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(71) Applicant *(for all designated States except US)*: MYOCOR, INC. [US/US]; Suite 200W–B, 1380 Energy Lane, St. Paul, MN 55108 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: SCHWEICH, Cyril, J., Jr. [US/US]; 1685 Hillcrest Avenue, St. Paul, MN 55116 (US). MORTIER, Todd, J. [US/US]; 3008 Colfax Avenue South, Minneapolis, MN 55408 (US). VIDLUND, Robert, M. [US/US]; 1811 Kennard Street, Maplewood, MN 55109 (US). KEITH, Peter, T. [US/US]; 1477 Grantham Street, St. Paul, MN 55108 (US). PAULSON, Thomas, M. [US/US]; 4322 York Avenue South, Minneapolis, MN 55410 (US).

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

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(54) Title: HEART WALL TENSION REDUCTION APPARATUS AND METHOD

(57) Abstract

An apparatus for treatment of a failing heart by reducing the wall tension therein. In one embodiment, the apparatus includes a tension member for drawing at least two walls of a heart chamber toward each other. Methods for placing the apparatus on the heart are also provided.

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HEART WALL TENSION REDUCTION APPARATUS AND METHOD

Cross Reference to Related Application

This application is a continuation-in-part of U.S. Application Serial No. 08/933,456, filed September 18, 1997, which in turn is a continuation-in-part of U.S. Application Serial No. 08/778,277, filed January 2, 1997. This application is related to U.S. Application Serial 09/123,977, filed on date even herewith and entitled "Transventricular Implant Tools and Devices" and U.S. Application Serial No. 09/124,321, filed on date even herewith and entitled "Stress Reduction Apparatus and Method," both of which are incorporated herein by reference.

Field of the Invention

The present invention pertains to the field of apparatus for treatment of a failing heart. In particular, the apparatus of the present invention is directed toward reducing the wall stress in the failing heart.

Background of the Invention

The syndrome of heart failure is a common course for the progression of many forms of heart disease. Heart failure may be considered to be the condition in which an abnormality of cardiac function is responsible for the inability of the heart to pump blood at a rate commensurate with the requirements of the metabolizing tissues, or can do so only at an abnormally elevated filling pressure. There are many specific disease processes that can lead to heart failure. Typically resulting in dilatation of the left

ventricular chamber. Etiologies that can lead to this form of failure include idiopathic cardiomyopathy, viral cardiomyopathy, and ischemic cardiomyopathy.

The process of ventricular dilatation is generally the result of chronic volume overload or specific damage to the myocardium. In a normal heart that is exposed to long term increased cardiac output requirements, for example, that of an athlete, there is an adaptive process of slight ventricular dilation and muscle myocyte hypertrophy. In this way, the heart fully compensates for the increased cardiac output requirements. With damage to the myocardium or chronic volume overload, however, there are increased requirements put on the contracting myocardium to such a level that this compensated state is never achieved and the heart continues to dilate.

The basic problem with a large dilated left ventricle is that there is a significant increase in wall tension and/or stress both during diastolic filling and during systolic contraction. In a normal heart, the adaptation of muscle hypertrophy (thickening) and ventricular dilatation maintain a fairly constant wall tension for systolic contraction. However, in a failing heart, the ongoing dilatation is greater than the hypertrophy and the result is a rising wall tension requirement for systolic contraction. This is felt to be an ongoing insult to the muscle myocyte resulting in further muscle damage. The increase in wall stress is also true for diastolic filling. Additionally, because of the lack of cardiac output, there is generally a rise in ventricular filling pressure from several physiologic mechanisms. Moreover, in diastole there is both a diameter increase and a pressure increase over normal, both contributing to higher wall stress levels. The increase in diastolic wall stress is felt to be the primary contributor to ongoing dilatation of the chamber.

Prior art treatments for heart failure fall into three generally categories. The first being pharmacological, for example, diuretics. The second being assist systems, for example, pumps. Finally, surgical treatments have been experimented with, which are described in more detail below.

With respect to pharmacological treatments, diuretics have been used to reduce the workload of the heart by reducing blood volume and preload. Clinically, preload is defined in several ways including left ventricular end diastolic pressure (LVEDP), or left ventricular end diastolic volume (LVEDV). Physiologically, the preferred definition is the length of stretch of the sarcomere at end diastole. Diuretics reduce extra cellular fluid which builds in congestive heart failure patients increasing preload conditions. Nitrates, arteriolar vasodilators, angiotensin converting enzyme inhibitors have been used to treat heart failure through the reduction of cardiac workload through the reduction of afterload. Afterload may be defined as the tension or stress required in the wall of the ventricle during ejection. Inotropes like digoxin are cardiac glycosides and function to increase cardiac output by increasing the force and speed of cardiac muscle contraction. These drug therapies offer some beneficial effects but do not stop the progression of the disease.

Assist devices include mechanical pumps. Mechanical pumps reduce the load on the heart by performing all or part of the pumping function normally done by the heart. Currently, mechanical pumps are used to sustain the patient while a donor heart for transplantation becomes available for the patient.

There are at least three surgical procedures for treatment of heart failure: 1) heart transplant; 2) dynamic cardiomyoplasty; and 3) the Batista partial left ventriculectomy. Heart transplantation has serious limitations including restricted availability of organs

and adverse effects of immunosuppressive therapies required following heart transplantation. Cardiomyoplasty includes wrapping the heart with skeletal muscle and electrically stimulating the muscle to contract synchronously with the heart in order to help the pumping function of the heart. The Batista partial left ventriculectomy includes surgically remodeling the left ventricle by removing a segment of the muscular wall. This procedure reduces the diameter of the dilated heart, which in turn reduces the loading of the heart. However, this extremely invasive procedure reduces muscle mass of the heart.

Summary of the Invention

The present invention pertains to a non-pharmacological, passive apparatus and method for the treatment of a failing heart. The device is configured to reduce the tension in the heart wall. It is believed to reverse, stop or slow the disease process of a failing heart as it reduces the energy consumption of the failing heart, decreases isovolumetric contraction, increases isotonic contraction (sarcomere shortening), which in turn increases stroke volume. The device reduces wall tension during diastole and systole.

Those apparatus of the present invention which reduce heart wall stress by changing chamber wall geometry can be referred to as "splints". Splints can be grouped as either "full cycle splints" which engage the heart to produce a chamber shape change throughout the cardiac cycle, or "restrictive splints" which do not engage the heart wall at end systole to produce a chamber shape change.

In one embodiment, the apparatus includes a tension member for drawing at least two walls of the heart chamber toward each other to reduce the radius or area of the heart chamber in at least one cross sectional plane. The tension member has anchoring members disposed at opposite ends for engagement with the heart or chamber wall.

In another embodiment, the apparatus includes a compression member for drawing at least two walls of a heart chamber toward each other. In one embodiment, the compression member includes a balloon. In another embodiment of the apparatus, a frame is provided for supporting the compression member.

Yet another embodiment of the invention includes a clamp having two ends biased toward one another for drawing at least two walls of a heart chamber toward each other. The clamp includes at least two ends having atraumatic anchoring member disposed thereon for engagement with the heart or chamber wall.

In yet another embodiment, a heart wall tension reduction apparatus is provided which includes a first tension member having two oppositely disposed ends and first and second elongate anchor members. A second tension member can be provided. One of the elongate anchors may be substituted for by two smaller anchors.

In an alternate embodiment of the heart wall tension reduction apparatus, an elongate compression member can be provided. First and second elongate lever members preferably extend from opposite ends of the compression member. A tension member extends between the first and second lever members.

The compression member of the above embodiment can be disposed exterior to, or internally of the heart. The tension member extends through the chamber or chambers to bias the lever members toward the heart.

In yet another embodiment of a heart wall tension reduction apparatus in accordance with the present invention, a rigid elongate frame member is provided. The frame member can extend through one or more chambers of the heart. One or more cantilever members can be disposed at opposite ends of the frame member. Each cantilever member includes at least one atraumatic pad disposed thereon. The atraumatic pads disposed at opposite ends of the frame member can be biased toward each other to compress the heart chamber.

One method of placing a heart wall tension apparatus or splint on a human heart includes the step of extending a hollow needle through at least one chamber of the heart such that each end of the needle is external to the chamber. A flexible leader is connected to a first end of a tension member. A second end of the tension member is connected to an atraumatic pad. The leader is advanced through the needle from one end of the needle to the other. The leader is further advanced until the second end of the tension member is proximate the heart and the first end of the tension member is external to the heart. A second atraumatic pad is connected to the first end of the tension member such that the first and second atraumatic pads engage the heart.

Yet another method of placing a heart wall tension apparatus on a heart includes the step of extending a needle having a flexible tension member releasably connected thereto through at least one chamber of the heart such that opposite ends of the tension member are external to the chamber and exposed on opposite sides of the chamber. The needle is removed from the tension member. Then first and second atraumatic pads are connected to the tension member at opposite ends of the tension member.

Brief Description of the Drawings

Figure 1 is a transverse cross-section of the left and right ventricles of a human heart showing the placement of a splint in accordance with the present invention;

Figure 2 is a transverse cross-section of the left and right ventricles of a human heart showing the placement of a balloon device in accordance with the present invention;

Figure 3 is a transverse cross-section of the left and right ventricles of a human heart showing the placement of an external compression frame structure in accordance with the present invention;

Figure 4 is a transverse cross-section of the left and right ventricles of a human heart showing a clamp in accordance with the present invention;

Figure 5 is a transverse cross-section of the left and right ventricles of a human heart showing a three tension member version of the splint of Figure 1;

Figure 6 is a transverse cross-section of the left and right ventricles of a human heart showing a two tension member version of the splint shown in Figure 1;

Figure 7 is a vertical cross-sectional view of the left ventricle of a human heart showing an alternate version of the splint in accordance with the present invention;

Figure 8 is an end of the splint shown in Figure 7;

Figure 9 is a vertical cross-sectional view of a chamber of a human heart showing another alternative embodiment of the splint in accordance with the present invention;

Figure 10 is a vertical cross-section of a chamber of a human heart showing another alternative configuration of splints in accordance with the present invention;

Figure 11 is a vertical cross-sectional view of a chamber of a human heart showing another embodiment of a splint in accordance with the present invention;

Figure 12 is a vertical cross-sectional view of a chamber of a human heart showing another embodiment of the splint in accordance with the present invention;

Figure 13 is a vertical cross-sectional view of a chamber of a human heart showing a compression member version of the splint in accordance with the present invention;

Figure 14 is a vertical cross-sectional view of a chamber of a human heart showing another version of the splint shown in Figure 13;

Figure 15 is a vertical cross-sectional view of a chamber of a human heart showing a frame member version of the splint in accordance with the present invention;

Figure 16 is an end view of the splint of Figure 15;

Figure 17 is a vertical cross-section of the left ventricle and atrium, the left ventricle having scar tissue;

Figure 18 is a vertical cross-section of the heart of Figure 17 showing the splint of Figure 1 drawing the scar tissue toward the opposite wall of the left ventricle;

Figure 19 is a vertical cross-section of the left ventricle and atrium of a human heart showing a version of the splint of Figure 1 having an elongate anchor bar;

Figure 20 is a side view of an undeployed hinged anchor member;

Figure 21 is a side view of a deployed hinged anchor member of Figure 10;

Figure 22 is a cross-sectional view of an captured ball anchor member;

Figure 23 is a perspective view of a cross bar anchor member;

Figure 24 is a cross sectional view of an alternate anchor pad;

Figure 25 is a cross sectional view of an alternate anchor pad;

Figure 26 is a perspective view of yet another alternate embodiment of an anchor pad including an anchor pad loosening device;

Figure 27 is a perspective view of a tension member clip;

Figure 28 is a cross sectional view of an alternate embodiment of a tension member clip;

Figure 29 is a cross sectional view of a heart including a tension member having a heat set end;

Figure 30 is a cross sectional view of the pad including an envelope;

Figure 31 shows the envelope of Figure 30;

Figure 32 is a side view of a multifilament twisted cable;

Figure 33 is a cross sectional of the cable of Figure 32;

Figure 34 is a side of a multifilament braided tension member;

Figure 35 is a schematic generally horizontal cross sectional view of the heart showing preferred tension member alignments;

Figure 36 is a idealized cylindrical model of a left ventricle of a human heart;

Figure 37 is a splinted model of the left ventricle of Figure 14;

Figure 38 is a transverse cross-sectional view of Figure 15 showing various modeling parameters;

Figure 39 is a transverse cross-section of the splinted left ventricle of Figure 15 showing a hypothetical force distribution; and

Figure 40 is a second transverse cross-sectional view of the model left ventricle of Figure 15 showing a hypothetical force distribution.

Detailed Description of the Invention

Referring now to the drawings wherein like reference numerals refer to like elements throughout the several views, Figure 1 shows a transverse cross-section of a left ventricle 10 and a right ventricle 12 of a human heart 14. Extending through the left ventricle is a splint 16 including a tension member 18 and oppositely disposed anchors 20. Splint 16 as shown in Figure 1 has been positioned to draw opposite walls of left ventricle 10 toward each other to reduce the "radius" of the left ventricular cross-section or the cross-sectional area thereof to reduce left ventricular wall stresses. It should be understood that although the splint 16 and the alternative devices disclosed herein are described in relation to the left ventricle of a human heart, these devices could also be used to reduce the radius or cross-sectional area of the other chambers of a human heart in transverse or vertical directions, or at an angle between the transverse and vertical.

Those apparatus of the present invention which reduce heart wall stress by changing chamber wall geometry can be referred to as "splints". "Full cycle splints" engage the heart to produce a chamber shape change throughout the cardiac cycle. "Restrictive splints" do not engage the heart wall at end systole to produce a chamber shape change.

Figure 2 discloses an alternate embodiment of the present invention, wherein a balloon 200 is deployed adjacent the left ventricle. The size and degree of inflation of the balloon can be varied to reduce the radius or cross-sectional area of left ventricle 10 of heart 14.

Figure 3 shows yet another alternative embodiment of the present invention deployed with respect to left ventricle 10 of human heart 14. Here a compression frame

structure 300 is engaged with heart 14 at atraumatic anchor pads 310. A compression member 312 having an atraumatic surface 314 presses against a wall of left ventricle 10 to reduce the radius or cross-sectional area thereof.

Figure 4 is a transverse cross-sectional view of human heart 14 showing yet another embodiment of the present invention. In this case a clamp 400 having atraumatic anchor pads 410 biased toward each other is shown disposed on a wall of left ventricle 10. Here the radius or cross-sectional area of left ventricle 10 is reduced by clamping off the portion of the wall between pads 410. Pads 410 can be biased toward each other and/or can be held together by a locking device.

Each of the various embodiments of the present invention disclosed in Figures 1-4 can be made from materials which can remain implanted in the human body indefinitely. Such biocompatible materials are well-known to those skilled in the art of clinical medical devices.

Figure 5 shows an alternate embodiment of the splint of Figure 1 referred to in Figure 5 by the numeral 116. The embodiment 116 shown in Figure 5 includes three tension members 118 as opposed to a single tension member 18 as shown in Figure 1. Figure 6 shows yet another embodiment of the splint 216 having four tension members 218. It is anticipated that in some patients, the disease process of the failing heart may be so advanced that three, four or more tension members may be desirable to reduce the heart wall stresses more substantially than possible with a single tension member as shown in Figure 1.

Figure 7 is a partial vertical cross-section of human heart 14 showing left ventricle 10. In Figure 7, another splint embodiment 316 is shown having a tension

member 318 extending through left ventricle 10. On opposite ends of tension member 318 are disposed elongate anchors or pads 320. Figure 8 is an end view of tension member 318 showing elongate anchor 320.

Figure 9 shows another embodiment of a splint 416 disposed in a partial vertical cross-section of human heart 14. Splint 416 includes two elongate anchors or pads 420 similar to those shown in Figures 7 and 8. In Figure 9, however, two tension members 418 extend through left ventricle 10 to interconnect anchors 420 on opposite sides of heart 14.

Figure 10 is a vertical cross section of heart 14 showing left ventricle 10. In this case, two splints 16 are disposed through left ventricle 10 and vertically spaced from each other to resemble the configuration of Figure 9.

Figure 11 is a vertical cross sectional view of the left ventricle of heart 14. Two alternate embodiment splints 516 are shown extending through left ventricle 10. Each splint 516 includes two tension members 518 interconnecting two anchors or pads 520.

Figure 12 is yet another vertical cross sectional view of left ventricle 10 of heart 14. An alternate embodiment 616 of the splint is shown extending through left ventricle 10. Splint 616 includes an elongate anchor pad 620 and two shorter anchors or pads 621. Splint 616 includes two tension members 618. Each tension member 618 extends between anchors 620 and respective anchors 621.

Figure 13 is a vertical cross sectional view of left ventricle 10 of heart 14. A splint 50 is shown disposed on heart 14. Splint 50 includes a compression member 52 shown extending through left ventricle 10. Opposite ends of compression member 52 are disposed exterior to left ventricle 10. Lever members 54 extend from each end of

compression member 52 upwardly along the exterior surface of ventricle 10. A tension member 56 extends between lever members 54 to bias lever members 54 toward heart 14 to compress chamber 10. Compression member 52 should be substantially rigid, but lever members 54 and to some degree compression member 52 should be flexible enough to allow tension member 56 to bias lever members 54 toward heart 14. Alternately, lever members 54 could be hinged to compression member 52 such that lever members 54 could pivot about the hinge when biased toward heart 14 by tension member 56.

Figure 14 shows an alternate embodiment 156 of the splint shown in Figure 13. In this case lever members 154 are longer than members 54 as compression member 152 of splint 150 has been disposed to the exterior of left ventricle 10.

Figure 15 is a vertical cross sectional view of left ventricle 10 of heart 14. An alternate embodiment 250 of the splint is shown on heart 14. A preferably relatively rigid frame member 256 extends through ventricle 10. Disposed on opposite ends of frame 256 are cantilever member 254. Disposed on cantilever members 254 are atraumatic pads 258. Cantilever members 254 can be positioned along frame member 256 such that atraumatic pads 258 press against heart 14 to compress chamber 10. Figure 16 is an end view of frame member 256 showing cantilever members 254 and pads 258.

It should be understood that each of the embodiments described above should be formed from suitable biocompatible materials known to those skilled in the art. The tension members can be formed from flexible or relatively more rigid material. The compression members and frame member should be formed from generally rigid material which may flex under load, but generally hold its shape.

Figure 17 is a partial vertical cross-section of human heart 14 showing left ventricle 10 and left atrium 22. As shown in Figure 7, heart 14 includes a region of scar tissue 24 associated with an aneurysm or ischemia. As shown in Figure 7, the scar tissue 24 increases the radius or cross-sectional area of left ventricle 10 in the region affected by the scar tissue. Such an increase in the radius or cross-sectional area of the left ventricle will result in greater wall stresses on the walls of the left ventricle.

Figure 18 is a vertical cross-sectional view of the heart 14 as shown in Figure 7, wherein a splint 16 has been placed to draw the scar tissue 24 toward an opposite wall of left ventricle 10. As a consequence of placing splint 16, the radius or cross-sectional area of the left ventricle affected by the scar tissue 24 is reduced. The reduction of this radius or cross-sectional area results in reduction in the wall stress in the left ventricular wall and thus improves heart pumping efficiency.

Figure 19 is a vertical cross-sectional view of left ventricle 10 and left atrium 22 of heart 14 in which a splint 16 has been placed. As shown in Figure 9, splint 16 includes an alternative anchor 26. The anchor 20 is preferably an elongate member having a length as shown in Figure 9 substantially greater than its width (not shown). Anchor bar 26 might be used to reduce the radius or cross-sectional area of the left ventricle in an instance where there is generalized enlargement of left ventricle 10 such as in idiopathic dilated cardiomyopathy. In such an instance, bar anchor 26 can distribute forces more widely than anchor 20.

Figures 20 and 21 are side views of a hinged anchor 28 which could be substituted for anchors 20 in undeployed and deployed positions respectively. Anchor 28 as shown in Figure 20 includes two legs similar to bar anchor 26. Hinged anchor 28

could include additional legs and the length of those legs could be varied to distribute the force over the surface of the heart wall. In addition there could be webbing between each of the legs to give anchor 28 an umbrella-like appearance. Preferably the webbing would be disposed on the surface of the legs which would be in contact with the heart wall.

Figure 22 is a cross-sectional view of a capture ball anchor 30. Capture ball anchor 30 can be used in place of anchor 20. Capture ball anchor 30 includes a disk portion 32 to distribute the force of the anchor on the heart wall, and a recess 34 for receiving a ball 36 affixed to an end of tension member 18. Disk 32 and recess 34 include a side groove which allows tension member 38 to be passed from an outside edge of disk 32 into recess 34. Ball 36 can then be advanced into recess 34 by drawing tension member 18 through an opening 38 in recess 34 opposite disk 32.

Figure 23 is a perspective view of a cross bar anchor 40. The cross bar anchor 40 can be used in place of anchors 20. The anchor 40 preferably includes a disk or pad portion 42 having a cross bar 44 extending over an opening 46 in pad 42. Tension member 18 can be extended through opening 46 and tied to cross bar 42 as shown.

Figure 24 is a cross sectional view of an alternate embodiment of anchor pad 340 in accordance with the present invention. Anchor pad 340 preferably includes a disc shaped pad portion 342. Disc shape pad portion 342 includes side 343, which in use is disposed toward the heart. A conical aperture 348 having sloping sides 346 extends through pad 342. Collet 344 is disposed within orifice 348. A threaded portion 350 of collet 344 extends from orifice 348 opposite side 343, nut 352 is threaded over threaded portion 350. Lumen 345 extends through collet 344. A tension member 354 is shown extending through lumen 345. Lumen 345 has a diameter such that when nut 352 is not

tightened on threaded portion 350, tension member 354 can slide freely through lumen 345. When nut 352 is tightened, it draws collet 344 away from side 343. Collet 344 is then pinched between walls 346 of orifice 348. When collet 344 is pinched, the size of lumen 345 is reduced such that tension member 354 can no longer move freely within lumen 345, fixing the position of pad 340 on tension member 354.

Figure 25 is a cross sectional view of an alternate embodiment an anchor pad 360 in accordance with the present invention. Anchor pad 360 includes a generally disc-shaped pad portion 362. Pad 362 includes a side 363 which when the pad is in use, is disposed toward the heart. A tension member lumen 364 extends through pad 362. Lumen 364 preferably has a generally conical shaped portion 365 disposed toward side 363. Tension member 370 is shown disposed through lumen 364 in Figure 25. Pad 362 includes a threaded passage 366 extending from an edge of pad 362 to lumen 364. A set screw 368 is threaded into passage 366. Set screw 368 can be tightened to engage tension member 370 to fix the position of anchor pad 360. When set screw 368 is not tightened, the size of lumen 364 is preferably large enough that anchor pad 360 can slide relatively freely over tension member 370.

Figure 26 is a perspective view of yet another embodiment of anchor pad 380 in accordance with the present invention. Anchor pad 380 preferably includes a generally disc-shaped pad portion 382 having a first side 383 which in use would be disposed toward the heart and a second side 385. Pad 382 as well as pads 342 and 362 are preferably formed from a metal such as stainless steel alloys or titanium alloys.

A tension member fastener 384 is formed in pad 382 by cutting a series of grooves and apertures through pad 382 from side 385 to side 383. A first groove 386 has

a generally horseshoe shape. Second groove 388 extends between opposite portions of horseshoe shaped groove 386 to form two oppositely disposed cantilever members 387. A relatively large aperture 394 is formed between cantilever members 387 proximate their free ends. A second and smaller aperture 390 is formed closer to the fixed ends of cantilever members 387. Tension member 392 is shown extending through aperture 390.

As shown in Figure 26, tension member 392 is clamped between cantilever members 387 such that the location of pad 382 is fixed along tension member 392. Pad 382 can be released by using a spreading device 396 to spread cantilever members 387 apart. Spreading device 396 includes handle 398 to spreading arms 400 each having a finger 402. Fingers 402 can be placed within aperture 394 then arms 400 and fingers 402 can be spread apart by pivoting them around a pin 404 such that cantilevers 387 are spread apart and pad 382 can move freely along tension member 392. It can be appreciated that although spreader 396 is shown extending transversely from tension member 392, it could also be configured such that fingers 402 do not curve transversely from arms 400 and thus spreader 396 could be disposed parallel to tension member 392. This would be particularly desirable in a situation where anchor pad 380 was being placed through a port or window during a less invasive splint implantation procedure. It can be appreciated that cantilever members 387 can be held apart such that pad 380 can be moved along tension member 392 by placement of a temporary wedge or pin in groove 388. For example, grooves 388 may include an additional small aperture disposed between aperture 390 and aperture 394 into which a pin could be placed to hold open members 387. When it is desired to fix the position of anchor pad 380 on tension member 392, device 396 could be used to spread cantilever members 387 to remove the

pin. The cantilever members could then be released to engage tension member 392. Aperture 390 of pad 380 can also include a conical portion disposed toward side 383 such as conical portion 365 of pad 360.

Cantilever arms 384 are preferably configured such that they do not stress tension member 392 beyond its elastic limit. It can also be appreciated that the force developed by cantilever members 387 impinging on tension member 392 is operator independent and defined by the geometry and material characteristics of members 387.

Figure 27 is a perspective view of an anchor pad 360 having a tension member 370 extending therethrough. After pad 360 is secured to tension member 370, that portion of tension member 370 which extends from the side of anchor pad 360 opposite side 363 is preferably removed. This can be accomplished by trimming tension member 370 with wire cutter 414 or scissors. Although anchor pad 360 is used here to illustrate trimming tension member 370, it can be appreciated that in each of the embodiments disclosed herein there may be an excess portion of tension member extending from an anchor, which is preferably removed or trimmed.

Figure 28 is a cross sectional view of an alternate embodiment 420 of a tension member cutter. Device 420 includes an elongate outer tube 422 having a distal end 424. Tube 424 defines a lumen 423 through which extends a second tube 430 having a distal end 428. Extending distally from distal end 428 are two cutting arms 424 and 426 which are shown partially withdrawn into lumen 423 and transversely restrained by distal end 424 of outer tube 422. When unrestrained by distal end 424, arms 424 and 426 are biased apart. Each arm 424 and 426 has a cutting element 425 and 427, respectively. Elements 425 and 427 are shown in contact with each other in Figure 28. A tension member 370

extends between arms 424 and through lumen 432 of inner tube 430. A representative anchor pad 360 is disposed adjacent elements 425 and 427. Device 420 of Figure 28 is particularly useful when trimming excess tension member using less invasive techniques as it can be readily advanced over a tension member through a port or window trocar.

Figure 29 is a vertical cross sectional view of left ventricle B of heart A. A transventricular splint 443 including a tension member 370 and anchor pads 360 are shown disposed on heart A. To the left of heart A as shown in the figure is a coiled portion 442 of tension member 470. As an alternative to trimming an excess length of tension member, tension member 370 could be formed from a shape memory alloy such that portion 442 could be preset to assume a coil shape when warmed to near body temperature.

Once the length of the tension member has been adjusted, the anchors are secured in place along the tension member and the excess length of tension member removed if desired, the anchor or anchor pads are preferably secured in place on the heart. The anchor or anchor pads are secured such that relatively movement between the anchors or anchor pads and the heart is limited to reduce abrasion of the heart wall. To secure the anchor or anchor pads to heart A, a biocompatible adhesive could be placed between the pad and the heart to adhere the pad to the heart. Alternately, apertures could be provided in the pad such that sutures could be extended through the apertures and into the heart to secure the pad. In addition to sutures, the pad could include threaded apertures into which anchor screws could be advanced through the pad and into the heart wall to secure the pad to the heart.

Figure 30 illustrates yet another alternative approach to securing the anchors or anchor pads to the heart surface. Figure 30 is a cross sectional view of an anchor pad 340 disposed on heart A. Anchor pad 340 is disposed within an envelope 446. Envelope 446 includes a bottom layer 447 disposed between anchor pad 340 and heart A and a top layer 448 disposed on the opposite side of anchor pad 340. Layers 347 and 340 are held together by sutures 449. Bottom layer 447 is preferably a mesh or expanded PTFE which has a pore size or intranodial dimension sufficient to promote tissue ingrowth. The pore size is preferably between about 10 and about 100 microns and more preferably, between about 20 and about 40 microns. With respect to expanded PTFE, the intranodial dimension is preferably between about 10 to about 100 microns and more preferably between about 20 to about 40 microns. The top material could also be expanded PTFE or the like having a pore size which preferably does not promote ingrowth and thus resists adhesion to surrounding tissue. As an alternative embodiment, the pores could be formed directly in the pad surface.

Envelope 446 would preferably be placed around pad 340 prior to placing pad 340 on tension member 354. A window 450 can be provided to provide access to nut 352 to secure pads to tension member 354. After tightening nut 352, window 450 can be closed by suture 452. Figure 31 is a top view of pad 340 and envelope 446 of Figure 30. It can be appreciated that a similar envelope can be placed around the various anchor pads disclosed herein. The location of the window may have to vary, however, to provide access to the respective means for securing the anchor pads to the tension member.

The splints of the present invention can be implanted acutely or chronically. When the splints are implanted chronically, it is particularly important that the tension member or members be highly fatigue resistant. Typical materials for the tension member can include, among other biocompatible materials, stainless steel, titanium alloys, NiTi alloys such as Nitinol or elgiloy. In a preferred embodiment, the tension member is a wire having a diameter of between 0.005 to 0.035 inches in diameter or, more preferably, between 0.01 and 0.02 inches in diameter and, most preferably, about 0.014 inches in diameter. The length of the tension member between the pads is preferably about 0.6 to 4 inches, and more preferably, between about 1 to 3 inches and, most preferably, about 2 inches. To improve the fatigue resistance of the metallic tension members, their surface can be electro-polished, buffed or shot peened. Drawing or annealing of the metal will also improve fatigue resistance.

The tension member, in a preferred embodiment, articulates with respect to the anchor pad to reduce bending of the tension member at the pad. This can be accomplished by a ball and socket joint shown in Figure 22, for example. The tension member itself can be made more flexible or bendable by providing a multi-filament tension member such as a braided or twisted wire cable tension member. A multifiber filament structure of numerous smaller wires can then easily, while reducing the stress level on any individual wire as compared to a solid wire of the same diameter as the multifilament bundle. Such a multi-filament tension member can be made from biocompatible materials such as, but not limited to, stainless steel, Nitinol, titanium alloys, LCP (liquid crystal polymer), Spectra™ fiber, kevlar fiber, or carbon fiber. In a preferred embodiment, the multi-filament structure is coated or covered to substantially

seal the multi-filament structure. Coatings such as silicone, urethane or PTFE are preferred.

Figure 32 is a side view of multifilament twisted cable 400. Cable 400 includes a plurality of wires or filaments 402 twisted about the longitudinal axis of cable 400. Figure 33 is a transverse cross sectional view of cable 400. In Figure 33, cable 400 includes a surrounding coating 404 not shown in Figure 32.

Figure 34 is a side view of a braided multifilament tension member 410. Tension member 410 includes a plurality of filaments or wires 412. It can be appreciated that numerous braiding patterns are known to those skilled in the art of multifilament members. It is anticipated that in a preferred embodiment, braided member 410 can have an optional core of fibers running parallel to an elongate axis of tension member 410. In yet another preferred embodiment, tension member 410 could have a solid wire core extending parallel to and along the longitudinal axis of tension member 410.

The tension members and anchors or anchor pads are preferably bio-resistant, i.e., resistant to physiologic attack. To improve bio-resistance, tension member and/or anchors or anchor pads can be coated with carbon material such as glass, pyrolytic carbon, diamond or graphite, zirconium nitrate or oxide. Roughened or porous urethanes, silicone or polymer coatings or sheaths can be used to promote tissue ingrowth to create a biological seal. Hydrophilic and albumin coatings can also be used. Drugs incorporated into a binder coating can also be used to reduce biological attack on the splint and irritation of tissue by the splint. Such drugs include heparin, coumadin, anti-inflammatory steroid or ASA-aspirin. The oxide layer of the underlying metal could also be optimized to improve bio-resistance. This is particularly true for stainless steel,

titanium, or nickel titanium on which an oxide layer can be formed by heating the component to improve biocompatibility. Further coatings include calcium hydroxy appetite, beta tricalcium phosphate and aluminum oxide can be applied to the tension member. The tension member and/or pad or anchor pad can at least be, in part, formed from titanium to enhance electronegativity.

The anchors or anchor pads and, particularly the tension members are biocompatible, preferably antithrombogenic and made to prevent hemolysis. The coatings used to enhance bio-resistance described above can generally be used to improve biocompatibility. Since the tension member is exposed to significant blood flows through the left ventricle, in a preferred embodiment, the tension member has a generally small size and shape elliptical cross sectional shape to reduce turbulence or drag over the tension member. If such elliptical, transverse cross section tension member were used, it can be appreciated that the narrow end would be preferably oriented toward the direction of blood flow. It is also desirable to select a tension member material and shape which would not vibrate at resonant frequency under the influence of blood flow.

Where the tension member passes through the heart wall, various approaches can be taken to reduce or prevent bleeding. For example, the surface of the anchor or anchor pad and/or tension member in contact with the heart wall can be coated or include an ingrowth inducing covering such as collagen, dacron, expanded PTFE or a roughened/porous surface. A clotting inducing substance may also be bound to the tension member and/or anchor or anchor pads, such as avitene or collagen. It is also contemplated that the portion of the heart wall where the tension member passes through could be cauterized. In a preferred embodiment, the tissue can be cauterized by heating

the tension member. A glue such as cyanoacrylate can also be disposed between the tension member and the heart wall to reduce or prevent bleeding from the heart wall. Mechanical means such as an O-ring or compression fitting could also be disposed between the heart wall and the tension member to reduce bleeding. A purse string suture can be placed on the heart, around the tension member adjacent the pad as well.

The tension member is preferably flexible enough to allow for changing interface conditions between the heart and the splint, and alternating pad orientation throughout the cardiac cycle. The flexibility should be sufficient enough to avoid injury to the heart or bleeding. It is also preferable that if the heart were to contract sufficiently enough to put the tension member in compression that it would readily buckle. Buckling could be promoted by providing a ribbon shaped tension member, chain link tension member, thin wire tension member, bent tension member or multi-filament tension.

The tension member is preferably radiopaque, echo cardiographic compatible, or MRI compatible or includes a marker which is radiopaque, echo compatible, or MRI compatible. The preferred locations for markers would include the center of the tension member and at the ends of the tension member disposed at the heart walls. The radiopaque markers could be gold or platinum or other biocompatible metal or heavy metal filled polymeric sleeves. With respect to echo compatible or MRI compatible tension members or markers, the tension or marker are preferably non-interfering or visible. Having radiopaque echo compatible or MRI compatible tension members or markers is particularly desirable for follow-up, non-invasive monitoring of the tension member after implantation. The presence of the tension member can be visualized and

the distance between two or more markers measured. Integrity of the tension member can be confirmed as well.

In a preferred embodiment, the tension member is not conductive to the action potential of muscle. This can be accomplished by insulating the tension member, anchor and/or anchor pad interface or fabricating the tension member anchor and/or anchor pad from a non-conductive metal such as titanium.

In addition to monitoring the performance of the tension member by visualization techniques such as fluoroscopy or echo imagery, sensors can advantageously be incorporated into the splints. For example, a strain gauge can be disposed on a tension member to monitor the loading on the member in use. Strain can be related to load as known to those skilled in the art by developing a stress/strain relationship for a given tension member. The strain gauge can be connected by a biocompatible lead to a conventional monitoring device. A pressure gauge formed from, for example, piezo electric material can also be disposed on the tension member to monitor filling pressures or muscle contractility.

In a preferred embodiment, a tension member can be slidably enclosed within a tube. If the tension member were to fail, the tube would contain the tension member therein.

It is anticipated that the tension member could be connected to a pacing lead. In such an instance, if the tension member were conductive, pacing signals could be conveyed along the tension member from one heart wall to another.

In use, the various embodiments of the present invention are placed in or adjacent the human heart to reduce the radius or cross-section area of at least one chamber of the

heart. This is done to reduce wall stress or tension in the heart or chamber wall to slow, stop or reverse failure of the heart. In the case of the splint 16 shown in Figure 1, a cannula can be used to pierce both walls of the heart and one end of the splint can be advanced through the cannula from one side of the heart to the opposite side where an anchor can be affixed or deployed. Likewise, an anchor is affixed or deployed at the opposite end of splint 16. Additional methods for splint placement are described in more detail in U.S. Application Serial No. 09/123,977, filed on date even herewith and entitled "Transventricular Implant Tools and Devices" and incorporated herein by reference.

It can be appreciated that the methods described above to advance the tension members through the ventricles can be repeated to advance the desired number of tension members through the ventricle for a particular configuration. The length of the tension members can be determined based upon the size and condition of the patient's heart. It should also be noted that although the left ventricle has been referred to here for illustrative purposes, that the apparatus and methods of this invention can also be used to splint multiple chambers of a patient's heart as well as the right ventricle or either atrium.

Figure 35 is a schematic view of generally horizontal cross section of heart A including left ventricle B and right ventricle C. Also shown are left anterior descending artery E, posterior descending artery F, obtuse marginal artery G, postero-medial papillary muscle H and antero-lateral papillary muscle I. Shown in Figure 35 are three generally horizontal preferred alignments for tension member placement for the splints of the present invention. These alignments generally met three goals of splint positioning including good bisection of the left ventricle, avoidance of major coronary vessels and

avoidance of valve apparatus including chordae leaflets and papillary muscles. Alignment 420 can be referred to as the anterior/posterior (AP) position. Alignment 422 can be referred as the posterior septal/lateral wall (PSL) position. Alignment 424 can be referred to as the anterior septal/lateral wall (ASL) position.

It can be appreciated that the alignments shown illustrative only and that the alignments may be shifted or rotated about a vertical axis generally disposed through the left ventricle and still avoid the major coronary vessels and papillary muscles. When the alignment passes through a substantial portion of right ventricle C, it may be desirable to dispose not only two pads on the exterior of the heart at opposite ends of a tension member, but also a third pad within right ventricle C on septum J. The spacing between the third pad and the pad disposed outside the heart proximate left ventricle B preferably defines the shape change of left ventricle B. This will allow the spacing of the third pad relative to the pad disposed outside the heart proximate right ventricle C to define a shape change if any of right ventricle C in view of the spacing between those pads. With the alignments as shown in Figure 35, the third pad will be unnecessary. It is likely, however, that with alignments 422 and 424 in order to achieve the desired shape change of left ventricle B, the exterior pad of the wall proximate the right ventricle C will be drawn into contact with septum J. This will consequently somewhat reduce the volume of right ventricle C.

Figure 36 is a view of a cylinder or idealized heart chamber 48 which is used to illustrate the reduction of wall stress in a heart chamber as a result of deployment of the splint in accordance with the present invention. The model used herein and the calculations related to this model are intended merely to illustrate the mechanism by

which wall stress is reduced in the heart chamber. No effort is made herein to quantify the actual reduction which would be realized in any particular in vivo application.

Figure 37 is a view of the idealized heart chamber 48 of Figure 36 wherein the chamber has been splinted along its length L such that a "figure eight" cross-section has been formed along the length thereof. It should be noted that the perimeter of the circular transverse cross-section of the chamber in Figure 36 is equal to the perimeter of the figure eight transverse cross-section of Figure 37. For purposes of this model, opposite lobes of the figure in cross-section are assumed to be mirror images.

Figure 38 shows various parameters of the Figure 1 cross-section of the splinted idealized heart chamber of Figure 37. Where l is the length of the splint between opposite walls of the chamber, R_2 is the radius of each lobe, θ is the angle between the two radii of one lobe which extends to opposite ends of the portion of the splint within chamber 48 and h is the height of the triangle formed by the two radii and the portion of the splint within the chamber 48 (R_1 is the radius of the cylinder of Figure 36). These various parameters are related as follows:

$$h = R_2 \, COS \, (\theta/2)$$

$$l = 2 \, R_2 \, SIN \, (\theta/2)$$

$$R_2 = R_1 \pi / (2\pi - \theta)$$

From these relationships, the area of the figure eight cross-section can be calculated by:

$$A_2 = 2\pi(R_2)^2 \, (1-\theta/2\pi) + hl$$

Where chamber 48 is unsplinted as shown in Figure 36 A_1, the original cross-sectional area of the cylinder is equal to A_2 where $\theta = 180°$, $h = 0$ and $l = 2R_2$. Volume equals A_2 times length L and circumferential wall tension equals pressure within the chamber times R_2 times the length L of the chamber.

Thus, for example, with an original cylindrical radius of four centimeters and a pressure within the chamber of 140 mm of mercury, the wall tension T in the walls of the cylinder is 104.4 newtons. When a 3.84 cm splint is placed as shown in Figures 37 and 38 such that $l = 3.84$ cm, the wall tension T is 77.33 newtons.

Figures 39 and 40 show a hypothetical distribution of wall tension T and pressure P for the figure eight cross-section. As θ goes from 180° to 0°, tension T_s in the splint goes from 0 to a 2T load where the chamber walls carry a T load.

In yet another example, assuming that the chamber length L is a constant 10 cm, the original radius R_1 is 4 cm, at a 140 mmHg the tension in the walls is 74.7 N. If a 4.5 cm splint is placed such that $l = 4.5$ cm, the wall tension will then be 52.8 N.

When a splint is actually placed on the heart, along an alignment such as those shown in Figure 35, the length l between the two pads as measured along the tension member is preferably 0.4 to about 0.8 and more preferably between about 0.5 to about 0.7 and most preferably about 0.6 times the distance along the length of the tension member at end diastole if the pads were not secured to the tension member and provided no resistance to expansion of the heart. A more detailed discussion of tension member length can be found in U.S. Application Serial No. 09/123,977, filed on date even

herewith and entitled "Transventricular Implant Tools and Devices" which is incorporated herein by reference.

It will be understood that this disclosure, in many respects, is only illustrative. Changes may be made in details, particularly in matters of shape, size, material, and arrangement of parts without exceeding the scope of the invention. Accordingly, the scope of the invention is as defined in the language of the appended claims.

What is claimed is:

1. A transventricular splint, comprising:

an elongate tension member having two axially disposed ends; and

substantially atraumatic anchors disposed at each end, such that the length of the tension member between the anchors is about 1 to 4 inches.

2. The transventricular splint in accordance with claim 1, wherein the tension member comprises a multi-filament elongate member.

3. The transventricular splint in accordance with claim 1, wherein the tension member is substantially radiopaque.

4. The transventricular splint in accordance with claim 1, further comprising a radiopaque marker disposed on the tension member.

5. The transventricular splint in accordance with claim 1, wherein the tension member is echo cardiograph.

6. The transventricular splint in accordance with claim 1, further comprising an echogenic marker disposed on the tension member.

7. The transventricular splint in accordance with claim 1, wherein the tension member has a substantially antithrombogenic surface.

8. The transventricular splint in accordance with claim 7, wherein the tension member has a substantially antithrombogenic coating.

9. The transventricular splint in accordance with claim 1, wherein the tension member has a length of between about 0.6 and 2.0 inches.

10. The transventricular splint in accordance with claim 1, wherein the tension member has a diameter of between about 0.01 and 0.02 inches.

FIG. 1

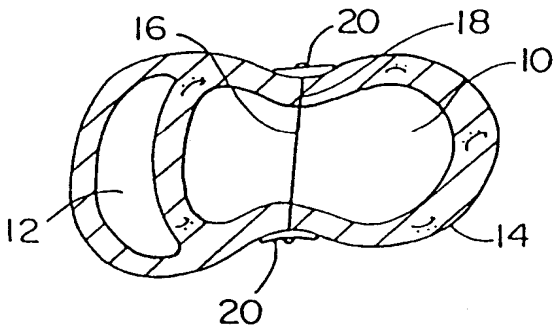


FIG. 2

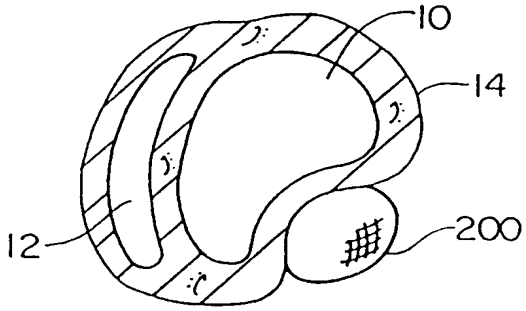


FIG. 3

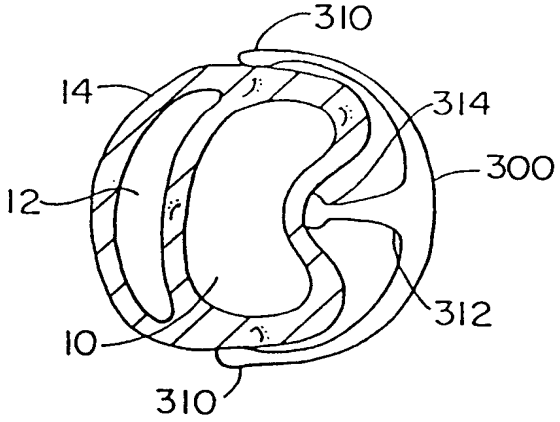


FIG. 4

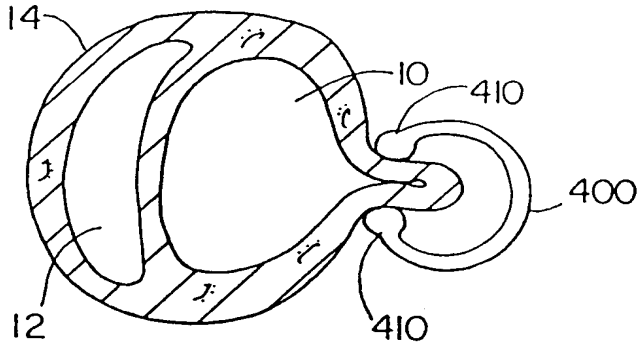


FIG. 5

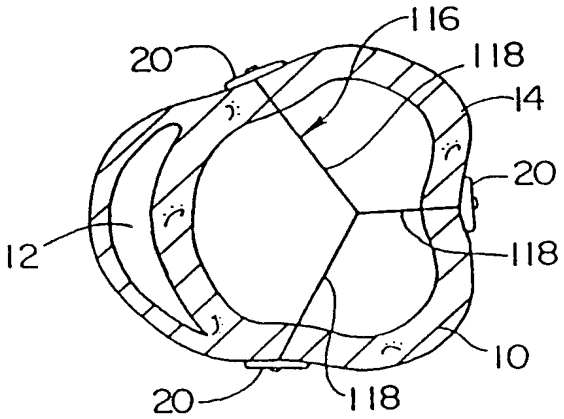


FIG. 6

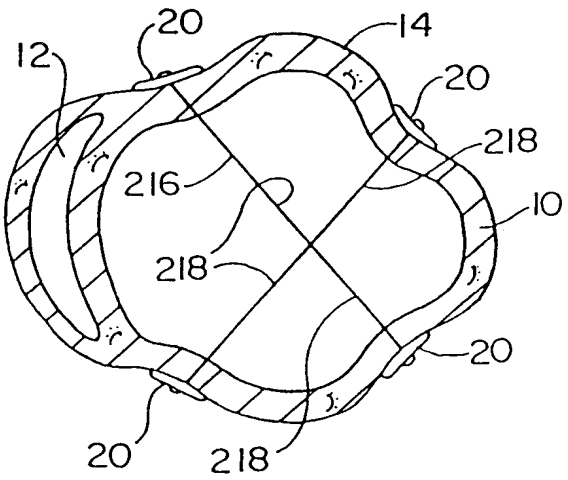


FIG. 8

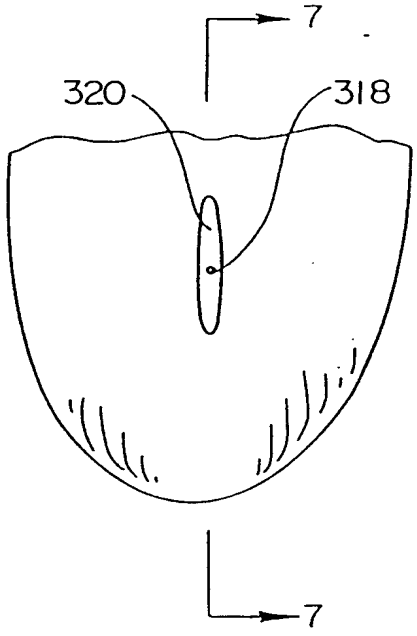


FIG. 7

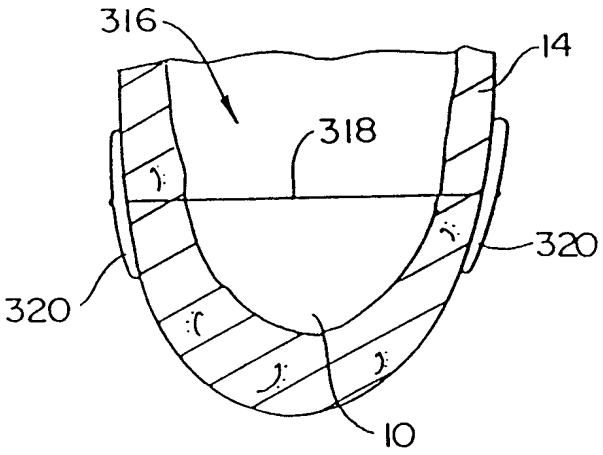


FIG. 9

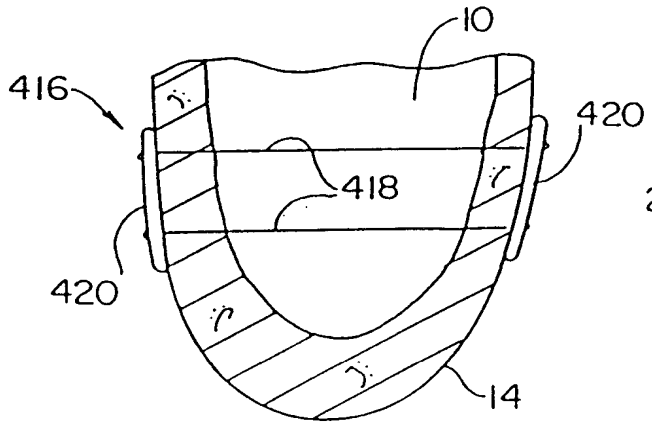


FIG. 10

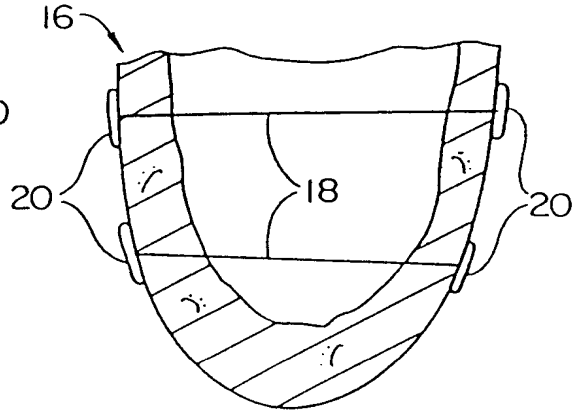


FIG. 11

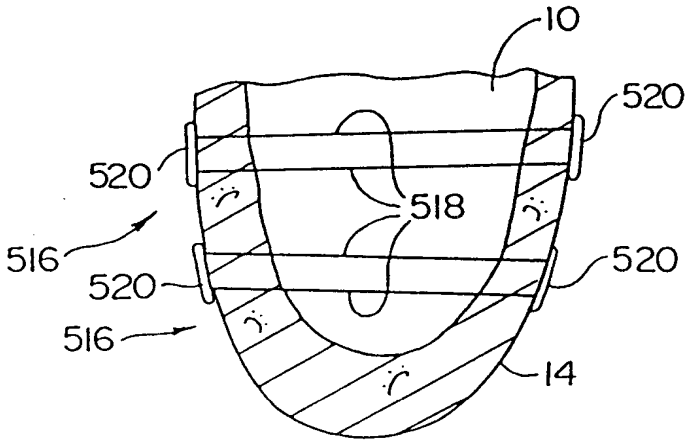


FIG. 12

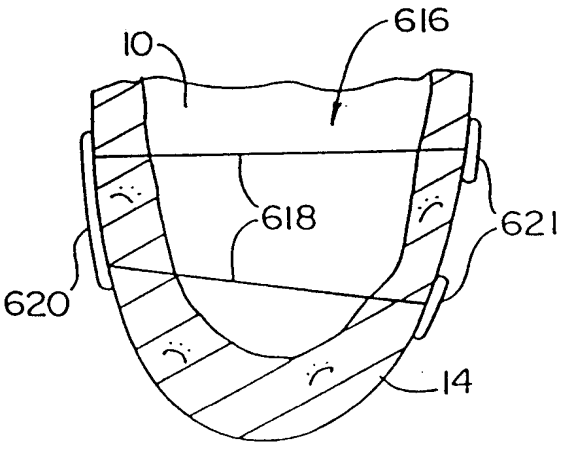


FIG. 13

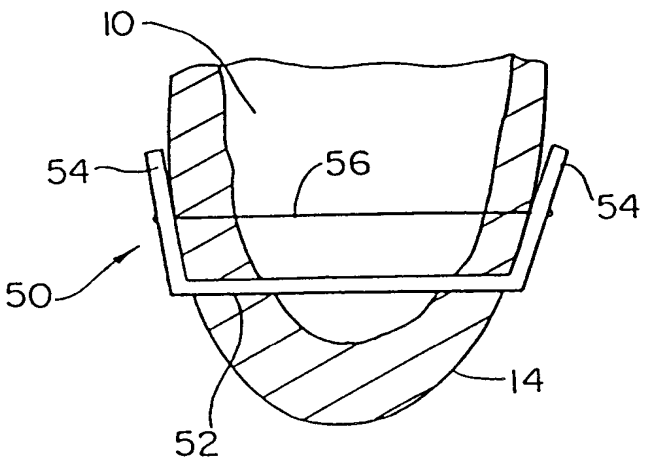


FIG. 14

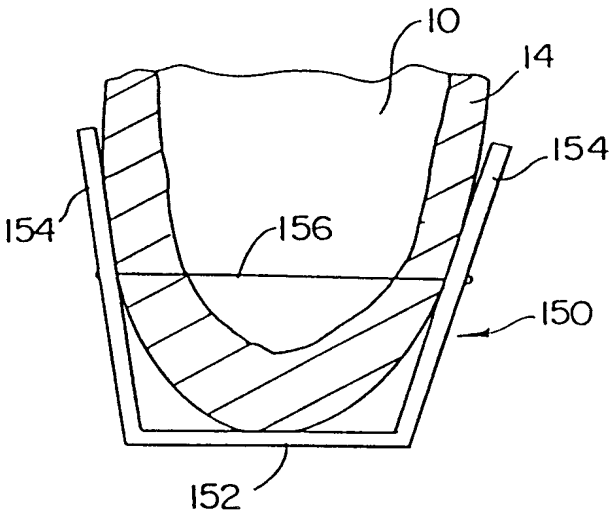


FIG. 15

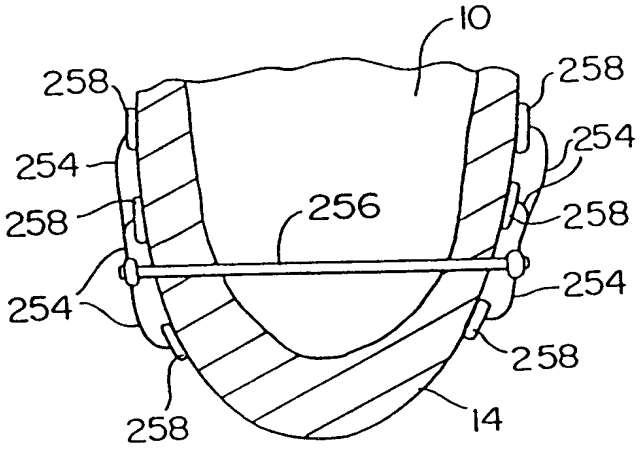


FIG. 16

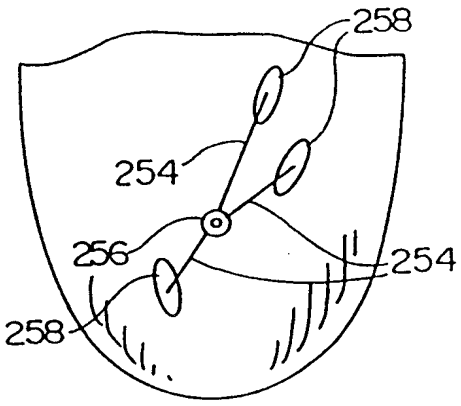


FIG. 17

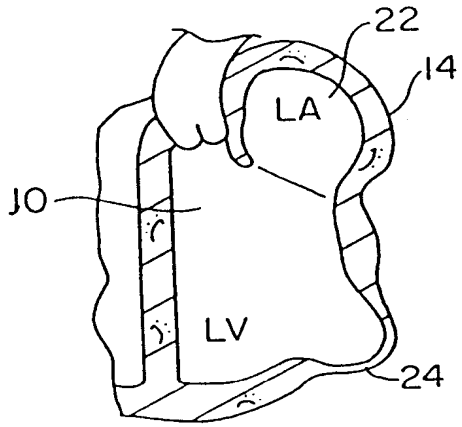


FIG. 18

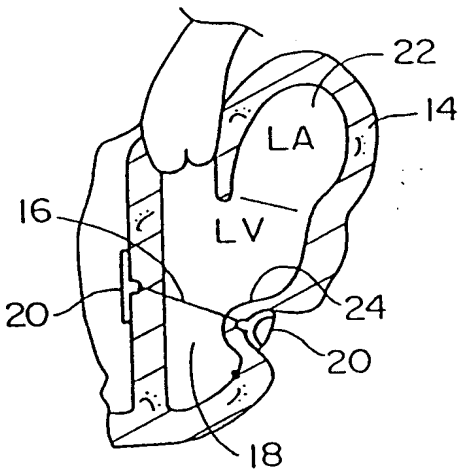


FIG. 19

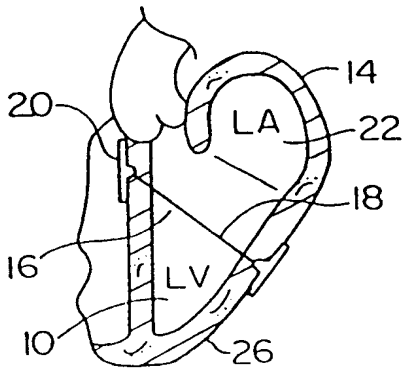


FIG. 20

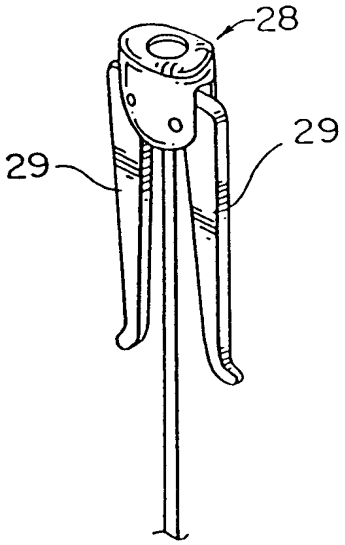


FIG. 21

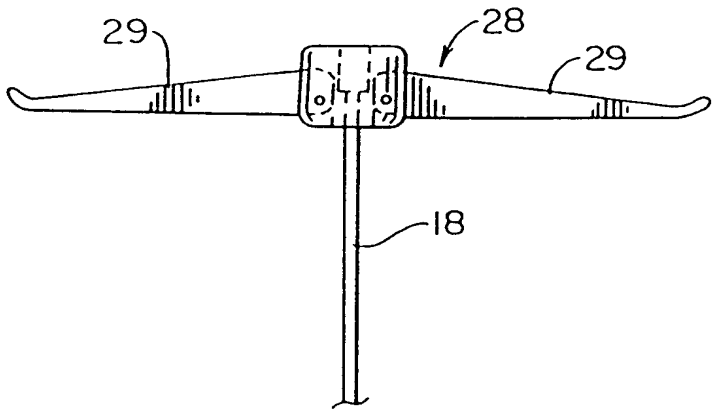


FIG. 22

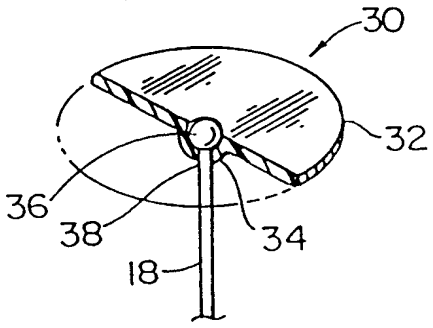
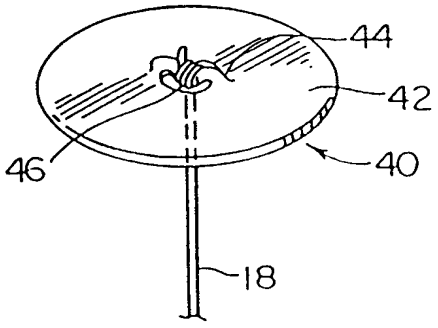


FIG. 23



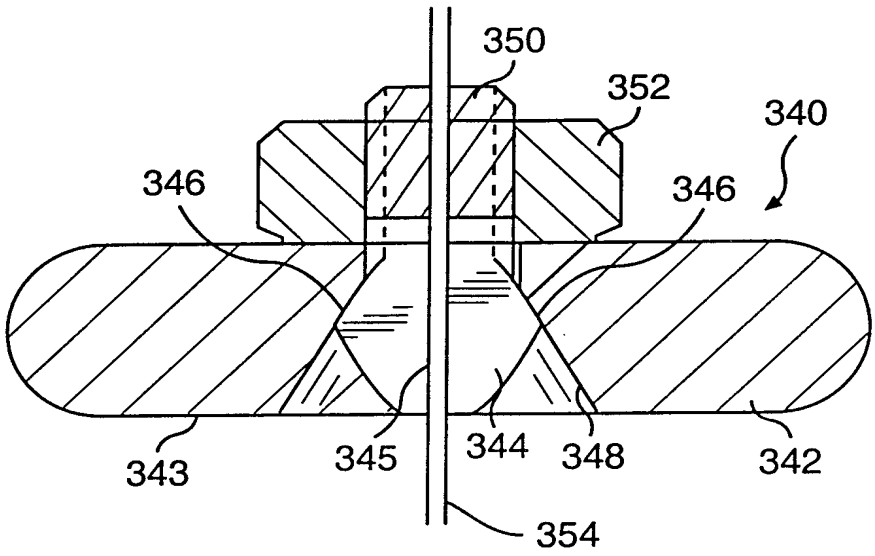

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FIG. 24

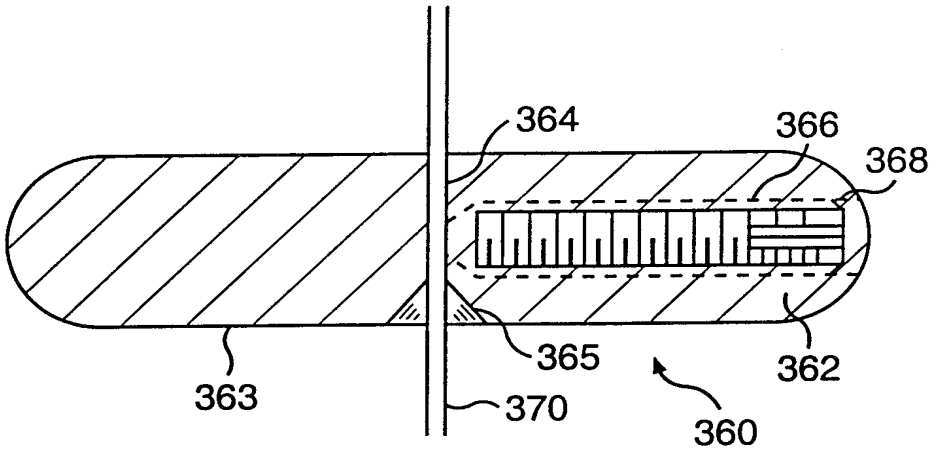
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FIG. 25

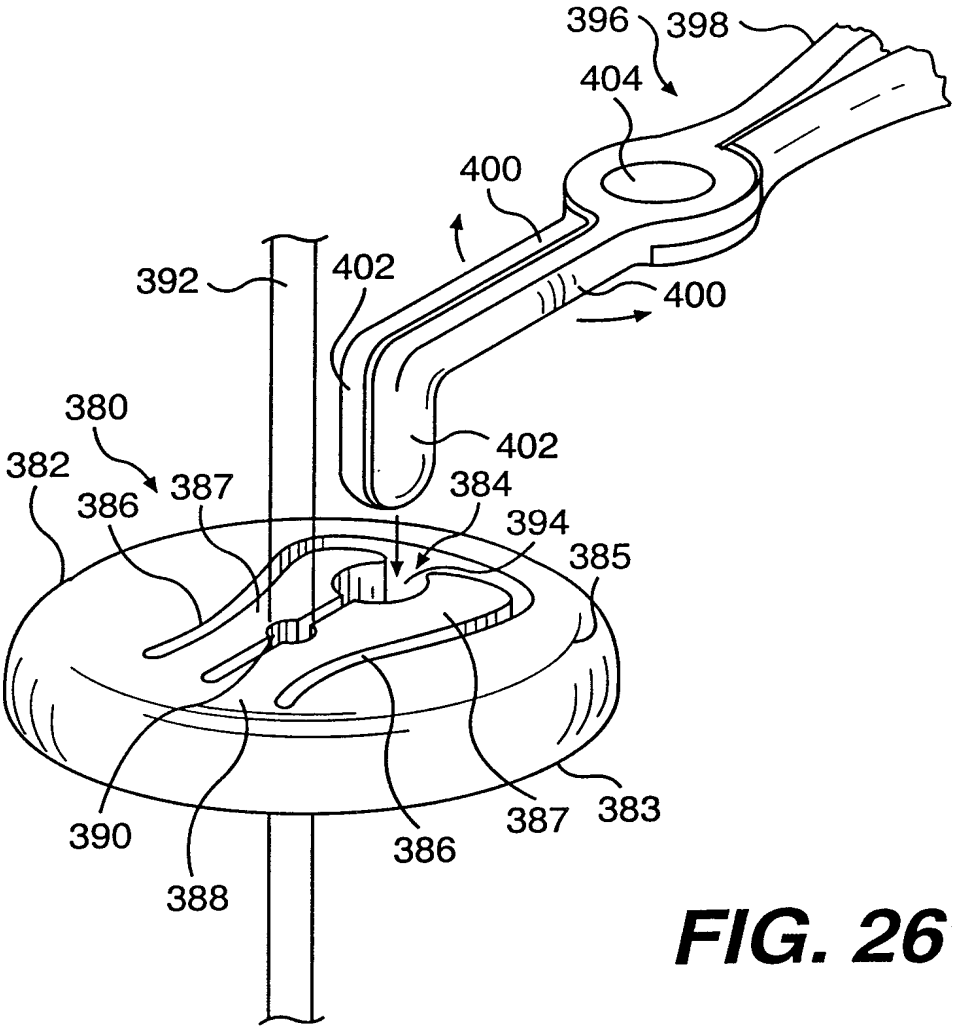
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FIG. 26

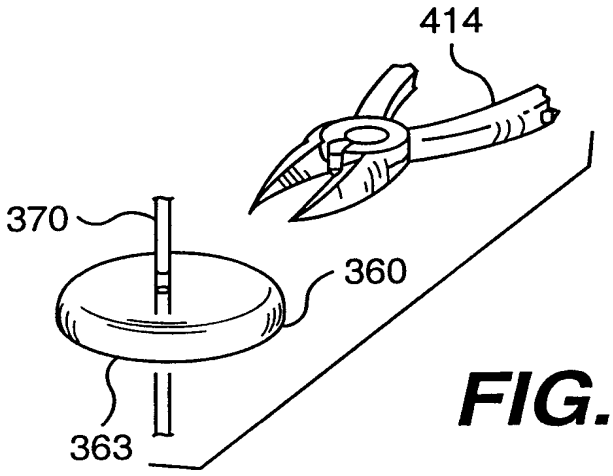
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FIG. 27

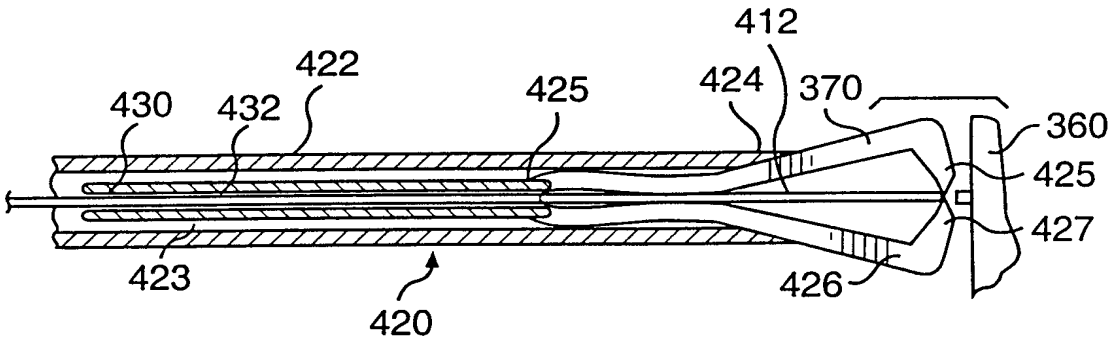
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FIG. 28

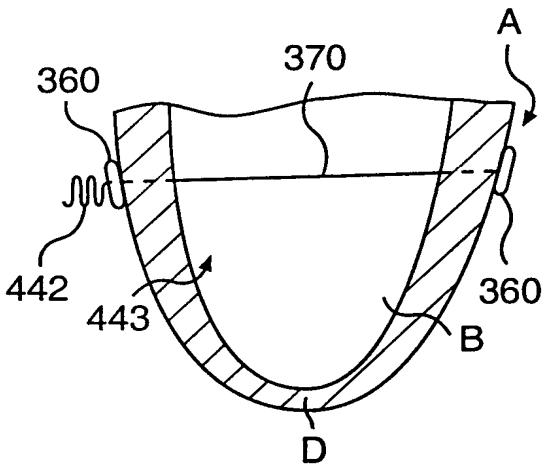
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FIG. 29

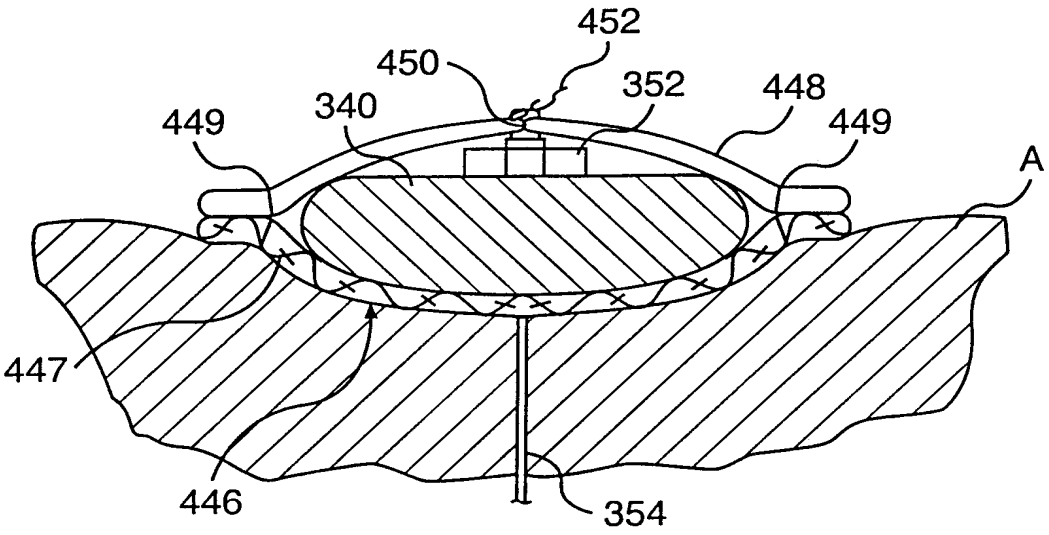


FIG. 30

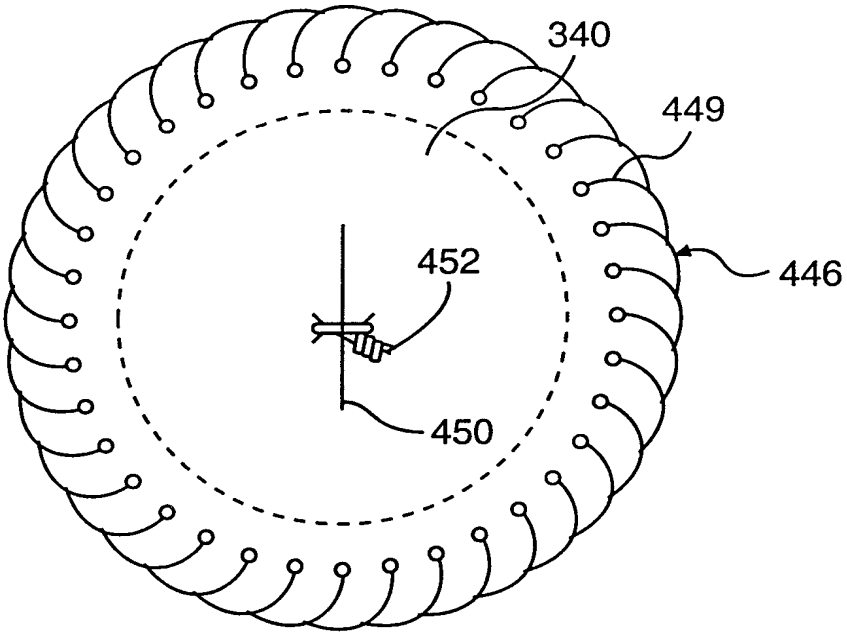


FIG. 31

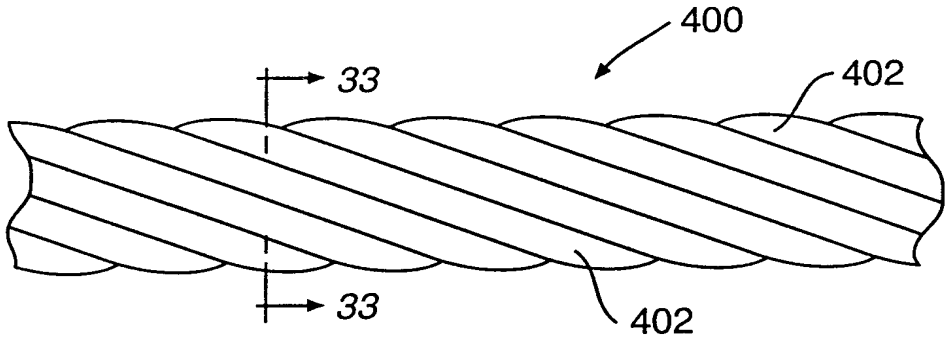


FIG. 32

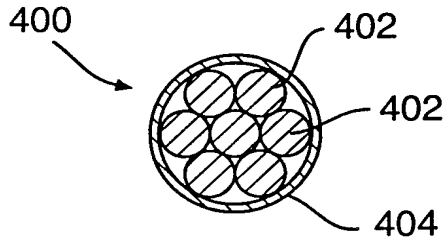
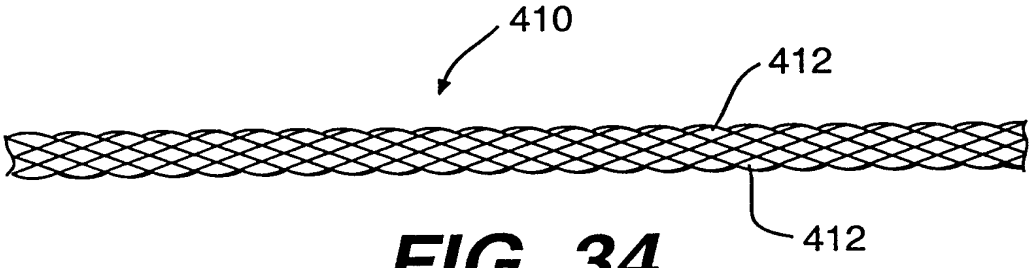


FIG. 33



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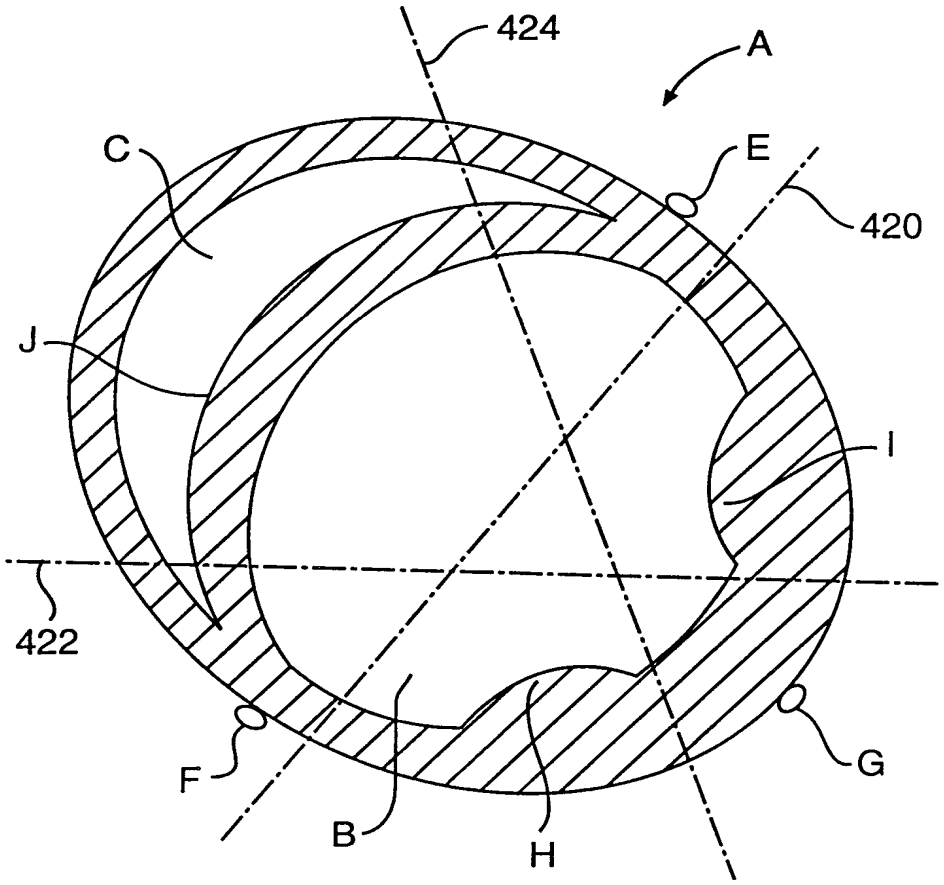


FIG. 35

FIG. 36

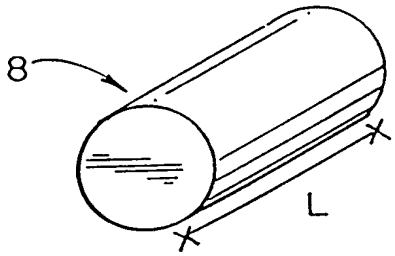


FIG. 37

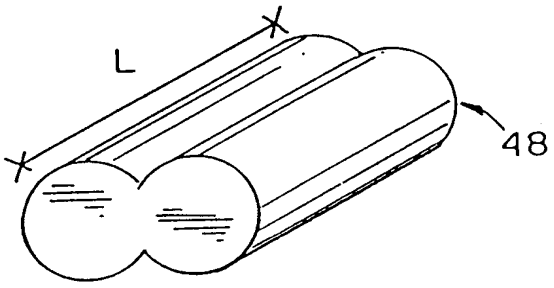


FIG. 38

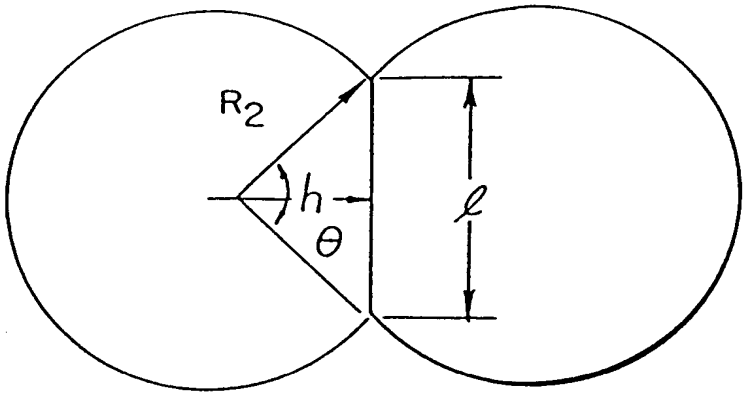


FIG. 39

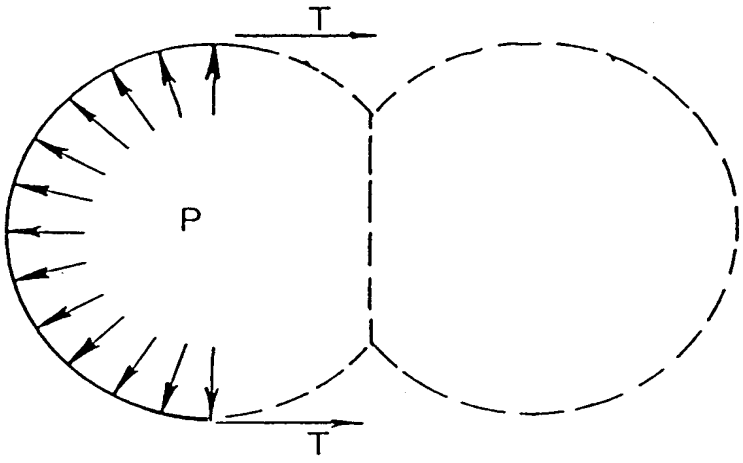
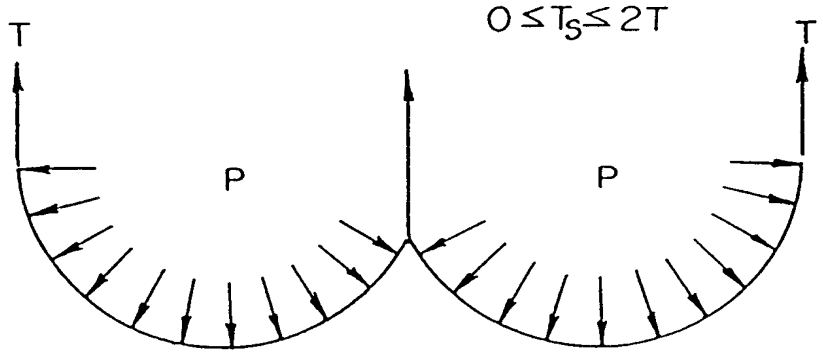


FIG. 40



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(71) Applicant *(for all designated States except US)*: MYOCOR, INC. [US/US]; Suite 200W–B, 1380 Energy Lane, St. Paul, MN 55108 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: SCHWEICH, Cyril, J., Jr. [US/US]; 1685 Hillcrest Avenue, St. Paul, MN 55116 (US). MORTIER, Todd, J. [US/US]; 3008 Colfax Avenue South, Minneapolis, MN 55408 (US). VIDLUND, Robert, M. [US/US]; 1811 Kennard Street, Maplewood, MN 55109 (US). KEITH, Peter, T. [US/US]; 1477 Grantham Street, St. Paul, MN 55108 (US). PAULSON, Thomas, M. [US/US]; 4322 York Avenue South, Minneapolis, MN 55410 (US).

