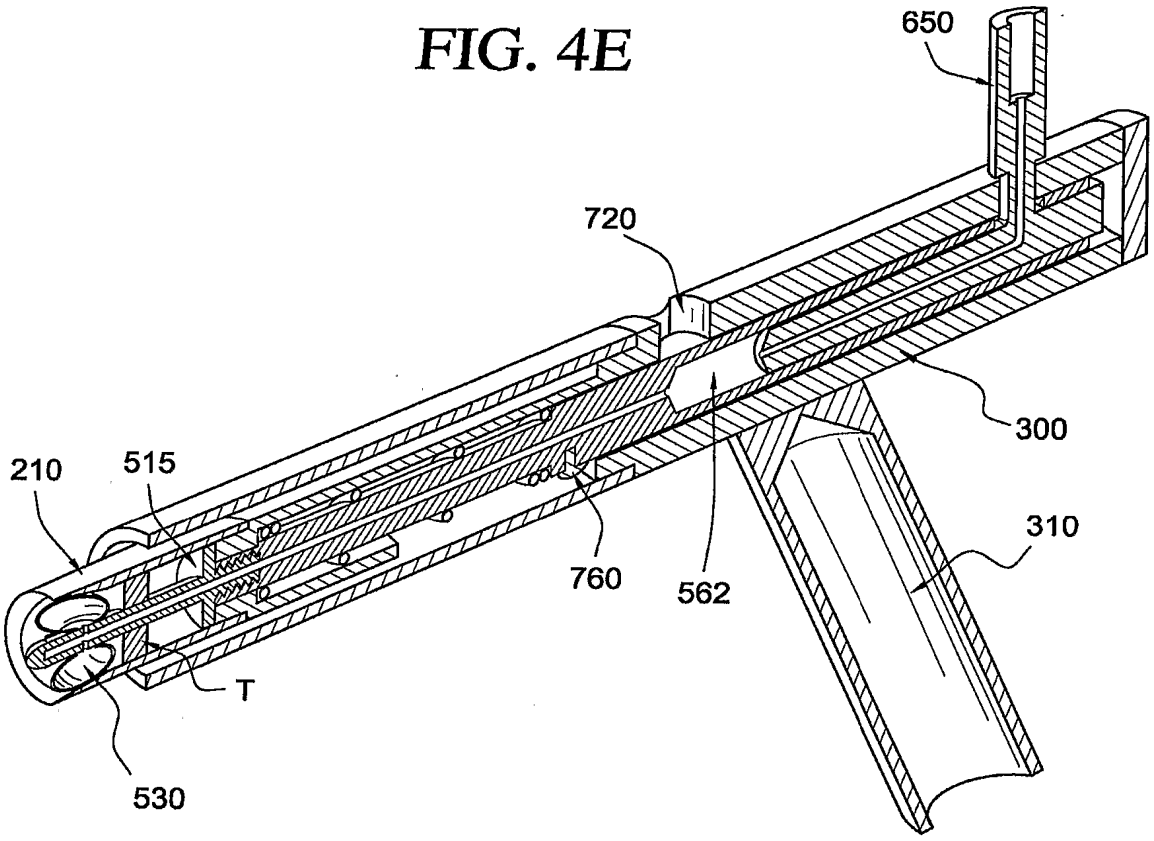


FIG. 4E



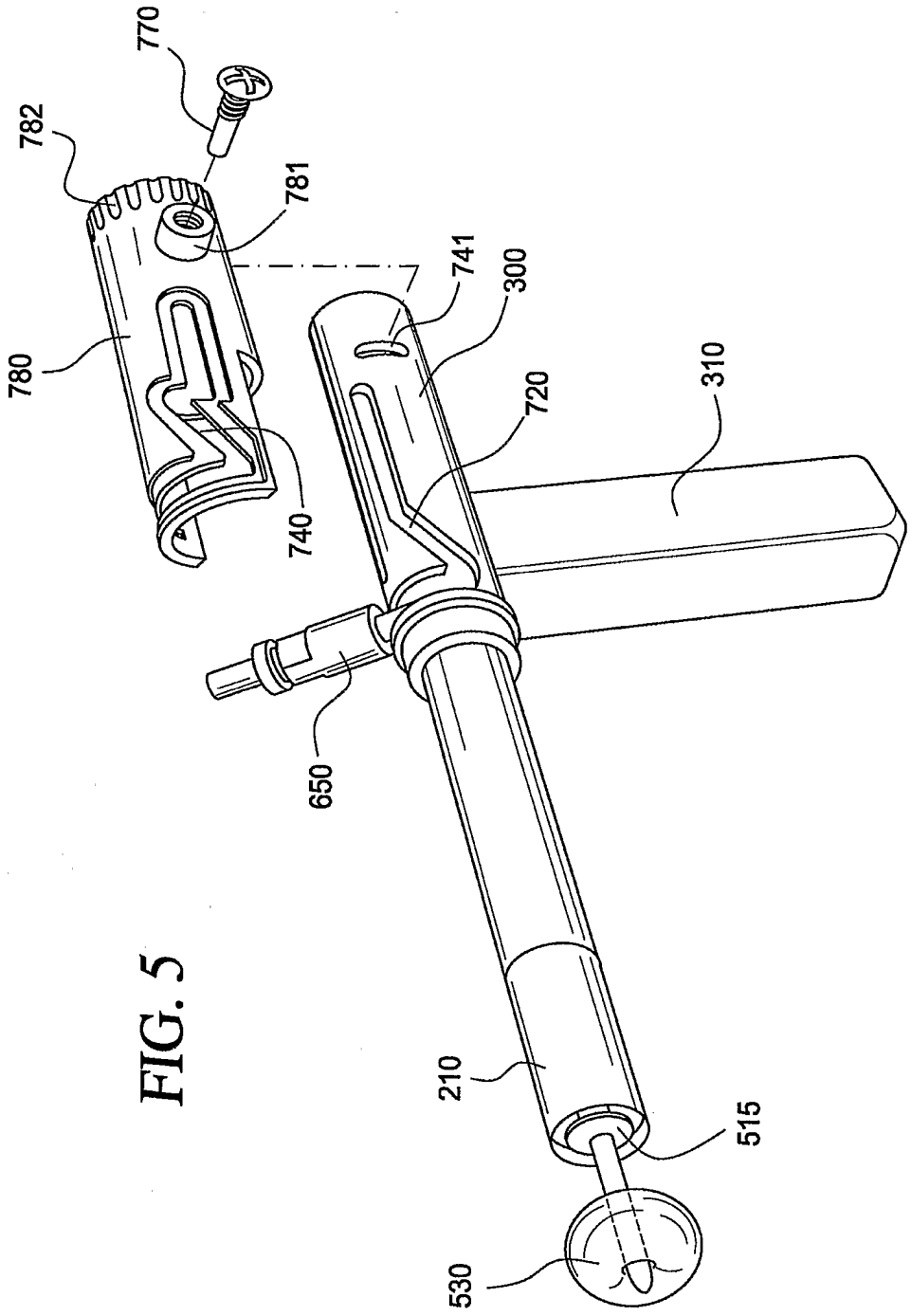


FIG. 5

FIG. 6A

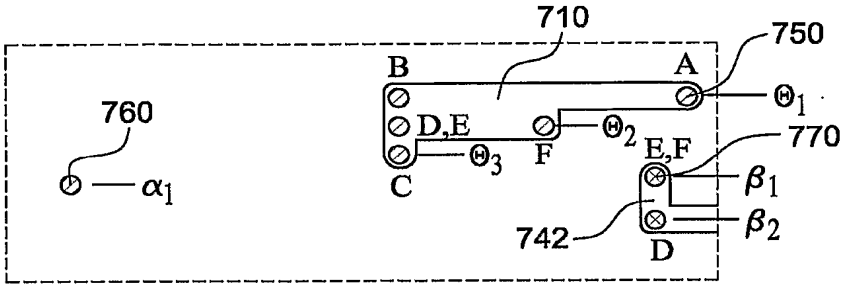


FIG. 6B

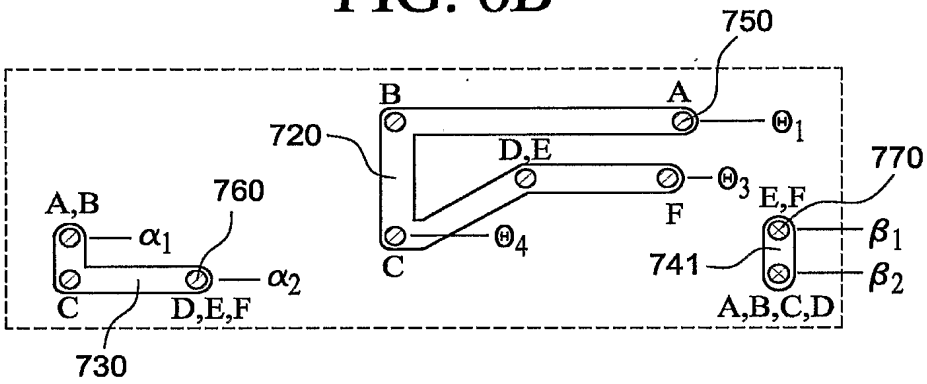


FIG. 6C

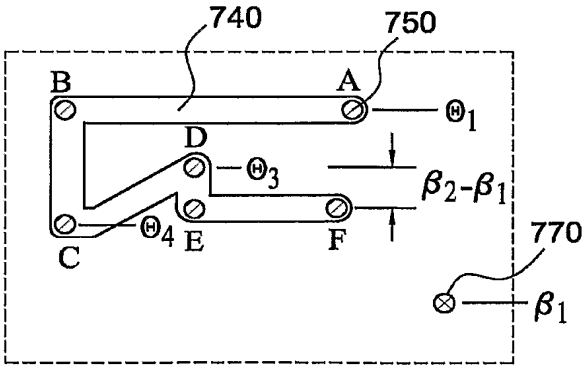
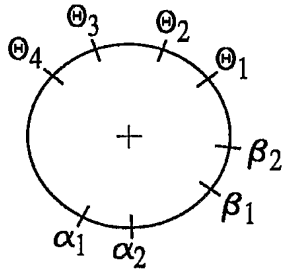


FIG. 6D



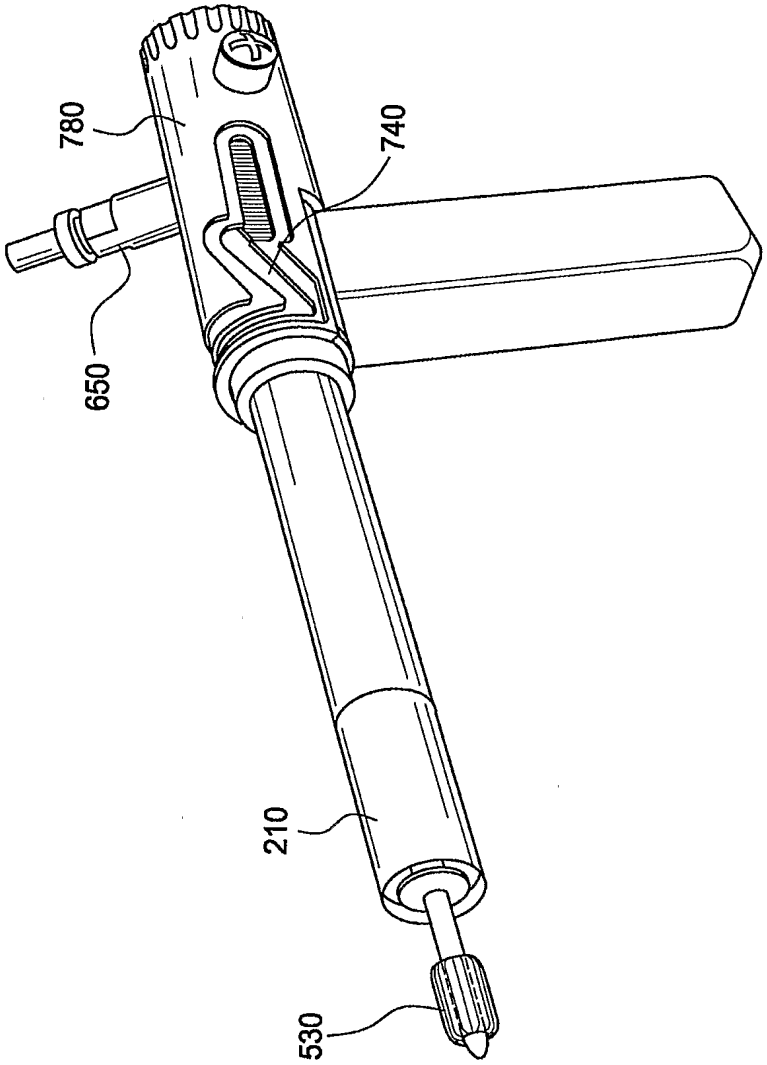


FIG. 7A

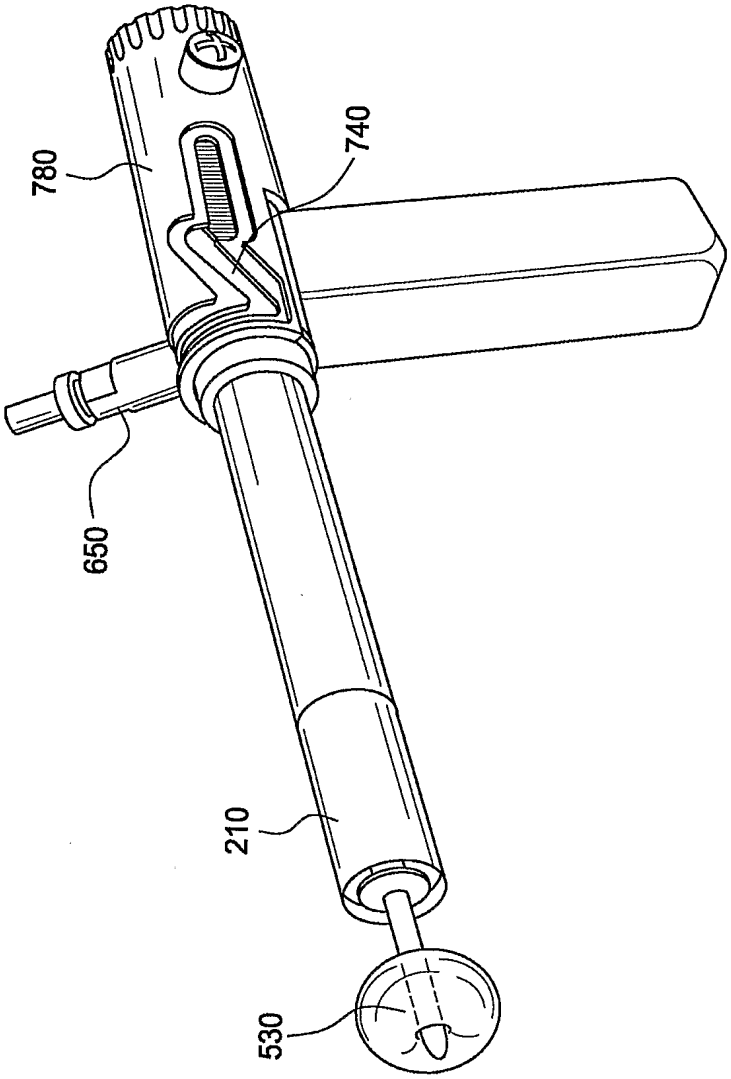


FIG. 7B

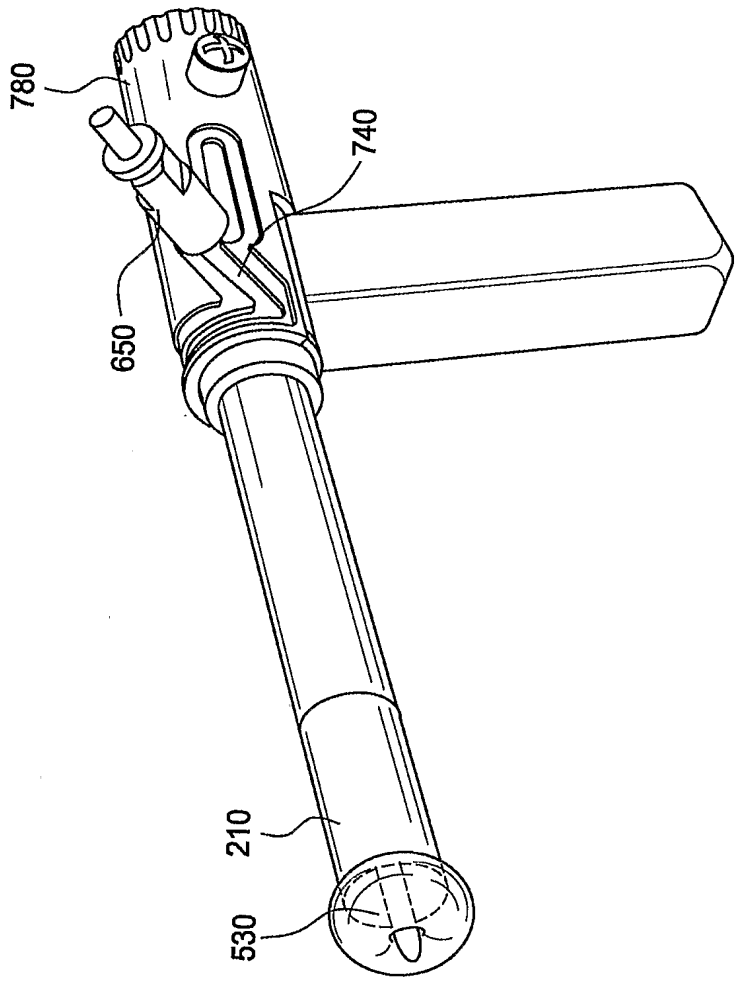


FIG. 7C

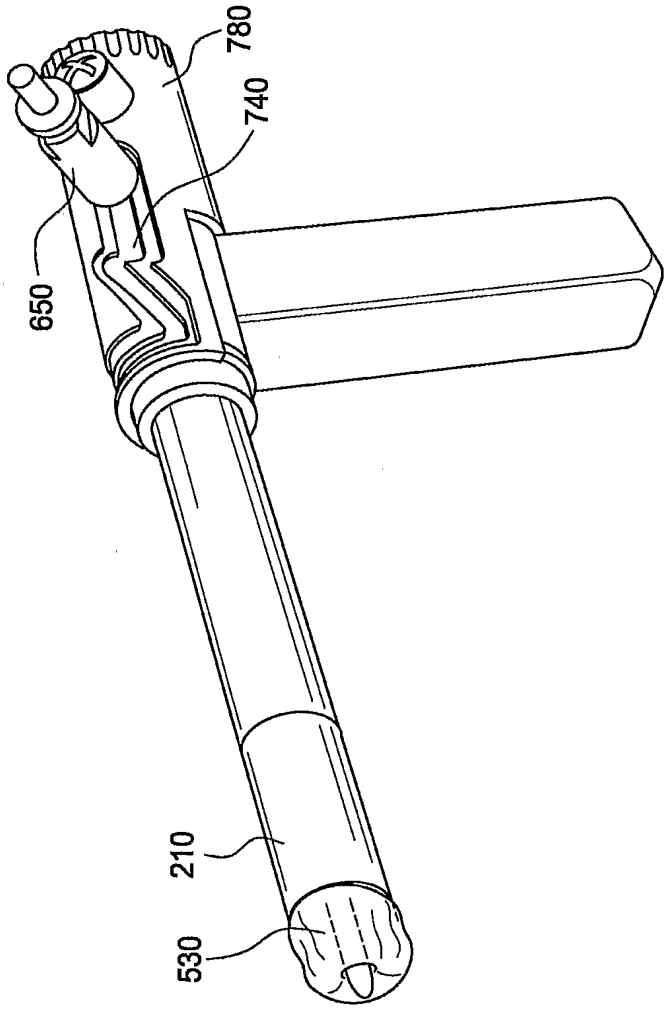


FIG. 7D

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/040230

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/11

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 2005/094525 A (CORREX INC [US]; BEANE RICHARD M [US]; BROWN JOHN W [US]; CRUNKLETON J) 13 October 2005 (2005-10-13) page 15, paragraph 46 claims 1,4,5,17-19,21-23,30-32,34,94	1-5,8-16
P,X	US 2005/251187 A1 (BEANE RICHARD M [US] ET AL) 10 November 2005 (2005-11-10) page 6, paragraph 53 claims 1,4,5,17-19,21-23,30-32,34	1-5,8-16

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

☒ See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 March 2007	15/03/2007

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Kakoullis, Marios

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/040230

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

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

1. [X] Claims Nos.: 17-32
because they relate to subject matter not required to be searched by this Authority, namely:

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

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

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

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

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

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

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

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

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

Remark on Protest

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

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2006/040230

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2005094525 A	13-10-2005	NONE	
US 2005251187 A1	10-11-2005	NONE	

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

(19) World Intellectual Property Organization
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(43) International Publication Date
18 October 2007 (18.10.2007)

PCT

(10) International Publication Number
WO 2007/117612 A1

(51) International Patent Classification:
A61F 2/06 (2006.01) *A61B 17/11* (2006.01)

(21) International Application Number:
PCT/US2007/008600

(22) International Filing Date: 6 April 2007 (06.04.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/789,563 6 April 2006 (06.04.2006) US
60/821,019 1 August 2006 (01.08.2006) US

(71) Applicant *(for all designated States except US)*: **CORREX, INC.** [US/US]; 46 Sunset Road, Weston, Massachusetts 02493 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **BEANE, Richard M.** [US/US]; 52 Burr Road, Hingham, Massachusetts 02043 (US). **BROWN, John W.** [US/US]; 7970 N. Illinois Street, Indianapolis, Indiana 46260 (US). **CRUNKLETON, James Alan** [US/US]; 46 Sunset Road, Weston, Massachusetts 02493 (US). **GAMMIE, James S.** [US/US]; 2207 Wiltonwood Road, Stevenson, Maryland 21153 (US). **SMITH, JR., Joseph L.** [US/US]; 113 Oak Road, Concord, Massachusetts 01742 (US).

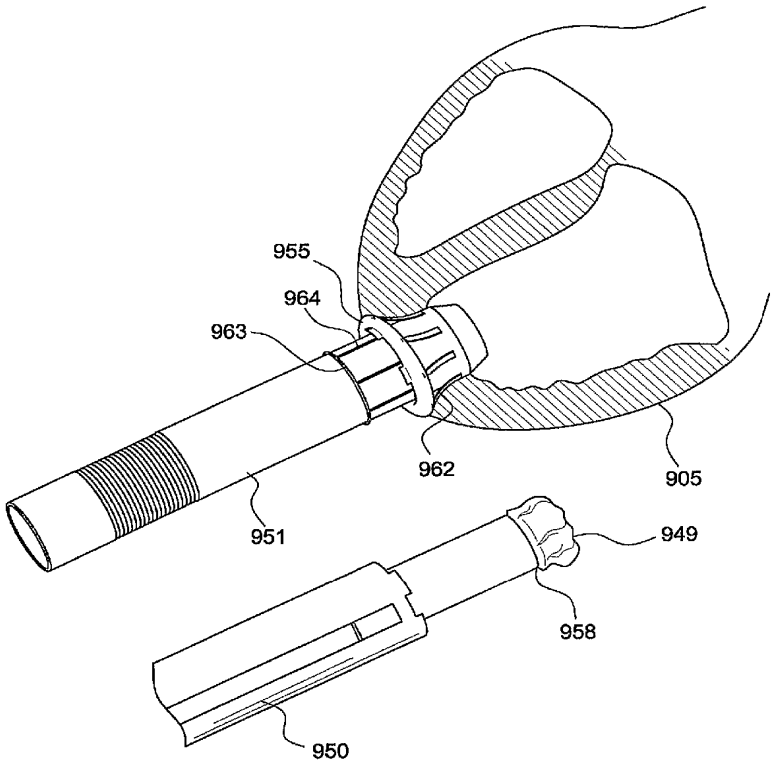
(74) Agents: **HERTZLER, Stephen M.** et al.; Nixon Peabody Llp, 401 9th Street, N.W., Suite 900, Washington, DC 20004 (US).

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

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH,

[Continued on next page]

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



(57) Abstract: The present invention relates to an apparatus and method for securing a connector conduit to a hollow organ. The method comprises forming a hole in a wall of the organ; inserting a connector conduit through the hole in the wall of the organ until a flange element comes into contact with the wall of the organ, the flange element being positioned on the connector conduit; and engaging a retention means with the wall of the organ to prevent movement of the connector conduit relative to the wall of the organ, the retention means being positioned on the connector conduit. Exemplary retaining means include a plurality of retaining pins positioned circumferentially around the connector conduit, a plurality of prongs positioned circumferentially around the connector conduit, a balloon positioned on the connector conduit, a torsion spring positioned on the connector conduit, a spiral spring positioned on the connector conduit, or combinations thereof.

WO 2007/117612 A1

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

Published:

— *with international search report*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

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

APPARATUS AND METHOD FOR SUTURELESSLY CONNECTING A CONDUIT TO A HOLLOW ORGAN

FIELD OF THE INVENTION

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

BACKGROUND

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

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

[0004] The patient is placed on the table in the supine position. Anesthesia is induced, and the patient is intubated with a double-lumen endotracheal tube, this facilitates one-lung ventilation and allows the surgeon to work within the left chest. The patient is positioned with the left side up (90 degrees). The pelvis is rotated about 45 degrees, such that the femoral vessels are accessible. An incision is made over the femoral vessels, and the common femoral artery and vein are dissected out. Heparin is administered. Pursestring sutures are placed in the femoral artery and vein. The artery is cannulated first, needle is inserted into the artery, and a guidewire is then inserted. Transesophageal echo is used to

ascertain that the wire is in the descending aorta. Once this is confirmed, a Biomedicus arterial cannula is inserted over the wire, into the artery (Seldinger technique). The arterial cannula is typically 19 or 21 French. Once inserted, the pursestring sutures are snugged down over tourniquets. A similar procedure is followed for the femoral vein. The venous cannula is usually a few French larger than the arterial cannula. Once both vein and artery are cannulated, the cannulae are connected to the cardiopulmonary bypass, and the capability to initiate cardiopulmonary bypass at any time is present.

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

[0006] On the back table, the apicoaortic conduit is prepared: a Medtronic 21 Freestyle valve is sutured to an 18 mm Medtronic apical connector. The valve is also sutured to a 20 mm Hemashield graft. The Dacron associated with the apical connector is pre-clotted with thrombin and cryoprecipitate. The assembly is brought to the field, and a measurement made from the apex of the heart to the descending aorta. The assembly is trimmed appropriately. A partial-occluding clamp is then placed on the descending aorta, and the aorta opened with a knife and scissors. The conduit (the end with the 20 mm Hemashield graft) is then sutured to the descending aorta using 4-0 prolene suture, in a running fashion. Once this is complete, the clamp is removed and the anastomosis checked for hemostasis. Blood is contained by the presence of the freestyle aortic valve. The apical connector is placed on the apex, and a marker is used to trace the circular outline of the connector on the apex, in the planned location of insertion. Four large pledgeted sutures (mattress sutures) of 2-0 prolene are placed; one in each quadrant surrounding the marked circle. The sutures are then brought through the sewing ring of the apical connector. A stab wound is made in the

apex in the center of the circle, and a tonsil clamp is used to poke a hole into the ventricle. To date, bypass has been initiated at this point, but doing so may not be necessary. A Foley catheter is inserted into the ventricle, and the balloon expanded. A cork borer is then used to cut out a plug from the apex. The connector is then parachuted down into position. A rotary motion is necessary to get the connector to seat in the hole. The four quadrant sutures are tied, and hemostasis is checked. If there is a concern regarding hemostasis, additional sutures are placed. The retractor is removed, chest tubes are placed, and the wound is closed.

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

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

SUMMARY OF THE INVENTION

[0008] The present invention relates to an apparatus and method for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ.

[0009] A preferred apparatus of the invention comprises a connector conduit operable to be inserted through a hole in a wall of the organ, a flange element positioned on the connector conduit adapted to prevent over-insertion of the connector conduit, and a retention means positioned on the connector conduit, the retention means being adapted to be engaged with the wall of the organ to prevent movement of the connector conduit relative to the wall of the organ after the connector conduit is inserted through the hole in the wall of the organ. The connector conduit is inserted through the hole in the wall of the organ until the flange element comes into contact with the wall of the organ, and the retention means is engaged with the wall of the organ after the connector conduit is inserted through the hole in

the wall of the organ. The hole in the wall of the organ (i.e. a heart) may be formed by a hole forming element having a cutting element on a distal end thereof and being adapted for coupling with the connector conduit, and the flange element may be integrally formed on the connector conduit.

[0010] Similarly, a preferred method of the invention relates to a method for securing a connector conduit to a hollow organ, the method comprising forming a hole in a wall of the organ, inserting a connector conduit through the hole in the wall of the organ until a flange element comes into contact with the wall of the organ, the flange element being positioned on the connector conduit, and engaging a retention means with the wall of the organ to prevent movement of the connector conduit relative to the wall of the organ, the retention means being positioned on the connector conduit.

[0011] According to one embodiment of the invention, the retention means may comprise a plurality of retaining pins positioned circumferentially around the connector conduit, such that the retaining pins are inserted into the hole in the wall of the organ when the connector is inserted through the hole in the wall of the organ. In this configuration, the apparatus may include a means for causing the retaining pins to engage the wall of the organ to prevent movement of the connector conduit relative to the wall of the organ. The means for causing the retaining pins to engage the wall of the organ to prevent movement of the connector conduit relative to the wall of the organ may comprise a plurality of skid elements and pull wires, for example. In addition, the retaining pins are preferably maintained in a passive state adjacent to an outer surface of the connector conduit until entering into engagement with the wall of the organ.

[0012] According to another embodiment of the invention, the retention means may comprise a plurality of prongs positioned circumferentially around the connector conduit such that the prongs, when in an initial passive state, are positioned outside of the organ after the connector conduit has been inserted through the hole in the wall of the organ. In this configuration, after the connector conduit has been inserted through the hole in the wall of the organ, the prongs are adapted to be inserted through a plurality of holes in the flange element into the wall of the organ, thereby entering into engagement with the wall of the organ. A prong installation element may be used which is adapted to insert the prongs through the holes in the flange element into the wall of the organ, thereby causing the prongs to enter into engagement with the wall of the organ. The prongs may have a curved shape that causes engagement of the prongs with the wall of the organ by the insertion of the prongs into the wall of the organ.

[0013] According to a further embodiment of the invention, the retention means may comprise a balloon positioned on the connector conduit, such that the balloon is inserted through the hole in the wall of the organ as the connector conduit is inserted through the hole in the wall of the organ. The balloon is preferably maintained in an initial deflated state until after the balloon and the connector conduit are inserted through the hole in the wall of the organ. After the connector conduit has been inserted through the hole in the wall of the organ, the balloon may be inflated from the initial deflated state to an expanded state, thereby entering into engagement with the wall of the organ and preventing movement of the connector conduit relative to the hole in the wall of the organ. In addition, the flange element may be replaced with a second balloon positioned on the connector conduit such that, after insertion of the connector conduit through the hole in the wall of the organ, the two balloons are inflated, and the wall of the organ is compressed between the two balloons, thereby preventing movement of the connector conduit relative to the wall of the organ. Similarly, the flange element may be replaced with a torsion spring positioned on the connector conduit, such that, after insertion of the connector conduit through the hole in the wall of the organ, the balloon is inflated, and the wall of the organ is compressed between the torsion spring and the balloon, thereby preventing movement of the connector conduit relative to the wall of the organ.

[0014] According to a further embodiment of the invention, the retention means may comprise a torsion spring positioned on the connector conduit, such that the torsion spring, when in an initial compressed state, is inserted through the hole in the wall of the organ as the connector conduit is inserted through the hole in the wall of the organ. In this configuration, a sheath may be used to retain the torsion spring in a compressed state. After the connector conduit has been inserted through the hole in the wall of the organ, the sheath may be withdrawn from the hole in the wall of the organ, thereby allowing the torsion spring to expand from the initial compressed state to an expanded state, thereby entering into engagement with the wall of the organ and preventing movement of the connector conduit relative to the wall of the organ. The flange element may be replaced with a second torsion spring positioned on the connector conduit such that, after insertion of the connector conduit through the hole in the wall of the organ, and withdrawal of the sheath from the wall of the organ, the two torsion springs are in their respective expanded states, and the wall of the organ is compressed between the two torsion springs, thereby preventing movement of the connector conduit relative to the wall of the organ. Furthermore, the flange element may be replaced by a plurality of torsion springs positioned on the connector conduit such that, after

insertion of the connector conduit through the hole in the wall of the organ, and withdrawal of the sheath from the wall of the organ, at least one torsion spring resides inside the organ, at least one torsion spring resides within the wall of the organ, and at least one torsion spring resides outside of the organ, thereby compressing the wall of the organ between the two torsion springs and preventing movement of the connector conduit relative to the wall of the organ. Also, the flange element may be replaced with a balloon positioned on the connector conduit such that, after insertion of the connector conduit through the hole in the wall of the organ, withdrawal of the sheath from the wall of the organ, and inflation of the balloon, the torsion spring is in its expanded state, the balloon is in its inflated state, and the wall of the organ is compressed between the torsion spring and the balloon, thereby preventing movement of the connector conduit relative to the wall of the organ.

[0015] According to a further embodiment of the invention, a spiral spring may be positioned on the connector conduit, such that the spiral spring, when in an initial compressed state, is inserted through the hole in the wall of the organ as the connector conduit is inserted through the hole in the wall of the organ. In this configuration, a smooth frame cover may be used to retain the spiral spring in a compressed state. After the connector conduit has been inserted through the hole in the wall of the organ, the smooth frame cover can be withdrawn from the hole in the wall of the organ, thereby allowing the spiral spring to expand from the compressed state to an expanded state, thereby entering into engagement with the wall of the organ and preventing movement of the connector conduit relative to the wall of the organ. The flange element may be replaced by a compression ring, which is positioned circumferentially around the connector conduit on the outside of the organ, such that, after the connector conduit is inserted through the hole in the wall of the organ, the spiral spring expands from the compressed state to an expanded state, and the compression ring is moved longitudinally along the surface of the connector conduit along one or more ratchet steps formed on the surface of the connector conduit towards the wall of the organ, thereby compressing the wall of the organ between the spiral spring and the compression ring, and preventing movement of the connector conduit relative to the wall of the organ.

[0016] Thus, the present invention provides an apparatus and method that may be used by a surgeon in accordance with connector conduit and applicator systems, such as those disclosed in U.S. Patent Application Nos. 11/086,577 filed March 23, 2005 and 11/300,589 filed December 15, 2005, and U.S. Provisional Patent Application Nos. 60/726,222 and 60/726,223, both filed October 14, 2005, the disclosures of which are hereby incorporated by

reference in their entirety. The securing means of the present application may be used, for example, with any type of suitable system, such as the system of the '577 application.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] FIG. 1 illustrates an apicoaortic conduit.

[0018] FIG. 2A is a cross-sectional view another embodiment of the structural frame of the connector, covered in fabric, with an incorporated sewing flange and shown in the bent configuration.

[0019] FIG. 2B is a cross-sectional view of the structural frame of the connector of FIG. 3A shown in a straight configuration.

[0020] FIG. 2C is a cross-sectional view of the connector of FIG. 2A shown in the straight configuration, and with a fabric conduit in place.

[0021] FIG. 3 is a cross-sectional view of an embodiment of the device showing the coring element and the retractor element in place within the straightened connector.

[0022] FIG. 4 is a cross-sectional view of a cylinder plug tool that slides over the retractor element and into the coring element, which is used to load the connector-conduit onto the coring element.

[0023] FIG. 5 is a cross-sectional view of an embodiment of the device showing the placement of a compression spring between the retractor element and the coring element.

[0024] FIG. 6 is a cross-sectional view of another embodiment of the device showing the placement of a pushing element.

[0025] FIG. 7A is a cross-sectional view of yet another embodiment of the device showing the attachment of a handle to the pushing element with an access means for the expandable element integrated into the pushing element, wherein the expandable element is shown contracted.

[0026] FIG. 7B shows the embodiment of FIG. 7A with the expandable element expanded.

[0027] FIG. 8 is a cross-sectional view of an embodiment of the device showing the inclusion of a sliding bolt on the retractor element and related indexed slots on the pushing device.

[0028] FIG. 9 is a partial view the pushing element of FIG. 8 showing the indexed slots on the pushing device.

[0029] FIG. 10A is a perspective view of a flexible structural frame of another embodiment of the connector conduit shown in a straight configuration.

[0030] FIG. 10B is a perspective view of the structural frame of FIG. 10A shown in a bent configuration.

[0031] FIG. 10C is a perspective view of the structural frame of FIG. 10B shown with a beveled and tapered leading edge.

[0032] FIG. 11 is a perspective view of an alternative embodiment of FIG. 9B.

[0033] FIG. 12A is a perspective view of the flexible structural frame of FIG. 10B shown in the straightened configuration and incorporating a bending means.

[0034] FIG. 12B is a perspective view of the structural frame of FIG. 12A after activating the bending means.

[0035] FIG. 13 is a perspective view of a non-bendable structural frame of a connector conduit.

[0036] FIG. 14 is a cross-sectional view of a connector conduit shown in a bent configuration.

[0037] FIG. 15 is a cross-sectional view of a non-bendable connector conduit.

[0038] FIG. 16A is a cross-sectional view of a mounting element (including a coring element) and a pushing element of the applicator with a loaded connector conduit.

[0039] FIG. 16B is a cross-sectional view FIG. 16A without the connector conduit.

[0040] FIG. 17A is a perspective view of a squeeze ring for a locking means to secure the connector conduit within the applicator.

[0041] FIG. 17B is a perspective view of a locking means shown in the locked position.

[0042] FIG. 17C is a perspective view of a locking means shown in the unlocked position.

[0043] FIG. 18 is a cross-sectional view of the device of FIG. 16B including a retractor element.

[0044] FIG. 19 is a cross-sectional view of a folding and mounting tool.

[0045] FIG. 20 is a cross-sectional view of an assembly including an applicator having a syringe.

[0046] FIG. 21A is a cross-sectional view of a sequencing bolt.

[0047] FIG. 21B is a cross-sectional view of the retractor body and expanding element.

[0048] FIG. 21C is a cross-sectional view of the positioning mans and coring element.

[0049] FIGS. 22A - 22C the sequencing can mechanism in various states.

[0050] FIGS. 23A - 23E illustrate the applicator in various states.

[0051] FIG. 24 is a perspective view of an integrated connector conduit and cutting elements.

[0052] FIG. 25 is the device of FIG. 24 with the cutting element withdrawn.

[0053] FIGS. 26A – 26D illustrate components of a retractor having an expandable umbrella element.

[0054] FIGS. 27A-27E illustrate an embodiment of the invention wherein the connector conduit is attached to the organ using one or more retaining pins.

[0055] FIGS. 28A-28E illustrate an embodiment of the invention wherein the connector conduit is attached to the organ using one or more prongs.

[0056] FIGS. 29A-29D illustrate a prong deployment mechanism operable to install the prongs illustrated in FIGS 28A-28E.

[0057] FIGS. 30A-30C illustrate an embodiment of the invention wherein a balloon is used to retain the connector conduit securely within the organ.

[0058] FIGS. 31A-31B illustrate an exemplary balloon that may be used in the system of FIGS. 30A-30B.

[0059] FIGS. 32A-32C illustrate an embodiment of the invention wherein a torsion spring is used to retain the connector conduit securely within the organ.

[0060] FIGS. 33A-33C illustrate an embodiment of the invention wherein a spiral spring is used to retain the connector conduit securely within the organ.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0061] FIG. 1 is an illustration of an apicoaortic conduit, which extends from the apex of the left ventricle to the descending aorta with a prosthetic valve positioned within the conduit. The preferred embodiment of the present invention includes aspects of the connector conduit and an applicator used to implant the connector conduit.

[0062] The connector-conduit with applicator of the present invention is best described as consisting of five major parts: a connector-conduit, a retractor, hole forming device such as a coring element, a pushing component, and a handle. A fabric material pleated conduit of a type common and well known in the field is permanently fixed to the inner surface of a rigid connector to form the connector-conduit. The conduit extends from

the forward edge of the connector and continues beyond the connector, as a flexible portion, for some distance.

[0063] The connector-conduit includes a rigid portion defined by an internal support structure made of a suitably flexible material that is preferentially biased to assume a bent configuration upon applying a bending force or that is preferentially biased to assume a bent configuration (such as a right angle) upon removal of restraining forces. In one embodiment, the connector internal support structure is covered with fabric, such as knitted or woven Dacron, for example. A suturing ring is integrated into the covering fabric and provides a suitable flange for suturing the connector to the surface of the heart. The leading edge of the connector is tapered to facilitate insertion of the connector-conduit component. The "rigid" portion is rigid enough to facilitate insertion as described below and to maintain the hole in an open position. However, the rigid portion can be flexible. Accordingly, the term "rigid" as defined herein means relatively rigid and can include flexibility.

[0064] As shown in FIG. 10B, the structural frame 140 of the connector-conduit is a series of circular rings 141 joined to a curved spine 142. During implantation, the curved spine 142 is straightened, as shown in FIG. 10A, resulting in a straight pathway for the passage of instruments. As an alternative, the connector-conduit could include circular rings 141 without curved spine 142. As such, the circular rings would prevent collapse of the conduit, but the curved conduit would be formed manually after implantation, rather than by being formed by the curved spine 142. As another alternative, a modified coil spring in the shape of a curve could be used instead of circular rings 141 and curved spine 142. Properties of the coil spring would be chosen to prevent radial collapse and to provide appropriate stiffness of the curved position.

[0065] The leading edge of structural frame 101 is a tapered leading edge 110 which allows for easy insertion of the connector through the ventricle wall. The material of the structural frame 101 could be a shape memory alloy (e.g., Nitinol), plastic, or other similar biocompatible material.

[0066] FIG. 2A illustrates a fabric covering 24 over the outside surface of structural frame 101 (not shown). Because connector surface 22 is in contact with the myocardial hole after implantation, a suturing ring or flange 26 is incorporated into the fabric covering 24 to provide an attachment site for sutures to anchor the connector to the heart. The fabric covered suture ring 26 could be made of a biocompatible foam or rubber.

[0067] FIG. 2B shows the fabric covered structural frame 101 (not shown) and suturing flange 26 in a straightened position. The straightened position can be achieved by,

for example, inserting a straight instrument through the lumen of the frame. Alternately, the structure can be held in the open position through the use of stay stitches 28, or the like, placed such that the circular rings 141 (not shown) are held in close proximity.

[0068] FIG. 2C is a view similar to FIG. 2B, showing the structural frame in the straightened position with a pleated fabric conduit 30. Conduit 30 extends from tapered leading edge 110 of the structural frame 101 (not shown), through the length of the structural frame 101, and for some additional length beyond the structural frame 101 to define a flexible portion of the connector conduit. An orientation marker (not shown) on connector surface 22, for example, is used to identify the direction that conduit 30 will be oriented once implanted into the heart. The orientation marker is visible at all times to assist the surgeon while placing the connector-conduit 32 into the connector-conduit applicator and to facilitate implantation at an appropriate angle into the heart. Also, a radiopaque marker(s) (not shown) may be integrated into the entire length of fabric covering 24 and conduit 30 to facilitate identification and location of the structure by X-ray or other means.

[0069] Referring to FIG. 3, in accordance with another embodiment of the present invention, a hole forming device such as coring element 40, is placed concentrically within the lumen of the connector-conduit 32. The coring element 40 preferably consists of a tubular structure, which could be made entirely of metal (such as stainless steel) or primarily of a plastic material with a metal insert for the leading edge 42. In a preferred configuration, the leading edge 42 of coring element 40 may be suitably sharpened such that it cuts a plug of tissue of approximately the same diameter as the outer diameter of the coring element 40. Note that the hole forming device can be any known mechanism for forming a hole, such as a laser cutter, a thermal ablation device, a chemical ablation device, or the like.

[0070] An interference fit between connector surface 22 and the hole created by the coring element 40 is necessary to reduce bleeding from the cut myocardial surface and to reduce blood leakage from the left ventricle. The amount of such interference fit is the difference between the diameters of the hole created by the coring element 40 and the outer surface of the connector 22.

[0071] In a preferred embodiment of the device, the coring element 40 has an outer diameter that closely matches the inner diameter of the connector-conduit 32. Such construction allows removal of the coring element 40 through the connector-conduit 32 while presenting only a small blood pathway between these two elements. Such construction is intended to minimize blood loss from the left ventricle when the coring element 40 has completed its cut.

[0072] FIG. 3 further illustrates the concentric placement of the retractor element 50 within the coring element 40. Retractor element 50 includes a blunt tip 52, a tubular body 54, an expanding element 56, such as a balloon, and an access means 58 for engageably expanding element 56. Access means 58 can be a plunger 58a in a cylinder 58b configuration, whereby displacement of the plunger expands or contracts expanding element 56. A centering plug 60 is shown concentrically positioned within and rigidly attached to coring element 40. The centering plug 60 concentrically positions retractor element 50, which slideably moves within the centering plug 60. The centering plug 60 also presents a barrier to the flow of blood through coring element 40, once the tissue plug is formed. Proper placement of centering plug 60 within coring element 40 should consider tradeoffs between two different parameters. First, centering plug 60 should be placed at a position within coring element 40, which allows ample space for the expanding element 56 and the tissue plug. Second, since radial force from the heart wall tends to deflect the expanding element 56, retractor element 50 must have a sufficient stiffness to substantially resist such deflection. Such deflection may also be reduced by limiting the axial distance between the expanding element 56 and centering plug 60.

[0073] FIG. 4 shows a cylinder plug tool 45 for insertion into coring element 40 prior to loading connector-conduit 32 onto coring element 40. Cylinder plug tool 45 facilitates loading connector-conduit 32 without damage from leading edge 42 of coring element 40. Once the connector-conduit 32 is loaded, cylinder plug tool 45 is removed and placed aside. As a safety measure, cylinder plug tool 45 has an extended length with a tapered blunted end 45a, which extends to cover retractor element 50, preventing insertion of the retractor element 50 into the left ventricle before cylinder plug 45 is removed.

[0074] Referring to FIG. 5, another embodiment of the present invention shows a compression spring 70 placed around the retractor element 50. One end of the compression spring 70 seats on the centering plug 60, and the other end seats on a sliding plug 72. Sliding plug 72 is rigidly connected to retractor element 50. Spring 70 ensures that expanding element 56 seats snugly against the inside wall of the ventricle to symmetrically displace the ventricle wall from the path of the coring element. Once the tissue plug is cut from the ventricle by coring element 40, spring 70 also pulls the tissue plug fully within the coring element 40.

[0075] FIG. 6 illustrates a further embodiment, wherein a cylinder-shaped pushing element 80 is positioned concentrically outside the connector-conduit element 32. Pushing element 80 is used to apply force to the coring element 40 and connector-conduit element 32.

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

[0076] Referring to FIGS. 7A and 7B, a handle 90 is rigidly attached to pushing element 80. As shown, handle 90 is configured similar to a pistol grip, for example, handle 90 having an angle of about 70 degrees, with the pushing element 80. Handle 90 provides a user-friendly interface for the surgeon to hold with one hand, to position the coring element 40, to apply axial force to the connector-conduit element and to provide a back-and-forth rotational motion of around 90 degrees. Of course, many alternatives exist for the user interface. For example, the pushing element 80 itself could be used as the handle. As another example, a handle could form a "T" shape on the end of the pushing element 80.

[0077] Also shown in FIG. 7A, an access means 58 is used to expand or contract expanding element 56. Access means 58, for example, can be a trigger-type mechanism integrated into handle 90. As such, the user can use a finger to pull plunger 58a into the cylinder 58b, thereby displacing the fluid (such as saline) inside the cylinder 58b into the balloon 56. FIG. 7B shows the inflation of the balloon 56. As a safety feature, the plunger can have a latching device (not shown) that latches the plunger 58a with the balloon fully inflated, thereby preventing deflation of the balloon before intended.

[0078] FIGS. 8 and 9 show a mechanism for controlling deployment of the retractor element 50. A slot 84 is cut into pushing element 80. Slot 84 has an index 84a to lock retractor element 50 at full extension and an index 84b to lock retractor element 50 at full retraction. Bolt 72a is rigidly attached to sliding plug 72. Bolt 72a can be manually displaced within slot 84 to position the retractor element 50. In operation, bolt 72a is positioned in index 84a until the retractor element 50 is fully inserted into the left ventricle and the expanding element 56 is at full expansion. At that time, bolt 72a is manually released from index 84a, which allows compression spring 70 to retract retractor element 50 until expanding element 56 contacts the inside wall of the left ventricle. A damping means (not shown) may be included to prevent sudden retraction of the retractor element upon release

from index 84a. Also not shown is a safety latch or other means to prevent manual release of the bolt 72a until the expanding element 56 is fully expanded.

[0079] As the surgeon applies force and rotation using handle 90, compression spring 70 continues to displace retractor element 50. When retractor element 50 is fully retracted, the surgeon can rotate bolt 72a into index 84b to lock the retractor element 50 in place. Moreover, when retractor element 50 is fully retracted, the expanding element 56 is also fully retracted into coring element 40, indicating that the tissue plug has been successfully removed from the left ventricle and is within the coring element 40.

[0080] Referring to the embodiment of FIGS. 10A - 10C, the connector conduit has a structural frame 101 defining a rigid portion, which may be constructed from a single material or a combination of materials. The structural frame 101 includes a tapered leading edge 110 designed to reduce the effort needed to push the connector through the heart wall located at one end of a cage section 120 and a bend portion 140 that is normally biased into a bent configuration. As shown in FIG. 10C, a tapered and beveled leading edge 150 may further reduce the required effort. During use, cage 120 resides primarily within the heart wall, so it must be constructed so as to be rigid enough to not collapse due to radial forces exerted by the heart wall. The cage 120 may include cage slots 121. The cage slots 121 allow the passage of thread to secure the conduit or the sewing flange.

[0081] A holder 130 is formed at one end of cage 120 and may be used to grasp the connector during implantation. As will be described further herein, holder 130 can have a slot-and-key configuration with the applicator. As such, the holder 130 utilizes holder slots 431 or a holder button 430 (FIG. 11). Holder button 430 may be a separate part that is anchored (e.g., by thread or glue) to structural frame 101. If desired, the holder slots 431 or holder button 430 may be designed to place the flexible bend 140 or rigid bend 145 (FIG. 13) at a preferred angle relative to the applicator. Alternatively, the holder 130 may rely upon a tight friction fit with the applicator. In a preferred configuration, the holder 130 relies upon both a slot-and-key and a tight friction fit to lock the holder 130 relative to the applicator.

[0082] Referring again to FIGS. 10A and 10B, bend portion 140 includes circular rings 141 and a curved spine 142. The circular rings 141 prevent radial collapse of the conduit, and the curved spine 142 holds the conduit in a preferred shape to direct blood flow from the heart to the aorta. The curved spine 142 may be at the outer radius of bend portion 140 (as shown) or at the inner radius of the flexible bend. As an alternative, flexible bend 140 may include two curved spines at the mean radius. As another alternative, the structural frame 101 could include circular rings 141 without curved spine 142. As another alternative,

a modified coil spring in the shape of a preferred bend could be used instead of circular rings 141 and curved spine 142. Properties of the coil spring would be chosen to prevent radial collapse and to provide appropriate stiffness of the curved position.

[0083] The structural frame of FIGS. 10A - 11 is intended for mounting onto the outer diameter of a straight mounting element. As such, the bend portion 140 must be constructed to allow straightening of the curved spine 142. If curved spine 142 is made of a material or combination of materials with higher modulus of elasticity (e.g., PEEK, metal), the flexible bend 140 is stiffer. As such, the flexible bend 140 may be biased to resume a preferred shape (e.g., a 90° bend) when removed from the mounting element. If the curved spine 142 is made of a material with a lower modulus of elasticity (e.g., polypropylene, polyethylene), the bend portion 140 is less stiff. As such, the bend portion 140 may be biased relatively straight when removed from the straight mounting element. In such case, some bending means may be needed to position the bend portion 140 into the preferred shape.

[0084] One embodiment of a bending means is shown in FIGS. 12A and 12B, which illustrate use of threads 143 that are secured to the holder 130 (for example) and weaved through circular rings 141. When threads 143 are pulled, the bend portion 140 changes from the normally biased, straight configuration of FIG. 12A to the bent configuration of FIG. 12B. When the flexible bend 140 reaches the preferred shape, the threads may be tied to form a knot or crimped. If desired, the bending means can be used with a curved spine 142 constructed of a high modulus of elasticity material to prevent straightening beyond the preferred angle.

[0085] As discussed previously, structural frame 101 may be constructed with a fixed bend 145, as shown in FIG. 13. A port 146 allows the mounting of structural frame 101 with a fixed bend 145 onto a straight mounting element.

[0086] FIG. 14 is a cross-section of a connector conduit 100 that includes a rigid portion defined by structural frame 101 with bend portion 140, and a flexible portion defined by conduit 160. The rigid portion also includes outer fabric 161, and sewing flange 170. Orientation marks (not shown) may be included on the conduit 160 or outer fabric 161. Conduit 160 may be a pleated vascular graft constructed of woven Dacron. Outer fabric 161 could be a knitted Dacron fabric material that stretches to accommodate contours of the structural frame 101. Sewing flange 170 could be constructed of a soft silicone rubber, for example, to allow easy passage of a needle when fastening sewing flange (or sewing ring) 170 to the outer surface of the heart. To allow visualization on x-ray, for example, the sewing flange could be made radiopaque, such as by mixing barium sulfate into the silicone

rubber. The sewing flange may have a cloth covering such as that used for outer fabric 161. Alternatively, the sewing flange 170 may consist entirely of folded cloth. The components of the connector conduit 100 may be fastened together as needed, such as with thread.

[0087] Referring to FIG. 15, a cross-section of a connector conduit 100 is similar to that shown in FIG. 14, except that the structural frame 101 is constructed with fixed bend 145. A conduit branch 162 intersects with conduit 160 through port 146 of rigid bend 145 to allow passage of a straight mounting element through the connector conduit 100. Once the connector conduit 100 is implanted into the ventricle, branch 162 may be occluded at the intersection with conduit 160. Branch 162 may then be cut off.

[0088] FIG. 14 and FIG. 15 further illustrate a quick connect coupler 180 for expediting attachment of the connector conduit 100 to the remainder of the prosthesis, which may include a prosthetic valve or ventricular assist device, as examples. As shown, the male end of quick connect coupler 180 is a continuation of or is attached to vascular graft 160. The male end of quick connect coupler 180 includes rigid connector frame 181, which may be constructed of a biocompatible plastic or metal. Vascular graft 160 covers the inner diameter of connector frame 181, and an outer fabric 165 covers the outer diameter of connector frame 181. Outer fabric 165 may be continuous with vascular graft 160. Outer fabric 165 is not of a pleated construction, such as is typical of vascular graft 160. The cloth-covered connector frame 181 provides a rigid surface onto which the female end of quick connect coupler 180 may be mounted. The female end of quick connect coupler 180 includes vascular graft 186 and pull ring 185. Vascular graft 186 attaches on its downstream end to the remainder of the prosthesis, which may include a prosthetic valve or ventricular assist device, as examples. Vascular graft 186 may be a pleated vascular graft constructed of woven Dacron, for example. Graft extension 186a is a continuation portion of or is attached to vascular graft 186. A rigid pull ring 185 (which may be constructed of a biocompatible plastic or metal) is attached to graft extension 186a. The male end of quick connect coupler 180 has a larger outer diameter than vascular graft 186. This construction provides a stop so that the male end of quick connect coupler 180 reaches an abrupt change to a smaller diameter provided by vascular graft 186. In this way, the surgeon knows when the male end is fully inserted into the female end of quick connect coupler 180. In use, the surgeon may grasp pull ring 185 with one hand and connector frame segment 181a of connector frame 181 with the other hand. Pull ring 185 is pulled over outer fabric 165 until the male end of quick connect coupler 180 contacts the smaller diameter vascular graft 186. A large suture or umbilical tape 187 may then be tied around graft extension 186a to reduce blood loss by

occluding the annular gap between the outer diameter of outer fabric 165 and the inner diameter of graft extension 186a. Stay sutures may also be used to connect outer fabric 165 to graft extension 186a, thereby preventing separation of the male and female ends of quick connect coupler 180.

[0089] FIG. 14 and FIG. 15 further illustrate a collapsible portion 160a between connector conduit 100 and quick connect coupler 180. Such collapsible portion 160a allows use of a cross clamp, for example, to fully collapse portion 160a to occlude flow after the applicator is removed beyond collapsible portion 160a. Collapsible portion 160a can be made of the same material as the rest of the flexible portion, or can be made of a different material.

[0090] In use, the applicator of the present invention is used to implant the connector conduit 100 into the ventricle wall or other organ wall. FIG. 16A shows a cross-section of the connector conduit 100 (FIG. 14) loaded onto a mounting element 200. For clarity, the applicator is shown without the connector conduit 100 in FIG. 16B. Mounting element 200 includes a cylindrical coring element 210, serving as a hole forming element, that is concentric with and has the same diameter as the mounting element 200. The mounting element 200 and coring element 210 are placed concentrically within the lumen of the connector conduit 100. Coring element 210 includes a thin-walled tube and a sharpened cutting edge 210a, which may be tapered on the inner diameter, for example, to form the sharpened cutting edge 210a. The coring element 210 is used to cut a cylindrical-shaped core (or hole) in the heart wall, producing a plug from the heart wall that resides within the coring element 210. The mounting element 200 could be constructed of plastic (e.g., ABS), and the coring element 210 could be constructed of metal (e.g., stainless steel). In a preferred embodiment, the mounting element 200 and coring element 210 have an outer diameter that closely matches the inner diameter of the connector conduit 100. One purpose of such a construction is to minimize blood loss from the left ventricular chamber when the coring element 210 has completed its cut. Also in order to reduce blood loss from the left ventricular chamber and from the cut myocardial surface and to yield a snug fit of the connector conduit within the ventricular myocardium, the cutting diameter of the coring element 210 is chosen to produce a core that is smaller in diameter than the outer surface 163 of the of the connector conduit 100.

[0091] FIGS. 16A and FIG. 16B further illustrate a cylinder-shaped pushing element 300 positioned concentrically outside the connector conduit 100. In a preferred embodiment, the pushing element 300 transmits pushing force and rotation to the connector conduit 100.

In further accordance with a preferred embodiment, the pushing element 300 is rigidly attached to mounting element 200, such that pushing element 300 transmits pushing force and rotation to the mounting element 200 and coring element 210. Pushing element 300 may be constructed of plastic (e.g., ABS) or metal (e.g., stainless steel). However, it should be appreciated that the present invention contemplates the use of other materials.

[0092] In further accordance with a preferred embodiment, a locking means provides an interface that prevents movement of the connector conduit 100 relative to the pushing element 300. Such locking means may include components that are integral with the pushing element 300, connector conduit 100, mounting element 200, and coring element 210. FIGS. 17A to 17C illustrate one embodiment of such a locking means. This embodiment combines a slot-and-key arrangement with a friction enhancing arrangement. The slot-and-key arrangement includes notch 421 (the slot) of pushing element 300 and holder button 430 (the key) of structural frame 101. Positioning holder button 430 into notch 421 prevents rotation of connector conduit 100 relative to pushing element 300 and prevents axial motion in one direction. Axial motion allowing removal of the connector conduit 100 from the applicator is not prevented in this embodiment. Rather, this axial motion is reduced by providing a friction enhancing arrangement consisting of squeeze ring 410 (which includes two groove pins 411) and squeeze arms 425a and 425b that cantilever from pushing element 300 to form wide groove 420a and narrow groove 420b. Alternatively, notch 421 could fit tightly around the circumference of holder button 430 to prevent movement of the connector conduit 100 relative to the pushing element 300 in both rotational and axial directions. As shown, notch 421 is divided, with one half cut from squeeze arm 425a and the other half from squeeze arm 425b. Alternatively, notch 421 could reside entirely within either squeeze arm. Alternatively, several notches 421 could be used.

[0093] When squeeze ring 410 is positioned at or near notch 421 as shown in FIG. 17B, squeeze ring 410 holds squeeze arms 425a and 425b tightly against connector conduit 100, creating a tight friction fit. In this position, groove pins 411 within wide groove 420a do not tend to separate squeeze arms 425a and 425b. When squeeze ring 410 is positioned as shown in FIG. 17C, groove pins 411 within narrow groove 420b tend to separate squeeze arm 425a and 425b to allow the connector conduit to be easily moved into position or removed. In a similar embodiment (not shown), the slot-and-key arrangement could include teeth (keys) that extend radially inwards from the inner diameter of squeeze arms 425a and 425b to fit into holder slots 431 of holder 130 of structural frame 101 (see FIG. 10A). In this embodiment, a squeeze ring (with groove pins) and squeeze arms similar to those shown in

FIGS. 17A to 17C would be used to engage and disengage the teeth from holder slots 431, rather than to provide a tight friction fit.

[0094] In accordance with a further embodiment of the present invention, a retractor component/element 500 with a generally tubular structure is located concentrically within the mounting element 200, as shown in FIG. 18. The retractor element 500 can slide axially relative to the mounting element 200. The retractor element 500 consists of a blunt tip 510, a tubular body 520, and an expanding element 530 that includes an access passage 531. The expanding element 530 is shown as a balloon in FIG. 18, which may be inflated and deflated with fluid (e.g., saline) through access passage 531 using a plunger and cylinder arrangement.

[0095] Retractor element 500 is held concentric within the mounting element 200 by centering plug 220 and sliding plug 521. Centering plug 220 is rigidly attached to mounting element 200, and sliding plug 521 is rigidly attached to tubular body 520. Since radial force from the heart wall tends to deflect the expanding element 530, tubular body 520 must have a sufficient stiffness to substantially resist such deflection. Such deflection may also be reduced by limiting the axial distance between the expanding element 530 and centering plug 220.

[0096] A coupling element, such as compression spring 540, slideably couples retractor element 500 to mounting element 200. Compression spring 540 biases refractor element proximally to ensure that expanding element 530 seats snugly against the inside wall of the ventricle to shape and partially flatten the ventricle wall (particularly at the apex) so that coring element 210 may cut perpendicular to the ventricle wall. Once the tissue plug is cut from the ventricle by coring element 210, spring 540 pulls the tissue plug fully within the coring element 210. In the preferred embodiment, expanding element 530 is a balloon in the shape of a circular torrid.

[0097] FIG. 19 illustrates a mounting and folding tool 900, which includes coring element taper 910, balloon taper 920, conduit taper 930, and retractor element port 940. Tool 900's outer diameter may be equal to or slightly larger than coring element 210's outer diameter to prevent damage to fabrics of the vascular graft 160 and outer fabric 161, when the connector conduit 100 is being mounted onto or demounted from mounting element 200. As an alternative, a thin-walled tube, such as a plastic shrink tube, may be positioned over outer diameters of tool 900 and coring element 210 to further prevent damage to fabrics slid past the sharpened edge 210a of the coring element. Coring element taper 910 fits snugly within coring element 210 to ensure a concentric fit between tool 900 and coring element 210, thereby further reducing the likelihood of damage to vascular graft 160 and outer fabric

161. Conduit taper 930 eases placement of vascular graft 160 onto tool 900. Tool 900 may be used to deflate and fold expanding element 530 by placing tool 900 onto retractor element 500 and by pushing and rotating (in one direction) tool 900 until coring element taper 910 contacts coring element 210. Balloon taper 920 provides a surface for controlled deflation and folding of the expanding element 530. Once the balloon is deflated and folded and the connector conduit 100 is fully mounted onto the applicator, tool 900 may be removed.

[0098] FIG. 20 illustrates an embodiment of an applicator assembly (connector conduit 100 not shown). In this assembly, the surgeon has independent control of the position of retractor element 500 and the volume of expanding element 530. Handle 310, which extends from pushing element 300 to form a pistol grip, provides a means for the surgeon to apply axial force and back-and-forth rotary motion while implanting connector conduit 100. The position of retractor element 500 is controlled by the position of retractor bolt 522 in slot 320 of pushing element 300. Retractor bolt 522 is rigidly attached to sliding plug 521 of retractor element 500. Slot 320 is extended circumferentially to form index 321, which may be used to hold the retractor element 500 fully extended (i.e., with expanding element 530 at maximum distance from coring element 210). Expanding element 530 is connected to cylinder 562 by access passage 531 and flexible tube 550. Expanding element 530 volume is controlled by the position of plunger 600 in cylinder 562. Cylinder 562 is oriented in handle 310 so that plunger 600 with trigger 563 forms a pistol handle with trigger arrangement. Expanding element 530 can be inflated with saline, when trigger 563 is squeezed. Plunger spring 565 may be used to deflate expanding element 530 when the trigger is released. Alternatively, trigger 563 could be replaced with a finger ring so that the user must apply force to control both inflation and deflation of expanding element 530, thereby eliminating the need for plunger spring 565. As a safety feature, the plunger 600 may include a latching device (not shown) that latches the plunger 600 with the balloon fully inflated, thereby preventing premature deflation of the balloon. A related safety feature may include another latching device (not shown) that latches plunger 600 with the balloon partially inflated, such as to prevent the tissue plug from coming off of retractor element 500. As one of many alternatives to handle 310, the handle could form a "T" with pushing element 300.

[0099] In operation, retractor bolt 522 is positioned in index 321 until the retractor element 500 is fully inserted into the ventricle and expanding element 530 is fully inflated. At that time, retractor bolt 522 is manually released from index 321, which allows compression spring 540 to retract retractor element 500 until expanding element 530 contacts

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

[00100] FIG. 21A to FIG. 21C are components of a preferred embodiment shown in FIGS. 23A-23E, that uses a sequencing element to coordinate the position of retractor element 500 with the expansion of expanding element 530 (FIG. 21B). In this embodiment, the sequencing element is a cam mechanism. The cam mechanism helps to ensure proper use of the applicator during implantation of connector conduit 100 (not shown). As shown in FIG. 21B, retractor element 500, referred to as the retractor assembly, includes cylinder portion 562 integrated therein. The retractor assembly is positioned concentrically within pushing element 300 during use. The retractor assembly contains elements of the cam mechanism formal therein, including cylinder cam slot 710, which is a slot cut completely through the cylinder 562 wall, and a retractor cam follower 760, which may be a pin or screw in cylinder 562 (as shown) or may be an integral part of cylinder 562. Retractor element 500 may include a section of increased diameter such as stopper disk 515 to prevent cutter element 210 from cutting the heart when retractor element 500 is initially inserted. FIG. 21A illustrates plunger 600 (in the form of a sequencing bolt as described below), which is positioned concentrically within cylinder 562 during use. Plunger 600 contains elements of the cam mechanism, including bolt portion 650 with plunger cam follower 750. Plunger cam follower 750 moves within cylinder cam slot 710 and pusher cam slot 720. Plunger 600 includes passage 610 and purge/fill valve 630 (valve body not shown). Valve 630 can be opened to allow fluid flow into and out of passage 610. When closed, valve 630 allows no fluid flow in either direction. Valve 630 may be connected (such as with a catheter) to a reservoir of saline, for example, to purge the expanding element 530, access passage 531 and any other volume in the flow circuit of air before filling these volumes with fluid (such as saline). O-ring groove 620 of plunger 600 contains an o-ring (not shown) to prevent loss of fluid.

[00101] FIG. 21C illustrates a positioning assembly, which is made up of rigidly connected components including pushing element 300, cutting element 210, and handle 310.

The pusher assembly contains elements of the cam mechanism, including pusher cam slot 720 and retractor cam slot 730. The pusher cam slot 720 is a slot cut completely through the pushing element 300 wall to accommodate plunger cam follower 750.

[00102] FIG. 22A to FIG. 22C illustrate operation of the cam mechanism. FIG. 22A illustrates cylinder cam slot 710 cut into cylinder 562 of FIG. 21B. Cylinder cam slot 710 contains three interconnected axial cam slots at angles Θ_1, Θ_2 and Θ_3 around the circumference of cylinder 562, as further illustrated in FIG. 22C. The axial cam slot at each angle corresponds to a range of allowable axial positions of plunger 600 within cylinder 562. At angle Θ_1, the axial length of the cam slot corresponds to the maximum stroke of plunger 600 within cylinder 562. This maximum stroke allows filling the expanding element 530 from minimum volume to maximum volume. At angle Θ_2, the axial cam slot allows plunger 600 movement to provide expanding element 530 volumes ranging from maximum volume to an intermediate volume (at an intermediate stroke) that is greater than minimum volume but less than maximum volume. At angle Θ_3, the axial cam slot retains plunger 600 at the position of maximum volume of the expanding element 530. FIG. 22A also illustrates positions A, B, C, D and E of plunger cam follower 750 within cylinder cam slot 710 during the steps of operation.

[00103] FIG. 22B illustrates pusher cam slot 720 and retractor cam slot 730 cut into the pusher assembly of FIG. 21C. FIG. 22B also illustrates positions A, B, C, D and E of plunger cam follower 750 within pusher cam slot 720 and retractor cam follower 760 within retractor cam slot 730 during the steps of operation. FIG. 22C illustrates angles Θ_1 to Θ_6 for cylinder 562 and the pusher assembly. For purposes of description, the value of the angles increases from Θ_1 to Θ_6. Pusher cam slot 720 includes angles Θ_1 and Θ_3, which may correspond with angles Θ_1 and Θ_3 of cylinder 562 (see FIG. 22A). Pusher cam slot 720 includes angle Θ_4, which is larger than Θ_3. The axial length of pusher cam slot 720 from position A to position B corresponds to the maximum stroke of the plunger 600, as described above. The axial length of pusher cam slot 720 from position C to position E corresponds to the intermediate stroke (as described above) plus the axial distance traversed by retractor cam follower 760 from position C to position E in retractor cam slot 730. Retractor cam slot 730 includes angles Θ_5 and Θ_6. Positions A and B at angle Θ_5 prevent compression spring 540 from displacing cylinder 562 within the pusher assembly.

[00104] In operation, retractor cam slot 730 controls the motion of cylinder 562 within the pusher assembly. As shown in FIG. 22A and FIG. 22B, when plunger cam follower 750 (of sequencing bolt 600) is moved circumferentially from position B to position C in both

cylinder cam slot 710 and pusher cam slot 720, retractor cam follower 760 is forced from position B to position C in retractor cam slot 730, which allows compression spring 540 (see FIG. 18) to push cylinder 562 axially within the pusher assembly. Retractor cam follower 760 within retractor cam slot 730 holds cylinder 562 at a constant angular position relative to the pusher assembly during movement from position C to positions D and E; therefore, movement of plunger cam follower 750 from position C to position D within pusher cam slot 720 forces cam follower 750 into the axial slot corresponding to angle Θ_2 of cylinder 562.

[00105] Referring to FIGS. 23A to 23E, the applicator of the present invention is shown at various steps during use. Note that these figures do not include details of the locking means to securely hold the connector conduit 100. FIG. 23A to FIG. 23E correspond to positions A to E, respectively, which are described in FIG. 22A to FIG. 22C. Recognizing that individual surgeons may find alternative steps to properly use the invention, a representative sequence of steps for use of the applicator to implant a connector conduit is described. These steps include first preparing the applicator with the connector conduit. With the retractor assembly in the fully extended position as shown in FIG. 23A, a mounting and folding tool 900 is positioned into the coring element 210, as shown in FIG. 19. The connector conduit 100 of FIG. 14 is then loaded into the applicator by sliding connector conduit 100 over the folding tool 900 until sewing flange 170 contacts notch 421 (see FIG. 17). The connector conduit is then locked into place using the locking means. Tool 900 is then removed. A catheter is attached to purge/fill valve 630 and to a reservoir of saline. Valve 630 is opened. Sequencing bolt 600 is then moved back and forth from position A to position B several times to purge the fluid system of air and to fill the system with fluid, such as saline. Once the air is purged, sequencing bolt 600 is placed at position A, and tool 900 is again positioned into the coring element 210 – this time to squeeze fluid from the balloon and to fold the balloon. When tool 900 is in place, valve 630 is closed, and the catheter is removed. Tool 900 is removed. The applicator with connector conduit is now ready for use, as shown in FIG. 23A.

[00106] Before implanting the connector conduit 100 into the ventricle wall, the portion of the prosthesis that includes the prosthetic valve or ventricular assist device, as examples, is connected to the aorta. This portion of the prosthesis also includes the female end of quick connect coupler 180. By implanting this portion of the prosthesis first, the time between insulting the heart by cutting a hole and beginning blood flow through the complete prosthesis is minimized.

[00107] A template with similar dimensions as connector conduit 100 is placed on the apex of the heart, and a marker is used to trace the circular outline of the connector onto the apex, in the planned location of insertion. Multiple (8 to 12) large pledgeted sutures (mattress sutures) of for example, 2-0 prolene, are placed in the apex surrounding the marked circle. With the connector conduit 100 loaded in the applicator of FIG. 23A, the sutures are brought through sewing flange 170 of the connector conduit 100. A knife is used to make a stab wound in the apex at the center of the circle. With the applicator in the position shown in FIG. 23A, blunt tip 510 of retractor element 500 is inserted into the stab wound and pushed through the apex into the left ventricle chamber until stopper disk 515 contacts the epicardium (outside surface of the heart). Sequencing bolt 600 is moved from position A to position B to inflate the balloon behind tissue T of the heart wall (see FIG. 23B). The surgeon moves sequencing bolt 600 from position B to position C (see FIG. 23C) and then releases sequencing bolt 650. Beginning at position C of FIG. 23C, compression spring 540 pushes the retractor assembly from position C to position D (see FIG. 23D). When the retractor assembly moves from position C to position D, tissue T of the heart wall is first sandwiched between the balloon and the sharpened edge of the coring element 210a. By the surgeon using handle 310 to apply axial force and back-and-forth rotary motion, the sharpened edge of the coring element 210a cuts though the heart wall to form a plug of tissue T that resides in the coring element 210. At position D, the retractor assembly has been retracted until the balloon is in contact with coring element 210 and the tissue plug is fully within coring element 210. Also at position D, cylinder cam slot 710 has forced plunger cam follower 750 circumferentially to angle Θ_2, thereby allowing deflation of the balloon to begin. Between position D (FIG. 23D) and position E (FIG. 23E), the balloon deflates to the intermediate volume (described earlier), and the retractor assembly retracts to its final position. If necessary, the surgeon may pull sequencing bolt 600 to its final position E.

[00108] Connector conduit 100 is now fully implanted. The sutures are tied, and hemostasis is checked. Additional sutures may be placed if needed. The locking means (not shown) holding the connector conduit in the applicator is released, and the applicator is partially removed to a position where a clamp can be placed directly on collapsible graft 160a to prevent blood flow through the conduit 160. Once the clamp is in place, the applicator may be completely removed from connector conduit 100. The male and female ends of quick connect coupler 180 may now be connected. Umbilical tape 187 may be tied around graft extension 186a to reduce any blood leakage, and stay sutures may be used to secure graft extension 186a to outer fabric 165. Once the flow passage of the prosthesis is purged of air,

the clamp may be released to allow blood flow through the prosthesis. Flexible bend 140 is formed by pulling threads 143 and tying a knot. The connector conduit 100 is now fully implanted.

[00109] As illustrated in FIG. 24, an alternative embodiment, can use a connector conduit having an integral hole forming element. Hole forming element 210' is integrally formed, i.e. formed as a single component, with respect to connector conduit 100'. Connector conduit 100' can be loaded on an applicator (not having a separate hole forming element) in a manner similar to that disclosed above. After forming the hole and inserting the connector conduit into the hole, hole forming element 210' can be withdrawn into a distal end of connector conduit 100', as illustrated in FIG. 25, to reduce the possibility of unintended tissue damage. Such withdrawal can be accomplished by the sequencing means, a manual mechanism on the applicator, or with a separate instrument.

[00110] In the preferred embodiment described above, the expansion element is a balloon. However, an alternative expansion element, in the form of an umbrella mechanism, is illustrated in FIGS. 26A-26D. Retractor 500' includes cylinder 810 (shown in cross section), and piston element 820 slideably disposed in cylinder 810. Bolt 650 having follower 750 is formed on cylinder 810. Shaft 830 extends from piston element 820 and has umbrella mechanism 850 formed on an end thereof. Umbrella mechanism 85 included plural bendable leaf elements 852 that are fixed to shaft 830 at the end of shaft 830. Leaf elements 852 are fixed to ring 854 at the other end thereof. Ring 854 is slideably disposed on shaft 830. Accordingly, movement of shaft 830 to the right in the FIGS. causes ring 854 to be pushed toward the end of shaft 830 as ring 854 abuts an end of cylinder 810, as shown in FIG. 26 D. Slot 710 guides follower 750, and bolt 650 cooperates with remaining elements in the sequencing mechanism in the manner described above, to coordinate the expansion state of expansion element 850.

[00111] As illustrated in FIGS. 27-29, the invention also relates to a connector conduit with applicator that eliminates the need to sew the connector conduit to the apex. This apparatus of the invention generally includes a connector conduit operable to be inserted through a hole in a wall of the organ, a flange element positioned on the connector conduit adapted to prevent over-insertion of the connector conduit, and a retention means positioned on the connector conduit. The retention means is preferably adapted to be engaged with the wall of the organ to prevent movement of the connector conduit relative to the wall of the organ after the connector conduit is inserted through the hole in the wall of the organ.

[00112] As described in the embodiments illustrated in FIGS. 1-26 above, during operation, the tip of a retractor element 948 is pushed through the wall of an organ 905. An expansion element 949, such as a balloon element, is attached to retractor element 948 near the tip. As the tip of retractor element 948 is pushed through the wall of organ 905, expansion element 949 is also pushed through the wall of organ 905. After expansion element 949 is positioned within organ 905, expansion element 949 is expanded from a compressed or deflated state to an expanded or inflated state, and retractor element 948 is withdrawn from the organ 905 until expansion element 949 is adjacent to the inner surface of the wall of organ 905, and coring element 958 is adjacent to the outer surface of the wall of organ 905. At this point, coring element 958 is used to form a hole in the wall of organ 905, the resulting tissue plug is removed, and connector conduit 951 is push through the hole in organ 905 until the leading edge of a flange element 955 (previously referred to as the sewing flange 170) is adjacent to the outer surface of organ 905.

[00113] Generally, during operation, the connector conduit is inserted through the hole in the wall of the organ until the flange element comes into contact with the wall of the organ, and the retention means is engaged with the wall of the organ after the connector conduit is inserted through the hole in the wall of the organ. The retention means is operative to prevent movement of the connector conduit relative to the hole in the wall of the organ after insertion of the connector conduit into the organ. In particular, the retention means generally prevents the force resulting from blood pressure within the organ (i.e. within the ventricle if the organ is a heart) from pushing the connector conduit out of the hole in the wall of the organ.

[00114] FIGS. 27A-27E illustrate an embodiment of the invention in which the retention means consists of a plurality of retaining pins 962. The retaining pins 962 improve homeostasis by providing a squeezing force to press the heart wall against connector conduit 951. Retaining pins 962 are preferably positioned circumferentially around the connector conduit, such that they are inserted into the hole in the wall of the organ when the connector conduit is inserted through the hole in the wall of the organ. In addition, the retaining pins are preferably maintained in a passive state adjacent to an outer surface of the connector conduit until entering into engagement with the wall of the organ.

[00115] In particular, the plurality of retaining pins 962 are connected to a ring 972, which is positioned circumferentially around connector conduit 951, and contained below the surface of connector conduit 951 (See FIGS. 27C-27D). A plurality of tabs 961 are also connected to ring 972 in a similar manner to retaining pins 962. Both retaining pins 962 and

tabs 961 extend axially along connector conduit 962 as is shown in FIGS. 27C-27E. Retaining pins 962 preferably have a sharpened tip.

[00116] In addition, a means for causing the retaining pins to engage the wall of the organ to prevent movement of the connector conduit relative to the wall of the organ may also be used. The means for causing the retaining pins to engage the wall of the organ to prevent movement of the connector conduit relative to the wall of the organ may comprise a plurality of skid elements and pull wires, for example. For example, a plurality of pull wires 964 are connected to the ends of tabs 961, such that when an axial force is applied to pull wires 964, pull wires 964, retaining pins 962, and ring 972 are all subjected to the same force, and can move axially upon application of sufficient force. Each pull wire 964 is attached to a pull ring 963, which provides a means to apply an equal pulling force to each pull wire simultaneously. Pull wire 963 is preferably connected to applicator 950 such that extraction of applicator 950 results in application of an axial force on pull ring 963, and, accordingly, on retaining pins 962.

[00117] Furthermore, as is shown in FIG. 27C, connector conduit 951 is slightly modified in this embodiment to include a plurality of skids 965, which are positioned circumferentially around connector conduit 951 in such a way that each retaining pins 962 is preferably positioned in axial alignment with at least one skid 965. Each skid 965 comprises a sloping or curved surface that extends tangentially upwards from the axial plane of the connector conduit 951 in which the retaining pins 962 are positioned towards the outer surface of connector conduit 951.

[00118] During operation, when applicator 950 is extracted after installation of connector conduit 951, an axial force is applied to pull ring 963, and pull ring 963 slides axially along connector conduit 951 away from organ 905. As pull ring 963 moves along connector conduit 951, pull wires 964 exert a force on tabs 961, causing ring 972, and retaining pins 962, to slide axially along connector conduit 951 as well. As is illustrated in FIG. 27D, as retaining pins 962 slide along connector conduit 951, the tips of retaining pins 962 come into contact with skids 965, and are guided along the curved or angled surface of skids 965. As movement of retaining pins 962 continues, the tips of retaining pins 962 pierce the outer surface of connector conduit 951 and the wall of organ 905 (See FIG. 27E). Axial movement of pull ring 963 and retaining pins 962 continues until retaining pins 962 come into contact with flange element 955, at which point pull ring 963 disengages from applicator 950. The barb-like connection between retaining pins 962 and the wall of organ 905 prevent disengagement of connector conduit 951 from organ 905 without the use of additional

sutures. In addition, the engagement of the retaining pins with the wall of the organ radially squeezes the wall of the organ against the connector conduit, thereby preventing any leakage of blood or fluids from within the organ around the engagement of the wall of the organ and the connector conduit.

[00119] FIGS. 28A-28E illustrate an embodiment of the invention in which a plurality of prongs 966 are used as the retention means to prevent dislodgement of the connector conduit 951 from the wall of organ 905. The prongs are preferably positioned circumferentially around the connector conduit such that the prongs, when in an initial passive state, are positioned outside of the organ after the connector conduit has been inserted through the hole in the wall of the organ. Prongs 966 may also improve homeostasis by providing a squeezing force to press the heart wall against connector conduit 951.

[00120] Prongs 966, which are preferably shaped like curved staples, are positioned around the surface of applicator 950 in such a manner that the tips of each prong 966 is generally adjacent to the outer surface of flange element 955. After connector conduit 951 is inserted through the wall of organ 905 (as is shown in FIG. 28B), prongs 966 are inserted through flange element 955 and the outer surface of organ 905 (see FIG. 28C-28D), thereby securing connector conduit 951 to organ 905. Thus, it is clear that, after the connector conduit has been inserted through the hole in the wall of the organ, the prongs are adapted to be inserted through a plurality of holes in the flange element into the wall of the organ, thereby entering into engagement with the wall of the organ.

[00121] A prong installation element may be used which is adapted to insert the prongs through the holes in the flange element into the wall of the organ, thereby causing the prongs to enter into engagement with the wall of the organ. For example, the axial force needed to insert prongs 966 through flange element 955 and into organ 905 may be provided by a plurality of one or more prong deployment mechanisms 971. Each prong deployment mechanism 971, illustrated in FIGS. 29A-29D, generally comprises two components including a prong installation lever 970 and a prong installation element 967. Each prong installation element 967 is connected to a prong installation lever 970 with a hinge such that movement of a prong installation lever 970 results in movement of the corresponding prong installation element 967. Each prong installation element 967 extends longitudinally along surface of applicator 950. As is illustrated in FIGS. 29A-29D, each prong installation element 967 includes a curved slot 969 near one end, which serves as a deployment means for a prong 966.

[00122] In the preferred embodiment illustrated in FIGS. 28, a plurality of prong installation elements 967 are arranges in a radial fashion around applicator 950. Any number of prongs may be used, for example, six or eight prongs. Most preferably, there are equal numbers of prong installation elements 967 and prongs 966. The installation and application of an exemplary prong will now be described with reference to the FIGS. 28-29. During operation, prong 966 is predisposed within slot 969 of prong installation element 967, with the tips of prong 966 being positioned generally adjacent to flange element 955. As a force is applied to prong installation lever 970, prong installation element 967 slides axially along applicator 950 towards flange element 955. Because prong 966 is positioned within slot 969, the movement of prong installation element 967 along applicator 950 results in axial movement of prong 966 as well. The tips of prong 966 are pressed through flange element 955 and into the wall of organ 905. Slot 969 is designed such that the curved characteristics of prong 966 result in prong 966 sliding out of slot 969 as prong 966 is pressed further and further through flange element 955 and into organ 905. Thus, when prong 966 has been fully inserted through flange element 955, prong 966 will no longer be positioned within slot 969. At this point, applicator 950 and prong deployment mechanism 971 may be removed from connector conduit 951, and prong 966 will remain inserted through flange element 955 and within the wall of organ 905. The curved connection between prong 966 and the wall of organ 905 prevent disengagement of connector conduit 951 from organ 905 without the use of additional sutures. In addition, the engagement of the prongs with the wall of the organ radially squeezes the wall of the organ against the connector conduit, thereby preventing any leakage of blood or fluids from within the organ around the engagement of the wall of the organ and the connector conduit.

[00123] FIGS. 30A-30B illustrate an embodiment of the invention wherein a balloon 976 is used as the retention means to retain connector conduit 975 securely within the organ. Balloon 976 should be positioned on the connector conduit, such that the balloon is inserted through the hole in the wall of the organ as the connector conduit is inserted through the hole in the wall of the organ. FIGS. 31A-31B provide a more detailed view of balloon 976.

[00124] During operation, connector conduit 975 is inserted through the wall of the organ as is described above with balloon 976 preferably being in a initial deflated state until after the balloon and the connector conduit are inserted through the hole in the wall of the organ. (FIG. 30A). After insertion of the connector conduit through the wall of the organ, with balloon 976 residing within the organ, balloon 976 is inflated from the initial deflated state to an expanded state to prevent the pressure in the organ from pushing connector

conduit 975 out, and to enter into engagement with the wall of the organ and preventing movement of the connector conduit relative to the hole in the wall of the organ. (FIG. 30B). In addition, the engagement of the inflated balloon with the wall of the organ axially squeezes the wall of the organ between the balloon and the flange element, thereby preventing any leakage of blood or fluids from within the organ around the engagement of the wall of the organ and the connector conduit. A coring knife may be used as a hole forming element to cut a hole in the organ through which connector conduit 975 is inserted.

[00125] Balloon 976, which may be formed of any suitable materials including, for example, polyurethane or polyethylene terephthalate (PET, polyester), is packaged in a deflated state (FIG. 30A) between an outer fabric sleeve 980 and a stent 979 of the connector conduit 975. Outer fabric sleeve 980 and vascular graft 160 are connected by any suitable connection means, for example, sutures.

[00126] As is shown in FIG. 31A -31B, balloon 976 is preferably formed from a single piece of material, such as a generally cylindrical sleeve, to minimize the possibility of leakage. The cylindrical sleeve may be folded back on itself longitudinally and fused to form balloon 975 as it is shown in the figures. In particular, the cylindrical sleeve may have a substantially constant diameter except for the portion of the sleeve that will be used for the expanding portion of the balloon. This portion should have a larger diameter to allow for the expansion of the balloon when inflating from the initial deflated state to the inflated state. In addition, the diameter of the remaining portions of the sleeve should not significantly change in response to the inflation of the balloon portion of the sleeve because the inner and outer portions of the sleeve are sandwiched between the outer fabric sleeve 980 and stent 979.

[00127] After connector conduit 975 is inserted through the wall of the organ, balloon 976 is inflated using a suitable biocompatible material provided by a fill tube 977. FIGS. 31A-31B show balloon 976 in its expanded state. It is preferred that balloon 976 be filled to a predetermined pressure (for example, 15 psi), thereby allowing the balloon to inflate and tightly engage the wall of the organ. In this manner, the inflation of the balloon consistently creates a tight seal against the wall of the organ regardless of variation in the shape of the organ or the thickness of the wall of the organ. In particular, since the degree of inflation is preferably based on the pressure within the balloon, different balloons will be inflated to different volumes until the predetermined pressure is reached.

[00128] Directional arrow 978 indicates the direction of flow for the biocompatible material during inflation of balloon 976. As balloon 976 expands, the shape of outer fabric sleeve 980 conforms with the expanding shape of balloon 976. Thus, it is preferred that outer

fabric sleeve 980 be formed into a shape that allows for the expansion of balloon 976 without any significant deformation or stretching. To facilitate this, outer fabric sleeve 980 may have folds or the like prior to expansion of balloon 976. A removable sheath (not shown) may also be placed over outer fabric sleeve 980 while the connector is inserted into the heart wall to reduce any effects of the folded outer fabric. An exemplary material for outer fabric sleeve 980 is Dacron.

[00129] Balloon 976 may be filled with any suitable biocompatible material. Examples of suitable biocompatible materials include saline, or a silicone or polyurethane foam that is injected as a polymer and solvent which solidifies into a sponge-like permanent implant. An example of use of such a material is described in U.S. Patent No. 6,098,629, which describes an endoscopic procedure to treat GERD (gastro esophageal reflux disease) by injecting this liquid polymer directly into the lower esophageal sphincter using a needle catheter. In the case of saline, it is possible that the saline could leak out of the balloon over time. Since the implant is grown in or chronic after about 8 weeks (i.e. the tissue has grown into the outer fabric sleeve), the saline would have to reliably remain in the balloon for at least that amount of time. Once the implant is chronic, it can only be removed by cutting it out, so the saline-filled balloon is not needed. Also, since the balloon is completely enclosed between the outer fabric sleeve and the inner portion of the connector conduit, a failed balloon after the implant is chronic cannot escape to cause problems, such as an embolus.

[00130] In an alternative embodiment shown in FIG. 30C, connector conduit may include a plurality of balloons 976 and 976A. For example, balloon 976 could reside inside the organ and balloon 976A could reside outside the organ, where the suture ring has been located for the other embodiments described above. When two balloons are used as expansion elements in this configuration, the balloons effectively compress the wall of the organ, thereby securing the connector conduit to the organ. It should be noted that it is preferred that a flange element still be used in this configuration to prevent over-insertion of the connector conduit into the organ. In this arrangement, the flange element can be positioned on the pusher assembly of the applicator instead of on the connector conduit. As such, the second balloon 976A could be positioned immediately adjacent to the flange element. Each balloon used in this manner preferably has its own fill tube to prevent migration of saline out of the organ. For example, in FIG. 30C, balloon 976 is inflated via fill tube 977, and balloon 976A is inflated via fill tube 977A.

[00131] FIGS. 32A-32B illustrate an embodiment of the invention wherein a torsion spring is used as the retention means to retain the connector conduit securely within the

organ. In particular, the torsion spring is preferably positioned on the connector conduit such that the torsion spring, when in an initial compressed state, is inserted through the hole in the wall of the organ as the connector conduit is inserted through the hole in the wall of the organ.

[00132] As is shown in the figures, a stent 981 is attached to a vascular graft 986 for insertion through the wall 905 of the organ. A torsion spring 984 is positioned, in a compressed state, in a circumferential groove 987 around stent 981. Vascular graft 986 extends around the tip of stent 981 and is connected to an outer fabric sleeve 983 by any suitable means, for example, sutures. Outer fabric sleeve 983 also covers torsion spring 984, and torsion spring 984 is preferably retained in a compressed state by a sheath 985 which is positioned over torsion spring 984 and outer fabric sleeve 983. FIG. 32A shows torsion spring 984 in a compressed state.

[00133] During operation, the connector conduit is inserted through the wall of the organ until flange element 982 contacts the outer surface of wall 905, as is described above. After being properly positioned, with torsion spring 984 residing inside the organ, sheath 985 is withdrawn through the wall of the organ and torsion spring 984 is allowed to expand from the initial compressed state to an expanded state, thereby entering into engagement with the wall of the organ and preventing movement of the connector conduit relative to the wall of the organ. In addition, the engagement of the expanded torsion spring with the wall of the organ axially squeezes the wall of the organ between the torsion spring and the flange element, thereby preventing any leakage of blood or fluids from within the organ around the engagement of the wall of the organ and the connector conduit.

[00134] As torsion spring 984 expands, the shape of outer fabric sleeve 983 conforms with the expanding shape of torsion spring 984. Thus, it is preferred that outer fabric sleeve 983 be formed into a shape that allows for the expansion of torsion spring 984 without any significant deformation or stretching. To facilitate this, outer fabric sleeve 983 may have folds or the like prior to expansion of torsion spring 984. FIG. 32B shows an exemplary shape of outer fabric 983 when torsion spring 984 is in an expanded state.

[00135] As described above with reference to balloons, the connector conduit may also include a plurality of torsion springs to secure the connector conduit relative to the organ. For example, as is shown in FIG. 32C, torsion spring 984 is positioned within the organ, and torsion spring 984A is positioned outside the wall of the organ, where the suture ring has been located for the other embodiments described above. When two torsion springs are used as expansion elements in this configuration, the torsion springs effectively compress the wall

of the organ, thereby securing the connector conduit to the organ. It should be noted that is preferred that a flange element still be used in this configuration to prevent over-insertion of the connector conduit into the organ. In this arrangement, the flange element can be positioned on the pusher assembly of the applicator instead of on the connector conduit. As such, the second torsion spring 984A could be positioned immediately adjacent to the flange element. In addition, while FIG. 32C only shows the use of two torsion springs, three or more torsion springs may also be used. For example, depending on the thickness of the wall of the organ, torsion springs may reside inside the organ, within the wall of the organ, and/or outside of the organ, resulting in a ribbed effect that facilitates engagement of the connector conduit to the organ. In addition, torsion springs may be used in combination with balloons.

[00136] FIGS. 33A-33C illustrate an embodiment of the invention wherein a spiral spring is used as the retention means to retain the connector conduit securely within the organ. As is shown in the figures, a stent 988 is attached to connector conduit 998 for insertion through the wall of the organ. A spiral spring 989 is positioned, in a compressed state, in a circumferential groove 997 around stent 988, and is covered by an outer fabric sleeve 999, which is adapted to expand as the spiral spring expands from its compressed state to its expanded state. Spiral spring 989 is maintained in a compressed state by a smooth frame cover 990, which also includes a insertion stop 991. Spiral spring 989 should be formed of a strong material, such as a metal or plastic, such as PEEK.

[00137] During operation, the connector conduit is inserted through the wall of the organ, using cutter 993, until insertion stop 991 contacts the outer surface of the wall of the organ, as is described above with reference to the flange element. The spiral spring, which is initially in the compressed state, is inserted through the hole in the wall of the organ as the connector conduit is inserted through the hole in the wall of the organ. After the connector conduit has been inserted through the hole in the wall of the organ, with spiral spring 989 residing inside the organ, smooth frame cover 990 is withdrawn through the wall of the organ and spiral spring 989 is allowed to expand from the compressed state to an expanded state, thereby preventing the pressure in the organ from pushing the connector conduit back out the hole and preventing movement of the connector conduit relative to the wall of the organ. FIG. 33B shows an exemplary shape of spiral spring 989 when in an expanded state, and clearly shows the positioning of outer fabric sleeve 999 relative to spiral spring 989. After spiral spring 989 is expanded, a compression ring 995, which may be positioned circumferentially around the connector conduit on the outside of the organ, may be moved longitudinally along the surface of the connector conduit until being compressed down onto

the external surface of the wall of the organ via a plurality of ratchet steps 992, which allows for a tight, compressed seal on the wall of the organ to be achieved between compression ring 995 and spiral spring 989. The engagement of the expanded spiral spring with the wall of the organ axially squeezes the wall of the organ between the expanded spiral spring and the sewing ring, thereby preventing any leakage of blood or fluids from within the organ around the engagement of the wall of the organ and the connector conduit.

[00138] Spiral spring 989 may also be used as a direct replacement for torsion spring 984 shown in FIG. 32A-32B. In this case, with reference to FIGS. 32A-32B, spiral spring 989 is positioned, in a compressed state, in a circumferential groove 987 around stent 981. An outer fabric sleeve 983 covers stent 981 and spiral spring 989. Spiral spring 989 is retained in a compressed state by a sheath 985 which is positioned over spiral spring 989 and outer fabric sleeve 983. During operation, the connector conduit is inserted through the wall of the organ until flange element 982 contacts the outer surface of wall 905, as is described above. After being properly positioned, with spiral spring 989 residing inside the organ, sheath 985 is withdrawn through the wall of the organ and spiral spring 989 is allowed to expand, thereby preventing the pressure in the organ from pushing the connector conduit back out the hole. As spiral spring 989 expands, the shape of outer fabric sleeve 983 conforms with the expanding shape of spiral spring 989. Thus, it is preferred that outer fabric sleeve 983 be formed into a shape that allows for the expansion of spiral spring 989 without any significant deformation or stretching. To facilitate this, outer fabric sleeve 983 may have folds or the like prior to expansion of spiral spring 989. FIG. 32B shows an exemplary shape of outer fabric 983 when spiral spring 989 is in an expanded state.

[00139] Although the present invention has been described in relation to particular embodiments thereof, many other variations and modifications and other uses will become apparent to those skilled in the art. It is preferred therefore, that the present invention be limited not by the specific disclosure herein, but only by the appended claims.

What is claimed is:

1. An apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ, the apparatus comprising:

a connector conduit operable to be inserted through a hole in a wall of the organ;

a flange element positioned on the connector conduit adapted to prevent over-insertion of the connector conduit; and

a retention means positioned on the connector conduit, the retention means being adapted to be engaged with the wall of the organ to prevent movement of the connector conduit relative to the wall of the organ after the connector conduit is inserted through the hole in the wall of the organ,

wherein the connector conduit is inserted through the hole in the wall of the organ until the flange element comes into contact with the wall of the organ, and

wherein the retention means is engaged with the wall of the organ after the connector conduit is inserted through the hole in the wall of the organ.

2. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 1, wherein the hole in the wall of the organ is formed by a hole forming element having a cutting element on a distal end thereof and being adapted for coupling with the connector conduit.

3. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 1, wherein the organ is a heart.

4. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 1, wherein the flange element is integrally formed on the connector conduit.

5. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 1, wherein the retention means comprises a plurality of retaining pins positioned circumferentially around the connector conduit, such that the retaining pins are inserted into the hole in the wall of the organ when the connector is inserted through the hole in the wall of the organ.

6. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 5, further comprising a means for causing the retaining pins to engage the wall of the organ to prevent movement of the connector conduit relative to the wall of the organ.

7. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 6, wherein the means for causing the retaining pins to engage the wall of the organ to prevent movement of the connector conduit relative to the wall of the organ comprises a plurality of skid elements and pull wires.

8. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 6, wherein the retaining pins are maintained in a passive state adjacent to an outer surface of the connector conduit until entering into engagement with the wall of the organ.

9. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 1, wherein the retention means comprises a plurality of prongs positioned circumferentially around the connector conduit such that the prongs, when in an initial passive state, are positioned outside of the organ after the connector conduit has been inserted through the hole in the wall of the organ.

10. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 9, wherein, after the connector conduit has been inserted through the hole in the wall of the organ, the prongs are adapted to be inserted through a plurality of holes in the flange element into the wall of the organ, thereby entering into engagement with the wall of the organ.

11. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 10, further comprising a prong installation element adapted to insert the prongs through the holes in the flange element into the wall of the organ, thereby causing the prongs to enter into engagement with the wall of the organ.

12. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 10, wherein the prongs have a curved shape that causes engagement of the prongs with the wall of the organ by the insertion of the prongs into the wall of the organ.

13. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 1, wherein the retention means comprises a balloon positioned on the connector conduit, such that the balloon is inserted through the hole in the wall of the organ as the connector conduit is inserted through the hole in the wall of the organ.

14. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 13, wherein the balloon is maintained in an initial deflated state until after the balloon and the connector conduit are inserted through the hole in the wall of the organ.

15. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 14, wherein, after the connector conduit has been inserted through the hole in the wall of the organ, the balloon is inflated from the initial deflated state to an expanded state, thereby entering into engagement with the wall of the organ and preventing movement of the connector conduit relative to the hole in the wall of the organ.

16. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 13, wherein the flange element is replaced with a second balloon positioned on the connector conduit such that, after insertion of the connector conduit through the hole in the wall of the organ, the two balloons are inflated, and the wall of the organ is compressed between the two balloons, thereby preventing movement of the connector conduit relative to the wall of the organ.

17. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 13, wherein the flange element is replaced with a torsion spring positioned on the connector conduit, such that, after insertion of the connector conduit through the hole in the wall of the organ, the balloon is inflated, and

the wall of the organ is compressed between the torsion spring and the balloon, thereby preventing movement of the connector conduit relative to the wall of the organ.

18. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 1, wherein the retention means comprises a torsion spring positioned on the connector conduit, such that the torsion spring, when in an initial compressed state, is inserted through the hole in the wall of the organ as the connector conduit is inserted through the hole in the wall of the organ.

19. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 18, further comprising a sheath adapted to retain the torsion spring in a compressed state.

20. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 19, wherein, after the connector conduit has been inserted through the hole in the wall of the organ, the sheath is withdrawn from the hole in the wall of the organ, thereby allowing the torsion spring to expand from the initial compressed state to an expanded state, thereby entering into engagement with the wall of the organ and preventing movement of the connector conduit relative to the wall of the organ.

21. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 19, wherein the flange element is replaced with a second torsion spring positioned on the connector conduit such that, after insertion of the connector conduit through the hole in the wall of the organ, and withdrawal of the sheath from the wall of the organ, the two torsion springs are in their respective expanded states, and the wall of the organ is compressed between the two torsion springs, thereby preventing movement of the connector conduit relative to the wall of the organ.

22. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 19, wherein the flange element is replaced by a plurality of torsion springs positioned on the connector conduit such that, after insertion of the connector conduit through the hole in the wall of the organ, and withdrawal of the sheath from the wall of the organ, at least one torsion spring resides inside the organ, at least one torsion spring resides within the wall of the organ, and at least one torsion spring

resides outside of the organ, thereby compressing the wall of the organ between the two torsion springs and preventing movement of the connector conduit relative to the wall of the organ.

23. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 19, wherein the flange element is replaced with a balloon positioned on the connector conduit such that, after insertion of the connector conduit through the hole in the wall of the organ, withdrawal of the sheath from the wall of the organ, and inflation of the balloon, the torsion spring is in its expanded state, the balloon is in its inflated state, and the wall of the organ is compressed between the torsion spring and the balloon, thereby preventing movement of the connector conduit relative to the wall of the organ.

24. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 1, wherein the retention means comprises a spiral spring positioned on the connector conduit, such that the spiral spring, when in an initial compressed state, is inserted through the hole in the wall of the organ as the connector conduit is inserted through the hole in the wall of the organ.

25. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 24, further comprising a smooth frame cover adapted to retain the spiral spring in a compressed state.

26. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 25, wherein, after the connector conduit has been inserted through the hole in the wall of the organ, the smooth frame cover is withdrawn from the hole in the wall of the organ, thereby allowing the spiral spring to expand from the compressed state to an expanded state, thereby entering into engagement with the wall of the organ and preventing movement of the connector conduit relative to the wall of the organ.

27. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 24, wherein the flange element is replaced by a compression ring, which is positioned circumferentially around the connector

conduit on the outside of the organ, such that, after the connector conduit is inserted through the hole in the wall of the organ, the spiral spring expands from the compressed state to an expanded state, and the compression ring is moved longitudinally along the surface of the connector conduit along one or more ratchet steps formed on the surface of the connector conduit towards the wall of the organ, thereby compressing the wall of the organ between the spiral spring and the compression ring, and preventing movement of the connector conduit relative to the wall of the organ.

28. A method for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ, the method comprising:

forming a hole in a wall of the organ;

inserting a connector conduit through the hole in the wall of the organ until a flange element comes into contact with the wall of the organ, the flange element being positioned on the connector conduit; and

engaging a retention means with the wall of the organ to prevent movement of the connector conduit relative to the wall of the organ, the retention means being positioned on the connector conduit.

29. The method for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 28, wherein the hole in the wall of the organ is formed by a hole forming element having a cutting element on a distal end thereof and being adapted for coupling with the connector conduit.

30. The method for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 28, wherein the organ is a heart.

31. The method for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 28, wherein the flange element is integrally formed on the connector conduit.

32. The method for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 28, wherein the retention means comprises a plurality of retaining pins positioned circumferentially around the connector conduit, such

that the retaining pins are inserted into the hole in the wall of the organ when the connector is inserted through the hole in the wall of the organ.

33. The method for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 32, wherein the step of engaging comprises causing the retaining pins to penetrate the wall of the organ to prevent movement of the connector conduit relative to the wall of the organ.

34. The method for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 33, wherein the retaining pins are maintained in a passive state adjacent to an outer surface of the connector conduit until entering into engagement with the wall of the organ.

35. The method for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 28, wherein the retention means comprises a plurality of prongs positioned circumferentially around the connector conduit such that the prongs, when in an initial passive state, are positioned outside of the organ after the connector conduit has been inserted through the hole in the wall of the organ.

36. The method for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 35, wherein the step of engaging comprises inserting the prongs through a plurality of holes in the flange element into the wall of the organ, thereby engaging the wall of the organ and preventing movement of the connector conduit relative to the wall of the organ..

37. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 28, wherein the retention means comprises a balloon positioned on the connector conduit, such that the balloon is inserted through the hole in the wall of the organ as the connector conduit is inserted through the hole in the wall of the organ.

38. The method for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 37, wherein the balloon is maintained in an initial

deflated state until after the balloon and the connector conduit are inserted through the hole in the wall of the organ.

39. The method for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 38, wherein step of engaging comprises inflating the balloon from the initial deflated state to an expanded state, thereby engaging the wall of the organ and preventing movement of the connector conduit relative to the wall of the organ.

40. The method for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 37, wherein the flange element is replaced with a second balloon positioned on the connector conduit such that the step of engaging comprises inflating both of the balloons to compress the wall of the organ between the two balloons, thereby preventing movement of the connector conduit relative to the wall of the organ.

41. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 37, wherein the flange element is replaced with a torsion spring positioned on the connector conduit, such that the step of engaging comprises inflating the balloon and expanding the torsion spring from a compressed state to an expanded state to compress the wall of the organ between the torsion spring and the balloon, thereby preventing movement of the connector conduit relative to the wall of the organ.

42. The method for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 28, wherein the retention means comprises a torsion spring positioned on the connector conduit, such that the torsion spring, when in an initial compressed state, is inserted through the hole in the wall of the organ as the connector conduit is inserted through the hole in the wall of the organ.

43. The method for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 42, wherein the torsion spring is retained in the initial compressed state by a sheath.

44. The method for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 43, wherein the step of engaging comprises

withdrawing the sheath from the hole in the wall of the organ, thereby allowing the torsion spring to expand from the initial compressed state to an expanded state and enter into engagement with the wall of the organ, thereby preventing movement of the connector conduit relative to the wall of the organ.

45. The method for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 43, wherein the flange element is replaced with a second torsion spring positioned on the connector conduit such that the step of engaging comprises withdrawing the sheath from the wall of the organ, thereby allowing the torsion springs to expand from the compressed state to the expanded states to compress the wall of the organ between the two torsion springs, thereby preventing movement of the connector conduit relative to the wall of the organ.

46. The method for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 43, wherein the flange element is replaced by a plurality of torsion springs positioned on the connector conduit such that the step of engaging comprises withdrawing the sheath from the wall of the organ, wherein at least one torsion spring resides inside the organ, at least one torsion spring resides within the wall of the organ, and at least one torsion spring resides outside of the organ, thereby compressing the wall of the organ between the two torsion springs and preventing movement of the connector conduit relative to the wall of the organ.

47. The method for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 43, wherein the flange element is replaced with a balloon positioned on the connector conduit such that the step of engaging comprises withdrawing the sheath from the wall of the organ, thereby allowing the torsion spring to expand from the compressed state to the expanded state, and inflating the balloon, to compress the wall of the organ between the torsion spring and the balloon, thereby preventing movement of the connector conduit relative to the wall of the organ.

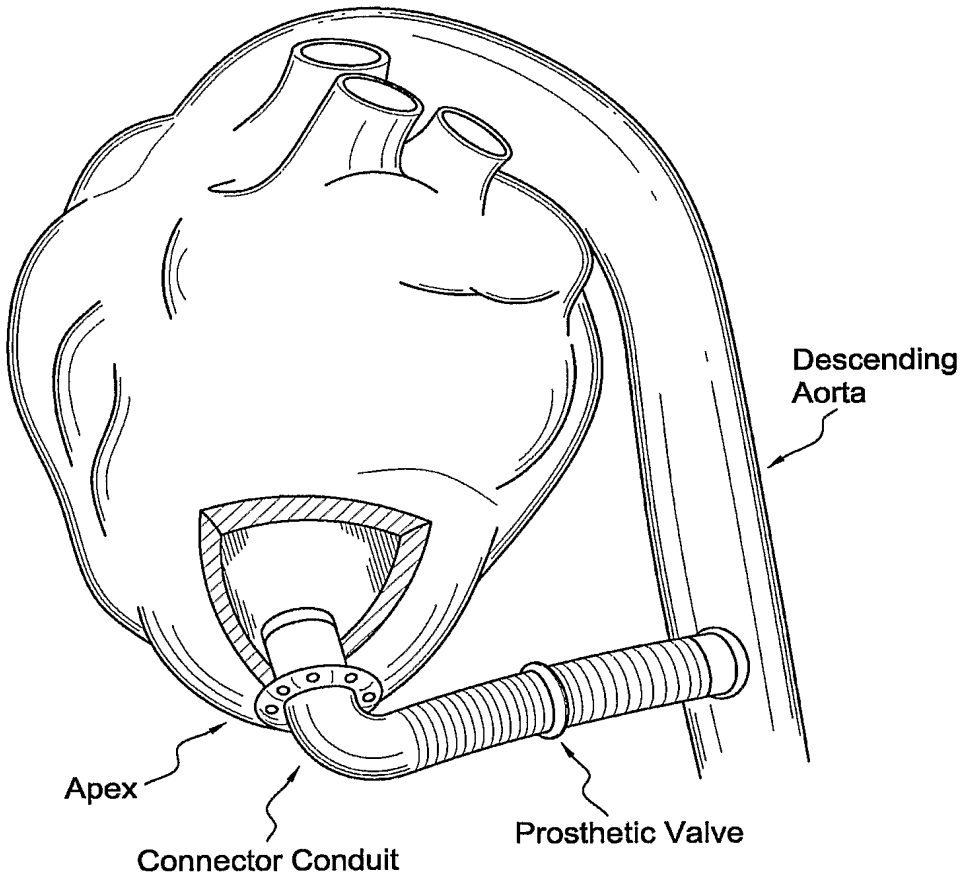
48. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 28, wherein a spiral spring is positioned on the connector conduit, such that the spiral spring, when in an initial compressed state, is inserted through the hole in the wall of the organ as the connector conduit is inserted through the hole in the wall of the organ.

49. The method for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 48, further comprising a smooth frame cover adapted to retain the spiral spring in a compressed state.

50. The method for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 49, wherein the step of engaging comprises withdrawing the smooth frame cover from the hole in the wall of the organ, thereby allowing the spiral spring to expand from the compressed state to an expanded state, thereby entering into engagement with the wall of the organ and preventing movement of the connector conduit relative to the wall of the organ.

51. The apparatus for securing a connector conduit to a hollow organ and preventing blood loss from the hollow organ of claim 49, wherein the flange element is replaced by a compression ring, which is positioned circumferentially around the connector conduit on the outside of the organ, such that the step of engaging comprises withdrawing the smooth frame cover to allow the spiral spring to expand from the compressed state to an expanded state, and moving the compression ring longitudinally along the surface of the connector conduit along one or more ratchet steps formed on the surface of the connector conduit towards the wall of the organ, thereby compressing the wall of the organ between the spiral spring and the compression ring, and preventing movement of the connector conduit relative to the wall of the organ.