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

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(54) Title: HEART WALL TENSION REDUCTION APPARATUS AND METHOD

(57) Abstract

An apparatus for treatment of a failing heart by reducing the wall tension therein. In one embodiment, the apparatus includes a tension member for drawing at least two walls of a heart chamber toward each other. Methods for placing the apparatus on the heart are also provided.

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HEART WALL TENSION REDUCTION APPARATUS AND METHOD

Cross Reference to Related Application

This application is a continuation-in-part of U.S. Application Serial No. 08/933,456, filed September 18, 1997, which in turn is a continuation-in-part of U.S. Application Serial No. 08/778,277, filed January 2, 1997. This application is related to U.S. Application Serial 09/123,977, filed on date even herewith and entitled "Transventricular Implant Tools and Devices" and U.S. Application Serial No. 09/124,321, filed on date even herewith and entitled "Stress Reduction Apparatus and Method," both of which are incorporated herein by reference.

Field of the Invention

The present invention pertains to the field of apparatus for treatment of a failing heart. In particular, the apparatus of the present invention is directed toward reducing the wall stress in the failing heart.

Background of the Invention

The syndrome of heart failure is a common course for the progression of many forms of heart disease. Heart failure may be considered to be the condition in which an abnormality of cardiac function is responsible for the inability of the heart to pump blood at a rate commensurate with the requirements of the metabolizing tissues, or can do so only at an abnormally elevated filling pressure. There are many specific disease processes that can lead to heart failure. Typically resulting in dilatation of the left

ventricular chamber. Etiologies that can lead to this form of failure include idiopathic cardiomyopathy, viral cardiomyopathy, and ischemic cardiomyopathy.

The process of ventricular dilatation is generally the result of chronic volume overload or specific damage to the myocardium. In a normal heart that is exposed to long term increased cardiac output requirements, for example, that of an athlete, there is an adaptive process of slight ventricular dilation and muscle myocyte hypertrophy. In this way, the heart fully compensates for the increased cardiac output requirements. With damage to the myocardium or chronic volume overload, however, there are increased requirements put on the contracting myocardium to such a level that this compensated state is never achieved and the heart continues to dilate.

The basic problem with a large dilated left ventricle is that there is a significant increase in wall tension and/or stress both during diastolic filling and during systolic contraction. In a normal heart, the adaptation of muscle hypertrophy (thickening) and ventricular dilatation maintain a fairly constant wall tension for systolic contraction. However, in a failing heart, the ongoing dilatation is greater than the hypertrophy and the result is a rising wall tension requirement for systolic contraction. This is felt to be an ongoing insult to the muscle myocyte resulting in further muscle damage. The increase in wall stress is also true for diastolic filling. Additionally, because of the lack of cardiac output, there is generally a rise in ventricular filling pressure from several physiologic mechanisms. Moreover, in diastole there is both a diameter increase and a pressure increase over normal, both contributing to higher wall stress levels. The increase in diastolic wall stress is felt to be the primary contributor to ongoing dilatation of the chamber.

Prior art treatments for heart failure fall into three generally categories. The first being pharmacological, for example, diuretics. The second being assist systems, for example, pumps. Finally, surgical treatments have been experimented with, which are described in more detail below.

With respect to pharmacological treatments, diuretics have been used to reduce the workload of the heart by reducing blood volume and preload. Clinically, preload is defined in several ways including left ventricular end diastolic pressure (LVEDP), or left ventricular end diastolic volume (LVEDV). Physiologically, the preferred definition is the length of stretch of the sarcomere at end diastole. Diuretics reduce extra cellular fluid which builds in congestive heart failure patients increasing preload conditions. Nitrates, arteriolar vasodilators, angiotensin converting enzyme inhibitors have been used to treat heart failure through the reduction of cardiac workload through the reduction of afterload. Afterload may be defined as the tension or stress required in the wall of the ventricle during ejection. Inotropes like digoxin are cardiac glycosides and function to increase cardiac output by increasing the force and speed of cardiac muscle contraction. These drug therapies offer some beneficial effects but do not stop the progression of the disease.

Assist devices include mechanical pumps. Mechanical pumps reduce the load on the heart by performing all or part of the pumping function normally done by the heart. Currently, mechanical pumps are used to sustain the patient while a donor heart for transplantation becomes available for the patient.

There are at least three surgical procedures for treatment of heart failure: 1) heart transplant; 2) dynamic cardiomyoplasty; and 3) the Batista partial left ventriculectomy. Heart transplantation has serious limitations including restricted availability of organs

and adverse effects of immunosuppressive therapies required following heart transplantation. Cardiomyoplasty includes wrapping the heart with skeletal muscle and electrically stimulating the muscle to contract synchronously with the heart in order to help the pumping function of the heart. The Batista partial left ventriculectomy includes surgically remodeling the left ventricle by removing a segment of the muscular wall. This procedure reduces the diameter of the dilated heart, which in turn reduces the loading of the heart. However, this extremely invasive procedure reduces muscle mass of the heart.

Summary of the Invention

The present invention pertains to a non-pharmacological, passive apparatus and method for the treatment of a failing heart. The device is configured to reduce the tension in the heart wall. It is believed to reverse, stop or slow the disease process of a failing heart as it reduces the energy consumption of the failing heart, decreases isovolumetric contraction, increases isotonic contraction (sarcomere shortening), which in turn increases stroke volume. The device reduces wall tension during diastole and systole.

Those apparatus of the present invention which reduce heart wall stress by changing chamber wall geometry can be referred to as "splints". Splints can be grouped as either "full cycle splints" which engage the heart to produce a chamber shape change throughout the cardiac cycle, or "restrictive splints" which do not engage the heart wall at end systole to produce a chamber shape change.

In one embodiment, the apparatus includes a tension member for drawing at least two walls of the heart chamber toward each other to reduce the radius or area of the heart chamber in at least one cross sectional plane. The tension member has anchoring members disposed at opposite ends for engagement with the heart or chamber wall.

In another embodiment, the apparatus includes a compression member for drawing at least two walls of a heart chamber toward each other. In one embodiment, the compression member includes a balloon. In another embodiment of the apparatus, a frame is provided for supporting the compression member.

Yet another embodiment of the invention includes a clamp having two ends biased toward one another for drawing at least two walls of a heart chamber toward each other. The clamp includes at least two ends having atraumatic anchoring member disposed thereon for engagement with the heart or chamber wall.

In yet another embodiment, a heart wall tension reduction apparatus is provided which includes a first tension member having two oppositely disposed ends and first and second elongate anchor members. A second tension member can be provided. One of the elongate anchors may be substituted for by two smaller anchors.

In an alternate embodiment of the heart wall tension reduction apparatus, an elongate compression member can be provided. First and second elongate lever members preferably extend from opposite ends of the compression member. A tension member extends between the first and second lever members.

The compression member of the above embodiment can be disposed exterior to, or internally of the heart. The tension member extends through the chamber or chambers to bias the lever members toward the heart.

In yet another embodiment of a heart wall tension reduction apparatus in accordance with the present invention, a rigid elongate frame member is provided. The frame member can extend through one or more chambers of the heart. One or more cantilever members can be disposed at opposite ends of the frame member. Each cantilever member includes at least one atraumatic pad disposed thereon. The atraumatic pads disposed at opposite ends of the frame member can be biased toward each other to compress the heart chamber.

One method of placing a heart wall tension apparatus or splint on a human heart includes the step of extending a hollow needle through at least one chamber of the heart such that each end of the needle is external to the chamber. A flexible leader is connected to a first end of a tension member. A second end of the tension member is connected to an atraumatic pad. The leader is advanced through the needle from one end of the needle to the other. The leader is further advanced until the second end of the tension member is proximate the heart and the first end of the tension member is external to the heart. A second atraumatic pad is connected to the first end of the tension member such that the first and second atraumatic pads engage the heart.

Yet another method of placing a heart wall tension apparatus on a heart includes the step of extending a needle having a flexible tension member releasably connected thereto through at least one chamber of the heart such that opposite ends of the tension member are external to the chamber and exposed on opposite sides of the chamber. The needle is removed from the tension member. Then first and second atraumatic pads are connected to the tension member at opposite ends of the tension member.

Brief Description of the Drawings

Figure 1 is a transverse cross-section of the left and right ventricles of a human heart showing the placement of a splint in accordance with the present invention;

Figure 2 is a transverse cross-section of the left and right ventricles of a human heart showing the placement of a balloon device in accordance with the present invention;

Figure 3 is a transverse cross-section of the left and right ventricles of a human heart showing the placement of an external compression frame structure in accordance with the present invention;

Figure 4 is a transverse cross-section of the left and right ventricles of a human heart showing a clamp in accordance with the present invention;

Figure 5 is a transverse cross-section of the left and right ventricles of a human heart showing a three tension member version of the splint of Figure 1;

Figure 6 is a transverse cross-section of the left and right ventricles of a human heart showing a two tension member version of the splint shown in Figure 1;

Figure 7 is a vertical cross-sectional view of the left ventricle of a human heart showing an alternate version of the splint in accordance with the present invention;

Figure 8 is an end of the splint shown in Figure 7;

Figure 9 is a vertical cross-sectional view of a chamber of a human heart showing another alternative embodiment of the splint in accordance with the present invention;

Figure 10 is a vertical cross-section of a chamber of a human heart showing another alternative configuration of splints in accordance with the present invention;

Figure 11 is a vertical cross-sectional view of a chamber of a human heart showing another embodiment of a splint in accordance with the present invention;

Figure 12 is a vertical cross-sectional view of a chamber of a human heart showing another embodiment of the splint in accordance with the present invention;

Figure 13 is a vertical cross-sectional view of a chamber of a human heart showing a compression member version of the splint in accordance with the present invention;

Figure 14 is a vertical cross-sectional view of a chamber of a human heart showing another version of the splint shown in Figure 13;

Figure 15 is a vertical cross-sectional view of a chamber of a human heart showing a frame member version of the splint in accordance with the present invention;

Figure 16 is an end view of the splint of Figure 15;

Figure 17 is a vertical cross-section of the left ventricle and atrium, the left ventricle having scar tissue;

Figure 18 is a vertical cross-section of the heart of Figure 17 showing the splint of Figure 1 drawing the scar tissue toward the opposite wall of the left ventricle;

Figure 19 is a vertical cross-section of the left ventricle and atrium of a human heart showing a version of the splint of Figure 1 having an elongate anchor bar;

Figure 20 is a side view of an undeployed hinged anchor member;

Figure 21 is a side view of a deployed hinged anchor member of Figure 10;

Figure 22 is a cross-sectional view of an captured ball anchor member;

Figure 23 is a perspective view of a cross bar anchor member;

Figure 24 is a cross sectional view of an alternate anchor pad;

Figure 25 is a cross sectional view of an alternate anchor pad;

Figure 26 is a perspective view of yet another alternate embodiment of an anchor pad including an anchor pad loosening device;

Figure 27 is a perspective view of a tension member clip;

Figure 28 is a cross sectional view of an alternate embodiment of a tension member clip;

Figure 29 is a cross sectional view of a heart including a tension member having a heat set end;

Figure 30 is a cross sectional view of the pad including an envelope;

Figure 31 shows the envelope of Figure 30;

Figure 32 is a side view of a multifilament twisted cable;

Figure 33 is a cross sectional of the cable of Figure 32;

Figure 34 is a side of a multifilament braided tension member;

Figure 35 is a schematic generally horizontal cross sectional view of the heart showing preferred tension member alignments;

Figure 36 is a idealized cylindrical model of a left ventricle of a human heart;

Figure 37 is a splinted model of the left ventricle of Figure 14;

Figure 38 is a transverse cross-sectional view of Figure 15 showing various modeling parameters;

Figure 39 is a transverse cross-section of the splinted left ventricle of Figure 15 showing a hypothetical force distribution; and

Figure 40 is a second transverse cross-sectional view of the model left ventricle of Figure 15 showing a hypothetical force distribution.

Detailed Description of the Invention

Referring now to the drawings wherein like reference numerals refer to like elements throughout the several views, Figure 1 shows a transverse cross-section of a left ventricle 10 and a right ventricle 12 of a human heart 14. Extending through the left ventricle is a splint 16 including a tension member 18 and oppositely disposed anchors 20. Splint 16 as shown in Figure 1 has been positioned to draw opposite walls of left ventricle 10 toward each other to reduce the "radius" of the left ventricular cross-section or the cross-sectional area thereof to reduce left ventricular wall stresses. It should be understood that although the splint 16 and the alternative devices disclosed herein are described in relation to the left ventricle of a human heart, these devices could also be used to reduce the radius or cross-sectional area of the other chambers of a human heart in transverse or vertical directions, or at an angle between the transverse and vertical.

Those apparatus of the present invention which reduce heart wall stress by changing chamber wall geometry can be referred to as "splints". "Full cycle splints" engage the heart to produce a chamber shape change throughout the cardiac cycle. "Restrictive splints" do not engage the heart wall at end systole to produce a chamber shape change.

Figure 2 discloses an alternate embodiment of the present invention, wherein a balloon 200 is deployed adjacent the left ventricle. The size and degree of inflation of the balloon can be varied to reduce the radius or cross-sectional area of left ventricle 10 of heart 14.

Figure 3 shows yet another alternative embodiment of the present invention deployed with respect to left ventricle 10 of human heart 14. Here a compression frame

structure 300 is engaged with heart 14 at atraumatic anchor pads 310. A compression member 312 having an atraumatic surface 314 presses against a wall of left ventricle 10 to reduce the radius or cross-sectional area thereof.

Figure 4 is a transverse cross-sectional view of human heart 14 showing yet another embodiment of the present invention. In this case a clamp 400 having atraumatic anchor pads 410 biased toward each other is shown disposed on a wall of left ventricle 10. Here the radius or cross-sectional area of left ventricle 10 is reduced by clamping off the portion of the wall between pads 410. Pads 410 can be biased toward each other and/or can be held together by a locking device.

Each of the various embodiments of the present invention disclosed in Figures 1-4 can be made from materials which can remain implanted in the human body indefinitely. Such biocompatible materials are well-known to those skilled in the art of clinical medical devices.

Figure 5 shows an alternate embodiment of the splint of Figure 1 referred to in Figure 5 by the numeral 116. The embodiment 116 shown in Figure 5 includes three tension members 118 as opposed to a single tension member 18 as shown in Figure 1. Figure 6 shows yet another embodiment of the splint 216 having four tension members 218. It is anticipated that in some patients, the disease process of the failing heart may be so advanced that three, four or more tension members may be desirable to reduce the heart wall stresses more substantially than possible with a single tension member as shown in Figure 1.

Figure 7 is a partial vertical cross-section of human heart 14 showing left ventricle 10. In Figure 7, another splint embodiment 316 is shown having a tension

member 318 extending through left ventricle 10. On opposite ends of tension member 318 are disposed elongate anchors or pads 320. Figure 8 is an end view of tension member 318 showing elongate anchor 320.

Figure 9 shows another embodiment of a splint 416 disposed in a partial vertical cross-section of human heart 14. Splint 416 includes two elongate anchors or pads 420 similar to those shown in Figures 7 and 8. In Figure 9, however, two tension members 418 extend through left ventricle 10 to interconnect anchors 420 on opposite sides of heart 14.

Figure 10 is a vertical cross section of heart 14 showing left ventricle 10. In this case, two splints 16 are disposed through left ventricle 10 and vertically spaced from each other to resemble the configuration of Figure 9.

Figure 11 is a vertical cross sectional view of the left ventricle of heart 14. Two alternate embodiment splints 516 are shown extending through left ventricle 10. Each splint 516 includes two tension members 518 interconnecting two anchors or pads 520.

Figure 12 is yet another vertical cross sectional view of left ventricle 10 of heart 14. An alternate embodiment 616 of the splint is shown extending through left ventricle 10. Splint 616 includes an elongate anchor pad 620 and two shorter anchors or pads 621. Splint 616 includes two tension members 618. Each tension member 618 extends between anchors 620 and respective anchors 621.

Figure 13 is a vertical cross sectional view of left ventricle 10 of heart 14. A splint 50 is shown disposed on heart 14. Splint 50 includes a compression member 52 shown extending through left ventricle 10. Opposite ends of compression member 52 are disposed exterior to left ventricle 10. Lever members 54 extend from each end of

compression member 52 upwardly along the exterior surface of ventricle 10. A tension member 56 extends between lever members 54 to bias lever members 54 toward heart 14 to compress chamber 10. Compression member 52 should be substantially rigid, but lever members 54 and to some degree compression member 52 should be flexible enough to allow tension member 56 to bias lever members 54 toward heart 14. Alternately, lever members 54 could be hinged to compression member 52 such that lever members 54 could pivot about the hinge when biased toward heart 14 by tension member 56.

Figure 14 shows an alternate embodiment 156 of the splint shown in Figure 13. In this case lever members 154 are longer than members 54 as compression member 152 of splint 150 has been disposed to the exterior of left ventricle 10.

Figure 15 is a vertical cross sectional view of left ventricle 10 of heart 14. An alternate embodiment 250 of the splint is shown on heart 14. A preferably relatively rigid frame member 256 extends through ventricle 10. Disposed on opposite ends of frame 256 are cantilever member 254. Disposed on cantilever members 254 are atraumatic pads 258. Cantilever members 254 can be positioned along frame member 256 such that atraumatic pads 258 press against heart 14 to compress chamber 10. Figure 16 is an end view of frame member 256 showing cantilever members 254 and pads 258.

It should be understood that each of the embodiments described above should be formed from suitable biocompatible materials known to those skilled in the art. The tension members can be formed from flexible or relatively more rigid material. The compression members and frame member should be formed from generally rigid material which may flex under load, but generally hold its shape.

Figure 17 is a partial vertical cross-section of human heart 14 showing left ventricle 10 and left atrium 22. As shown in Figure 7, heart 14 includes a region of scar tissue 24 associated with an aneurysm or ischemia. As shown in Figure 7, the scar tissue 24 increases the radius or cross-sectional area of left ventricle 10 in the region affected by the scar tissue. Such an increase in the radius or cross-sectional area of the left ventricle will result in greater wall stresses on the walls of the left ventricle.

Figure 18 is a vertical cross-sectional view of the heart 14 as shown in Figure 7, wherein a splint 16 has been placed to draw the scar tissue 24 toward an opposite wall of left ventricle 10. As a consequence of placing splint 16, the radius or cross-sectional area of the left ventricle affected by the scar tissue 24 is reduced. The reduction of this radius or cross-sectional area results in reduction in the wall stress in the left ventricular wall and thus improves heart pumping efficiency.

Figure 19 is a vertical cross-sectional view of left ventricle 10 and left atrium 22 of heart 14 in which a splint 16 has been placed. As shown in Figure 9, splint 16 includes an alternative anchor 26. The anchor 20 is preferably an elongate member having a length as shown in Figure 9 substantially greater than its width (not shown). Anchor bar 26 might be used to reduce the radius or cross-sectional area of the left ventricle in an instance where there is generalized enlargement of left ventricle 10 such as in idiopathic dilated cardiomyopathy. In such an instance, bar anchor 26 can distribute forces more widely than anchor 20.

Figures 20 and 21 are side views of a hinged anchor 28 which could be substituted for anchors 20 in undeployed and deployed positions respectively. Anchor 28 as shown in Figure 20 includes two legs similar to bar anchor 26. Hinged anchor 28

could include additional legs and the length of those legs could be varied to distribute the force over the surface of the heart wall. In addition there could be webbing between each of the legs to give anchor 28 an umbrella-like appearance. Preferably the webbing would be disposed on the surface of the legs which would be in contact with the heart wall.

Figure 22 is a cross-sectional view of a capture ball anchor 30. Capture ball anchor 30 can be used in place of anchor 20. Capture ball anchor 30 includes a disk portion 32 to distribute the force of the anchor on the heart wall, and a recess 34 for receiving a ball 36 affixed to an end of tension member 18. Disk 32 and recess 34 include a side groove which allows tension member 38 to be passed from an outside edge of disk 32 into recess 34. Ball 36 can then be advanced into recess 34 by drawing tension member 18 through an opening 38 in recess 34 opposite disk 32.

Figure 23 is a perspective view of a cross bar anchor 40. The cross bar anchor 40 can be used in place of anchors 20. The anchor 40 preferably includes a disk or pad portion 42 having a cross bar 44 extending over an opening 46 in pad 42. Tension member 18 can be extended through opening 46 and tied to cross bar 42 as shown.

Figure 24 is a cross sectional view of an alternate embodiment of anchor pad 340 in accordance with the present invention. Anchor pad 340 preferably includes a disc shaped pad portion 342. Disc shape pad portion 342 includes side 343, which in use is disposed toward the heart. A conical aperture 348 having sloping sides 346 extends through pad 342. Collet 344 is disposed within orifice 348. A threaded portion 350 of collet 344 extends from orifice 348 opposite side 343, nut 352 is threaded over threaded portion 350. Lumen 345 extends through collet 344. A tension member 354 is shown extending through lumen 345. Lumen 345 has a diameter such that when nut 352 is not

tightened on threaded portion 350, tension member 354 can slide freely through lumen 345. When nut 352 is tightened, it draws collet 344 away from side 343. Collet 344 is then pinched between walls 346 of orifice 348. When collet 344 is pinched, the size of lumen 345 is reduced such that tension member 354 can no longer move freely within lumen 345, fixing the position of pad 340 on tension member 354.

Figure 25 is a cross sectional view of an alternate embodiment an anchor pad 360 in accordance with the present invention. Anchor pad 360 includes a generally disc-shaped pad portion 362. Pad 362 includes a side 363 which when the pad is in use, is disposed toward the heart. A tension member lumen 364 extends through pad 362. Lumen 364 preferably has a generally conical shaped portion 365 disposed toward side 363. Tension member 370 is shown disposed through lumen 364 in Figure 25. Pad 362 includes a threaded passage 366 extending from an edge of pad 362 to lumen 364. A set screw 368 is threaded into passage 366. Set screw 368 can be tightened to engage tension member 370 to fix the position of anchor pad 360. When set screw 368 is not tightened, the size of lumen 364 is preferably large enough that anchor pad 360 can slide relatively freely over tension member 370.

Figure 26 is a perspective view of yet another embodiment of anchor pad 380 in accordance with the present invention. Anchor pad 380 preferably includes a generally disc-shaped pad portion 382 having a first side 383 which in use would be disposed toward the heart and a second side 385. Pad 382 as well as pads 342 and 362 are preferably formed from a metal such as stainless steel alloys or titanium alloys.

A tension member fastener 384 is formed in pad 382 by cutting a series of grooves and apertures through pad 382 from side 385 to side 383. A first groove 386 has

a generally horseshoe shape. Second groove 388 extends between opposite portions of horseshoe shaped groove 386 to form two oppositely disposed cantilever members 387. A relatively large aperture 394 is formed between cantilever members 387 proximate their free ends. A second and smaller aperture 390 is formed closer to the fixed ends of cantilever members 387. Tension member 392 is shown extending through aperture 390.

As shown in Figure 26, tension member 392 is clamped between cantilever members 387 such that the location of pad 382 is fixed along tension member 392. Pad 382 can be released by using a spreading device 396 to spread cantilever members 387 apart. Spreading device 396 includes handle 398 to spreading arms 400 each having a finger 402. Fingers 402 can be placed within aperture 394 then arms 400 and fingers 402 can be spread apart by pivoting them around a pin 404 such that cantilevers 387 are spread apart and pad 382 can move freely along tension member 392. It can be appreciated that although spreader 396 is shown extending transversely from tension member 392, it could also be configured such that fingers 402 do not curve transversely from arms 400 and thus spreader 396 could be disposed parallel to tension member 392. This would be particularly desirable in a situation where anchor pad 380 was being placed through a port or window during a less invasive splint implantation procedure. It can be appreciated that cantilever members 387 can be held apart such that pad 380 can be moved along tension member 392 by placement of a temporary wedge or pin in groove 388. For example, grooves 388 may include an additional small aperture disposed between aperture 390 and aperture 394 into which a pin could be placed to hold open members 387. When it is desired to fix the position of anchor pad 380 on tension member 392, device 396 could be used to spread cantilever members 387 to remove the

pin. The cantilever members could then be released to engage tension member 392. Aperture 390 of pad 380 can also include a conical portion disposed toward side 383 such as conical portion 365 of pad 360.

Cantilever arms 384 are preferably configured such that they do not stress tension member 392 beyond its elastic limit. It can also be appreciated that the force developed by cantilever members 387 impinging on tension member 392 is operator independent and defined by the geometry and material characteristics of members 387.

Figure 27 is a perspective view of an anchor pad 360 having a tension member 370 extending therethrough. After pad 360 is secured to tension member 370, that portion of tension member 370 which extends from the side of anchor pad 360 opposite side 363 is preferably removed. This can be accomplished by trimming tension member 370 with wire cutter 414 or scissors. Although anchor pad 360 is used here to illustrate trimming tension member 370, it can be appreciated that in each of the embodiments disclosed herein there may be an excess portion of tension member extending from an anchor, which is preferably removed or trimmed.

Figure 28 is a cross sectional view of an alternate embodiment 420 of a tension member cutter. Device 420 includes an elongate outer tube 422 having a distal end 424. Tube 424 defines a lumen 423 through which extends a second tube 430 having a distal end 428. Extending distally from distal end 428 are two cutting arms 424 and 426 which are shown partially withdrawn into lumen 423 and transversely restrained by distal end 424 of outer tube 422. When unrestrained by distal end 424, arms 424 and 426 are biased apart. Each arm 424 and 426 has a cutting element 425 and 427, respectively. Elements 425 and 427 are shown in contact with each other in Figure 28. A tension member 370

extends between arms 424 and through lumen 432 of inner tube 430. A representative anchor pad 360 is disposed adjacent elements 425 and 427. Device 420 of Figure 28 is particularly useful when trimming excess tension member using less invasive techniques as it can be readily advanced over a tension member through a port or window trocar.

Figure 29 is a vertical cross sectional view of left ventricle B of heart A. A transventricular splint 443 including a tension member 370 and anchor pads 360 are shown disposed on heart A. To the left of heart A as shown in the figure is a coiled portion 442 of tension member 470. As an alternative to trimming an excess length of tension member, tension member 370 could be formed from a shape memory alloy such that portion 442 could be preset to assume a coil shape when warmed to near body temperature.

Once the length of the tension member has been adjusted, the anchors are secured in place along the tension member and the excess length of tension member removed if desired, the anchor or anchor pads are preferably secured in place on the heart. The anchor or anchor pads are secured such that relatively movement between the anchors or anchor pads and the heart is limited to reduce abrasion of the heart wall. To secure the anchor or anchor pads to heart A, a biocompatible adhesive could be placed between the pad and the heart to adhere the pad to the heart. Alternately, apertures could be provided in the pad such that sutures could be extended through the apertures and into the heart to secure the pad. In addition to sutures, the pad could include threaded apertures into which anchor screws could be advanced through the pad and into the heart wall to secure the pad to the heart.

Figure 30 illustrates yet another alternative approach to securing the anchors or anchor pads to the heart surface. Figure 30 is a cross sectional view of an anchor pad 340 disposed on heart A. Anchor pad 340 is disposed within an envelope 446. Envelope 446 includes a bottom layer 447 disposed between anchor pad 340 and heart A and a top layer 448 disposed on the opposite side of anchor pad 340. Layers 347 and 340 are held together by sutures 449. Bottom layer 447 is preferably a mesh or expanded PTFE which has a pore size or intranodial dimension sufficient to promote tissue ingrowth. The pore size is preferably between about 10 and about 100 microns and more preferably, between about 20 and about 40 microns. With respect to expanded PTFE, the intranodial dimension is preferably between about 10 to about 100 microns and more preferably between about 20 to about 40 microns. The top material could also be expanded PTFE or the like having a pore size which preferably does not promote ingrowth and thus resists adhesion to surrounding tissue. As an alternative embodiment, the pores could be formed directly in the pad surface.

Envelope 446 would preferably be placed around pad 340 prior to placing pad 340 on tension member 354. A window 450 can be provided to provide access to nut 352 to secure pads to tension member 354. After tightening nut 352, window 450 can be closed by suture 452. Figure 31 is a top view of pad 340 and envelope 446 of Figure 30. It can be appreciated that a similar envelope can be placed around the various anchor pads disclosed herein. The location of the window may have to vary, however, to provide access to the respective means for securing the anchor pads to the tension member.

The splints of the present invention can be implanted acutely or chronically. When the splints are implanted chronically, it is particularly important that the tension member or members be highly fatigue resistant. Typical materials for the tension member can include, among other biocompatible materials, stainless steel, titanium alloys, NiTi alloys such as Nitinol or elgiloy. In a preferred embodiment, the tension member is a wire having a diameter of between 0.005 to 0.035 inches in diameter or, more preferably, between 0.01 and 0.02 inches in diameter and, most preferably, about 0.014 inches in diameter. The length of the tension member between the pads is preferably about 0.6 to 4 inches, and more preferably, between about 1 to 3 inches and, most preferably, about 2 inches. To improve the fatigue resistance of the metallic tension members, their surface can be electro-polished, buffed or shot peened. Drawing or annealing of the metal will also improve fatigue resistance.

The tension member, in a preferred embodiment, articulates with respect to the anchor pad to reduce bending of the tension member at the pad. This can be accomplished by a ball and socket joint shown in Figure 22, for example. The tension member itself can be made more flexible or bendable by providing a multi-filament tension member such as a braided or twisted wire cable tension member. A multifiber filament structure of numerous smaller wires can then easily, while reducing the stress level on any individual wire as compared to a solid wire of the same diameter as the multifilament bundle. Such a multi-filament tension member can be made from biocompatible materials such as, but not limited to, stainless steel, Nitinol, titanium alloys, LCP (liquid crystal polymer), Spectra™ fiber, kevlar fiber, or carbon fiber. In a preferred embodiment, the multi-filament structure is coated or covered to substantially

seal the multi-filament structure. Coatings such as silicone, urethane or PTFE are preferred.

Figure 32 is a side view of multifilament twisted cable 400. Cable 400 includes a plurality of wires or filaments 402 twisted about the longitudinal axis of cable 400. Figure 33 is a transverse cross sectional view of cable 400. In Figure 33, cable 400 includes a surrounding coating 404 not shown in Figure 32.

Figure 34 is a side view of a braided multifilament tension member 410. Tension member 410 includes a plurality of filaments or wires 412. It can be appreciated that numerous braiding patterns are known to those skilled in the art of multifilament members. It is anticipated that in a preferred embodiment, braided member 410 can have an optional core of fibers running parallel to an elongate axis of tension member 410. In yet another preferred embodiment, tension member 410 could have a solid wire core extending parallel to and along the longitudinal axis of tension member 410.

The tension members and anchors or anchor pads are preferably bio-resistant, i.e., resistant to physiologic attack. To improve bio-resistance, tension member and/or anchors or anchor pads can be coated with carbon material such as glass, pyrolytic carbon, diamond or graphite, zirconium nitrate or oxide. Roughened or porous urethanes, silicone or polymer coatings or sheaths can be used to promote tissue ingrowth to create a biological seal. Hydrophilic and albumin coatings can also be used. Drugs incorporated into a binder coating can also be used to reduce biological attack on the splint and irritation of tissue by the splint. Such drugs include heparin, coumadin, anti-inflammatory steroid or ASA-aspirin. The oxide layer of the underlying metal could also be optimized to improve bio-resistance. This is particularly true for stainless steel,

titanium, or nickel titanium on which an oxide layer can be formed by heating the component to improve biocompatibility. Further coatings include calcium hydroxy appetite, beta tricalcium phosphate and aluminum oxide can be applied to the tension member. The tension member and/or pad or anchor pad can at least be, in part, formed from titanium to enhance electronegativity.

The anchors or anchor pads and, particularly the tension members are biocompatible, preferably antithrombogenic and made to prevent hemolysis. The coatings used to enhance bio-resistance described above can generally be used to improve biocompatibility. Since the tension member is exposed to significant blood flows through the left ventricle, in a preferred embodiment, the tension member has a generally small size and shape elliptical cross sectional shape to reduce turbulence or drag over the tension member. If such elliptical, transverse cross section tension member were used, it can be appreciated that the narrow end would be preferably oriented toward the direction of blood flow. It is also desirable to select a tension member material and shape which would not vibrate at resonant frequency under the influence of blood flow.

Where the tension member passes through the heart wall, various approaches can be taken to reduce or prevent bleeding. For example, the surface of the anchor or anchor pad and/or tension member in contact with the heart wall can be coated or include an ingrowth inducing covering such as collagen, dacron, expanded PTFE or a roughened/porous surface. A clotting inducing substance may also be bound to the tension member and/or anchor or anchor pads, such as avitene or collagen. It is also contemplated that the portion of the heart wall where the tension member passes through could be cauterized. In a preferred embodiment, the tissue can be cauterized by heating

the tension member. A glue such as cyanoacrylate can also be disposed between the tension member and the heart wall to reduce or prevent bleeding from the heart wall. Mechanical means such as an O-ring or compression fitting could also be disposed between the heart wall and the tension member to reduce bleeding. A purse string suture can be placed on the heart, around the tension member adjacent the pad as well.

The tension member is preferably flexible enough to allow for changing interface conditions between the heart and the splint, and alternating pad orientation throughout the cardiac cycle. The flexibility should be sufficient enough to avoid injury to the heart or bleeding. It is also preferable that if the heart were to contract sufficiently enough to put the tension member in compression that it would readily buckle. Buckling could be promoted by providing a ribbon shaped tension member, chain link tension member, thin wire tension member, bent tension member or multi-filament tension.

The tension member is preferably radiopaque, echo cardiographic compatible, or MRI compatible or includes a marker which is radiopaque, echo compatible, or MRI compatible. The preferred locations for markers would include the center of the tension member and at the ends of the tension member disposed at the heart walls. The radiopaque markers could be gold or platinum or other biocompatible metal or heavy metal filled polymeric sleeves. With respect to echo compatible or MRI compatible tension members or markers, the tension or marker are preferably non-interfering or visible. Having radiopaque echo compatible or MRI compatible tension members or markers is particularly desirable for follow-up, non-invasive monitoring of the tension member after implantation. The presence of the tension member can be visualized and

the distance between two or more markers measured. Integrity of the tension member can be confirmed as well.

In a preferred embodiment, the tension member is not conductive to the action potential of muscle. This can be accomplished by insulating the tension member, anchor and/or anchor pad interface or fabricating the tension member anchor and/or anchor pad from a non-conductive metal such as titanium.

In addition to monitoring the performance of the tension member by visualization techniques such as fluoroscopy or echo imagery, sensors can advantageously be incorporated into the splints. For example, a strain gauge can be disposed on a tension member to monitor the loading on the member in use. Strain can be related to load as known to those skilled in the art by developing a stress/strain relationship for a given tension member. The strain gauge can be connected by a biocompatible lead to a conventional monitoring device. A pressure gauge formed from, for example, piezo electric material can also be disposed on the tension member to monitor filling pressures or muscle contractility.

In a preferred embodiment, a tension member can be slidably enclosed within a tube. If the tension member were to fail, the tube would contain the tension member therein.

It is anticipated that the tension member could be connected to a pacing lead. In such an instance, if the tension member were conductive, pacing signals could be conveyed along the tension member from one heart wall to another.

In use, the various embodiments of the present invention are placed in or adjacent the human heart to reduce the radius or cross-section area of at least one chamber of the

heart. This is done to reduce wall stress or tension in the heart or chamber wall to slow, stop or reverse failure of the heart. In the case of the splint 16 shown in Figure 1, a cannula can be used to pierce both walls of the heart and one end of the splint can be advanced through the cannula from one side of the heart to the opposite side where an anchor can be affixed or deployed. Likewise, an anchor is affixed or deployed at the opposite end of splint 16. Additional methods for splint placement are described in more detail in U.S. Application Serial No. 09/123,977, filed on date even herewith and entitled "Transventricular Implant Tools and Devices" and incorporated herein by reference.

It can be appreciated that the methods described above to advance the tension members through the ventricles can be repeated to advance the desired number of tension members through the ventricle for a particular configuration. The length of the tension members can be determined based upon the size and condition of the patient's heart. It should also be noted that although the left ventricle has been referred to here for illustrative purposes, that the apparatus and methods of this invention can also be used to splint multiple chambers of a patient's heart as well as the right ventricle or either atrium.

Figure 35 is a schematic view of generally horizontal cross section of heart A including left ventricle B and right ventricle C. Also shown are left anterior descending artery E, posterior descending artery F, obtuse marginal artery G, postero-medial papillary muscle H and antero-lateral papillary muscle I. Shown in Figure 35 are three generally horizontal preferred alignments for tension member placement for the splints of the present invention. These alignments generally met three goals of splint positioning including good bisection of the left ventricle, avoidance of major coronary vessels and

avoidance of valve apparatus including chordae leaflets and papillary muscles. Alignment 420 can be referred to as the anterior/posterior (AP) position. Alignment 422 can be referred as the posterior septal/lateral wall (PSL) position. Alignment 424 can be referred to as the anterior septal/lateral wall (ASL) position.

It can be appreciated that the alignments shown illustrative only and that the alignments may be shifted or rotated about a vertical axis generally disposed through the left ventricle and still avoid the major coronary vessels and papillary muscles. When the alignment passes through a substantial portion of right ventricle C, it may be desirable to dispose not only two pads on the exterior of the heart at opposite ends of a tension member, but also a third pad within right ventricle C on septum J. The spacing between the third pad and the pad disposed outside the heart proximate left ventricle B preferably defines the shape change of left ventricle B. This will allow the spacing of the third pad relative to the pad disposed outside the heart proximate right ventricle C to define a shape change if any of right ventricle C in view of the spacing between those pads. With the alignments as shown in Figure 35, the third pad will be unnecessary. It is likely, however, that with alignments 422 and 424 in order to achieve the desired shape change of left ventricle B, the exterior pad of the wall proximate the right ventricle C will be drawn into contact with septum J. This will consequently somewhat reduce the volume of right ventricle C.

Figure 36 is a view of a cylinder or idealized heart chamber 48 which is used to illustrate the reduction of wall stress in a heart chamber as a result of deployment of the splint in accordance with the present invention. The model used herein and the calculations related to this model are intended merely to illustrate the mechanism by

which wall stress is reduced in the heart chamber. No effort is made herein to quantify the actual reduction which would be realized in any particular in vivo application.

Figure 37 is a view of the idealized heart chamber 48 of Figure 36 wherein the chamber has been splinted along its length L such that a "figure eight" cross-section has been formed along the length thereof. It should be noted that the perimeter of the circular transverse cross-section of the chamber in Figure 36 is equal to the perimeter of the figure eight transverse cross-section of Figure 37. For purposes of this model, opposite lobes of the figure in cross-section are assumed to be mirror images.

Figure 38 shows various parameters of the Figure 1 cross-section of the splinted idealized heart chamber of Figure 37. Where l is the length of the splint between opposite walls of the chamber, R_2 is the radius of each lobe, θ is the angle between the two radii of one lobe which extends to opposite ends of the portion of the splint within chamber 48 and h is the height of the triangle formed by the two radii and the portion of the splint within the chamber 48 (R_1 is the radius of the cylinder of Figure 36). These various parameters are related as follows:

$$h = R_2 \, COS \, (\theta/2)$$

$$l = 2 \, R_2 \, SIN \, (\theta/2)$$

$$R_2 = R_1\pi \, / \, (2\pi - \theta)$$

From these relationships, the area of the figure eight cross-section can be calculated by:

$$A_2 = 2\pi(R_2)^2 \, (1-\theta/2\pi) + hl$$

Where chamber 48 is unsplinted as shown in Figure 36 A_1, the original cross-sectional area of the cylinder is equal to A_2 where $\theta = 180°$, $h = 0$ and $l = 2R_2$. Volume equals A_2 times length L and circumferential wall tension equals pressure within the chamber times R_2 times the length L of the chamber.

Thus, for example, with an original cylindrical radius of four centimeters and a pressure within the chamber of 140 mm of mercury, the wall tension T in the walls of the cylinder is 104.4 newtons. When a 3.84 cm splint is placed as shown in Figures 37 and 38 such that $l = 3.84$ cm, the wall tension T is 77.33 newtons.

Figures 39 and 40 show a hypothetical distribution of wall tension T and pressure P for the figure eight cross-section. As θ goes from 180° to 0°, tension T_s in the splint goes from 0 to a 2T load where the chamber walls carry a T load.

In yet another example, assuming that the chamber length L is a constant 10 cm, the original radius R_1 is 4 cm, at a 140 mmHg the tension in the walls is 74.7 N. If a 4.5 cm splint is placed such that $l = 4.5$ cm, the wall tension will then be 52.8 N.

When a splint is actually placed on the heart, along an alignment such as those shown in Figure 35, the length l between the two pads as measured along the tension member is preferably 0.4 to about 0.8 and more preferably between about 0.5 to about 0.7 and most preferably about 0.6 times the distance along the length of the tension member at end diastole if the pads were not secured to the tension member and provided no resistance to expansion of the heart. A more detailed discussion of tension member length can be found in U.S. Application Serial No. 09/123,977, filed on date even

herewith and entitled "Transventricular Implant Tools and Devices" which is incorporated herein by reference.

It will be understood that this disclosure, in many respects, is only illustrative. Changes may be made in details, particularly in matters of shape, size, material, and arrangement of parts without exceeding the scope of the invention. Accordingly, the scope of the invention is as defined in the language of the appended claims.

What is claimed is:

1. A transventricular splint, comprising:

an elongate tension member having two axially disposed ends; and

substantially atraumatic anchors disposed at each end, such that the length of the tension member between the anchors is about 1 to 4 inches.

2. The transventricular splint in accordance with claim 1, wherein the tension member comprises a multi-filament elongate member.

3. The transventricular splint in accordance with claim 1, wherein the tension member is substantially radiopaque.

4. The transventricular splint in accordance with claim 1, further comprising a radiopaque marker disposed on the tension member.

5. The transventricular splint in accordance with claim 1, wherein the tension member is echo cardiograph.

6. The transventricular splint in accordance with claim 1, further comprising an echogenic marker disposed on the tension member.

7. The transventricular splint in accordance with claim 1, wherein the tension member has a substantially antithrombogenic surface.

8. The transventricular splint in accordance with claim 7, wherein the tension member has a substantially antithrombogenic coating.

9. The transventricular splint in accordance with claim 1, wherein the tension member has a length of between about 0.6 and 2.0 inches.

10. The transventricular splint in accordance with claim 1, wherein the tension member has a diameter of between about 0.01 and 0.02 inches.

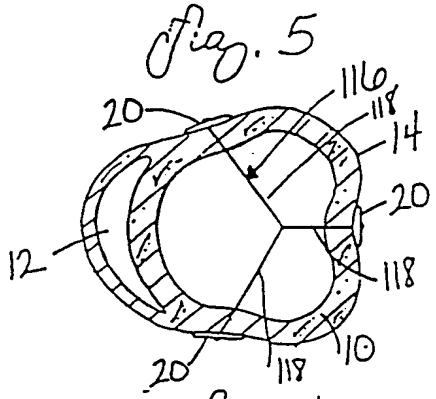


Fig. 5

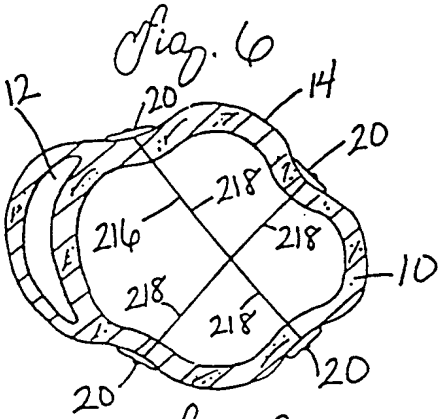


Fig. 6

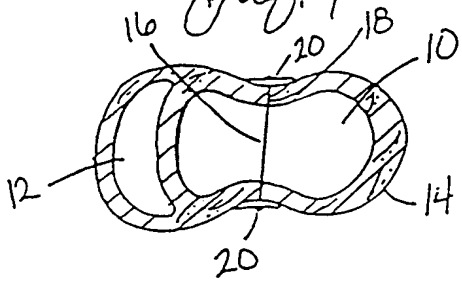


Fig. 1

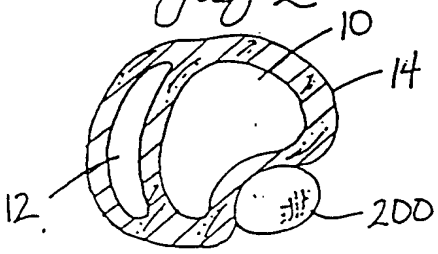


Fig. 2

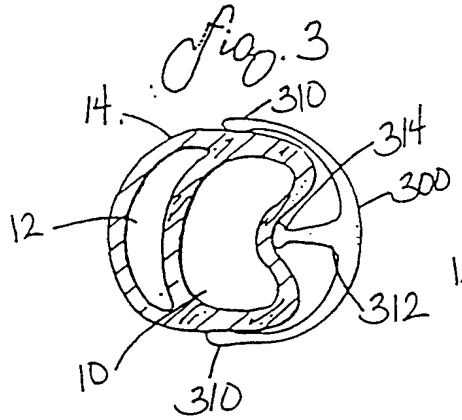


Fig. 3

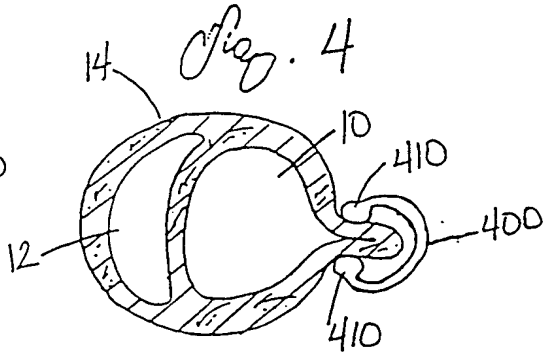
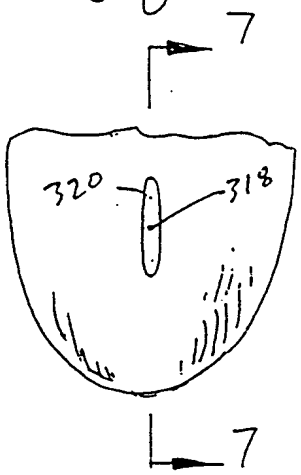


Fig. 4

Fig. 8



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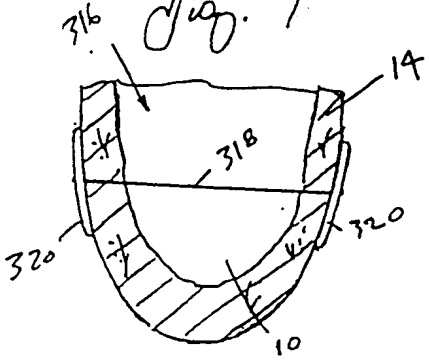


Fig. 9

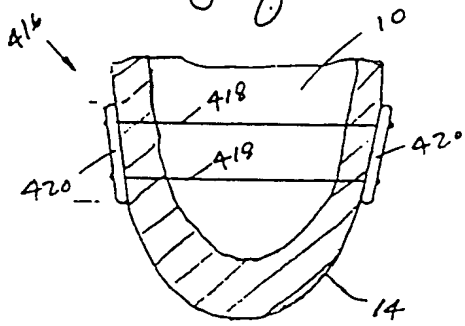


Fig. 10

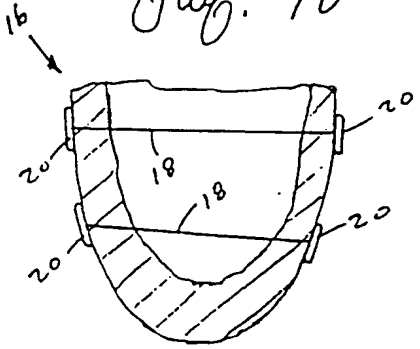


Fig. 11

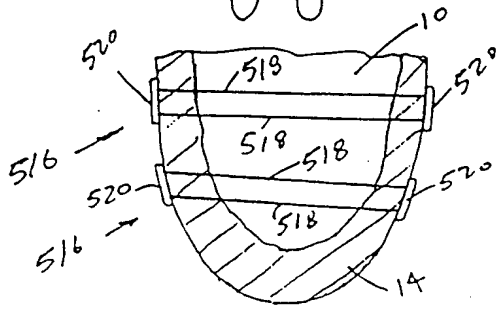


Fig. 12

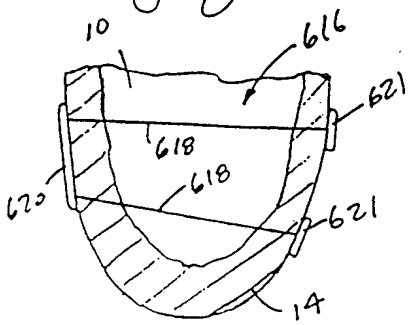


fig. 13

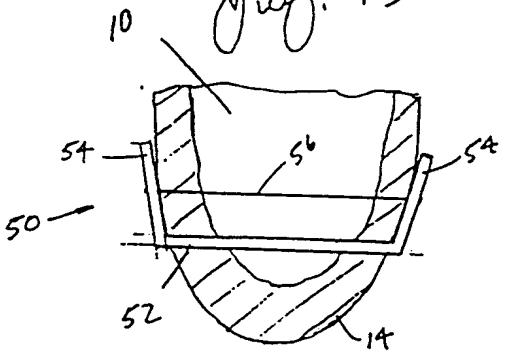


fig. 14

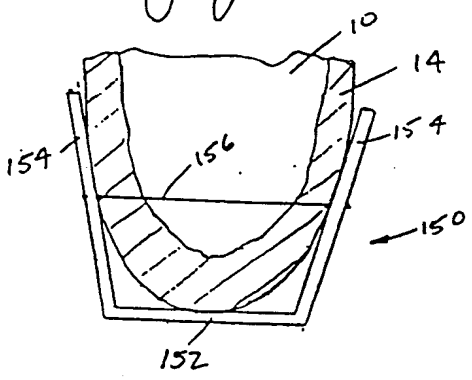


fig. 15

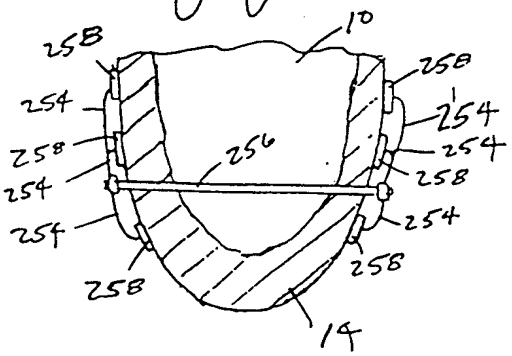


fig. 16

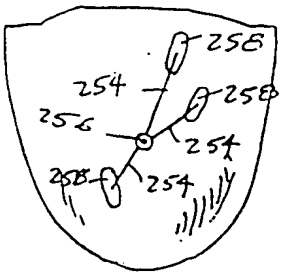


Fig. 17

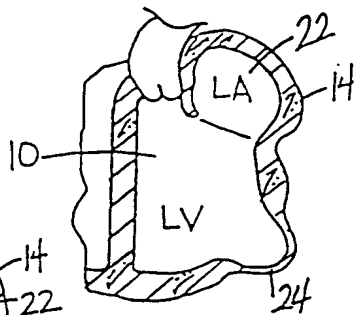


Fig. 19

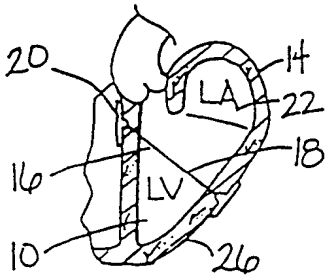
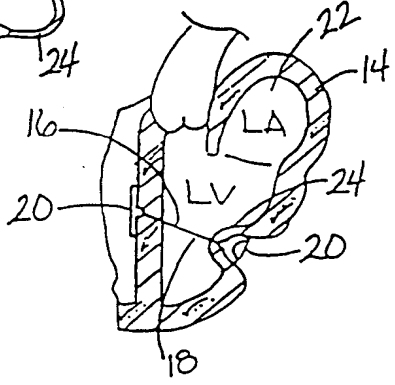


Fig. 18



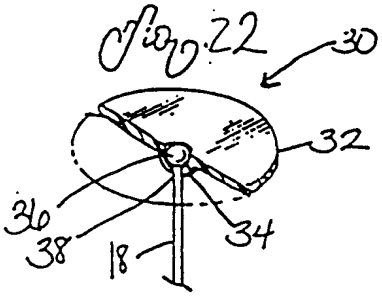


Fig. 22

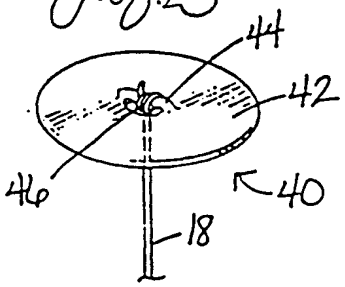


Fig. 23

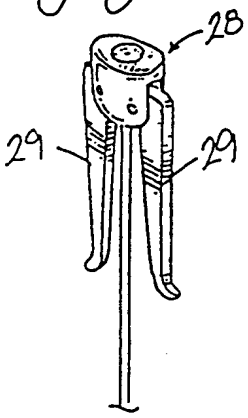


Fig. 20

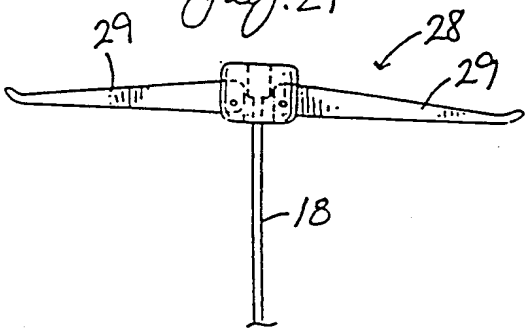


Fig. 21

Fig. 24

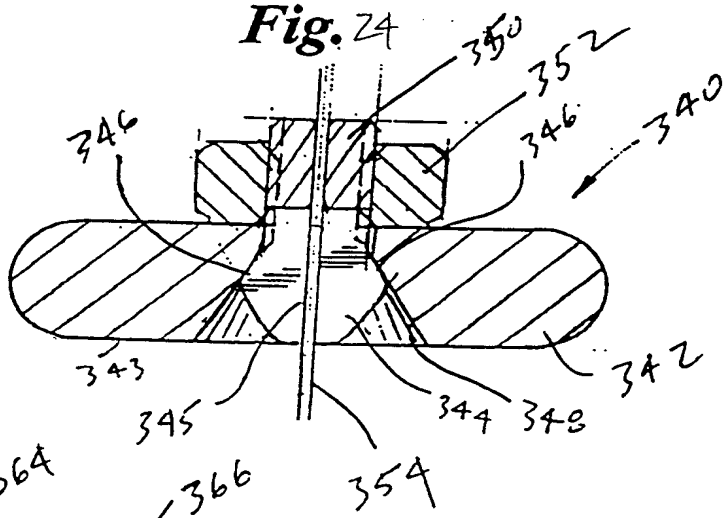
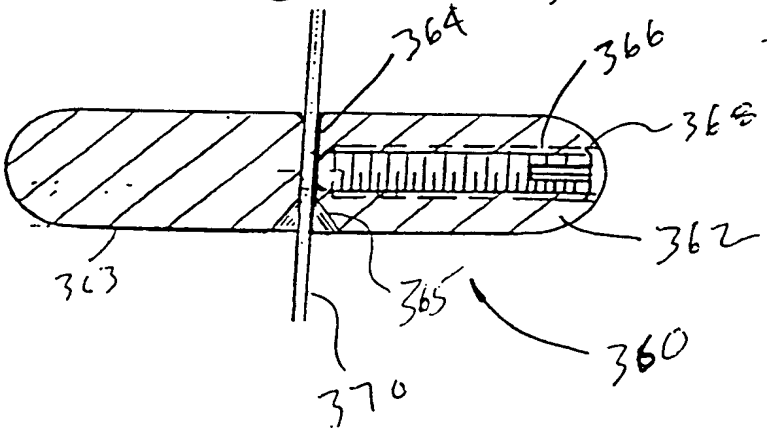


Fig. 25



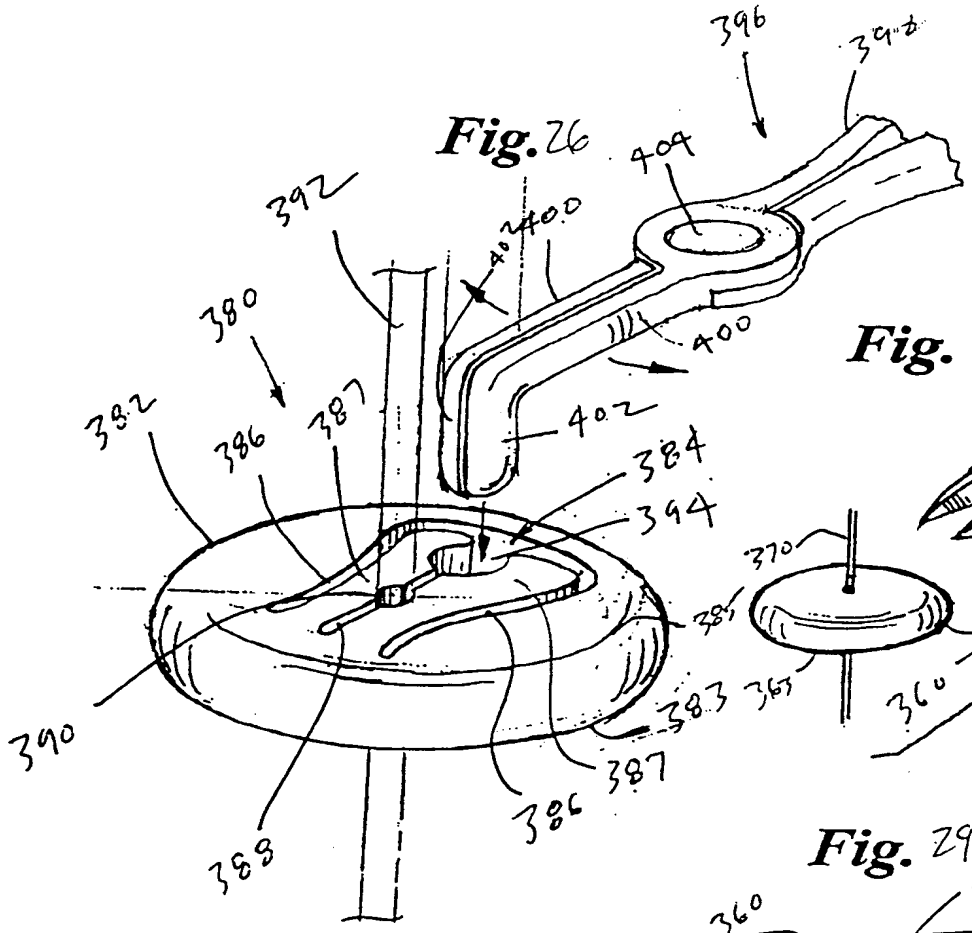


Fig. 26

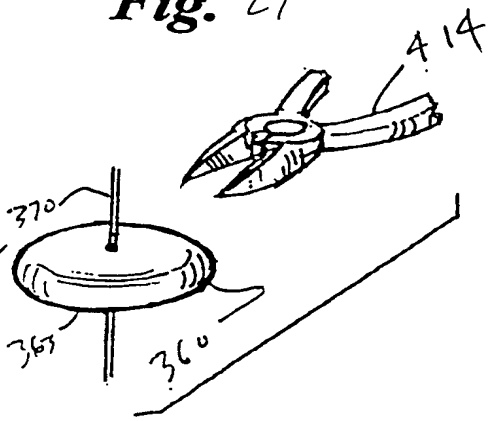


Fig. 27

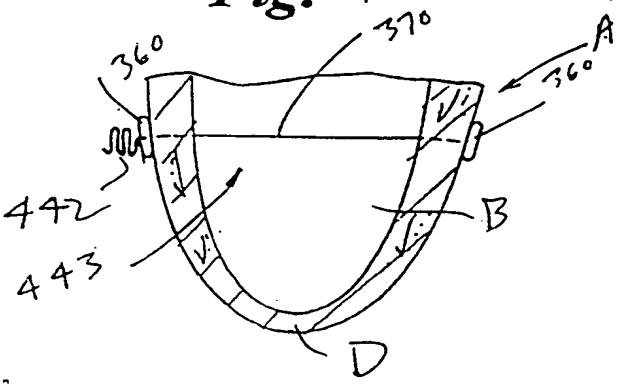


Fig. 29

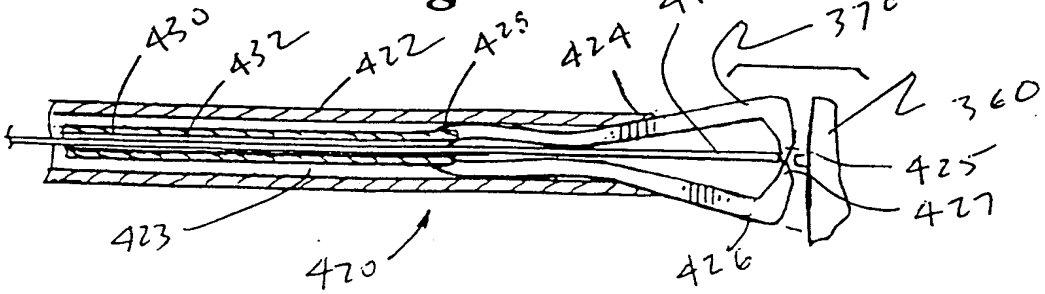


Fig. 28

Fig.

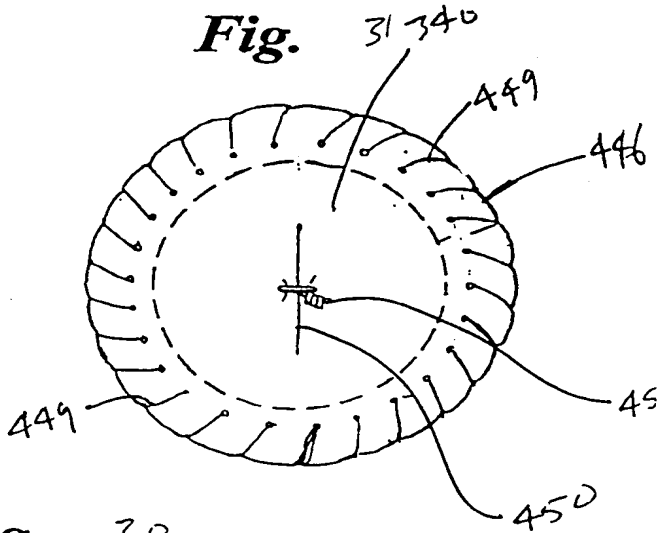
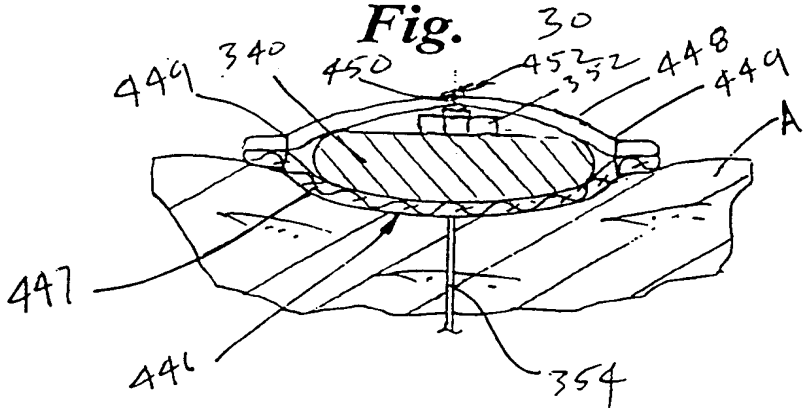


Fig.



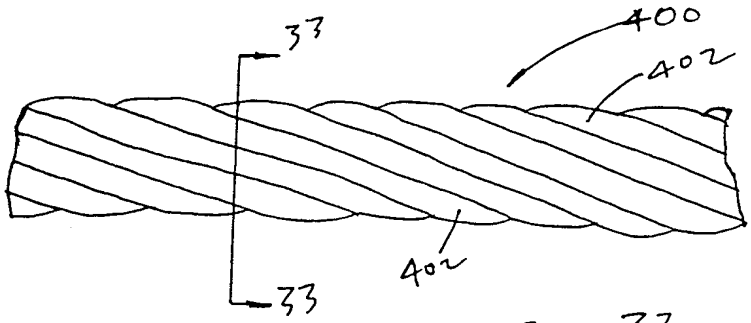


FIG. 32

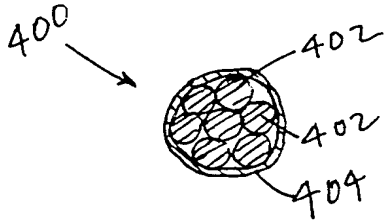


FIG. 33

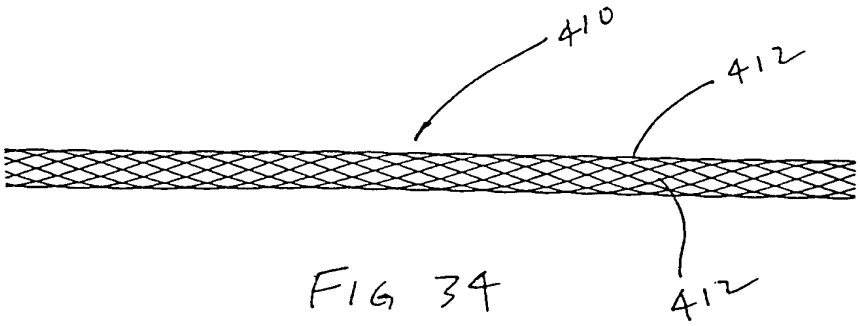


FIG 34

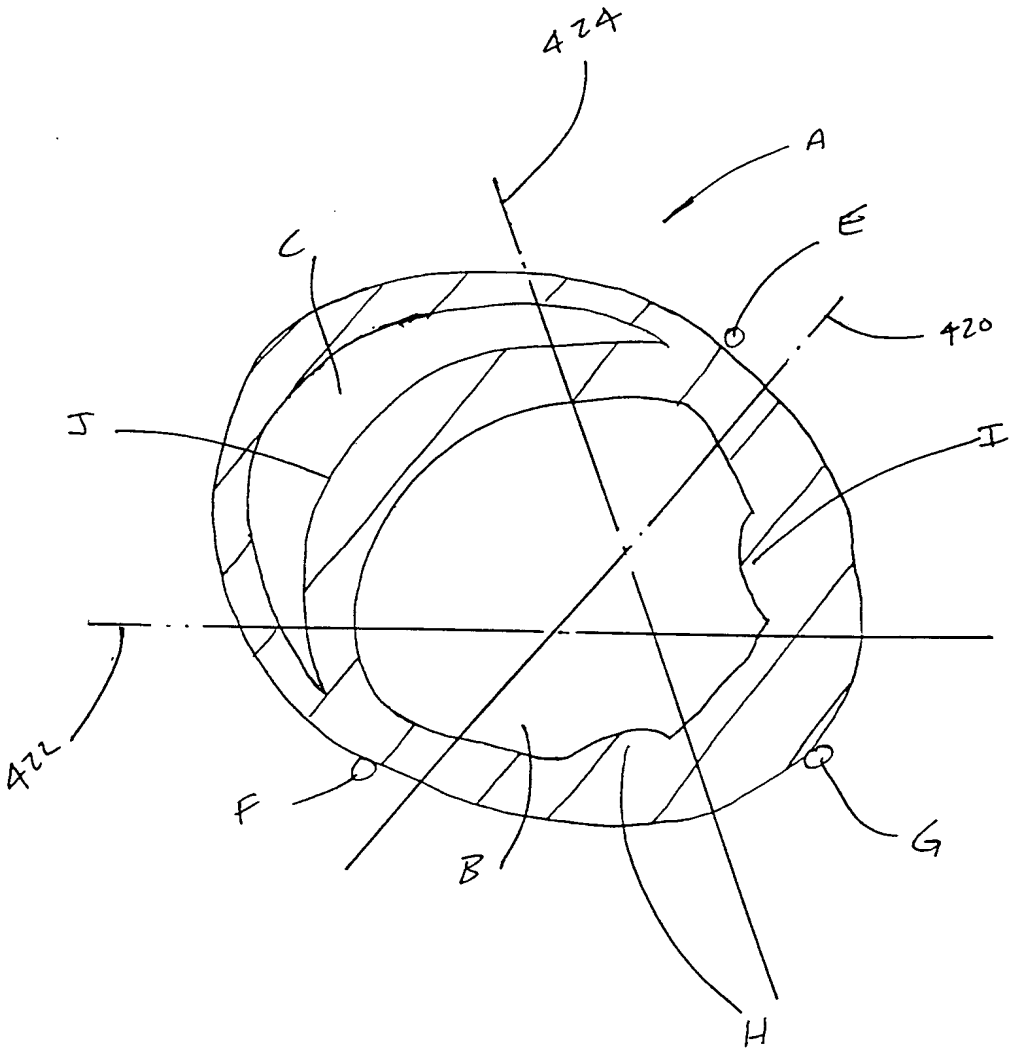


FIG. 35

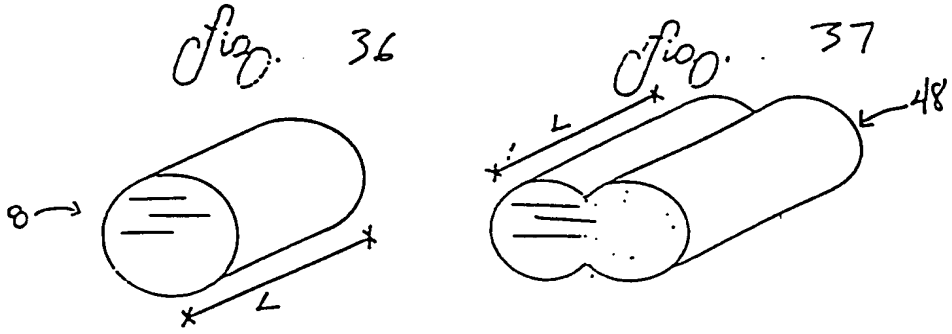


Fig. 38

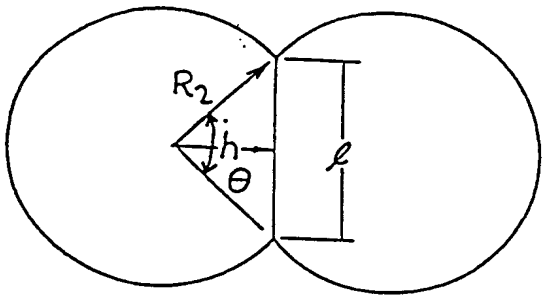


Fig. 39

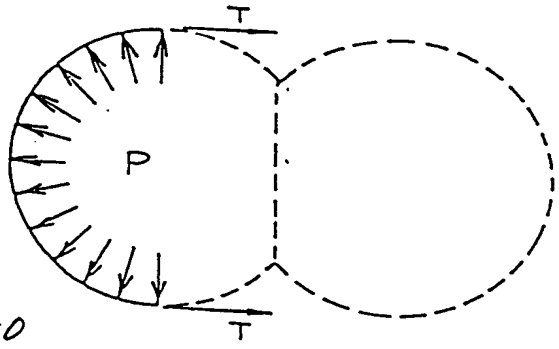
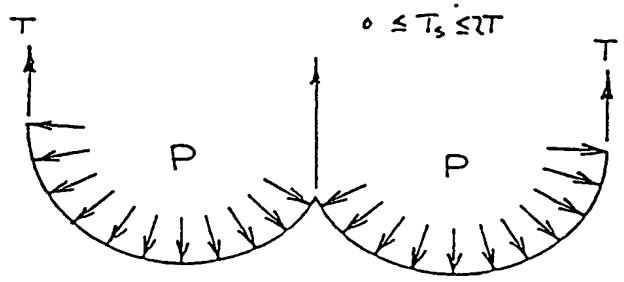


Fig. 40



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(71) Applicant *(for all designated States except US)*: **MYOCOR, INC.** [US/US]; Suite 212, 14505 21st Avenue North, Plymouth, MN 55447-5602 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **SCHWEICH, Cyril, J., Jr.** [US/US]; 1685 Hillcrest Avenue, St. Paul, MN 55116 (US). **MORTIER, Todd, J.** [US/US]; 3008 Colfax Avenue South, Minneapolis, MN 55408 (US). **VIDLUND, Robert, M.** [US/US]; 1811 Kennard Street, Maplewood, MN 55109 (US). **KEITH, Peter, T.** [US/US]; 1477 Grantham Street, St. Paul, MN 55108 (US). **PAULSON, Thomas, M.** [US/US]; 4322 York Avenue South, Minneapolis, MN 55410 (US).

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

(81) Designated States *(national)*: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, 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, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW.

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Published:
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(88) Date of publication of the international search report:
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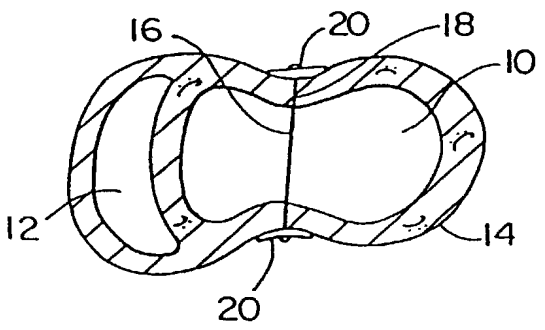
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: HEART WALL TENSION REDUCTION APPARATUS AND METHOD



(57) Abstract: An apparatus for treatment of a failing heart by reducing the wall tension therein. In one embodiment, the apparatus includes a tension member for drawing at least two walls of a heart chamber toward each other. Methods for placing the apparatus on the heart are also provided.

WO 00/06026 A3

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/16874

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/00

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61F

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 29041 A (MYOCOR, INC.) 9 July 1998 (1998-07-09) cited in the application the whole document	1,7-10
Y		2-6

Y	US 4 372 293 A (VIJIL-ROSALES) 8 February 1983 (1983-02-08) column 2, line 66 -column 3, line 14; figures	2

Y	US 5 450 860 A (O'CONNOR) 19 September 1995 (1995-09-19) abstract; figures column 12, line 6-29	3-6

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Date of the actual completion of the international search	Date of mailing of the international search report
3 November 1999	11/11/1999

Name and mailing address of the ISA	Authorized officer
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Int[illegible]tional Application No
PCT/US 99/16874

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 96 40356 A (EP TECHNOLOGIES, INC.) 19 December 1996 (1996-12-19) the whole document	1,3,5, 7-10
A	WO 98 03213 A (HEARTPORT, INC.) 29 January 1998 (1998-01-29) abstract; figures 6A-9B page 17, line 7 -page 18, line 18	1
A	US 5 593 424 A (NORTHRUP III) 14 January 1997 (1997-01-14) abstract; figures	1

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int tional Application No
PCT/US 99/16874

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US 4372293 A	08-02-1983	NONE	
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(71) Applicant *(for all designated States except US)*: MYOCOR, INC. [US/US]; Suite 200W–B, 1380 Energy Lane, St. Paul, MN 55108 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: MORTIER, Todd, J. [US/US]; 3008 Colfax Avenue South, Minneapolis, MN 55408 (US). SCHWEICH, Cyril, J., Jr. [US/US]; 1685 Hillcrest Avenue, St. Paul, MN 55116 (US). VIDLUND, Robert, M. [US/US]; 1811 Kennard Street, Maplewood, MN 55109 (US).

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

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(57) Abstract

The device and method for reducing heart wall stress. The device can be one which reduces wall stress throughout the cardiac cycle or only a portion of the cardiac cycle. The device can be configured to begin to engage, to reduce wall stress during diastolic filling, or begin to engage to reduce wall stress during systolic contraction. Furthermore, the device can be configured to include at least two elements, one of which engages full cycle and the other which engages only during a portion of the cardiac cycle.

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STRESS REDUCTION APPARATUS AND METHOD

Related Applications

This application is related to U.S. Application Serial No. 09/123,977, filed on date even herewith and entitled "Transventricular Implant Tools and Devices" and U.S. Application Serial No. 09/124,286, filed on date even herewith and entitled "Heart Wall Tension Reduction Apparatus and Method", both of which are incorporated herein by reference

Field of the Invention

The present invention pertains to the field of apparatus for treatment of a failing heart. In particular, the apparatus of the present invention is directed toward reducing the wall stress in the failing heart.

Background of the Invention

The syndrome of heart failure is a common course for the progression of many forms of heart disease. Heart failure may be considered to be the condition in which an abnormality of cardiac function is responsible for the inability of the heart to pump blood at a rate commensurate with the requirements of the metabolizing tissues, or can do so only at an abnormally elevated filling pressure. There are many specific disease processes that can lead to heart failure with a resulting difference in pathophysiology of the failing heart, such as the dilatation of the left ventricular chamber. Etiologies that can lead to this form of failure include idiopathic cardiomyopathy, viral cardiomyopathy, and ischemic cardiomyopathy.

The process of ventricular dilatation is generally the result of chronic volume overload or specific damage to the myocardium. In a normal heart that is exposed to long term increased cardiac output requirements, for example, that of an athlete, there is an adaptive process of ventricular dilation and myocyte hypertrophy. In this way, the heart fully compensates for the increased cardiac output requirements. With damage to the myocardium or chronic volume overload, however, there are increased requirements put on the contracting myocardium to such a level that this compensated state is never achieved and the heart continues to dilate.

The basic problem with a large dilated left ventricle is that there is a significant increase in wall tension and/or stress both during diastolic filling and during systolic contraction. In a normal heart, the adaptation of muscle hypertrophy (thickening) and ventricular dilatation maintain a fairly constant wall tension for systolic contraction. However, in a failing heart, the ongoing dilatation is greater than the hypertrophy and the result is a rising wall tension requirement for systolic contraction. This is felt to be an ongoing insult to the muscle myocyte resulting in further muscle damage. The increase in wall stress is also true for diastolic filling. Additionally, because of the lack of cardiac output, there is generally a rise in ventricular filling pressure from several physiologic mechanisms. Moreover, in diastole there is both a diameter increase and a pressure increase over normal, both contributing to higher wall stress levels. The increase in diastolic wall stress is felt to be the primary contributor to ongoing dilatation of the chamber.

Prior art treatments for heart failure fall into three generally categories. The first being pharmacological, for example, diuretics. The second being assist systems, for

example, pumps. Finally, surgical treatments have been experimented with, which are described in more detail below.

With respect to pharmacological treatments, diuretics have been used to reduce the workload of the heart by reducing blood volume and preload. Clinically, preload is defined in several ways including left ventricular end diastolic pressure (LVEDP), or left ventricular end diastolic volume (LVEDV). Physiologically, the preferred definition is the length of stretch of the sarcomere at end diastole. Diuretics reduce extra cellular fluid which builds in congestive heart failure patients increasing preload conditions. Nitrates, arteriolar vasodilators, angiotensin converting enzyme inhibitors have been used to treat heart failure through the reduction of cardiac workload through the reduction of afterload. Afterload may be defined as the tension or stress required in the wall of the ventricle during ejection. Inotropes such as digoxin are cardiac glycosides and function to increase cardiac output by increasing the force and speed of cardiac muscle contraction. These drug therapies offer some beneficial effects but do not stop the progression of the disease.

Assist devices include, for example, mechanical pumps. Mechanical pumps reduce the load on the heart by performing all or part of the pumping function normally done by the heart. Currently, mechanical pumps are used to sustain the patient while a donor heart for transplantation becomes available for the patient.

There are at least three surgical procedures for treatment of heart failure: 1) heart transplant; 2) dynamic cardiomyoplasty; and 3) the Batista partial left ventriculectomy. Heart transplantation has serious limitations including restricted availability of organs and adverse effects of immunosuppressive therapies required following heart transplantation. Cardiomyoplasty includes wrapping the heart with skeletal muscle and

electrically stimulating the muscle to contract synchronously with the heart in order to help the pumping function of the heart. The Batista partial left ventriculectomy includes surgically remodeling the left ventricle by removing a segment of the muscular wall. This procedure reduces the diameter of the dilated heart, which in turn reduces the loading of the heart. However, this extremely invasive procedure reduces muscle mass of the heart.

Summary of the Invention

The present invention pertains to a device and method for reducing mechanical heart wall muscle stress. Heart muscle stress is a stimulus for the initiation and progressive enlargement of the left ventricle in heart failure. Reduction of heart wall stress with the devices and methods disclosed herein is anticipated to substantially slow, stop or reverse the heart failure disease process. Although the primary focus of the discussion of the devices and methods of the present invention herein relates to heart failure and the left ventricle, these devices and method could be used to reduce stress in the heart's other chambers.

The devices and methods of the present invention can reduce heart wall stress throughout the cardiac cycle including end diastole and end systole. Alternatively, they can be used to reduce wall stress during the portions of the cardiac cycle not including end systole. Those devices which operate throughout the cardiac cycle are referred to herein as "full cycle splints". Those devices which do not operate to reduce wall stress during end stage systole are referred to as "restrictive devices". Restrictive devices include both "restrictive splints" which alter the geometric shape of the left ventricle, and

"wraps" which merely limit the magnitude of the expansion of the left ventricle during diastolic filling without a substantial shape change.

While it is desirable to reduce wall stress for the treatment of heart failure, to slow or reverse the disease process and to increase heart wall muscle shortening and pumping efficiency, it is also desirable to maintain or improve stroke volume and allow for variable preload.

Improving muscle shortening both total length change and extent at end systole, is particularly important in symptomatic heart failure wherein the heart has decreased left ventricle function and has enlarged. Full cycle splinting can be used to obtain a substantial increase in muscle shortening. Improved shortening will lead to an increase in pump function, and chronically may result in muscle strengthening and reversal of the disease because of increased pumping efficiency. The increase in shortening should be balanced against a reduction in chamber volume.

In asymtomatic, early stage heart failure, it may be possible to use only a restrictive device or method as elevated wall stress is considered to be an initiator of muscle damage and chamber enlargement. Restrictive devices and methods acting during diastole will reduce the maximum wall stress experience during end diastole and early systole. It should be understood that restrictive devices and methods can be used in combination with full cycle splinting to more precisely control or manipulate stress reduction throughout the cardiac cycle.

Brief Description of the Drawings

Figure 1 is a vertical side view of a heart including a transventricular splint and band splint;

Figure 2 is a horizontal cross section of the heart, splint and band splint of Figure 1;

Figure 3 is a graph showing the relationship between stress and strain for the sarcomeres of the left ventricle for a normal and failing heart throughout the cardiac cycle;

Figure 4 is an idealized horizontal cross section of a left ventricle splinted to form two lobes;

Figure 5 is an idealized horizontal cross sectional left ventricle splinted to form three lobes;

Figure 6 is a vertical view of a heart including two transventricular splints and two band splints;

Figure 7 is a cross sectional view of the heart, a band splint and a splint of Figure 6;

Figure 8 is a vertical view of a heart including a transventricular splint and a partial band splint;

Figure 9 is a horizontal cross sectional view of the heart, splint and band splint of Figure 8;

Figure 10 is a horizontal cross section of a heart including a splint having full cycle and restrictive elements at the beginning of diastolic filling;

Figure 11 is a view of the splint of Figure 10 at end diastole;

Figure 12 is a horizontal cross section of the left ventricle including a full cycle transventricular splint and a restrictive transventricular splint at the beginning of diastolic filling;

Figure 13 is a view of the splints of Figure 12 at end diastole;

Figure 14 is a horizontal cross sectional view of the left ventricle including a restrictive splint at the beginning of diastolic filling;

Figure 15 is a view of the splint of Figure 14 at end diastole;

Figure 16 is a vertical view of the heart in phantom line including a band splint;

Figure 17 is an alternate embodiment of the band splint of Figure 16;

Figure 18 is an alternate embodiment of the band splint of Figure 16;

Figure 19 is an alternate embodiment of the band splint of Figure 16;

Figure 20 is a vertical view of a heart including a partial circumferential strap;

Figure 21 is a horizontal cross sectional view of the heart and strap of Figure 20;

Figure 22 is a vertical view of a heart including a vertical partial strap;

Figure 23 is a horizontal cross sectional view of a heart including a transventricular splint passing through the papillary muscles;

Figure 24 is a horizontal cross sectional view of a heart including a transventricular splint passing through the left ventricle to lateral the papillary muscles;

Figure 25 is a horizontal cross sectional view of the left ventricle including a plurality of transventricular splints;

Figure 26 is a vertical view of a heart in phantom line including a single element wrap including longitudinal axis securing points;

Figure 27 is an alternate embodiment of the wrap of Figure 26;

Figure 28 is an alternate embodiment of the wrap of Figure 26;

Figure 29 is an alternate embodiment of the wrap of Figure 26;

Figure 30 is a vertical view of the heart including a mesh wrap;

Figure 31 is a cross sectional view of a patient's torso and heart showing a band splint anchored to the patient's ribs;

Figure 32 is a partial vertical view of the heart and band splint of Figure 31;

Figure 33 is a partial vertical view of a failing heart;

Figure 34 is a cross sectional view of the heart of Figure 33;

Figure 35 is a vertical view of the heart for decreasing the horizontal radius of the ventricles and increasing their vertical length;

Figure 36 is an exaggerated vertical view of the heart of Figure 33 elongated by the device of Figure 35;

Figure 37 is a view of the cross section of Figure 34 showing the decrease in radius of the ventricles;

Figure 38 is a horizontal cross sectional view of the heart showing the left and right ventricles and a splint disposed within the myocardium;

Figure 39 is a vertical cross section of the left ventricle showing a splint within the myocardium;

Figure 40 is a partial cross section of the left ventricle showing a splint extending through a portion of the myocardium;

Figure 41 is a partial vertical view of a heart showing the splint of Figure 40 extending horizontally through the myocardium;

Figure 42 is a horizontal cross sectional view of the left and right ventricles including reinforcement loops;

Figure 43 is an alternate embodiment of the reinforcing loops of Figure 43;

Figure 44 shows a vertical view of the heart including the reinforcement loops of Figure 43 and a rigid shape changing member; and

Figure 45 is a vertical cross sectional view of a heart showing a ring around the chordae.

Detailed Description of the Preferred Embodiments

The present invention is directed at reducing wall stress in a failing heart. Diastolic wall stress is considered to be an initiator of muscle damage and chamber enlargement. For this reason, it is desirable to reduce diastolic wall stress to prevent the progression of the disease. The significant impact of stress occurs at all stages and functional levels of heart failure, however, independent of the original causes. For example, in asymtomatic early stages of heart failure mechanical stress can lead to symptomatic heart failure marked by an enlarged heart with decreased left ventricle function. As the heart enlarges, mechanical stress on the heart wall increases proportionally to the increasing radius of the heart in accordance with LaPlace's Law. It can thus be appreciated that as stress increases in symptomatic heart failure, those factors that contributed to increasing stress also increase. Thus, the progression of the disease accelerates to late stage heart failure, end stage heart failure and death unless the disease is treated.

Three parameters influence mechanical stress on the muscle. These are: (1) muscle mass, i.e., as reflected by the thickness of the muscle; (2) pressure in the chamber which is a function of the resistance to blood flow of the patient's vasculature and the volume of blood within the patient; and (3) chamber of geometry. The present invention pertains to devices and methods for directly and passively changing chamber geometry to lower wall stress. In addition to treatment of heart failure, the devices and methods of the present invention also lend themselves to application in the case of a decrease in cardiac function caused by, for example, acute myocardial infarction.

The device's disclosed herein for changing chamber geometry are referred to as "splints". In addition to splints, wraps which can be placed around the heart can limit muscle stress without the chamber shape change. When a wrap is used, wall stress is merely transferred to the wrap, while the generally globular shape of the heart is maintained. A wrap could be used in conjunction with a splint to modulate heart wall stress reduction at various stages of the cardiac cycle.

The present invention includes a number of splint embodiments. Splints and wraps can be classified by where in the cardiac cycle they engage the heart wall, i.e., mechanically limit the size of the left ventricle in the case of wraps and change the geometry of the ventricle in the case of splints. If a splint or wrap only begins to engage during diastolic filling, the splint can be termed a "restrictive splint". If the splint or wrap is engaged throughout the cardiac cycle, both during diastolic filling and systolic contraction and ejection, the splint can be termed a "full cycle splint". The wrap will generally be a restrictive device which begins to engage during diastolic filling to increase the elastance (reduces compliance) of the chamber. If a wrap is made from

elastic material it may engage full cycle, but the force required to elongate the wrap will increase as diastolic filling progresses, preload strain will be reduced without an improvement in systolic contraction.

Figure 1 is a view of a heart A in a normal, generally vertical orientation. A wrap 11 surrounds heart A and a transventricular splint 12 extends through the heart and includes an anchor or anchor pad 13 disposed on opposite sides of the heart. Figure 2 is a horizontal cross sectional view of heart A taken through wrap 11 and splint 12. Splint 12 includes a tension member 15 extending through left ventricle B. Anchor pads 13 are disposed at each end of tension member 15. Right ventricle C is to the left of left ventricle B.

In Figure 1, wrap 11 and splint 12 are shown engaged with heart A. In Figure 2, heart A is shown spaced from wrap 11 except at anchor pads 13. In Figure 2, heart A is thus at a point in the cardiac cycle where the muscles are shortening during systole, or have yet to stretch sufficiently during diastolic expansion to reach wrap 11. Accordingly, wrap 11 can be considered a restrictive device as it does not engage the heart full cycle. Although wrap 11 is in contact with heart A at pads 13, only the splint is providing a compressive force to change the shape of the heart and limiting the stress of the heart in Figure 2.

If heart A, as shown in Figure 2 is at end systole, transventricular splint 12 is a full cycle device as the cross section of left ventricle B does not have the generally circular unsplinted shape. It can be appreciated that transventricular splint 12 can be used without wrap 11. Alternately, wrap 11 could be secured to heart A by sutures or other means than splint 12, in which case wrap 11 would be merely a restrictive device. It

should be noted that unless wrap 11 extends vertically along heart A a sufficient amount, as heart A expands and engages wrap 11, the portion of left ventricle B disposed above or below wrap 11 could expand substantially further than that portion of the left ventricle wall restrained by wrap 11. In such a case, left ventricle B could have a bi-lobed shape in a vertical cross section. As such, the wrap 11 would not be merely limiting the size of the left ventricle, but rather inducing a shape change in the left ventricle. In such a case, the element 11 would not be a wrap, but rather a splint which could be referred to as a "band splint".

Each of the splints, wraps and other devices disclosed in this application preferably do not substantially deform during the cardiac cycle such that the magnitude of the resistance to the expansion or contraction of the heart provided by these devices is reduced by substantial deflection. It is, however, contemplated that devices which deflect or elongate elastically under load are within the scope of the present invention, though not preferred. The materials from which each device are formed must be biocompatible and are preferably configured to be substantially atraumatic.

The distinction between restrictive devices, such as restrictive splints and wraps, and full cycle splints and wraps, can be better understood by reference to Figure 3. Figure 3 is a plot of sarcomere, i.e., heart wall muscle, stress in (g/cm^2) versus strain throughout a normal cardiac cycle N, and a failing heart cardiac cycle F. The cardiac cycles or loops shown on Figure 3 are bounded by the normal contractility curve N_c and failing heart contractility curve F_c above and to the left, and the diastolic filling curve 12 toward the bottom and right. Contractility is a measure of muscle stress at an attainable systolic stress at a given elongation or strain. It can be appreciated that the muscle

contractility N_c of normal muscle tissue is greater than the contractility F_c of the muscle tissue of a failing heart. The diastolic filling curve 12 is a plot of the stress in the muscle tissue at a given elongation or strain when the muscle is at rest.

An arbitrary beginning of the normal cardiac cycle N can be chosen at end diastole 14, where the left ventricle is full, the aortic valve is closed. Just after end diastole 14, systole begins, the sarcomere muscles become active and the mitral valve closes, increasing muscle stress without substantially shortening (sometimes referred to as "isovolumic contraction"). Stress increases until the aortic valve opens at 16. Isotonic shortening begins and stress decreases and the muscles shorten until end systole 18, where the blood has been ejected from the left ventricle and the aortic valve closes. After end systole 18, diastole begins, the muscles relax without elongating until diastolic filling begins when the mitral valve opens at 20. The muscles then elongate while the mitral valve remains open during diastolic filling until end diastole 14. The total muscle shortening and lengthening during the normal cycle N is N_s.

An analogous cycle F also occurs in a failing heart. As the left ventricle has dilated, in accordance with LaPlace's Law, the larger radius of a dilated left ventricle causes stress to increase at a given blood pressure. Consequently, a failing heart must compensate to maintain the blood pressure. The compensation for the increased stress is reflected in the shift to the right of failing heart cardiac cycle F relative to the normal cycle N. The stress at end diastole 22 is elevated over the stress at end diastole 14 of the normal heart. A similar increase can be seen for the point at which the aortic valve opens 24, end systole 26 and the beginning of diastolic filling 28 relative to the analogous points for the normal cycle N. Muscle shortening and elongation F_s throughout the cycle

is also reduced in view of the relative steepening of the diastolic curve 12 to the right and the flatter contractility curve F_c relative to the normal contractility N_c.

By reference to the heart cycle stress strain graph of Figure 3, the effect on mechanical muscle stress and strain caused by the use of the devices and methods of the present invention can be illustrated. Restrictive devices begin to engage during diastolic filling, which in the case of a failing heart occurs along diastolic filling curve 12 between point 28 and 22. Restrictive devices do not engage at end systole 26. Thus, the acute effect of placement of a restrictive device is to reduce muscle stress at end diastole relative to the stress at point 22, and shift the line 22-24 to the left reducing muscle shortening and elongation F_s. Acutely, the cardiac cycle will still operate between the failing heart contractility curve F_c and the diastolic filling curve 12. If chronic muscle contractility increases such that the muscle contractility curve F_c shifts back toward the normal heart contractility curve N_c as a consequence of the stress reduction, the stress/strain curve F of the cardiac cycle will shift to the left reducing mechanical stress still further.

The effect on the stress/strain relationship of a full cycle splint will acutely shift the entire stress/strain curve F for the cycle to the left. That is, stress is reduced at both end diastole 22 and end systole 26. Muscle shortening and elongation F_s will increase acutely. If, as in the case of a restrictive splint, muscle contractility F_c improves, the entire cardiac cycle curve F will shift further to the left reducing mechanical stress still further.

The type and magnitude of shape change are important factors in determining the effectiveness of splinting. There are several types of lower stress cardiac geometries that

can be created from an enlarged globular left ventricular chamber typically associate with heart failure. They include lobed, disc-like, narrowed elongate, and multiple vertically stacked bulbs.

Figure 4 shows an idealized horizontal cross section of a left ventricle 30 subdivided into two symmetrical lobes 32 and 34 having an arc passing through an angle $\theta > \pi$, and a radius R. Lobes 32 and 34 can be formed using a splint, such as transventricular splint 12 shown in Figures 1 and 2. Lobes 32 and 34 are joined at points 36 and 38. Points 36 and 38 are separated by a distance ℓ.

Figure 5 is an idealized horizontal cross section of a left ventricle 40 subdivided into three generally equal sized lobes 42, 44 and 46. Each lobe has an equal radius and has an arc passing through an angle less than π. Adjacent ends of the lobes 48, 50 and 52 are separated by a distance ℓ. A plurality of transventricular splints such as splint 12 as shown in Figures 1 and 2 could be extended between adjacent ends 48, 50 and 52 to form lobes 42, 44 and 46.

For a restrictive splint, the horizontal cross sections 30 and 40 will have a generally circular shape, i.e., a non-splinted shape at end systole. As diastolic filling proceeds, the radius of the circular shape will continue to increase until the splint engages. At the point the splint engages, the lobed shape will begin to form. In the case of the two lobe splinting of Figure 4, the radius will continue to increase as diastolic filling proceeds. In the case of the three or more lobed shape, such as the three lobed configuration of Figure 5, radius R will decrease as diastolic filling proceeds. The radius will continue to decrease unless or until the pressure in the heart causes the heart to expand such that the arc of the lobe passes through an angle θ greater than π.

In the case of a full cycle splint, at end systole, the splint will already be engaged. Thus, for a full cycle splint at end systole, the horizontal cross section of the chamber will not have the normal generally circular shape. Rather, at end systole, the horizontal cross sections 30 and 40 will have a lobed shape such as shown in Figures 4 and 5. Subsequent shape change during diastolic filling for a full cycle splint will be similar to that described with respect to restrictive splints.

In view of LaPlace's Law which states that stress is directly proportional to radius of curvature, it can be appreciated that whether the radius is increasing or decreasing during diastolic filling, will have an impact on heart pumping performance. Where R is increasing during diastolic filling, wall stress will increase more rapidly than where R is decreasing. The number of lobes that are created can significantly influence the level of end diastolic muscle stress reduction achieved through splinting. Eventually adding additional lobes forms a configuration which approaches a behavior similar to a wrap. If a wrap is substantially inelastic, or of sufficient size, a wrap will only engage the heart wall at some stage of diastolic filling. If the wrap is substantially inelastic, as pressure increases in the chamber during diastolic filling, stress in the heart wall muscle will increase until the wrap fully engages and substantially all additional muscle elongating load created by increased chamber pressure will be shifted to the wrap. No further elongation of the chamber muscles disposed in a horizontal cross section through the wrap and the chamber will occur. Thus, inelastic wraps will halt additional preload muscle strain (end diastolic muscle stretch).

The type of shape change illustrated in Figures 4 and 5 is of substantial significance for restrictive splints. It is undesirable in the case of restrictive splints, to

excessively limit preload muscle strain. The Frank-Starling Curve demonstrates the dependence and need for variable preload muscle strain on overall heart pumping performance. During a person's normal activities, their body may need increased blood perfusion, for example, during exertion. In response to increased blood perfusion through a person's tissue, the heart will compensate for the additional demand by increasing stroke volume and/or heart rate. When stroke volume is increased, the patient's normal preload strain is also increased. That is, the lines 14-16 and 22-24 of the normal and failing hearts, respectively, will shift to the right. An inelastic wrap will, at engagement, substantially stop this shift. In the case of the bi-load shape change of Figure 4 or a multiple lobed change having a small number of lobes of Figure 5, significant stress reduction can be achieved while allowing for variable preload strain. If the number of lobes is increased substantially, however, variable preload will decrease as the multi-lobed configuration approaches the performance of an inelastic wrap.

The magnitude of shape change in the case of full cycle splinting becomes very important as full cycle splinting generally reduces chamber volume more than restrictive splinting. Although as with restrictive devices, the type of shape change is also important to allow for variable preload strain. Both restrictive device and full cycle splints reduce chamber volume as they reduce the cross sectional area of the chamber during the cardiac cycle. The magnitude of the shape change can vary from very slight at end diastole, such that chamber volume is only slightly reduced from the unsplinted end diastolic volume, to an extreme reduction in volume, for example, complete bifurcation by transventricular splint. The magnitude of the shape change, for example, as measured by the ratio of splint length to non-splinted ventricular diameter, is preferably modulated to reduce

muscle stress while not overly reducing chamber volume. For full cycle splint, the reduction of chamber volume is compensated for by increased contractile shortening, which in turn leads to an increased ejection fraction, i.e., the ratio of the stroke volume to chamber volume. For given stress/volume and stress/shortening relationships, there will be a theoretical optimum maximal stroke volume. Clinically, 20% to 30% stress reduction is expected to be attainable through full cycle bi-lobe splinting. See U.S. Patent Application Serial No. 08/933,456, filed September 18, 1997 for calculation of stress reduction for idealized bi-lobe splinting.

When using the full cycle and restrictive devices described herein, caution should be exercised to limit the pressure on the coronary vasculature. In the case of transventricular splints, valve structure, electrical pathways and coronary vasculature should be avoided.

Figure 6 is a vertical view of a heart A similar to that shown in Figure 1. Rather than having a single band splints surrounding heart A, there are two band splints 51 affixed to the heart by two transventricular splints 52. Splints 52 include oppositely disposed anchors or anchor pads 53. Figure 7 is a horizontal cross sectional view of heart A of Figure 6, wraps 51 and splint 52. Splints 52 include a tension member 54 disposed through left ventricle B. Pads 53 are disposed on the opposite ends of tension members 54. Right ventricle C is shown to the left of left ventricle B.

Splints 52 can be restrictive or full cycle splints. Band Splints 51 are shown as restrictive band splints as in Figure 6, heart A is shown engaged with the band splints 51, where as in Figure 7, heart A has contracted to move away from band splints 51. Wraps 51 and splints 52 should be made from biocompatible materials. Band Splints 51 are

preferably made from a pliable fabric or other material which resists elongation under normal operating loads. Band splints 51 can, however, be made from an elastic material which elongates during the cardiac cycle. Tension members 54 also preferably resist elongation under normal operating loads. Tension members 54 can, however, be made from an elastic material which elongates during the cardiac cycle.

Figure 8 is a vertical view of heart A, partial wrap 61 and transventricular splint 62. Transventricular splint 62 includes anchor pads 63. Figure 9 is a horizontal cross sectional view of heart A, partial band splint 61 and splint 62. Splint 62 is essentially similar to wrap or band splint 12 shown in Figure 1 and 2. Partial band splint 61 is also essentially similar to wrap or band splint 11 shown in Figures 1 and 2 except that band splint 61 only surrounds a portion of heart A. This portion is shown in Figures 8 and 9 to the left including a portion of left ventricle B.

Figure 10 is a horizontal cross sectional view of left ventricle B and right ventricle C of heart A taken at a similar elevation as that shown in Figure 2. A splint 70 is shown disposed on heart A. Splint 70 includes a frame having two heart engaging anchors or pads 72 disposed at its opposite ends. A third heart engaging pad 73 is disposed along frame 70 approximately midway between pads 72.

Pads 72 are shown engaged with heart A to change the shape of ventricle B in Figure 10. Pads 73 are not engaged with heart A in Figure 10. Figure 11 is the same horizontal cross sectional view as Figure 10 except that heart A has to contact pad 73 to create a further shape change of left ventricle B.

Frame 70 is preferably rigid enough that pads 72 could be disposed on the heart for full cycle splinting and sufficiently adjustable that pads 72 could be spaced further

apart for restrictive splinting. Pad 73 accomplishes restrictive splinting. Frame 71, pads 72 and 73 of splint 70 are made of a biocompatible material. Pads 72 and 73 are preferably substantially atraumatic.

Figure 12 is a horizontal cross sectional view of the left ventricle B of heart A. A transventricular splint 80 having a tension member 81 and oppositely disposed anchor pads 82 is shown extending across left ventricle B. Another transventricular splint 83 having a tension member 84 and oppositely disposed anchor pads 85 extends generally perpendicularly to splint 80, across left ventricle B.

It can be appreciated that in Figure 12 splint 83 is engaging heart A to deform left ventricle B. Splint 80, however, includes a tension member 81 made of a flexible filament, line or the like which is shown in a relaxed state in Figure 12. In Figure 13, tension member 81 is shown in an elongated, taunt configuration as heart A has expanded into engagement with pads 82.

Transventricular splints 80 and 83 can be made as described above with respect to the transventricular splint of Figures 1 and 2. Tension member 81 may be elastic or inelastic.

Figure 14 is a horizontal cross section of left ventricle B of heart A including a transventricular splint 90. Splint 90 includes a tension member 91 including three branches extending to atraumatic anchors or anchor pads 92. Similarly to tension member 81 of Figure 12, tension member 90 is shown in a relaxed state. Splint 90 can be made in a similar way as splint 80 of Figures 12 and 13.

Figure 15 is the same horizontal cross section of heart A as shown in Figure 14 except that heart A has expanded to engage atraumatic pads 92 of splint 90. Tension

member 91 is now drawn taunt to form a three lobed cross sectional configuration of left ventricle B.

Figure 16 is a vertical view of heart A shown in phantom line. Shown disposed about the ventricles of heart A is a basket-like band splint 100. Band splint 100 includes a horizontal encircling band 101 around an upper region of the ventricles and four bands 102 which extend downward toward the apex of heart A. It can be appreciated that bands 102 can act as splints to form four lobes in heart A in a horizontal plane. Depending on the placement of bands 102 around heart A, lobes could be created only in the left ventricle or in the left ventricle and/or other chambers of the heart. Band 102 is joined at the apex Band 101 and band 102 can be made from a webbing, fabric or other biocompatible material.

If band splint 100 substantially elongated elastically under normal operating loads, it could be friction fit to heart A and act full cycle, limiting muscle stress at end diastole as well end systole. Band splint 100 could be sutured into place or otherwise held on heart A and act as a restrictive device. If band 101 were securely fastened to heart A, bands 102 could limit the vertical elongation of heart A during diastolic filling.

Figure 17 is an alternate embodiment 110 of the band splint of Figure 16. Band splint 110 includes a horizontally heart encircling band 111 and four bands 113 extending downward from band 111. Bands 113, however, unlike bands 102 of band splint 100 do not extend to the apex of heart A, but rather to a second horizontally heart encircling band 112.

Band splint 110 could be made of the same materials as band splint 100. Band splint 110 can also be used in a manner similar to band splint 100 except that band splint 110 would limit the vertical elongation of the ventricles less than band splint 100.

Figure 18 is yet another alternate embodiment 120 of the wrap of Figure 16. Band splint 120 closely resembles alternate embodiment 110 of Figure 17, except that rather than having four vertically extending web members, band splint 120 includes two substantially rigid members 123 interconnecting two horizontally encircling web members 121 and 122.

Figure 19 is yet another alternate embodiment 130 of the band splint of Figure 16. Like the wrap of Figure 16, band splint 130 includes a horizontally encircling member 131 and four downwardly extending members 132. At a location proximate of the apex of heart A, members 132 are joined by a ring 133. Members 132 extend through ring 133. Ring 133 can be used to adjust the length of members 132 between band 131 and ring 133. Ring 133 can be formed from metallic material and crimped inwardly to fix its position along members 132. Other means of holding ring 133 in position would be readily apparent to those skilled in the art.

Figure 20 is a vertical view of heart A including a partial band splint 140 secured around a substantial portion of left ventricle B. Band splint 140 includes a vertically elongating anchor member 141 which sutures 142 can encircle to anchor member 141 to heart A. A band 143 extends generally horizontally from anchor member 141 to an opposite anchor 141.

The length of band 143 can be seen in its entirety in Figure 21 which is a horizontal cross sectional view of heart A through band 143, left ventricle B and right

ventricle C. In Figure 20, heart A is shown engaged with band 143, however, in Figure 21, band 143 is shown spaced from heart A. Thus, in this configuration, wrap 140 would be acting as a restrictive device. If band splint 140 were made from a material that substantially deforms elastically under normal loads, band splint 140 could also be secured sufficiently snuggly to heart A to act as a full cycle device. Preferably, however, band 143 of band splint 140 is formed from a webbing or substantially inelastic fabric.

Figure 22 is a vertical view of heart A including band splint 140 disposed vertically on left ventricle B. In this position, band splint 140 can limit the vertical elongation of left ventricle B during diastolic filling.

Figure 23 is a horizontal cross section of heart A through left ventricle B, right ventricle C and the papillary muscles D of left ventricle B. A transventricular splint 150 including an elongate tension member 151 and oppositely disposed anchor pads 152 extends through left ventricle B and papillary muscles D. Splint 150 could be similar to splint 12 of Figure 1 and 2. Figure 24 is a horizontal cross section similar to that of Figure 23. In Figure 24, however, transventricular splint 150 is shown avoiding papillary muscles D.

Figure 25 is a horizontal cross section of left ventricle B of heart A. Here three splints 150 have been placed to form six lobes. Three of the lobes 153 have an arc length which passes through an angle greater than π. Disposed between each lobe 153 are three lobes 154 which have an arc length which passes through an angle less than π. Consequently, during diastolic filling, the effective radius of lobes 153 will be increasing while the radius of lobes 154 will be decreasing.

Figure 26 is a vertical view of heart A including a wrap 160. Wrap 160 can include a single thread or line 161 encircling the heart several times. After line 161 encircles heart A, line 161 can be threaded through a bar 162, including a plurality of eyelets 163 spaced along its length in pairs. Bar 162 is preferably rigid enough to substantially maintain the distance between eyelets 163 under normal operating loads.

When line 161 is placed in heart A, one end of line 161 can be tied to bar 162 at 164. Line 161 can then encircle the heart and be drawn through eyelet 162 adjacent the beginning of line 161 at 164. Line 161 can then be drawn through one eyelet 163 of a lower pair of eyelets to encircle the heart again. This process continues until line 161 is tied to an eyelet 163 at 165. It can be appreciated that wrap 160 could be used as a restrictive or full cycle device depending on the diameter of loop formed by line 161.

Figure 27 is an alternate embodiment 170 of the wrap of Figure 26. Wrap 170, however, includes two vertically extending bars 172 having eyelets 173 through which line 171 is threaded. Line 171 can be tied to one of the bars 172 at 174 and 175.

Figure 28 is a vertical view of heart A including yet another embodiment 180 of the wrap of Figure 26. Wrap 180 includes a line 181 encircling heart A a plurality of times. Rather than having a single vertically extending bar 162 to position line 180 on heart A, wrap 180 includes a plurality of horizontal bars 182 including a pair of eyelets 183. One end of line 181 is tied to an upper bar 182 at 184 and the opposite end of line 181 is tied to a lower bar 182 at 185. Between 184 and 185, line 181 is threaded through eyelets 182 to form the heart encircling pattern shown in Figure 28.

Figure 29 is a vertical view of heart A including yet another alternate embodiment 190 of the wrap of Figure 26. Wrap 190 closely resembles 180 of Figure 28. Line 181

has, however, been threaded through eyelets 183 of bars 182 in a pattern which, unlike that of Figure 28, bars 182 are disposed at various selected locations around the circumference of heart A.

Figure 30 is a vertical view of heart A including a wrap 200. Wrap 200 is substantially similar to wrap 11 of Figures 1 and 2, except that wrap 200 extends vertically a greater distance than wrap 11. Wrap 200 is not shown with a transventricular splint. It can be appreciated that wrap 200 could be used as restrictive or full cycle device.

Figure 31 is a horizontal cross section of a human torso including heart A, left ventricle B, right ventricle C, lungs E and ribs G. A wrap 210 is shown partially encircling heart A. Opposite ends of wrap 210 are anchored at 211 to ribs G. At 211, wrap 210 can be anchored to ribs G by bone screw, knot or other means of fastening. It can be appreciated that band splint 210 could be used as a restrictive or full cycle device.

Figure 33 is a vertical view of heart A having a W_1. Figure 34 is an idealized horizontal cross sectional view of heart A of Figure 33. Heart A includes left ventricle B and right ventricle C. Left ventricle B has a radius R_1.

Figure 35 is a view of a device 220. Device 220 includes a horizontally encircling band 222 which can be affixed to heart A by sutures, other attachment means or friction fit. Extending from band 222 is a substantially rigid elongate member 224. Member 224 extends to the apex of heart A. Pin 226 extends into left ventricle B of the apex. An anchor or pad 228 is disposed within left ventricle B to anchor the apex of heart A to elongate member 224. Elongate member 224 can be made of sufficient length such that heart A is vertically elongate full cycle, or alternately not at end diastole.

Figure 36 is a vertical view of an elongate heart A having a horizontal width W_2 less than W_1. Figure 37 is a horizontal cross section of the heart A of Figure 36 including left ventricle B and right ventricle C. In Figure 37, the radius R_2 of left ventricle B is less than R_1 of Figure 34. Assuming that the hearts of Figures 33 and 36 are at the same point in the cardiac cycle, it can be appreciated that the wall stress in heart A is less in Figure 37 as R_2 is shorter R.

If elongate bar 224 is sized such that device 220 does not engage at end diastole, but rather anchor pad 228 first engages during systolic contraction, device 220 can fall into a third class of device neither full cycle nor restrictive. Such a device would reduce wall stress during a portion of systolic contraction including end systole, but not reduce wall stress during end diastole, thus maintaining maximum preload.

Band 222 of device 220 is preferably formed from a web material or other fabric. Band 220 is preferably does not elongate substantially during diastolic filling. Members 224, 226 and 228 are formed from materials which remain substantially rigid under the influences of the forces encountered during the cardiac cycle.

Figure 38 is a horizontal cross section of heart A including left ventricle B and right ventricle C. Advanced through the myocardium of heart A is a device including a tubular member 231 and thread or line 232 disposed within tubular member 231. In Figure 38, the free ends of thread 232 are disposed outside of heart A. The free ends of thread 232 could be drawn toward each other to reduce the diameter of device 230 in heart A. After a desired reduction in diameter, the free ends could be tied together.

Tube 231 is preferably highly flexible, yet durable enough to prevent thread 232 from "cheese cutting" through the myocardium of heart A. Tube 231 and line 232 are

preferably formed from biocompatible atraumatic materials which do not substantially elongate under the influence of forces encountered during expansion and contraction of heart A. In an alternate embodiment, tube 231 and line 232 could be made from materials which readily elongate under the influence of the forces encountered during the cardiac cycle. It can be appreciated that device 230 could be used as a full cycle device or restrictive device.

Figure 39 is a vertical cross sectional view of heart A including left ventricle B. A substantially V-shaped or U-shaped member having arms 241 is shown substantially advanced into the myocardium of heart A. Device 240 includes an apex 242 disposed adjacent the apex of heart A. The spacing of arms 241 from each other is preferably such that device 240 can form lobes in horizontal cross sections of left ventricle B.

Device 240 is preferably formed from biocompatible materials which preferably do not deform substantially under the influence of the forces encountered during the cardiac cycle. It can be appreciated that device 240 could be used as a restrictive or full cycle device.

Figure 40 is a partial cross section of heart A and left ventricle B. A device 250 extends through a portion of the myocardium of heart A. Device 250 can be configured similarly to splint 12 of Figures 1 and 2. Device 250 accordingly includes two tension members 251 and oppositely disposed anchors pad 252. Tension members 251, however, do not extend transventricularly.

Figure 41 is a vertical view of heart A including device 250. Splint 250 can act as a full cycle device or a restrictive device, to shorten a portion of the left ventricle heart wall.

Figure 42 is a horizontal cross sectional view of heart A including left ventricle B and C. A device 260 including a thread or line 261 is disposed transventricularly and transmyocardially through heart A. A portion of line 261 is disposed outside of heart A. Opposite ends of line 261 are connected at 262. Those portions of line 261 outside heart A form loops 263. The size of loops 263 are exaggerated for purposes of illustration. It is assumed that heart A in the process of diastolic filling in Figure 42, and loops 263 are sufficiently small, eventually heart A will engage loops 263. In such a configuration, device 260 is used as a restrictive device. Loops 263 could be sized, however, such that they engage full cycle.

Line 261 is preferably made from atraumatic biocompatible material. The diameter of line 261 is preferably sufficiently great that cutting of heart A does not occur during diastolic filling.

Figure 43 is a horizontal cross sectional view of heart A including left ventricle B and right ventricle C and an alternate embodiment 270 of the device of Figure 42. Device 270 includes a line 271 which does not extend transventricularly but extends through the myocardium of heart A to form four loops 273.

Device 270 can be formed from material similar to that used to form device 260. Additionally, device 270 can be made to function as a restrictive device or full cycle device in a manner similar to that of device 260.

Line 261 and line 267 could be disposed within a tube such as tube 231 of Figure 38 to avoid cheese cutting of the myocardium. Devices 260 and 270 could extend through the septum or right ventricle to avoid forming lobes in right ventricle C.

Figure 44 is a vertical view of heart A including three devices 270 disposed at three spaced elevations. An elongate generally rigid bar 274 is disposed through loops 273 to distribute the load on heart A from loops 273 across a larger area than lines 271 can alone.

Figure 45 is a vertical cross section of heart A showing left ventricle B including papillary muscles D and chordae H. Joining chordae H is a ring 290. Ring 290 is preferably strong and rigid enough to hold chordae H, papillary muscles D and consequently the wall of left ventricle B inward during diastolic expansion. It can be appreciated that loop 290 could be configured to operate as a full cycle or a restrictive device. Preferably loop 229 is formed from an atraumatic biocompatible material.

Numerous characteristics and advantages of the invention covered by this document have been set forth in the foregoing description. It will be understood, however, that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size and ordering of steps without exceeding the scope of the invention. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A device for reducing heart wall stress, comprising:

a first means for reducing heart wall stress which engages throughout the cardiac cycle; and

second means for reducing heart wall stress which begins to engage the heart wall during diastolic filling.

2. The device in accordance with claim 1, wherein the first means includes a splint having an elongate tension member, the elongate tension member having a first end and a second end, the splint having a first anchor member connected at the first end of the tension member and a second anchor member connected at the second end of the tension member.

3. The device in accordance with claim 1, wherein the second means includes a splint having an elongate tension member, the elongate tension member having a first end and a second end, the splint having a first anchor member connected at the first end of the tension member and a second anchor member connected at the second end of the tension member.

4. The device in accordance with claim 1, wherein the second means includes an elongate member sized to surround the heart and begin to engage a portion of the left ventricle wall during diastolic filling.

5. The device in accordance with claim 1, wherein the first means includes a frame including at least two means for engaging the wall of the left ventricle.

6. The device in accordance with claim 5, wherein the means for engaging include pads.

7. The device in accordance with claim 5, wherein the second means for reducing heart wall stress includes a means for engaging connected to the frame.

8. The device in accordance with claim 7, wherein the means for engaging of the second means includes a pad.

9. A method of reducing heart wall stress, comprising the steps of:

providing a device having at least one heart engaging member;

placing the heart engaging member on the heart such that the shape of a cross section of the left ventricle is changed throughout the cardiac cycle;

providing a second device having at least one heart engaging member; and

placing the heart engaging member of the second device on the heart such that a second device begins to engage the heart during diastolic filling.

Fig. 1

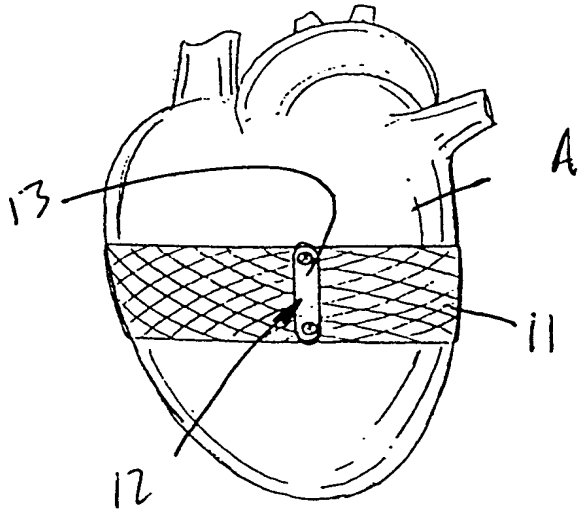
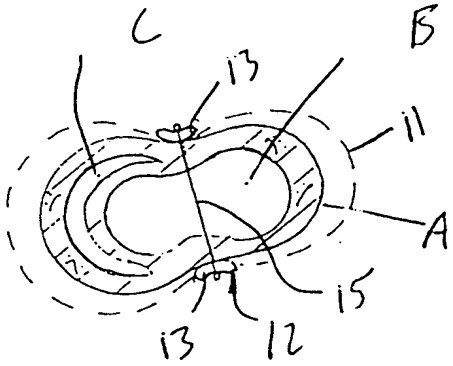


Fig. 2



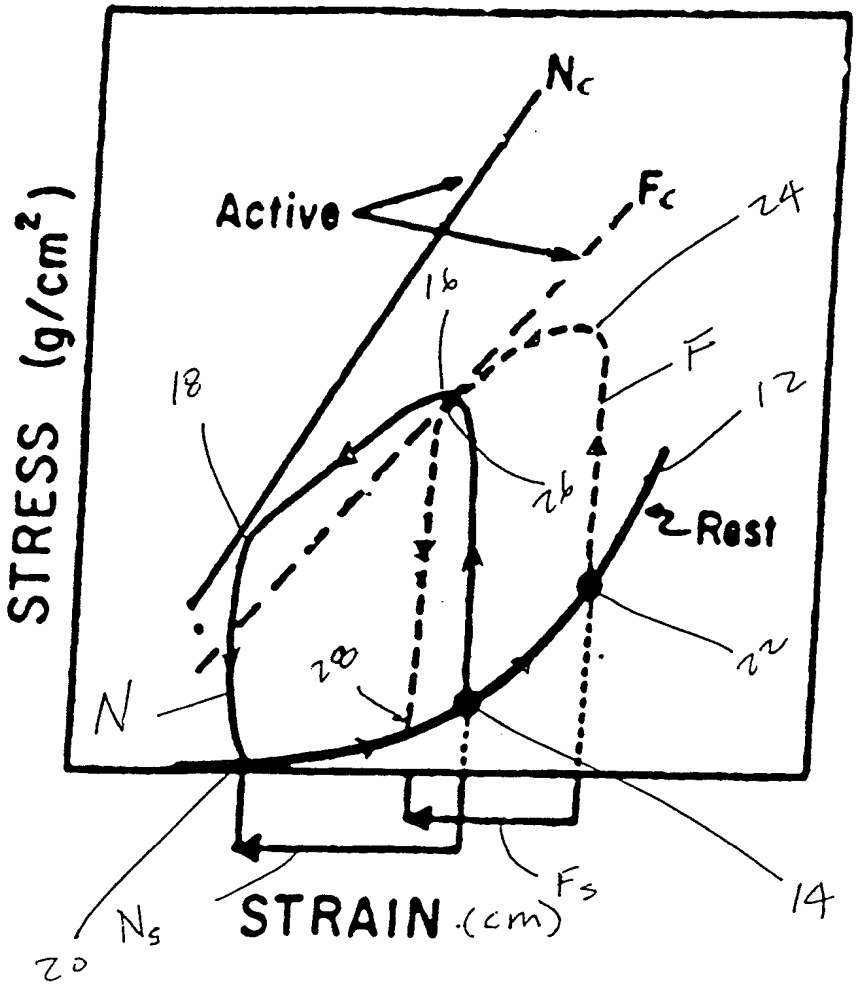
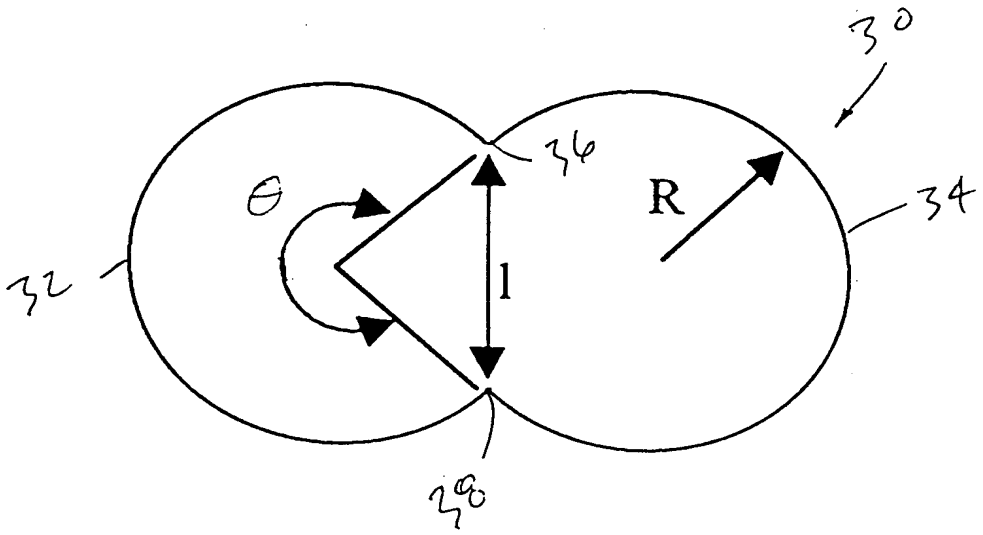
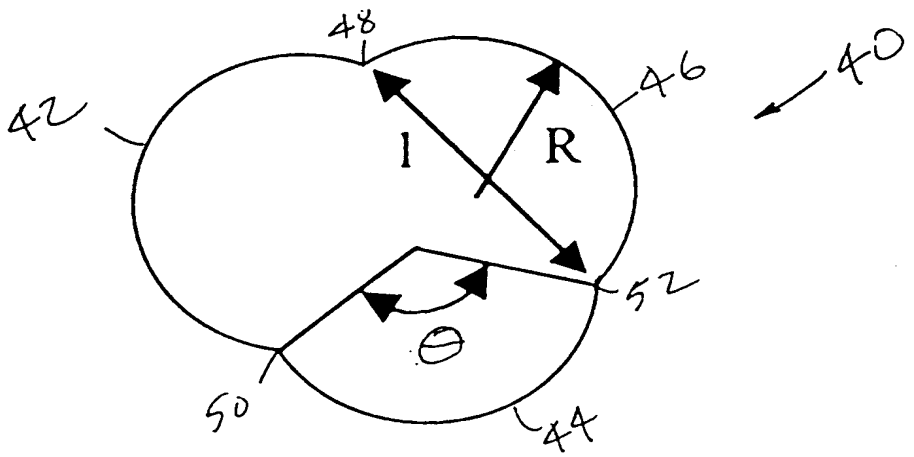


FIG. 3



$\theta > \pi$

FIG. 4



$\theta < \pi$

FIG. 5

Fig. 7

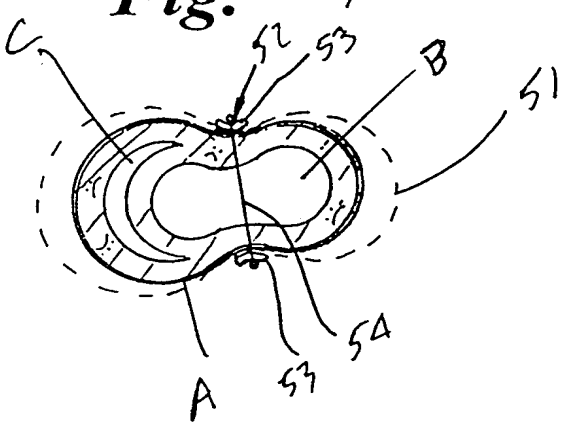


Fig. 6

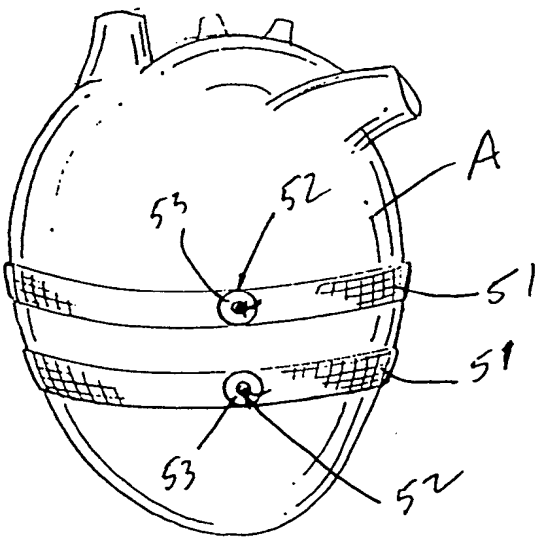


Fig. 8

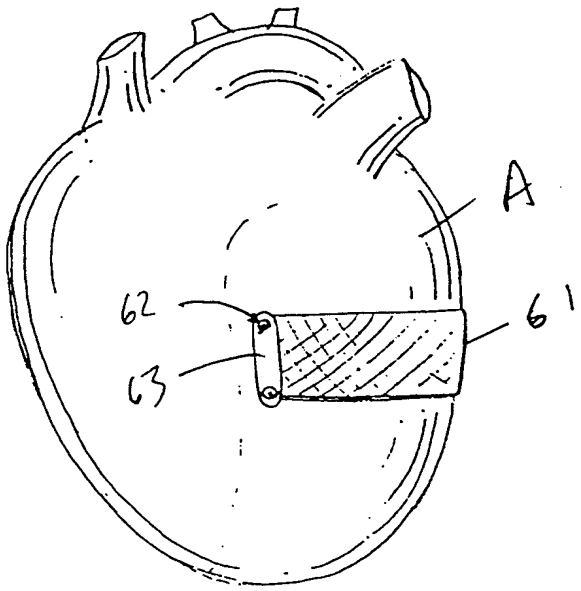


Fig. 9

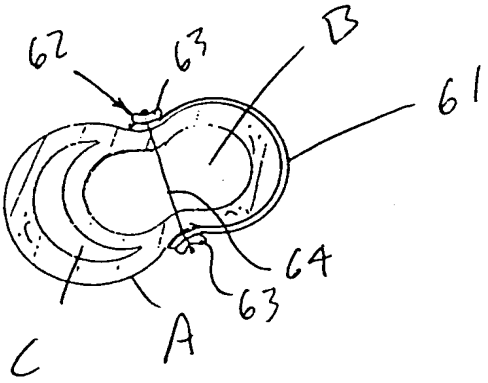


Fig. 10

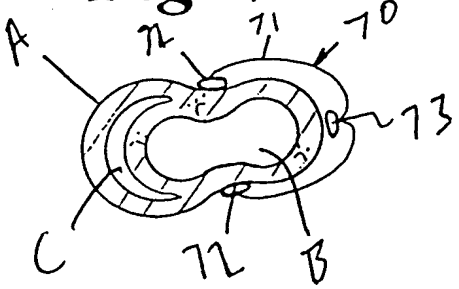


Fig. 11

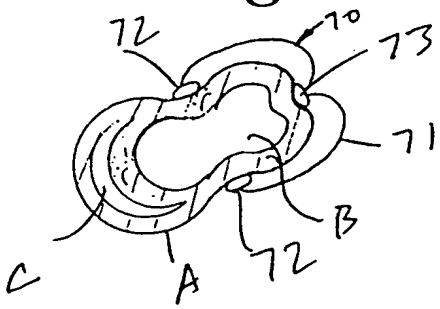


Fig. 12

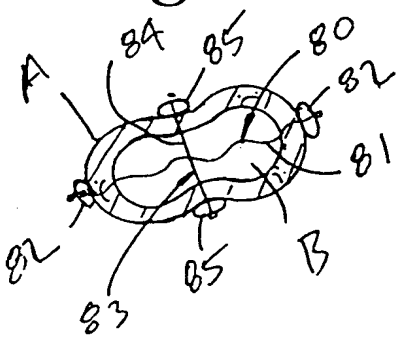


Fig. 13

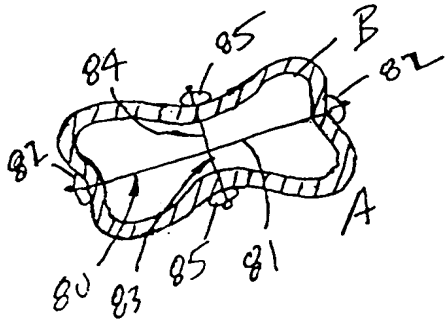


Fig. 14

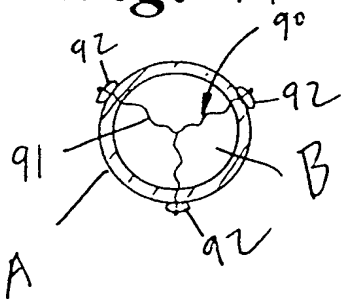


Fig. 15

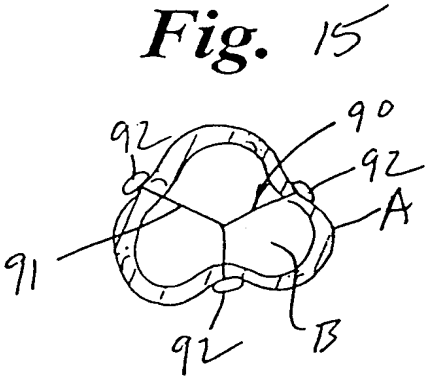


Fig.16

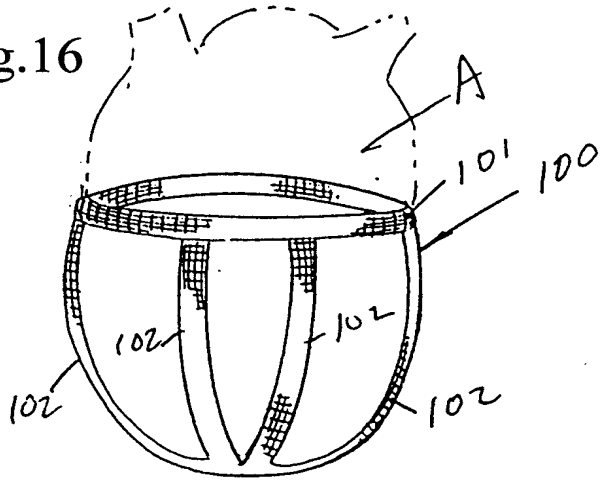


Fig. 17

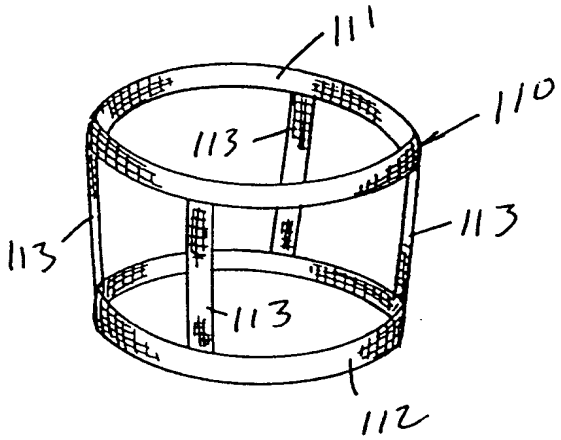


Fig. 18

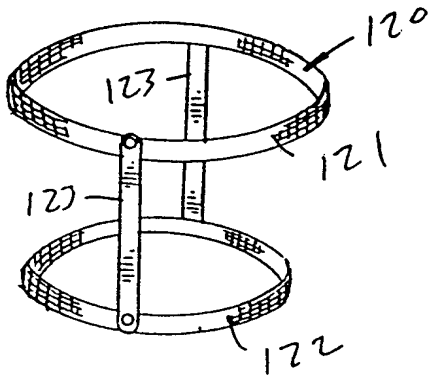


Fig. 19

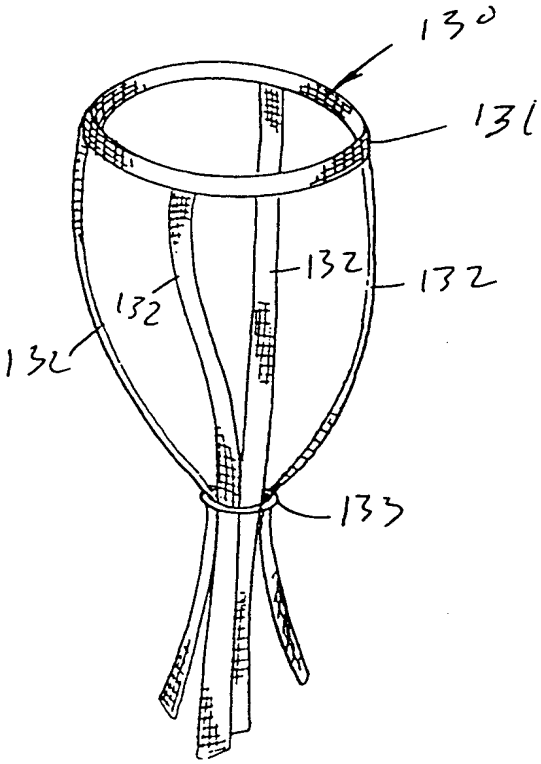


Fig. 20

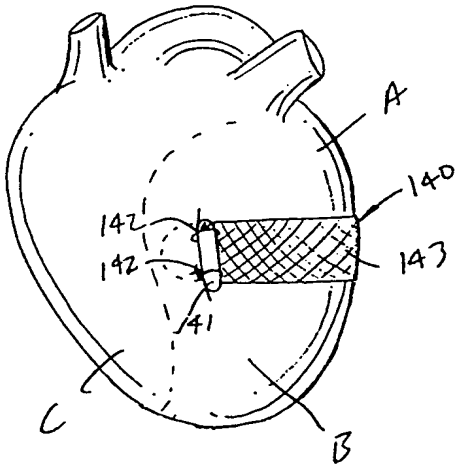


Fig. 21

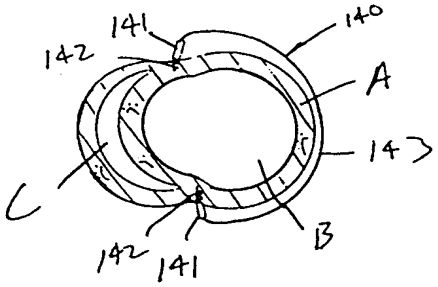


Fig. 22

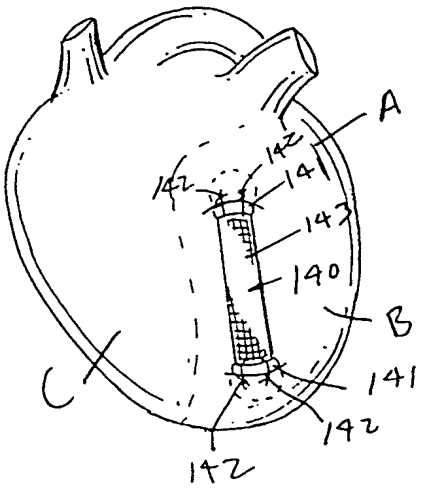


Fig. 23

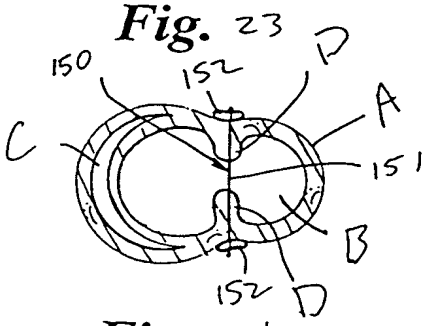


Fig. 24

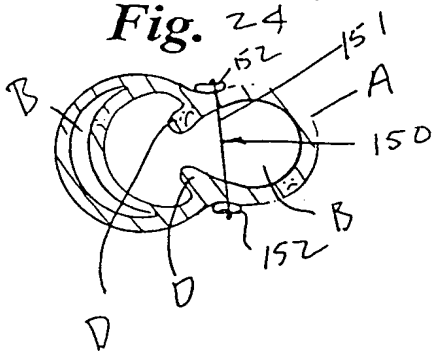


Fig. 25

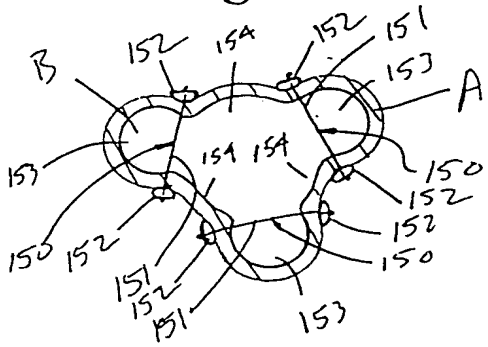


Fig. 26

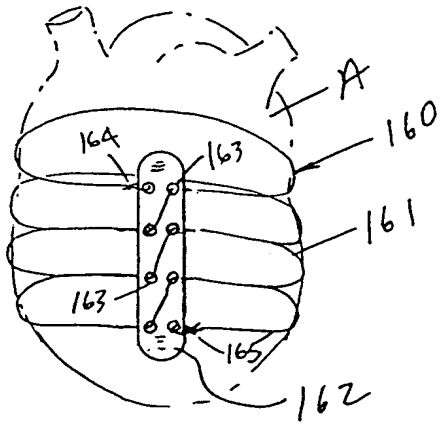


Fig. 27

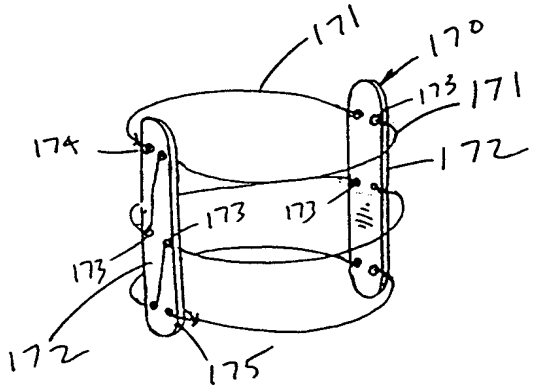


Fig. 28

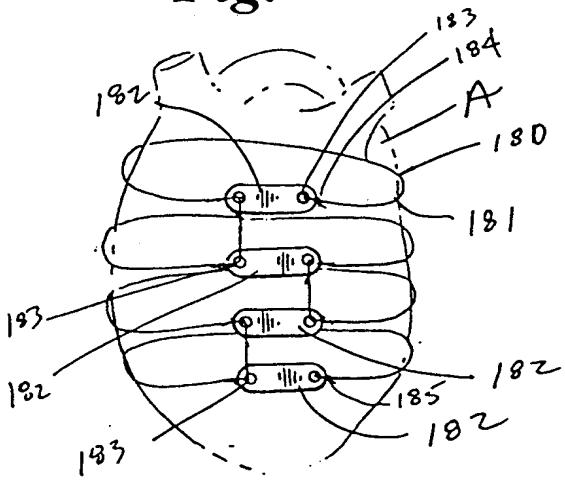


Fig. 30

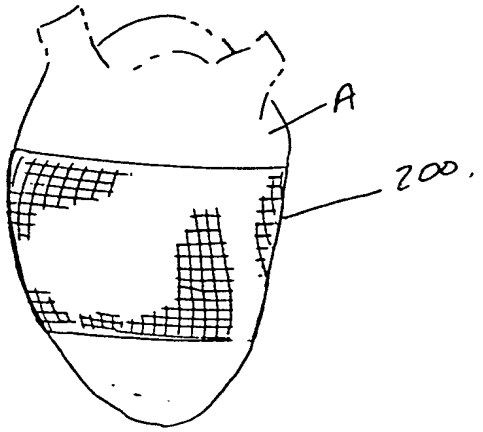


Fig. 29

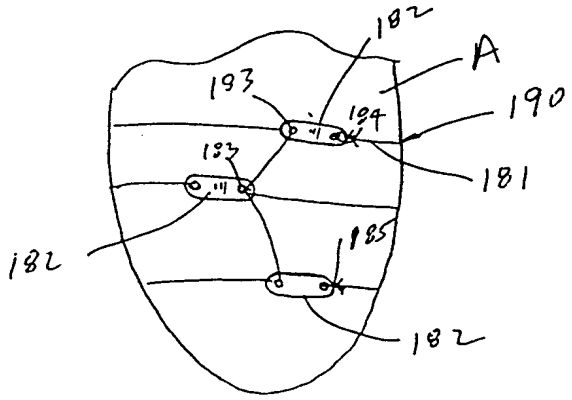


Fig. 31

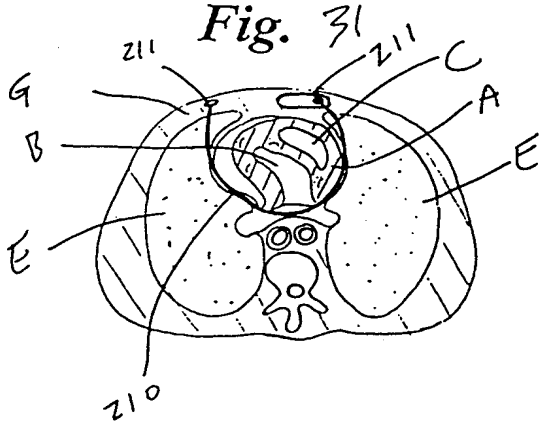


Fig. 32

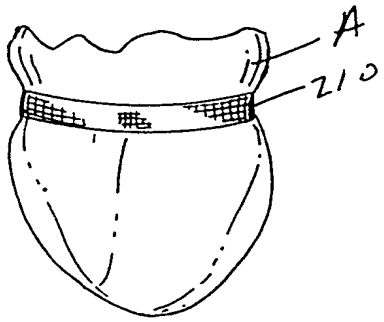


Fig. 33

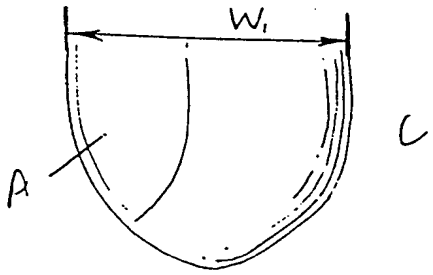


Fig. 34

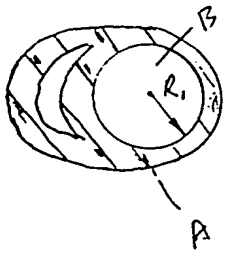


Fig. 35

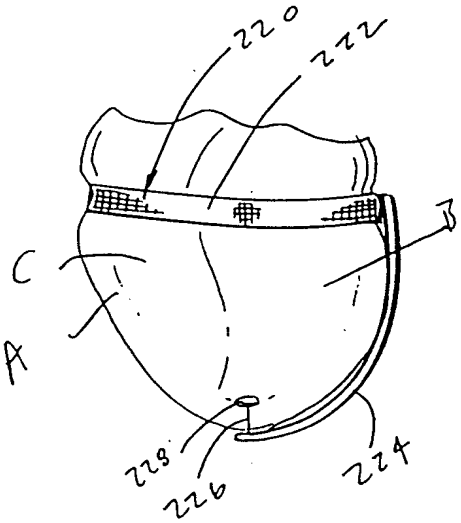


Fig. 36

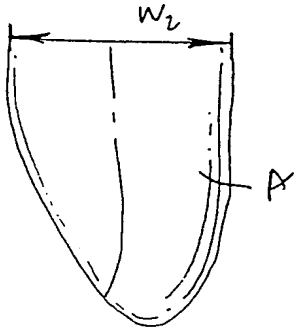


Fig. 37

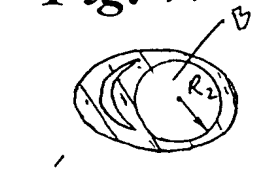


Fig. 38

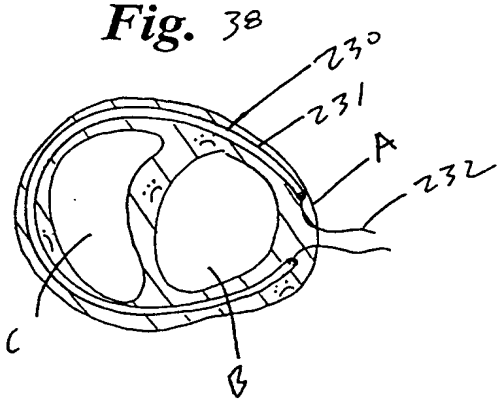


Fig. 40

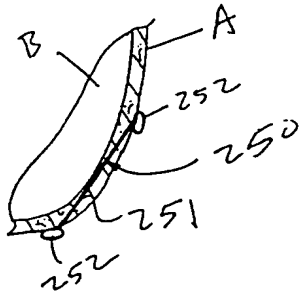


Fig. 39

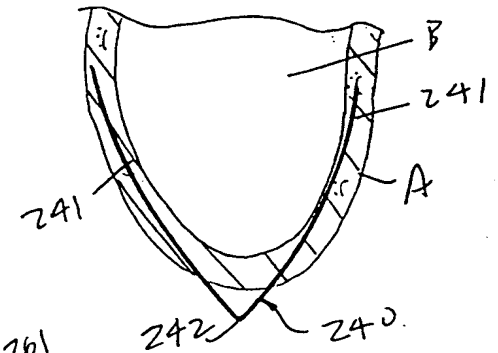


Fig. 41

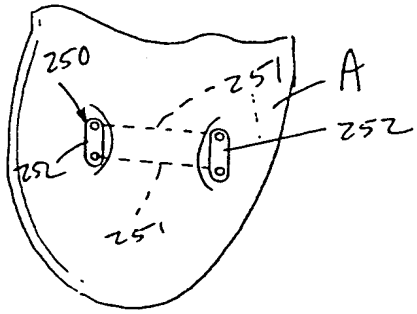


Fig. 42

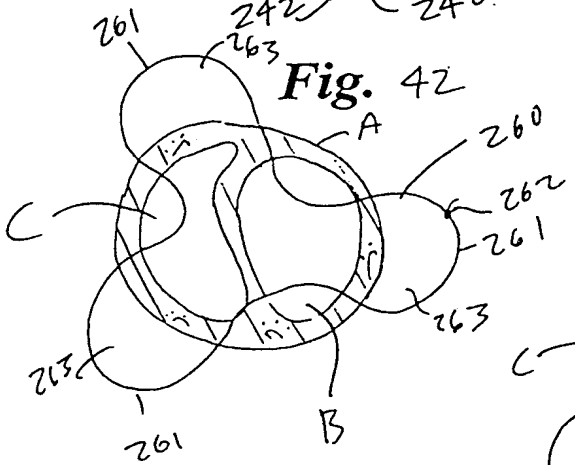


Fig. 43

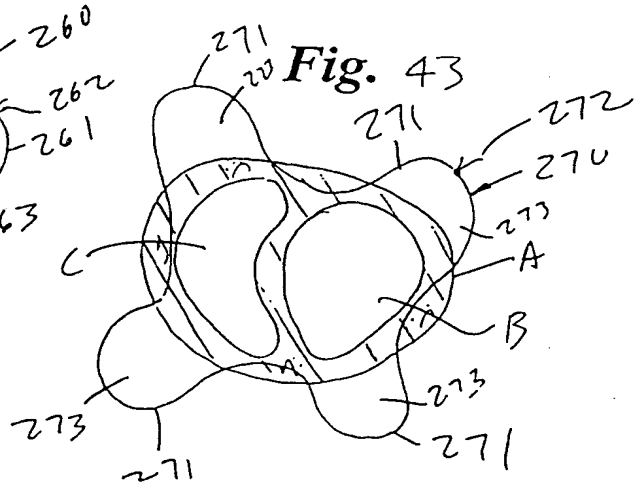


Fig. 44

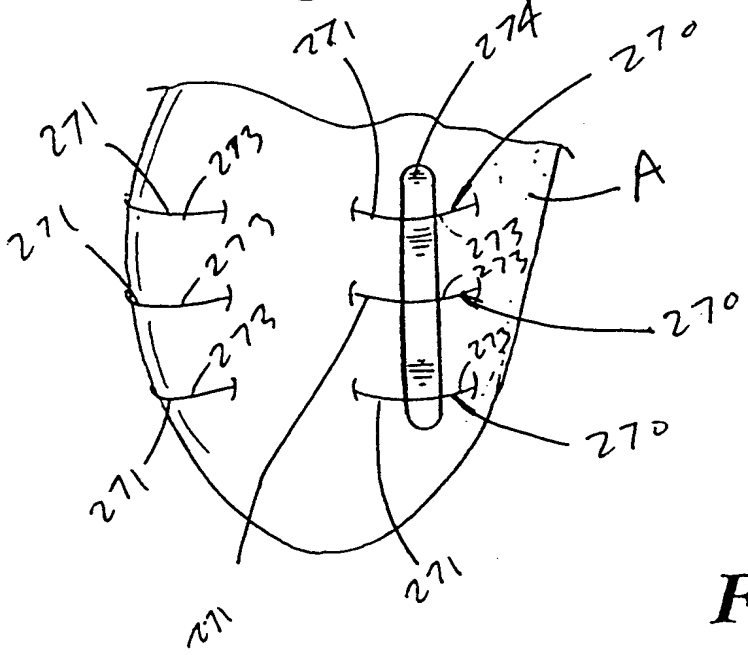
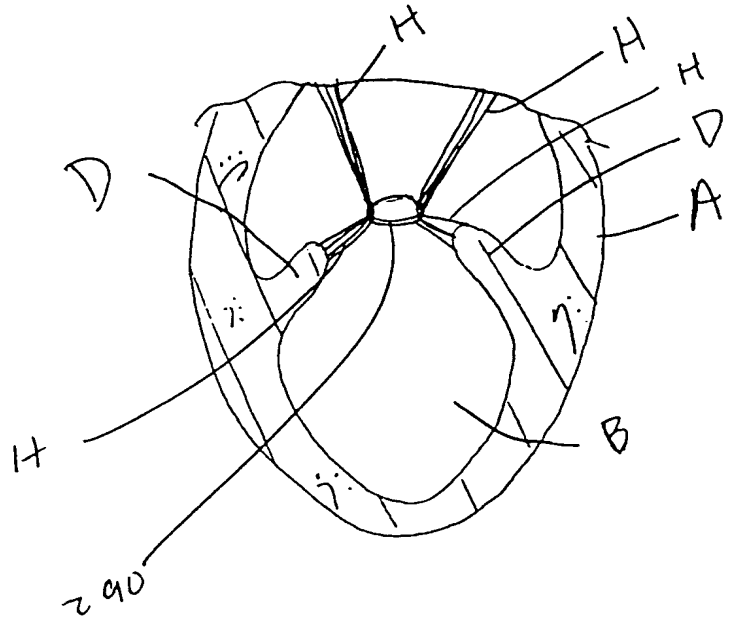


Fig. 45



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

(19) World Intellectual Property Organization
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10 February 2000 (10.02.2000)

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(10) International Publication Number
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(30) Priority Data:
09/124,321 29 July 1998 (29.07.1998) US

(71) Applicant *(for all designated States except US)*: **MYOCOR, INC.** [US/US]; Suite 212, 14505 21st Avenue North, Plymouth, MN 55447-5602 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **MORTIER, Todd, J.** [US/US]; 3008 Colfax Avenue South, Minneapolis, MN 55408 (US). **SCHWEICH, Cyril, J., Jr.** [US/US]; 1685 Hillcrest Avenue, St. Paul, MN 55116 (US). **VIDLUND, Robert, M.** [US/US]; 1811 Kennard Street, Maplewood, MN 55109 (US).

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

(81) Designated States *(national)*: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, 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, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), 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), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

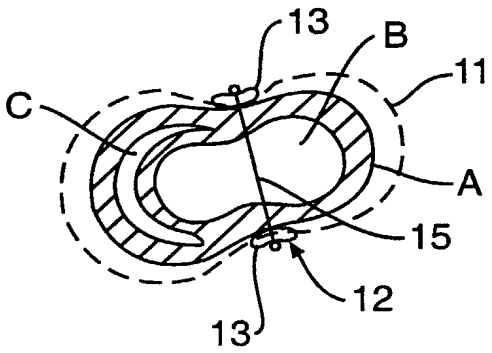
Published:
— *with international search report*

(88) Date of publication of the international search report:
8 November 2001

(15) Information about Correction:
Previous Correction:
see PCT Gazette No. 31/2000 of 3 August 2000, Section II

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

(54) Title: HEART STRESS REDUCTION APPARATUS AND METHOD



(57) Abstract: The device and method for reducing heart wall stress. The device can be one which reduces wall stress throughout the cardiac cycle or only a portion of the cardiac cycle. The device can be configured to begin to engage, to reduce wall stress during diastolic filling, or begin to engage to reduce wall stress during systolic contraction. Furthermore, the device can be configured to include at least two elements, one of which engages full cycle and the other which engages only during a portion of the cardiac cycle.

WO 00/06027 A3

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/16875

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/00

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61F

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 29041 A (MYOCOR, INC.) 9 July 1998 (1998-07-09) the whole document	1-3,5-8
X	WO 96 40356 A (EP TECHNOLOGIES, INC.) 19 December 1996 (1996-12-19) the whole document	1-5
X	US 5 702 343 A (ALFERNESS) 30 December 1997 (1997-12-30) column 1, line 53 -column 2, line 21; figures	1,4
A	EP 0 303 719 A (BLAGOVESHCHENSKY GOSUDARSTVENNY MEDITSINSKY INSTITUT, UL) 22 February 1989 (1989-02-22) claims; figures	1

-/--

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

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
3 November 1999	11/11/1999

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	Giménez Burgos, R

2

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/16875

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98 03213 A (HEARTPORT, INC.) 29 January 1998 (1998-01-29) page 17, line 7 -page 18, line 18 abstract; figures 6A-9B	1

INTERNATIONAL SEARCH REPORT

ternational application No.
PCT/US 99/16875

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

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

1. [X] Claims Nos.: 9
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 II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

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

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

national Application No
PCT/US 99/16875

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9829041 A	09-07-1998	US 5961440 A	05-10-1999
WO 9640356 A	19-12-1996	CA 2223152 A	19-12-1996
		EP 0836507 A	22-04-1998
		JP 11507262 T	29-06-1999
		US 5865791 A	02-02-1999
US 5702343 A	30-12-1997	AU 4745097 A	24-04-1998
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		WO 9814136 A	09-04-1998
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		WO 8806027 A	25-08-1988
		US 4936857 A	26-06-1990
WO 9803213 A	29-01-1998	AU 3737397 A	10-02-1998

CORRECTED VERSION*

PCT

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International Bureau

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(51) International Patent Classification 7 : A61B 17/00

A1

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(30) Priority Data:
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(71) Applicant *(for all designated States except US)*: MYOCOR, INC. [US/US]; Suite 200W–B, 1380 Energy Lane, St. Paul, MN 55108 (US).