FIG. 1



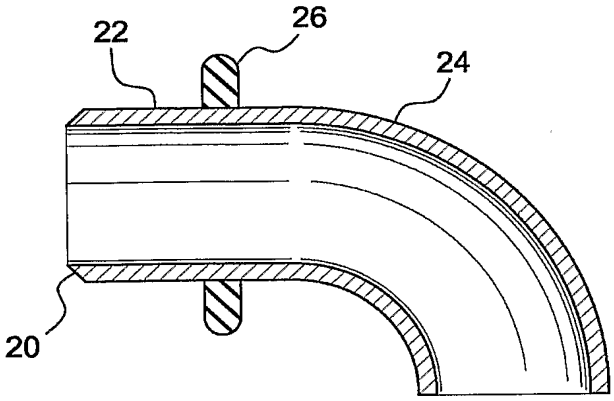


FIG. 2A

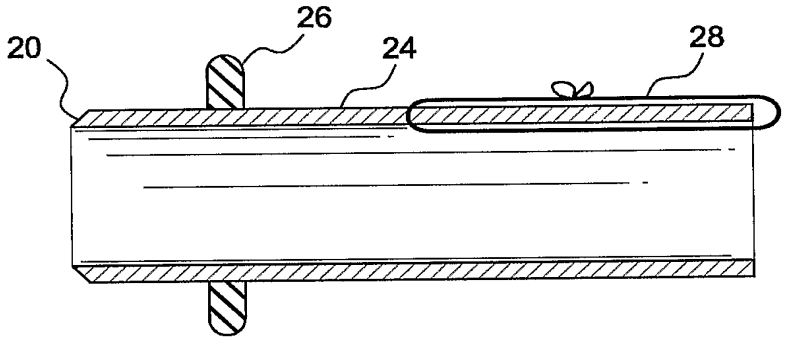


FIG. 2B

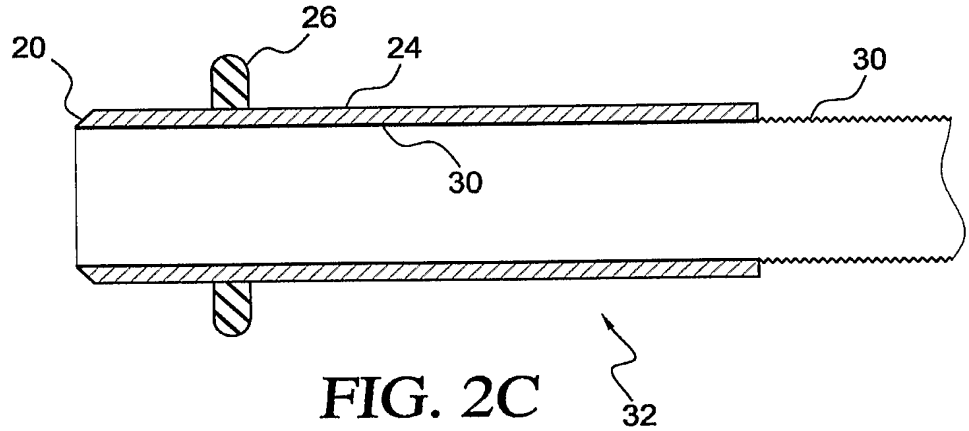


FIG. 2C

FIG. 3

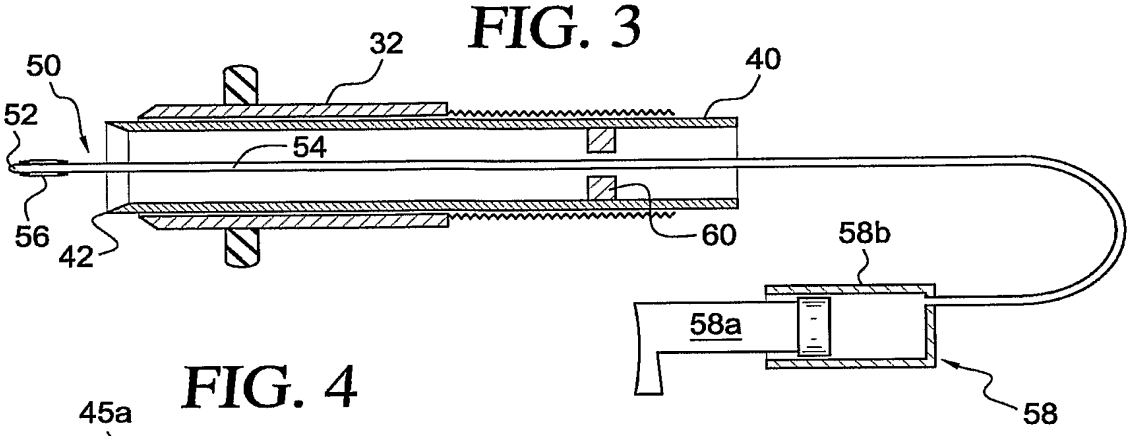


FIG. 4

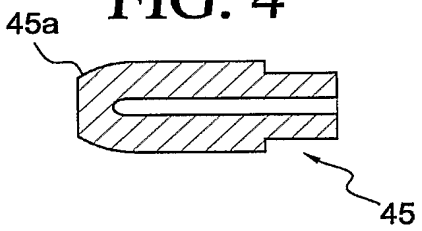


FIG. 5

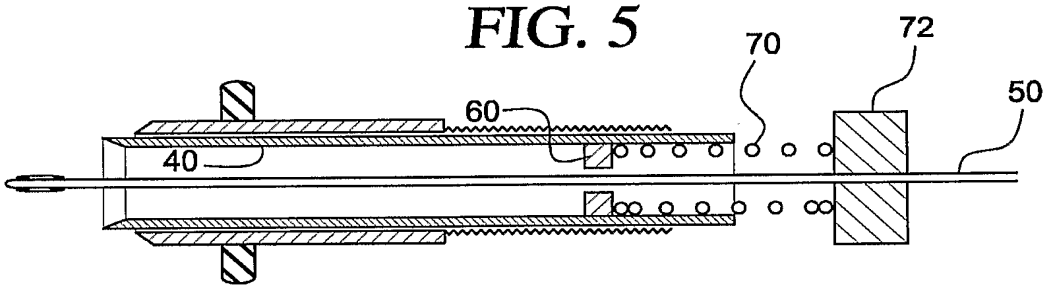


FIG. 6

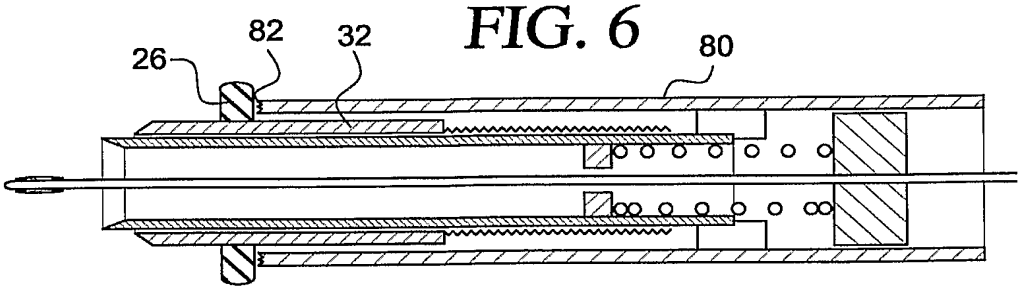


FIG. 7A

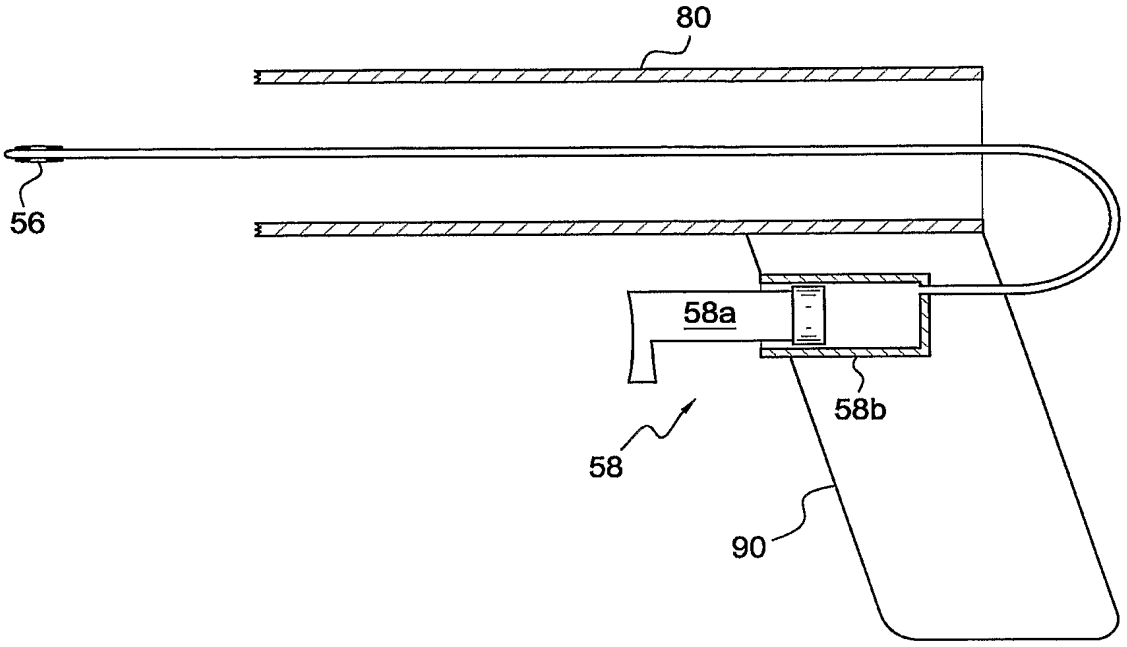


FIG. 7B

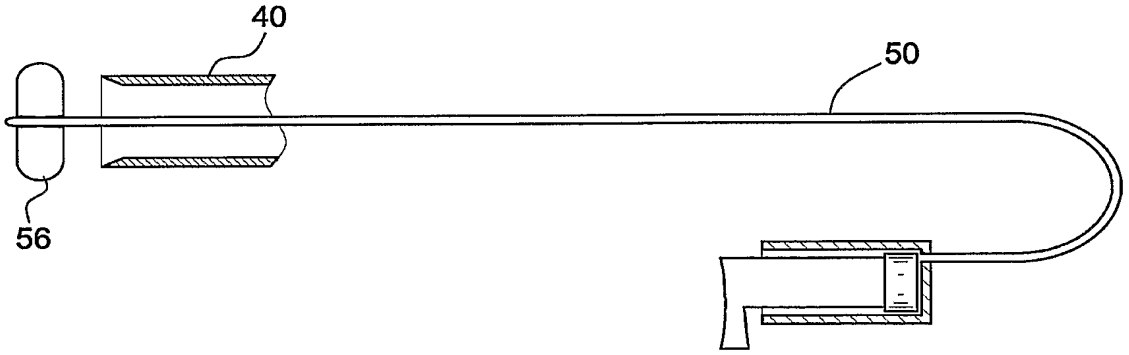


FIG. 8

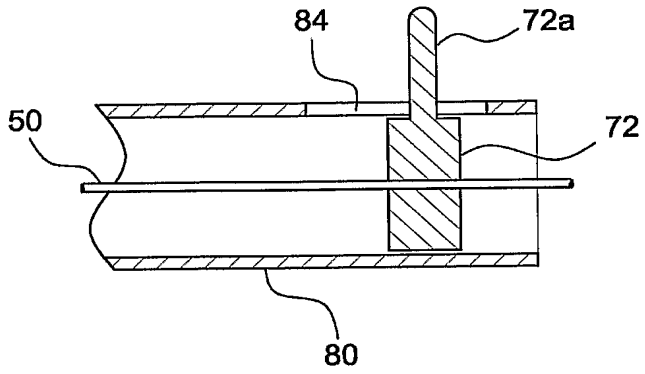
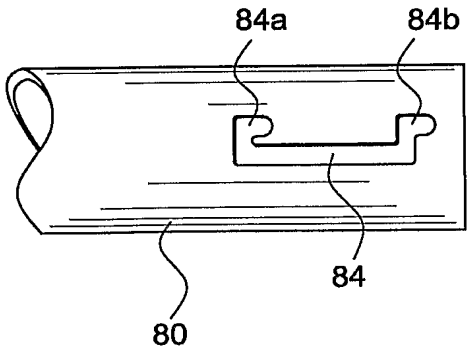


FIG. 9



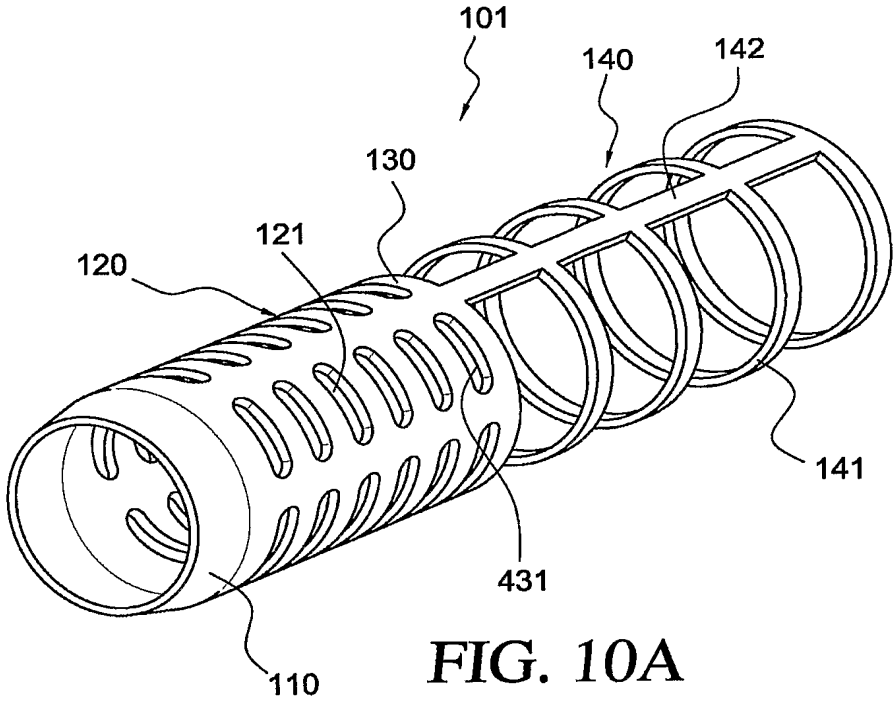


FIG. 10A

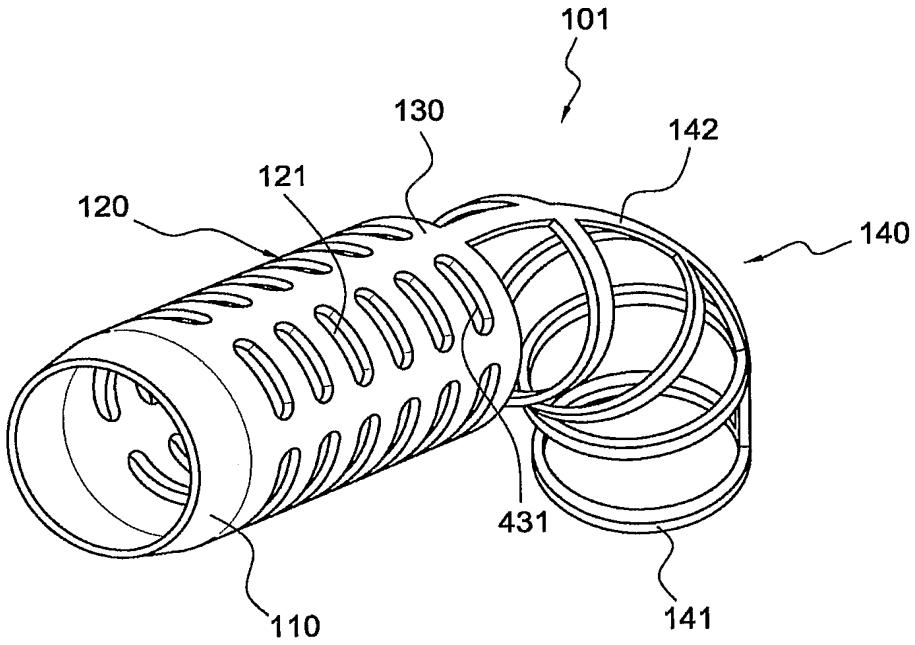


FIG. 10B

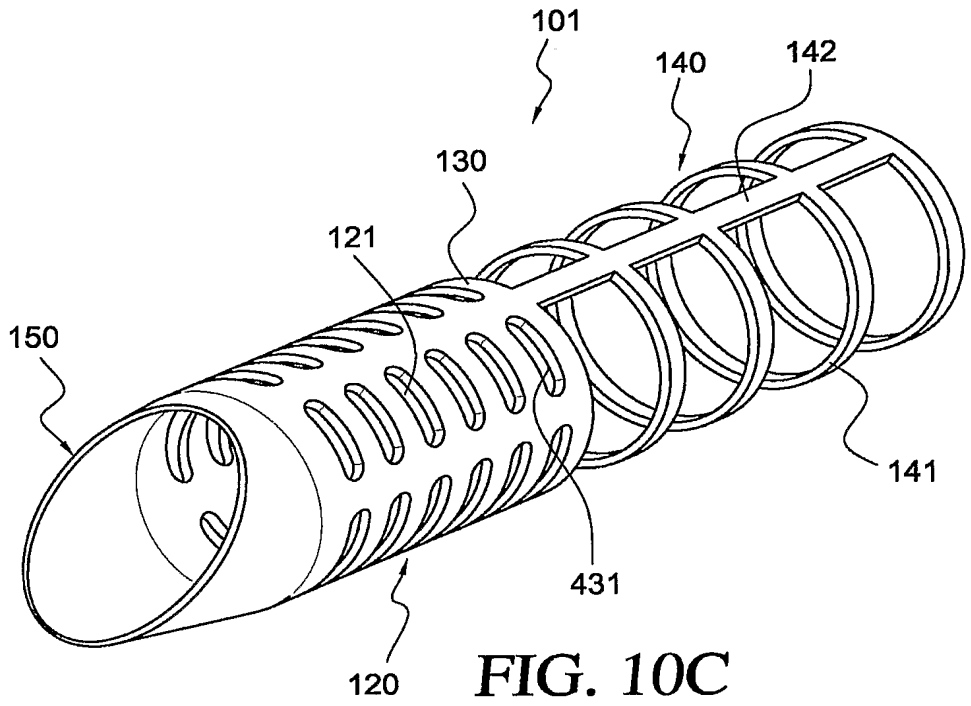


FIG. 10C

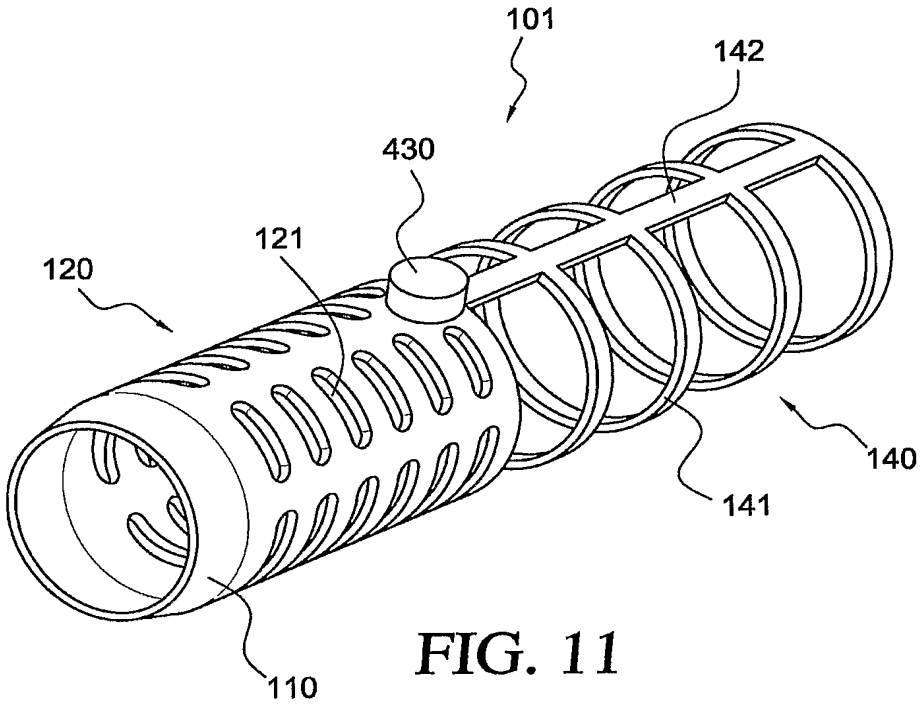


FIG. 11

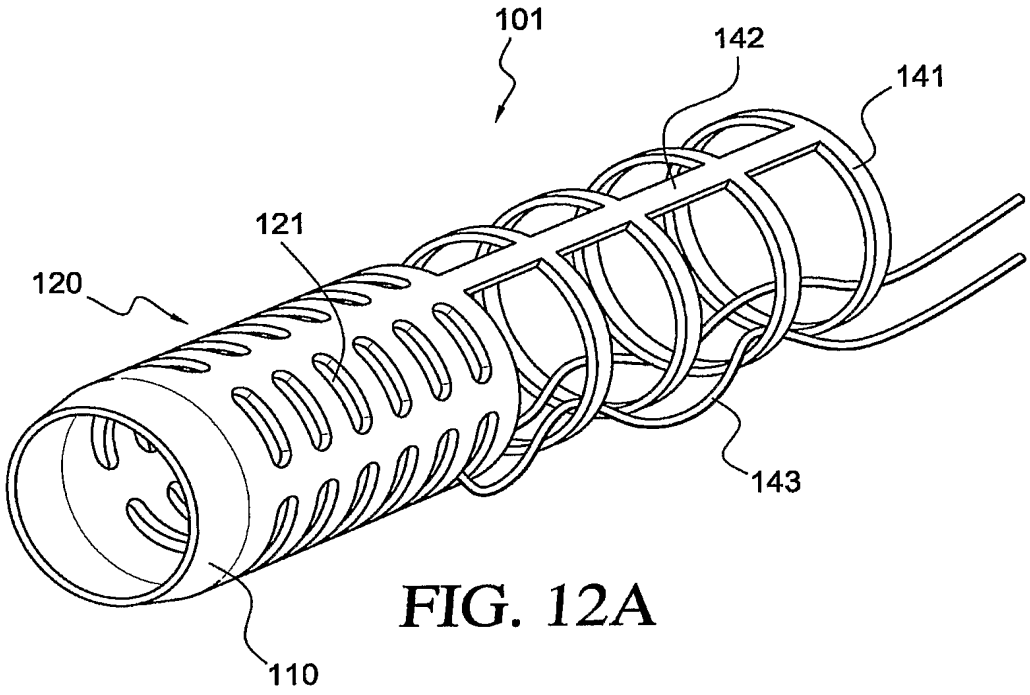


FIG. 12A

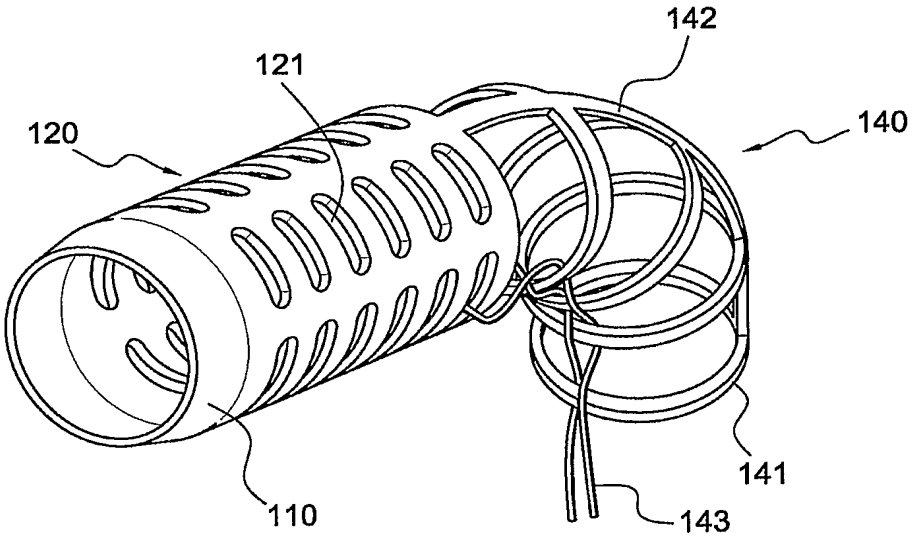


FIG. 12B

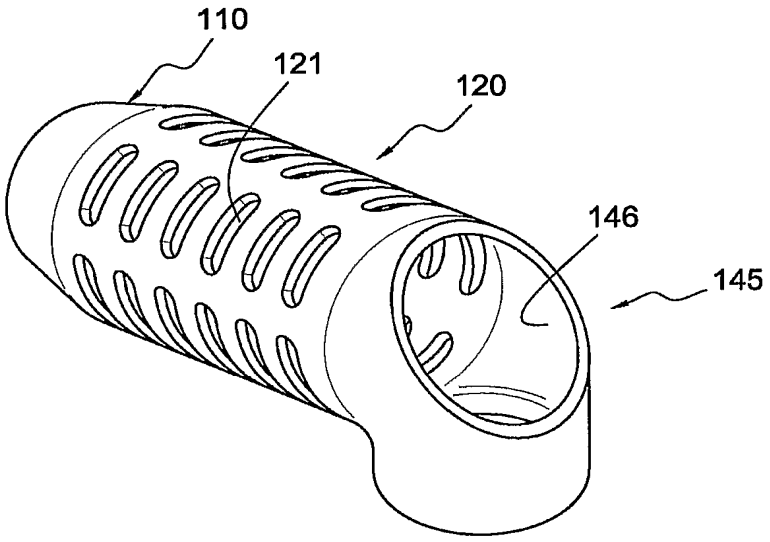


FIG. 13

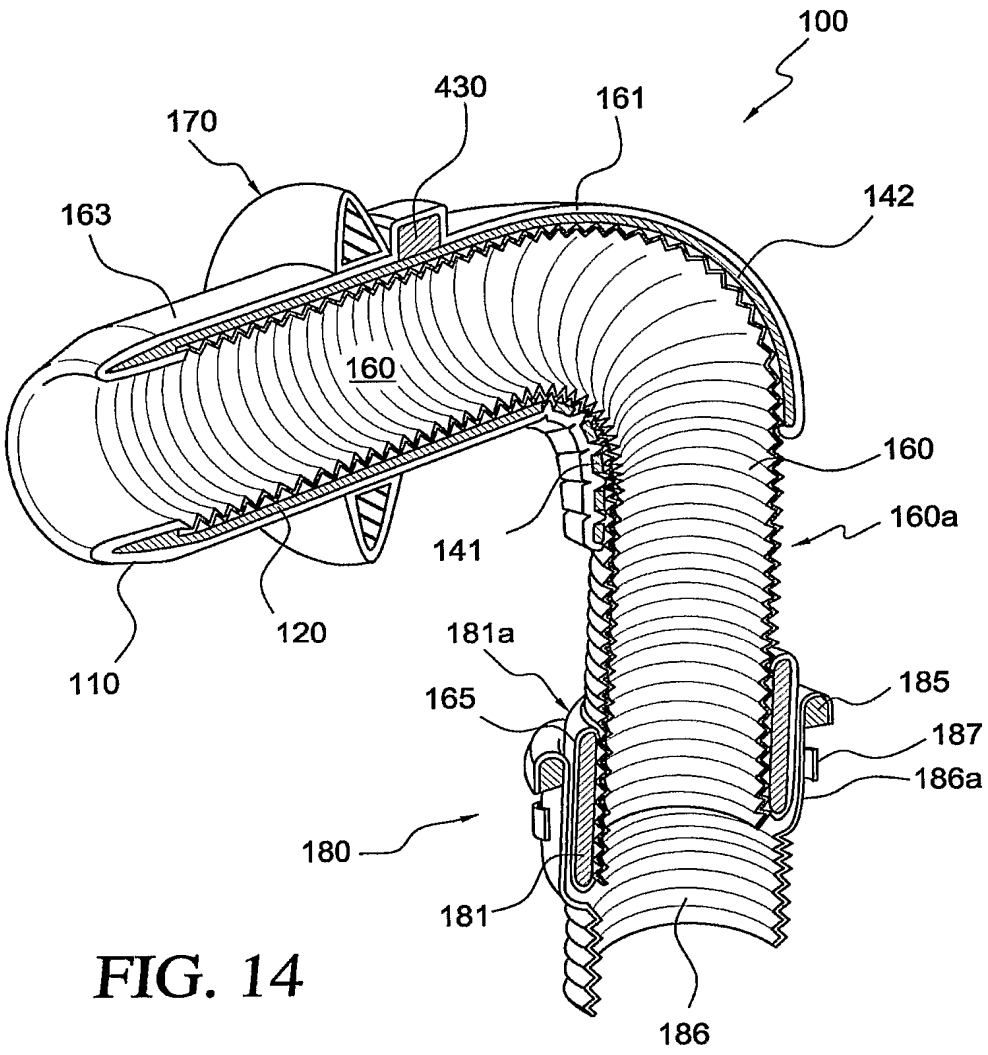


FIG. 14

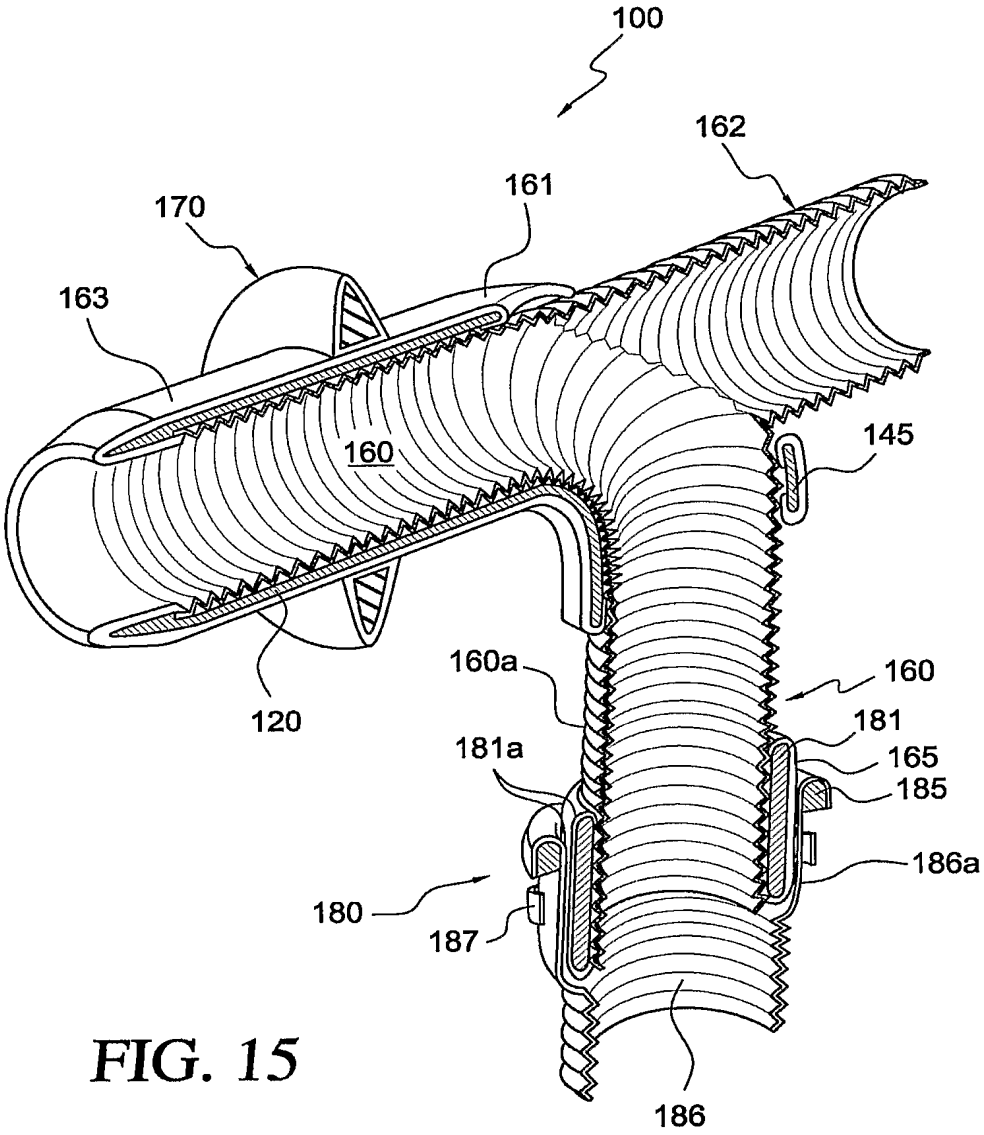


FIG. 15

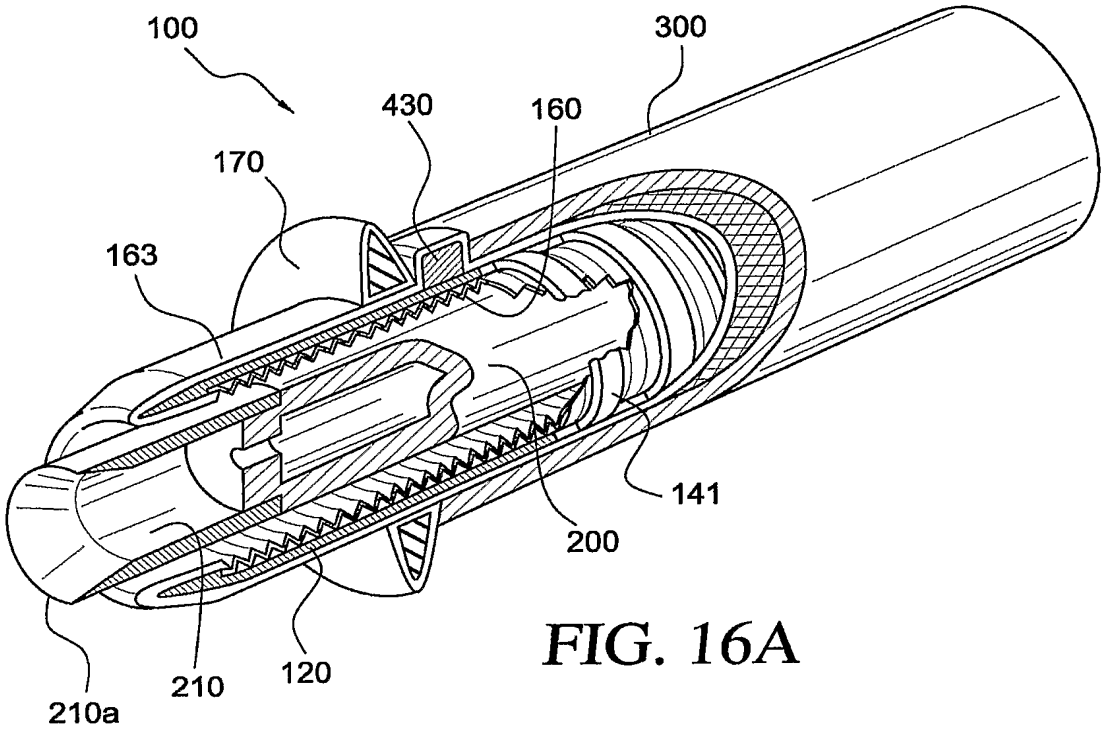


FIG. 16A

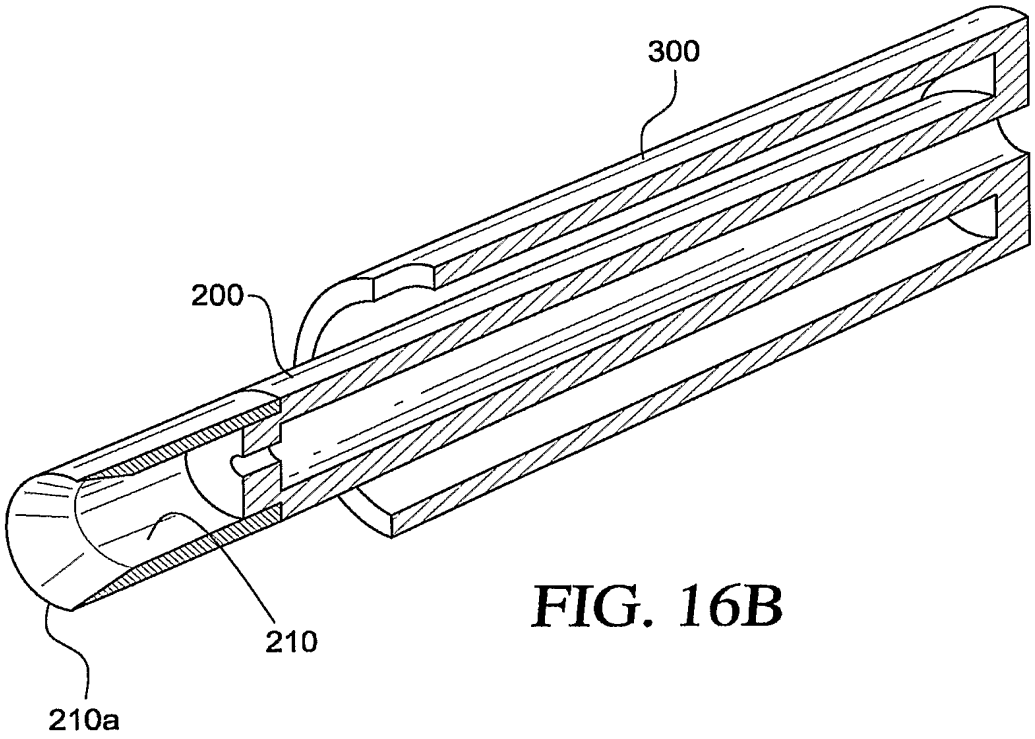


FIG. 16B

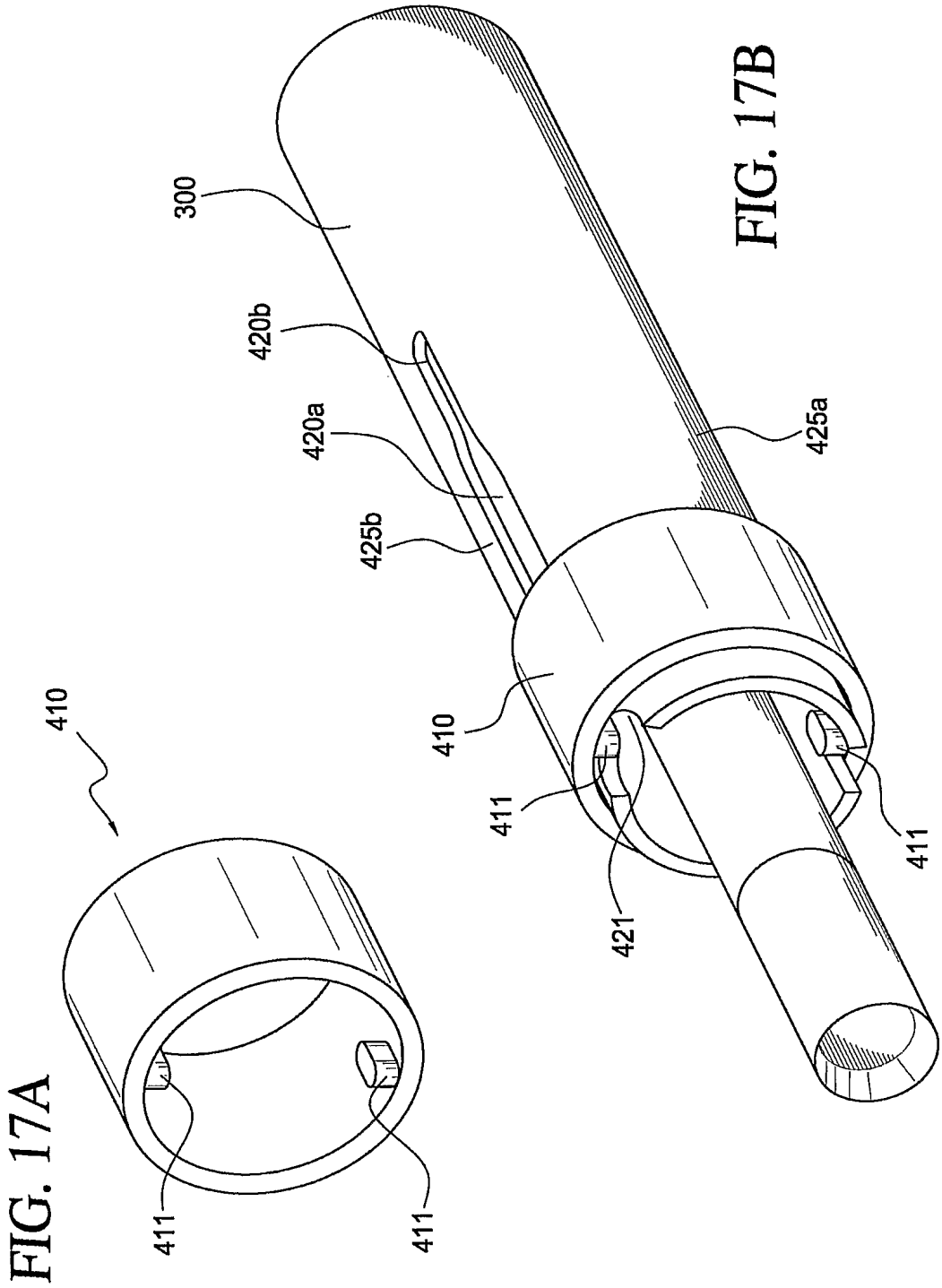


FIG. 17A

FIG. 17B

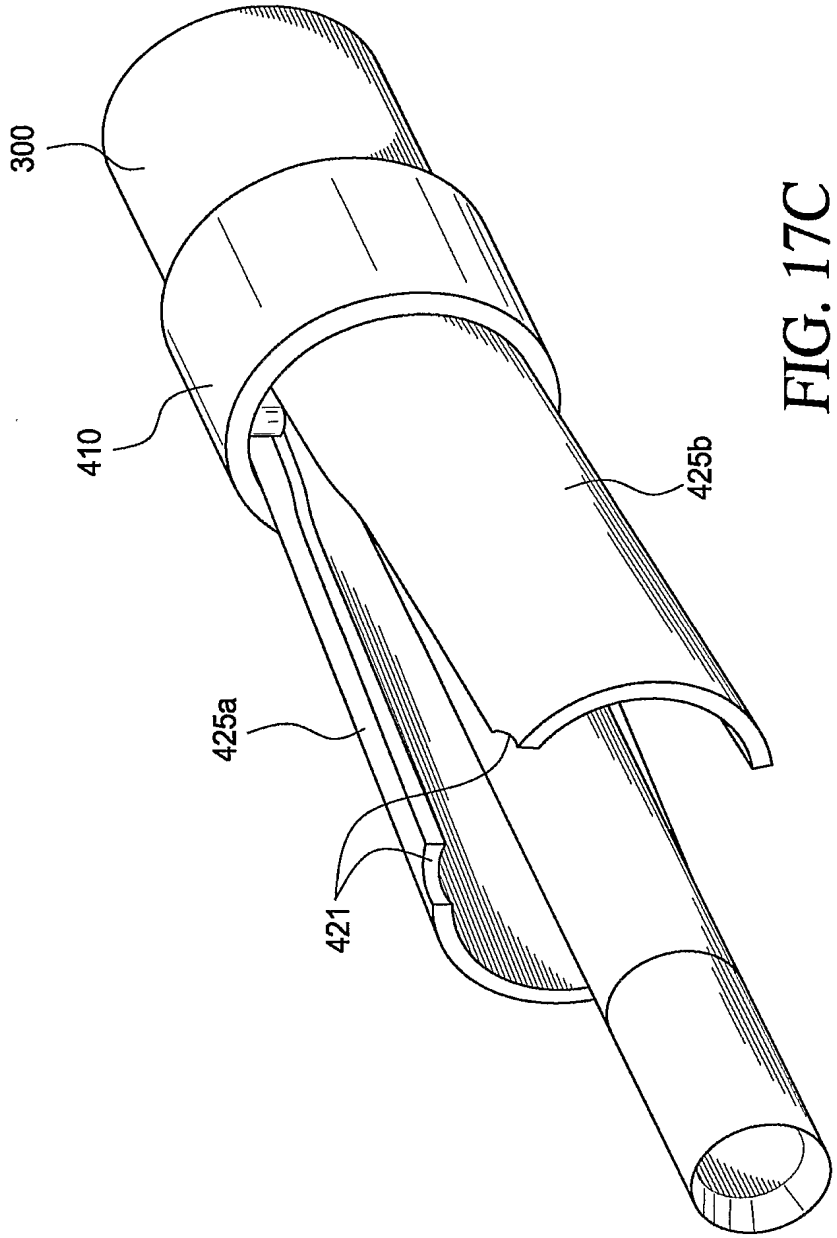


FIG. 17C

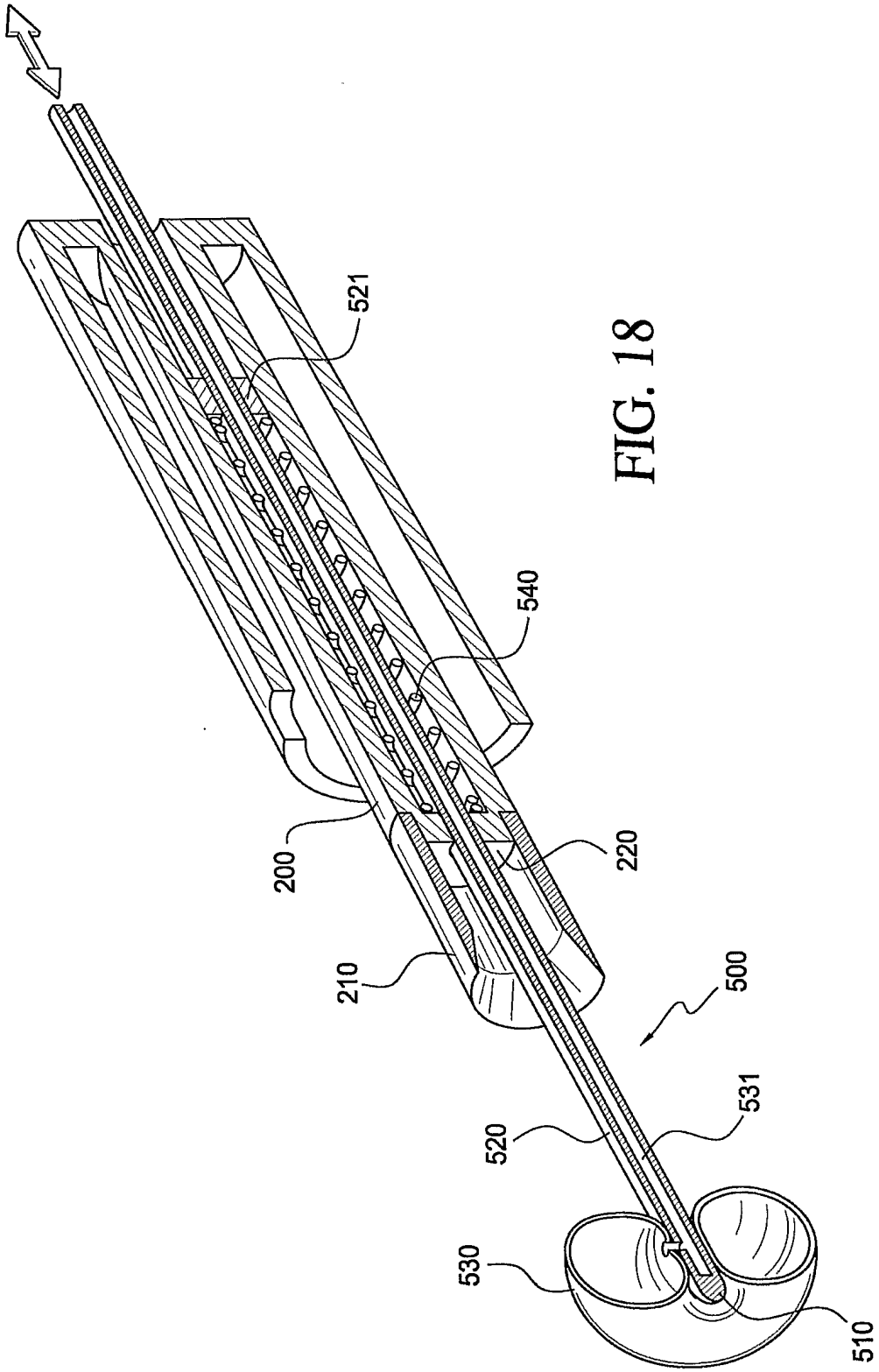


FIG. 18

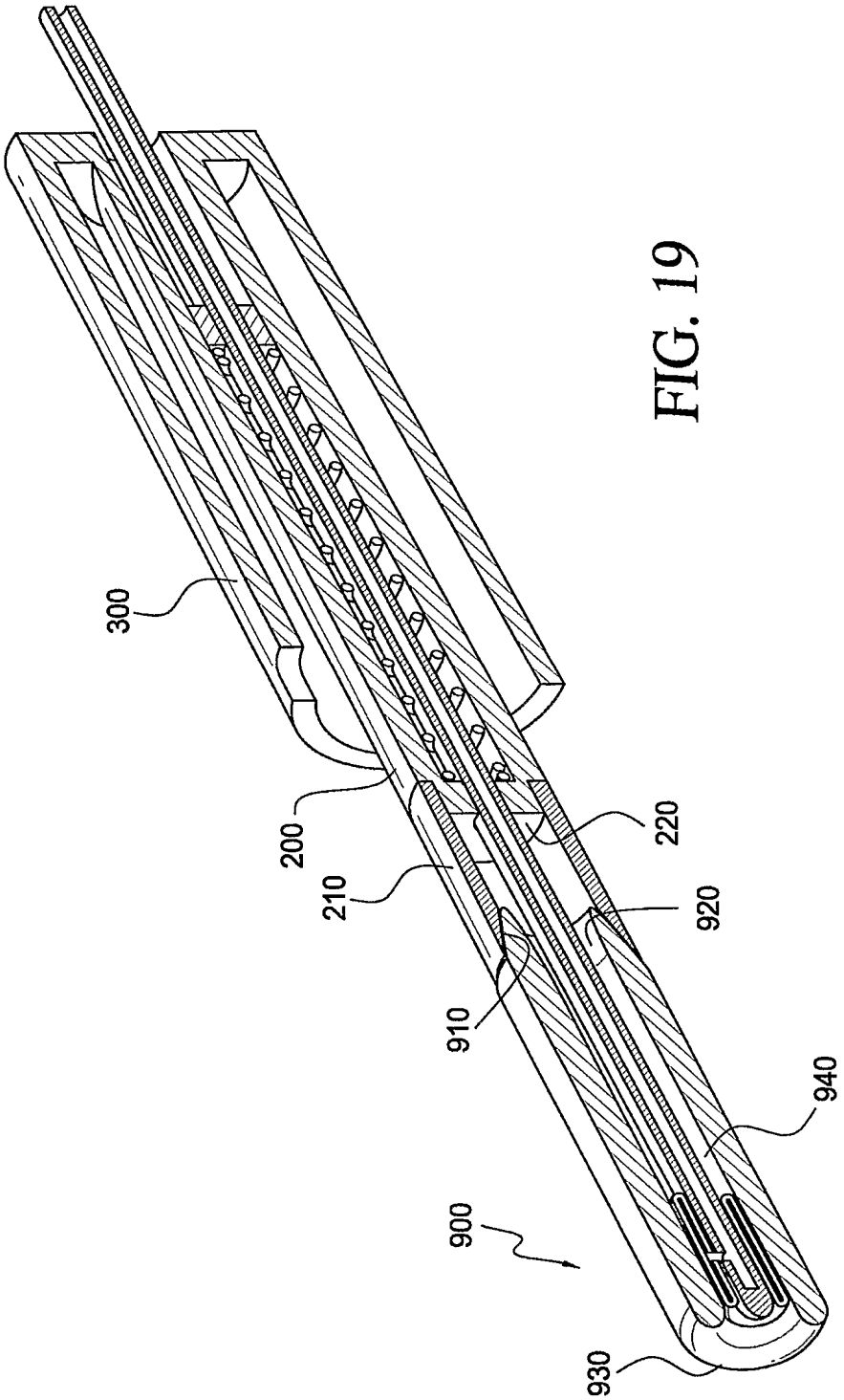


FIG. 19

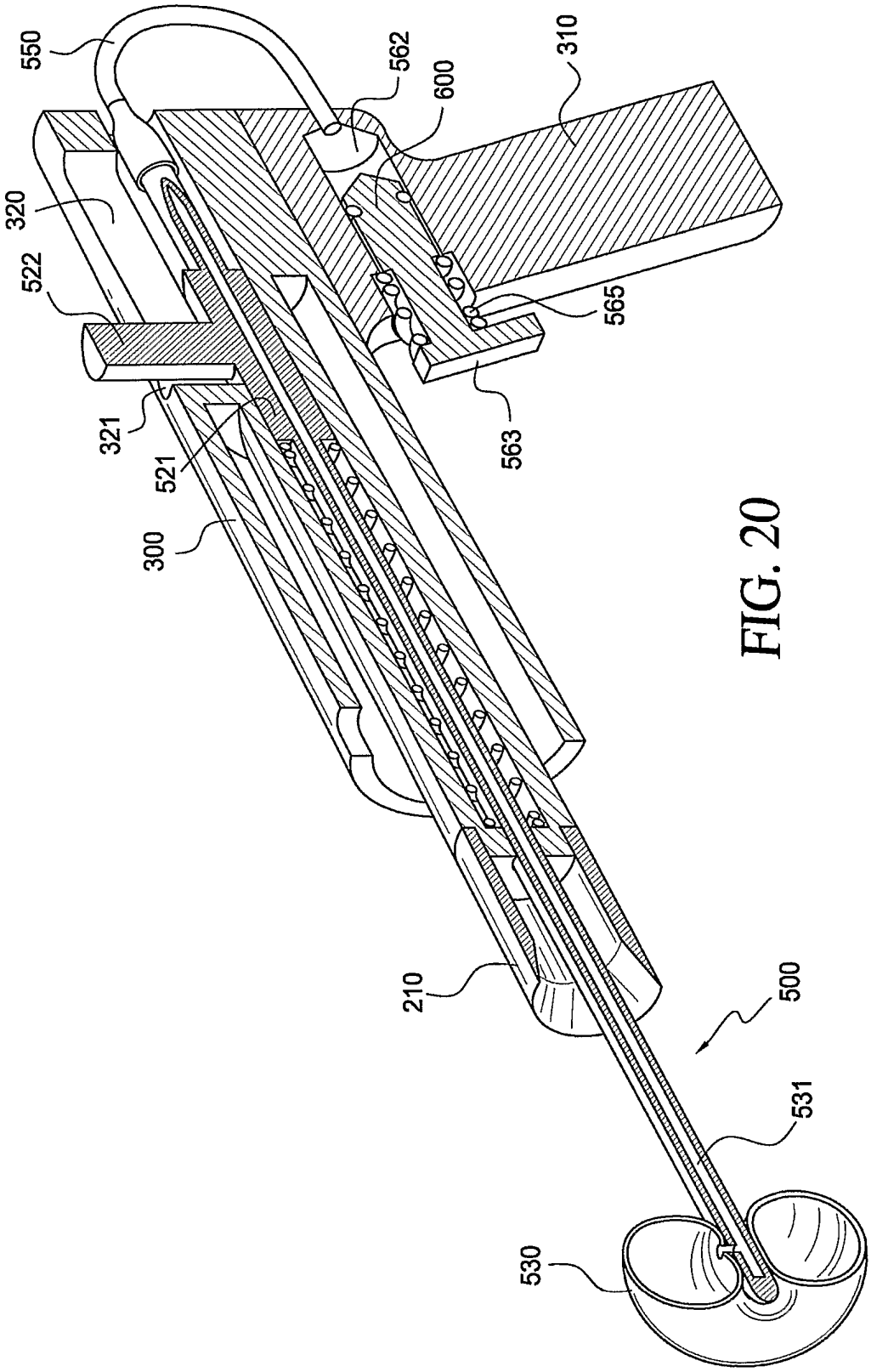


FIG. 20

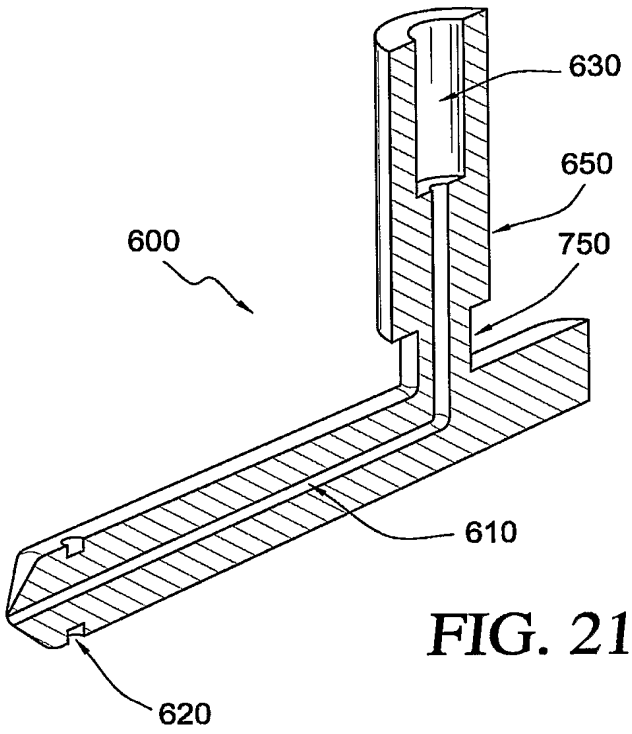


FIG. 21A

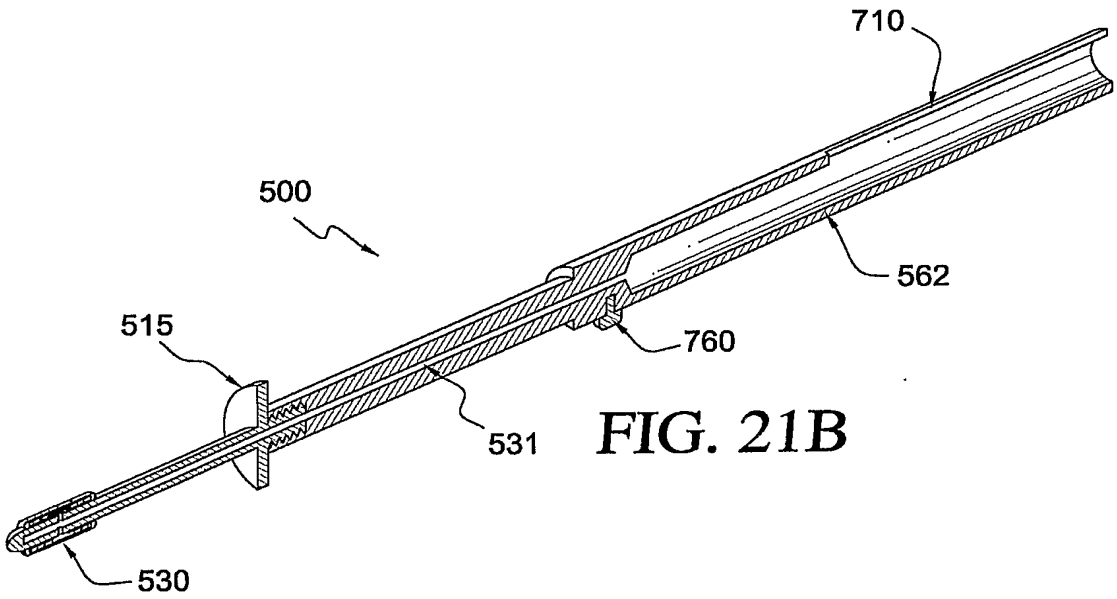


FIG. 21B

FIG. 21C

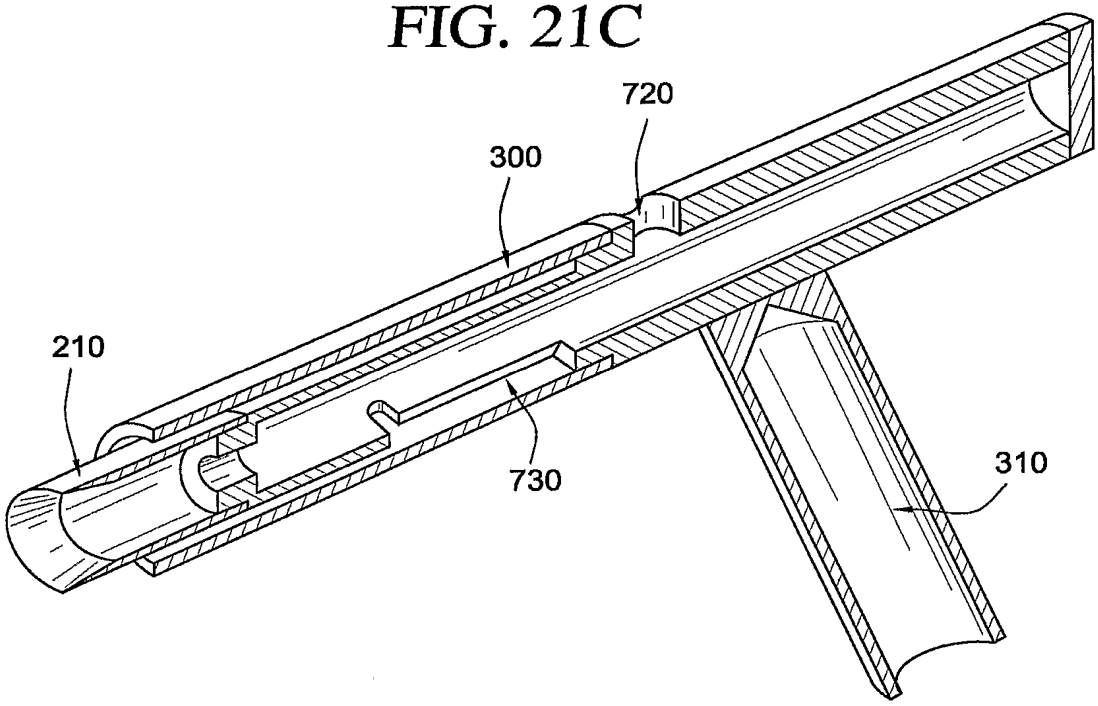


FIG. 22A

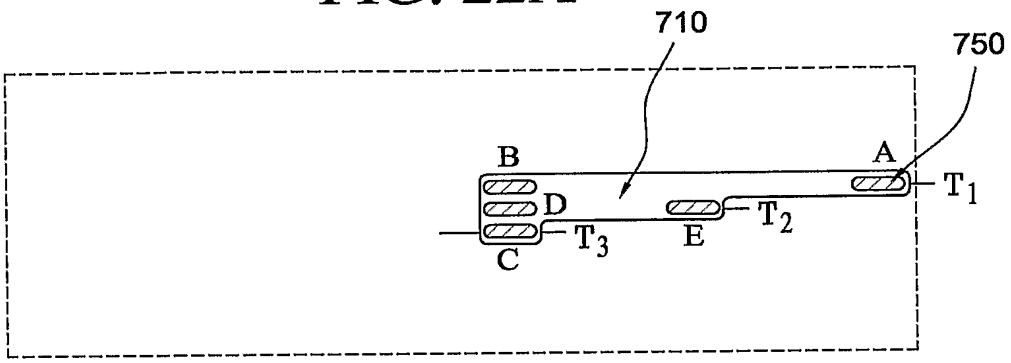


FIG. 22B

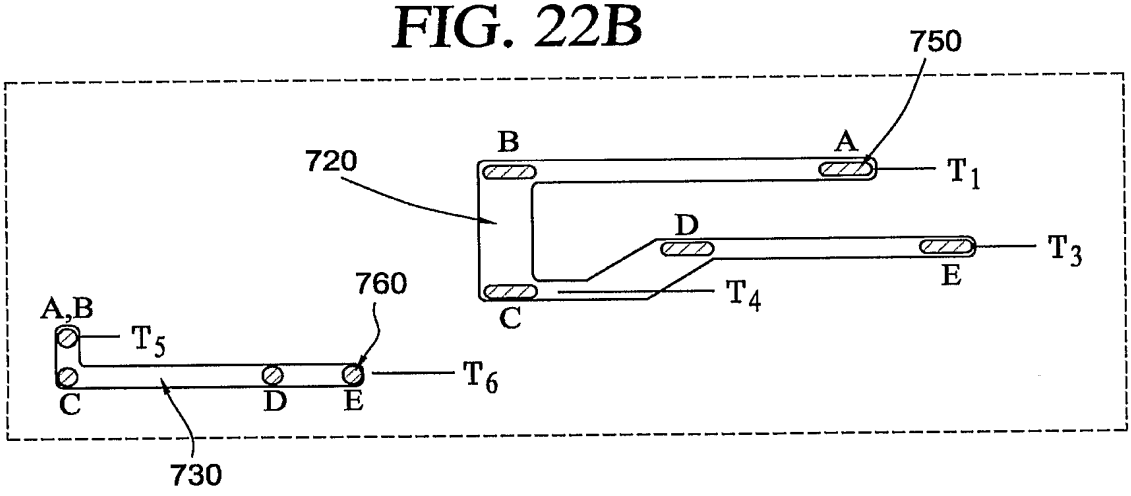


FIG. 22C

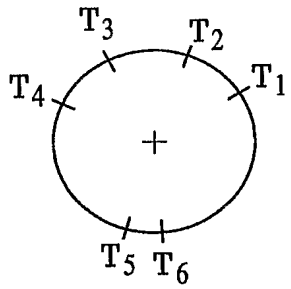


FIG. 23A

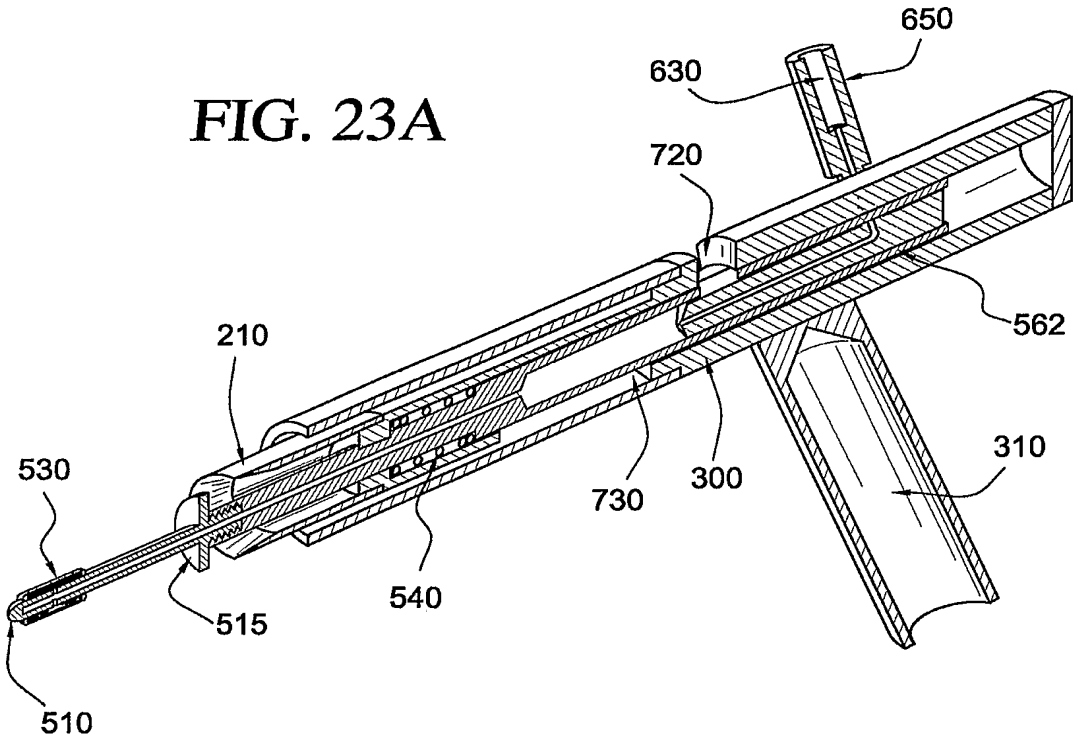


FIG. 23B

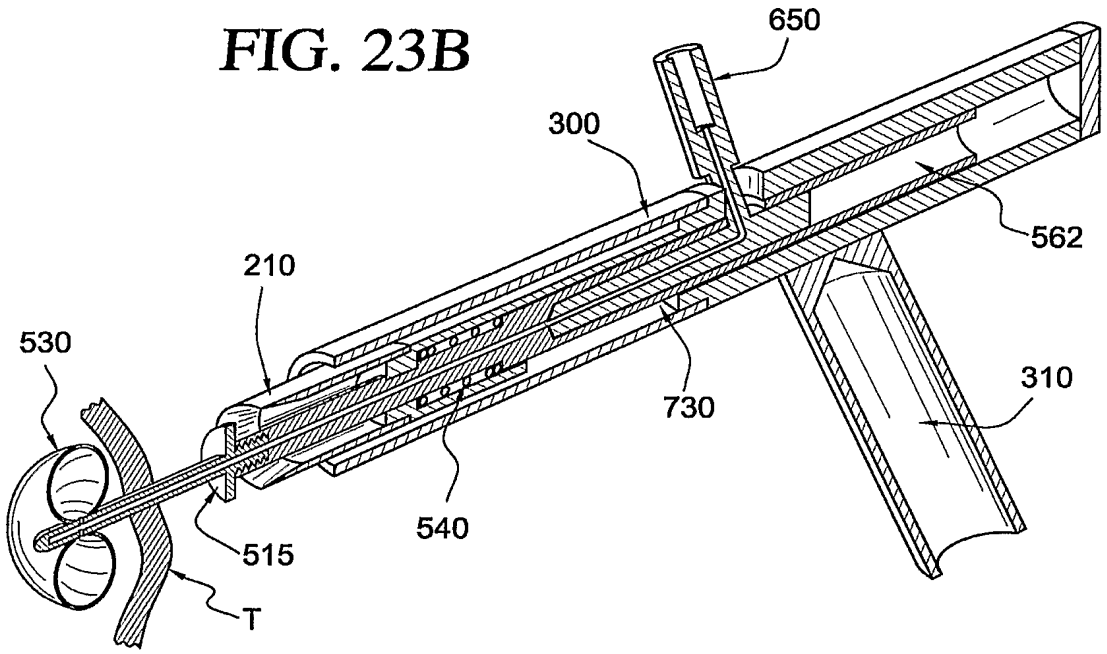


FIG. 23C

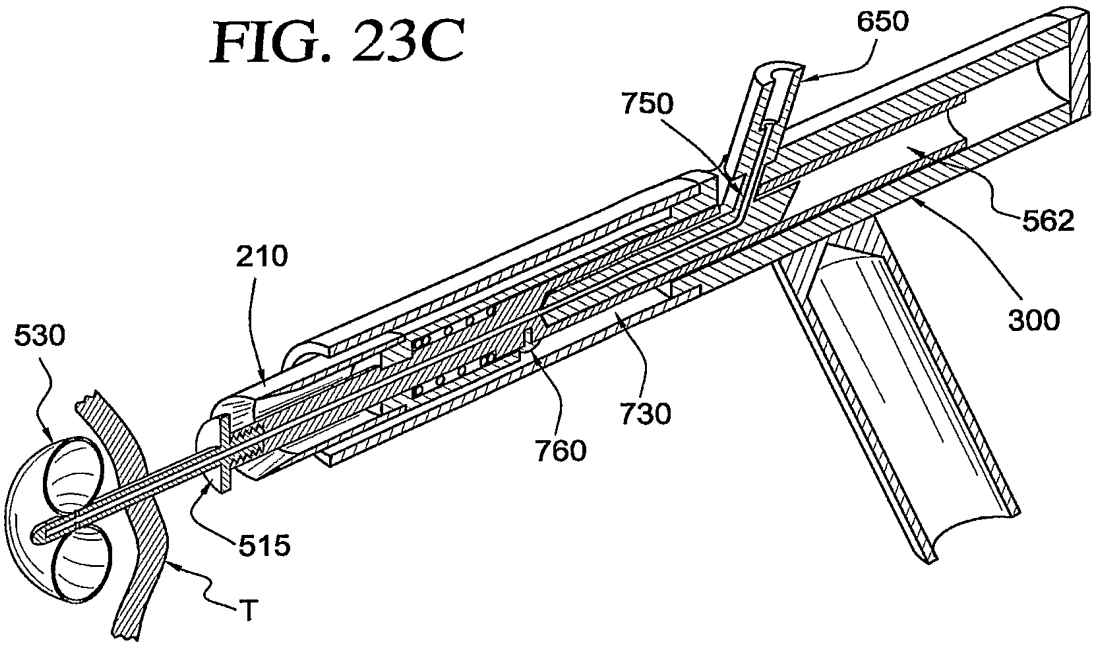


FIG. 23D

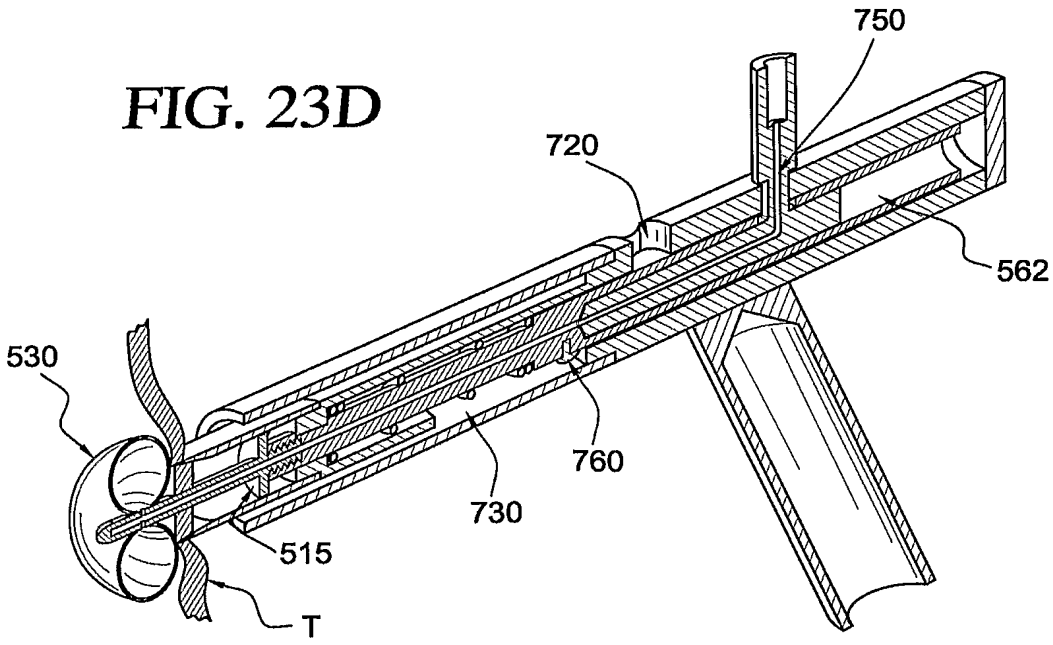
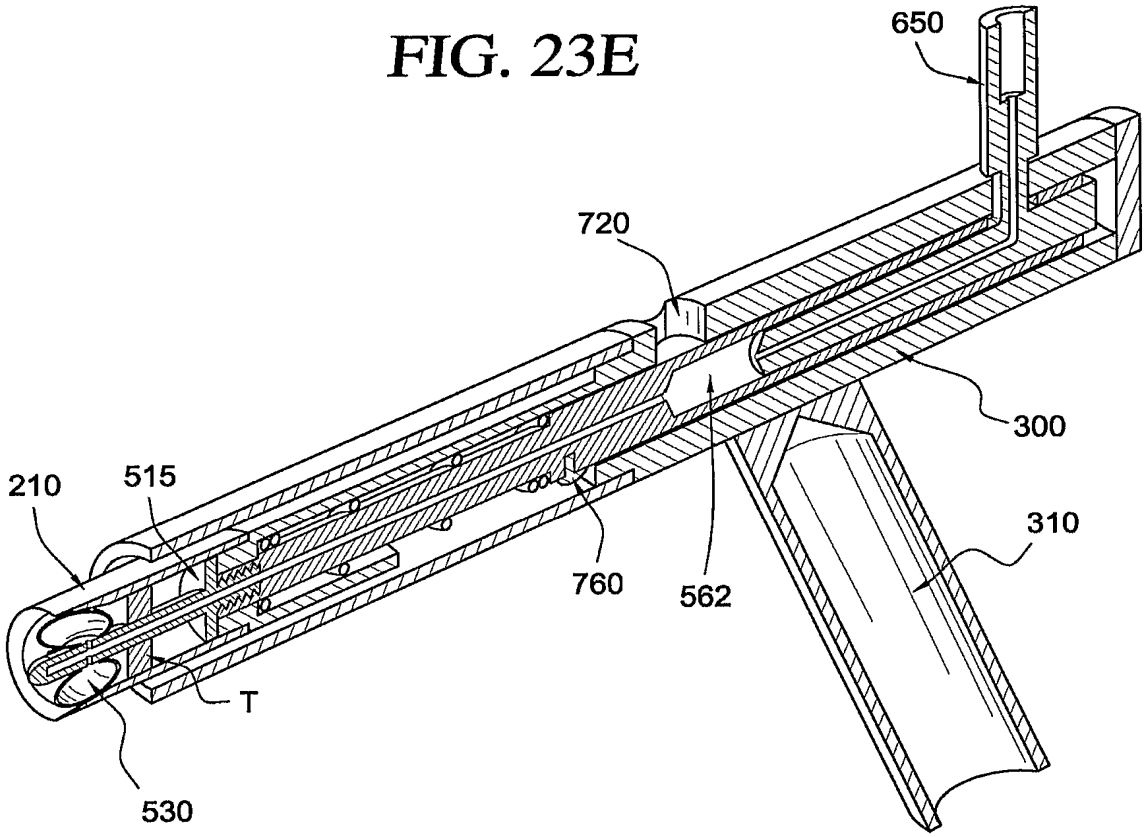


FIG. 23E



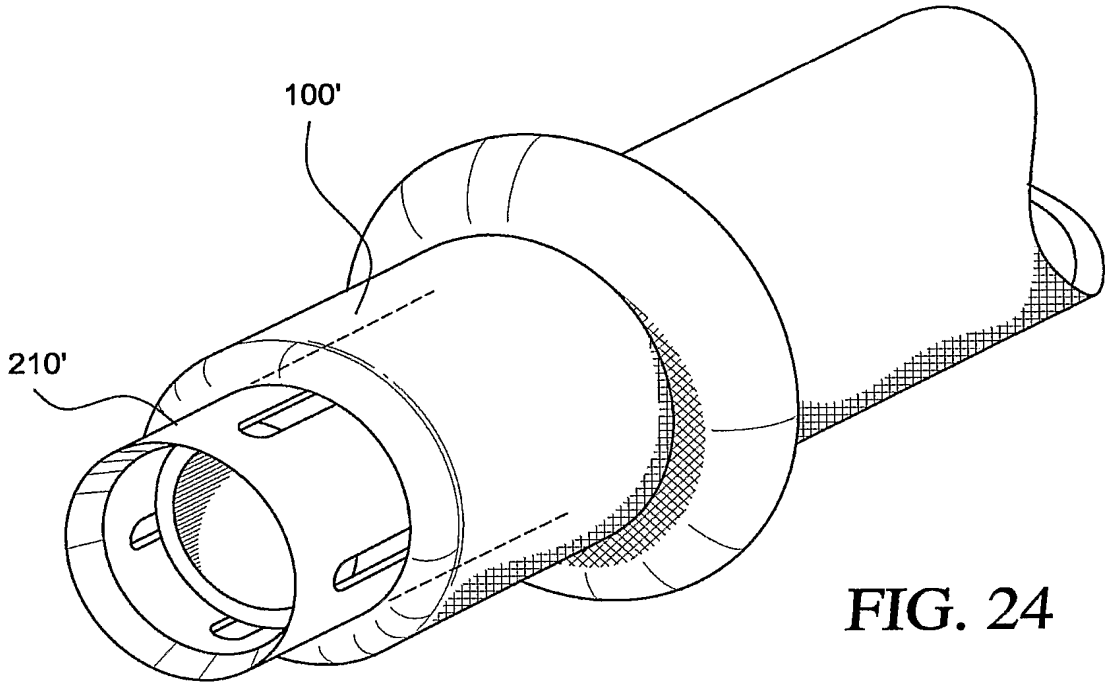


FIG. 24

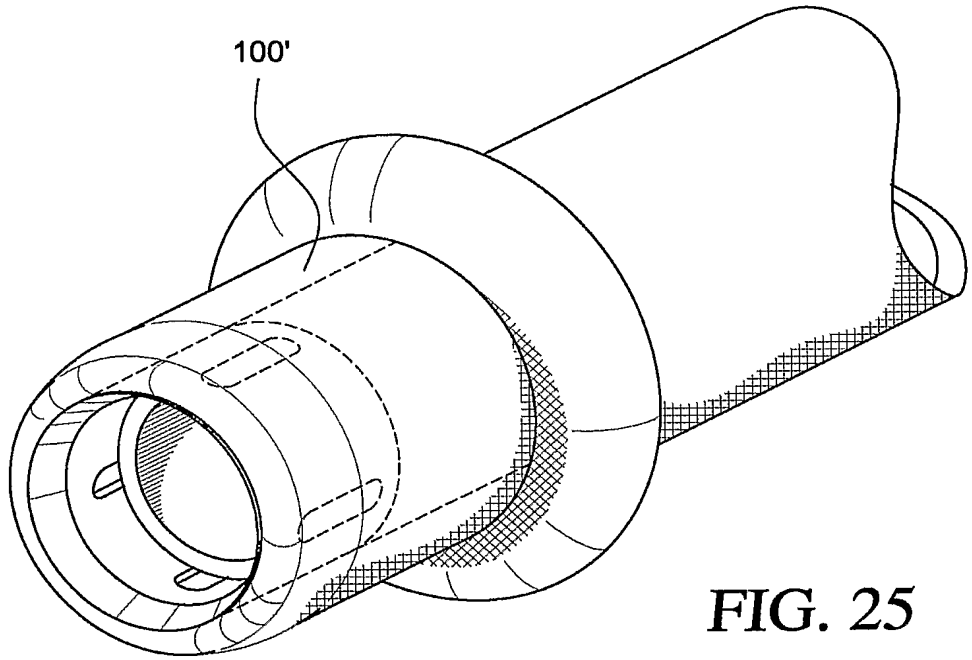


FIG. 25

FIG. 26A

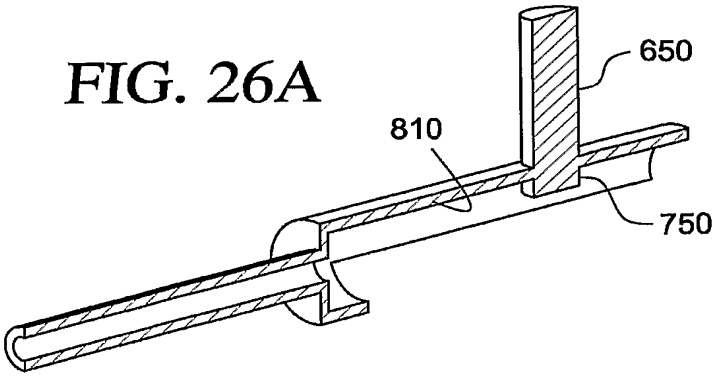


FIG. 26B

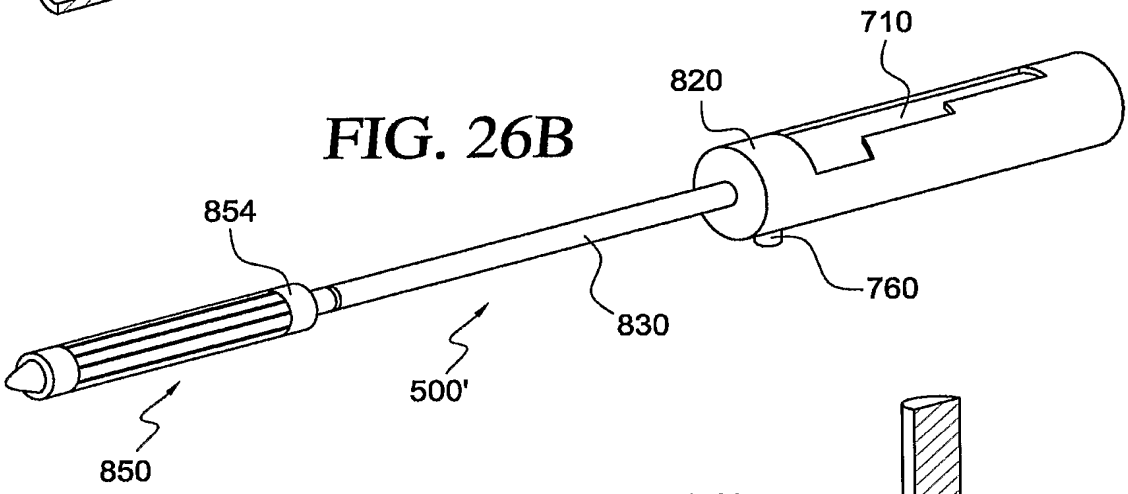
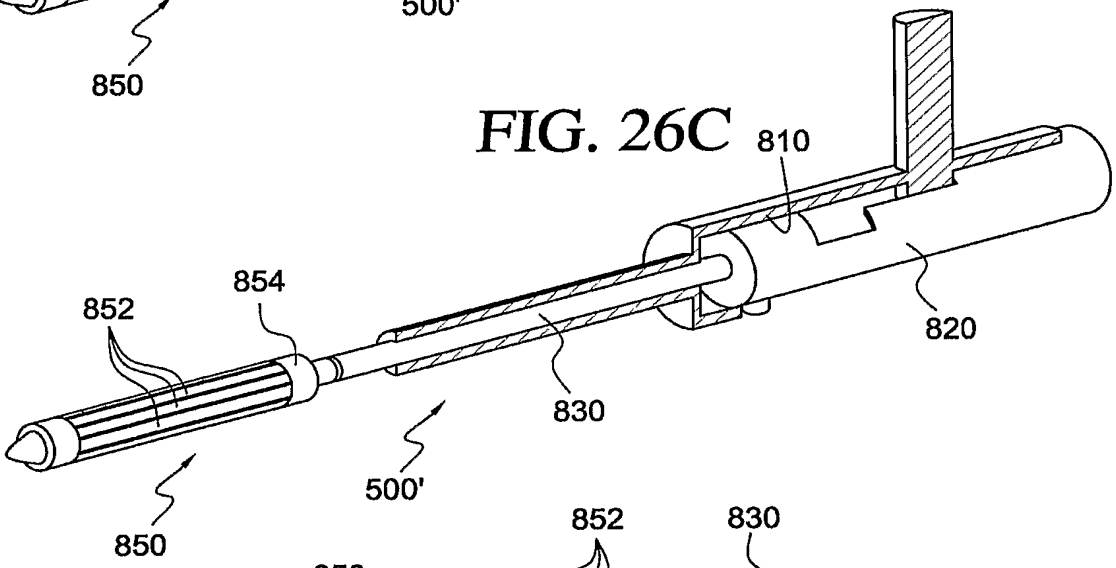


FIG. 26C



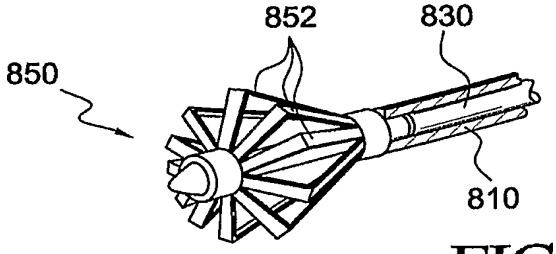


FIG. 26D

FIG. 27A

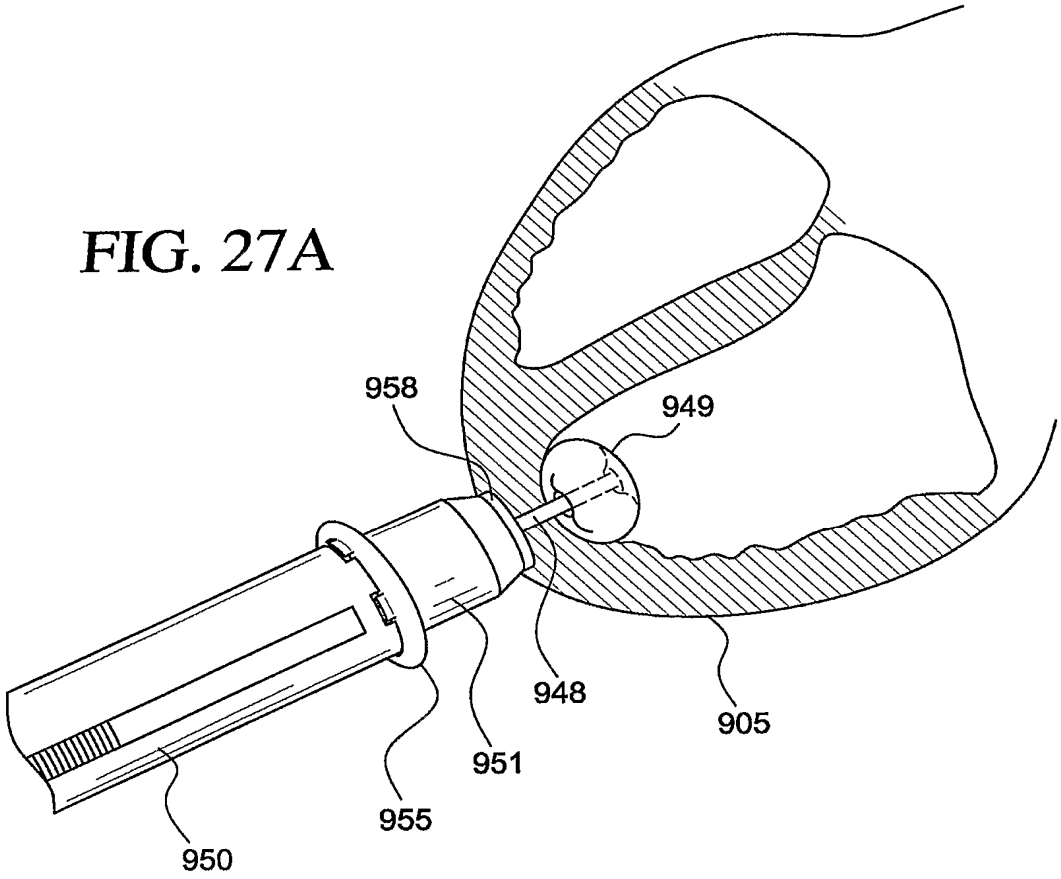


FIG. 27B

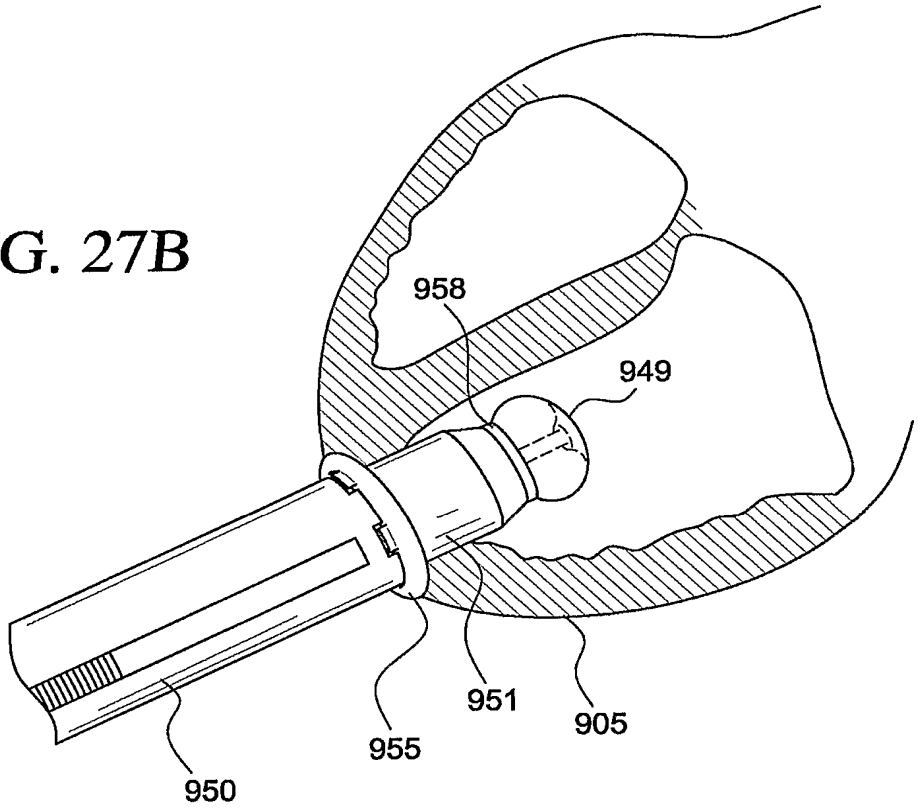


FIG. 27C

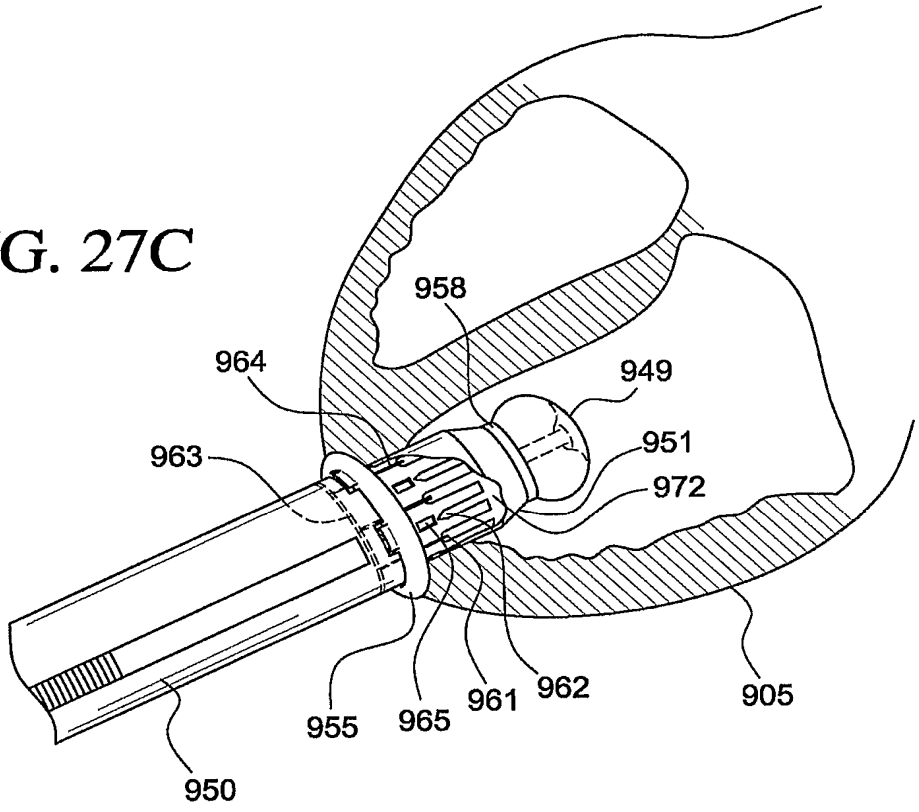


FIG. 27D

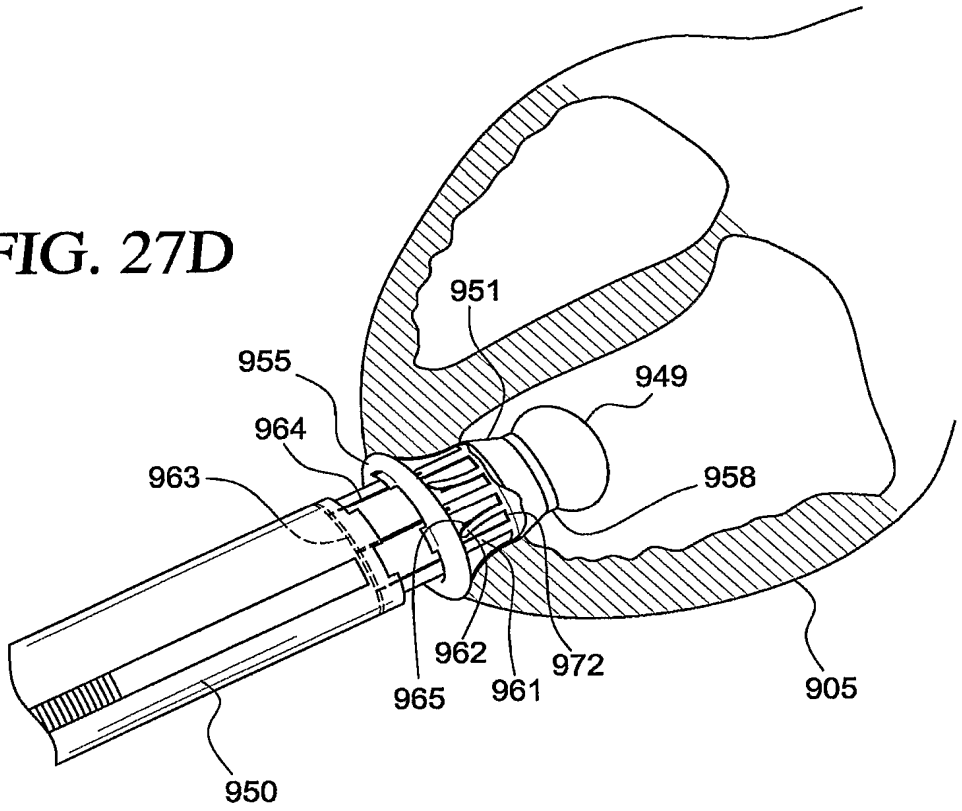


FIG. 27E

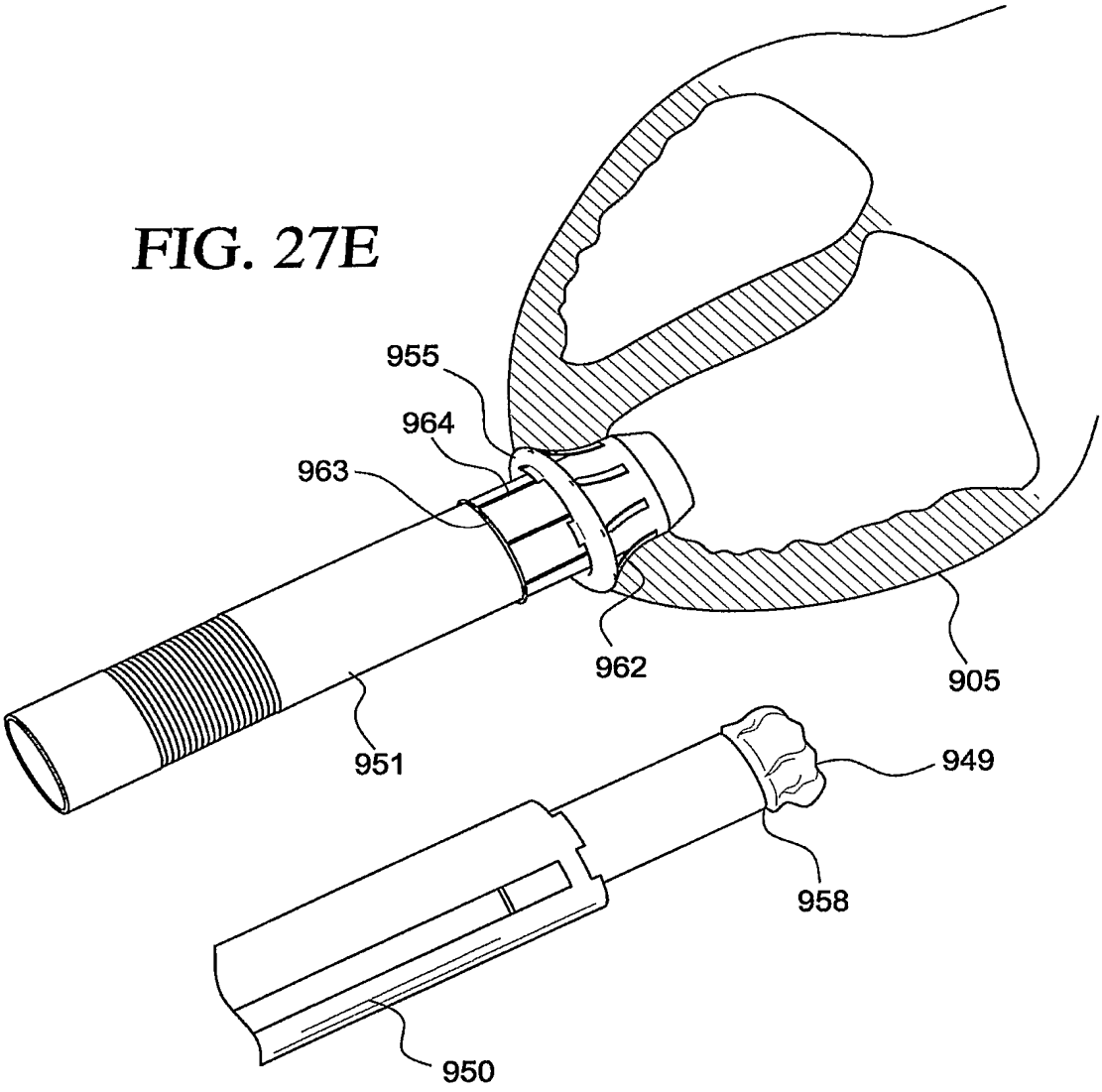


FIG. 28A

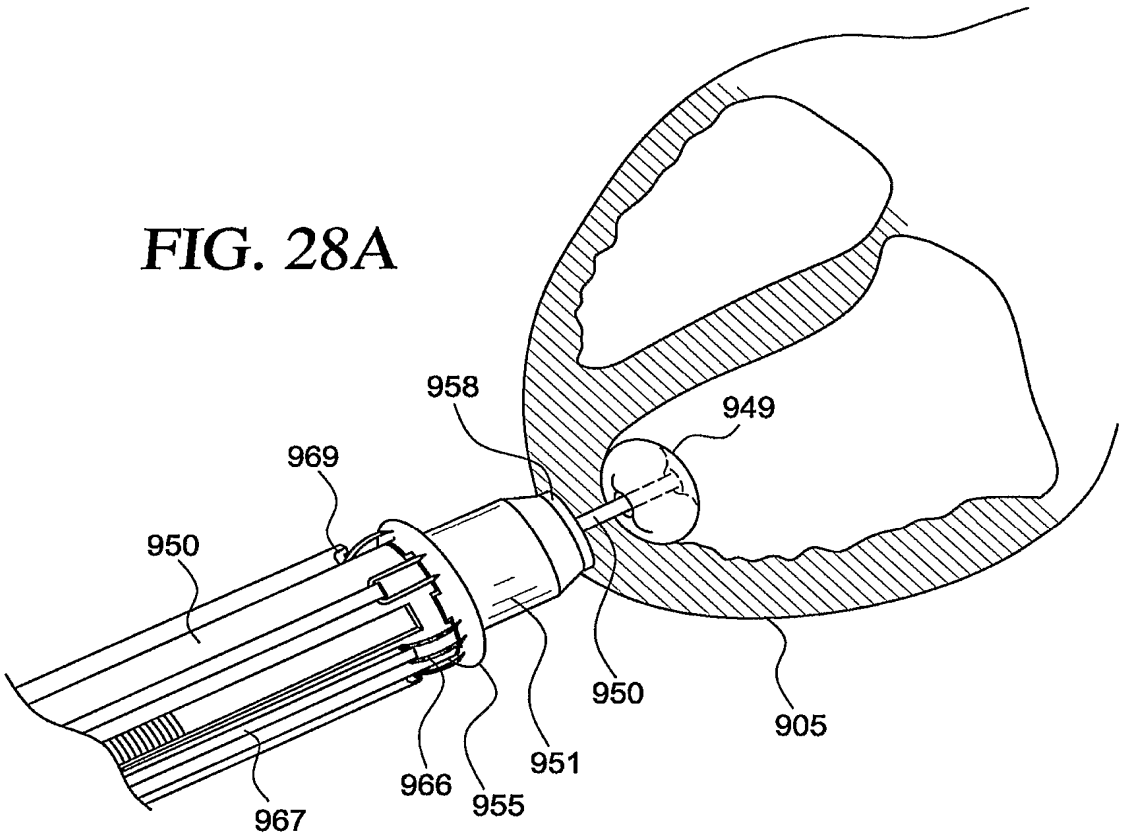


FIG. 28B

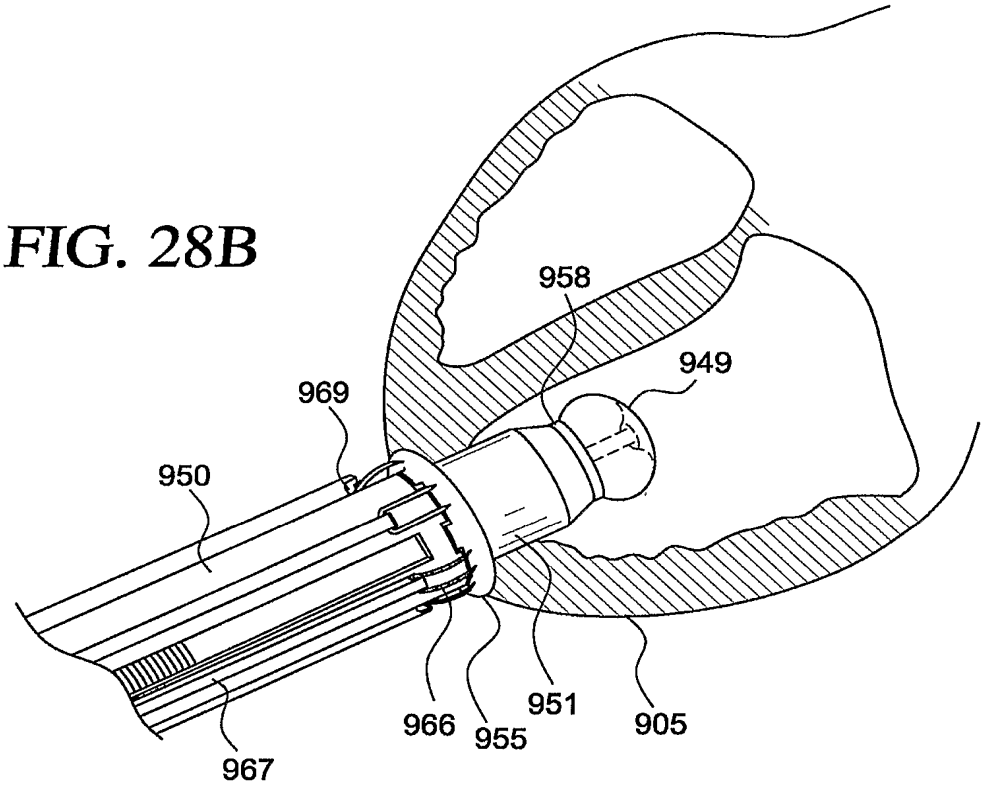


FIG. 28C

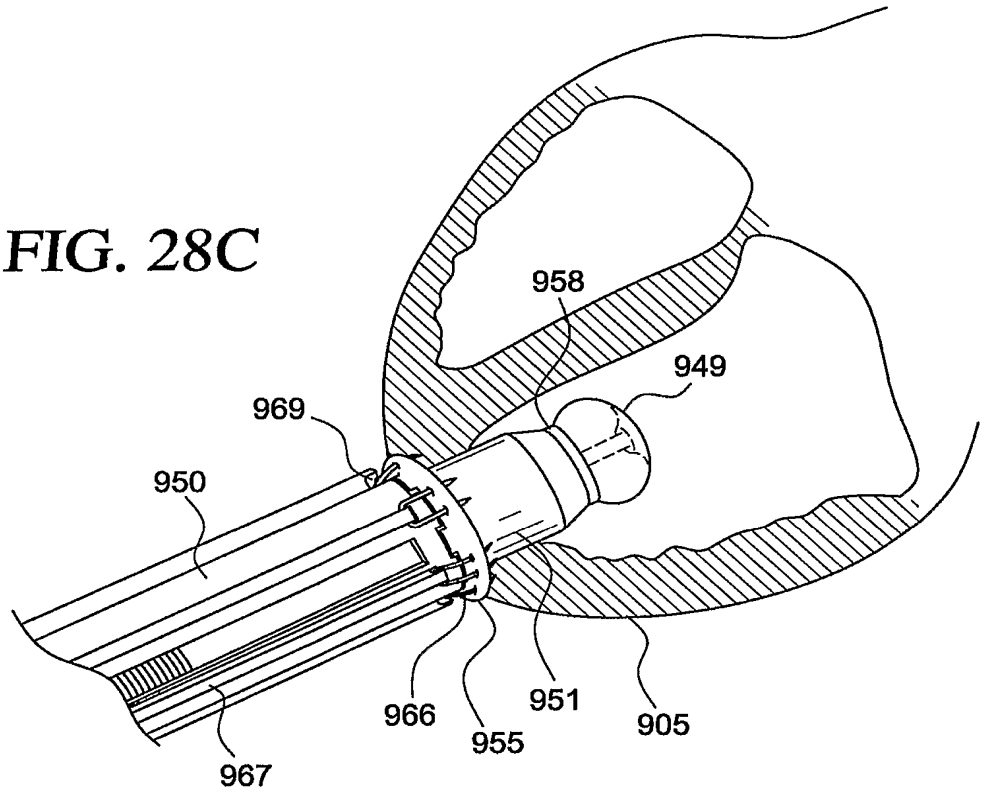


FIG. 28D

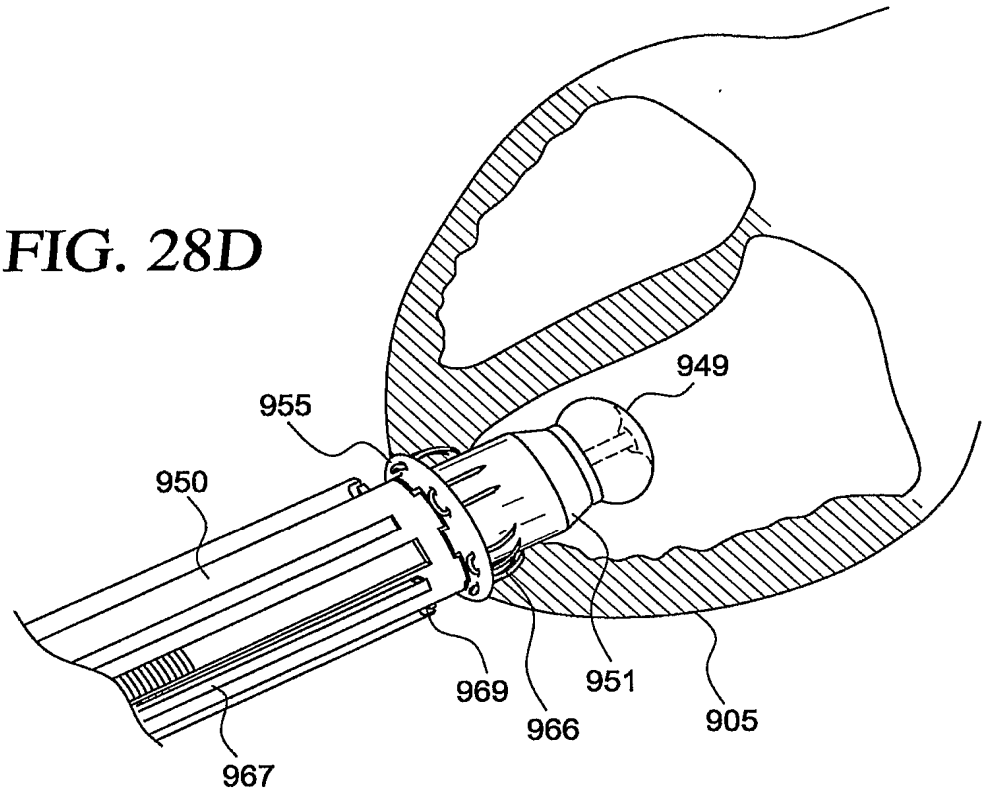


FIG. 28E

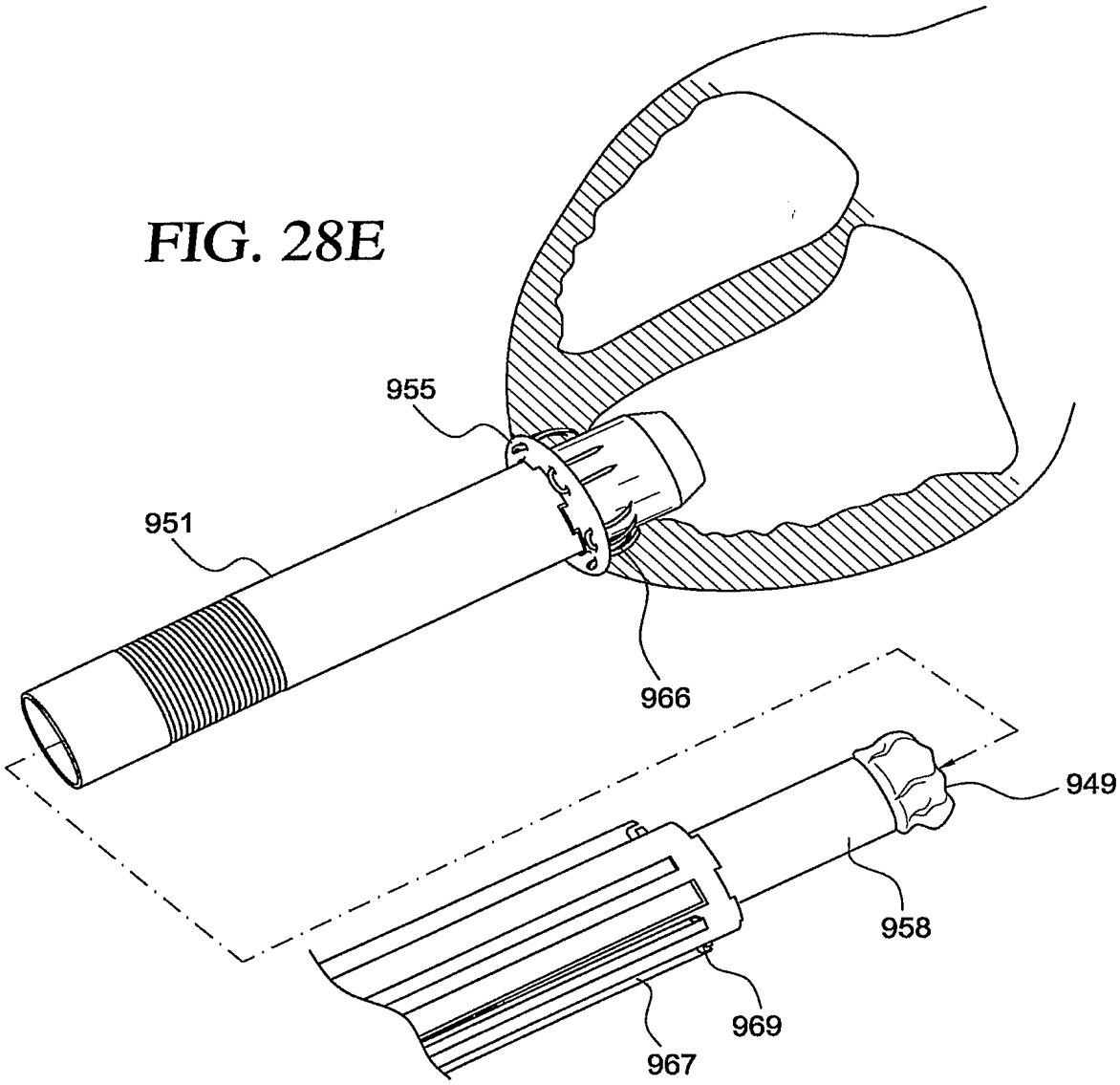


FIG. 29A

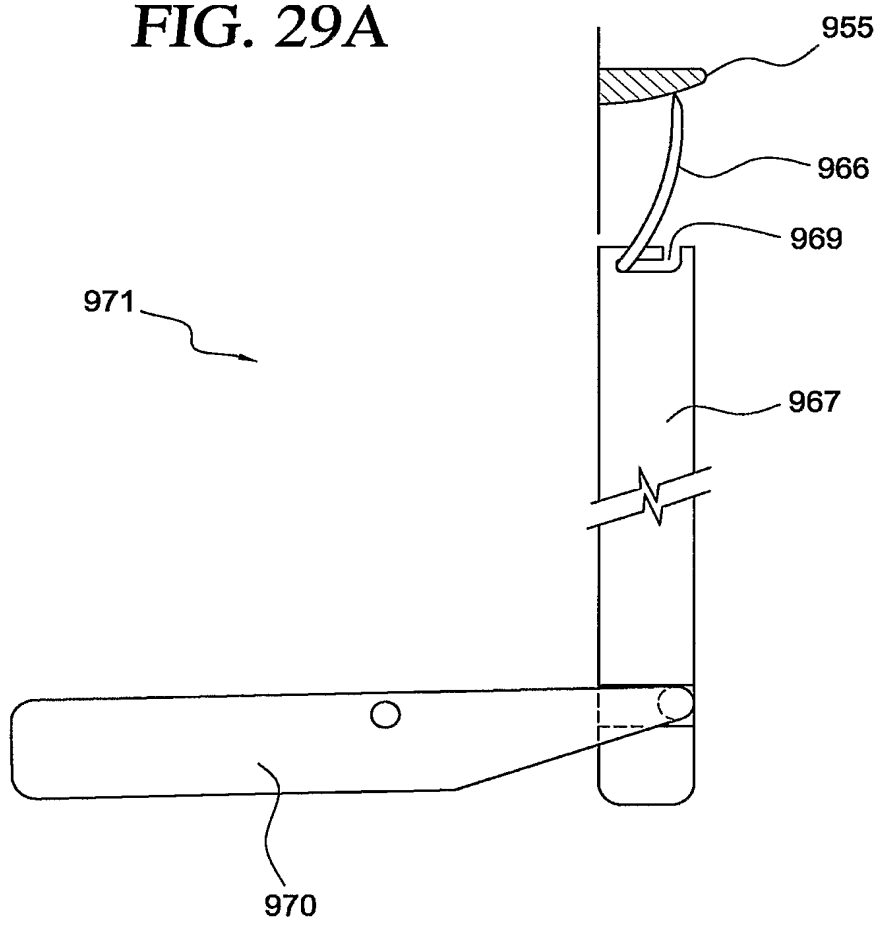


FIG. 29B

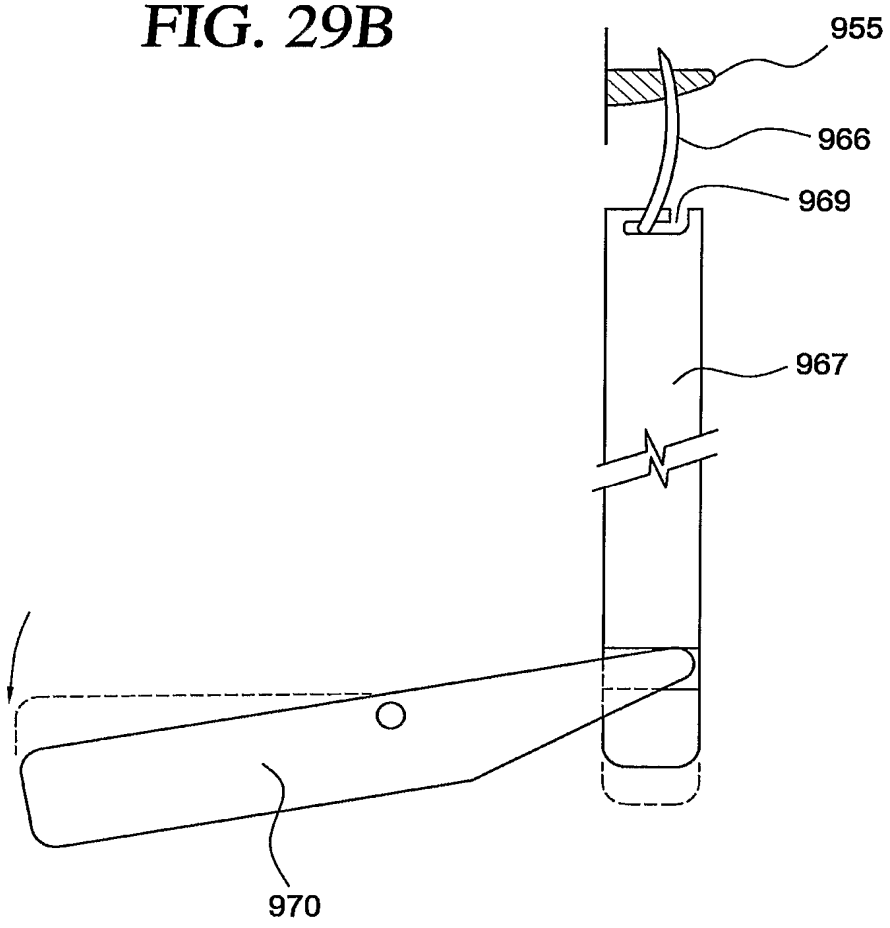


FIG. 29C

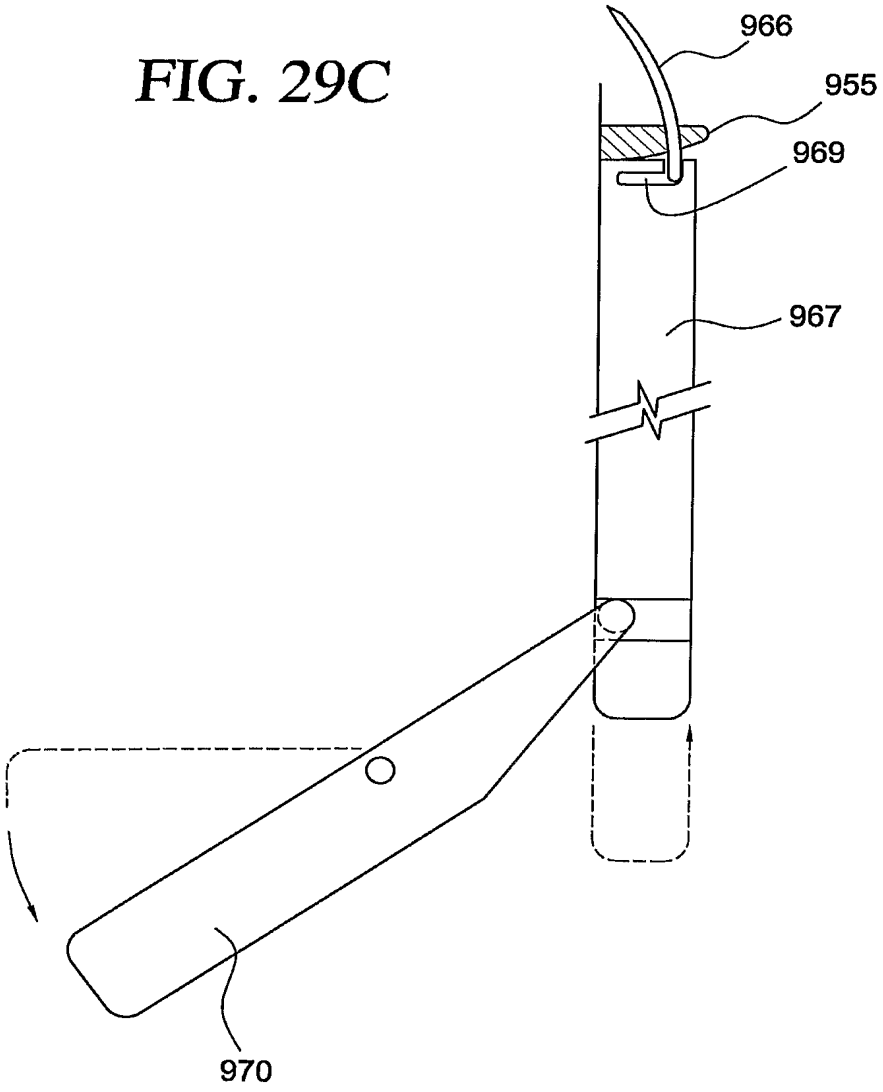
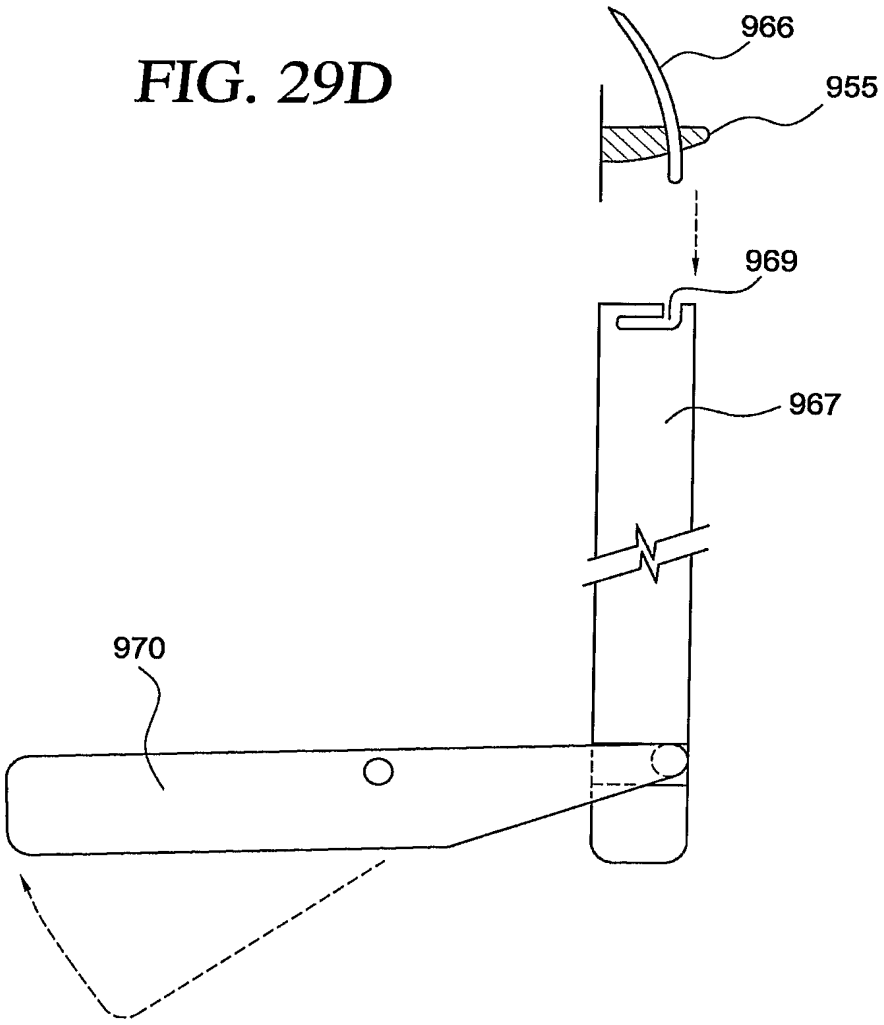


FIG. 29D



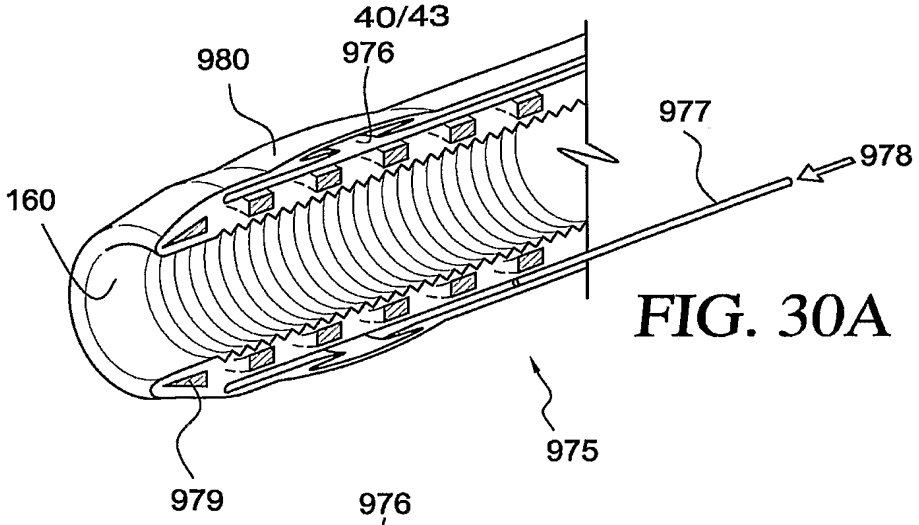


FIG. 30A

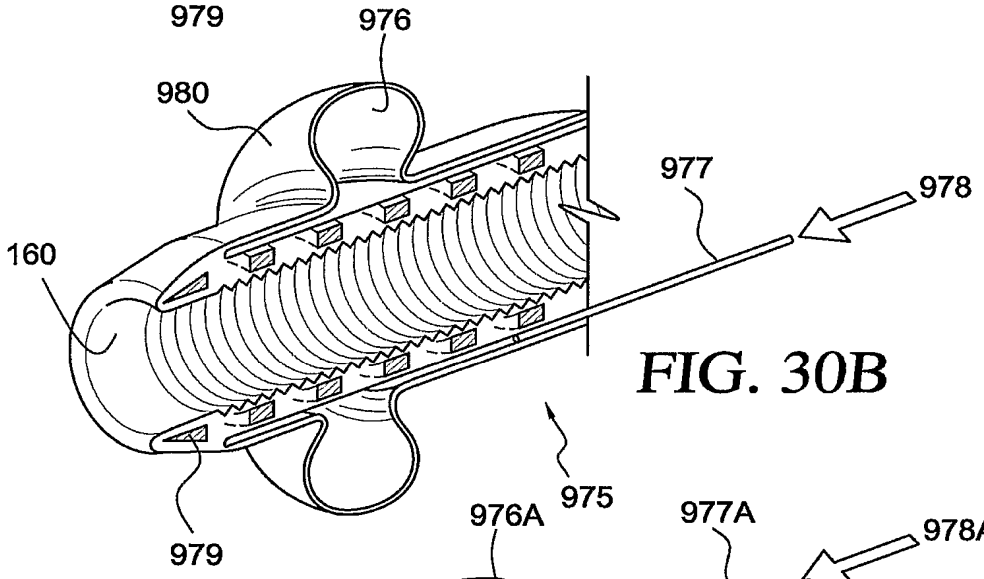


FIG. 30B

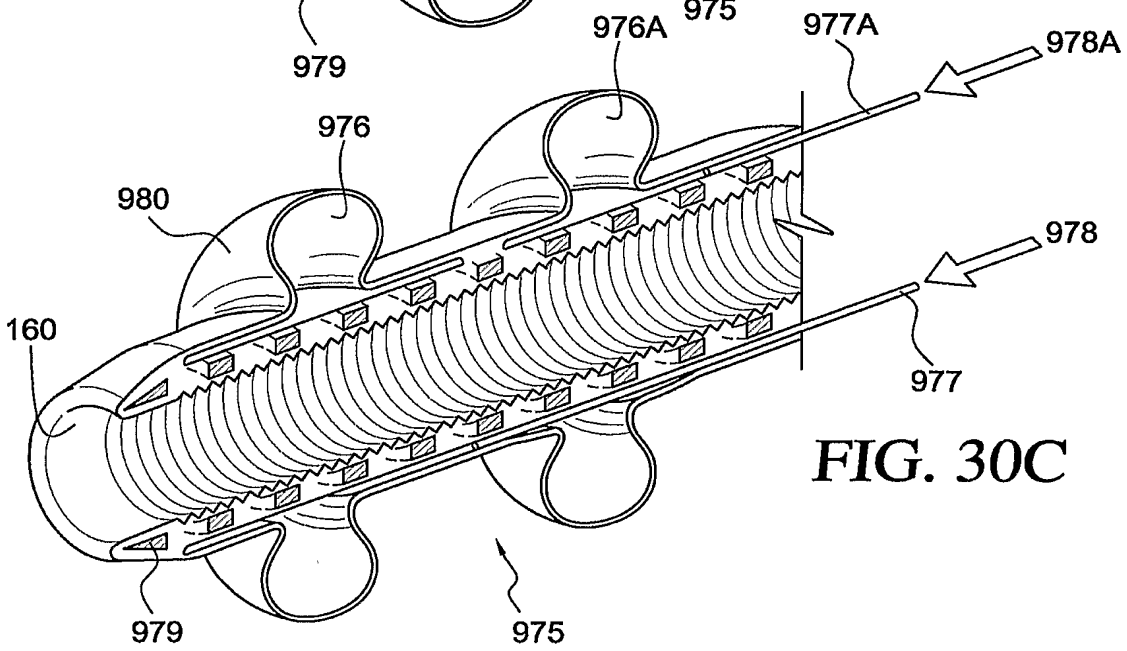


FIG. 30C

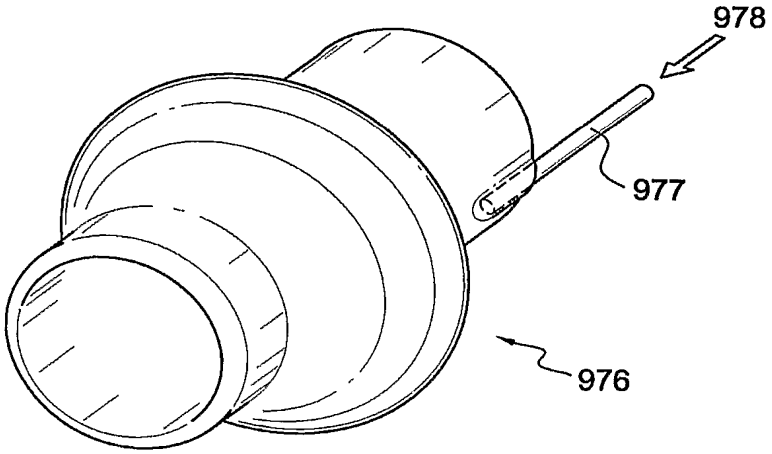


FIG. 31A

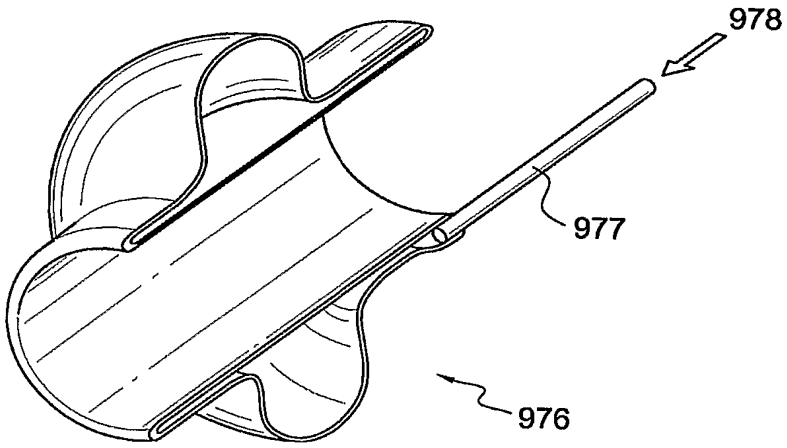


FIG. 31B

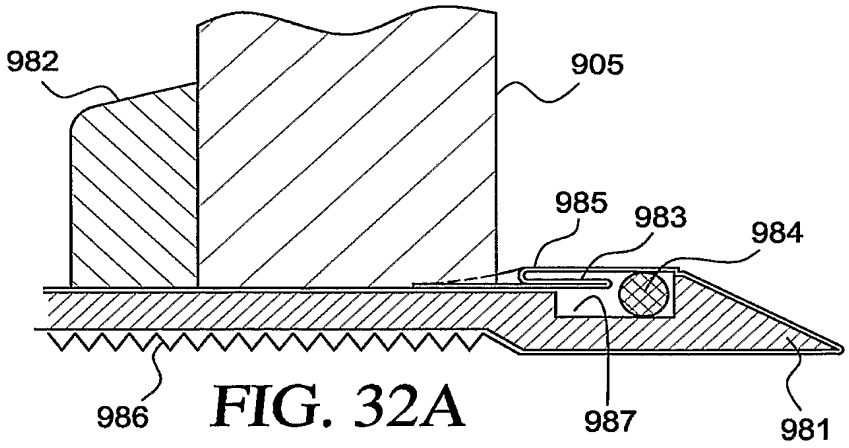


FIG. 32A

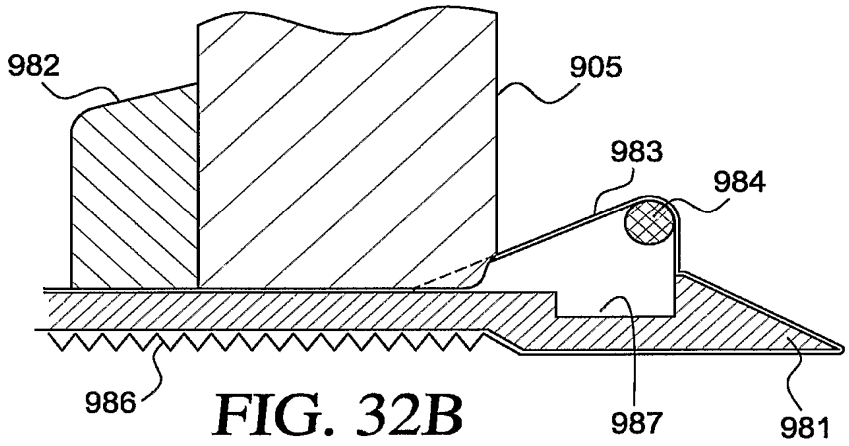


FIG. 32B

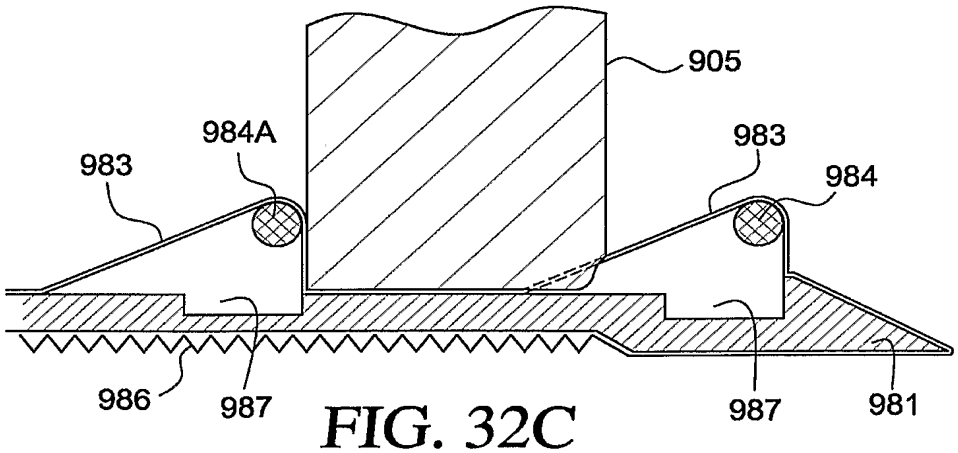


FIG. 32C

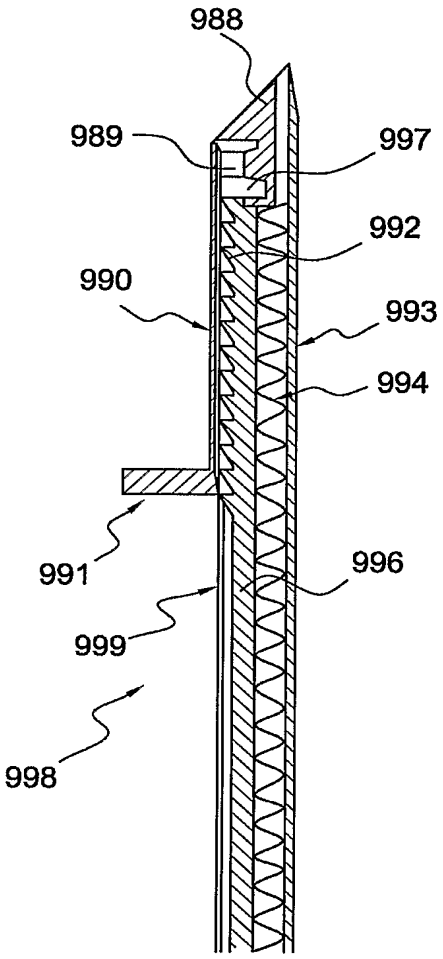


FIG. 33A

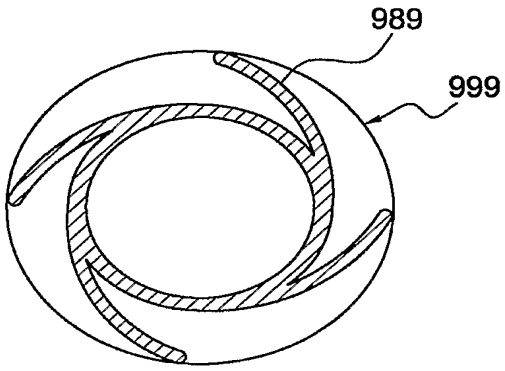


FIG. 33B

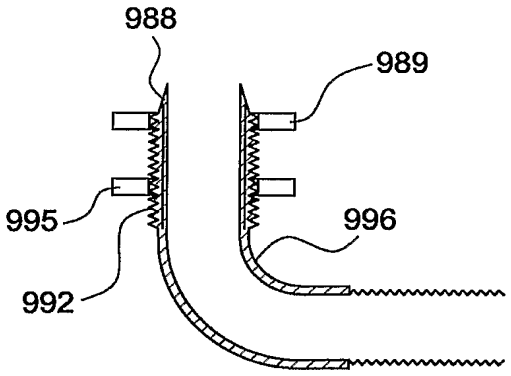


FIG. 33C

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/008600

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/06 A61B17/11

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F A61B

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/162608 A1 (HAVERICH A.) 19 August 2004 (2004-08-19) figures 2A-C,4,8B,10A-B paragraphs [0034], [0047], [0065], [0066], [0068]	1-4,9
X	US 2005/251187 A1 (BEANE R.M. ET AL.) 10 November 2005 (2005-11-10) cited in the application paragraphs [0092], [0100]; figures 2A-C,3,24	1-4
A	WO 93/00868 A (OWEN E.R.) 21 January 1993 (1993-01-21) figures 5,6	1
A	WO 82/01644 A (KASTER R.L.) 27 May 1982 (1982-05-27) figure 7	1

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

☒ See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 September 2007	18/09/2007

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Nice, Philip

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/008600

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

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

1. [X] Claims Nos.: 28-51
because they relate to subject matter not required to be searched by this Authority, namely:

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

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

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

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

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

see additional sheet

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

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

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

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

Remark on Protest

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

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

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-9

   Connector conduit with retention means comprising pins inserted into the conduit insertion hole

   ---

2. claims: 10-12

   Connector conduit with retention means comprising prongs inserted through holes in the conduit flange

   ---

3. claims: 13-17

   Connector conduit with retention means comprising a balloon

   ---

4. claims: 18-27

   Connector conduit with retention means comprising a spring

   ---

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2007/008600

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2004162608 A1	19-08-2004	EP 1599151 A1	30-11-2005
		WO 2004073555 A1	02-09-2004
		JP 2006518624 T	17-08-2006
US 2005251187 A1	10-11-2005	NONE	
WO 9300868 A	21-01-1993	AT 175568 T	15-01-1999
		CA 2112474 A1	21-01-1993
		DE 69228184 D1	25-02-1999
		DE 69228184 T2	16-09-1999
		EP 0593600 A1	27-04-1994
		JP 7500023 T	05-01-1995
		US 5456714 A	10-10-1995
WO 8201644 A	27-05-1982	CA 1175726 A1	09-10-1984
		EP 0064535 A1	17-11-1982
		US 4366819 A	04-01-1983

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
23 April 2009 (23.04.2009)

PCT

(10) International Publication Number
WO 2009/052528 A2

(51) International Patent Classification: Not classified

(21) International Application Number:
PCT/US2008/080560

(22) International Filing Date: 20 October 2008 (20.10.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/999,431	18 October 2007 (18.10.2007)	US
60/999,635	19 October 2007 (19.10.2007)	US
60/999,873	22 October 2007 (22.10.2007)	US

(71) Applicant *(for all designated States except US)*: **NEOCHORD INC.** [US/US]; 11100 Bren Road West, Minnetonka, MN 55343 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **ZENTGRAF, John** [US/US]; C/o Neochord Inc., 11100 Bren Road West, Minnetonka, MN 55343 (US).

(74) Agents: **BIASCO, Tye** et al.; Patterson, Thuente, Skaar & Christensen, P.a., 4800 Ids Center, 80 South Eighth Street, Minneapolis, MN 55402-2100 (US).

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

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

Published:
— *without international search report and to be republished upon receipt of that report*

(54) Title: MINIMIALLY INVASIVE REPAIR OF A VALVE LEAFLET IN A BEATING HEART

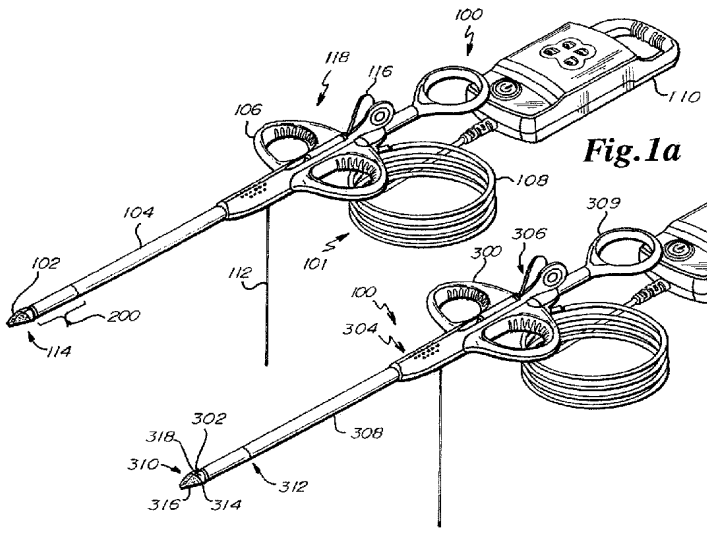


Fig.1a

Fig.1b

(57) Abstract: A device for performing minimially invasive repair of mitral valve leaflets in a beating heart through the delivery and implantation of artifical chordae tendinae includes a handle for positioning the device into a chest cavity of the patient, a capture assembly adapted to capture a valve leaflet between distal an proximal tip portions, a needle adapted to penetrate the valve leaflet, and a capture confirmation system for verifying capture of the valve leaflet between the distal and proximal tip potions.

WO 2009/052528 A2

MINIMALLY INVASIVE REPAIR OF A VALVE LEAFLET IN A BEATING HEART

RELATED APPLICATIONS

The present application claims the benefit of U.S. Provisional Application No. 60/999,431, filed October 18, 2007, U.S. Provisional Application No. 60/999,635, filed October 19, 2007, and U.S. Provisional Application No. 60/999,873, filed October 22, 2007, which are incorporated herein in their entirety by reference.

FIELD OF THE INVENTION

The present invention relates to minimally invasive delivery of a suture. More particularly, the present invention relates to attaching artificial chordae tendineae to a flailing or prolapsing leaflet in a beating heart.

BACKGROUND OF THE INVENTION

Various types of surgical procedures are currently performed to investigate, diagnose, and treat diseases of the heart and the great vessels of the thorax. Such procedures include repair and replacement of mitral, aortic, and other heart valves, repair of atrial and ventricular septal defects, pulmonary thrombectomy, treatment of aneurysms, electrophysiological mapping and ablation of the myocardium, and other procedures in which interventional devices are introduced into the interior of the heart or a great vessel.

Using current techniques, many of these procedures require a gross thoracotomy, usually in the form of a median sternotomy, to gain access into the patient's thoracic cavity. A saw or other cutting instrument is used to cut the sternum longitudinally, allowing two opposing halves of the anterior or ventral portion of the rib cage to be spread apart. A large opening into the thoracic cavity is thus created, through which the surgical team may directly visualize and operate upon the heart and other thoracic contents.

Surgical intervention within the heart generally requires isolation of the heart and coronary blood vessels from the remainder of the arterial system, and arrest of cardiac function. Usually, the heart is isolated from the arterial system by introducing an external aortic cross-clamp through a sternotomy and applying it to the aorta between the brachiocephalic artery and the coronary ostia. Cardioplegic fluid is then injected into the coronary arteries, either directly into the coronary ostia or through a puncture in the aortic root, so as to arrest cardiac function.

In some cases, cardioplegic fluid is injected into the coronary sinus for retrograde perfusion of the myocardium. The patient is placed on cardiopulmonary bypass to maintain peripheral circulation of oxygenated blood.

Of particular interest to the present invention are intracardiac procedures for surgical treatment of heart valves, especially the mitral and aortic valves. According to recent estimates, more than 79,000 patients are diagnosed with aortic and mitral valve disease in U.S. hospitals each year. More than 49,000 mitral valve or aortic valve replacement procedures are performed annually in the U.S., along with a significant number of heart valve repair procedures.

Various surgical techniques may be used to repair a diseased or damaged valve, including annuloplasty (contracting the valve annulus), quadrangular resection (narrowing the valve leaflets), commissurotomy (cutting the valve commissures to separate the valve leaflets), shortening mitral or tricuspid valve chordae tendonae, reattachment of severed mitral or tricuspid valve chordae tendonae or papillary muscle tissue, and decalcification of valve and annulus tissue. Alternatively, the valve may be replaced by excising the valve leaflets of the natural valve and securing a replacement valve in the valve position, usually by suturing the replacement valve to the natural valve annulus. Various types of replacement valves are in current use, including mechanical and biological prostheses, homografts, and allografts.

The mitral valve, located between the left atrium and left ventricle of the heart, is most easily reached through the wall of the left atrium, which normally resides on the posterior side of the heart, opposite the side of the heart that is exposed by a median sternotomy. Therefore, to access the mitral valve via a sternotomy, the heart is rotated to bring the left atrium into a position accessible through the sternotomy. An opening, or atriotomy, is then made in the left atrium, anterior to the right pulmonary veins. The atriotomy is retracted by means of sutures or a retraction device, exposing the mitral valve directly posterior to the atriotomy. One of the aforementioned techniques may then be used to repair or replace the valve.

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

The mitral and tricuspid valves inside the human heart include an orifice (annulus), two (for the mitral) or three (for the tricuspid) leaflets and a subvalvular apparatus. The subvalvular apparatus includes multiple chordae tendineae, which connect the mobile valve leaflets to muscular structures (papillary muscles) inside the ventricles. Rupture or elongation of the chordae tendineae result in partial or generalized leaflet prolapse, which causes mitral (or tricuspid) valve regurgitation. A commonly used technique to surgically correct mitral valve regurgitation is the implantation of artificial chordae (usually 4-0 or 5-0 Gore-Tex sutures) between the prolapsing segment of the valve and the papillary muscle. This operation is generally carried out through a median sternotomy and requires cardiopulmonary bypass with aortic cross-clamp and cardioplegic arrest of the heart.

Using such open-chest techniques, the large opening provided by a median sternotomy or right thoracotomy enables the surgeon to see the mitral valve directly through the left atriotomy, and to position his or her hands within the thoracic cavity in close proximity to the exterior of the heart for manipulation of surgical instruments, removal of excised tissue, and/or introduction of a replacement valve through the atriotomy for attachment within the heart. However, these invasive open-chest procedures produce a high degree of trauma, a significant risk of complications, an extended hospital stay, and a painful recovery period for the patient. Moreover, while heart valve surgery produces beneficial results for many patients, numerous others who might benefit from such surgery are unable or unwilling to undergo the trauma and risks of current techniques.

One alternative to open heart surgery is a robotically guided, thoracoscopically assisted cardiotomy procedure marketed under the tradename of the DaVinci® system. Instead of requiring a sternotomy, the DaVinci® system uses a minimally invasive approach guided by camera visualization and robotic techniques. Unfortunately, the DaVinci® system is not approved for mitral valve repair procedures on a beating heart. Thus, the use of the DaVinci® system for mitral valve repair still requires a cardiopulmonary bypass with aortic cross-clamp and cardioplegic arrest of the heart.

While there are other laparoscopic and minimally invasive surgical techniques and tools that have been developed, none of these devices are useable for the unique requirements of mitral valve repair on a beating heart. Suturing devices like the Superstich™ vascular suturing device or the Gore® suture passer are designed to permit manual placement of sutures as part of a surgical procedure, but are not designed for use on a beating heart. While certain annuloplasty techniques and instruments that can suture an annuloplasty ring as part of vascular repair or heart

bypass surgery may be used in conjunction with a beating heart, these annuloplasty procedures do not involve the capture or retention of a constantly moving leaflet. Consequently, the design and use of annuloplasty techniques and instruments are of little help in solving the problems of developing instruments and techniques for minimally invasive thoracoscopic repair of heart valves.

Recently, a technique has been developed for minimally invasive thoracoscopic repair of heart valves while the heart is still beating. Int'l Pub. No. WO 2006/078694 A2 to Speziali discloses a thoracoscopic heart valve repair method and apparatus. Instead of requiring open heart surgery on a stopped heart, the thorascopic heart valve repair methods and apparatus taught by Speziali utilize fiber optic technology in conjunction with transesophageal echocardiography (TEE) as a visualization technique during a minimally invasive surgical procedure that can be utilized on a beating heart. U.S. Publication No. 2008/0228223 to Alkhatib also discloses a similar apparatus for attaching a prosthetic tether between a leaflet of a patient's heart valve and another portion of the patient's heart to help prevent prolapse of the leaflet and/or to otherwise improve leaflet function.

While the Speziali invention represents a significant advance over open heart techniques for heart valve repair, it would be advantageous to further improve upon this new technique.

SUMMARY OF THE INVENTION

Embodiments of the present invention are generally directed to apparatus and methods for minimally invasive surgical procedures. Although embodiments of the present invention disclosed herein may be adapted or used for any number of purposes, the present invention can generally be used to repair mitral valve leaflets by delivering an implanting one or more sutures to function as artificial chordae tenindae.

In an embodiment, a device for repairing a valve leaflet in a beating heart of a patient comprises a handle assembly, a capture assembly, and a needle head. The handle assembly includes a shaft extending from a distal end of the handle adapted to be extended into a chest cavity of the patient and an actuator mechanism positioned proximate a proximal end of the handle assembly. The shaft has a diameter and a generally circular cross-section along a longitudinal axis at a distal portion of the shaft that is adapted to pass through an incision in the beating heart. The capture assembly extends from the distal portion of the shaft and is adapted to be positioned within the beating heart. The capture assembly has a distal portion including a clamping mechanism adapted to grasp and release the valve leaflet and a proximal portion

operably connected to the shaft. The distal portion of the capture assembly has a maximum diameter of an asymmetric cross section transverse to the longitudinal axis of the capture assembly that is greater than the diameter of the shaft. One of a first clamping jaw or a second clamping jaw of the clamping mechanism is selectively positionable along a longitudinal axis of the capture assembly in response to actuation of the actuator mechanism to create a space between interior surfaces of the first clamping jaw and the second clamping jaw having an asymmetric perimeter. The needle head is slidably positionable within the capture assembly to engage a suture at least partially carried by the capture assembly in response to selective activation of a needle by the actuator mechanism as the needle penetrates the valve leaflet. The area of the interior surfaces is increased relative to an interior surface area of a circular clamping jaw having a diameter equal to the diameter of the shaft. The capture assembly is rotatable within the heart with reduced blood loss relative to blood loss of rotation of the asymmetric perimeter of the first clamping jaw and the second clamping jaw in the incision of the heart.

In further embodiments the first clamping jaw and the second clamping jaw may be separable along a bifurcation plane. The bifurcation plane may form a bifurcation angle with the longitudinal axis of the capture assembly. The bifurcation angle may be between approximately forty-five degrees and ninety degrees, or between approximately fifty-five degrees and approximately sixty-five degrees. The area of the interior surfaces may be increased relative to the interior surface area of a circular clamping jaw having a diameter equal to the diameter of the shaft by between 20% and 100%, or between 30% and 50%. The diameter of the shaft may be less than 12 mm, or less than 9 mm. The space between interior surfaces of the first clamping jaw and the second clamping jaw of the distal tip portion, when positioned in an open position, may provides a distance along the longitudinal axis of the capture assembly between interior surfaces of the first clamping jaw and the second clamping jaw of between 1 and 5 cm, or between 2 and 3 cm. The capture assembly may be configured to penetrate the valve leaflet with the needle head from a distance of between approximately one millimeter and approximately four millimeters from a leading edge of the valve leaflet. The distal portion of the shaft may be isodiametric and the proximal portion of the capture assembly may include a tapered region having cross sections that transition from a substantially circular cross section of the distal portion of the shaft to the asymmetric perimeter of the first clamping jaw and the second clamping jaw. The distal portion of the capture assembly may have a generally oblong asymmetric egg three dimensional shape, with the bifurcation angle being approximately 60

degrees and the asymmetric perimeter of the first clamping jaw and the second clamping jaw being generally loaf shaped cross section.

In an embodiment, a device for repairing a valve leaflet in a beating heart of a patient comprises a shaft, a handle, a capture assembly, and a needle. The shaft has a proximal end outside the patient and a distal end adapted for insertion into the beating heart of the patient. The handle has an actuator operably connected to the proximal end of the shaft. The capture assembly is adapted to penetrate the beating heart, operably coupled to the distal end of the shaft, and includes a clamping mechanism, bifurcated tip, adapted to grasp the valve leaflet in response to selective actuation of the actuator. The needle is slidably positionable within the capture assembly to penetrate the valve leaflet. The shaft is generally isodiametric. The capture assembly has a cross-sectional perimeter that is asymmetric at the bifurcated tip. A maximum diameter of the cross sectional perimeter at the bifurcated tip is greater than a diameter of a portion of the shaft adapted to be positioned proximate a wall of the beating heart.

In further embodiments, the handle may include a first actuator extending generally outwardly the handle for lateral operation and a second actuator generally axially along the handle for inline operation. The first actuator may be operably connected to the needle assembly and the second actuator may be operably connected to the capture assembly. The handle may define a first and second spaced-apart aperture and the actuator may define a third aperture. The first, second, and third apertures may be adapted to receive fingers of an operator. The handle and the actuator may also be adapted for robotic control. The robotic control may be performed by a multi-axis control system. The capture assembly may include a pivot joint operably controllable by the multi-axis control system. The capture assembly may be pivotable about at least two axes of rotation.

In an embodiment, device for repairing a valve leaflet in a beating heart of a patient comprises a handle assembly, a capture assembly, a needle head, and a capture confirmation system. The handle assembly includes a shaft extending from a distal end of the handle adapted to be extended into a chest cavity of the patient and an actuator mechanism positioned proximate a proximal end of the handle assembly. The capture assembly extends from the distal portion of the shaft and is adapted to be positioned within the beating heart. The capture assembly has a distal portion including a clamping mechanism adapted to grasp and release the valve leaflet. The capture assembly also has a proximal portion operably connected to the shaft. A first clamping jaw of the clamping mechanism is selectively positionable along a longitudinal axis of the capture assembly in response to actuation of the actuator mechanism to create a space

between interior surfaces of the first clamping jaw and a second clamping jaw. The clamping mechanism has an asymmetric perimeter. The capture assembly further includes a plurality of pairs of fiber optic fibers. Each pair of fibers has a transmission fiber and a return fiber terminated on a distal end at an interior surface of the clamping mechanism where the fiber extends through the shaft and out of the handle assembly to a proximal end beyond the handle assembly. The needle head is slidably positionable within the capture assembly to engage a suture at least partially carried by the capture assembly in response to selective activation of a needle by the actuator mechanism as the needle penetrates the valve leaflet. The capture confirmation system verifies capture of the valve leaflet in the space between the interior surfaces of the first clamping jaw and the second clamping jaw. The capture confirmation system includes a housing separate from the handle assembly and at least one lense. The housing separate from the handle assembly contains a battery powered optical light source in optical communication with a proximal end of each transmission fiber. The at least one lens is visible from an exterior surface of the housing and in optical communication with a proximal end of each return fiber to display light received from the space between the interior surfaces of the first clamping jaw and the second clamping jaw corresponding to the distal end of each return fiber as an indication of whether there is capture of the valve leaflet by the capture assembly.

In further embodiments, the capture confirmation system may provide a binary indication of whether the valve leaflet is grasped between the interior surfaces of the first clamping jaw and the second clamping jaw by displaying a first color when a surface of the valve leaflet confronts the fiber optic pairs at the interior surfaces and a second color when the valve leaflet does not confront the fiber optic pairs at the interior surfaces. The first color may be indicative of blood and the second color is indicative of valve leaflet. The optical light source may be a light-emitting diode (LED) and the proximal end of the transmission fiber may be positioned less than approximately 0.5 cm from the LED, or between approximately 0.1 cm and approximately 0.2 cm from the LED. Each lens may have a thickness of between approximately 0.2 cm and approximately 0.5 cm, or between approximately 0.3 cm and approximately 0.35 cm. The proximal end of each return fiber may be positioned within approximately .3 cm of the corresponding lens, or between approximately .15 cm and approximately .2 cm of the corresponding lens. The shaft may define a needle lumen adapted to receive the needle and the pairs of fiber optic fibers may be carried by the shaft outside the needle lumen. Each pair of fiber optic fibers may include at least approximately 1 m of length external to the handle such

that the housing of the capture confirmation system is positionable proximal a separate patient display apparatus after insertion of the device into the chest cavity of the patient.

In an embodiment, a device for repairing a valve leaflet in a beating heart of a patient comprises a handles assembly, a capture assembly, and a needle head. The handle assembly includes a shaft extending from a distal end of the handle and is adapted to be extended into a chest cavity of the patient. The shaft includes a first channel adapted to receive a suture and a second channel adapted to receive a needle. The handle assembly also includes an actuator mechanism and a suture retention mechanism. The capture assembly extends from a distal portion of the shaft and is adapted to be positioned within the beating heart. The capture assembly has a distal portion including a clamping mechanism adapted to grasp and release the valve leaflet and a proximal portion operably connected to the shaft. The needle head is slidably positionable within the capture assembly to engage the suture at least partially carried by the capture assembly in response to selective activation of the needle by the actuator mechanism as the needle penetrates the valve leaflet. The suture retention mechanism selectively tensions the suture across a path of travel of the needle through the needle head prior to engagement by the needle.

In further embodiments, the capture assembly may define a needle detent and the suture may be substantially taught across the needle detent. The needle head may present a hook adapted to receive the suture.

In an embodiment, a device for repairing a valve leaflet in a beating heart of a patient may comprise a handle assembly, a capture assembly, and a needle head. The handle assembly includes a shaft and an actuator mechanism. The shaft extends from a distal end of the handle and is adapted to be extended into a chest cavity of the patient. The actuator mechanism is positioned proximate a proximal end of the handle assembly. The capture assembly extends from the distal portion of the shaft and is adapted to be positioned within the beating heart. The capture assembly has a distal portion and a proximal portion. The distal portion includes a clamping mechanism adapted to grasp and release the valve leaflet. The proximal portion is operably connected to the shaft. A first clamping jaw of the clamping mechanism is selectively positionable along a longitudinal axis of the capture assembly in response to actuation of the actuator mechanism to create a space between interior surfaces of the first clamping jaw and a second clamping jaw. The needle head is slidably positionable within the capture assembly to engage a suture at least partially carried by the capture assembly in response to selective activation of a needle by the actuator mechanism as the needle penetrates the valve leaflet. At

least one of the handle assembly or the capture assembly includes a biasing member adapted to bias at least one of the first clamping jaw and the second clamping jaw with respect to one another such that selective actuation of the actuator mechanism overcomes the biasing member before the space is created or closed between the interior surfaces of the first clamping jaw and the second clamping jaw.

In further embodiments, the first clamping jaw and the second clamping jaw may be biased toward a closed position. The biasing member may exert a force of between approximately one pound per square-inch and approximately ten pounds per square-inch, or approximately five pounds per square-inch.

In an embodiment, a method of repairing a valve leaflet in a beating heart of a patient includes using any of the embodiments of the devices described heretofore.

In an embodiment, a method of providing instruments and instructions for repairing a valve leaflet comprises any of the embodiments of the described heretofore and providing instructions for operating any of the embodiments described heretofore to repair the valve leaflet.

In an embodiment of the invention, a valve repair device with a replaceable suture cartridge for repair of a valve leaflet in a beating heart of a patient comprises a valve repair device and a replaceable suture cartridge. The valve repair device includes a main shaft, a handle, a capture assembly, and a needle head. The main shaft has a proximal end outside the patient and a distal end adapted for insertion into the beating heart of the patient. The handle has an actuator operably connected to the proximal end of the main shaft. The capture assembly is operably coupled to the distal end of the main shaft and includes one portion of a jaw assembly adapted to grasp the valve leaflet in response to selective actuation of the actuator. The needle head is slidably positionable within the capture assembly to penetrate the valve leaflet. The replaceable suture cartridge includes a secondary shaft having a distal portion and a proximal portion. The distal portion includes a second portion of the jaw assembly integrally couplable to the capture assembly. The proximal portion is releasably couplable to the handle and the actuator. The secondary shaft is adapted to slidingly engage structure defined along the main shaft such that the actuator is actuatable to selectively position the second portion of the jaw assembly along a longitudinal axis the capture assembly. The replaceable suture cartridge includes structure defining a channel within which a suture is carried, the suture having a loop portion presented proximate the jaw assembly when the replaceable suture cartridge is engaged with the valve repair device.

In further embodiments, the replaceable suture cartridge further may include a means for retaining the suture. The secondary shaft may define a proximally located suture channel adapted to receive the suture and the replaceable suture cartridge may further include a biasing member adapted forceably retain a portion of the suture within the suture channel. The needle head may be slidably positionable within the channel to engage the suture at a fully extended position. The suture retention system may be adapted to release the suture from the biasing member when the needle head reaches the fully extended position. The handle may include a release button and the replaceable suture cartridge may be configured such that actuation of the release button causes the secondary shaft to disengage from the handle. The loop portion of the suture may be adapted for the formation of a girth knot or an Alfieri stitch. The distal portion of the secondary shaft may include a first channel adapted to receive the loop portion and a second channel adapted to receive the needle head when actuated to an extended position. The second channel may interface with the first channel to present the loop portion to the needle head in the extended position.

In an embodiment, a plurality of the replaceable suture cartridges and the valve repair device may be provided together as a kit.

In an embodiment, a method includes using any of the embodiments of the valve repair device and the replaceable suture cartridge as described heretofore as part of a valve repair operation.

In an embodiment, a method includes providing any of the embodiments of the valve repair device and the replaceable suture cartridges as described heretofore and providing instructions for using the replaceable suture cartridge together with the valve repair device to perform a valve repair operation.

In further embodiments, the device can be used in conjunction with external transesophageal echocardiography (TEE) to visualize a valve leaflet to verify leaflet capture. In various embodiments, the device can provide assistance in performing repair of heart valves through a midline sternotomy during cardiopulmonary by-pass thoracotomy modalities, including anterolateral thoracotomy, in addition to minimally invasive procedures.

Throughout the specification, any references to such relative terms as top and bottom, and the like are intended for convenience of description and are not intended to limit the present invention or its components to any one positional or spatial orientation. It will be further understood that various dimensions of the components in the attached figures may vary

depending upon specific applications and intended use of the invention without departing from the scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The embodiments of the present invention may be more completely understood in consideration of the following detailed description of various embodiments in connection with the accompanying drawings, in which:

FIG. 1A is a perspective view of a device for delivering and manipulating a suture in a beating heart, according to an embodiment of the present invention;

FIG. 2 is a front/top perspective view of the handheld suture deployment device depicted in FIG. 1A;

FIG. 3 is a front/top perspective view of the handheld suture deployment device depicted in FIG. 1A;

FIG. 4A is a front/top perspective view of the distal tip of the handheld suture deployment device depicted in FIG. 1A;

FIG. 4B is a front/top perspective view of the distal tip of the handheld suture deployment device depicted in FIG. 2;

FIG. 4C is a side elevation view of the distal tip of the handheld suture deployment device depicted in FIG. 2;

FIG. 4D is a rear/side perspective view of the open distal tip of the handheld suture deployment device depicted in FIG. 2;

FIG. 4E is a front/side perspective view of the open distal tip of the handheld suture deployment device depicted in FIG. 2;

FIG. 4F is a front/bottom perspective view of the upper clamp jaw and shaft of the handheld suture deployment device depicted in FIG. 2;

FIG. 4G is a front/side perspective view of the open distal tip of the handheld suture deployment device depicted in FIG. 2;

FIG. 4H is a side elevation view of the open distal tip of the handheld suture deployment device depicted in FIG. 2;

FIG. 4I is a rear/top perspective view of the open distal tip of the handheld suture deployment device depicted in FIG. 2;

FIG. 4J is a rear/top perspective view of the open distal tip of the handheld suture deployment device depicted in FIG. 2;

FIG. 5 is a front/top perspective view of the pre-loaded suture cartridge depicted in FIG. 2;

FIG. 5A (view A cartridge in phantom) is a front/top perspective view of the distal end of a pre-loaded suture cartridge;

FIG. 5C (view A, rotated, cartridge in phantom) is a rear/top perspective view of the distal end of a pre-loaded suture cartridge;

FIG. 5D (view A, rotated) is a rear/top perspective view of the distal end of a pre-loaded suture cartridge;

FIG. 5B (view B) is a front/top perspective view of the proximal end of a pre-loaded suture cartridge;

FIG. 5E (view B, cartridge in phantom) is a front/top perspective view of the proximal end of a pre-loaded suture cartridge;

FIG. 6 is a front/top perspective view of the operating room loaded cartridge depicted in FIG. 3;

FIG. 6A (rotated) is a rear/top perspective view of the distal end of a operating room loaded cartridge;

FIG. 7 is a front/top perspective view of the needle assembly depicted in FIG. 1A;

FIG. 7A is a front/top perspective view of the distal end of a needle assembly;

FIG. 8 is a rear/top perspective view of an extended needle within the open distal tip of the handheld suture deployment device depicted in FIG. 1A;

FIG. 8A is a front/top perspective view of the proximal end of the handheld suture deployment device depicted in FIG. 1A with the needle assembly in the start position;

FIG. 8B is a front/top perspective view of the proximal end of the handheld suture deployment device depicted in FIG. 1A with the needle assembly in the start position;

FIG. 8C is a front/top perspective view of the proximal end of the handheld suture deployment device depicted in FIG. 1A with the needle assembly in the fully advanced position;

FIG. 8D is a front/top perspective view of the proximal end of the handheld suture deployment device depicted in FIG. 1A with a retracted needle assembly;

FIG. 9 is a front/top perspective view of the proximal end of the handheld suture deployment device depicted in FIG. 1A (with certain parts omitted for clarity);

FIG. 10 is a rear/bottom perspective view of the proximal end of the handheld suture deployment device depicted in FIG. 1A;

FIG. 11 is a front/top perspective view of the plunger assembly depicted in FIG. 8A;

FIG. 12 is a front/top perspective view depicting fiber optic cable assembly depicted in FIG. 1A and leaflet capture verification monitor depicted in FIG. 1A;

FIG. 13 is an exploded front/top perspective view of the fiber optic cable assembly depicted in FIG. 12;

FIG. 14 is a front/bottom perspective view of a mitral valve leaflet in need of repair, and the distal end of the handheld suture deployment device depicted in FIG. 1A;

FIG. 15 is a front/bottom perspective view of a mitral valve leaflet in need of repair, and the distal end of the handheld suture deployment device depicted in FIG. 1A;

FIG. 16 is a front/bottom perspective view of a mitral valve leaflet in need of repair captured by the clamp of the handheld suture deployment device depicted in FIG. 1A;

FIG. 17 is a front perspective view of the leaflet capture verification monitor depicted in FIG. 1A;

FIG. 18 is a front perspective view of the leaflet capture verification monitor depicted in FIG. 1A;

FIG. 19 is a side/bottom perspective view of a mitral valve leaflet captured by the clamp of the handheld suture deployment device depicted in FIG. 1A;

FIG. 20 is a side/bottom perspective view of a mitral valve leaflet captured by the clamp of the handheld suture deployment device depicted in FIG. 1A;

FIG. 21 is a side/bottom perspective view of a mitral valve leaflet captured by the clamp of the handheld suture deployment device depicted in FIG. 1A, with the clamp shown in phantom;

FIG. 22 is a side/bottom perspective view of a mitral valve leaflet captured by the clamp of the handheld suture deployment device depicted in FIG. 1A, with the clamp shown in phantom;

FIG. 23 is a side/bottom perspective view of a mitral valve leaflet in need of repair captured by the clamp of the handheld suture deployment device depicted in FIG. 1A, with the clamp shown in phantom;

FIG. 24 is a side/bottom perspective view of a mitral valve leaflet in need of repair captured by the clamp of the handheld suture deployment device depicted in FIG. 1A, with the clamp shown in phantom;

FIG. 25 is a side/bottom perspective view of a mitral valve leaflet in need of repair captured by the clamp of the handheld suture deployment device depicted in FIG. 1A, with the clamp shown in phantom;

FIG. 26 is a side/bottom perspective view of a mitral valve leaflet in need of repair captured by the clamp of the handheld suture deployment device depicted in FIG. 1A, with the clamp shown in phantom;

FIG. 27 is a side/bottom perspective view of a mitral valve leaflet in need of repair captured by the clamp of the handheld suture deployment device depicted in FIG. 1A, with the clamp shown in phantom;

FIG. 28 is a top/rear perspective view of the handheld suture deployment device depicted in FIG. 1A;

FIG. 29 is a top/rear perspective view of the handheld suture deployment device depicted in FIG. 1A;

FIG. 30 is a top/rear perspective view of the handheld suture deployment device depicted in FIG. 1A and the needle assembly depicted in FIG. 1A partially retracted from the handheld suture deployment device;

FIG. 31 is a top/rear perspective view of the handheld suture deployment device depicted in FIG. 1A, the needle assembly depicted in FIG. 1A retracted from the handheld suture deployment device, and the suture depicted in FIG. 1A;

FIG. 32 is a top/rear perspective view of the handheld suture deployment device depicted in FIG. 1A, the needle assembly depicted in FIG. 1A retracted from the handheld suture deployment device, and the suture depicted in FIG. 1A;

FIG. 33 is a front/bottom perspective view of a mitral valve leaflet in need of repair, and the distal end of the handheld suture deployment device depicted in FIG. 1A partially retracted from the heart chamber;

FIG. 34 is a front/bottom perspective view of a mitral valve leaflet in need of repair, and the distal end of the handheld suture deployment device depicted in FIG. 1A partially retracted from the heart chamber;

FIG. 35 is a front/bottom perspective view of a mitral valve leaflet in need of repair, and the distal end of the handheld suture deployment device depicted in FIG. 1A partially retracted from the heart chamber;

FIG. 36 is an perspective view of the loop and non-loop ends of the suture depicted in FIG. 1A;

FIG. 37 is an perspective view of the loop and non-loop ends of the suture depicted in FIG. 1A;

FIG. 38 is an perspective view of the loop and non-loop ends of the suture depicted in FIG. 1A;

FIG. 39 is a front/bottom perspective view of a mitral valve leaflet in need of repair, and a loose girth hitch on the leaflet;

FIG. 40 is a front/bottom perspective view of a mitral valve leaflet in need of repair, and a loose girth hitch on the leaflet;

FIG. 41 is a front/bottom perspective view of a mitral valve leaflet in need of repair, and an adjusted girth hitch on the leaflet;

FIG. 42 is screen capture of the display of an external transesophageal echocardiography showing a reduction in MR;

FIG. 43 is a schematic top plan view of a mitral valve;

FIG. 44 is a cross-sectional view of a heart;

FIG. 45A is a cross-sectional view of a heart with a normal mitral valve;

FIG. 45B is a partial cross-sectional view of a heart with an abnormal mitral valve;

FIG. 46 is an perspective partial cut-away front view of apical access of a heart with insets showing the mitral valve leaflets and chordae tendonae;

FIG. 47 is a view of a surgeon tensioning a suture and of a suture securing a leaflet;

FIG. 48 is a view of a suture securing a leaflet;

FIG. 49 is a series of side elevation views of the open distal tip of the handheld suture deployment device depicted in FIG. 2 capturing a leaflet, and two front perspective views of the leaflet capture verification monitor depicted in FIG. 1A;

FIG. 50 is a top/rear perspective view of the open distal tip of the handheld suture deployment device depicted in FIG. 2;

FIG. 51 is a top/front perspective view of the open distal tip of the handheld suture deployment device depicted in FIG. 2;

FIG. 52 is a top plan view of the open distal tip of the handheld suture deployment device depicted in FIG. 2;

FIG. 53 is a front perspective view of the open distal tip of the handheld suture deployment device depicted in FIG. 2.

FIG. 54 is a top plan view and a side elevation view of the suture cartridge depicted in FIG. 1A; and

FIG. 55 is a side elevation view and a front/bottom perspective view of the shaft depicted in FIG.1A.

While the present invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit the present invention to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the present invention.

DETAILED DESCRIPTION OF THE DRAWINGS

Certain embodiments of the present invention are directed to apparatus, systems and methods for performing thoracotomy modalities to repair heart valves in either a beating heart or a heart during cardiopulmonary by-pass; or thoracoscopic repair of heart valves in a beating heart. A device that can be used for these purposes is depicted generally with reference numeral 100.

Although the methods and apparatuses of the present invention can be used for any number of treatments requiring the delivery and manipulation of a suture, the present invention, according to certain embodiments, is generally intended for use in treating a heart condition known as mitral valve regurgitation (MR). Mitral valve regurgitation, which is also commonly referred to as mitral insufficiency or mitral incompetence, is a condition characterized by failure of the mitral valve to close properly. When the mitral valve does not close tightly, blood is allowed to flow backward in relation to its normal flow path within the heart. As many as one in five people over fifty-five years of age have some degree of mitral valve regurgitation.

As depicted in Figures 44–45, the heart has four chambers. The two upper chambers, called the left and right atria, receive blood. The two lower chambers, called the left and right ventricles, pump blood. Four valves aid in directing blood flow through the heart's chambers. These heart valves open and close, allowing blood to flow in only one direction.

A mitral valve is depicted illustratively in Figures 43–45. Situated between the left atrium and left ventricle, the mitral valve consists of two flaps of tissue, or leaflets. The mitral valve annulus forms a ring around the valve leaflets, thereby connecting the leaflets to the heart muscle. Papillary muscles are located at the base of the left ventricle. Anchoring the mitral valve leaflets to the papillary muscles are tendon-like cords called chordae tendineae. Normal chordae tendineae prevent the leaflets from prolapsing, or inverting, into the left atrium, as depicted in Figure 45A.

Under normal cardiac conditions, the left atrium contracts and forces blood through the mitral valve and into the left ventricle. As the left ventricle contracts, hemodynamic pressure forces the mitral valve shut and blood is pumped through the aortic valve into the aorta. For the mitral valve to shut properly, the valvular edges of the valve leaflets must form a non-prolapsing seal that prevents the backflow of blood during left ventricular contraction.

A properly functioning mitral valve opens and closes fully. When the mitral valve fails to fully close, as depicted in Figure 45B, blood from the left ventricle is able to flow backward into the left atrium instead of flowing forward into the aorta. This backflow of blood through the heart valve is called regurgitation. The regurgitation of blood through the heart due to the failure of the mitral valve to close properly is the condition known as mitral valve regurgitation. A common symptom of mitral valve regurgitation is congestion of blood within the lungs.

When blood regurgitates from the left ventricle into the left atrium, such as due to MR, less blood is pumped into the aorta and throughout the body. In an attempt to pump adequate blood to meet the blood needs of the body, the left ventricle tends to increase in size over time to compensate for this reduced blood flow. Ventricular enlargement, in turn, often leads to compromised contractions of the heart, however, thereby exacerbating the congestion of blood within the lungs. If left untreated, severe MR can eventually lead to serious cardiac arrhythmia and/or congestive heart failure (CHF).

Mitral valve regurgitation can be caused by any number of conditions, including mitral valve prolapse (a condition in which the leaflets and chordae tendineae of the mitral valve are weakened resulting in prolapse of the valve leaflets, improper closure of the mitral valve, and the backflow of blood within the heart with each contraction of the left ventricle), damaged chords (wherein the chordae tendineae become stretched or ruptured, causing substantial leakage through the mitral valve), rheumatic fever (the infection can cause the valve leaflets to thicken, limiting the valve's ability to open, or cause scarring of the leaflets, leading to regurgitation), endocarditis (an infection inside the heart), deterioration of the mitral valve with age, prior heart attack (causing damage to the area of the heart muscle that supports the mitral valve), and a variety of congenital heart defects. Normally, mitral valve regurgitation does not pose a serious health threat. As MR becomes exacerbated over time, however, the condition can become more severe, resulting in life-threatening complications, including atrial fibrillation (an irregular heart rhythm in which the atria beat chaotically and rapidly, causing blood clots to develop and break loose and potentially result in a stroke), heart arrhythmias, and congestive heart failure

(occurring when the heart becomes unable to pump sufficient blood to meet the body's needs due to the strain on the right side of the heart caused by fluid and pressure build-up in the lungs).

According to certain embodiments, the present invention generally reduces the need to treat mitral valve regurgitation in most individuals with a sternotomy and cardiopulmonary bypass surgery. Specifically, the present invention can provide a minimally invasive treatment of MR. This treatment significantly decreases trauma to surgical patients by facilitating transapical access of a beating heart via a lateral thoracotomy, as depicted in Figure 46, in a manner that eliminates certain surgical steps normally required to complete mitral valve repair procedure by sternotomy.

Transapical access to a heart includes all entry points that are within approximately the bottom third of the heart. As used in this patent application, transapical access to a heart includes all directions of entry and points of entry, as well as all angles of entry at each entry point.

According to certain embodiments, the present invention is compatible with, and directed to percutaneous access to the heart. According to other embodiments, the present invention is compatible with, and directed to other access points to a heart.

Referring to Figure 1B, device 100 may include handle assembly 300, capture assembly 302, and needle 138 according to an embodiment of the present invention. Handle assembly 300 generally has distal end 304 and proximal end 306. Handle assembly includes shaft 308 and actuator 309. Shaft 308 extends from distal end 304 of handle assembly 300 and is generally adapted to be extended into the chest cavity of a patient. Actuator 309 is positioned proximate proximal end 306. Capture assembly 302 generally has distal portion 310 and proximal portion 312. Distal portion 310 includes clamping mechanism 314 formed by first clamping jaw 316 and second clamping jaw 318. In an embodiment, clamping mechanism 314 is adapted to grasp and release a valve leaflet. In a further embodiment, first clamping jaw 316 or second clamping jaw 318 is selectively positionable along a longitudinal axis of capture assembly 302 in response to actuation of actuator mechanism 314 to create a space between the interior surfaces (not shown) of the first and second clamping jaws 316, 318.

Referring to Figure 1A, device 100 can deliver and manipulate a suture in a beating heart and generally includes a handheld suture deployment device 118, and capture confirmation system 101, according to an embodiment of the invention. The handheld suture deployment device 118 generally includes a suture cartridge 102, a shaft 104, a handle 106, and a needle assembly 116. Capture confirmation system 101 generally includes fiber optic cable assembly 108, and leaflet capture verification (LCV) monitor 110. Although device 100 can be used for

any number of purposes without departing from the spirit or scope of the present invention, the aforementioned platform of components, as is described hereinafter in further detail, enable the extending of a shaft through the chest cavity and into a beating heart chamber to capture a valve leaflet of a valve needing repair, and to further provide a needle to operably penetrate the captured valve leaflet and draw a suture therethrough

Suture cartridge 102 may be pre-loaded suture cartridge 120 or operating room-loaded cartridges 122. Referring to Figure 5, pre-loaded suture cartridge 120 can include a tapered lower clamp jaw 124, a suture 112, a suture retention system 130, a handle interface 174, a channel 131, and a groove on the clamp surface 162a. Suture cartridge 120 has proximal 198 and distal 196 ends. The lower clamp jaw 124 is located at the distal end 196 of suture cartridge 120. The handle interface 174 is located at the proximal end 198 of suture cartridge 120. Channel 131 is provided with a pair of openings, a first opening which is located on the top surface, and a second opening which is located on the bottom surface of suture cartridge 120. Channel 131 runs vertically through suture cartridge 120, and is located near the proximal end 198 of suture cartridge 120, such that channel 131 and handle interface 174 are located generally adjacent to one another. Intermediate channel 131 and lower clamp jaw 124 is a cartridge shaft 176.

Referring to Figures 4A–4E, 4G–4J and Figure 5, lower clamp jaw, or distal tip portion, 124 is provided on the distal end of suture cartridge 120 according to an embodiment of the invention. For example, lower clamp jaw 124 and upper clamp jaw 128 may work cooperatively to form a low profile, tapered tip grasping device. Lower clamp jaw 124 generally includes a low profile tip 180, a lumen 182, a groove 162, a lower clamp surface 126 and two channels 163. Lumen 182 extends from the distal end to the proximal end of lower clamp jaw 124, parallel to the axis of cartridge shaft 176. Lumen 182 can be substantially straight, with an inner diameter adapted to receive needle end 146. Groove 162 can be either groove 162a or groove 162b.

According to an embodiment of this invention, groove 162a is disposed on lower clamp surface 126, and is located laterally along surface 126, as depicted in Figure 4D. The depth and width of groove 162a is generally equal to, or greater than, the diameter of suture 112.

According to an embodiment, groove 162b is disposed on the upper surface of lower clamp surface 126, as depicted in Figures 4G–4J. The depth and width of groove 162b is generally equal to, or greater than, the diameter of suture 112. For embodiment of this invention where groove 162 is groove 162b, cutout 161 is provided, as depicted in Figures 4G, 4I, and 4J. Cutout 161 is generally a groove that is parallel with, and has a width that is generally at least equal to the diameter of lumen 182. The distal end of cutout 161 joins with groove 162b and the

proximal end extends to surface 126. The depth of cutout 161 extends from the surface of lower clamp jaw 124 to the centerline of lumen 182.

According to an embodiment, a lower clamp surface 126 is defined by the generally planar canted surface of lower clamp jaw 124. Clamping plane 129 is the planar distal face of upper clamp jaw 128. Clamp 114 is in a closed position when lower clamp surface 126 contacts clamping plane 129. Lower clamp surface 126 has a surface finish generally suitable for retaining a grasped valve leaflet. Suitable surface finishes include a striated or textured surface finish. As depicted in Figures 4D, 4I–4J, and 5, a suitable surface finish may include a series of groves and ridges.

According to an embodiment, the proximal opening of lumen 182 is located to intersect groove 162a, as depicted in Figure 4D and view A of Figure 5. According to another embodiment, the proximal opening of lumen 182 is located to intersect groove 162b, as depicted in Figures 4I and 4J.

According to an embodiment, the low profile tip 180 is generally smooth in shape and surface finish, and is generally free of sharp edges or points. The low profile tip 180 is sufficiently large so that when needle assembly 116 is in a fully extended position, needle end 146 does not protrude from the distal opening of lumen 182.

According to an embodiment, cartridge shaft 176 is provided with a cross-sectional profile that is compatible to be slidably retained within cartridge channel 172. Cartridge shaft 176 is relatively wide, in comparison to the diameter of shaft 104, as depicted in Figures 50–53. In an embodiment, the width of cartridge shaft 176 is approximately 65% of the diameter of shaft 104. In another embodiment, the width of cartridge shaft 176 is between approximately 65% and approximately 100% of the diameter of shaft 104. In another embodiment, the width of cartridge shaft 176 is less than approximately 65% of the diameter of shaft 104. A wide cartridge shaft 176 can prevent body tissue from entering clamp 114 from the bottom and presenting a false capture by capture confirmation system 101.

According to an embodiment, groove 178 is longitudinally disposed along the centerline of the top surface of shaft 176. The depth of groove 178 is generally equal to, or greater than, the diameter of suture 112. The cross-sectional area is generally sufficient to simultaneously encompass the cross-sectional area of two sutures 112.

According to certain embodiments of this invention, channels 163 are provided along a portion of the proximal surface of lower clamp jaw 124, as depicted in Figure 5A. The depth of channels 163 is generally equal to, or greater than, the diameter of suture 112. As depicted in

Figure 5A (view A cartridge in phantom), channels 163 also form a combined cavity that extends generally from the bottom surface of lower clamp jaw 124 to the distal top surface of cartridge shaft 176. The proximal ends of channels 163 open to groove 178, and the proximal end of groove 178 opens to channel 131, thus providing a continuous path for suture 112.

According to an embodiment of this invention, suture 112 is fed through the suture cartridge 120, as depicted in Figure 5. The length of suture 112 is generally divided into two halves, with the mid-point of the suture length generally located within groove 162a. Suture 112 runs along the entire length of groove 162a and channels 163. Suture 112 is also located within groove 178 and channel 131. The two free ends of suture 112 extend through channel 131.

The suture retention system 130 may generally include a J-shaped flat spring located near the proximal end of suture cartridge 120. The straight portion of the "J" is generally parallel with, and located near, the top surface of suture cartridge 120. The curved portion of the "J" generally descends into channel 131. The suture retention system 130 is positioned such that the curved portion of the "J" forms an interference fit with the distal wall of channel 131. The suture retention system 130 acts to retain suture 112 in place within suture cartridge 102 by applying a frictional force on the portion of suture 112 that passes through channel 131. The frictional force generally acts to retain suture 112 as fed within suture cartridge 102. Suture retention system 130 can release suture 112 once needle 138 has been advanced to a fully extended position, as depicted in Figure 8C.

According to an embodiment, handle interface 174 is located on the proximal end 198 of suture cartridge 120. Handle interface 174 is provided with suitable structure for being releasably retained within handle 106. Handle interface 174 may also be provided with suitable structure for being releasably retained within plunger assembly 152. Suitable structure may include, for example, latches, screws, friction fit attachments, and the like.

As depicted in Figures 5B, 9 and 10, a cavity located on the lower surface of handle interface 174 is provided. This cavity mates with a catch mechanism located on the lower surface of suture cartridge interface 184. Thus, handle interface 174 is releasably retained to suture cartridge interface 184, within the housing of handle 106, due to the catch mechanism mating with the cavity. Retention of handle interface 174 can be released through operation of release button 160.

According to an embodiment, operating room loaded cartridges 122 are substantially similar in form fit and function to pre-loaded suture cartridges 120, except that operating room loaded cartridges 122 are not provided with a suture 112.

According to certain embodiments of the invention, shaft 104 has a distal end and a proximal end, as depicted in Figure 1A. Shaft 104 generally includes lumen 134, upper clamp jaw 128, cartridge channel 172 and at least one fiber optic bundle 136. In one embodiment, shaft 104 includes two or more fiber optic bundles 136. In an embodiment, shaft 104 includes four fiber optic bundles 136.

Shaft 104 generally has a diameter that is approximately 6.5 millimeters. The diameter can be greater or less than approximately 6.5 millimeters, however, without departing from the spirit or scope of the present invention. Upper clamp jaw, or proximal tip portion, 128 is located at the distal end of shaft 104, and handle 106 is located at the proximal end. Referring to Figure 4F, cartridge channel 172 defines an opening at the distal end of shaft 104. Cartridge channel 172 may be a keyed channel that runs for substantially the full length of shaft 104, and is substantially axially parallel to shaft 104. As a result of its profile, which generally includes two shoulders, cartridge channel 172 acts to retain suture cartridge 102.

In one embodiment, shaft 104 generally has a diameter that is less than 12 millimeters. In another embodiment, shaft 104 generally has a diameter that is less than 9 millimeters.

In one embodiment, shaft 104 generally has a tapered region 200 at the distal end of shaft 104 and a substantially uniform region extending proximally from the tapered region, as depicted in Figure 1A. The uniform region being substantially uniformly cylindrical and the tapered region transitioning from a substantially circular end to a substantially oblong end. In one embodiment, tapered region 200 is between approximately one centimeter and ten centimeters in length. In another embodiment, tapered region 200 is between approximately two centimeters and five centimeters in length. In another embodiment, tapered region 200 is between approximately four centimeters and five centimeters in length.

In one embodiment, tapered region 200 has a substantially uniform top-to-bottom height that is between approximately one quarter of one centimeter and two centimeters. In another embodiment, tapered region 200 has a substantially uniform top-to-bottom height that is between approximately one-half-of-one centimeter and one and one-quarter-of-one centimeters. In another embodiment, tapered region 200 has a substantially uniform top-to-bottom height that is approximately 0.81 centimeters.

In one embodiment, the uniform region of shaft 104 has a substantially circular cross-section, and the substantially oblong end of tapered region 200 has a side-to-side width that is less than the diameter of the uniform region. In another embodiment, the side-to-side width of

the oblong end of tapered region 200 is approximately between approximately twenty-five millimeters and two and one-half millimeters less than the diameter of the uniform region.

Lumen 134 is substantially axially parallel with both shaft 104 and cartridge channel 172, according to certain embodiments of the invention. Lumen 134 defines an opening 135 on the planar distal surface of upper clamp jaw 128 and a proximal opening in handle 106. Lumen 134 is generally substantially straight. The inner diameter of lumen 134 is generally appropriately sized to accommodate needle assembly 116 when inserted alone, and needle assembly 116 when extracted with a captured suture 112. Lumen 134 is substantially co-axial with lumen 182

According to certain embodiments of the invention, fiber optic bundles 136 are positioned within shaft 104. Each fiber optic bundle 136 generally includes two fiber optic strands. Each fiber optic bundle 136 functionally terminated at clamping plane 129, such that a light input to one of the fiber optic strands results in a reflected, or refracted optical signal that is detectable by the other fiber optic strand within a fiber optic bundle 136. Such a reflected or refracted optical signal may correspond to the nature and color of any material that is present at, or in proximity to, clamping plane 129. Fiber optic bundles 136 are operably connected through fiber optic cable assembly 108 to the leaflet capture verification (LCV) monitor 110.

As depicted in Figures 4A–4E and 4G–4J, lower clamp jaw 124 and upper clamp jaw 128 work cooperatively to form clamp, or bifurcated tip, 114. According to certain embodiments of the invention, clamp 114 which is generally bifurcated, low-profile, and tapered so as to perform any number of grasping functions.

Through the actuation of plunger assembly 152, lower clamp jaw 124 can be extended distally from upper clamp jaw 128, and can be retracted. When lower clamp jaw 124 is fully retracted, clamp 114 is in a closed position. In the closed position, lower clamp surface 126 contacts clamping plane 129. In the closed position, the outer surfaces of upper clamp jaw 128 and the outer surfaces of lower clamp jaw 124 are substantially coextensive. In a closed position, the outside surfaces of lower clamp jaw 124 and upper clamp jaw 128 form a substantially smooth surface such that no snagging, rough or sharp edges or overlaps are formed. When lower clamp jaw 124 is extended, clamp 114 is in an open position. In an open position, lower clamp jaw 124, and upper clamp jaw 128 can be positioned around a piece of tissue, such as a mitral valve leaflet. Through the relative movement of lower clamp jaw 124, clamp 114 is operable to capture a valve leaflet, and needle 138 can penetrate the captured valve leaflet via lumens 134, 182.

According to certain embodiments of the invention, clamp 114 presents an oversized leaflet capture area compared to the cross-sectional area of shaft 104.

In a closed position, the outside surfaces of lower clamp jaw 124 and upper clamp jaw 128 form a substantially smooth surface, according to certain embodiments of the invention. This smooth surface can facilitate the insertion of clamp 114 into a tissue opening that is smaller than the clamp's cross-sectional area due to the elasticity of tissue over short periods of time. For the embodiments of the invention depicted in Figures 4A–4E and 8, the shaft diameter is approximately 85% of the maximum diameter of clamp 114. By employing this ratio of clamp-to-shaft diameters, body tissues can be stretched within their elastic limits, which permits an oversized leaflet capture area within clamp 114 as compared to the cross-sectional area of shaft 104.

An oversized leaflet capture area, as compared to the shaft's 104 cross-sectional area, is presented due to the clamping angle θ, according to certain embodiments of the invention. Clamping angle θ is the angle that clamping plane 129 makes with a horizontal plane through the centerline of shaft 104 as indicated by θ on Figure 4C. For the embodiments of the invention depicted in Figure 4C, clamping angle θ is approximately 120 degrees. In other embodiments of the invention, clamping angle θ is approximately between 115 degrees and 125 degrees. In other embodiments of the invention, clamping angle θ is approximately between 90 degrees and 135 degrees. In still other embodiments of the invention, clamping angle θ is approximately between 135 degrees and 155 degrees. A clamping angle that is greater than 90 degrees may result in a leaflet capture area of clamp 114 that is larger, relative to shaft's 104 cross-sectional area, than would be possible were the clamping angle 90 degrees. For a clamping angle that is approximately 120 degrees, the leaflet capture area of clamp 114 will be approximately 30% to 40% larger than if the clamping angle were 90 degrees.

In an embodiment of the present invention, a canted tip with increased clamp travel improves leaflet capture. In another embodiment of the present invention, an exchangeable cartridge improves the simplicity and reliability of suture deployment. In another embodiment of the present invention, a suture deployment and manipulator mechanism is integrated with a visualization and verification system to deploy sutures within a suture zone of a valve leaflet.

According to certain embodiments of the invention, clamp 114 is a low profile tapered tip grasping device. The shape of the tapered tip facilitates leaflet capture by providing a large surface area for leaflet capture, relative to the diameter of the shaft. In one embodiment, the surface area for leaflet capture is between 30% and 50% greater than the cross-sectional area of

the shaft 104. In another embodiment, the surface area for leaflet capture is between 20% and 100% greater than the cross-sectional area of the shaft 104.

According to certain embodiments of the invention, clamp 114 is a low profile canted tip grasping device. Clamp 114 can be canted in any number of directions. Generally, however, the canted tip is canted up, as depicted in Figures 54–55. A large surface area of the canted tip, relative to the diameter of the shaft, facilitates leaflet capture.

A large leaflet capture area can provide a surgeon with certain advantages as compared to a smaller leaflet capture area. These advantages include improved ability to capture a leaflet that may be damaged or enlarged and a leaflet capture that is more stable. Greater stability in turn can provide a surgeon enhanced control of a captured leaflet.

According to an embodiment of the invention, the maximum linear travel of lower clamp jaw 124 in relation to upper clamp jaw 128 is between approximately one and five centimeters. According to another embodiment of the invention, the maximum linear travel of lower clamp jaw 124 in relation to upper clamp jaw 128 is between approximately two and three centimeters.

According to certain embodiments of the invention, handle 106 is formed to be manipulated by an operator. Operator may be, for example, a surgeon, or the controllable device-interfacing end of a robotic system. In one embodiment, handle 106 is adapted to be grasped by the index and middle finger of a surgeon. Shaft 104 extends from the distal end of handle 106, and plunger assembly 152 is retained in the proximal end. As depicted in Figure 9, structure is provided within handle 106 to retain plunger assembly 152 such that plunger assembly 152 is permitted to engage with suture cartridge 102, and to translate in both the distal and proximal directions. Suitable structure for retaining plunger assembly 152 within handle 106 include, for example, a pin and shackle arrangement, a retaining collar, a boss within a groove, and the like. As depicted in Figures 9 and 11, a pin and retaining shackle arrangement is employed, with the pin biased against spring 158 within slot 132 of plunger shaft 156, in order to permit translational movement of plunger assembly 152. Release button 160 is located on the bottom surface of handle 106, as depicted in Figure 10. Release button 160 transfers an operator's input to the retaining structure of handle interface 174 in order to uncouple suture cartridge 102 from plunger assembly 152. A track may also be provided on the top surface of handle 106 that accepts needle carriage 144. Markings are provided on the top surface of the handle, adjacent to the track, to aid an operator in positioning needle carriage 144.

As depicted in Figures 9 and 11, plunger assembly 152 generally includes plunger thumb handle 154, plunger shaft 156, suture cartridge interface 184 and spring 158, according to certain

embodiments of the invention. Plunger thumb handle 154 is formed to be grasped by the thumb of an operator and is provided on the proximal end of plunger assembly 152. Suture cartridge interface 184 is provided on the distal end of plunger assembly 152 and is formed to engage and releasably retain suture cartridges 102. Intermediate suture cartridge interface 184 and plunger thumb handle 154 is plunger shaft 156. Slot 132 is located along a portion of the length of plunger shaft 156. Spring 158 is located within slot 132 of plunger shaft 156, and in cooperation with a pin and retaining structure within handle 106, serves to bias plunger assembly 152 to a proximal position relative to handle 106. As a result of the releasable retention between suture cartridge interface 184 and suture cartridges 102, the biasing action of spring 158 is translated to suture cartridge 102. This biasing action favors retention of clamp 114 in a closed or grasping position. Biasing of plunger 152 in this manner facilitates slow and incremental clamp extension and contraction.

In one embodiment, spring 158 favors retention of clamp 114 in a closed or grasping position with a force in the range of approximately zero pounds per inch of travel to twenty pounds per inch of travel. In one embodiment, spring 158 favors retention of clamp 114 in a closed or grasping position with a force of approximately five pounds per inch of travel.

As illustrated in Figure 7, certain embodiments of needle assembly 116 generally include needle 138, needle handle 140, and needle head, or needle end, 146. Needle 138 is formed from 304 stainless steel wire or other suitable material, is generally circular in shape, and has a distal end and a proximal end. Needle end 146 is provided on the distal end of needle 138 and needle handle 140 is provided on the proximal end of needle 138. Needle end 146 is flattened and a notch 148 is provided to create hook 150. Notch 148 is equal to, or greater than, the diameter of suture 112. Needle handle 140 generally includes finger tabs 142, and needle carriage 144. Needle carriage 144 is permitted to travel along a track that is provided within the top housing of handle 106. Such travel permits needle 138 from moving from a starting position (needle end 146 is within upper clamp jaw 128, as depicted in Figure 51) to a fully extended position (needle hook 150 within lumen 182). Needle carriage 144 is also permitted to travel in a proximal direction along the track, such proximal travel extending to a position where needle carriage 144 disengages from the track, and needle assembly 116 is removed from the handheld device 118. Markings provided adjacent to the track aid an operator in selecting the correct position of the needle carriage 144 in order to achieve a desired position of needle 138. A detent is also provided to aid in locating the starting position of needle assembly 138. Finger tabs 142 fan out from the centerline of needle assembly 116 and in so doing, act to prevent needle carriage 144

from being inadvertently displaced. In order for an operator to displace needle carriage 144, an operator must first grasp and press finger tabs 142 together, and then needle carriage 144 can be displaced along the track. In one embodiment, a biasing member opposes the movement of needle carriage 144 to a distal position.

According to certain embodiments of the invention, fiber optic cable assembly 108 generally includes fiber optic cable 166 and strain relief 164. Fiber optic cable 166 generally includes four (4) fiber optic bundles 136 that run from the distal surface of upper clamp jaw 128 to the leaflet capture verification (LCV) monitor 110. The four (4) fiber optic bundles 136 are bundled together within fiber optic cable 166 and are jacketed with a medical grade PVC cover, or other suitable covering material. Strain relief 164 is provided at the interface between fiber optic cable 166 and leaflet capture verification (LCV) monitor 110 as depicted in Figure 12.

According to certain embodiments of the invention, fiber optic cable assembly 108 is at least two-hundred-and-twenty centimeters long. For these embodiments, in an operating room setting, LCV monitor 110 can be placed outside of the sterile field, which results in the option to package device 100 in such a manner that LCV monitor 110 need not be sterilized.

According to another embodiment, a fiber optic connector (not depicted) can be used to operably connect fiber optic cable assembly 108 to LCV monitor 110. The use of such a connector permits the sterilization and sterile packaging of the handheld device 118 and fiber optic cable assembly 108, while the LCV monitor 110 can be separately packaged in an unsterilized condition. In an operating room setting, handheld device 118 and fiber optic cable assembly 108 can be introduced into the sterile field, while LCV monitor 110 can be placed outside of the sterile field, within surgical line-of-sight of a TEE monitor, and the fiber optic connector used to operably connect LCV monitor 110 and fiber optic cable assembly 108.

As depicted in Figures 12 and 13, leaflet capture verification (LCV) monitor 110 generally includes power button 168, four (4) LED displays 170, housing 186, circuit board 188, and an internal power supply 190, according to certain embodiments of the invention. Housing 186 includes an integrated loop which is adapted to be securely clipped or hung such that the LED displays 170 of LCV monitor 110 can be placed within surgical line-of-sight of a TEE monitor. Disposed on circuit board 188 is internal power supply 190, power button 168 and a light source, such as an LED. For other embodiments, more than one light source can be used. Circuit board 188, internal power supply 190, power button 168 and the light source are all operably connected in a manner familiar to those who are skilled in the art. Activation of power button 168 results in the light source being turned on/off. Four sets of fiber optic bundles 136

enter housing 186 via fiber optic cable 166 and strain relief 164. Each fiber optic bundle 136 generally includes two fiber optic strands. For each fiber optic bundle 136, one of the fiber optic strands is operably connected to the light source, while the other fiber optic strand is operably connected to one of the four (4) LED displays 170. Power button 168, the four (4) LED displays 170, circuit board 188, the an internal power supply 190, and the light source(s) are all contained within housing 186. The four (4) LED displays 170 are visible to an operator from outside of housing 186, and power button 168 is operable from outside of housing 186.

In operation, device 100 can be used to attach a suture within the suture target zone 194 of a valve leaflet, as depicted in Figure 43. To accomplish this, the device 100 may employ a visualization and verification system. The visualization and verification system integrates external transesophageal echocardiography (TEE) to visualize a valve leaflet in multiple axes and fiber optics to verify leaflet capture. In an embodiment, suture target zone 194 is generally two millimeters from the leading (prolapsing) edge of the leaflet. In another embodiment, suture target zone 194 is one millimeter wide and has a centerline that is located two millimeters from the leading (prolapsing) edge of the leaflet. In another embodiment, suture target zone 194 is one millimeter wide and has a centerline that is located three millimeters from the leading (prolapsing) edge of the leaflet. In another embodiment, suture target zone 194 is one millimeter wide and has a centerline that is located four millimeters from the leading (prolapsing) edge of the leaflet. In another embodiment, suture target zone 194 is greater than one millimeter wide and has a centerline that is located between two millimeters and five millimeters from the leading (prolapsing) edge of the leaflet. In another embodiment, suture target zone 194 is less than one millimeter wide and has a centerline that is located between two millimeters and five millimeters from the leading (prolapsing) edge of the leaflet. In one embodiment, the fiber optics include a leaflet capture verification (LCV) monitor 110 and a fiber optic cable assembly 108, as depicted in Figures 1A and 12.

Referring to Figures 4E and 4F, in an embodiment, fiber optic bundles 136 terminate at upper clamp jaw 128 in a configuration that surrounds lumen opening 135. In another embodiment, fiber optic bundles 136 terminate at upper clamp jaw 128 in a configuration that is near lumen opening 135. Those skilled in the art will realize that many variations in the configuration of the placement of the terminations of fiber optic bundles 136 at clamping plane 129 are possible in order to meet the spirit and scope of the present invention. The identification of certain configurations is not intended to exclude others which are not identified, but are provided as examples of possible configurations.

Fiber optic bundles 136 are operably connected through fiber optic cable assembly 108 to the leaflet capture verification (LCV) monitor 110, according to certain embodiments of the invention. When a valve leaflet has been grasped in clamp 114, the LCV monitor 110 displays a light transmission that corresponds to the configuration of fiber optic bundles 136 at clamping plane 129, and which identifies whether the valve leaflet is properly captured in clamp 114.

According to certain embodiments, the present invention can be used with robotic multi-axis control and manipulation of the device. Proximal control of the instrument can be achieved with a system interface comprised of the necessary electrical and electro-mechanical interconnects to actuate the mechanical operations of the instrument. According to an embodiment, the distal tip of the device can have a rigid shaft. According to another embodiment, the distal end of the device can have an articulating, multiple axis tip for orientation of the clamp and suture delivery.

According to certain embodiments of the invention, the movable tip typically remains in the closed position during thoracoscopic insertion and manipulation of the handheld device 118. As desired by an operator, plunger 152 can be manipulated to separate the two portions of the moveable tip, as depicted in, for example, Figures 4D–4E, 4G–4J and 49.

According to certain embodiments of the invention, clamp 114 is biased to a closed position through the use of spring 158, or other biasing member. A clamp that is biased closed aids in leaflet capture verification as it can provide a surgeon with a distinctive tactile feedback when a leaflet has been captured, as compared to when the result is a failed or partial leaflet capture.

In practice, certain embodiments of the present invention can be used to attached a suture to the suture zone of a valve leaflet in a beating heart, as depicted in Figures 14–42 and 46–48. In one embodiment, the apex of the left ventricle is accessed. Such access can be obtained by thoracotomy or other suitable surgical technique. Shaft 104 of the handheld suture deployment device 118 is then inserted through the apex of the heart into the left ventricle using transesophageal echocardiography (TEE) to guide the surgeon. A purse string suture at the site of left ventricular apical access can be used to control blood loss.

As depicted in Figures 14–16, while the heart is beating, the movable tip of the platform is used to guide the capture of a flailing leaflet as clamp 114 is closed. A surgeon can use external transesophageal echocardiography to guide the placement of the movable tip relative to a target leaflet. Through further use of transesophageal echocardiography, as well as the tactile feel of plunger 152, and LCV monitor 110, a surgeon can verify leaflet capture.

Once the leaflet is captured, a surgeon can verify capture by examining the leaflet capture verification (LCV) monitor 110 to assure leaflet tissue is present. In an embodiment, the four LED displays 170 of the LCV monitor 110 present red when blood is present at clamping plane 129, as depicted in Figure 17, while a display of four white lights indicates that the tissue has been fully captured by the movable tip, as depicted in Figure 18.

In one embodiment, an operator can penetrate the leaflet with needle 138 and retrieve secured suture 112 from the lower clamp jaw 124 by engaging needle assembly 116. First, needle 138 is advanced by guiding the needle assembly carriage 144 forward, or toward the distal end of the platform as depicted in Figures 19–24 (the movable tip is illustrated in phantom in Figures 21–24 so that the advancement of needle 138 can be visibly depicted). Once needle 116 is fully advanced, the needle assembly is rotated to engage suture 112 as depicted in Figures 25–27 (the movable tip is illustrated in phantom in Figures 25–27 so that the rotation of needle 138 can be visibly depicted). The suture loop is retrieved by retracting (movement is in the proximal direction) the needle assembly entirely from handheld device 118 as depicted in Figures 28–32. The handheld device 118 can then be extracted from the ventricle while maintaining control of both ends of the suture as depicted in Figures 33–35.

In another embodiment, no rotation of needle 138 is necessary. A surgeon advances needle 138 by guiding the needle assembly carriage 144 forward, or toward the distal end of the platform as depicted in Figure 8C. Once needle 116 is fully advanced, needle hook 150 engages with suture 112, as depicted in Figure 8, when needle assembly carriage 144 is retracted as depicted in Figure 8D. Needle hook 150 can advance past suture 112 without dislodging suture 112 from groove 162 because suture retention system 130 acts to retain suture 112 as threaded on and within suture cartridge 102. Suture retention system 130 releases suture 112 once needle 138 has been is fully advanced.

In embodiments of the invention that have cutout 161, handheld device 118 can be extracted with clamp 114 in a closed position. This is because cutout 161 permits suture 112 to be clear of clamp 144 after the suture loop is retrieved from handheld device 118. Extracting handheld device 118 with clamp 114 in a closed position facilitates the extraction.

In one embodiment, the non-loop end of the suture 112 is passed through the loop to create a girth hitch on the leaflet as depicted in Figures 36–41 and 47–48. The girth hitch provides for distributed stress on the leaflet with two suture legs and avoids the need for a knot at the site of leaflet capture.

In one embodiment, a surgeon can thread one of the free ends of the suture 112 into an operating-room loaded cartridge 122 and repeat the capture process on an adjacent (non-flailing) leaflet to create leaflet plication or what is commonly known as the Alfieri stitch.

In other embodiments, the handheld device 118 can be adapted to form different types of knots or stitches that can be used for mitral valve repair. This can be accomplished through changes to one or more of: the relative location of the needle within the shaft; the relative orientation of the suture within the distal tip; the configuration of the suture within the distal tip; the relative orientation of the needle hook; the addition of one or more needle ends to the needle assembly; and the relative locations of multiple needle ends within the shaft.

At this stage, the surgeon can visualize the function of the mitral valve leaflet using TEE as depicted in Figure 42. An operator can then incrementally adjust the tension on the suture, while monitoring the corresponding mitral valve regurgitation through the use of TEE, to allow for ideal coaptation of the mitral valve leaflets and consequently a reduction or elimination of MR. If the competency of the mitral valve is satisfactory, the suture can be secured to a suitable location. Suitable locations for this purpose can include the epicardium, a papillary muscle and other like locations. Securing the suture can be accomplished using a standard surgical knot and pledget.

In one embodiment of the present invention, the process can be repeated by removing exchangeable cartridge 102 from the handheld device 118 and replacing it with a pre-loaded suture cartridge 120. In another embodiment, the process can be repeated by removing exchangeable cartridge 102 from the handheld device 118 and threading a suture 112 into operating room loaded cartridge 122 which can then be installed into handheld device 118.

CLAIMS

1. A device for repairing a valve leaflet in a beating heart of a patient, comprising:

a handle assembly including a shaft extending from a distal end of the handle adapted to be extended into a chest cavity of the patient and an actuator mechanism positioned proximate a proximal end of the handle assembly, the shaft having a diameter and a generally circular cross-section along a longitudinal axis at a distal portion of the shaft that is adapted to pass through an incision in the beating heart;

a capture assembly extending from the distal portion of the shaft and adapted to be positioned within the beating heart, the capture assembly having a distal portion including a clamping mechanism adapted to grasp and release the valve leaflet and a proximal portion operably connected to the shaft, the distal portion of the capture assembly having a maximum diameter of an asymmetric cross section transverse to the longitudinal axis of the capture assembly that is greater than the diameter of the shaft, wherein one of a first clamping jaw or a second clamping jaw of the clamping mechanism is selectively positionable along a longitudinal axis of the capture assembly in response to actuation of the actuator mechanism to create a space between interior surfaces of the first clamping jaw and the second clamping jaw having an asymmetric perimeter; and

a needle head slidably positionable within the capture assembly to engage a suture at least partially carried by the capture assembly in response to selective activation of a needle by the actuator mechanism as the needle penetrates the valve leaflet,

such that an area of the interior surfaces is increased relative to an interior surface area of a circular clamping jaw having a diameter equal to the diameter of the shaft and the capture assembly is rotatable within the heart with reduced blood loss relative to blood loss of rotation of the asymmetric perimeter of the first clamping jaw and the second clamping jaw in the incision of the heart.

2. The device of claim 1, wherein the first clamping jaw and the second clamping jaw are separable along a bifurcation plane, the bifurcation plane forming a bifurcation angle with the longitudinal axis of the capture assembly, the bifurcation angle being between approximately forty-five degrees and ninety degrees.

3. The device of claim 2, wherein the bifurcation angle is between approximately fifty-five degrees and approximately sixty-five degrees.

4. The device of claim 1, wherein the area of the interior surfaces is increased relative to the interior surface area of a circular clamping jaw having a diameter equal to the diameter of the shaft by between 20% and 100%.

5. The device of claim 4, wherein the area of the interior surfaces is increased relative to the interior surface area of a circular clamping jaw having a diameter equal to the diameter of the shaft by between 30% and 50%.

6. The device of claim 1, wherein the diameter of the shaft is less than 9 mm.

7. The device of claim 1, wherein the space between interior surfaces of the first clamping jaw and the second clamping jaw of the distal tip portion when positioned in an open position provides a distance along the longitudinal axis of the capture assembly between interior surfaces of the first clamping jaw and the second clamping jaw of between 1 and 5 cm.

8. The device of claim 7, wherein the distance along the longitudinal axis of the capture assembly between interior surfaces of the first clamping jaw and the second clamping jaw is between 2 and 3 cm.

9. The device of claim 1, wherein the capture assembly is configured to penetrate the valve leaflet with the needle head from a distance of between approximately one millimeter and four millimeters from a leading edge of the valve leaflet.

10. The device of claim 1, wherein the distal portion of the shaft is isodiametric and the proximal portion of the capture assembly includes a tapered region having cross sections that transition from a substantially circular cross section of the distal portion of the shaft to the asymmetric perimeter of the first clamping jaw and the second clamping jaw.

11. The device of claim 2, wherein the distal portion of the capture assembly has a generally oblong asymmetric egg three dimensional shape, with the bifurcation angle approximately 60

degrees and the asymmetric perimeter of the first clamping jaw and the second clamping jaw generally loaf shaped cross section.

12. A device for repairing a valve leaflet in a beating heart of a patient, comprising:

a shaft having a proximal end outside the patient and a distal end adapted for insertion into the beating heart of the patient;

a handle with an actuator operably connected to the proximal end of the shaft;

a capture assembly adapted to penetrate the beating heart, the capture assembly being operably coupled to the distal end of the shaft and including a bifurcated tip adapted to grasp the valve leaflet in response to selective actuation of the actuator; and

a needle slidably positionable within the capture assembly to penetrate the valve leaflet;

wherein the shaft is generally isodiametric and the capture assembly has a cross sectional perimeter that is asymmetric at the bifurcated tip and a maximum diameter of the cross sectional perimeter at the bifurcated tip that is greater than a diameter of a portion of the shaft adapted to be positioned proximate a wall of the beating heart.

13. The device of claim 12, wherein the handle includes a first actuator extending generally outwardly the handle for lateral operation and a second actuator generally axially along the handle for inline operation.

14. The device of claim 13, wherein the first actuator extending is operably connected to the needle assembly and the second actuator is operably connected to the capture assembly.

15. The device of claim 12, wherein the handle defines a first and second spaced-apart aperture and the actuator defines a third aperture, the first, second, and third apertures being adapted to receive fingers of an operator.

16. The device of claim 12, wherein the handle and the actuator are adapted for robotic control.

17. The device of claim 16, wherein the robotic control is performed by a multi-axis control system.

18. The device of claim 17, wherein the capture assembly includes a pivot joint, the pivot joint being operably controllable by the multi-axis control system.

19. The device of claim 18, wherein the capture assembly is pivotable about at least two axes of rotation.

20. A device for repairing a valve leaflet in a beating heart of a patient, comprising:

a handle assembly including a shaft extending from a distal end of the handle adapted to be extended into a chest cavity of the patient and an actuator mechanism positioned proximate a proximal end of the handle assembly;

a capture assembly extending from the distal portion of the shaft and adapted to be positioned within the beating heart, the capture assembly having a distal portion including a clamping mechanism adapted to grasp and release the valve leaflet and a proximal portion operably connected to the shaft, wherein one of a first clamping jaw or a second clamping jaw of the clamping mechanism is selectively positionable along a longitudinal axis of the capture assembly in response to actuation of the actuator mechanism to create a space between interior surfaces of the first clamping jaw and the second clamping jaw having an asymmetric perimeter, the capture assembly further including a plurality of pairs of fiber optic fibers, each pair of fibers having a transmission fiber and a return fiber terminated on a distal end at an interior surface of the clamping mechanism where the fiber extends through the shaft and out of the handle assembly to a proximal end beyond the handle assembly; and

a needle head slidably positionable within the capture assembly to engage a suture at least partially carried by the capture assembly in response to selective activation of a needle by the actuator mechanism as the needle penetrates the valve leaflet, and

a capture confirmation system that verifies capture of the valve leaflet in the space between the interior surfaces of the first clamping jaw and the second clamping jaw, the capture confirmation system including a housing separate from the handle assembly that contains a battery powered optical light source in optical communication with a proximal end of each transmission fiber and at least one lens visible from an exterior surface of the housing and in optical communication with a proximal end of each return fiber to display light received from the space between the interior surfaces of the first clamping jaw and

the second clamping jaw corresponding to the distal end of each return fiber as an indication of whether there is capture of the valve leaflet by the capture assembly.

21. The device of claim 20, wherein the capture confirmation system provides a binary indication of whether the valve leaflet is grasped between the interior surfaces of the first clamping jaw and the second clamping jaw by displaying a first color when a surface of the valve leaflet confronts the fiber optic pairs at the interior surfaces and a second color when the valve leaflet does not confront the fiber optic pairs at the interior surfaces.

22. The device of claim 21, wherein the first color is indicative of blood and the second color is indicative of valve leaflet.

23. The device of claim 20, wherein the optical light source is a light-emitting diode (LED), and wherein the proximal end of the transmission fiber is positioned less than 0.5 cm from the LED.

24. The device of claim 23, wherein the proximal end of the transmission fiber is positioned 0.1 cm and 0.2 cm from the LED

25. The device of claim 20, wherein each lens has a thickness of between approximately 0.2 cm and 0.5 cm.

26. The device of claim 25, wherein the thickness of each lens is between 0.3 cm and 0.35 cm.

27. The device of claim 20, wherein the proximal end of each return fiber is positioned within approximately three millimeters of the corresponding lens.

28. The device of claim 27, wherein the proximal end of each return fiber is position within approximately 1.5 to 2.0 millimeters of the corresponding lens.

29. The device of claim 20, wherein the shaft defines a needle lumen adapted to receive the needle and the pairs of fiber optic fibers are carried by the shaft outside the needle lumen.

30. The device of claim 20, wherein each pair of fiber optic fibers includes at least 1 m of length external to the handle such that the housing of the capture confirmation system is positionable proximal a separate patient display apparatus after insertion of the device into the chest cavity of the patient.

31. A device for repairing a valve leaflet in a beating heart of a patient, comprising:

a handle assembly including a shaft extending from a distal end of the handle and adapted to be extended into a chest cavity of the patient, the shaft including a first channel adapted to receive a suture and a second channel adapted to receive a needle, the handle assembly including an actuator mechanism and a suture retention mechanism;

a capture assembly extending from a distal portion of the shaft and adapted to be positioned within the beating heart, the capture assembly having a distal portion including a clamping mechanism adapted to grasp and release the valve leaflet and a proximal portion operably connected to the shaft; and

a needle head slidably positionable within the capture assembly to engage the suture at least partially carried by the capture assembly in response to selective activation of the needle by the actuator mechanism as the needle penetrates the valve leaflet, wherein the suture retention mechanism selectively tensions the suture across a path of travel of the needle through the needle head prior to engagement by the needle.

32. The device of claim 31, wherein the capture assembly defines a needle detent, the suture being substantially taught across the needle detent.

33. The device of claim 32, wherein the needle head presents a hook adapted to receive the suture.

34. A device for repairing a valve leaflet in a beating heart of a patient, comprising:

a handle assembly including a shaft extending from a distal end of the handle adapted to be extended into a chest cavity of the patient and an actuator mechanism positioned proximate a proximal end of the handle assembly;

a capture assembly extending from the distal portion of the shaft and adapted to be positioned within the beating heart, the capture assembly having a distal portion including

a clamping mechanism adapted to grasp and release the valve leaflet and a proximal portion operably connected to the shaft, wherein one of a first clamping jaw or a second clamping jaw of the clamping mechanism is selectively positionable along a longitudinal axis of the capture assembly in response to actuation of the actuator mechanism to create a space between interior surfaces of the first clamping jaw and the second clamping jaw; and

a needle head slidably positionable within the capture assembly to engage a suture at least partially carried by the capture assembly in response to selective activation of a needle by the actuator mechanism as the needle penetrates the valve leaflet,

wherein at least one of the handle assembly or the capture assembly includes a biasing member adapted to bias at least one of the first clamping jaw and the second clamping jaw with respect to one another such that selective actuation of the actuator mechanism overcomes the biasing member before the space is created or closed between the interior surfaces of the first clamping jaw and the second clamping jaw.

35. The device of claim 34, wherein the first clamping jaw and the second clamping jaw are biased toward a closed position.

36. The device of claim 34, wherein the biasing member exerts a force of between approximately one pounds per square-inch and ten pounds per square-inch.

37. The device of claim 36, wherein the biasing member exerts a force of approximately five pounds per square-inch.

38. A method of repairing a valve leaflet in a beating heart of a patient by using any of the devices of claims 1-37.

39. A method of providing instruments and instructions for repairing a valve leaflet comprising:

providing the devices of claims 1-37; and

providing instructions for operating the devices of claims 1-37 to repair the valve leaflet.

40. A valve repair device with a replaceable suture cartridge for repair of a valve leaflet in a beating heart of a patient, comprising:

a valve repair device including a main shaft with a proximal end outside the patient and a distal end adapted for insertion into the beating heart of the patient, a handle with an actuator operably connected to the proximal end of the main shaft, a capture assembly operably coupled to the distal end of the main shaft including one portion of a jaw assembly adapted to grasp the valve leaflet in response to selective actuation of the actuator, and a needle head slidably positionable within the capture assembly to penetrate the valve leaflet; and

a replaceable suture cartridge including a secondary shaft having a distal portion including a second portion of the jaw assembly integrally couplable to the capture assembly and a proximal end releasably couplable to the handle and the actuator, the secondary shaft being adapted to slidingly engage structure defined along the main shaft such that the actuator is actuatable to selectively position the second portion of the jaw assembly along a longitudinal axis the capture assembly, the replaceable suture cartridge including structure defining a channel within which a suture is carried, the suture having a loop portion presented proximate the jaw assembly when the replaceable suture cartridge is engaged with the valve repair device.

41. The valve repair device of claim 40, wherein the replaceable suture cartridge further comprises a means for retaining the suture.

42. The valve repair device of claim 40, wherein the secondary shaft defines a proximally located suture channel adapted to receive the suture, the replaceable suture cartridge further comprising a biasing member adapted forceably retain a portion of the suture within the suture channel.

43. The valve repair device of claim 42, wherein the needle head is slidably positionable within the channel to engage the suture at a fully extended position, the suture retention system being adapted to release the suture from the biasing member when the needle head reaches the fully extended position.

44. The valve repair device of claim 40, wherein the handle includes a release button, and wherein the replaceable suture cartridge is configured such that actuation of the release button causes the secondary shaft to disengage from the handle.

45. The valve repair device of claim 40, wherein the loop portion of the suture is adapted for the formation of a girth knot.

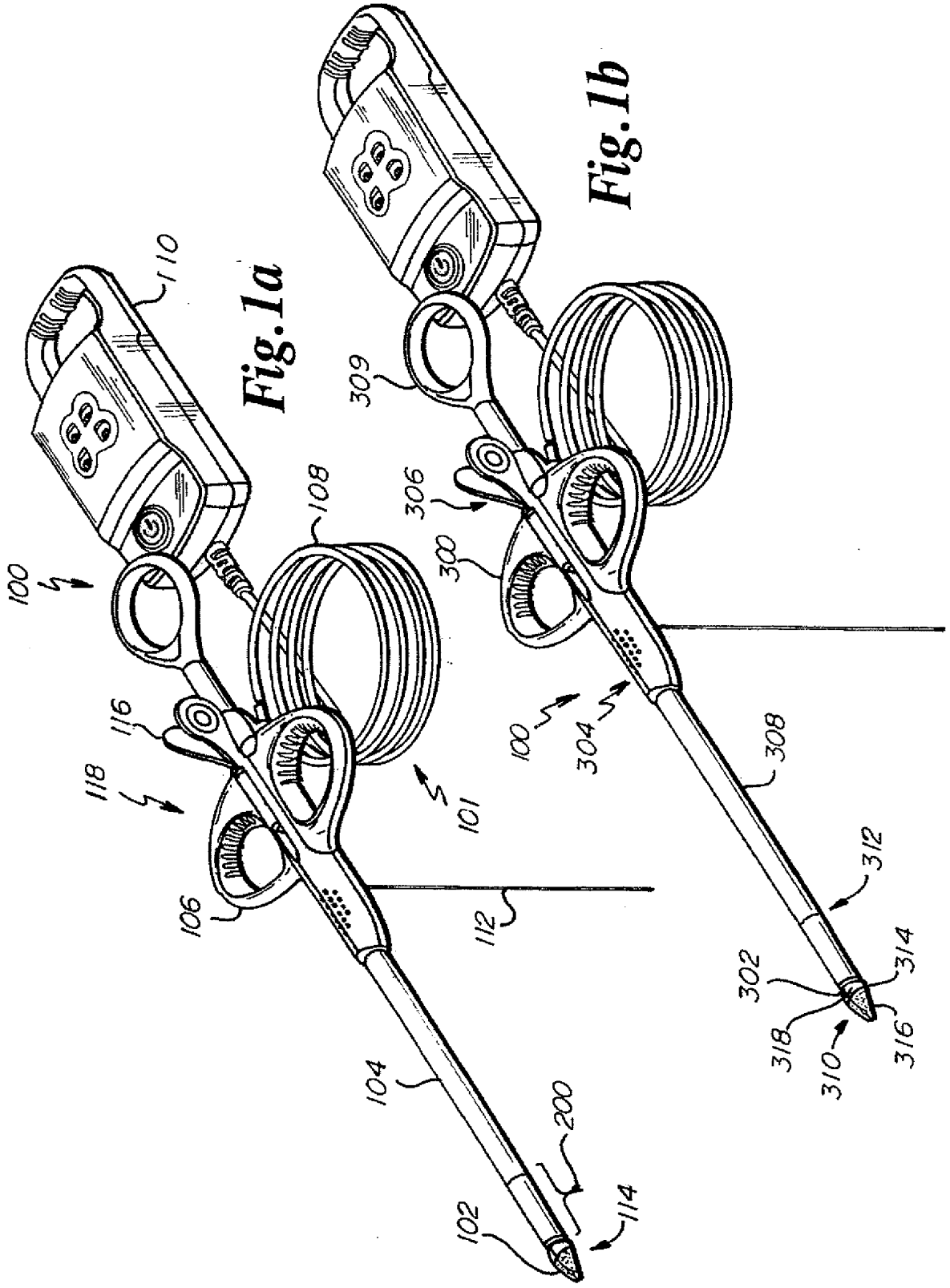
46. The valve repair device of claim 40, wherein the loop portion of the suture is adapted for the formation of an Alfieri stitch.

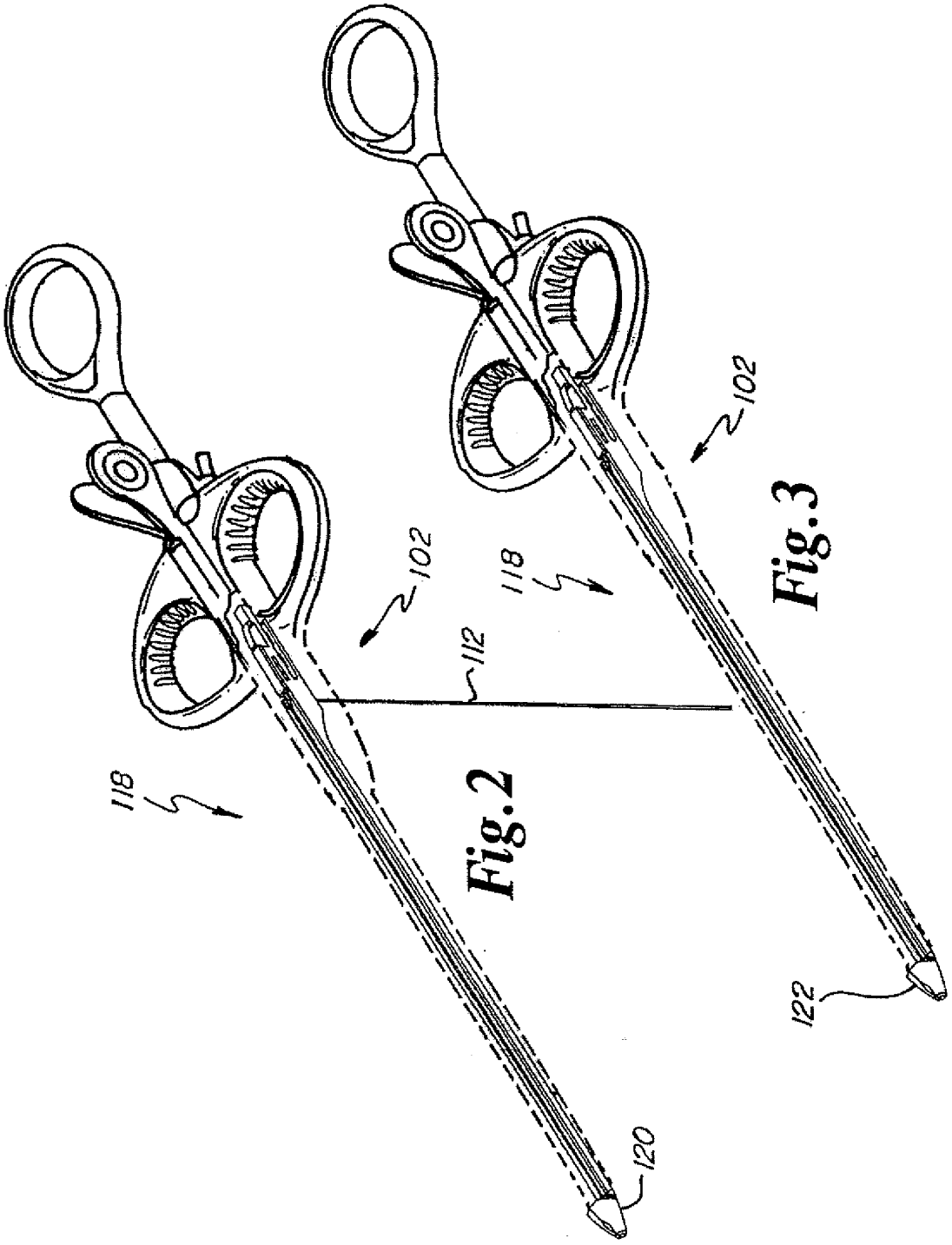
47. The valve repair device of claim 40, wherein the distal portion of the secondary shaft includes a first channel adapted to receive the loop portion and a second channel adapted to receive the needle head when actuated to an extended position, the second channel interfacing with the first channel to present the loop portion to the needle head in the extended position.

48. The valve repair device of claim 40 wherein a plurality of the replaceable suture cartridges and the valve repair device are provided together as a kit.

49. A method of using the valve repair device and the replaceable suture cartridge of claim 1 as part of a valve repair operation.

50. A method of providing the valve repair device and the replaceable suture cartridges of claim 1 and providing instructions for using the replaceable suture cartridge together with the valve repair device to perform a valve repair operation.