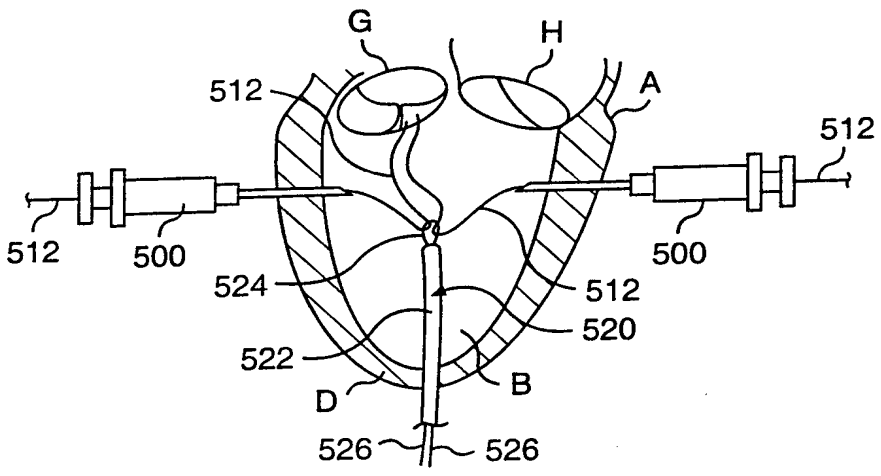
(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: MORTIER, Todd, J. [US/US]; 3008 Colfax Avenue South, Minneapolis, MN 55408 (US). SCHWEICH, Cyril, J., Jr. [US/US]; 1685 Hillcrest Avenue, St. Paul, MN 55116 (US). VIDLUND, Robert, M. [US/US]; 1811 Kennard Street, Maplewood, MN 55109 (US). KEITH, Peter, T. [US/US]; 1477 Grantham Street, St. Paul, MN 55108 (US). PAULSON, Thomas, M. [US/US]; 4322 York Avenue South, Minneapolis, MN 55410 (US). KUSZ, David, A. [US/US]; 3229 – 39th Avenue South, Minneapolis, MN 55406 (US).

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

(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, 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, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), 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), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: TRANSVENTRICULAR IMPLANT TOOLS AND DEVICES



(57) Abstract

A method and implantation tools for placing a transventricular splint including a tension member. The method includes gaining access to the patient's hearts and identifying entry or exit points for the tension member, marking those locations and delivering the tension member. Anchors for the tension member are also delivered. The length of the tensions member is measured and the walls of the heart drawn together. The pads are secured to the tension member and the tension member is trimmed to length. The pads are secured to the heart surface.

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TRANSVENTRICULAR IMPLANT TOOLS AND DEVICES

Related Applications

This application is related to U.S. Application Serial No. 09/124,321, filed on date even herewith and entitled "Stress Reduction Apparatus and Method" and U.S. Application Serial No. 09/124,286, filed on date even herewith and entitled "Heart Wall Tension Reduction Apparatus and Method," both of which are incorporated herein by reference.

Field of the Invention

The present invention pertains to the field of apparatus for treatment of a failing heart. In particular, the apparatus of the present invention is directed toward implanting a device for reducing wall stress in the failing heart.

Background of the Invention

The syndrome of heart failure is a common course for the progression of many forms of heart disease. Heart failure may be considered to be the condition in which an abnormality of cardiac function is responsible for the inability of the heart to pump blood at a rate commensurate with the requirements of the metabolizing tissues, or can do so only at an abnormally elevated filling pressure. There are many specific disease processes that can lead to heart failure with a resulting difference in pathophysiology of the failing heart, such as the dilatation of the left ventricular chamber. Etiologies that can lead to this form of failure include idiopathic cardiomyopathy, viral cardiomyopathy, and ischemic cardiomyopathy.

The process of ventricular dilatation is generally the result of chronic volume overload or specific damage to the myocardium. In a normal heart that is exposed to long term increased cardiac output requirements, for example, that of an athlete, there is an adaptive process of ventricular dilation and myocyte hypertrophy. In this way, the heart fully compensates for the increased cardiac output requirements. With damage to the myocardium or chronic volume overload, however, there are increased requirements put on the contracting myocardium to such a level that this compensated state is never achieved and the heart continues to dilate.

The basic problem with a large dilated left ventricle is that there is a significant increase in wall tension and/or stress both during diastolic filling and during systolic contraction. In a normal heart, the adaptation of muscle hypertrophy (thickening) and ventricular dilatation maintain a fairly constant wall tension for systolic contraction. However, in a failing heart, the ongoing dilatation is greater than the hypertrophy and the result is a rising wall tension requirement for systolic contraction. This is felt to be an ongoing insult to the muscle myocyte resulting in further muscle damage. The increase in wall stress is also true for diastolic filling. Additionally, because of the lack of cardiac output, there is generally a rise in ventricular filling pressure from several physiologic mechanisms. Moreover, in diastole there is both a diameter increase and a pressure increase over normal, both contributing to higher wall stress levels. The increase in diastolic wall stress is felt to be the primary contributor to ongoing dilatation of the chamber.

Prior art treatments for heart failure fall into three generally categories. The first being pharmacological, for example, diuretics. The second being assist systems, for

example, pumps. Finally, surgical treatments have been experimented with, which are described in more detail below.

With respect to pharmacological treatments, diuretics have been used to reduce the workload of the heart by reducing blood volume and preload. Clinically, preload is defined in several ways including left ventricular end diastolic pressure (LVEDP), or left ventricular end diastolic volume (LVEDV). Physiologically, the preferred definition is the length of stretch of the sarcomere at end diastole. Diuretics reduce extra cellular fluid which builds in congestive heart failure patients increasing preload conditions. Nitrates, arteriolar vasodilators, angiotensin converting enzyme inhibitors have been used to treat heart failure through the reduction of cardiac workload through the reduction of afterload. Afterload may be defined as the tension or stress required in the wall of the ventricle during ejection. Inotropes such as digoxin are cardiac glycosides and function to increase cardiac output by increasing the force and speed of cardiac muscle contraction. These drug therapies offer some beneficial effects but do not stop the progression of the disease.

Assist devices include, for example, mechanical pumps. Mechanical pumps reduce the load on the heart by performing all or part of the pumping function normally done by the heart. Currently, mechanical pumps are used to sustain the patient while a donor heart for transplantation becomes available for the patient.

There are at least three surgical procedures for treatment of heart failure: 1) heart transplant; 2) dynamic cardiomyoplasty; and 3) the Batista partial left ventriculectomy. Heart transplantation has serious limitations including restricted availability of organs and adverse effects of immunosuppressive therapies required following heart transplantation. Cardiomyoplasty includes wrapping the heart with skeletal muscle and

electrically stimulating the muscle to contract synchronously with the heart in order to help the pumping function of the heart. The Batista partial left ventriculectomy includes surgically remodeling the left ventricle by removing a segment of the muscular wall. This procedure reduces the diameter of the dilated heart, which in turn reduces the loading of the heart. However, this extremely invasive procedure reduces muscle mass of the heart.

Summary of the Invention

The present invention relates to methods and devices for placing a transventricular splint to reduce mechanical heart wall muscle stress. Heart wall muscle stress is a stimulus for the initiation and progressive enlargement of the left ventricle in heart failure. Although the primary focus of the methods of the present invention is heart failure and thus placement of a splint on the left ventricle, the methods and devices of the present invention could be used to place a splint or reduce stress in the heart's other chambers.

The transventricular splints placed by the tools and methods of the present invention can reduce heart wall stress throughout the cardiac cycle including end diastole and end systole. Alternately, they can be used to reduce wall stress during the portions of the cardiac cycle not including end systole. The splints which operate throughout the cardiac cycle are referred to herein as "full cycle splints". Those splints which do not operate to reduce wall stress during end systole are referred to as "restrictive devices" or, more specifically, "restrictive splints". Splints reduce left ventricle wall stress by altering the geometric shape of the left ventricle.

In the preferred embodiment of the present invention, tools are provided to interconnect oppositely disposed ventricular walls by a transventricular splint, including a tension member and anchors disposed on opposite ends of the tension member. First access is gained to the heart either by opening a patient's chest or less invasively by port or trocar. The points on the ventricular walls to be interconnected by the splint are then identified. The locations are preferably marked. The tension member is then placed to extend between the marked locations. The distance between the marked location is preferably measured. The wall of the ventricles are drawn toward each other. The anchors are secured to the tension member. The tension member is trimmed or cut to size in view of the relative spacing of the anchors. The anchors are then secured to the heart.

In this manner, portions of the walls of the ventricle are fixed in a drawn position reducing the radius of curvature of the majority of the ventricle and thereby reducing the tension within the ventricle wall.

Brief Description of the Figures

Referring now to the drawings wherein like reference numerals refer to like elements throughout the several views, Figure 1 is a cross sectional view of the left ventricle including a transventricular splint;

Figure 1A is a generally horizontal cross sectional view of a left ventricle including the transventricular splint of Figure1;

Figure 2 is an exterior view of the heart of Figure 1 and anchor pad of the transventricular splint;

Figure 3 is a location device with bars;

Figure 4 is an exterior view of a heart including the location device of Figure 3;

Figure 5 is a hand including a finger echo locator device;

Figure 6 is a top view of the echo locator device of Figure 5;

Figure 7 is a side view of the echo locator device of Figure 6;

Figure 8 is a side view of a balloon locator device;

Figure 9 is a side view of balloon locator device with balloon inflated;

Figure 10 is a view of a mechanical locator disposed within and outside of a left ventricle;

Figure 11 is a clamp locator device;

Figure 12 is a view of the device of Figure 11 disposed on a left ventricle;

Figure 13 is a view of an alignment tool;

Figure 14 is a view of an alternative alignment tool;

Figure 15 is yet another alternative alignment tool;

Figure 15A is a detail of the alignment tool of Figure 15;

Figure 16 is a cross sectional view of an alignment tool pad with stabilizing apparatus;

Figure 17 is a side view of an alternate embodiment of an alignment device pad with stabilizing apparatus;

Figure 18 is a perspective view of an alignment device pad;

Figure 19 is a perspective view of an alternate embodiment of an alignment device pad;

Figure 20 is yet another alternate embodiment of an alignment device receiving pad;

Figure 21 is a perspective view of an alignment device guide tube;

Figure 22 is a side view of a splint delivery guide;

Figure 23 is an alternate embodiment of a splint delivery guide;

Figure 24 is an alternate embodiment of a stylet;

Figure 25 is yet another alternate embodiment of a stylet including a retractable sheath in a retracted position;

Figure 26 is a view of the stylet of Figure 25 showing the sheath covering the tip of the stylet;

Figure 27 is a yet another alternate embodiment of a stylet including a balloon disposed proximate the tip;

Figure 28 is a view of the stylet of Figure 27 wherein the balloon is inflated to cover the tip of the stylet;

Figure 29 is a view of yet another alternate embodiment of a splint delivery guide including an optical fiber;

Figure 30 is a view of the tip of the guide of Figure 29;

Figure 31 is an alternate embodiment of a guide including an optical fiber;

Figure 32 is a view of yet another alternate embodiment of a guide including an optical fiber;

Figure 33 is a perspective view of a guide clamp;

Figure 34 is a perspective view of a wire guide clamp connected to a delivery tube;

Figure 35 is a view of an alternate embodiment of a splint and delivery device;

Figure 36 is a view of yet another alternate embodiment of a splint and delivery device;

Figure 37 is a view of the device of Figure 36 connected in a left ventricle;

Figure 38 is a tension member delivery catheter shown in a left ventricle;

Figure 39 is a view of a hypotube placed in the left ventricle using the catheter of Figure 38;

Figure 40 is a view of the hypotube of Figure 39 being removed from the left ventricle;

Figure 41 is a view of two guide members placed in the left ventricle using the catheter of Figure 38;

Figure 42 is a view of a tension member being advanced over the guide members of Figure 41;

Figure 43 is a view of a tension member and leads placed in a left ventricle using the catheter of Figure 38;

Figure 44 is a view of a connector for connecting the lead and tension member of Figure 43;

Figure 45 is a view of the connector of Figure 44 connecting a lead and tension member;

Figure 46 is a view of the tension member measuring and tightening device;

Figure 47 is a cross sectional view of an anchor pad;

Figure 48 is a cross sectional view of an alternate anchor pad;

Figure 49 is a perspective view of yet another alternate embodiment of an anchor pad including an anchor pad loosening device;

Figure 50 is a perspective view of a tension member clip;

Figure 51 is a cross sectional view of an alternate embodiment of the tension member clip;

Figure 52 is a cross sectional view of a heart including a tension member having a heat set end;

Figure 53 is a cross sectional view of a pad including an anchor envelope;

Figure 54 shows the envelope of Figure 53;

Figure 55 is a view of a heart including a external locating device;

Figure 56 is a perspective view of the external locating device of Figure 55;

Figure 57 is a cross sectional view of the locating device of Figure 55 including inflated locating balloons;

Figure 58 is a transverse cross section of Figure 57;

Figure 59 is a vertical cross section of the heart including an internal locating device;

Figure 60 is a cross section of a torso taken through the left and right ventricles including a locating clamp;

Figure 61 is a view of the locating clamp of Figure 60;

Figure 62 is a view of an alternate embodiment of a marking clamp;

Figure 63 is a cross sectional view of a thread pusher;

Figure 64 is a cross sectional view of the left ventricle including two thread pushers and a snare;

Figure 65 is a subsequent view of the devices of Figure 64;

Figure 66 is a subsequent view of the device of Figure 65;

Figure 67 is a subsequent view of the device of Figure 66;

Figure 68 is a cross sectional view of a left ventricle including a snare and thread pusher;

Figure 69 is a subsequent view of the device of Figure 68;

Figure 70 is a cross sectional view of an alternate embodiment of a thread pusher;

Figure 71 is a cross sectional view of a snare insertion tube;

Figure 72 is yet another alternate anchor pad embodiment;

Figure 73 is yet another alternate anchor pad embodiment;

Figure 74 is yet another alternate anchor pad embodiment;

Figure 75 is yet another alternate anchor pad embodiment;

Figure 76 is yet another alternate anchor pad embodiment;

Figure 77 is a view of an anchor screw;

Figure 78 is a view of yet another alternate anchor pad embodiment;

Figure 79 is a view of an anchor epicardial jaw embodiment;

Figure 80 is vertical cross sectional view of the heart including anchors deployed from within the heart; and

Figure 81 is a vertical cross sectional view of a heart showing tension members deployed from within the heart connected within the heart.

Detailed Description of the Invention

The present invention relates to methods and tools for implanting a transventricular splint. The transventricular splint reduces heart wall stress by changing ventricular geometry. A splint can be full cycle or restrictive. If a splint is full cycle, it

engages, i.e., alters the generally globular ventricular shape throughout the cardiac cycle. If the splint is restrictive, it does not change the generally globular shape of the ventricle at end systole.

Figure 1 is a vertical cross sectional view of a left ventricle view B of a heart A. A typical transventricular splint 10 is disposed across ventricle B. Splint 10 includes a tension member 12. Connected to opposite ends of tension member 12 are anchors 14. Anchors 14 engage the walls of ventricle B to create a shape change either full cycle or restrictively. Figure 1A is a horizontal cross sectional view of left ventricle B taken from Figure 1 showing left ventricle B in a bi-lobe shape as a result of the implantation of splint 10. Figure 2 is a vertical exterior view of heart A showing splint 10, one end of tension member 12 and an anchor 14.

In a preferred method of implanting a transventricular splint, access is gained to the heart. The entry and/or exit points for the splint's tension member are identified. These locations are preferably marked. The tension member is then delivered transventricularly either from outside the heart to the inside, or from the inside of the heart to the outside. The anchors are delivered or deployed. The epicardial length is preferably measured to calibrate the magnitude of the shape change, tension member length, and thus heart wall stress reduction. The magnitude of the stress reduction is a function of the tension member length. (See U.S. Patent Application Serial No. 08/933,456, filed September 18, 1997 and incorporated herein by reference.) The heart walls are then drawn together by adjusting the tension member length and/or anchor spacing. The heart walls are drawn toward each other in view of the desired tension member length. The anchors are secured to maintain the length of the tension member.

Preferably any portion of the tension member not lying between the anchors is removed. The anchors are preferably secured to the heart to limit relative movement between the anchors and the heart.

Some of the devices and methods disclosed in this application lend themselves to open chest procedures, whereas others lend themselves either to open chest procedures or less invasive procedures. Various cardiac surgical procedures are being done via partial thoracotomy between ribs. Thoroscopes and trocars are often utilized. Certain embodiments of the invention are amenable to these types of less invasive surgery. As is known to one skilled in the art, ports, windows and trocars are available to access the heart to limit patient trauma relative to open chest procedures. One or more access sites can be used during a less invasive procedure to gain access to the heart through the chest wall from a left lateral direction, right lateral direction, anterior and/or posterior direction. For example, during a less invasive splint implantation procedure, opposite ends of a tension member can be accessed by left and right lateral ports, where an anterior port is used to deliver the tension member. During less invasive procedures, the surgeon's hands preferably remain outside of the patient's body.

When gaining access to the heart by way of a window trocar, both the diaphragm and lungs should be avoided. If the lungs are an obstruction to placement of the trocar and tension member, in some instances they may be moved without deflation. In yet other instances, if the lungs are substantially disposed between the selected chest access point and the heart, the patient may be placed on heart lung bi-pass and the patient's lungs deflated. Ventilation with or without deflation of the lungs may be desirable.

Once access to the heart through the chest wall has been gained, the splint placement location should be determined. Determining the desirable location of the splint is important to the performance and safety of the device. It is desirable to avoid external structures such as coronary vessels to avoid negatively effecting the perfusion of blood through the heart wall muscle. It is also desirable to avoid internal structures such as valve apparatus including chordae. To determine where to place the splint, the heart can be viewed with the naked eye, echo imaging, echo transesophageally or epicardially and fluoroscopy. Various devices can be used to locate entry or exit points by echo imaging or fluoroscopy.

Figure 3 is a perspective view of a locating device 20 including two knurled bars 22 interconnected by an elastic member 24. Figure 4 is a view of a heart A including a left ventricle B and right ventricle C. Device 20 is shown disposed on left ventricle B. Bars 22 can be echo imaged or viewed by fluoroscopy simultaneously with the left ventricle. When viewed by fluoroscopy, coronary vessels can be advantageously visualized by introducing contrast medium therein. Additionally, bars 22 should be made from a substantially radiopaque material if used for fluoroscopic imaging.

In use, bars 22 are placed on heart A as shown in Figure 4. Bars 22 appear to be positioned such that the coronary vessels and internal structures would be avoided, were the tension member to be extended through the heart between the location of bars 22. The location of the bars can be the location of the splint tension member. If not, the bars should be shifted into a better location until an acceptable location is found.

In addition to avoiding coronary vessels and internal anatomical structures, imaging can be used to determine if the proposed location of the splint will produce the

desired shape change of the chamber. This could be accomplished with device 20 by pushing knurled bars 22 into the left ventricle and observing the change in chamber geometry by imaging.

Figure 5 is a view of a human hand X including a thumb Y and a forefinger Z. An alternate locating device 30 is shown attached to thumb Y and forefinger Z by rings 32. Device 30 also includes a echo visible pad 34. Pads 34 can be used in the same way as knurled bars 22, but rather than being held together by a string 24, pads 34 can be held in place by the user. Figure 6 is a view of the surface of pad 34 which would be in contact with heart A during use. Pad 34 preferably includes an echogenic marker 36 enclosed within a material which has a similar density to the heart wall. The similar density material will reduce echo scatter/reflection versus transmission at the surface and provide easier visualization of echo marker 36. Figure 7 is a side view of pad 34 of Figure 6.

Figure 8 is a side view of a locating device 40. Device 40 can include a syringe 44 having a hypodermic needle 42 in which end 47 preferably does not include an exit lumen or orifice. The lumen does, however, extend through the remainder of hypodermic needle 42. A balloon envelope is connected to a portion of hypodermic needle 42 proximate its end 47. An orifice provides fluid communication between the lumen through hypodermic needle 42 and inside balloon 46. Balloon 46 can be inflated with a echo visible or fluoroscopic visible medium.

Figure 9 is a view of locating device 40 in which balloon 46 is shown inflated within left ventricle B of heart A. By using locator 40 tension member entry/exit points

can be evaluated in closer proximity to internal structures than when a locator is placed on the external surface of the heart.

Figure 10 is a vertical cross sectional view of heart A including left ventricle B, right ventricle C and an apex D. A locator device 50 is shown disposed on heart A. Locator device 50 includes apical insert branch 52 which preferably includes an elongate shaft having an inflation lumen and a tension member delivery lumen extending therethrough. The shaft preferably bends transversely near its distal end 54. A balloon 55 similar to the balloon of locator device 40 of Figures 8 and 9 is connected to the distal end of branch 52. Balloon 55 can be inflated with a medium visible by echo imagery or fluoroscopy to locate a tension member entry or exit point on the internal surface of the ventricle wall in a manner similar to locating device 40 of Figures 8 and 9. An optical fiber could be extended through branch 52 and used as described with respect to the device of Figure 29.

Locator device 50 preferably includes an external branch arm 56 connected to branch 52 at connector 59. Branch 56 is bent such that its distal end 57 is disposed adjacent distal end 54 of branch arm 52. An additional marker 58 is preferably connected to distal end 57 of branch arm 56. Marker 58 is preferably made of material visible either through echo imaging or fluoroscopy. Branch arm 56 is preferably connected to branch arm 52 such that as branch arm 52 is rotated, marker 55 and marker 58 will maintain their relative position to each other, even as their position changes with respect to left ventricle B.

Figure 11 is a perspective view of a scissor-like clamp 60 which has a handle 61 and two clamps ends 62 which are made of a material which is echogenic or by

fluoroscopy. Clamp 60 can be opened or closed freely as a pair of scissors or have a locking mechanism to releasably fix the spacing between ends 62. Figure 12 is a vertical view of a heart A similar to that view of heart A in Figure 4. Here rather than placing bars 22 on the heart, ends 62 of clamp 60 are placed on the heart. Ends 62 can be used in a manner similar to bars 22 as described above to locate a desirable positioning of a splint on left ventricle B.

After the tension member entrance/exit points or anchor points on the heart have been identified for the transventricular splint, the locations can be marked in various ways to assist a surgeon in accurate placement of a splint when the locator has been removed. Tissue marking pens can be used to mark the location for splint placement. Additionally, sutures can also be placed to provide a marker. For example, a purse string suture with or without pledgets could be used to enhance sealing of the tissue around the tension member to reduce bleeding as the tension member is advanced through the heart wall.

After marking tension member entry/exit points or anchoring points, an open chest alignment device, such as alignment device 70 of Figure 13, can be placed on the heart to aid in the insertion of the tension member through the chamber from outside of the heart. Alignment device 70 includes a handle 71 including holes 72 for the thumb and index finger of an operator. Alignment device 70 includes two alignment arms having distal pad ends 75. Ends 75 include apertures 76 for receiving a tension member guide and/or tension member therethrough. Pads 75, arm 74 and handles 71 are preferably aligned on shaft 77 such that as handle 71 are drawn toward each other by an operator. Arms 74 and pads 75 will remain generally parallel to each other. A spring 78

biases handles 71 apart, and arms 74 and pads 75 together. A locking mechanism can be provided to fix pads 75 in position when a desired spacing has been achieved. Apertures 76 preferably remain axially aligned throughout the operational spacing of pads 75.

In use, pads 75 are disposed on the heart such that apertures 76 are placed over the location or markings previously determined for the exit/entry points. Handles 71 are pulled apart until pads 75 are in engagement with the exterior surface of the heart. Alignment device 70 is now in position for the next step of the splint placement procedure.

Figure 14 is an alternate embodiment of an alignment device 80. Alignment device 80 includes handles 81 and an arm 84 and 86 which are pivotable about a pin 89. Disposed at the end of arm 82 is an alignment pad 83. An alignment pad 85 is rotatably connected by pin 86 to arm 84. A third arm 87 is pivotally connected to arm 82 by pin 90 and pivotally connected to pad 85 by a pin 88. Pads 83 and 85 each have an aperture 91 therethrough. Pads 83 and 85 have heart engaging surfaces 92 which are preferably parallel to each other within an operational spacing of pads 83 and 85. Apertures 91 are preferably axially aligned within that operational spacing of pads 83 and 85.

The spacing of pads 83 and 85 can be manipulated by moving handles 81 toward each other to increase the spacing of pads 83 and 85 or away from each other to decrease the spacing. Pads 83 and 85 preferably engage the heart such that apertures 91 are axially aligned and disposed on the desired entry/exit point for the tension member. The closer handles 81 are moved together, the further pads 83 and 85 move apart.

Figure 15 is yet an another alternate embodiment of an alignment device 100. Alignment device 100 includes handles 101 and elongate arms 102 pivotable about pin

104. At the end of elongate arms 102, opposite handles 101, are alignment pads 103 having orifices 106 extending therethrough. A flexible band 105 extends between pads 103.

As described above with respect to the alignment devices of Figures 13 and 14, the opposite pad orifices should be in axial alignment when placed on the heart. In the case of device 100, this can be accomplished by pivotally mounting pads 103 on arms 102 about a pin 107. Figure 15A is a detail of a pad 103 pivotally mounted about pin 107 to arm 102. The arrow in Figure 15A shows the direction that pad 13 can pivot about point 107. It can be appreciated that if opposite pads 103 are mounted as shown in Figure 15A and if band 105 is sufficiently rigid, band 105 can hold orifices 106 of opposite pads 103 in axial alignment while arms 102 are pivoted about pin 104.

Since during the typical implant procedure the heart is still beating, it is preferable to equip the pads of the alignment devices 70, 80 and 100 with stabilizing apparatus. The apparatus of Figures 16-20 could be incorporated into the pads of alignment devices 70, 80 and 100.

Figure 16 is a cross sectional view of a pad 111 disposed at an end of an alignment device arm 110. The pad is shown in engagement with the external wall of left ventricle B. Pad 111 includes an aperture 114 extending therethrough for receiving a tension member guide (described in more detail below) and/or tension member. An annular trough 112 is disposed around aperture 114. Annular trough 112 is connected to a vacuum source line 113 such that a vacuum source can be fluidly connected to trough 112. When the vacuum source is applied to trough 112 as shown in Figure 16, a suction

force will be created in trough 112 drawing pad 111 and the wall of the left ventricle B together.

Figure 17 is a side view of an alignment device pad 121 disposed at the end of an arm 120 including an alternate stabilization device 122. An aperture 123 for receiving a tension member guide and/or tension member extends through pad 121. Stabilization apparatus 122 is preferably a roughened surface disposed on pad 121 to increase the friction between pad 121 and the external wall surface of left ventricle B. Apparatus 122 could be made from, for example, either the hook or the loop portion of a hook and loop type fastener.

If a tension member guide or tension member is inserted into the heart using alignment device 70, 80 or 100, it is preferable that the pad of the aperture through the pad at the tension member exit point is over sized in comparison to the pad aperture of the alignment device at the tension member entry point. This is because as the tension member guide or tension member passes through the heart, motion of the heart may cause some minor misalignment of the tension member guide or tension member where it exits the heart.

Figure 18 is a perspective view of a pad 131 disposed on the end of an alignment device arm 130. Pad 131 includes an aperture 132 therethrough. This aperture has a diameter preferably between 1.5 and 15 times greater than the aperture to the opposite pad. Figure 18 also shows a notch 133 through pad 131 which extends from the exterior of the pad into aperture 132. Notch or opening 133 would preferably allow a tension member guide or tension member to be removed transversely from aperture 132 without

aperture 132 having to moved over an end of the tension member guide or tension member.

Figure 19 is a perspective view of an alternate embodiment of an alignment device pad 141. Alternate embodiment 141 is disposed at the end of an alignment device arm 140. Pad 141 includes a funnel shape aperture 142. Aperture 142 includes a large diameter end 144 and a small diameter end 143. Large diameter end 144 is preferably disposed adjacent the heart and tension member exit point during use. A guide tube 145 can lead out from smaller diameter end 143 of aperture 142. Guide tube 145 preferably includes a bend passing through an arc of preferably between about 45° to about 135° and more preferably about 90°. The radius of the bend is preferably long enough that devices advanced through guide tube 145 are not permanently bent as a consequence of being advanced through the arc of guide tube 145. The radius of the arc is preferably about .05 inches to about 2 inches, and more preferably between about 0.75 inches and, most preferably about 1 inch as measured to the central axis of guide tube 145.

Figure 20 is a perspective view of yet another alternate pad embodiment 151. Pad 151 has a similar shape to that of Figure 18 and is disposed at the end of an alignment device arm 156. Pad 151 has an aperture 152 therethrough and a side notch 153 for transverse removal of a tension member guide and/or tension member. Extending from arm 156 is a stop arm 155 having a tension member guide stop 154 aligned with aperture 156 and spaced from pad 151. In use, stop 154 is disposed on the opposite side of pad 151 from the heart. As a tension member guide 157 is advanced from the heart through aperture 152, advancement of the tip of guide 157 is limited by needle stop 154. Stop

154 thus can limit additional advancement of guide 157 which might injure tissue adjacent to the heart.

Figure 21 is a perspective view of an alignment device guide tube 165. Alignment device guide tube 165 preferably includes a luer lock or similar coupling 166 releasably connectable to a corresponding coupling 161 connected to an alignment device such as 70, 80 or 100 shown above. Coupling 161 of Figure 21 is shown connected to an alignment branch arm 160. The end of the alignment branch arm 160 opposite coupling 161 preferably includes a heart engaging pad or surface such as those shown in Figures 16 and 17. An aperture 169 extends through coupling 161 in the end of arm 160. A transverse aperture or notch extends into aperture 169 such that a tension member guide or tension member can be withdrawn from aperture 169 transversely without moving aperture 169 over the end of the tension member guide or tension member. Guide tube 165 preferably includes a funnel shaped guide tube entry port 167 opposite connector 166. Guide tube 165 preferably includes a bend passing through an arc of preferably between about 45° to about 135° or more preferably about 90°. The radius of the bend is preferably long enough that the devices advanced through guide tube 165 are not permanently bent as a consequence of being advanced through the arc of guide tube 165. The radius of the arc is preferably about 0.25 inches to about 2 inches, and more preferably between about 0.75 inches to about 1.5 inches and, most preferably about 1 inch as measured to the central axis of guide tube 165.

In use, aperture 169 is preferably aligned with the desired entry point for the tension member. Guide tube 165 can be coupled to coupling 161 of the alignment device. If it is difficult to gain access to aperture 169 in order to insert the tension

member therethrough because coupling 161 is directed transversely or posteriorly within the patient's chest cavity, guide tube 165 can be adjusted to dispose guide tube entry port 167 generally anteriorly for improved access.

Once alignment device 70, 80 or 100 is in place on the entry/exit points, a tension member guide or the tension member can be advanced through the alignment device transventricularly through the heart. Preferably, a tension member guide is used to advance the tension member transventricularly. It is anticipated, however, that if the tension member were sufficiently rigid that it could be advanced transventricularly without a guide.

Figure 22 is a side view of a tension member guide 170 including a guide tube 176 and stylet 171. Stylet 171 preferably includes a sharpened distal end 172 for advancement into and from the heart. The proximal end of stylet 171 can include a luer lock or similar type connector. A tube 176 defines an elongate lumen therethrough sized to receive stylet 171 or a tension member. Tube 176 preferably includes a luer fitting at its proximal end 175 opposite its distal end 173.

In use, stylet 171 is advanced through tube 176 as shown by the arrow in Figure 22. Distal tip 172 of stylet 171 preferably extends distally beyond distal end 173 of tube 176. Stylet 171 and tube 176 can be coupled by fittings 174 and 175. Then with one of the alignment devices 70, 80 or 100 in place, the tension member guide 170, including tube 176 and stylet 171 is advanced either directly through one of the alignment device apertures or by way of a guide tube such as guide tube 165 of Figure 21. Tension member guide 170 is then advanced through the opposite aperture of the alignment device such as shown in, for example, Figure 20. The length of tube 176 should be long

enough to extend through the heart such that proximal end 175 and distal end 173 are disposed outside of the heart. If the alignment device includes transverse notches or slots such as notch 133 of Figure 18, the alignment device can be removed transversely from needle 170. Stylet 171 is preferably removed from tube 176. The lumen through tube 176 is now unobstructed, providing a passageway for advancing a tension member therethrough.

The primary function of guide 170 and, in particular, tube 176, is to provide a passageway across the heart. Guide 170 should be flexible and resilient such that guide 170 could be advanced through the bend of, for example, guide tube 165. Yet, to maintain accurate delivery of guide 170, it preferably does not permanently bend when passing through tube 165. Column/buckling strength of tension member guide 170 is preferably sufficiently high such that the needle is not deflected as it engages the heart wall as guide 170 is advanced from the heart.

Tube 176 is preferably made from Nitinol, polyimide, reinforced polyimide or other sufficiently flexible biocompatible material. Tube 176 preferably has an inside diameter of about 0.01 inch to about 0.05 inch and, more preferably between about 0.02 inches to about 0.03 inches. The outside diameter of tube 176 is preferably between about 0.015 inches to about 0.07 inches and more preferably between about 0.02 inches and about 0.05 inches. Stylet 171 is preferably formed from Nitinol, stainless steel or other sufficiently rigid biocompatible material. Stylet 171 preferably has a diameter of between about 0.005 inches and about 0.05 inches and more preferably about 0.26 inches.

Figure 23 is an alternate embodiment of a tension member guide 180 including a stylet 181 having a handle 184 disposed at its proximal end and a sharpened point 182

disposed at its distal end. Stylet 181 is shown extending through a tube 186 having a proximal end 185 and a distal end 183. Guide 180 is essentially similar to guide 170 of Figure 22 except that tube 186 and stylet 181 do not include a coupling mechanism.

Figure 24 shows a distal end of a stylet 190 similar to stylet 171 of Figure 22. The sharpened tip 191 is shown rounded in comparison to the sharp tip 172 of stylet 171 shown in Figure 22. Tip 191 is rounded such that it can be advanced through the heart wall without undue pressure or trauma yet be deflected from, i.e., not pierce, chordae within the left ventricle which may be encountered as the guide is being advanced transventricularly. It should be understood that such a tip could be used on stylets of guides 170 or 180 above.

As an alternative to providing a rounded tip for stylets such as tip 191 of stylet 90, a retractable sheath 203 can be placed around a stylet 200 having a sharpened tip 202. In Figure 25, sheath 203 is shown in a first position retracted away from sharpened tip 202, such that tip 202 is exposed. In Figure 26, sheath 203 is shown in a second position covering sharpened tip 202. Sheath 203 and stylet 202 are preferably advanced transventricularly in a tube similar to tubes 176 or 186 of tension member guides 170 and 180. Sheath 203 is preferably spring biased into the second position shown in Figure 26 and moved into the first position as shown in Figure 25 only as it is advanced through the heart wall. To bias sheath 203 into the second position, a helical coil spring could be placed around stylet 200 between a proximal end of sheath 203 and the stylet handle.

Figure 27 is a view of yet another alternate embodiment 210 of a stylet for a tension member guide. Stylet 210 includes a sharpened tip 211 at the distal end of a shaft 214 which defines an inflation lumen therethrough. Tip 211 is sealed such that inflation

fluid forced through stylet 214 will exit an orifice 213 disposed within a balloon 212 connected to stylet 210 proximate its distal end.

Figure 28 is a view of stylet 210 of Figure 27 wherein balloon 212 has been inflated to cover sharpened tip 211. In use, balloon 212 would be inflated after stylet 214 has been advanced into the left ventricle and deflated prior to being advanced from the heart and ventricle through the heart wall. Stylet 214 preferably is used in conjunction with a guide tube in a manner similar to stylets 171 and 181.

Figure 29 is yet another alternate embodiment 215 of a tension member guide 215 in accordance with the present invention. Guide 215 is shown including an elongate tube 220 having a distal tip 222 partially advanced through left ventricle B of heart A. Figure 30 is a view of distal tip 222 of guide 215. By reference to Figure 30, it can be seen that shaft 222 defines a lumen therethrough in which an optical fiber 224 is disposed.

To guide 215 transventricularly, rather than advancing guide 215 through an alignment device, such as devices 70, 80 or 100, guide 215 is advanced through a first left ventricular wall where a tension member entry point has previously been identified. Light is transmitted axially through the lumen within shaft 220 by optical fiber 224. The light axially exits distal end 222. If the light is sufficiently bright, it should be visible from outside of the heart when guide 215 is being advanced through the left ventricle. If the visible light is directed at a predetermined exit point, marked on the outside of the heart, needle 215 can be advanced through the exit point to outside the heart. Fiber optic 214 can then be removed from the lumen through shaft 212. The lumen can then be used as the passageway for advancement of a tension member therethrough.

Figure 31 is an alternate embodiment of a tension member guide 230 including an optical fiber 232 disposed around a shaft 231. Shaft 231 is essentially similar shaft 220. Guide 230 can be advanced transventricularly in a manner similar to that described with respect to guide 215 except that optical fiber 232 need not be removed and shaft 231 which defines an elongate lumen extending therethrough.

Figure 32 is yet another embodiment of a tension member guide 235 having a shaft 236 essentially similar to shaft 220. An optical fiber 237 is disposed parallel to shaft 236 and connected thereto. In addition to the fiber optic guides of Figures 29-32, real time guidance of the tension member guide transventricularly can be accomplished by echo imagery or fluoroscopy. The guide in such instances should be echogenic or substantially radiopaque.

The fiber optic guides of Figures 29-30 lend themselves particularly well to both open chest and less invasive procedures. When the fiber optic guides are configured for less invasive procedures, the shaft is preferably advanced through the heart through a lateral port and advanced out the opposite side of the heart and body through an oppositely disposed lateral port. Opposite ends of the shaft then preferably extend outside of the body through the oppositely disposed lateral ports.

Figure 33 is a perspective view of a scissor-like guide clamp 240 which can be used to guide a tension member 249 into the tube 248 of a tension member guide. Device 240 includes scissor-like handles 241. Handles 241 extend to respective arms 242. Each handle 241 and arms 242 form a unit which are pivotable about a pin 243. At an end of arms 242 opposite handles 241, a half conical recess is formed in arm 242. Recess 247 leads to a generally semi-circular cross sectional channel 246 which in turn leads distally

to a generally semi-circular cross sectional tube receiving groove at distal end 244 of arm 242.

When arms 242 are brought together as shown in Figure 34, receiving grooves 245 form a receiving aperture to receive an end of tension member guide 248. Recesses 247 form a tension member receiving opening leading to a tube formed by channels 246. A tension member 249 is shown being advanced through tube 248 in the direction of the arrows. Tension member 249 could also be advanced from tube 248 through device 240. Channel 246 preferably includes a bend passing through an arc of between about 45° and 135° and more preferably through about 90°.

Once a tension member guide has been delivery transventricularly, and a passageway is created across the chamber, the tension member is delivered through the passageway. When delivering the tension member, the end of the tension member not being advanced through the passageway preferably has an anchor or anchor pad fixably connected thereto. This eliminates the need to attach the pad later, but it may not be possible in the case where the guide includes a hub such as hub 175 of tube 176 of Figure 22. In the case of guide 180 where tube 186 does not include a hub, tube 186 can be withdrawn from the heart over the end of the tension member which was advanced transventricularly. In order to remove a tube 176 from a tension member which has been advanced therethrough and has an anchor pad fixably connected to the end of the tension member which was not advanced through tube 176, the tension member should be advanced through tube 176 beginning at distal end 173 such that the end of the tension member not having the anchor pad emerges from the heart at hub 175. Then tube 176

can be removed over the end of the tension member to which a pad has not yet been attached.

Rather than using a tension member guide and/or tension alignment device to align the tension member for delivery through the preselected exit and entry points, tubular members 250 such as those shown in Figure 35 can be advanced into the left ventricle from oppositely disposed predetermined entry points on the heart wall to form a splint 253'. Members 250 preferably have ends 250' which are sufficiently sharp that members 250 can advanced through the heart wall without excessively injuring the wall. Members 250 preferably have anchor pads 252' fixed at their opposite ends 250'. Members 250 preferably have a lumen define therethrough in fluid communication with a lumen defined through pads 252'.

After members 250 are advanced into the ventricle through the predetermined entrance points, a wire hook 253 is advanced from one tension 250 and a wire loop 251 is advanced from the opposite member 250. Hook 253 is then guided into loop 251 either by feel, or by echo imagery or fluoroscopy. Loop 251 preferably has a hook guide 252 to channel hook 253 into the member 250 disposed to the left in Figure 35, as loop 251 is drawn through that member 250 by pulling ends 251' of loop 251 to the left. Loop 253 is preferably drawn through member 250 disposed to the left in drawing Figure 35 such that it can be knotted to the left of pad 252' to form a tension member. The knot will restrain hook 253 from being pulled back in the heart. The opposite ends 253' of hook 253 can be knotted to the right of the pad 252' disposed to the right in Figure 35. The knot should be sufficiently large to prevent ends 253' from being pulled into ventricle B.

It can be appreciated that members 250 can be placed as shown without pads 252'. Loop 256 can be placed across left ventricle B to form a tension member as described above. Members 250 can then be withdrawn and pads placed on opposite ends of hook or tension member 253. Alternately, hook 253, once placed across left ventricle B, could be used as a tension member lead by fastening a tension member to one end of hook 253 and drawing the attached tension member across left ventricle B by withdrawing hook 253 from the left ventricle B.

Figure 36 is an alternate embodiment of a splint 260'. A tension member 255 is advanced into left ventricle B. An anchor pad 255' is shown connected to one end of tension member 255 outside of chamber B. Tension member 255 includes a sharpened end 256 which is advanced through the myocardium. Proximate sharpened tip 256 are a plurality of circumferential grooves 256. To the left in Figure 36 is a tension member 258' extending into chamber B. Connected to one end of tension member 258' is a anchor pad 257'. Tension member 258' includes an outer tube 257 and inner receiving tube 258. A loop 259 extends to a side of receiving tube 258 and out of the ventricle through a lumen defined between tube 257 and 258. Ends 259' of loop 259 are shown to the left of pad 257'. An end 261 of tube 258 is preferably thin or sharp enough to be advanced through heart wall of chamber B.

Tension members 255 and 258' are advanced into chamber B similarly to tension members 250 of splint 253'. Once tension members 258' and 255 have been advanced into chamber B, end 256' of tension member 255 is advanced into loop 259. This can be accomplished by feel, or echo imaging or fluoroscopy if loop 259 and tension member 255 are echogenic or radiopaque respectively. After tension member 255 is advanced

into loop 259, loop 259 is drawn to the left by pulling ends 259' to the left. Tension member loop guide 260 engages with a groove 265 and tension member 255 and end 256' are drawn into receiving tube 258 to unite tension members 258' and 255. Ends 259' are then tied to prevent loop 259 from shifting to the right in Figure 37.

It can be appreciated that members 255 and 258' can be advanced into left ventricle B while not having pads 255' and 257' attached thereto, respectively. Once members 255 and 258' are placed across left ventricle B and connected as shown in Figure 37 they can be used as a tension member guide tube such as guide tube 176 of Figure 22.

Figure 38 is a vertical cross sectional view of left ventricle B of heart A including apex D showing an alternate device for placing a tension member. A catheter 265 having an elongate shaft 265' is disposed in part within ventricle B. Shaft 265' has a distal end 266 and a transverse bend proximate end 266. Shaft 265' has a proximal end 267. An elongate lumen is defined through shaft 265' between proximal end 267 and distal end 266. Shaft 265' is sufficiently rigid that distal end 266 can be advanced through apex D. A purse string suture is preferably placed on apex D around shaft 265' to control bleeding. Catheter 265 is advanced into ventricle B such that distal tip 266 is brought into contact with the ventricular wall at a location where the tension member will exit chamber B. Catheter 265 preferably include a retractable brace wire 268' having a distal end fixably connected to shaft 265 proximate the transverse bend. Brace wire 268' extends proximally outside of shaft 265' to an orifice where it enters shaft 265. Wire 268' then extends within shaft 265' proximal to the proximal end of shaft 265'. When advancing catheter 265 into ventricle B, wire 268' can be pulled proximally drawing wire

268' parallel and adjacent to shaft 265'. Once catheter 265 is disposed within ventricle B, wire 268' can be shifted distally to bow transversely and brace catheter 265 against a ventricular wall opposite distal end 266.

Distal tip 266 preferably includes a radiopaque marker such as that shown in Figure 10, so that tip 266 can be viewed by fluoroscopy or an echo marker for echo visualization. The radiopaque or echo marker can be used to locate the tension member exit points. Once a tension member exit point is determined, a tension member 268 can be advanced through the lumen of catheter 265. The tension member should be sufficiently rigid and have a distal end sufficiently narrow or sharpened that it can be advanced through the ventricular wall. After tension member 268 is passed through the ventricular wall, catheter 265 is removed from ventricle B and wire 268. Catheter 265 is then reinserted into left ventricle B through apex D along side tension member 268.

The location of a second tension member exit point is determined, this time rather than advancing a tension member through the lumen of catheter 265, a hypotube 269 having a distal tip 270 and shown in Figure 39, is advanced through catheter 265. Distal tip 270 passes through the heart wall at the location of the second tension member exit point. Tube 269 need not be a hypotube but could be another tube having sufficient pushability to be advanced through the heart wall at the second tension member exit point. Distal tip 270 should be narrow enough or sufficiently sharpened to traverse the heart wall. A proximal end of hypotube 268 should remain outside the heart and proximal apex D. In Figure 39, catheter 265 has been removed proximally from hypotube 269 as it was from tension member 268. After hypotube 269 has been placed as shown in Figure 39, the proximal end of tension member 268 is advanced into

proximal end 271 of hypotube 269. The proximal end of tension member 268 is advanced through hypotube 269 until it exits chamber B by way of the distal end 270 of hypotube 269.

In Figure 40, tension member 268 is shown extending from distal end 270 of hypotube 269. Hypotube 269 is shown being withdrawn in the direction of the arrow over tension member 268. After hypotube 269 is withdrawn, the tension member 268 is then in place across ventricle B It can appreciated that tension member 268 has been placed without an alignment device such as alignment devices 70, 80 or 100. Anchors or anchor pads can be placed on the tension member on opposite sides of the heart and adjusted as described in more detail below. The remainder of the steps necessary to complete the placement of the transventricular splint will be discussed in detail below.

Figure 41 is a vertical cross section of left ventricle B of heart A including apex D showing an alternate method of placing a tension member. Two guide members 270 and 271 are shown advanced through apex D and out opposite sides of chamber B. Guide members 270 and 271 have been placed in this position in a manner similar to the way that tension member 268 was placed as shown in Figure 39.

Figure 42 is a view of a tension member 272 including guide tubes 273 disposed at each of its ends. Guide tubes 273 have distal ends 274 which must be sufficiently narrow or sharpened to penetrate the ventricular walls. Guide tubes 273 as shown, have been advanced through apex D over guide members 270 and 271. Tension member 272 must be sufficiently rigid to provide sufficient pushability to advance guide tubes 273 through apex D over guidewires 270 and 271 and through the ventricular walls. Once guide tubes 273 have been advanced through oppositely disposed ventricular walls,

tension member 272 can be pulled taunt across ventricle B. Once tension member 272 is drawn across ventricle B, anchors can be disposed on tension member 272 on opposite sides of heart A as described in more detail below.

Figure 43 is a vertical cross section of left ventricle B of heart A including apex D. As shown in Figure 43, leads 275 and 276 have been advanced through apex D and opposite ventricular walls in a manner similar to guidewires 270 and 271 as shown in Figure 41. Connected to leads 275 and 276 by connectors 278 is a tension member 277. This arrangement may be used in a situation wherein tension member 277 is substantially less pushable or rigid than leads 275 and 276. Leads 275 and 276 must first be placed in a manner similar to guide members 270 and 271 of Figure 41, such that the ends of leads 275 and 276 extend through the side walls of ventricle B and apex D. Then the relatively flexible tension member can be drawn into ventricle B. As shown in Figure 43, tension member 277 is partially drawn into ventricle B. Ultimately leads 275 and 276 are drawn in opposite directions until tension member 277 extends transventricularly across ventricle B and passes through the ventricular wall to the exterior of heart A. Once tension member 277 is disposed on opposite sides of the heart, anchors or pads can be attached to opposite ends of the tension member to form the transventricular splint. The splint can be adjusted as described in more detail below.

Figure 44 is a view of connector 278 of Figure 43. Lead 275 includes a loop 280 disposed at one end. Tension member 277 includes a hook 279 disposed at one end. A locking tube 281 is slidably disposed over a portion of hook 279. To complete the connection between lead 275 and tension member 277, hook 279 is hooked to loop 280.

Hook 279 is then collapsed such that hook lock 281 can be slid over the collapsed portion of hook 279 to retain loop 280 in place on hook 279 as shown in Figure 45.

The tools and methods shown and described with respect to Figures 38-43 lend themselves both to open chest and less invasive implantation procedures. They are particularly suited to less invasive procedures where the apex of the heart is accessed through an anterior port and the ventricular walls are accessed through oppositely disposed lateral ports such that opposite ends of the tension member can extend into oppositely disposed lateral ports. Rather than gaining access through the apex, those tools shown in Figure 38-43 gaining access the left ventricle through the apex could instead access to the left ventricle through the aortic valve or mitral valve. Access through the aortic valve is preferably obtained through the aorta by way of either a carotid or femoral artery access point. Access to the mitral valve can be obtained by way of a port, window or the like and may be a particularly desirable route if mitral valve replacement or repair is done in conjunction with splint implantation.

With respect to those tension members placed ventricularly through tension member guides as described above, it was indicated that it is preferable to connect an anchor or anchor pad to the end of the tension member not being advanced through the guide tube prior to advancing the tension member through the guide tube. It is not necessary to connect the pad to the tension member at that time, however. In the case of those embodiments where the tension member is advanced into the ventricle from opposite sides as shown in Figures 35-37, it is preferable that the anchors or anchor pads are connected to the tension members prior to advancement of the tension members into the ventricle. Here again, having the anchors connected to the tension members at this

time is not required, however. With respect to those methods and tools shown in Figures 38-43, the pads are preferably placed on opposite ends of the tension member after the tension member is disposed transventricularly and both ends of the tension member are exposed outside of the heart.

Once the pads or anchors are disposed on the tension member, the length of the tension member disposed between the pads is preferably adjusted. This adjustment is preferably made by fixing the position of one of the pads on the tension member and allowing the other pad to slide along the tension member. With respect to the splints of Figures 35-37, however, both pads can be affixed to the respective tension members prior to adjusting the overall length of the splint (by placement of the knots as described above). The pad which is fixed to the tension member is drawn into engagement with the external wall of the heart by pulling on the end of the tension member opposite the fixed pad. Then the other pad is brought into engagement with the external wall of the heart by sliding it along the tension member toward the pad which is fixed on the tension member. The pads can be placed on opposite ends of the tension member by way of left lateral and right lateral ports to perform the transventricular splint implant less invasively.

The effective length of the tension member, i.e., the distance between the pads measured along the tension member, can be correlated with the magnitude of heart wall stress reduction. For an idealized calculation of this relationship, please see U.S. Patent Application Serial No. 08/933,456, filed September 18, 1997, and incorporated herein by reference. It is also anticipated that the force exerted axially along the tension member by the heart engaging the pads can also be correlated with heart wall stress reduction.

Figure 46 is a view of a measuring device 300 through which a tension member 302 has been threaded. One end of tension member 302 extends through left ventricle B of heart A. An anchor pad 304 has been fixedly attached to tension member 302 and end 303 and drawn into engagement with heart A. The second pad 306 has been placed on tension member 302 but has not been tightened, i.e., fixedly attached to tension member 302. Pad 306 is free to slide along tension member 302. Extending from anchor pad 306 is a tether or string 308. In general, it may be desirable to attach a tether to the anchor pads as shown herein. This would make them easier to retrieve if they were dropped within the chest cavity during a splint implantation procedure.

Measuring device 300 includes an elongate tension member receiving tube 310 having a distal end including a pad engagement member 312 and a proximal end 316 connected to a preferably clear measuring tube 314 having a measuring scale 315 marked thereon. Tension member 302 has been threaded through tube 310 and tube 314. Tension member 302 has also been threaded through a tube 318 having a retaining block 319 and a screw 320 at one end tightened to releasably hold tension member 302. Screw 320 is preferably connected to a force transducer. Another block 322 disposed at the opposite end of tube 318. A screw 326 extends into block 322 to releasably hold guidewire 302. Block 322 is disposed adjacent block 324 connected to tube 314. Interconnecting block 322 and 324 is a guide rail 330 and adjustment screw 328. Adjustment screw 328 can be rotated to move screw and block 320, tube 318, block 322, screw 326 and thus, tension member 302 through tube 314.

Tension member 302 preferably has a visible index mark 332 placed along its length a known distance from end 303 of tension member 302. Measuring tube 314

preferably magnifies mark 332. The length of tube 310 and pad engaging member 312 as well as tube 314 should also be known and correlated to scales 315 such that by determining the location of mark 332 relative to scale 315, the length of tension member disposed between pads 304 and 306 can be determined. Set screw 328 can be adjusted until the desired length of tension member 302 between pads 304 and 306 is achieved. Then pad 306 can be fixed in place along tension member 302. Tether 308 is preferably removed. It can be appreciated that tube 310 can be sufficiently long to be advanced through a port for adjusting the length of tension member 302 less invasively.

The distance between pads 304 and 306 is preferably related to the radius R_1 of the unsplinted left ventricle. For purposes of this explanation, $2R_1$ can be viewed as the length of the tension member between pads 34 and 36 at end diastole where the pads are spaced such that no shape change is induced by the splint. When pads 306 and 304 are fixed along tension member 302 the distance along the tension member between the pads can be considered ℓ. It can be appreciated that if ℓ were greater than $2R_1$ no shape change to the left ventricle would be induced throughout the cardiac cycle. At the opposite extreme, ℓ could be so short that the opposite walls of the left ventricle are held or pressed together between pads 304 and 306 throughout the cardiac cycle. Preferably, however, the ratio $\ell/2R_1$ is preferably between about 0.4 to about 0.8 and more preferably between about 0.5 to about 0.7 and most preferably about 0.6.

In addition to measuring the length of tension member 302 between pads 304 and 306 to determine their desired spacing, it is anticipated that device 300 can be used to measure axial force on the tension member as pad 306 is engaged against heart A and advanced toward 304 along tension member 302. To accomplish this, in the preferred

embodiment, the device 300 also includes a force transducer 334 and pin vice 336. Pin vice 336 can be tightened to fixably hold tension member 302. If screws 320 and 326 are loosened such that only pin vice 336 retains tension member 302 from sliding distally within the device 300, the distally directed force in tension 302 will be transferred by pin vice 336 to force transducer 334. The axial force detected by the transducer can be observed by calibrating the transducer or connecting it to a monitor in a manner known to those skilled in the art of force transducers. Set screw 328 can be adjusted until the desired force is obtained. The surface of the pad itself could also be centered to create pores for tissue ingrowth. When the desired force level is achieved, pad 306 could be fixed in place along tension member 302.

With respect to any of the transventricular splints disclosed herein, the length of the tension member can be adjusted to form a full cycle splint or restrictive splint. If the length of the tension member is such that the anchors or anchor pads engage the heart to create a shape change throughout the cardiac cycle, the splint created is a full cycle splint. If the anchor or anchor pads do not engage at end systole to create a shape change, the splint formed is a restrictive splint.

Figure 47 is a cross sectional view of an embodiment of anchor pad 340 in accordance with the present invention. Anchor pad 340 preferably includes a disc shaped pad portion 342. Disc shape pad portion 342 includes side 343, which in use is disposed toward the heart. A conical aperture 348 having sloping sides 346 extends through pad 342. Collet 344 is disposed within orifice 348. A threaded portion 350 of collet 344 extends from orifice 348 opposite side 343, nut 352 is threaded over threaded portion 350. Lumen 345 extends through collet 344. A tension member 354 is shown extending

through lumen 345. Lumen 345 has a diameter such that when nut 352 is not tightened on threaded portion 350, tension member 354 can slide freely through lumen 345. When nut 352 is tightened, it draws collet 344 away from side 343. Collet 344 is then pinched between walls 346 of orifice 348. When collet 344 is pinched, the size of lumen 345 is reduced such that tension member 354 can no longer move freely within lumen 345, fixing the position of pad 340 on tension member 354.

Figure 48 is a cross sectional view of an alternate embodiment an anchor pad 360 in accordance with the present invention. Anchor pad 360 includes a generally disc-shaped pad portion 362. Pad 362 includes a side 363 which when the pad is in use, is disposed toward the heart. A tension member lumen 364 extends through pad 362. Lumen 364 preferably has a generally conical shaped portion 365 disposed toward side 363. Tension member 370 is shown disposed through lumen 364 in Figure 48. Pad 362 includes a threaded passage 366 extending from an edge of pad 362 to lumen 364. A set screw 368 is threaded into passage 366. Set screw 368 can be tightened to engage tension member 370 to fix the position of anchor pad 360. When set screw 368 is not tightened, the size of lumen 364 is preferably large enough that anchor pad 360 can slide relatively freely over tension member 370.

Figure 49 is a perspective view of yet another embodiment of anchor pad 380 in accordance with the present invention. Anchor pad 380 preferably includes a generally disc-shaped pad portion 382 having a first side 383 which in use would be disposed toward the heart and a second side 385. Pad 382 as well as pads 342 and 362 are preferably formed from a metal such as stainless steel alloys or titanium alloys.

A tension member fastener 384 is formed in pad 382 by cutting a series of grooves and apertures through pad 382 from side 385 to side 383. A first groove 386 has a generally horseshoe shape. Second groove 388 extends between opposite portions of horseshoe shaped groove 386 to form two oppositely disposed cantilever members 387. A relatively large aperture 394 is formed between cantilever members 387 proximate their free ends. A second and smaller aperture 390 is formed closer to the fixed ends of cantilever members 387. Tension member 392 is shown extending through aperture 390.

As shown in Figure 49, tension member 392 is clamped between cantilever members 387 such that the location of pad 382 is fixed along tension member 392. Pad 382 can be released by using a spreading device 396 to spread cantilever members 387 apart. Spreading device 396 includes handle 398 to spreading arms 400 each having a finger 402. Fingers 402 can be placed within aperture 394 then arms 400 and fingers 402 can be spread apart by pivoting them around a pin 404 such that cantilevers 387 are spread apart and pad 382 can move freely along tension member 392. It can be appreciated that although spreader 396 is shown extending transversely from tension member 392, it could also be configured such that fingers 402 do not curve transversely from arms 400 and thus spreader 396 could be disposed parallel to tension member 392. This would be particularly desirable in a situation where anchor pad 380 was being placed through a port or window during a less invasive splint implantation procedure. It can be appreciated that cantilever members 387 can be held apart such that pad 380 can be moved along tension member 392 by placement of a temporary wedge or pin in groove 388. For example, grooves 388 may include an additional small aperture disposed between aperture 390 and aperture 394 into which a pin could be placed to hold

open members 387. When it is desired to fix the position of anchor pad 380 on tension member 392, device 396 could be used to spread cantilever members 387 to remove the pin. The cantilever members could then be released to engage tension member 392. Aperture 390 of pad 380 can also include a conical portion disposed toward side 383 such as conical portion 365 of pad 360.

Cantilever arms 384 are preferably configured such that they do not stress tension member 392 beyond its elastic limit. It can also be appreciated that the force developed by cantilever members 387 impinging on tension member 392 is operator independent and defined by the geometry and material characteristics of members 387.

Figure 50 is a perspective view of an anchor pad 360 having a tension member 370 extending therethrough. After pad 360 is secured to tension member 370, that portion of tension member 370 which extends from the side of anchor pad 360 opposite side 363 is preferably removed. This can be accomplished by trimming tension member 370 with wire cutter 414 or scissors. Although anchor pad 360 is used here to illustrate trimming tension member 370, it can be appreciated that in each of the embodiments disclosed herein there may be an excess portion of tension member extending from an anchor, which is preferably removed or trimmed.

Figure 51 is a cross sectional view of an alternate embodiment 420 of a tension member cutter. Device 420 includes an elongate outer tube 422 having a distal end 424. Tube 424 defines a lumen 423 through which extends a second tube 430 having a distal end 428. Extending distally from distal end 428 are two cutting arms 424 and 426 which are shown partially withdrawn into lumen 423 and transversely restrained by distal end 424 of outer tube 422. When unrestrained by distal end 424, arms 424 and 426 are biased

apart. Each arm 424 and 426 has a cutting element 425 and 427, respectively. Elements 425 and 427 are shown in contact with each other in Figure 51. A tension member 370 extends between arms 424 and through lumen 432 of inner tube 430. A representative anchor pad 360 is disposed adjacent elements 425 and 427. Device 420 of Figure 51 is particularly useful when trimming excess tension member using less invasive techniques as it can be readily advanced over a tension member through a port or window.

Figure 52 is a vertical cross sectional view of left ventricle B of heart A. A transventricular splint 443 including a tension member 370 and anchor pads 360 are shown disposed on heart A. To the left of heart A as shown in the figure is a coiled portion 442 of tension member 470. As an alternative to trimming an excess length of tension member, tension member 370 could be formed from a shape memory alloy such that portion 442 could be preset to assume a coil shape when warmed to near body temperature.

Once the length of the tension member has been adjusted, the anchors are secured in place along the tension member and the excess length of tension member removed if desired, the anchor or anchor pads are preferably secured in place on the heart. The anchor or anchor pads are secured such that relatively movement between the anchors or anchor pads and the heart is limited to reduce abrasion of the heart wall. To secure the anchor or anchor pads to heart A, a biocompatible adhesive could be placed between the pad and the heart to adhere the pad to the heart. Alternately, apertures could be provided in the pad such that sutures could be extended through the apertures and into the heart to secure the pad. In addition to sutures, the pad could include threaded apertures into

which anchor screws could be advanced through the pad and into the heart wall to secure the pad to the heart.

Figure 53 illustrates yet another alternative approach to securing the anchors or anchor pads to the heart surface. Figure 53 is a cross sectional view of an anchor pad 340 disposed on heart A. Anchor pad 340 is disposed within an envelope 446. Envelope 446 includes a bottom layer 447 disposed between anchor pad 340 and heart A and a top layer 448 disposed on the opposite side of anchor pad 340. Layers 347 and 340 are held together by sutures 449. Bottom layer 447 is preferably a mesh dacron or expanded PTFE which has a pore size or intranodial dimension sufficient to promote tissue ingrowth. The pore size is preferably between about 10 and about 100 microns and more preferably, between about 20 and about 40 microns. With respect to expanded PTFE, the intranodial dimension is preferably between about 10 to about 100 microns and more preferably between about 20 to about 40 microns. The top material could also be dacron or expanded PTFE or the like having a pore size which preferably does not promote ingrowth and thus resists adhesion to surrounding tissue.

Envelope 446 would preferably be placed around pad 340 prior to placing pad 340 on tension member 354. A window 450 can be provided to provide access to nut 352 to secure pads to tension member 354. After tightening nut 352, window 450 can be closed by suture 452. Figure 54 is a top view of pad 340 and envelope 446 of Figure 53. It can be appreciated that a similar envelope can be placed around the various anchor pads disclosed herein. The location of the window may have to vary, however, to provide access to the respective means for securing the anchor pads to the tension member.

Figure 55 shows an alternate embodiment of a splint locating device 460 disposed on heart A. It can be appreciated, however, that alternate locating device such as that shown in Figures 13-15 could also be used. Heart A includes left ventricle B, right ventricle C and apex D. Splint locating device 460 which is particularly useful in performing less invasive procedures. Device 460 can be advanced through an anterior port or window to apex D and onto heart A as shown in Figure 55. Device 460 includes an elongate catheter shaft 462 having a lumen extending therethrough. Extended from the distal end of catheter shaft 462, are two arms 464 preferably biased to spread apart from each other when advanced distally from catheter shaft 462. Connected to the distal end of wires 464 is a band 466. Band 466 preferably readily elongates, i.e., increases in diameter as it is advanced onto heart A, such that band 466 does not substantially alter the pumping performance of heart A.

Figure 56 is a view of the device 460 disposed on heart A. Wires 464 are shown extending from catheter shaft 462 distally to band 466 and proximally from catheter shaft 462. Prior to advancing catheter 460 through a port or window to apex D, wires 464 are preferably pulled proximally into shaft 462. Band 466 can also be folded and pulled into shaft 462 or folded and disposed parallel to shaft 462 for advancement through the port or window. Once the distal end of shaft 462 is advanced to apex D of heart A, wires 464 can be shifted distally to deploy band 466 and the adjacent portions of wires 464 in heart A.

Figure 57 is a generally vertical cross sectional view of left ventricle B of heart A including apex D. Catheter 460 is shown deployed on heart A. Band 466 has been advanced sufficiently high on heart A such that the adjacent portions of wires 464 will lie proximate potential entry/exit points for the tension member guide or tension member.

As can be seen in Figure 57, two balloon catheters 468 have been advanced over wires 464. Those skilled in the art will recognize that catheters 468 could be configured similarly to an over-the-wire or rapid exchange angioplasty catheter. Balloon catheters 468 include a distally disposed balloon 469 which would be larger than angioplasty balloons, however.

Figure 58 is a transverse cross sectional view of chamber B and catheter 460 taken from Figure 57. Balloons 469 have been inflated to induce a shape change in chamber B similar to that shown in Figure 1A. Balloons 469 can be inflated with a radiopaque or echogenic inflation fluid such that they can be visualized by fluoroscope or echo imagery. If the balloons are imaged in this way, a portion 469' of each balloon 469 engages heart A can be considered as a location for the exit/entry points for the tension member. The criteria for evaluating the location is similar to that described above with respect to the locators of Figures 3-12 above. Device 460 can also be used acutely as a temporary splint.

Figure 59 is a vertical cross sectional view of left ventricle B of heart A having an apex D on which another alternate embodiment 470 of a locator device is shown disposed within chamber B. Locator device 470 includes an elongate catheter shaft 472 having a distal end 478. Extending from distal end 478 is a wire or elastic ribbon 476. Wire 476 is shown extending transversely from distal end 478 to radiopaque or echogenic markers 479. Additional wires or leads 474 extend proximally from markers 479 to a ring or hub 475 disposed outside of heart A. To advance catheter 470 into chamber B or withdraw it therefrom, hub 475 is pulled distally along shaft 472 to draw wires 474, markers 479 and wires 476 generally parallel to and adjacent shaft 472. In this position, catheter 470 can

be advanced through or withdrawn from chamber B by way of a port or window used for less invasive procedures. Catheter 470 and markers 479 can be used to locate the entry/exit points similarly to the locators shown in Figures 4-12 and in particular, the marker 55 of Figure 10.

Figure 60 is a transverse cross section of a human torso through heart A, left ventricle B and right ventricle C, right lung E and left lung F. Locator 60 of Figure 11 is shown being advanced less invasively to heart A. Figure 61 is a same human torso cross section as shown in Figure 60, except that locator 60 has been brought into engagement with heart A as shown from a different perspective in Figure 12. Figure 62 is yet another view of the same torso cross section where a locator 485 having scissor-like handle 486 and arms 488 are coupled by an elongate linkage 487. As can be appreciated by those skilled in art, arms 488 can be drawn together or spread apart by an operating handle 486. The distal end of arms 488 should be echogenic or radiopaque such that they can be viewed by echo imaging or fluoroscopy similarly to end 62 of locator 60. Locator 485 is shown advanced to heart A through a lateral left approach. Locator 485 is preferably advanced through a port not shown of a type known to those skilled in the art. It can be appreciated that locator 485 can be used to locate a splint at a different location than locator 60.

An alternate method of splint placement could advantageously use a thread pusher and snare. Figure 63 is a view of a thread pusher 500. Thread pusher 500 includes a housing 502 defining a lumen 503 therethrough. Extending from lumen 503 is a shaft 504 having a sharpened distal tip 506. Shaft 504 defines a lumen 507 in fluid communication with lumen 503 of housing 502. Shown disposed within lumen 503 and

advancable into lumen 507 is a plunger 508. Plunger 508 has a distal end 510. Plunger 508 defines an elongate lumen 511 extending the length of plunger 508. Disposed through lumens 503, 511 and 507 is a thread 512. Lumen 511 preferably has a diameter just slightly greater than the diameter of thread 512. Lumen 507, however, has a diameter great enough to coil a substantial length of thread 512 therein. The necessary length of thread 512 can be appreciated in view of the discussion which follows regarding the use of thread pusher 500.

Figure 64 is a generally vertical cross sectional view of left ventricle B of heart A having apex D, aortic valve G and mitral valve H. Disposed within chamber B is a catheter 520 having an elongate catheter shaft 522 extending through apex D of heart A to proximate aortic valve G. A wire or line 526 extends through an elongate lumen through shaft 522, loops to form a snare 524 at the distal end of shaft 522 and returns back through the lumen. As shown in Figure 64, snare 524 is disposed generally around or preferably through the orifice of aortic valve G. Two thread pushers have been advanced from opposite sides of heart A such that distal tips 506 of shafts 504 are disposed within chamber B. Plunger 508 of thread pusher 500 has been advanced to release previously coiled portion 514 of thread 512 into chamber B. As shown by the arrows, blood flow leaving chamber B exits through aortic valve G. As shown in Figure 64, this blood flow has carried threads 512 through snare 524 and aortic valve G.

Figure 65 shows the same cross sectional view of left ventricle B as Figure 64, except that snare 524 has been partially retracted by pulling line 526 proximally. Catheter 520 has also been partially withdrawn in a proximal direction from chamber B. Figure 66 is yet another view of the cross section of left ventricle B as shown in Figure

64, except that snare 524 has been withdrawn proximally from catheter 522 such that an end of each thread 512 is disposed proximally of shaft 522.

Figure 67 is yet another view of the cross section of left ventricle B shown in Figure 64, except that threads 512 have been joined and extend across left ventricle B. To achieve the configuration of Figure 67, the ends of threads 512 disposed proximally of shaft 522 in Figure 66 are tied together. Then the opposite ends of thread 522 are pulled proximally relative to respective thread pushers 500 until threads 512 are withdrawn from catheter shaft 522 and extend across chamber B. Thread pushers 500 can be withdrawn proximally from threads 512. Joined threads 512 can be used as a tension member to assemble a transventricular splint. Preferably, however, after thread pushers 500 are removed from threads 512, a tension member is connected to one of the free ends of thread 512 by, for example, tying the end of thread 512 to a loop formed in an end of a tension member. Then the remaining free end of thread 512 can be withdrawn proximally until both threads 512 are pulled from chamber B and the tension member extends across the chamber. Once the tension member extends across the chamber, the remainder of the splint can be assembled in a manner similar to that contemplated for the tension members placed in accordance with Figures 38-43.

It can be appreciated that the method of placing a tension member described with respect to Figure 64 can advantageously be performed by an open chest or less invasive route. The method described, however, lends itself particularly well to a less invasive approach where oppositely disposed lateral ports are used to manipulate string pushers 500 and an anterior port is used to access apex D by catheter 520. As an alternative to the apical approach, snare 524 could be placed from an aortic or mitral valve approach. If

the approach is by way of the aortic valve, the snare may be advanced thereto by way of the aorta from a carotid or femoral artery access point. The mitral valve approach could be made by way of a port or window. The mitral valve port may be particularly desirable if mitral valve repair or replacement is preformed in conjunction with splint implantation.

Figures 68 and 69 illustrate yet another method of placing a tension member across ventricle B using snare 524, and a thread pusher 500. Unlike the method described with respect to Figures 64-67, the lateral approaches are preferably used without requiring access to apex D. Catheter 520 is advanced from one side of chamber B and placed generally around distal tip 506 of shaft 504 of thread pusher 500 which is advanced into chamber B from the opposite side. Plunger 508 is depressed to push the coiled portion of thread 512 into chamber B. Thread 512 drifts toward aortic valve G and through snare 524 under the influence of blood flow.

As shown in Figure 69, snare 524 is tightened around thread 512 and withdrawn from chamber B. It can be appreciated that catheter 520 and thread pusher 512 can be removed from thread 512 and a splint assembled in the manner described above with respect to the tension member placed in accordance with the method described in Figures 64-67. It can also be appreciated that this method can advantageously be applied to implant a splint either by an open chest or less invasively using two oppositely disposed lateral ports.

Figure 70 is a longitudinal cross sectional view of an alternate embodiment of a thread pusher 610. Thread pusher 610 includes a thread insertion shaft 612 having a lumen 612 extending therethrough. Shaft 612 can have a curved distal end 614 which preferably includes a sharpened portion 618 for insertion through the heart wall into the

left ventricle. A handle 620 is preferably disposed at the proximal end of shaft 612. A plunger 622 is preferably disposed within shaft lumen 616. Plunger 622 includes a distal end 626 and a proximal end preferably including a handle 628. A lumen 624 extends through plunger 622. A thread or filament 611 is shown disposed within shaft lumen 616 and plunger lumen 624. Unlike thread pusher 500 of Figure 63, the length of shaft 612 is preferably long enough that the portion of thread 611 to be advanced into the left ventricle can be disposed within lumen 616 without being coiled.

In use, distal tip 618 of thread pusher 610 is disposed in left ventricle B in a manner similar to that of tip 506 of thread pusher 500. Plunger 622 is then advanced into shaft lumen 616 to advance thread 611 into the left ventricle. Thread 612 is preferably lightly friction within lumen 624 or held within lumen 624 by the user or holding cap 629.

Figure 71 is a generally vertical cross section of left ventricle B showing a longitudinal cross sectional of a snare insertion tube 630 disposed through apex D. Insertion tube 630 preferably includes an elongate shaft 632 having an elongate lumen extending therethrough. An annular flange 638 is preferably disposed at the proximal end of shaft 632. Disposed in engagement with, and distally of flange 638 is an annular felt pad 636. A stylet 640 having an elongate shaft 642 and a hub 644 can be inserted within the lumen of shaft 632.

In use, snare insertion tube 630 can be used to provide a stable access through apex D for catheter 520 when performing the procedure shown in Figures 64-67 above. Insertion tube 630 can be advanced into apex D as shown. As insertion tube 630 is advanced into apex D, stylet 640 is preferably disposed therein to limit bleeding through

the lumen through shaft 632. Felt pad 636 is preferably sutured to apex D to limit bleeding around shaft 632 and stabilize insertion tube 630 on apex D. Stylet 640 is then removed and then catheter 520 can be advanced through insertion tube 630 to perform the splint implantation.

Up to this point, it has been assumed that access was obtained or obtainable to each end of the tension member for placement of an anchor or anchor pad thereon. Access to each end of the tension member placed across the left ventricle is generally obtainable by open chest access or lateral, anterior or posterior ports. It is contemplated, however, that under some circumstances, however, it may be difficult or undesirable to obtain access to one or both ends of the tension member. Under such circumstances, it may be desirable to be able to deliver an anchor or anchor pad to a wall of the ventricle to which direct access by open chest or port has not been obtained. In such an instance, it may be desirable to deliver the anchor or anchor pad from inside the heart to the outside.

Figure 72 is a cross sectional view of a portion of left ventricle B including a distal portion of a tension member 532 having a balloon anchor 536 disposed at its distal end and outside of chamber B of heart A. Tension member 532 is preferably a tubular member such as a hypotube sealed at its distal end except for an orifice 534 disposed within balloon 536. The distal end of tension member 532 including balloon 536 can be advantageously and preferably advanced to the position shown by using any of the methods and devices disclosed above which advance the tension member from inside the heart to outside, for example, the method and device described above with respect to Figures 38-40. Once the distal end of tension member 532 is advanced to the position shown, balloon 536 can be inflated from a collapsed position to the expanded position

shown. Balloon 536 is preferably expanded using quick cure polymer such as cyanoacrylate or mixed two-part epoxy or other biocompatible substance which will allow balloon 536 to remain in an expanded position chronically. Saline is preferably used as inflation fluid if the balloon is inflated acutely.

Figure 73 is a similar view to that of Figure 72 except a tension member 542 having a pad 544 is shown disposed in left ventricle B. Pad 544 is preferably a coiled pad which can be delivered as described above with respect to the balloon of Figure 72, except that it may be preferable to advance pad 544 through the heart wall through a tube. Coil 544 can be compressed within the tube and upon emerging from the tube and the heart, expand. Coil 544 could also could be formed from a shape memory alloy and be preset to expand at approximately body temperature.

Figure 74 is yet another example of an anchor pad deployable from inside the heart to outside the heart. Pad 554 is shown disposed at the end of the tension member 552. Pad 554 includes two arms pivotally connected to tension member 522 by hinge 556. Hinge 556 preferably allows arms 555 to rotate from a first position parallel and adjacent to tension member 552, to a second position approximately perpendicular to tension member 552 as shown. To deploy pad 554, pad 554 is advanced from the heart through the heart wall with arms 555 disposed in the first position until the arms are completely advanced to the outside of the wall. Then tension member 552 is drawn in the opposite direction such that the ends of arms 555 engage the heart wall and pivot into the second position as tension member 552 continues to be pulled.

Figure 75 is yet another embodiment of an anchor pad 565 which can be placed from inside the heart to outside by the methods applicable to the device of Figure 72. Pad

565 includes two arms 564 hingably connected to tension member 562. Arms 564 include a hinge 566. Pad 565 can be advanced through the heart wall while arms 564 are parallel and adjacent to each other. Once arms 564 have been advanced to the outside of the heart, a wire or line 568 connected to the distal end of arms 566 and extending proximally through tension member 562 can be pulled proximately to shorten the distance between the ends of arms 564 and bend arms 564 outward at hinges 566.

Figure 76 is yet another embodiment of an anchor pad 574 disposed on a distal end of tension member 572. Pad 574 has an umbrella-like shape, the top of the umbrella being disposed away from the heart wall and the broad base of the umbrella being disposed toward the heart wall. Pad 574 is advanced through the heart wall in a collapsed position. Pad 574 can be biased to expand upon passing through the heart wall or can be expanded in a manner similar to pad 554 of Figure 74.

Figure 77 is a view of anchor or anchor screw 584 disposed at the distal end of a tension member 582. Screw 584 unlike the anchor pads of Figures 72-76 does not have to pass through the heart wall to secure tension member 582 in place. Rather, anchor 584 has a corkscrew or auger shape. Screw 584 is anchored to the myocardium by rotating tension member 582 while advancing anchor 584 into the myocardium.

Figure 78 is a view of yet another embodiment of anchor pad 612 disposed on an end of a tension member 610. Pad 612 is preferably a fabric such as dacron or PTFE. A fast acting adhesive can secure pad 612 to the heart wall as shown. The adhesive can be, for example, cyanoacrylate. The adhesive can be triggered by reaction with the heart wall tissue, be pressure sensor, be activated by an accelerator or energy source.

Figure 79 is a cross section of a portion of left ventricle B similar to that shown in Figure 72-78 except that the epicardium I is shown. The device of Figure 79 includes a tubular tension member 592 including an anchor or an epicardial jaw anchor 594 disposed at its distal end. Jaw anchor 594 is connected to a wire or line disposed through the lumen of tension member 592. The jaw anchor 594 is biased to open when unrestrained by the distal end of tension member 592. If wire 596 is pulled proximally, jaws 594 will engage the distal end of tension member 592 tending to close anchor jaws 594, by a mechanism similar to that of the device of Figure 51, except that anchor jaws 594 are not intended to cut but rather grip.

It should be noted that not only can the anchors and anchor pads of Figures 72-79 be advantageously employed when one of the ends of the tension member extending outside the heart will not be directly accessible to deploy a pad thereon, but also where neither end of the tension member will be accessible to place a pad thereon. In such an instance, two tension members having anchors or anchor pads as shown in Figures 72-79 can be placed through an apical approach similarly to how guide members 270 and 271 were placed in Figure 41. Once the anchors or anchor pads are deployed, however, the two tension members are preferably connected to form effectively a single tension member.

Figure 80 is a vertical cross sectional view of the left ventricle B of heart A having apex D. For purposes of illustrating the deployment of two tension members and anchors or anchor pads without direct access to the distal ends of the tension members, outside the heart, for placement of the pads thereon, two tension members 532 having balloons 536 disposed at their distal ends are shown placed on left ventricle B. It can be

appreciated that tension members 532 and balloons 536 can be placed on the heart in a manner similar to guide members 270 and 271 of Figure 41. Then catheter tube 600 can be advanced over tension members 532. Tension members 532 can then be drawn proximally to reduce the distance between pads 536 to create either a full cycle or restrictive splint.

Figure 81 is the same cross sectional view as Figure 80 except that catheter 600 has been removed from chamber B and a tension member fastener 602 has been placed to interconnect tension members 532. Fastener 602 can be formed from a disc similar to pad 382 of Figure 49, but form with an additional tension member receiving aperture 390. To place fastener 602, fastener 602 can be advanced through catheter 600 over tension members 532 by an elongate spreader. The spreader can be removed and fastener 602 clamped to tension members 532. Then the catheter 600 can be removed to obtain the configuration shown in Figure 80. It should also be noted that prior to removing catheter 600, tension member cutter 420 of Figure 1 could be advanced over the tension members to remove the excess length shown extending through apex D.

It can be appreciated that the method of Figures 80 and 81 can be preformed open chest or less invasively. When preformed less invasively, an anterior access port is preferably used. In addition to performing the methods of Figures 80 and 81 by way of apex D, access could be gained to left ventricle B by way of the aortic valve or mitral valve as described above.

The effective length of the tension member between anchor pads 536 can be determined by knowing the overall length of each tension member and the length of catheter 600. The effective length of the tension member will be the sum of the lengths

of the tension members less two times the length of catheter 600 and less the length of each tension member extending proximally from catheter 600 when the distal end of catheter 600 abuts fastener 602. If pads 536 were made from echogenic or radiopaque material the effective length of the tension could be estimated by echo imaging or fluoroscopic techniques. It can also be appreciated that the length of the tension member can be measured directly be advancing a measuring device into chamber B.

Numerous characteristics and advantages of the invention covered by this document have been set forth in the foregoing description. It will be understood, however, that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size and ordering of steps without exceeding the scope of the invention. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A method of implanting a transventricular splint having an elongate tension member and two oppositely disposed anchors, comprising the steps of:

selecting the location on the ventricle for placement of the splint;

advancing a first tension member through a first side of the ventricle;

advancing a second tension member through a second side of the ventricle;

deploying an anchor on each tension member; and

connecting the tension members.

2. The method in accordance with claim 1, wherein the tension members are connected within the heart.

3. The method in accordance with claim 1, wherein the first tension member is advanced into the heart from the first side.

4. The method in accordance with claim 3, wherein the second tension member is advanced into the heart from the second side.

5. The method in accordance with claim 1, wherein the first tension member is advanced into the heart proximate the apex.

6. The method in accordance with claim 5, wherein the first tension member is then advanced through the first side.

7. The method in accordance with claim 5, wherein the second tension member is advanced into the heart proximate the apex.

8. The method in accordance with claim 7, wherein the second tension member is then advanced through the second side.

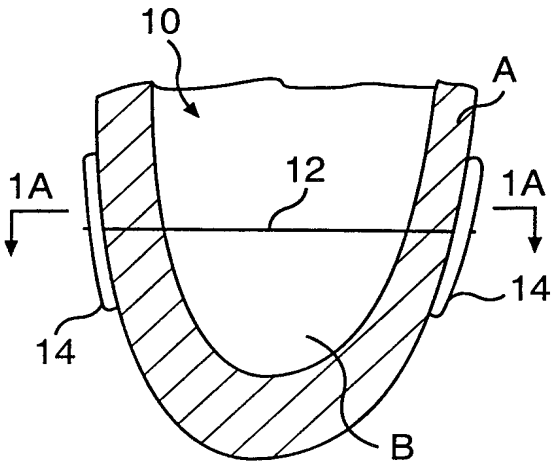

FIG. 1

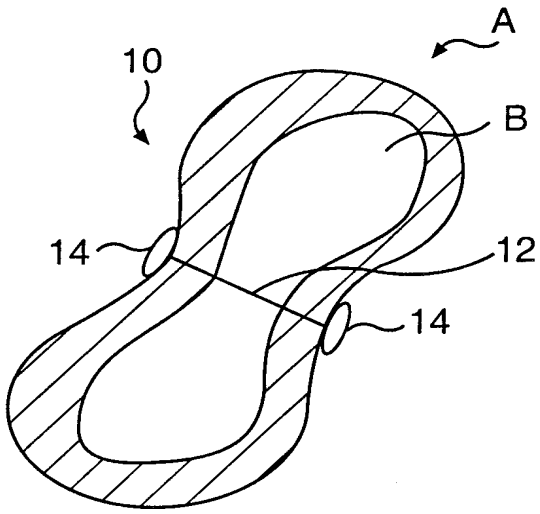

FIG. 1A

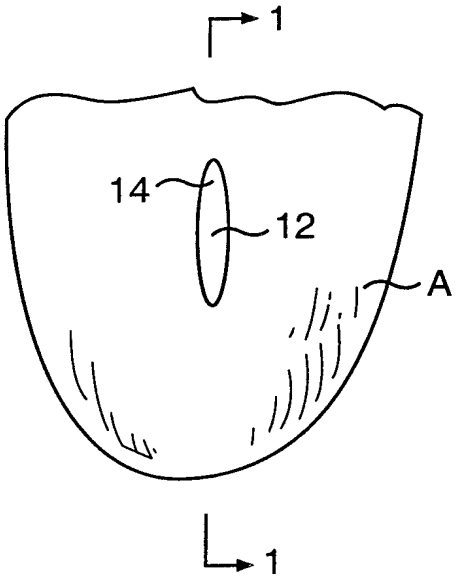

FIG. 2

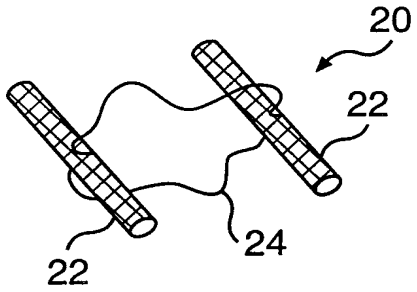

FIG. 3

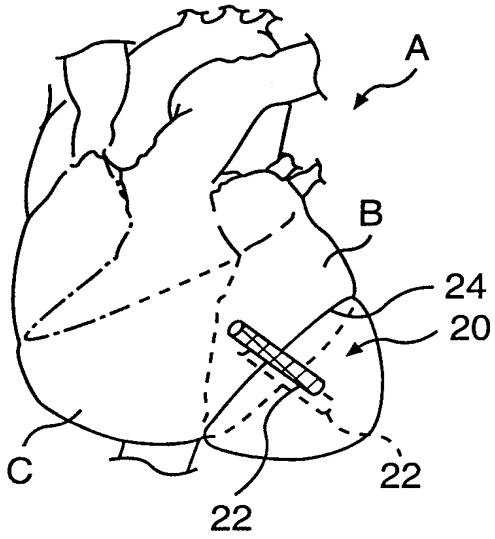

FIG. 4

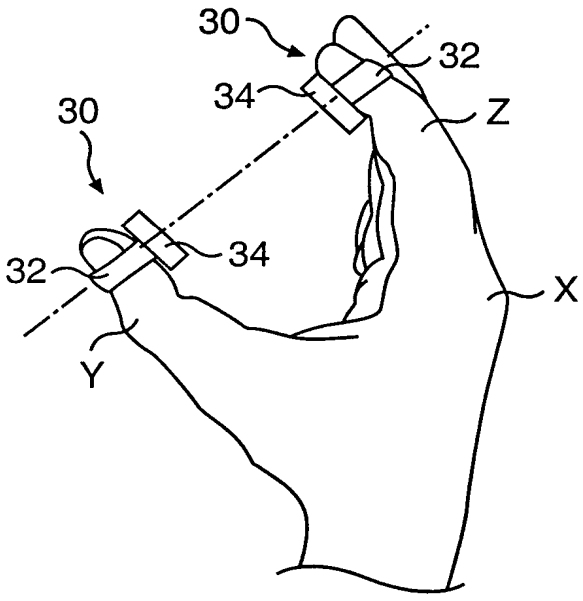

FIG. 5

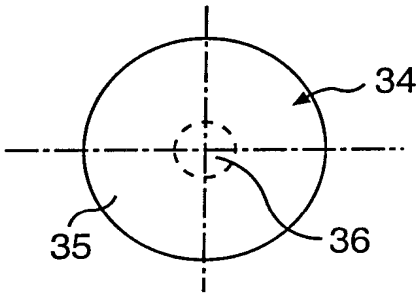

FIG. 6

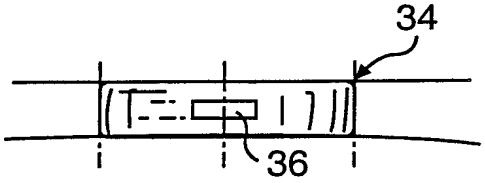

FIG. 7

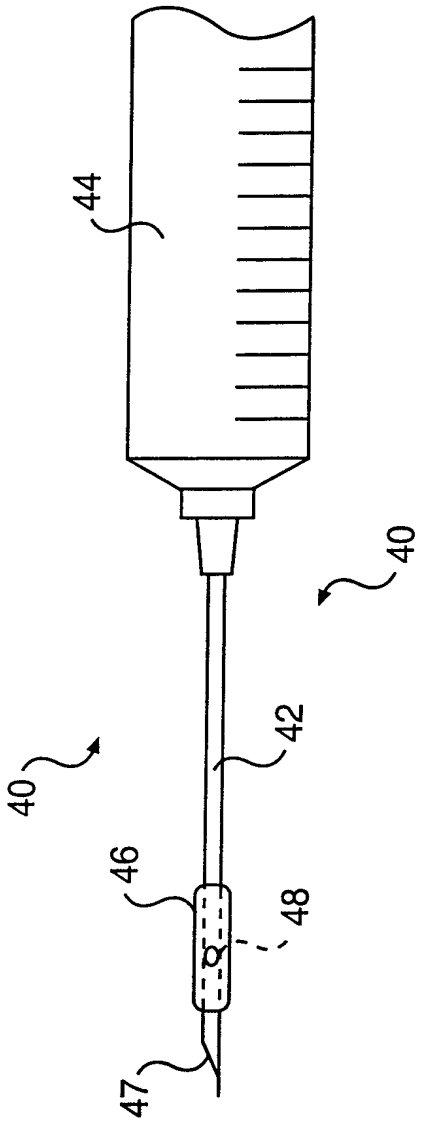

FIG 8

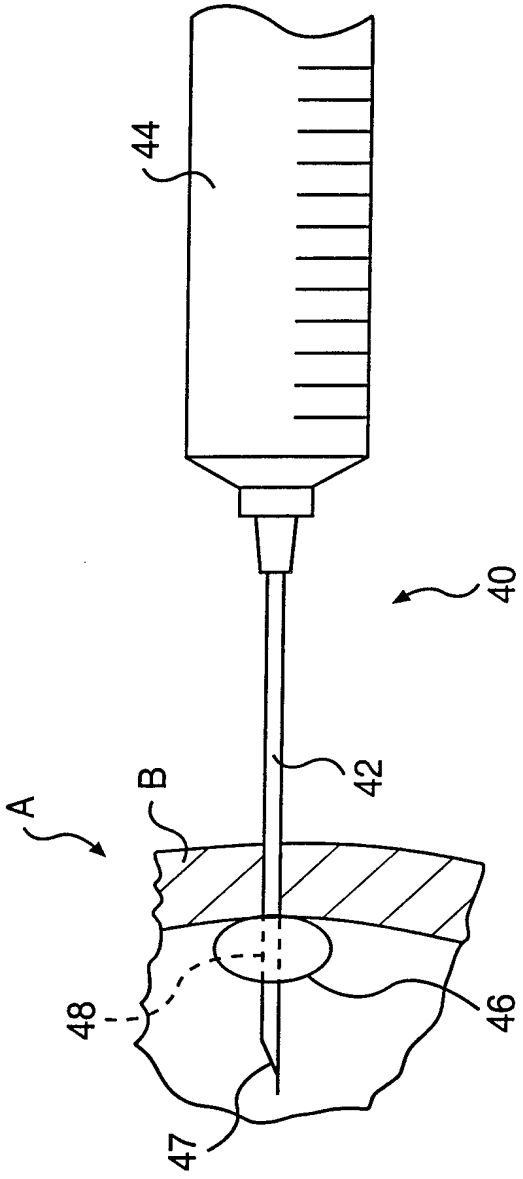

FIG 9

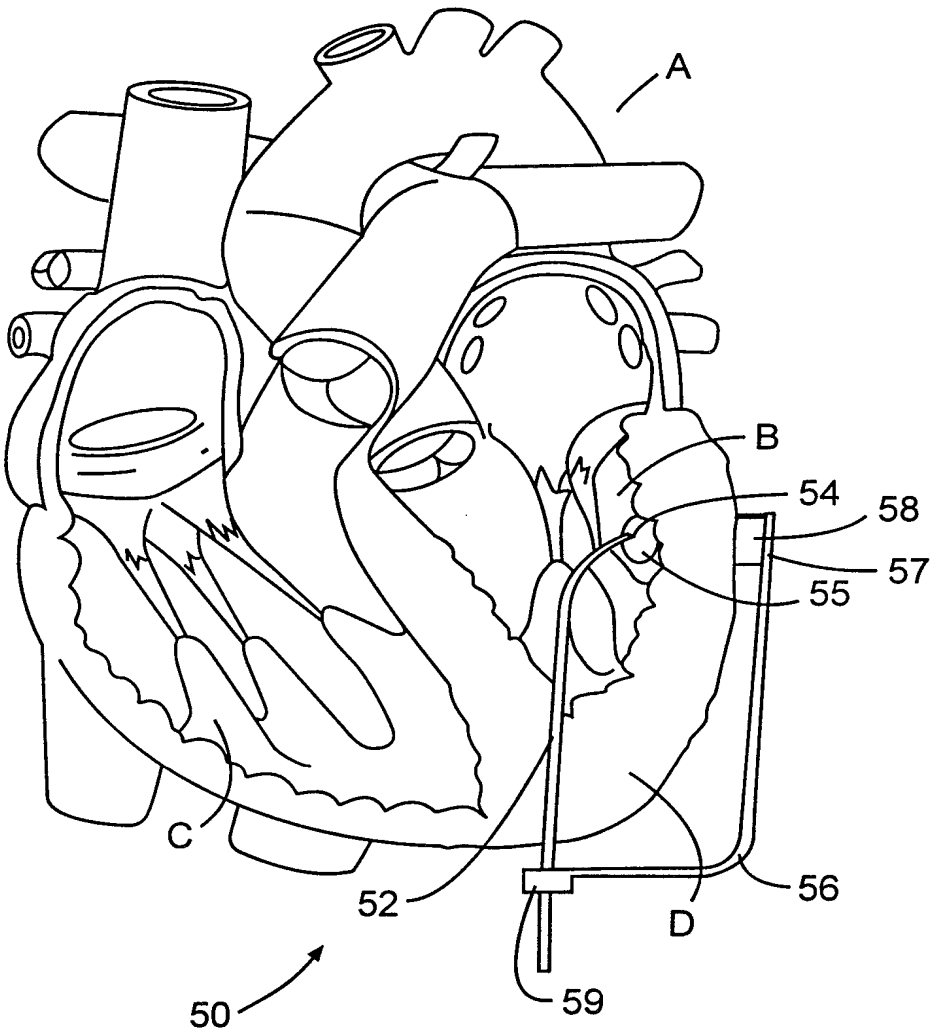

FIG. 10

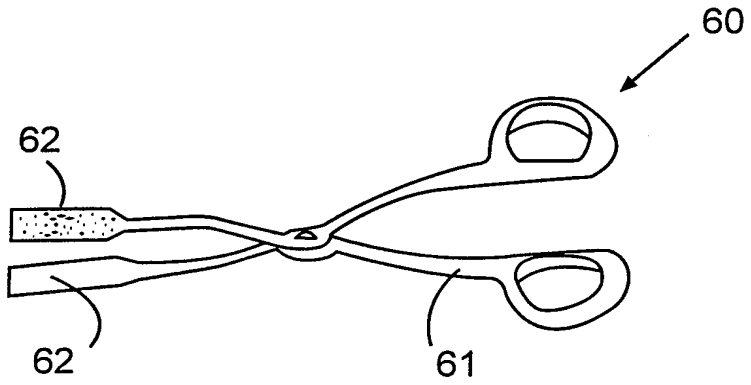

FIG. 11

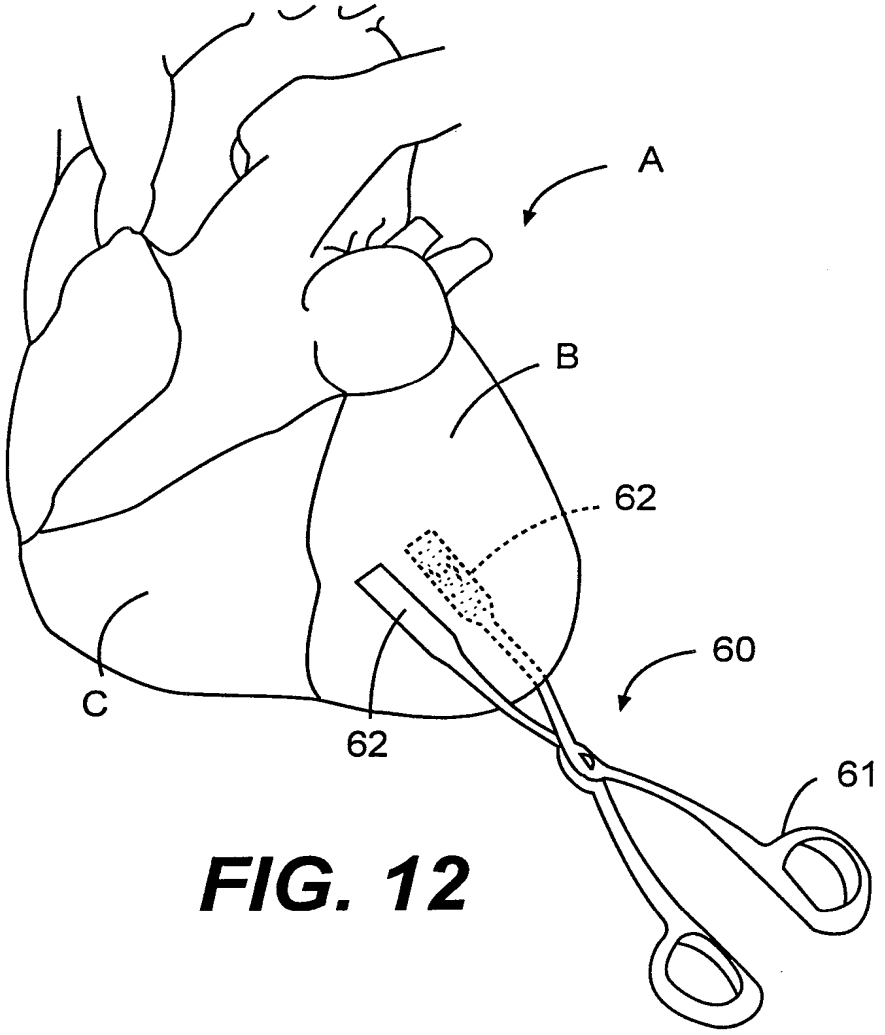

FIG. 12

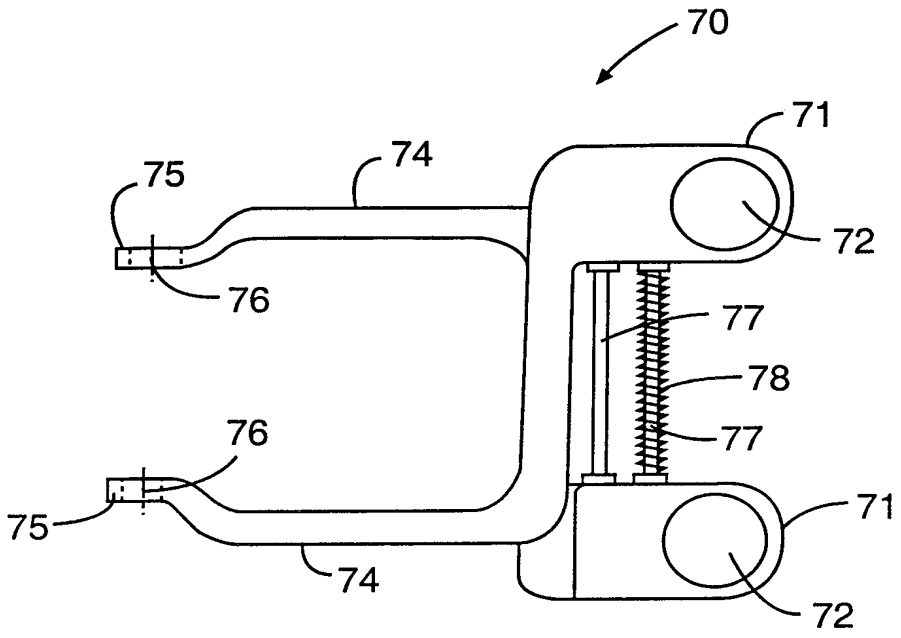
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FIG. 13

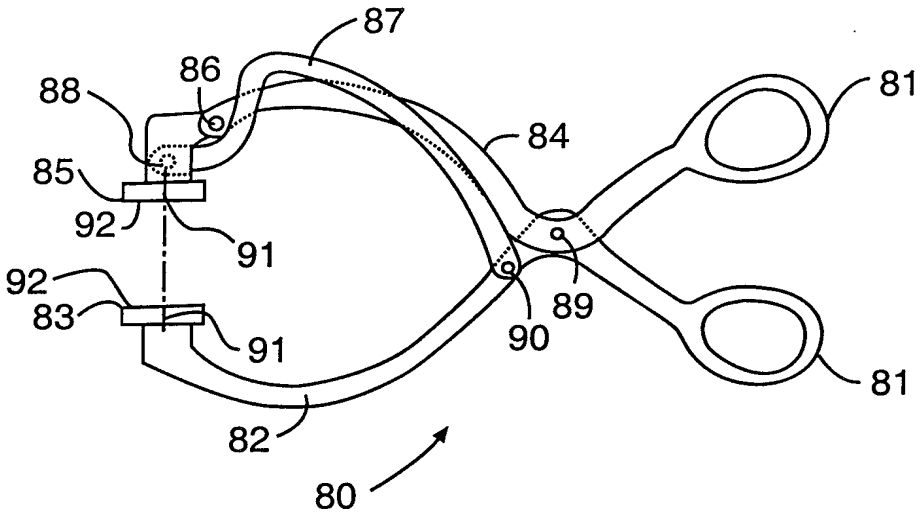
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FIG. 14

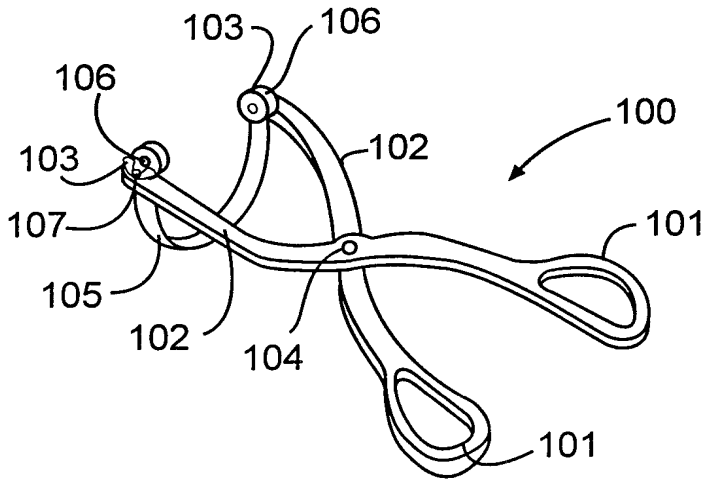


FIG. 15

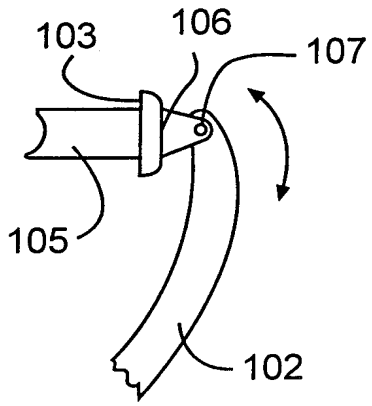


FIG. 15A

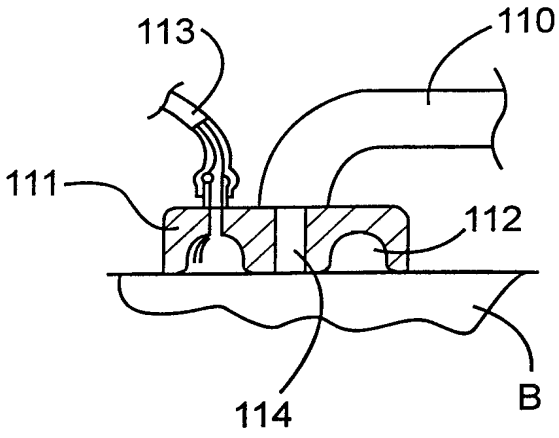


FIG. 16

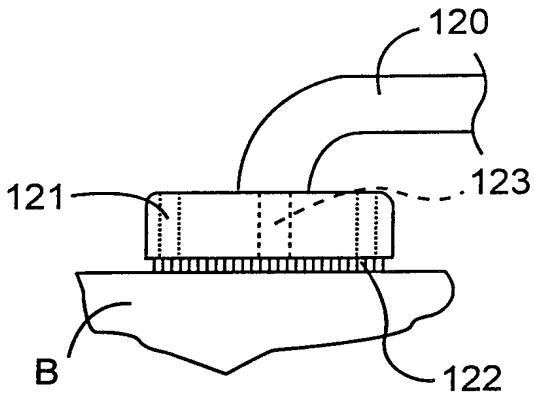


FIG. 17

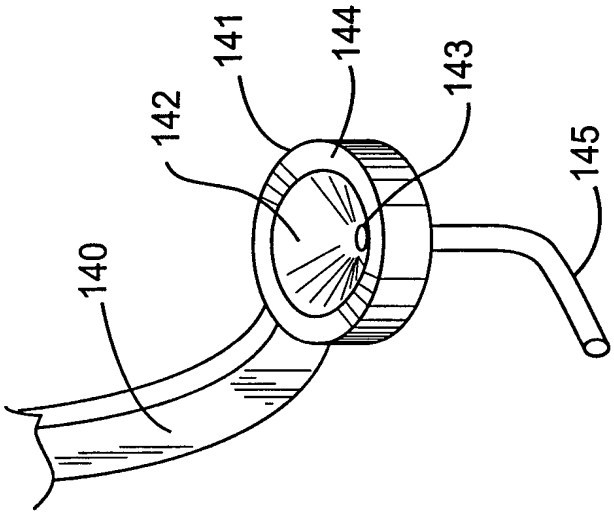


FIG. 19

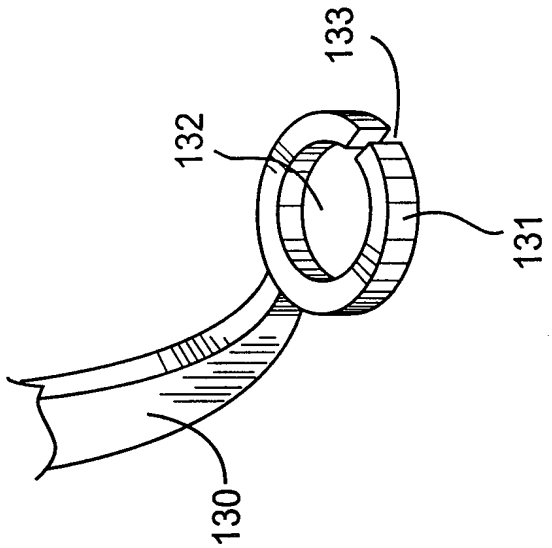


FIG. 18

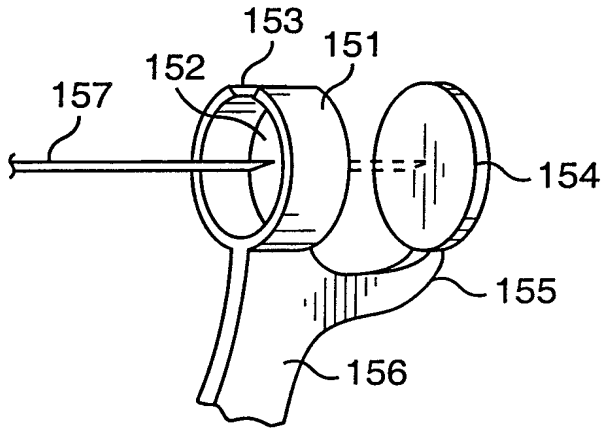


FIG. 20

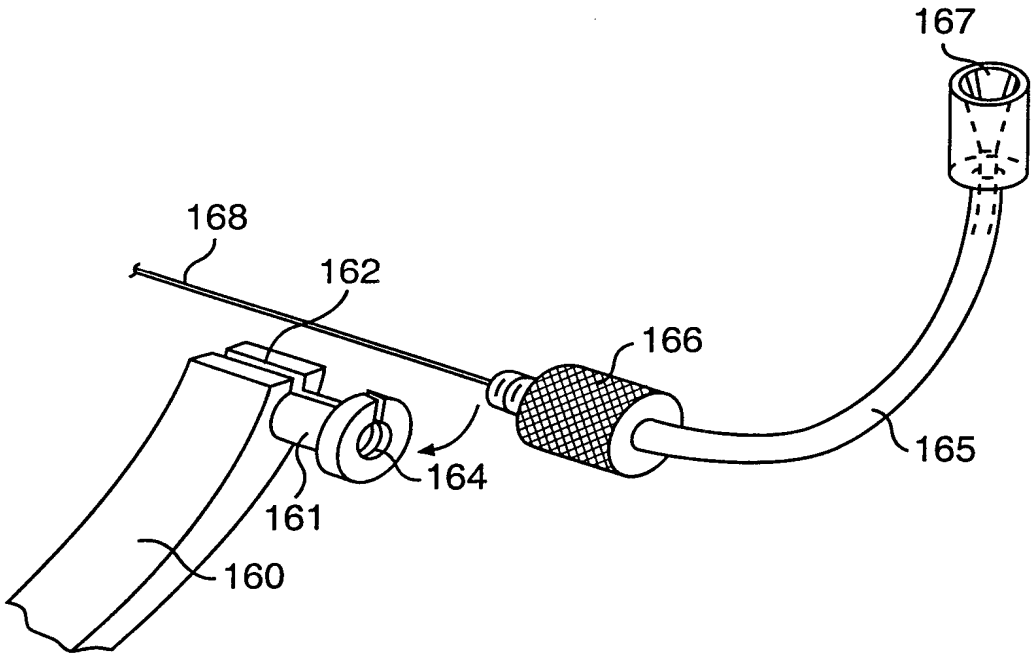


FIG. 21

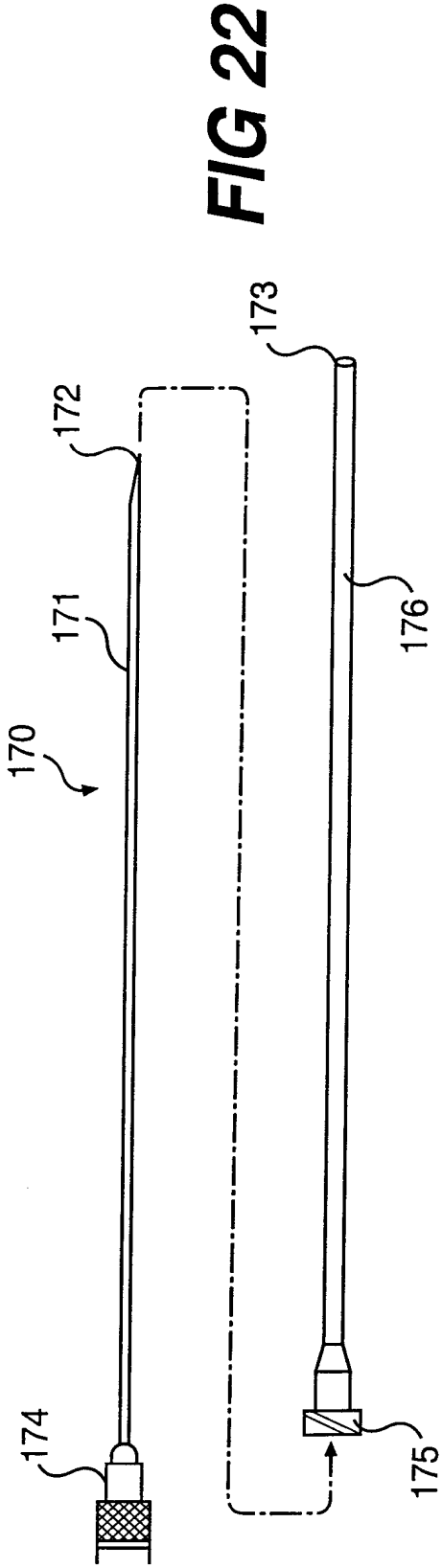


FIG 22

FIG 23

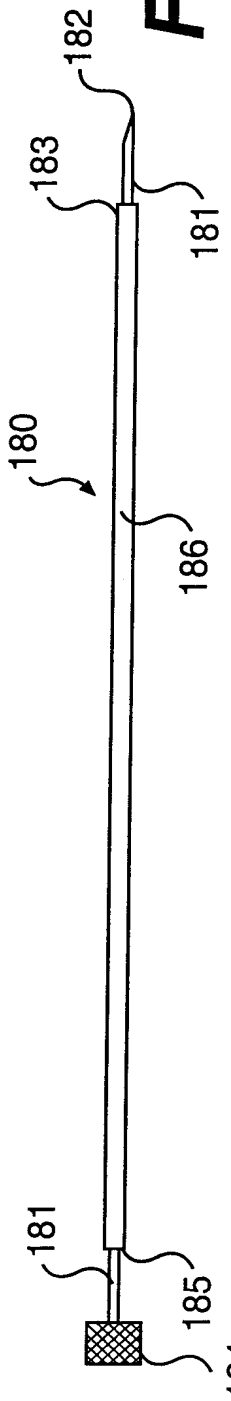


FIG 24

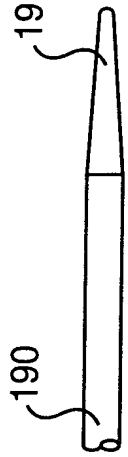


FIG 25

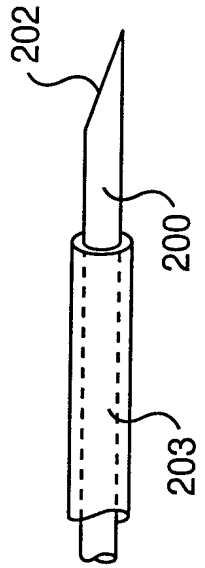
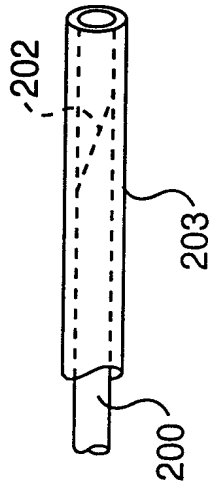


FIG 26



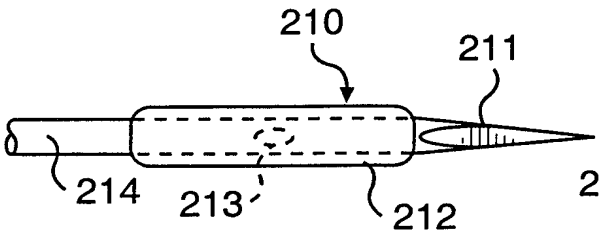


FIG. 27

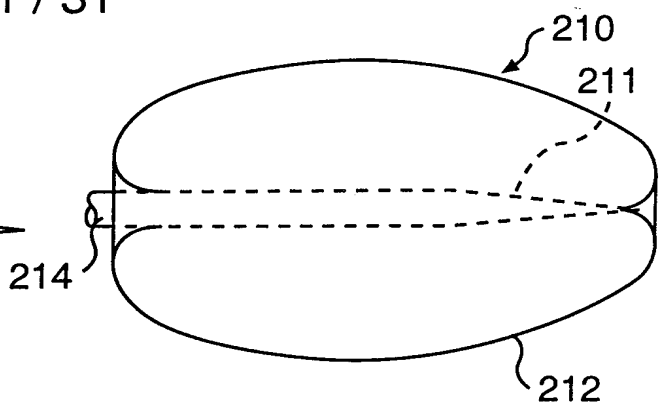


FIG. 28

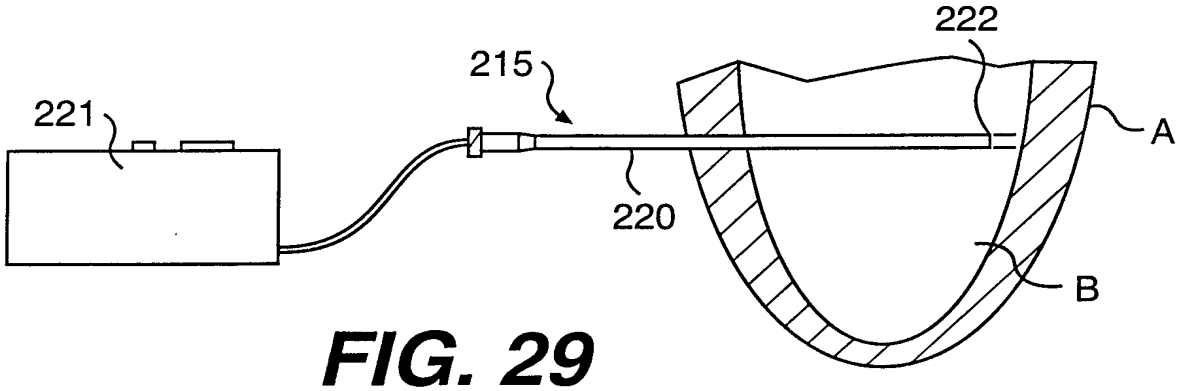


FIG. 29

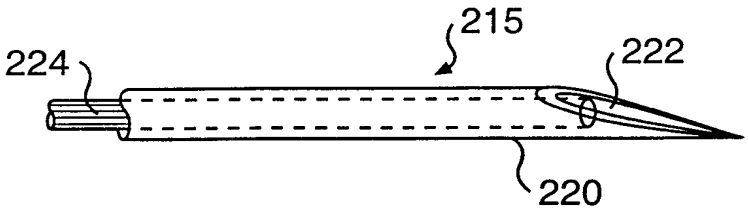


FIG. 30

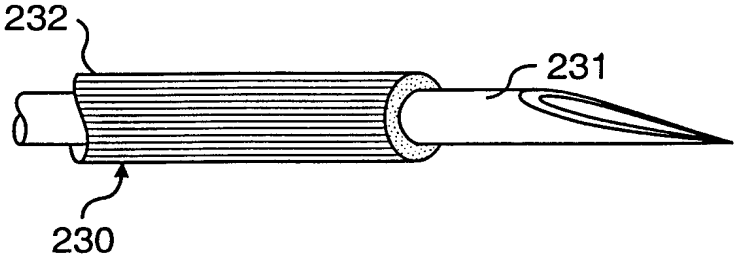


FIG. 31

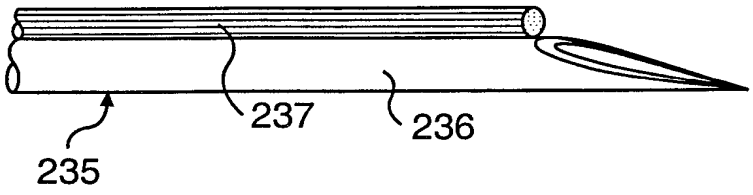


FIG. 32

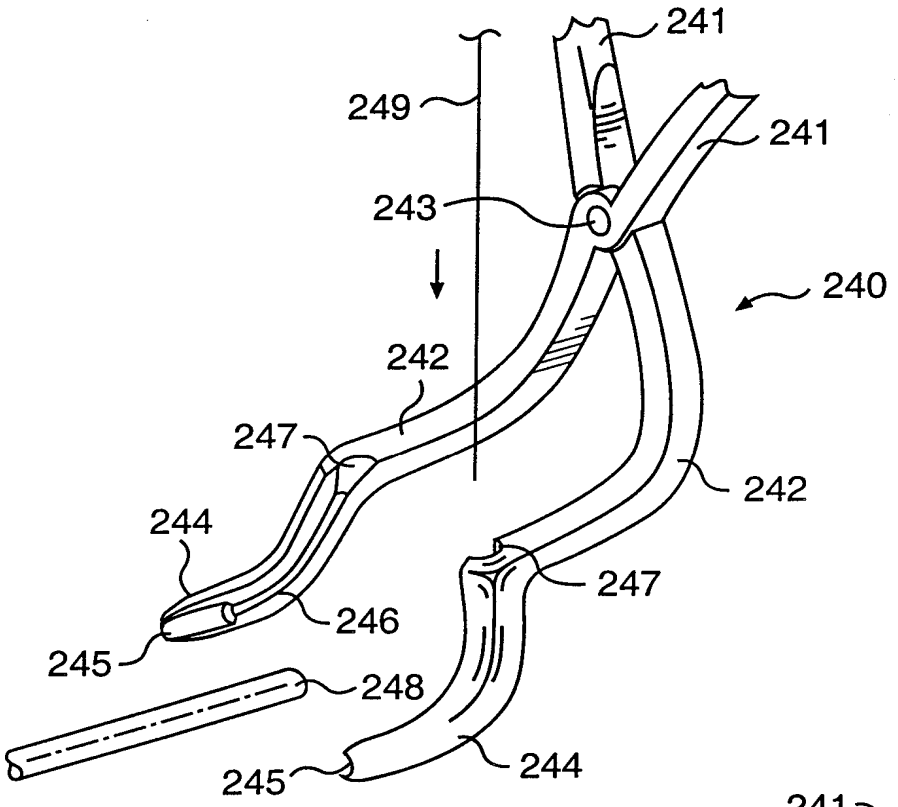


FIG. 33

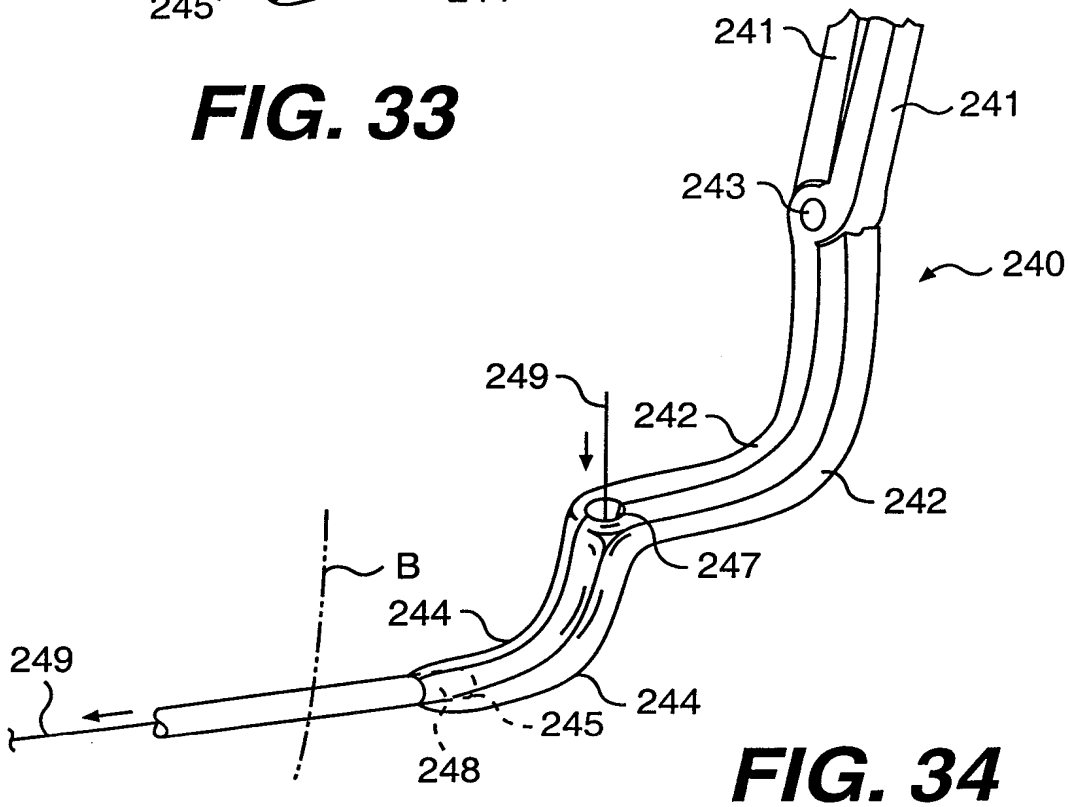


FIG. 34

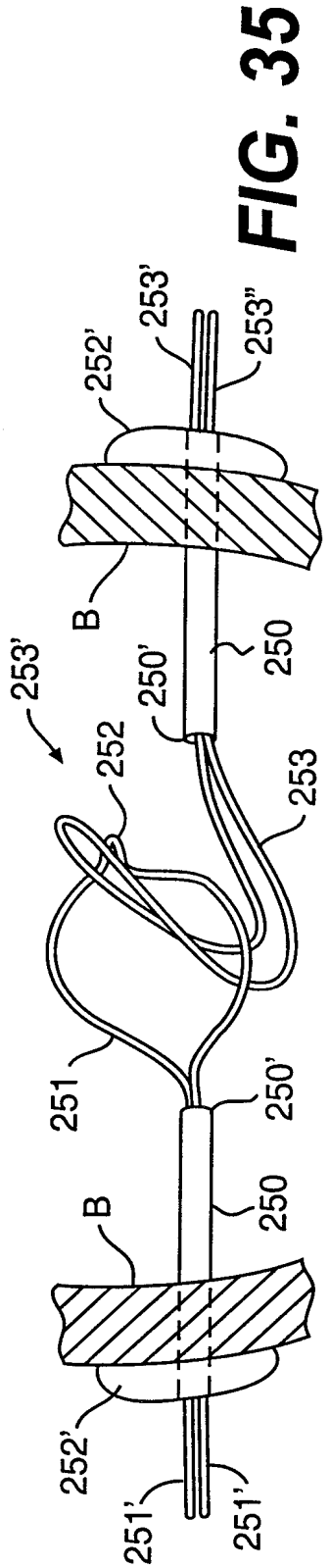


FIG. 35

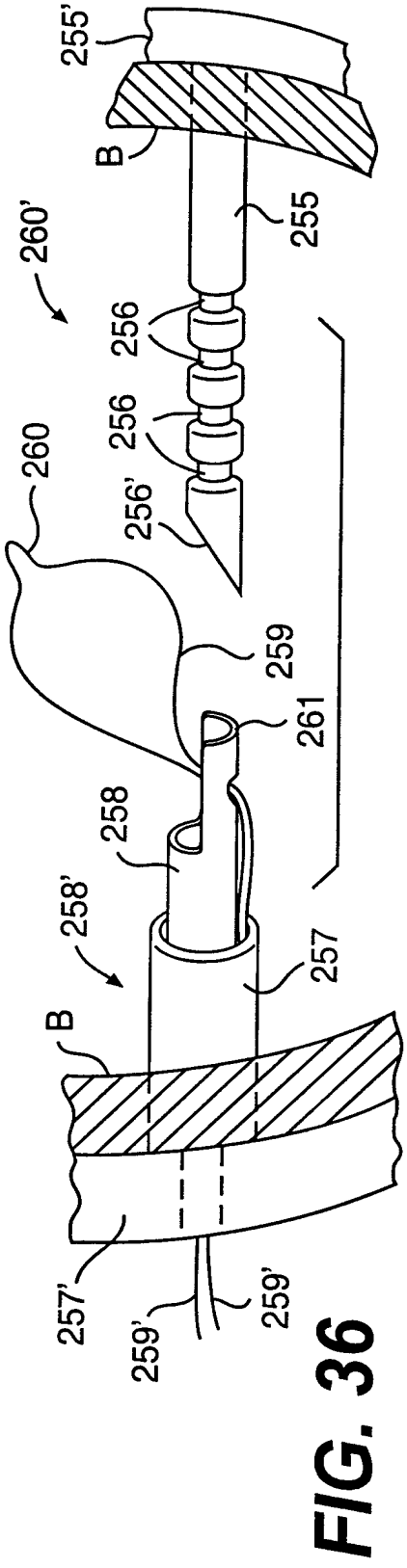


FIG. 36

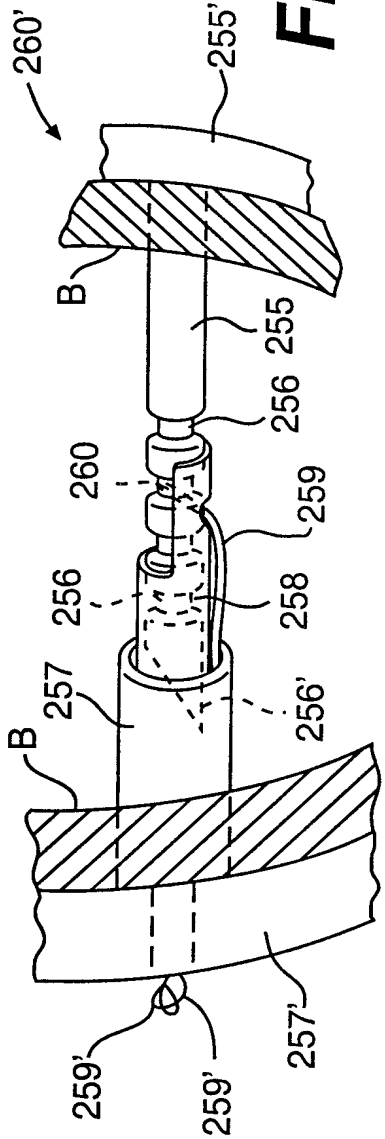


FIG. 37

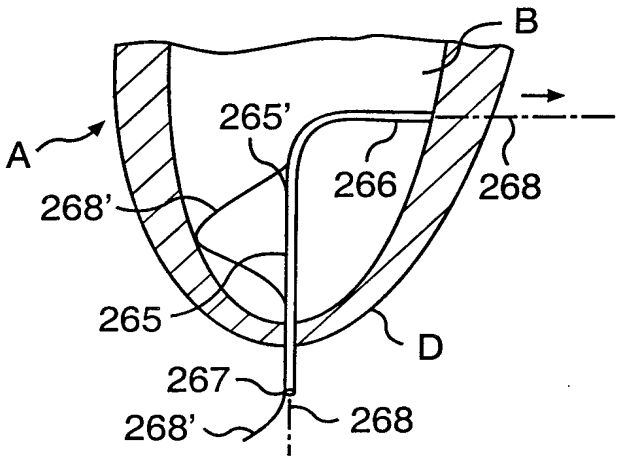


FIG. 38

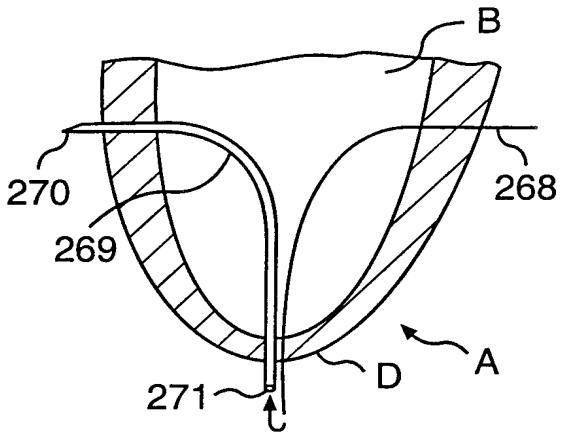


FIG. 39

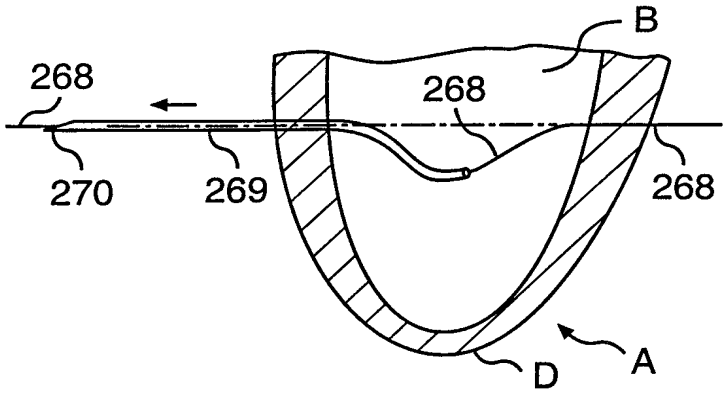


FIG. 40

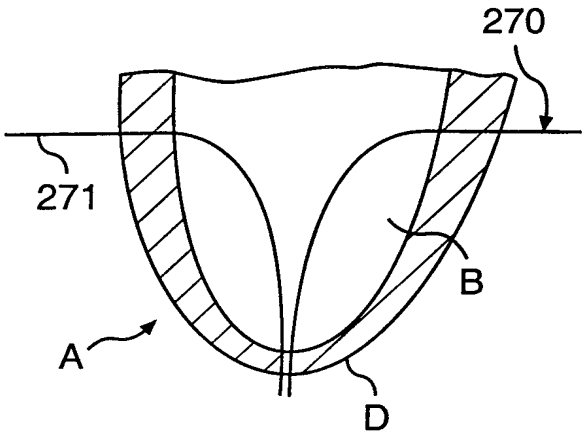


FIG. 41

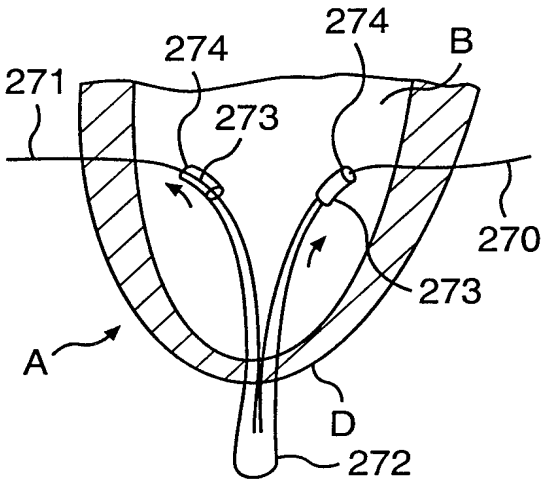


FIG. 42

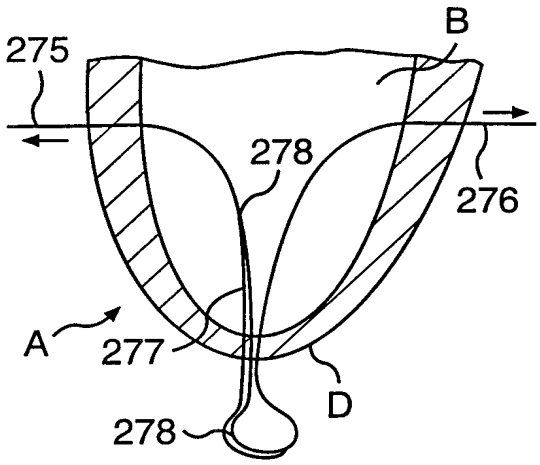


FIG. 43

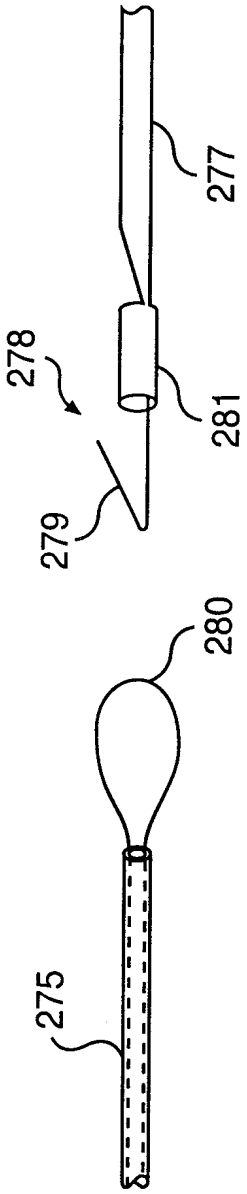


FIG 44

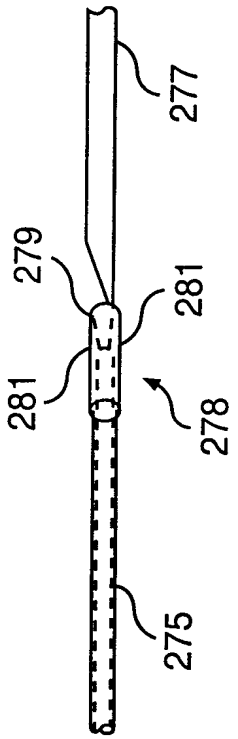


FIG 45

FIG 46

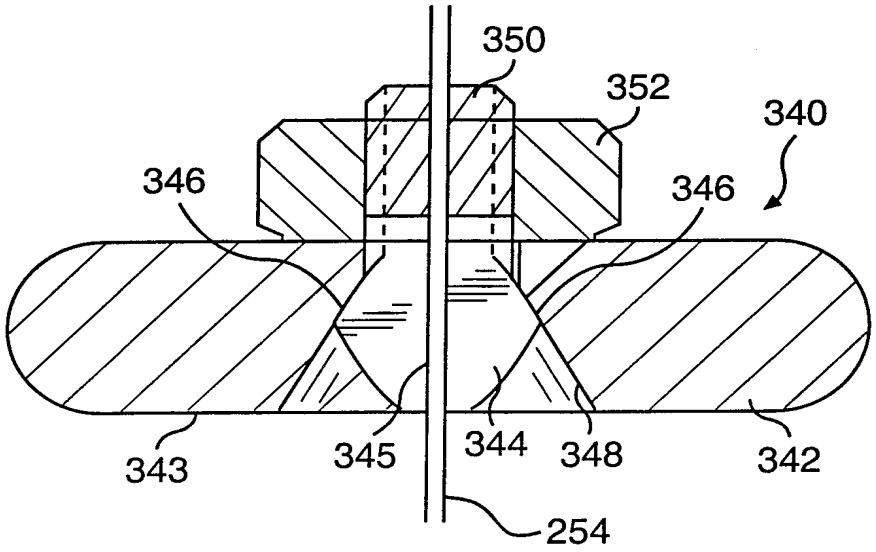


FIG. 47

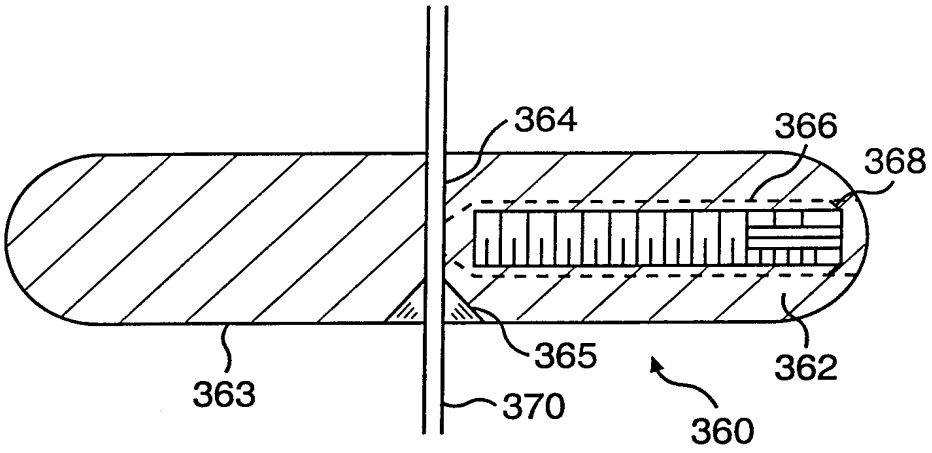


FIG. 48

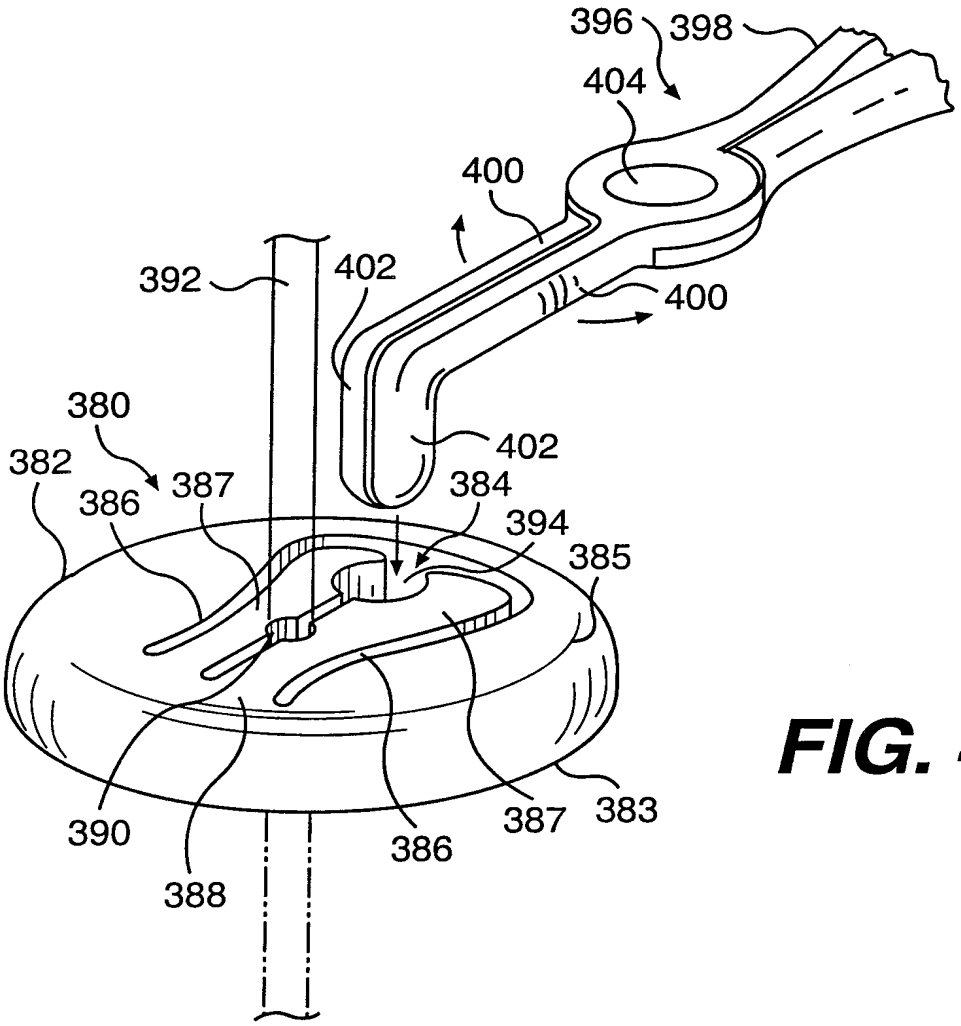


FIG. 49

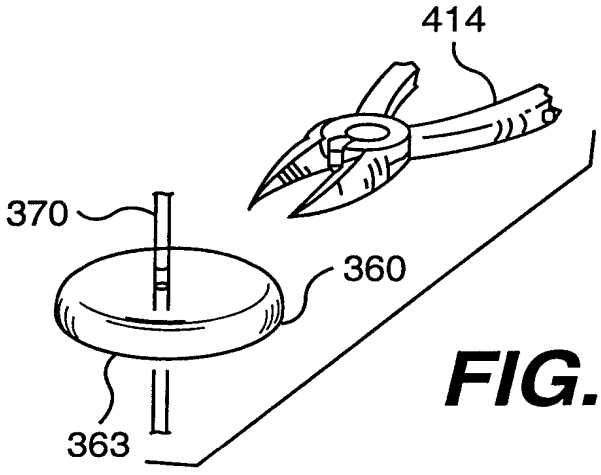
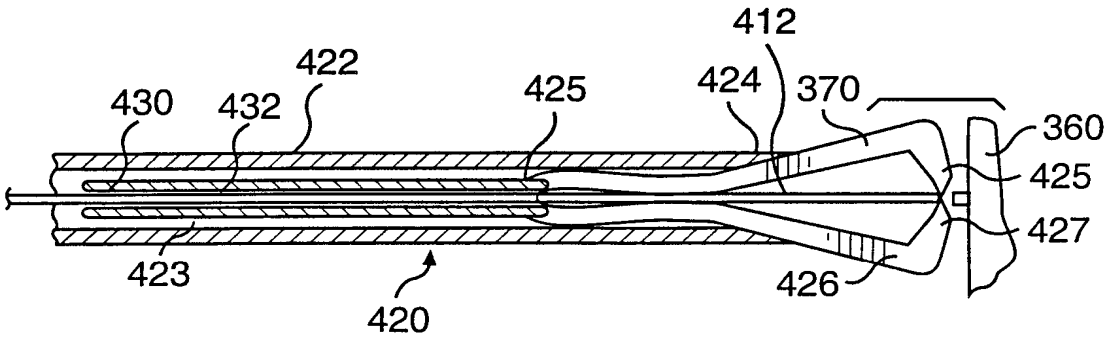


FIG. 50


412
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425
424
370
360
425
427
423
420
426

FIG. 51

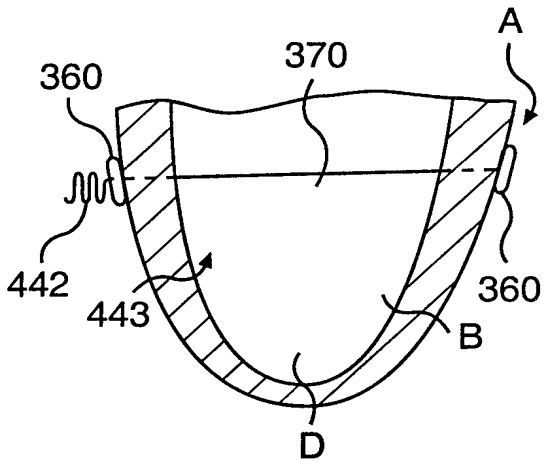

A
370
360
442
443
360
B
D

FIG. 52

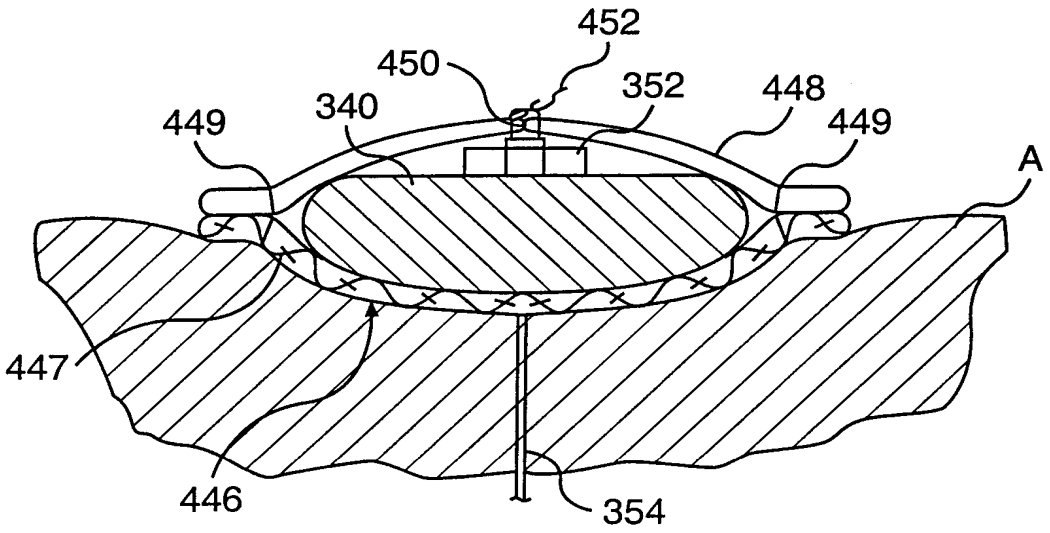


FIG. 53

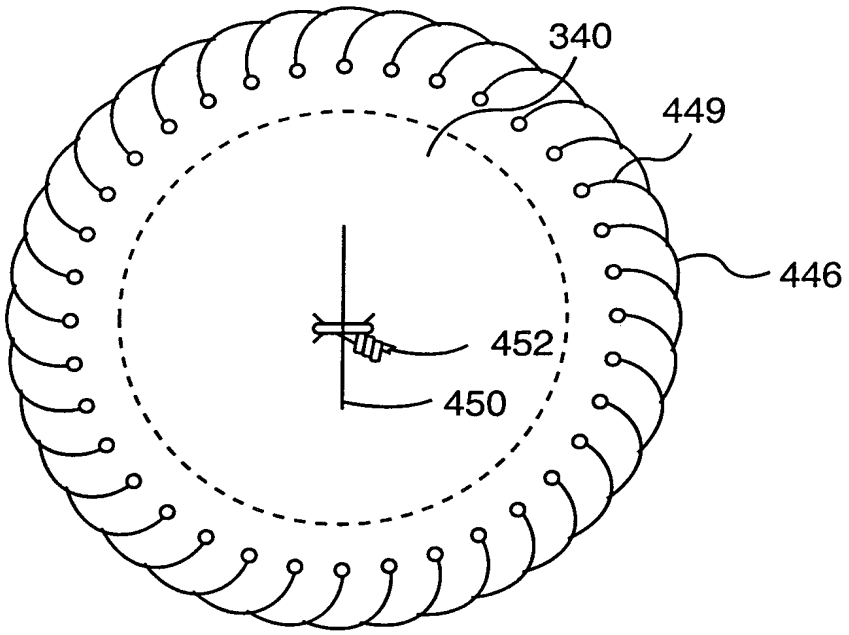


FIG. 54

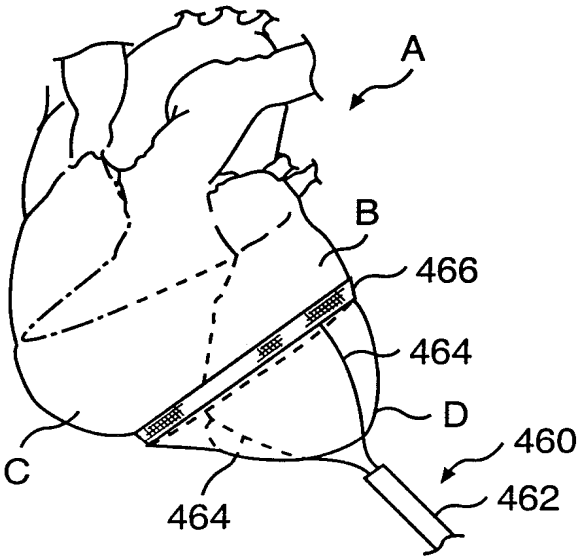


FIG. 55

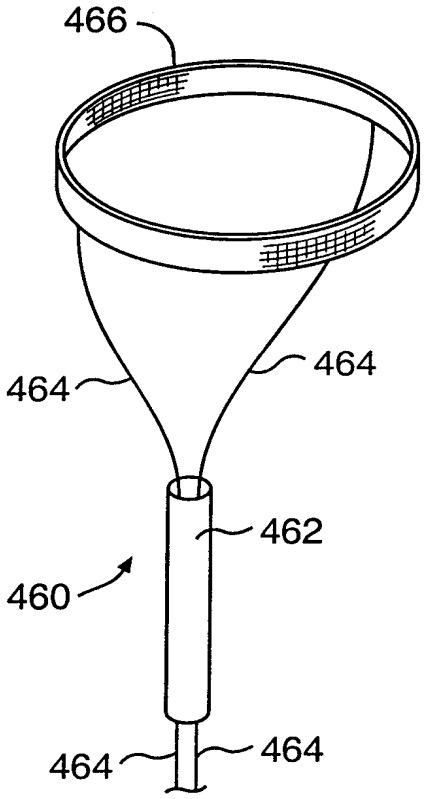


FIG. 56

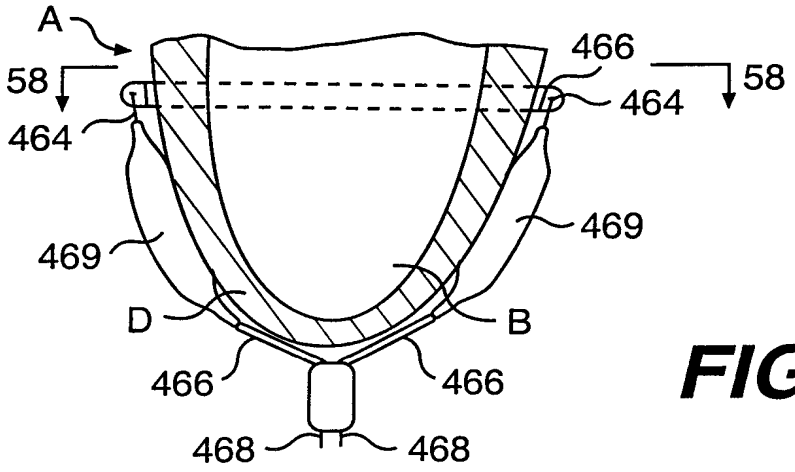
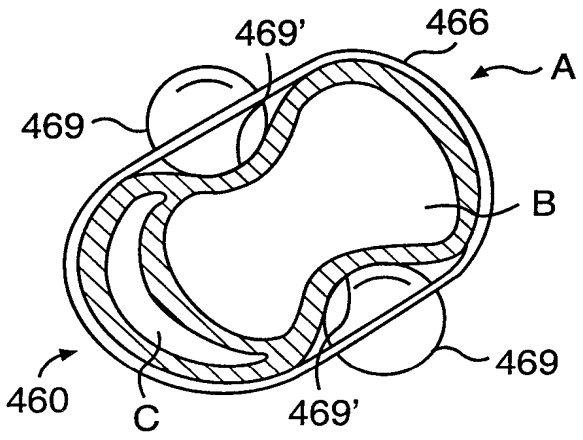


FIG. 57


469'
466
A
469
B
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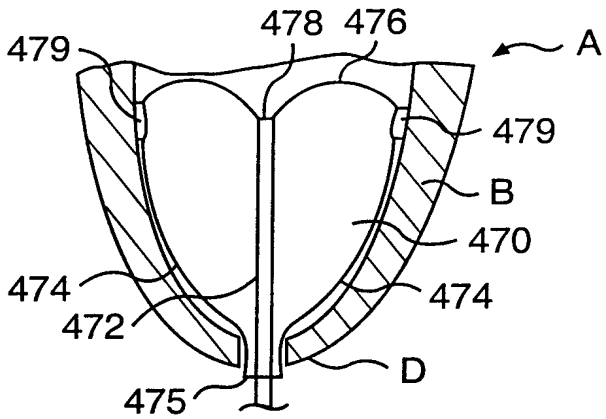
460
C
469'

FIG. 58


478
476
479
A
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B
470
474
474
472
D
475