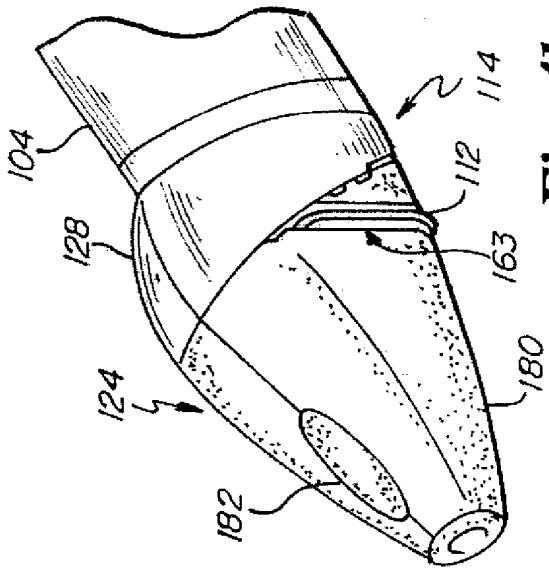


Fig.4b

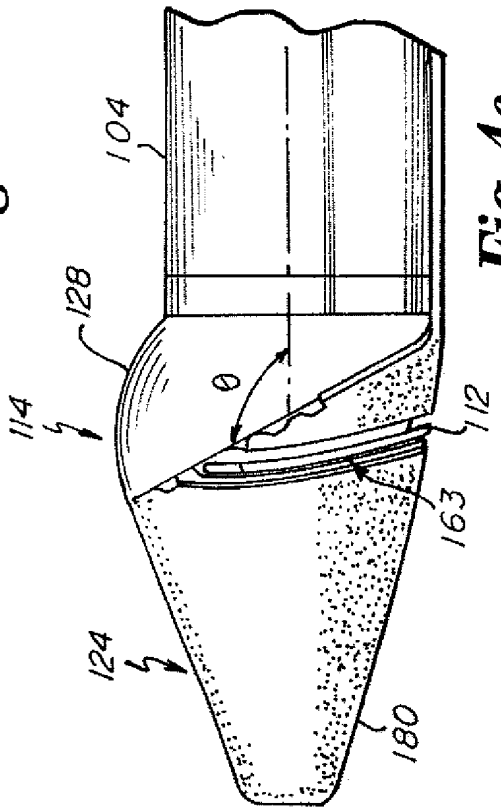


Fig.4c

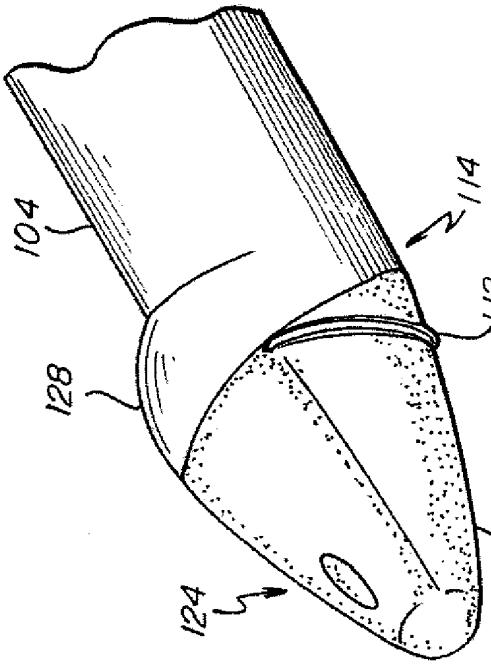


Fig.4a

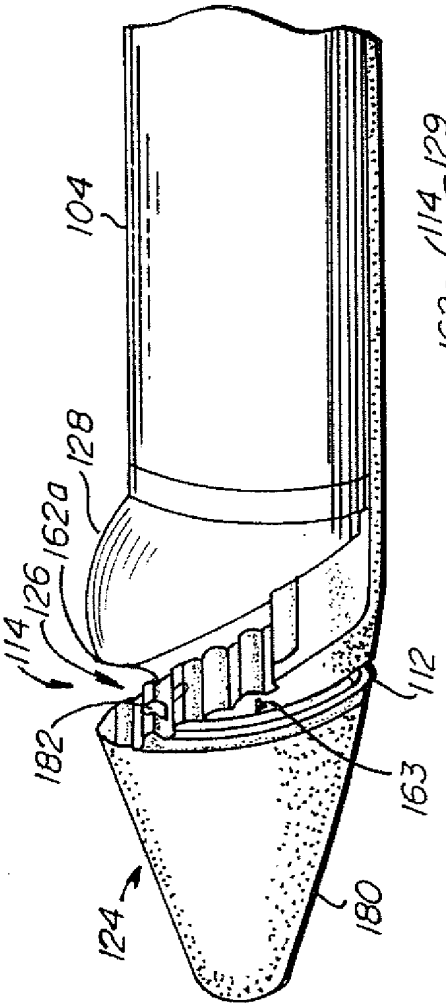


Fig. 4d

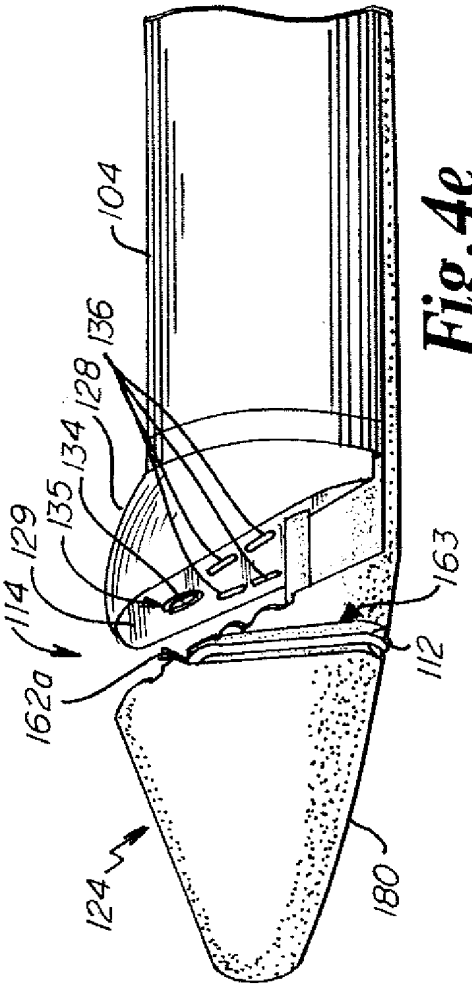


Fig. 4e

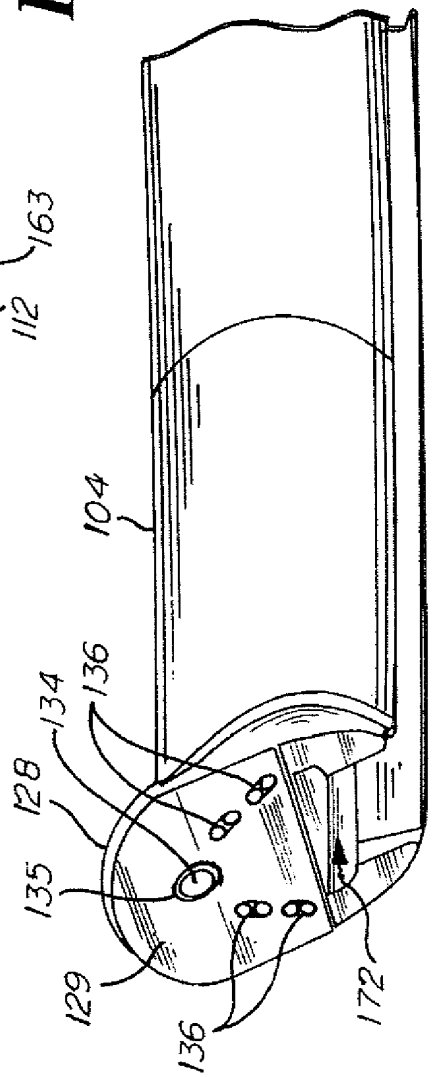
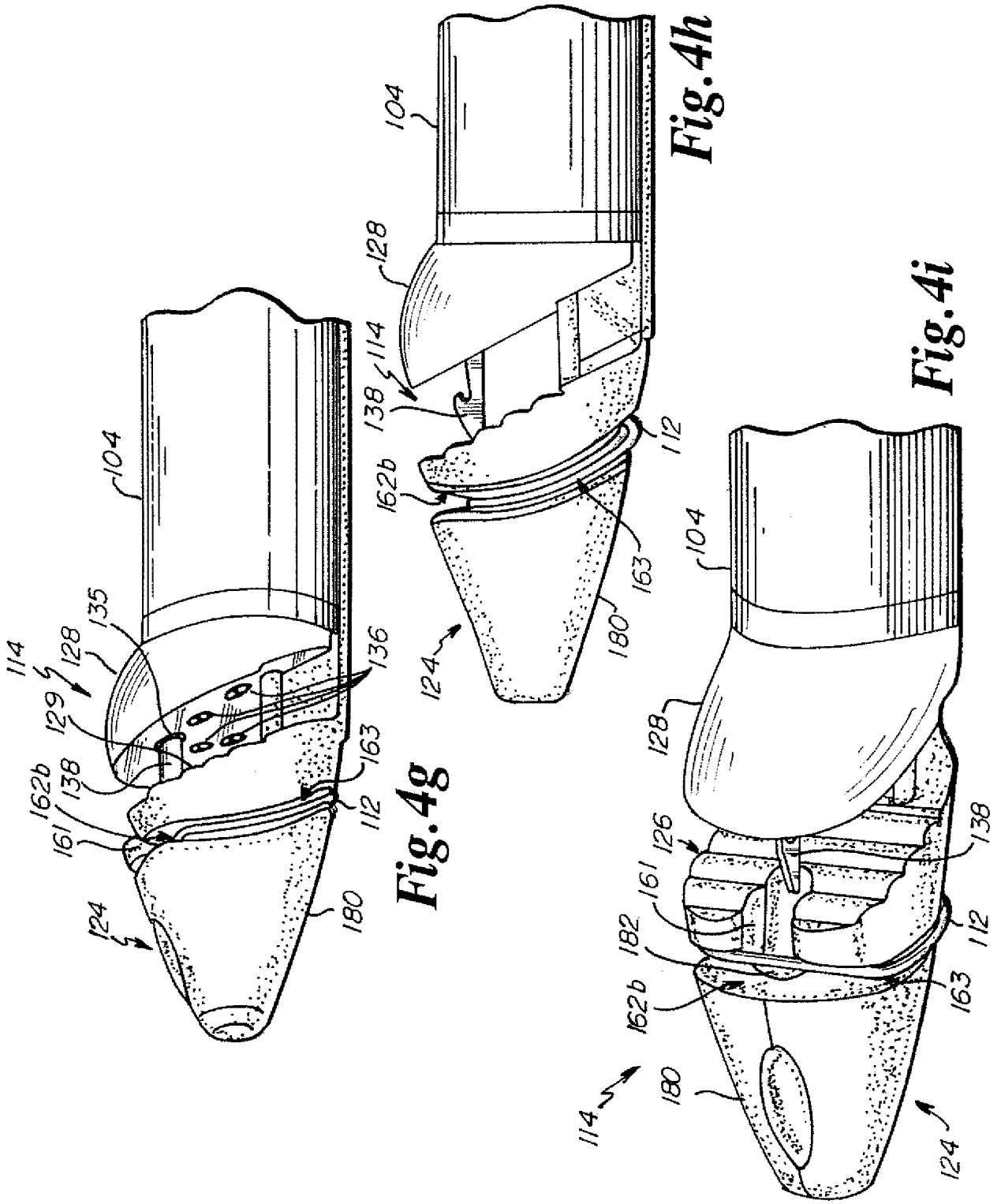


Fig. 4f


104
128
114
138
112
162b
163
180
124
135
136
129
161
Fig.4g
Fig.4h
126
182
Fig.4i

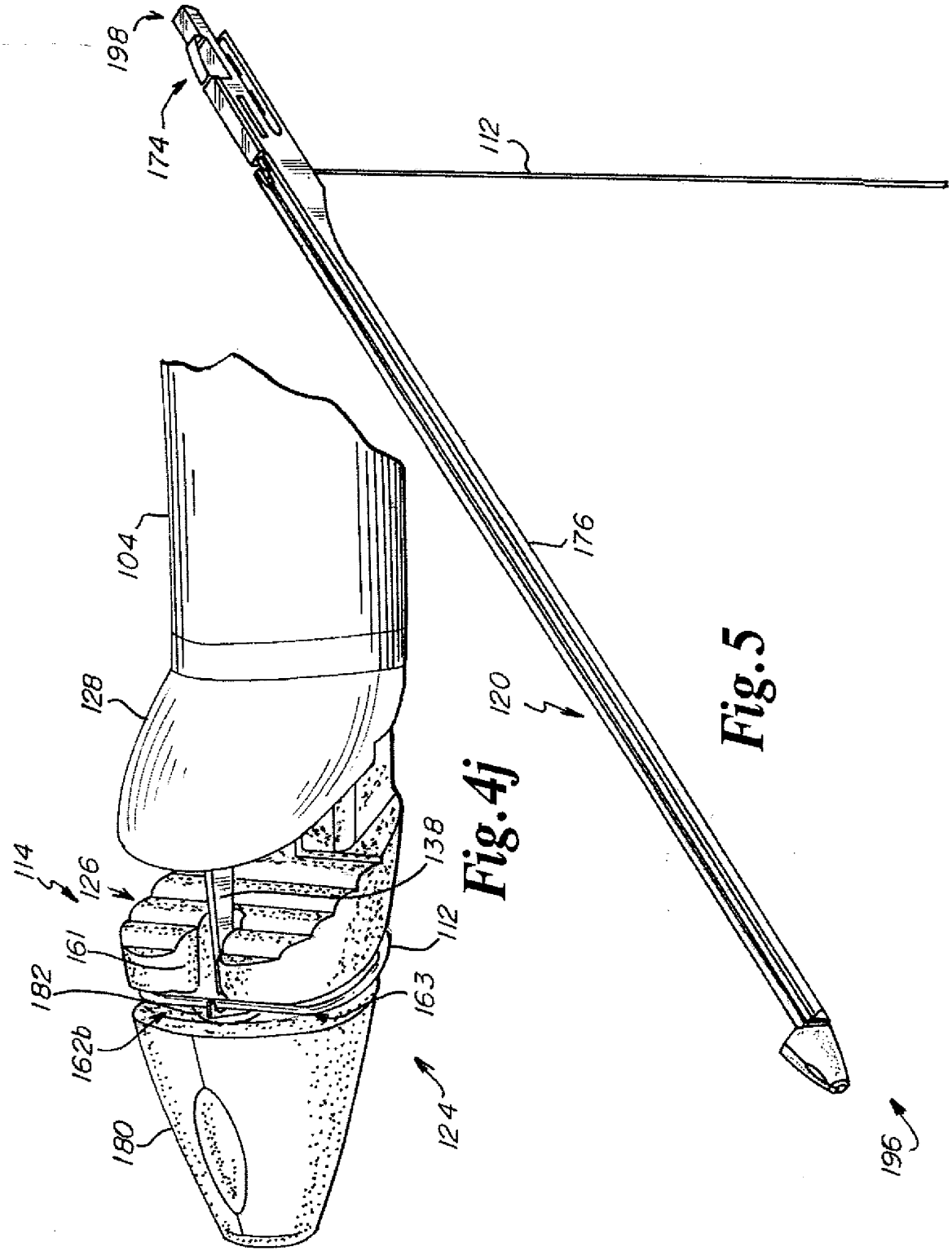
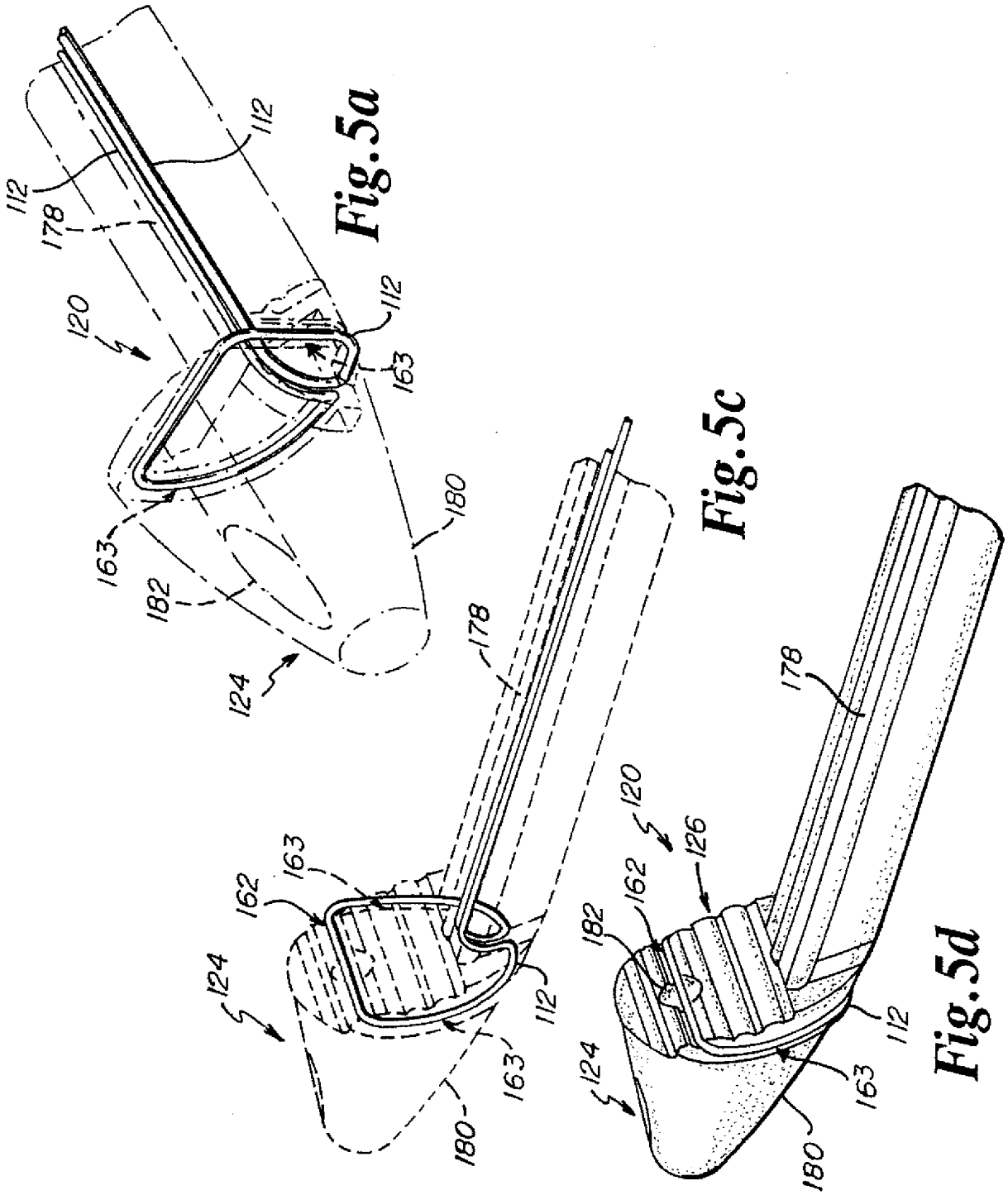


Fig.4j

Fig.5



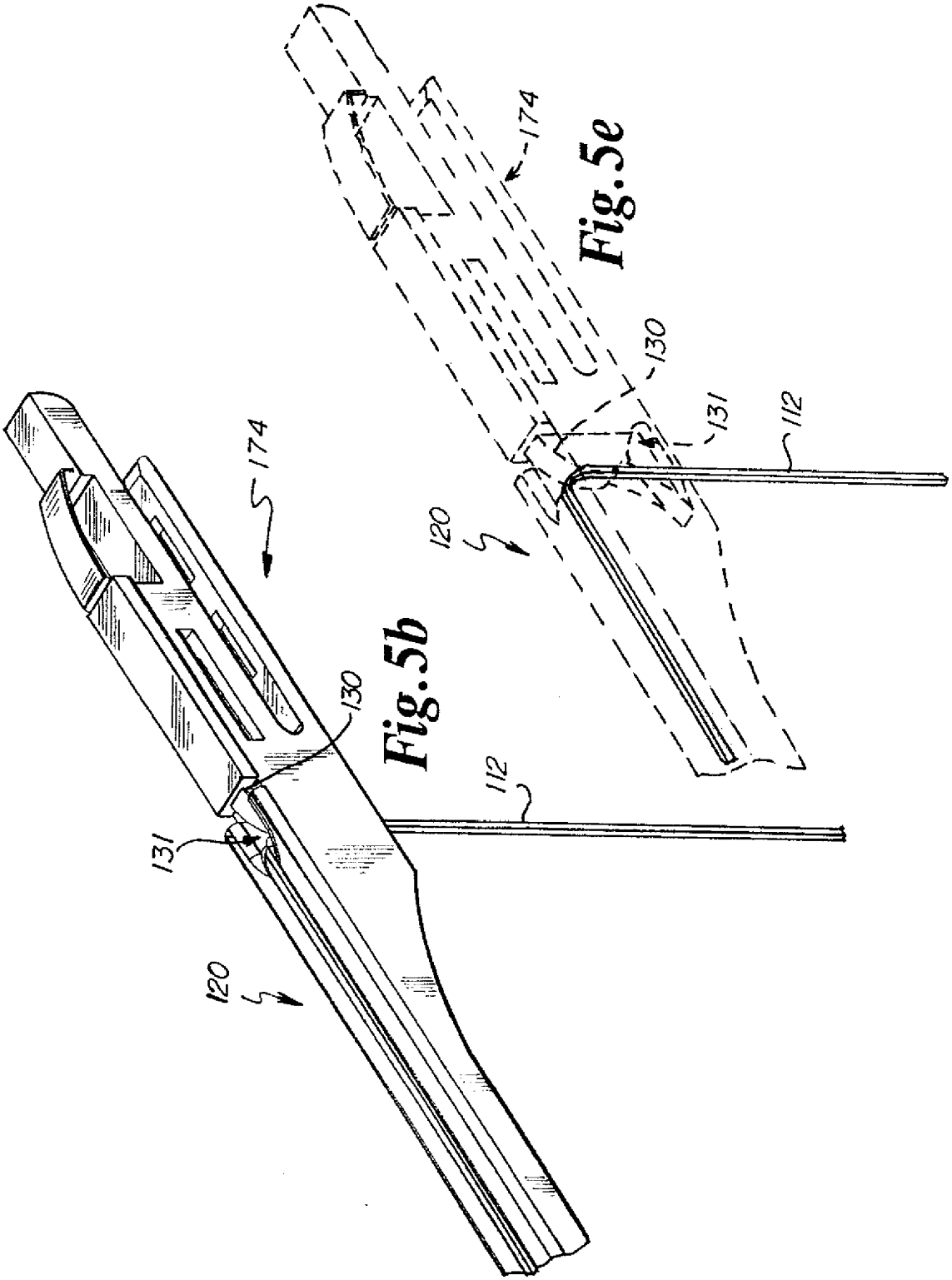


Fig. 5e

Fig. 5b

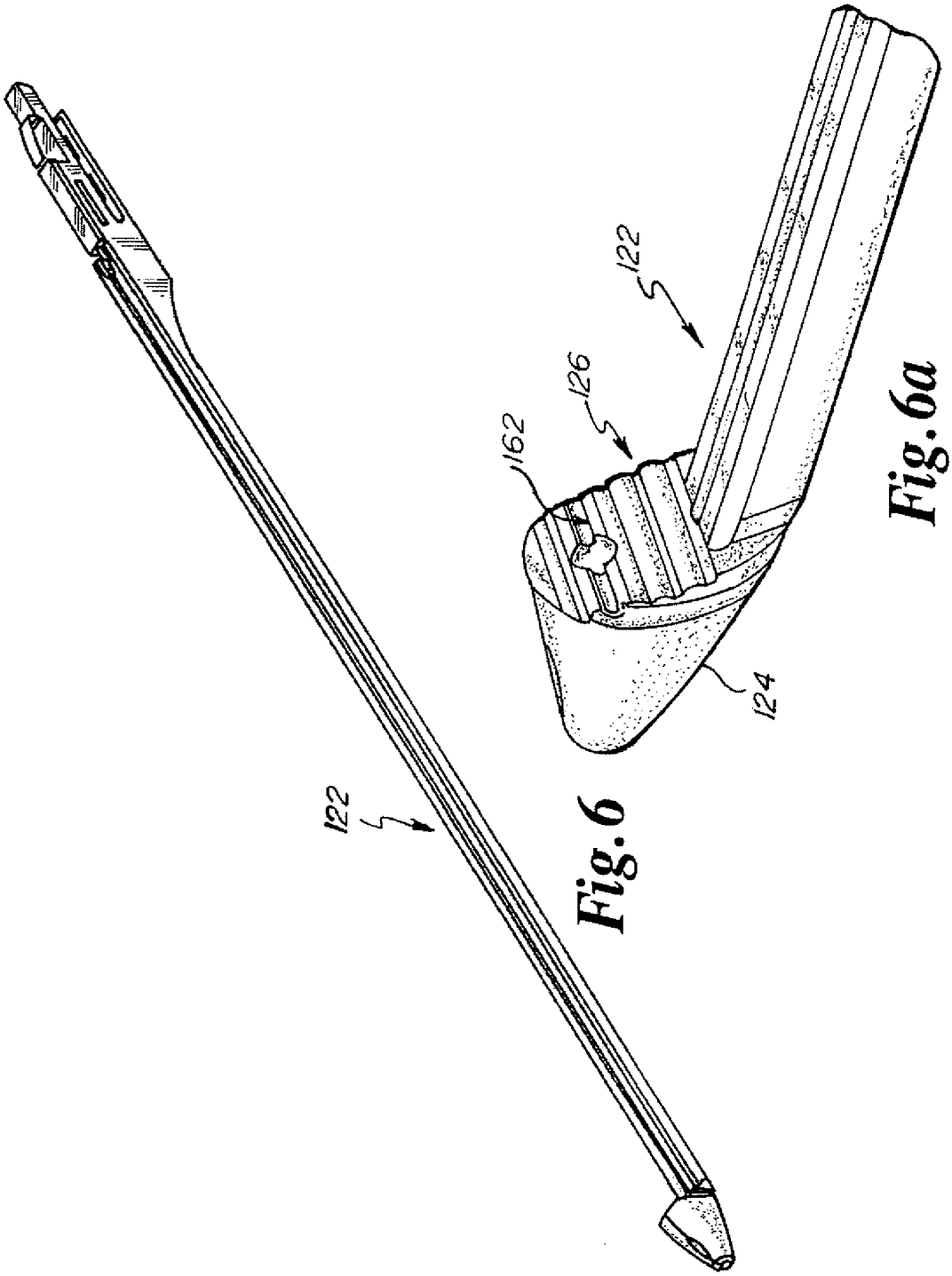


Fig. 6a

Fig. 6

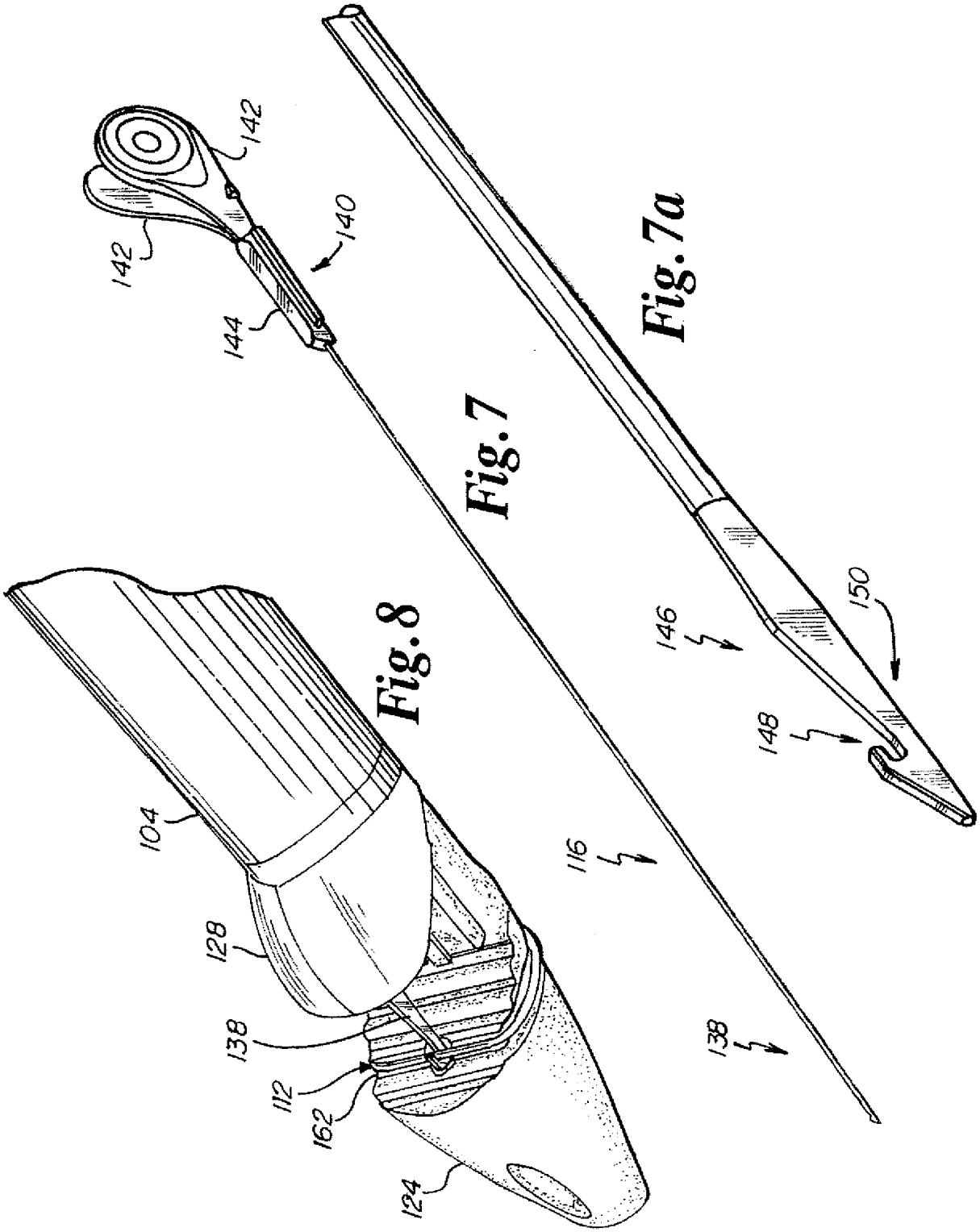


Fig. 7

Fig. 7a

Fig. 8

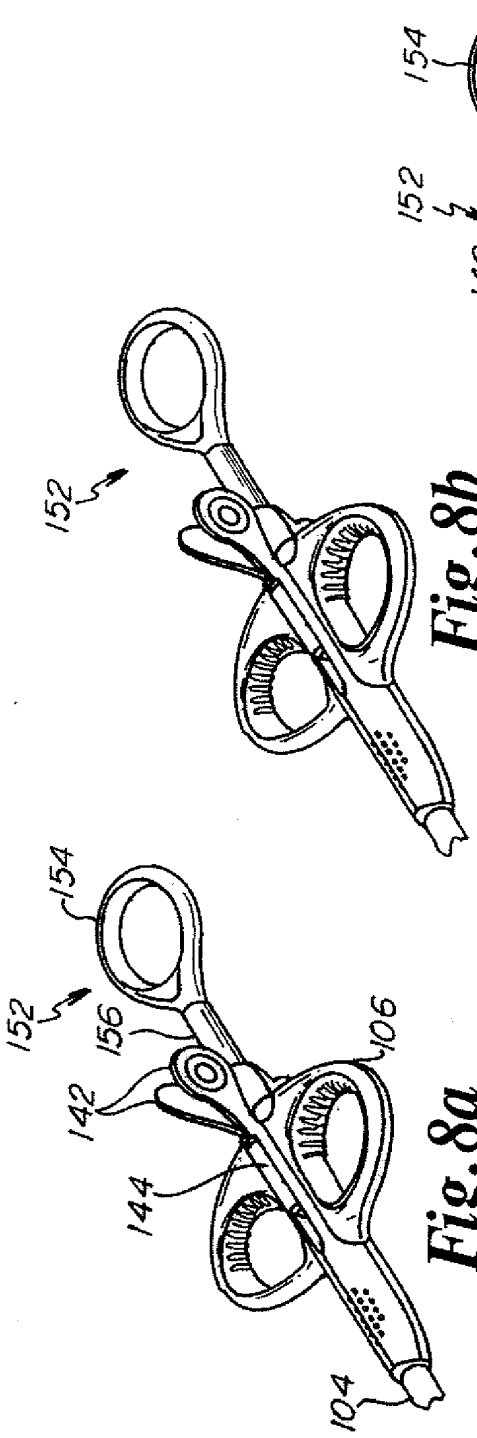


Fig. 8a

Fig. 8b

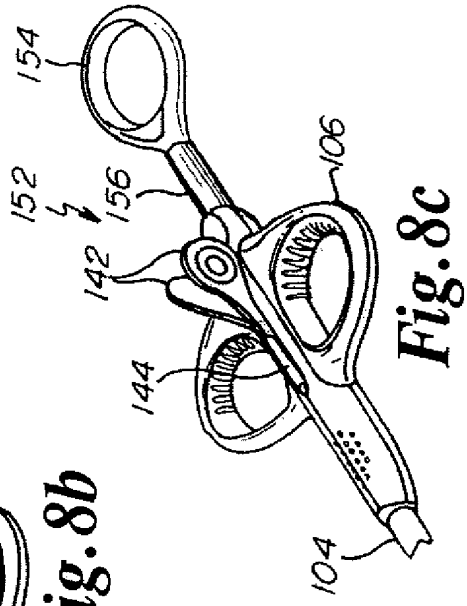


Fig. 8c

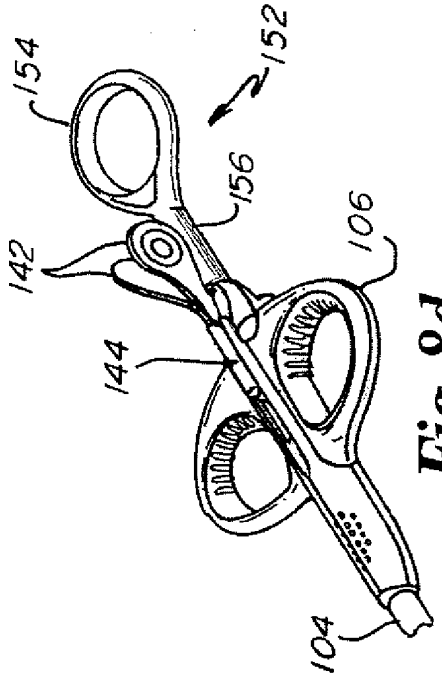


Fig. 8d

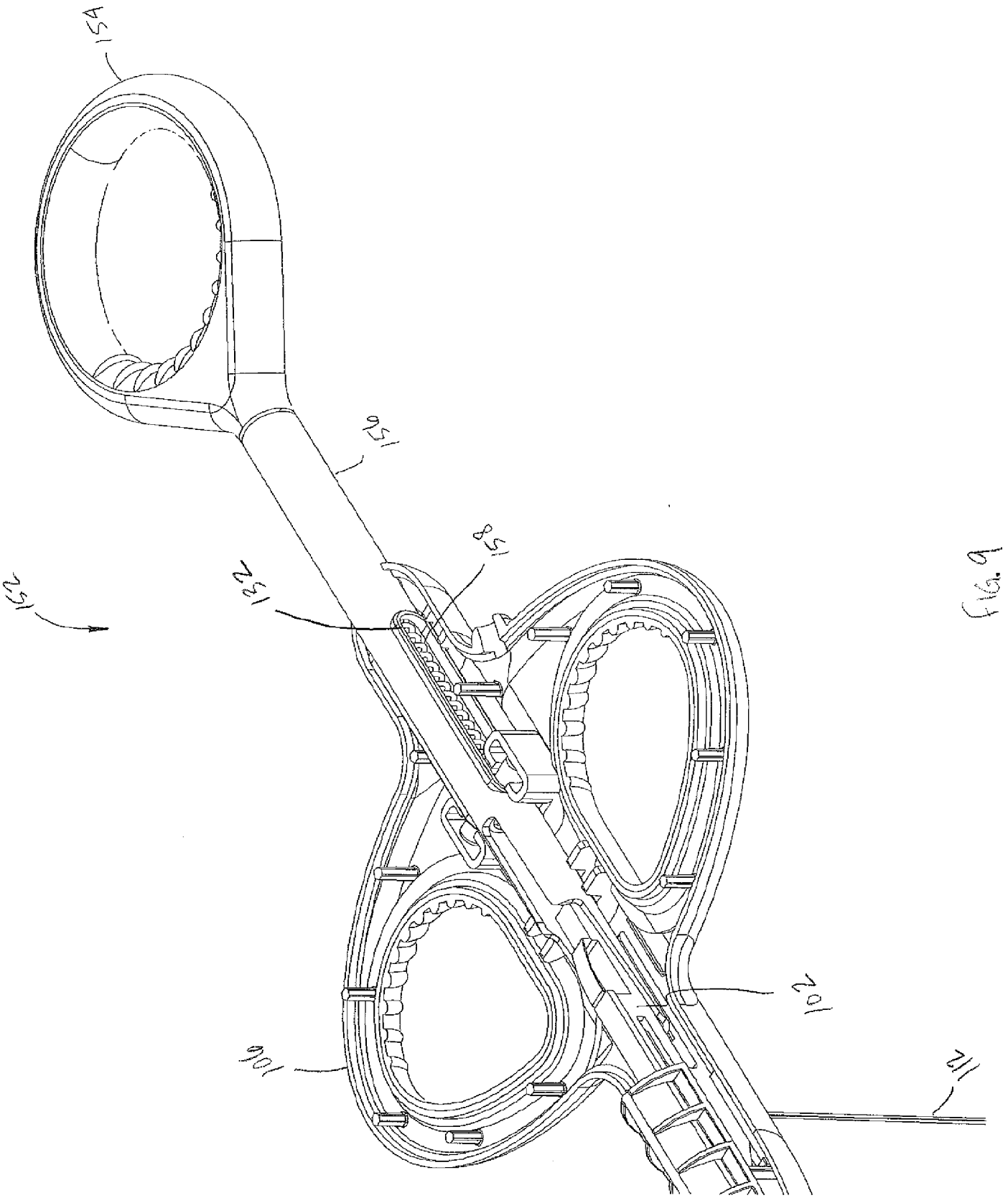


FIG. 9

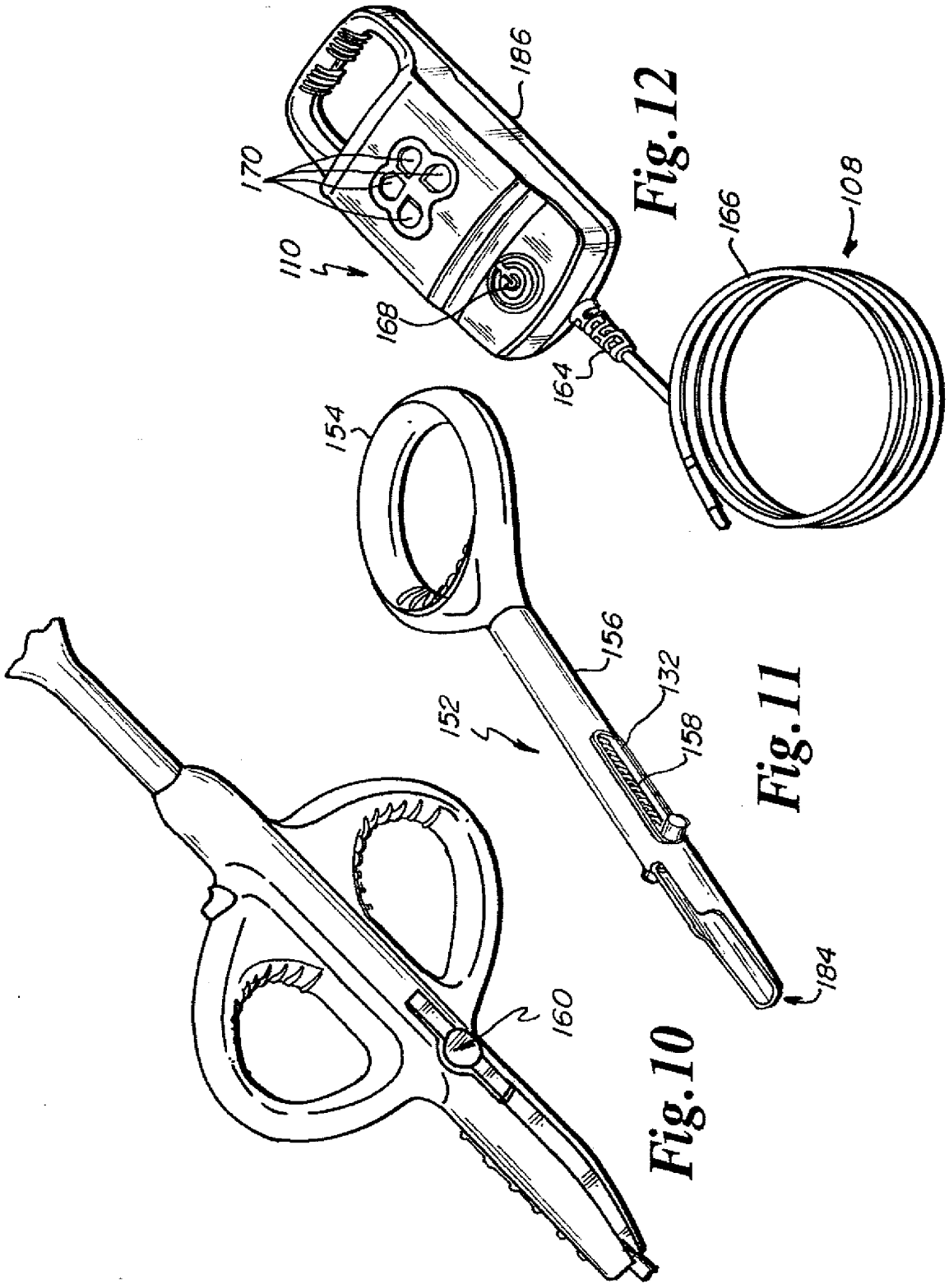


Fig. 12

Fig. 11

Fig. 10

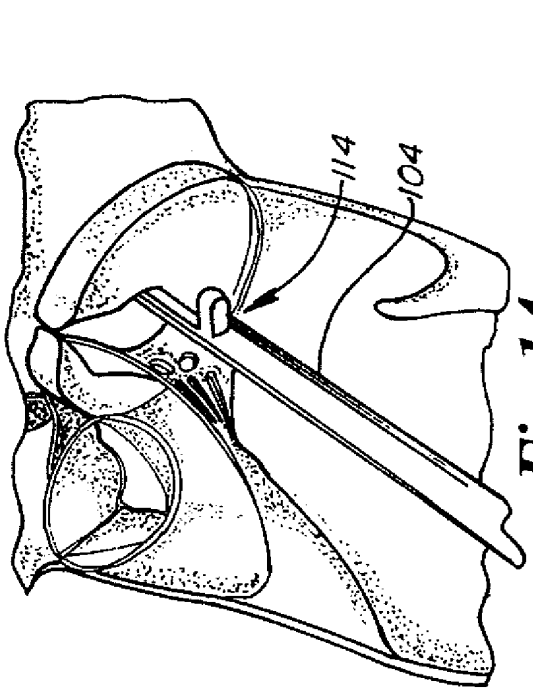


Fig. 14

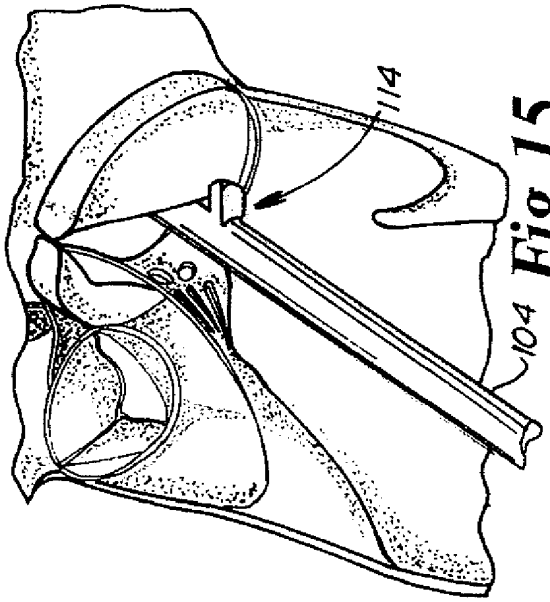


Fig. 15

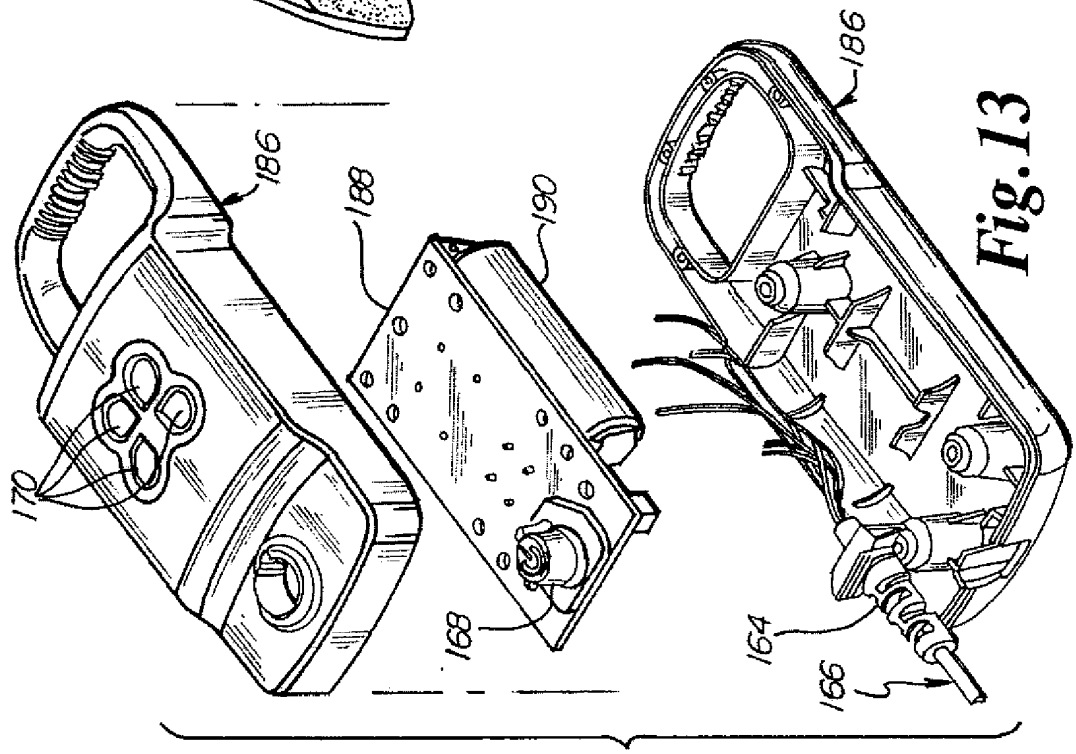


Fig. 13

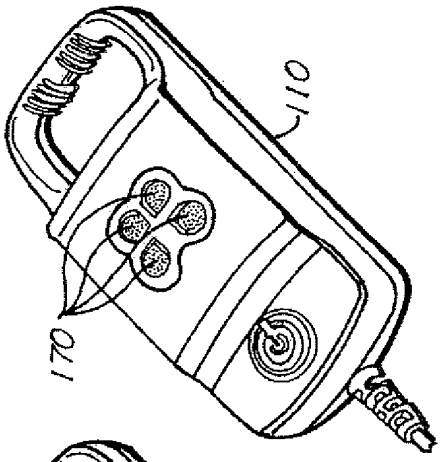


Fig.18

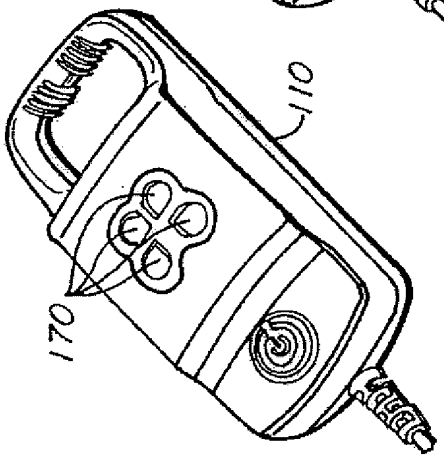


Fig.17

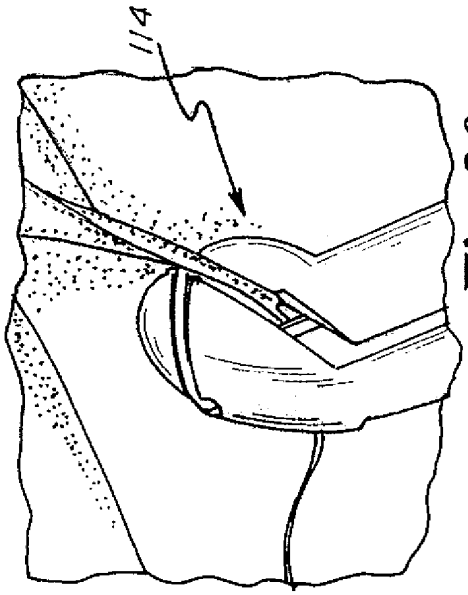


Fig.20

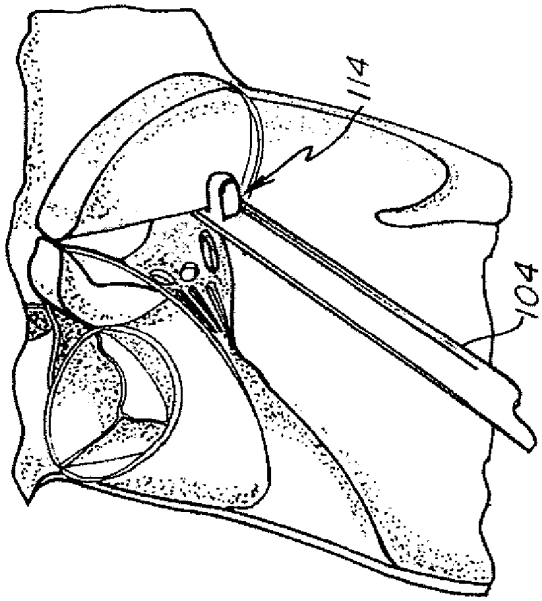
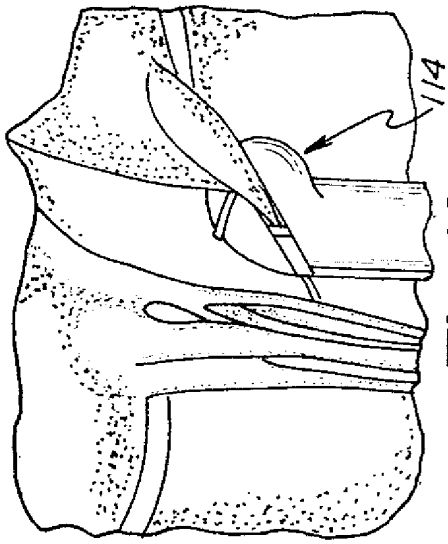


Fig.16



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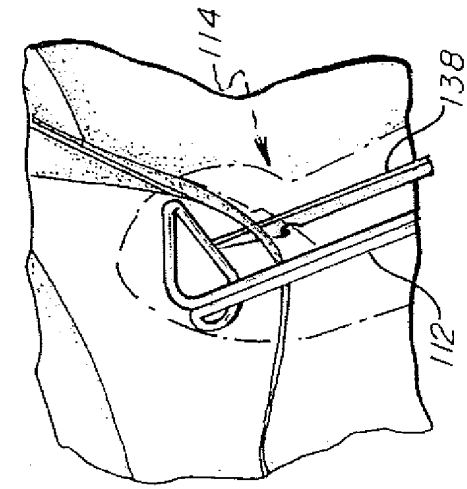
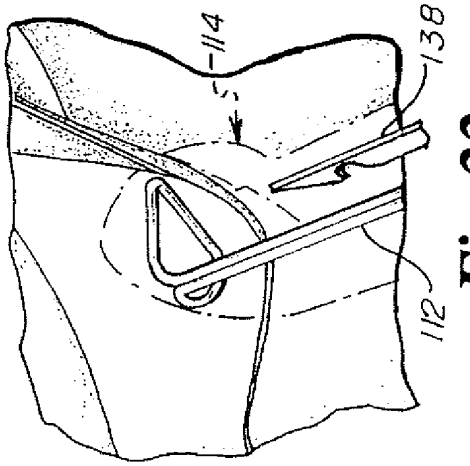


Fig.23



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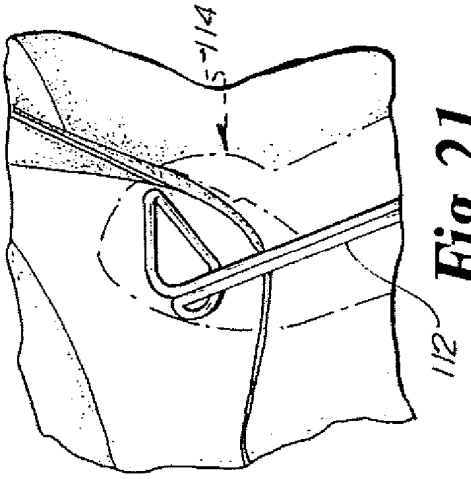

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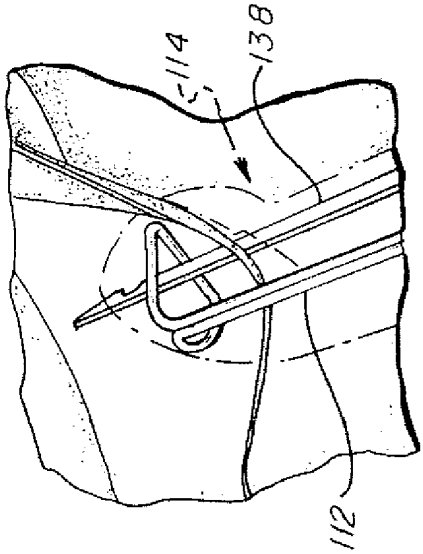

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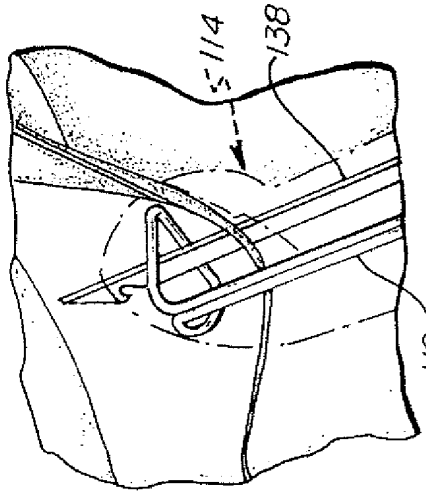
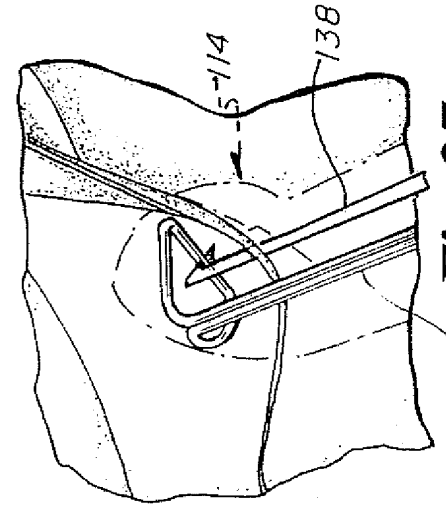


Fig.24.



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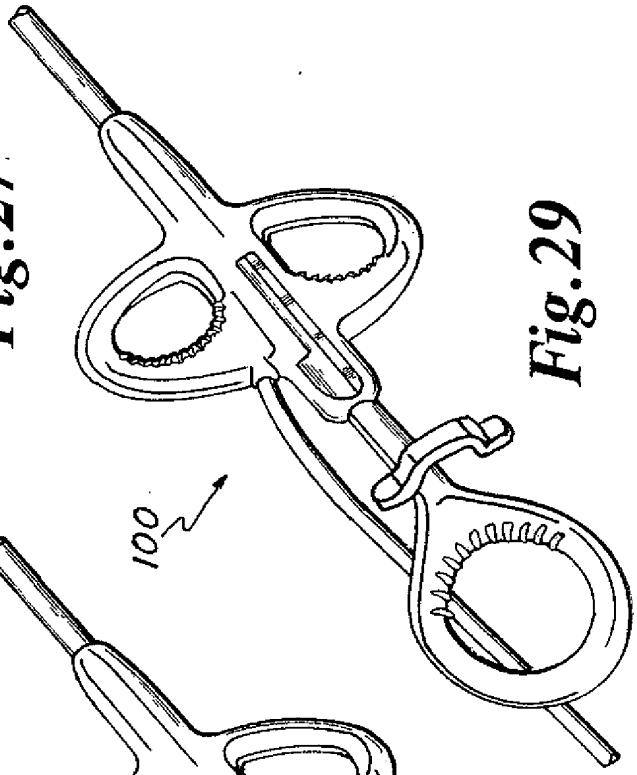

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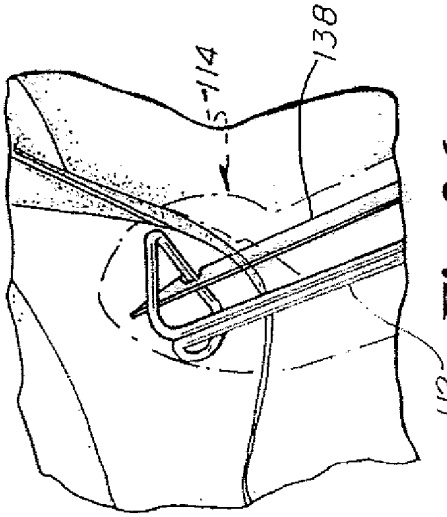

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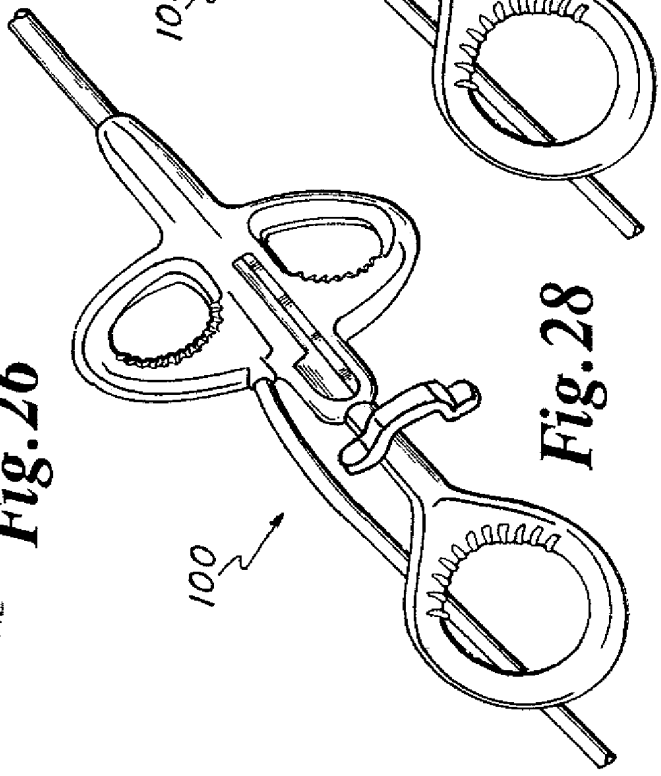

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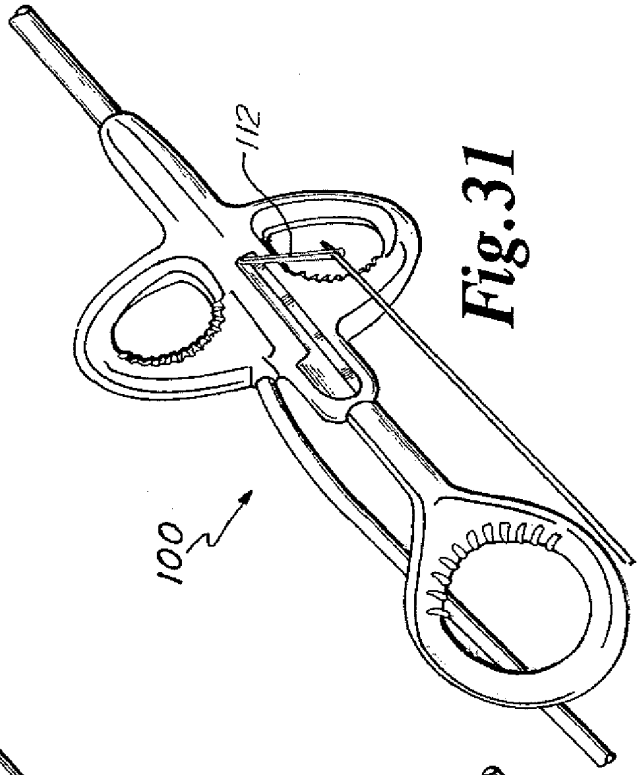


Fig.31

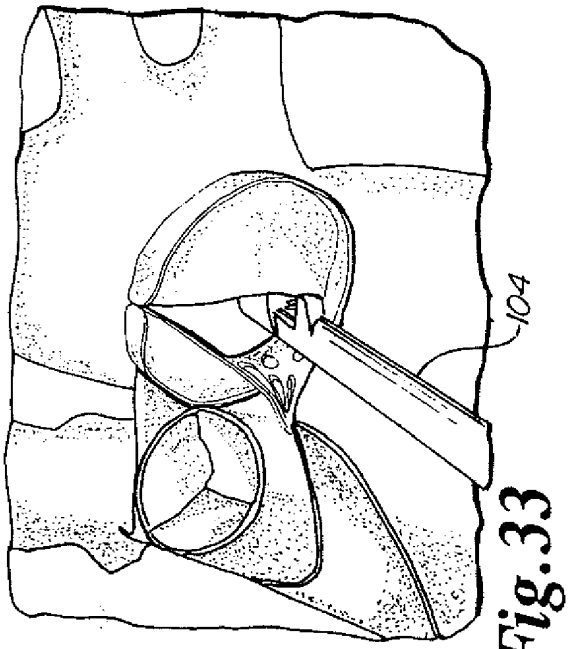


Fig.33

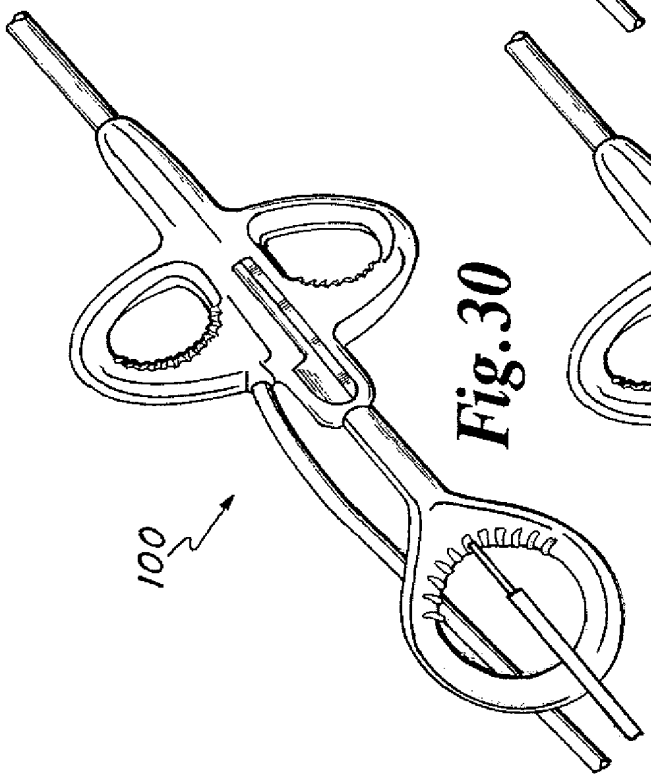


Fig.30

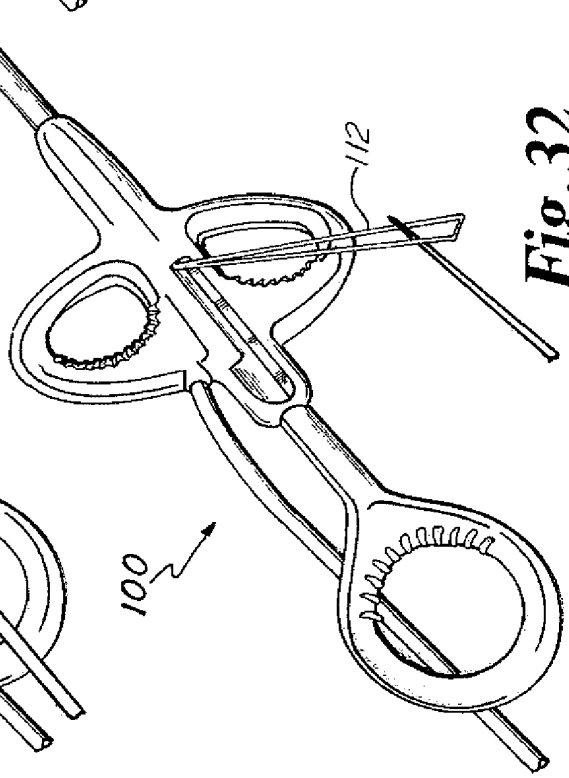


Fig.32

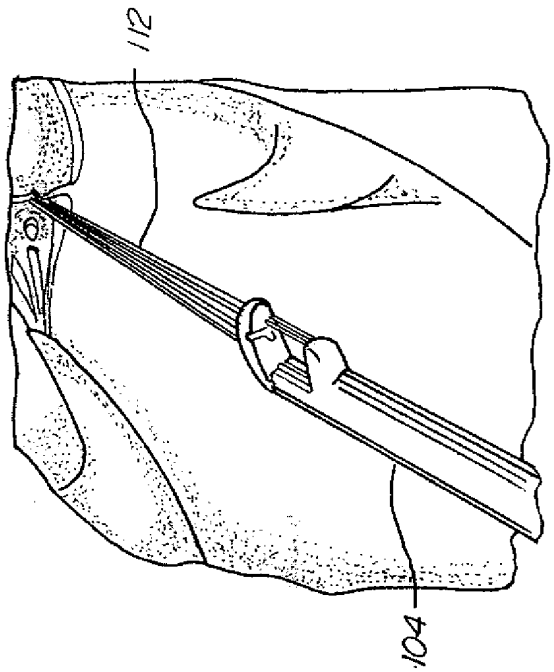


Fig.35

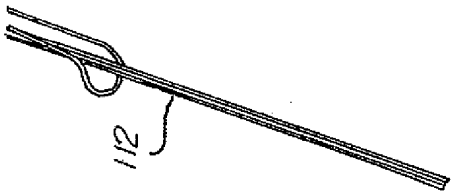


Fig.38

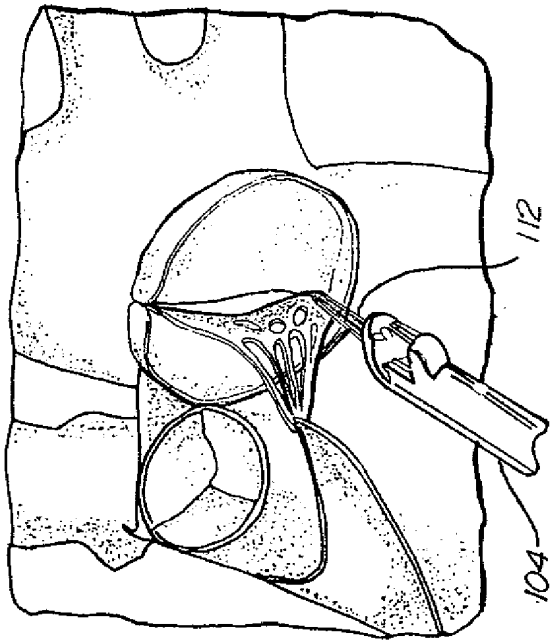
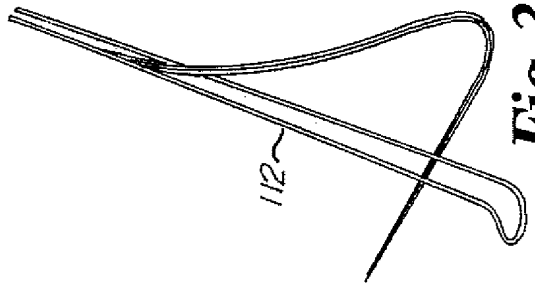


Fig.34



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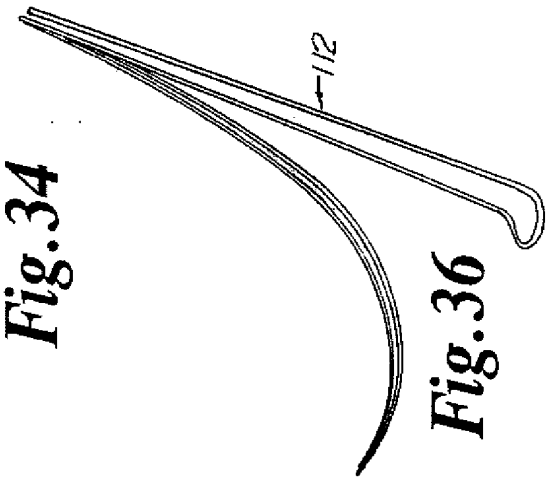

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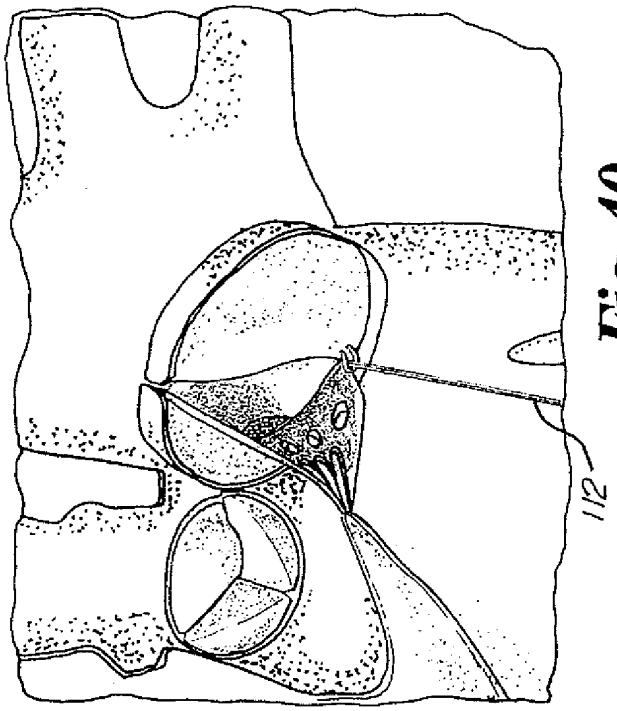
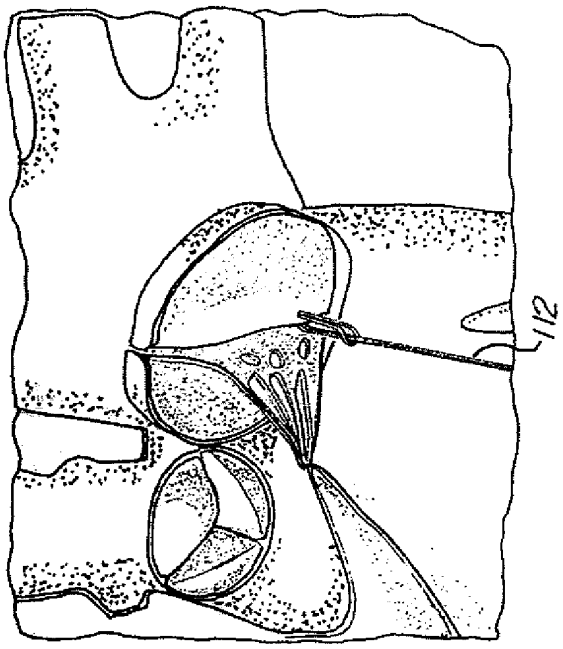


Fig.40



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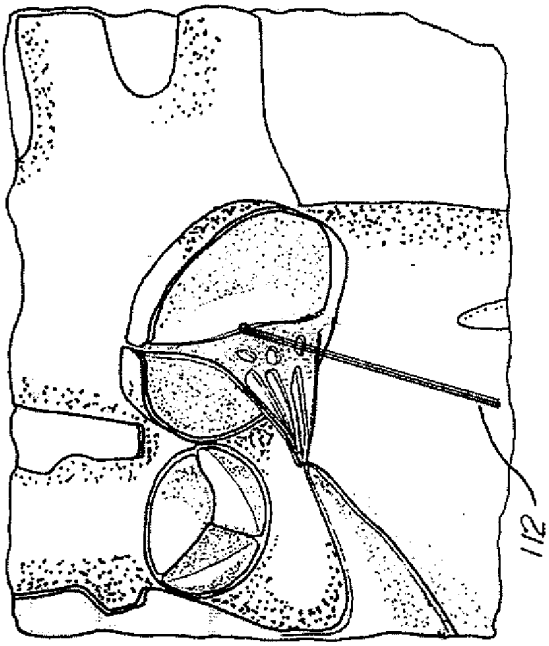

Fig.41

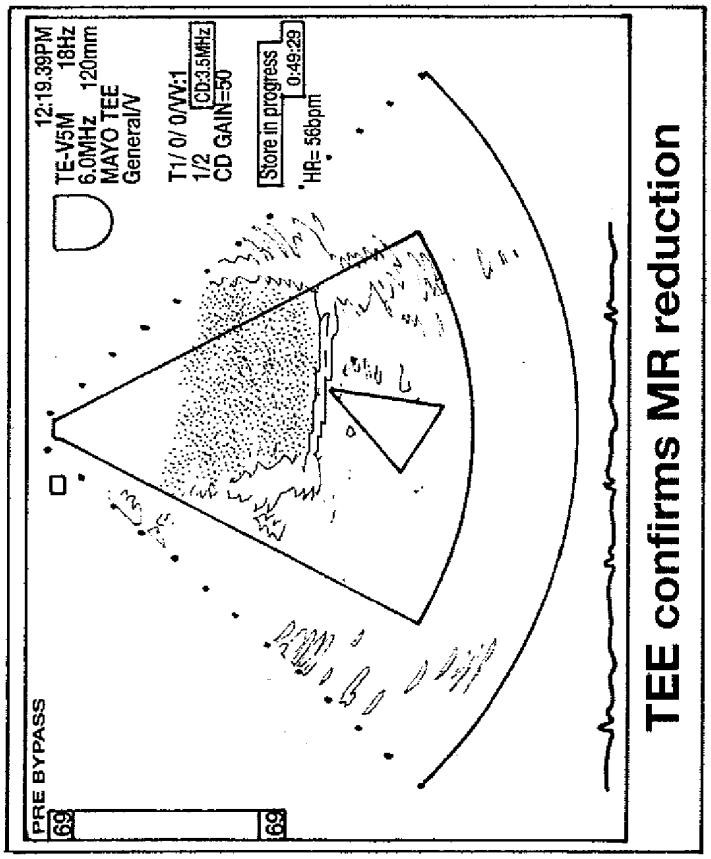

Fig.42

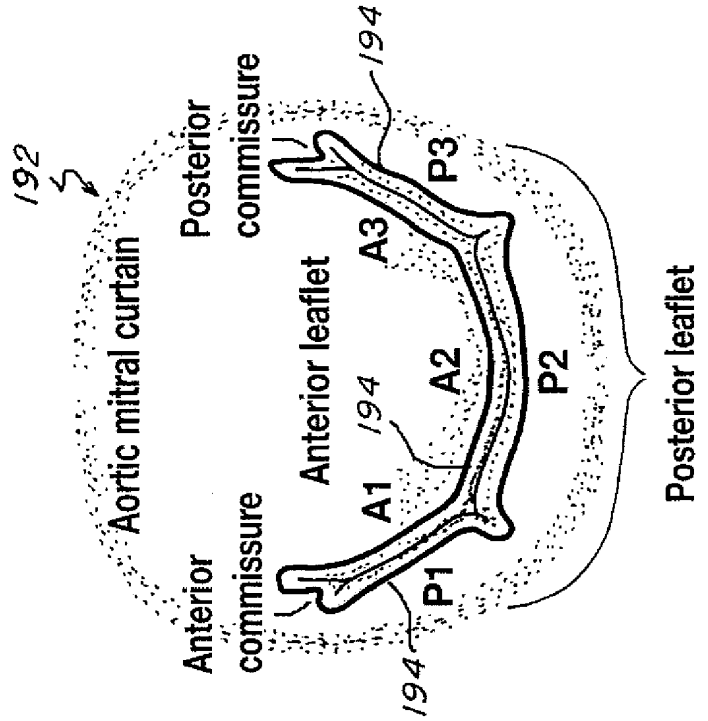

Fig.43
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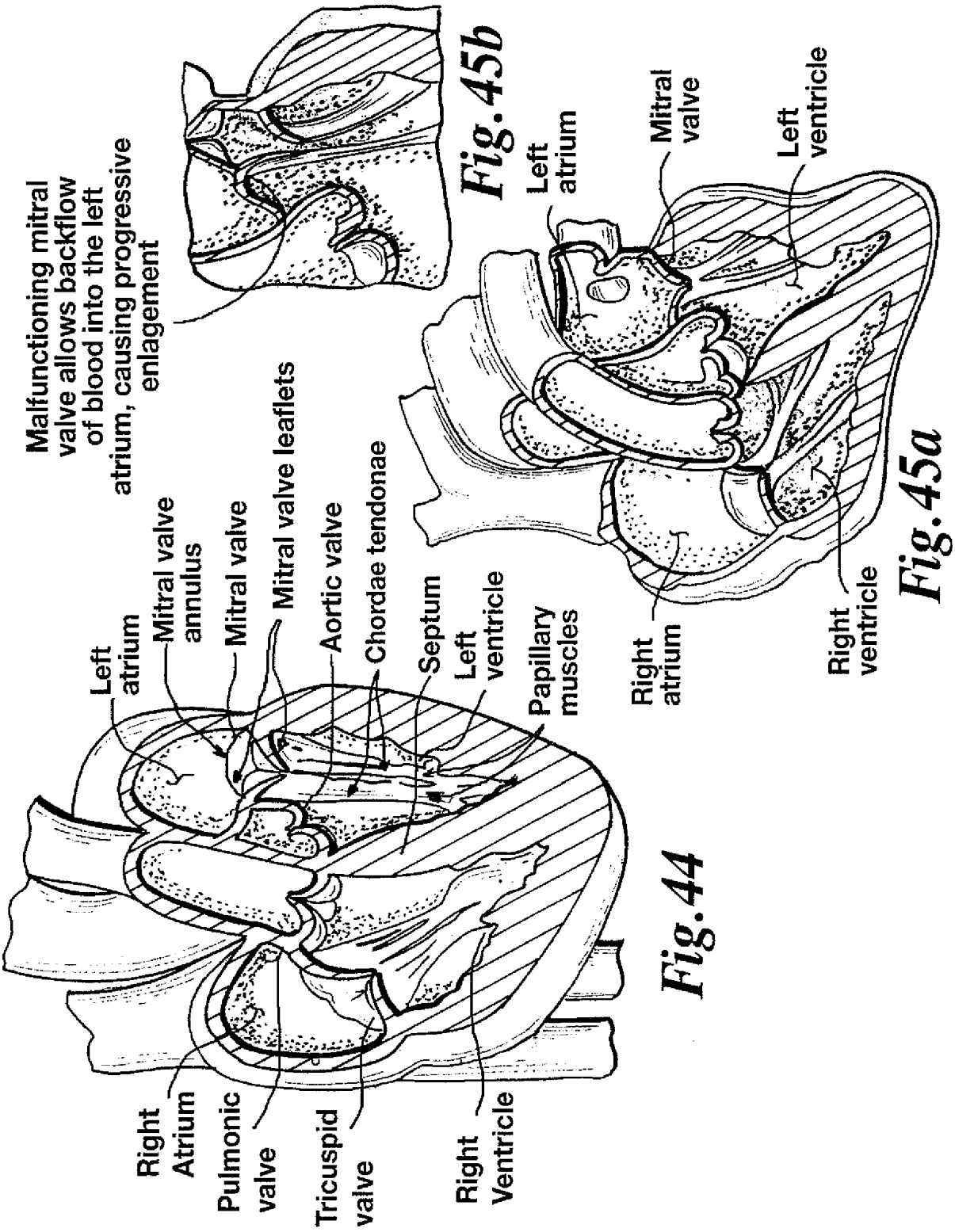

Fig. 45b

Fig. 45a

Fig. 44

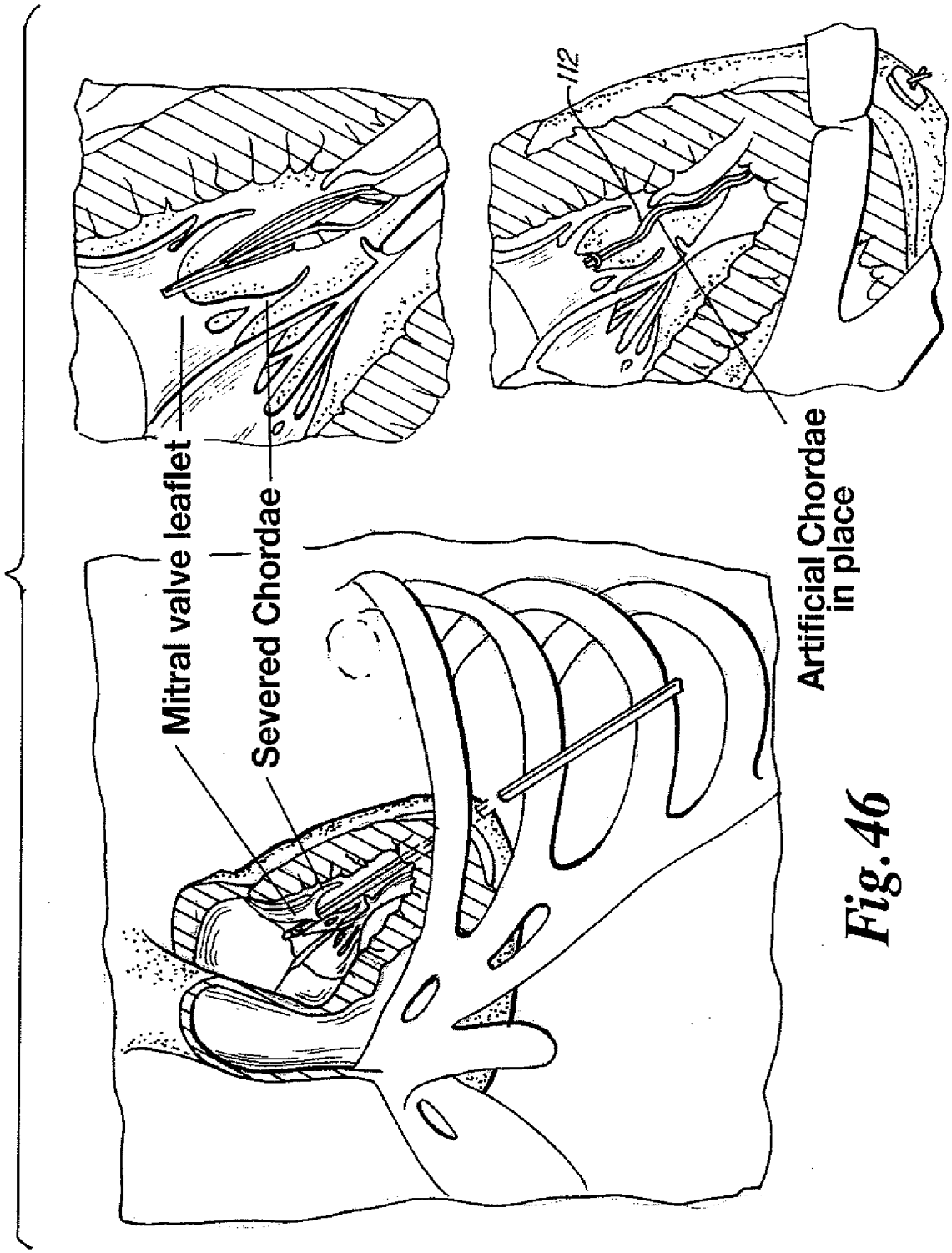

Fig. 46

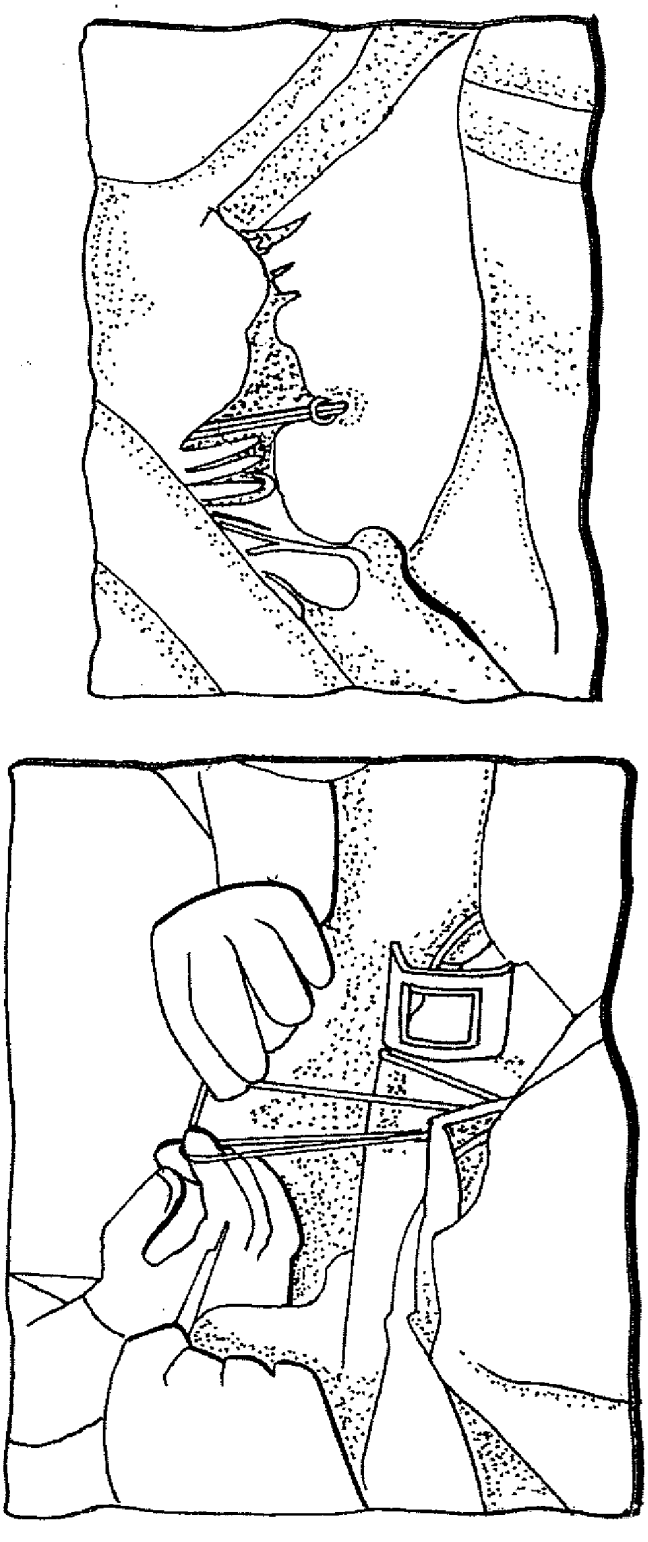

Fig.47

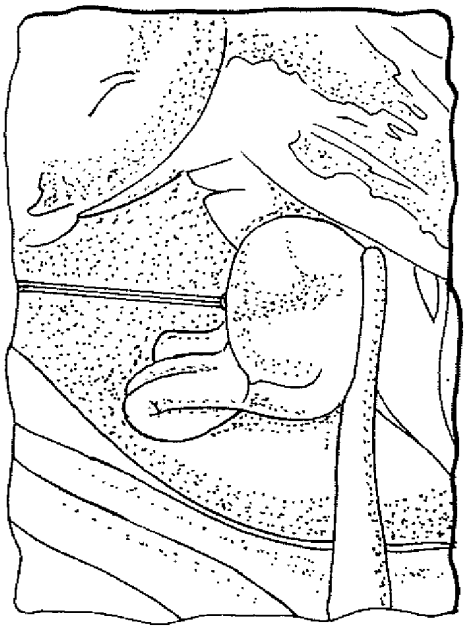

Fig.48

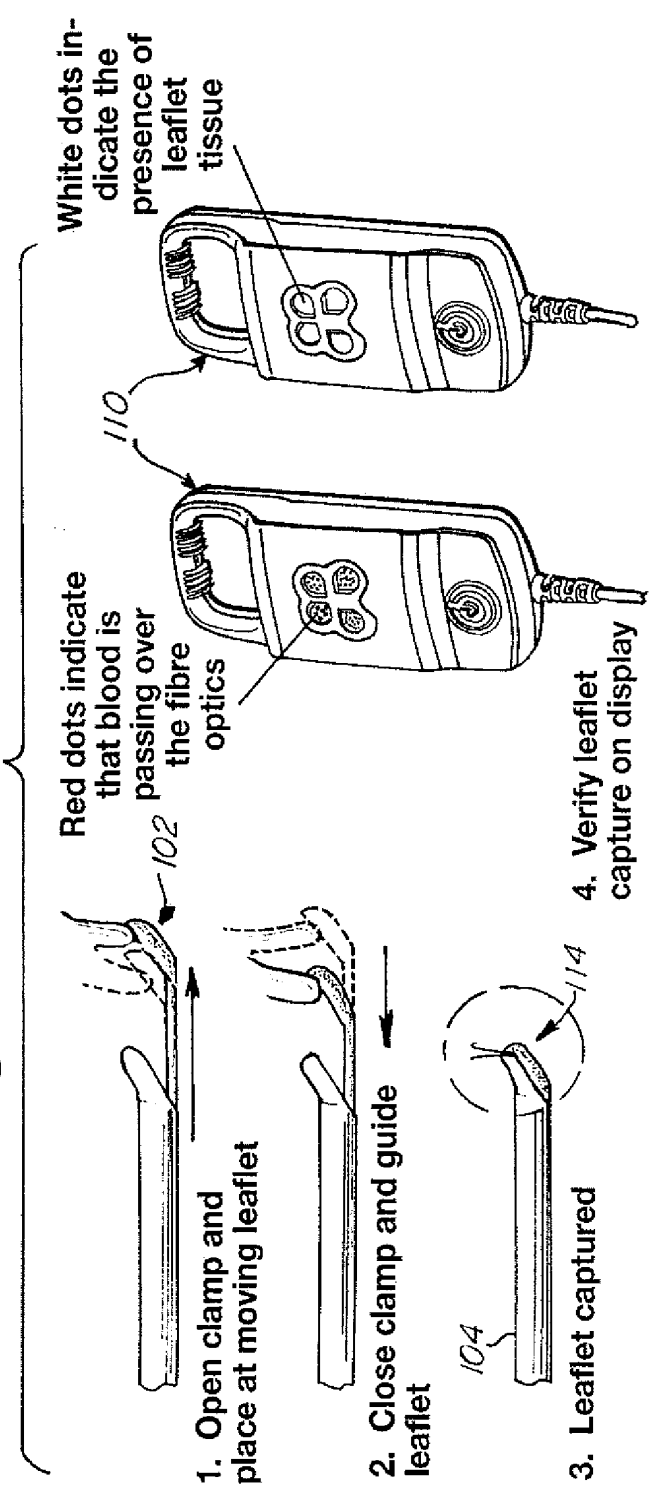

Fig.49

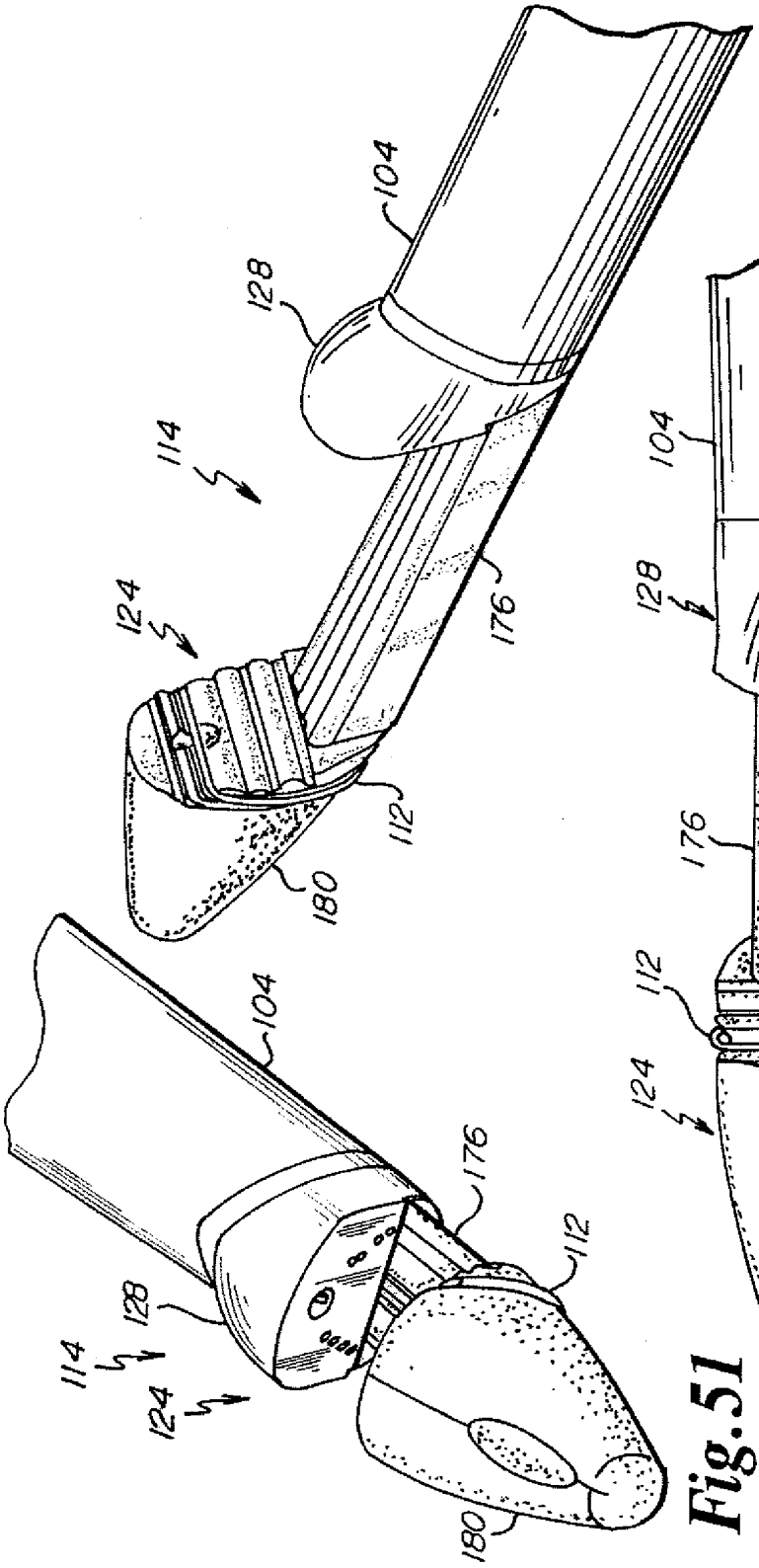

Fig.50

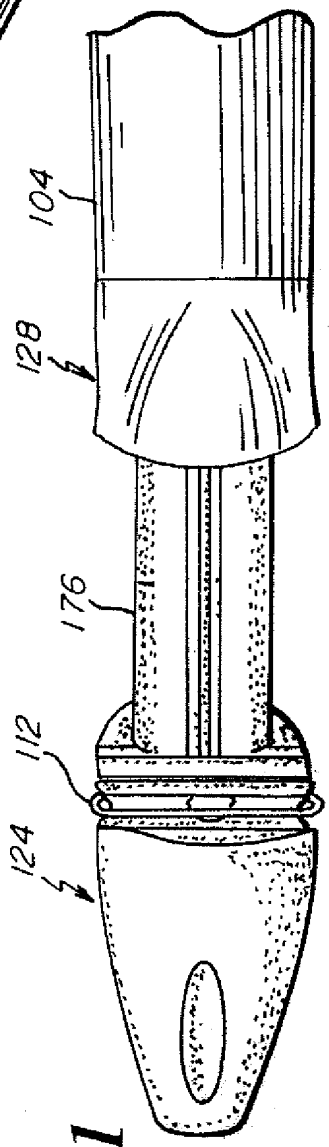

Fig.52

Fig.51

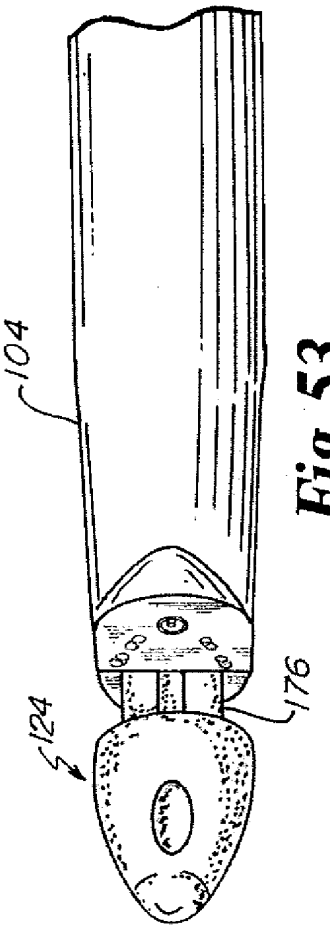

Fig.53

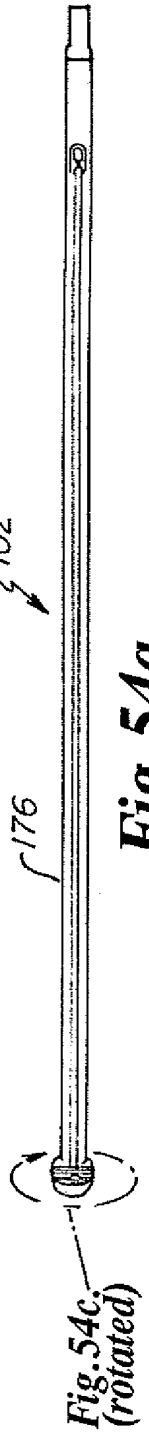

Fig.54a

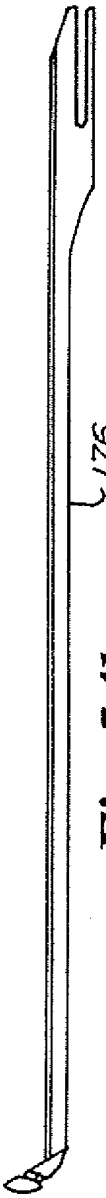

Fig.54b

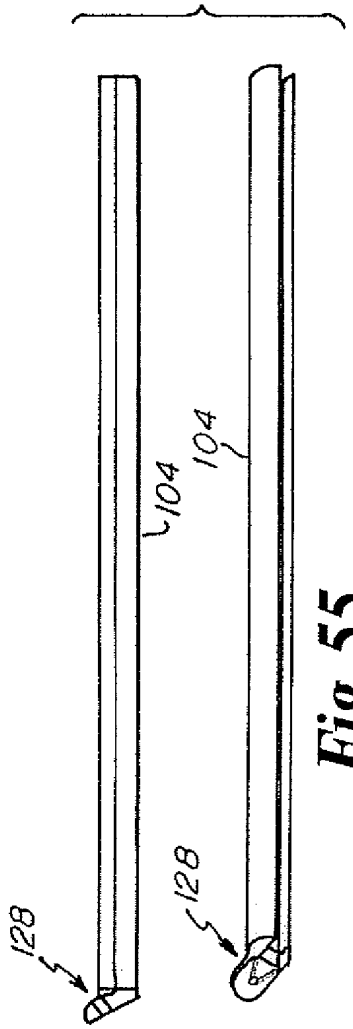

Fig.55

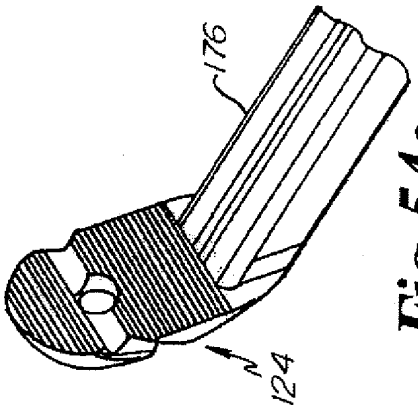

Fig.54c

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(71) Applicant *(for all designated States except US)*: **NEOCHORD INC.** [US/US]; 11100 Bren Road West, Minnetonka, MN 55343 (US).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **ZENTGRAF, John** [US/US]; C/o Neochord Inc., 11100 Bren Road West, Minnetonka, MN 55343 (US).

(74) Agents: **BIASCO, Tye** et al.; Patterson, Thuente, Skaar & Christensen, P.a., 4800 Ids Center, 80 South Eighth Street, Minneapolis, MN 55402-2100 (US).

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

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

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(88) Date of publication of the international search report:
24 September 2009

(54) Title: MINIMIALLY INVASIVE REPAIR OF A VALVE LEAFLET IN A BEATING HEART

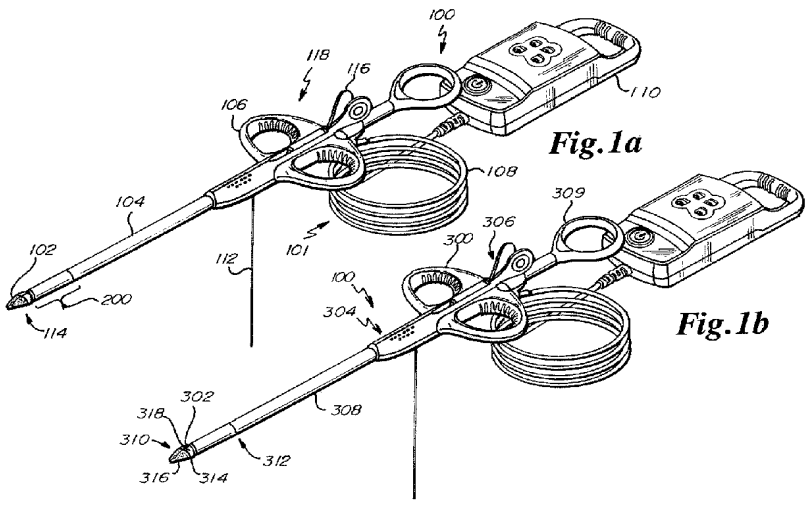

Fig.1a

Fig.1b

(57) Abstract: A device for performing minimially invasive repair of mitral valve leaflets in a beating heart through the delivery and implantation of artifical chordae tendinae includes a handle for positioning the device into a chest cavity of the patient, a capture assembly adapted to capture a valve leaflet between distal an proximal tip portions, a needle adapted to penetrate the valve leaflet, and a capture confirmation system for verifying capture of the valve leaflet between the distal and proximal tip potions.

WO 2009/052528 A3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/080560

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/068(2006.01)i, A61B 17/04(2006.01)i, A61B 17/29(2006.01)i, A61B 17/34(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC : A61B 17/062, A61B 17/04, A61B 17/92, A61B 17/34

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

- Korean Utility models and applications for Utility models since 1975
- Japanese Utility models and applications for Utility models since 1975

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

eKOMPASS(KIPO internal) & keywords : "heart", "valve leaflet", "repair", and "needle"

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	WO 2006-078694 A2 (MAYO FOUNDATION FOR MEDICLA EDUCATION AND RESEARCH) 27 July 2006	
X	See Paragraphs 1-31; Claims 7-9; Figs. 4-9A	20, 23 - 33
---		---
A	The whole documents.	1 -19, 21, 22, 34 - 37, 40 -48
	US 2004-0044365 A1 (BACHMAN, ALAN B.) 4 Mar. 2004	
A	The whole documents.	1 - 37, 40 - 48
	US 2007-0049952 A1 (WEISS, STEVEN J.) 1 Mar. 2007	
A	The whole documents.	1 - 37, 40 -48

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☒ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
24 AUGUST 2009 (24.08.2009)	**25 AUGUST 2009 (25.08.2009)**

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YANG, Seong Ji

Telephone No. 82-42-481-5624

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/080560

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 38, 39, 49, 50
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 38-39 and 49-50 pertain to methods for treatment of human body by surgery, and thus relate to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT.

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

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

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

1. ☐ As all required addtional search fees were timely paid by the applicant, this international search report covers all searchable claims.

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

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

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

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2008/080560

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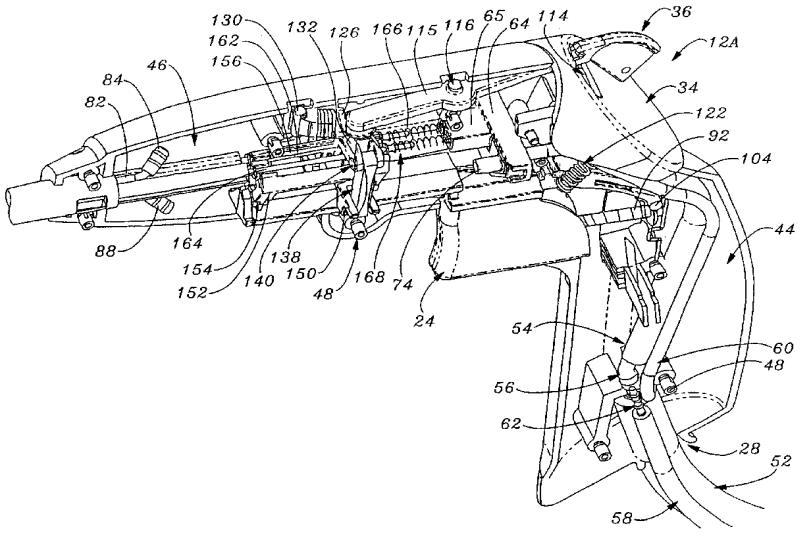
(54) Title: SEQUENTIAL HEART VALVE LEAFLET REPAIR DEVICE AND METHOD OF USE



(57) Abstract: A heart valve and tissue repair device for independently, selectively and sequentially grasping heart valve leaflets and independently, selectively and sequentially applying one or more fasteners thereto is disclosed. The device includes a leaflet engaging tip having one or more graspers capable of individually and sequentially grasping leaflets, and one or more deployable fasteners capable of fastening the leaflets. An actuation system for the device individually and selectively controls the graspers and deploys the one or more fasteners. Vacuum pressure from an external vacuum source can be used to grasp the leaflets via a selector system that controls the actuation system so as to individually and sequentially apply vacuum force to the graspers.

WO 03/082157 A2

SEQUENTIAL HEART VALVE LEAFLET REPAIR DEVICE AND METHOD OF USE

CROSS REFERENCE TO RELATED APPLICATIONS

This application discloses subject matter related to co-pending United States Patent Application No. 09/562,406, filed May 1, 2000, entitled "Minimally Invasive Mitral Valve Repair Method And Apparatus", and co-pending United States Patent Application No. 09/778,392, filed February 6, 2001, entitled "Method and System for Tissue Repair Using Dual Catheters. The entire disclosures of the aforementioned United States patent applications are incorporated herein by reference.

BACKGROUND OF THE INVENTION

In vertebrate animals, the heart is a hollow muscular organ having four pumping chambers: the left atrium, the left ventricle, the right atrium and the right ventricle. The atria are isolated from their respective ventricles by one-way valves located at the respective atrial-ventricular junctions. These valves are identified as the mitral (or bicuspid) valve on the left side of the heart, and tricuspid valve on the right side of the heart. The exit valves from the left and right ventricles are identified as the aortic and pulmonary valves, respectively.

The valves of the heart are positioned in valvular annuluses that comprise dense fibrous rings attached either directly or indirectly to the atrial and ventricular muscle fibers. Valve leaflets comprising flexible collagenous structures are attached to, and extend inwardly from, the annuluses to meet at coapting edges. The aortic, tricuspid and pulmonary valves each have three leaflets, while the mitral valve only has two. In normal operation, the leaflets of the mitral valve open as left ventricle dilates thereby permitting blood to flow from the left atrium into

the left ventricle. The leaflets then coapt (i.e. close) during the contraction cycle of the left ventricle, thereby preventing the blood from returning to the left atrium and forcing the blood to exit the left ventricle through the aortic valve. Similarly, the tricuspid valve regulates flow from the right atrium into the right ventricle, and the pulmonary valve regulates blood exiting the right ventricle.

For a number of clinical reasons various problems with heart valves can develop. One common form of heart disease involves the deterioration or degradation of the heart valves which leads to stenosis and/or insufficiency. Heart valve stenosis is a condition in which the valve does not open properly. Insufficiency is a condition in which the valve does not close properly. Insufficiency of the mitral valve, most common because of the relatively high fluid pressures in the left ventricle, results in mitral valve regurgitation ("MR"), a condition in which blood reverses its intended course and flows "backward" from the left ventricle to the left atrium during heart contractions.

A number of surgical techniques have been developed to repair degraded or otherwise incompetent heart valves. A common procedure involves replacement of a native aortic or mitral valve with a prosthetic heart valves. These procedures require the surgeon to gain access to the heart through the patient's chest (or possibly percutaneously), surgically remove the incompetent native heart valve and associated tissue, remodel the surrounding valve annulus, and secure a replacement valve in the remodeled annulus. While such procedures can be very effective, there are significant shortcomings associated with such replacement valves. For example, the highly invasive nature of the implantation procedure typically results in substantial patient discomfort and requires patients to remain

hospitalized for extended recovery periods. In addition, the two basic types of commercially available replacement valves, mechanical valves and tissue valves, each have shortcomings of their own. Mechanical replacement valves typically offer extended operational lifetimes, but the patient is usually required to maintain a regimen of anti-coagulant drugs for the remainder of his or her life. Tissue valves typically offer a higher degree of acceptance by the body which reduces or eliminates the need for anti-coagulants. However, the operational lifetimes of tissue valves are typically shorter than mechanical valves and thus may require a subsequent replacement(s) during the patient's lifetime.

As an alternative to prosthetic heart valve replacement, it is often preferable to remodel the native heart valve and/or surrounding tissue. Remodeling of the valve often preserves left ventricular function better than mitral valve replacement because the subvalvular papillary muscles and chordae tendineae are preserved (most prosthetic valves do not require these muscles to operate). Typically, valvular remodeling is accomplished by implanting a prosthetic ring (a.k.a. "annuloplasty ring") into the valve annulus to reduce and/or stabilize the structure of the annulus in order to correct valvular insufficiency. Annuloplasty rings are typically constructed of a resilient core covered with a fabric sewing material. Annuloplasty procedures can be performed alone, or they can be performed in conjunction with other procedures such as leaflet repair. Although such annuloplasty procedures have become popular and well accepted, reshaping the surrounding annulus and traditional leaflet repairs do not always lead to optimum leaflet coaptation. As a result, some patients may still experience residual mitral valve regurgitation following such annuloplasty procedures.

A recently developed technique known as a "bow-tie" repair has also been advocated for repairing insufficient heart valves, in particular the mitral valve. The mitral valve bow-tie technique involves suturing the anterior and posterior leaflets together near the middle of their coapting edges, thereby causing blood to flow through two newly formed side openings. While this does reduce the volume of blood that can flow from the atrium to the ventricle, this is compensated by improved leaflet coaptation which reduces mitral regurgitation. This process as originally developed by Dr. Ottavio Alfieri involved arresting the heart and placing the patient on extracorporeal bypass and required invasive surgery to access and suture the leaflets together. More recently, however, some have advocated a "beating heart" procedure in which the heart is accessed remotely and remains active throughout the bow-tie procedure.

A particular method for performing a beating heart bow-tie procedure (i.e. without extracorporeal bypass) has been proposed by Dr. Mehmet Oz, of Columbia University. A method and device for performing the method are described in PCT publication WO 99/00059, published January 7, 1999. In one embodiment of the disclosed procedure, the associated device consists of a forceps-like grasper used to grasp and hold the mitral valve leaflets in a coapted position for the suturing step. Since the mitral valve leaflets meet and curve toward and slightly into the left ventricular cavity at their mating edges, the grasper device is passed through a sealed aperture in the apex of the left ventricle. The edges of the mating mitral valve leaflets are then grasped and held together, and a fastening device such as a clip or suture is utilized to fasten them. The fastening devices should be applied to the leaflet tissue with sufficient tissue purchase to prevent tearout or other failure, but close enough to the edges to ensure that the newly created

side holes are as large as possible. The Mehmet Oz disclosure thus teaches that teeth of the grasper device can be linearly slidable with respect to one another so as to permit alignment of the mitral valve leaflets prior to fastening. Since the procedure is done on a beating heart, it will be readily understood that the pressures and motions within the left ventricle and mitral valve leaflets are severe. Thus the procedure taught by Dr. Mehmet Oz is very skill-intensive.

The bow-tie technique has proved to be a viable alternative for treating otherwise incompetent heart valves. Nonetheless, several shortcomings associated with the current bow-tie procedures have been identified. Current systems include devices having mechanical graspers, barbed members, and vacuum devices that simultaneously capture and retain the valve leaflets prior to applying a fastening device thereto. Often, use of these devices results in the less than optimal leaflet stabilization and fastener placement. Many of these problems arise from the fact that the surgeon is required to capture, retain and fasten the leaflets in one relatively inflexible procedure. These difficulties are compounded when the leaflets are small or calcified making them difficult to pull together, and in beating heart procedures in which the leaflets are actively functioning throughout the surgery. In light of the foregoing, there is presently a need for improved systems for stabilizing multiple tissue heart valve leaflets and placing a fastening device therebetween. More specifically, there is a present need for an improved bow-tie procedure for repairing a patient's mitral valve.

SUMMARY OF THE INVENTION

The present invention provides a device capable of effectively stabilizing at least one heart valve leaflets, or portions of a single leaflet, and applying a fastener thereto. Those skilled in the art will appreciate that the present invention enables a user to apply such a fastener in vivo to a remote location within the patient's heart.

In one aspect, the repair device of the present invention comprises a leaflet engaging tip, a leaflet grasping mechanism positioned on the leaflet engaging tip, a deployable fastener positioned on the leaflet engaging tip, and an actuation system in communication with the grasping mechanism and the fastener. The actuation system has at least two actuation modes and is capable of independently and sequentially operating in each actuation mode. In the first actuation mode the actuation system is capable of causing the grasping mechanism to grasp a first leaflet, deploying a first fastening element into the first leaflet, and subsequently causing the grasping mechanism to release the first leaflet. In the second actuation mode the actuation system is capable of causing the grasping mechanism to grasp a second leaflet, deploying a second fastening element into the second leaflet, and subsequently causing the grasping mechanism to release the second leaflet.

In another aspect, the present invention comprises multiple fasteners having multiple fastening elements and wherein the actuation system is capable of independently and sequentially deploying the multiple fastening elements into the leaflets.

In another aspect, the present invention utilizes an external vacuum source to enable the grasping mechanism to grasp a leaflet by applying vacuum force thereto. In this aspect the grasping mechanism comprises a vacuum port, the actuation system is in fluid communication

with both the vacuum port and the vacuum source, and the actuation system is capable of selectively restricting or transmitting vacuum force from the vacuum source to the vacuum port.

In another aspect, the present invention comprises one or more vacuum ports, each having at least one vacuum vane capable of directing vacuum force through the vacuum port while supporting a leaflet attached thereto.

In another aspect, the present invention includes one or more vacuum ports, each having a fastener catch capable of engaging and retaining the fastening elements.

In another aspect, the present invention utilizes an external vacuum source to enable the grasping mechanism to independently and sequentially grasp leaflets by applying vacuum force to multiple vacuum ports. In this aspect the grasping mechanism comprises first and second vacuum ports, the actuation system is in fluid communication with the vacuum ports and the vacuum source. In a first actuation mode the actuation system is capable of selectively restricting or transmitting vacuum force from the vacuum source to the first vacuum port and, in a second actuation mode the actuation system is capable of selectively restricting or transmitting vacuum force from the vacuum source to the second vacuum port.

In a related aspect, the present invention comprises a user-operable selector capable of being placed in a first position that places an actuation system in a first actuation mode and a second position that places the actuation system in the second actuation mode.

In a related aspect, the present invention comprises a user-operable vacuum actuator having an open position in which vacuum

force is transmitted from a vacuum source to a selected port and a closed position in which vacuum force is isolated from the ports.

In another aspect, the present invention comprises at least one deployable fastener comprising a length of suture material and fastening elements comprising needles connected to opposite ends of the suture material.

In another aspect, the present invention comprises an actuation system having a user-operable fastener actuator capable of individually and sequentially deploying fastening elements.

In another aspect, the present invention comprises an actuation system coupled to a user-operable selector capable of being placed in multiple positions. In a first position the selector places the actuation system in a first actuation mode, and a second position the selector places the actuation system in a second actuation mode.

In another aspect, the present invention comprises a selector and fastener actuator having a trigger mechanism coupled to a force transmitter. In this aspect, a selector selectively couples the force transmitter with a first or second fastening element.

In another aspect, the present invention comprises at least one deployable fastener selected from the group consisting of needles, sutures, staples, buttons, tissue-graspers, tissue clasps, and barbs.

In another aspect, the present invention comprises an elongated body in communication with a tissue engaging tip, a handle portion in communication with the elongated body, and a user-operable selector coupled to the handle and capable of being placed in multiple positions. Placing the selector in a first position places an actuation system in a first actuation mode; and, placing the selector in a second position places the actuation system in the second actuation mode.

In a related aspect, the present invention comprises a rigid elongated body.

In a related aspect, the present invention comprises a flexible elongated body.

In a related aspect, the present invention comprises an elongated body having at least one conduit therein.

In another aspect, the repair device of the present invention comprises a leaflet engaging tip, at least two leaflet grasping mechanisms positioned on the leaflet engaging tip, at least one deployable fastener having multiple fastening elements positioned on the leaflet engaging tip, and an actuation system in communication with the grasping mechanism and the fastener. The actuation system has at least two actuation modes and is capable of independently and sequentially operating in each actuation mode. In the first actuation mode the actuation system is capable of causing a first grasping mechanism to grasp a first leaflet, deploying a first fastening element into the first leaflet, and subsequently causing the first grasping mechanism to release the first leaflet. In the second actuation mode the actuation system is capable of causing a second grasping mechanism to grasp a second leaflet, deploying a second fastening element into the second leaflet, and subsequently causing the second grasping mechanism to release the second leaflet.

In another aspect, the present invention utilizes an external vacuum source to enable multiple grasping mechanisms to grasp leaflets by applying vacuum force thereto. In this aspect each grasping mechanism comprises a vacuum port, the actuation system is in fluid communication with each vacuum port and the vacuum source, and the

actuation system is capable of selectively restricting or transmitting vacuum force from the vacuum source to each vacuum port.

In another aspect, the present invention discloses a method of repairing a heart valve having multiple leaflets. The method includes stabilizing a first leaflet with the repair device, deploying a first fastener element into the stabilized first leaflet, disengaging the first leaflet from the repair device while leaving the first fastener element deployed therein, stabilizing a second leaflet with the repair device, deploying a second fastener element into the second leaflet, disengaging the second leaflet from the repair device while leaving the second fastener element deployed therein, and joining the first and second leaflets by reducing the distance between the first and second fastener elements. Additional leaflet portions may also be attached in a similar manner.

In another aspect, the present invention discloses a method of controllably and selectively stabilizing multiple heart valve leaflets with vacuum force.

In another aspect, the present invention discloses a method of stabilizing multiple heart valve leaflets with a piece of suture material by first fastening the suture material to the leaflets and then tying the suture material into a knot.

In another aspect, the present invention comprises a method of adjusting the position of a repair device relative to a heart valve by monitoring fluid pressure around a distal end of the repair device.

In another aspect, the present invention comprises a method of adjusting the position of a repair device relative to an atrial-ventricular junction by observing pressure differentials between blood in an adjacent ventricle and an adjacent atrium.

Other objects, features, and advantages of the present invention will become apparent from a consideration of the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

The apparatus of the present invention will be explained in more detail by way of the accompanying drawings, wherein:

Figure 1 shows a perspective view of the repair device of the present invention;

Figure 2 shows a perspective view of handle portion of the repair device of the present invention;

Figure 3 shows a perspective cross-sectional view of the internal components located within the handle portion of the repair device of the present invention;

Figure 4 shows a perspective view of the vacuum system of the repair device of the present invention;

Figure 5 shows a perspective view of the trigger assembly of the repair device of the present invention prior to actuation;

Figure 6 shows a perspective view of the trigger assembly of the repair device of the present invention during actuation;

Figure 7 shows a perspective view of the vacuum actuation assembly of the repair device of the present invention;

Figure 8 shows a perspective view of the vacuum actuation assembly of the repair device of the present invention positioned within the handle portion;

Figure 9 shows a side view of the vacuum actuation assembly of the repair device of the present invention positioned within the handle portion;

Figure 10 shows a perspective view of the exterior of the elongated body and tissue engaging tip of the repair device of the present invention;

Figure 11 shows a perspective view of the internal components of the elongated body of the repair device of the present invention; and

Figure 12 shows a perspective view of the internal components of the engaging tip of the repair device of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Disclosed herein is a description of various illustrated embodiments of the present invention. This description is not to be taken in a limiting sense, but is made merely for the purpose of illustrating the general principles of the invention. The section titles and overall organization of the present description are for the purpose of convenience only and do not limit the present invention.

The methods and devices of the present invention were primarily designed for use in the surgical treatment of heart valves. As those skilled in the art will appreciate, the exemplary sequential repair device disclosed herein is designed to minimize trauma to the patient before, during, and subsequent to a surgical procedure, while providing improved heart valve leaflet stabilization and enhanced placement of a fastening device thereon. The repair device of the present invention is

particularly useful in repairing dysfunctional mitral valves by stabilizing the discrete valvular tissue pieces of the anterior and posterior leaflets and deploying a fastening device(s) thereto.

Figure 1 shows the sequential repair device of the present invention. As illustrated, the repair device 10 comprises a handle portion 12 in communication with an elongated body 14. A leaflet engaging tip 16 is positioned on the distal portion of the elongated body 14. Those skilled in the art will appreciate that the present invention may be manufactured from a plurality of materials including, without limitation, various metals, plastics, thermoplastics, silicones, elastomers, ceramics, composite materials, or various combinations of the aforementioned materials. For example, the handle portion 12 may be manufactured from acrylic, while the elongated body 14 may be manufactured from stainless steel.

Figure 2 shows a perspective view of the handle portion 12. As shown in Figure 2, the handle portion 12 comprises a grip portion 18 in communication with a housing body 20. The grip portion 18 includes a trigger recess 22 capable of receiving a trigger 24 therein. A trigger guide 26 is positioned proximate to the trigger recess 22. In addition to supporting the trigger 24, the trigger guide 26 isolates the trigger 24 from the grip portion 18 thereby preventing the accidental actuation of the trigger 24. In one embodiment, the grip portion 18 is perpendicularly attached to the housing body 20, thereby forming a pistol-type grip. Those skilled in the art will appreciate that the handle portion 14 of the present invention may be manufactured in a plurality of shapes as desired by the operator. At least one external conduit recess 28 capable of receiving at least one external conduit 30 therein may be formed on the repair device 10.

The handle portion 12 further comprises a vacuum actuator recess 32 capable of receiving a vacuum actuator 34 and a vacuum selector 36 therein. As shown in Figure 2, the vacuum actuator recess 32 may be positioned adjacent to the trigger recess 22 thereby permitting the user to single-handedly operate the vacuum actuator 34, the vacuum selector 36, and the trigger 24 simultaneously. In an alternate embodiment, the vacuum actuator recess 32 may be positioned remotely from the trigger recess 22 to prevent the accidental actuation of the vacuum actuator 34 or the vacuum selector 36.

An elongated body aperture 38 capable of receiving the elongated body 14 therein is formed in the housing body 20. At least one coupling member receiver 40 capable of receiving at least one coupling member 42 therein is formed in the housing body 20 proximate to the elongated body aperture 38 to effect coupling of the elongated body 14 to the handle portion 12. Those skilled in the art will appreciate that the at least one coupling member 42 may include, without limitation, screws, rivets, pins, or locking members, thereby permitting the elongated body 14 to be detachable from the handle portion 12. In another embodiment, the elongated body 14 may be permanently attached to handle portion 12 with in a plurality of ways, such as welding or gluing.

Figures 3 and 7 show the internal components in more detail. As shown in Figure 3 the handle portion may be split into two hollow halves comprising a first handle portion 12A and a second handle portion 12B which cooperatively form a handle cavity 44 and a housing cavity 46 within the handle portion 12. At least one assembly device receiver 48 capable of receiving at least one assembly device (not shown) therein may be formed, e.g. molded, in the first and/or second

handle portions 12A, 12B. Exemplary assembly devices include, but are not limited to, screws, rivets, assembly pins or adhesives.

Figures 3 and 4 show vacuum system 50. An external vacuum conduit 52, positioned within the at least one external conduit recess 28 formed in the repair device 10, is attached to a compressible main vacuum line 54 through a vacuum coupler 56. The external vacuum conduit 52 is in communication with a vacuum source (not shown), thereby providing suction (i.e. vacuum pressure) to the repair device 10. In addition, an external positioning conduit 58 is positioned within the at least one external conduit recess 28 and is attached to an internal positioning line 60 through a positioning coupler 62. The external positioning conduit 58 may be in communication with a positioning system. In one embodiment, the external positioning conduit 58 may be in communication with a pressure sensing device. Those skilled in the art will appreciate that a pressure sensing device can be used to assist the user in the precise placement of the repair device 10 within the patient based on a determination of pressure levels within the various parts of the body. For example, such a pressure sensing system would assist the user in determining the position of the leaflet engaging tip 16 of the repair device 10 relative to the atrial-ventricular junction of the patient's heart by sensing variations in the internal pressure between the atrium and the ventricle. In other embodiments, the present invention may be easily adapted to utilize a plurality of alternate positioning systems, including, without limitation, optical systems, ultrasonic systems, echogenic systems, microwave positioning systems, radio-frequency positioning systems, or radio-opaque positioning devices.

As shown in Figures 3 and 4, the main vacuum line 54 is attached to a vacuum manifold 64 through a vacuum coupler 66. The internal positioning line 60 is similarly attached to the vacuum manifold 64 through a positioning line coupler 68. The vacuum manifold 64 includes a first vacuum conduit coupler 70 capable of coupling to a first vacuum conduit 72 and a second vacuum conduit coupler 74 capable of coupling to a second vacuum conduit 76 thereby permitting the first and second vacuum conduits 72, 76 to communicate with the main vacuum line 54. A positioning conduit 78 is attached to the vacuum manifold 64 through a positioning coupler 80, thereby permitting the positioning conduit 78 to communicate with the internal positioning line 60. The first vacuum conduit 72 attaches to the first elongated body vacuum conduit 82 through a coupling member 84. Similarly, the second vacuum conduit 76 is attached to a second elongated body vacuum conduit 86 through a coupling member 88.

Figures 3, 5, and 6 show the various components comprising trigger assembly 90. The trigger assembly 90 includes a trigger rod 92 which in communication with the trigger 24 and includes a bias member 94, illustrated as a spring, positioned thereon. A trigger safety 96 is positioned proximate to the trigger 24 and comprises a safety body 98 having a safety actuator 100 located thereon and a trigger catch 102 capable of engaging the trigger 24. The trigger safety 96 is coupled to the repair device 10 with an attachment member 104. An actuation tray 106 having an attachment unit 108 is attached thereto is in communication with the trigger 24. Figure 6 shows the trigger assembly 90 during actuation. As shown, during actuation the trigger safety 96 is forced to deflect downwardly by the vacuum actuator (not shown in this figure), thereby causing the trigger catch 102 to disengage the trigger 24. The trigger safety 96 enters the internal cavity 110 formed in the

trigger 24 thereby, permitting the user to actuate the trigger 24 rearwardly, which results in compression of the bias member 94. Once the actuation pressure on the trigger has been released, the bias member biases the trigger 24 to a non-actuated position, thereby permitting the trigger catch 102 to re-engage the trigger 24. Those skilled in the art will appreciate the trigger safety 90 may be manufactured from a plurality of materials having sufficient resiliency to permit the repeated deflection thereof without a substantial loss of resiliency.

Figures 3, 7, and 8 show the various components comprising vacuum actuator assembly 112. As shown, the vacuum actuator assembly 112 includes a vacuum actuator 34 and a vacuum selector 36 positioned on or proximate to a vacuum actuator 34. For example, a vacuum selector port 114 capable of receiving the vacuum selector 36 therein may be formed in the vacuum actuator 34. The vacuum selector 36, which is capable of a first position and a second position, is in communication with a vacuum selector shaft 115 which includes a selector pivot 116, which attaches the vacuum selector shaft to the housing body 20, and an attachment orifice 118 located near the distal end thereof. Compression member 120 capable of engaging and compressing the main vacuum line 54 is in communication with the vacuum actuator 34. Vacuum bias member 122 biases the vacuum actuator 34 outwardly. Ideally, the bias member 122 applies sufficient outward force to the vacuum actuator 34 to enable the compression member 120 to compressively squeeze the main vacuum line 54 against a stop, in this case the housing 12, to seal the main vacuum line. Those skilled in the art will appreciate that the application of inward force by the user to the vacuum actuator 34 results in the compression of the vacuum bias member 122 and causes the compression member 120 to

move inwardly thereby disengaging and unsealing the main vacuum line 54. As the inward movement of the vacuum actuator 34 continues the compression member 120 engages the safety actuator 100 located on the trigger safety body 98, thereby causing the trigger safety 96 to deflect downwardly which in turn permits full actuation of the trigger 24. Thus, according to the illustrated embodiment, the trigger 24 may be actuated only when the vacuum actuator 34 is actuated.

Figures 3, 8, and 9 show the components of the force transmission system 124. The force transmission system 124 comprises a selector toggle 126 which is attached to or otherwise in communication with the attachment orifice 118 located on the vacuum selector shaft 114. The selector toggle 126 further includes a biasing member 128 positioned thereon, and a pivoting attachment member 130 to pivotally couple the selector toggle to the housing body 20. The force transmission system 124 further comprises a transmission bridge 132 which is in communication with the selector toggle 126. A first connecting rod 134 is attached to the transmission bridge 132 with a pivot pin 136. Similarly, a second connecting rod 138 is attached to the transmission bridge 132 with a pivot pin 140. The first and second connecting rods 134, 138 are connected to a first and second connecting rod mount 144, 150 located on a rocker bridge 142. The rocker bridge 142 is in communication with a first and second pivoting actuation member catches 146, 152, which are attached to the attachment unit 108 of the trigger actuation tray 106 with pins 148, 154. At least one actuation member is capable of engaging the first and second pivoting catches 146, 152. As shown in the present embodiment, first and second actuation members or rods 156, 158 each include at least one actuation flange 160 positioned thereon thereby forming a first capture region 162 on the first actuation member 156 and

a second capture region 164 on the second actuation member 158 which are located proximate to the first and second actuation member catches 146, 152. The distal portion of the each actuation member 156, 158 is in communication with the leaflet engaging tip 16 through the elongated body 14. The proximal portion of the first and second actuation members 156, 158 includes a biasing members 166, 168, respectively. A support member 65, positioned on the vacuum manifold 64 supports the bias members 166, 168 and receives the actuation members 156, 158 during actuation.