FIG. 59

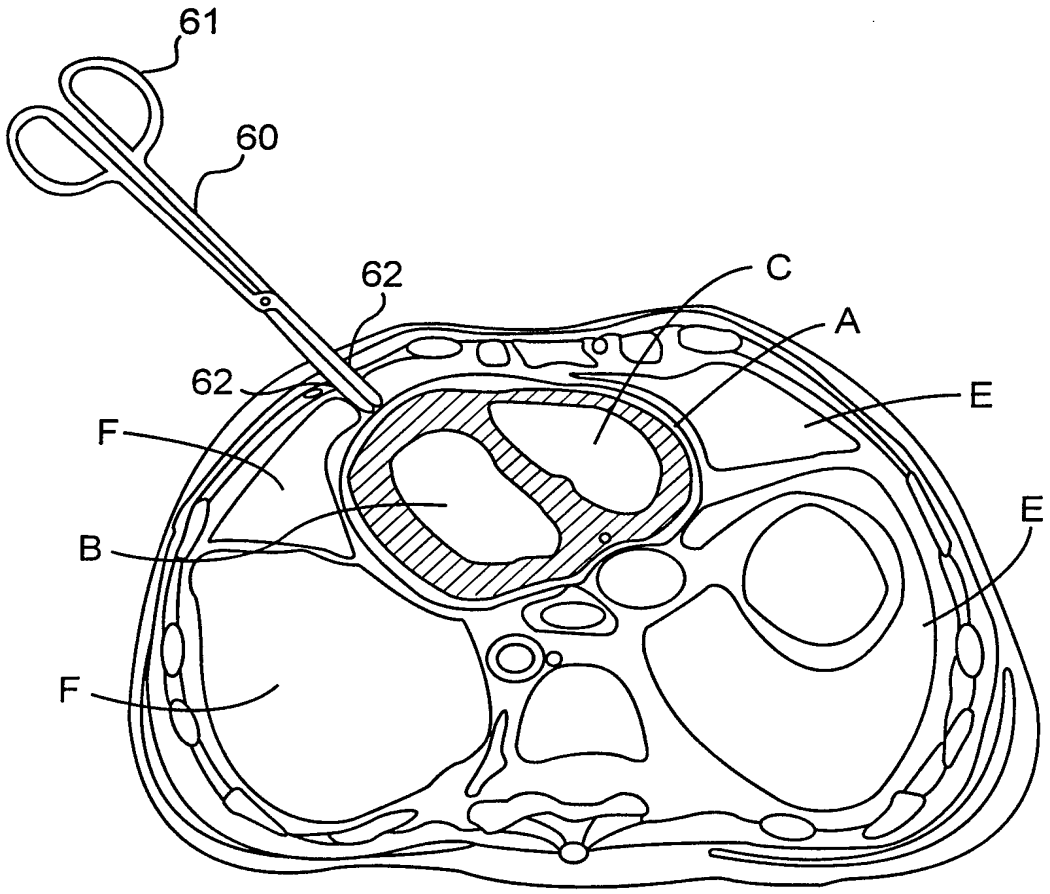


FIG. 60

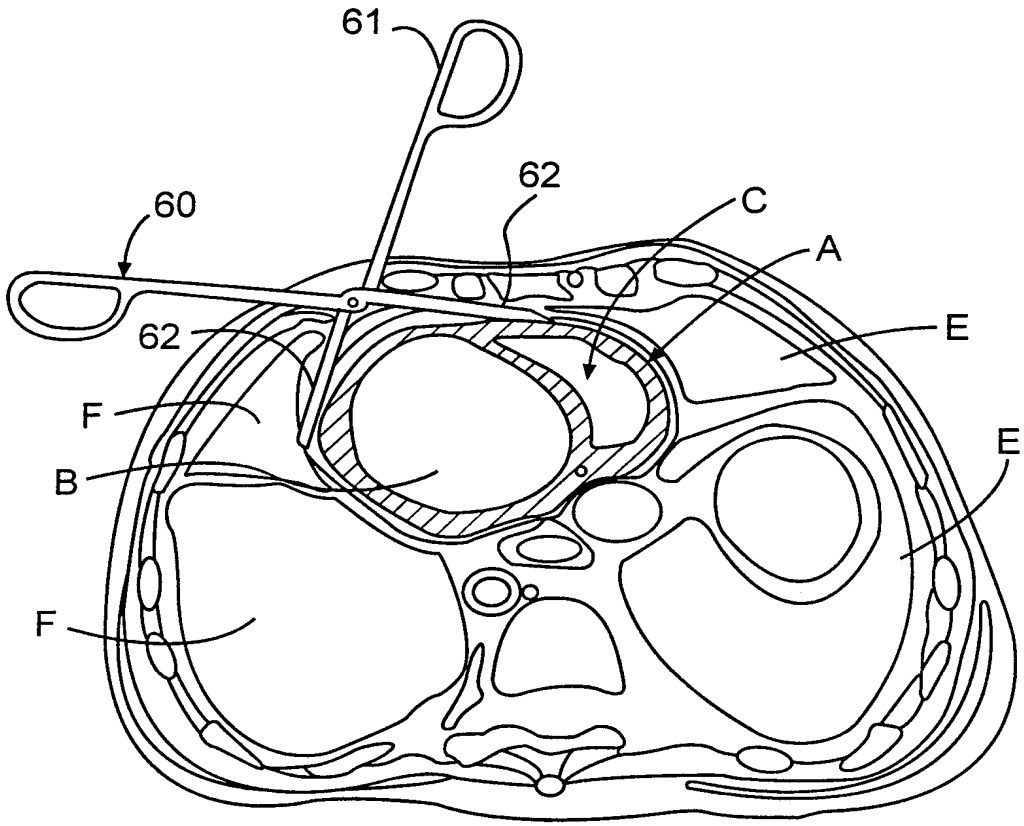


FIG. 61

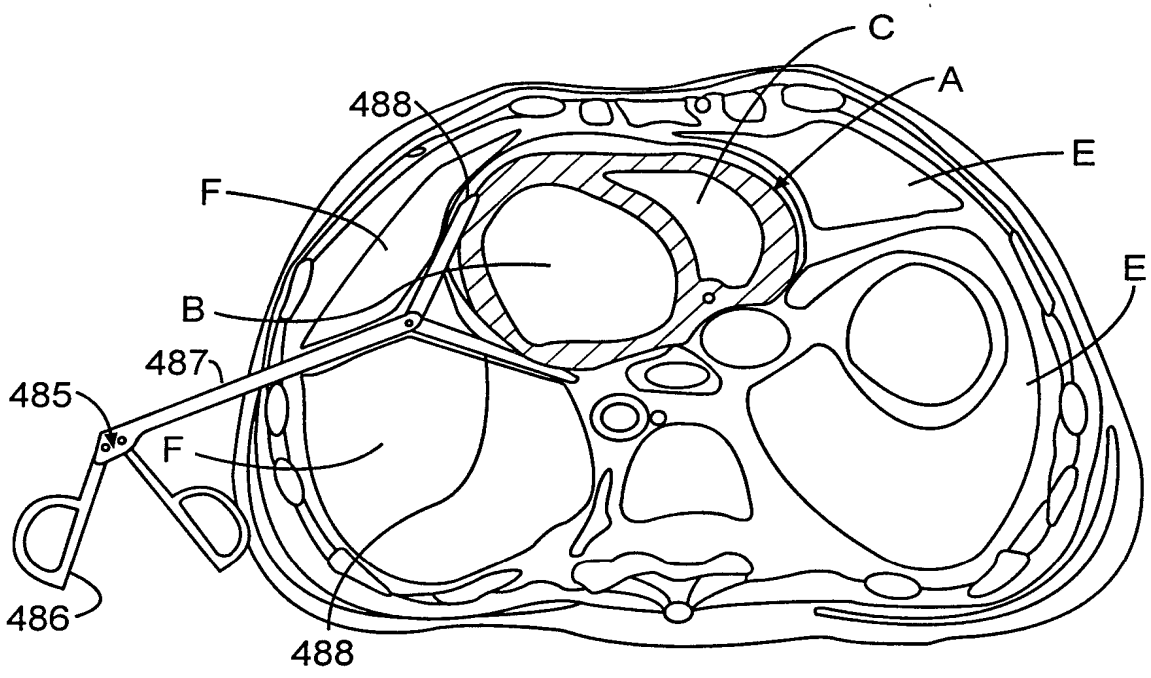


FIG. 62

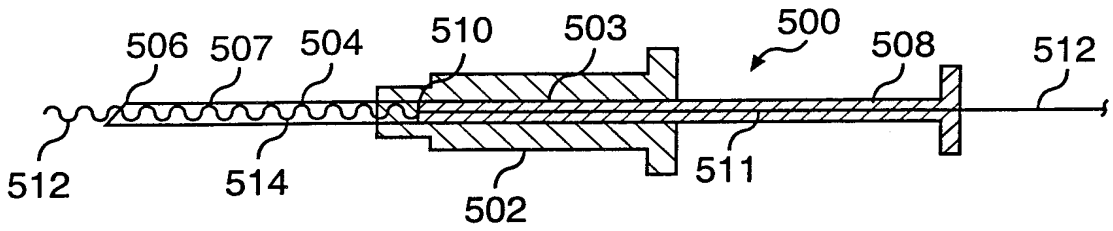


FIG. 63

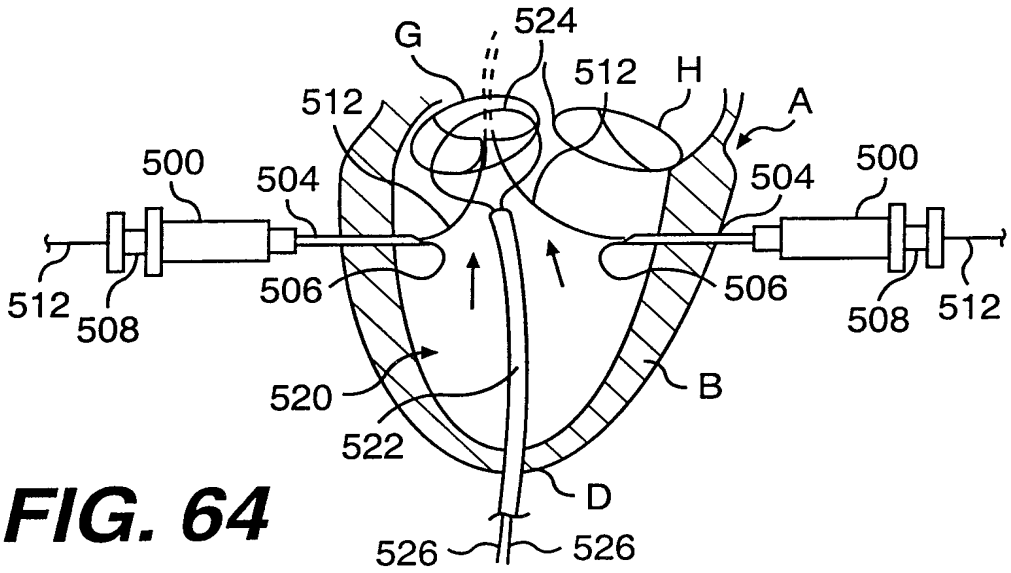


FIG. 64

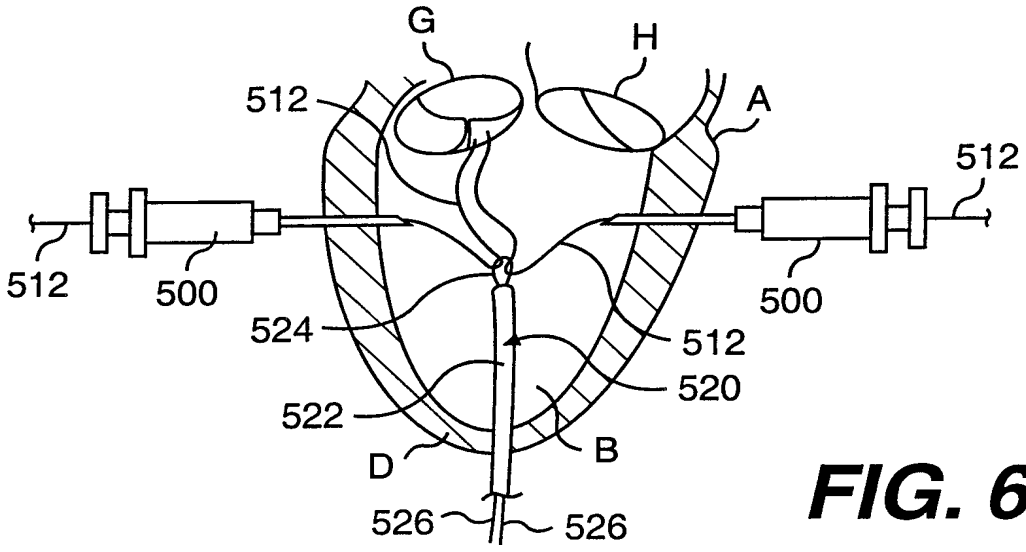
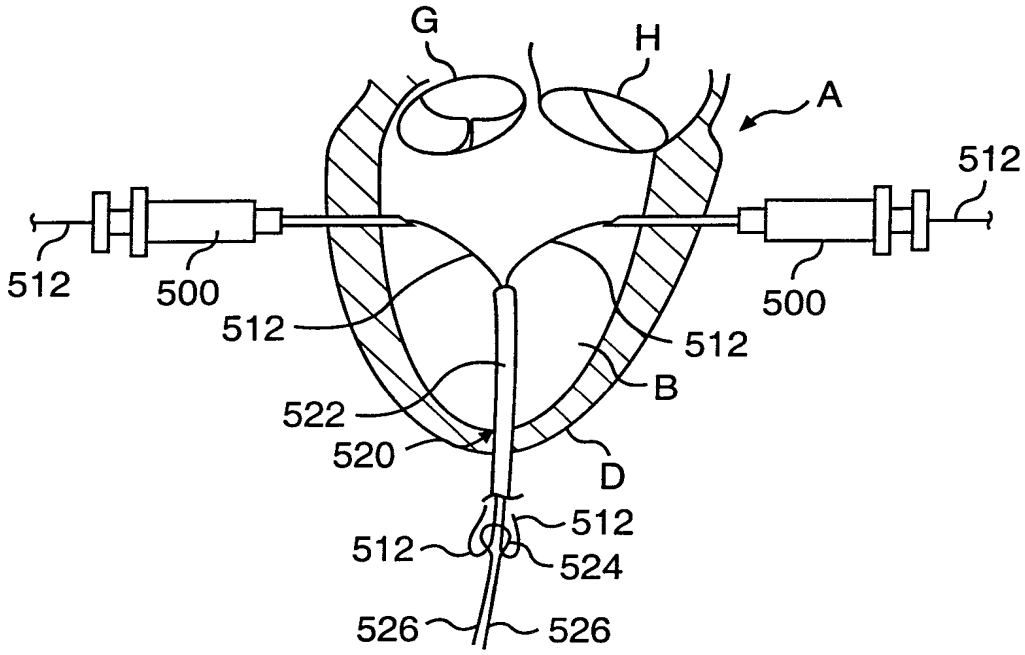


FIG. 65


G
H
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D
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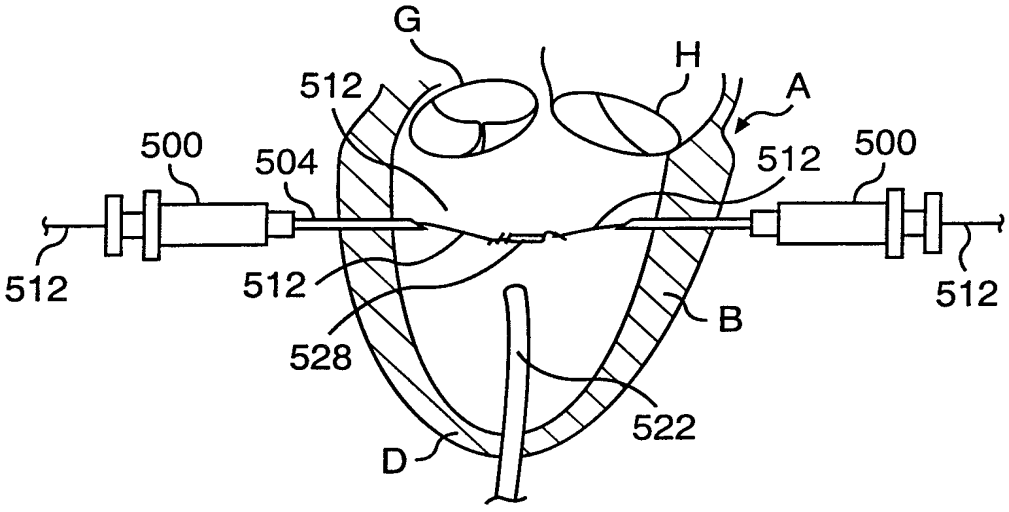
526
526

FIG. 66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512
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528
522
D

FIG. 67

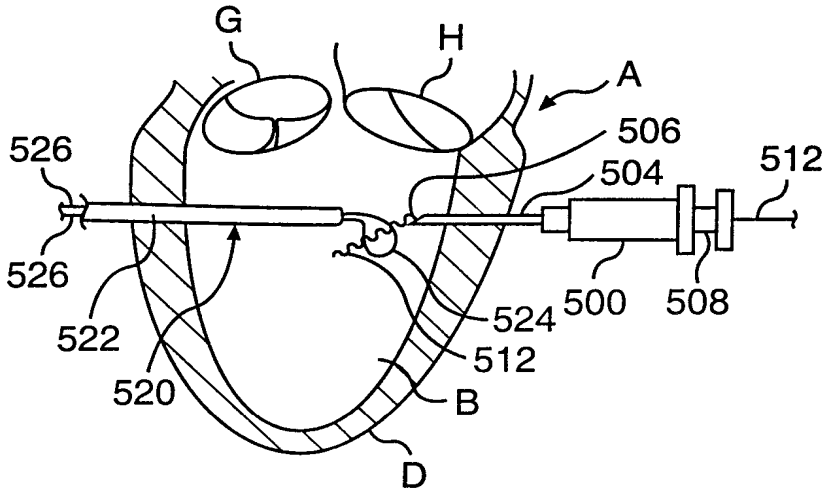

FIG. 68

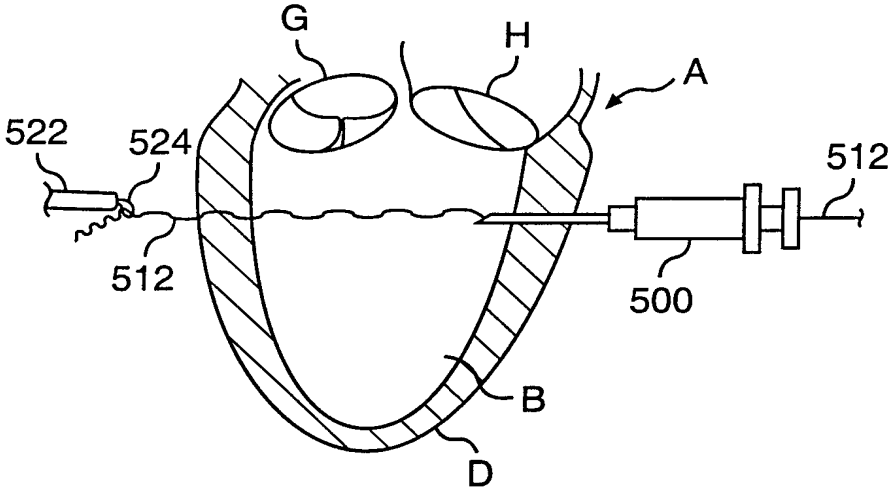

FIG. 69

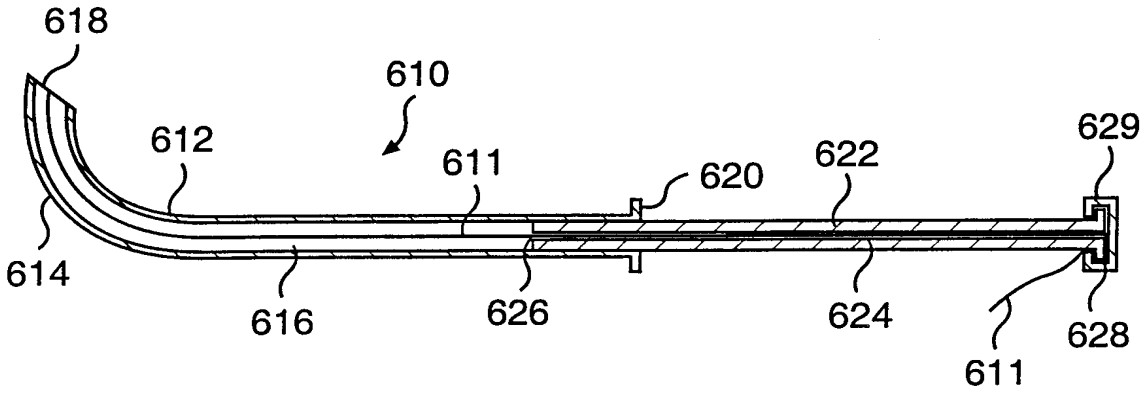

FIG. 70

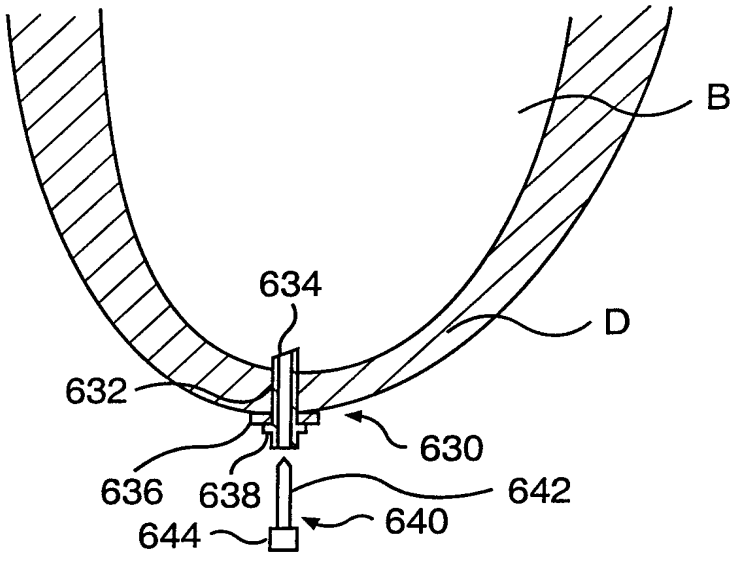

FIG. 71

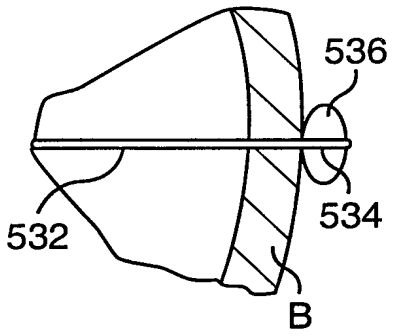

FIG. 72

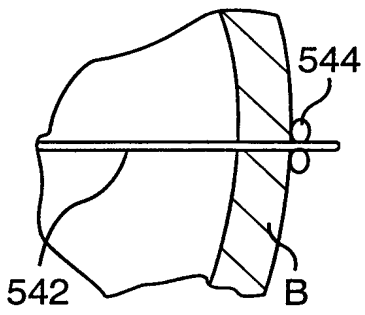

FIG. 73

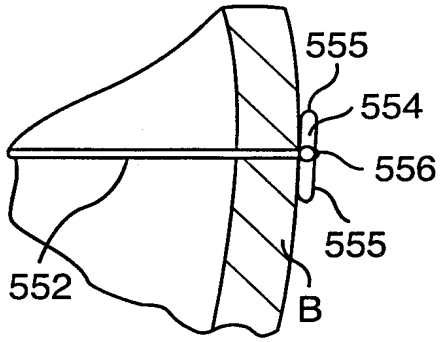

FIG. 74

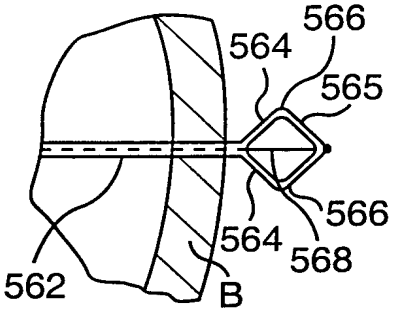

FIG. 75

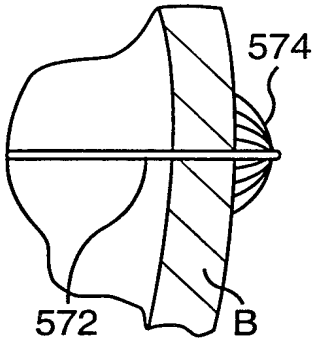

FIG. 76

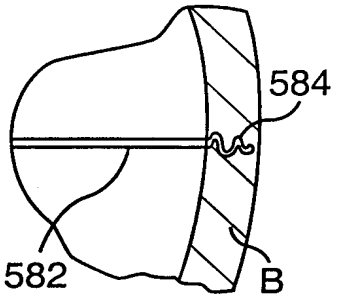

FIG. 77

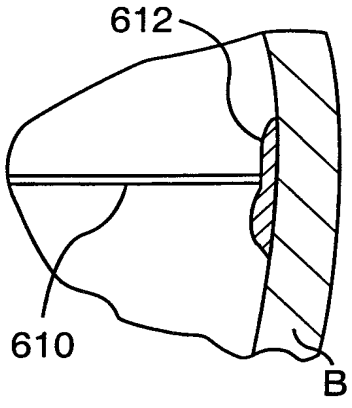

FIG. 78

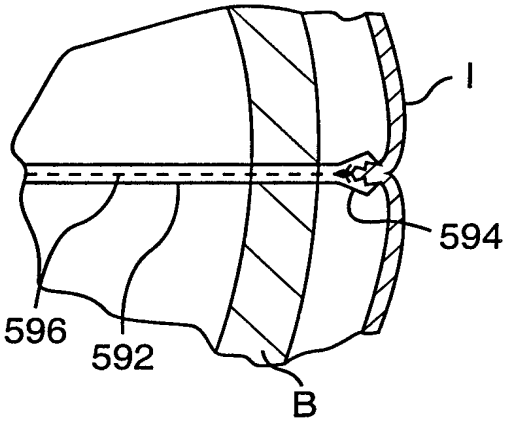

FIG. 79

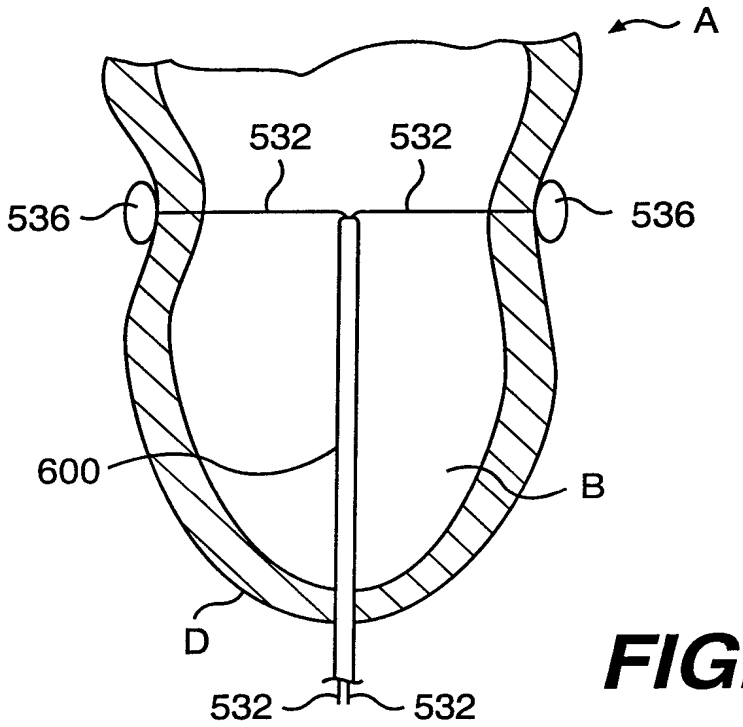

FIG. 80

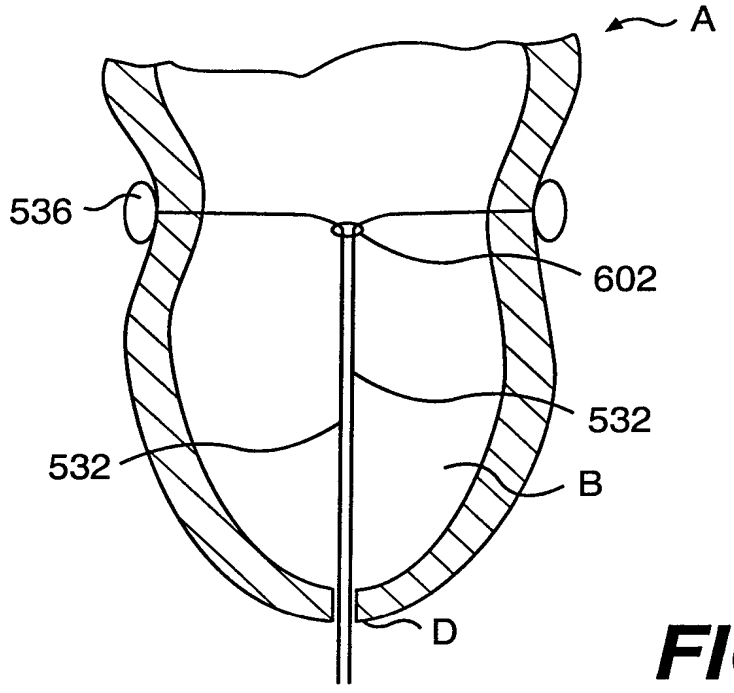

FIG. 81

INTERNATIONAL SEARCH REPORT

International Application No
PC./US 99/16876

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/00

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61F

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98 29041 A (MYOCOR, INC.) 9 July 1998 (1998-07-09) the whole document ---	
A	WO 96 40356 A (EP TECHNOLOGIES, INC.) 19 December 1996 (1996-12-19) the whole document ---	
A	WO 98 03213 A (HEARTPORT, INC.) 29 January 1998 (1998-01-29) page 17, line 7 -page 18, line 18 abstract; figures 6A-9B ---	
A	US 4 705 040 A (MUELLER ET AL.) 10 November 1987 (1987-11-10) abstract; figures --- -/--	

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

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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

"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
4 November 1999	12/11/1999

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	Giménez Burgos, R

2

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/16876

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A,P	FR 2 768 324 A (SEGUIN) 19 March 1999 (1999-03-19) abstract; figures	

INTERNATIONAL SEARCH REPORT

national application No.
PCT/US 99/16876

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

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

1. [X] Claims Nos.: 1-8
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 1-8 are directed to a method of treatment of the human body, Rule 39.1(iv) PCT. The search has been carried out and based on the tools and devices used for performing the claimed method of implanting a transventricular splint.

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

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

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

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

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/US 99/16876

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9829041 A	09-07-1998	US 5961440 A	05-10-1999
WO 9640356 A	19-12-1996	CA 2223152 A	19-12-1996
		EP 0836507 A	22-04-1998
		JP 11507262 T	29-06-1999
		US 5865791 A	02-02-1999
WO 9803213 A	29-01-1998	AU 3737397 A	10-02-1998
US 4705040 A	10-11-1987	US RE34021 E	04-08-1992
FR 2768324 A	19-03-1999	WO 9913777 A	25-03-1999

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
13 September 2001 (13.09.2001)

PCT

(10) International Publication Number
WO 01/66018 A1

(51) International Patent Classification[7]: A61B 17/00

(21) International Application Number: PCT/US01/06835

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(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/186,771	3 March 2000 (03.03.2000)	US
60/186,650	3 March 2000 (03.03.2000)	US
60/187,275	6 March 2000 (06.03.2000)	US

(71) Applicant *(for all designated States except US)*: **C. R. BARD, INC.** [US/US]; 730 Central Avenue, Murray Hill, NJ 07974 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **GAMBALE, Richard, A.** [US/US]; 382 Dunstable Road, Tyngsboro, MA 01879 (US). **WEISER, Michael, F.** [US/US]; 516 Martins Pond Road, Groton, MA 01450 (US). **PAGE, Edward, C.** [US/US]; 359 State Road, Baldwinville, MA 01436 (US). **LUKIN, Peter, J.** [US/US]; 28 Russell Lane, Lancaster, MA 01523 (US).

(74) Agent: **PERULLO, John, F.**; Kirkpatrick & Lockhart LLP, 75 State Street, Boston, MA 02109-1808 (US).

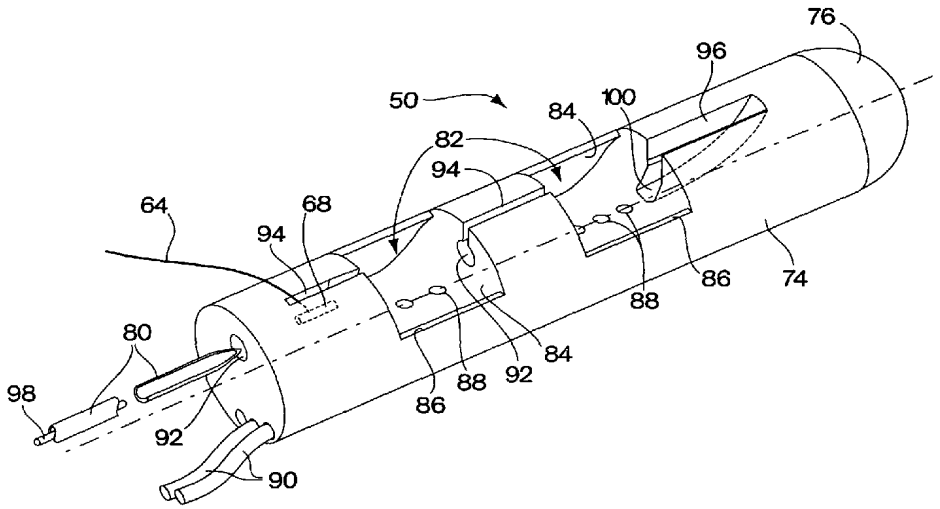
(81) Designated States *(national)*: JP, US.

(84) Designated States *(regional)*: European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).

Published:
— *with international search 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: ENDOSCOPIC TISSUE APPOSITION DEVICE WITH MULTIPLE SUCTION PORTS



(57) Abstract: An improved endoscopic tissue apposition device (50) having multiple suction ports (86) permits multiple folds of tissue to be captured in the suction ports (86) with a single positioning of the device (50) and attached together by a tissue securement mechanism such as a suture (14), staple or other form of tissue bonding. The improvement reduces the number of intubations required during an endoscopic procedure to suture tissue or join areas of tissue together. The suction ports (86) may be arranged in a variety of configurations on the apposition device (50) to best suit the desired resulting tissue orientation. The tissue apposition device (50) may also incorporate tissue abrasion means (852) to activate the healing process on surfaces of tissue areas that are to be joined by operation of the device to promote a more secure attachment by permanent tissue bonding.

WO 01/66018 A1

ENDOSCOPIC TISSUE APPOSITION DEVICE WITH MULTIPLE SUCTION PORTS

Field of the Invention

The present invention relates to improvements for endoscopic tissue apposition devices. Specifically, the invention provides an endoscopic apposition devices configured to collect a plurality of tissue portions with a single operation of the device so that the tissue can be joined together by a tissue securing means.

Background of the Invention

Endoscopic apposition devices are devices that can be used in the body of a patient without the need to make an external incision in the patient, the device being controlled externally of the patient by endoscopic means. Apposition devices may comprise a sewing or stapling device for use in flexible endoscopy, though it is also applicable to devices for use in rigid endoscopy.

Endoscopic tissue apposition devices are useful to help perform a gastroplasty procedure to correct gastro-esophageal reflux disease (GERD). This condition results from the inability of the valve at the junction between the stomach and the esophagus to function properly. Such malfunction enables reflux of stomach acid into the esophagus. The object of the gastroplasty procedure is to stitch together certain portions of stomach tissue in a manner that forms a valve-like structure adapted to prevent such reflux.

To perform the procedure, an apposition device, such as a sewing capsule is attached to the end of a viewing endoscope and is inserted through a patient's esophagus to form a plurality of stitches in stomach tissue slightly below the lower end of the esophagus. A first stitch is made through stomach tissue to one side of the esophagus, and a second stitch is made, with the same suture thread, in stomach tissue adjacent to the first stitch. The two stitches then are drawn together to pull together the diametrically opposed, stitched stomach portions. In a preferred procedure, a tubular configuration having a somewhat figure-eight cross-sectional

configuration is formed.

After the sutures are applied, the endoscope is removed from the patient and a knot is tied with the free ends of the suture thread that extend outside of the patient to maintain the figure-eight configuration. The knot is pushed down to the site of the sutures by the thread guide device that has been positioned at the distal end of the endoscope. To help navigate the knot to a location where it will effectively hold the tissue, it is helpful to view the knot through the viewing channel of the endoscope as it is guided to the stomach. To be visible through the endoscope, the knot must be maintained in front of the viewing channel port at the distal face of the endoscope, yet the structure of the thread guide device must not block the viewing channel.

The suturing and knotting procedure is repeated several times at longitudinally spaced intervals to create a plurality of figure-eight configurations extending longitudinally of the esophagus into the stomach. Suturing the stomach tissue in this manner essentially lengthens the esophageal passage and defines a structure having a valving action that is effective to prevent gastro-esophageal reflux. After a sufficient number of knots and sutures have been placed, a thread cutter, also operable through the endoscope, may be employed to cut the suture thread at points that are close to the tissue.

Endoscopic sewing devices are described in, for example, U.S. Pat. Nos. 5,080,663 and 5,792,153. Those patents disclose a sewing device for passing a thread through a tissue portion, which comprises a hollow needle movable between a first position in which it is out of the said tissue portion and a second position in which it passes through the said tissue portion, and a thread carrier adapted to be attached to the thread and being receivable within the hollow needle. The sewing device comprises a body, which defines a cavity within which the tissue portion can be held by means of suction, and the hollow needle is mounted for movement in the body between the first and second positions.

U.S. patent no. 5,792,153 discloses two suturing device embodiments: a single stitch sewing device and a multiple stitch sewing device. In the single stitch device, a thread carrier is transported by the needle through the tissue as the latter passes from its first position to its second position. When the needle returns to its

first position, the thread carrier is left behind in the distal end of the sewing capsule. In the multiple stitch device, the same procedure occurs, but it is followed by a further step in which the hollow needle travels from its first position to its second position, picks up the thread carrier, and returns it. A second stitch may be formed during the next step. The whole sequence of steps is repeated as many times as may be required to form the desired number of stitches.

Minimizing the number of intubations and reducing the procedure time during which the patient must be kept under conscious sedation are important considerations in any endoscopic procedure. The prior art suturing device must be withdrawn from the patient for each successive stitch made with the single-stitch embodiment and must otherwise be repositioned for each stitch made with the multi-stitch embodiment. The use of the devices is, thus, long and cumbersome. It would be desirable to provide an endoscopic tissue apposition device that minimizes procedure time and the number of intubations while still joining the same number of tissue plications together during the procedure. The present invention endeavors to provide such an improvement with a multiple suction port tissue apposition device.

A variable in the success of keeping tissue joined together with the above-described suturing procedure is the quality of the surgical knot tied to secure the tissue. Surgical knots are difficult to tie successfully, especially for non-surgical physicians that may be performing the endoscopic suturing procedure. It would be desirable to improve the reliability of the suture knot to increase the level of confidence in the procedures performed using the above-mentioned endoscopic devices. To improve the reliability of know methods of securing tissue together, the methods should be improved, or safeguarded with a secondary securement operation or eliminated entirely in favor of another procedure. The present invention is intended to provide an improved mechanism for joining internal tissue.

Summary of the Invention

The present invention pertains to improvements to an endoscopic apposition device. The improvements may be embodied in a tissue apposition device similar to those disclosed in U.S. patent nos. 5,792,153 or 5,080,663, or a stapling device such as is disclosed in U.S. patent no. 5,037,021. The disclosures of the above

listed patents are incorporated by reference herein, in their entirety. The prior art endoscopic tissue apposition devices provided a mechanism for capturing only a single fold, double thickness of tissue through which a needle and suture were passed. The present invention provides a multiple suction port tissue apposition device is capable of capturing two or more separate folds of tissue simultaneously so that a tissue securement device, such as a suture, permanent suture tag and or tag lock system, implant clip or staple, may be passed through the multiple folds with one endoscopic intubation.

The device is comprised of a capsule attachable to the distal end of an endoscope, preferably a flexible viewing endoscope. The capsule comprises a body having multiple suction ports into which can be captured multiple portions of tissue. Each suction port defines an opening to an independent vacuum chamber or a vacuum chamber shared commonly with another suction port. Independent vacuum chambers may be operated simultaneously, through one vacuum source line, or sequentially, with each chamber in communication with an independent vacuum source.

Alternatively, the capsule may be configured such that multiple suction ports are in communication with a single, common vacuum chamber. Because only one vacuum chamber is provided, tissue is sucked into all suction ports simultaneously, when vacuum is applied to the common chamber. However, although a common vacuum chamber is used, tissue is collected into distinct multiple portions drawn through the separately defined suction ports. The multiple portions of collected tissue may then be secured by a tissue securement device such as a suture, permanent tag, implant, clip, staple or other means.

The several suction ports maybe arranged in a variety of configurations on the capsule. Ideally, the ports are arranged to coincide with desired final arrangement of secured tissue portions. Therefore, with appreciation for how the capsule will approach the subject tissue area being navigated at the distal end of an endoscope, the capsule should be configured such that the suction ports are positioned in relation to each other where the captured tissue portions are desired to be secured in relation to each other. In addition to the desired arrangement of tissue portions, consideration must be given to how securement means will be applied to

the tissue portion given the arrangement of suction ports in relation to the working channel or channels of the endoscope.

In the example of a cylindrically shaped capsule, the ports are configured as arc shaped openings formed into the outside surface of the capsule. In one embodiment, the openings may be arranged in-line, parallel to the longitudinal axis of the capsule. Alternatively, the ports may be arranged to be side by side such that they are angularly displaced about the circumference of the capsule, but not displaced longitudinally along the length of the capsule. In one embodiment, four ports are arranged around the circumference of the capsule at equally spaced angular intervals. Ports can be arranged to be spaced apart at virtually any angular or longitudinal distance apart on the suturing capsule. For example ports arranged 90 degrees apart angularly and slightly apart longitudinally are positioned diagonally across the circumference of the capsule. The description of several various arrangements below is believed to be sufficient to enable one to extrapolate the requisite parameters to construct capsules having any desired arrangement of suction ports.

In the side-by-side tissue apposition embodiments, novel needle arrangements may be employed to penetrate tissue portions that are captured in the suction ports that are arranged away from the longitudinal axis of the capsule. A forked needle capable of simultaneously penetrating tissue portions held side-by-side is provided. For independent penetration of the tissue portions held captured in a side-by-side arrangement, a capsule design having a diverter in the needle track serves to guide independent needles to the selected suction port as they are advanced distally to penetrate tissue.

The multiple port apposition device of the present invention offers another advantage over previous designs in that the entire capsule body may be injection molded from a polymer material. A single piece injection molded unit is easier to produce than previous capsule designs, which were machined from metal and comprise several assembled components.

Another feature of the present invention is increased flexibility of the body. One or more points of longitudinal flexibility may be provided along the length of the capsule body by means of hinge. Due to the added length of the sewing capsule

required to house two or more suction ports, the capsule may be too long to pass comfortably through natural body passageways such as the esophagus during an endoscopic procedure. To address the issue of passing a long rigid instrument through a curved natural body lumen, the present invention incorporates one or more hinged points along the length of the sewing capsule. The hinged portion permits the sewing capsule body to bend longitudinally, in at least one direction, so that the capsule body can be passed around a curve in the body lumen. If the hinge operates in only one direction, the endoscope and, thus, the sewing capsule body can be rotated upon reaching a curved portion of the body lumen so that the direction of bending flexibility coincides with the direction of the curve. After being navigated to the intended treatment location, a reinforcing rod may be advanced distally through all segments of the tissue apposition capsule body, locking the hinged body in place so that no bending at the hinges occurs during the procedure.

In another aspect of the invention, the tissue apposition capsule body is modified to utilize special tissue securement mechanisms. One tissue securement mechanism embodiment comprises sutures having anchoring elements at one end that permit them to be passed through tissue and then become anchored behind the tissue layer to permit suturing and retention of the fold of tissue. The anchoring element of the special suture material, such as polypropylene, may comprise a T-structure. The anchoring element is arranged in a T-structure in that the anchoring element is perpendicular to the longitudinal axis of the main portion of the suture element. In this arrangement the T-portion may be easily deformed so that it lies parallel to the main portion of the suture so that it may be passed through tissue when carried by a hollow needle that is part of the sewing capsule. After passing through the tissue, the T-portion of the suture may be ejected from the needle and the needle withdrawn from the tissue so that the T-portion resiliently returns to an orientation that is perpendicular to the axis of the main body portion of the suture, thus becoming anchored on the through side of the tissue.

The sewing capsule body can be modified to facilitate the operation of such a T-style suture anchor by formation of a ramp positioned distal to the most distal vacuum chamber that guides the T-portion of a suture being ejected from an advanced needle upward and outward, away from the sewing capsule so that it

becomes oriented perpendicular to the longitudinal axis of the suture behind tissue through which the suture has been passed.

Another aspect of the invention provides for a multiple suture or staple magazine incorporated in the capsule body. The magazine helps to reduce a number of intubations required to place multiple tissue securement devices such as staples or sutures by holding several such devices and incorporating a mechanism to automatically and sequentially advance new securement devices into position for insertion into the tissue. Specifically, in the case of the suturing device having a reciprocating needle, multiple suture tags, or T's may be stored within the magazine during an endoscopic procedure. After the needle advances the first suture tag through tissue portions, the needle may be retracted to a proximal position whereby a spring loaded advancement mechanism may cue forward the next suture tag stored in the magazine into position to be carried by the needle through the next tissue location.

Another tissue securement device for use with the multiple suction port devices employs a suture tag lock system. The tag lock system uses a series of sutures and associated suture tags and tag lock blocks to hold the tissue portions in the desired plication orientation after the completing the procedure. The tag lock system hold sutures in a pre-arranged orientation on the suture capsule during navigation to the treatment site. Delivery of suture carrying tags through captured tissue by the needles serves to lock the tags into the lock blocks on the through side of the tissue, thereby completing the preconceived arrangement of sutures necessary to accomplish the plication form desired. A tag lock band may alternatively be employed to capture the suture tags on the through side of the tissue in place of the lock blocks.

Another tissue securement device for the multiple suction port embodiments comprises a helical coil implant that is threaded into the captured portions of tissue to hold them together. The coil implant embodiment may be used in a variety of procedure where endoscopic delivery of a tissue implant may be desirable. An example of other uses for the tissue implant may be to achieve tissue bulking in a region of gastro-intestinal tissue to treat GERD. The implant may also facilitate the

delivery of bulking agents to a treatment site if the implant is configured to carry the agent by such means as coating.

In another aspect of the invention, tissue abrasion means are provided with the capsule to improve the adherence of tissue surfaces that are joined together. The abrasion means serves to create a slight injury to the tissue surfaces that will be joined by the apposition capsule. The injury initiates a healing process on those tissue surfaces that will lead to common tissue ingrowth between the surfaces over time to permanently join the tissues. The improved tissue apposition device and methods provided by the present invention can be used to join internal tissues via an endoscope for a wide variety of purposes such as: attaching a feeding tube to the small intestine; enclosing intestinal openings in the case of the fistula, repairing esophageal tears and suturing tissue sites of localized bleeding. However, the present invention is believed to be especially useful in endoscopic treatment of gastroesophageal reflux disease (GERD).

The abrasion means provided by the present invention may operate by a variety of mechanisms. Mechanical abrasion means may be provided by providing a roughened surface area to frictionally engage and abrade the tissue near the suction ports of the device. Alternatively, mechanical abrasion means may be employed by ejecting from the device an abrasive substance such as salt or sugar crystals. Chemical abrasion may be provided by releasing a chemically abrasive substance such as a suitably high concentration of hydrochloric acid. Electrical abrasion may be actuated by providing electrical elements near the suction port through which electrical current is passed to heat and abrade areas of tissue. Laser energy may also be applied to tissue to abrade and initiate the healing process. Alternatively, ultrasonic energy may be applied near the suction port opening. However, a preferred method of abrading a tissue is through the use of radio frequency (RF) energy adjacent the opening of the suction port.

The abrasion means may be incorporated in devices having a single suction port as those disclosed in the patents referenced above, but preferably the abrasion means is incorporated in an apposition device having multiple suction ports such as described herein. The arrangement and operation of the suction ports facilitates use of the abrasion means in that tissue can be held in place, in contact with the

abrasion means, by applying light vacuum pressure through the vacuum chambers to collect tissue into the suction ports. By positioning the abrasion means adjacent the suction ports, tissue is reliably brought into contact with the abrasion means. Also facilitated is the correct positioning of the abrasion in the tissue area that will be brought into contact during the apposition procedure.

It is believed that joining area of tissue that have been injured slightly or abraded will undergo a healing process that promotes tissue ingrowth between the joined tissue surfaces resulting in a new, unified tissue mass rather than two separate tissues attached together by a tissue securement mechanism that could be subject to failure over time. Another advantage of the tissue ingrowth process is that biodegradable tissue securement means can be used which will degrade over time. In this situation, the tissue securement need only hold the tissues together temporarily, for sufficient time for the healing tissues to join together to form a unified tissue segment. In abrading the tissue to a sufficient degree to initiate the healing process, it is believed that only slight abrasion affecting the mucosal layer of the tissue is required. Accordingly, the tissue abrasion means discussed herein are intended to inflict only a slight amount of abrasion.

It is an object of the invention to provide an endoscopic tissue apposition device that reduces the number of intubations required to attach or repair internal tissue by a tissue securement mechanism comprising suture or staples.

It is another object of the invention to provide an endoscopic apposition device that is simple and economical to fabricate by injection molding techniques.

It is another object of the invention to provide a tissue apposition device having longitudinal flexibility to be easily navigable through a natural body lumen while mounted at the distal end of an endoscope.

It is another object of the invention to provide a tissue apposition device having multiple suction ports into which subject tissue may be collected and joined by a tissue securement device.

It is another object of the invention to provide a simplified tissue suture means having an anchor at one end which can remain on the through side of tissue during the process of tissue securement.

It is another object of the invention to provide an endoscopic tissue apposition device having a multiple suction ports in communication with a common vacuum chamber that operates to collect tissue into the multiple ports by applying vacuum to the common vacuum chamber.

It is another object of the invention to provide an endoscopic tissue apposition device having multiple suction ports in communication with multiple vacuum chambers that are independently operable to collect tissue sequentially into the multiple ports.

It is still another object of the invention to provide a tissue apposition device having a tissue securing device magazine configured to automatically and sequentially advance tissue securement devices into position for advancement through the tissue.

It is another object of the invention to provide a tissue apposition device with improved tissue suction capability.

Another object of the invention is to provide a method of joining internal tissue that comprises capturing at least two areas of tissue simultaneously to delivery tissue securement device through the areas of tissue to join them together.

It is an object of the present invention to provide an improvement to endoscopic tissue apposition devices that will provide a more reliable securement of internal tissues by promoting common ingrowth between those tissues in addition to attachment of tissue securement means.

It is another object of the invention to provide an endoscopic tissue apposition device that incorporates an abrasion means that utilizes a mechanical, electrical, chemical, laser, ultrasonic or radio frequency energy to abrade the subject tissue.

It is another object of the invention to provide an endoscopic tissue apposition device that safely abrades tissue sufficiently to initiate an injury response in that tissue without adversely and permanently damaging the tissue.

It is another object of the invention to provide an abrasion means that may be employed with an endoscopic tissue apposition device having a single or multiple suction ports.

It is another object of the invention to provide a tissue abrasion means that is equally applicable to tissue apposition devices utilizing a staple, suture, or suture tag securement means.

It is another object of the invention to provide a method for joining internal tissues of the human body comprising the abrading an area of tissue and joining multiple tissue portions such that the abraded area of tissue is brought into contact with itself or other tissue and undergoes a healing process that unites results in the bonding of the multiple tissue portions.

Brief Description of the Drawings

The foregoing and other objects and advantages of the invention will be appreciated more fully from the following further description thereof, with reference to the accompanying diagrammatic drawings wherein:

FIGS. 1-3 show successive steps in the operation of a prior art single stitch sewing device;

FIG. 4 is a diagrammatic side view of a tissue apposition device mounted to an endoscope;

FIG. 5 is a diagrammatic side view of a tissue apposition device mounted to an endoscope;

FIGS. 6-8 are isometric views of a multiple suction port apposition device in various stages of operation;

FIG. 9 is an isometric and partial cutaway view of a multiple suction port apposition device with a suture magazine;

FIG. 10 is an isometric view of a modified multiple suction port apposition device;

FIGS. 11A-11D are various cross-sectional views taken along the representative line 11A-11D – 11A-11D of FIG. 10;

FIGS. 12A –12B are isometric view of a hinged multiple suction port apposition device;

FIG. 13 is an isometric view of a multiple suction port, single chamber tissue apposition device;

FIG. 14 is an isometric view of a multiple suction port, single vacuum chamber tissue apposition device;

FIG. 15 is an isometric view of a side-by-side multiple suction port device having a forked needle;

FIG. 16 is an isometric view of a side-by-side multiple suction port device having a forked needle attached to the distal end of an endoscope shown in phantom;

FIG. 17 is a sectional isometric view of a side-by-side multiple suction port device having a forked needle;

FIG. 18 is a sectional isometric view of a side-by-side multiple suction port device having a forked needle;

FIG. 19 is a top view of a side-by-side multiple suction port device having independently controlled needles;

FIG. 20 is a sectional view of a side-by-side multiple suction port device having independently controlled needles;

FIG. 21 is a top view of a side-by-side multiple suction port device having independently controlled needles;

FIG. 22 is an isometric view of a tissue apposition device having multiple suction ports that are angularly and longitudinally offset;

FIG. 23 is a sectional view of a tissue apposition device having multiple suction ports that are angularly and longitudinally offset;

FIG. 24 is an isometric view of a tissue apposition device having four suction ports;

FIG. 25 is an isometric view of a tissue apposition device having four suction ports;

FIG. 26 is a sectional view of the tissue apposition device of FIG. 25 taken along the line A-A;

FIG. 27 is a sectional view of the tissue apposition device of FIG. 25 taken along the line B-B;

FIG. 28 is an isometric view of a multiple suction port tissue apposition device employing a suture tag lock system;

FIG. 29A is a bottom isometric view of a suture tag lock;

FIG. 29B is a top isometric view of a suture tag lock;

FIG. 30 is an isometric view of a multiple suction port tissue apposition device employing a suture tag lock system;

FIG. 30A is a highly diagrammatic illustration of the tissue orientation after application of the suture tag lock system and depicted in FIG. 30;

FIG. 31 is an isometric view of a multiple suction port tissue apposition device employing a suture tag lock system having a sliding suture passage;

FIG. 31A is a highly diagrammatic illustration of the tissue orientation after application of the suture tag lock system and depicted in FIG. 31;

FIG. 32 is an isometric view of a multiple suction port tissue apposition device employing a suture tag lock system using three suture leads;

FIG. 32A is a highly diagrammatic illustration of the tissue orientation after application of the suture tag lock system and depicted in FIG. 32;

FIG. 33 is an isometric view of a multiple suction port tissue apposition device employing a suture tag lock system using three suture leads;

FIG. 33A is a highly diagrammatic illustration of the tissue orientation after application of the suture tag lock system and depicted in FIG. 33;

FIG. 34 is an isometric view of a multiple suction port tissue apposition device employing a suture tag lock system using a single suture lead;

FIG. 34A is a highly diagrammatic illustration of the tissue orientation after application of the suture tag lock system and depicted in FIG. 34;

FIG. 35 is an isometric view of a multiple port tissue apposition device employing a tag lock band;

FIG. 35A is a detailed illustration of a tag lock band;

FIG. 36 is a multiple suction port tissue apposition device employing a helical wire tissue securement mechanism;

FIG. 37 is a multiple suction port tissue apposition device employing a helical wire tissue securement means;

FIG. 38 is an isometric view of a single suction port tissue apposition device having mechanical abrasion means;

FIG. 39 is an isometric view of a single suction port tissue apposition device having radio frequency abrasion means;

Fig. 40 is an isometric view of a dual suction port tissue apposition device without tissue abrasion means.

FIG. 41 is an isometric view of a dual suction port tissue apposition device having mechanical abrasion means;

FIG. 42 is an isometric view of a dual suction port tissue apposition device having electrical and radio frequency abrasion means;

FIG. 43 is an isometric view of a side-by-side multiple suction port tissue apposition device having tissue abrasion means; and

FIG. 44 is an isometric view of a tissue apposition device having multiple suction ports that are angularly and longitudinally offset and having tissue abrasion means.

Description of the Illustrative Embodiments

A description of the embodiments of the present invention is best presented in conjunction with an explanation of the operation of a prior art tissue apposition device, which this invention serves to improve. FIGS. 1-3 depict a prior art endoscopic suturing device disclosed in U.S. patent no. 5,792,153. FIG. 1 shows the distal end of a flexible endoscope 1, on which a sewing device 2 is attached. The endoscope is provided with a viewing channel, which is not shown, but which terminates at a lens on the distal face of the endoscope. The endoscope is further provided with a biopsy or working channel 3, and a suction channel 4 the proximal end of which is connected to a source of vacuum (not shown). The suction channel 4 may comprise a separate tube that runs along the exterior of the endoscope, rather than an internal lumen as shown. The sewing device 2 has a tube 5, which communicates with the suction pipe 4 and has a plurality of perforations 6 therein. These perforations communicate with an upwardly open vacuum chamber 7 formed in the sewing device.

A hollow needle 8 is mounted in the biopsy channel 3, with its beveled tip extending into the sewing device. The needle has a channel 9 extending therethrough. A flexible, wire-wound cable 10 has its forward end attached to the rear of the needle 8, and a center wire 11 runs within the cable 10, along the entire length thereof, and is longitudinally movable with respect thereto. The diameter of

the wire 11 is such that it is longitudinally movable within the channel 9 and, in the position shown in FIG. 1, the forward end portion of the wire 11 extends into the rear end portion of the channel 9. A thread carrier in the form of a tag 12 is slidably and releasably mounted in the channel 9. The tag is shown in detail in FIG 1A. The tag is hollow and has an aperture 13 extending through the sidewall thereof. As can also be seen in FIG. 1, one end of a thread 14 is secured to the tag by passing it through the aperture 13 and tying in the end of a knot 15 of sufficient size to prevent the thread escaping from the tag. The tag may be made from a relatively rigid material such as stainless steel.

At the distal end of the sewing device is defined a hollow head portion 16 defining a chamber 20 therein. Between the chamber 20 and the cavity 7 is a wall 17, in which an aperture 18 is formed. The aperture 18 has a diameter that is marginally greater than the external diameter of the needle 8, and is aligned therewith. The clearance between the needle 8 and the aperture 18 must be sufficiently small to prevent tissue being forced through the aperture and causing the needle to jam. Finally, FIG. 1 shows a portion of the patient's tissue 19, in which a stitch is to be formed.

In operation, suction is applied to the suction pipe 4, and thence, via the perforations 6 in the tube 5 to the cavity 7. This sucks into the cavity a U-shaped portion 19a of the tissue 19, as shown in FIG. 2. The hollow needle 8 is pushed through the U-shaped tissue portion 19a by extending distally the wire-wound cable 10 and associated needle 8. After full advancement of the needle through both folds of the U-shaped tissue portion, the tip potion of the needle 8 is distal to the wall 17 and within the chamber 20 in the hollow head portion 16. Distal movement of wire 11, slidably received within the wound cable 10, pushes the tag 12 out of the channel 9 and into the chamber 20 where it rotates out of alignment with aperture 18 to become captured in the chamber.

The wire 11 is then withdrawn proximally, followed by proximal withdrawal of the cable 10, to withdraw the needle 8 from the tissue portion 19a. The suction is then discontinued allowing the U-shaped tissue portion 19a to be released from the cavity 7. As shown in FIG. 3, the released tissue is left with a suture thread 14 passing through the two layers of tissue that form the U-shaped fold 19a. One end

of the suture is joined to the tag 12 that remains captured in the chamber 20 and the other end of the suture extends through the patient's esophagus and out of the mouth. Finally, the endoscope and dewing device are withdrawn from the patient. In so doing, the thread 14 is pulled partially through the tissue portion 19a, as the captured tag 12 is withdrawn proximally and brought outside the patient.

With both ends of the thread 14 outside of the patient, the thread can be knotted and the knot endoscopically pushed down to the suture site and severed by an endoscopic knot pusher such as that disclosed in U.S. Pat. No. 6,010,515 (Swain et al). As an alternative to tying a knot, a suture lock or clip may be guided over the suture thread, down the esophagus and secured via an endoscope or suitable delivery catheter to hold the suture thread tight against the tissue. Examples of suitable suture locks and delivery systems are disclosed in U.S. Patent Application entitled Suture Lock, Delivery Systems and Methods filed February 2, 2001.

In using the endoscopic suturing device to treat G.E.R.D. it is believed that capture of multiple tissue portions and suturing and gathering them together provide an effective treatment. To accomplish this using the prior art device, multiple intubations of the endoscope down the patient's esophagus are required. Once, multiple (tissue portions, have been captured and sutured with thread, they are gathered together and secured by tying of surgical knots in the thread or application of suture lock devices. It should be noted that a multiple stitch embodiment also is disclosed in U.S. Pat. No. 5,792,153. However, that embodiment requires the user to release the currently sutured tissue portion and relocate the device to collect a new tissue portion before making the second stitch. It is an object of the present invention to reduce the number of intubations required to capture multiple tissue portions and to enhance the security of the attachment of the tissue portions.

FIGS. 4 - 5 illustrates the advantages provided by the operation of a multiple suction port apposition device 50. Specifically, the device can secure multiple tissue portions 52 simultaneously for application of a tissue securing device, such as a suture, tag or staple. Securing two tissue portions 52 in the same number of steps that the prior art device requires to secure a single tissue portion doubles efficiency, reducing the total number of endoscopic intubations required to complete the procedure and reducing the time needed to complete the procedure. Though dual

suction port embodiments are discussed for illustration purposes, it should be understood that the multiple port device could be configured to have three or more suction ports.

The dual suction port tissue apposition device shown in FIG. 4 passes through both tissue portions a suture 56 with a tag 58 capturable in the end cap 60 of the sewing capsule 62, in similar fashion to the prior art device discussed above. The dual suction port tissue apposition device shown in FIG. 5 passes through both tissue portions a suture 64 having a permanent tag 66 at its end. The permanent tag is not captured by the suturing device to later provide a lead for tying a surgical knot. Rather, the permanent tag remains in the body, anchored on the through side 68 of the distal tissue portion. The tissue portions are then secured tightly together, not by a surgical knot, but by a frictionally engageable two piece suture lock device 70 advanced along the single suture lead 64 to abut the proximal side 72 of the tissue portion.

In one embodiment of the invention, multiple suction ports are defined in line on the sewing device, along a common longitudinal axis that is parallel to the longitudinal axis of the device. An isometric view of an in-line dual suction port endoscopic tissue apposition device 50 is shown in FIGS. 6-8, in various stages of operation.

In FIG. 6, a slotted and beveled hypodermic suturing needle 80 is in the fully retracted position, with suture tag 68 not yet loaded, and the capsule ready to receive tissue. The sewing device 50 is characterized by a tubular body or capsule 74 that is machined from metal or injection molded from a rigid polymer material. The body may be formed with an atraumatic distal tip 76 to avoid injury to the walls of a body lumen through which the device is delivered. A plurality of suction ports 86 are formed into the body along its length. Suction ports 86 are large openings defined through the capsule 74, and open to one or more vacuum chambers 82. The chambers are defined in the capsule by surfaces forming sidewalls 84. Communication of the suction ports with the vacuum chambers 82 permits vacuum to reach tissue that is adjacent to the ports to accomplish capture of tissue portions 52 into the chamber. Any number of suction ports can be formed on the capsule body. However, two suction port devices are shown here as illustrative examples

because often in the treatment of GERD, a series of two sutures joined together are formed along the stomach wall, below the Z-line. Though more ports and chambers can be formed on the body, the extra body length they would require in the in-line embodiment could potentially present difficulty during navigation of the rigid body through the curves of a natural body lumen.

Tissue portions are drawn into the suction ports and into the vacuum chambers by suction introduced to the chambers through air passages 88. The air passages are open to independent internal channels in the body that are joined to vacuum lines 90. The vacuum lines extend from the proximal end of the capsule body, external to the endoscope, to the proximal end of the scope. Outside the patient, the vacuum lines can be joined to a portable or institutional vacuum source (not shown). A control valve may be inserted in-line near the proximal end of the tubes for selective control of the vacuum by the user. The air passages of all cambers may be joined and controlled by a single vacuum line. Alternatively, as shown in FIG. 6, separate vacuum lines may be used to supply suction to the air passages of different vacuum chambers. Use of separate vacuum lines permits independent control of suction provided to the several chambers by the use of separate control valves for each vacuum tube at their proximal ends.

Independent vacuum supply to the air passages of each chamber not only helps to ensure adequate vacuum pressure to each chamber, but also permits sequential suctioning of tissue into the chambers. When tissue is collected into both chambers simultaneously, the distal chamber is blocked from the viewing lens 48 on the distal face 46 of the endoscope 1, as shown in FIG. 5. Therefore, the physician is unable to visually determine whether tissue has been adequately collected into the vacuum chamber so that the needle 80 can be safely advanced through. By applying vacuum first to the distal chamber, tissue collection into that chamber can be visually verified before the view is blocked by tissue entering the proximal chamber. Next, vacuum can be applied to the proximal chamber to capture tissue so that tissue is collected in both chambers simultaneously and held in readiness for penetration by the suture needle (or staple) through both tissue portions with one stroke. However, even with independent vacuum lines, it is possible, and may be desirable to apply a vacuum to all chambers simultaneously.

The needle 80 is longitudinally slidable through the capsule body 50, as in the prior art devices. In the in-line dual chamber embodiment shown in FIGS. 6-8, a tunnel-like needle track 92 extends longitudinally through solid portions in the upper half of the body, not otherwise defined by the vacuum chambers. From the needle track, a thin suture channel 94 extends upwardly through the top surface of the capsule body to provide a space through which the suture lead 64 may pass as the suture tag 68 is advanced by the needle through the needle track 92. The channel 94 is only a sufficient width to permit the suture to pass but is too small to permit passage of the larger needle or suture tag 68. The small dimension of the channel helps maintain the needle and suture tag with in the needle track until they are extended distal to the most distal chamber. An enlarged exit channel 96 extends upwardly from the needle track along the body a short distance distally from the distal chamber 82. The enlarged channel facilitates exit of the suture tag 68 from the body, to follow the released tissue to which it has been attached after being ejected from the extended needle 80 by pusher wire 98, as is shown in FIGS. 7 and 8. It is noted that tissue portions normally captured in the vacuum chambers during advancement of the needle and ejection of the tag are not shown in FIG. 7 for clarity. Additionally, a ramp 100 may be formed in the bottom surface of the needle track along the length of the exit channel 96. Extending upwardly as it extends distally, the ramp 100 helps guide an ejected tag up and out from the exit channel and away from the capsule body.

Another feature that may be integrated into the multiple chamber tissue apposition device to reduce intubations and procedure time is a magazine 102, shown in FIG. 9. The magazine is configured to hold multiple suture tags or permanent tags or staples in readiness for automatic and sequential loading into the needle or other advancement device during the procedure. The magazine may comprise a rectangular cavity 104 extending from the suture channel 94 down through the needle track 82. Several tags 68 can be preloaded into the cavity 104 before the procedure. Spring-loaded support tray 106 provides an upwardly biasing force on the stack of tags by virtue of the resiliency of several springs 108 supporting the tray from the bottom of the cavity. Upward travel of the tags in the cavity is

limited by the limited clearance of the suture channel 94, which is too small to accept a suture tag. Therefore, the top tag is biased into position along the needle track.

When the needle advances distally from its starting position shown in FIG. 9, it receives the top tag within its lumen and carries it through the tissue portions. When the needle is withdrawn proximally again, vacating the needle track, the next tag is free to move upward under the biasing force of the springs 106, into cue in the needle track. Because the endoscope does not have to be withdrawn for reloading after delivery of each suture, the number of intubations made during a procedure can be greatly reduced. In the case of permanent suture tags 68, the several suture leads 64 may each be preloaded with suture lock devices 70 to further hasten the tissue apposition procedure. For additional details regarding suitable suture lock devices see related provisional application entitled "Suture Lock, Delivery Devices and Methods" filed March 2, 2001. Alternatively, with some embodiments of the apposition device, the suture tags may be driven into one or more tag lock devices that remain in the body, on the through side of the tissue and are joined to another tag or to a suture lead extending back outside the patient. Embodiments employing multiple suture tags are best suited to use tag locks, which will be described in greater detail below.

FIG. 10 shows additional modifications that may be made to a multiple suction port capsule body 110 to improve tissue suction and retention. First, circumferential ridges 112 can be formed around the chamber openings defining suction ports 86 during formation of the body. The ridges protrude from the surface of the body slightly and are believed to improve sealing contact with surrounding tissue thereby increasing suction efficiency. The improved suction helps to ensure that tissue is drawn fully into the chamber so that suture is properly located through the tissue fold.

Another aspect of the invention, shown in FIG. 10, is the addition of capture recesses on the surfaces of the sidewalls 84 of the vacuum chambers, just below the suction port 86. It is believed that the addition of the recesses 114 will help retain tissue fully within the chamber after it has been sucked in initially. It is believed that after tissue has been sucked in, it will fill the chamber under vacuum, including the recesses. After the recesses have become filled, the upper surface of

the recesses will act as a flange to hold the tissue in the chamber. The modifications shown in FIG. 10 may be employed in any of the apposition device embodiments illustrated herein.

FIGS. 12A and 12B show another aspect of the invention. A hinge 122 may be incorporated into the capsule body 120, along its length to permit bending of the otherwise rigid body during navigation through curved body passages. In the case of an injection molded polymer body, the hinge 122 may be a living hinge defined by a thin line of material joining the two halves 126 and 128. The living hinge permits the halves to articulate relative to each other, in one direction, providing some longitudinal flexibility to the rigid body having an increased length due to the incorporation of additional suction ports. Articulation in one direction about only one hinged line is expected to provide adequate flexibility for the various curves encountered in a body lumen because, regardless of the direction of the curve encountered, the endoscope can simply be rotated until the direction of bending freedom of the capsule body coincides with the direction of the curve. Multiple hinges can be provided along one body and though they could be oriented in different directions, such varied positioning may be unnecessary in light of the forgoing statements.

Because the capsule body must aligned and straight to accept passage of the reciprocating needle during the procedure, a remotely operable locking mechanism is provided to lock the hinged halves 126 and 128. A locking rod 124 is longitudinally slidable through a locking channel 130, which extends longitudinally through both articulating halves 126 and 128 of the hinged body 120. The rod 124 extends to the proximal end of the endoscope to be operable by the physician. In its retraced position, shown in FIG. 12A, the rod occupies channel 13 only in the first half 126 of the hinged body, permitting half 128 to articulate freely about the hinge 122. In the advanced position, shown in FIG. 12B, the rod occupies the channel 130 in both halves 126 and 128 of the body 120, locking them together in a straight configuration.

FIG. 13 shows an alternate embodiment of the present invention that operates multiple suction ports from a single vacuum chamber 142 that is common to multiple ports 144. A multiple port tissue apposition device 140 comprises a

capsule body 148 having an outer surface 150 through which several suction ports144 are formed. Suction to collect the tissue through the ports 144 is provided through a single vacuum chamber 142 within the interior of the capsule body 148 that is common to at least two of the suction ports 144. As in the embodiments discussed above, vacuum is provided through air passages 88 at the bottom of the vacuum chamber 142. Those vacuum ports are joined to a vacuum line 50 that is in communication with a source of vacuum external to the patient.

In the embodiment shown in FIG. 13, two tissue suction ports 144 are provided on the capsule body 148 and a single vacuum chamber 142 is common to both suction ports. However, any number of ports may be formed into the capsule body surface 150 to provide the desired number of individual ports through which tissue can be collected and formed. It may be desirable to provide other combinations of ports 144 and vacuum chambers 142. For example, it may be preferred to provide a single vacuum chamber 142 in communication with two ports 144 and provide a separate vacuum chamber in communication with a third port at another location on the capsule body 148. Alternatively, if four ports were desired, two vacuum chambers could be provided, each serving two ports. Regardless of the configuration of vacuum chambers to tissue suction ports, the purpose of the invention is achieved with the present embodiment because multiple portions of tissue can be collected by the device at one time to permit attachment of a tissue securement device (such as a suture, permanent tag, or staple) with one operation of the device.

The operation of the present embodiment is essentially the same as has been outlined above for the previous embodiment. Specifically, the device 140 is secured to the distal end of an endoscope and is navigated to a site of internal tissue intended to be sutured. Using the viewing capability of the endoscope, the suction ports 144 are positioned adjacent tissue to be treated. Vacuum is introduced through vacuum line 50, in communication with air passages 88 to provide suction to the vacuum chamber 142, commonly shared by suction ports 144. Tissue is collected into the chamber 142 through individual suction ports 144, forming distinct portions of tissue within each chamber. Because the suction ports 144 share a common vacuum chamber, sequential suctioning of tissue into individual suction

ports is not possible with this embodiment, unless several vacuum chambers are provided, each serving multiple suction ports.

A tissue securement advancement mechanism such as a hollow and slotted needle 80 carrying a pusher wire 98 may then be advanced distally through needle track 92 and through the vacuum chamber 142 where the tissue has been collected. As the needle 80 is advanced distally, it receives in its lumen 81 a suture tag 68, which is joined to a suture 64. As the needle penetrates the individual portions of tissue that have been collected in the vacuum chamber 142, it passes the suture tag and suture through the tissue as well. After passing through all portions of tissue, the suture tag is ejected from the distal end of the needle into exit channel 96 extending distally of the most distal suction port 144. Ramp 100 of the exit channel guides the suture tag 68 upward and outward from the device when the vacuum is discontinued and tissue is released from the suction ports 144. The suture 64 passes through the suture chamber 94 extending along the top surface of the capsule 148. The suture and tag then remain permanently with the tissue as is described in detail above in connection with the preferred embodiments.

FIG. 14 illustrates another alternate embodiment of the multiple suction port concept described above in FIG. 13. The multiple suction port tissue apposition device shown in FIG. 14; however, is configured to utilize a capturable suture tag 168 as was employed in the prior art devices described above. In comparison to the embodiment of FIG. 13, the suture tag 168 is ejected from the advanced needle into a capture chamber 174 where it is retained and removed from the patient with withdrawal of the endoscope so that a surgical knot may be tied in advance to secure the suture. The capture chamber 174 is defined by a removable end cap 178 that is secured to the distal end of the capsule 162. The suture tag 168 is advanced into the capture chamber 174 after the needle has been advanced through portions of tissue captured through suction ports 144 into chamber 142 and passed through the capture chamber entrance 170. After the pusher wire 98 is advanced through the lumen 81 of the needle to eject the tag into the capture chamber 174, the tag becomes trapped because it is free to rotate out of alignment with the capture chamber entry 170. It is noted that needle track 92 need not extend through the entire length of the vacuum chamber but may optionally be provided

through areas of the chamber not defined by suction ports 144 to provide longitudinal directional stability for the needle as it passes through the mounds of tissue 144.

FIG. 15 shows another embodiment of the multiple port tissue apposition device in which the suction ports are arranged side-by-side rather than longitudinally in line as were the above-described embodiments. The suturing capsule 200 has a tissue capture mechanism comprising two or more suction ports 202 that arranged side-by-side, angularly offset but substantially aligned with each other longitudinally (referring to the longitudinal axis of the capsule and endoscope). The suction ports 202 define openings into the capsule 200 and are separated by partition 204. As with the previous embodiments, suction ports 202 open to a vacuum chamber 206 defined by sidewalls 208 inside the capsule 200. As with the above embodiments, vacuum is created in the vacuum chambers through negative pressure introduced by air passages 88 (not shown) to cause tissue to be drawn into the vacuum chambers through suction ports 202. The air passages are in communication with vacuum channel 234 formed through the capsule body and joinable to a vacuum channel 4 of the endoscope or an independent vacuum line.

As tissue is drawn into the suction ports 202 under vacuum, the partition 204 causes the tissue to be separated into two distinct mounds or portions into which tissue securement means such as sutures may be driven as is described below. The suction ports 202 may be in communication with a single, common vacuum chamber 206 (as shown in FIG. 15) or each suction port may open to independent, dedicated vacuum chambers that can be separately evacuated. Separate vacuum chambers would further be defined by a sidewall extending from partition 204 into the vacuum chamber 206.

As shown in FIGS. 15 and 16, the side-by-side suturing capsule 200 may be formed to have a substantially D-shaped cross-section, as opposed to the cylindrical cross-sectional shape of the above-described embodiments. The D-shaped cross-sectional shape of the capsule provides a tissue engagement surface 210 that is effectively more flat and wide than would be presented by a cylindrical capsule having side-by-side suction port arrangement. The added width of the tissue engagement surface 210 provides a wider area in which the suction ports 202 may

be formed. The wider tissue engagement surface 210 maximizes the width of the side-by-side suction ports 202 to insure that an adequate amount of tissue can be drawn into the vacuum chamber 206 during the procedure. Additionally, as shown in FIG. 15, the D-shaped cross-section of the capsule body 200 preserves the viewing capability through viewing lens 48 and lights 44 on the distal face 46 of an endoscope 1 (shown in phantom) to which the capsule is attached. Preservation of the viewing capability of the endoscope is important in design of the capsule body so that the physician can visually verify the positioning of the suturing capsule and verify that tissue portions have been fully captured within the vacuum chamber 206 prior to suturing.

With the side-by-side capsule embodiment 200, there are several possible mechanisms for tissue securement may be employed. Tissue securement may comprise suture material passed through the tissue portions. Alternatively, the tissue securement mechanism may comprise a clip that is driven into the tissue to secure the portions and remains in the patient, such as a helical wire coil described below. Several tissue securement advancement mechanisms are also possible. Specifically, several needle configurations and suture tag securement embodiments are possible with the multiple suction port capsule 200.

In one embodiment of the side-by-side device, shown in FIGS. 15-18, a forked needle 212 slidably mounted in the capsule 200 is employed to penetrate simultaneously the tissue portions captured in suction ports 202 for suture delivery. As best shown in the sectional isometric view of the capsule 200, shown in FIG. 18, the forked needle 212 may comprise a forked stainless steel structure having a base 214 and two fork prongs 216 that are hollow and terminate in sectioned tips 218 that define U-shaped receptacles 220 for receiving and frictionally engaging pointed suture tags 222 (shown in FIG. 15). Alternatively, the tags may be carried within the hollow fork prongs during delivery and ejected out with a pusher wire on the through side of the tissue after tissue penetration (as with the prior art device of FIGS. 1-3).

The forked needle 212 is slidable within the capsule and track 224, best shown in the sectional views of the capsule in FIGS. 17 and 18. The track 224 is comprised of a rectangular section 228 that accommodates the needle prongs 216 and the needle based 214 during sliding movement. Distal to the rectangular

portion, the track also comprises needle guideways 230, which locate the prongs 216 of the needle in its sliding movement proximal to traversing the vacuum chamber 206. It is noted that the sectional views in FIGS. 17 and 18 do not show the partition 204, which is formed in the top surface 210 of the capsule 200. The base 214 of the fork needle may be joined to a cable 10, which extends through the working channel 3 of an endoscope 1 (as shown in FIG. 2) to control longitudinal movement of the needle.

In use, the side-by-side suture capsule 200 is advanced into the patient at the distal end of an endoscope. The forked needle 212 is withdrawn proximally so that the needle prongs 216 reside within the fork guides 230, to keep the suction ports 202 open and ready to receive tissue. The forked needle 212 is placed sufficiently proximal so that the pointed suture tags 222 are also withdrawn into the fork guides 230. Sutures 236 joined to tags 222 are also partially withdrawn into the fork guides 230 slightly and are permitted to extend outward from the fork guides and out from the suction ports 202 then extend along the endoscope and outside of the patient's body. The sutures 236 are securely fastened to the center of the suture tags 221 either by heat bonding in the case of polymer tag, or by a knot formed internal of the tag if formed of a hollow rigid material such as stainless steel. The tags are located in the tag receptacles 220 or within the inside diameter of the needle by a friction fit.

The capsule is maneuvered to the treatment site and the suction ports 202 are placed against tissue to be joined. After positioning the capsule, suction is applied through the vacuum channel 234 causing tissue to be drawn into the suction ports 202 and into the vacuum chamber 206. The partition 204 and sidewalls 208 cause the tissue to conform into two equally shaped mounds or portions, useful in forming a plication once sutures have been applied and secured. Next, the forked needle 212 is advanced distally through the tissue that has been captured and retained in the vacuum chamber 206. The prongs 216 of the distally advancing needle continue across the suction ports 202 as the pointed suture tags 222 pierce and penetrate the tissue.

After exiting the tissue portions the prongs of the needle continue distally slightly into the area of tag catches 238 located at the distal side of each suction port 202. The sutures 236 will have been drawn through the tissue along the pathway

that has been created by the forks 216 of the needle 212. The tag catches are formed as notches in the top surface of the capsule that are aligned with the path of the advancing forked needle. The tags may be expelled from the needle forks on the through side of the tissue by several mechanisms. The suture catches may be sized so that the suture tags become temporarily frictionally engaged in the suture catches such that when the forked needle 212 withdraws proximally, the tags remain in the catches 238, being withdrawn from the tag receptacles 220 of the withdrawing needle. Alternatively, the suture tags may be ejected from the hollow needle forks by a distal movement of a pusher wire 11 slidable within the control cable and needle (as shown in the prior art device of FIGS. 1-3).

After the needle has been withdrawn so that both forks 216 are again concealed within fork guides 230, proximal to the suction ports 202, suction may be discontinued to release the tissue portions, now with sutures 236 passing through the tissue portions. As the tissue withdraws from the capsule and the capsule is withdrawn from the patient, suture tags 222 are pulled from the suture catches 238, overcoming the force of the frictional engagement with the sidewalls of the catches. The freed catches 222 will tend to rotate perpendicular to the longitudinal axis of the suture that is passing through the suture. Accordingly, the suture and suture tag form a T-shape that effectively anchors the suture in the tissue. The tag 222 becomes oriented to transverse to the path of the suture through the tissue so that penetration into the tissue is resisted when a pulling force is applied to the suture material in the proximal direction. Alternatively the tags 222 may be driven into securement device that remains in the patient, such as a tag lock device described in greater detail below. The free ends of the sutures passed through the two portions of tissue may then be tied in a knot that that is advanced to the suture location or may be secured by a suture lock device in order to secure and hold the tissue portions together to form a plication.

An alternative side-by-side capsule embodiment utilizes separate vacuum chambers 206 for each suction port 202 that may be opened to vacuum independently. In this embodiment (not shown in the figures), separate vacuum chambers may be formed by extending the partition 204 downward through the chamber 206 dividing it into two separate chambers that may be independently

opened to negative pressure. An advantage provided by separate vacuum chambers 206 is the ability to draw tissue portions into the chambers separately and sequentially. Sequential capturing of the tissue portions permits the physician to verify that the first tissue section has been fully captured in the vacuum chamber before attempting to capture a second tissue portion. The physician may verify complete tissue capture visually by using the viewing capability of the endoscope. Additionally, the physician may capture a first tissue section then reposition the capsule slightly against the tissue to alter where the second captured tissue section will be to better orient the placement of the sutures and the configuration of the resulting tissue plication.

In another embodiment of the side-by-side tissue apposition device shown in FIGS. 19-21, independently advanceable flexible needles are employed for each suction port. The side-by-side capsule 300 is configured substantially the same as the side-by-side embodiment described above, but defines a unique needle guide structure that causes each flexible needle 302 to be diverted slightly from a longitudinal axis of the capsule to cross each suction port 304 as it is advanced distally. The needles 302 are longitudinally slidable through the capsule 300 within needle track 306. At the proximal end of the needle track 306, the needles lie parallel to the longitudinal axis of the capsule, located to be in alignment with the working channel 3 of the endoscope 1 when the capsule is mounted to the distal end of the endoscope. Elongate cable 10 may be joined to the proximal end of the needles 302 so that longitudinal movement can be effected from the proximal end of the endoscope, outside the patient.

During distal advancement, the needles are diverted from their path along the longitudinal axis of the capsule by a diverter 310 placed within the needle track 306, as best shown in the sectional views of the capsule in FIGS. 20 and 21. The diverter 310 creates a fork in the needle track pathway that causes the distally bound needles 302 to diverge away from the longitudinal path parallel to each other, so that they will pass across the center of the suction ports that are spaced away from the longitudinal axis of the capsule due to their side-by-side arrangement. As the piercing distal tips 312 of the parallel needles 302 approach the tip 314 of the diverter 310 with the right needle 316 will be directed into the right needle pathway

318 and the left needle 320 will be directed into the left needle pathway 322. The right and left needle pathways 318 and 322 define an internal diameter that is slightly larger than the diameter of the needles to permit sliding movement, yet provide a secure directional control over the needles as they advance through the vacuum chamber 324. The proximal end 308 of the needle track 306 defines an internal diameter that is large enough to accommodate both needles 302 for slidable movement while the needles are in close parallel arrangement, prior to reaching the diverter 310. Alternatively, the proximal end 308 of the needle track may define separate lumens extending in parallel to guide the needles.

The needles of the diverter capsule embodiment 300 may be moved independently. The proximal ends of the needles may be joined to two independently movable elongate pushing cables extending through the working channel 3 of an endoscope in place of the single elongate cable 10 that serve to move the single needle of the previously described embodiments. Two cables of a reduced diameter may be placed within a single working channel endoscope to provide independent movement of the needles. Alternatively, an endoscope having dual working channels may be used with a pusher cable for each needle 302 placed in each working channel and joined to the proximal ends of the needles to provide independent control over their movement through the capsule 300. Alternatively, the needles 302 of the diverter capsule embodiment 300 may be joined to a single elongate cable to provide tandem, unified movement of the needles through the capsule with movement of the single cable.

In use, the diverter capsule 300 is navigated to an internal tissue location within a patient at the distal end of an endoscope. The needles 302 are maintained proximally withdrawn inside the left and right needle pathways 320 and 318 during delivery. Sutures 326 extend from tags 328 frictionally located at the distal tips of the needles 312. As with the embodiments described above, the tags 328 may form the piercing distal tip of the needle that is later separated from the needle to become a cylindrical anchor that later rotates to be perpendicular to the pathway of the suture extending through the tissue. Alternatively, if the needles are hollow, the tags 328 may be frictionally held within the tip of the needle and later ejected from the needle by a pusher wire slidably contained therein as with the embodiment 200

described above. Receptacles 330 formed distal to the suction ports 304 provides space for the tags to be ejected from the needle to rotate free of the capsule after being driven through the tissue portions. Alternatively, rather than receptacles, a passageway may be formed at the distal end of the suction ports 304 that permits the tags to be ejected into a chamber at the distal tip of the capsule where the tags will become captured, in similar fashion to the embodiments and prior art devices described above in FIGS. 1-3. A further alternative embodiment comprises use of tag lock devices that are temporarily frictionally engaged in receptacles 330 and receive suture tags 326, anchoring them in the tissue after the needles are withdrawn. The tag lock devices will be described in greater detail below.

Continuing with the operation of the diverter capsule embodiment, after the capsule is navigated to a tissue location, suction is applied to the vacuum chamber 324 through vacuum channel 332 to draw tissue portions into the suction ports 304 so that the tissue becomes seated in vacuum chamber 328. In the case of a diverter capsule embodiment having separate vacuum chambers 324 for each suction port 304, tissue portions may be drawn into the suction port sequentially as vacuum may be selectively open to each of the side-by-side chambers. If vacuum is open to one of the chambers to draw in tissue to that chamber, the needle 302 corresponding to that chamber may then be advanced distally to immediately capture the tissue section without necessitating that the needle for the other chamber be activated. After one tissue section has been sucked into the suction port 304 and pierced by the needle 302 driven distally through it, the physician can be assured that the tissue section will remain captured if repositioning of the capsule is required to capture the second section of tissue in the remaining suction port. Next, vacuum is introduced into the remaining free vacuum chamber 324 to capture a second section of tissue through the suction port 304. The second needle 302 may then be advanced distally to penetrate and capture the second tissue portion. The suture tags 328 may then be ejected from the needles 312 either by a pusher wire slidably received in one or both of the needles or by frictional engagement with the receptacles 330 or tag locks as will be described below. After the suture tags 328 have been ejected on the through side of the tissue, the needles may be withdrawn proximally from the tissue and vacuum is discontinued to release the tissue portions from the device.

The free ends of the sutures, which extend outside the patient's mouth may then be secured by surgical knots or suture locks to secure the tissue.

FIG. 22 shows an alternate embodiment of a tissue apposition device having multiple suction ports that are longitudinally and angularly offset from each other. The offset capsule embodiment 400 may have a cylindrical shape having at least two suction ports 402 formed through the surface of the capsule that are spaced longitudinally on the capsule and angularly offset from each other. The exact placement of the ports on the suction chamber may be varied to obtain the preferred tissue plication shape for the given procedure. In the example of the offset capsule shown in FIG. 22, the suction ports 402 are arranged to be slightly spaced longitudinally of a distance of less than half the length of a suction port and are angularly displaced at less than 90°. This arrangement of suction ports offers a physician an alternative configuration of formed tissue plications that may better achieve the objective of the particular treatment. The arrangement of suction ports 402 is believed to be suitable for tissue plication formation useful in GERD treatment.

As with the previous embodiments, suction ports 402 open to vacuum chambers 404 into which tissue is drawn when vacuum is applied. It is preferred that in the offset embodiment 400 that the vacuum chambers 404 be configured to operate separately, each serving only one suction port 402 so that tissue can be selectively captured in the suction ports. Additionally, it is preferred that the needles 408 be separate and independently operable.

FIG. 23 shows a sectional view of the offset capsule embodiment 400 having a diverging needle guide path 410, similar to the diverter capsule embodiment 300. As with the previous embodiment, separately advanceable needles 408 reside in parallel in the base portion 420 of the needle guide path so that the proximal ends of the needles can be joined to elongate cables 10 that extend through a common working channel 3 of an endoscope. The needle path 410 also has formed a diverter 412 that serves to direct a left needle 409 into a left needle path 406 and the right needle 411 into a right needle path 405 having been diverted into the left and right needle paths 405 and 406 during distal advancement. Proceeding distally, the needles each cross the center of the suction port to which the given needle path has

been configured to access. After tissue has been drawn into a vacuum chamber 404 under negative pressure, the appropriate needle 408 may be advanced through the guide path 410 in a distal direction where it will be diverted as it passes the point 414 of the diverter 412 to enter the appropriate needle path to access the appropriate vacuum chamber containing the tissue. After penetrating one tissue section, the physician may verify that the remaining vacuum or suction port 402 is properly aligned to receive tissue, then activate the vacuum source to draw tissue into that vacuum chamber 404. During suctioning of the second tissue section, the presence of the first advanced needle through the first tissue section insures that the captured tissue section will not migrate from the capsule so that the location of the next tissue section relative to the first tissue section will be known. After the second tissue section has been sucked into the vacuum chamber 404, the second needle may be advanced through the needle path where it will be guided by diverter 412 to the appropriate needle path (406 or 405) to penetrate tissue captured in the vacuum chamber. After the tissue portions have been penetrated by the needles, a tissue securement device such as a suture carrying tag may be ejected from the needle by the mechanisms described above in connection with the previous embodiments. The needle recesses 416 and 418 defined distal to the suction ports 402 provide clearance for the needles 408 to extend slightly distal to the suction ports 402, not only to insure complete penetration of the tissue, but also to permit space for the suture tags to be ejected distally from the needle. Additionally, tag locks may be utilized with this embodiment as will be described below.

FIG. 24 shows another alternate embodiment of the multiple suction port tissue apposition device having four suction ports. The quad port apposition device 500 is similar to the side-by-side apposition device 300 described above, but comprises an additional set of two suction ports and two needles on the opposite side of the capsule. Additionally, the quad port embodiment 500 may have a cylindrical shape having a circular cross-section with suction ports 502 spaced around the circumference of the capsule. Preferably, each suction port 502 opens to an independent vacuum chamber 504 serviced by an independently operable needle 506. Preferably, the quad port capsule is used in conjunction with an endoscope 1 having multiple working channels 3 to accommodate the movement of

the multiple needles 506. For example, an endoscope having two working channels 3 could accommodate two pusher cables 10 slidable within each working channel 3. Each pusher cable could then be joined to a separate needle 506 for independent movement of that needle through the capsule to a particular vacuum chamber 504. As shown in FIGS. 24 and 25, the capsule is similar to the side-by-side capsule 300 in that a partition wall 508 separates the chambers 504. As best shown in FIG. 26, a sectional view of the quad port device taken along the line A-A of FIG. 25, the capsule may be considered to have a top side 520 having two vacuum chambers 504 and a bottom side 522 having two vacuum chambers. A narrow partition 508 is employed between the two chambers oriented on one side. Wide partitions 510 define the space between the two sides. With this arrangement, the chambers 504 are not arranged 90° apart from one another but more appropriately characterized as two sets of side-by-side chambers arranged on top and bottom sides of the suturing capsule. However the capsule may be arranged in other configurations, such as equal spacing between all four vacuum chambers 504.

As best shown in FIG. 27, which is a sectional view taken along the line B-B of FIG. 25, a needle path 512 is defined by a diverter 514 creating a left needle path 516 and a right needle path 518 to divert the needles into the appropriate vacuum chamber 504 after tissue has been collected under the force of the vacuum. As with the embodiments described above, needle receptacles 520 at the distal side of the suction ports provide a space for the needles to advance distal of the captured tissue portions to insure complete penetration and permit suture tags to be ejected from the needles after penetration. The arrangement of the needle track and vacuum chambers 504 is mirrored on the opposite side of the capsule 500 shown in FIG. 27 to provide four independently operable suction ports and suturing needles. Independent operation of the suction port and needles is especially important in the quad port embodiment because the broad area of tissue that will ultimately be captured by the single intubation of the endoscope. Operation of the device is optimized if each section of tissue is separately drawn in and secured before suctioning of the next portion of tissue to avoid risk of inadvertently losing contact with a section of tissue already captured. However, simultaneous activation of some or all vacuum chambers to collect tissue portions is possible if the physiology of

treatment area is such that the device can be positioned to have tissue adjacent each suction port simultaneously.

An alternative tissue securement device for the captured tissue portions is shown in FIG. 28. A tag lock device 600 may be detachably mounted to a suturing capsule of any of the embodiments described above in order to receive and hold a suture tag 602 inserted by a distally advancing needle 604. The tag lock remains at the suture site to keep the suture tag secured at the through side of the tissue so that the sutures may be manipulated to tighten connection of the tissue portions. In FIGS. 28-34, various embodiments of the tag lock 600 are shown, each illustrated in combination with the side-by-side suture capsule 200 using a forked needle 212. Each embodiment uses at least one tag lock block 608 having one or more tag receptacles 612 that each receive in frictional locking engagement a suture tag 602 or preloaded suture tag 606. In each of the embodiments, the lock block 608 is frictionally received in a tag lock receptacle 610 formed on the capsule tissue engagement surface 210 adjacent to a suction port 202. The differences between the various embodiments is defined in how many lock blocks and tags are utilized in securing a captured tissue section and the arrangement of those components on the capsule during suturing.

FIGS. 29A and 29B show the components of a tag lock device 600 in detail. The tag lock components are preferably made from a material that is relatively rigid, biocompatible, resistant to stress failure under compression and tension, resistant to the corrosive effects of internal bodily substances, such as acid in the stomach, and conducive to frictional engagement when in contact with like surfaces. Suitable materials may be polymers such as PEEK or metals such as stainless steel. The preferred material is PEEK. PEEK is a trade designation for a linear aromatic semi-crystalline polymer, polyaryletherketone, available from Victrex. The dimensions of the tag lock block 608 may be on the order of about .10 by .10 by .050 inches. The dimensions of the tag lock receptacles formed on the surface 210 of the capsule 200 approximately match the shape and size of lock blocks 608 so that they retain the lock blocks by temporary frictional engagement during delivery of the sutures to the tissue. The suture tags 602 may be on the order of .035 inches in diameter. The tag receptacles 612 formed into the lock block that receive the suture tags are sized

closely to match the tag size so that a frictional fit is created when the suture tag 602 is inserted into the receptacle. The opening 614 of the receptacles may be flared to a slightly larger diameter to facilitate entry of the suture tag into the receptacle.

The suture material 616 is conventional surgical suture of about .010 inches in diameter. The suture material may be joined to the tags by heat bonding if a polymer material such as PEEK is used to form the tags. Sutures may be attached to stainless steel tags by forming the tags to be hollow and forming a hole through the surface of the tag. The suture material may be passed through the hole and knotted to create a diameter that will not pass back through the hole. This securement mechanism is also used for the prior art suture tag described in connection with FIG. 1A.

As an alternative to capturing the suture tags by frictional engagement, the tag receptacles 614 may be sized to permit the tag to pass completely through the lock block 608 and become captured on the through side of the lock block. To accomplish successful capture of the tag by this method, the suture should be joined to the center of the tag as shown in FIG 29A rather than to the end so that the tag will tend to rotate to be perpendicular to the suture line and receptacle passage after passing through the receptacle, thereby preventing passage of the tag back through the receptacle. Attachment of the suture to the center of the tag may also facilitate temporary frictional securement of the tags to the needle, when retained either in the inside diameter of a hollow needle or in tag receptacles 220 shown in FIG. 18.

FIG. 29A shows another optional configuration of the tag lock device that permits sliding passage of a suture through the lock block. A sliding passage 618 may be formed in the block 608 in addition to the tag receptacle 612. The sliding passage may be formed through the block in any orientation relative to the receptacle 612 but should not interfere with the passage formed for the receptacle. The sliding passage should be of a diameter sufficient to permit free sliding movement of a suture. A lock block 608 formed to receive a tag 602 in the receptacle 612 and having a sliding passage 618 oriented transverse to the longitudinal axis of the receptacle and associated suture may be used in similar fashion to a lasso to tighten the tag lock against tissue with the sutures as will be described in greater detail below.

FIG 28 shows one of several various tag lock configurations that may be employed with the multiple suction port devices of the present invention to secure tissue. Lock blocks 608 are frictionally engaged with lock receptacle 610 at the distal side of suction ports 202 of the capsule 200. The right lock block 620 is formed to have two tag receptacles 612. One tag receptacle is preloaded prior to the procedure with a tag 606 having a suture 616 that is joined with an appropriate amount of slack to left suture tag 642 that is attached to left needle fork 624. An appropriate amount of slack is such that the length of suture between right preloaded tag 606 and left tag 642 is sufficient to permit the left tag to traverse a portion of tissue collected in the vacuum chamber 206, yet hold the tissue portion securely collected after the tissue and tag are released from the capsule. Left needle fork 624 is aligned to place left tag 642 into the receptacle 612 of left lock block 622. Left lock block 622 holds another preloaded tag 606 having a suture 616 that extends out of the patient. The right needle fork 628 is aligned with the open receptacle 612 of right lock block 620. The right suture tag 630 is releasably attached to the right needle fork 628 and is aligned to be driven into the open receptacle 612 of right lock block 620 when the fork needle is advanced distally. Right tag 630 also has a suture 616 that extends outside of the patient's body.

FIG. 30 shows the arrangement of the tag lock system after the needle has been advanced distally to secure the suture tags 630 and 642 into the previously open receptacles 612. It should be recognized that in actual use, the needles will have penetrated tissue portions that were maintained in the vacuum chambers 206 during the distal advancement of the needle. After advancement of the needle, both left and right lock blocks 622 and 620 each contain one preloaded suture tag 606 and one needle driven suture tag 602 frictionally secured in tag receptacles 612. The tissue section penetrated by the left needle fork 624 will have passing through it a suture 616 that joins the left and right lock blocks 622 and 620. The tissue section penetrated by the right tissue fork 628 will have passing through it the suture 616 secured at one end in the right lock block 620 and extending at the other end outside the patient. Likewise, lock block 622, will have a free suture lead 616 that passes outside of the patient. After the tissue is released and the capsule 200 is

withdrawn, the sutures may be tightened to form plications in the tissue that are best shown diagrammatically in FIG. 30A.

In the diagrammatic representation of the resulting tissue configuration shown in FIG. 30A, the left tissue portion (penetrated by the left needle fork 624) is represented by reference numeral 654 and the right tissue portion (penetrated by right needle fork 628) is represented by reference numeral 656. It is expected that the tissue segments will be secured together to form a plication by the figure eight arrangement of sutures 616, preloaded as described above, using the tag lock system 600. The sutures and tag lock device are secured tightly against the tissue by a suture lock 650 comprising a ring into which is frictionally engageable a pin to capture suture leads therebetween. It is noted that the lines shown in phantom represent suture material that is passing through the tissue.

FIG. 31 shows another possible configuration of the tag lock system 600 in which a lock block 608 having a sliding suture passage 618 (shown in phantom) is used. In particular, a right lock block 620 is placed in the lock receptacle 610 in line to receive a suture tag 630 from the right needle fork 628. The suture tag 630 loaded into the right needle fork 628 holds a suture 616 that extends outside the patient. The left fork 624 releasably holds the left suture tag 642 that is joined to a suture 616 that passes through the sliding suture passage 618 of right lock block 620. In this embodiment, the suture tag 642 of the left needle fork 624 will not be inserted into a lock block 608 upon distal advancement of the fork needle, but rather will itself serve as a T-shaped anchor after penetrating the tissue as it rotates to become perpendicular to the suture passage created through the tissue. The tag receptacle 238 is formed in the capsule body 200 to permit the tag 602 to be ejected from the needle 624 and be released from the capsule.

FIG. 31A shows a schematic drawing of the expected orientation of the tissue portions having received a suture tag lock system configured as shown in FIG. 31. The left tissue portion 654 will be twisted slightly as the suture 616 passing through a sliding suture passage 618 is pulled taut and secured with suture lock 650. As described above, the suture tag 642, alone, provides anchoring for the suture 616 in the left tissue section 654 while the right lock block 620, will provide the suture anchor support for right tissue portion 656.

FIG. 32 shows yet another potential configuration for the tag lock system 600 that utilizes three suture leads 616 that extend outside of the patient for securement of the internal tissue. In this embodiment, the left lock block 622 receives a suture tag 642 from the left needle fork 624 upon distal advancement of the needle. The left lock block 622 is joined to the right lock block 620 by suture 616, which passes through a sliding suture passage 618 of the right lock block 620. Right lock block 620 also receives the suture tag 630 from the right needle fork 628 upon distal advancement of the needle.

FIG. 32A shows a diagram of the expected tissue orientation after delivery of the sutures with the present tag lock configuration. Because the left and right lock blocks 622 and 620 are joined together by a suture that can slide through sliding suture passage 618, the left and right tissue portions 654 and 656 are drawn together at the ends closest to the lock block devices as the joining suture is tightened in the suture lock 650 along with the two sutures 616 passing through the tissue portions.

FIG. 33 shows another configuration of the tag lock system 600 in which three suture leads 616 extend from the patient for securement of the internal suture tissue. The left suture lock block 622 receives the left suture tag 642 having joined to it a suture 616 that passes through a sliding suture passage 618 formed in the right lock block 620. The right lock block 620 is releasably secured on the proximal side of the suction port rather than the distal side of the suction port as in the previously described embodiments. Additionally, left lock block 622 has fixedly joined to it a suture 616 that passes through a second sliding suture passage 618 formed into the right lock block 620. The suture tag 630 delivered through the tissue by the right needle fork 628 is received in tag receptacle 238, which permits the tag to release freely to rotate to be perpendicular to the suture line passed through the tissue so that the tag 630 serves as its own anchor. In FIG. 33A, it can be seen that the suture extending from the left lock block 622 through the sliding suture passage 618 of the right lock block 620 tends to pull the left tissue section 654 into a twisted configuration slightly when the three sutures 616 are secured by suture lock 650.

FIG. 34 shows another configuration of the tag lock system 600 in which only a single suture lead 616 extends from the patient body for tightening to secure the

tissue. The left suture lock block 622 has a permanently affixed suture 618 extending from its side over to right lock block 620 through which it passes in a sliding suture passage 618 formed in the right lock block. That suture continues proximally and further passes through a second right lock block 634 releasably positioned at the proximal side of the suction port 202. The suture passes through the lock block 634 via a sliding suture passage 618 and continues to extend outside of the patient. The left needle fork 624 carries a suture tag 642 that becomes secured into the left lock block 622 upon distal advancement of the needle. The suture tag 642 delivered by the left needle fork 624 has joined to it a suture 616 that is securely fastened to right lock block 620. It is noted that sutures of fixed length between lock blocks and suture tags described in this section are measured to be of an appropriate length that will accommodate the expected tissue portion size that is collected in the vacuum chamber of the capsule so as not to put too great or too little stress on the tissue portion when finally secured in a plication form.

Suture tag 630 is delivered by the right needle fork 628, through the lock block 634 and into the right lock block 620 where it becomes secured in receptacle 612. Tag 630 carries with it a length of suture 616 (not shown) only sufficiently long to traverse the right tissue section 656 as the suture is also securely fastened at the other end to the second right lock block 634. FIG. 34A shows the expected tissue configuration after applying the tag lock embodiment of FIG. 34. The suture lock 650 need only be secured to a single suture 616 extending from the patient to effectively secure the entire tag lock system of this embodiment.

FIG. 35 shows the side-by-side tissue apposition device using a fork needle 200 employing a tag lock band 660 to secure suture tags 602 in place on the through side of the tissue portions penetrated by the forked needle 212. The tag lock band 660 may be flexible or rigid and may be formed from any suitable material mentioned in connection with the tag lock devices described above. The tag lock band is releasably located at the distal side of the suction ports 202 of the capsule 200 and is held in place by frictional engagement. The tag lock band 660 may have a cylindrical or rectangular shape and has two tag receptacles 662 formed through it, as is best shown in the detailed drawing of FIG. 35A. When positioning the tag lock band in receptacle 664 at the distal end of the suction port, the tag receptacles 662

align with the path of left and right needle forks 624 and 628. When the fork needle 212 is advanced distally, the suture tags 602 are driven into the tag receptacles 662 of the band 660. The tags may be frictionally engaged in the receptacles 662 or may pass completely through and rotate to be transverse to the receptacle openings to prevent passage back through the receptacles.

After the tags are ejected from the needles and the needles are withdrawn proximally, the tag lock band and captured tags may be pulled from the capsule. The tag lock band 660 is easily removed from its receptacle 664 and tag receptacles 234 are sized to easily release the tags as the capsule is withdrawn from the patient. The tag lock band offers a broader tissue contact surface area that offers better support and confinement of tissue that is being secured, which may help to form more usefully shaped tissue plications.

FIG. 36 shows another embodiment of a multiple suction port tissue apposition device using an alternate tissue securement mechanism. The capsule 700 uses a helical coil wire implant 708 to secure and hold captured tissue portions together. The helical coil may be formed from stainless steel wire and may be provided with a piercing sharpened tip 722 at the end of its distal most coil for piercing tissue. As with previous embodiments, the capsule 700 utilizes multiple suction ports 702 formed into the surface of a cylindrical capsule separated by a partition 704. However, in the present embodiment, the partition 704 has a series of radially extending slots 710 that serve to divide the partition 704 into a series of prongs 706 creating a comb-like partition. The slots 710 in the partition wall 704 are created to provide a passageway for the advancement of the helical coil 708 distally through the vacuum chamber 712 of the capsule as is shown in FIG. 37.

FIG. 37 shows the helical wire 708 being advanced through the openings 710 formed in the partition 704. The helical coil advances distally and rotates as it advances to become threaded between the prongs 706 that divide the vacuum chamber 712 of the capsule. Rotational movement of the helical wire may be imparted by drive connector 714 having a drive surface 718 that contacts the proximal end of the helical wire 708 to impart a rotational force upon the wire. The drive connector 714 is rotated by rotating shaft 716 that extends through the working channel 3 of an endoscope to be rotationally and longitudinally driven, preferably, by

external electric motor means. Alternatively, the shaft 716 may be manually operated by use of an operator handle connected at its proximal end that enables a physician to push and rotate the coil through the captured tissue portions.

In use, the capsule 700 is delivered to a tissue location at the distal end of an endoscope as with the previous embodiments described above. Suction is applied to the vacuum chamber 712 to draw tissue through the suction ports 702 and into the chamber. The tissue is divided into two sections by partition 704. Despite the presence of slots 710, broad surfaces 720 at the top of each prong 706 help to hold tissue back along the partition wall 704 so that it does not herniate into the openings of the slots 710. After the tissue has been captured within the vacuum chamber 712 through each suction port 702, the helical coil 708 is rotated and advanced distally through the vacuum chamber and along the center partition 704, threading into left and right tissue portions captured in the vacuum chambers to hold them together. The leading tip of the helical wire 722 is sharpened to facilitate penetration through the tissue. A stop may be provided at the distal end of the partition to prevent further rotation and distal advancement of the coil once it has been threaded through all slots that are open to the suction ports 702. After the helical wire has been completely threaded through the tissue portions, spaces 710 permit the helical wire to move upward and out from the vacuum chamber without interference with the partition 704 when vacuum is discontinued to release the tissue. It is believed that the helical wire securement device may provide a more reliable securement of the tissue portions because of its multiple penetration points through both portions of tissue in comparison to the single penetration a suture thread may provide.

In addition to securing tissue, the present embodiment may be used to endoscopically deliver implants to internal tissue locations for other purposes. Implants such as coil implant 708 may be delivered into tissue to promote bulking of the tissue area. Tissue bulking in certain regions of tissue may achieve a similar effect in the treatment of GERD that tissue plication formation achieves. Use of implants to achieve bulking may be useful in the Z-line region between the esophagus and stomach, which is easily reachable by an endoscope carrying capsules of the present invention. Additionally the implant may configured to carry bulking agents to the tissue site, by coating or other means.

In another aspect of the present invention the tissue apposition device may incorporate tissue abrasion means in the capsule body. It is believed that abrading the portions of tissue sufficiently to initiate a healing process, before securing the tissue portions into contact, will lead to combined tissue ingrowth throughout the tissue surface interface. The tissue will heal together, eventually becoming one tissue portion. Such connective strength would be an improvement over the reliability and strength of means currently available to secure tissue plications together in procedures such as endoscopic suturing for GERD treatment.

FIG. 38 shows an embodiment of a single suction port apposition device 850 having mechanical abrasion means on its external surface 852. Though the abrasion means can be implemented on any configuration of single or multiple suction port device, examples of the abrasion means are illustrated in connection with a single port device for simplicity. The mechanical abrasion means comprises a plurality of surface ridges 854 formed directly into the surface of the device and located adjacent the suction port 860 to score tissue lying near the chamber. Additionally, mechanical abrasion means may comprise an abrasion block 856 having a plurality of sharp protrusions 858 to frictionally abrade the tissue adjacent the suction port. With the abrasion block, the rough surface need not be formed directly into the material of the capsule body, but may be applied later during a secondary operation. The mechanical abrasion means may be actively rubbed against the tissue by moving the device back and forth to score the tissue.

It is noted that with the mechanical abrasion means, as well as with all abrasion means discussed herein, light vacuum is applied at the vacuum chamber to hold tissue in or against the suction ports and in contact with the surface 852 of the device 850 during the abrasion activity. Holding the tissue against the device not only insures that abrasion takes place, but also insures that the abrasion is applied to the tissue surfaces that will placed into contact with each other when the tissue portions are joined. After the abrasion action is complete, a full vacuum is applied to fully draw tissue into the vacuum chamber for tissue securement means attachment such as by needle and suture or staple placed through the tissue or other form of tissue adhesion.

Alternatively, or in addition to, the mechanical abrasion caused by structural elements applied to the capsule body 852, abrasive substances may be ejected from the capsule through an ejection port 862 arranged near the suction ports. Abrasive substances include salt or sugar or any biocompatible crystalline substance capable of flowing adequately to be injected through a tube running the length of the endoscope and being ejected through the small port 862. The substance may be carried in an aqueous media to facilitate delivery. It is expected that the presence of the abrasive substance will abrade the tissue adequately through its motion rubbing against itself and against the device to initiate a healing response.

FIG. 39 shows an isometric view of another single suction port tissue apposition device displaying various types of abrasion means on the capsule body surface 852 adjacent the suction port 860. Specifically, the capsule body surface 852 has several radio frequency (RF) transmitting elements 866 located around the suction port, which holds the subject tissue. The RF energy can be transmitted to the element 866, from a source outside of the patient, through small wires (not shown) that are insulated and extend through a channel of the endoscope 1. RF is believed to provide a level of energy that is well suited to creating the light injury desired to initiate the healing process in tissue. As mentioned above, it is desired to only damage or destroy the mucosal layer of tissue in this process.

Alternative means can be used for abrading the tissue with elements, such as element 866 that transmit other types of energy such as laser, ultrasonic or electrical energy. In the case of laser energy, an optical fiber can be extended through the endoscope to transmit the laser energy to a lens on the capsule surface. Ultrasonic energy may be transmitted through a small vibratory horn element, also positioned on the surface of the capsule, adjacent the suction port. Electrical energy, which injures the tissue by heat generated from electrical resistance at the element 866 may be transmitted from a source outside the patient through small wires led through a channel of the endoscope, as can be arranged for the transmission of RF energy or ultrasonic energy.

Chemical abrasion is also possible with the above-described devices. To utilize chemical abrasion, a chemically abrasive substance such as hydrochloric acid of a greater concentration than which naturally occurs in the stomach may be

ejected from a port adjacent the suction port similar to port 862 discussed above with reference to FIG. 38.

Utilizing abrasion techniques in conjunction with a single suction port tissue apposition requires that the procedure be carried out in a specific manner in order to achieve the desired result of tissue segments healing together and bonding as one. Specifically, a tissue portion is first captured by the capsule body by applying light pressure through the suction port 860. The vacuum is achieved through suction ports 870 at the bottom of chamber 860, which are in communication with vacuum lines connected to a vacuum source external to the patient. A light vacuum applied should be sufficient only to hold the tissue against the opening 872 of the suction port, without sucking tissue inside the chamber. With the tissue held against the surface 852 of the capsule, the abrasion mechanism can be activated with assurance that it will be in contact with the tissue and that the tissue will not move relative to the abrasion mechanism. After the abrasion is complete, the tissue may be sucked into the vacuum chamber under full vacuum and a tissue securement device applied such as a suture, permanent tag or staple as is described in the prior art.

The tissue abrasion mechanism should be spaced from the suction port an appropriate distance so that when the tissue is later sucked completely into the chamber, and the suture is passed through the tissue portion, the abraded tissue will be near the suture entry point or otherwise in an area on the tissue surface that will be placed in contact with other abraded tissue when the plications are secured together. After a tissue securement device has been placed through the collected tissue, the vacuum may be terminated to release the tissue from the device, and the device moved to an adjacent area of tissue where the same process will be undertaken. After the second tissue securement device is placed through the second tissue portion, the tissue securement devices may be joined together by a surgical knot or suture lock component to hold the tissue plications together as a group. It is between these plications that tissue ingrowth and bonding is desired to supplement the connective force of the tissue securement device (suture, permanent tag or staple). Accordingly, the second and subsequent tissue treatment sites should be selected carefully so that the abrasion and tissue securement device

are positioned in such a manner that the several tissue portions will align and have an opportunity to heal together. Ensuring proper alignment of the multiple tissue portions is made easier when the abrasion means is employed with a multiple suction port tissue apposition device as is described below.

As shown in FIG. 40, a multiple suction port apposition device is similar in construction to the single chamber device, but accepts two tissue portions under suction simultaneously. A detailed discussion of various embodiments of multiple suction port apposition devices is provided above. All embodiments may employ the tissue abrasion means discussed here. A multiple port device is the preferred platform for implementing the tissue abrasion means because it facilitates placement of the tissue abrasion between the two adjoining plications of tissue that are to be bonded together through tissue healing. Abrasion placement is facilitated because both tissue portions are captured simultaneously in fixed positions by vacuum chambers 860 during application of the abrasion technique.

As shown in FIG. 41, a dual suction port suturing capsule 868 may be modified to have mechanical abrasion elements formed directly on the adjacent ends of the suction ports 872. Barbs 884 are formed on the port openings to achieve mechanical abrasion. FIG. 42 shows use of a RF transmitting element 888 located centrally between the two suction port openings 872. Positioning of the abrasion means near the center of the two suction ports results in the abraded tissue becoming aligned and placed in contact after the two tissue portions 890 are formed in the vacuum chambers 860 and a tissue securement device such as a suture 878 with permanent suture tag 874 is inserted through the two portions as is shown in FIGS. 41 and 42. When the suture 878 is pulled tight and the two plications are brought in contact, abraded tissue areas 892 will be placed in contact and tissue ingrowth between the abraded areas 892 will be facilitated.

Accordingly, the process for utilizing the multiple suction port tissue apposition devices with abrading means as shown in FIGS. 40-42 is discussed below. First, the dual chamber device is brought into contact with subject tissue and light vacuum applied through the suction port 872 of each vacuum chamber 860 to draw tissue into secure contact with the top surface 852 of the capsule. Next, the tissue abrasion mechanism is used to abrade tissue area lying between the two areas 890

of tissue captured over the vacuum chambers 860. Note that, although mechanical means 884 and RF means 888 are shown in FIGS. 41 through 44, any of the previously discussed abrasion means may be applied through the dual suction port device in similar fashion to that described in connection with the single suction port device above.

After the tissue abrasion is complete, full vacuum may be applied through the suction ports 872 to draw the tissue portions 890 fully into each vacuum chamber 860. The needle 880 may then be advanced through the double folds of tissue simultaneously, carrying the suture 878 and suture tag 874 through the two double fold portions of tissue. After the tag is ejected on the through side of the tissue and the needle 880 is withdrawn, the vacuum may be discontinued to release the double folds of tissue or plications 890 newly formed by the suction into the vacuum chamber. The securement mechanism for the anchored suture will later be tightened to draw the plications into close contact.

After the tissue is released from the device, the suture material 878 passes through channel 894 formed between the suction ports to permit release of the system in the in-line embodiment of FIG. 40. Later, a suture lock such as the two-piece plug and ring frictional lock member 650 shown in FIGS. 30A – 34A and 41 and 42 may be advanced along the suture 878 to the proximal side 900 of the tissue. For a complete discussion of suitable suture lock devices, see co-pending PCT patent application entitled "Suture Locks, Delivery Systems and Methods" filed March 5, 2001. The suture 878 can be pulled tight through the suture lock and the lock engaged to hold the suture taut with the tissue plications 890 sandwiched between abraded regions 892 held in close contact to promote healing between them. The tissue is held tightly together because suture tag 874 and suture lock 898 serve as anchors on both sides of the double plicated tissue with the suture 878 in tension between them.

Because the tissue healing that will occur at tissue areas 892 is believed to ultimately bond the tissue portions 890 together, the suture material 878, tag 874 and lock 650 may be fabricated from biodegradable materials such as polymers of the poly-l-lactide family, configured to degrade after sufficient time for healing has occurred.

FIG. 43 shows a side-by-side multiple suction port apposition device 902 having an abrasion means 904 integrated with a partition 906 that divides the suction ports 908. In the figure, the abrasion means 904 comprises an RF energy transmitting source integrated into the partition 906. The partition may include a lens through which RF energy is transmitted to tissue. Specifically, the abrasion means 904 will contact the area directly between tissue portions that are to be joined after release from the vacuum chamber 910 of the capsule. However, other types of tissue abrasion means, such as those described above may be employed in the partition 906.

FIG. 44 shows yet another embodiment of the tissue apposition device having multiple suction ports 930 employing abrasion means 932. As with the embodiment described in connection with FIG. 43, the abrasion means may comprises an RF energy transmitting element 932 positioned midway between two suction ports 940. In this embodiment, the suction ports are angularly and longitudinally offset and do not form a uniform partition between them as was defined in the previous embodiment. However, the abrasion means may be positioned on the apposition device at any point between suction ports that will experience contact with the tissue surfaces that are to be joined during the procedure. As noted above other types of abrasion means may be employed in the location of the RF means 932.

From the forgoing it should be understood that novel and useful tissue apposition devices employing multiple suction ports and methods for their use have been provided. Various mechanisms and methods for tissue capture and tissue securement that are compatible with the apposition devices have also been presented. It should also be understood that while the inventive embodiments have illustrated in the context of forming tissue plications for GERD treatment, the invention may be used in a variety of other endoscopic procedures where tissue manipulation is required. Examples include: segregating portions of the stomach to reduce it's size in obese patients; delivery of radiopaque elements for use as fluoroscopic markers used to identify sections of cancerous colon that need to be resected by a surgeon; attachment of sensor devices, such as pH, to the gastro-intestinal wall; closure of perforations or ulcers; and creation of anastomoses.

It should be understood however, that the foregoing description of the invention is intended merely to be illustrative thereof and that other modifications, embodiments and equivalents may be apparent to those who are skilled in the art without departing from its spit. Having thus described the invention what we desire to claim and secure by letters patent is:

Claims

1. An endoscopic tissue apposition device comprising:

a capsule body having a plurality of suction ports and at least one vacuum chamber in communication with a suction port and having an air passage, the chamber configured to capture a plurality of tissue sections through the plurality of suction ports when vacuum is applied in the vacuum chamber through the air passage;

at least one needle longitudinally advanceable through the capsule body and configured to deliver a tissue securement device through the captured tissue to a though side of the tissue;

means to maintain one end of the suture on the through side of the tissue after the needle is withdrawn from the captured tissue.

2. An endoscopic tissue apposition device as defined in claim 1 wherein the capsule body comprises an injection molded polymer.

3. An endoscopic tissue apposition device as defined in claim 1 further comprising at least one hinge incorporated in the capsule body permitting longitudinal flexure of the body in at least one direction to permit passage of the capsule body through a natural body lumen.

4. An endoscopic tissue apposition device as defined in claim 3 further comprising:

selectively engageable locking rods operable to prevent the capsule body from flexing about the hinge.

5. An endoscopic tissue apposition device as defined in claim 1 further wherein:

the tissue securement mechanism comprises a suture body and the

capsule is configured to have an ejection ramp oriented to guide a suture up and away from the capsule as it is ejected from the needle.

6. An endoscopic tissue apposition device as defined in claim 1 where in the tissue securement device comprises:

a magazine configured to hold a plurality of sutures in readiness for sequential and automatic loading into the needle with each full length stroke of the needle through the suture body.

7. An endoscopic tissue apposition device as defined in claim 1 further comprising independent vacuum chambers each in dedicated communication with a suction port and configured to be independently activated to capture tissue sequentially into the suction ports.

8. An endoscopic tissue apposition device as defined in claim 1 further comprising:

a circumferential ridge surrounding and protruding from the suction port to engage and form a seal with surrounding tissue during tissue suction.

9. An endoscopic tissue apposition device as defined in claim 1 further comprising:

a capture recess formed in surfaces that define the vacuum chambers to help mechanically retain tissue captured into the chamber under vacuum.

10. An endoscopic tissue apposition device comprising:

a suturing capsule body having at least one suction port and at least one vacuum chamber in communication with a suction port to receive tissue and having an air passage, the chamber configured to capture a section of tissue within the chamber when vacuum is applied through the air passage;

at least one needle longitudinally advanceablele through the capsule

body and configured to carry suture material through the captured tissue;

means to eject the suture from the needle after it has passed through the captured tissue;

a magazine configured to hold a plurality of sutures in readiness for sequential and automatic loading into the needle with each full length stroke of the needle through the suture body.

11. An endoscopic tissue apposition device comprising:

a sewing capsule body having at least one suction port and at least vacuum chamber to receive tissue having a plurality of surfaces and an air passage, the vaccum chamber configured to capture tissue within the chamber when vacuum is applied through the air passage;

a needle longitudinally advanceable through the capsule body and configured to carry suture material through the captured tissue;

a suture ejection mechanism operably associated with the needle to eject the suture from the needle after it has passed through the captured tissue;

a hinge incorporated in the capsule body permitting longitudinal flexure of the body in at least one direction to permit passage of the body through a natural body lumen.

12. A method of fabricating an endoscopic tissue apposition device comprising:

injection molding a polymer material into a configuration of a sewing capsule body having at least one suction port in communication with at least one vacuum chamber defined by at least one surface and having an air passage for communication with a source of vacuum, each port configured to receive a section of tissue into the chamber when vacuum is applied through the air passage

the capsule also configured to guide at least one needle in longitudinal movement along a path that traverses a suction port.

13. A method of joining internal body tissue endoscopically comprising:

providing an endoscopic tissue apposition device having multiple suction ports attached to a distal end of an endoscope;

navigating the distal end of the endoscope and tissue apposition device to the treatment site;

applying vacuum to the tissue apposition device to capture at least two portions of tissue through the suction ports

advancing a tissue securement mechanism through at least one of the tissue portions to secure the portions together in a plication form.

14. A method of joining internal body tissue endoscopically as defined in claim 13 where in the step of advancing a tissue securement mechanism further comprises:

passing a needle carrying a suture through at least one section of tissue to a through side of the tissue;

ejecting one end of the suture from the needle on the through side of the tissue;

withdrawing the needle from the tissue;

discontinuing vacuum to release the tissue from the apposition device;

tightening and securing the suture in the tissue.

15. A method of joining internal body tissue endoscopically as defined in claim 14 further comprising:

providing in the tissue apposition device a magazine capable of holding multiple sutures that is operatively associated with the needle to reload the needle with a suture after each complete stroke of the needle through the tissue apposition device;

advancing the needle to deliver a suture through the portions of tissue;

withdrawing the needle from the tissue;

releasing the tissue from the tissue apposition device;

relocating the tissue apposition device to a new area of tissue and capturing that tissue in the sewing device by reapplying a vacuum;

reloading the needle with a suture from the magazine;

repeating the method of claim 13 to place a plurality of sutures in a plurality of tissue locations.

16. A method as defined in claim 14 wherein one end of the suture remains anchored against the through side of the tissue and the free end of the suture is secured against the tissue in a secondary step.

17. An endoscopic tissue apposition device comprising a capsule body having a plurality of suction ports, each having a vacuum chamber to receive tissue having an air passage, each chamber configured to capture a section tissue within the chamber when vacuum is applied through the air passage;

a tissue securement device;

and a tissue securement device advancement mechanism configured to place the tissue securement device through the portions captured tissue and release from the securement device after advancement.

18. An endoscopic tissue apposition device comprising:

a capsule body having a plurality of suction ports to receive tissue;

at least one vacuum chamber in communication with at least two suction ports;

a tissue securement device; and

a tissue securement device advancement mechanism configured to place a tissue securement device through a section of captured tissue and release from the securement device after advancement.

19. An endoscopic tissue apposition device comprising:

a tissue capture mechanism;

a tissue securement device for securing captured tissue; and
tissue abrasion means.

20. An endoscopic tissue apposition device as defined in claim 19 wherein the tissue abrasion mechanism comprises an electrically activated element.

21. An endoscopic tissue apposition device as defined in claim 19 wherein the tissue abrasion mechanism further comprises a transmitter of radio frequency energy.

22. An endoscopic tissue apposition device as defined in claim 19 wherein the tissue abrasion mechanism further comprises a transmitter of laser energy to abrade tissue.

23. An endoscopic tissue apposition device as defined in claim 19 wherein the tissue abrasion mechanism further comprises a transmitter of ultrasonic energy to abrade tissue.

24. An endoscopic tissue apposition device as defined in claim 19 wherein the tissue abrasion mechanism comprises means for releasing a chemically abrasive substance.

25. A tissue apposition device as defined in claim 19 wherein the tissue abrasion mechanism includes means for releasing a biomedical substance to cause tissue abrasion.

26. An endoscopic tissue apposition device as defined in claim19 wherein the tissue abrasion mechanism abrades tissue mechanically by causing frictional contact with the tissue.

27. An endoscopic tissue apposition device as defined in claim 26 wherein mechanical abrasion is achieved by delivering through the abrasion mechanism a biocompatible mechanically abrasive substance to the tissue.

28. An endoscopic tissue apposition device as defined in claim 26 wherein the tissue abrasion mechanism further comprises a mechanical element configured to frictionally engage tissue.

29. An endoscopic tissue apposition device as defined in claim 19 wherein the capture mechanism comprises at least one vacuum chamber adapted to receive a double fold of tissue.

30. An endoscopic tissue apposition device as defined in claim 19 wherein the tissue securement device comprises a staple.

31. An endoscopic tissue apposition device as defined in claim 19 wherein the tissue securement mechanism comprises a suture.

32. An endoscopic suturing device comprising:

a sewing capsule body having a plurality of suction ports, an opening to receive tissue and at least one vacuum chamber in communication with the suction ports and in communication with a source of vacuum, each chamber configured to hold a double layer of tissue within the chamber when vacuum is applied through the suction ports;

a needle longitudinally slidable through the capsule body and configured to carry suture materials through the captured tissue;

means to eject the suture from the needle after it has passed through the captured tissue;

at least one tissue abrasion mechanism on the sewing capsule body adjacent to the opening of at least suction port.

33. An endoscopic suturing device as defined in claim 32 wherein the abrasion mechanism is positioned centrally between adjacent suction port on the capsule body.

34. An endoscopic suturing device as defined in claim 32 wherein the tissue abrasion mechanism comprises an electrically activated element.

35. An endoscopic tissue device as defined in claim 32 wherein the tissue abrasion mechanism comprises a transmitter of radio frequency energy.

36. An endoscopic suturing device as defined in claim 32 wherein the tissue abrasion mechanism comprises a transmitter of laser energy to abrade tissue.

37. An endoscopic suturing device as defined in claim 32 wherein the tissue abrasion mechanism comprises a transmitter of ultrasonic energy to abrade tissue.

38. An endoscopic suturing device as defined in claim 32 wherein the tissue abrasion mechanism comprises means for releasing a chemically abrasive substance.

39. A tissue suturing device as defined in claim 32 wherein the tissue abrasion mechanism includes means for releasing a biomedical substance to cause tissue abrasion.

40. An endoscopic tissue apposition device as defined in claim 32 wherein the tissue abrasion mechanism abrades tissue mechanically by causing frictional contact with the tissue.

41. An endoscopic tissue apposition device as defined in claim 40 wherein mechanical abrasion is achieved by delivering through the abrasion mechanism a biocompatible mechanically abrasive substance to the tissue.

42. An endoscopic tissue apposition device as defined in claim 40 wherein the tissue abrasion mechanism further comprises a mechanical element configured to frictionally engage tissue.

43. A method of adjoining adjacent areas of internal tissue comprising:

providing an endoscopic tissue apposition device configured to temporarily capture at least one area of internal tissue, abrade an area of the tissue and apply a tissue securement device to hold captured areas of tissue in apposition, at least temporarily;

capturing at least one area of tissue;

abrading an area of the tissue;

applying a securement device through the captured tissue;

releasing the tissue;

repositioning the apposition device to an adjacent area of tissue;

capturing a portion of the adjacent tissue;

abrading an area of the adjacent tissue;

applying a tissue securement device through the tissue;

releasing the tissue and withdrawing the apposition device from the patient;

joining the tissue securement devices together to bring the subject tissue areas into contact, at least in the areas that have been abraded.

44. A method of adjoining adjacent areas of internal tissue as defined in claim 25 further comprising:

the step of increasing the amount of captured tissue after the abrasion step and prior to applying the tissue securement device.

45. A method of adjoining adjacent areas of internal tissue comprising:

providing a tissue apposition device configured to capture a plurality of tissue areas in a single positioning, having a tissue abrasion mechanism and configured to deliver at least one tissue securement device through the areas of captured tissue;

capturing a plurality of tissue areas;

abrading an area of tissue at least between the areas of captured tissue;

applying a tissue securement device through the captured areas of tissue and releasing the captured areas of tissue.

46. A method of adjoining adjacent areas of internal tissue as defined in claim 45 further comprising:

the step of increasing the amount of captured tissue after the step of abrading the tissue and prior to the step of applying a tissue securement device through the areas of tissue.

47. An endoscopic tissue apposition device comprising:

a capsule body having a plurality of suction ports and at least one vacuum chamber in communication with a suction port and having an air passage, the chamber configured to capture a plurality of tissue sections through the plurality of suction ports when vacuum is applied in the vacuum chamber;

at least one needle longitudinally advanceable through the capsule body and configured to deliver a suture through the captured tissue to a though side of the tissue;

means to maintain one end of the suture on the through side of the tissue after the needle is withdrawn form the captured tissue.

48. An endoscopic tissue apposition device as defined in claim 1 wherein

the suction ports are arranged longitudinally in-line and the needle advances along a pathway that traverses both suction ports to penetrate captured tissue portions.

49. An endoscopic tissue apposition device as defined in claim 1 wherein two suction ports are arranged side by side and the needle is forked and arranged in the capsule such that each fork of the needle traverses a suction port during longitudinal advancement to penetrate captured tissue portions.

50 An endoscopic tissue apposition device as defined in claim 49 wherein the tissue securement device comprises sutures joined to suture tags that are releasably carried at the distal ends of the forks and are configured to be ejected from the needle after tissue penetration by the needle.

51. An endoscopic tissue apposition device as defined in claim 50 wherein the suture tags have sharp distal tips that serve to pierce the tissue during needle advancement.

52. An endoscopic tissue apposition device as defined in claim 50 wherein the tissue securement device additionally comprises a tag lock releasably securable to the capsule and comprising a lock block having at least one tag receptacle for receiving and capturing a suture tag that is being advanced through tissue at the distal end of a needle.

53. An endoscopic tissue apposition device as defined in claim 52 wherein the lock block of a tag lock aligned with one fork of the needle is joined to a tag carried by the opposing fork of the needle by a suture.

54. An endoscopic tissue apposition device as defined in claim 52 wherein the lock block further comprises a passage sized to permit suture material to slide through.

55. An endoscopic tissue apposition device as defined in claim 1 wherein two suction ports are arranged side by side and a plurality of independently advanceable needles are provided and arranged so that each needle may be advanced to traverse a single dedicated suction port to penetrate captured tissue portions.

56. An endoscopic tissue apposition device as defined in claim 55 wherein the capsule is configured to provide a needle pathway having a diverter that causes the needles to divert from a path along the longitudinal axis of the capsule to a path away from the longitudinal axis but directed to the suction port to which the given needle is dedicated.

57. An endoscopic tissue apposition device as defined in claim 55 wherein each suction port is in communication with a dedicated vacuum chamber.

58. An endoscopic tissue apposition device as defined in claim 56 wherein four suction supports are provided arranged in two sets of two on the top and bottom of the capsule.

59 An endoscopic tissue apposition device as defined in claim 55 wherein the tissue securement device comprises sutures joined to suture tags that are releasably carried at the distal ends of the needles and are configured to be ejected from the needles after tissue penetration by the needles.

60. An endoscopic tissue apposition device as defined in claim 55 wherein the suture tags have sharp distal tips that serve to pierce the tissue during needle advancement.

61. An endoscopic tissue apposition device as defined in claim 55 wherein the tissue securement device additionally comprises a tag lock releasably securable to the capsule and comprising a lock block having at least one tag receptacle for receiving and capturing a suture tag that is being advanced through tissue at the distal end of a needle.

62. An endoscopic tissue apposition device as defined in claim 61 wherein the lock block of a tag lock aligned with one fork of the needle is joined to a tag carried by the needle dedicated to the other suction port.

63. An endoscopic tissue apposition device as defined in claim 61 wherein the lock block further comprises a passage sized to permit suture material to slide through.

64. An endoscopic tissue apposition device as defined in claim 1 wherein two suction ports are arranged on the capsule to be angularly and longitudinally offset from each other and a plurality of independently advanceable needles are provided and arranged so that each needle may be advanced to traverse a single dedicated suction port to penetrate captured tissue portions.

65. An endoscopic tissue apposition device comprising:

a capsule body having a plurality of suction ports and at least one vacuum chamber in communication with a suction port and the chamber having an air passage, the chamber configured to capture a plurality of tissue sections through the plurality of suction ports when vacuum is applied in the vacuum chamber through the air passage;

at least one tissue implant longitudinally advanceable through the capsule body and configured to penetrate tissue during advancement and

configured to be released from the capsule to hold the plurality of tissue portions together after advancement completed.

66. An endoscopic tissue apposition device as defined in claim 65 wherein the implant comprises a helical coil.

67. An endoscopic tissue apposition device as defined in claim 66 wherein the coil is coated with a bulking agent.

68. A method of joining internal body tissue endoscopically as defined in claim 13 wherein the step of advancing a tissue securement mechanism further comprises:

passing a forked needle carrying a sutures at its forks through a plurality of sections of tissue to a through side of the tissues;

ejecting one end of each suture from the forks of the needle on the through side of the tissue;

withdrawing the needle from the tissue;

discontinuing vacuum to release the tissue from the apposition device;

tightening and securing the suture in the tissue.

69. A method of joining internal body tissue endoscopically as defined in claim 13 where in the step of advancing a tissue securement mechanism further comprises:

independently advancing a plurality of needles each carrying a sutures at through a plurality of sections of tissue to a through side of the tissues;

ejecting one end of each suture from the forks of the needle on the through side of the tissue;

withdrawing the needle from the tissue;

discontinuing vacuum to release the tissue from the apposition device;

tightening and securing the suture in the tissue.

70. A method of joining internal body tissue endoscopically as defined in claim 13 wherein four tissue sections are captured through four suction ports and secured together with one intubation of the endoscope.

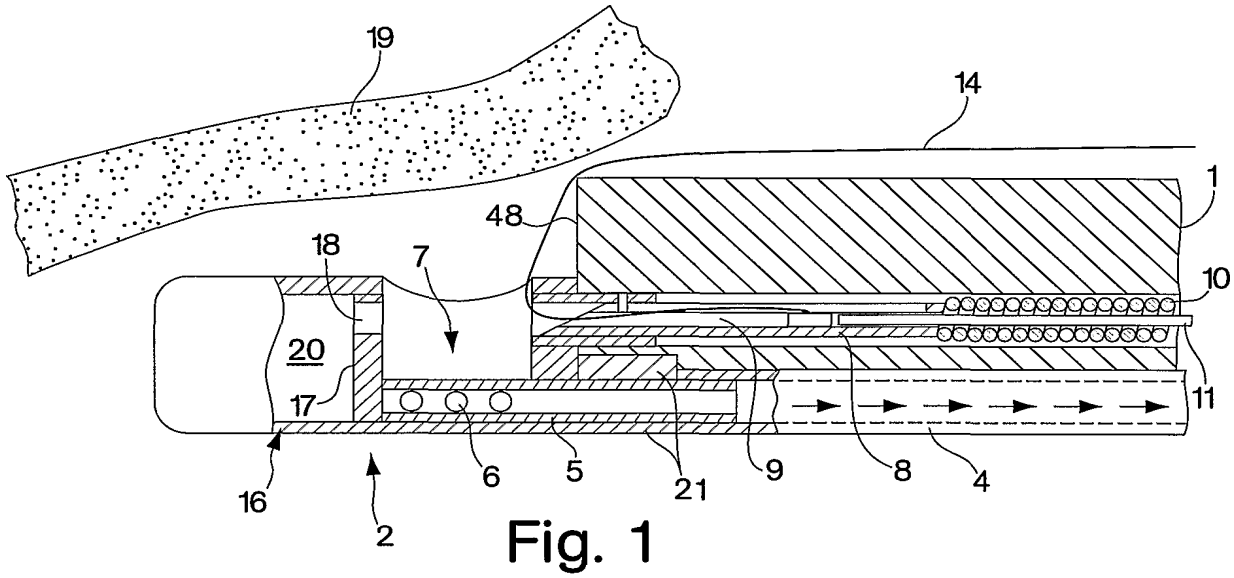


Fig. 1
(PRIOR ART)

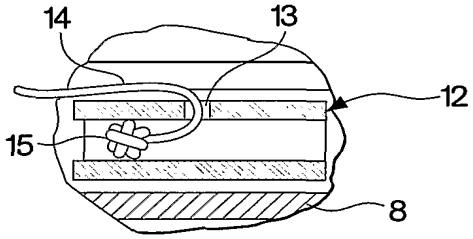


Fig. 1A
(PRIOR ART)

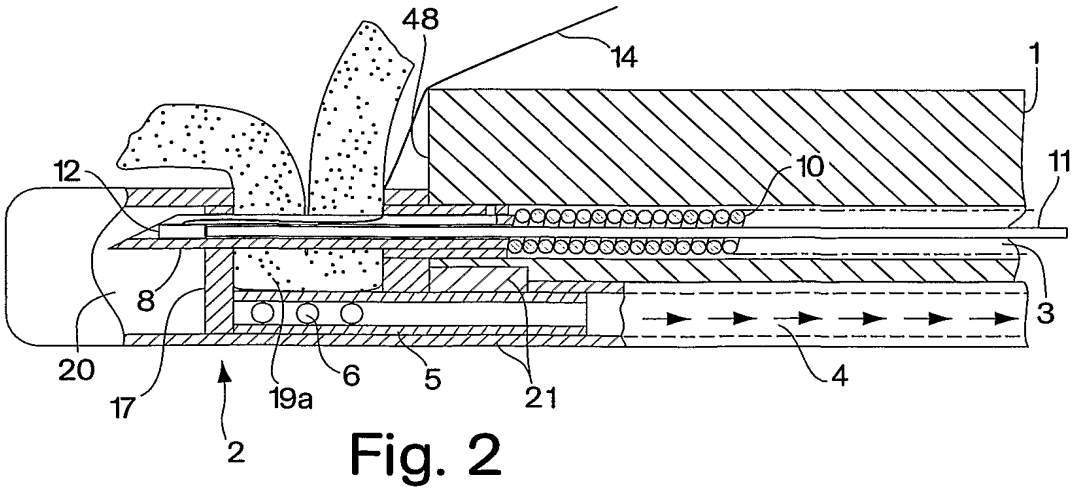


Fig. 2
(PRIOR ART)

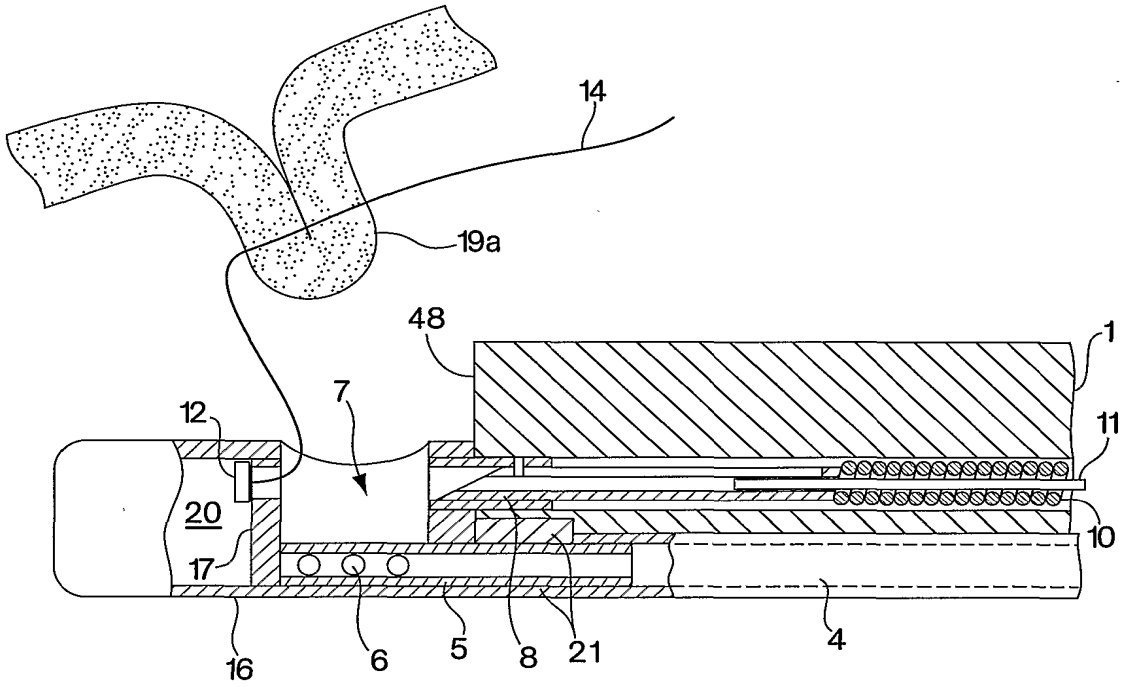


Fig. 3
(PRIOR ART)