Figure 10 shows the external components of the elongated body 14 and the leaflet engaging tip 16. The elongated body 14 may be manufactured from a plurality of materials in various widths and length. Those skilled in the art will appreciate that the elongated body 14 can comprise a rigid body or, in the alternative, may be manufactured from a flexible material thereby enabling the repair device 10 to be delivered through a catheter to a repair site in vivo. As shown in Figure 10, the outer surface of the elongated body 14 comprises an outer sheath 170 capable of coupling to the handle portion 12. A guidewire retainer (not shown) may be included on the exterior surface of the outer sheath 170, the guidewire retainer (not shown) capable of engaging a guidewire (not shown) for catheter based surgical procedures. A tip retainer 172 is located on the distal portion of the outer sheath 170 of the elongated body 14. The tip retainer 172 is adapted to engage and retain the attachment device 174 of the tip engaging tip 16. Those skilled in the art will appreciate that the tip retainer 172 may include screw receivers, ports, snap fit members, or threads adapted to receive the leaflet engaging tip 16.

As shown in Figure 10, the external components of the leaflet engaging tip 16 include a proximal portion 178 and a distal portion 180. A first and second engaging channel 182, 184 separate the proximal portion 178 from the distal portion 180. The proximal portion 178 includes a first port or vacuum recess 186 located within the first engaging channel 182. Similarly, a second port or vacuum recess 188 is located within the second engaging channel 184. The proximal portion 178 also includes a mounting member 190 capable of being sealably received within the elongated body 14, thereby effectively coupling the leaflet engaging tip 16 to the elongated body 14. The attachment device 174 may be located on or otherwise in communication with the mounting member 190 to effectuate the coupling process. Those skilled in the art will appreciate that the leaflet engaging tip 16 of the present invention may be attached to the elongated body 14 in a plurality of ways including, without limitation, detachably coupled or permanently attached.

The distal portion 180 of the leaflet engaging tip 16 includes a first and second actuation ports 194, 196 located within the first and second engaging channel 182, 184. The actuation ports 194, 196 located on the distal portion 180 are capable of passing at least one fastening device (not shown in Figure 11) therethrough.

Figure 11 shows the internal components of the elongated body 14. As shown in Figure 11, a first and second elongated body vacuum conduits 82, 86, respectively, and a first and second actuation members 156, 158 are located within an inner lumen 176 formed by the outer sheath 170. The first and second elongated body vacuum conduits 82, 86 are in fluid communication with the first and second vacuum conduits 72, 76 located within the housing body 20 of the

handle portion 12. Similarly, the first and second actuation members 156, 158 are in communication with the force transmission system 124 positioned within the housing body 20 of the handle portion 12. The positioning conduit 78 may be positioned within the elongated body inner lumen 176.

Figure 12 shows the internal components of the leaflet engaging tip 16 of the present invention. A first vacuum recess device 198, which is located within the first vacuum recess 186, includes a vane member 200 capable of directing suction force through the first vacuum recess 186. At least one first fastener catch 202 is formed on or otherwise in communication with the first vacuum recess device 198. The at least one first fastener catch 202 is capable of receiving and retaining therein at least fastener device (described in more detail below). Similarly, the second vacuum recess device 204, which is located within the second vacuum recess 188, includes a vane member 206 capable of directing suction force through the second vacuum recess 188. At least one second fastener catch 208 is formed on or otherwise in communication with the second vacuum recess device 204. The at least one second fastener catch 208 is capable of receiving and retaining at least fastener device therein.

First and second vacuum ports 210, 212 (210 not visible) are located within the first and second vacuum recesses 186, 188. The first vacuum port 210 is in fluid communication with the first elongated body vacuum conduit 82, while the second vacuum port 212 is in fluid communication with the second elongated body vacuum conduit 86. A positioning port 213 in fluid communication with the positioning conduit 78 may be positioned on the proximal portion 178 or on the distal portion 180 of the engaging tip 16.

As shown in Figure 12, the distal portion 180 of the leaflet engaging tip 16 communicates with the proximal portion 178 thereof through the first and second actuation members 156, 158. The first actuation device 214 is in communication with the first actuation member 156, while the second actuation device is in communication with the second actuation member 158. The first actuation device 214 comprises at least one fastener device 218 positioned thereon. The at least one fastener device 218 is capable of engaging the at least one first catch 202 located within the first vacuum recess 186. Similarly, the second actuation device 216 comprises at least one fastener device 220 positioned thereon. The at least one fastener device 220 is capable of engaging the at least one second catch 208 located within the second vacuum recess 188. The illustrated embodiment shows each actuation device 214, 216, respectively, having two fastener devices 218, 220, respectively, mounted thereon. Those skilled in the art will appreciate that the present invention may be manufactured with a one or more fastener devices located on the actuation devices 214, 216. The fastener devices 218, 220 may be attached to suture material (not shown) positioned within the actuation devices 214, 216. It will be appreciated that the actuation devices 214, 216 of the present invention may be actuated independently. In addition, the illustrated embodiment includes needles and suture material as tissue fasteners, but those skilled in the art will appreciate that the invention may be easily adapted to apply a plurality of fasteners. Exemplary fasteners include staples, graspers, buttons, and toggles.

Also disclosed herein is a method of using the sequential repair device of the present invention to repair discreet heart valve leaflets in vivo. While those skilled in the art will appreciate that the present invention may be adapted for use in many procedures

throughout a patient's body, the inventive repair device 10 is particularly well suited for procedures to repair dysfunctional heart valves without requiring the patient's heart to be arrested. Following is a description of the inventive method for such a repair of a dysfunctional heart valve.

To use the present invention, the external vacuum conduit 52 and external positioning conduit 58 are connected to an external vacuum source (not shown) and a selected positioning device. Thereafter, the operator gains access to the repair site in vivo. For example, in procedures involving the heart, one approach to the heart requires the patient be positioned for a left anterolateral thoracotomy. An incision is made in the patient's chest and the chest is entered through the bed of the fifth rib. The pericardium is incised posterior and parallel to the left phrenic nerve, such that the incision extends from the left pulmonary artery to the apex of the left ventricle. Thereafter, a sealing cannula may be positioned on the exterior atrial wall of the patient's heart. An exemplary sealing cannula is described in United States Patent Application No. 09/800,390, entitled "Sealing Access Cannula System", filed on March 5, 2001, which is incorporated herein by reference. An incision is made in the atrial tissue once the sealing cannula is sufficiently anchored to the heart wall. The leaflet engaging tip 16 of the present invention then inserted into the sealing cannula and advanced to a position proximate the mitral valve.

One embodiment of the present invention includes a pressure transducer as a positioning device. The surgeon may determine the position of the leaflet engaging tip 16 with respect to the mitral valve based on various pressure readings from the pressure transducer. For example, the operator may determine the position of the leaflet engaging tip 16 with respect to the mitral valve by observing the pressure

differential between the atrium and the ventricle, as ventricular pressure within the heart is considerably greater than the pressure within the atrium.

Once the leaflet engaging tip 16 is positioned between the valve leaflets at the arterial-ventricular junction, the surgeon selects an actuation mode for the actuation system. In each successive actuation mode another leaflet, or portion of a leaflet, is to be grasped and a fastener attached thereto. The surgeon actuates the vacuum selector 36 to selectively apply a vacuum force to either the first or second vacuum recess 186, 188 located proximate to the first or second engaging channel 182, 184 (the actuated side will depend on which side the vacuum selector 36 is on). To apply suction to the first vacuum recess 186 the user positions the vacuum selector 36 to the first position, thereby causing the first pivoting catch 146 of the force transmission system 124 to engage the first capture region 162 located on the first actuation member 156. Simultaneously, the second connecting rod 138 compressively engages the second vacuum conduit 76 thereby preventing vacuum flow therethrough. Thereafter, the user depresses the vacuum actuator 34 causing the compression member 120 of the vacuum actuation assembly 112 to disengage the compressible main vacuum line 54, and permitting a vacuum flow through the first vacuum recess 186 which is in communication with the vacuum main line 54 through the first vacuum conduit 72. The valve leaflet, which is located near the first vacuum recess 186, is then captured by the vacuum force applied thereto. Once the leaflet has been captured, the user actuates the trigger assembly 90 of the repair device 10. By actuating the trigger 24, the user causes the first pivoting catch 146, which is in communication with the actuation tray 106 of the trigger assembly 90, to retract the first actuation member 156, thereby

causing the first actuation device 214 of the leaflet engaging tip 16 to retract. Continued actuation of the trigger 24 causes continued rearward movement of the first actuation device 214, which results in the first fastener device 218 engaging and traversing the captured valve leaflet. Thereafter, the first fastener device(s) 218 engages a fastener catch 202 located within the first vacuum recess 186 and is retained therein. The user then releases the trigger 24, which causes the first actuation device 214 to return to the extended position. Releasing the vacuum actuator 34 halts the application of vacuum force through the first vacuum recess 186 and releases the captured valve leaflet. The suture material remains positioned through the valve leaflet where the fastener device(s) 218 had traveled therethrough.

The user may then capture another portion of the same valve leaflet, or another leaflet, by changing the actuation system to another actuation mode. To capture another leaflet the user moves the vacuum selector 36 from the first position to the second position which causes the first pivoting catch 146 to disengage the first actuation member 156 and causes the second pivoting catch 152 of the force transmission system 124 to engage the second capture region 164 located on the second actuation member 158. Simultaneously, the first connecting rod 134 compressively engages the first vacuum conduit 72 thereby preventing vacuum flow therethrough while the second connecting rod 138 disengages the second vacuum conduit 76 thereby permitting a vacuum flow therethrough. Thereafter, the user depresses the vacuum actuator 34 causing the compression member 120 of the vacuum actuation assembly 112 to disengage the compressible main vacuum line 54, and permits a vacuum flow through the second vacuum recess 188 which is in communication with the vacuum main line 54 through the second vacuum conduit 76. The valve leaflet located near the second

vacuum recess 188 is then captured by the vacuum force applied thereto. Once the leaflet has been captured, the user actuates the trigger assembly 90 of the repair device. By actuating the trigger 24 the user causes the second pivoting catch 152, which is in communication with the actuation tray 106 of the trigger assembly 90, to retract the second actuation member 158 thereby causing the second actuation device 216 of the leaflet engaging tip 16 to similarly retract. Continued actuation of the trigger 24 causes continued rearward movement of the second actuation device 216 which results in the second fastener device(s) 220 engaging and traversing the captured leaflet. Thereafter, the second fastener device(s) 220 engages a second fastener catch 208 located within the second vacuum recess 188 and is retained therein. The user can then release the trigger 24 thereby returning the second actuation device 216 to an extended position. Release of the vacuum actuator 34 halts the application of vacuum force and releases the valve leaflet. The suture material remains positioned through the valve leaflet where the fastener device(s) 220 had traveled therethrough.

The user can remove the repair device 10 from the patient's heart. The suture material, which has been positioned through various portions of the valve tissue remains in place while the extraneous suture material is feed from the repair device 10 during removal. Thereafter, a surgical knot may be formed in the extraneous suture material and advanced to an area within the heart using a surgical knot pusher, thereby approximating the valve leaflet tissue. Once the final knot is applied to the area of interest the extraneous suture material is trimmed and the various incisions are closed.

In closing, it is noted that specific illustrative embodiments of the invention have been disclosed hereinabove. It is to be understood

that the invention is not limited to these specific embodiments. This specification has focused on the application of the present inventive devices and methods to the repair of heart valve leaflets. However, one of skill in the art will appreciate that the disclosed devices and methods could alternatively be used to approximate any two pieces of tissue throughout a patient's body. For example, the present invention may also used to repair Arterial Septal Defects (ASD), Ventricular Septal Defects (VSD), and defects associated with Patent Foramen Ovale (PFO). Accordingly, it should be recognized that the references to "leaflets" throughout could be equally substituted for other tissue segments that might require similar approximation procedures.

With respect to the claims, it is applicant's intention that the claims not be interpreted in accordance with the sixth paragraph of 35 U.S.C. § 112 unless the term "means" is used followed by a functional statement. Further, with respect to the claims, it should be understood that any of the claims described below can be combined for the purposes of the invention.

What is claimed is:

1. An apparatus for repairing a heart valve having multiple leaflets, comprising:

a leaflet engaging tip;

a leaflet grasping mechanism positioned on the leaflet engaging tip;

a deployable fastener positioned on the leaflet engaging tip, the fastener comprising first and second fastening elements; and,

an actuation system in communication with the grasping mechanism and the fastener, the actuation system having first and second actuation modes;

wherein the actuation system in the first actuation mode is capable of causing the grasping mechanism to grasp a first leaflet, deploying the first fastening element into the first leaflet, and subsequently causing the grasping mechanism to release the first leaflet;

wherein the actuation system in the second actuation mode is capable of causing the grasping mechanism to grasp a second leaflet, deploying the second fastening element into the second leaflet, and subsequently causing the grasping mechanism to release the second leaflet; and,

wherein the actuation system is capable of independently and sequentially operating in the first and second actuation modes.

2. The apparatus of claim 1, further comprising multiple fasteners having multiple fastening elements and wherein the actuation system is capable of independently and sequentially deploying the multiple fastening elements into the leaflets.

3. The apparatus of claim 1 for utilizing an external vacuum source:

wherein the grasping mechanism comprises a vacuum port;

wherein the actuation system is in fluid communication with both the vacuum port and the vacuum source; and,

wherein the actuation system is capable of selectively restricting or transmitting vacuum force from the vacuum source to the vacuum port;

whereby the grasping mechanism can grasp a leaflet by applying vacuum force thereto.

4. The apparatus of claim 3 wherein the vacuum port comprises at least one vacuum vane, the vacuum vane capable of directing vacuum force through the vacuum port while supporting a leaflet attached thereto.

5. The apparatus of claim 3 wherein the vacuum port comprises a fastener catch, the fastener catch capable of engaging and retaining the fastening elements.

6. The apparatus of claim 1 for utilizing an external vacuum source:

wherein the grasping mechanism comprises first and second vacuum ports;

wherein the actuation system is in fluid communication with the vacuum ports and the vacuum source;

wherein the actuation system in the first actuation mode is capable of selectively restricting or transmitting vacuum force from the vacuum source to the first vacuum port; and,

wherein the actuation system in the second actuation mode is capable of selectively restricting or transmitting vacuum force from the vacuum source to the second vacuum port;

whereby the grasping mechanism can independently and sequentially grasp individual leaflets by applying vacuum force thereto.

7. The apparatus of claim 6:

wherein the actuation system comprises a user-operable selector capable of being placed in a first position that places the actuation system in the first actuation mode and a second position that places the actuation system in the second actuation mode.

8. The apparatus of claim 7:

wherein the actuation system further comprises a user-operable vacuum actuator having an open position in which vacuum force is transmitted to a selected port and a closed position in which the vacuum force is isolated from the ports.

9. The apparatus of claim 8 wherein the actuation system further comprises a user-operable fastener actuator capable of deploying the fastening elements.

10. The apparatus of claim 9:

wherein the selector is coupled to the fastener actuator such that when the selector is in the first position the fastener actuator is coupled to and capable of deploying the first fastening element; and,

wherein the selector is coupled to the fastener actuator such that when the selector is in the second position the fastener actuator is coupled to and capable of deploying the second fastening element.

11. The apparatus of claim 10 wherein the fastener actuator comprises a user-operable trigger mechanism coupled to a force transmitter, and wherein the selector selectively couples the force transmitter with the first or second fastening element.

12. The apparatus of claim 6 wherein each vacuum port comprises at least one vacuum vane, the vacuum vane capable of directing the vacuum force through the vacuum port while supporting a leaflet attached thereto.

13. The apparatus of claim 6 wherein each vacuum port further comprises a fastener catch, the fastener catch capable of engaging and retaining the fastening elements.

14. The apparatus of claim 13 wherein the deployable fastener comprises a length of suture material and the fastening elements comprise needles connected to opposite ends of the suture material.

15. The apparatus of claim 1 wherein the actuation system further comprises a user-operable fastener actuator capable of deploying the fastening elements.

16. The apparatus of claim 15:

wherein the actuation system comprises a user-operable selector capable of being placed in a first position that places the actuation system in the first actuation mode and a second position that places the actuation system in the second actuation mode;

wherein the selector is coupled to the fastener actuator such that when the selector is in the first position the fastener actuator is coupled to and capable of deploying the first fastening element; and,

wherein the selector is coupled to the fastener actuator such that when the selector is in the second position the fastener actuator is coupled to and capable of deploying the second fastening element.

17. The apparatus of claim 16 wherein the fastener actuator comprises a trigger mechanism coupled to a force transmitter, and wherein the selector selectively couples the force transmitter with the first or second fastening element.

18. The apparatus of claim 16 wherein the deployable fastener comprises a length of suture material and the fastening elements comprise needles connected to opposite ends of the suture material.

19. The apparatus of claim 1 wherein the deployable fastener is selected from the group consisting of needles, sutures, staples, buttons, tissue-graspers, tissue clasps, and barbs.

20. The apparatus of claim 1 wherein the deployable fastener comprises a length of suture material and the fastening elements comprise needles connected to opposite ends of the suture material.

21. The apparatus of claim 1 further comprising:

an elongated body in communication with the tissue engaging tip;

a handle portion in communication with the elongated body; and,

a user-operable selector coupled to the handle and capable of being placed in a first position that places the actuation system in the first actuation mode and a second position that places the actuation system in the second actuation mode.

22. The apparatus of claim 21 wherein the elongated body is rigid.

23. The apparatus of claim 21 wherein the elongated body is flexible.

24. The apparatus of claim 21 wherein the elongated body contains at least one conduit therein.

25. An apparatus for repairing a heart valve having multiple leaflets, comprising:

a leaflet engaging tip;

at least two leaflet grasping mechanisms positioned on the leaflet engaging tip;

at least one deployable fastener positioned on the leaflet engaging tip, the fastener comprising at least two fastening elements; and,

an actuation system in communication with the grasping mechanism and the fastener, the actuation system having at least two actuation modes;

wherein the actuation system in a first actuation mode is capable of causing a first grasping mechanism to grasp a first leaflet,

deploying a first fastening element into the first leaflet, and subsequently causing the first grasping mechanism to release the first leaflet;

wherein the actuation system in the second actuation mode is capable of causing a second grasping mechanism to grasp a second leaflet, deploying a second fastening element into the second leaflet, and subsequently causing the second grasping mechanism to release the second leaflet; and,

wherein the actuation system is capable of independently and sequentially operating in the first and second actuation modes.

26. The apparatus of claim 25, further comprising multiple fasteners having multiple fastening elements and wherein the actuation system is capable of independently and sequentially deploying the multiple fastening elements into multiple leaflets.

27. The apparatus of claim 25 for utilizing an external vacuum source:

wherein each grasping mechanism comprises a vacuum port;

wherein the actuation system is in fluid communication with the vacuum ports and the vacuum source; and,

wherein the actuation system is capable of independently and sequentially restricting or transmitting vacuum force from the vacuum source and each vacuum port;

whereby each grasping mechanism can independently and sequentially grasp individual leaflets by applying vacuum force thereto.

28. The apparatus of claim 27:

wherein the actuation system comprises a user-operable selector capable of being placed in a first position that places the

actuation system in the first actuation mode and a second position that places the actuation system in the second actuation mode.

29. The apparatus of claim 28:

wherein the actuation system further comprises a user-operable vacuum actuator having an open position in which vacuum force is transmitted to a selected port and a closed position in which the vacuum force is isolated from the ports.

30. The apparatus of claim 29 wherein the actuation system further comprises a user-operable fastener actuator capable of deploying the fastening elements.

31. The apparatus of claim 30:

wherein the selector is coupled to the fastener actuator such that when the selector is in the first position the fastener actuator is coupled to and capable of deploying the first fastening element; and,

wherein the selector is coupled to the fastener actuator such that when the selector is in the second position the fastener actuator is coupled to and capable of deploying the second fastening element.

32. The apparatus of claim 31 wherein the fastener actuator comprises a user-operable trigger mechanism coupled to a force transmitter, and wherein the selector selectively couples the force transmitter with the first or second fastening element.

33. The apparatus of claim 27 wherein each port comprises at least one vacuum vane, the vacuum vane capable of

directing the vacuum force through the vacuum port while supporting a leaflet attached thereto.

34. The apparatus of claim 27 wherein each vacuum port further comprises a fastener catch, the fastener catch capable of engaging and retaining the fastening elements.

35. The apparatus of claim 34 wherein the deployable fastener comprises a length of suture material and the fastening elements comprise needles connected to opposite ends of the suture material.

36. The apparatus of claim 25 wherein the actuation system further comprises a user-operable fastener actuator capable of deploying the fastening elements.

37. The apparatus of claim 36

wherein the actuation system comprises a user-operable selector capable of being placed in a first position that places the actuation system in the first actuation mode and a second position that places the actuation system in the second actuation mode;

wherein the selector is coupled to the fastener actuator such that when the selector is in the first position the fastener actuator is coupled to and capable of deploying a first fastening element; and,

wherein the selector is coupled to the fastener actuator such that when the selector is in the second position the fastener actuator is coupled to and capable of deploying a second fastening element.

38. The apparatus of claim 37 wherein the fastener actuator comprises a trigger mechanism coupled to a force transmitter, and wherein the selector selectively couples the force transmitter with the first or second fastening element.

39. The apparatus of claim 38 wherein the deployable fastener comprises a length of suture material and the fastening elements comprise needles connected to opposite ends of the suture material.

40. The apparatus of claim 25 wherein the deployable fastener is selected from the group consisting of needles, sutures, staples, buttons, tissue-graspers, tissue clasps, and barbs.

41. The apparatus of claim 25 wherein the deployable fastener comprises a length of suture material and the fastening elements comprise needles connected to opposite ends of the suture material.

42. A method of repairing a heart valve having multiple leaflets, comprising:

stabilizing a first leaflet with the repair device;

deploying a first fastener element into the stabilized first leaflet;

disengaging the first leaflet from the repair device while leaving the first fastener element deployed therein;

stabilizing a second leaflet with the repair device;

deploying a second fastener element into the second leaflet;

disengaging the second leaflet from the repair device while leaving the second fastener element deployed therein; and

joining the first and second leaflets by reducing the distance between the first and second fastener elements.

43. The method of claim 42 further comprising controllably and selectively stabilizing the first and second leaflets with vacuum force.

44. The method of claim 42 wherein the first and second fastener elements are portions of a piece of suture material and wherein the step of reducing the distance between the first and second fastener elements is performed by tying the suture material into a knot.

45. The method of claim 42 further comprising adjusting the position of the repair device relative to the leaflets by monitoring fluid pressure around a distal end of the repair device.

46. The method of claim 45 wherein the adjusting step is performed while the distal end of the repair device is in an atrial-ventricular junction and wherein the monitor step is performed by observing pressure differentials between blood in an adjacent ventricle and an adjacent atrium.

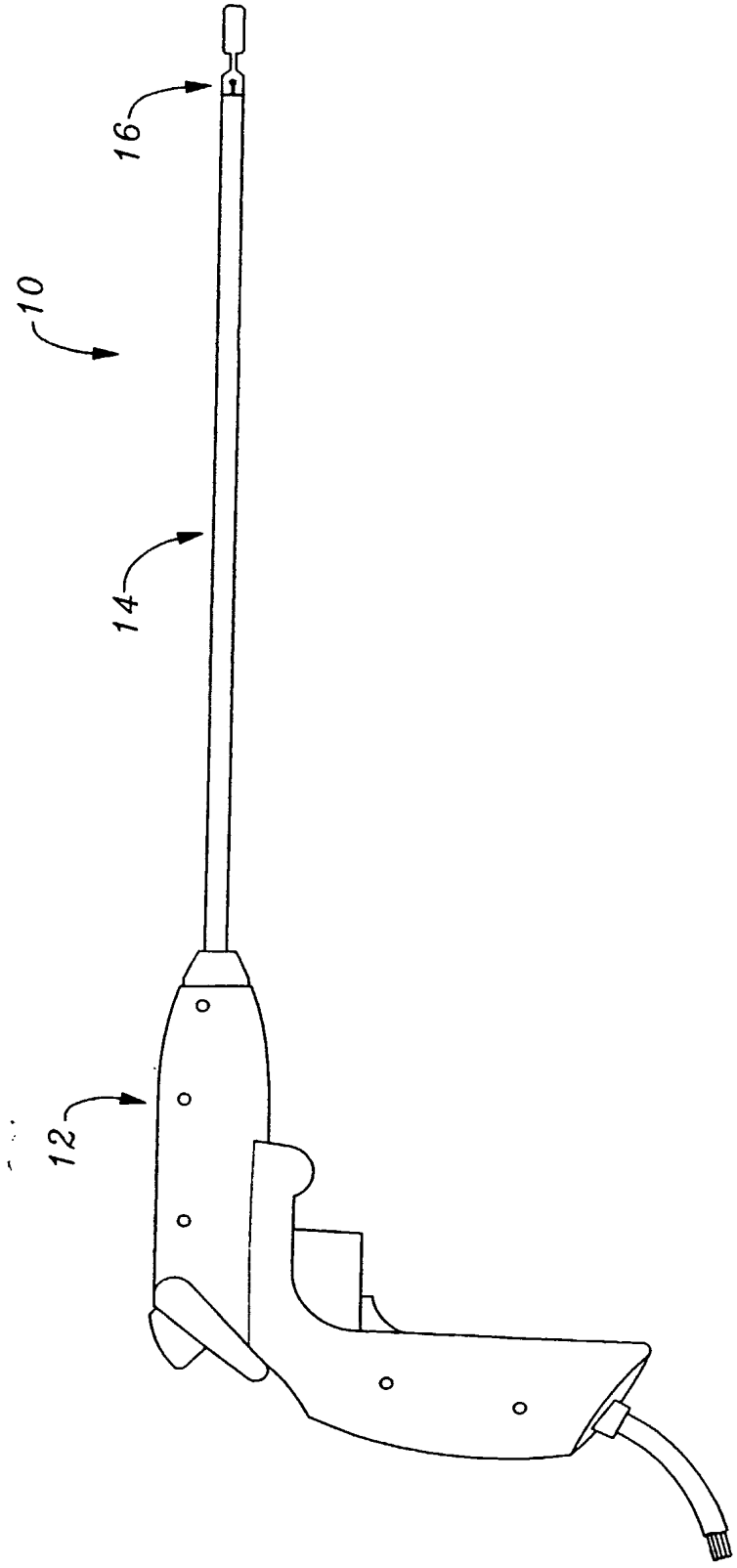
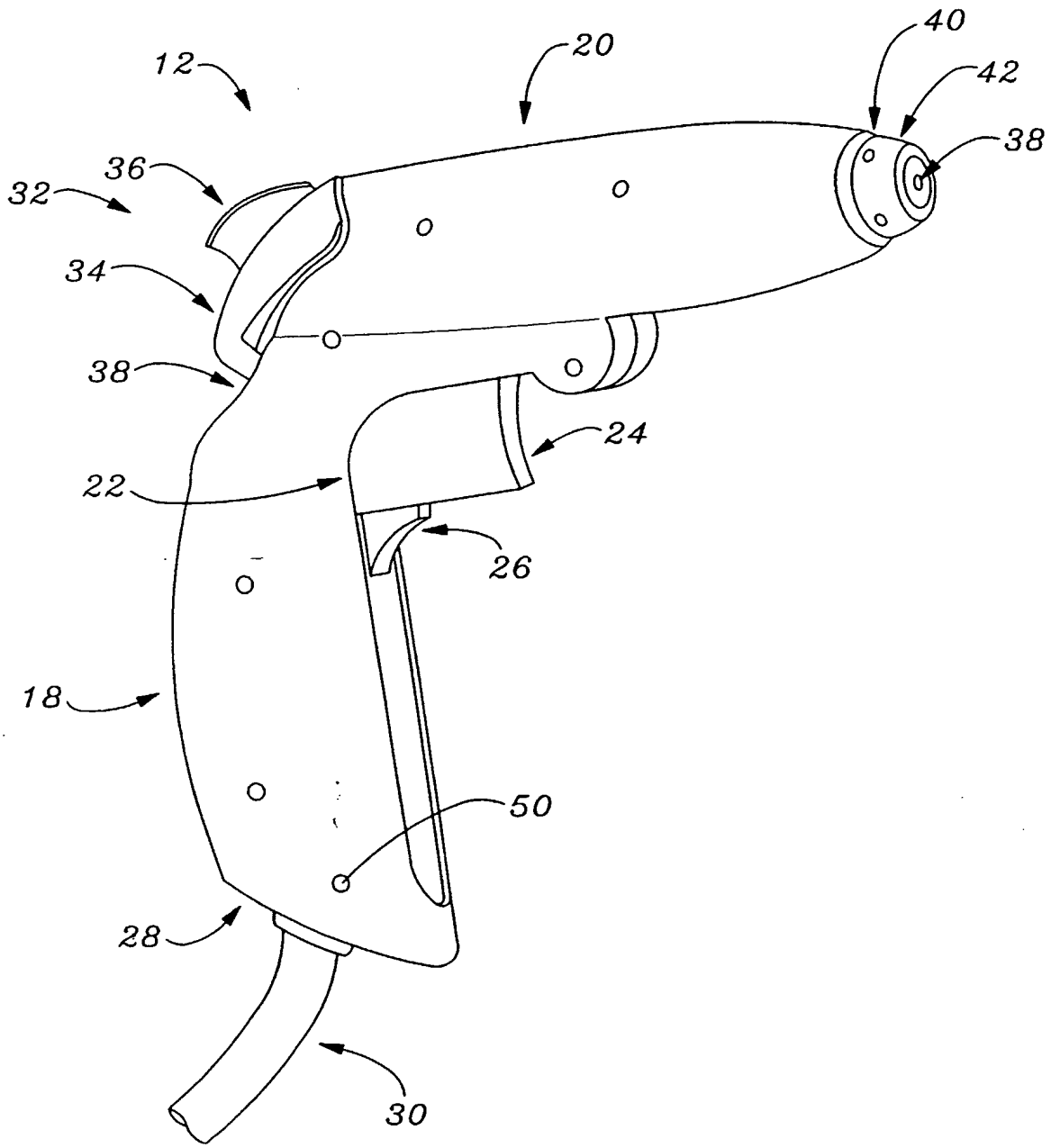


Fig. 1

Fig. 2



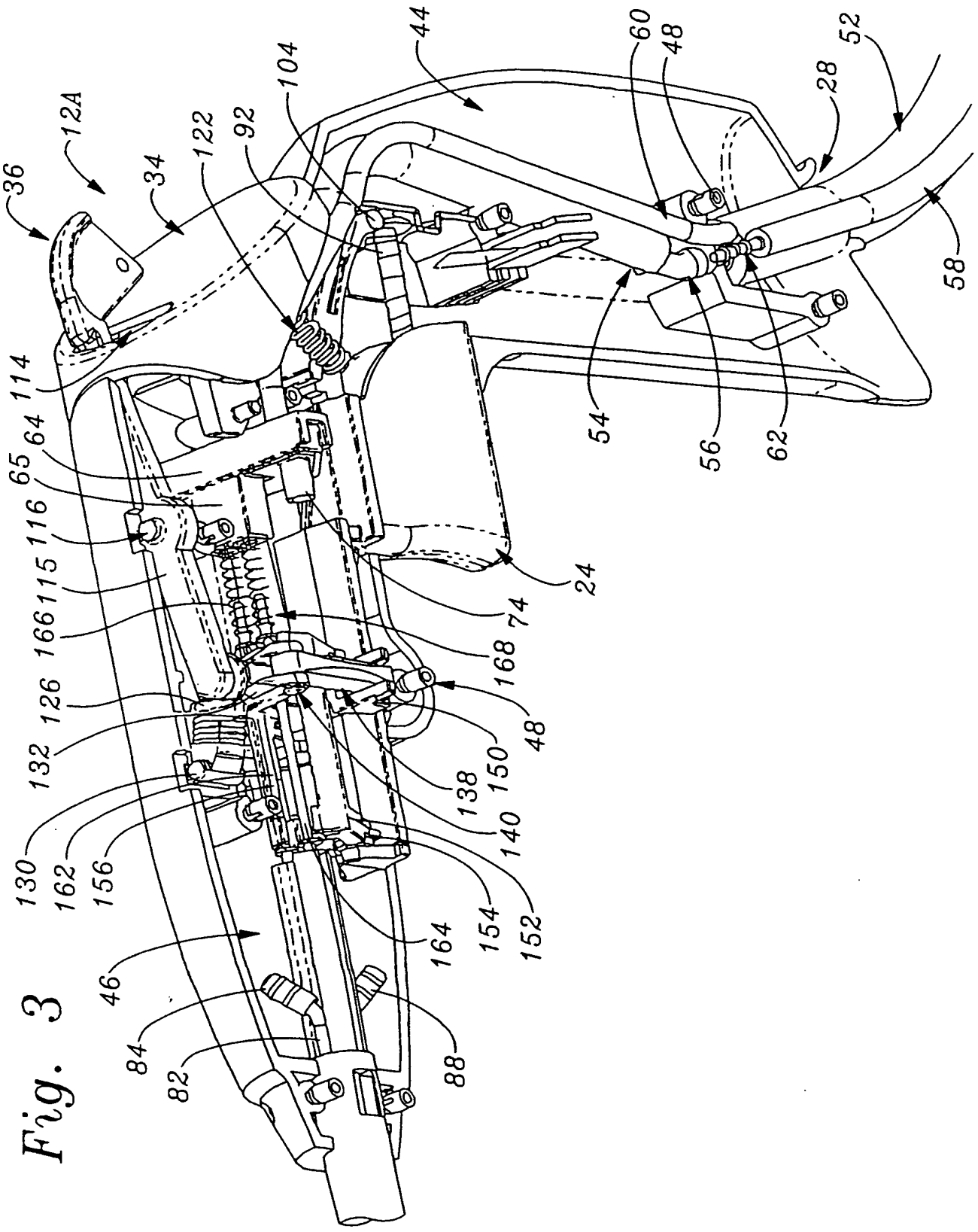

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Fig. 3

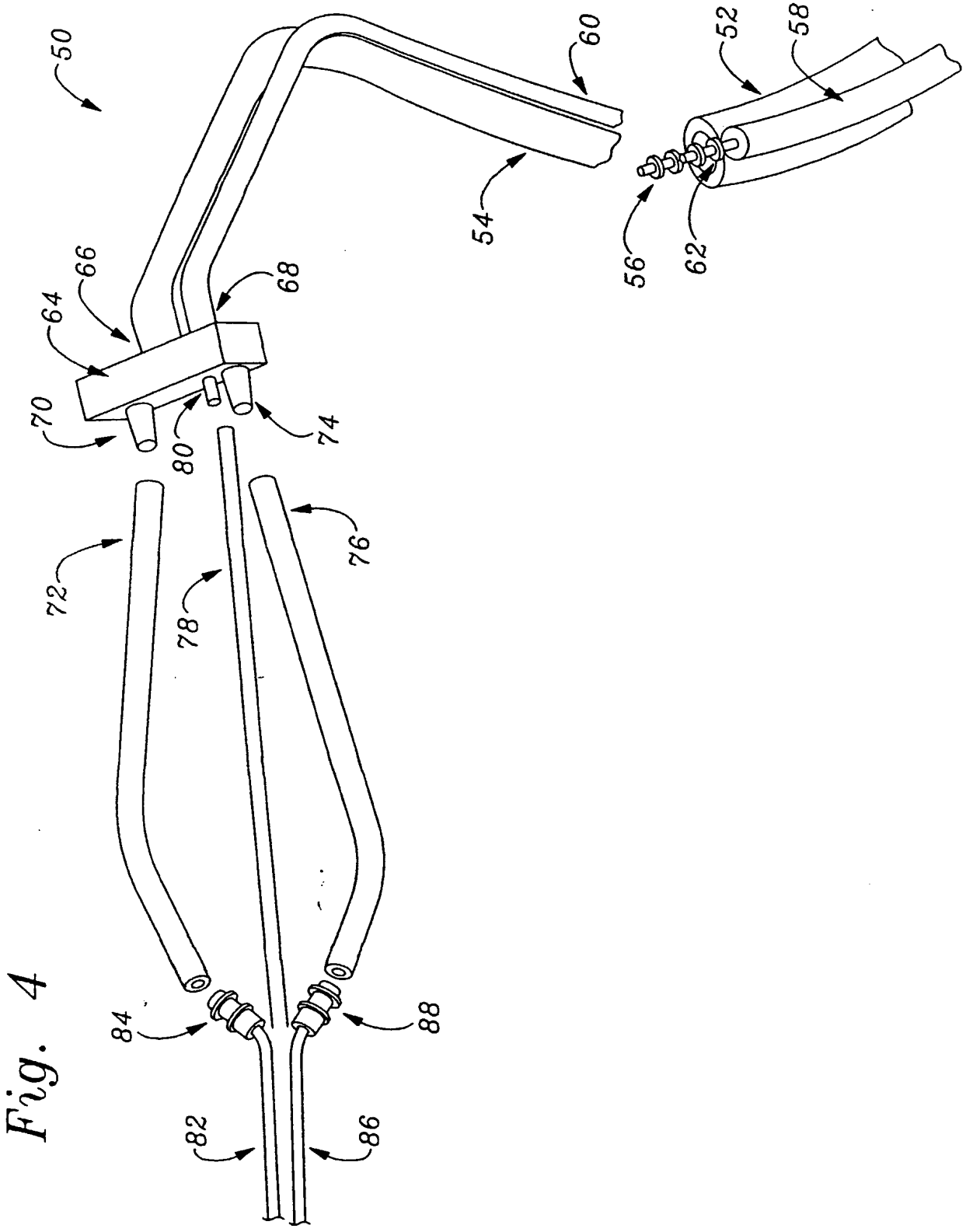

Fig. 4

Fig. 5

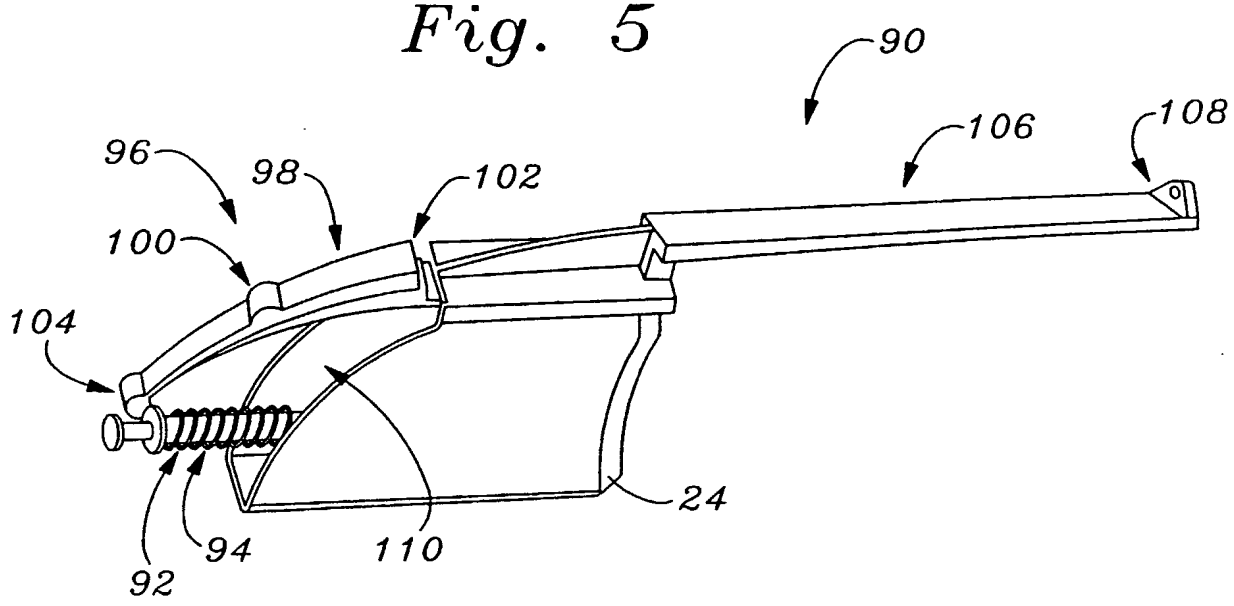
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Fig. 6

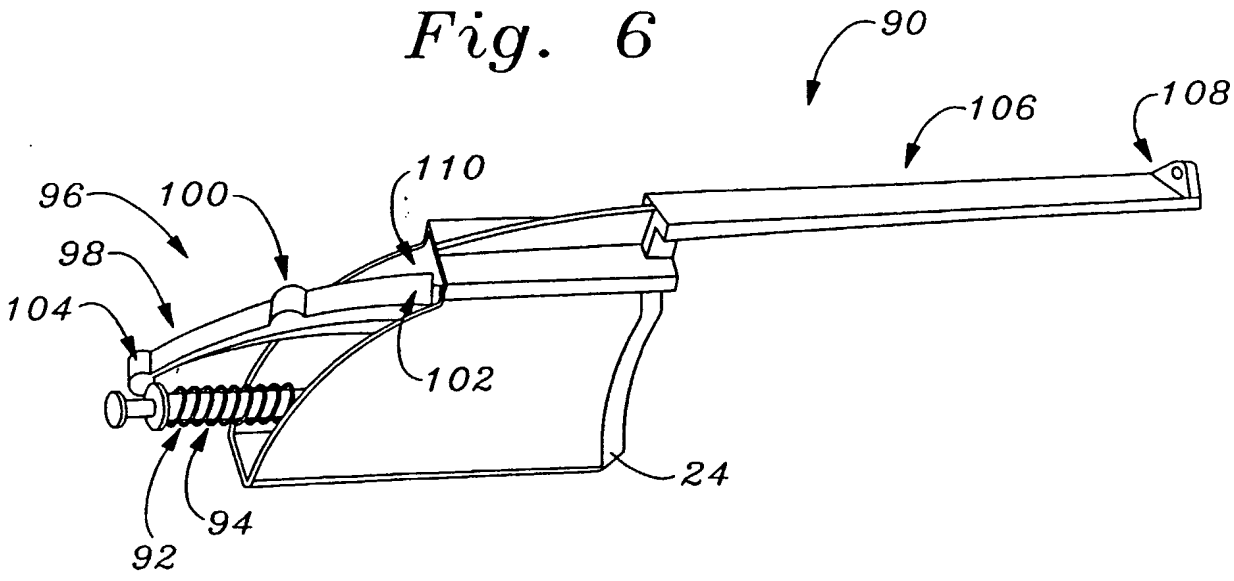
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Fig. 7

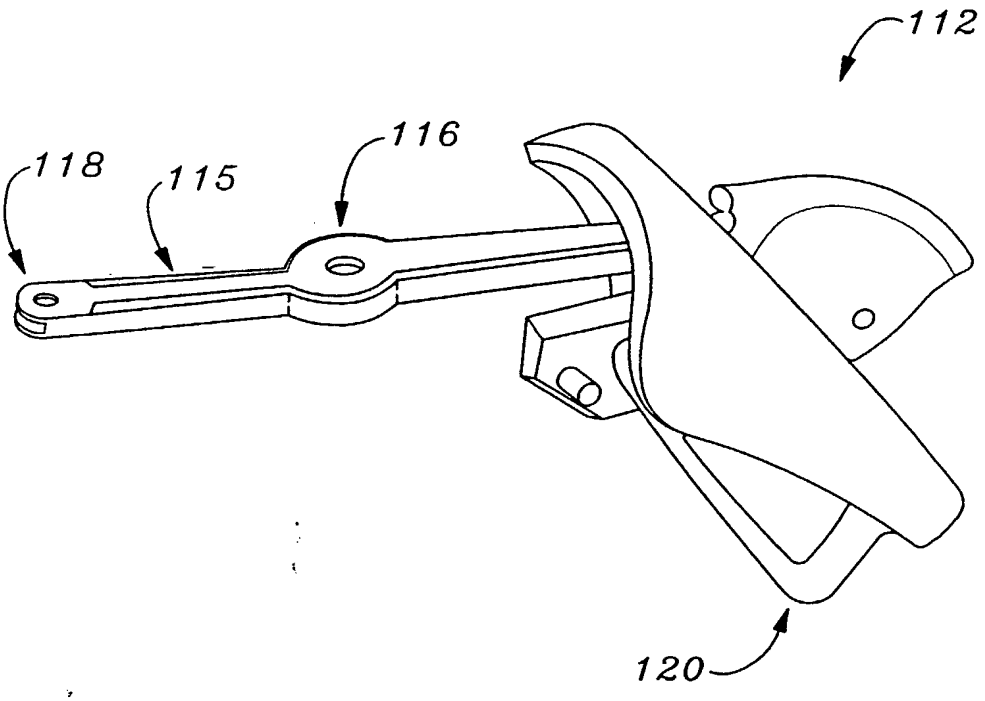
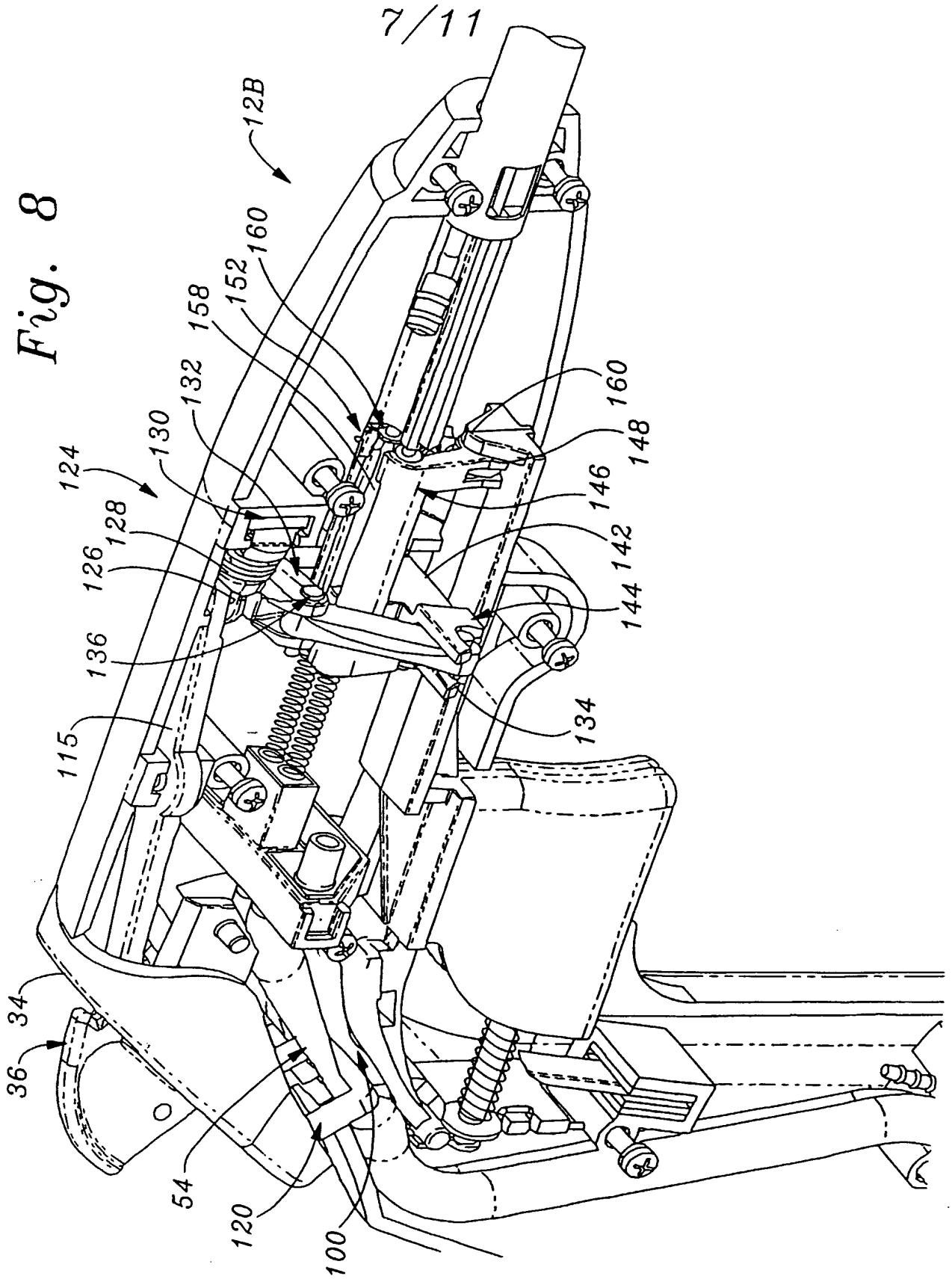


Fig. 8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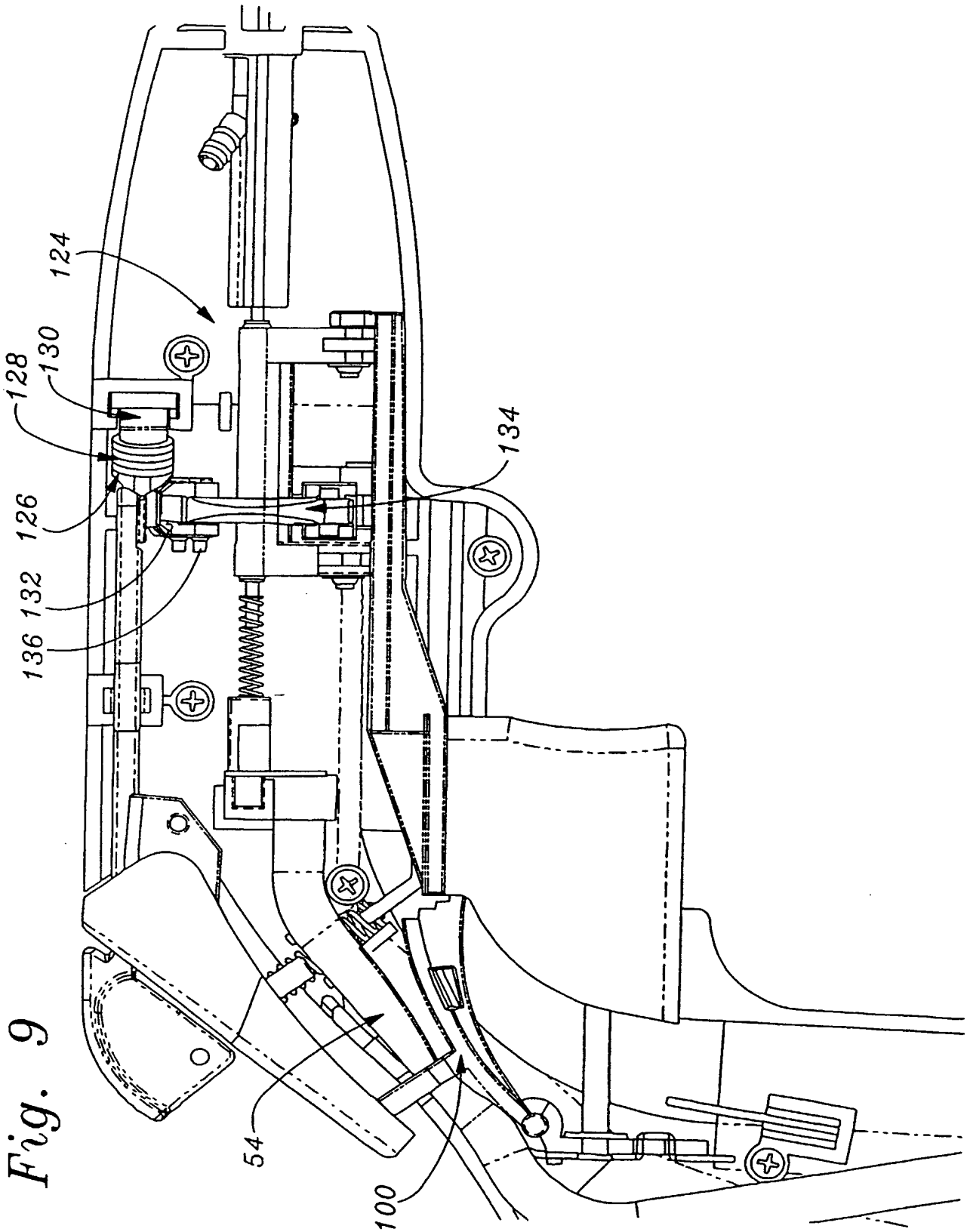


Fig. 9

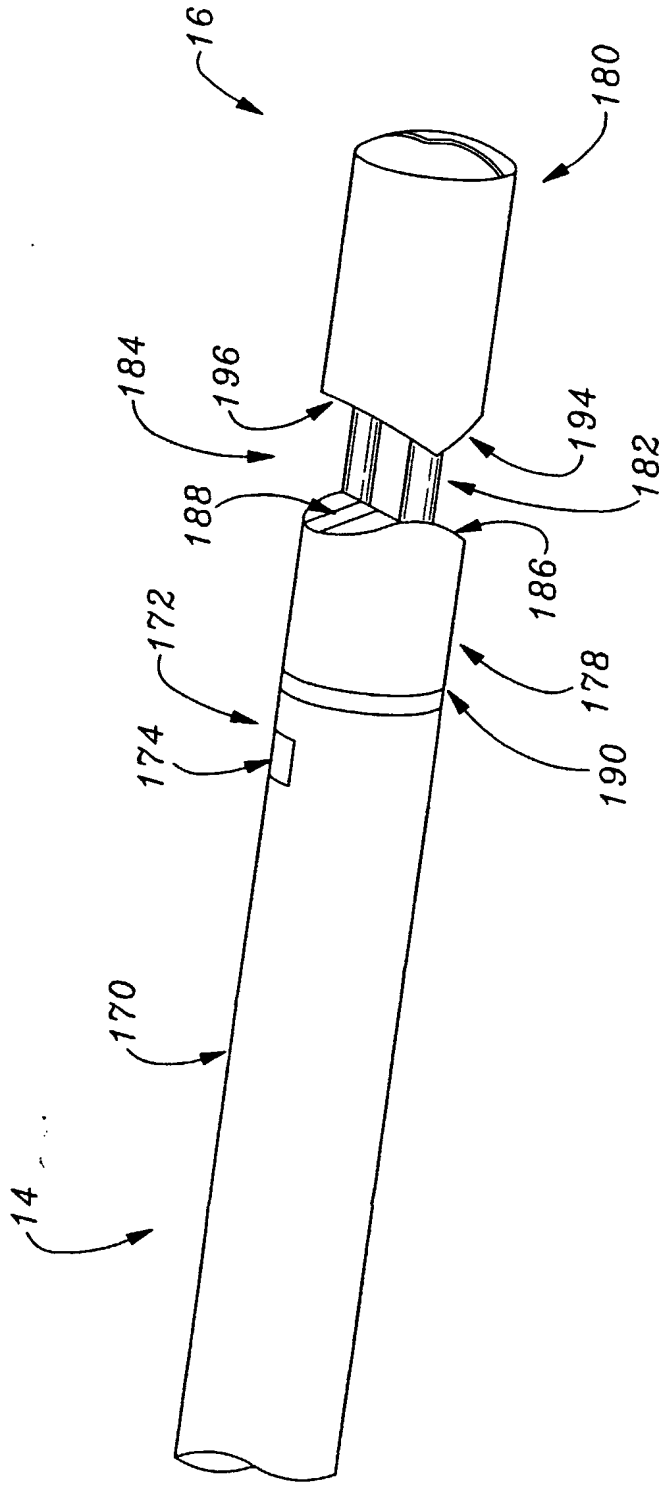


Fig. 10

Fig. 11

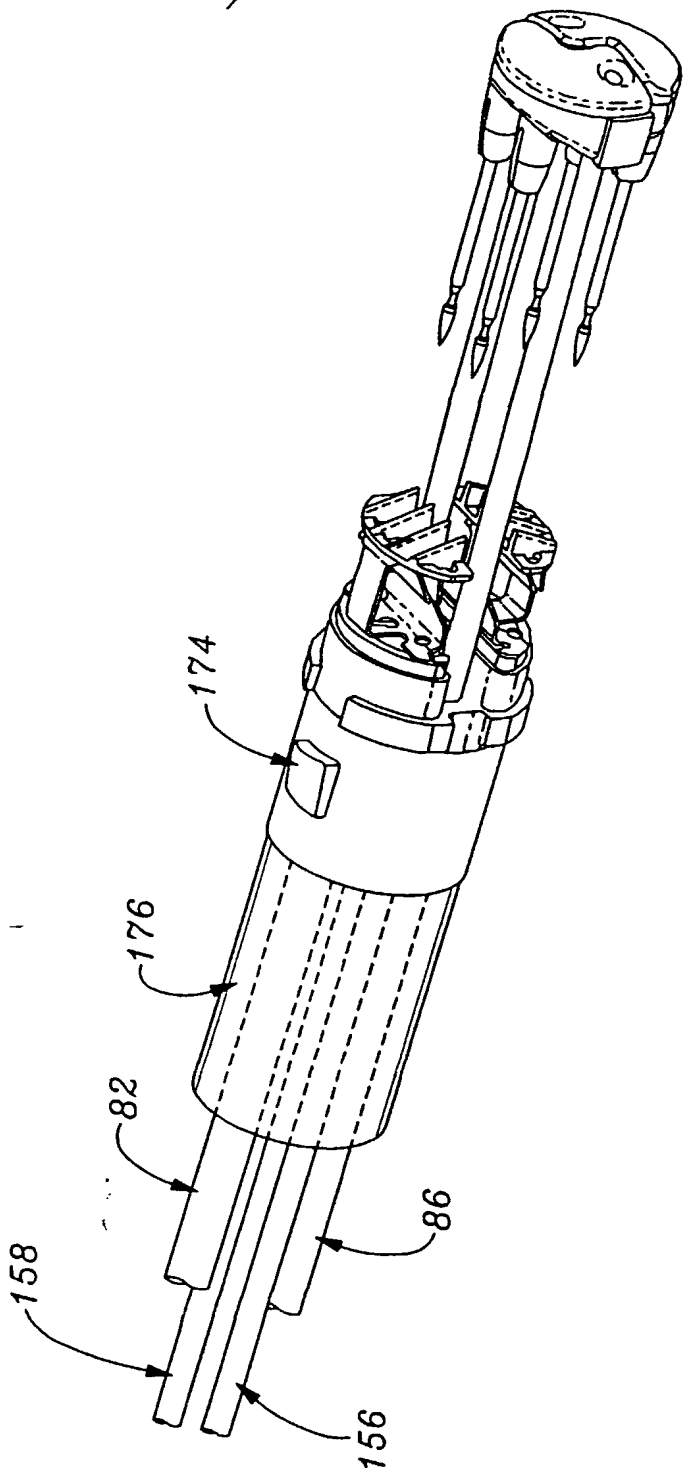
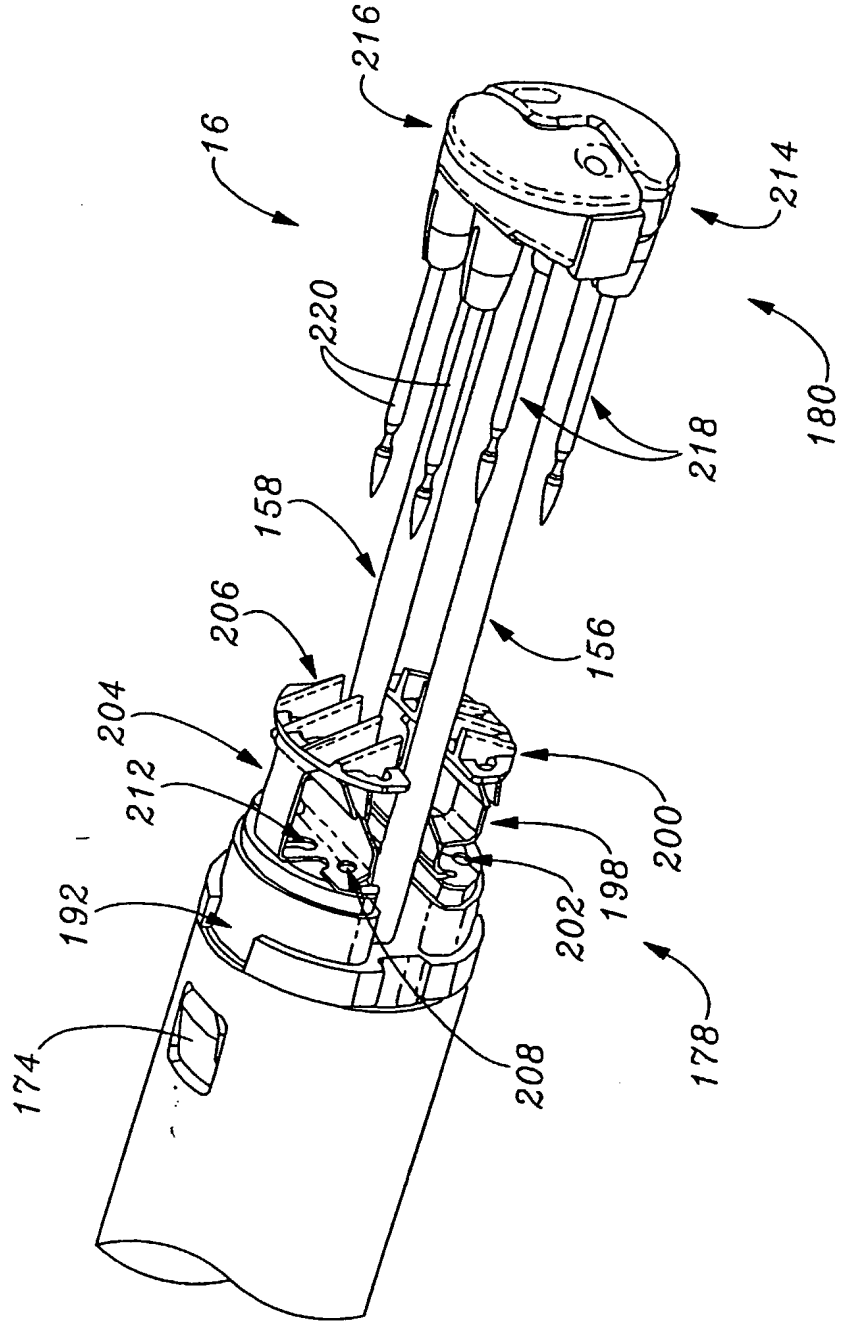


Fig. 12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WO 2008/010738 A2

(54) **Title:** PATENT FORAMEN OVALE OCCLUDER WITH SUTURE BASED ANCHOR

(57) **Abstract:** A harness for generating an elongation of the penis comprises a belt (1), adapted to be worn around one's waist, connected at the rear portion via small rotating snap-hooks with two inextensible cinching straps (8,15), said straps each having a pair of half-rings (9,16) for length adjustment. One said strap (8) on lower end carrying adjustable rope loop (13) to be placed around penis base. Second said strap (15) on lower end is connected via L-shaped connecting member (17) with flexible adjustable loop (19) being encircled and tightened around penis next to the penis head. Penis stretching force is easily and quickly managed by tightening or loosening said straps, even while walking and even over the clothing.

Patent foramen ovale occluder with suture based anchor

Technical Field

This invention relates generally to devices for catheter based occlusion of heart defects such as a patent foramen ovale (PFO) and other morphologically similar defects within the cardiovascular system. The invention relates also to delivery system and technique for device implantation.

Background

A patent Foramen Ovale is a flap- like or tunnel-like opening between the right atrium (RA) and left atrium (LA). This opening functions during fetal life and is usually closed in adults. However it can remain potentially open in about a quarter of adults without having consequences.

Recently, there is evidence that patients with PFO may suffer cerebrovascular events due to paradoxical embolism via this opening. Many studies have confirmed a strong association between the presence of PFO and the risk for recurent cerebrovascular events.

Treatment of such patients includes oral anticoagulation, surgical closure of PFO or catheter based PFO closure using different occlusion systems (Pat. No. WO03103476, US Pat. 20061226, Amplatzer device- US Pat.5846261, Sideris device- US Pat.4917089). All these occlusion devices are made of metal frame (nickel-titanium based alloys, or stainless steel). In order to be safely anchored to the rim of residual tissue around the defect the device must be double the size of the defect.

Complications reported include frame fracture, thrombus formation within the LA and /or RA, cardiac arrhythmias and disturbances of conduction system, perforation of heart tissue, infection, device dislodgement and device embolization. Many devices have a large profile and include large masses of metal material within the left –and right atrium, which may lead to unfavorable body adaptation of the device and is prone to thrombus formation. Some of these implant related complications occur soon after the implantation but heart perforation has been reported even years afterwards (Divekar A,Gaamanwe T,Shaick N,Raabe M,Ducas J. Cardiac perforation after device closure of atrial septal defects with Amplatzer septal occluder. J Am Coll Cardiol 2005;45:1213-8. Hanzel GS: Complications of Patent Foramen Ovale and Atrial Septal Defect Closure Devices Interven Cardiol 2006; 19:160-162). All patients with an implanted device may require life-long surveillance, since complications are difficult to predict

The device and technique disclosed herein are designed to address the aforementioned deficiencies of presently existing devices for PFO closure per catheter.

Summary of the invention

It is the principal object of this invention to provide an intracardiac occlusion device which is made of non-metallic components. It is object of this invention to provide an occlusion device which can be fastened to the tissue by catheter based suture-knot that would prevent device dislodgement and embolization. Yet another object of this invention is to provide the delivery system composed of catheter based thread transporters and knot tying- and pushing instruments for completion of a knot within a remote intravascular/intracardial location.

In a preferred embodiment, the occlusion device is made of compressible sponge occluder made of polyurethane or polyvinylalcohol (Ivalon) with integrated suture length made preferable of monofilament such as nylon on proximal and distal occluder end. The distal end of the suture length is incorporated into one piece of "stent –like" spiral wire that serves as

a docking adapter. The proximal end of the suture length is preformed into a loop knot. ("bowline loop knot";Palstek, Peter Oven: Knoten,Idee&Konzept Verlag, Muenchen 1993:pp 38.). Between the proximal part of the suture length and the sponge occluder a silicon tube of variable length is interposed.

In this application, "distal" refers to the direction away from a catheter insertion location (or away from the operators' hand) , "proximal" refers to the direction nearer the insertion site (or nearer to operators' hand), and "medial" refers to central (middle) portion of an item.

Through the single femoral venous sheath (preferable 12-14 Fr) a 0.014 inch (0.35 mm) guide wire with flexible atraumatic J tip is placed across the PFO into left pulmonary vein or LA. Over this wire a snare catheter is advanced into the LA and opened while the wire is left within the LA. Through the same venous sheath the atrial septum adjacent the PFO is punctured under echocardiography and fluoroscopy guidance as reported (Hoepp HW, Deutsch HJ,Babic U.Transseptal puncture for transcatheter closure of an eccentric atrial septal defect. J Interv Cardiol, 1999;12:367-369.). A low profile catheter is placed through the atrial septal puncture site into the LA. A wire of appropriate length (i.e. 200 cm) and thickness 0.014 inch (0.35mm) is advanced through this catheter to the LA where is caught with a snare catheter and exteriorized via the PFO to the RA and out of the body through the same venous sheath. In this way a continuous wire track is created from the femoral vein through the punctured atrial septum back via the PFO to the RA and out of body through the same venous sheath. The device system is mounted onto the exteriorized tip of the wire track. This maneuver is done by crimping the "stent-like" docking adapter onto the exteriorized tip of tracking wire. The loop of the preformed bowline loop knot is placed over the proximal extracorporeal end of the transseptal catheter (through which inner lumen the continuous wire track runs). The occlusion device is then pushed with a pusher catheter over the 0.014 inch guide wire through the same sheath and placed into the PFO position by simultaneous retracting the wire track and pushing the bowline loop knot by separate pusher catheter. During this maneuver the distal suture end of the device is exteriorized through the transseptal catheter and the sponge occluder is positioned onto the RA-side of the PFO. The guide wire is removed and the bowline knot tied with a catheter. The proximal end of the bowline loop is"threaded" through a catheter and pulled while the catheter is being pushed. Hereby the so called "tourniquet technique", well known in open cardiovascular surgery (Netter HF. The Ciba Collection of medical illustrations volume 5 Heart, Ciba Pharmaceutical Company, 1969; pp 192; Kasegawa H,Shimokawa T,Shibazaki I,Hayashi H et al. Mitral Valve Repair for Anterior Leaflet Prolapse With Expanded Polytetrafluoroethylene Sutures. Ann Thorac Surg 2006; 81:1625-31.), is adapted for application at distant intravascular site. An extra "stopper knot "is created externally and slided over the bowline loop knot pusher catheter to the RA site of septal puncture where is tied using the newly developed catheter based knot pusher. The free suture ends are tied together with catheter-based tourniquet- technique and severed by catheter based cutter leaving the occlusion device in place within the PFO location secured to the septal tissue.

To prevent back bleeding through the single access entry/exit site during complex manipulation with a plurality of catheters, wires and sutures traversing the passageway of the single introducer sheath a haemostatic valve apparatus comprising a compliant endoluminal balloon for sealing is provided. The technology of manufacturing such a highly compliant balloon is reported in Pat. No. WO9220280 and WO0137897 wherein the balloon catheter was used for sizing maneuver of cardiac and /or cardiovascular defects per catheter under ultrasound and x-ray guidance.

Brief description of the figures

Fig. 1 is a schematic perspective view of the PFO occlusion device system.

Fig. 2 A, B, C, D show perspective view of instrument for insertion of an exteriorized suture end into a cardiovascular catheter and its modification which is used as a knot pusher within cardiovascular system.

Fig. 3 is a schematic cross sectional view as seen by transoesophageal echocardiography (TEE), presenting the arrangement of continuous veno-venous wire track from the venous entry site through the atrial septal puncture site back via the PFO to RA and out of body through the same venous sheath using snare catheter for withdrawal maneuver.

Fig. 4 shows a docking of the exteriorized track- wire tip onto the distal suture end of the device system by crimping the docking adapter.

Fig. 5 a 6 show schematic perspective view of the device during "loading" (Fig. 5) and 'over the wire" insertion (Fig. 6) into the venous sheath (lower part), and a cross sectional view of the heart as seen by TEE showing the arranged continuous suture looping and the occluder guiding wire within the LA (upper part).

Fig. 7 illustrates the over the wire advancement of the occlusion system towards the PFO as seen by schematic TEE cross sectional view of the heart.

Fig. 8 shows occlusion device in place and its two suture ends secured to the septal tissue by bowline loop knot.

Fig. 9 Illustrates the creation of an additional "stopper" knot out of the body (lower part) and its advancement through the introducer sheath with the "sliding" technique (upper part).

Fig. 10 illustrates the catheter-based knot tying maneuver within the heart by catheter-based "tourniquet technique".

Fig. 11 is cross sectional view of the heart as seen by the TEE after fastening the PFO occluder to the septal tissue with a suture knot and during the catheter based intracardiac cutting off of the exteriorized sutures' end.

Fig. 12 is cross sectional view of the heart as seen by the TEE showing the device secured to the septal tissue by suture knot with occluder covering the right atrial side of the PFO.

Fig. 13 is a schematic perspective view of a prepared individually transportable knot assembly consisting of a pledget bowline loop knot with suture extension threaded through a pushing catheter.

Fig. 14 is a schematic cross sectional view of the heart as seen by TEE showing the application of the individually transportable pledget loop knot assembly for alternative tying together of the two suture ends during PFO closure.

Fig. 15 is a schematic perspective (A, C) and cross sectional (B,D) view of a haemostatic valve apparatus with a compliant balloon attached endoluminally to provide sealing around the plurality of devices within the passageway showing the balloon initially inflated (A,B) and balloon inflated sufficiently to provide sealing around two catheters (C,D).

Fig. 16 is a schematic perspective (A) and cross sectional (B) view of haemostatic apparatus comprising two individual compliant balloons within the lumen of the apparatus wherein the balloons are inflated sufficiently to provide a barrier against fluid backflow while 2 catheters are placed through the passageway.

Detailed description of the invention

The present invention provides a device for occluding an aperture within body tissue. In particular, the device system of the present invention may be used for closing a PFO in the atrial septum of a heart but it is not considered limited to any particular anatomic structure. The present invention provides also accessories and methods for catheter-based suture-mediated securing of an occlusion device to the surrounding tissue within the remote intravascular-intracardial location of a patient's body. The invention provides also methods and means for catheter based delivering a suture and tying a knot within a remote cardiovascular location.

The essential part of this invention is a sponge occluder without metal components with integrated suture length on both ends. The distal suture ends as a docking connector, while the proximal suture is preformed as a bowline loop knot situated close to the occluder. The proximal suture free end is threaded through a cardiovascular catheter. Between the bowline loop knot and the basal part of the occluder a short tubular piece preferably made of silicon is interposed.

Referring to Fig.1 there is shown a sponge-occluder 2 preferably made of polyurethane or polyvinyl alcohol (Ivalon) with a narrow distal part 4 and wider proximal part 3 reinforced with a thin polyester fabric both of which can vary in size and shape. The sponge extends proximally as the short piece of a narrow tube (preferable made of silicone) 7. The lumen of the tube 7 accepts a thin wire of 0.014-0.018 inch (0.35-0.45mm). The sponge occluder extends distally as a suture thread 5 preferably made of medical nylon that ends as a stent-like "docking" connector 6 made preferably of stainless steel (a stent is an extendable & compressible spiral wire, a stainless tube with slots. It is mounted on a balloon catheter in a "crimped" or collapsed state and it can be expanded with a balloon).
This stent-like connector 6 with lumen 60, distal 62 – and proximal 61 opening can be crimped manually onto the end of a suture or a guiding wire of appropriate thickness connecting them with the occluder assembly in order to extend their individual length. The connector 6 has a small outer diameter e.g. < 0.038 inch (=<0.95 mm) which is compatible with the lumen of conventional cardiovascular catheters. The silicon tube 7 extends proximally as a suture thread 8 with a preformed loop knot (bowline loop knot) 9. A lumen 70 runs axially through tube 7. The length of the tube 7 corresponds to the distance between the PFO 170 and the tissue puncture site 171. It determines the point where the knot is tied to secure both sutures to the septal tissue 17. This tube prevents suture related folding and/or tearing of the septal tissue between the aperture 170 and the tissue perforation site 171 during knot tying.

The procedure of insertion and deployment of the occluder necessitates an extension of an extra corporeally exteriorized suture end which is achieved by inserting it across the lumen of a narrow cardiovascular catheter. An instrument for insertion of a suture end into a narrow cardiovascular catheter is illustrated in Fig 2.
Fig. 2 A, B, C, D illustrate instrument for insertion of a suture end into a narrow lumen of a cardiovascular catheter 24. The instrument unit 21 consists of an elongated metal cannula 22 and a looped nylon thread 23 running through the central lumen 220 of the cannula 22; short portion of thread looping (noose) 230 protrudes over the distal cannula opening 221 while the looping position with a constant diameter of the noose is being kept in place by fastener 223 located on the proximal end 222 of the cannula 22 where both ends of the looping are tied to each other by a knot 231 and fastened with fastener screw 223 as illustrated in Fig.2A. The outer diameter of the cannula is adapted to fit into a narrow lumen (0.038 inch=0.95 mm) of standard cardiovascular catheters, while the cannula's lumen 220 accepts looped suture thread made of thin medical nylon e.g.2x0.0072 inch (=2x0.18mm). The instrument is first advanced through the catheter 24 such that it protrudes over catheter's distal end. An exteriorized end of extracorporeal suture 25 is passed through the noose 230 of the instrument 21 (Fig.2B) and the cannula 22 is pulled back into the lumen of the catheter from the distal - to the proximal opening of the catheter as illustrated in Fig. 2 C. Alternatively, after passage of the suture end across the noose 230, the cannula can be held in place and the catheter can be advanced into the body over the cannula and further over the exteriorized thread to reach a remote target location by ,in this way created, extended guidance.
Additionally, this instrument can be used as a reliable knot pusher within cardiovascular system. Hereby the suture end of an extra corporeally created knot is placed across the loop and the whole instrument is pushed as a unit sliding the knot towards the target site over the

second suture member (Fig.2D). Its pushability is high and the friction during knot sliding is low. Repeating this maneuver as many as necessary throws of individual knots can be accomplished.

Fig. 3A illustrates a section of human heart, as seen by short axis transoesophageal echocardiography (TEE- ultrasound from oesophagus), having a right atrium (RA) 16, aorta 18, left atrium (LA) 15, atrial septum 17, septal puncture site 171, and the PFO 170. This TEE view is typically used during the closure procedure of defects within the atrial septum. An introducer sheath 14 of appropriate diameter (e.g.12- 14 Fr) is placed into the inferior caval vein from the femoral vein in usual manner. Through this sheath the interatrial septum is punctured in a conventional way under TEE guidance (for this purpose a smaller diameter assembly of transseptal elongated needle/catheter custom made kit may be used e.g. 4-5 Fr). The transseptal needle is removed and the catheter 12 is left within the LA 15; a long track wire 11 with a flexible tip is advanced through the catheter until its radiopaque distal end appears in the LA cavity. A snare catheter 13 is placed through the same venous sheath over a separate guidewire across the PFO 170 and opened within the LA 15; the tip of the track wire is caught with the snare catheter and is pulled back towards the RA 16 across the PFO 170 and is exteriorized through the same sheath 14 out of the body. In this way the continuous wire track is created from the femoral vein to the right atrium 16, across the punctured atrial septal site 171, left atrium 15, back via the PFO 170 to the RA 16, and out of the body through the same femoral venous sheath 14. The tip of exteriorized track wire 11 is placed through the distal opening 62 into the lumen 60 of the docking connector 6 of the system device 1 and coupled to the end of the distal suture 5 by crimping the stent like docking adapter manually as illustrated in Fig. 4. Retracting the wire track a suture length looping in reverse direction is created.

In an alternative application, the described method may be used for suturing two margins of an anatomical aperture together (not shown). Hereby two tissue margins adjacent the aperture are punctured sequentially through the same introducer sheath with the elongated needle/catheter assembly. Using the snare catheter placed through the anatomical aperture two suture looping are created sequentially from the single access port through the first and second puncture site respectively back via the aperture and out of the body through the same access sheath leaving 4 suture ends out of the body in front of the single port access. The external suture ends are coupled to each other by knots created and delivered as described bellow and illustrated in Fig. 2D,9,10 or utilizing the device assembly 29 as illustrated in Fig.13 and 14.

Alternatively, the method may be used for suturing a remote tissue which has no existing anatomical aperture (not shown): Hereby the said tissue is punctured at two adjacent sites sequentially through the same introducer sheath with the elongated needle/catheter assembly. Using the snare catheter placed through one puncture site the suture length looping is created from the single introducer sheath through the first puncture site back via the second puncture site and out of the body through the same port access leaving 2 suture ends out of the body. The external suture ends are coupled to each other by knot created and delivered as described bellow.

It is understood that this method is applicable to the remote tissue which is accessible for puncture with elongated slightly curved needle catheter assembly. The said tissue (such is heart septal wall) typically has a proximal- and a distal side and cavities proximally and distally from the proximal and distal tissue side respectively wherein et least one side is accessible per catheter.

Fig. 5 shows perspective view of insertion of the device into the introducer sheath (lower part) and cross sectional schematic view of the heart (upper part): After docking onto the system device, the wire track is pulled back. Following the wire track, the distal suture length 5 of the device is pulled backwards into the introducer sheath across the PFO 170, LA 15, through the atrial septal puncture site 171 through the transseptal catheter 12 out of the body. The length of the suture of the device corresponds to the length of this route (usually 180-200 cm). The occluder sponge 2 is in front of the introducer sheath 14; a guiding wire 19 for device pushing is placed through the same sheath 14 through the PFO 170 into the LA 15.
Fig.6 shows further step during device insertion into the introducer sheath; the proximal end of the guiding wire 19 is placed across the sponge occluder and through the central channel of the short silicon tube 7. The loop of the bowline loop knot 9 is placed over the transseptal catheter 12, device pushing catheter 20 is placed over the wire 19 and catheter 10 is placed over the proximal suture 8 for pushing the bowline loop knot. Braided (with reinforced wall for better pushability) 4 or 5 Fr cardiovascular catheters, well known in catheterization practice, can be used as pusher catheters. These catheters usually have stainless steel wire embedded in their wall.
Fig. 7 shows advancement of the occluder through the venous sheath 14 being pushed over the guiding wire 19 , while the bowline loop knot 9 is being pushed with a catheter 10 over the transseptal catheter 12 in which lumen distal device suture length 5 is situated.

Fig. 8 shows the tying maneuver of the bowline loop knot: the occluder 2 is in place. Short part of the distal suture length 5 is running inside the LA 15 leaning on to the septal tissue 17 between the PFO 170 and septal puncture site 171, the transseptal catheter 12 is withdrawn to the RA 16 , distal exteriorized end of the suture 5 is being pulled to adjust its length so as not to fold the septal tissue between the PFO 170 and puncture site 171 as controlled by the TEE ; the bowline loop knot pushing catheter 10 is advanced while the bowline proximal suture end 8 is being pulled slightly. The aim of this maneuver is to tie the bowline loop knot without folding of the septal tissue between the puncture site 171 and PFO 170. The tube 7 prevents suture related damage of septal tissue. After completion of the bowline loop knot 9x5 tying maneuver, the transseptal catheter 12 is withdrawn and the distal suture end 5 is wrapped (knotted) over the circumference of the bowline loop pushing catheter 10 (in which lumen the proximal device suture length 8 is situated) and the knot 5x8 is created by sliding it over the catheter 10 with the knot pusher catheter (Fig.9) or with the unit 210 as illustrated in Fig. 2D.

Fig. 10 illustrates the tying maneuver of the additional stopper knot 5x8 created externally and advanced to the target site by catheter based tourniquet technique: both ends of the sutures 5 and 8 are being pulled while both pusher catheters 10 and 12 are being pushed. In this way a considerable pushing and tensile strength is applied onto both suture's part providing an effective knot tightening at distant intravascular location.

Fig. 11 shows the occlusion device placed within the PFO 170 secured with the suture knot 5x9+5x8 to the atrial septal tissue 17; both suture ends are free out of the body; the free ends of the sutures are severed one after the another with instrument 28 for cutting off of the free ends of surgical knot at minimal invasive or catheter based procedures 36 (Pat. No. P-209/94: Serbia &Montenegro Belgrade, Intellectual Property Gazette 2006;2:258-259).

Fig. 12 illustrates occlusion device in place after complete deployment ; note that there is only a short run of the suture 5 within the LA while the knots 5x9+5x8 and the sponge occluder 2 with silicon tube 7 cover the PFO 170 from the RA 16 septal side.

In an alterative embodiment the occlusion unit 1 can be introduced and deployed without an integrated loop knot on the proximal suture. After device placement the proximal and distal sutures are tied together with an individually transportable pledget loop knot unit 29 as illustrated in Fig. 13. The unit consists of a pledget 30 made preferably of felt or Teflon with an integrated suture which extends proximally as a prepared bowline loop knot 31 and further as a free suture end 32 over which a pusher catheter 33 is placed. Two suture ends may be advanced through the pledget 30 (not shown) and through the loop of looped knot unit.
The individually transportable loop knot is delivered over the suture ends 5 and 8 through a guiding sheath as illustrated in Fig.14. The end of the loop knot passage is identified by fluoroscopy and TEE and by the feel of a "stop" by the operator. Tying the bowline knot is accomplished as described above. Additional "stopper knots" are delivered as described above.
The described method of securing the device to the tissue necessitates simultaneous passage of plurality of catheters and/or wires or sutures via a single passageway i.e. introducing sheath placed within the vasculature. During this maneuver there is a need for preventing of back bleeding.
Fig.15 A,B,C,D illustrate a haemostatic apparatus 35 comprising a housing with a haemostatic elastomeric valve 3621 situated at the proximal end 362 of the housing and a compliant balloon 3601 disposed endoluminally and longitudinally within the lumen 360 of the housing. Channels for balloon inflation and deflation 36011 and a channel for flushing the lumen of the housing (not shown) are also incorporated. Distal end of the housing 361 is adapted for connection with the proximal extracorporeal end of conventional introducer sheath or port access cannula. During passage of 2 cardiovascular catheters 37 and 38 through the access pathway, the endoluminal compliant balloon is inflated via side arm with clear saline solution. The inflated balloon expands inwardly, centripetally and axially – longitudinally contacting all the items within the lumen of the housing sufficiently to provide an effective barrier against the back bleeding and against air aspiration and pushing additionally the elastomeric valve towards closing position. The balloon may be made of a highly compliant material such as latex or polyurethane membrane and the tubular shaft may be constructed of a polymer composite. The balloon is constructed and arranged so that it is capable of conforming upon inflation to all items within a room in which is situated. Since this apparatus is aimed for external (extracorporeal) application its shape and size may vary. Many variant technologies may be used to attach a balloon endoluminally into a tubular apparatus. In one embodiment, the compliant balloon membrane is attached onto one side of a piece of plane polymer composite of appropriate dimensions of which the outer wall (shaft) of the apparatus housing is to be made. Then, the polymer composite piece is formed into a tubular member by longitudinal joining (e.g. welding) such that the side covered with balloon is positioned inwardly. The longitudinal apposition zone of the free margins of the shaft of the apparatus and the apposition zone of the free margins of the endoluminal balloon membrane will not alter the balloon sealing function. It is understood that the endoluminal balloon does not need to be attached to the full circumference of the tubular inner wall. It has to attach only partly to the inner wall surface, but enough to provide stable attachment. In an another embodiment, instead of one endoluminally attached balloon, one or two compliant balloons 3602 , 3603 with individual shafts are situated into the free lumen of the housing comprising inflation/deflation channels 36021, 36031 and side arms incorporated into the housing wall 36 (Fig.16 A,B).

Claims

1. A medical device system for occluding an anatomical aperture comprising a sponge occluder with suture length integrated into both proximal and distal occluder ends for catheter- based introduction, advancement- and device securing to the tissue.
2. The medical device of claim 1, wherein a short flexible polymer tube made preferable but not exclusively of silicone is incorporated between the proximal basal part of the sponge occluder and its integrated proximal suture part.
3. The medical device of claim 1, wherein said proximal suture length has a preformed loop knot situated close to the said polymer tube of claim 2.
4. The device of claim 1, wherein a "stent like" docking connector is integrated into the distal suture end.
5. An instrument for insertion (back loading) of a free suture end into a narrow lumen of cardiovascular catheter comprising: an elongated metal cannula made preferably of surgical grade stainless steel with a looped thread made preferably of nylon in its lumen such that the distal looping end with a constant diameter of the noose is protruding over the distal opening of the cannula while the proximal free ends of the looped thread are fastened by a knot and by a screw mechanism located on the proximal opening of the cannula wherein the said instrument is sized and shaped for introduction into the lumen of conventional cardiovascular catheter.
6. A medical device for knot pushing and knot tying maneuver within a patient's vasculature comprising the instrument of claim 5 situated within the lumen of a braided cardiovascular catheter wherein the said catheter covers the total length of the metal cannula leaving only the static nylon noose to protrude over the distal catheter end.
7. A method for catheter based delivering a suture at cardiac septal tissue comprising:
puncturing the septal tissue at one or two sites adjacent the anatomical aperture and
creating a looping of the suture length from the access sheath through one puncture site, back via the another puncture site or via the aperture and out of the body through the same sheath leaving both ,proximal and distal, ends of the suture looping extra corporeally
utilizing conventional transseptal catheter- and snare technique.
8. A method for creating and delivering of an extra corporeally made knot for tying together two exteriorized ends of a suture delivered at the target tissue within a remote cardiovascular location comprising: inserting one exteriorized suture end into a lumen of a narrow catheter using the device of claim 5 and advancing the catheter over the first suture until it contacts the target tissue; forming a knot externally with the second suture end by wrapping it around the circumference of the catheter covering the first suture part; placing the second suture end across the noose of the pusher device of claim 6 ; advancing the knot by sliding it over the catheter by pushing the pusher device up to the target tissue; pulling the second suture end while simultaneously pushing the knot pusher device; withdrawing the pusher device; inserting the second suture end into a narrow catheter lumen using the device of claim 5 and advancing the catheter over the second suture close to the target site to be sutured; Tying the knot by pulling both suture ends while simultaneously pushing both catheters over them ; repeating this maneuver as many times as necessary; severing the free suture ends with catheter based cutter.
9. An individually transportable pledget- knot assembly for use within the remote cardiovascular locations consisting of a surgical pledget preferably made of felt or Teflon with integrated suture length which creates a preformed loop knot (preferable but not exclusively bowline loop) and extends proximally through a cardiovascular catheter, wherein the said assembly is shaped and sized for introduction into cardiovascular delivery sheath.

10. A method for tying together two exteriorized ends of a suture for suturing a target tissue site within a remote cardiovascular location utilizing the medical device of claim 9 comprising: advancing the assembly of claim 9 over both exteriorized suture ends up to the target tissue; tightening of the loop knot by puling the suture of the assembly and pushing its catheter; creating and delivering additional stopper knots with methods of claim 8.

11. An apparatus for preventing fluid backflow from a cardiovascular access sheath or port access cannula comprising: a tubular member comprising a proximal end, a distal end, and a lumen extending between both ends sized and shaped for external connection with the proximal end of a cardiovascular access sheath or port access cannula; a haemostatic elastomeric valve incorporated into proximal end, and an endoluminally attached compliant balloon extending longitudinally between proximal and distal end wherein the said balloon expands when inflated inwardly ,centripetally, and axially within the passageway and is adapted to contact one- or plurality of medical devices passing through the lumen sufficiently to prevent fluid backflow; comprising further connecting channels and side arms for balloon inflation/deflation and lumen flushing.

12. The apparatus of claim 11 wherein one or two balloons with individual shafts are situated into the free lumen of the housing, instead of one endoluminally attached balloon, comprising further one or two inflation /deflation channels traversing laterally through the outer housing wall.

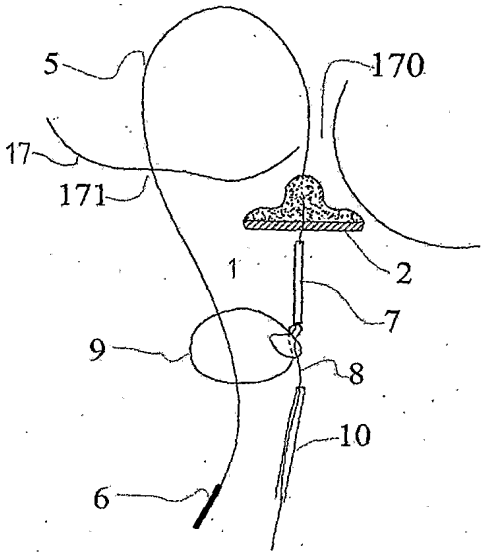

FIG.1

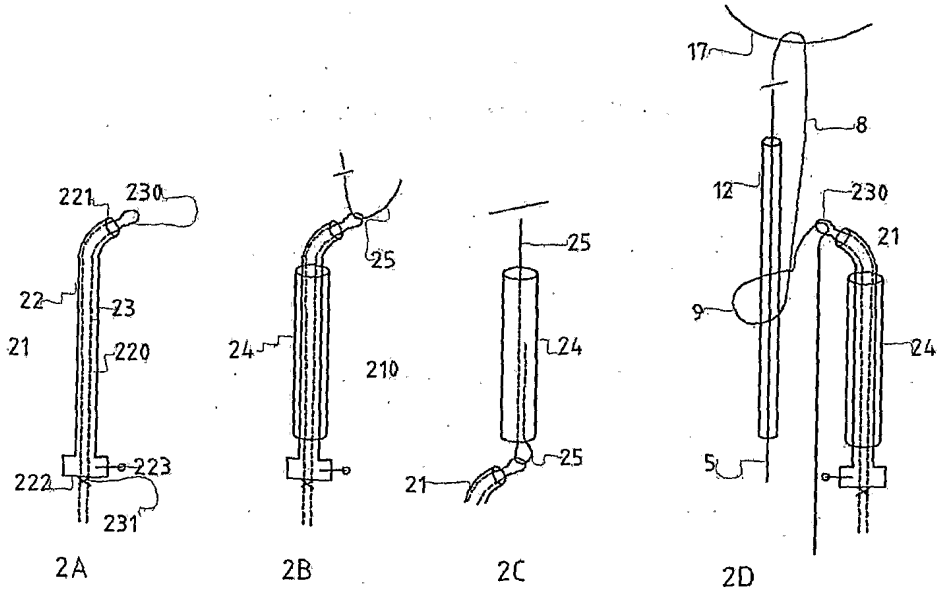

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FIG.2

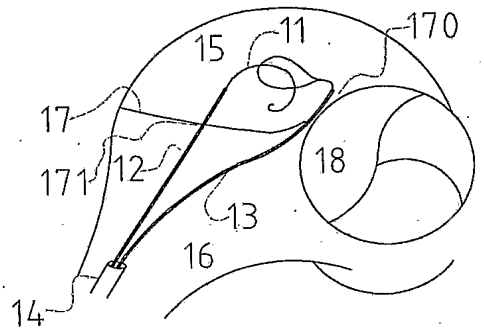


FIG.3

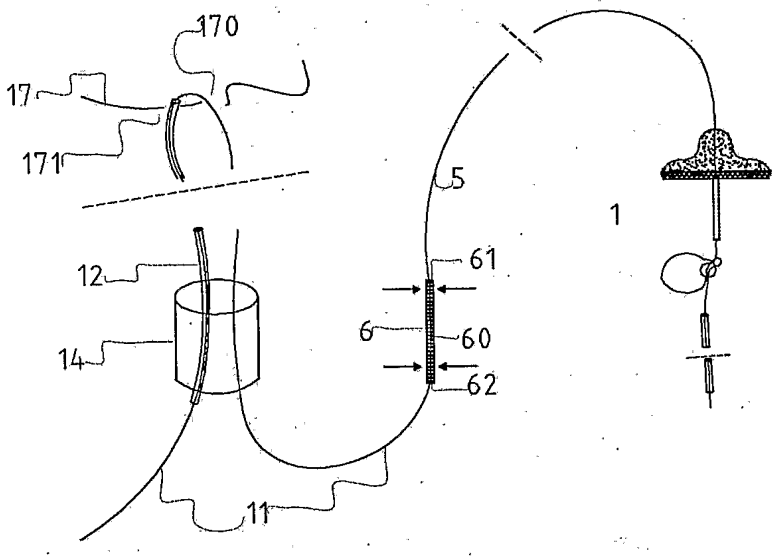
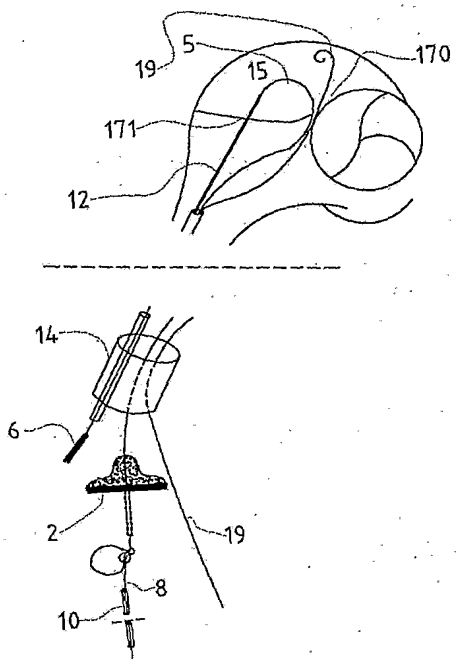


FIG.4



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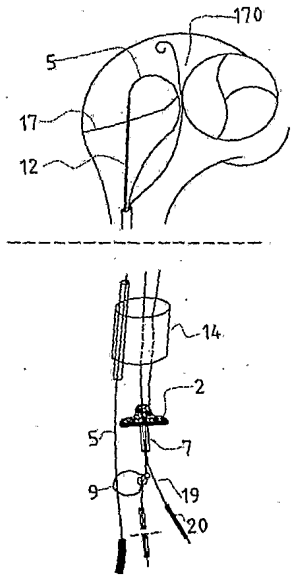

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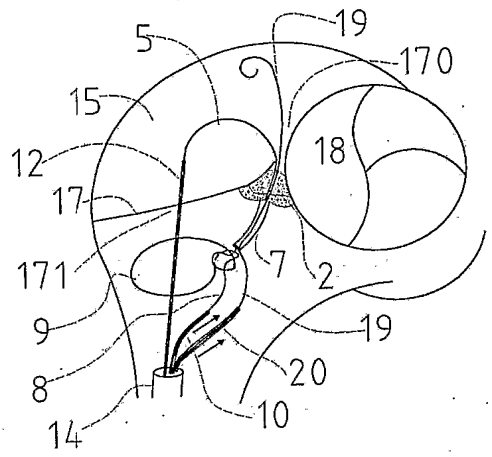
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FIG.7

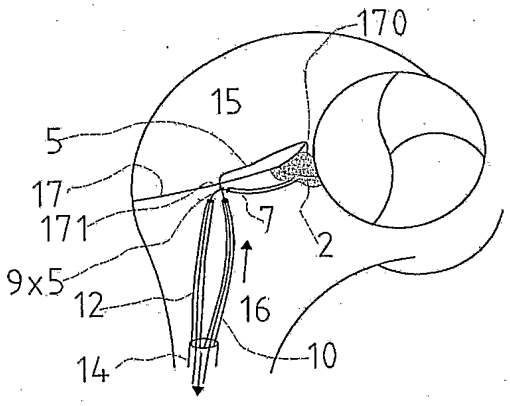
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FIG.8

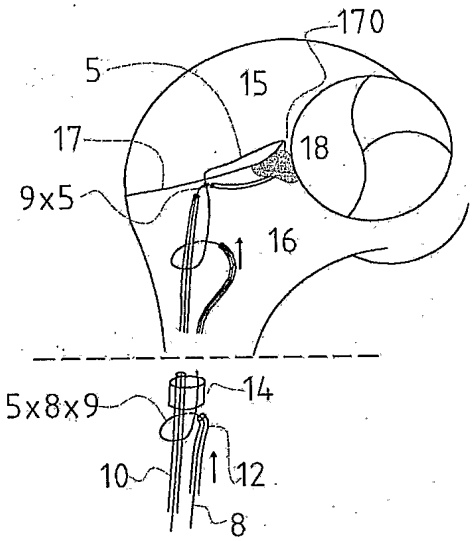


FIG.9

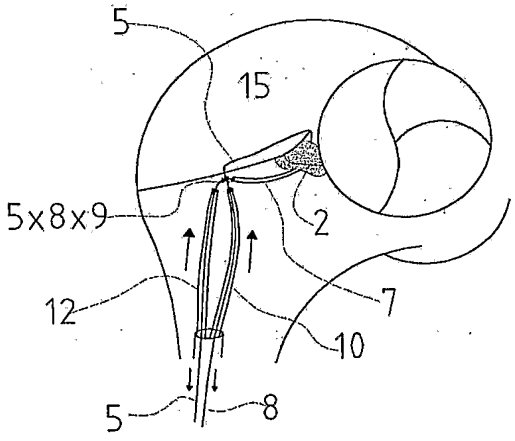


FIG.10

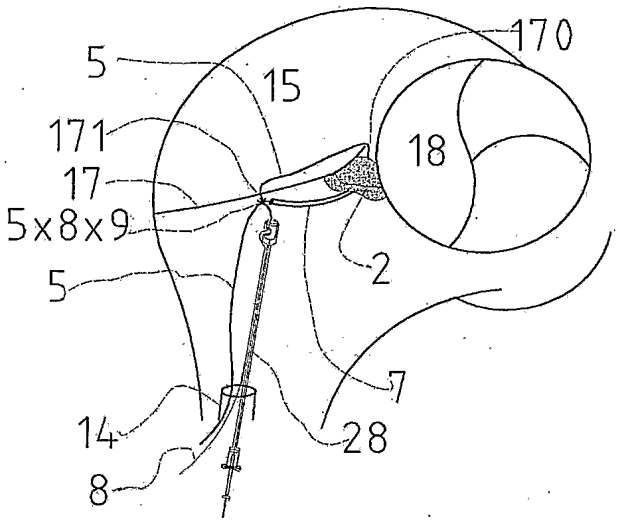


FIG.11

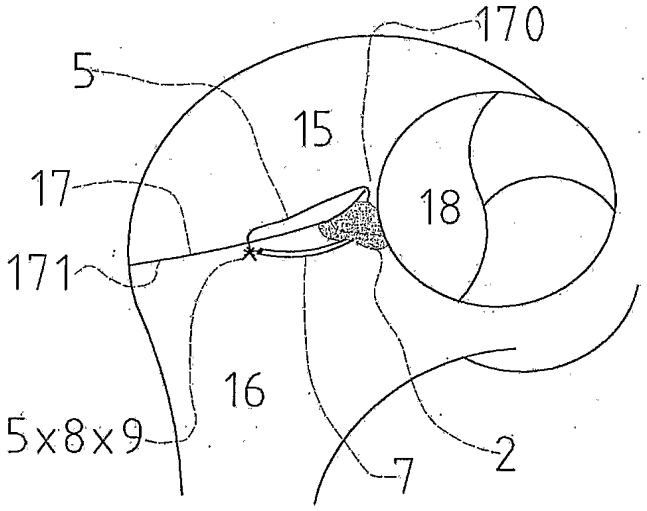


FIG.12

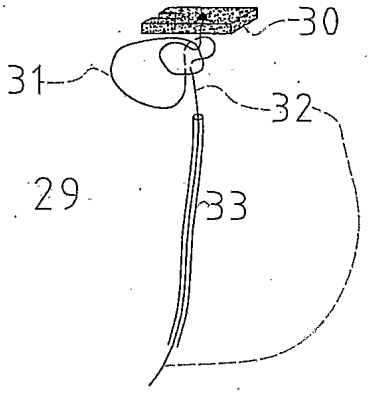


FIG.13

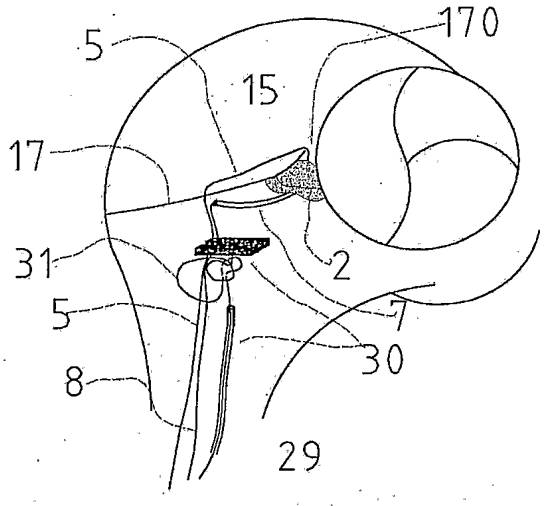


FIG.14

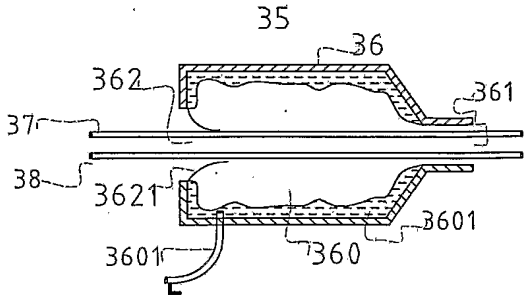


FIG.15A

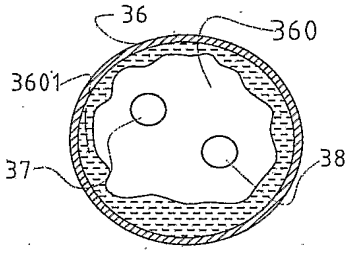


FIG.15B

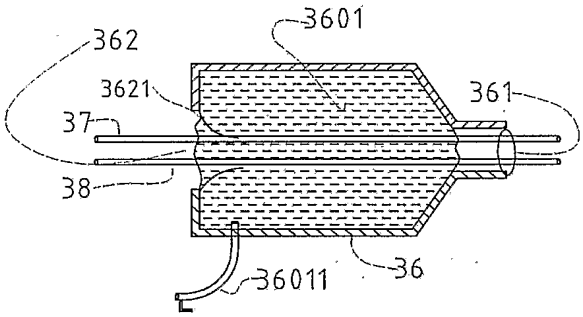
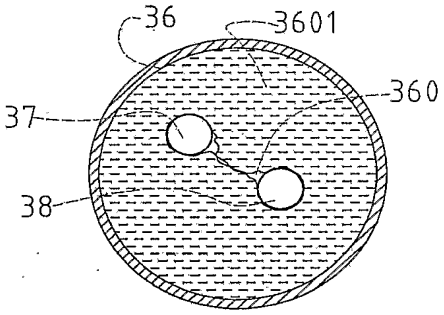


FIG.15C



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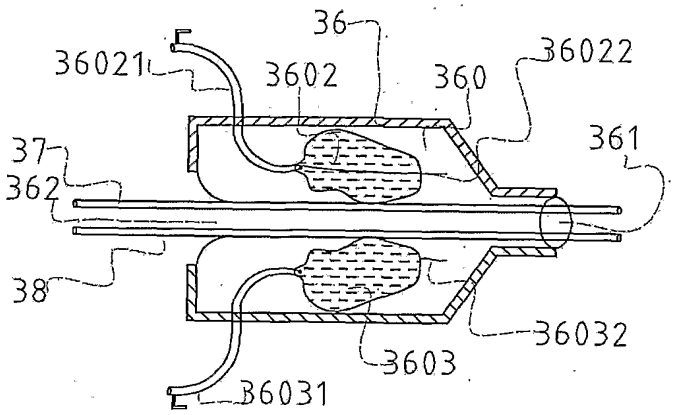

FIG.16A

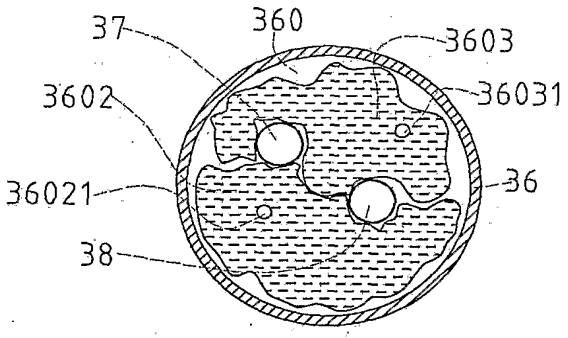

FIG.16B

Electronic Acknowledgement Receipt

EFS ID:	6970213
Application Number:	11813695
International Application Number:	
Confirmation Number:	6073
Title of Invention:	Thorascopic Heart Valve Repair Method and Apparatus
First Named Inventor/Applicant Name:	Giovanni Speziali
Customer Number:	26710
Filer:	Richard T. Roche
Filer Authorized By:	
Attorney Docket Number:	630666.00074
Receipt Date:	08-FEB-2010
Filing Date:	11-JUL-2007
Time Stamp:	16:12:25
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Filed (SB/08)	Mayo-00074-Supp-IDS.pdf	1133114 bef8f795b77ea2189491070ca8a15f50bace5cb0	no	15

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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New International Application Filed with the USPTO as a Receiving Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/813,695	07/11/2007	Giovanni Speziali	630666.00074	6073

26710 7590 01/26/2010

QUARLES & BRADY LLP
411 E. WISCONSIN AVENUE
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MILWAUKEE, WI 53202-4497

EXAMINER	
TEMPLETON, CHRISTOPHER L	
ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
01/26/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pat-dept@quarles.com

Office Action Summary	Application No.	Applicant(s)	
	11/813,695	SPEZIALI, GIOVANNI	
	Examiner	Art Unit	
	CHRISTOPHER L. TEMPLETON	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, drawn to a method for repairing a heart valve, classified in class 606, subclass 139.

II. Claims 7-17, drawn to an instrument for repairing a heart valve, classified in class 606, subclass 145.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process, such as without step e. An anchor could be applied to the suture or a knot could be formed in the suture.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. In the case that applicant elects group I, it is noted that this application contains claims directed to the following patentably distinct species:

a. Species A: Figures 8A-F

b. Species B: Figures 9A-10D.

5. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would

not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

6. A telephone call was made to Richard Roche on 22 December 2009 to request an oral election to the above restriction requirement, but did not result in an election being made.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during

prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER L. TEMPLETON whose telephone number is (571) 270-1477. The examiner can normally be reached on Monday - Friday 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie T. Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. L. T./
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11813695	SPEZIALI, GIOVANNI
	Examiner	Art Unit
	CHRISTOPHER L TEMPLETON	3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	01/15/2010								
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PTO/SB/08a (05-07)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11813695
Filing Date	2007-07-11
First Named Inventor	Giovanni Speziali
Art Unit	3773
Examiner Name	Christopher Templeton
Attorney Docket Number	630666.00074

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5667472		1997-09-16	Finn et al.	

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	1	20030078600		2003-04-24	O'Quinn et al.	
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	1	03/001893	WO	A2	2003-01-09	Evalve		☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11813695
	Filing Date	2007-07-11
	First Named Inventor	Giovanni Speziali
	Art Unit	3773
	Examiner Name	Christopher Templeton
	Attorney Docket Number	630666.00074

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Extended European Search Report for EP 06718728.6.	☐

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11813695
	Filing Date	2007-07-11
	First Named Inventor	Giovanni Speziali
	Art Unit	3773
	Examiner Name	Christopher Templeton
	Attorney Docket Number	630666.00074

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Richard T. Roche/	Date (YYYY-MM-DD)	2009-12-22
Name/Print	Richard T. Roche	Registration Number	38599

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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

(19) World Intellectual Property Organization
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9 January 2003 (09.01.2003)

PCT

(10) International Publication Number
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09/894,463 27 June 2001 (27.06.2001) US

(71) Applicant: **EVALVE, INC.** [US/US]; 2761A Fair Oaks Avenue, Redwood City, CA 94063 (US).

(72) Inventors: **GOLDFARB, Eric, A.**; 545 Peralta Avenue, San Francisco, CA 94110-5338 (US). **DELL, Kent, D.**; 1131 Grand, Redwood City, CA 94061 (US). **FAN, Sylvia, Wen-Chin**; 3868 21st Street, #2, San Francisco, CA 94114 (US). **MARTIN, Brian, B.**; 315 Alder Road, Boulder Creek, CA 95006 (US). **POWELL, Ferolyn, T.**; 55 Caselli Avenue, San Francisco, CA 94114 (US). **RASCHDORF, Alfred, H.**; 3421A 16th Street, San Francisco, CA 94114 (US). **THORNTON, Troy, L.**; 743 Carolina, San Francisco, CA 94107 (US).

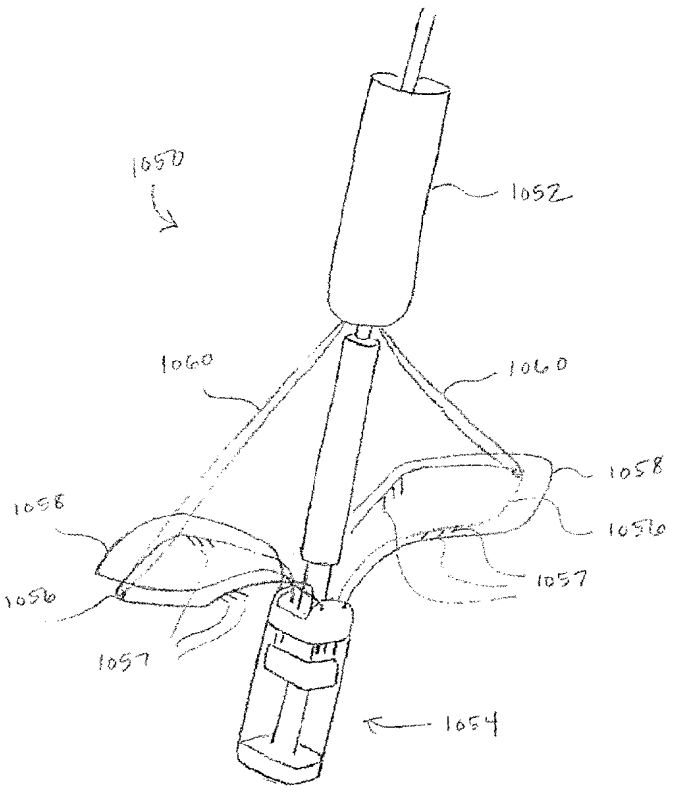
(74) Agents: **THOMPSON, Lynn, M.** et al.; Townsend and Townsend and Crew LLP, Two Embarcadero Center, 8th Floor, San Francisco, CA 94111-3834 (US).

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

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),

[Continued on next page]

(54) Title: METHODS AND DEVICES FOR CAPTURING AND FIXING LEAFLETS IN VALVE REPAIR



(57) Abstract: The present invention provides methods and devices for grasping, and optional repositioning and fixation of the valve leaflets to treat cardiac valve regurgitation, particularly mitral valve regurgitation. Such grasping will typically be atraumatic providing a number of benefits. For example, atraumatic grasping may allow repositioning of the devices relative to the leaflets and repositioning of the leaflets themselves without damage to the leaflets. However, in some cases it may be necessary or desired to include grasping which pierces or otherwise permanently affects the leaflets. In some of these cases, the grasping step includes fixation.

WO 03/001893 A2

Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report*

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

METHODS AND DEVICES FOR CAPTURING AND FIXING LEAFLETS IN VALVE REPAIR

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to medical methods, devices, and systems. In particular, the present invention relates to methods, devices, and systems for the endovascular or minimally invasive surgical repair of the valves of the heart, particularly the mitral valve.

Mitral valve regurgitation is characterized by retrograde flow from the left ventricle of a heart through an incompetent mitral valve into the left atrium. During a normal cycle of heart contraction (systole), the mitral valve acts as a check valve to prevent flow of oxygenated blood back into the left atrium. In this way, the oxygenated blood is pumped into the aorta through the aortic valve. Regurgitation of the valve can significantly decrease the pumping efficiency of the heart, placing the patient at risk of severe, progressive heart failure.

Mitral valve regurgitation can result from a number of different mechanical defects in the mitral valve. The valve leaflets, the valve chordae which connect the leaflets to the papillary muscles, or the papillary muscles themselves may be damaged or otherwise dysfunctional. Commonly, the valve annulus may be damaged, dilated, or weakened limiting the ability of the mitral valve to close adequately against the high pressures of the left ventricle.

The most common treatments for mitral valve regurgitation rely on valve replacement or strengthening of the valve annulus by implanting a mechanical support ring or other structure. The latter is generally referred to as valve annuloplasty. A recent technique for mitral valve repair which relies on suturing adjacent segments of the opposed valve leaflets together is referred to as the "bow-tie" or "edge-to-edge" technique. While all these techniques can be very effective, they usually rely on open heart surgery where the patient's chest is opened, typically via a sternotomy, and the patient placed on cardiopulmonary bypass. The need to both open the chest and place the patient on bypass is traumatic and has associated morbidity.

For these reasons, it would be desirable to provide alternative and additional methods, devices, and systems for performing the repair of mitral and other cardiac valves, particularly the tricuspid and aortic valves. Such methods, devices, and systems should

preferably not require open chest access and be capable of being performed either endovascularly, i.e., using devices which are advanced to the heart from a point in the patient's vasculature remote from the heart or by a minimally invasive approach. Still more preferably, the methods, devices, and systems should not require that the heart be bypassed, although the methods, devices, and systems should be useful with patients who are bypassed and/or whose heart may be temporarily stopped by drugs or other techniques. At least some of these objectives will be met by the inventions described hereinbelow.

2. Description of the Background Art

Minimally invasive and percutaneous techniques for coapting and modifying mitral valve leaflets to treat mitral valve regurgitation are described in WO 98/35638; WO 99/00059; WO 99/01377; and WO 00/03759.

Maisano et al. (1998) Eur. J. Cardiothorac. Surg. 13:240-246; Fucci et al. (1995) Eur. J. Cardiothorac. Surg. 9:621-627; and Umana et al. (1998) Ann. Thorac. Surg. 66:1640-1646, describe open surgical procedures for performing "edge-to-edge" or "bow-tie" mitral valve repair where edges of the opposed valve leaflets are sutured together to lessen regurgitation. Dec and Fuster (1994) N. Engl. J. Med. 331:1564-1575 and Alvarez et al. (1996) J. Thorac. Cardiovasc. Surg. 112:238-247 are review articles discussing the nature of and treatments for dilated cardiomyopathy.

Mitral valve annuloplasty is described in the following publications. Bach and Bolling (1996) Am. J. Cardiol. 78:966-969; Kameda et al. (1996) Ann. Thorac. Surg. 61:1829-1832; Bach and Bolling (1995) Am. Heart J. 129:1165-1170; and Bolling et al. (1995) 109:676-683. Linear segmental annuloplasty for mitral valve repair is described in Ricchi et al. (1997) Ann. Thorac. Surg. 63:1805-1806. Tricuspid valve annuloplasty is described in McCarthy and Cosgrove (1997) Ann. Thorac. Surg. 64:267-268; Tager et al. (1998) Am. J. Cardiol. 81:1013-1016; and Abe et al. (1989) Ann. Thorac. Surg. 48:670-676.

Percutaneous transluminal cardiac repair procedures are described in Park et al. (1978) Circulation 58:600-608; Uchida et al. (1991) Am. Heart J. 121: 1221-1224; and Ali Khan et al. (1991) Cathet. Cardiovasc. Diagn. 23:257-262.

Endovascular cardiac valve replacement is described in U.S. Patent Nos. 5,840,081; 5,411,552; 5,554,185; 5,332,402; 4,994,077; and 4,056,854. See also U.S. Patent No. 3,671,979 which describes a catheter for temporary placement of an artificial heart valve.

Other percutaneous and endovascular cardiac repair procedures are described in U.S. Patent Nos. 4,917,089; 4,484,579; and 3,874,338; and WO 91/01689.

Thoracoscopic and other minimally invasive heart valve repair and replacement procedures are described in U.S. Patent Nos. 5,855,614; 5,829,447; 5,823,956; 5,797,960; 5,769,812; and 5,718,725.

SUMMARY OF THE INVENTION

The present invention provides methods, devices, and systems for the endovascular repair of cardiac valves, particularly the atrioventricular valves which inhibit back flow of blood from a heart ventricle during contraction (systole), most particularly the mitral valve between the left atrium and the left ventricle. By "endovascular," it is meant that the procedure(s) of the present invention are performed with interventional tools and supporting catheters and other equipment introduced to the heart chambers from the patient's arterial or venous vasculature remote from the heart. The interventional tools and other equipment may be introduced to the vasculature percutaneously, i.e., through an access sheath placed through the skin, or may be introduced via a surgical cut down, and then advanced from the remote access site through the vasculature to the heart. Thus, the procedures of the present invention will generally not require penetrations made directly through the exterior heart muscle, i.e., myocardium, although there may be some instances where penetrations will be made interior to the heart, e.g., through the interatrial septum to provide for a desired access route. While the procedures of the present invention will usually be percutaneous and intravascular, many of the tools will find use in minimally invasive and open surgical procedures as well. In particular, the tools for repositioning the valve leaflets prior to attachment can find use in virtually any type of procedure for modifying cardiac valve function.

Although the methods, devices, and systems of the present invention may be used for the endovascular repair of any of the cardiac valves, the majority of the description will be in regards to the repair of atrioventricular valves. The atrioventricular valves are located at the junctions of the atria and their respective ventricles. The atrioventricular valve between the right atrium and the right ventricle has three valve leaflets (cusps) and is referred to as the tricuspid or right atrioventricular valve. The atrioventricular valve between the left atrium and the left ventricle is a bicuspid valve having only two leaflets (cusps) and is generally referred to as the mitral valve. In both cases, the valve leaflets are connected to the base of the atrial chamber in a region referred to as the valve annulus, and the valve leaflets extend generally downwardly from the annulus into the associated ventricle. In this way, the valve leaflets open during diastole when the heart atria fills with blood, allowing the blood to

pass into the ventricle. During systole, however, the valve leaflets are pushed together and closed to prevent back flow of blood into the atria. Thus, the valve leaflets each have generally two planar surfaces, a surface facing the atrium which may be referred to as the atrial surface and a surface facing the ventricle which may be referred to as the ventricular surface. Such terminology may be used with cardiac valves which do not straddle an atrium and a ventricle. In these cases, it is understood that such terminology may be used to suitably describe the corresponding valve surfaces.

Alternatively, the surfaces of the valves may be described in relation to flow direction. For example, since valve leaflets each have two planar surfaces, a surface facing upstream may be referred to as the upstream surface and a surface facing downstream may be referred to as the downstream surface. In the case of the mitral valve, the atrial surface would be the upstream surface and the ventricular surface would be the downstream surface. In the case of the aortic valve, the ventricular surface would be the upstream surface and the surface facing the aorta would be the downstream surface. Such terminology may be most relevant when considering the natural shape of the leaflets since the shape is more related to direction of flow than orientation of the valve in the heart.

Interventions according to the present invention are generally directed at the valve leaflets. It will be the general purpose of such interventions to modify the manner in which the valve leaflets coapt or close during systole so that back flow or regurgitation is minimized or prevented. While the procedures of the present invention will be most useful with the atrioventricular valves, at least some of the tools described hereinafter may be useful in the repair of other cardiac valves, particularly the aortic valve.

The methods of the present invention will usually include accessing a patient's vasculature at a location remote from the heart and advancing an interventional catheter having a capturing device through the vasculature to a location near a cardiac valve to be repaired. The methods may include applying an upward force against a downstream surface of at least one leaflet of the cardiac valve with the capturing device. Such application of force will reposition at least one leaflet so as to reduce leakage through the valve during ventricular systole. Typically, two or more leaflets are repositioned in this manner to achieve desired coaptation. The interventional tool may comprise an elongate shaft having a proximal end and a distal end wherein the capture device is disposed near the distal end. The capture device may comprise at least one distal element capable of protruding radially outward from the shaft. The above described application of force may be achieved by pressing a distal element of the capture device against the downstream surface of the leaflet.

In a first aspect of the methods of the present invention, the distal element may be adjusted prior to or after pressing the distal element against the surface of the leaflet. Such adjustment may include adjusting the length of protrusion of the distal element from the shaft. This may be achieved by retracting or extending the distal element. This allows the capture device to be advanced to the valve in a low profile arrangement and the distal elements to be extended for use once the capture device has been positioned in a desired orientation in relation to the valve. When adjustment of the length is performed after the distal element is in contact with the valve leaflet, such adjustment may serve to reposition the valve leaflet. In addition, adjustment may include adjusting the curvature of the distal element. Adjustment of the curvature may also be achieved by retracting or extending the distal element. Again, if this adjustment step is performed after the distal element is in contact with the leaflet, such adjustment in curvature may serve to reposition the valve leaflet. In some embodiments, the capture device may optionally comprise at least one proximal element capable of protruding radially outward from the shaft and the methods of the present invention may further include holding one or more leaflets between the proximal and distal elements. In this case, adjusting the length and/or curvature of the proximal or distal elements may serve to reposition the captured valve leaflets. Such adjustment of the proximal and distal elements may be achieved simultaneously. In an additional aspect, the proximal and distal elements may interlock for added grasping strength.

In a second aspect of the methods of the present invention, flow through the valve may be observed to determine if regurgitation has been inhibited by the leaflet repositioning. Such observation may be achieved by any suitable means. If the regurgitation has not been sufficiently inhibited, the application of upward force on at least one valve leaflet with the capturing device may be adjusted. This may be achieved with any of the adjustment steps previously described and/or by decreasing or removing any of the upward force against one or more valve leaflets. The observation and adjustment steps may be repeated any number of times until the regurgitation has been sufficiently inhibited.

In a third aspect of the methods of the present invention, the leaflets may optionally be fixed together. Fixing may include fastening, suturing, clipping, stapling, riveting, gluing, or fusing the leaflets together. Alternatively, the capturing tool may be detached from the interventional tool to serve as a fixation device. This involves activating a detachment or decoupling mechanism which allows the capture tool to separate from the interventional tool to be left behind as a permanent implant.

In a fourth aspect of the methods of the present invention, one or more valve leaflets may be atraumatically captured with the capturing device and the captured leaflets may be repositioned independently of each other. When the capture device comprises at least one distal element capable of protruding radially outward from the shaft, a leaflet may be atraumatically captured by pressing the distal element against the leaflet surface. The captured leaflets may be independently repositioned by independently adjusting the distal elements. Likewise, when the capture device comprises at least one proximal element and one distal element, each capable of protruding radially outward from the shaft, the atraumatically capturing step comprises holding the leaflet between the proximal and distal elements. The captured leaflets may be independently repositioned by simultaneously retracting or extending the proximal element and distal element disposed on opposite sides of the leaflet. Again, once the leaflets have been repositioned to a desired orientation, the leaflets may be fixed together by any suitable means including detaching the capture device from the interventional tool and leaving it behind.

In a fifth aspect of the methods of the present invention, the valve leaflets, each leaflet comprising a proximal side and a distal side, may be repaired with the use of sutures having attached anchors. To begin, a first leaflet may be penetrated from the proximal side to the distal side of the leaflet with a penetrating device. In this case, at least a portion of first anchor having a first attached suture is then deployed on the distal side of the first leaflet. A second leaflet is penetrated from the proximal side to the distal side with a penetrating device. Such a penetrating device may be the same penetrating device as penetrated the first leaflet or a separate penetrating device. At least a portion of a second anchor having a second attached suture is deployed on the distal side of the second leaflet. The first and second sutures are then secured together. By securing the sutures together, the valve is repaired by fixing the leaflets together in the desired coapted orientation. Typically, the anchors are disposed in or on the penetrating devices. For example, the anchors may be loaded within a lumen in the penetrating devices or mounted externally on a penetrating device. In any case, the deploying steps comprise releasing the anchors from the respective penetrating devices. In many cases, the anchors are expanded to provide anchoring support on the distal side of the leaflet to prevent the anchor from passing through the penetration and releasing the suture. The anchors may be self-expanding or the deploying steps may further comprise expanding the anchors.

As an alternative, anchors may be used simply to aid in the placement of sutures wherein the anchors are removed prior to securing the sutures together. In this case,

again, a first leaflet is penetrated from the proximal side to the distal side of the leaflet with a penetrating device. And, at least a portion of a first anchor having a first attached suture is deployed on the distal side of the first leaflet. The first leaflet is again penetrated from the proximal side to the distal side with a penetrating device, however, this time at a new location. At this new location, a snare is deployed on the distal side of the leaflet so that the snare captures at least part of the first anchor. The snare is then retracted so that the anchor is drawn through the penetration of the snare. By drawing the anchor through the penetration to the proximal side of the leaflet, the suture line effectively passes from the proximal side of the leaflet through a penetration to the distal side traversing a portion of the distal side of the leaflet and then passing through a separate penetration back to the proximal side of the leaflet. This may be repeated on a second leaflet in a similar manner. The four portions of suture on the proximal side of the leaflets may then be secured together. This method may be repeated at any number of locations on the leaflet to create any number of suture lines on the proximal side of the leaflet for securing together. Additional suture lines may provide added fixation strength or possible repositioning of the leaflets. Likewise, the anchor and snare may be deployed on separate leaflets, respectively, so that a suture line may penetrate a first leaflet from the proximal side to the distal side traverse on the distal side of the leaflet to a second leaflet and then cross back through a penetration on the second leaflet to the proximal side. One or more sutures may be positioned in this manner and secured together as previously described. Also, it may be appreciated that such suture placement may be achieved on the opposite side of the leaflets so that the sutures are secured on the distal side of the leaflets.

The penetrating devices described above may be advanced through guide conduits on the interventional tool. Such guide conduits may be adjusted to direct the penetrating device toward the desired location on the valve leaflet. Adjustment may include extending or retracting the guide conduits or angularly adjusting the guide conduits in relation to the shaft. When the capture device comprises at least one loop which is protrudable radially outward from the shaft, the guide conduit may be positioned so that the conduit guides the penetration device through the loop when the penetration device is advanced. Once the penetrating device has penetrated the leaflet, the loops may be retracted to radially translate the penetration devices and the penetrated leaflets toward the shaft. This may serve to reposition the leaflets in a more desired coapted orientation.

The devices of the present invention will usually include an interventional catheter configured to pass from the remote vasculature of a patient to a position within the heart adjacent to the cardiac valve to be repaired and a capture device on the interventional

catheter for capturing at least one valve leaflet. Typically, the capture device includes at least one distal element and optionally includes at least one proximal element. The distal element or proximal elements may be comprised of a number of materials, including wire, ribbon, filaments, or fibers which are made from stainless steel, metals, nitinol, Elgiloy® (Elgiloy Corporation), shape memory alloy, polymers, silk, polyester or nylon, to name a few. Elgiloy® is a Cobalt-Chromium-Nickel alloy which gives a combination of high strength, ductility and good mechanical properties and is age hardenable.

In a first aspect of the devices of the present invention, the distal elements of the capture devices may take a number of forms and these forms can take a number of shapes. In some embodiments, the distal elements have the form of loops. For clarity, loops include any shape wherein the form surrounds or nearly surrounds an opening. Loops may have circular, oval or petal shapes, or may include irregular shapes of any type, including pointed or angular edges and/or invaginations. The loops may have a petal shape so that when the loops are positioned on opposite sides of the shaft, the loops will form a "figure 8" shape when viewed from the top or bottom. This loop configuration is most suitable for use with valves having two leaflets. It may be appreciated that more than two loops may be present and arranged around the shaft having various distances between the loops. Thus, the looped distal elements may be configured for valves having three leaflets. In another embodiment, the distal element has the form of a block, rod or bar disposed perpendicularly to the shaft. The bar may pivot around a pivot point at the base of the shaft to manipulate the position of the bar. Such manipulation may be achieved with the use of a pullwire extending from the shaft to the bar. Retracting or pulling upwards on the pullwire may pivot the bar around the pivot point. Such pivoting orients the bar to a low profile position so that the interventional tool may more easily be passed through a guide catheter, and further between a set of valve leaflets so that the bar is disposed below the valve. The bar may then be pressed against the downstream surface of the leaflets to grasp and reposition the leaflets.

In a second aspect of the devices of the present invention, the distal elements may be individually repositionable or adjustable. The elements may be extended or retracted by variable amounts for protrusion of various distances from the shaft. Such extension and retraction may also adjust the width of the exposed elements if the width varies radially from the shaft, such as with a petal shape. Further, the elements may have differing angles of curvature. This may be achieved by heat-shaping the elements to have different curvatures, or the curvatures may be adjusted by manipulation by the user. Individual manipulation of the elements allows individually protruding the elements prior to capturing the leaflets to

ensure proper orientation and includes individually adjusting the elements after grasping the leaflets to reposition the leaflets. In addition, it may be appreciated that the elements may be extended and retracted simultaneously, if desired.

In a third aspect of the devices of the present invention, the interventional tool comprises proximal elements which are capable of protruding radially outward from the shaft at a location which is proximal to the distal elements. The proximal elements may have any of the forms, shapes, material compositions, features or capabilities described in relation to the distal elements. Thus, the proximal elements may be extended, retracted or similarly adjusted to further orient the captured leaflets. The proximal elements may be deployed separately from the distal elements. For example, the proximal elements may be constrained within a shaft while the distal elements are extended radially outward. The proximal elements may then be released by retracting the shaft. Release of the proximal elements allows them to extend radially outward and downward to contact the valve leaflet. In this arrangement, the valve leaflets are held between the proximal and the distal elements. To assist in holding the leaflets the proximal and/or distal elements may included various friction accessories, such as prongs or windings around the elements such as bands or barbs. Alternatively or in addition, the proximal elements and distal elements may interlock to prevent relative motion between the elements and more securely hold the leaflets.

In some embodiments, the proximal and distal elements are formed from a continuous structure. The continuous structure may be held in a low profile position under tension. When the continuous structure is released and allowed to relax, the reforming of the structure allows the structure to protrude outward at various points along the structure. Each protrusion is similar to an above-described proximal or distal element and functions in a similar manner.

In a fifth aspect of the devices of the present invention, the interventional catheter may include a fixation tool or device. In one embodiment, the capture device may function as a fixation device when left in place. To this end, the capture device may be detachable and be left behind as a permanent or temporary implant. Detachment may be achieved by a variety of different mechanisms and design features.

In other embodiments, the fixation tools are used with the capture device either incorporated into the interventional tool or used in combination with the interventional tool. In many of these embodiments, the fixation tools are advanceable through guide conduits disposed near the distal end of the interventional tool. The guide conduits are used to guide the fixation tools to specific locations on the surfaces of the leaflets. The guide

conduits are located proximal to the distal elements and are capable of extending and retracting axially and angularly outward from the shaft. Any angle may be used to target the leaflets at points which are approximately one to twelve millimeters inward or away from the free edge of each leaflet. Typically, the guide conduit is used to introduce a fixation tool comprising a penetrating device or needle. The needle may house a suture having an anchor disposed at the distal end of the suture. The needle is advanced toward a valve leaflet to penetrate the leaflet and emerge from the other side. The anchor may be deployed on the opposite side of the leaflet by passing the anchor through the needle and expanding or allowing it to self-expand after it has exited the needle. Alternatively, the anchor may be mounted on the outside of the needle and covered by a sheath. Retraction or removal of the sheath would allow expansion of the anchor. In any case, after anchor deployment, the needle is then retracted while maintaining the anchor on the distal side of the leaflet. A number of different types of anchors may be used during fixation of the leaflets. Typically the anchor is expandable from a compressed, low profile state, for delivery to the anchoring site, to an expanded state to provide a large enough surface for anchoring support. In addition, the fixation tools may include snares which are deployable on the distal side of the leaflet for capturing at least part of an anchor. The snare may then be retracted to move the anchor, such as to draw the anchor through a penetration in the leaflet. Once the suture is placed through the leaflets, either attached to anchors or free from anchors, the suture ends or lines may then be fixed together by conventional knot tying or any suitable method, including positioning suture fasteners.

The methods, devices and systems of the present invention may be provided in one or more kits for such use. The kits may include an interventional catheter configured to pass from the remote vasculature of a patient to a position within the heart adjacent to a cardiac valve to be repaired, wherein the catheter has a capture device comprising at least one distal element, and instructions for use. The instructions for use may set forth any of the methods of the present invention. Optionally, such kits may further include any of the other systems components described in relation to the present invention and any other materials or items relevant to the present invention.

Other objects and advantages of the present invention will become apparent from the detailed description to follow, together with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic illustration of the left ventricle of a heart showing blood flow during systole with arrows.

Fig. 2A shows normal closure of the leaflets, while Fig. 2B shows abnormal closure of the leaflets.

Fig. 3 is a perspective side view of the mitral valve showing an interventional tool approaching the valve leaflets from the atrial side.

Fig. 4 illustrates a short axis view if the mitral valve from the atrial side wherein elements of the interventional tool are shown in dashed outline as they are positioned on the ventricular side of the valve.

Fig. 5 illustrates the mitral valve as in Fig. 4 during diastole.

Fig. 5A illustrates the valve leaflets fixed together as in a surgical bow tie repair.

Figs. 6-7 show exemplary antegrade approaches to the mitral valve from the venous vasculature.

Figs. 8-9 show exemplary retrograde approaches to the mitral valve through the aortic valve and atrial vasculature.

Figs. 10A-10C show a number of embodiments of capture devices which may be disposed at the distal end of an interventional catheter.

Figs. 11A-11C and Fig. 12 show a number of embodiments of capture devices wherein an element is in the form of a block, rod, or bar.

Fig. 13 illustrates the extension of a first element independently of a second element.

Fig. 14 illustrates elements having differing angles of curvature.

Fig. 15 illustrates a capture device having extended elements pinched between the shaft and the cap.

Figs. 16A-16E illustrate an embodiment of the capture device wherein the distal elements are held in a retracted position under tension and are extendible upon release.

Figs. 16F-16G illustrate an embodiment of the capture device wherein the distal elements extend and retract together.

Figs. 17A-17D show a number of embodiments of the interventional tool comprising proximal elements which are capable of protruding outward from the shaft at a location proximal to the distal elements.

Figs. 18A-18D show embodiments of the capture device wherein the valve leaflets are pinched between a superior loop and an inferior loop.

Figs. 19A-19B are perspective views of a capture device wherein the proximal elements and the distal elements are interlockable, and Fig. 19C illustrates a top view showing the interlocked elements.

Figs. 20A-20B illustrate an embodiment of the capture device wherein the proximal and distal elements are formed by a continuous structure.

Fig. 21A illustrates leaflets captured by a capture device detached from the shaft and left behind as a fixation device.

Figs. 21B-21H illustrates a variety of embodiments of detachment mechanisms.

Figs. 21I-21J illustrate the use of capture devices having a pledget for use as a fixation device.

Fig. 22 illustrates an embodiment of the interventional tool having distal elements and guide conduits disposed near its distal end.

Figs. 23A-23B illustrates the placement of a suture having an anchor with the use of a penetrating device advanced through a guide conduit.

Figs. 24, 25, 26A-26B, 27A-27T illustrate various embodiments of anchors.

Figs. 27U-27V illustrate anchors deployed from a doubled barreled delivery device.

Figs. 28 depicts a perspective view of an embodiment of the interventional tool having more than one guide conduit.

Fig. 29 depicts a top view of the interventional tool of Fig. 28 positioned between the valve leaflets.

Fig. 30 illustrates target points through which sutures may be placed and drawn together in the direction of the arrows.

Fig. 31 illustrates an anchor placed through a target point and a snare placed through an adjacent target point, wherein the snare captures the anchor.

Fig. 32 illustrates sutures placed by the method illustrated in Fig. 31, wherein the sutures are fastened together to repair the valve.

Fig. 33 illustrates the method of Fig. 31 performed on two adjacent valve leaflets.

Fig. 34 illustrates an embodiment of the interventional tool having more than one guide conduit including at least two slotted needles for use in deploying a suture line.

Fig. 35 illustrates a continuous suture line placed according to the methods illustrated in Fig. 34.

Fig. 36 illustrates an embodiment of the interventional tool having a guide conduit wherein a penetrating device is advanced through the guide conduit having a suture holding feature disposed near its distal end.

Fig. 37 illustrates a distal element of a capture device comprising a loop having a second loop comprised of suture.

Fig. 38 shows a cross-sectional view of the element shown in Fig. 37.

Figs. 39-41 illustrate methods of using the interventional tool illustrated in Figs. 36-38.

Figs. 42-51 illustrate a first device embodiment and methods of use according to the aspects of the present invention.

Fig. 52-58 illustrate a second device embodiment and methods of use according to the aspects of the present invention.

Fig. 59 illustrates a kit constructed in accordance with the principles of the present invention.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

I. CARDIAC PHYSIOLOGY

The left ventricle LV of a normal heart H in systole is illustrated in Fig. 1. The left ventricle LV is contracting and blood flows outwardly through the tricuspid (aortic) valve AV in the direction of the arrows. Back flow of blood or "regurgitation" through the mitral valve MV is prevented since the mitral valve is configured as a "check valve" which prevents back flow when pressure in the left ventricle is higher than that in the left atrium LA. The mitral valve MV comprises a pair of leaflets having free edges FE which meet evenly to close, as illustrated in Fig. 1. The opposite ends of the leaflets LF are attached to the surrounding heart structure along an annular region referred to as the annulus AN. The free edges FE of the leaflets LF are secured to the lower portions of the left ventricle LV through chordae tendineae CT (referred to hereinafter as the chordae) which include plurality of branching tendons secured over the lower surfaces of each of the valve leaflets LF. The chordae CT in turn, are attached to the papillary muscles PM which extend upwardly from the lower portions of the left ventricle and interventricular septum IVS.

A number of structural defects in the heart can cause mitral valve regurgitation. Regurgitation occurs when the valve leaflets do not close properly allowing

leakage from the ventricle into the atrium. As shown in Fig. 2A, the free edges of the anterior and posterior leaflets normally meet along a line of coaptation C. An example of a defect causing regurgitation is shown in Fig. 2B. Here an enlargement of the heart causes the mitral annulus to become enlarged, making it impossible for the free edges FE to meet during systole. This results in a gap G which allows blood to leak through the valve during ventricular systole. Ruptured chordae can also cause a valve leaflet to prolapse since inadequate tension is transmitted to the leaflet via the chordae. While the other leaflet maintains a normal profile, the two valve leaflets do not properly meet and leakage from the left ventricle into the left atrium will occur. Such regurgitation can also occur in patients who have suffered ischemic heart disease where papillary muscles do not contract sufficiently to effect proper closure.

II. GENERAL OVERVIEW

The present invention provides methods and devices for grasping, and optional repositioning and fixation of the valve leaflets to treat cardiac valve regurgitation, particularly mitral valve regurgitation. Such grasping will typically be atraumatic providing a number of benefits. For example, atraumatic grasping may allow repositioning of the devices relative to the leaflets and repositioning of the leaflets themselves without damage to the leaflets. However, in some cases it may be necessary or desired to include grasping which pierces or otherwise permanently affects the leaflets. In some of these cases, the grasping step includes fixation. Although a number of embodiments are provided to achieve these results, a general overview of the basic features will be presented herein. Such features are not intended to limit the scope of the invention and are presented with the aim of providing a basis for descriptions of individual embodiments presented later in the application.

Generally, the valve leaflets are grasped and repositioned by pressing a capture device against the ventricular surface of the leaflets. The ventricular surface is the generally planar surface of the valve that faces the ventricle. Access to the ventricular surface will be described in the following section, however it is basically assumed that the ventricular surface is accessible by a retrograde approach through the ventricle or by an antegrade approach through the atrium and then passing through the valve to the ventricle. For illustration purposes, an antegrade approach will be described.

Referring to Fig. 3, a interventional tool 100, having a shaft 104 and a capture device 105 comprising two elements 106 protruding radially outward from the distal end 102 of the shaft 104, is shown approaching the mitral valve MV from the atrial side. The mitral

valve MV is shown in a perspective side view wherein the valve leaflets LF open through the valve annulus AN during diastole. In such a position, the chordae CT are can be seen attached along the free edge FE of the leaflet LF and the ventricular surface VS is visible.[Short-axis echocardiography may be used to visualize the interventional tool 100 and orient the elements 106 so that they are positioned substantially perpendicular to the line of coaptation C. The tool 100 may be moved roughly along the line of coaptation to the location of regurgitation. Under long-axis echo guidance, the elements 106 are then advanced through the valve, between the leaflets LF in the direction of the arrow 108, so that the elements 106 emerge beyond the valve. In this perpendicular position, the tool 100 is then retracted, pressing the elements 106 against the ventricular surface of the leaflets LF. This grasps the leaflets LF and pulls the leaflets up close to the annular plane so that the grasped free edges are coapted. This is illustrated in Fig. 4, a short-axis view of the mitral valve MV from the atrial side. Here the elements 106 are shown in dashed outline as the elements 106 are positioned on the ventricular side of the valve.

The interventional tool 100 is dimensioned at its waist 110 to fit between adjacent chordae where the chordae attach to the free edge. The elements 106 may be dimensioned to have a width 112 which is greater than the distance between the adjacent chordae, effectively trapping the chordae, however this is not necessary. In addition, the opposing tensioning force of the chordae on the free edge FE of the leaflets helps secure the leaflets LF on the elements 106. Such dimensioning and positioning prevents displacement of the leaflets LF from the interventional tool 100 due to the diastolic pressure gradient on the leaflets LF and relative movement of the annulus to the elements 106. This is shown in Fig. 5, a short-axis view of the mitral valve MV from the atrial side during diastole wherein the leaflets LF remain in position against the elements 106 surrounded by openings 114 which result from the diastolic pressure gradient. This simulates the double orifice geometry of a standard surgical bow-tie repair. Color Doppler echo will show if the regurgitation of the valve has been reduced. If the resulting mitral flow pattern is satisfactory, the leaflets may be fixed together in this orientation with a suture 115 or fixation device, as shown in Fig. 5A. If the resulting color Doppler image shows insufficient improvement in mitral regurgitation, the interventional tool 100 may be repositioned. This may be repeated until an optimal result is produced wherein the leaflets LF may then be fixed.

As will be discussed later, the interventional tool 100 may take a number of forms and may be comprised of a variety of materials, each design choice providing variations to the above described methods and devices. Further, the tool 100 may include

provisions for fixing the leaflets together after repositioning. Thus, the above provided description simply sets forth a sampling of basic features of the present invention.

III. ACCESS TO THE MITRAL VALVE

Access to the mitral valve or other cardiac valve will preferably be accomplished through the patient's vasculature in a "percutaneous" manner. By "percutaneous" it is meant that a location of the vasculature remote from the heart is accessed through the skin, such as using needle access through, for example, the Seldinger technique. However, it may also include using a surgical cut down procedure or a minimally invasive procedure. The ability to percutaneously access the remote vasculature is well-known and described in the patent and medical literature. Further, access may be achieved directly through the chest and the heart wall, wherein the heart is either beating or stopped. Depending on the type and point of access, the approach to the mitral valve may be antegrade or retrograde. Entry to the left atrium, for example, may be achieved via the pulmonary vein or by crossing the interatrial septum for an antegrade approach to the mitral valve. Alternatively, approach to the mitral valve can be retrograde, for example, where the left ventricle is entered through the aortic valve. Once access is achieved, the interventional tools and supporting catheter(s) may be advanced to the heart intravascularly where they may be positioned adjacent the target cardiac valve in a variety of manners, as described elsewhere herein. While the methods will be described as percutaneous and intravascular, many of the tools and catheters described herein will, of course, also be useful for performing surgical techniques where the heart is beating or stopped and the heart valve accessed through the myocardial tissue, either in an open heart or closed heart procedure. Many of the devices will also find use in minimally invasive procedures where access is achieved thorascopically and where the heart will usually be stopped but in some instances could remain beating.

A typical antegrade approach to the mitral valve is depicted in Fig. 6. The mitral valve MV may be accessed by a standard approach from the inferior vena cava IVC or superior vena cava SVC, through the right atrium RA, across the interatrial septum IAS and into the left atrium LA above the mitral valve MV. As shown, a catheter 120 having a needle 122 may be advanced from the inferior vena cava IVC into the right atrium RA. Once the catheter 120 reaches the interatrial septum IAS, the needle 122 may be advanced so that it penetrates through the septum at the fossa ovalis FO or the foramen ovale into the left atrium LA. At this point, a guidewire may be advanced out of the needle 122 and the catheter 120 withdrawn. As shown in Fig. 7, access through the interatrial septum IAS will usually be

maintained by the placement of a guide catheter 125, typically over a guidewire 124 which has been placed as described above. The guide catheter 125 affords subsequent access to permit introduction of the tool(s) which will be used for performing the valve or tissue modification, as described in more detail below.

A typical retrograde approach to the mitral valve is depicted in Fig. 8. Here the mitral valve MV may be accessed by an approach from the aortic arch AA, across the aortic valve AV, and into the left ventricle below the mitral valve MV. The aortic arch AA may be accessed through a conventional femoral artery access route, as well as through more direct approaches via the brachial artery, axillary artery, or a radial or carotid artery. As shown in Fig. 9, such access may be achieved with the use of a guidewire 128. Once in place, a guide catheter 126 may be tracked over the guidewire 128. The guide catheter 126 affords subsequent access to permit introduction of the tool(s) which will be used for performing the valve modification, as described in more detail below.

In some cases, access routes to the mitral valve may be established in both antegrade and retrograde approach directions. This may be useful when, for instance, grasping is performed with the use of specific devices introduced through one route and fixation is achieved with the use of separate devices introduced through another route. In one possible situation, the leaflets may be grasped and repositioned by pressing a interventional tool against the ventricular surface of the valve via a retrograde approach. While the interventional tool is in place, a fixation tool may be introduced via an antegrade approach to fix the leaflets in place. Thus, a variety of access routes may be used individually or in combination with the methods and devices of the present invention.

IV. LEAFLET CAPTURE DEVICE

Once the valve is accessed and the guidecatheter is positioned in place, the interventional catheter is introduced through the guidecatheter for use in capturing or holding the valve leaflets. The interventional catheter typically comprises a shaft, having a proximal end and a distal end, and an interventional tool disposed near its distal end. The interventional tool may take a number of forms to perform the methods of the present invention. Fundamentally, the interventional tool comprises a capture device comprising at least one distal element capable of protruding radially outward from the shaft. Typically, the tool will have two distal elements, one element to press upwardly against each leaflet of the two leaflet that are to be fixed together. However, the tool may have any number of such elements, including multiple elements pressing against each of the leaflets or one element

pressing against one leaflet and no element pressing against an adjacent leaflet. Any of these combinations may effectively coapt a pair of leaflets. Further, multiple elements may be present to reposition and coapt three leaflets, such as for use with the aortic valve.

Figs. 10A-10C show a number of embodiments of capture devices 204 that may be disposed at the distal end 202 of an interventional catheter 200. As described, each device 204 will typically have two distal elements 208 which are protrudable radially outward from the shaft 210. In many embodiments, the elements 208 extend from opposite sides of the shaft 210 so the elements 208 are approximately 180 degrees apart. However, it may be appreciated that the elements 208 may be spaced any distance apart and may be symmetrically or asymmetrically arranged.

In addition, the distal elements 208 may take a number of forms, including bars, rods, flaps, sheets, blocks or loops to name a few. These forms can in turn take a number of shapes, such as rectangular, circular, oblong, elliptical and petal. Thus, for clarity, loops include any shape wherein the form surrounds or nearly surrounds an opening 209. Loops may have circular, oval or petal shapes, as generally illustrated in Figs. 10A-10B, or may include irregular shapes of any type, including pointed or angular edges and/or invaginations. Further, these forms may be comprised of a number of materials, including wire, ribbon, filaments or fibers which are made from stainless steel, metals, nitinol, shape-memory alloy, polymers, silk, polyester or nylon, to name a few. Such materials may also be radiopaque to aid in visualization. Likewise, the elements may be comprised of a combination of such forms and/or materials. As an example, Fig. 10A illustrates elements 208 in the form of loops 212 having a petal shape. Here, the loops are positioned on opposite sides of the shaft 210 so as to form a "figure-8" shape in a top view or a bottom view. These loops 212 are preferably made from nitinol or shape-memory wire, however other materials may be suitable. The loops 212 may protrude from the shaft 210 by a means of a number of designs. For example, as illustrated in Fig. 10A, the loops may protrude from a space between the shaft 210 and a cap 238 located at its tip. Alternatively, the loops 212 may protrude through the shaft 210, as shown in Fig. 10B, or through the cap 238. This may lend support to the loops 212 during use. As will be discussed later, such loops 212 may be combined with a second set of loops comprised of suture that are detachable from these loops 212 for leaflet fixation. Fig. 10C illustrates elements 208 in the form of flaps or sheets 214 which are essentially rectangular such as made from ribbon or other flat materials. These sheet 214 are also preferably made from nitinol or shape-memory wire, however other materials may be suitable.

Fig. 11A illustrates a element 208 in the form of a block, rod or bar 216 disposed perpendicularly to the shaft 210. The bar 216 may be comprised of any number of materials, including metals, alloys, polymers or fibers, to name a few. When such a bar 216 forms one continuous element 208 which extends beyond the diameter of the shaft, as shown, the bar 216 may pivot (indicated by arrows) around a pivot point 218 at the base of the shaft 210 to manipulate the position of the bar 216. As shown in Fig. 11B, the bar 216 may further comprise a pull-wire 219 which extends from the shaft 210 to the bar 216 and loops through the bar 216 to connect with each end of the bar 216. By retracting or pulling upwards on the pull-wire 219 the bar 216 will pivot around a pivot point 218 at the base of the shaft 210. This orients the bar 216 to a low profile position so that the interventional tool may more easily be passed through a guidecatheter and further between a set of valve leaflets LF, as shown. Once the element 208 is advanced and disposed below the valve, as shown in Fig. 11C, the element 208 is then pressed against the ventricular surface 217 of the leaflets LF to grasp and reposition the leaflets. Since the bar 216 is pivotable around a center pivot point 218, the bar 216 may slightly pivot during grasping based on the anatomy of the valve. This may allow a more desirable application of force to the valve leaflets, as a less rigid leaflet may receive a larger force to draw the leaflet up to a coapted position. In a similar design, each element 208 may pivot independently of the other around a pivot point at the base of the shaft. This is possible when such a bar or rod forms two elements 208 extending 180 degrees apart outwardly from the shaft 210. This may provide an even higher degree of flexibility during grasping.

Referring to Fig. 12, the element 208 may be comprised of a combination of forms and materials. Here, the element has the form of a block 220 having cutouts 222 surrounded by wire loops 224. Such loops 224 may increase the area in which the element 208 may contact the leaflet LF. In addition, such loops 224 may be adjustable to aid in manipulation and repositioning of the leaflets. Further, the block 220 may be pivotable around a center pivot point 218 at the base of the shaft 210 to manipulate the position of the block 220 as in the manner described and shown in Figs. 11B-11C.

In many embodiments, the distal elements are individually extendable, retractable and repositionable. Fig. 13 illustrates the extension of a first element 230 independently of the second element 232. Such elements 230, 232 may be utilized in this arrangement or the second element 232 may be extended at any point during the procedure. Likewise, the elements 230, 232 may be extended or retracted by variable amounts for protrusion of various distances from the shaft 210. Such extension and retraction may also

adjust the width 231 of the exposed elements 230, 232 if the width of the element 230, 232 varies radially from the shaft, such as with a petal shape. In addition, the elements 230, 232 may be individually rotatable around the shaft 210 to vary the distance between the elements 230, 232. Further, as shown in Fig. 14, the elements 230, 232 may have differing angles of curvature. Here, the first element 230 has a first radius of curvature 234 which is larger than a second radius of curvature 236 of the second element 232. This may be achieved by heat shaping the elements 230, 232 to have different curvatures, or the curvatures may be adjusted by manipulation by the user at the proximal end of the interventional catheter 200. Consequently, each element 230, 232 will provide a different repositioning effect when pressed against a leaflet.

In some embodiments, the capture device 204 has a cap 238 located at its tip. Such a cap 238 has been shown in embodiments presented in Figs. 10A, 10C, 13, and 14 and may provide a variety of functions. For example, the cap 238 may serve as a blunt tip to assist in atraumatic passing of the device 204 through the valve, between valve leaflets, during placement of the device 204. The cap 238 may also be moveable to close a gap 240 between the cap 238 and the shaft 210 where the distal elements 230, 232 emerge. When the elements 230, 232 are retracted, movement of the cap 238 to close the gap minimizes the profile of the tool 204 and reduces the possibility of the elements 230, 232 or portions of the device 204 interfering with tissue or entangling with chordae. As shown in Fig. 15, when the elements 230, 232 are extended, movement of the cap 238 to close the gap 240 may increase rigidity of the elements 230, 232 by providing support for the elements 230, 232 or it may adjust the curvature of the elements 230, 232 by flexing a portion of the elements 230, 232 near the shaft 210. Further, when the elements 230, 232 are pressed against the ventricular surface of the valve leaflets, the leaflets may extend into the gap 240 between the cap 238 and the shaft 210. When the cap 238 is moved to close the gap 240, the leaflets may be pinched between the shaft 210 and the elements 230, 232 and cap 238. This may assist grasping of the leaflets for later fixation. It may be appreciated that although these elements have been illustrated as curving upwardly, away from the distal end, the elements may alternatively be uncurved, curve downwardly, include compound curvatures or more than one curvature along each element, or any other combination of curvatures.

In some embodiments, the distal elements are held in a retracted position under tension and are extendable upon release. For example, Figs. 16A-16C illustrate one embodiment of the interventional tool 204 in various states of deployment. The elements 230, 232 are disposed near a distal end 231 of an inner shaft 233 within the shaft 210. Fig.

16A shows the elements 230, 232 in a retracted position as they are held under tension by loops 221, each loop 221 threaded through an element 230, 232 and pulled upwardly within the shaft 210 as shown. The loops 221 may be comprised of any suitable material, including suture, wire or polymer strands. It may be appreciated that the tool 204 may be introduced in this state or the inner shaft 233 and elements 230, 232 may be retracted within the shaft 210 and later deployed to this state when near the valve. Fig. 16B shows the elements 230, 232 in an extended state of deployment. Here, the upward force on the loops 221 have been relaxed and the tension released. Consequently, the elements 230, 232 extend outwardly as shown and the relaxed loops 221 hang at any location. As shown in Fig. 16C, the loops 221 may then be slid to toward the inner shaft 233 so that the elements 230, 232 may more easily engage the valve leaflets LF.

Figs. 16D-16E illustrate another embodiment wherein the distal elements are held in a retracted position under tension and are extendable upon release. Here, the elements 230, 232 are disposed near the distal end the shaft 210. Fig. 16D shows the elements 230, 232 in a retracted position as they are held downward against the shaft 210 under tension by loops 221, each loop 221 threaded through an element 230, 232 and pulled upwardly within the shaft 210 as shown. The loops 221 may be comprised of any suitable material, including suture, wire or polymer strands. Fig. 16E shows the elements 230, 232 in an extended state of deployment. Here, the upward force on the loops 221 have been relaxed and the tension released. Consequently, the elements 230, 232 extend upwardly and outwardly as shown and the relaxed loops 221 are drawn upward to hang from the extended elements 230, 232.

In some embodiments, the distal elements extend and retract together, an example of which is illustrated in Figs. 16F-16G. Referring to Fig. 16A, the elements 230, 232 are disposed at the distal end 231 of the inner shaft 233 within the shaft 210. The elements 230, 232 pass through the shaft 210 wall and outside the shaft 210 at locations 235, 237 desired for element protrusion. Upon retracting the inner shaft 233, as shown in Fig. 16B, the elements 230, 232 together are guided radially outward through the shaft 210 at the locations 235, 237. It may be appreciated that although the elements 230, 232 in Figs. 16A-16G have been illustrated as curving downwardly, towards the distal end, the elements may alternatively be uncurved, curve upwardly, include compound curvatures or more than one curvature along each element, or any other combination of curvatures.

In a number of embodiments, an example of which is shown in Figs. 17A-17D, the interventional tool 204 also comprises proximal elements 240, 242 which are capable of protruding radially outward from the shaft at a location which is proximal to the

elements 230, 232 previously described. The proximal elements 240, 242 may have any of the forms, shapes, material compositions, features, or capabilities described in relation to the distal elements 230, 232. In Fig. 17A, such proximal elements 240, 242 are shown as loops. Such proximal elements 240, 242 would most commonly be used in embodiments of capture devices 204 designed for an antegrade approach to the valve wherein the device 204 crosses the valve to access the ventricular surface of the leaflets. Typically, once the distal elements 230, 232 are extended and positioned against the ventricular surface of the leaflets, the proximal elements 240, 242 are then extended and positioned against the artrial surface of the leaflets. As shown in Fig. 17B, the leaflets LF are thus secured between the proximal elements 240, 242 and distal elements 230, 232. The proximal elements 240, 242 and/or distal elements 230, 232 may then be extended, retracted or similarly adjusted to further orient the leaflets. In addition, the cap 238 may optionally be retracted toward the shaft 210 to further pinch the leaflets between the elements.

Referring to Fig. 17C, the proximal elements 240, 242 may be separately deployable from the distal elements 230, 232. Here, the elements 240, 242, 230, 232 are disposed near the distal end 231 of the inner shaft 233 within shaft 210. The proximal elements 240, 242 are constrained within the shaft 210 while the distal elements 230, 232 are extended radially outward. In this state, the distal elements 230, 232 may be positioned against the ventricular surface of the valve leaflets LF. The proximal elements 240, 242 may then be released by retracting the shaft 210. As shown in Fig. 17D, release of the proximal elements 240, 242 allows them to extend radially outward and downward, as illustrated by arrows. Depending on the curvature of the proximal elements 240, 242, they may remain proximal to, move to within the same plane of, or move beyond the plane of the distal elements 230, 232. In addition, the proximal elements may include various friction accessories 227, such as prongs, to assist in holding the valve leaflets LF. Other friction accessories 227 include windings around the elements, such as metal, polymer or suture windings, cuffs, bands, or barbs. Further, such accessories 227 may additionally or alternatively be included on the distal elements 230, 232. Likewise, such accessories 227 may be included on the elements of the capture devices in any of the embodiments of the interventional tool. In an additional embodiment, depicted in Figs. 18A-18D, the valve leaflets LF may be pinched between a proximal element or superior loop 720 and a distal element or inferior loop 721. In a preferred embodiment, the capture device or grasper is comprised of a nitinol flat ribbon heat set in the shape of double loops 720, 721. The ribbon may be mounted on a series of three coaxial shafts, an interior shaft 725, a central shaft 726

and an exterior shaft 727. The distal end of the ribbon may be attached to the distal end 730 of the interior shaft 725, a midportion of the ribbon may be attached to the distal end 731 of the central shaft 726, and the proximal end of the ribbon may be attached to the distal end 732 of the exterior shaft 727. One or more ribbons may be mounted on the coaxial shafts; in this example, two ribbons are shown 180 degrees apart. When extended, as shown in Fig. 18A, the grasper may be pulled flat against the shafts 725, 726 ,727 for ease of insertion through a guide catheter or tool and into a desired position between the valve leaflets LF. When the central shaft 726 is retracted or the exterior shaft 727 advanced, as shown in Fig. 18B, the superior loops 720 may extend radially from the shafts. The superior loops 720 may rest on the superior surface of the valve leaflets LF in the atrium, as shown in Fig. 18D. In this position, the superior loops 720 may aid in orientation assessment, as the superior loops may be echo or fluorogenic and may be easily visible in relation to the cardiac structures or other devices or components. When positioned in a desired location, the interior shaft 725 may then be retracted, as shown in Fig. 18C, to extend the inferior loops 721 radially from the shafts. The inferior loops 721 may be in contact with the inferior surface of the valve leaflets LF in the ventricle. Thus, the valve leaflets LF may be pinched between the inferior loop 721 and superior loop 720. It may also be appreciated that the inferior loops 721 may be deployed prior to the superior loops 720.

Further, the proximal elements 240, 242 and distal elements 230, 232 may interlock to prevent relative motion between the elements and more securely hold the leaflets LF. Referring to Fig. 19A, a distal element 230 is shown protruding radially outwardly from the shaft 210. In this example, the distal element 230 is shaped having a raised upwardly pointing tip portion 243 and two side portions 245. The proximal element 240 is shown protruding radially outwardly from the shaft 210 at a location proximal to the distal element 230. Here, the proximal element 240 is shaped having two downwardly pointing tip portions 247, 249. When the elements 230, 240 are drawn together, as shown in Fig. 19B, the raised upwardly pointing tip portion 243 fits between the two downwardly pointing tip portions 247, 249 locking the elements 230, 240 together. This may be more easily visualized in a top view of the interlocked elements 230, 240 shown in Fig. 19C. It may be appreciated that, in use, the distal element 230 is extended and positioned against a ventricular surface of a leaflet, the proximal element 240 is extended and positioned against an atrial surface of the leaflet. Thus, the leaflet is thus secured between the elements 230, 240 in the interlocked orientation.

In some embodiments, the proximal and distal elements are formed by a continuous structure. Referring to Fig. 20A, the continuous structure 260 is shown in a low profile position wrapped around the end portion 262 of the shaft 210 of the interventional catheter 200 under tension. In this profile position, the catheter 202 is advanced with an atrial approach through the valve, between the leaflets LF, so that the distal end 202 extends beyond the valve into the ventricle. Referring to Fig. 20B, the continuous structure 260 is then released and allowed to relax. Prior heat forming allows the structure 260 protrude radially outward at various points along the structure 260. Each protrusion is similar to an above described proximal or distal element and functions in a similar manner. The embodiment shown in Figs. 20A-20B includes protrusions similar to both proximal elements 240, 242 and distal elements 230, 232 as shown. These elements may protrude various distances and at various angles from the shaft, as previously described.

Many features of the distal elements 230, 232 and proximal elements 240, 242 have been described and illustrated with embodiments comprising wire loops. It may be appreciated that the described features are applicable to any of the above described embodiments, such as blocks, rods, ribbons, etc. Use of wire loops as examples are not intended to limit the scope of the present invention.

IV. LEAFLET FIXATION TOOL

With the valve leaflets grasped in a desired orientation using an embodiment of the capture device described above, the leaflets may be fixed together to maintain this orientation. This may be achieved by leaving the capture device in place to function as a fixation device. To this end, the capture device may be detachable from the interventional tool to be left behind as a permanent or temporary implant. Fig. 21A illustrates a capture device comprising distal elements 230, 232 and proximal elements 240, 242 wherein the leaflets LF are captured therebetween. As shown, the capture device may be detached from the shaft 210 and left behind as a fixation device. Detachment may be achieved by a variety of different mechanism and design features. Figs. 21B-21H illustrate embodiments of such detachment mechanisms. Fig. 21B shows an upper shaft 312 and a detachable lower shaft 313 which are interlocked at a joining line 314. The joining line 314 may have any shape or curvature which will allow or facilitate interlocking and later detachment. A snuggly fitting outer sheath 315 is positioned over the shafts 312, 313 to cover the joining line 314 as shown. Fig. 21C illustrates detachment of the lower shaft 313 from the upper shaft 312. This is achieved by retracting the outer sheath 315, so that the joining line 314 is exposed, which

allows the shafts 312, 313 to separate. Similarly, Fig. 21D illustrates a tubular upper shaft 316 and a detachable tubular lower shaft 317 which are interlocked at a joining line 314. Again, the joining line 314 may have any shape or curvature which will allow or facilitate interlocking and later detachment. A snuggly fitting rod 318 is inserted through the tubular shafts 316, 317 to bridge the joining line 314 as shown. Fig. 21E illustrates detachment of the lower shaft 317 from the upper shaft 316. This is achieved by retracting the rod 318 to a position above the joining line 314 which in turn allows the shafts 316, 317 to separate.

Figs. 21F-21H illustrate another embodiment of a detachment mechanism. Referring to Fig. 21F, an upper shaft 900 is shown attached to a detachable lower shaft 902. An outer tube 910 surrounds the upper shaft 900 and contacts the lower shaft 902 as shown. The upper shaft 900 is held in attachment to the lower shaft 902 by the presence of a ball 904 or similar device which is disposed in recess 906, shaped to receive a portion of the ball 904, in the lower shaft 902. The ball 904 is held in the recess 906 by an angular cutout 908 in the upper shaft 900. Referring to Fig. 21G, the upper shaft 900 may be retracted. This may be achieved by pulling the upper shaft 900 upwards within the outer tube 910 while the outer tube 910 applies force on the lower shaft 902 to aid separation. As the upper shaft 900 is retracted, the angular cutout 908 allows the ball 904 to move from the recess 906 to a position within the upper shaft 900. Referring to Fig. 21H, upper shaft 900 and ball 904 may retracted into the outer tube 910, completing the detachment from the lower shaft 902. It may be appreciated that this detachment mechanism concept may be used with other shaped shafts, recesses, and balls or similar devices and may function without the use of the outer tube.

In some cases, use of the capture device as a fixation device may create one or more small gaps between the leaflets LF at the coaptation line. If this is likely to occur, or as an added precaution, a block, disk or pledget 321 of material may be positioned such that it blocks possible flow through such a gap. As shown in Fig. 21I, the pledget 321 may be positioned between the proximal elements 240, 242 and distal elements 230, 232. When the leaflets LF are captured between the proximal elements 240, 242 and distal elements 230, 232, as shown in a top view in Fig. 21J, the pledget 321 is positioned between the leaflet LF edges to block flow therethrough.

Alternatively, fixation may be accomplished with the use of separate devices used in combination with an interventional tool having a capture device. And, many embodiments of the present invention incorporate a fixation tool into the interventional tool for such use. The fixation tools described herein below may be used with any of the capture

devices previously described. A few examples will be presented to illustrate possible embodiments.

In many embodiments, such as illustrated in Fig. 22, the interventional tool 100 has distal elements 302 and guide conduits 304 disposed near its distal end 306. Guide conduits 304 such as these may be used to guide a number of tools or devices to specific locations near the distal end 306. For example, in this case, the guide conduits 304 are used to guide fixation tools to specific locations on the surfaces of the leaflets. In addition, as will be described in a later section, the conduits 304 may be attached to the proximal loops. In addition to other benefits described later, the conduits 304 may provide added support or rigidity to the interventional tool which may aid in the fixation process.

As shown in Fig. 22, the guide conduits 304 are located proximal to the distal elements 302 and are capable of extending angularly outward from the shaft 308. It may be appreciated that the conduits 304 may be located at any point along the shaft 308 and may be capable of extending at any angle 310. Typically, such an angle 310 ranges from approximately 90 degrees, perpendicular to the shaft, to around zero degrees, essentially parallel to the shaft. Any angle 310 may be used to target the leaflets LF at points which are approximately 1-12 mm, preferably 3-5 mm, inward from the free edge FE of each leaflet LF. In a particular embodiment of the interventional tool 100, the guide conduit 304 is used for fixation. Here, the guide conduit 304 is used to introduce a fixation tool 305 comprising a penetrating device or needle 320 housing a suture 322 having an anchor 324 disposed at the distal end of the suture 322. The needle 320 is advanced toward a valve leaflet, either by extension of the guide conduit 304 or the needle 320 itself. In either case, the needle 320 is then advanced to penetrate the leaflet and emerge from the other side or the distal side of the leaflet . The needle 320 may be rigid, possibly made from a metallic material, or flexible, made from a flexible polymer, for example. As shown in Fig. 23A, an atrial approach would involve the needle 320 penetrating the atrial surface 326 of the leaflet LF, passing through the leaflet LF and emerging on the ventricular surface 327 of the leaflet LF. Once emerged, the anchor 324 is deployed as shown. The anchor 324 may be deployed by passing the anchor 324 through the needle 320 and expanding or allowing it to self-expand after it has exited the needle 320. Alternatively, the anchor 324 may be mounted on the outside of the needle 320 and covered by a sheath. Retraction or removal of the sheath would allow expansion of the anchor 324. In any case, after anchor deployment, the needle 320 is then retracted while maintaining the anchor 324 on the distal side of the leaflet LF. Consequently, the attached suture 322 remains in place, passing through the leaflet penetration. Once each fixation tool

305 has deployed its anchor 324 on the distal side of a leaflet LF, individually or simultaneously, the guide conduit 304 and interventional tool 204 are retracted. As shown in Fig. 23B, the ends of the sutures 322 may then be fixed together by conventional knot tying or any suitable method, including positioning fasteners. This may be achieved with the use of additional tools which are part of the interventional catheter 200, or this may be achieved by other methods after withdrawal and removal of the interventional catheter 200.

A number of different types of anchors 324 may be used during fixation of the leaflets. Typically, the anchor 324 is expandable from a compressed low profile state, for delivery to the anchoring site, to an expanded state to provide a large enough surface for anchoring support. One embodiment of the anchor 324, shown in Fig. 24, is comprised of a wire 360 curved into a ring shape. The wire 360 may be stainless steel, nitinol or other shape memory wire, polymer or similar material. Suture 322 is attached to the center 366 of the ring by a bonding material. The wire 360 has a first end 362 and a second end 364 wherein the first end 362 is disposed on top of the ring and the second end 364 is disposed underneath the ring as shown. This configuration provides support for the ring when the anchor 324 is pulled snuggly against a valve leaflet surface by the suture 322. In addition, the first end 362 and second end 364 may have radiopaque markers 365 disposed thereon. Referring to Fig. 25, this embodiment of the anchor 324 is shown in possible use for fixation of valve leaflets. As described previously, an atrial approach would involve the needle 320 penetrating the atrial surface 326 of the leaflet LF, passing through the leaflet LF and emerging on the ventricular surface 327 of the leaflet LF. When the anchor wire 360 is comprised of flexible materials, the anchor 324 is collapsible for loading within the needle 320. Once the needle 320 has emerged on the ventricular surface 327, the anchor 324 is deployed as shown. The needle 320 is then retracted while maintaining the anchor 324 on the distal side of the leaflet LF. Consequently, the attached suture 322 remains in place, passing through the leaflet penetration. Once each fixation tool 305 has deployed its anchor 324 on the distal side of a leaflet LF, individually or simultaneously, the guide conduit 304 and interventional tool 204 are retracted. The sutures 322 may be pulled tight so that the anchors 324 are disposed against the leaflets LF and the ends of the sutures 322 may then be fixed together by conventional knot tying or any suitable method, including positioning fasteners.

Another embodiment of the anchor 324, shown in Figs. 26A-26B, involves two parts which are disposed on opposite sides of a valve leaflet. Referring to Fig. 26A, the anchor 324 is comprised of a first part 370 and a second part 372 wherein the suture 322 is fixedly attached to the first part 370, slidably attached to the second part 372, and continues

to a free end 373 proximal to the second part 372. In addition, the first part 370 may have spikes 374 or other protrusions which interlock with receptacles 376 in the second part 372. It may be appreciated that such spikes 374 may be located on the second part 372 to interlock with receptacles 376 on the first part 370 or such spikes 374 and receptacles 376 may be located on both parts 370, 372. The anchor 324 may be comprised of flexible materials so that the anchor 324 is collapsible for loading within the needle 320. In this case, as previously described, the needle may penetrate the atrial surface 326 of the leaflet LF, pass through the leaflet LF and emerge on the ventricular surface 327 of the leaflet LF. Here the first part 370 of the anchor 324 is deployed, as shown in Fig. 26A. The needle 320 is then retracted while maintaining the first part 370 on the distal side of the leaflet LF. Consequently, the attached suture 322 remains in place, passing through the leaflet. Once the needle 320 is disengaged from the leaflet LF, the second part 372 of the anchor is deployed so the second part 372 is disposed on the atrial surface 326 as shown. Referring to Fig. 26B, the parts 370, 372 may then be drawn together so the spikes 374 pass through the leaflet LF and are received in the receptacles 376 locking the anchor in place. One or more sutures 322 with anchors 324 may be placed in other locations on the same or other leaflets LF. The ends of the sutures 322 may then be fixed together by conventional knot tying or any suitable method, including positioning fasteners.

Another embodiment of the anchor 324, shown in Figs. 27A-27B, involves a single structure having flanges which are disposed on opposite sides of a valve leaflet. Referring to Fig. 27A, the anchor 324 is comprised of a structure 381 having a first flange 380, a second flange 382 and a cylindrical portion 383 therebetween. The suture 322 is fixedly attached to the structure 381 as shown. In addition, the structure 381 may optionally include a compressible layer 384 on a surface of either the first flange 380, the second flange 382 or both facing the cylindrical portion 383. The anchor 324 may be comprised of flexible materials so that the anchor 324 is collapsible for loading within the needle 320. In this case, as previously described, the needle may penetrate the atrial surface 326 of the leaflet LF, pass through the leaflet LF and emerge on the ventricular surface 327 of the leaflet LF. Here the structure 381 is partially deployed so that the first flange 380 emerges and is positionable against the ventricular surface 327. The needle 320 is then retracted while maintaining the first flange 380 on the distal side of the leaflet LF. Consequently, cylindrical portion 383 emerges and is positioned through the leaflet. As the needle 320 is disengages from the leaflet LF, the second flange 382 is deployed so the second flange 382 is disposed on the atrial surface 326 as shown in Fig. 27B. One or more sutures 322 with anchors 324 may be

placed in other locations on the same or other leaflets LF. The ends of the sutures 322 may then be fixed together by conventional knot tying or any suitable method, including positioning fasteners.

Another embodiment of the anchor 324, shown in Figs. 27C-27D, involves a single tubular structure 800 having longitudinal slits 802 attached to the end of the suture 322. As shown in Fig. 27C, the structure 800 may be compressed to a low profile position so that it can be loaded within or on the outside of a catheter, needle or other delivery device. Upon delivery, as shown in Fig. 27D, the structure 800 may expand so that side-arms 804 project radially outward. This provides a broad surface to rest against the leaflets. A similar embodiment, shown in Figs. 27E-27F, comprises a tubular structure 810 having a central bar 812 to which the suture 322 is attached. As shown in Fig. 27F, the structure 810 may be compressed to a low profile position. Upon delivery, as shown in Fig. 27G, the structure 810 may expand so that side-arms 814 project radially outward. Such positioning of the suture 322 may provide allow the anchor 324 to be positioned more flush to the leaflets.

Another embodiment of the anchor 324, shown in Figs. 27G-27H, involves a tubular structure 820 attached to the end of the suture 322. As shown in Fig. 27G, the structure 820 may be mounted on the outside of a needle or introductory device 822 in a low profile position. Upon delivery, as shown in Fig. 27H, the structure 820 may expand radially outward. To achieve this, the structure 820 may be self expanding, wherein the structure 820 is released by retracting a sheath or similar restraining support. Or, the structure 820 may be mechanically expanded by action of a balloon or similar device mounted on the introductory device. In any case, introductory device 822 may then be removed.

Another embodiment of the anchor 324, shown in Figs. 27I-27J, involves a longitudinal structure 830 having a horizontal beam 832 attached to the end of the suture 322. As shown in Fig. 27I, the structure 830 may be compressed to a low profile position so that it can be loaded within a catheter, needle or other delivery device. Upon delivery, as shown in Fig. 27J, the structure 830 may expand so that side-arms 834 project radially outward. This may be achieved by expanding the horizontal beam 832 which in turn pushes the side-arms outward. Alternatively, this may be achieved by the side-arms 834 self-expanding which in turn expands the horizontal beam 832.

Another embodiment of the anchor 324, shown in Figs. 27K-27L, involves a thin disk 840 attached to the end of the suture 322. As shown in Fig. 27K, the disk 840 may be rolled to a cylinder shape, for either mounting on the outside of or for insertion through a lumen in a needle, catheter or other introductory device. Upon delivery, as shown in Fig.

27L, the disk 840 may then be flattened to provide a large surface area to rest against the leaflets.

Another embodiment of the anchor 324, shown in Figs. 27M-27N, involves a single tubular structure 850, having longitudinal slits 852 from one end to approximately midsection, attached to the end of the suture 322. As shown in Fig. 27M, the structure 850 may be compressed to a low profile position so that it can be loaded within or on the outside of a catheter, needle or other delivery device. Upon delivery, as shown in Fig. 27N, the slit structure portions 854 may curl or bend outwardly and/or downwardly. This provides a broad surface to rest against the leaflets.

Another embodiment of the anchor 324, shown in Figs. 27P-27Q, involves a tubular structure 860 attached to the end of the suture 322. As shown in Fig. 27P, the structure 860 may be mounted on the outside of a needle or introductory device 862 in a low profile position. Upon delivery, as shown in Fig. 27Q, the structure 860 may compress longitudinally, as in an accordion-type fashion. In doing so, the structure 860 additionally expands radially to provide added surface area to rest against the leaflets.

Another embodiment of the anchor 324, shown in Figs. 27R-27T, involves a bar 870 attached to the end of the suture 322. As shown in Fig. 27R, the suture 322 may rest flush against the bar 870 in a low profile position for loading within a needle, catheter or similar delivery device. Upon delivery, as shown in Fig. 27T, the bar 870 may reposition such that it is perpendicular to the suture line 322. In this way, the bar may rest against the leaflet in an anchoring fashion. Referring to Figs. 27U-27V, similar bars may be deployed from a double-barreled delivery device 880. As shown in Fig. 27U, a first bar 884 and a second bar 886 are loaded in parallel barrels separated by a partition 882. As shown in Fig. 17V, the first bar 884 may be deployed through the single lumen tip 888 of the delivery device 882. The device 882 may then be repositioned at another location where the second bar 886 may be deployed in a similar fashion.

In an additional embodiment of the interventional tool 100, more than one guide conduit 304 is present and directed at each leaflet for leaflet fixation. An example of such a tool 100 is shown in Fig. 28. Here the guide conduits 304 are shown attached to proximal elements 400 in a radially protruded position. Interconnection of the proximal elements 400 with the guide conduits 304 may allow one to deploy the other. For example, deployment and advancement of the guide conduits 304 angularly outward may draw the proximal elements 400 out from the shaft 402 effecting their deployment. Alternatively, the proximal elements 400 may be comprised of a material that is sufficiently rigid so that

deployment of the proximal elements 400 draws the guide conduits 304 downward and outward from the shaft 402 effecting their deployment. The proximal elements 400 may also serve to position the guide conduits 304 in a desired location. Distal elements 404 are also illustrated in a radially protruded position near the distal end 406 of the tool 100.

In use, the tool 100 is positioned between the valve leaflets LF, as shown in a top view in Fig. 29, so that the proximal elements 400 are disposed against the atrial surface (in an atrial approach) of the valve. The distal elements 404 are disposed against the ventricular surface of the valve and thus are out of view. Such placement of the proximal elements 400 provides four target points 406 on the valve leaflet LF, two target points 406 per leaflet LF. Advancement of one or more fixation tools through the guide conduits 304 allows placement of sutures and optionally anchors 324 through the leaflets LF at the target points 406 by the fixation tools. Once sutures and optionally anchors 324 are placed through each of the target points 406, the sutures may be pulled together, cinched and fastened in place. Fig. 30 illustrates such action as the target points 406 will be drawn together in the direction of the arrows. This may provide a more sturdy and effective fixation of the leaflets and therefore repair of the valve.

Sutures 233 may be placed through each of the target points 406 by a number of methods using a variety of fixation tools and devices. For example, Fig. 31 shows the placement of suture 233 through two adjacent target points 406 on one leaflet LF. Such illustrations assume an atrial approach with a top view of the atrial surface of the leaflet LF as depicted by shading. A first guide conduit 420 and a second guide conduit 422 protruding from the shaft 402 of an interventional tool 100 are shown directed toward the target points 406. Through the first guide conduit 420 a needle 423 or other device may be used to penetrate the leaflet LF and deploy a snare 424 on the ventricular side of the leaflet LF. Such a snare 424 may be comprised of any suitable material. Through the second guide conduit 422, a needle 423 or other device may be used to penetrate the leaflet LF and deploy an anchor 426 through the snare 424 on the ventricular side of the leaflet LF. Attached to the anchor 426 is a suture line 233 which passes through the penetration at the target point 406 and continues up through the second guide conduit 422. The snare 424 is then retracted back through the needle 423 pulling the anchor 426 and attached suture line 233 with it. Thus, the anchor 426 is drawn up through the first guide conduit 422 creating a continuous suture line 233 through the second guide conduit 422, across the ventricular surface of the leaflet LF and up through the first guide conduit 420. As shown in Fig. 32, this may be repeated on an adjacent leaflet LF and the suture lines 233 may be fixed together by conventional knot tying

or any suitable method, including positioning fasteners. Although such fixation is shown with the sutures in a relaxed position for clarity, such fixation will typically involve cinching the leaflets together so that the target points 406 are adjacent to one another.

It may be appreciated that the methods shown in relation to Fig. 31 may be similarly performed across two adjacent leaflets LF, as illustrated in Fig. 33. Here, a needle 423 or other device may be used to penetrate a leaflet LF and deploy a snare 424 on the ventricular side of the leaflet LF. Such a snare 424 may be comprised of any suitable material. Through the second guide conduit 422, a needle 423 or other device may be used to penetrate the adjacent leaflet LF and deploy an anchor 426 through the snare 424 on the ventricular side of the leaflet LF. Again, the anchor 426 is drawn up through the first guide conduit 422 creating a continuous suture line 233 through the second guide conduit 422, across the line of coaptation C of the leaflet LF and up through the first guide conduit 420. This may be repeated on two or more additional target points 406 in a similar manner and the suture lines 233 may be fixed together by conventional knot tying or any suitable method, including positioning fasteners.

Fig. 34 illustrates a similar embodiment of an interventional tool 100 having more than one guide conduit present and directed at each leaflet for leaflet fixation. This embodiment is used to place suture through target points in a method similar to that described above in relation to Figs. 31-33. However, this embodiment includes at least two slotted needles 440 or similar devices having slots 442 or openings which continue longitudinally from the needle 440 tip toward the shaft 443 for a desired distance. As shown, the tool 100 comprises a first, second, third and fourth guide conduit 451, 452, 453, 454 respectively. Through the first and fourth guide conduits 451, 454 needles 461 or other devices are introduced to penetrate the adjacent leaflets LF and deploy snares 456 on the ventricular side of the leaflets LF. Through the second and third guide conduit 452, 453 slotted needles 440 or other device are introduced to penetrate the leaflets LF and deploy anchors 458 through the snares 456 on the ventricular side of the leaflets LF. Attached to the anchors 458 is a continuous line of suture 459 which runs between the anchors 458. The suture line 459 passes through the penetrations at the target points 406, continues up through the slotted needles 440, out of the slots 442, into a lumen or compartment within the catheter shaft 443 where it forms a loop. Such a suture line 459 is illustrated in Fig. 34. Thus, a continuous line of suture 459 runs from one anchor 458 to another anchor 458 between adjacent leaflets LF. The anchors 458 are then drawn up through the first and fourth guide conduits 451, 454 by retracting the snares 456. As shown in Fig. 35, this results in a continuous suture line 459

across the line of coaptation C on the atrial surface, between adjacent target points 406 on the ventricular side surface of each leaflet LF and again across the line of coaptation C on the atrial surface where the free ends are fixed together by conventional knot tying or any suitable method, including positioning fasteners. It may be appreciated that the above described method and device may be adapted to fix the leaflets together using target points 406 in a variety of locations.

In another embodiment of the interventional tool 100, each guide conduit 304 comprises a penetrating device or needle 340 having a suture holding feature 341, in this example notch, disposed near its distal end, as shown in Fig. 36. This type of fixation tool 305 is used in combination with a interventional tool 204 having a specific type of distal element 302. This element 302 is similar to the loop 212 previously shown in Fig. 10A. As stated, these loops 212 are preferably made from nitinol or shape-memory wire, however other materials may be suitable. However, in this case, the loops 212 are combined with a second set of loops comprised of suture 342. The suture loops 342 are removably attached to the inside surface of the loops 212. Such attachment may be provided by a number device features. For example, as shown in Fig. 37, the suture loops 342 may be attached and held in place by heatshrink tubing 344 over the loops 212. The heatshrink tubing 344 has perforations 345 along the inside surface of the loop 212 to assist in release of the suture loop 342 when desired. Alternatively, the suture loop 342 may be held in place with a thin layer of material, such as polyurethane, which is applied by dipping or spraying. The suture loop 342 may also be attached by a combination of heatshrink tubing 344 and liquid polyurethane droplets in isolated sections. Further, as shown in cross-section in Fig. 38, the loops 212 themselves may be extruded with a cavity 346 to house the suture 342. The suture 342 may be held in place by the cavity 346 or by heatshrink tubing 344 and/or a layer of material such as polyurethane.

In any case, the interventional catheter 200 has fixation tools 305, comprising a needle 340 having a suture holding feature 341, and distal elements 302, comprising loops 212 combined with suture loops 342, as described above. The guide conduits 304 are located proximal to the distal elements 302 and are capable of extending angularly outward from the shaft 308 to protrude through the loops 212 and suture loops 342. Fig. 39 illustrates an atrial approach to the mitral valve. The interventional catheter 200 is positioned so that the distal element 302 is deployed beyond the valve leaflet LF and one of the loops 212 is pressed against the ventricular surface of the leaflet LF (shading illustrates its planar surface demarked by a leaflet edge 350). It may be appreciated that although the catheter 200 is

illustrated to suture one leaflet, the catheter 200 will typically comprise a duplicate arrangement symmetrically positioned on the opposite side of the shaft 308 to additionally suture the other leaflet. Only one leaflet LF is shown for clarity. The needle 340 is advanced toward the leaflet LF either by extension of the guide conduit 304 or the needle 340 itself. In either case, the needle 340 is then advanced to penetrate the leaflet LF and emerge from the other side or the distal side of the leaflet . The penetration hole 352 illustrates the point of entry through the leaflet LF. The needle 340 is further advanced so that the suture holding feature 341 is disposed in the same plane as the suture loop 342. As shown in Fig. 40, the suture loop 342 is then retracted so that it is released from the heatshrink tubing 344 and is disposed within the suture holding feature 341. The needle 340 is then retracted, as shown in Fig. 41, pulling the suture loop 342 through the penetration hole 352 to the atrial side of the valve. To aid in maintaining the suture loop 342 within the suture holding feature 341, a sheath or tubing may be slid over the suture holding feature 341 to hold the suture loop 342 in place. The other leaflet LF of the mitral valve is pierced in the same manner wherein the suture loop is threaded to the atrial side of the valve. The suture loops are then fixed together by conventional knot tying or any suitable method, including positioning suture fasteners.

V. DEVICE EMBODIMENTS

The following device embodiments depict complete device designs utilizing a variety of the specific features described above. In addition, new features are also introduced which provide additional device capabilities. The embodiments shown are designed for treatment of the mitral valve with an atrial approach. However, it may be appreciated that the design features may be adapted for other valves and other approaches.

The embodiments of the interventional catheter 500 will be described in conjunction with its method of use for repairing a regurgitive mitral valve. However, the device will be illustrated independently of the valve anatomy to more clearly illustrate the workings of the device. The relationship of the device to the valve anatomy throughout the steps of the method may be easily visualized based on description.

In the first embodiment, referring to Fig. 42, the interventional catheter 500 comprises an elongate shaft 502 having at least one capture device 504 and guide conduit 506 disposed near its distal end 508. The capture device 504 comprises distal loops 510 which are located near the tip 512 of the catheter. Two distal loops 510 are shown, one on each side of the catheter 500, for the capturing of two valve leaflets. The distal loops 510 are retracted for introduction of the catheter 500 through a previously placed guidecatheter. Proximal

loops 514 and guide conduits 506 are also shown. Since both the proximal loops 514 and the guide conduits 506 are located proximal to the distal loops and approach the atrial surface of the leaflets, they may be interconnected at the guide conduit cuff 516 as shown. In addition, such interconnectivity may provide advantages which have been presented earlier in relation to embodiments having similar interconnectivity. It may be appreciated, however, that these features may be independent in other embodiments. Similar to the distal loops 510, the proximal loops 514 and guide conduits 506 are retracted for introduction of the catheter 500 through the previously placed guidecatheter. In addition, portions of the catheter 500 may have an integral spring or flexible section 516 which may assist in passing the device through any curves in the guidecatheter during introduction.

After introduction, the catheter 500 is advanced so that the tip 512 of the catheter is positioned within the atrium, above the mitral valve. Referring to Fig. 43, the distal loops 510 are then deployed so that they protrude radially outward from the shaft 502. The device is then oriented so that the distal loops 510 are positioned substantially perpendicular to the line of coaptation between the two valve leaflets. This may be accomplished with the use of short-axis echocardiography. The tip 512 may be moved roughly along the line of coaptation to the location of regurgitation. After alignment, the tip 512 and distal loops 510 are advanced through the valve, between the leaflets, so that the loops 510 emerge beyond the valve. Perpendicular alignment is then reconfirmed using echocardiography. At this point, the distal end 508 is retracted so that the distal loops 510 move upward, toward the atrium, and press against the ventricular surface of the leaflets. This grasps the leaflets and holds the leaflets in place throughout the cardiac cycle. During diastole, a double orifice geometry may be visualized using short-axis echocardiography, as previously shown in Fig. 5.

Referring to Fig. 44, the proximal loops 514 and guide conduits 506 are co-deployed and advanced toward the atrial surface of the leaflets. As previously described, interconnection of the proximal loops 514 with the guide conduits 506 may allow one to deploy the other. For example, deployment and advancement of the guide conduits 506 angularly outward may draw the proximal loops 514 out from the shaft 502 effecting their deployment. Alternatively, the proximal loops 514 may be comprised of a material that is of sufficient rigidity so that deployment of the proximal loops 514 draws the guide conduits 506 downward and outward from the shaft 502 effecting their deployment. The proximal loops 514 may also serve to position the guide conduit cuffs 516 within the distal loop 510 as shown.

In any case, as shown in Fig. 45 in a side-view, the proximal loops 514 and guide conduits 506 are deployed to near or below the plane of the distal loops 510 so that they are in contact with the atrial surface of the leaflets. Although not illustrated, the valve leaflets would reside between the proximal loops 514 and the distal loops 510. In some cases, such as in severe prolapsing valves, the proximal loops 514 may be deployed prior to grasping the leaflets with the distal loops 510. In these cases, the proximal loops 514 may act to limit the extent of prolapse and to assist in trapping the leaflet between the proximal and distal loops.

Once the leaflets are securely grasped between the proximal and distal loops, the double orifice geometry is confirmed during diastole using short-axis echocardiography. If the positioning of the leaflets appears as desired, piercing devices or needles 520 are advanced from the guide conduit cuffs 516 to puncture and penetrate the valve leaflets. As shown in Fig. 46, the needles 520 are advanced through the distal loops 510 so that the distal loops 510 may support the leaflet during penetration. As shown in Fig. 47, the distal loops 510 are then retracted, pulling the needles 520 radially toward the shaft 502. Since each needle 520 is pierced through a leaflet, the radially inward movement of the needles 520 draws the leaflets together at the points of penetration. This simulates the methods of performing a standard surgical bow-tie repair. At this point, the proximal loops 514 may be removed from the valve surface and the mitral regurgitation may be evaluated to determine if the two pierced points are suitable for fixing the leaflets together. Color Doppler echo will show if the regurgitation of the valve has been reduced. If the resulting mitral flow pattern is satisfactory, the leaflets may be fixed together in this orientation. If the pattern is unsatisfactory, the above steps may be repeated until a satisfactory flow pattern is obtained.

Referring to Fig. 48, fixation may be achieved with the use of fixation pledgets or anchors 522 which are deployable from the needles 520. Push rods (not shown) may be advanced within the needles 520 to deploy the anchors 522 from the needles 520. Attached to each anchor 522 is a line of suture 524 which is captured within each needle 520, as shown. The needles 520 are then retracted back through the leaflet penetrations, leaving the anchors 522 on the ventricular side of the valve leaflets while threading the suture 524 through the penetrations. Simultaneously or subsequently, the tip 512 and/or distal end 508 is advanced distally to position the distal loops 510 slightly below the anchors 522. In this way, the distal loops 510 may be retracted inwardly without trapping the lines of suture 524 in the loops 510. The distal loops 510 are thus retracted to a low profile position and the proximal loops 514 and guide conduits 506 are also retracted to their original low profile

position. As shown in Fig. 49, the distal end 508 is then withdrawn from the valve, leaving the anchors 522 disposed on the ventricular side of the leaflets LF and the lines of suture 524 threaded through the penetrations 526, continuing up through the guide conduits 506.

Referring to Fig. 50, a holding tube 530 containing the free ends of both sutures 524 is separated from the shaft 502 and advanced toward the atrial surface of the leaflets LF. This holds tension on the anchors 522 to maintain the position of the anchors 522 against the ventricular surface of the leaflets LF and to maintain the coaptation of the leaflets LF along the line of coaptation C. A suture fixation device deployment catheter (not shown) is then inserted through, over or replacing the holding tube 530 to tie the sutures together with a knot or to deploy a fixation device 532 to hold the sutures 524 in place, as shown in Fig. 51. A suture cutter (not shown) is integral with the deployment catheter and is used to cut the suture lines 524 proximal to the fixation device 532. The deployment catheter is then removed leaving the fixed leaflets in a repaired condition.

In the second embodiment, referring to Fig. 52, the interventional catheter 1050 comprises an elongate shaft 1052 and a detachable capture device 1054. The capture device 1054 comprises, among others, proximal elements 1056 and distal elements 1058. Such a capture device 1054 is similar to that presented in Figs. 17C-17D. Again, the proximal elements 1056 may be separately deployable from the distal elements 1058. As shown, the distal elements 1058 are deployed so that they are extended radially outward from the shaft 1052. The proximal elements 1056 may be held against the shaft by sutures 1060 which are drawn up within the shaft 1052. In this orientation, the catheter 1050 may be manipulated between the leaflets so that the distal elements 1058 are positioned against the ventricular surface of the valve leaflets LF.

Referring to Fig. 53, the proximal elements 1056 may then be released by slacking the sutures 1060. This allows the preformed elements 1056 to extend radially outward and downward, as illustrated. Depending on the curvature of the proximal elements 1056, they may remain proximal to, move to within the same plane of, or move beyond the plane of the distal elements 1058. Here, the proximal elements 1056 are shown slightly beyond the plane of the distal elements 1058. Thus, the leaflets LF would be grasped and held in place between the elements 1056, 1058. In addition, the proximal elements 1056 include prongs 1057 to provide friction and assist in holding the leaflets LF.

The leaflets LF may then be repositioned by manipulating the elements 1056, 1058 while the leaflets LF are grasped therebetween. Referring to Fig. 54, the elements 1056, 1058 may be drawn inward by rotation of a torque shaft 1064, such rotation indicated

by an arrow. Rotation of the torque shaft 1064 drives a screw 1065 in the capture device 1054 which translates a nut 1066 downward within the capture device 1054. The translating nut 1066 draws the elements 1056, 1058 inward to assist in coaptation of the leaflets LF.

Fig. 55 more closely illustrates the workings of the capture device 1054. The nut 1066 is positioned on the screw 1065 between a top structure 1068 and a bottom structure 1069. The proximal and distal elements 1056, 1058 are fixedly attached in holes 1076 in the nut 1066 and pass through holes 1074 in the top structure 1068. The screw 1065 has a screw top 1070 which extends into a torque driver 1072. The inner diameter of the driver 1072 is square to receive the square screw top 1070. The torque shaft 1064 is attached to the driver 1072 so that rotation of the shaft 1064 rotates the screw 1065. This in turn translates the nut 1066 downward, drawing the elements 1056, 1058 inward through the holes 1074. Since the nut 1066 has flat sides, the nut 1066 will not rotate within an outer casing 1076 (shown in Fig. 54) which fits against the nut 1066.

During repositioning of the leaflets LF, imaging is used to verify that coaptation and mitral regurgitation reduction is suitable. Once the leaflets LF are suitably positioned, the capture device 1054 is ready for detachment. Figs. 56-57 illustrate an embodiment of the detachment mechanism which is similar in design and function to that previously described in relation to Figs. 21D-21E.. Fig. 56 illustrates a tubular upper shaft 1080 and a detachable lower shaft 1082 which are interlocked at a joining line 1084. Again, the joining line 1084 may have any shape or curvature which will allow or facilitate interlocking and later detachment. The torque driver 1072 bridges the joining line 1084 as shown. Such placement of the driver 1072 prevents twisting and translation of the upper and lower shafts 1080, 1082. Fig. 57 illustrates detachment of the lower shaft 1082 from the upper shaft 1080. This is achieved by retracting the driver 1072 to a position above the joining line 1084 which in turn allows the shafts 1080, 1082 to separate. Consequently, the capture device 1054 is detached from the shaft 1052 of the interventional catheter 1050, as shown in Fig. 58, and left behind as an implant to hold the leaflets LF in the desired coapted position.

Kits 1000 according to the present invention comprise any number of items related to the devices, systems and methods described above. As shown in Fig. 59, such kits 1000 typically include at least one interventional catheter 1002 having a capture device 1004. Optionally, the capture device 1004 may be detachable and, in such a case, a number of capture devices 1004 (or fixation devices) may be included in the kit 1000. The kits 1000 also include instructions for use IFU setting forth any of the methods according to the present

invention. Optionally, the kits 900 may further include any of the other system components described above, such as one or more guidecatheters 1006, guide wires 1008, dilators 1009, penetration devices 1010, sutures 1012, anchors 1014 optionally having sutures 1012 attached, snares 1016 optionally having sutures 1012 attached, and fasteners 1018 to fix sutures together, to name a few. Some or all kit components will usually be packaged together in a pouch 1020 or other conventional medical device packaging. Usually, those kit components which will be used in performing the procedure on the patient will be sterilized and maintained within the kit. Optionally, separate pouches, bags, trays or other packaging may be provided within a larger package, where the smaller packs may be opened separately to separately maintain the components in a sterile fashion.

Although the foregoing invention has been described in some detail by way of illustration and example, for purposes of clarity of understanding, it will be obvious that various alternatives, modifications and equivalents may be used and the above description should not be taken as limiting in scope of the invention which is defined by the appended claims.

WHAT IS CLAIMED IS:

1. A device for repairing a cardiac valve having leaflets, said device comprising:

an interventional catheter comprising a shaft having a proximal end, a distal end and a longitudinal axis therebetween, configured to pass to a position within the heart adjacent to the cardiac valve; and

a capture device disposed near the distal end of the interventional catheter comprising at least one distal element, wherein the distal element is protrudable radially outward and configured for pressing against a downstream surface of at least one leaflet.

2. A device as in claim 1, wherein the length of protrusion of the distal element is adjustable.

3. A device as in claim 1, wherein the radius of curvature of the distal element is adjustable.

4. A device as in claim 2 or 3, wherein the distal element is extendable or retractable.

5. A device as in claim 1, wherein the distal element is configured to reposition the at least one leaflet independently of the other leaflets.

6. A device as in claim 1, wherein the capture device comprises two distal elements disposed on opposite sides of the shaft.

7. A device as in claim 1, wherein the capture device further comprises at least one proximal element disposed proximal to the distal element.

8. A device as in claim 7, wherein the proximal element is protrudable radially outward from the shaft.

9. A device as in claim 7, wherein the proximal or distal elements are made from a material comprising stainless steel, metals, nitinol, Cobalt-Chromium-Nickel alloy, shape-memory alloy, polymer, silk, polyester, nylon or a combination of these.

10. A device as in claim 7, wherein the proximal element is interlockable with the distal element.

11. A device as in claim 7, wherein the capture device is detachable from the interventional catheter.

12. A device as in claim 1, wherein the interventional catheter further comprises at least one fixation tool for fixing the valve leaflet together.

13. A device as in claim 12, wherein the fixation tool is adapted for fastening, suturing, clipping, stapling, riveting, gluing, or fusing the leaflets together.

14. A device for repairing a cardiac valve having leaflets, said device comprising:

an interventional catheter comprising a shaft having a proximal end, a distal end and a longitudinal axis therebetween, configured to pass to a position within the heart adjacent to the cardiac valve; and

a capture device disposed near the distal end of the interventional catheter comprising at least one distal element, wherein the distal element is protrudable radially outward in the shape of a loop facing the proximal end and configured for pressing against a downstream surface of at least one leaflet.

15. A device as in claim 14, wherein the interventional tool further comprises at least one fixation tool for fixing the valve leaflet together.

16. A device as in claim 15, wherein the fixation tool comprises a penetrating device.

17. A device as in claim 16, wherein the penetrating device has a suture and an anchor disposed at the distal end of the suture.

18. A device as in claim 17, wherein the anchor is mountable on or in the penetrating device.

19. A device as in claim 18, wherein the anchor is deployable from the penetrating device.

20. A device as in claim 17, wherein the anchor is expandable.

21. A device as in claim 17, wherein the anchor comprises a wire curved into a ring shape.

22. A device as in claim 21, wherein the wire has a first end and a second end wherein the first end is disposed on top of the ring and the second end is disposed underneath the ring.

23. A device as in claim 16, wherein the penetrating device comprises a snare.

24. A device as in claim 16, wherein the penetrating device has a slot through which a suture is passable.

25. A device as in claim 14, wherein the interventional tool further comprises at least one guide conduit.

26. A device as in claim 25, wherein each guide conduit is capable of extending angularly outward from the shaft.

27. A device as in claim 25, wherein the guide conduit is positionable so that a tool advanced through the guide tube is directed toward the inside of the loop shaped distal element.

28. A device for repairing a cardiac valve, said device comprising:

an interventional catheter configured to pass to a position within the heart adjacent to the cardiac valve; and

a capture device on the interventional catheter comprising at least one distal element and at least one proximal element, wherein the distal and proximal elements are protrudable radially outward and configured to capture at least one leaflet between the elements and reposition the captured leaflet independently of the other leaflets.

29. A device as in claim 28, wherein the distal element is extendable or retractable to reposition the captured leaflet.

30. A device as in claim 28, wherein the proximal element is extendable or retractable to reposition the captured leaflet.

31. A device as in claim 28, wherein the proximal element is interlockable with the distal element.

32. A device as in claim 28, wherein the capture device is detachable from the interventional tool.

33. A device for repairing a cardiac valve, said device comprising:

an interventional catheter configured to pass from the remote vasculature of a patient to a position within the heart adjacent to the cardiac valve; and

a capture device on the interventional catheter comprising at least one radially expansible sheet and at least one radially expansible bar, wherein the sheet contacts a superior surface of the valve leaflet and the bar contacts an inferior surface of the valve leaflet when the sheet(s) and bar(s) are in an expanded position to capture a portion of the valve leaflet therebetween, and

wherein the capture device is detachable from the interventional catheter.

34. A device as in claim 33, wherein the at least one radially expansible sheet and at least one radially expansible bar are extendable or retractable to reposition the captured leaflet.

35. A device as in claim 34, wherein the at least one radially expansible sheet and at least one radially expansible bar are independently extendable or retractable.

36. A kit for repairing a cardiac valve having valve leaflets, said kit comprising:

an interventional catheter configured to pass from the remote vasculature of a patient to a position within the heart adjacent to the cardiac valve, said catheter having a capture device comprising at least one distal element; and

instructions for use setting forth a method comprising

accessing a patient's vasculature remote from the heart,

advancing the interventional tool through the vasculature to a location near the cardiac valve, and

applying an upward force against a downstream surface of at least one leaflet with the capturing device to reposition at least one leaflet so as to reduce leakage through the valve during ventricular systole.

37. A kit as in claim 36, further comprising a guide catheter configured to pass from the remote vasculature to a position within the heart adjacent to the cardiac valve, said guide catheter having a lumen sized to accept the interventional catheter.

38. A kit as in claim 36, further comprising a fixation tool.

39. A kit as in claim 38, wherein the fixation tool comprises a penetrating device having a suture and an anchor disposed at the distal end of the suture.

40. A kit for repairing a cardiac valve having valve leaflets, said kit comprising:

an interventional catheter configured to pass from the remote vasculature of a patient to a position within the heart adjacent to the cardiac valve, said catheter having a capture device comprising at least one distal element and at least one proximal element; and

instructions for use setting forth a method comprising

accessing a patient's vasculature remote from the heart;

advancing an interventional tool having a capturing device through the vasculature to a location near the cardiac valve;

capturing at least one leaflet between the proximal and distal elements; and

repositioning the captured leaflets independently of each other.

41. A kit as in claim 40, further comprising a guide catheter configured to pass from the remote vasculature to a position within the heart adjacent to the cardiac valve, said guide catheter having a lumen sized to accept the interventional catheter.

42. A kit as in claim 40, further comprising a fixation tool.

43. A kit as in claim 42, wherein the fixation tool comprises a penetrating device having a suture and an anchor disposed at the distal end of the suture.

44. A fixation device for repairing a cardiac valve having valve leaflets, said device comprising:

a shaft having a proximal end and a distal end;

at least one distal element disposed near the distal end, the distal element capable of protruding radially outward and shaped to contact a downstream surface of a leaflet;

at least one proximal element disposed near the proximal end, the proximal element capable of protruding radially outward and shaped to contact an upstream surface of a leaflet; and

a coupling mechanism disposed near the proximal end for coupling with an interventional catheter.

45. A fixation device as in claim 44, wherein the length of protrusion of the distal element and/or proximal element is adjustable.

46. A fixation device as in claim 44, wherein the radius of curvature of the distal element and/or proximal element is adjustable.

47. A fixation device as in claim 44, comprising two distal elements disposed on opposite sides of the shaft.

48. A fixation device as in claim 44, comprising two proximal elements disposed on opposite sides of the shaft.

49. A fixation device as in claim 44, wherein the proximal or distal elements are made from a material comprising stainless steel, metals, nitinol, Cobalt-Chromium-Nickel alloy, shape-memory alloy, polymer, silk, polyester, nylon or a combination of these.

50. A fixation device as in claim 44, wherein the proximal element is interlockable with the distal element.

51. A fixation device as in claim 44, wherein the proximal or distal element has at least one friction accessory.

52. A fixation device as in claim 51, wherein the friction accessory comprises prongs, windings, bands or barbs.

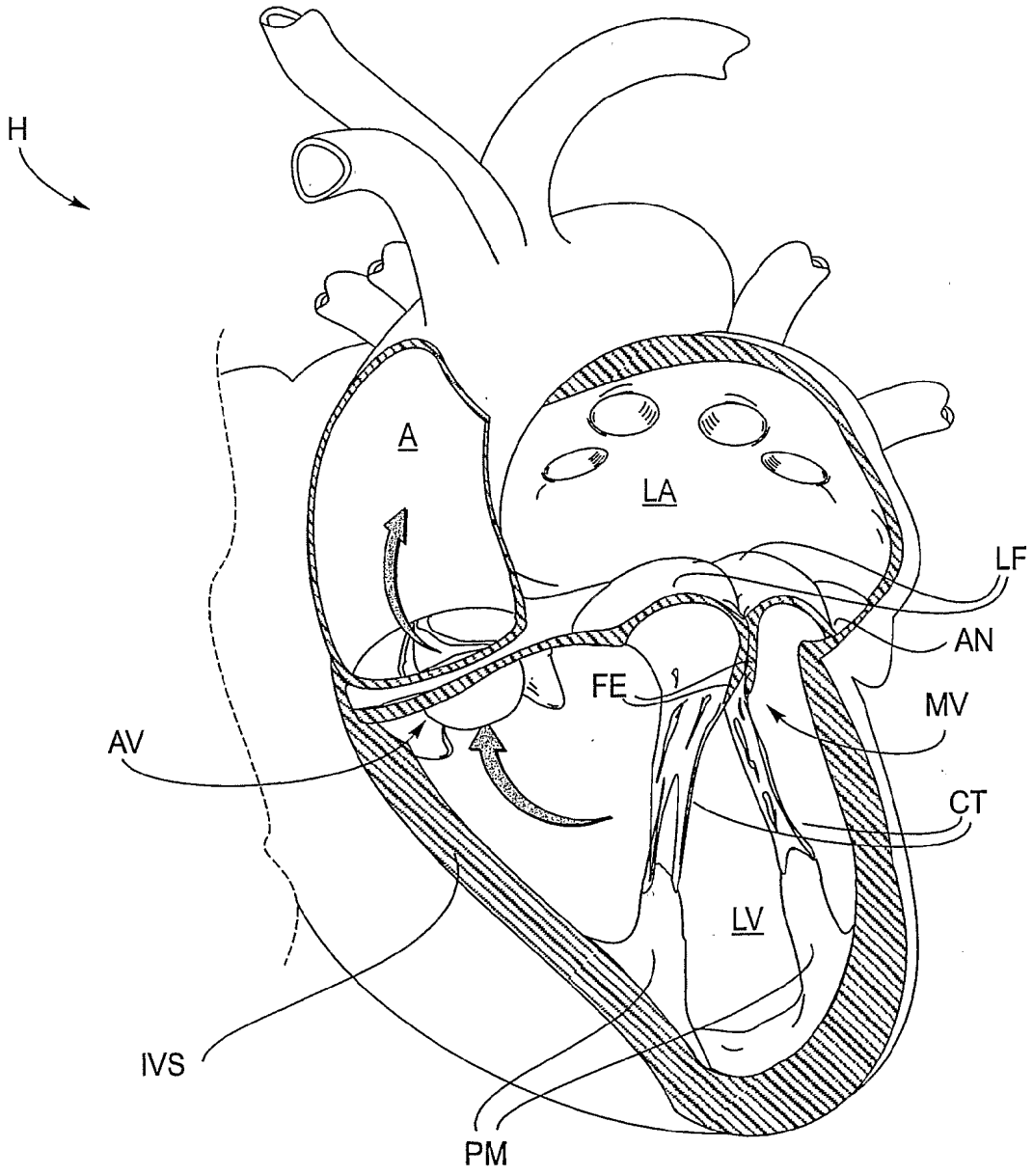


Fig. 1

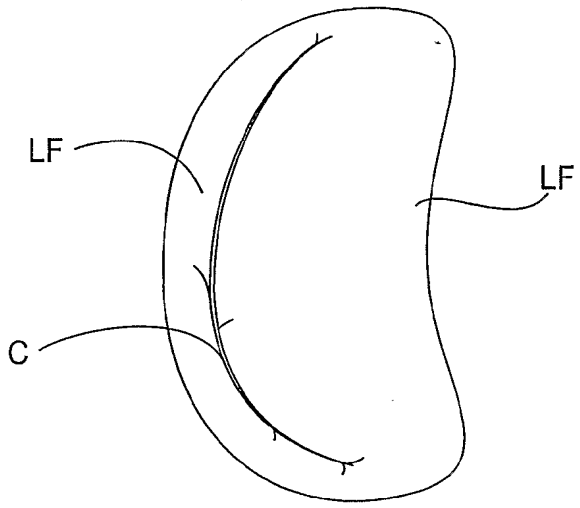


Fig. 2A

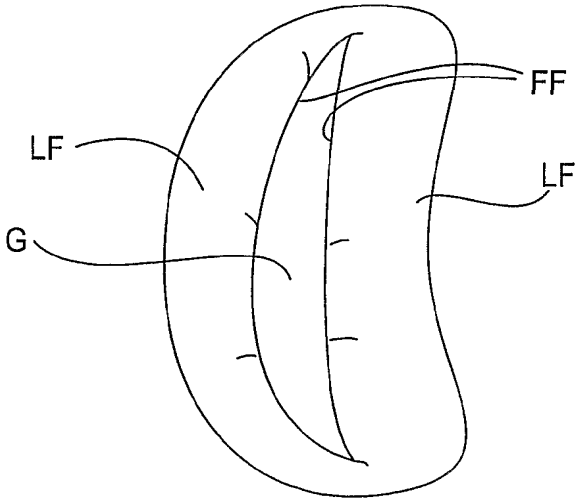


Fig. 2B

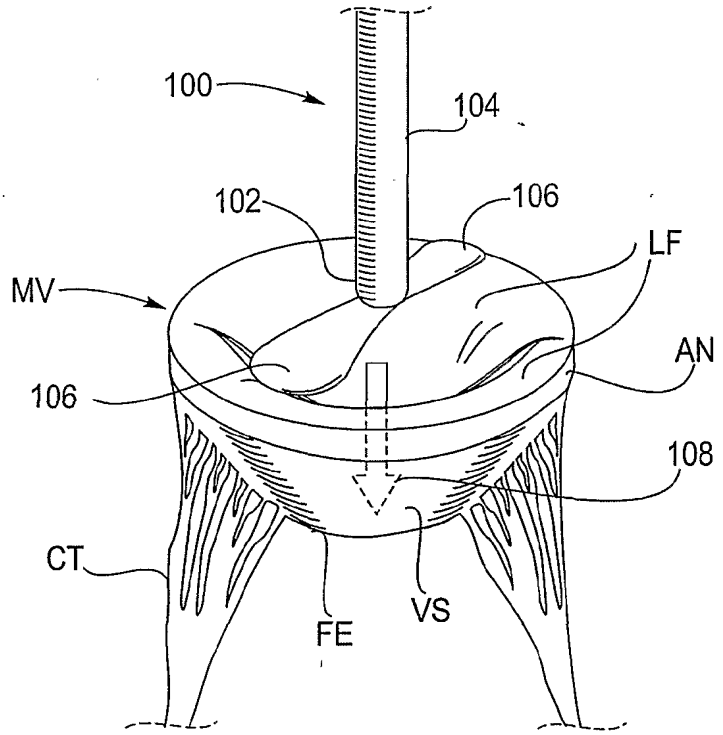


Fig. 3

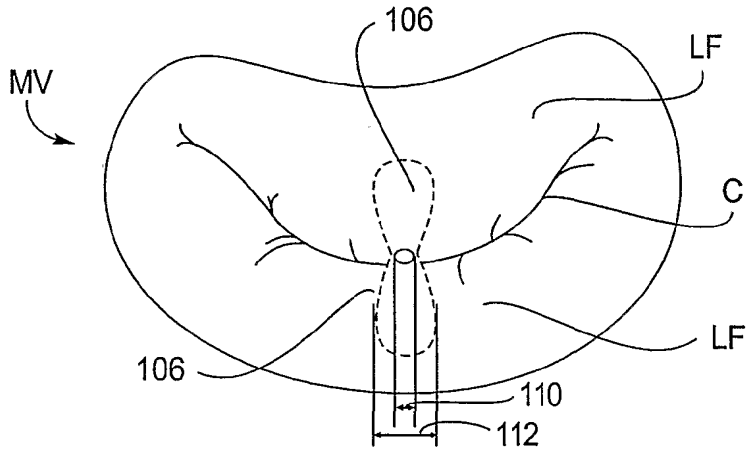


Fig. 4

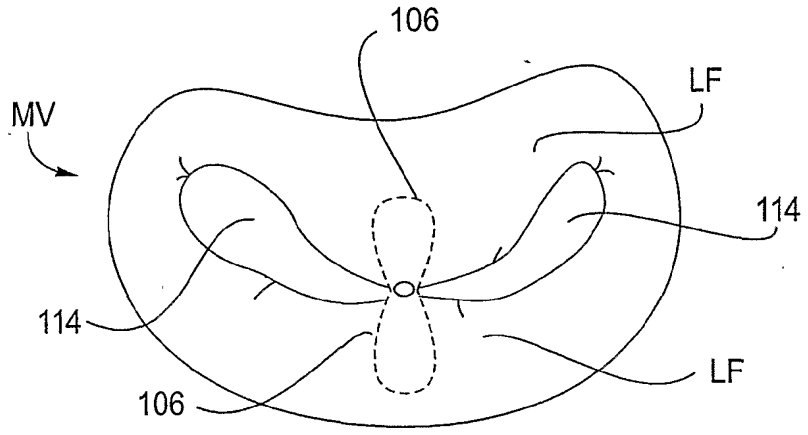


Fig. 5

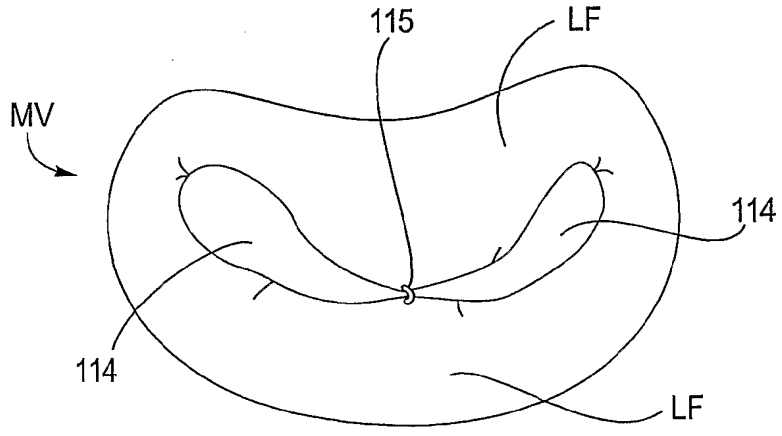


Fig. 5A

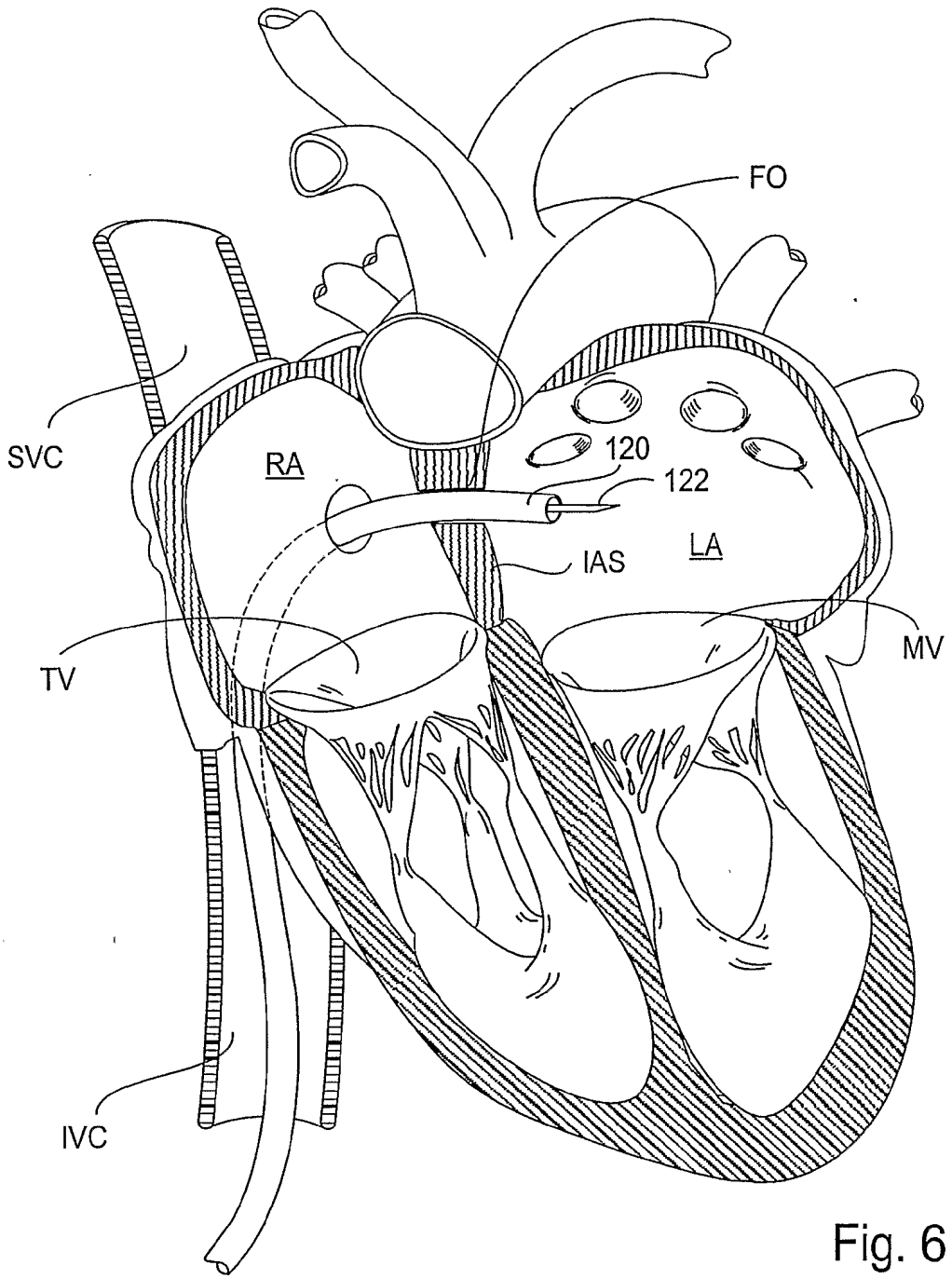


Fig. 6

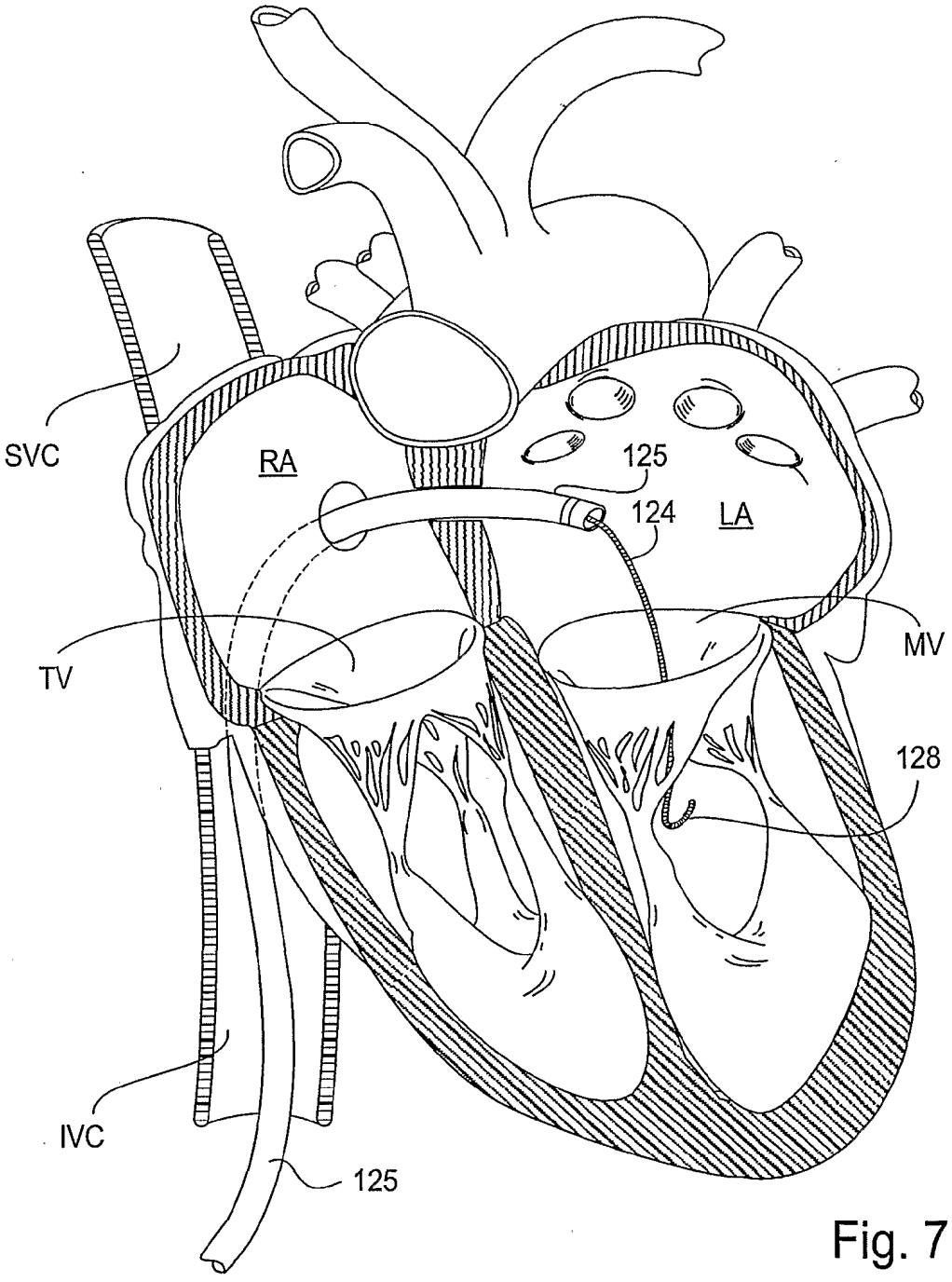


Fig. 7

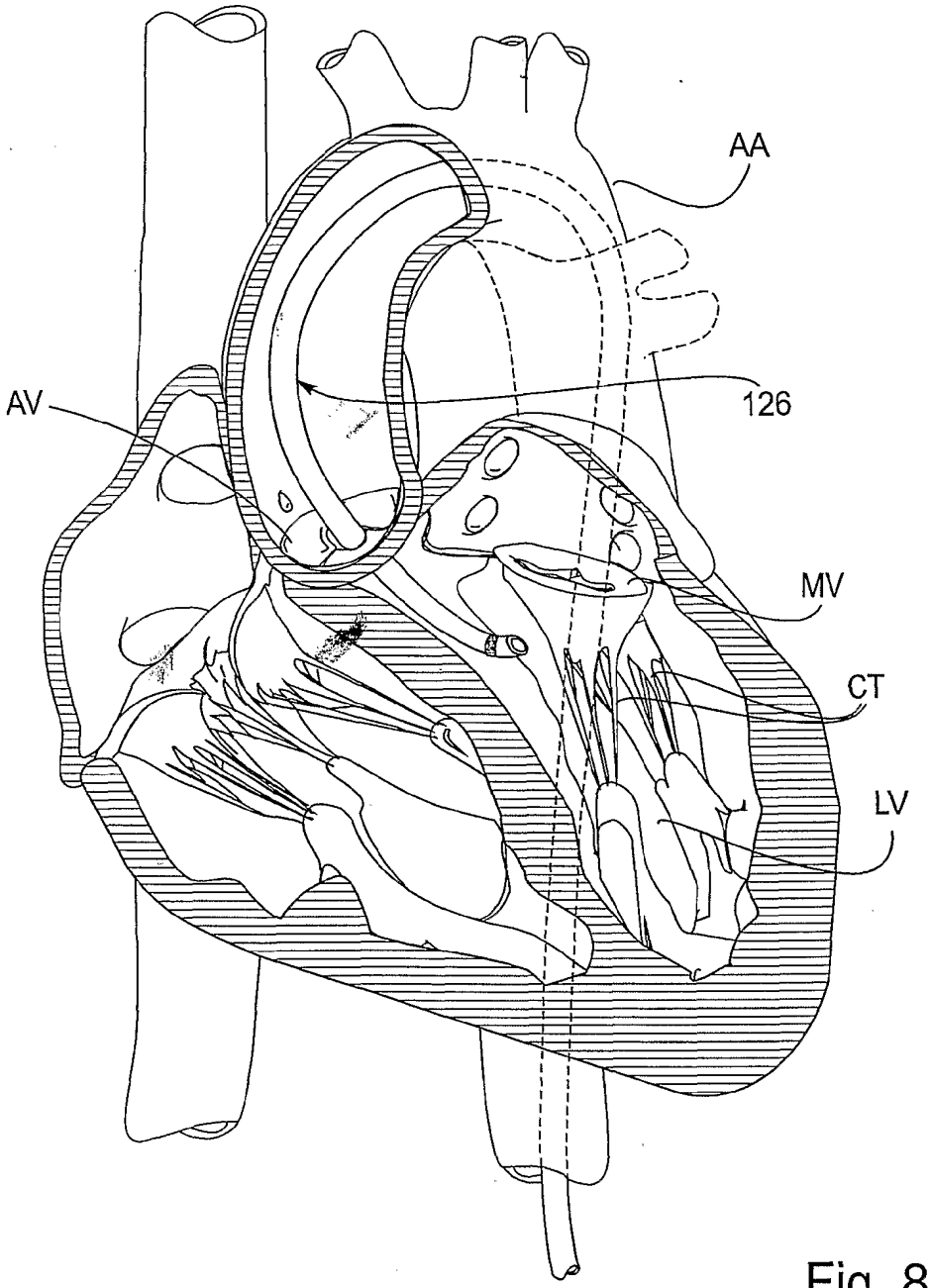


Fig. 8

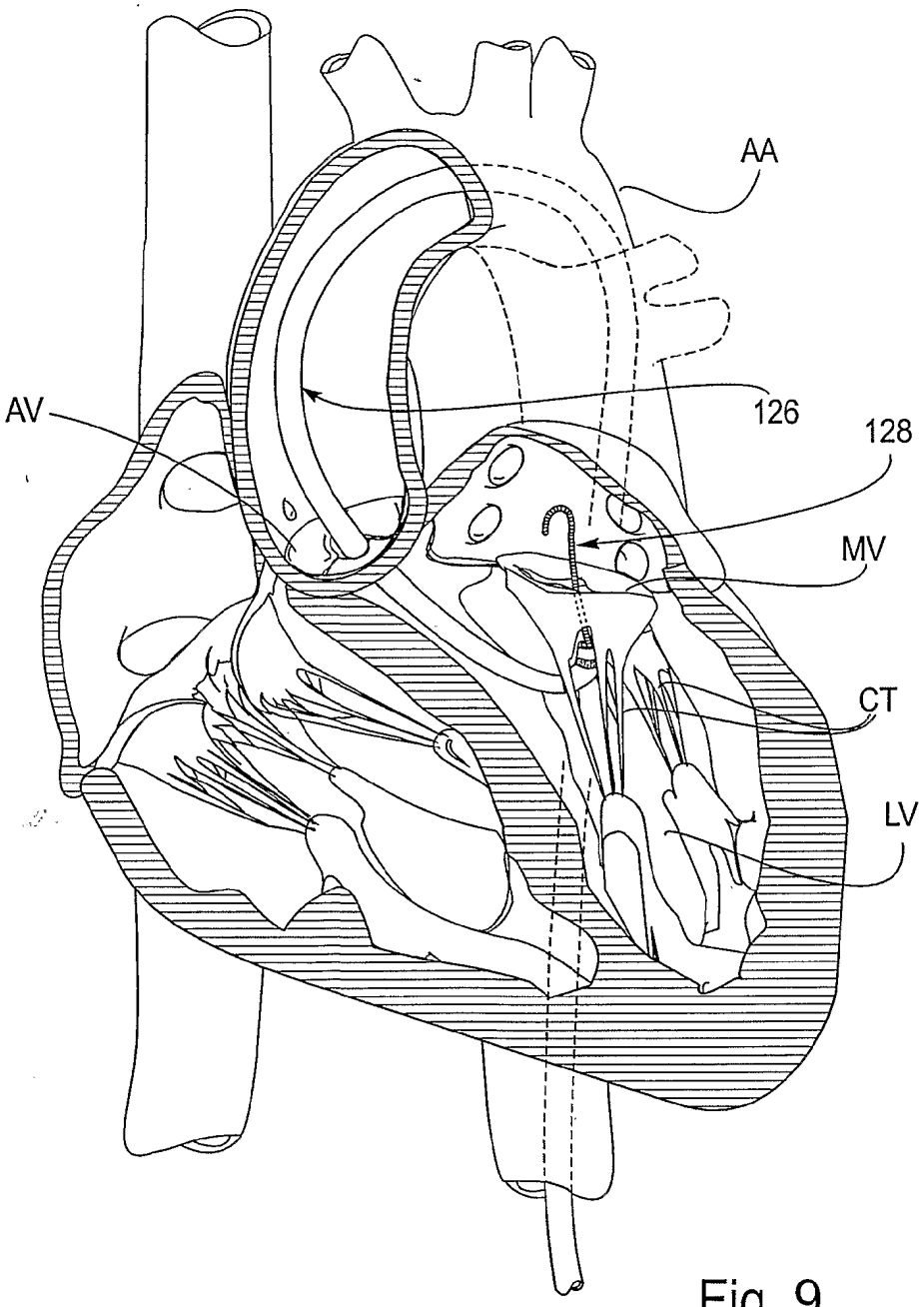


Fig. 9

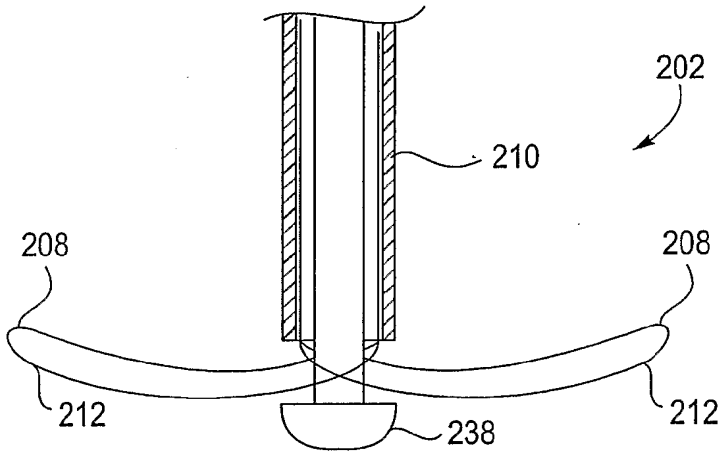


Fig. 10A

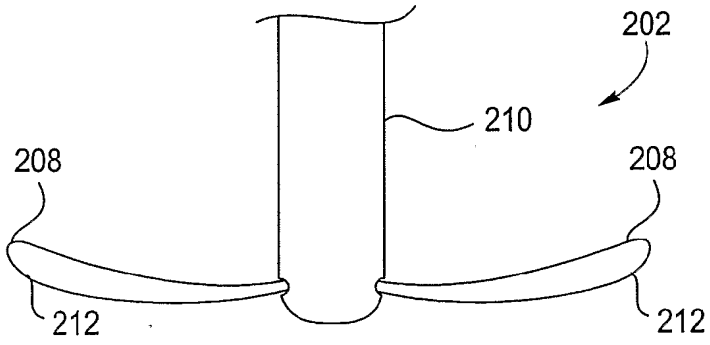


Fig. 10B

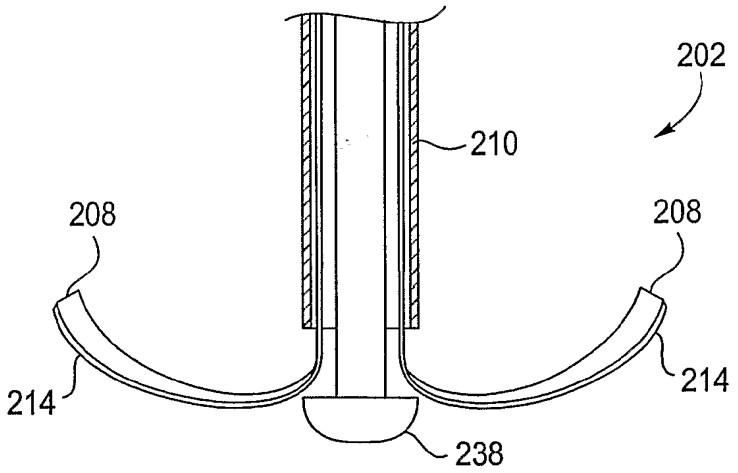


Fig. 10C

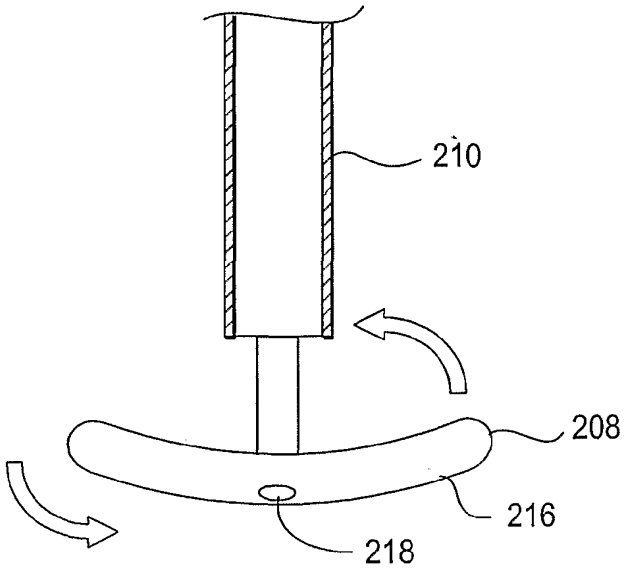


Fig. 11A

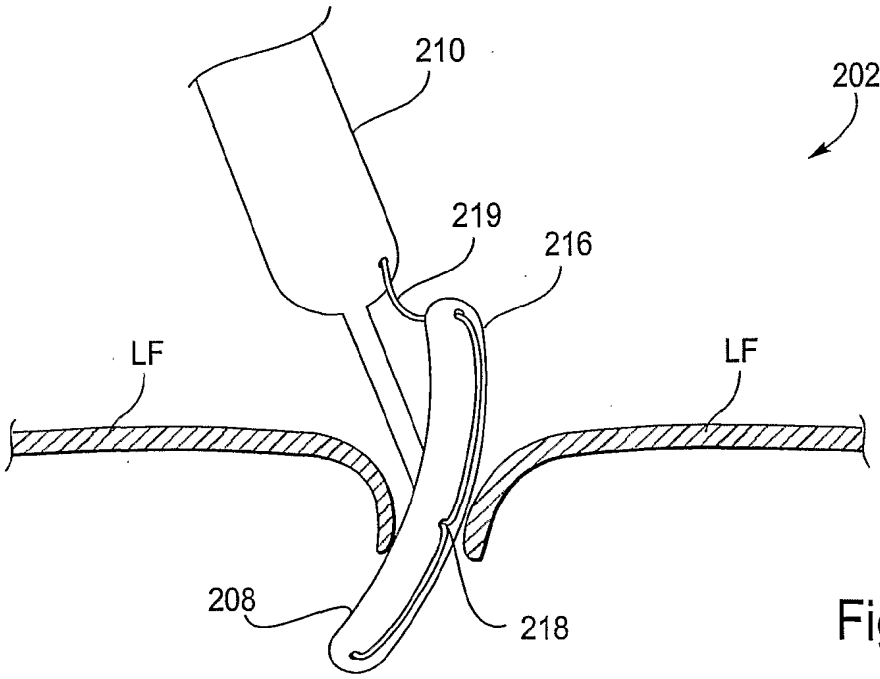


Fig. 11B

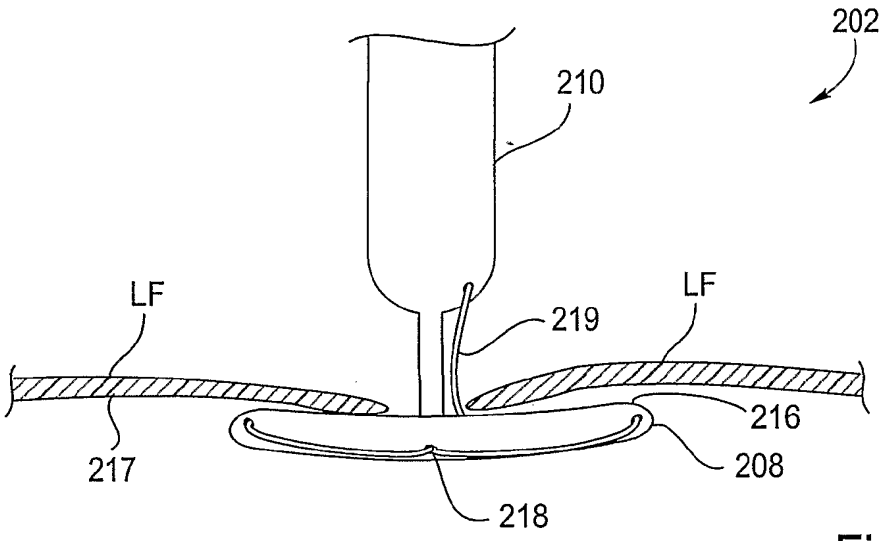


Fig. 11C

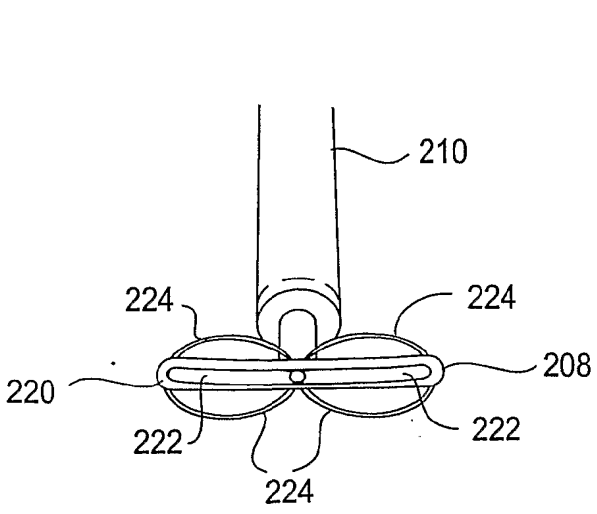


Fig. 12

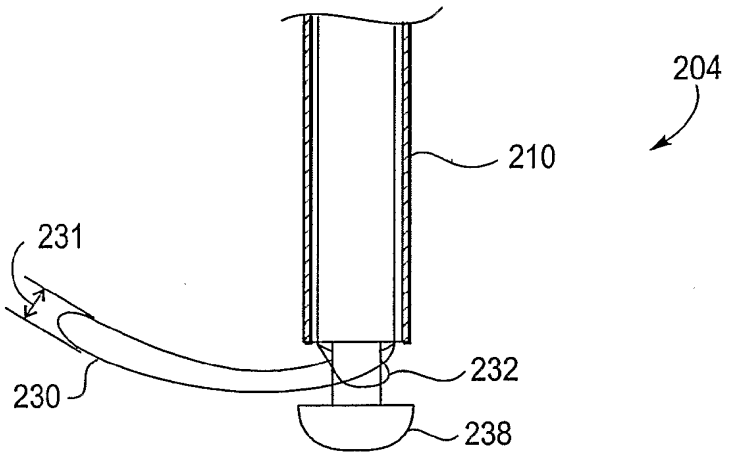


Fig. 13

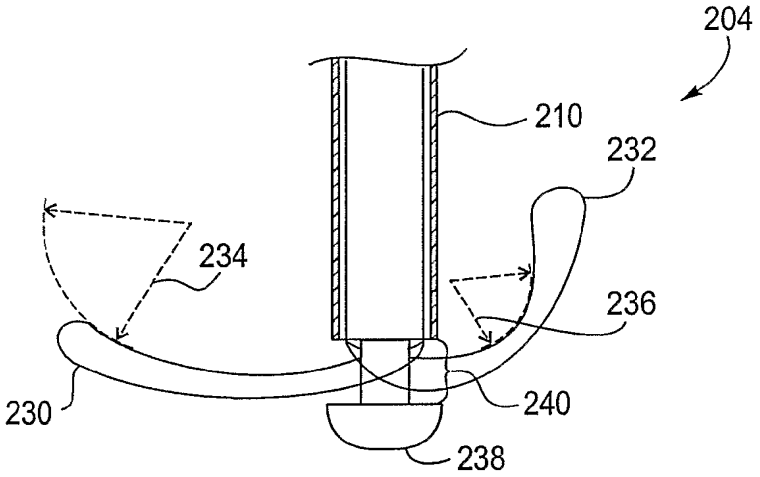


Fig. 14

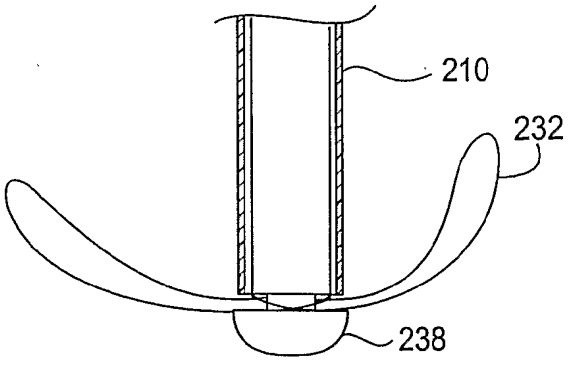


Fig. 15

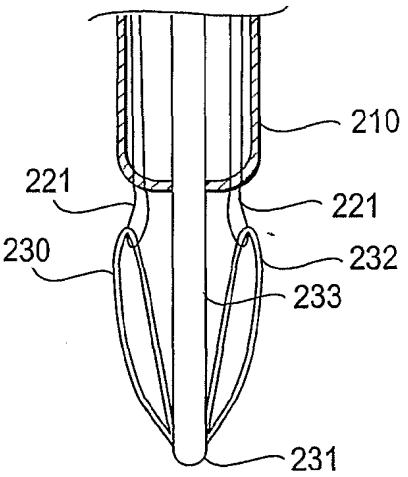


Fig. 16A

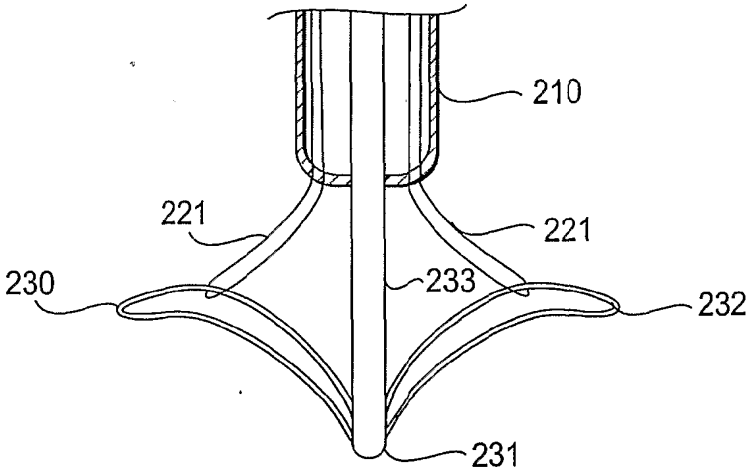


Fig. 16B

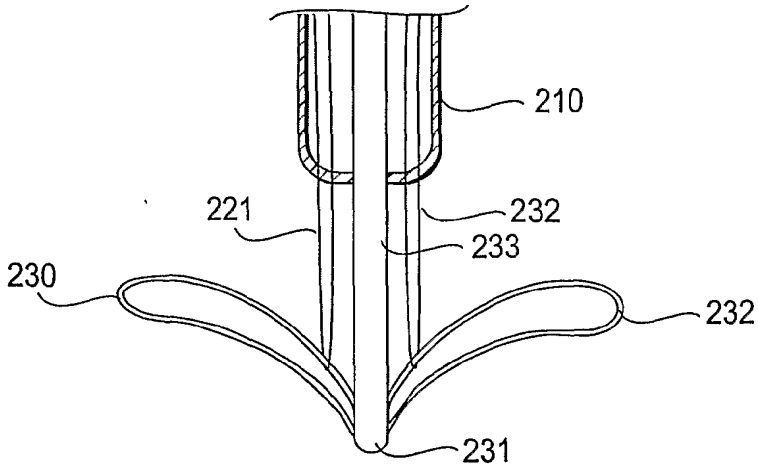


Fig. 16C

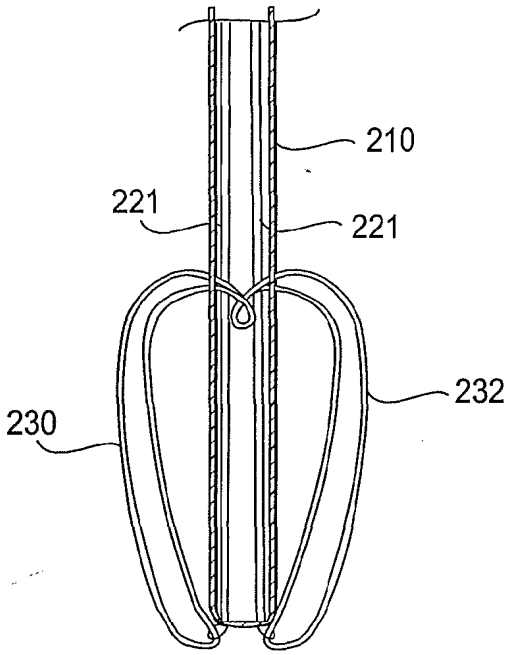


Fig. 16D

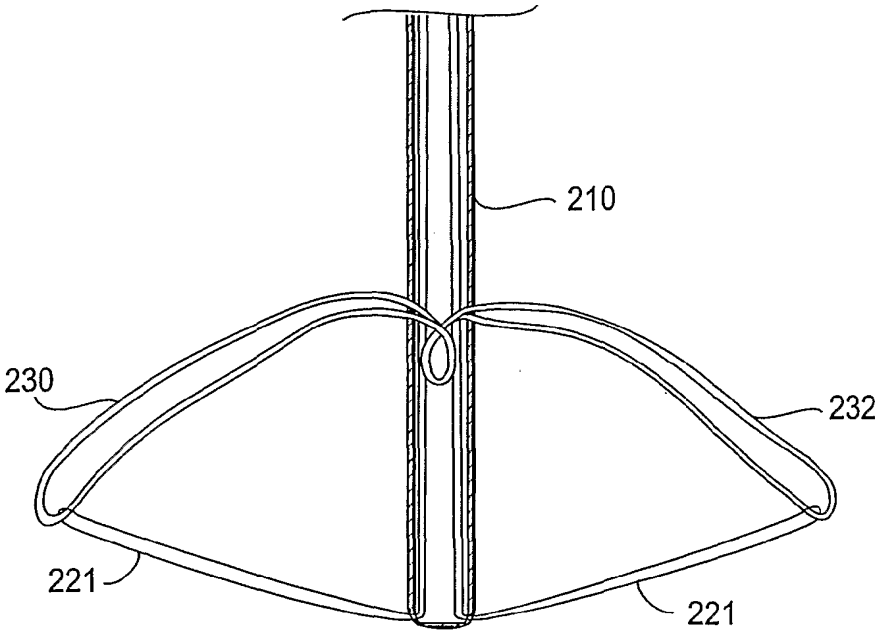


Fig. 16E

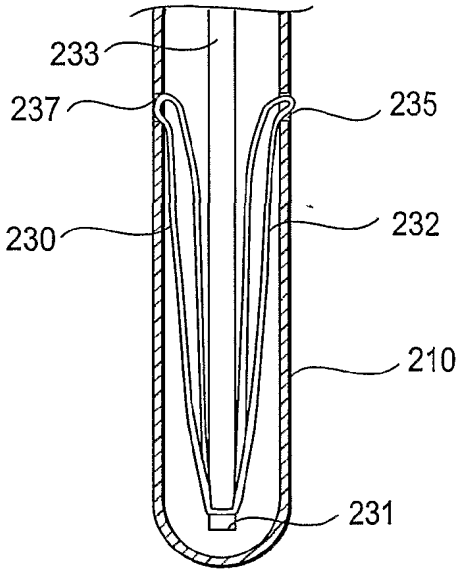


Fig. 16F

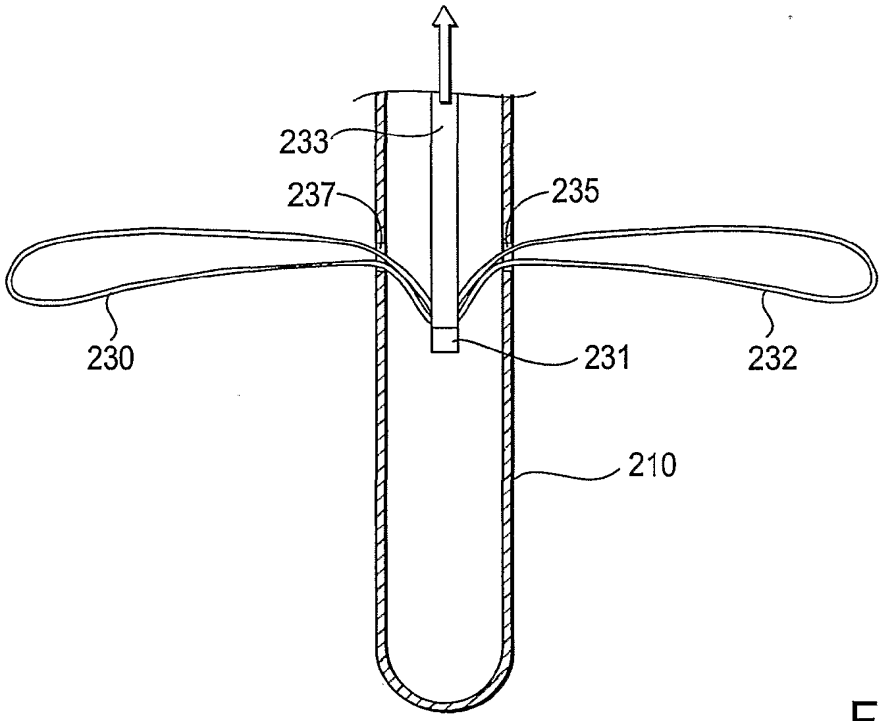


Fig. 16G

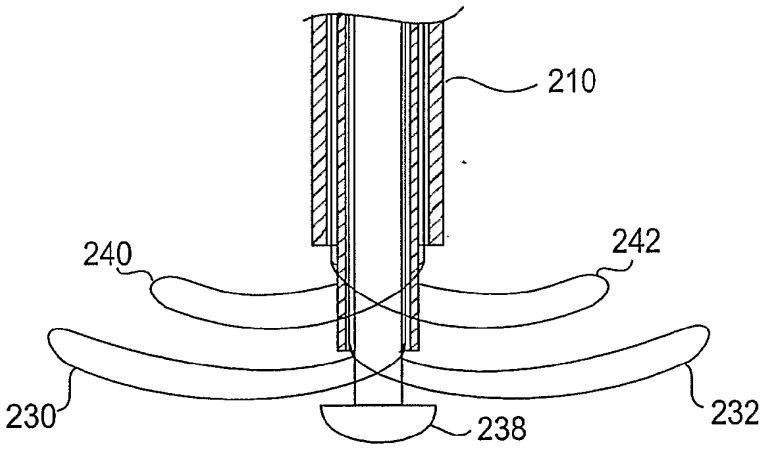


Fig. 17A

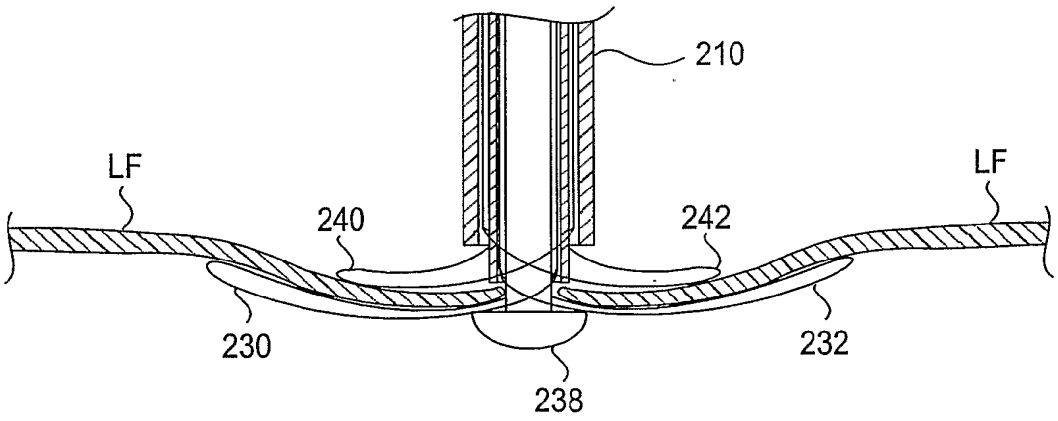


Fig. 17B

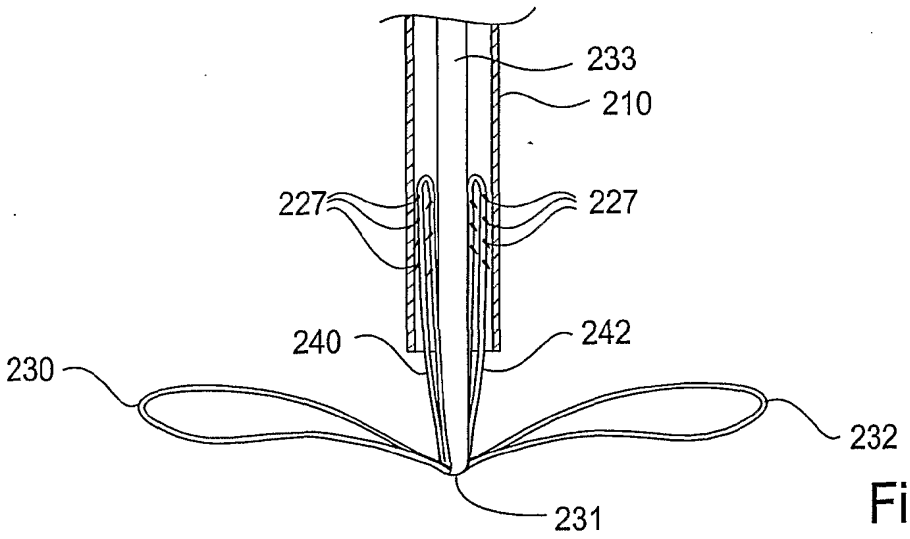


Fig. 17C

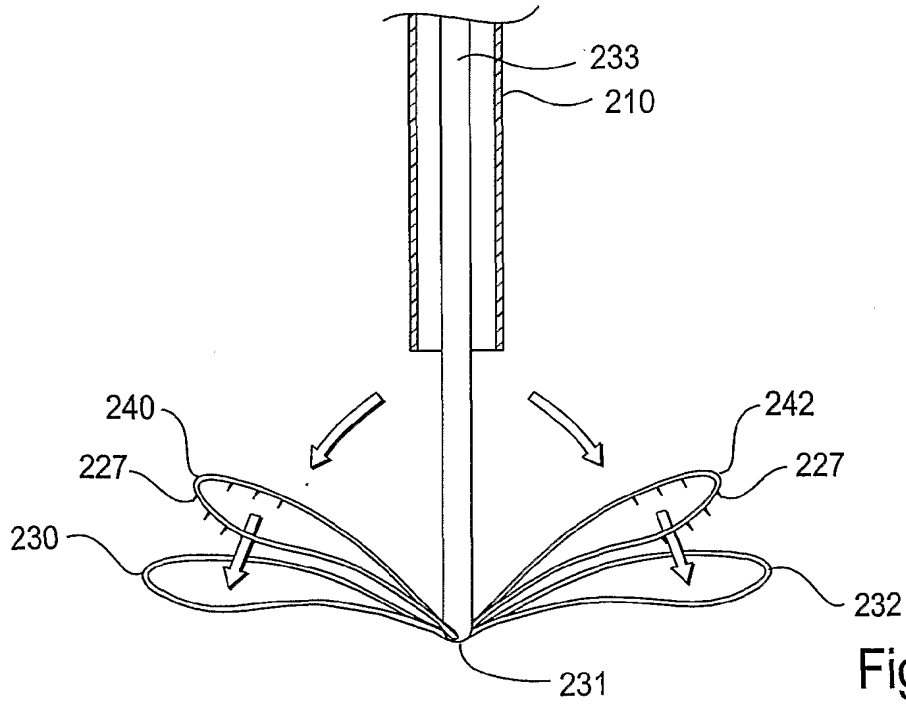


Fig. 17D

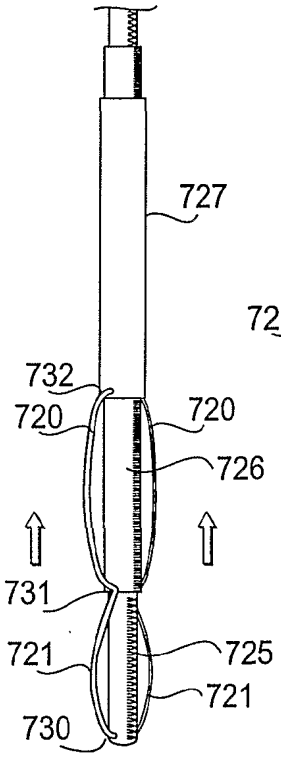


Fig. 18A

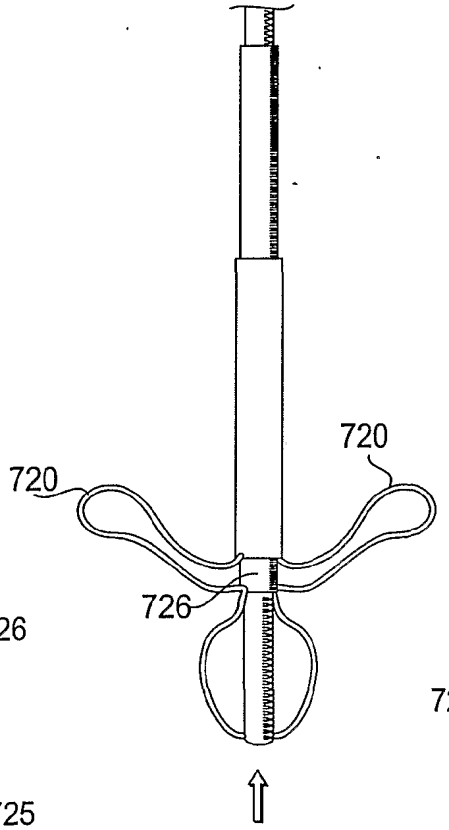


Fig. 18B

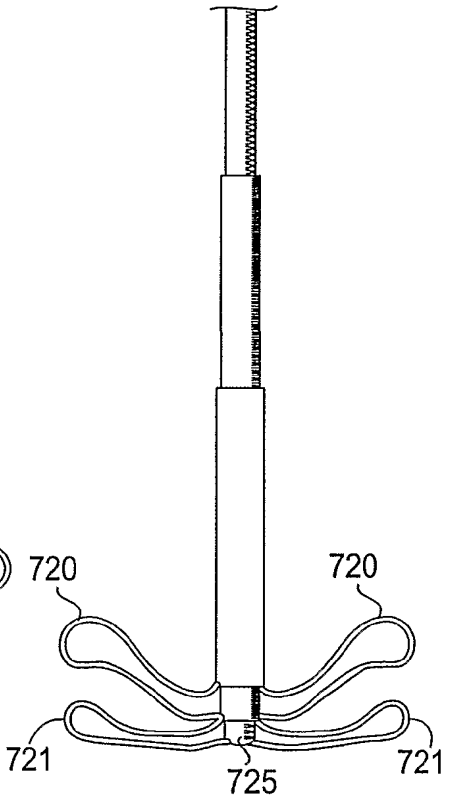


Fig. 18C

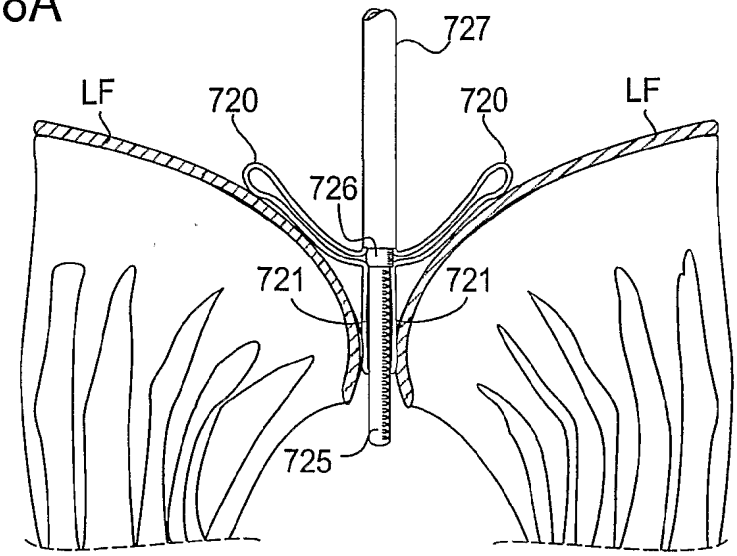


Fig. 18D

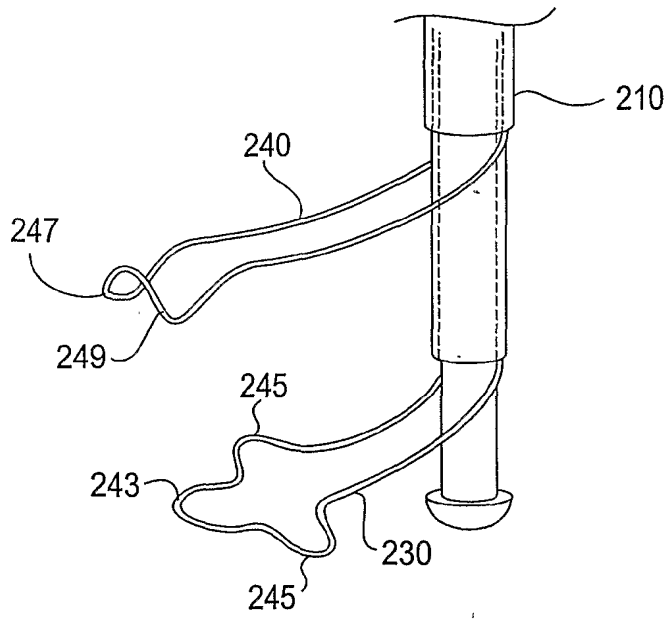


Fig. 19A

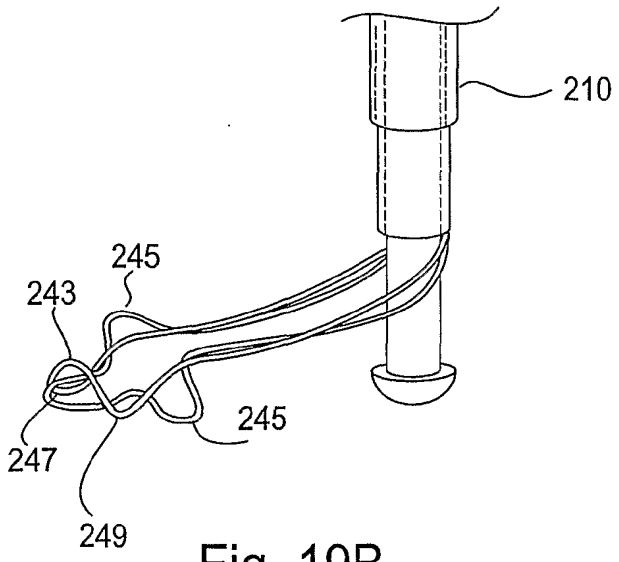


Fig. 19B

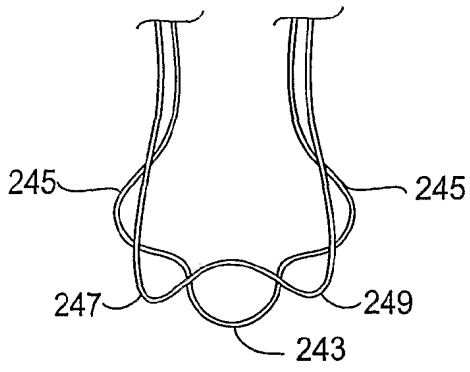


Fig. 19C

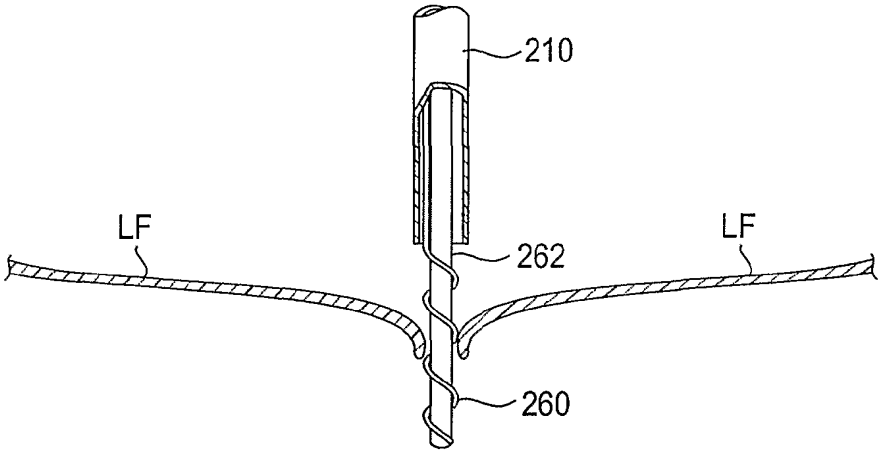


Fig. 20A

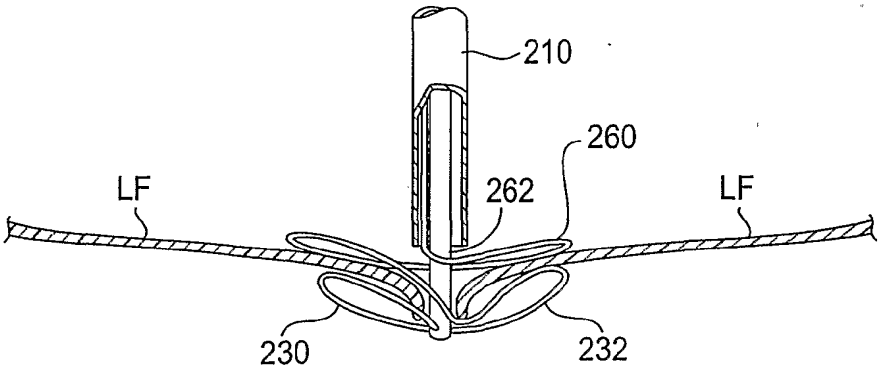


Fig. 20B

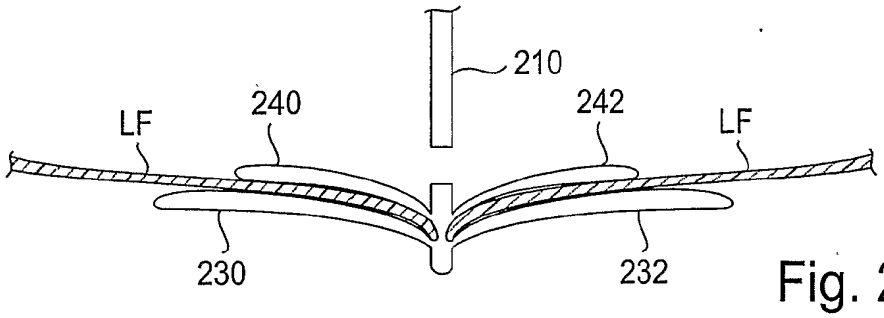


Fig. 21A

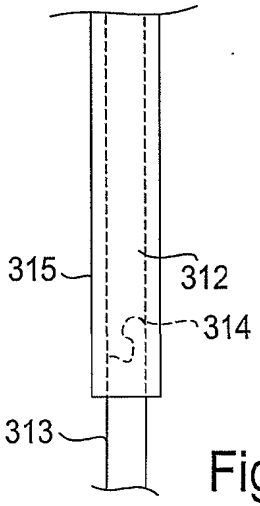


Fig. 21B

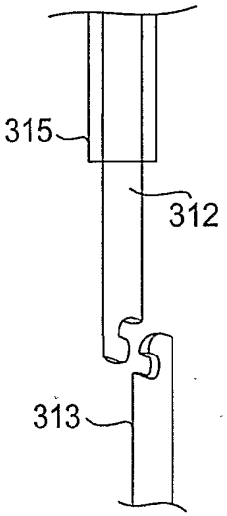


Fig. 21C

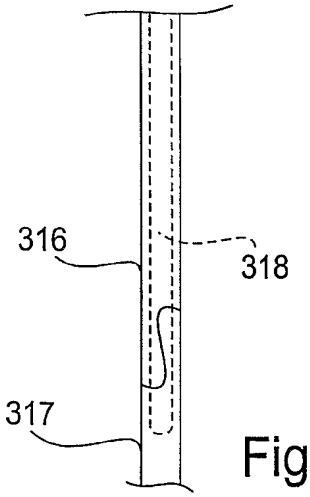


Fig. 21D

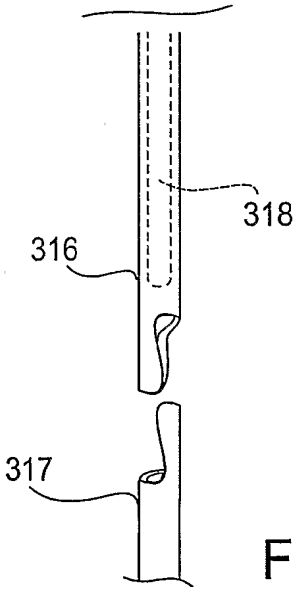


Fig. 21E

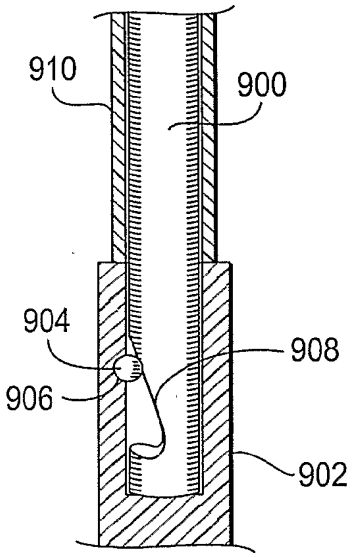


Fig. 21F

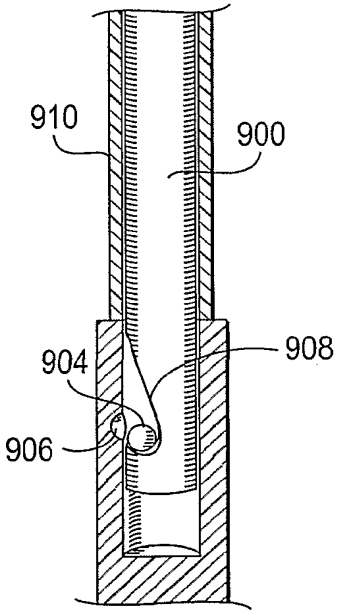


Fig. 21G

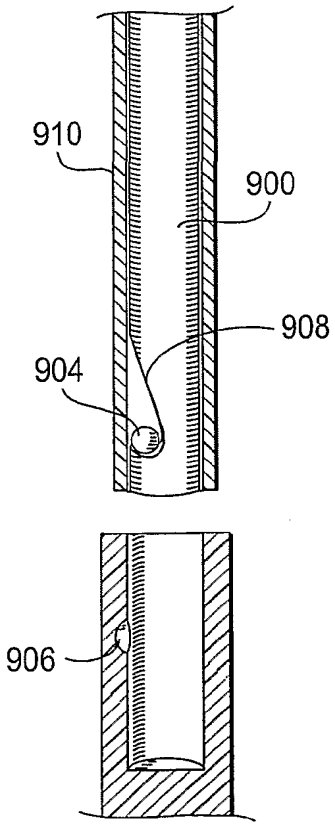


Fig. 21H

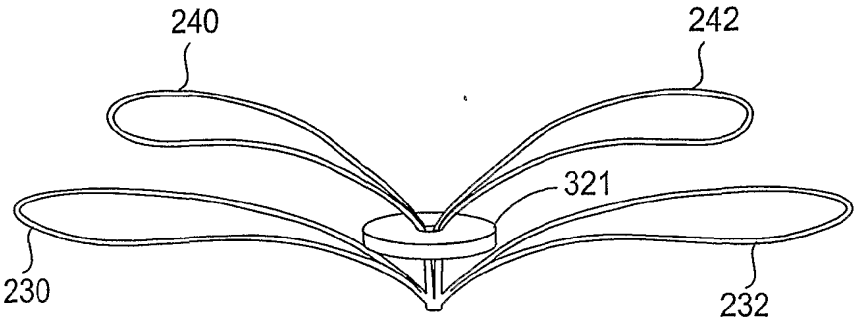


Fig. 21I

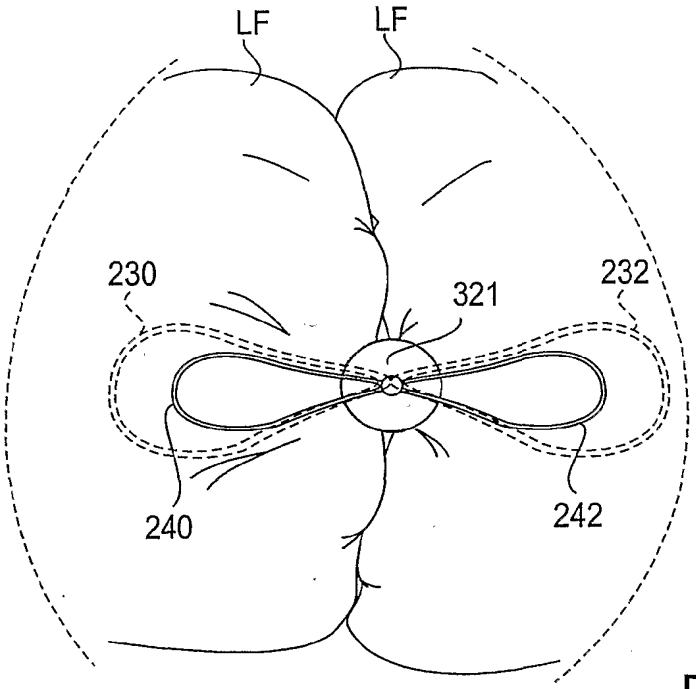


Fig. 21J

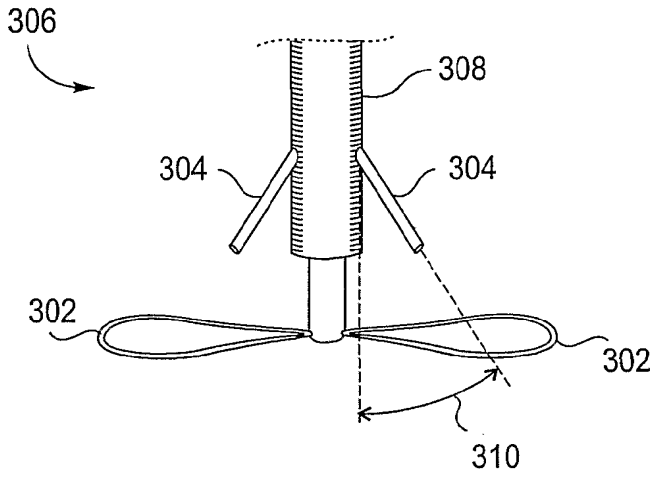


Fig. 22

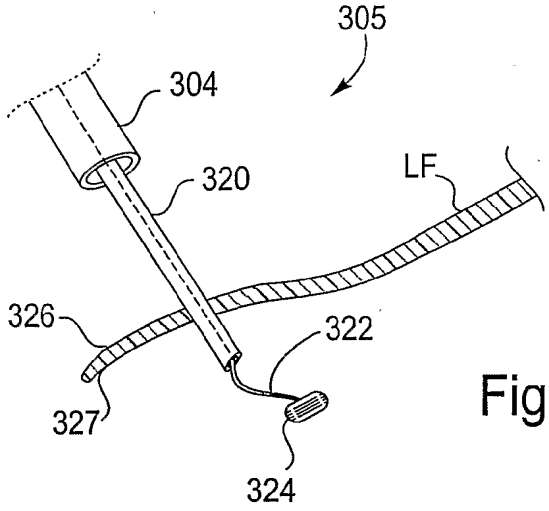


Fig. 23A

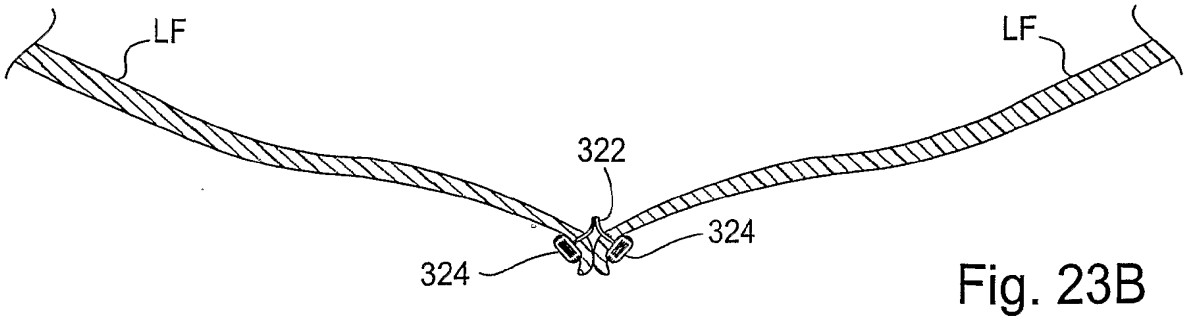


Fig. 23B

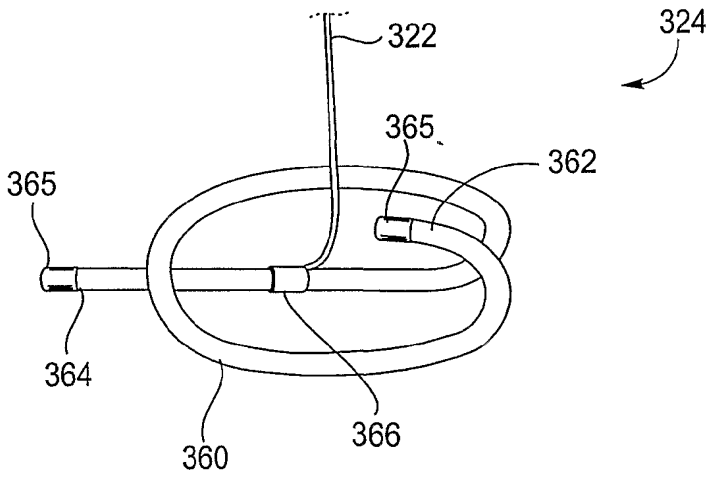


Fig. 24

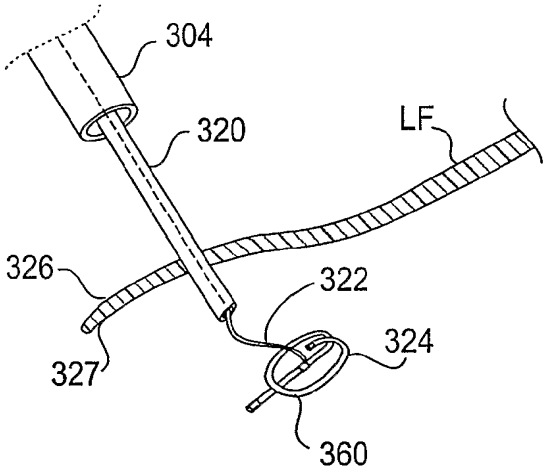


Fig. 25

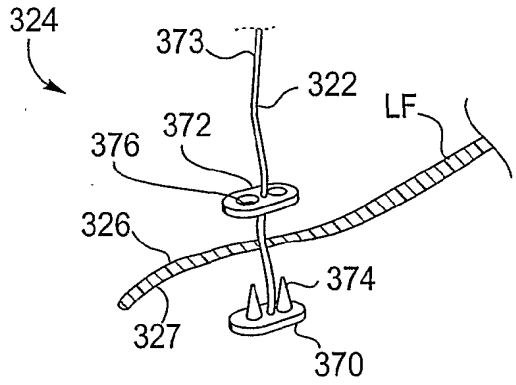


Fig. 26A

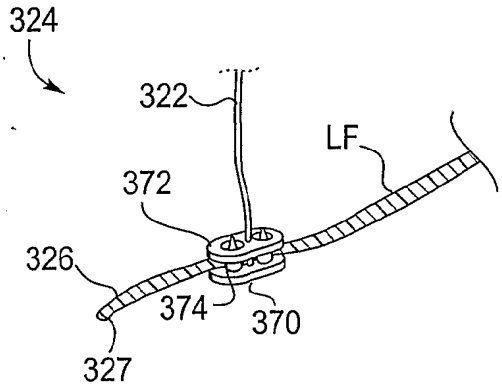


Fig. 26B

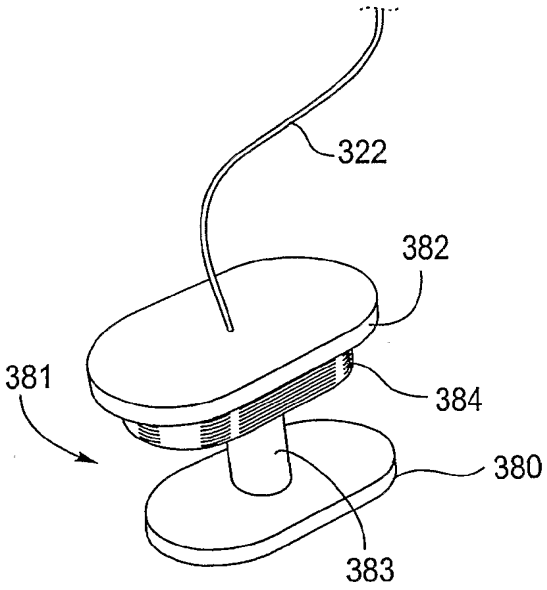


Fig. 27A

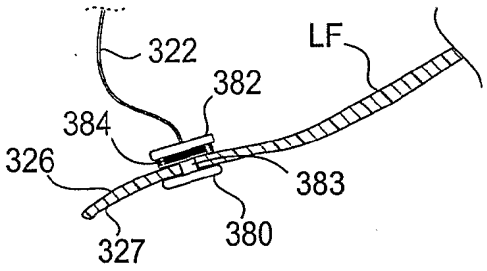


Fig. 27B

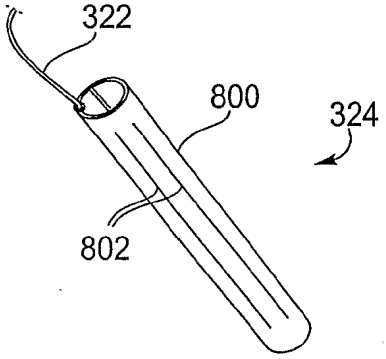


Fig. 27C

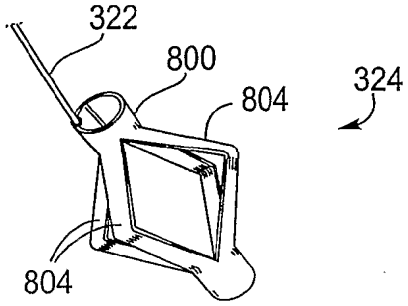


Fig. 27D

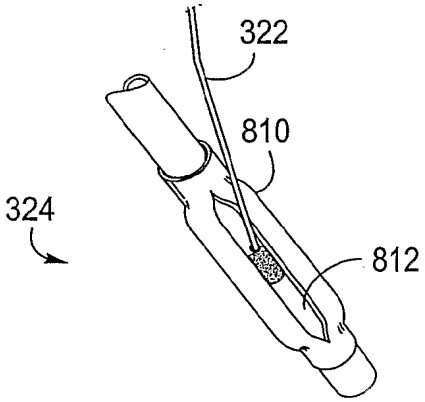


Fig. 27E

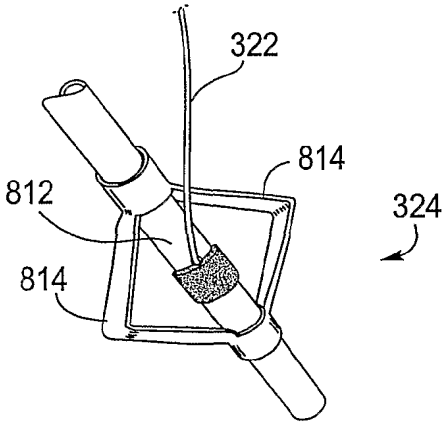


Fig. 27F

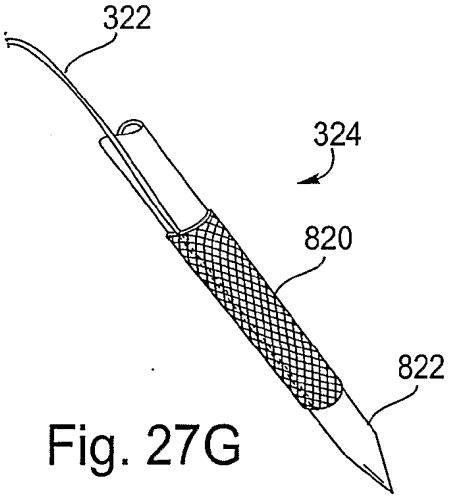


Fig. 27G

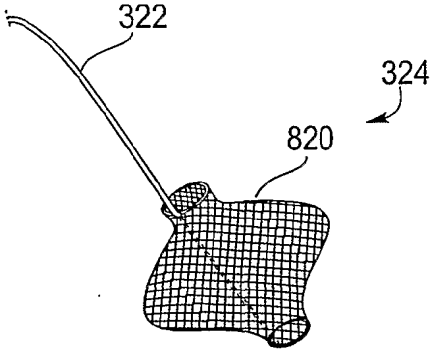


Fig. 27H

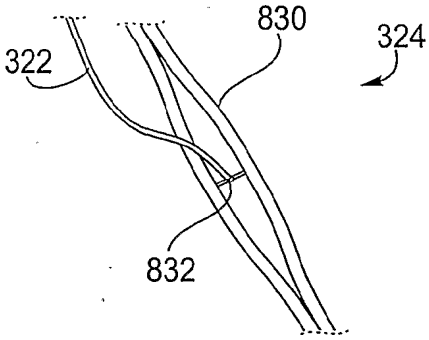


Fig. 27I

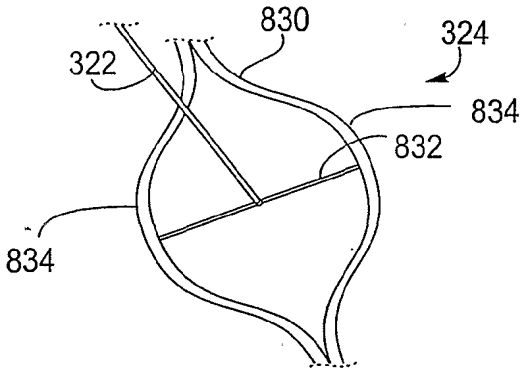


Fig. 27J

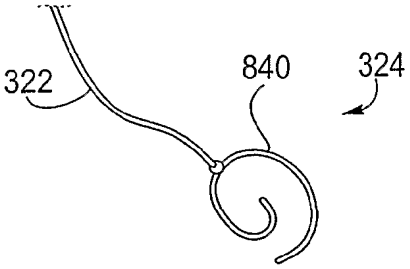


Fig. 27K

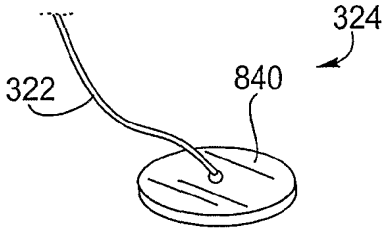


Fig. 27L

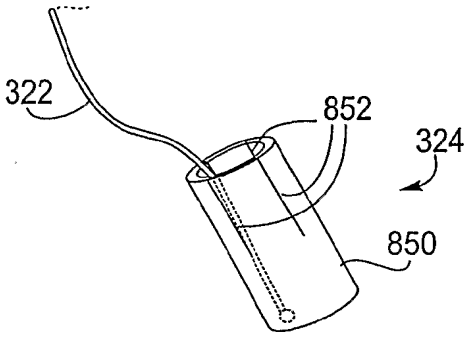


Fig. 27M

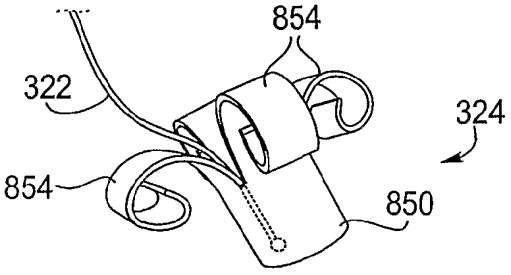


Fig. 27N

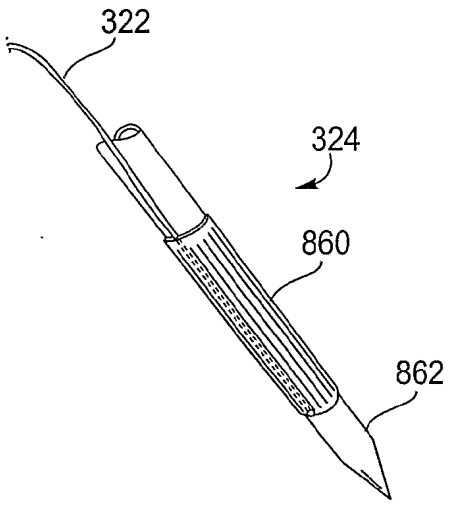


Fig. 27P

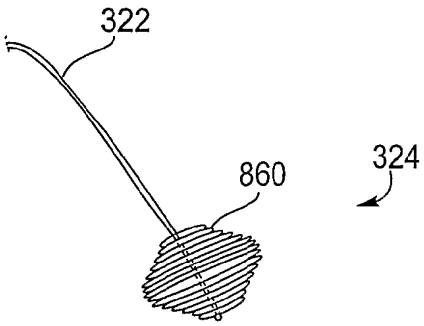


Fig. 27Q

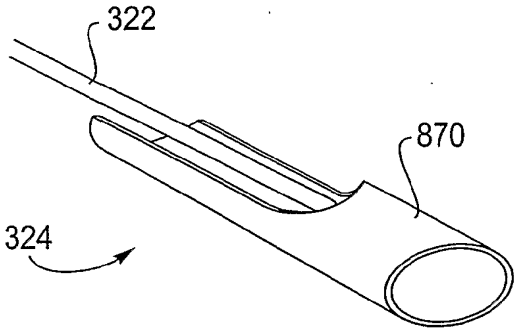


Fig. 27R

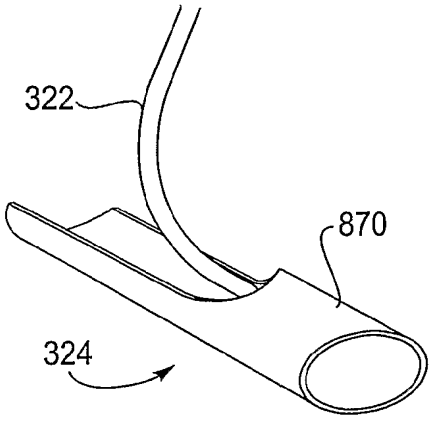


Fig. 27T

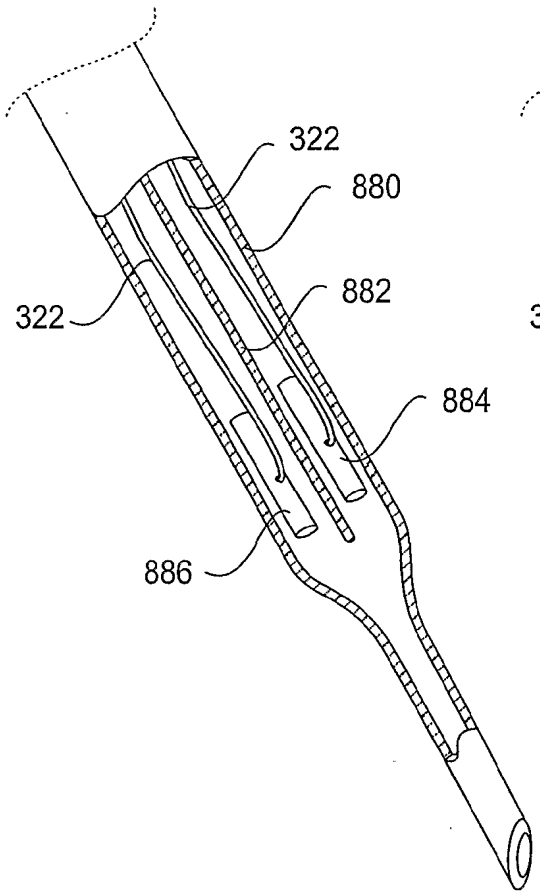


Fig. 27U

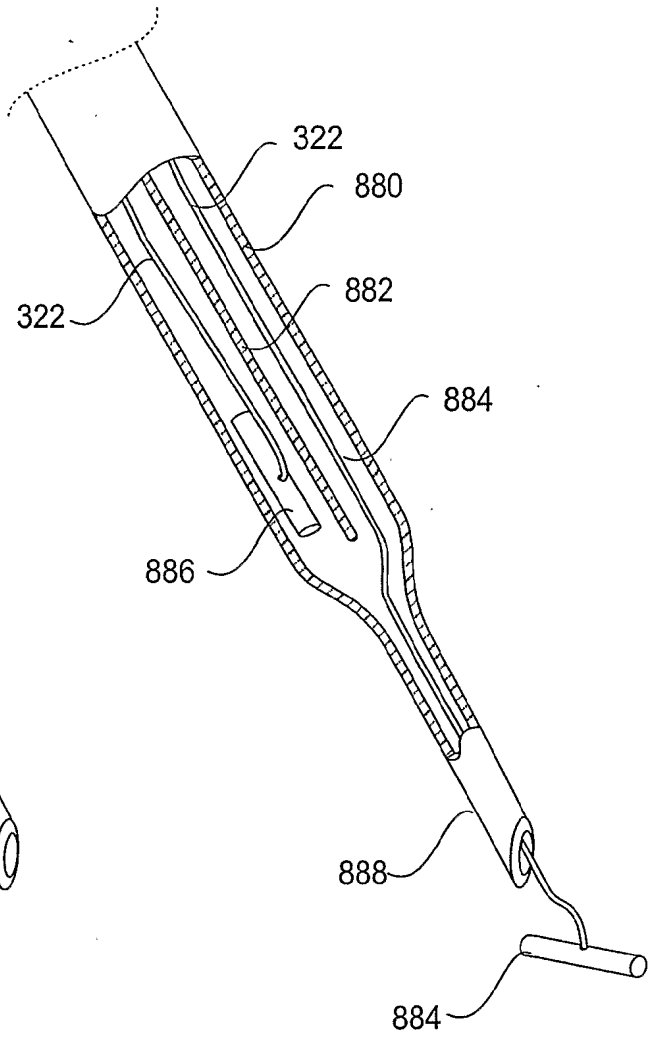


Fig. 27V

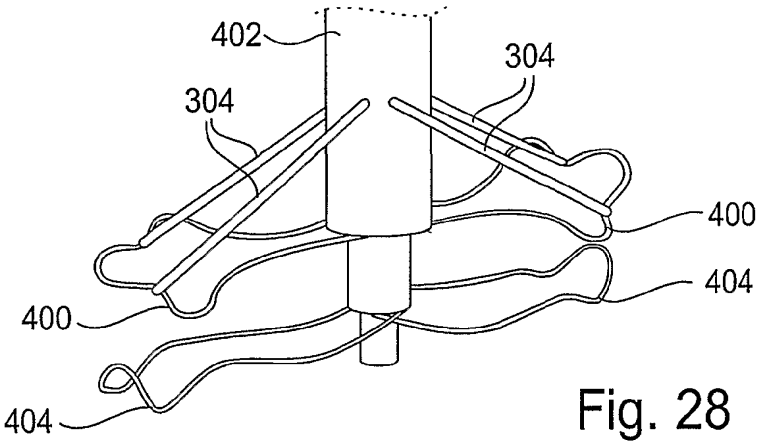


Fig. 28

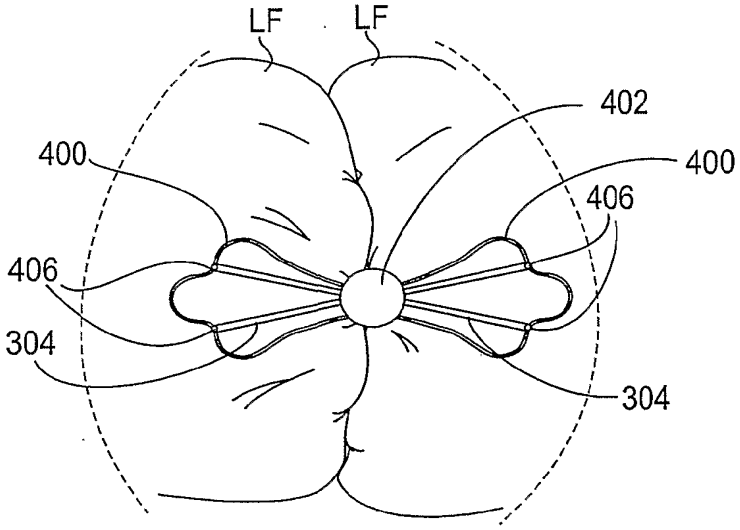


Fig. 29

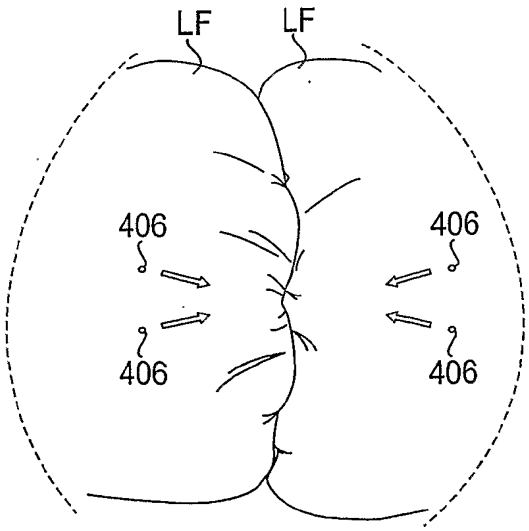


Fig. 30

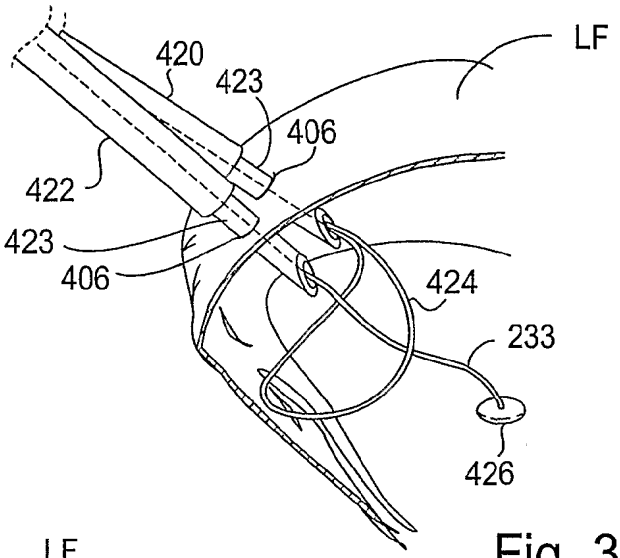


Fig. 31

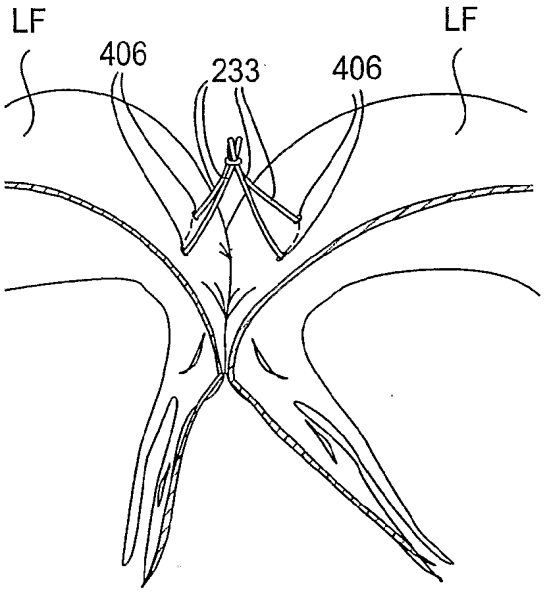


Fig. 32

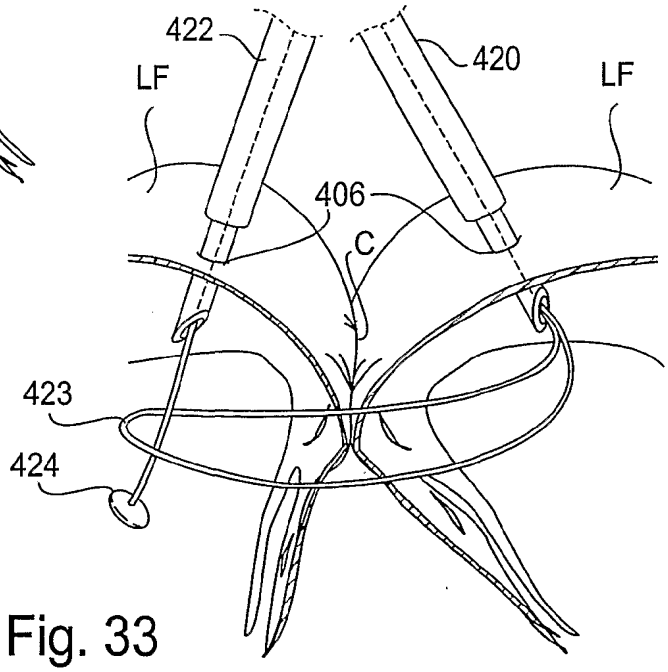


Fig. 33

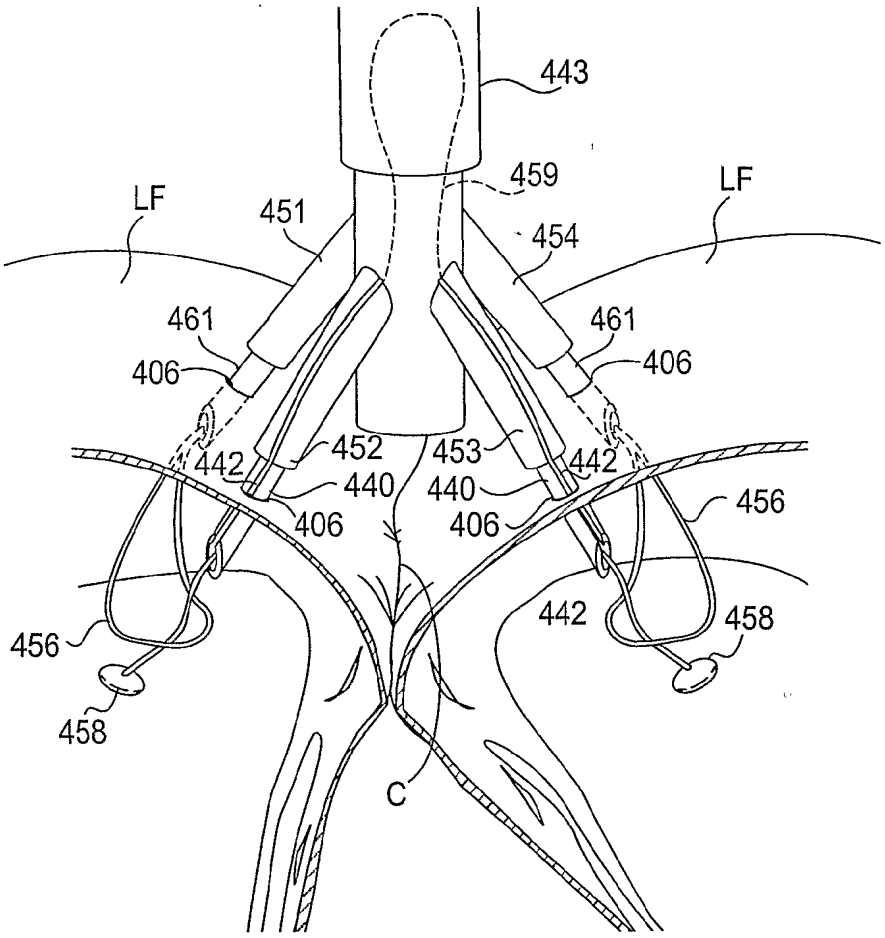


Fig. 34

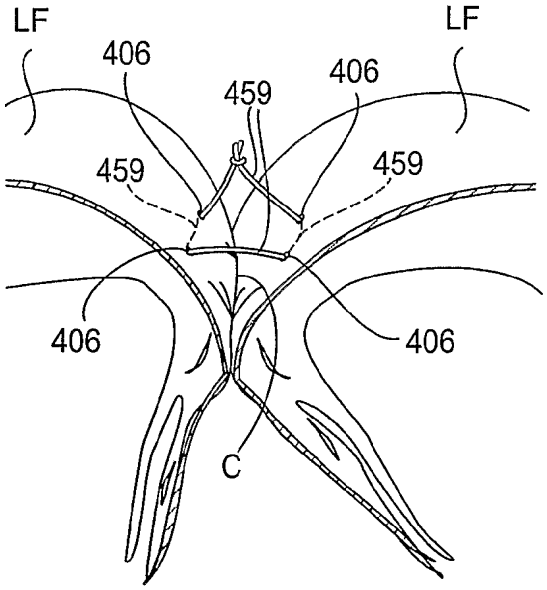


Fig. 35

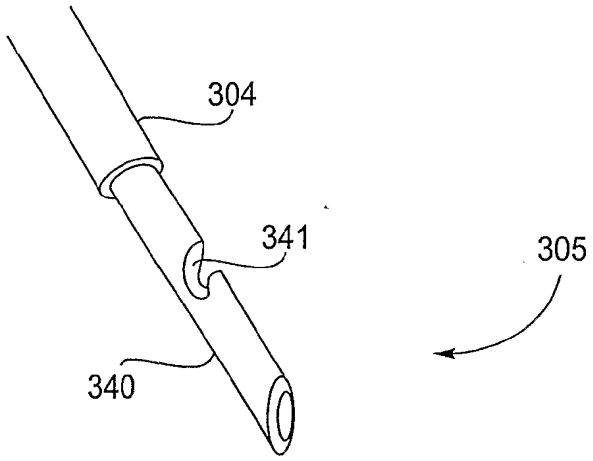


Fig. 36

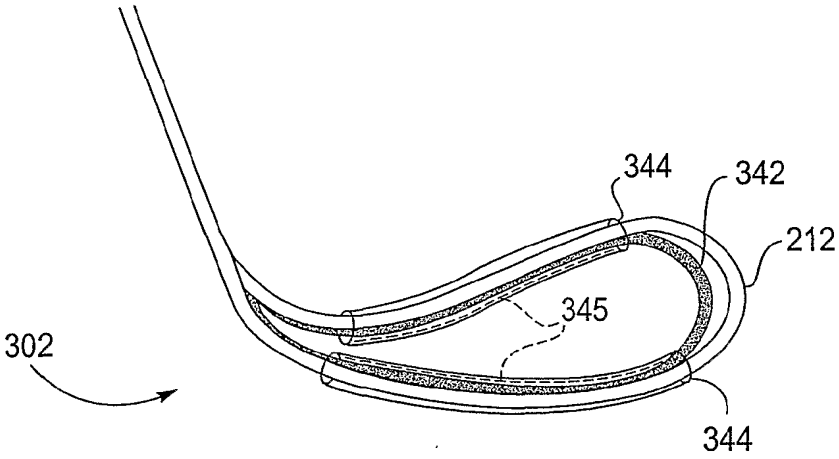


Fig. 37

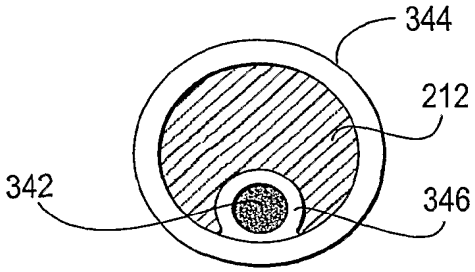


Fig. 38

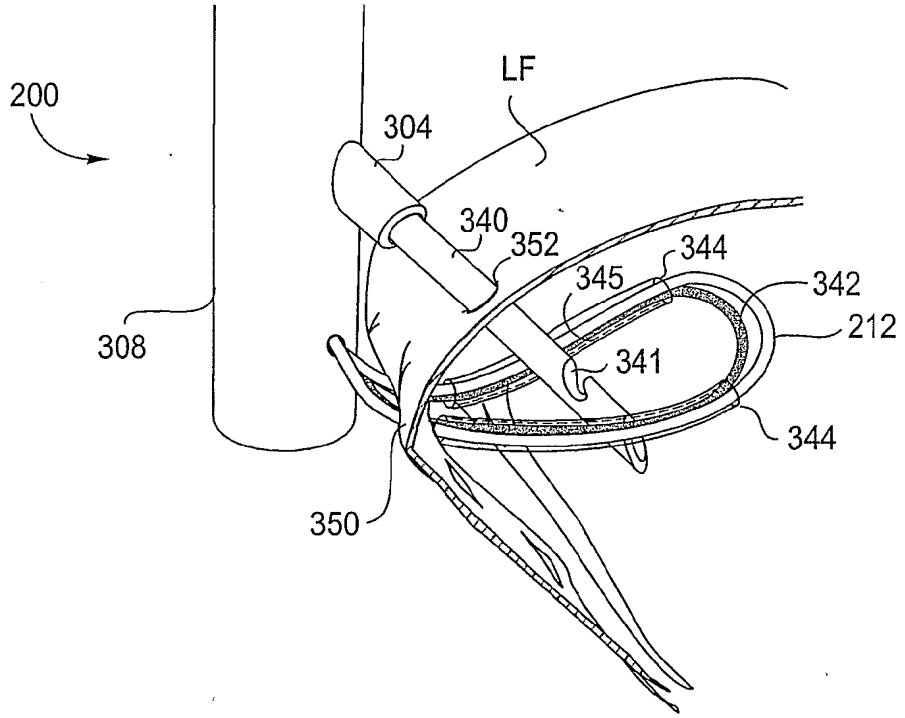


Fig. 39

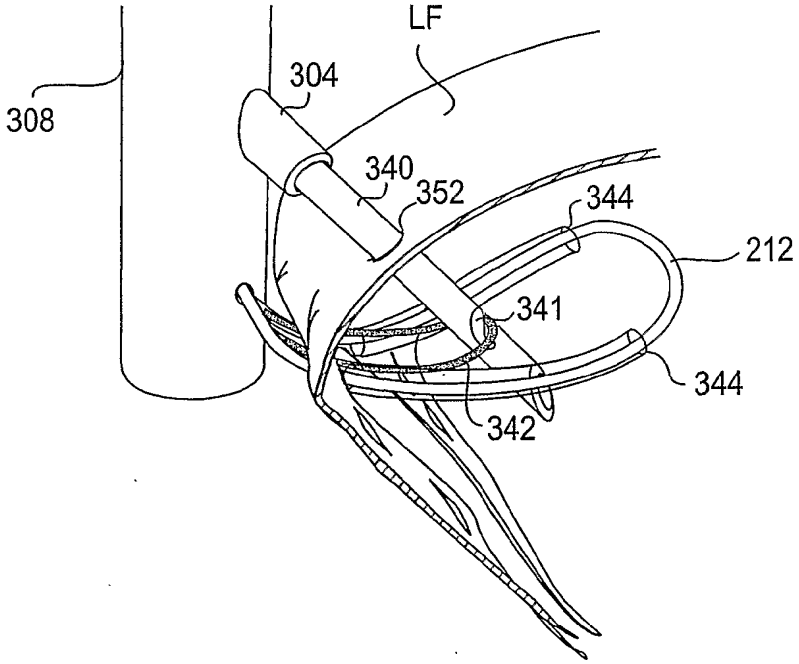


Fig. 40

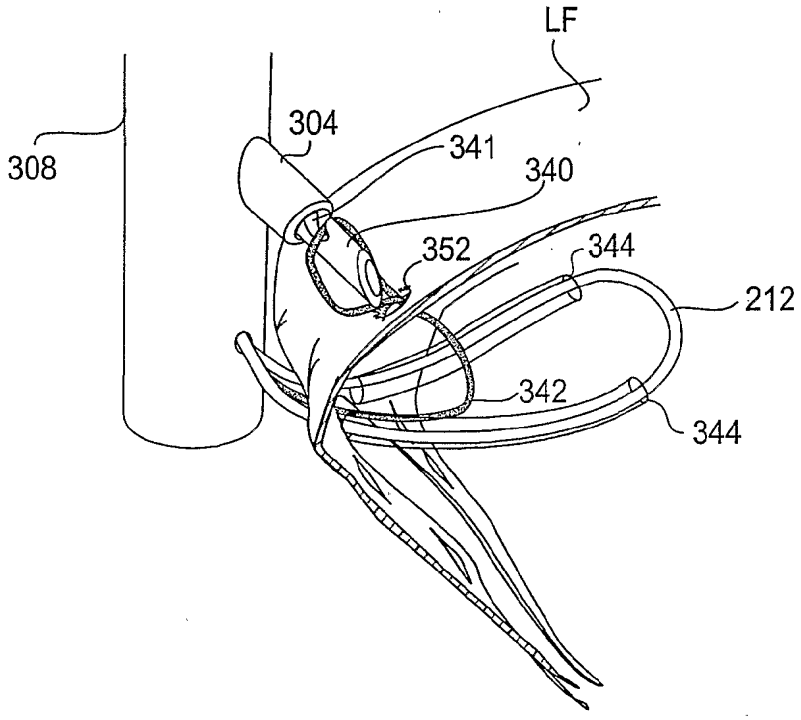


Fig. 41

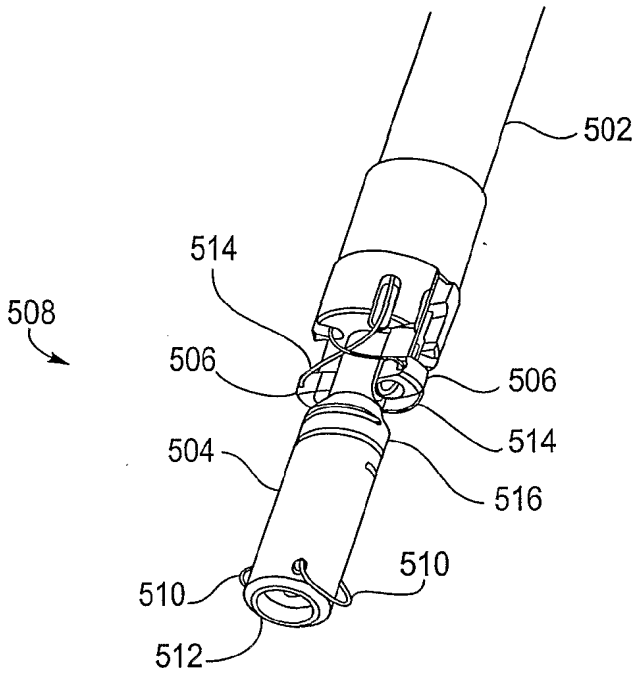


Fig. 42

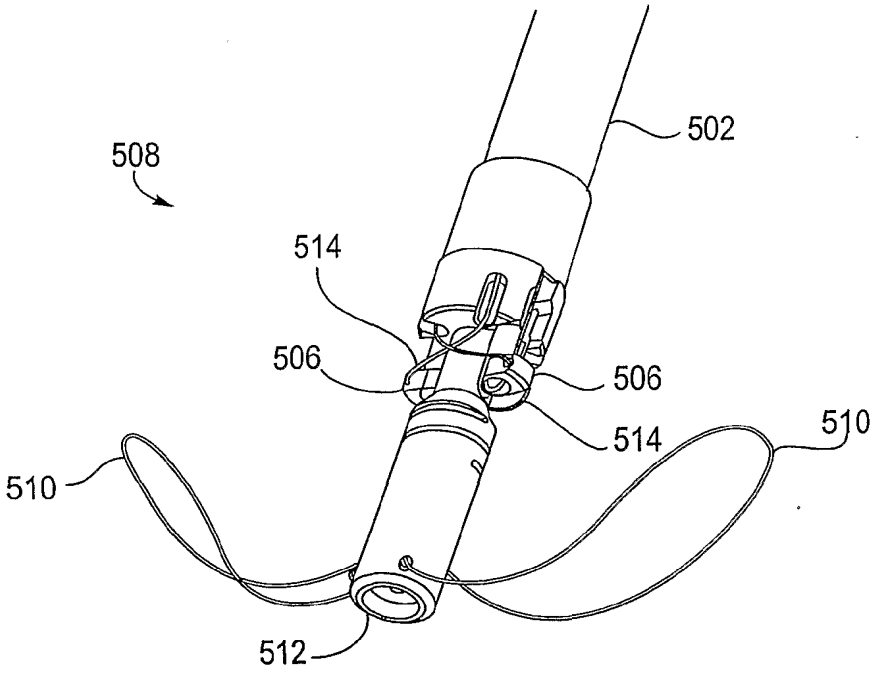


Fig. 43

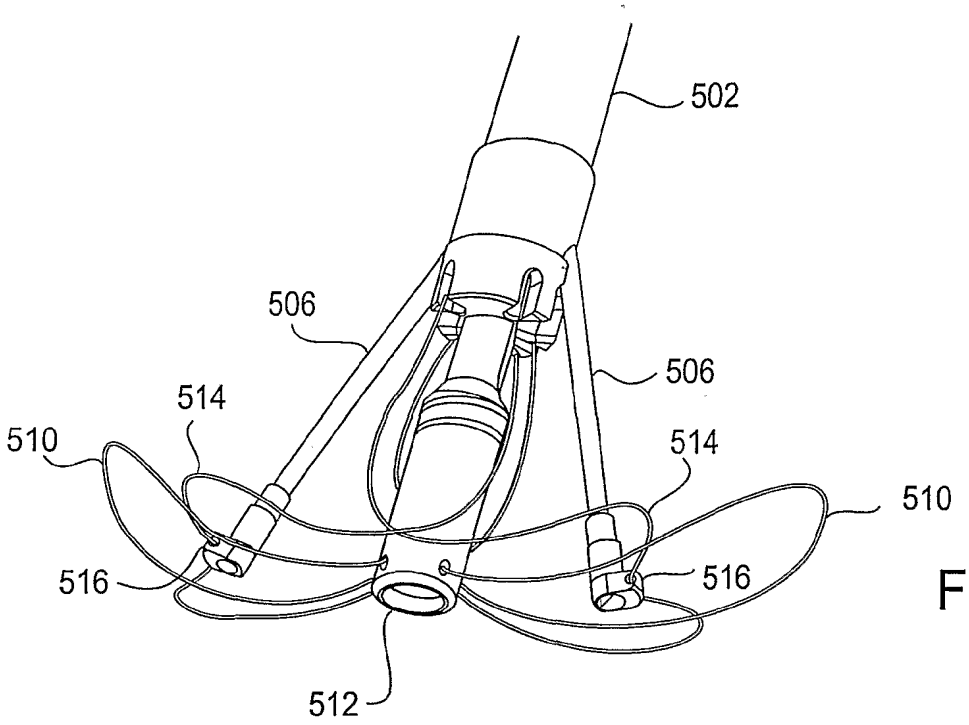


Fig. 44

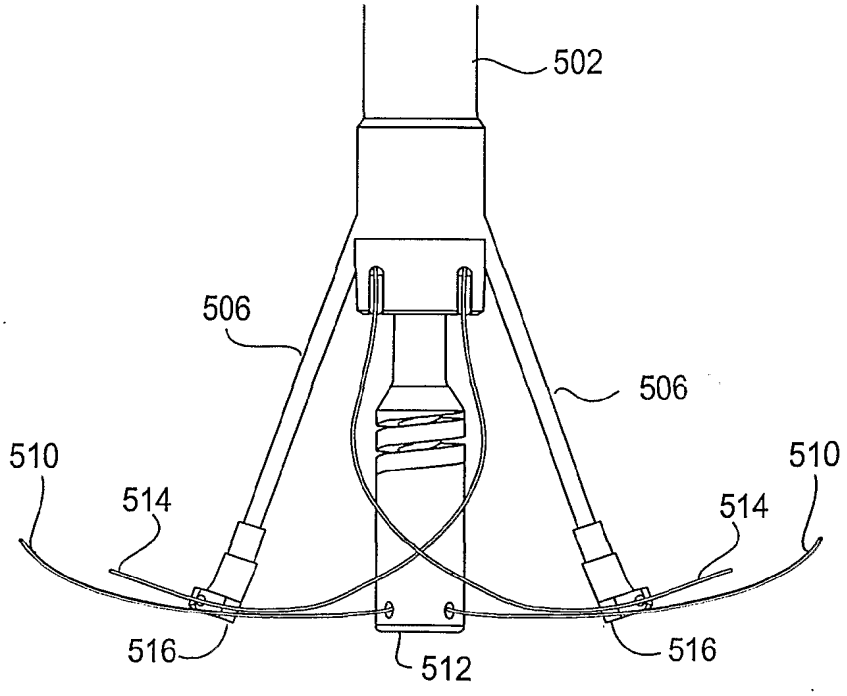


Fig. 45

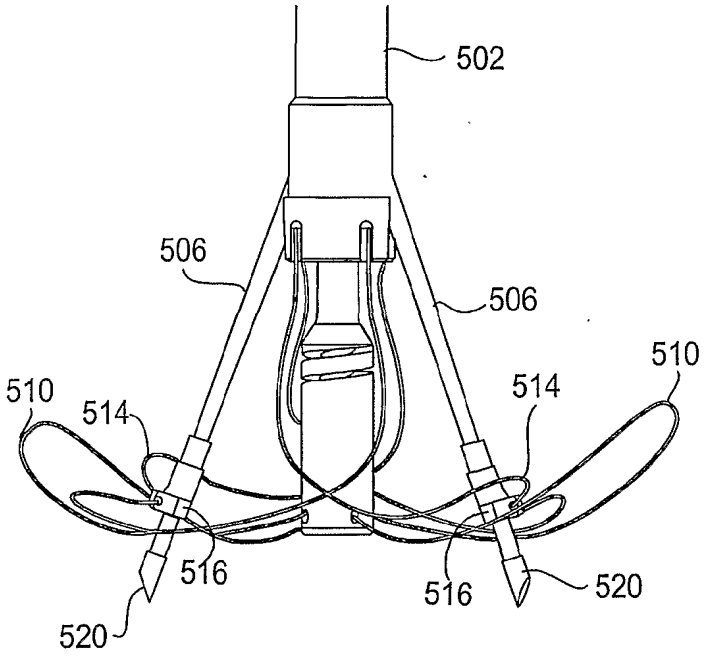


Fig. 46

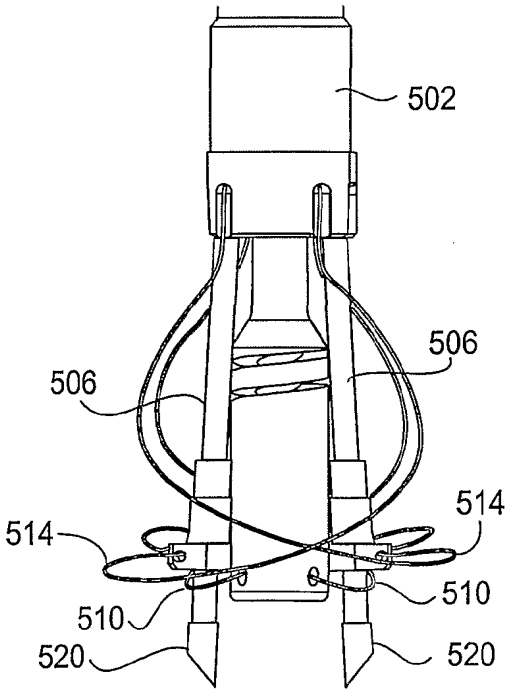


Fig. 47

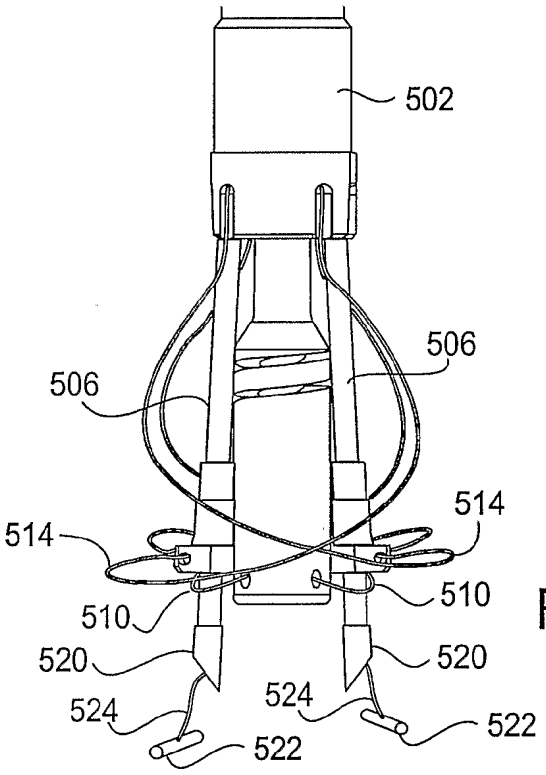


Fig. 48

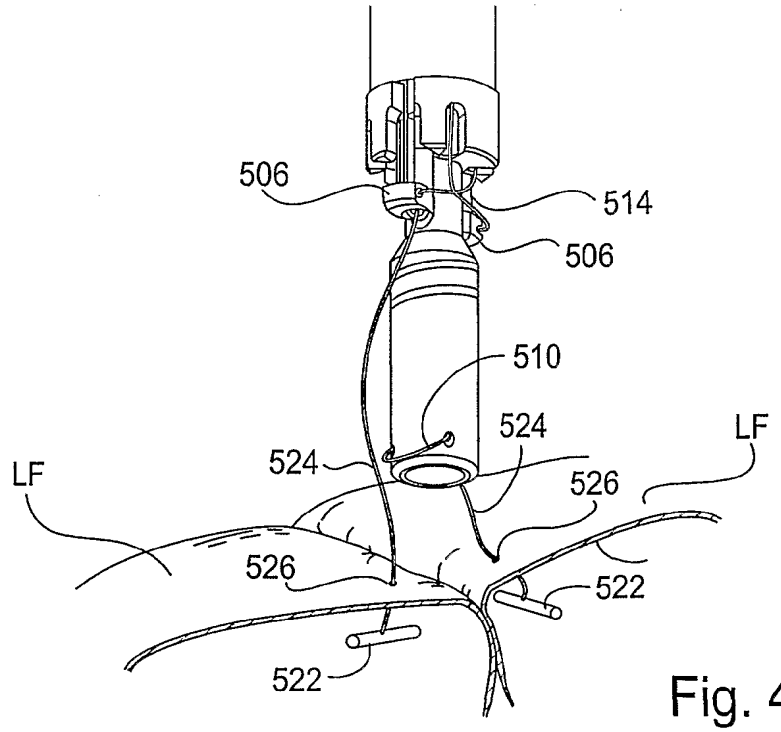


Fig. 49

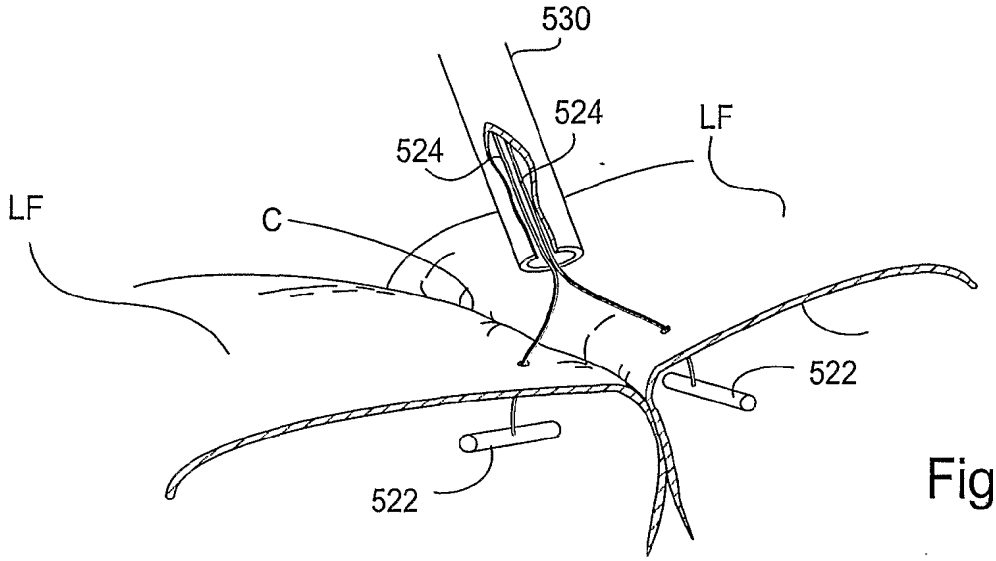


Fig. 50

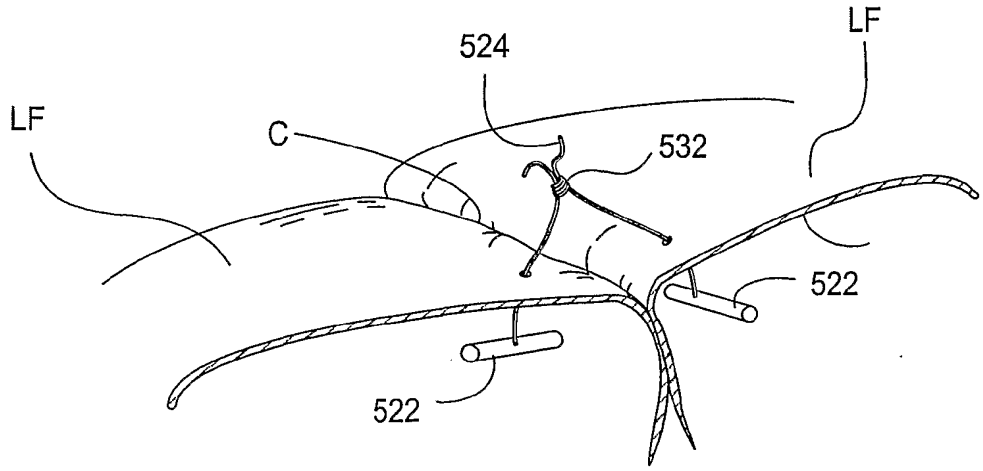


Fig. 51

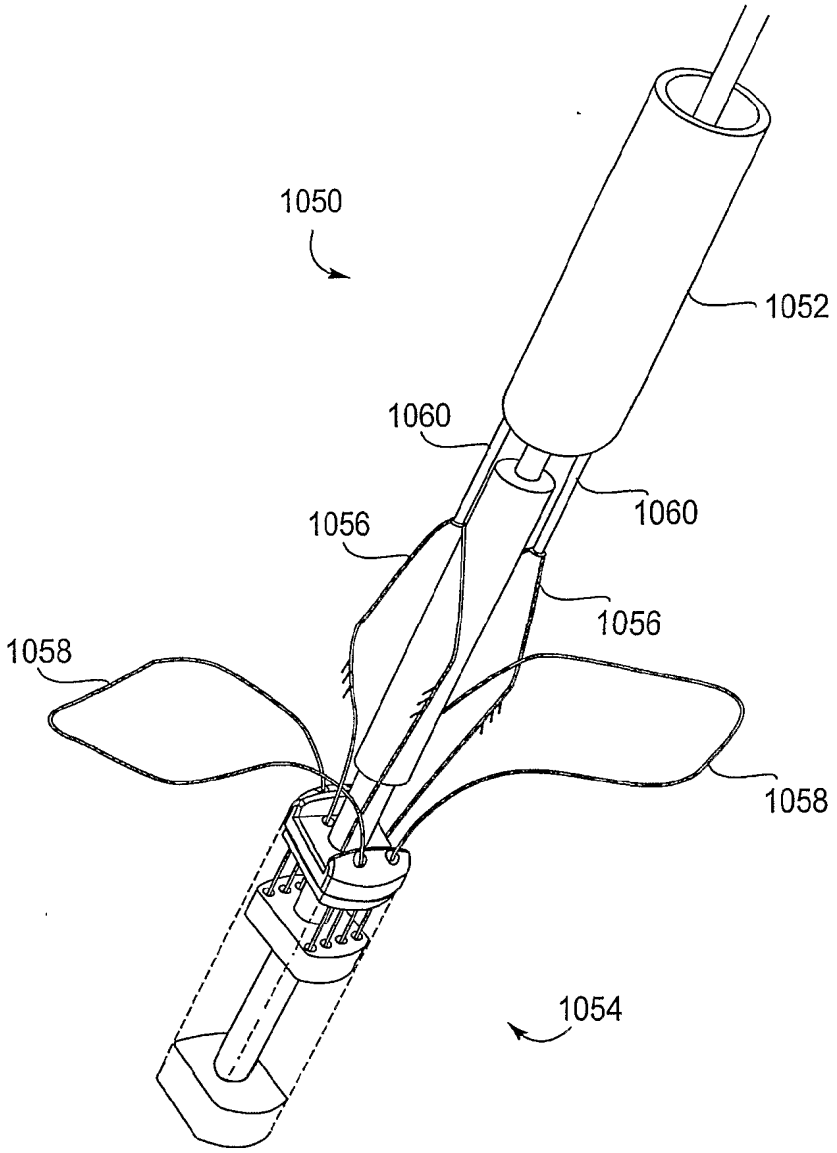


Fig. 52

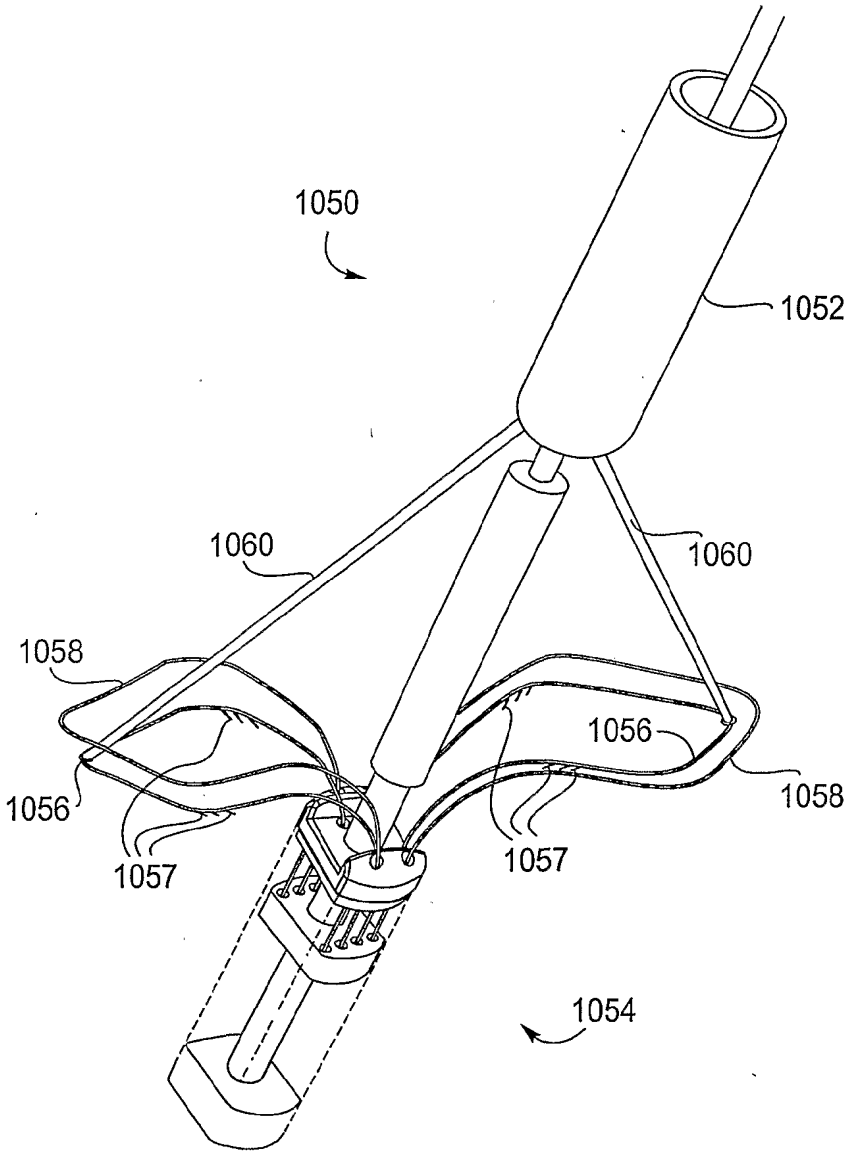


Fig. 53

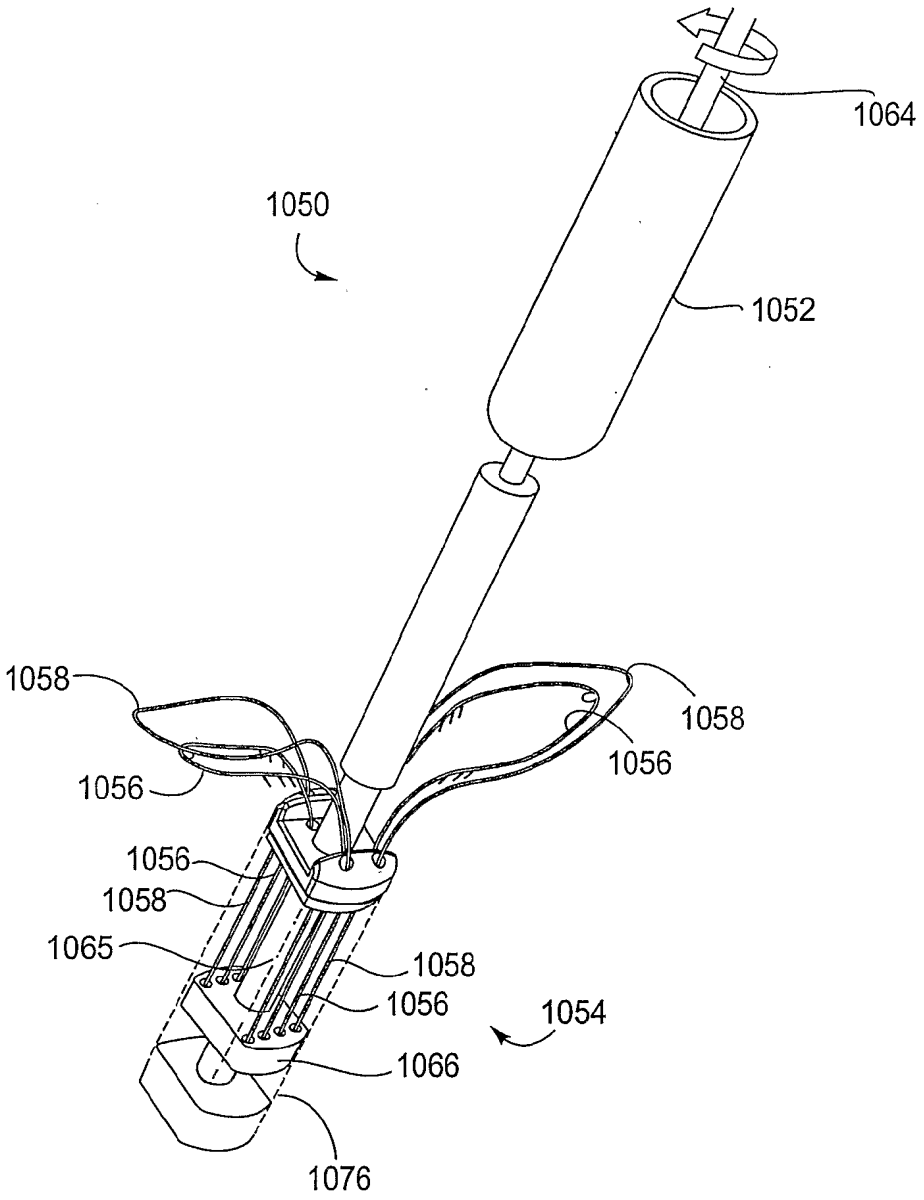


Fig. 54

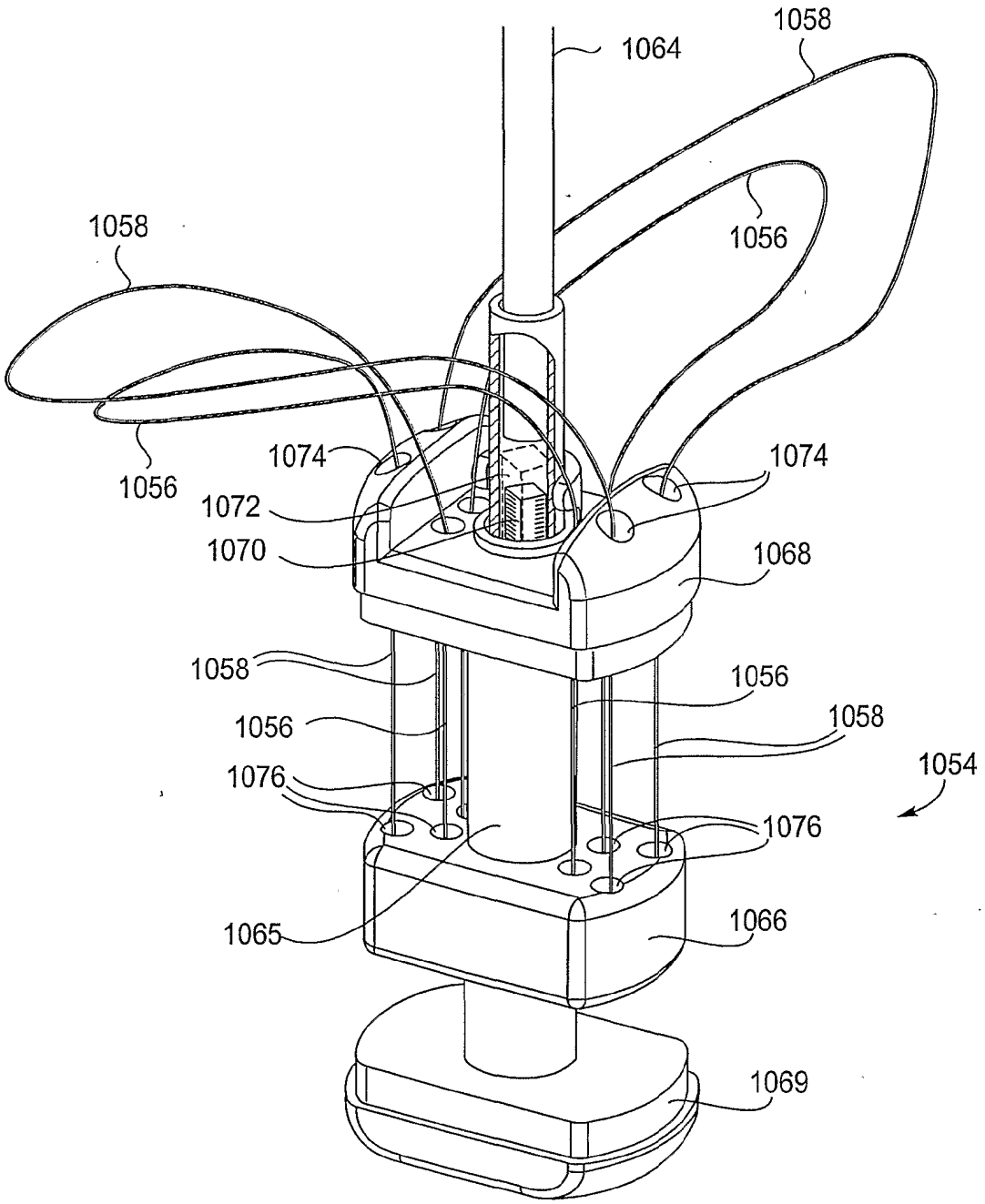


Fig. 55

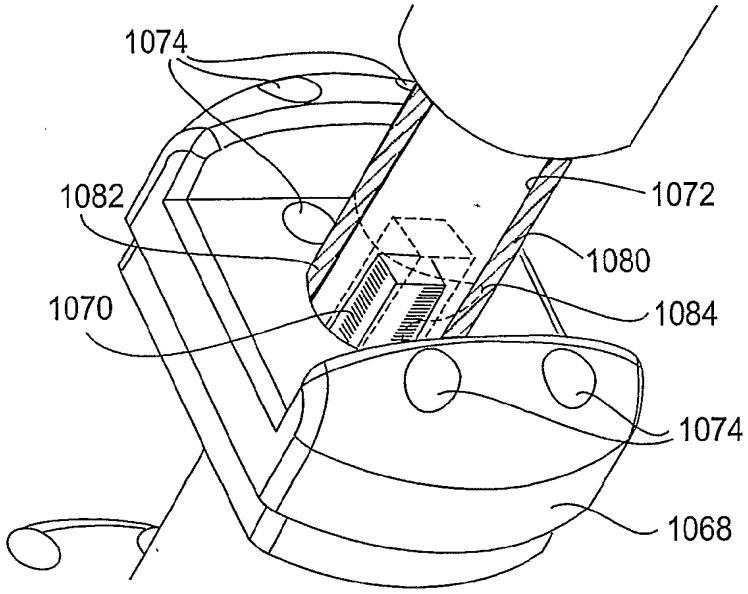


Fig. 56

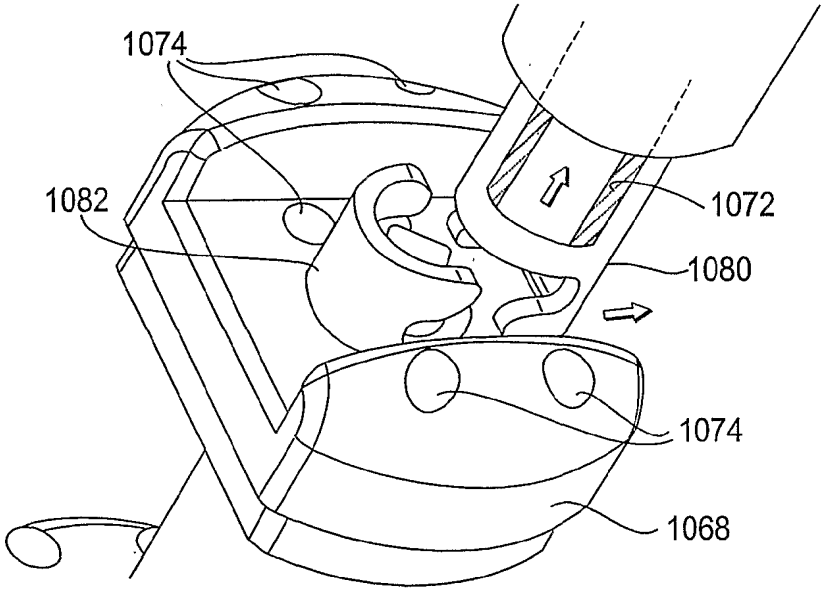


Fig. 57

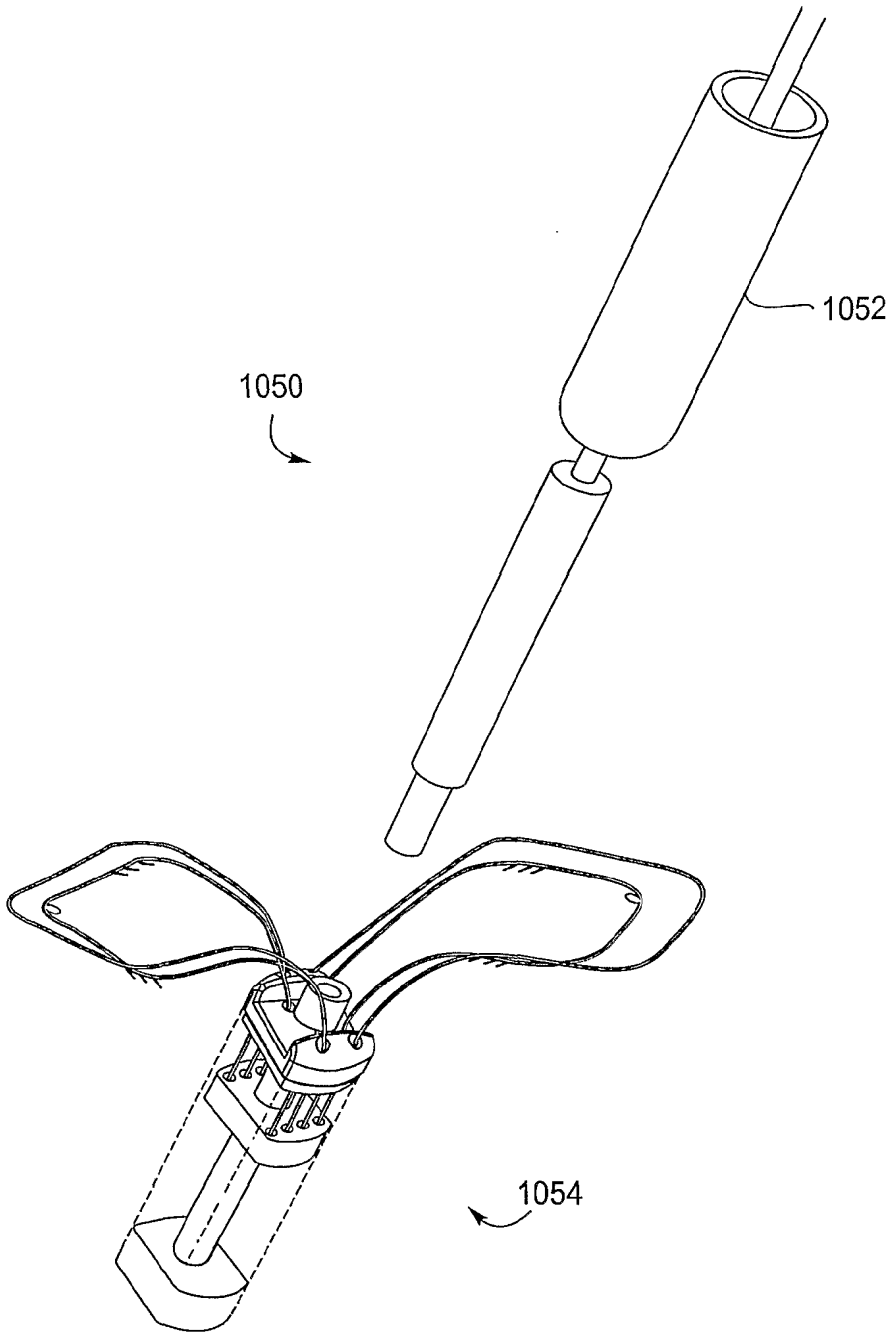


Fig. 58

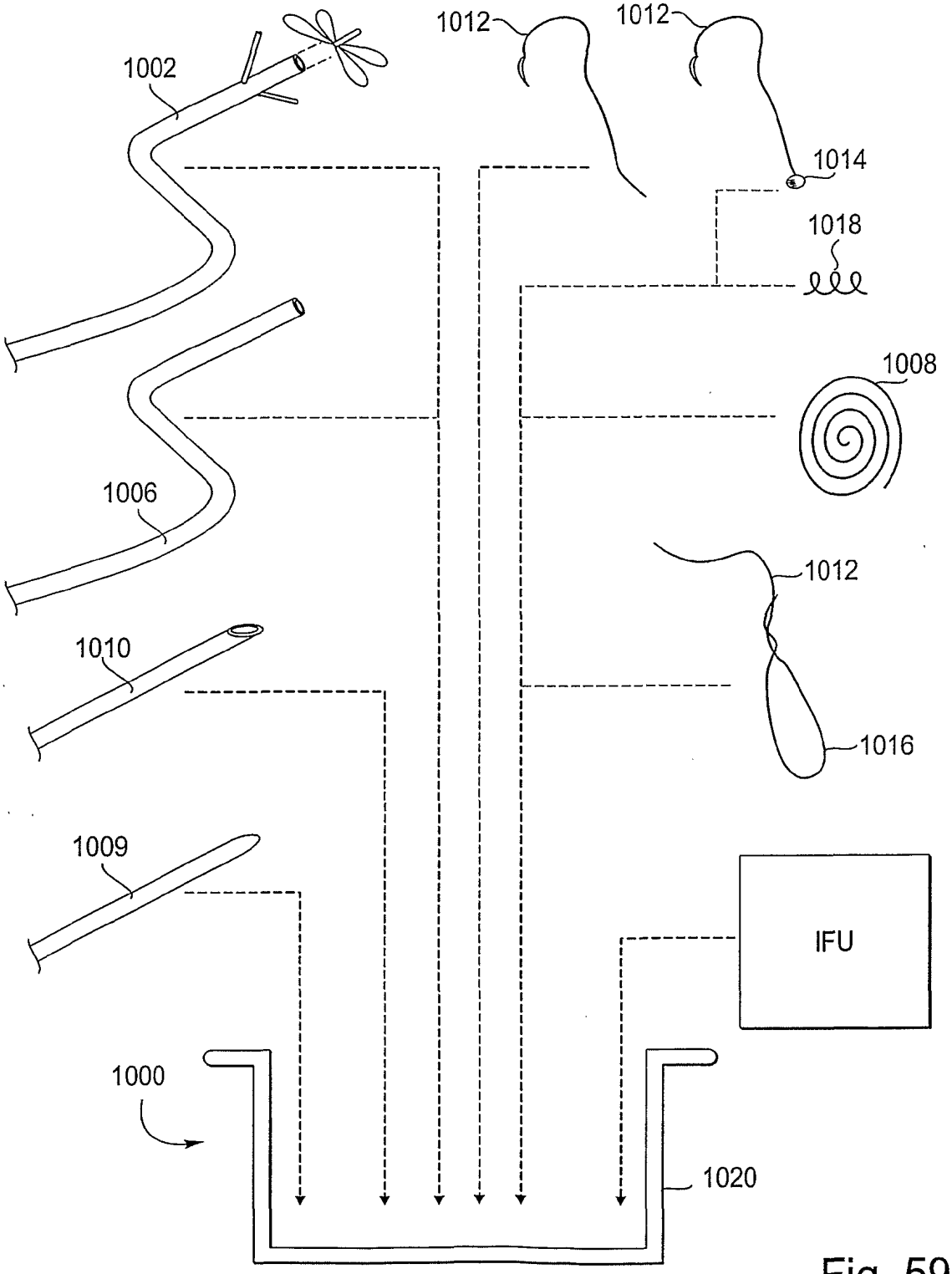


Fig. 59

Electronic Acknowledgement Receipt

EFS ID:	6691465
Application Number:	11813695
International Application Number:	
Confirmation Number:	6073
Title of Invention:	Thorascopic Heart Valve Repair Method and Apparatus
First Named Inventor/Applicant Name:	Giovanni Speziali
Customer Number:	26710
Filer:	Richard T. Roche
Filer Authorized By:	
Attorney Docket Number:	630666.00074
Receipt Date:	22-DEC-2009
Filing Date:	11-JUL-2007
Time Stamp:	16:13:09
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Filed (SB/08)	630666-00074-Supp-IDS.pdf	794114 7ff81cfa3ca96f769ff8c6e17809c80fcad713e5	no	4

Warnings:	
Information:	

2	Foreign Reference	WO-03-001893.PDF	3978959 256ebb003ee20d866f21125caf1607c8de0e39c3	no	95
Warnings:					
Information:					
3	NPL Documents	630666-00074-EP-Search-Report.pdf	215523 66cb5eecf28e3082984986264aec71a23996792e	no	7
Warnings:					
Information:					
			Total Files Size (in bytes):	4988596	

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/813,695	07/11/2007	Giovanni Speziali	630666.00074

CONFIRMATION NO. 6073

PUBLICATION NOTICE

26710
QUARLES & BRADY LLP
411 E. WISCONSIN AVENUE
SUITE 2040
MILWAUKEE, WI 53202-4497

OC00000031435970

Title: Thorascopic Heart Valve Repair Method and Apparatus

Publication No.US-2008-0188873-A1
Publication Date:08/07/2008

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently http://pair.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

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Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

PTO/SB/08a (05-07)
Approved for use through 11/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11813695
Filing Date	2007-07-11
First Named Inventor	Giovanni Speziali
Art Unit	3731
Examiner Name	
Attorney Docket Number	630666.00074

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5908428		1999-06-01	Scirica et al.	
	2	6149660		2000-11-21	Laufer et al.	

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

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NON-PATENT LITERATURE DOCUMENTS

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11813695
	Filing Date	2007-07-11
	First Named Inventor	Giovanni Speziali
	Art Unit	3731
	Examiner Name	
	Attorney Docket Number	630666.00074

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
	1	PCT Search Report and Written Opinion for PCT/US06/01699.	☐

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11813695
	Filing Date	2007-07-11
	First Named Inventor	Giovanni Speziali
	Art Unit	3731
	Examiner Name	
	Attorney Docket Number	630666.00074

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature		Date (YYYY-MM-DD)	2008-06-05
Name/Print	Richard T. Roche	Registration Number	38599

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Electronic Acknowledgement Receipt

EFS ID:	3407349
Application Number:	11813695
International Application Number:	
Confirmation Number:	6073
Title of Invention:	Thorascopic Heart Valve Repair Method and Apparatus
First Named Inventor/Applicant Name:	Giovanni Speziali
Customer Number:	26710
Filer:	Richard T. Roche
Filer Authorized By:	
Attorney Docket Number:	630666.00074
Receipt Date:	05-JUN-2008
Filing Date:	11-JUL-2007
Time Stamp:	18:12:26
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Filed	ids.pdf	123128 a6bf468a231801218739 2db2efd5cb5d345d7167	no	3

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Information:	

This is not an USPTO supplied IDS fillable form					
2	NPL Documents	WOopinion.pdf	231422 d05ffad0b9083dbf1a52ad850ec2bf0af1704781	no	5
Warnings:					
Information:					
			Total Files Size (in bytes):	354550	

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APPLICATION NUMBER	FILING OR 371(c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/813,695	07/11/2007	Giovanni Speziali	630666.00074

CONFIRMATION NO. 6073

26710
QUARLES & BRADY LLP
411 E. WISCONSIN AVENUE
SUITE 2040
MILWAUKEE, WI53202-4497

Date Mailed. 05/29/2008

NOTICE OF NEW OR REVISED PROJECTED PUBLICATION DATE

The above-identified application has a new or revised projected publication date. The current projected publication date for this application is 08/07/2008. If this is a new projected publication date (there was no previous projected publication date), the application has been cleared by Licensing & Review or a secrecy order has been rescinded and the application is now in the publication queue.

If this is a revised projected publication date (one that is different from a previously communicated projected publication date), the publication date has been revised due to processing delays in the USPTO or the abandonment and subsequent revival of an application. The application is anticipated to be published on a date that is more than six weeks different from the originally-projected publication date.

More detailed publication information is available through the private side of Patent Application Information Retrieval (PAIR) System. The direct link to access PAIR is currently http://pair.uspto.gov. Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Questions relating to this Notice should be directed to the Office of Patent Publication at 1-888-786-0101.

PART 1 - ATTORNEY/APPLICANT COPY

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United States Patent and Trademark Office
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U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
11/813,695	Giovanni Speziali	630666.00074

26710
QUARLES & BRADY LLP
411 E. WISCONSIN AVENUE
SUITE 2040
MILWAUKEE, WI 53202-4497

INTERNATIONAL APPLICATION NO.	
PCT/US06/01699	
I.A. FILING DATE	PRIORITY DATE

CONFIRMATION NO. 6073
371 ACCEPTANCE LETTER

OC000000028561312

Date Mailed: 03/03/2008

NOTICE OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C 371 AND 37 CFR 1.495

The applicant is hereby advised that the United States Patent and Trademark Office in its capacity as a Designated / Elected Office (37 CFR 1.495), has determined that the above identified international application has met the requirements of 35 U.S.C. 371, and is ACCEPTED for national patentability examination in the United States Patent and Trademark Office.

The United States Application Number assigned to the application is shown above and the relevant dates are:

07/11/2007	07/21/2007
DATE OF RECEIPT OF 35 U.S.C. 371(c)(1), (c)(2) and (c)(4) REQUIREMENTS	DATE OF COMPLETION OF ALL 35 U.S.C. 371 REQUIREMENTS

A Filing Receipt (PTO-103X) will be issued for the present application in due course. **THE DATE APPEARING ON THE FILING RECEIPT AS THE " FILING DATE" IS THE DATE ON WHICH THE LAST OF THE 35 U.S.C. 371 (c)(1), (c)(2) and (c)(4) REQUIREMENTS HAS BEEN RECEIVED IN THE OFFICE. THIS DATE IS SHOWN ABOVE.** *The filing date of the above identified application is the international filing date of the international application (Article 11(3) and 35 U.S.C. 363).* Once the Filing Receipt has been received, send all correspondence to the Group Art Unit designated thereon.

The following items have been received:

- Indication of Small Entity Status
- Copy of the International Application filed on 07/11/2007
- Preliminary Amendments filed on 07/11/2007
- Oath or Declaration filed on 07/11/2007
- U.S. Basic National Fees filed on 07/11/2007
- Priority Documents filed on 07/11/2007
- Specification filed on 07/11/2007
- Claims filed on 07/11/2007
- Abstracts filed on 07/11/2007
- Drawings filed on 07/11/2007

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

FREDERICK SMITH

Telephone: (703) 308-9140 EXT 210

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United States Patent and Trademark Office
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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
11/813,695	07/11/2007		500	630666.00074	17	2

CONFIRMATION NO. 6073

26710
QUARLES & BRADY LLP
411 E. WISCONSIN AVENUE
SUITE 2040
MILWAUKEE, WI 53202-4497

FILING RECEIPT

Date Mailed: 03/03/2008

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

Giovanni Speziali, Pittsburgh, PA;

Power of Attorney: The patent practitioners associated with Customer Number 26710

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/US06/01699 01/19/2006
which claims benefit of 60/645,677 01/21/2005

Foreign Applications

Projected Publication Date: 06/05/2008
Non-Publication Request: No
Early Publication Request: No
**** SMALL ENTITY ****
Title

Thorascopic Heart Valve Repair Method and Apparatus

Preliminary Class

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international

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Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

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Title 37, Code of Federal Regulations, 5.11 & 5.15

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The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

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No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	SPEZIALI, Giovanni
Serial No.:	NOT YET ASSIGNED
I.A. Filing Date:	19 January 2006 (19.01.06)
Priority Date:	21 January 2005 (21.01.05)
PCT Appl. No.:	PCT/US2006/001699
Title:	THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS
Docket No.	630666.00074

Preliminary Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Amendments to the Specification begin on page 2.
Remarks are found on page 3

AMENDMENTS TO THE SPECIFICATION:

Please replace Paragraph [0001], Cross-Reference To Related Applications, so that it reads as follows:

CROSS-REFERENCE TO RELATED APPLICATIONS

[001] This application claims the benefit of International Patent Application Number PCT/US2006/001699 filed 19 January 2006 and entitled "THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS", which claims priority of US Provisional Patent Application Serial No. 60/645,677 filed 21 January 2005 and entitled "THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS", both of which are incorporated by reference herein.

REMARKS

The above amendment is being made to incorporate the International Patent Application priority information. This amendment adds no new matter to the present application.

Although no additional fees are believed due, other than authorized on the accompanying fee sheet, if an additional fee is deemed due, please charge any additional fees due to deposit account no. 17-0055.

Respectfully submitted,

Dated: July 11, 2007

By: Barry E. Sammons

Barry E. Sammons
Reg. No. 25,608
Quarles & Brady LLP
411 East Wisconsin Avenue
Milwaukee, WI 53202-4497
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(09-04)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☑ Declaration Submitted With Initial Filing **OR** ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	630666.00074
First Named Inventor	SPEZIALI, Giovanni
COMPLETE IF KNOWN	
Application Number	
Filing Date	
Art Unit	
Examiner Name	

I hereby declare that:

Each inventor's residence, mailing address, and citizenship are as stated below next to their name.

I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS

(Title of the Invention)

the specification of which

☐ is attached hereto

OR

☑ was filed on (MM/DD/YYYY) 19 Jan 06 (19.01.06) as United States Application Number or PCT International Application Number PCT/US06/001699 and was amended on (MM/DD/YYYY) _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

6143953

(09-04)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION — Utility or Design Patent Application

Direct all correspondence to: ☑ The address associated with Customer Number: 26710 OR ☐ Correspondence address below

Name: SAMMONS, Barry E., QUARLES & BRADY LLP

Address: 411 E. Wisconsin Avenue

City	State	ZIP
Milwaukee	WI	53202

Country	Telephone	Fax
US	414-277-5705	414-271-3552

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
Giovanni	SPEZIALI

Inventor's Signature: Giovanni Speziali Date: 7/4/2007

Residence: City	State	Country	Citizenship
~~Rochester~~ PITTSBURGH	~~MN~~ PA	US	US

Mailing Address: ~~130 Cheval Lane NE~~ 418 WILLIAM ST GS 7/5/07

City	State	Zip	Country
~~Rochester~~ PITTSBURGH	~~MN~~ PA	~~55906~~ 15211	US

NAME OF SECOND INVENTOR: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname

Inventor's Signature: Date:

Residence: City	State	Country	Citizenship

Mailing Address:

City	State	Zip	Country

☐ Additional inventors or a legal representative are being named on the _____ supplemental sheet(s) PTO/SB/02A or 02LR attached hereto.

6143953

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS
First Named Inventor/Applicant Name:	Giovanni Speziali
Filer:	Barry E. Sammons/Tracey Baxter
Attorney Docket Number:	630666.00074

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Basic National Stage Fee	2631	1	150	150
Natl Stage Search Fee - U.S. was the ISA	2641	1	50	50
Natl Stage Exam Fee - all other cases	2633	1	100	100
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**300**

Electronic Acknowledgement Receipt

EFS ID:	1960179
Application Number:	11813695
International Application Number:	PCT/US06/01699
Confirmation Number:	6073
Title of Invention:	THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS
First Named Inventor/Applicant Name:	Giovanni Speziali
Customer Number:	26710
Filer:	Barry E. Sammons/Tracey Baxter
Filer Authorized By:	Barry E. Sammons
Attorney Docket Number:	630666.00074
Receipt Date:	11-JUL-2007
Filing Date:	
Time Stamp:	13:26:15
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment was successfully received in RAM	$300
RAM confirmation Number	7333
Deposit Account	170055
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 and 1.17	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1		63066600074usnatl.pdf	278832 4d3755e0288c74fc5099e90a04f194f01c9ca5fe	yes	7

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Documents submitted with 371 Applications	1	2
Preliminary Amendment	3	5
Oath or Declaration filed	6	7

Warnings:

Information:

2	Fee Worksheet (PTO-06)	fee-info.pdf	8430 eb0b045fe2b4a68047cf2296720cb833481dab61	no	2

Warnings:

Information:

Total Files Size (in bytes):	287262

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO-1390 (Rev. 02-2005)
Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

ATTTORNEY'S DOCKET NUMBER	
630666.00074	
U.S. APPLICATION NO. (If known, see 37 CFR 1.5)	
INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE
PCT/US2006/001699	19 Jan 2006 (19.01.06)
PRIORITY DATE CLAIMED	
21 Jan 2005 (21.01.05)	

TITLE OF INVENTION
THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS

APPLICANT(S) FOR DO/EO/US
SPEZIALI, Giovanni

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☑ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☐ The US has been elected (Article 31).
5. ☑ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☐ is attached hereto (required only if not communicated by the International Bureau).
   b. ☐ has been communicated by the International Bureau.
   c. ☑ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☐ is attached hereto.
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☑ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. ☐ are attached hereto (required only if not communicated by the International Bureau).
   b. ☐ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☑ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☑ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☑ A preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13*ter*.2 and 37 CFR 1.821- 1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☐ Other items or information:

Doc. 6142035

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
	PCT/US2006/001699	630666.00074

The following fees have been submitted	CALCULATIONS	PTO USE ONLY
21. ☑ Basic national fee..... **$300**	$ 300.00	
22. ☑ Examination fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)..... **$100** All other situations..... **$200**	$ 200.00	
23. ☑ Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... **$100** International Search Report prepared and provided to the Office..... **$400** All other situations..... **$500**	$ 100.00	
TOTAL OF 21, 22 and 23 =	$ 600.00	
☐ Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is **$250** for each additional 50 sheets of paper or fraction thereof.		

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round **up** to a whole number)	RATE	
- 100 =	/50 =		x **$250**	$

Surcharge of **$130.00** for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	17 - 20 =	0	x **$ 50**	$	
Independent claims	2 - 3 =	0	x **$200**	$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ **$360**	$	
			TOTAL OF ABOVE CALCULATIONS =	$ 600.00	
☑ Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.				300.00	
			SUBTOTAL =	$ 300.00	
Processing fee of **$130.00** for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)). +				$	
			TOTAL NATIONAL FEE =	$ 300.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +				$	
			TOTAL FEES ENCLOSED =	$ 300.00	
			Amount to be refunded:	$	
			Amount to be charged:	$ 300.00	

a. ☐ A check in the amount of $ _____ to cover the above fees is enclosed.

b. ☑ Please charge my Deposit Account No. 17-0055 in the amount of $ 300.00 to cover the above fees.
A duplicate copy of this sheet is enclosed.

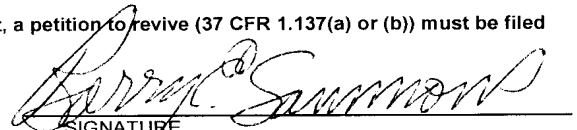
c. ☑ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit t Account No. 17-0055. A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

QUARLES & BRADY LLP
411 E. Wisconsin Ave.
Milwaukee, WI 53202
(414) 277-5000
(414) 271-3552 (Fax)


SIGNATURE

Barry E. Sammons
NAME

325,608
REGISTRATION NUMBER

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 July 2006 (27.07.2006)

PCT

(10) International Publication Number
WO 2006/078694 A2

(51) International Patent Classification: Not classified

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PCT/US2006/001699

(22) International Filing Date: 19 January 2006 (19.01.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/645,677 21 January 2005 (21.01.2005) US

(71) Applicant *(for all designated States except US)*: **MAYO FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH** [US/US]; 200 First Street SE, Rochester, MN 55905 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **SPEZIALI, Giovanni** [US/US]; 130 Cheval Lane NE, Rochester, MN 55906 (US).

(74) Agent: **SAMMONS, Barry, E.**; QUARLES & BRADY LLP, 411 East Wisconsin Avenue, Milwaukee, WI 53202 (US).

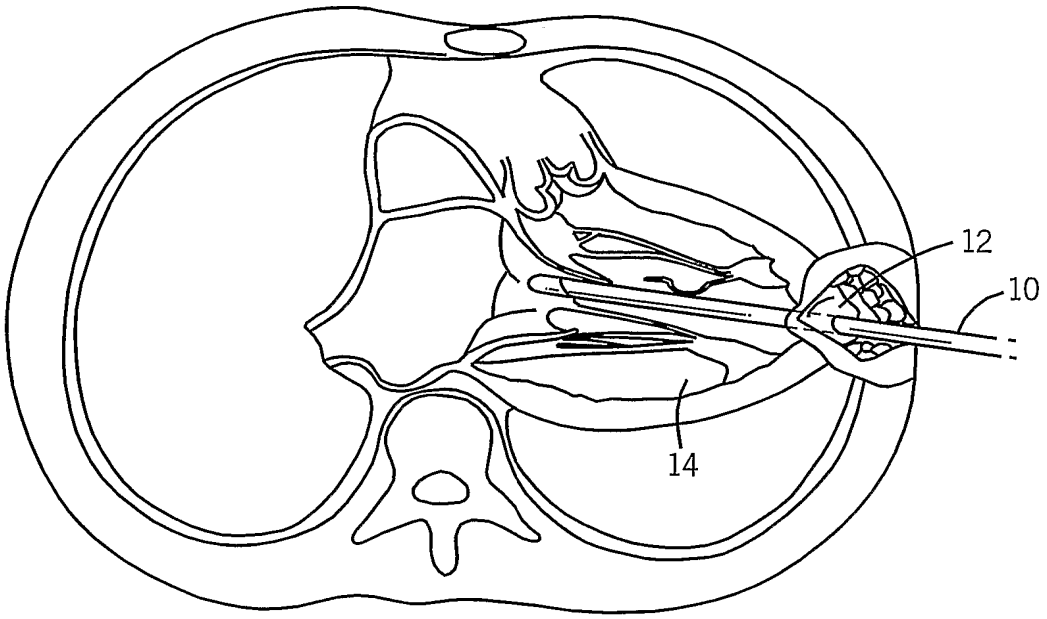
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC,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

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

Published:
— *without international search report and to be republished upon receipt of that report*

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

(54) **Title:** THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS



(57) **Abstract:** An instrument for performing thorascopic repair of heart valves includes a shaft for extending through the chest cavity and into a heart chamber providing access to a valve needing repair. A movable tip on the shaft is operable to capture a valve leaflet and a needle is operable to penetrate a capture valve leaflet and draw the suture therethrough. The suture is thus fastened to the valve leaflet and the instrument is withdrawn from the heart chamber transporting the suture outside the heart chamber. The suture is anchored to the heart wall with proper tension as determined by observing valve operation with an ultrasonic imaging system.

WO 2006/078694 A2

THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is based on U.S. Provisional Patent Application Serial No. 60/645,677 filed on January 21, 2005 and entitled "THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS."

BACKGROUND OF THE INVENTION

[0002] Various types of surgical procedures are currently performed to investigate, diagnose, and treat diseases of the heart and the great vessels of the thorax. Such procedures include repair and replacement of mitral, aortic, and other heart valves, repair of atrial and ventricular septal defects, pulmonary thrombectomy, treatment of aneurysms, electrophysiological mapping and ablation of the myocardium, and other procedures in which interventional devices are introduced into the interior of the heart or a great vessel.

[0003] Using current techniques, many of these procedures require a gross thoracotomy, usually in the form of a median sternotomy, to gain access into the patient's thoracic cavity. A saw or other cutting instrument is used to cut the sternum longitudinally, allowing two opposing halves of the anterior or ventral portion of the rib cage to be spread apart. A large opening into the thoracic cavity is thus created, through which the surgical team may directly visualize and operate upon the heart and other thoracic contents.

[0004] Surgical intervention within the heart generally requires isolation of the heart and coronary blood vessels from the remainder of the arterial system, and arrest of cardiac function. Usually, the heart is isolated from the arterial system by introducing an external aortic cross-clamp through a sternotomy and applying it to the aorta between the brachiocephalic artery and the coronary ostia. Cardioplegic fluid is then injected into the coronary arteries, either directly into the coronary ostia or through a puncture in the aortic root, so as to arrest cardiac function. In some cases, cardioplegic fluid is injected into the coronary sinus for retrograde perfusion of the myocardium. The patient is placed on cardiopulmonary bypass to maintain peripheral circulation of oxygenated blood.

[0005] Of particular interest to the present invention are intracardiac procedures for surgical treatment of heart valves, especially the mitral and aortic valves. According to recent estimates, more than 79,000 patients are diagnosed with aortic and mitral valve disease in U.S. hospitals each year. More than 49,000 mitral valve or aortic valve replacement procedures are performed annually in the U.S., along with a significant number of heart valve repair procedures.

[0006] Various surgical techniques may be used to repair a diseased or damaged valve, including annuloplasty (contracting the valve annulus), quadrangular resection (narrowing the valve leaflets), commissurotomy (cutting the valve commissures to separate the valve leaflets), shortening mitral or tricuspid valve chordae tendonae, reattachment of severed mitral or tricuspid valve chordae tendonae or papillary muscle tissue, and decalcification of valve and annulus tissue. Alternatively, the valve may be replaced, by excising the valve leaflets of the natural valve, and securing a replacement valve in the valve position, usually by suturing the replacement valve to the natural valve annulus. Various types of replacement valves are in current use, including mechanical and biological prostheses, homografts, and allografts, as described in Bodnar and Frater, Replacement Cardiac Valves 1-357 (1991), which is incorporated herein by reference. A comprehensive discussion of heart valve diseases and the surgical treatment thereof is found in Kirklin and Barratt-Boyes, Cardiac Surgery 323-459 (1986), the complete disclosure of which is incorporated herein by reference.

[0007] The mitral valve, located between the left atrium and left ventricle of the heart, is most easily reached through the wall of the left atrium, which normally resides on the posterior side of the heart, opposite the side of the heart that is exposed by a median sternotomy. Therefore, to access the mitral valve via a sternotomy, the heart is rotated to bring the left atrium into a position accessible through the sternotomy. An opening, or atriotomy, is then made in the left atrium, anterior to the right pulmonary veins. The atriotomy is retracted by means of sutures or a retraction device, exposing the mitral valve directly posterior to the atriotomy. One of the fore mentioned techniques may then be used to repair or replace the valve.

[0008] An alternative technique for mitral valve access may be used when a median sternotomy and/or rotational manipulation of the heart are undesirable. In this technique, a large incision is made in the right lateral side of the chest, usually in the region of the fifth intercostal space. One or more ribs may be removed from the patient, and other ribs near the incision are retracted outward to create a large opening into the thoracic cavity. The left atrium is then exposed on the posterior side of the heart, and an atriotomy is formed in the wall of the left atrium, through which the mitral valve may be accessed for repair or replacement.

[0009] Using such open-chest techniques, the large opening provided by a median sternotomy or right thoracotomy enables the surgeon to see the mitral valve directly through the left atriotomy, and to position his or her hands within the thoracic cavity in close proximity to the exterior of the heart for manipulation of surgical instruments, removal of excised tissue, and/or introduction of a replacement valve through the atriotomy for attachment within the heart. However, these invasive, open-chest procedures produce a high degree of trauma, a significant risk of complications, an extended hospital stay, and a painful recovery period for the patient. Moreover, while heart valve surgery produces beneficial results for many patients, numerous others who might benefit from such surgery are unable or unwilling to undergo the trauma and risks of current techniques.

[0010] The mitral and tricuspid valves inside the human heart include an orifice (annulus), two (for the mitral) or three (for the tricuspid) leaflets and a subvalvular apparatus. The subvalvular apparatus includes multiple chordae tendinae, which connect the mobile valve leaflets to muscular structures (papillary muscles) inside the ventricles. Rupture or elongation of the chordae tendinae result in partial or generalized leaflet prolapse, which causes mitral (or tricuspid) valve regurgitation. A commonly used technique to surgically correct mitral valve regurgitation is the implantation of artificial chordae (usually 4-0 or 5-0 Gore-Tex sutures) between the prolapsing segment of the valve and the papillary muscle. This operation is generally carried out through a median sternotomy and requires cardiopulmonary bypass with aortic cross-clamp and cardioplegic arrest of the heart.

SUMMARY OF THE INVENTION

[0011] The present invention is a method and apparatus for performing a minimally invasive thoracoscopic repair of heart valves while the heart is beating. More specifically the method includes inserting an instrument through the subject's chest wall and through the heart wall. The instrument carries on its distal end a movable element which is manipulated to grasp a valve leaflet and hold it while a needle mechanism punctures the valve leaflet and loops a suture around a portion of the valve leaflet. The instrument is withdrawn from the heart along with the suture and the suture is tied off at the apex of the heart after adjusting its tension for optimal valve operation as observed with an ultrasonic imaging system.

[0012] In addition to grasping and needle mechanisms, the instrument includes fiber optics which provide direct visual indication that the valve leaflet is properly grasped. A set of illuminating fibers terminate at the distal end of the instrument around the needle mechanism in close proximity to a set of sensor fibers. The sensor fibers convey light from the distal end of the instrument to produce an image for the operator. When a valve leaflet is properly grasped, light from the illuminating fibers is reflected off the leaflet surface back through the sensor fibers. On the other hand, if the valve leaflet is not properly grasped the sensor fibers see blood.

[0013] A general object of the invention is to provide an instrument and procedure which enables heart valves to be repaired without the need for open heart surgery. The instrument is inserted through an opening in the chest wall and into a heart chamber while the heart is beating. The instrument enables repair of a heart valve, after which it is withdrawn from the heart and the chest.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0014] Under general anesthesia and double-lumen ventilation, the patient is prepped and draped so as to allow ample surgical access to the right lateral, anterior and left lateral chest wall (from the posterior axillary line on one side to the posterior axillary line on the other side). As shown in Fig. 1, one or more thoracoscopic ports are inserted in the left chest through the intercostal spaces and an instrument 10 is inserted through one of these ports into the chest cavity. Alternatively, a small (3-5 cm) left thoracotomy is performed in the fifth or sixth intercostals space on the anterior axillary line. The patient is fully heparinized. After collapsing the left lung,

the pericardium overlying the apex 12 of the left ventricle 14 is opened and its edges are suspended to the skin incision line. This provides close access to the apex of the heart. Guidance of the intracardiac procedure is provided by a combination of transesophageal or intravascular echocardiography (not shown in the drawings) and with direct visualization through a fiber-optical system built into the instrument 10 as will be described in detail below. A double-pledgeted purse-string suture is placed on the apex of the left ventricle 12 and a stab incision is made at that location. The surgical instrument 10 is inserted through this incision, into the left ventricular chamber 14 of the beating heart.

[0015] Referring particularly to Fig. 2, the instrument 10 may be used to grasp a prolapsing segment of the mitral valve 16 and an artificial chorda 18 may be secured to its free edge. Accurate positioning of the implanted artificial chorda 18 is guaranteed by both echo and direct fiberoptic visualization as will be described in detail below. The instrument 10 is then withdrawn from the left ventricle chamber 14 pulling the unattached end of the neo-implanted chorda 18 with it. Hemostasis is achieved by tying the purse-string suture around the incision in the left ventricular apex 12 after the instrument 10 and chorda 18 are withdrawn. As shown in Fig. 3, the neo-implanted chorda 18 is appropriately tensioned under direct echo-Doppler visualization and secured outside the apex 12 of the heart. That is, a tension is placed on the neo-implanted chorda 18 and the operation of the repaired valve 16 is observed on the ultrasound image. The tension is adjusted until regurgitation is minimized.

[0016] While a single chorda 18 is implanted in the above description, additional chorda, or sutures, can be implanted and attached to the apex 12 of the heart wall with optimal tension. In this case the tensions in all the neo-implanted chorda 18 are adjusted until optimal valve operation is achieved.

[0017] As shown in Figs. 4 and 5, the instrument 10 used to perform the above procedure includes a rigid metal shaft 100 having a handle 120 at its extrathoracic (proximal) end which enables the instrument to be manipulated and guided into position. Actuating mechanisms for controlling the grasping mechanism and needle mechanism located at the distal end 140 of the instrument are also mounted near the handle 120. As will be described below, the grasping mechanism

is operated by squeezing the scissor-grip handle 120, and the needle mechanism is operated by moving an up-turned control shaft 122.

[0018] Located on the distal, intracardiac end 140 of the instrument 10 is a grasping mechanism which can be operated to hold a prolapsing valve leaflet. As shown in Figs. 6 and 7, in the preferred embodiment this mechanism is a tip 160 which is supported on the distal end of the shaft 100 by a set of rods 162. The rods 162 slide within the shaft 100 to move the tip 160 between an open position as shown in Figs. 6B and 7 and a closed position as shown in Fig. 6A when the scissor-grip handle 120 is operated. As will be explained below, a mitral valve leaflet is located in the gap between the open tip 160 and the distal end of shaft 100 and it is captured by closing the tip 160 to pinch the valve leaflet therebetween.

[0019] Disposed in a needle lumen 164 formed in the shaft 100 is a needle 180 which connects to the control shaft 122 at the proximal end of shaft 100. Needle mechanism 180 slides between a retracted position in which it is housed in the lumen 164 near the distal end of the shaft 100 and an extended position in which it extends into the sliding tip 160 when the tip is in its closed position. As a result, if a valve leaflet has been captured between the tip 160 and the distal end of shaft 100 the needle may be extended from the lumen 164 by moving control shaft 122 to puncture the captured leaflet and pass completely through it.

[0020] The distal end of the shaft 100 also contains an artificial chorda, or suture 18 that is to be deployed in the patient's heart. The suture 18 is typically a 4-0 or 5-0 suture manufactured by a company such as Gore-Tex. This suture 18 is deployed by the operation of the grasping mechanism and the needle mechanism 180 as described in more detail below.

[0021] The shaft 100 has a size and shape suitable to be inserted into the patient's chest and through the left ventricle cardiac wall and form a water-tight seal with the heart muscle. It has a circular or ellipsoidal cross-section and it houses the control links between the handle end and the intracardiac end of the instrument as well as a fiber optic visualization system described in more detail below.

[0022] As shown in Figs. 8A-8F, the preferred embodiment of the suture deployment system at the distal end of the instrument 10 is positioned around a valve leaflet 16 to be repaired as shown in Fig. 8A. The suture 18 is folded at the

middle to form a loop 19 that is positioned in the tip 160. Both ends of the suture 18 are disposed in a suture lumen 165 formed in the shaft 100 beneath the rods 162. As shown in Fig. 8B, the valve leaflet 16 is grasped by closing the tip 160, and the needle 180 is extended to puncture the leaflet 16 and extend into the tip 160. A notch 166 formed on one side of the needle 180 hooks the suture loop 19. The needle 180 is then retracted back through the leaflet 16 to pull the suture loop 19 through the puncture opening as shown in Fig. 8C. The leaflet 16 is then released and the instrument 10 is withdrawn from the heart as shown in Fig. 8D pulling both ends and the midpoint of the suture 18 with it. As shown in Fig. 8E, the suture 18 is released by the instrument 10 and the surgeon inserts the two suture ends 21 through the loop 19 at its midpoint. The ends 21 are then pulled and the loop 19 slides along the suture 18 back into the heart chamber 14 where it forms a Larks head around the edge of the valve leaflet as shown in Fig. 8F.

[0023] Multiple sutures 18 may be implanted in this manner until a satisfactory result is obtained. After deployment of the sutures 18, the heart wall incision is repaired by either a pre-positioned purse-string suture or by any kind of appropriate hemostatic device or technique. Hemostasis is checked, appropriate chest drainage tubes are positioned and secured, and all incisions are closed.

[0024] As shown in Figs. 9A-9D, a second embodiment of the suture deployment system at the distal end of the instrument 10 is positioned around a valve leaflet 16 to be repaired as shown in Fig. 9A. The suture 18 in this embodiment is a closed loop with one end of the loop disposed in the tip 160 and its other end disposed in the lumen 164 and wrapped around the needle 180. The needle 180 is extended through the grasped valve leaflet 16 into the instrument tip 160 where it hooks one end of the looped suture 18 in a notch 166 formed on one side of the needle as shown in Fig. 9B. The needle 180 is then retracted to pull the the looped suture 18 through the puncture opening in the leaflet 16. The leaflet is then released as shown in Fig. 9C by sliding the tip 160 to its open position. The instrument 10 is then withdrawn as shown in Fig. 9D to slide the unhooked end of the looped suture 18 along the length of the needle toward the leaflet 16 where it forms a Larks head around the leaflet edge.

[0025] The instrument 10 is then withdrawing from the heart chamber 14 pulling the hooked end of the suture 18 through the heart wall. The suture 18 is secured to the outside of the heart apex.

[0026] As shown in Figs. 10A-10D, a third embodiment of the suture deployment system at the distal end of the instrument 10 is positioned around a valve leaflet 16 to be repaired as shown in Fig. 10A. The midpoint 17 of the suture 18 is looped around the lumen 164 and its two loose ends 20 are coiled up in the tip 160. After the tip 160 is closed to capture the valve leaflet 16, the needle 180 is extended through the grasped valve leaflet 16 into the instrument tip 160. The free ends 20 of the suture 18 are positioned in the tip 160 to form a loop 19 and a notch 166 formed on one side of the needle extends through this loop 19 and "hooks" the free ends of the suture 18 as shown in Fig. 10B. The needle 180 is then retracted back into the lumen 164 to pull the hooked ends of the suture 18 through the puncture opening in the leaflet 16. The leaflet is then released as shown in Fig. 10C by sliding the tip 160 to its open position. The instrument 10 is then withdrawn from the heart as shown in Fig. 10D to pull the free ends 20 back through the valve leaflet 16 and a Larks head is formed around the leaflet edge by the midpoint 17 of the suture 18.

[0027] The instrument 10 is then withdrawn from the heart chamber 14 pulling the free ends 20 of the suture 18 through the heart wall. The free ends 20 of the suture 18 are secured to the outside of the heart apex.

[0028] Other suture deployment systems are possible where, for example, the needle may penetrate through the leaflet and link up with a snap fitting device that is attached to one end of the looped suture 18 in the instrument tip 160. The needle then withdraws pulling the device and looped suture back through the penetration opening in the leaflet as described above.

[0029] As shown in Fig. 7 to enhance visibility during this procedure, four fiberoptic channels 170 extend along the length of the instrument shaft 100 and terminate at its distal end. Each channel 170 contains at least one illuminating fiber which connects at its extrathoracic end to a white light source (not shown in the drawings). Each channel 170 also contains at least one sensor fiber which conveys reflected light from the distal end back to a visualization monitor (not shown in the

drawings) connected to its extrathoracic end. In the preferred embodiment each channel 170 includes two illuminating fibers and two sensor fibers.

[0030] The four fiberoptic channels 170 are disposed around the needle lumen 164 such that when a valve leaflet 16 is properly grasped, the valve leaflet tissue 16 rests against the distal end of all the fibers 170. As a result, light is reflected off the tissue back into the sensor fibers and four white circles are displayed on the visualization monitor. When the leaflet 16 is not properly pressed against the distal end of a channel 170, light is not reflected from the leaflet 16 and the visualization monitor displays the red color reflected from blood. When no valve tissue is captured, the monitor shows four red dots and when valve tissue is captured, the dots corresponding to the fiberoptic channels 170 contacting the tissue turn white. If the monitor shows all four dots as white, it means that the valve tissue capture is optimal. If only the upper two dots turn white and the bottom dots remain red, the "bite" on the valve leaflet 16 is too shallow for a proper attachment of the suture 18.

[0031] In addition to the fiberoptic visualization system that insures that a valve leaflet is properly captured, other real-time visualization systems are employed to help guide the instrument 10 to the valve leaflet 16. Preferably a transesophageal or intravascular color-Doppler echocardiography system is used for this purpose. As explained above, this imaging system is also used to determine the length of the neo-implanted artificial chordae in real-time by observing reduction or disappearance of regurgitation by transesophageal or intravascular color-Doppler echocardiography.

CLAIMS

1. A method for repairing a heart valve, the steps comprising:

a) inserting an instrument through the subject's chest wall and into the chest cavity;

b) inserting the distal end of the instrument through a heart wall and entering a heart chamber;

c) grasping a leaflet on the heart valve with a movable device on the distal end of the instrument;

d) puncturing the leaflet with a needle disposed on the distal end of the instrument and drawing a suture through the puncture to connect the suture thereto;

e) anchoring the suture to another structure in the heart;

f) withdrawing the instrument from the heart chamber; and

g) withdrawing the instrument from the chest cavity.

2. The method as recited in claim 1 in which step e) includes withdrawing the suture with the instrument from the heart chamber as recited in step f) and anchoring the suture to the outer surface of the heart wall.

3. The method as recited in claim 2 in which the tension on the suture is adjusted before anchoring by observing the operation of the heart valve using a medical imaging system.

4. The method as recited in claim 1 which includes placing a purse-string suture in the heart wall around the location of the instrument insertion.

5. The method as recited in claim 1 in which the distal end of the instrument is inserted in step b) through the apex of the heart.

6. The method as recited in claim 5 in which step e) includes withdrawing the suture with the instrument from the heart chamber as recited in step f) and anchoring the suture to the outer surface of the heart wall near the apex of the heart.

7. An instrument for repairing a heart valve the combination comprising:

a shaft for insertion through a chest wall and into a heart chamber;

a movable element mounted on the distal end of the shaft and being operable from the extrathoracic end of the shaft to capture and hold a valve leaflet against the distal end of the shaft;

a suture disposed in the distal end of the instrument; and

a needle mechanism mounted on the distal end of the shaft and being operable from the extrathoracic end of the shaft to penetrate through a captured valve leaflet and draw a suture back through the penetration.

8. The instrument as recited in claim 7 which includes:

an illumination fiberoptic that extends through the shaft and terminates at the distal end of the shaft; and

a sensor fiberoptic that extends through the shaft and terminates at the distal end of the shaft;

wherein the distal ends of the fiberoptics are positioned such that light is conveyed to the valve leaflet when the valve leaflet is captured and reflected back through the sensor fiberoptic.

9. The instrument as recited in claim 8 in which there are a plurality of illumination and sensor fiberoptics with their distal ends disposed around the needle mechanism.

10. The instrument as recited in claim 7 in which the movable element is a tip which is slidably mounted to the distal end of the shaft and slidable from an open position in which a space is created between the tip and the distal end of the shaft and a closed position in which the space is substantially reduced to grasp a valve leaflet therebetween.

11. The instrument as recited in claim 10 in which the needle mechanism is operable to extend outward from the distal and of the shaft, through a captured valve leaflet and into the tip.

12. The instrument as recited in claim 11 in which the suture is disposed in the tip and the needle mechanism includes means for attaching to the suture when extended into the tip.

13. The instrument as recited in claim 12 in which the means for attaching is a notch formed along one side of a needle that penetrates through the valve leaflet, the notch being positioned when the needle mechanism is extended into the tip to hook the suture.

14. The instrument as recited in claim 11 in which the suture is disposed in the shaft with a loop formed at its midpoint extending into the tip.

15. The instrument as recited in claim 14 in which the means for attaching is a notch formed along one side of a needle that penetrates through the valve leaflet, the notch being positioned when the needle mechanism is extended into the tip to hook the loop formed in the suture.

16. The instrument as recited in claim 11 in which the suture is a loop and the needle mechanism includes a notch formed along one side of the needle that penetrates through the valve leaflet, the notch being positioned when the needle mechanism is extended into the tip to hook one end of the suture loop disposed therein.

17. The instrument as recited in claim 16 in which another end of the suture loop wraps around the needle mechanism at a point proximal the valve leaflet.

FIG. 1

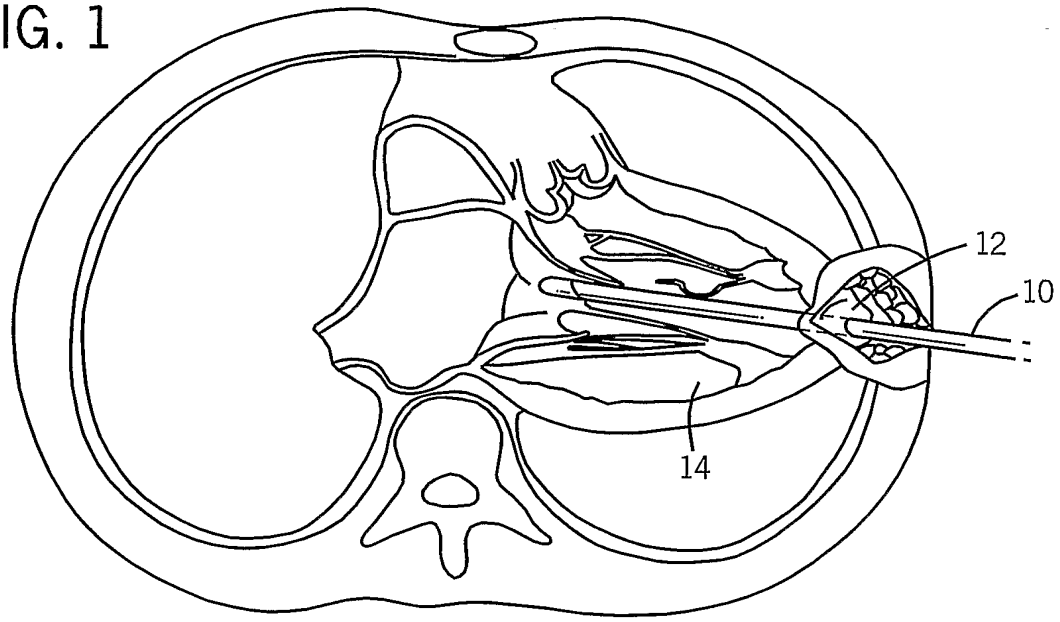


FIG. 2

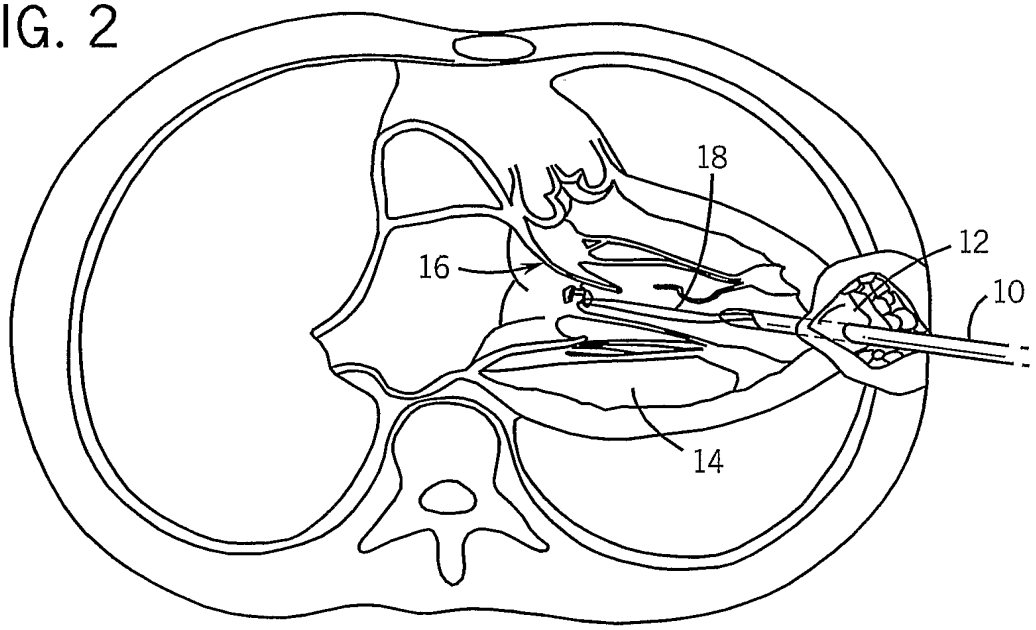
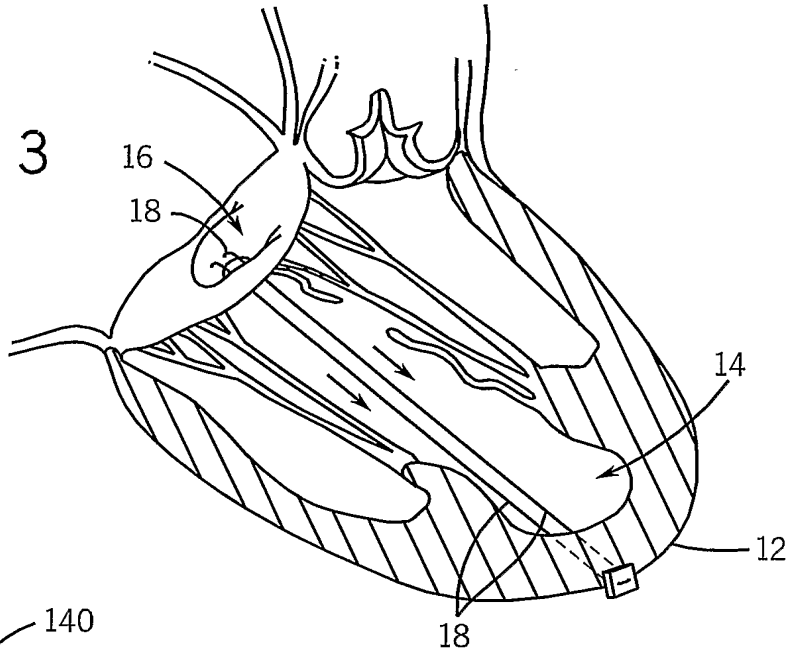


FIG. 3



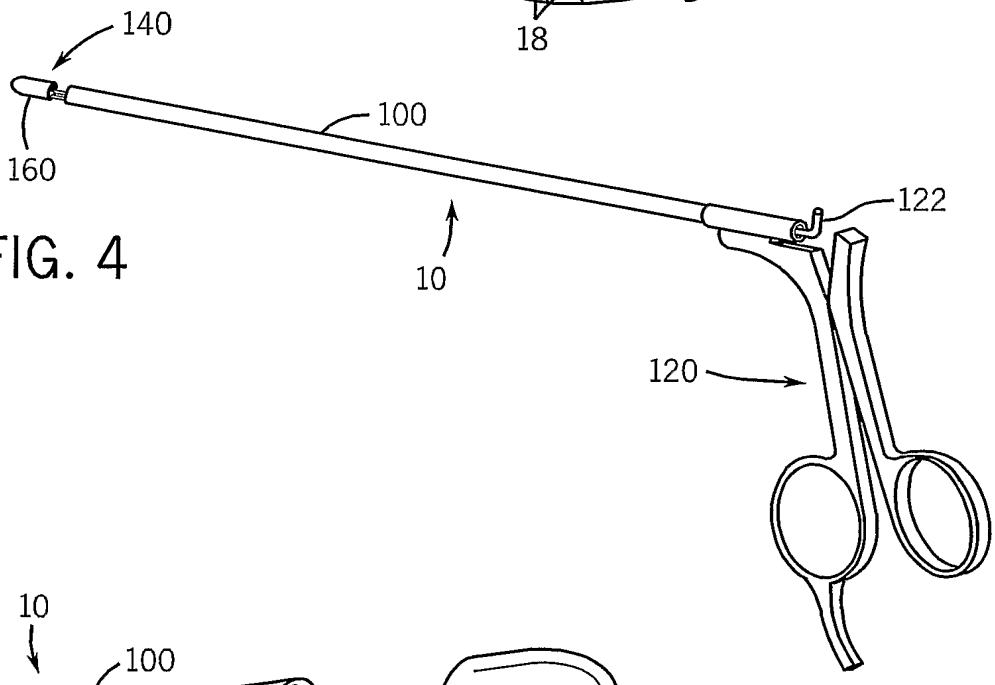


FIG. 4

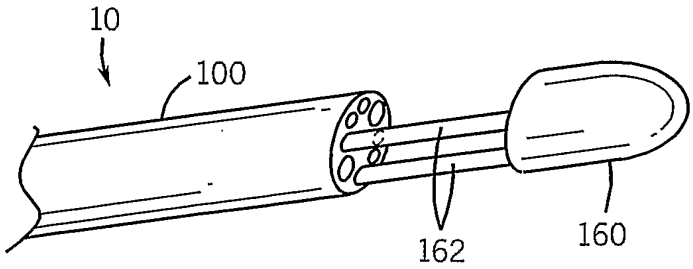


FIG. 5

FIG. 6A

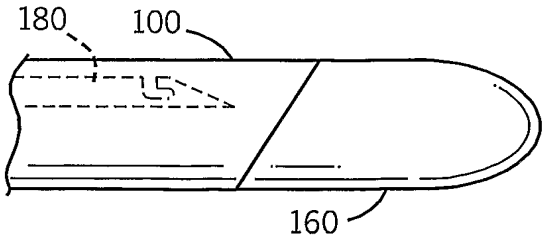
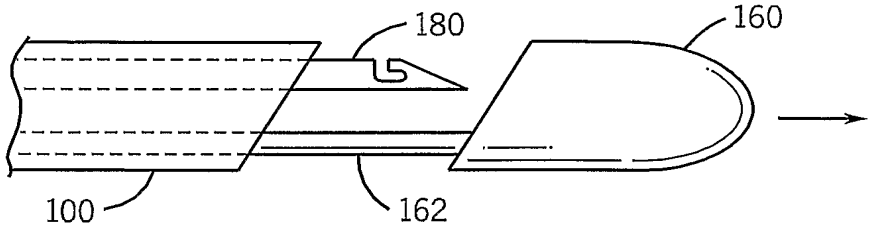


FIG. 6B



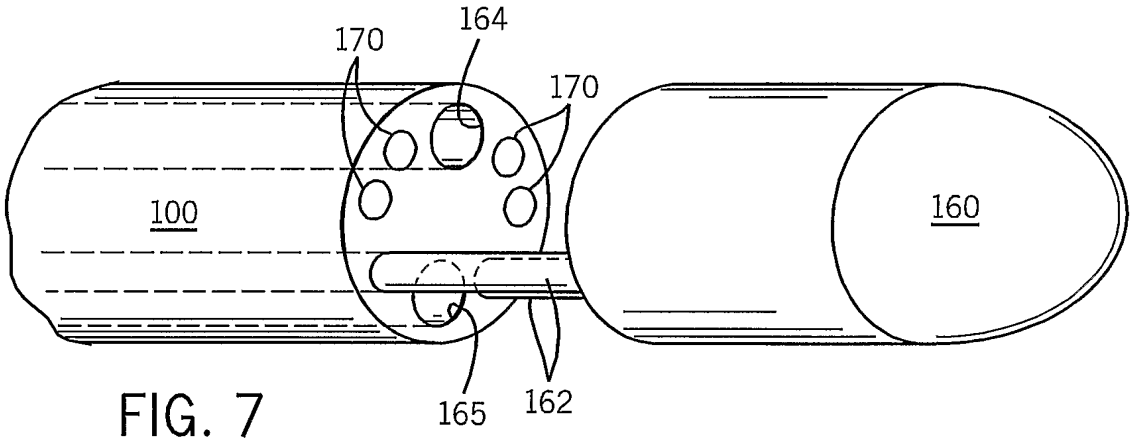


FIG. 7

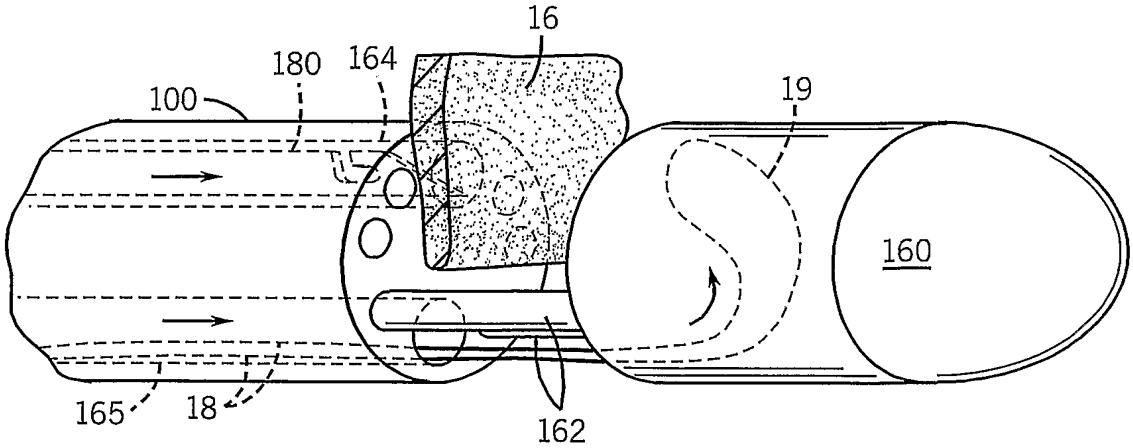


FIG. 8A

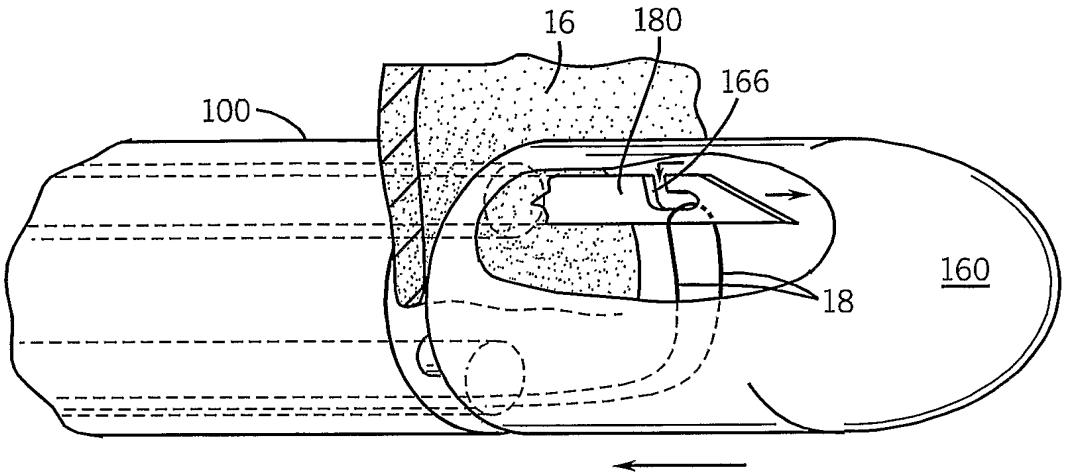


FIG. 8B

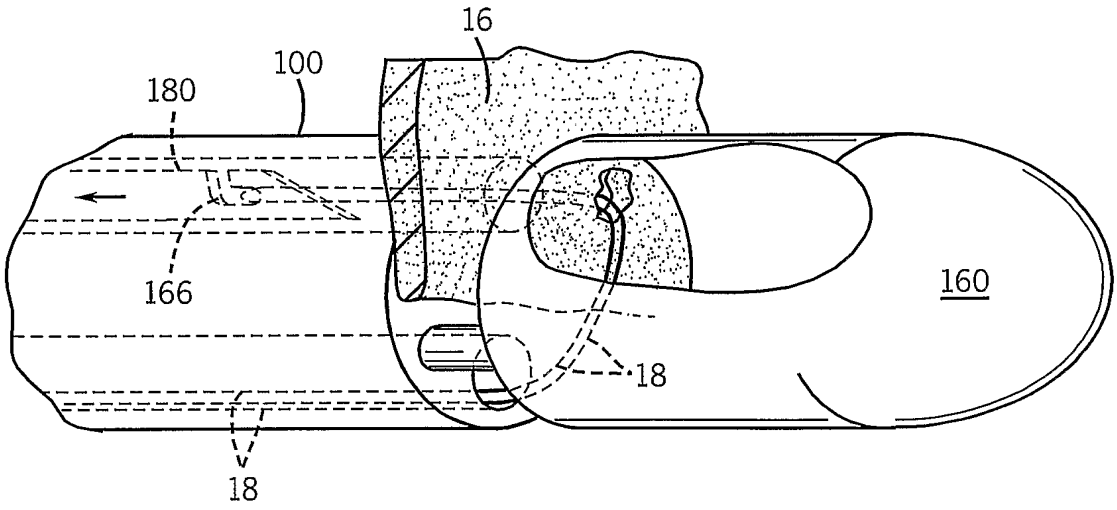


FIG. 8C

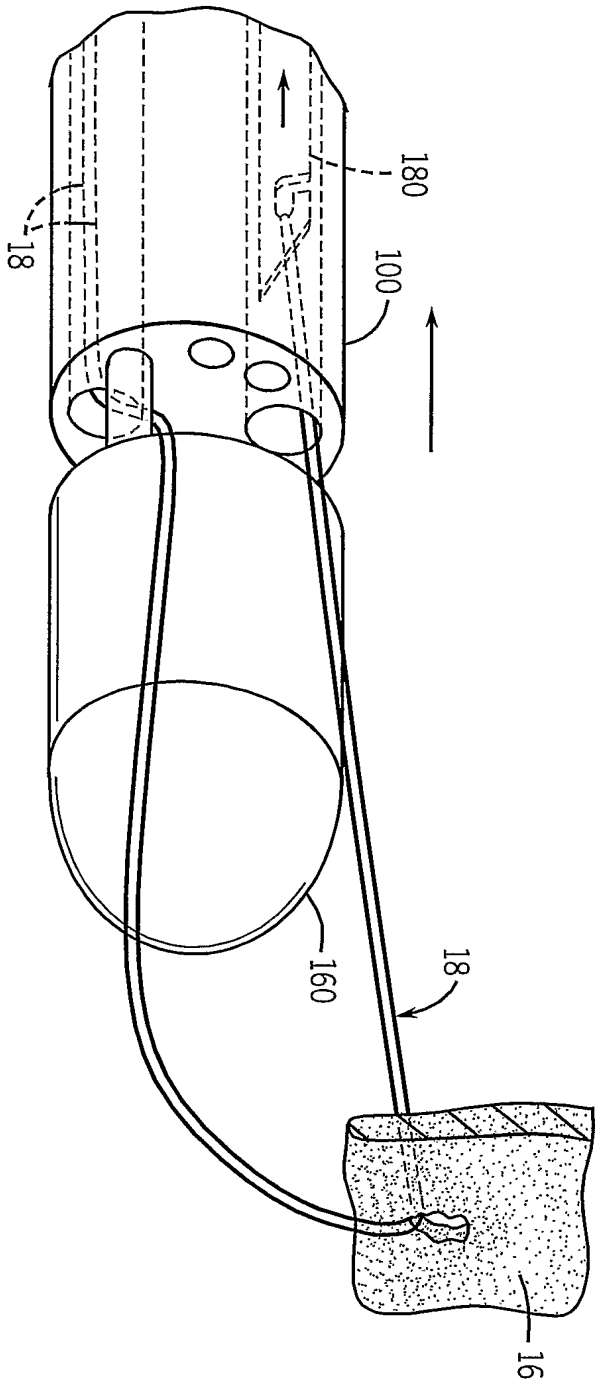


FIG. 8D

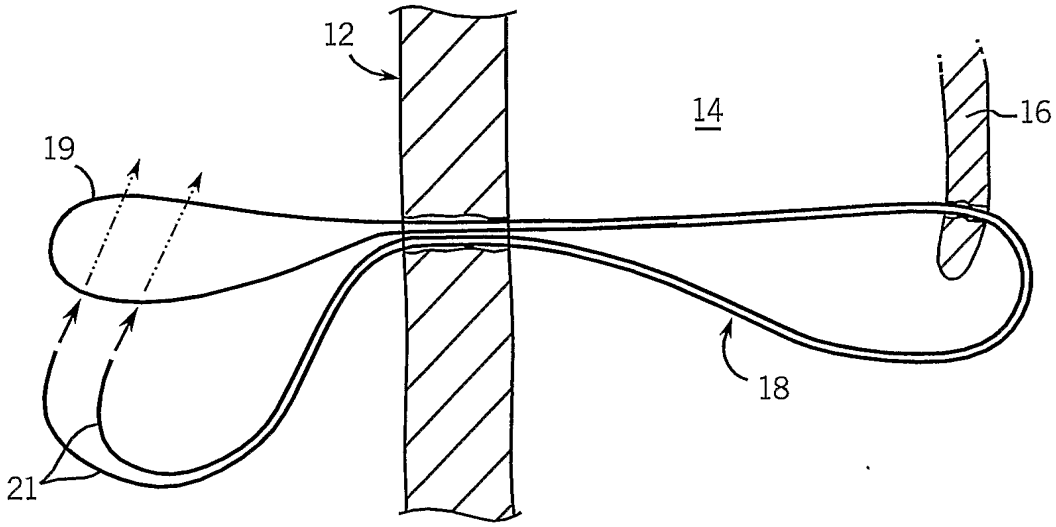


FIG. 8E

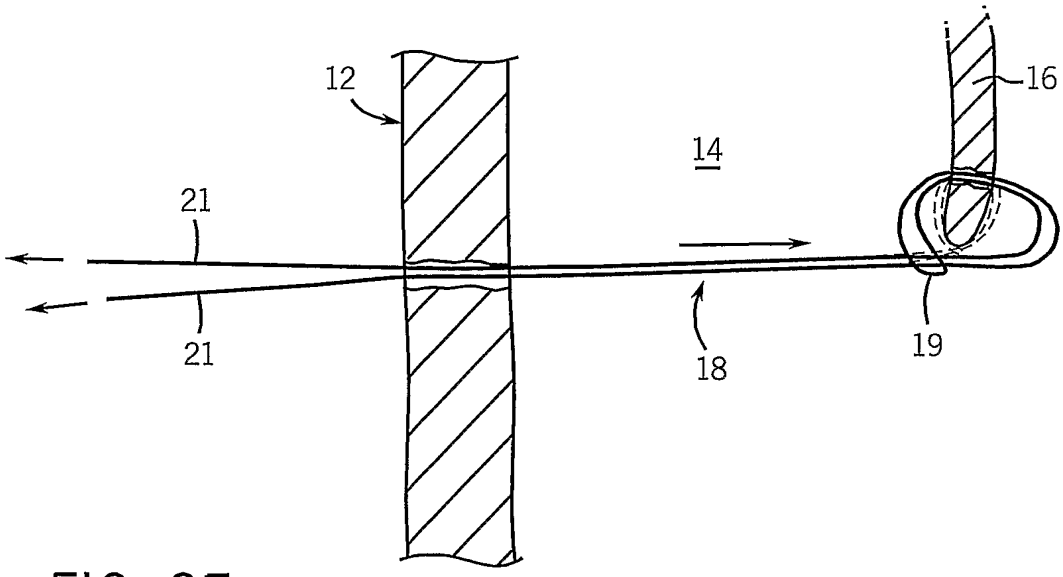


FIG. 8F

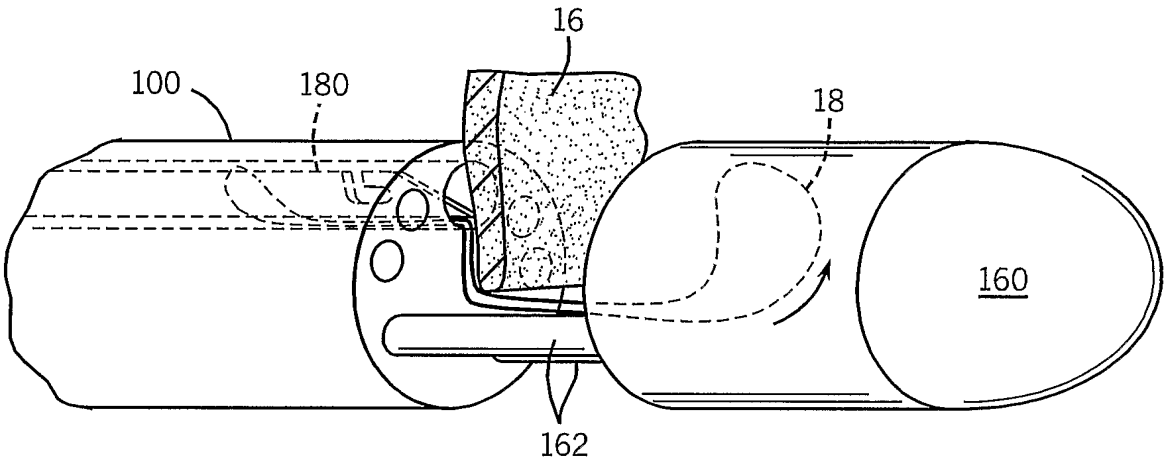


FIG. 9A

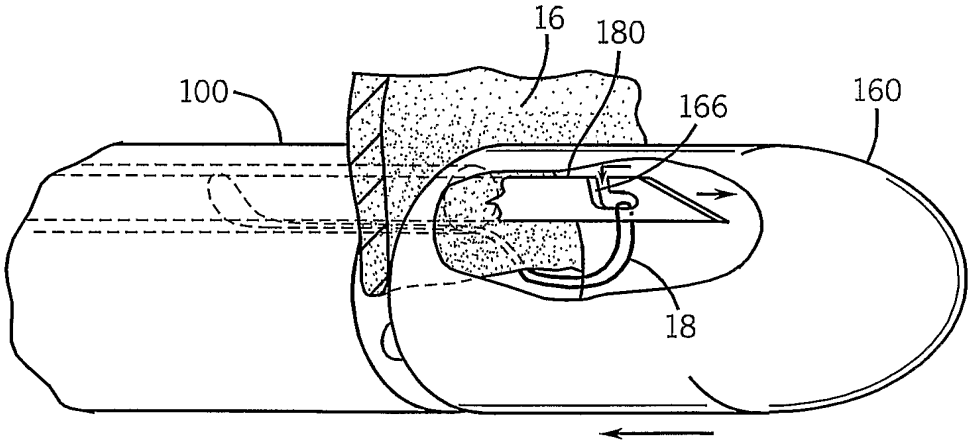


FIG. 9B

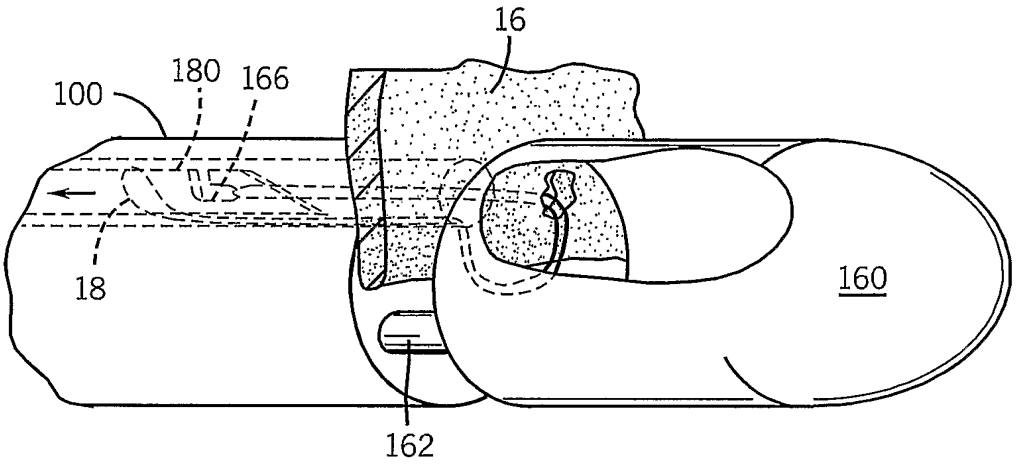


FIG. 9C

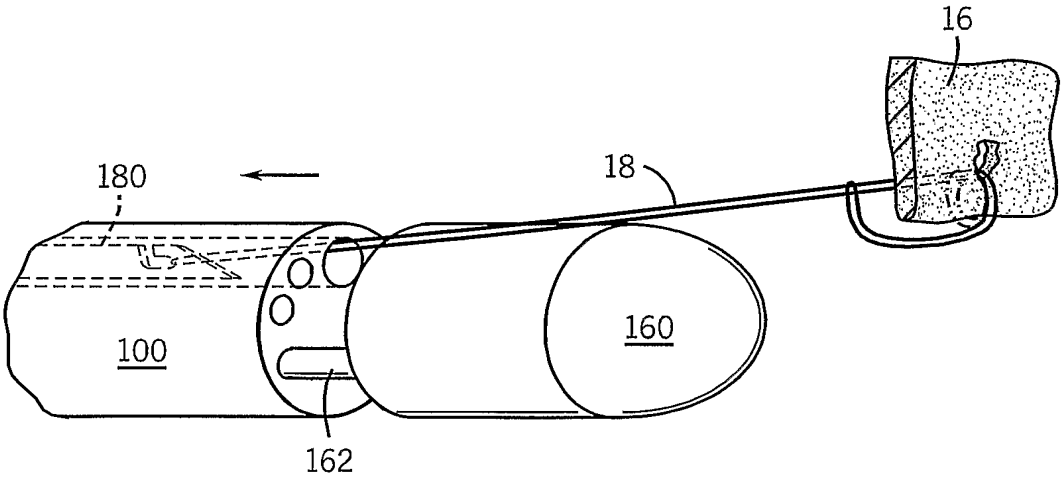


FIG. 9D

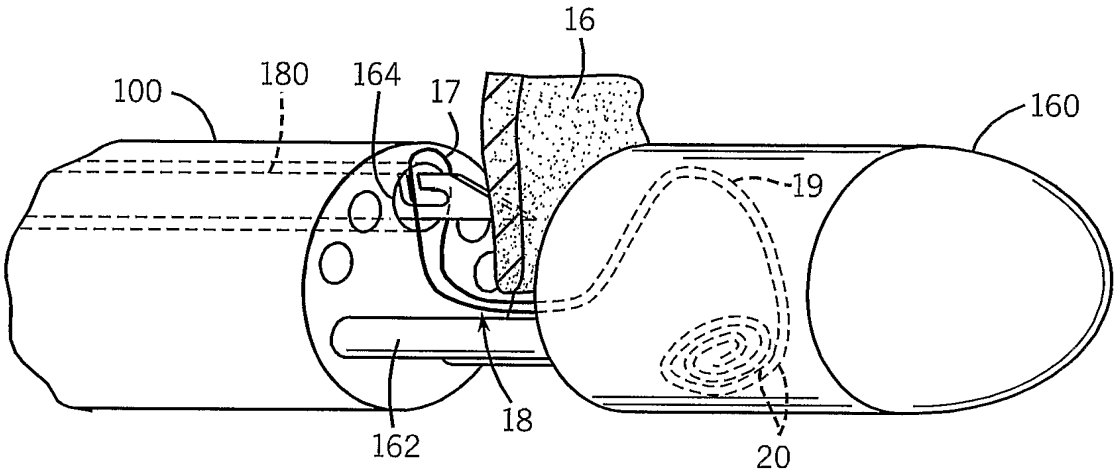


FIG. 10A

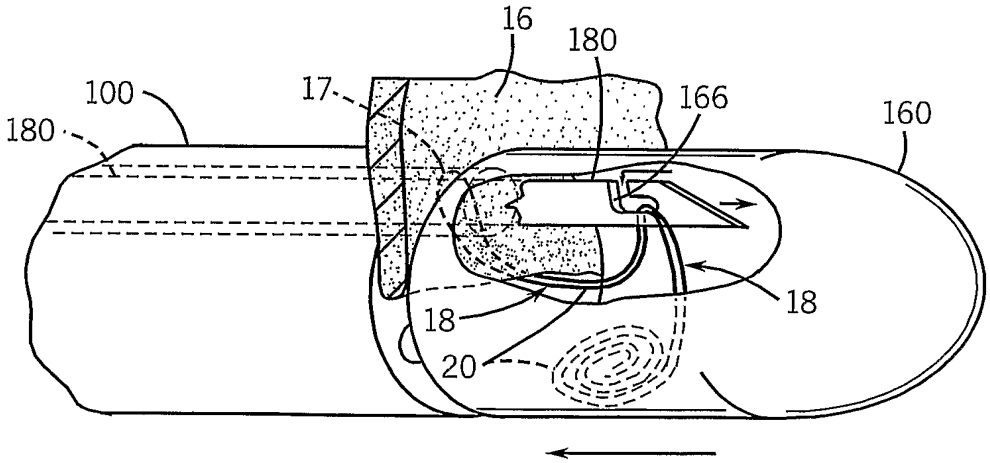


FIG. 10B

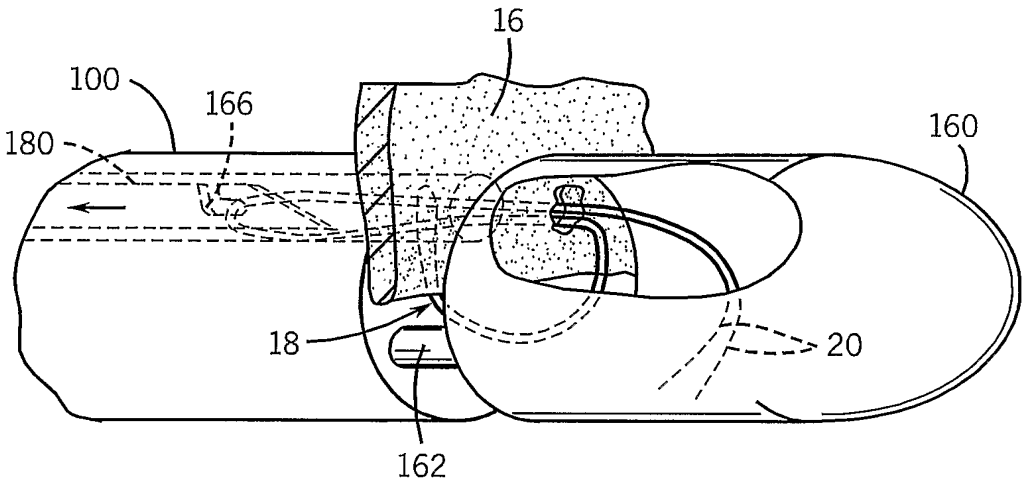


FIG. 10C

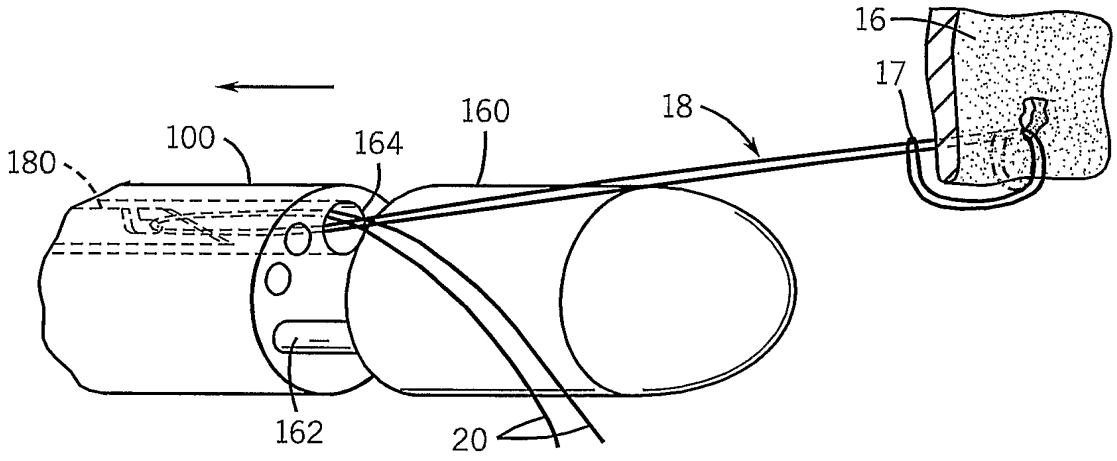


FIG. 10D

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International filing date: 19 January 2006 (19.01.2006)

Document type: Certified copy of priority document

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THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS *US60/645,677*

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Giovanni	Speziali	Rochester Minnesota

Additional inventors are being named on the ___ separately numbered sheets attached hereto

TITLE OF THE INVENTION (500 characters max)

THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☑ Specification *Number of Pages* 8

☑ Drawing(s) *Number of Sheets* 7

☐ Application Data Sheet. See 37 CFR 1.76

☐ CD(s), Number

☑ Other (specify) Return Postcard

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☐ Applicant claims small entity status. See 37 CFR 1.27.

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☑ No.

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Respectfully submitted,

SIGNATURE Barry E. Sammons Date 01/21/05

TYPED or PRINTED NAME Barry E. Sammons REGISTRATION NO. *(if appropriate)* 25,608

TELEPHONE 414.277.5705 Docket Number: ~~960296~~.00074 63dddd.00074

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Provisional Patent Application, Commissioner for Patents, Alexandria, VA 22313-1450.

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Client Ref.: MMV-03-072

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PATENT APPLICATION FOR

THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS

By

Giovanni Speziali

THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS

BACKGROUND OF THE INVENTION

[0001] Various types of surgical procedures are currently performed to investigate, diagnose, and treat diseases of the heart and the great vessels of the thorax. Such procedures include repair and replacement of mitral, aortic, and other heart valves, repair of atrial and ventricular septal defects, pulmonary thrombectomy, treatment of aneurysms, electrophysiological mapping and ablation of the myocardium, and other procedures in which interventional devices are introduced into the interior of the heart or a great vessel.

[0002] Using current techniques, many of these procedures require a gross thoracotomy, usually in the form of a median sternotomy, to gain access into the patient's thoracic cavity. A saw or other cutting instrument is used to cut the sternum longitudinally, allowing two opposing halves of the anterior or ventral portion of the rib cage to be spread apart. A large opening into the thoracic cavity is thus created, through which the surgical team may directly visualize and operate upon the heart and other thoracic contents.

[0003] Surgical intervention within the heart generally requires isolation of the heart and coronary blood vessels from the remainder of the arterial system, and arrest of cardiac function. Usually, the heart is isolated from the arterial system by introducing an external aortic cross-clamp through a sternotomy and applying it to the aorta between the brachiocephalic artery and the coronary ostia. Cardioplegic fluid is then injected into the coronary arteries, either directly into the coronary ostia or through a puncture in the aortic root, so as to arrest cardiac function. In some cases, cardioplegic fluid is injected into the coronary sinus for retrograde perfusion of the myocardium. The patient is placed on cardiopulmonary bypass to maintain peripheral circulation of oxygenated blood.

[0004] Of particular interest to the present invention are intracardiac procedures for surgical treatment of heart valves, especially the mitral and aortic valves. According to recent estimates, more than 79,000 patients are diagnosed with aortic and mitral valve disease in U.S. hospitals each year. More than 49,000 mitral valve or aortic valve replacement procedures are performed annually in the U.S., along with a significant number of heart valve repair procedures.

[0005] Various surgical techniques may be used to repair a diseased or damaged valve, including annuloplasty (contracting the valve annulus), quadrangular resection (narrowing the valve leaflets), commissurotomy (cutting the valve commissures to separate

the valve leaflets), shortening mitral or tricuspid valve chordae tendonae, reattachment of severed mitral or tricuspid valve chordae tendonae or papillary muscle tissue, and decalcification of valve and annulus tissue. Alternatively, the valve may be replaced, by excising the valve leaflets of the natural valve, and securing a replacement valve in the valve position, usually by suturing the replacement valve to the natural valve annulus. Various types of replacement valves are in current use, including mechanical and biological prostheses, homografts, and allografts, as described in Bodnar and Frater, Replacement Cardiac Valves 1-357 (1991), which is incorporated herein by reference. A comprehensive discussion of heart valve diseases and the surgical treatment thereof is found in Kirklin and Barratt-Boyes, Cardiac Surgery 323-459 (1986), the complete disclosure of which is incorporated herein by reference.

[0006] The mitral valve, located between the left atrium and left ventricle of the heart, is most easily reached through the wall of the left atrium, which normally resides on the posterior side of the heart, opposite the side of the heart that is exposed by a median sternotomy. Therefore, to access the mitral valve via a sternotomy, the heart is rotated to bring the left atrium into an anterior position accessible through the sternotomy. An opening, or atriotomy, is then made in the right side of the left atrium, anterior to the right pulmonary veins. The atriotomy is retracted by means of sutures or a retraction device, exposing the mitral valve directly posterior to the atriotomy. One of the fore mentioned techniques may then be used to repair or replace the valve.

[0007] An alternative technique for mitral valve access may be used when a median sternotomy and/or rotational manipulation of the heart are undesirable. In this technique, a large incision is made in the right lateral side of the chest, usually in the region of the fifth intercostal space. One or more ribs may be removed from the patient, and other ribs near the incision are retracted outward to create a large opening into the thoracic cavity. The left atrium is then exposed on the posterior side of the heart, and an atriotomy is formed in the wall of the left atrium, through which the mitral valve may be accessed for repair or replacement.

[0008] Using such open-chest techniques, the large opening provided by a median sternotomy or right thoracotomy enables the surgeon to see the mitral valve directly through the left atriotomy, and to position his or her hands within the thoracic cavity in close proximity to the exterior of the heart for manipulation of surgical instruments, removal of excised tissue, and/or introduction of a replacement valve through the atriotomy for

attachment within the heart. However, these invasive, open-chest procedures produce a high degree of trauma, a significant risk of complications, an extended hospital stay, and a painful recovery period for the patient. Moreover, while heart valve surgery produces beneficial results for many patients, numerous others who might benefit from such surgery are unable or unwilling to undergo the trauma and risks of current techniques.

[0009] The mitral and tricuspid valves inside the human heart include an orifice (annulus), two (for the mitral) or three (for the tricuspid) leaflets and a subvalvular apparatus. The subvalvular apparatus includes multiple chordae tendinae, which connect the mobile valve leaflets to muscular structures (papillary muscles) inside the ventricles. Rupture or elongation of the chordae tendinae result in partial or generalized leaflet prolapse, which causes mitral (or tricuspid) valve regurgitation.

[0010] The standard technique to surgically correct mitral valve regurgitation is the implantation of artificial chordae (usually 4-0 or 5-0 Gore-Tex sutures) between the prolapsing segment of the valve and the papillary muscle (Fig. 1). This operation is generally carried out through a median sternotomy and requires cardiopulmonary bypass with aortic cross-clamp and cardioplegic arrest of the heart.

SUMMARY OF THE INVENTION

[0011] The present invention is a method and apparatus for performing thorascopic repair of heart valves while the heart is beating. More specifically the method includes inserting an instrument through the subject's chest wall and through the heart wall at the apex of the heart. The instrument carries on its distal end a gripper which is manipulated to grasp a valve leaflet and hold it while a needle mechanism punctures the valve leaflet and loops a suture around a portion of the valve leaflet. The instrument is withdrawn from the heart along with the suture and the suture is tied off at the apex of the heart after adjusting its tension for optimal valve operation as observed with an ultrasonic imaging system.

[0012] In addition to a gripper and needle mechanism, the instrument includes fiber optics which provide direct visual indication that the valve leaflet is properly grasped. A set of illuminating fibers terminate at the distal end of the instrument around the needle mechanism in close proximity to a set of sensor fibers. The sensor fibers convey light from the distal end of the instrument to produce an image for the operator. When a valve leaflet is properly grasped, light from the illuminating fibers is reflected off the leaflet surface back

through the sensor fibers. On the other hand, if the valve leaflet is not properly grasped the sensor fibers see blood.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0013] Under general anesthesia and double-lumen ventilation, the patient is prepped and draped so as to allow ample surgical access to the right lateral, anterior and left lateral chest wall (from the posterior axillary line on one side to the posterior axillary line on the other side). One or more thoracoscopic ports are inserted in the left chest through the intercostal spaces. Alternatively, a small (3-5 cm) left thoracotomy is performed in the fifth or sixth intercostals space on the anterior axillary line. The patient is fully heparinized. After collapsing the left lung, the pericardium overlying the apex of the left ventricle is opened and its edges are suspended to the skin incision line. This provides close access to the apex of the heart.

[0014] Guidance of the intracardiac procedure is provided by a combination of transesophageal or intravascular echocardiography with direct visualization through a fiber-optical system built into the instrument utilized to implant the artificial chordae. A double-pledgeted purse-string suture is placed on the apex of the left ventricle. A stab incision is made in the apex of the left ventricle and the surgical instrument is inserted, under echo guidance, into the left ventricular chamber (Fig. 2).

[0015] The prolapsing segment of the mitral valve is grasped and the artificial chorda is secured to its free edge (Fig. 3). Accurate positioning of the implanted artificial chorda is guaranteed by both echo and direct fiberoptic visualization as will be described in detail below. The instrument is then withdrawn from the left ventricle chamber pulling the unattached end of the neo-implanted chorda with it. Hemostasis is achieved by tying the purse-string suture around the incision in the left ventricular apex after the instrument and chorda are withdrawn. The neo-implanted chorda is appropriately tensioned under direct echo-Doppler visualization and secured outside the apex of the heart. That is, a tension is placed on the neo-implanted chorda and the operation of the repaired valve is observed on the ultrasound image. The tension is adjusted until regurgitation is minimized.

[0016] While a single chorda is implanted in the above description, additional chorda, or suture, can be implanted and attached to the apex of the heart wall with optimal tension. In this case the tensions in all the neo-implanted chorda are adjusted until optimal valve operation is achieved.

THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS

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[0016] While a single chorda is implanted in the above description, additional chorda, or suture, can be implanted and attached to the apex of the heart wall with optimal tension. In this case the tensions in all the neo-implanted chorda are adjusted until optimal valve operation is achieved.

[0017] As shown in Fig. 9, the instrument used to perform the above procedure includes a rigid metal shaft 100 having a handle 120 at its extrathoracic (proximal) end which enables the instrument to be manipulated and guided into position. Actuating mechanisms for controlling the gripper and needle mechanism located at the distal end 140 of the instrument are also mounted near the handle.

[0018] Located on the distal, intracardiac end of the instrument is a gripper which can be operated to hold a prolapsing valve leaflet. As shown in Fig. 5, the gripper in the preferred embodiment is a sliding tip 160 which can be closed to capture a mitral valve leaflet between it and the distal end of the instrument shaft 100. This mechanism may function through a forceps-like mechanism, through strong suction (so as to hold the leaflet against the instrument itself by creating a vacuum), through any k ind of radial, axial, sliding, electro-magnetically or vacuum-actuated system or any combination of the above. A needle mechanism 180 also slides between a retracted position in which it is housed in the distal end of the shaft and an extended position in which it extends into the sliding tip 160 when the tip is closed on a captured leaflet. As a result, when the needle is extended, it punctures the captured leaflet.

[0019] The distal end of the shaft also contains a suture that is to be deployed in the patient's heart. The suture is typically a 4-0 or 5-0 suture manufactured by a company such as Gore-Tex and it is a continuous loop. This suture is deployed by the operation of the needle mechanism as described in more detail below.

[0020] The shaft 100 has a size and shape suitable to be inserted into the patient's chest and through the left ventricle cardiac wall and form a water-tight seal with the heart muscle. It has a circular or ellipsoidal cross-section and it houses the control links between the handle end and the intracardiac end of the instrument as well as a fiber optic visualization system described in more detail below.

[0021] As shown in Figs. 6A-6D, in one preferred embodiment of the suture deployment system the distal end of the instrument is positioned around the valve leaflet to be repaired (Fig. 6A) and then the gripper is closed to capture it. The needle is then extended through the trapped leaflet into the instrument tip where it snags one end of the looped suture in a notch formed on one side of the needle (Fig. 6b). The needle is then retracted to pull the one end of the looped suture through the puncture opening in the leaflet and the leaflet is released (Fig. 6C). The instrument is then withdrawn as shown in Fig. 6D to slide the other end of the looped suture toward the leaflet where it forms a half-hitch around the leaflet edge.

[0022] Other suture deployment systems are possible where, for example, the needle penetrates through the leaflet and links up with a snap fitting device that is attached to the looped suture in the instrument tip. The needle then withdraws pulling the device and looped suture back through the penetration opening in the leaflet as described above.

[0023] As shown in Fig. 7, four fiberoptic channels 10 extend along the length of the instrument shaft 100 and terminate at its distal end. Each channel 10 contains at least one illuminating fiber which connects at its extrathoracic end to a white light source. Each channel 10 also contains at least one sensor fiber which conveys reflected light from the distal end back to a visualization monitor connected to its extrathoracic end. In the preferred embodiment each channel 10 includes two illuminating fibers and two sensor fibers.

[0024] The four fiberoptic channels are disposed around the needle lumen 12 such that when a valve leaflet is properly grasped, the valve leaflet tissue rests against the distal end of all the fibers. As shown in Fig. 8C, as a result, light is reflected off the tissue and four white circles are displayed on the visualization monitor. When tissue is not pressed against their distal ends, the visualization monitor displays the red color reflected from blood as shown in Fig. 8B. When no valve tissue is grasped, the monitor shows four red dots. When the valve tissue is grasped, the dots corresponding to the fiberoptics contacting the tissue turn white. If the monitor shows all four dots as white, it means that the "bite" on the valve tissue is optimal. If only the upper two dots turn white and the bottom dots remain red, the "bite" on the valve tissue is too shallow.

[0025] In addition to the fiberoptic visualization system that insures that a valve leaflet is properly grasped, other real-time visualization systems are required to help guide the instrument to the valve leaflet. Preferably a transesophageal or intravascular color-Doppler echocardiography system is used for this purpose. As explained above, this imaging system is also used to determine the length of the neo-implanted artificial chordae in real-time by observing reduction or disappearance of regurgitation by transesophageal or intravascular color-Doppler echocardiography. The sutures are then secured outside the heart apex. Multiple sutures may be implanted until a satisfactory result is obtained. The instrument is then withdrawn from the ventricular cavity and the wall incision is repaired by either a pre-positioned purse-string suture or by any kind of appropriate hemostatic device or technique. Emostasis is checked, appropriate chest drainage tubes are positioned and secured, and all incisions are closed.

CLAIMS

1. A method for repairing a heart valve, the steps comprising:

a) inserting an instrument through the subject's chest wall and into the chest cavity;

b) inserting the distal end of the instrument through a heart wall at the apex of the heart and entering a heart chamber;

c) grasping a leaflet on the heart valve with a device on the distal end of the instrument;

d) puncturing the leaflet with a needle disposed on the distal end of the instrument and drawing a suture through the puncture to connect the suture thereto;

e) anchoring the suture to another structure in the heart;

f) withdrawing the instrument from the heart chamber; and

g) withdrawing the instrument from the chest cavity.

2. The method as recited in claim 1 in which step e) includes withdrawing the suture with the instrument from the heart chamber as recited in step f) and anchoring the suture to the outer surface of the heart wall.

3. The method as recited in claim 2 in which the tension on the suture is adjusted before anchoring by observing the operation of the heart valve using a medical imaging system.

4. The method as recited in claim 1 which includes placing a purse-string suture in the heart wall around the apex location of the instrument insertion.

5. An instrument for repairing a heart valve the combination comprising:

a shaft for insertion through a chest wall and into a heart chamber;

a gripper mounted on the distal end of the shaft and being operable from the extrathoracic end of the shaft to grasp and hold a valve leaflet against the distal end of the shaft;

a needle mechanism mounted on the distal end of the shaft and being operable from the extrathoracic end of the shaft to penetrate through a grasped valve leaflet and draw a suture through the penetration; and

a suture deployment system which transports the suture to a position to be drawn through the penetrated valve leaflet by operation of the needle mechanism and which enables the suture to fasten to the valve leaflet when the instrument is withdrawn from the valve leaflet.

6. The instrument as recited in claim 5 which includes:

an illumination fiberoptic that extends through the shaft and terminates at the distal end of the shaft and that connects to a light source at the extrathoracic end of the shaft; and

a sensor fiberoptic that extends through the shaft and terminates at the distal end of the shaft and that connects to a monitor at the extrathoracic end of the shaft;

wherein the distal ends of the fiberoptics are positioned such that they apply light to and sense light reflected from the valve leaflet when the valve leaflet is grasped by the gripper.

7. The instrument as recited in claim 6 in which there are a plurality of illumination and sensor fiberoptics with their distal ends disposed around the needle mechanism.

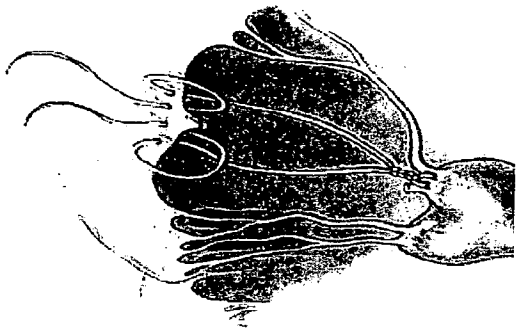


Figure 1:
Image of regurgitant mitral valve due to anterior leaflet prolapse secondary to a ruptured chorda. An artificial Gore-Tex chorda is being implanted between the papillary muscle and the prolapsing segment of the leaflet.

Figure 2

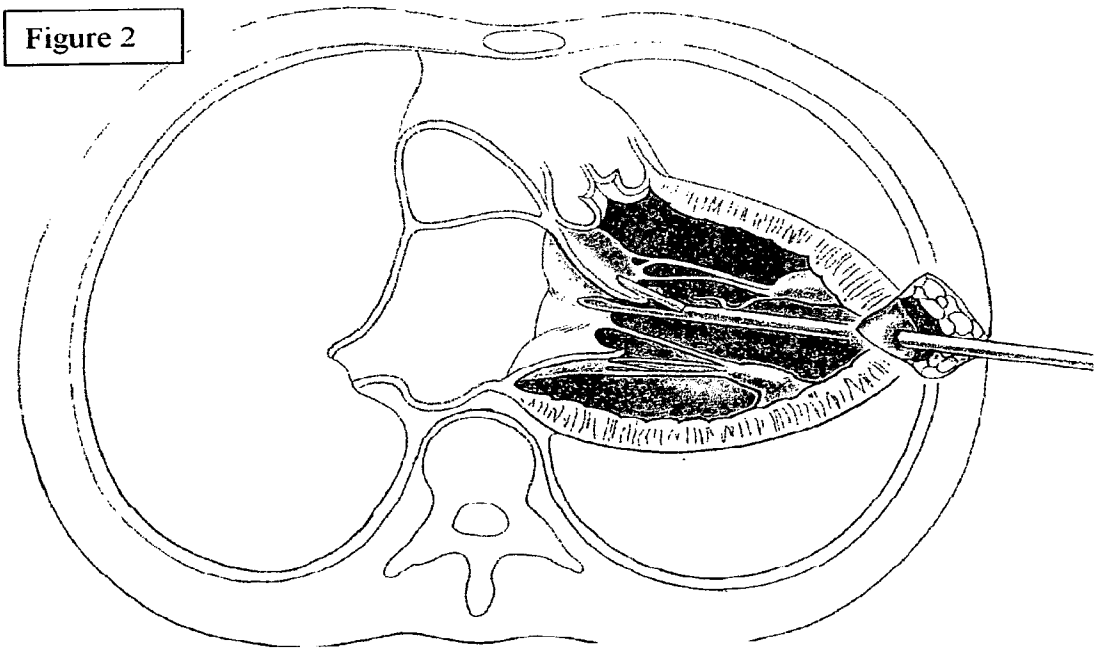


Figure 3

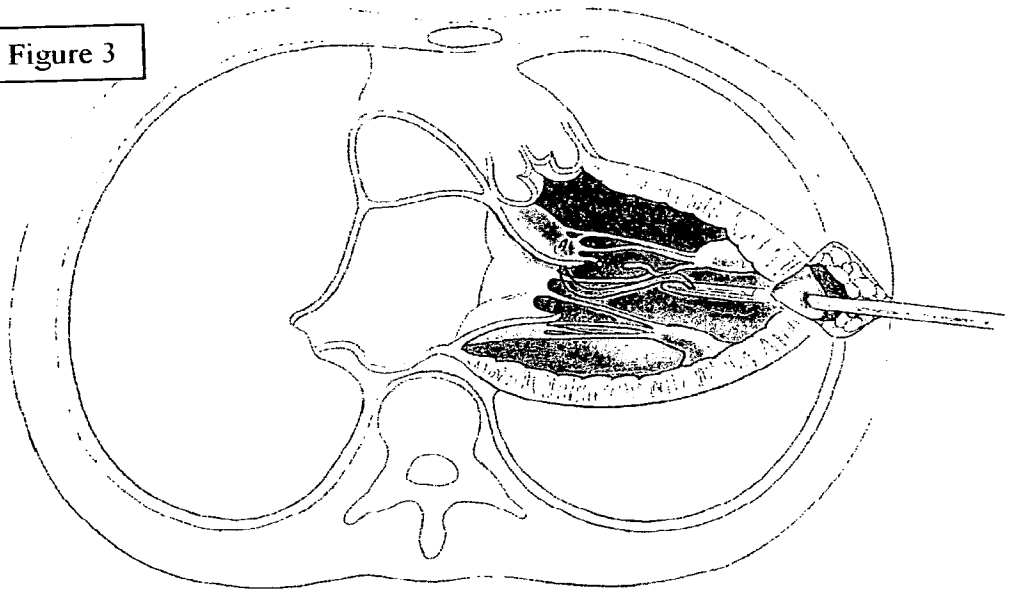


Figure 4

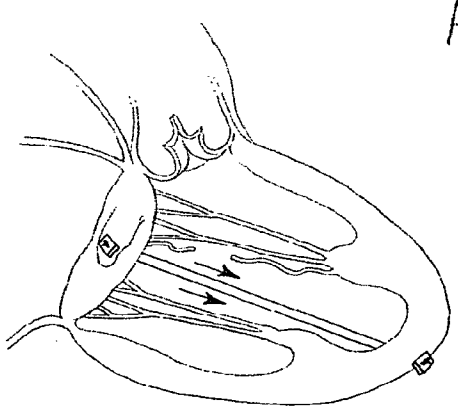


FIG. 5

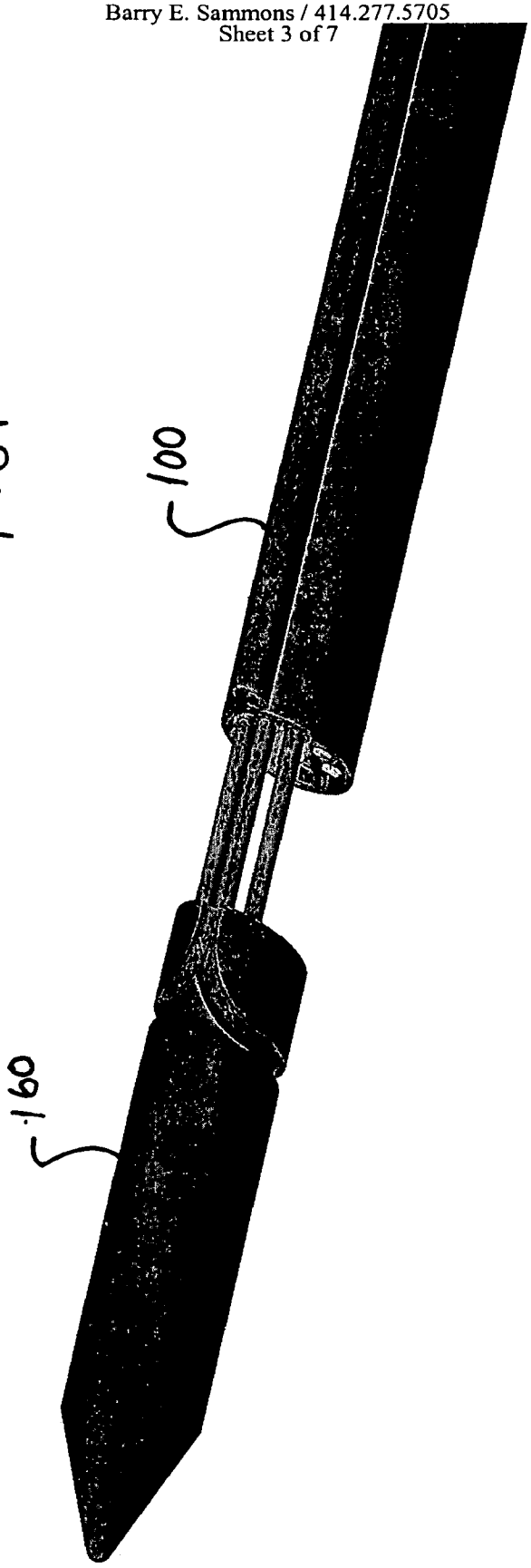


FIG. 5

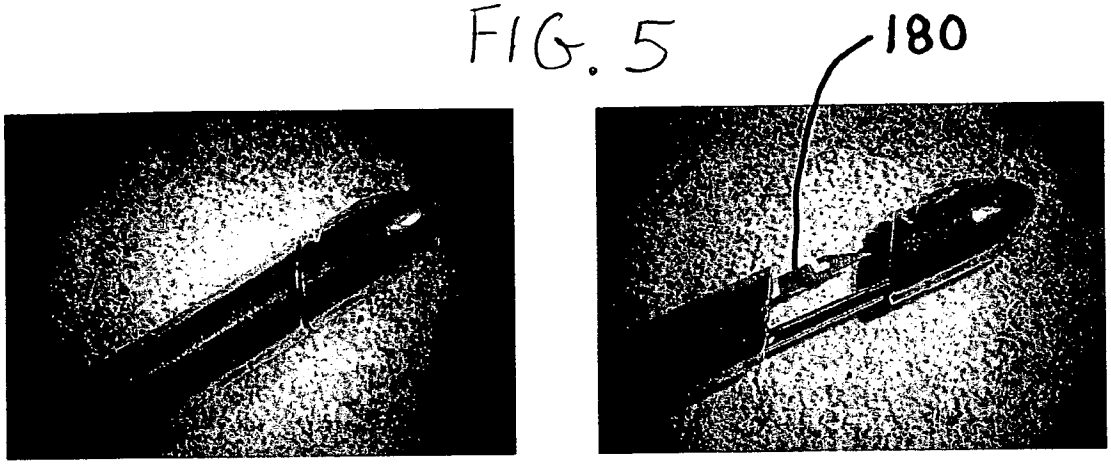


FIG. 7

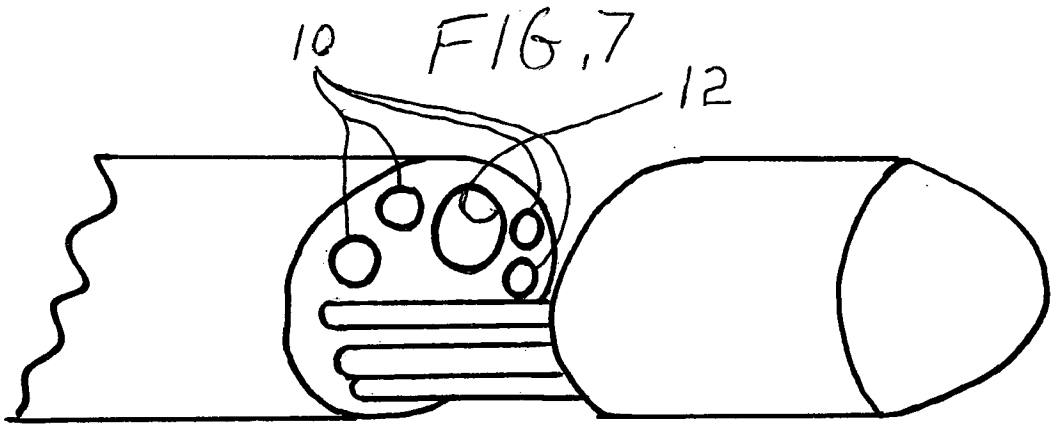


Fig. 6A

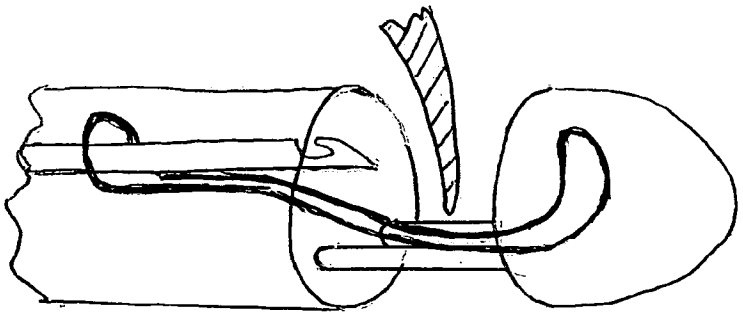


Fig. 6B

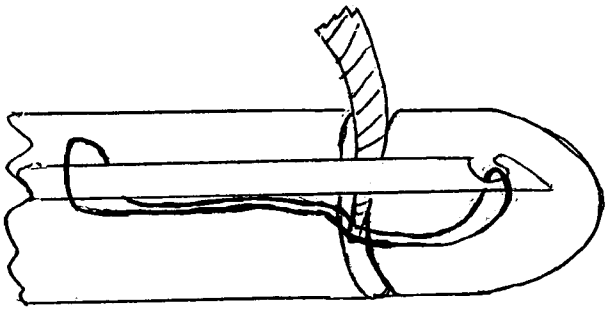


Fig. 6C

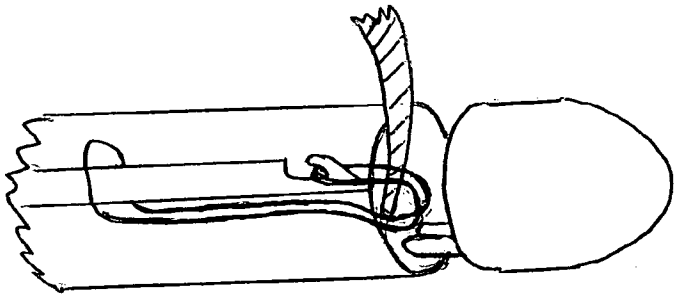


Fig. 6D

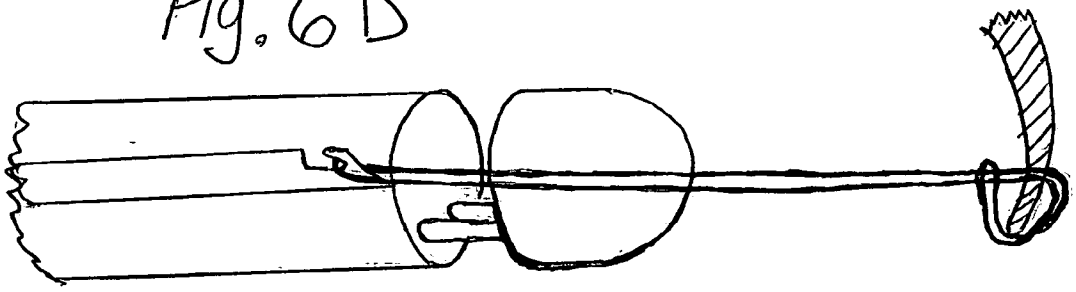


Fig. 8A

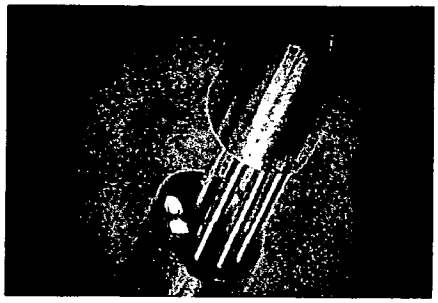


FIG. 8B

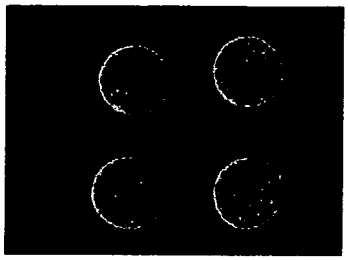
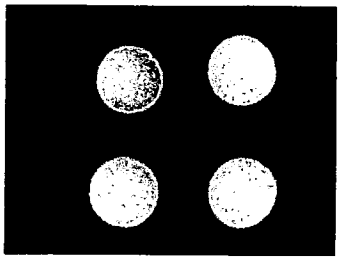


Fig. 8C



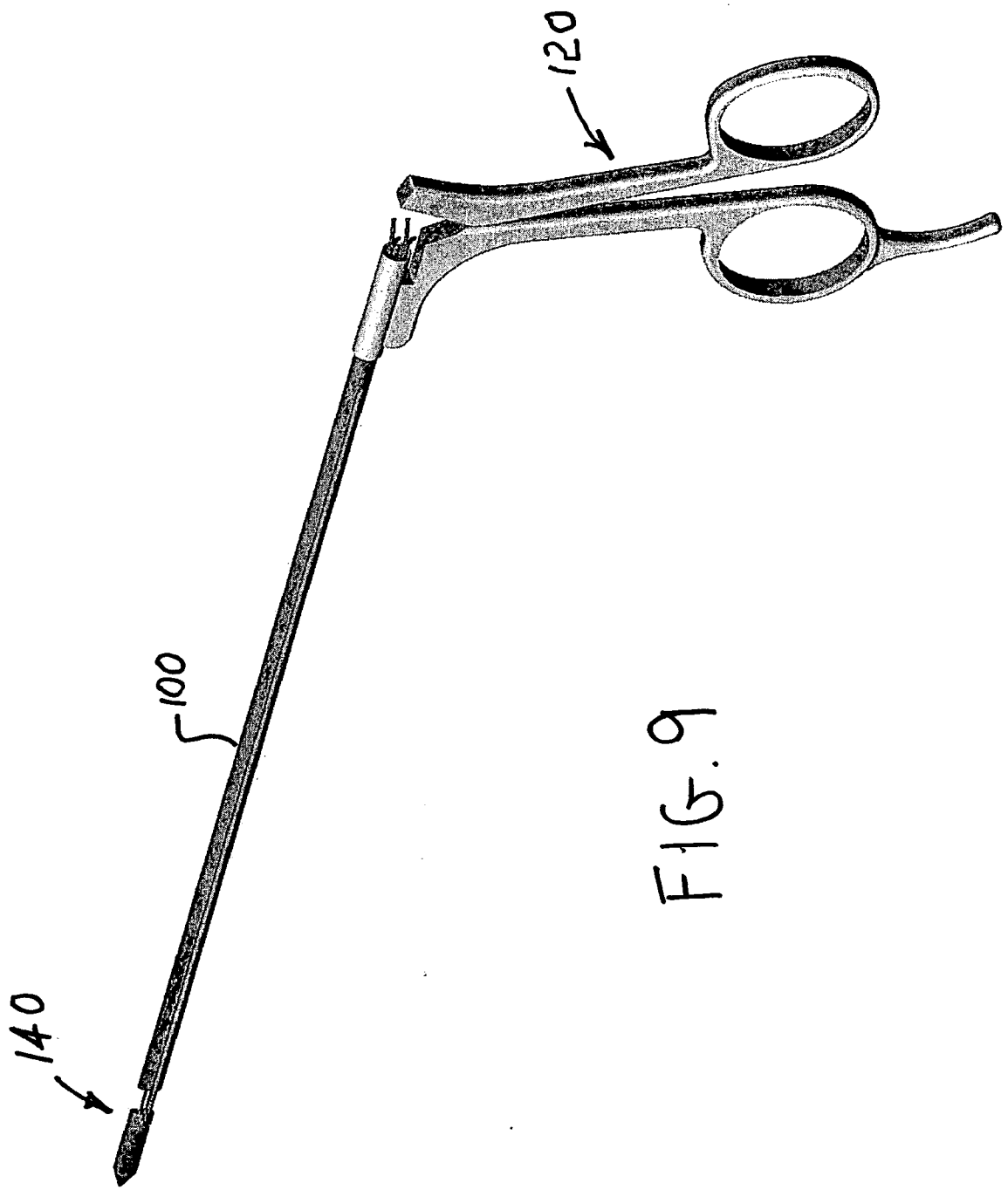


FIG. 9

Document code: WFEE

United States Patent and Trademark Office
Sales Receipt for Accounting Date: 02/28/2008

FSMITH ADJ #00000004 Mailroom Dt: 07/11/2007
Seq No: 7333 Sales Acctg Dt: 07/11/2007 170055 11813695
02 FC : 2641 50.00 CR

Document code: WFEE

United States Patent and Trademark Office
Sales Receipt for Accounting Date: 02/28/2008

FSMITH SALE #00000005 Mailroom Dt: 07/11/2007 170055 11813695
01 FC : 2632 250.00 DA

PATENT APPLICATION FEE DETERMINATION RECORD

Effective December 8, 2004

Application or Docket Number: 11/813695

CLAIMS AS FILED - PART I

SMALL ENTITY TYPE ☐ OR OTHER THAN SMALL ENTITY

	(Column 1)	(Column 2)	SMALL ENTITY RATE	SMALL ENTITY FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY FEE
U.S. NATIONAL STAGE FEES							
BASIC FEE	SMALL ENT. = $ 150	LARGE ENT. = $ 300	BASIC FEE	150	OR	BASIC FEE	
EXAMINATION FEE	Satisfies PCT Article 33(1)-(4) = $ 50 / $ 100	All other situations = $ 100 / $ 200	EXAM. FEE	100		EXAM. FEE	
SEARCH FEE	U.S. is ISA = $ 50 / $ 100 ALL other countries = $ 200 / $ 400	ALL other situations = $ 250 / $ 500	SEARCH FEE	250		SEARCH FEE	
FEE FOR EXTRA SPEC. PGS.	minus 100 =	/ 50 =	X $ 125 =			X $ 250 =	
TOTAL CHARGEABLE CLAIMS	17 minus 20 =	*	X $ 25 =		OR	X $ 50 =	
INDEPENDENT CLAIMS	2 minus 3 =	*	X $ 100 =		OR	X $ 200 =	
MULTIPLE DEPENDENT CLAIM PRESENT ☐			+ $ 180 =		OR	+ $ 360 =	
* If the difference in column 1 is less than zero, enter "0" in column 2			TOTAL		OR	TOTAL	

CLAIMS AS AMENDED - PART II

SMALL ENTITY OR OTHER THAN SMALL ENTITY

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
Total	*	Minus	**	=	X $ 25 =		OR	X $ 50 =	
Independent	*	Minus	***	=	X $ 100 =		OR	X $ 200 =	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐					+ $ 180 =		OR	+ $ 360 =	
					TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
Total	*	Minus	**	=	X $ 25 =		OR	X $ 50 =	
Independent	*	Minus	***	=	X $ 100 =		OR	X $ 200 =	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐					+ $ 180 =		OR	+ $ 360 =	
					TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than '20', enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than '3', enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

MULTIPLE DEPENDENT CLAIM FEE CALCULATION SHEET

(FOR USE WITH FORM PTO-875)

SERIAL NO.	FILING DATE
11/813695	
APPLICANT(S)	

CLAIMS

	AS FILED		AFTER 1st AMENDMENT		AFTER 2nd AMENDMENT	
	IND.	DEP.	IND.	DEP.	IND.	DEP.
1	1					
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TOTAL IND.	2	⬇		⬇		⬇
TOTAL DEP.	15	⬅		⬅		⬅
TOTAL CLAIMS	17					

	AS FILED		AFTER 1st AMENDMENT		AFTER 2nd AMENDMENT	
	IND.	DEP.	IND.	DEP.	IND.	DEP.
51						
52						
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TOTAL IND.		⬇		⬇		⬇
TOTAL DEP.		⬅		⬅		⬅
TOTAL CLAIMS						

DO/ EO WORKSHEET

Fred Smith, Patent Application Specialist/ National Stage Division

U.S. Appl. No. 11/813695 International Appl. No. PCT/US2006/001699

Application filed by : ☐ 20 months ☑ 30 months

WIPO PUBLICATION INFORMATION :

Publication No.: WO2006/078694 Publication Language : ☐ English ☐ German ☐ Japanese ☐ Chinese ☐ Korean ☐ French ☐ Spanish ☐ Russian ☐ Other : _____

Publication Date : 27 Jul 2006 Not Published : ☐ U.S. only designated ☐ EP request Published : ☐ EP request

INTERNATIONAL APPLICATION PAPERS IN THE APPLICATION FILE :

☑ International Application *(RECORD COPY)*

☐ Article 19 Amendments

☐ PCT/IPEA/409 IPER : ☐ EP ☐ JP ☐ SE ☐ AU ☐ US ☐ FR ☐ CN ☐ ES ☐ RU ☐ AT ☐ KR ☐ ___

☐ Annexes to 409

☐ PCT/ISA/237 : ☐ EP ☐ JP ☐ SE ☐ AU ☐ US ☐ FR ☐ CN ☐ ES ☐ RU ☐ AT ☐ KR ☐ ___

☐ PCT/IPEA/409 or PCT/ISA/237 was NOT AVAILABLE at the time of paralegal review

☐ PCT/IB/306

☐ Request form PCT/RO/101

☐ PCT/ISA/210 - Search Report : ☐ EP ☐ JP ☐ SE ☐ AU ☐ US ☐ FR ☐ CN ☐ ES ☐ RU ☐ AT ☐ KR ☐ ___ ☒ NONE

☐ Search Report References

☑ Priority Document (s) No. 1

☐ N/A

☐ Priority Document was NOT AVAILABLE at the time of paralegal review

☐ Other : _____

RECEIPTS FROM THE APPLICANT *(other than checked above) :*

☐ Basic National Fee *(or authorization to charge)*

☑ Description (9) ☑ Claims (3) ☑ Abstract (1)

☑ Drawing Figure(s) - (# of drwgs. 10)

☐ Translation of Article 19 Amendments ☐ entered ☐ not entered : ☐ not a page for page substitution ☐ replaced by Article 34 Amendment

☐ Annexes to 409 ☐ entered ☐ not entered : ☐ not a page for page substitution ☐ no translation ☐ other : _____

☐ Application Data Sheet

☐ Power of Attorney

☐ Change of Address

☑ Preliminary Amendment(s) Filed on : 1. ☑ same as 371 request date 2. _____ 3. _____

☐ Information Disclosure Statement(s) Filed on : 1. ☐ same as 371 request date 2. _____ 3. _____

☐ Assignment Document (forwarded to Assignment Branch)

☐ Assignee Statement Under 37 CFR 3.73(b)

☐ Assignee PG Publication Notice

☐ Substitute Specification Filed on : 1. ☐ same as 371 request date 2. _____ 3. _____

☐ Verified Small Status Statement

☑ Oath/ Declaration (executed)

☐ Oath/ Declaration ☐ unsigned ☐ no citizenship ☐ other

☐ DNA Diskette ☐ Sequence Listing

☐ Other : _____

NOTES : ☐ I.A. used as Specification ☐ Other :

35 U.S.C. 371 - Receipt of Request (PTO-1390)	mo. 7 / day 11 / yr. 2007
Date Acceptable Oath/ Declaration Received	☑ Same as 371 Req. Date; ☐ mo. / day / yr. 200
Date of Completion of requirements under 35 U.S.C. 371	☐ Same as 371 Req. Date; ☐ Same as OATH Date; ☐ mo. 7 / day 31 / yr. 2007
Date of Completion of DO/ EO 903 - Notification of Acceptance	
Date of Completion of DO/ EO 905 - Notification of Missing Requirements	
Date of Completion of DO/ EO 909 - Notification of Abandonment	
Date of Completion of DO/ EO 916 - Notification of Defective Response	
Date of Completion of DO/ EO 922 - Notification to Comply w/ Requirements for Patent Applications Containing Nucleotide and/or Amino Acid Sequence Disclosures	
Date of Completion of DO/ EO 923	

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/813,695	07/11/2007	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 07/11/2007	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 17	Minus	** 20	= 0	X $25 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $100 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/JACQUELINE E. COUPLIN/