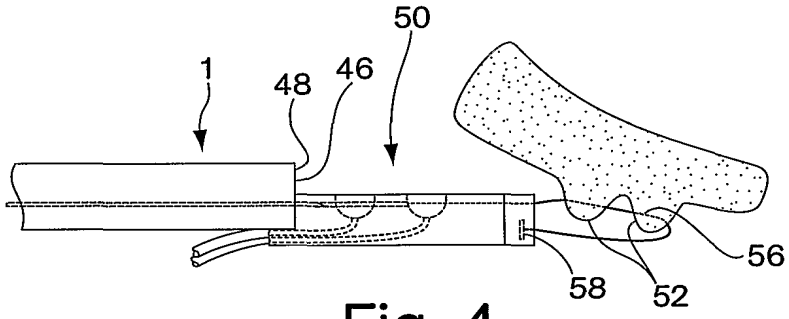


Fig. 4

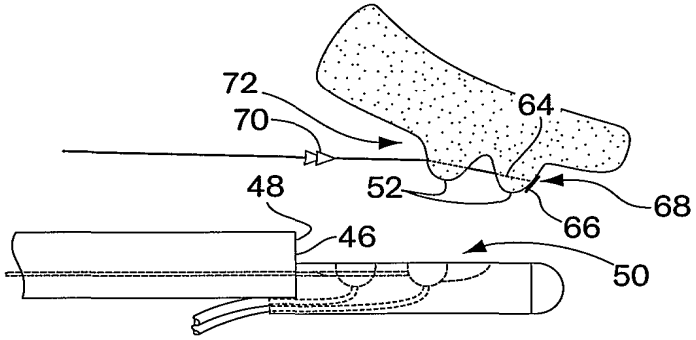


Fig. 5

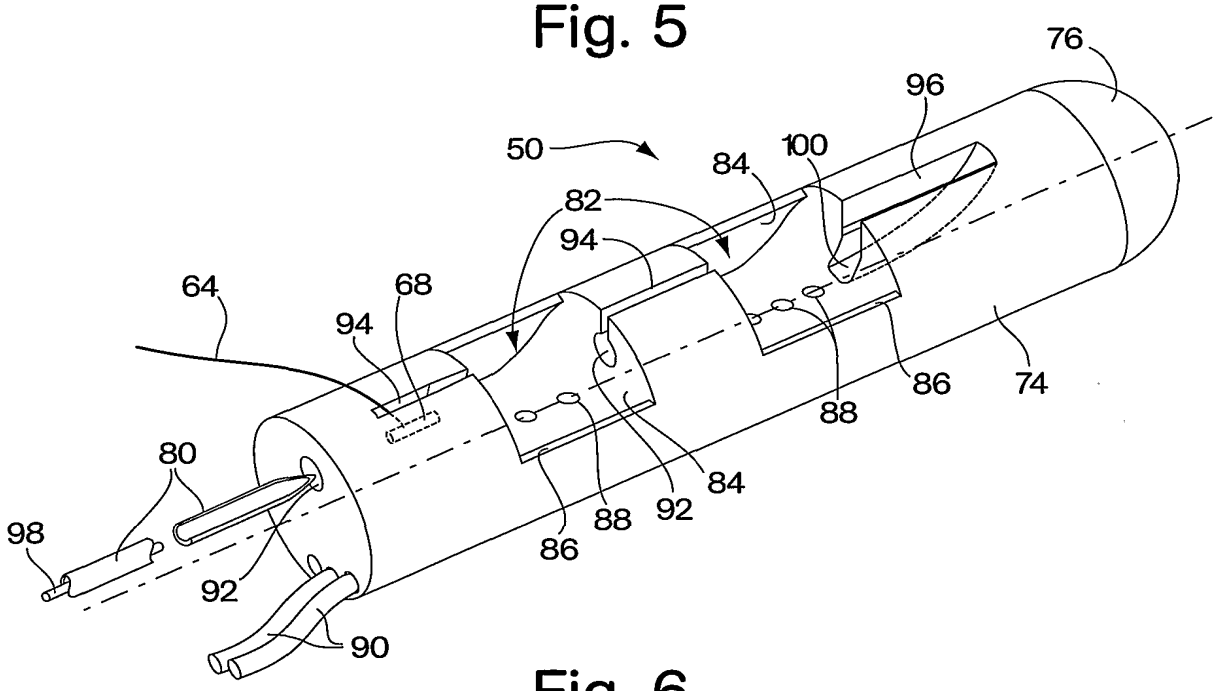


Fig. 6

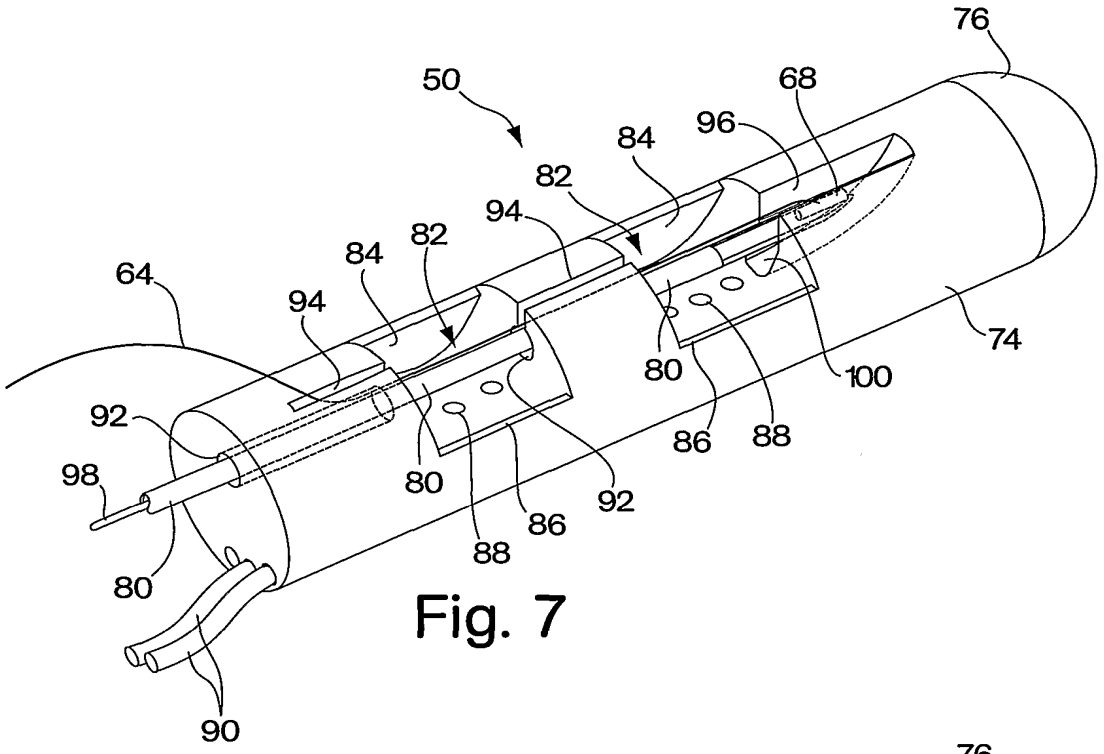


Fig. 7

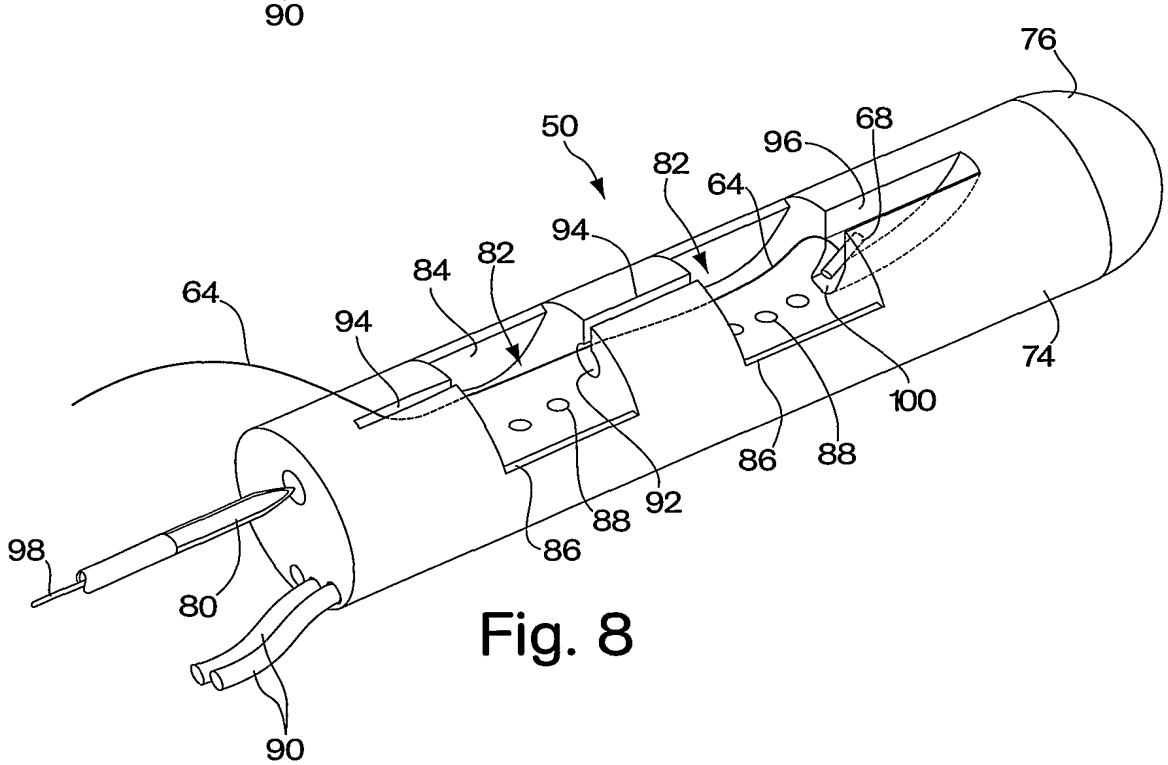


Fig. 8

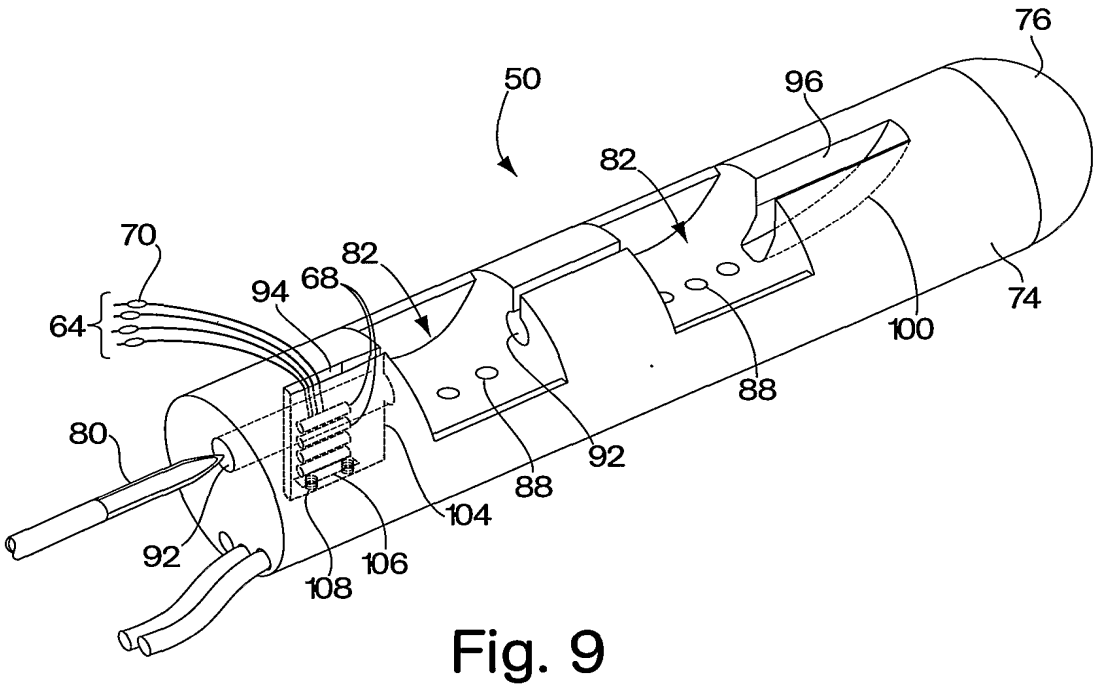


Fig. 9

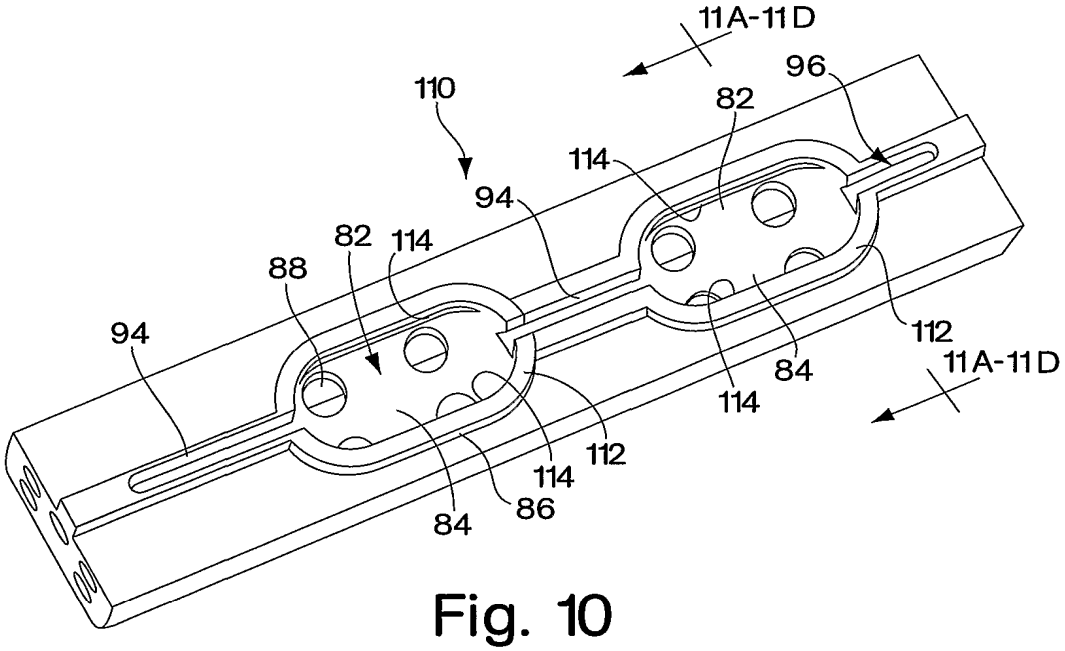


Fig. 10

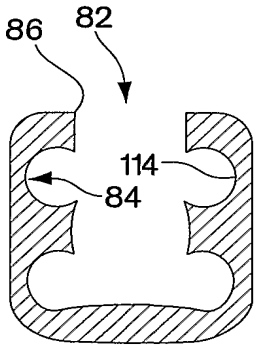


Fig. 11A

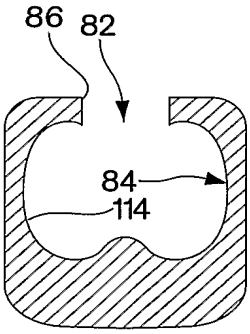


Fig. 11B

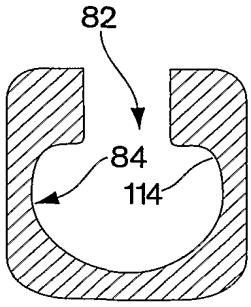


Fig. 11C

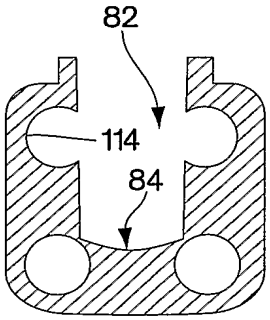


Fig. 11D

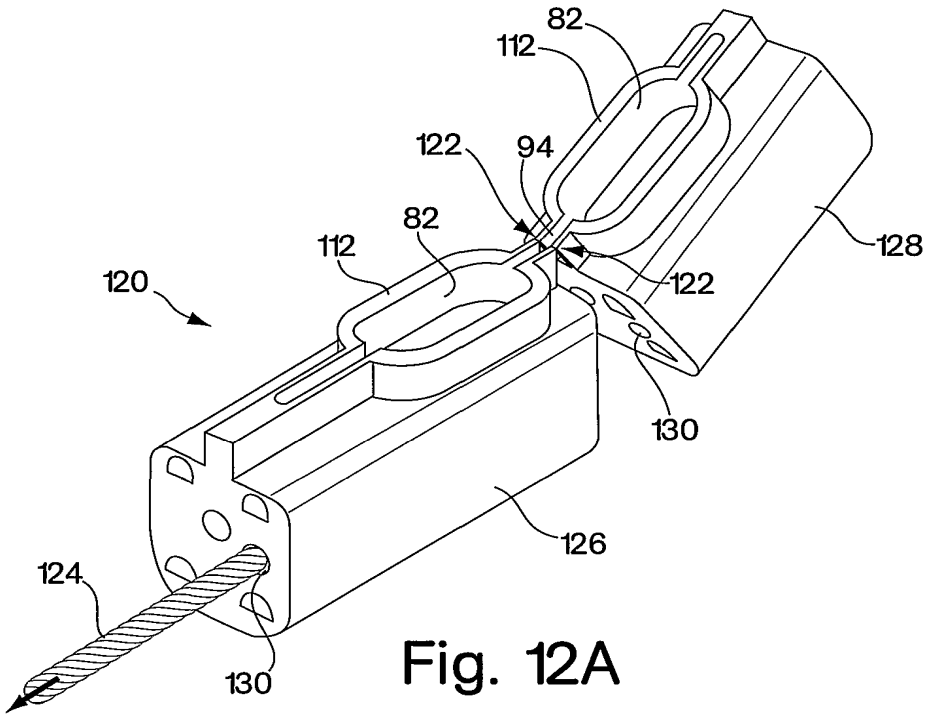


Fig. 12A

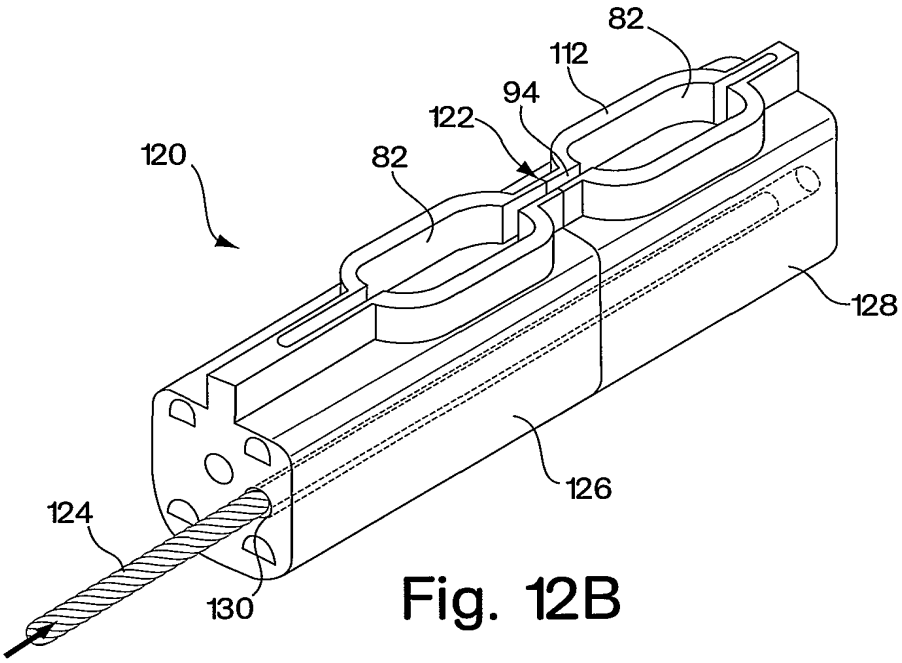


Fig. 12B

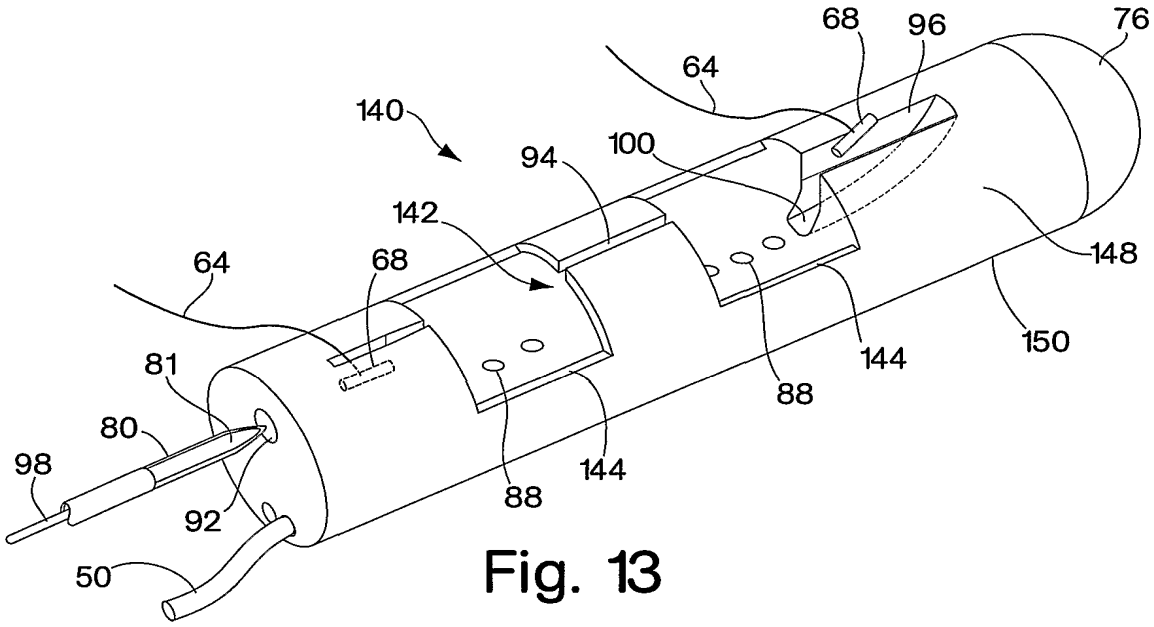


Fig. 13

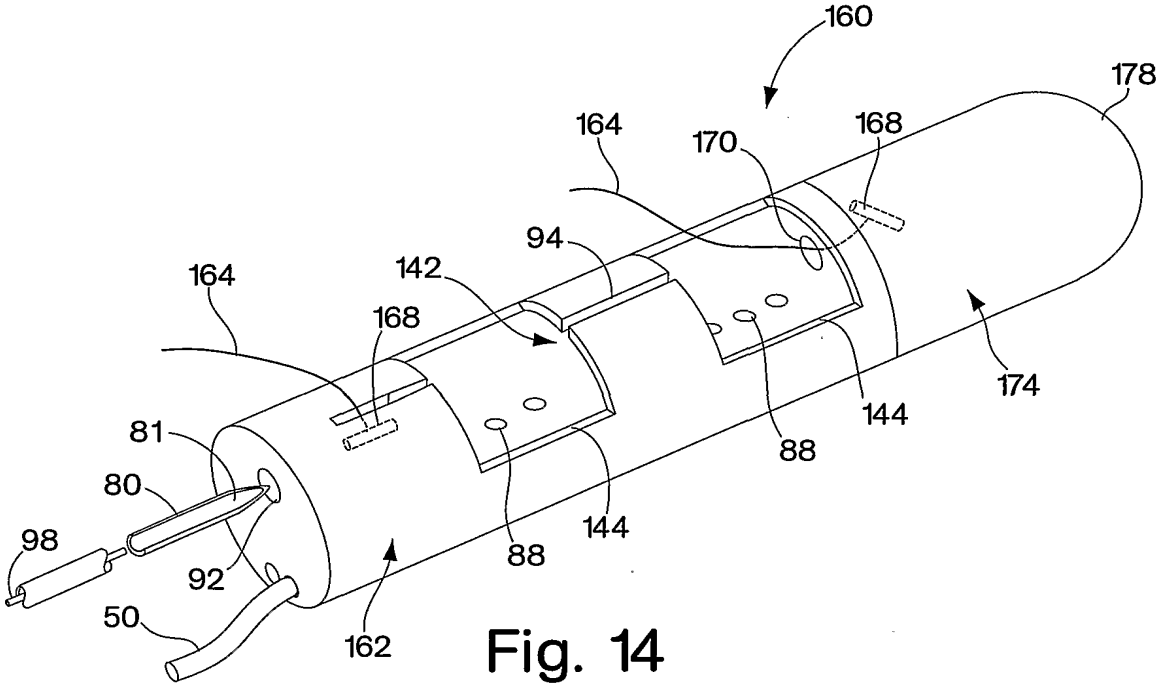


Fig. 14

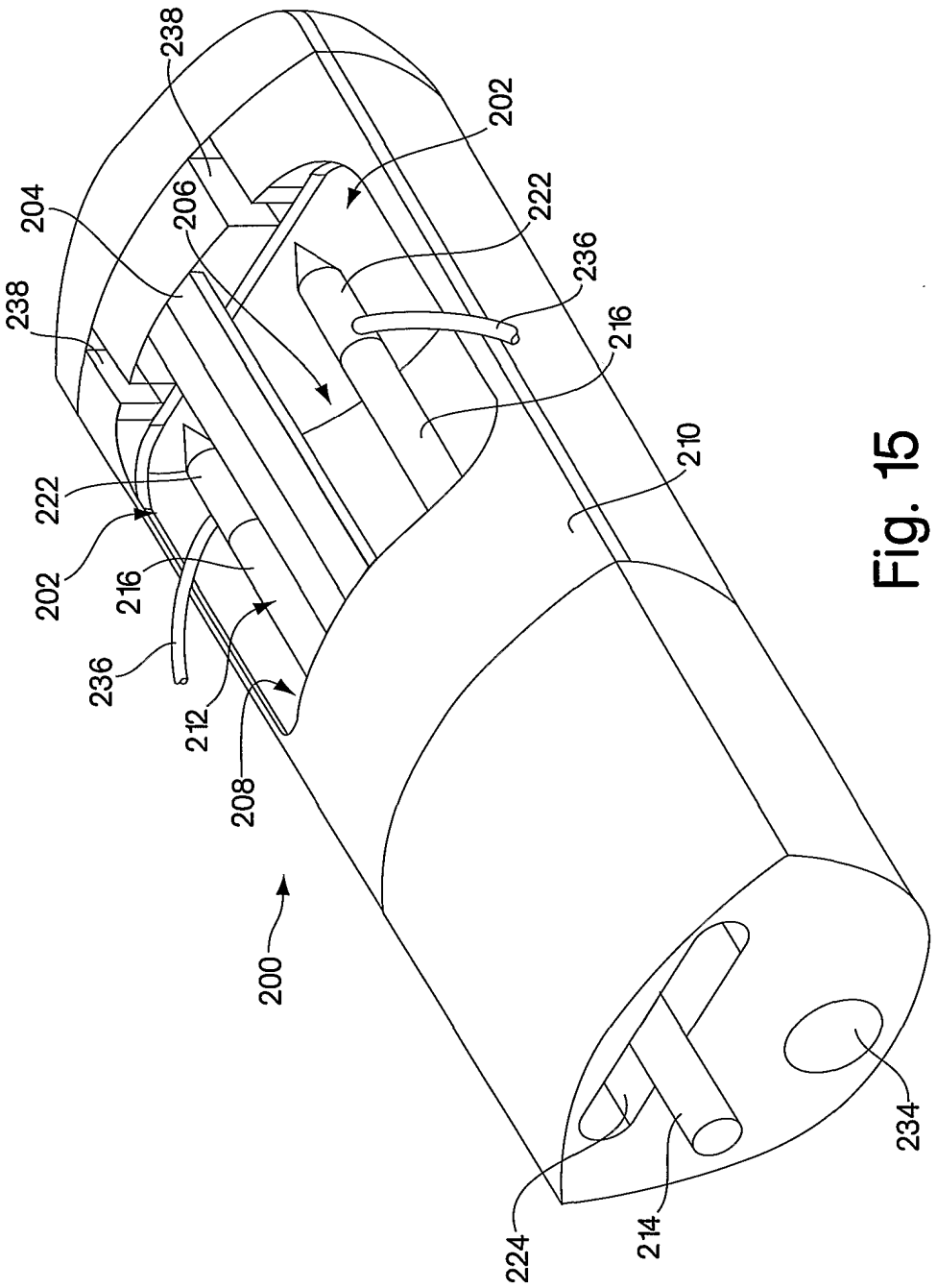


Fig. 15

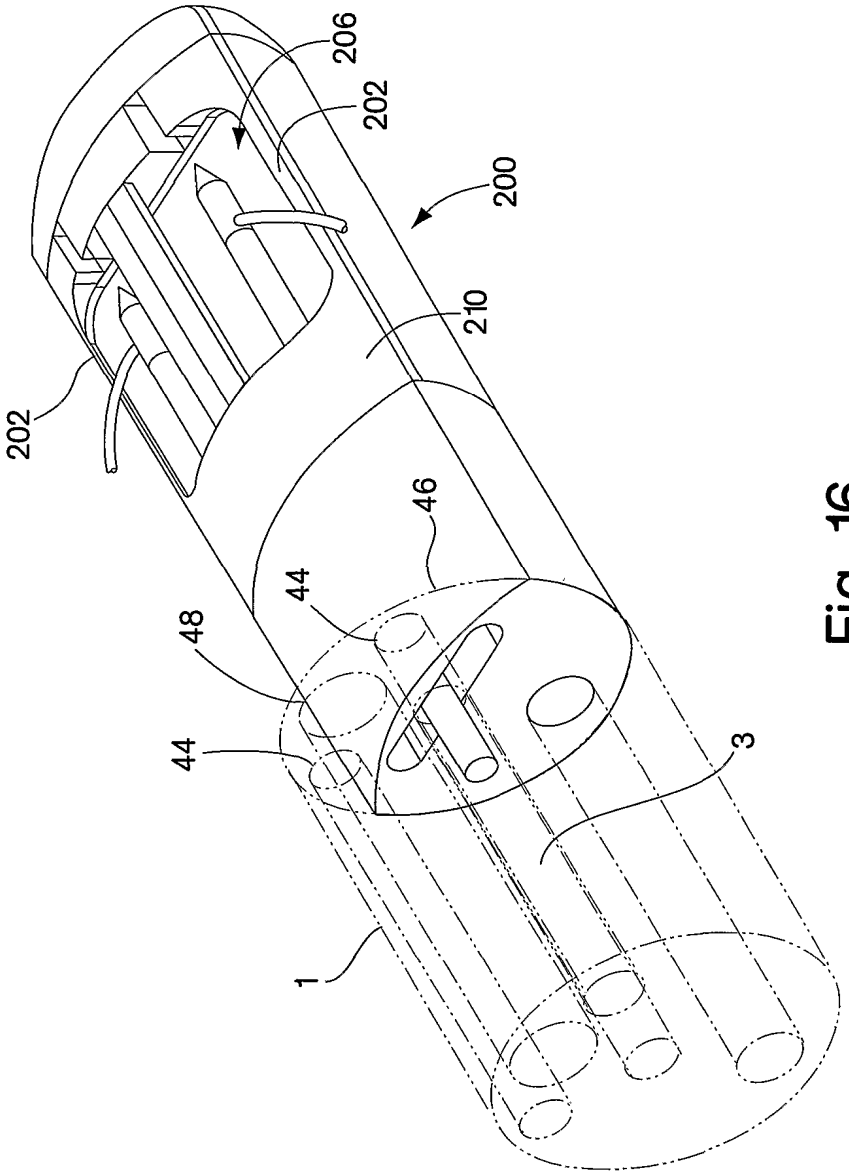


Fig. 16

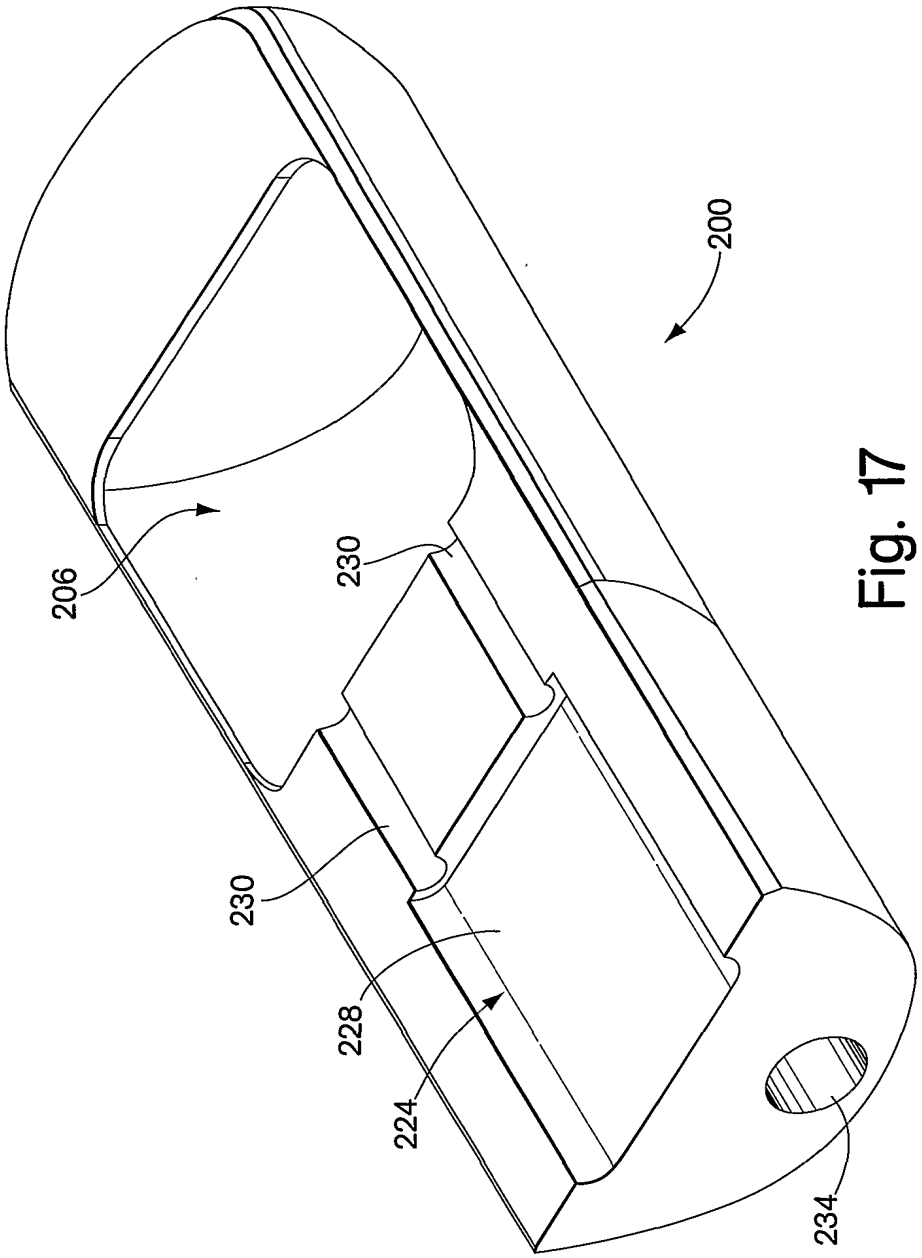
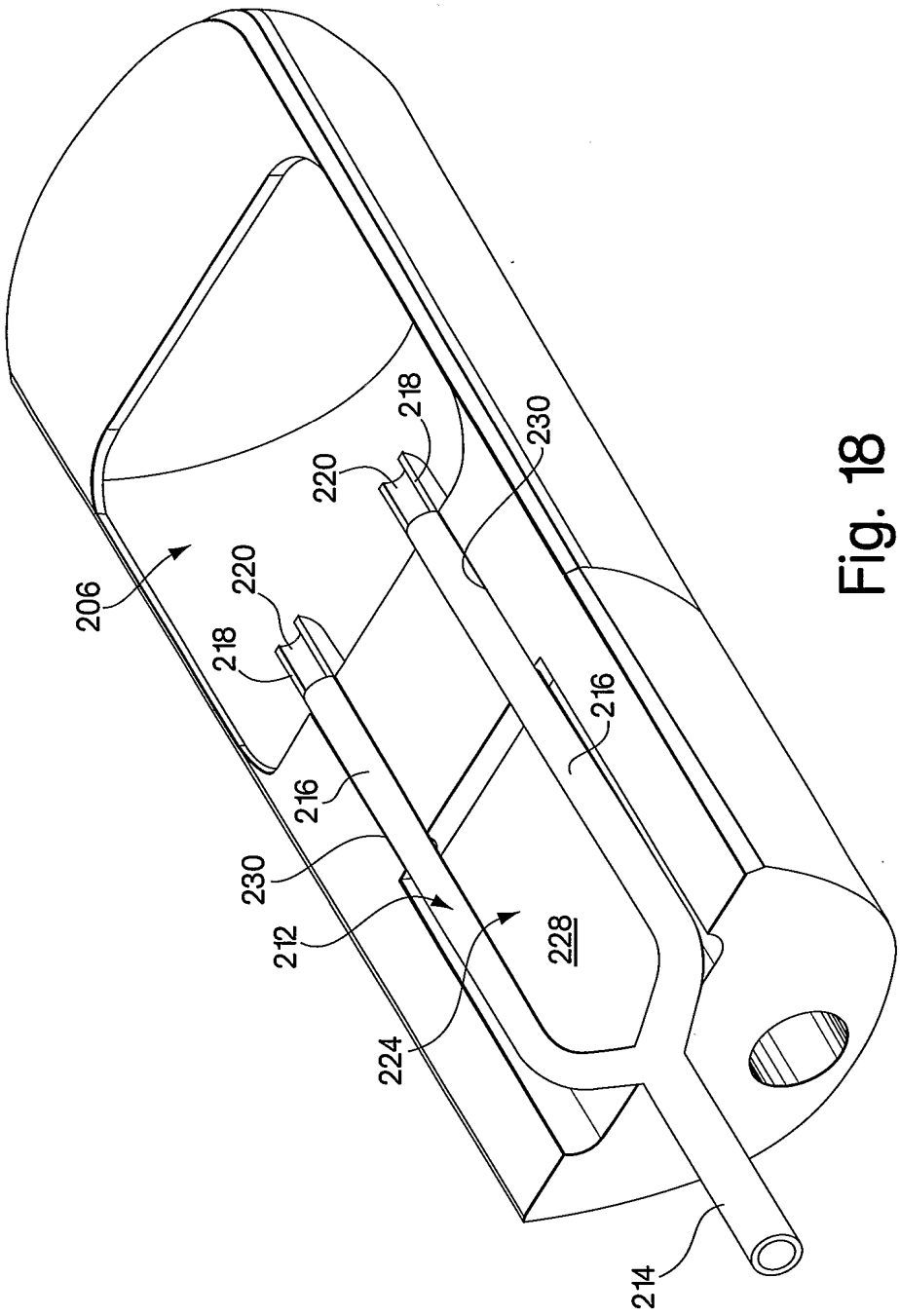


Fig. 17



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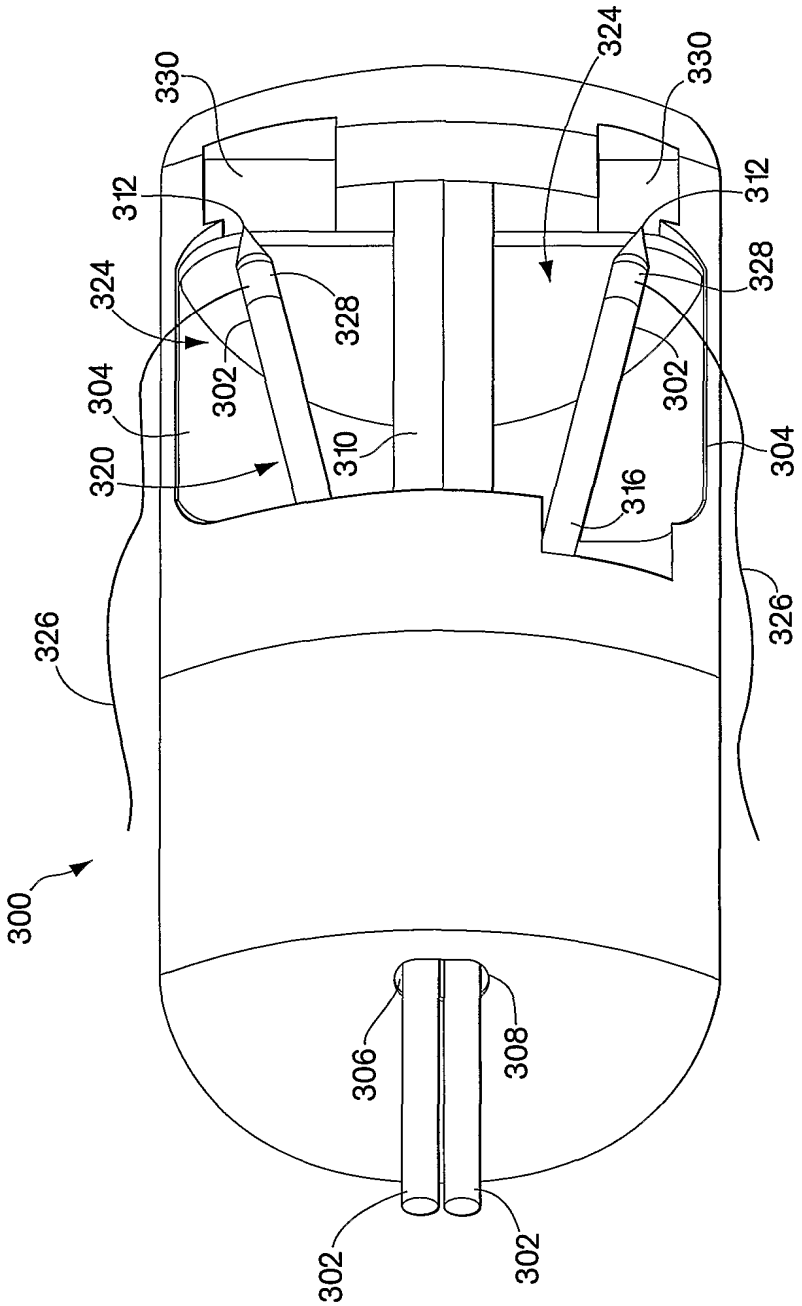

Fig. 19

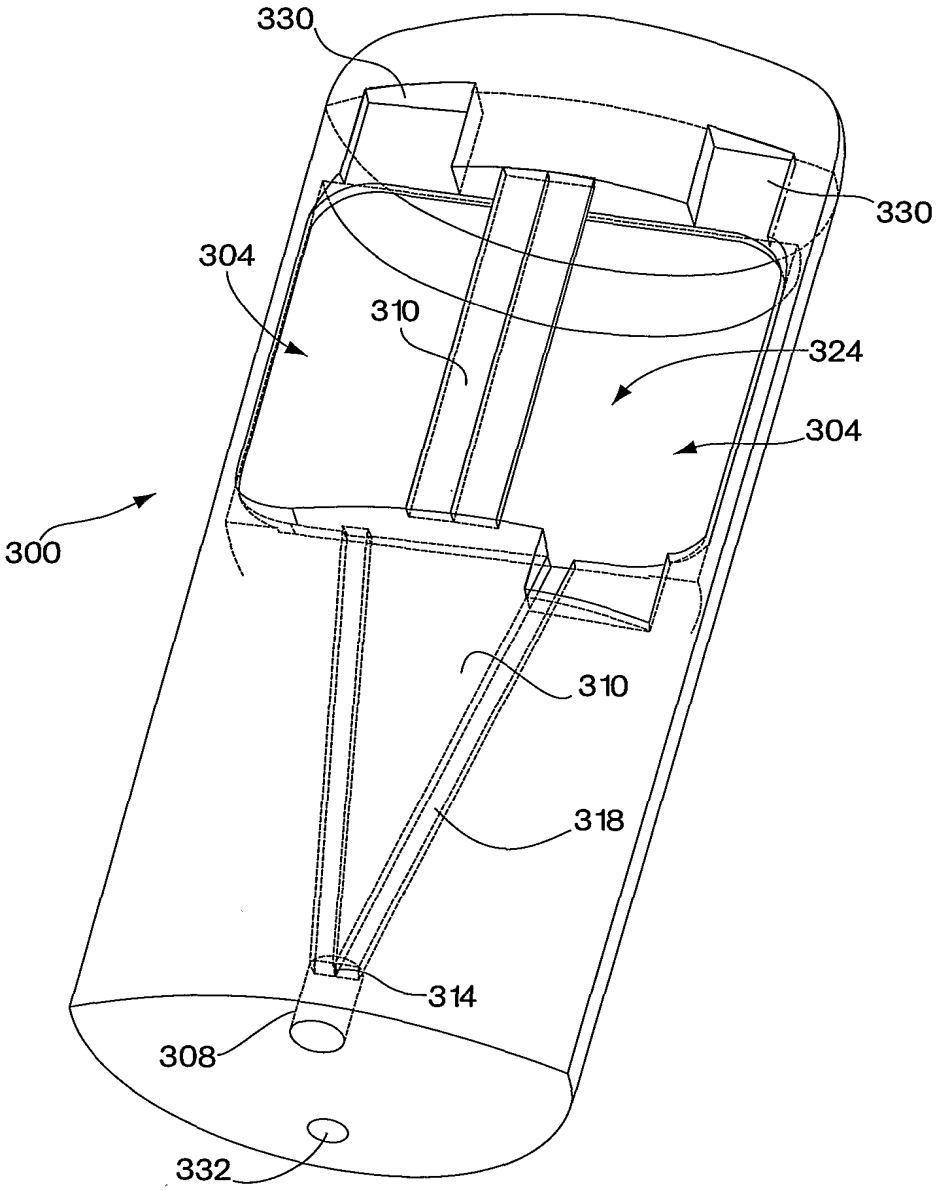

Fig. 20

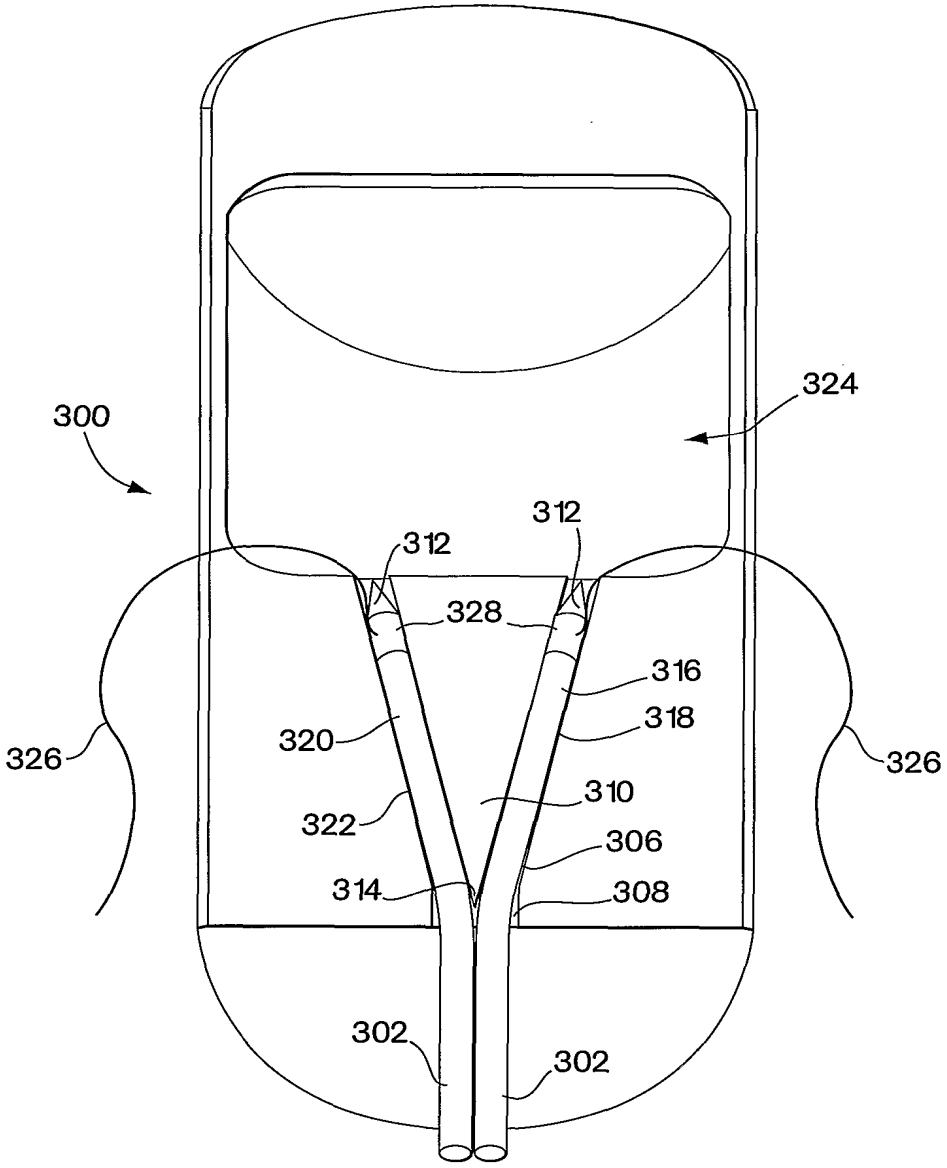

Fig. 21

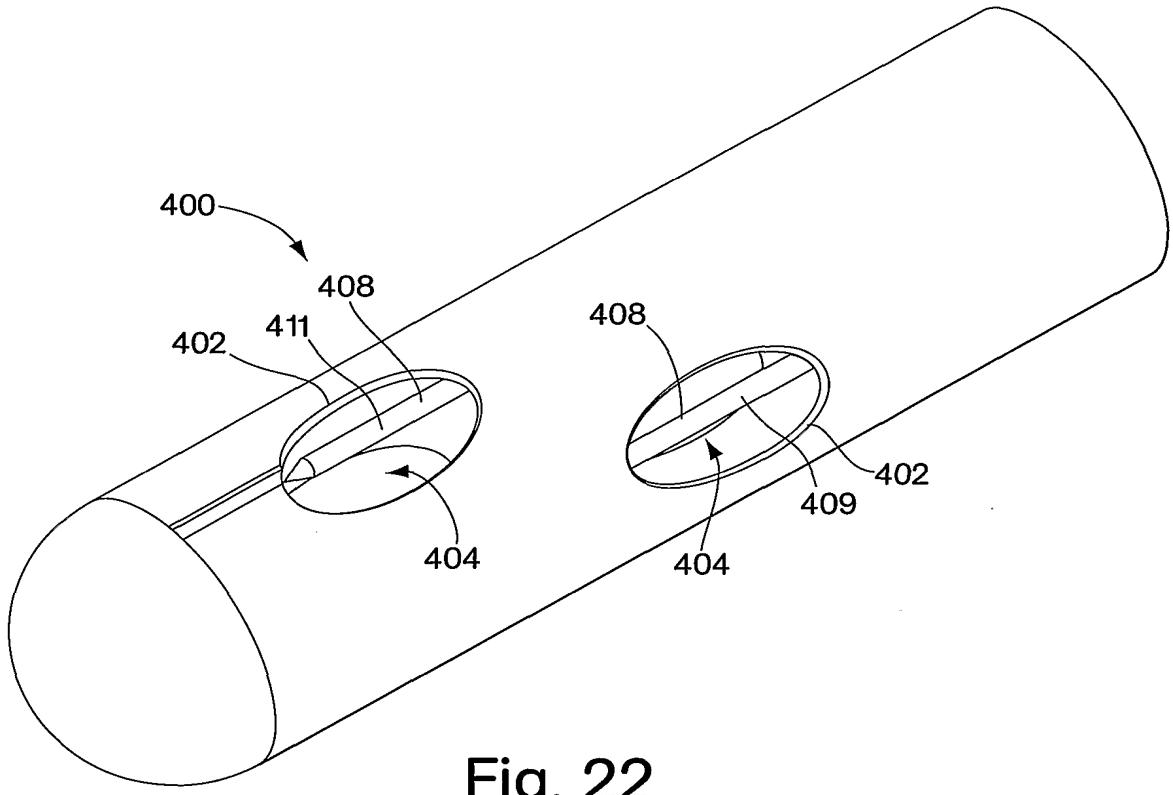

Fig. 22

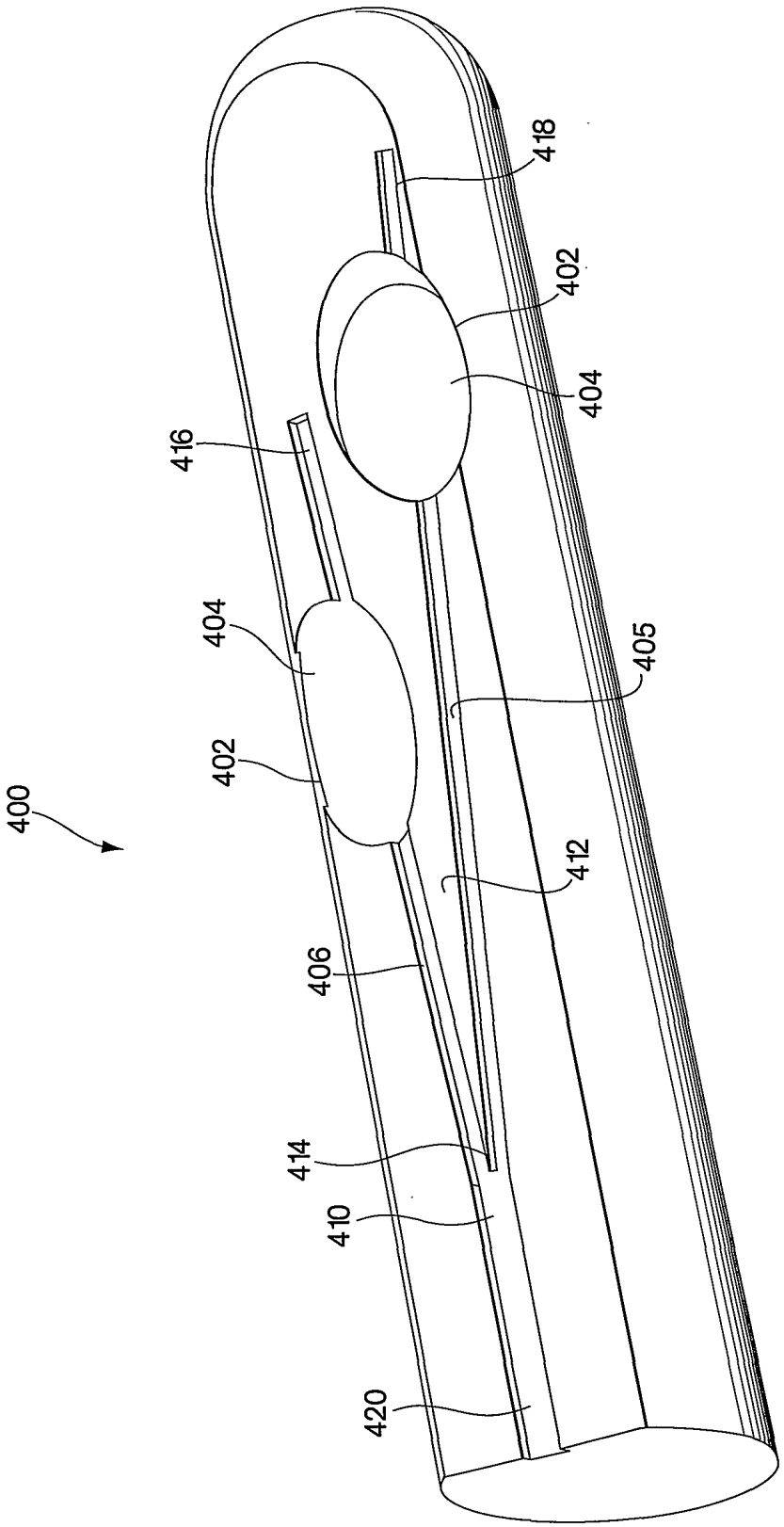

Fig. 23

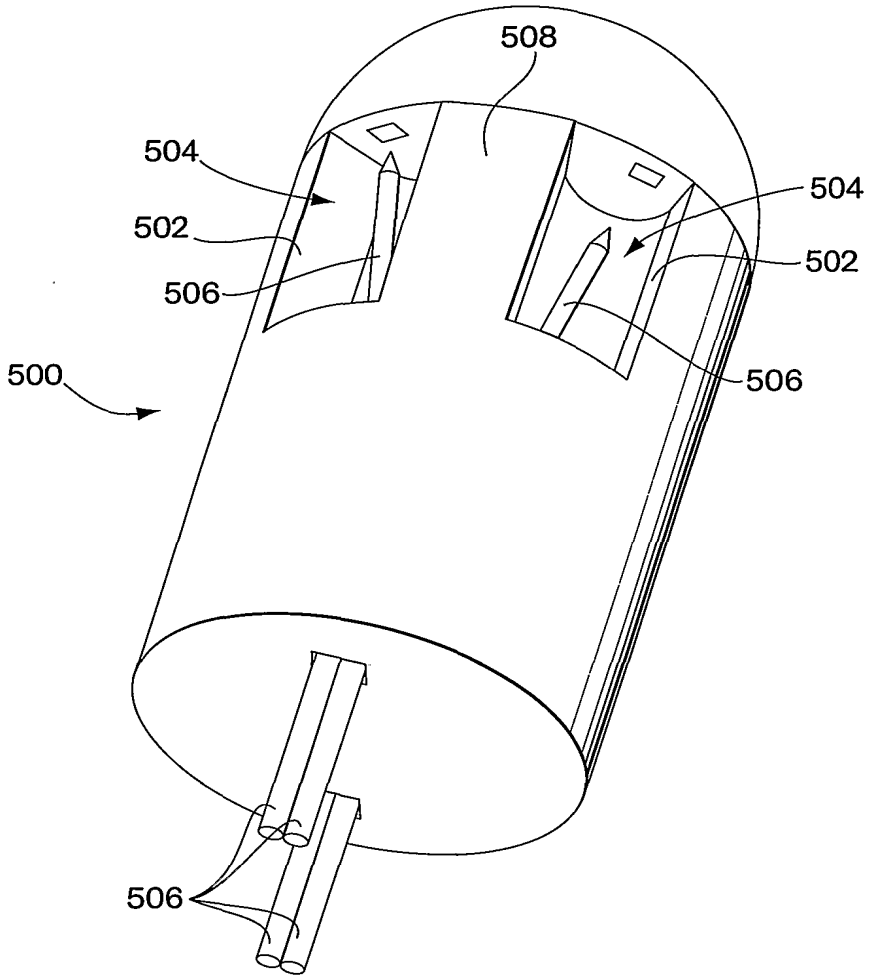

Fig. 24

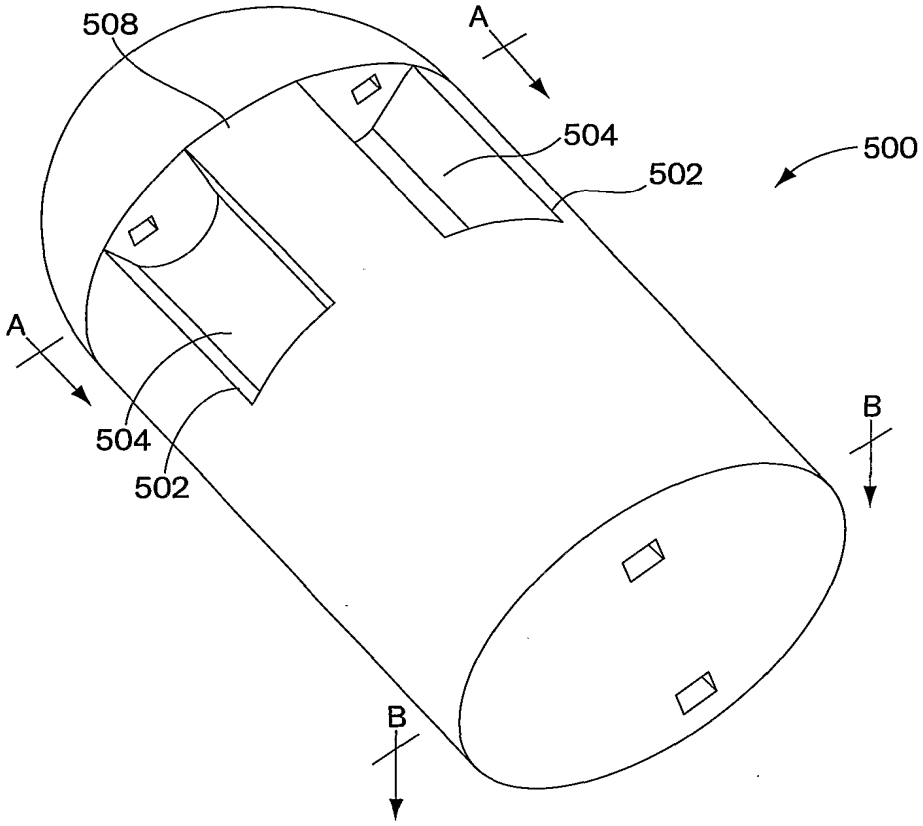

Fig. 25

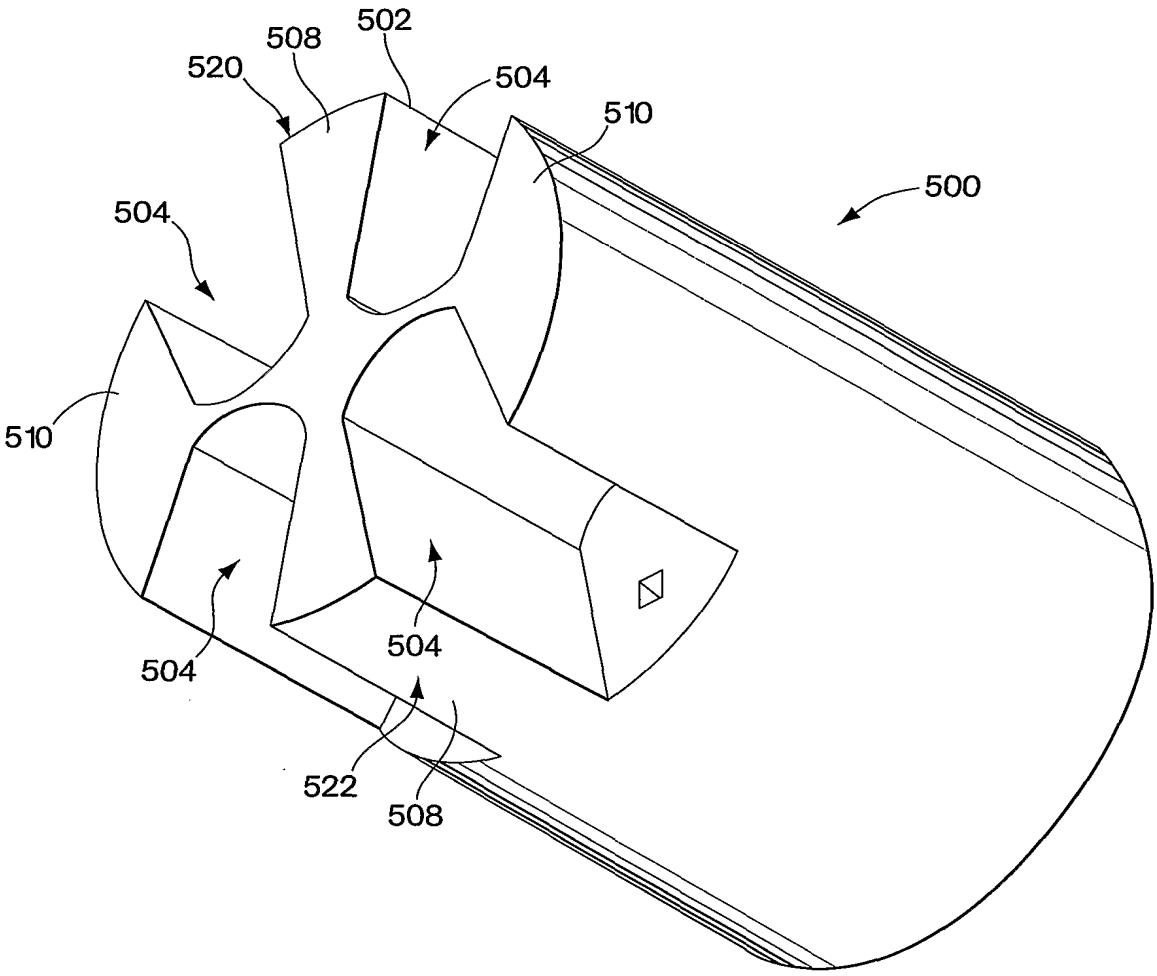

Fig. 26

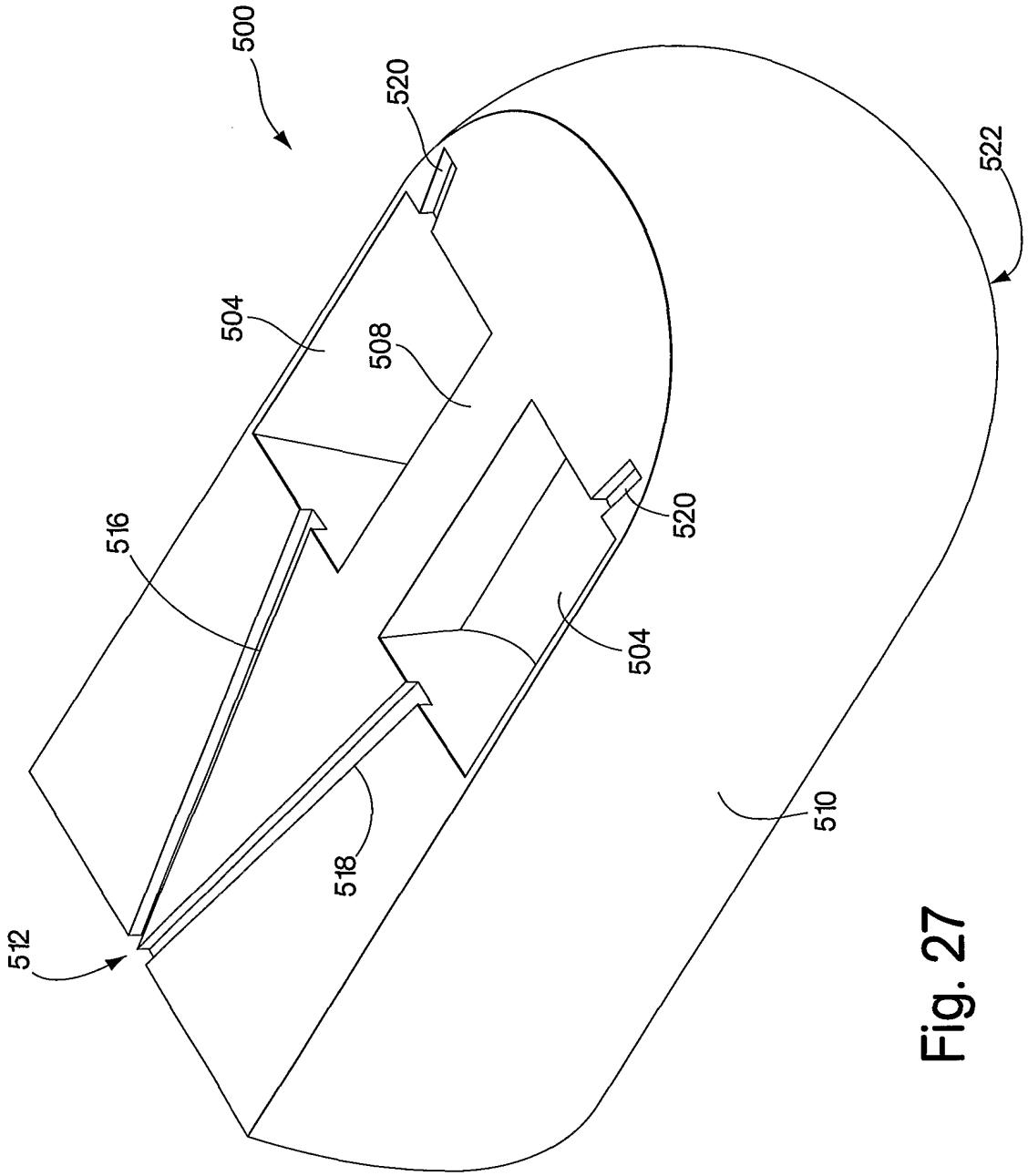

Fig. 27

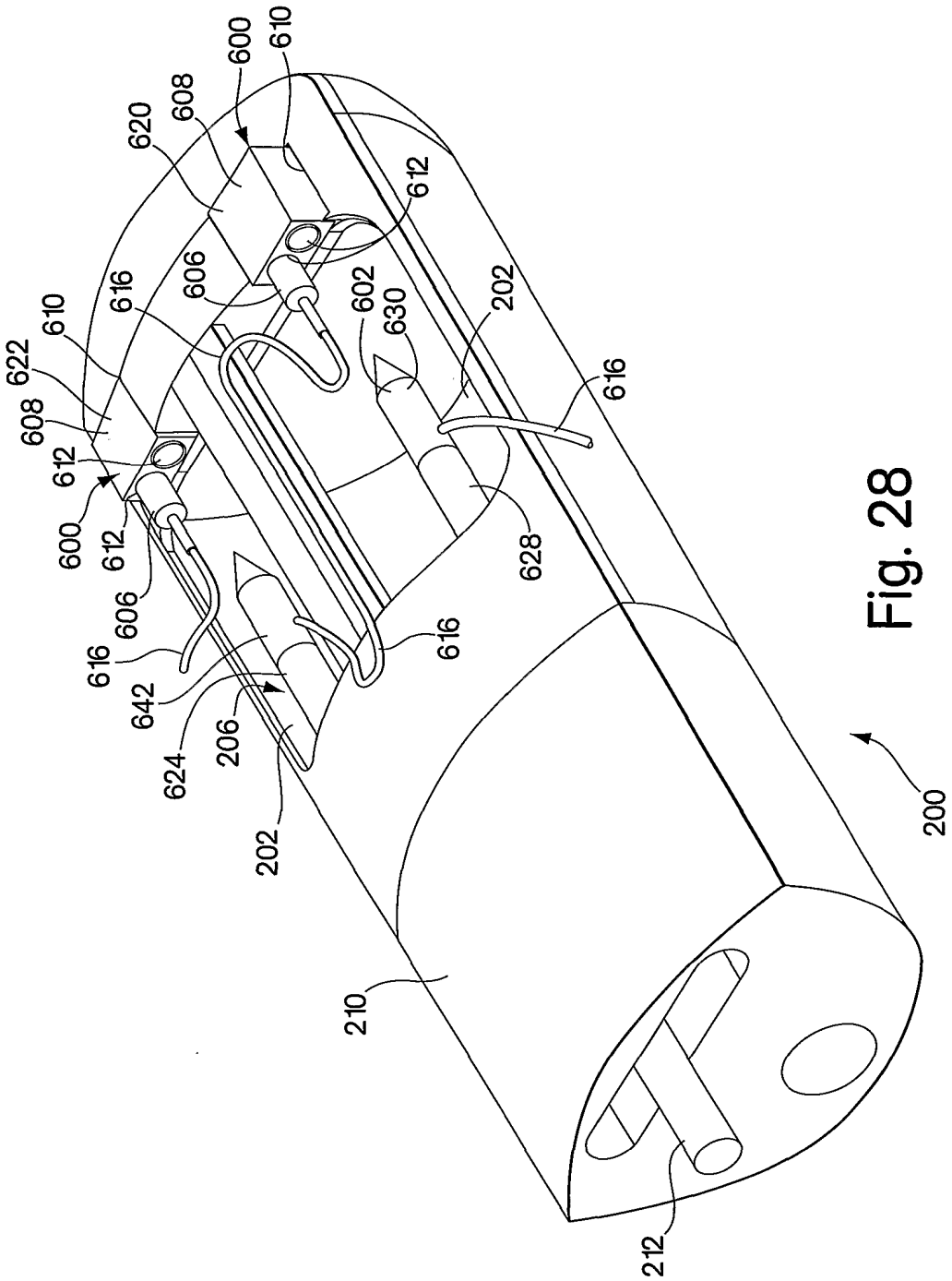

Fig. 28

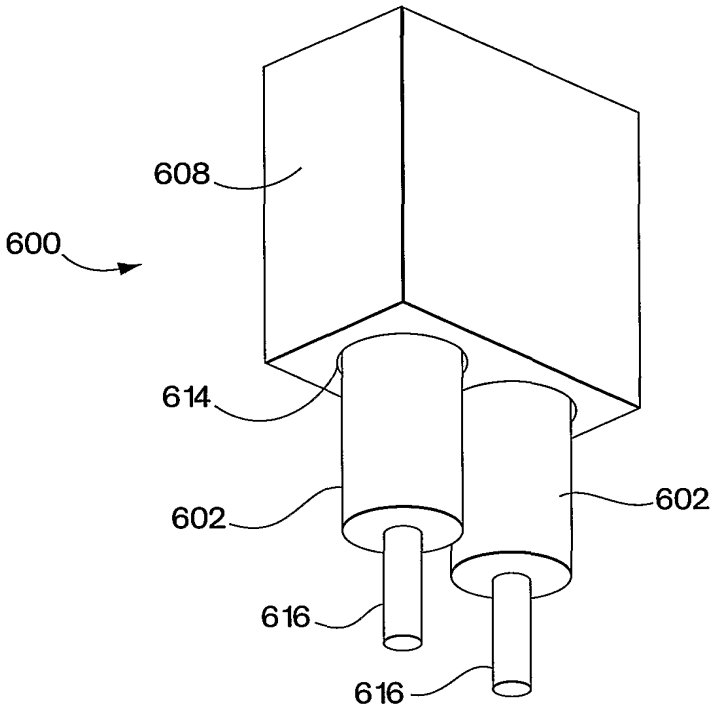

Fig. 29A

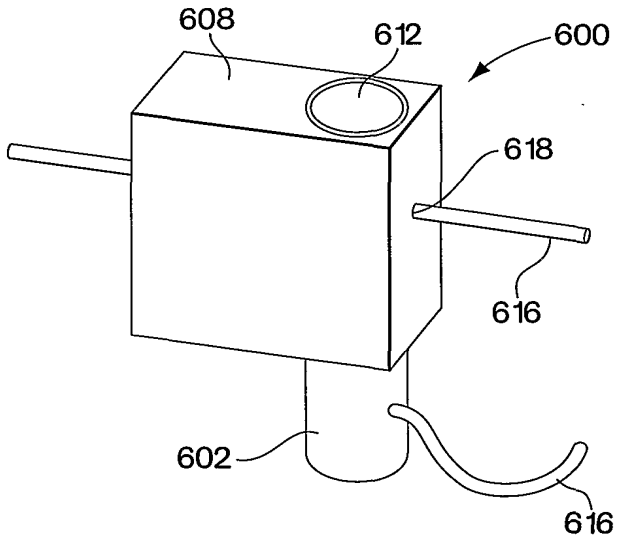

Fig. 29B

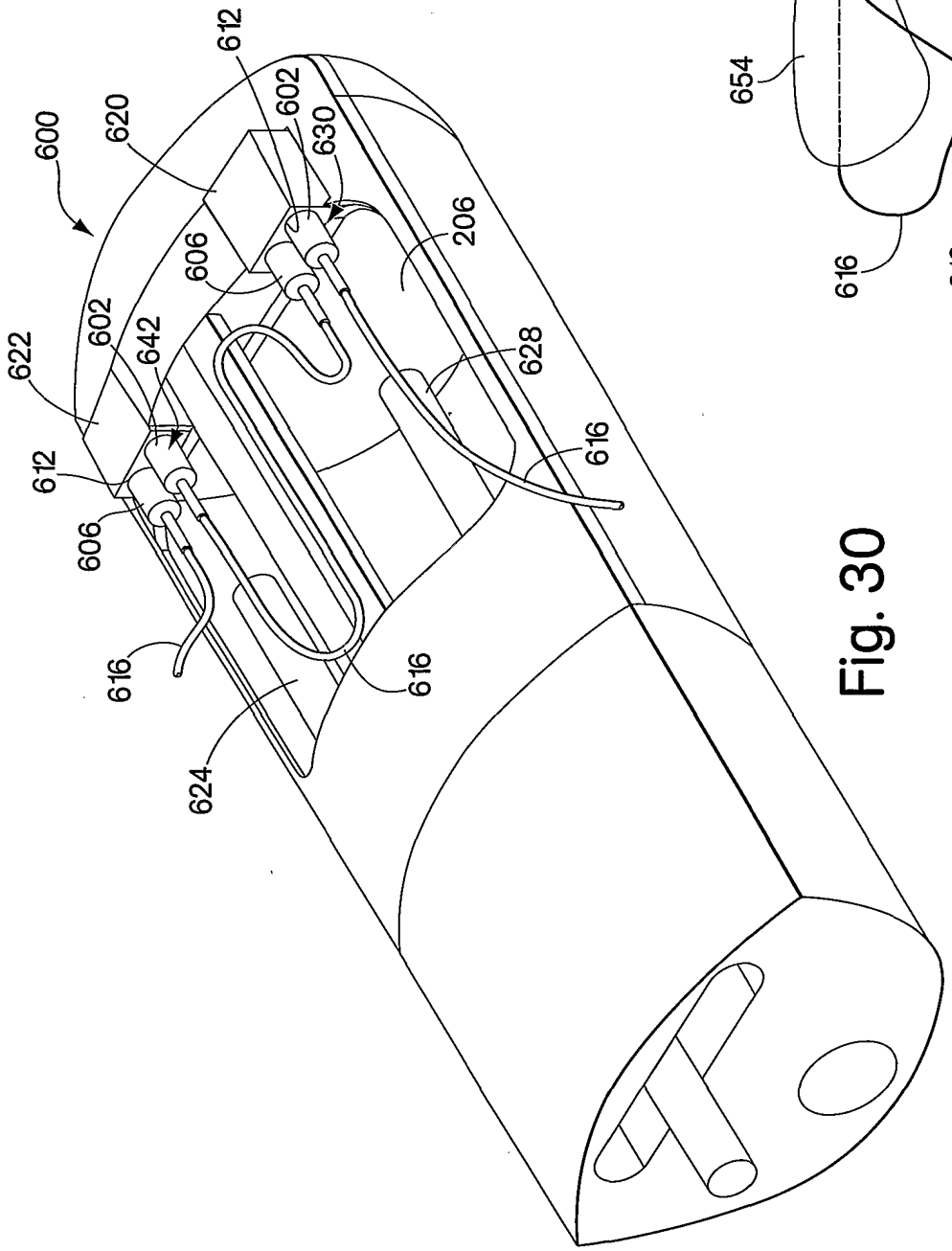

Fig. 30

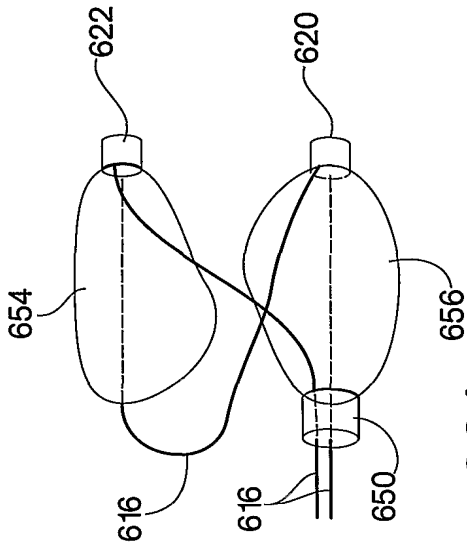

Fig. 30A

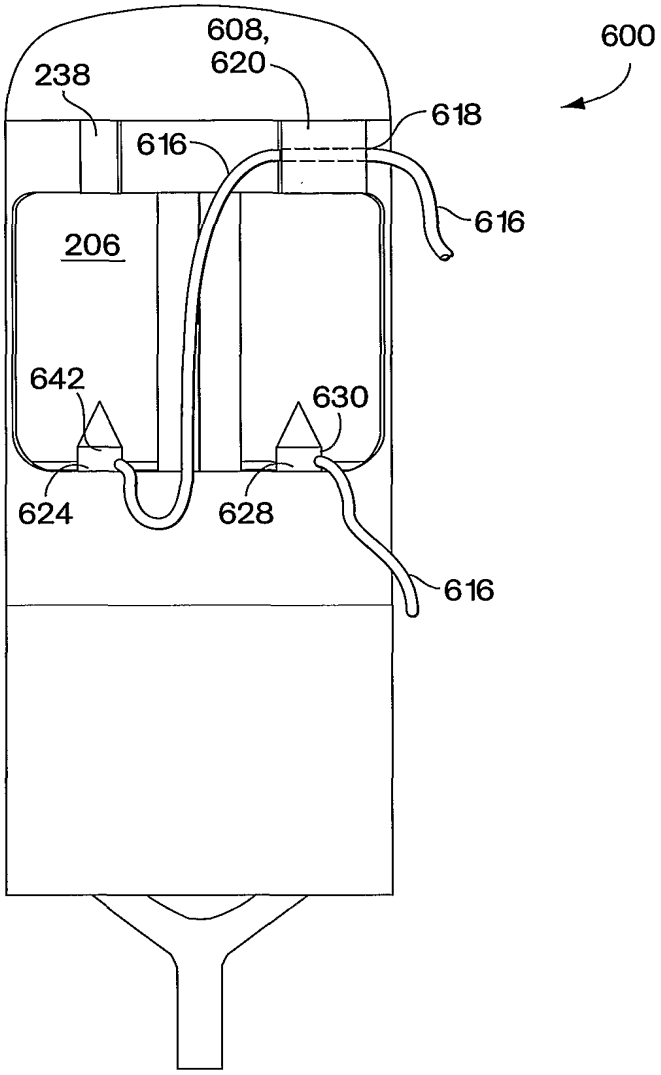

Fig. 31

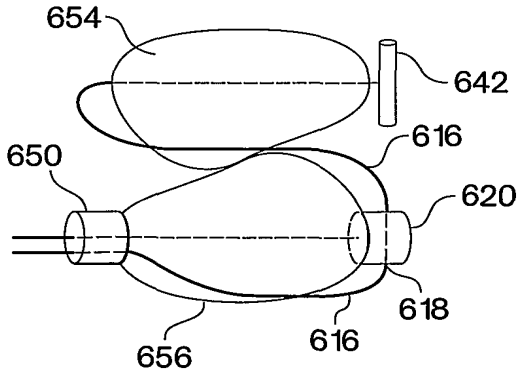

Fig. 31A

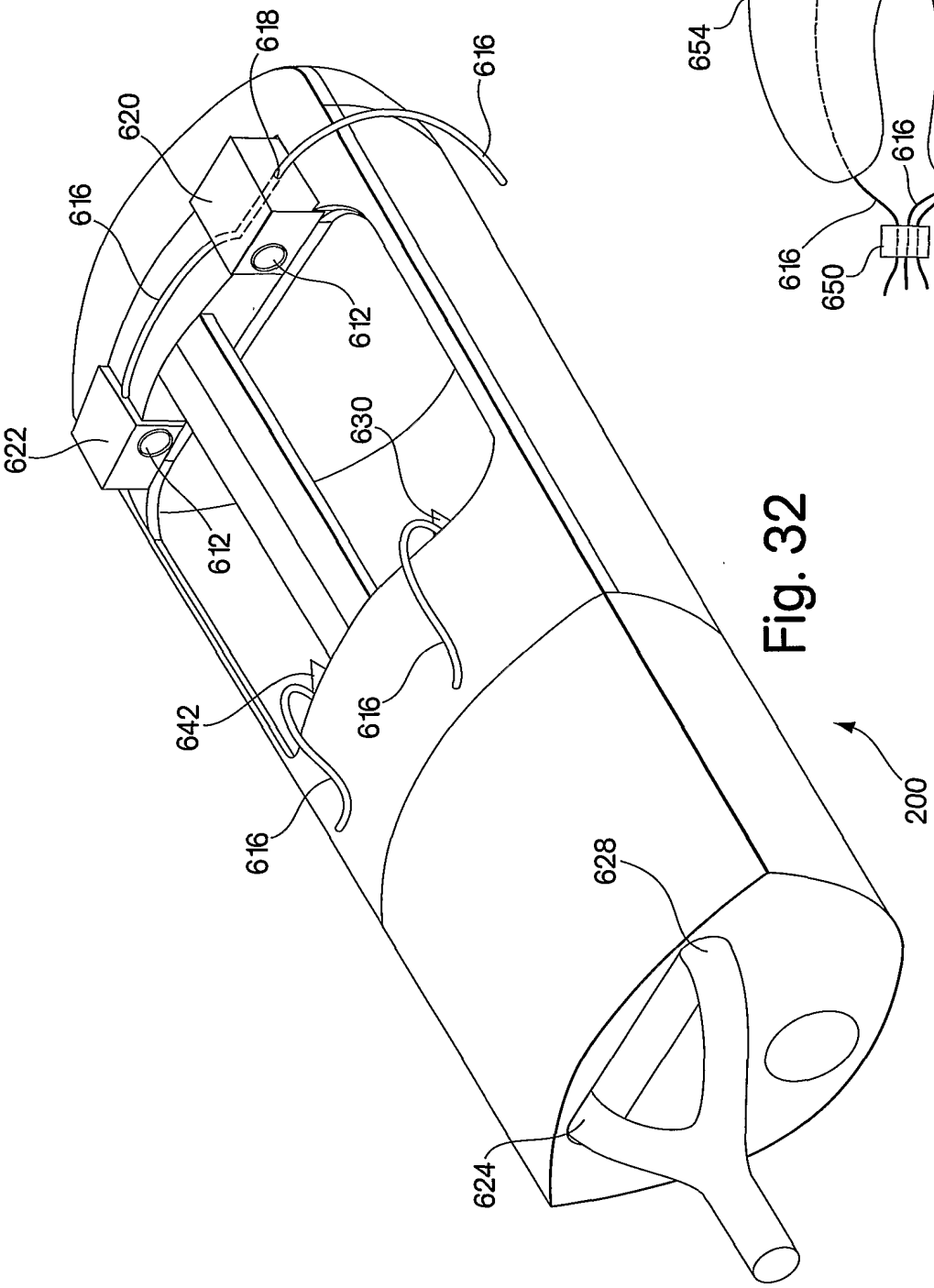

Fig. 32

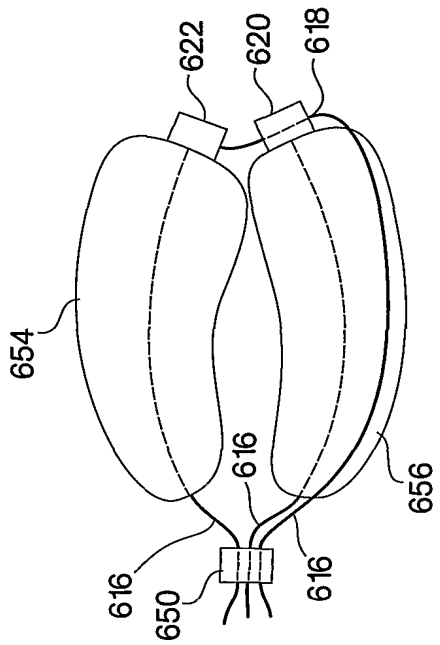

Fig. 32A

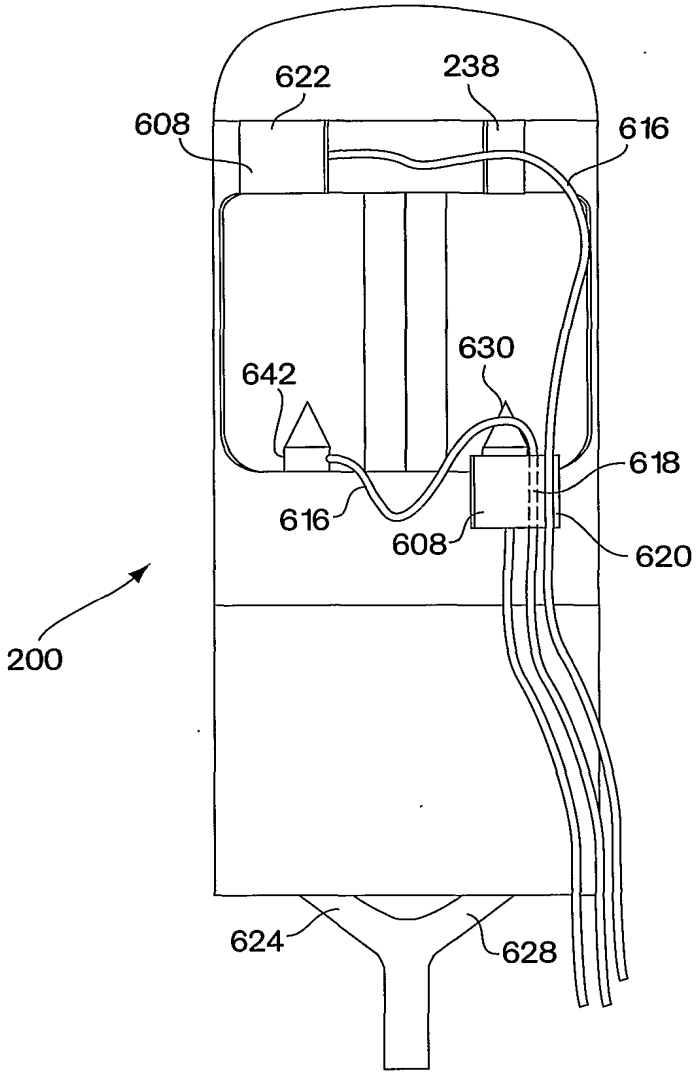

Fig. 33

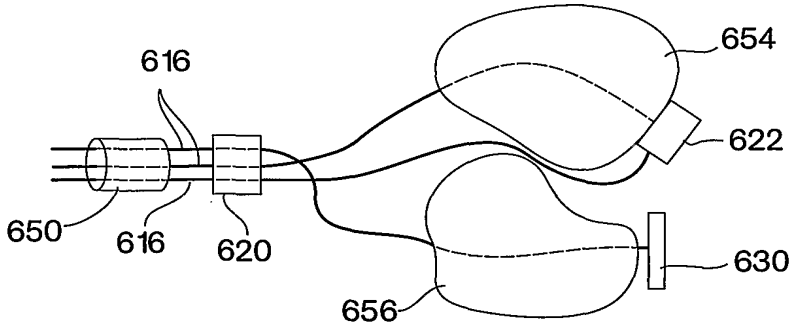

Fig. 33A

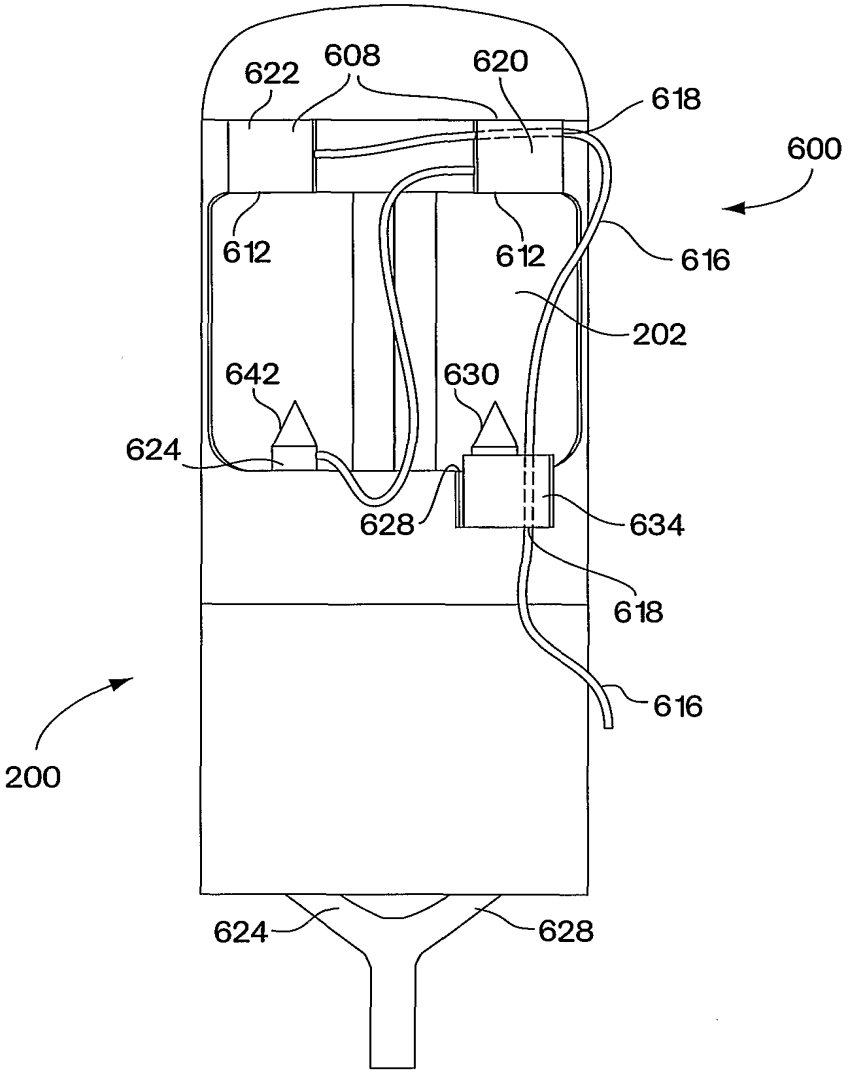

Fig. 34

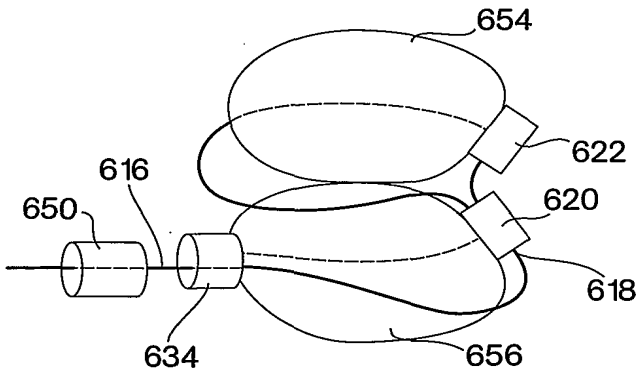

Fig. 34A

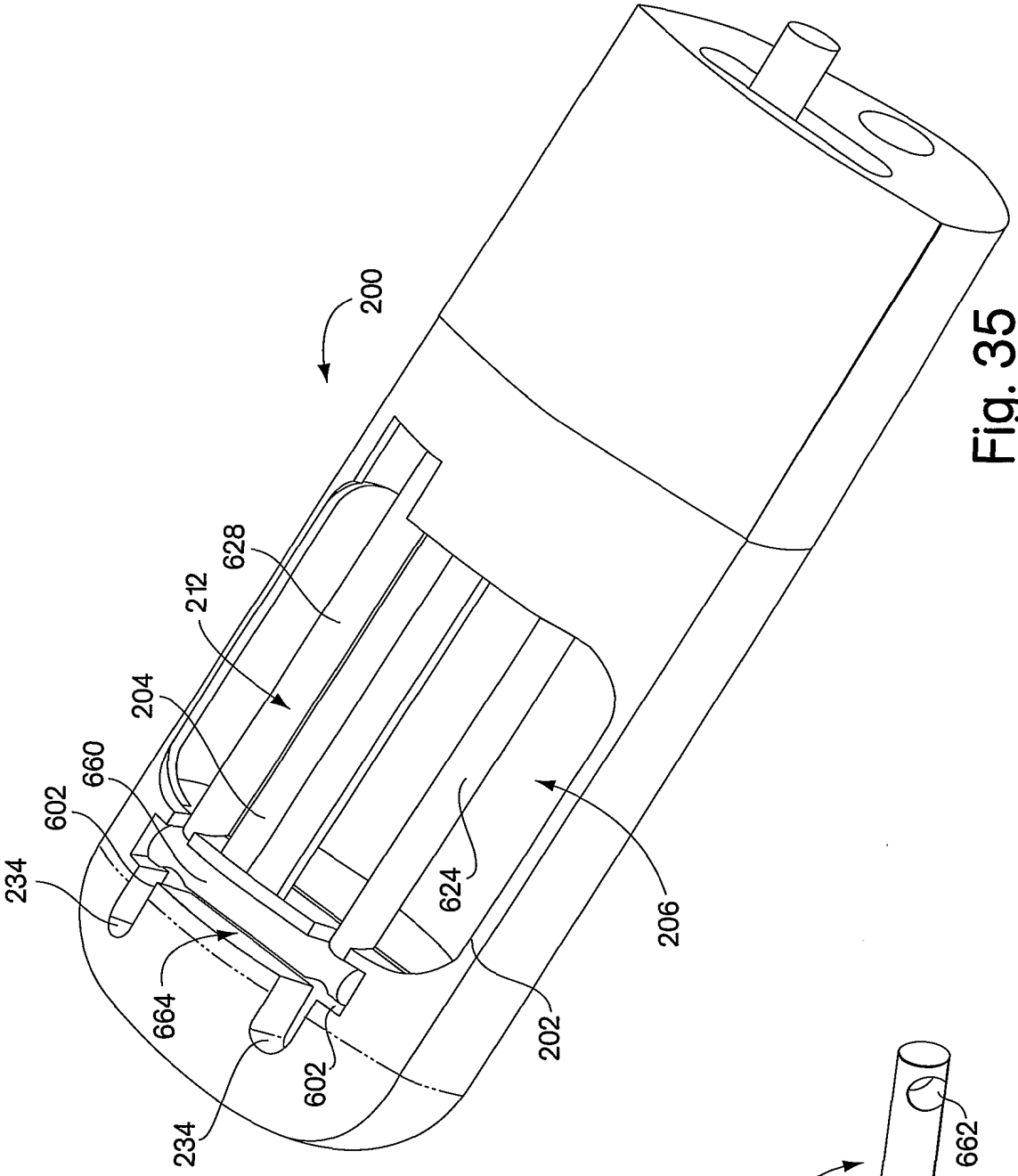

Fig. 35

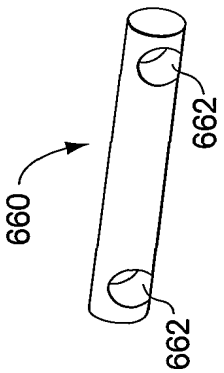

Fig. 35A

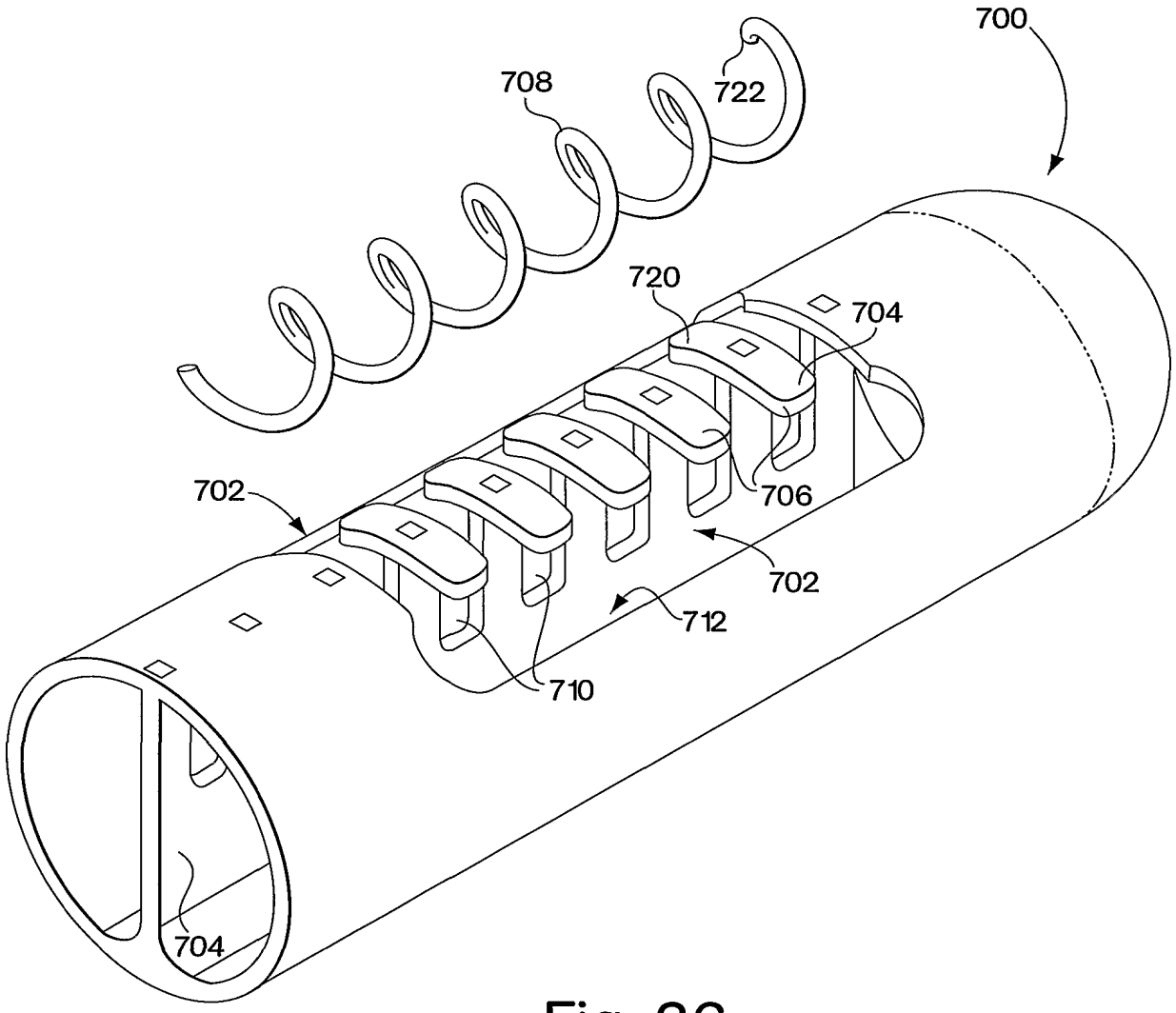

Fig. 36

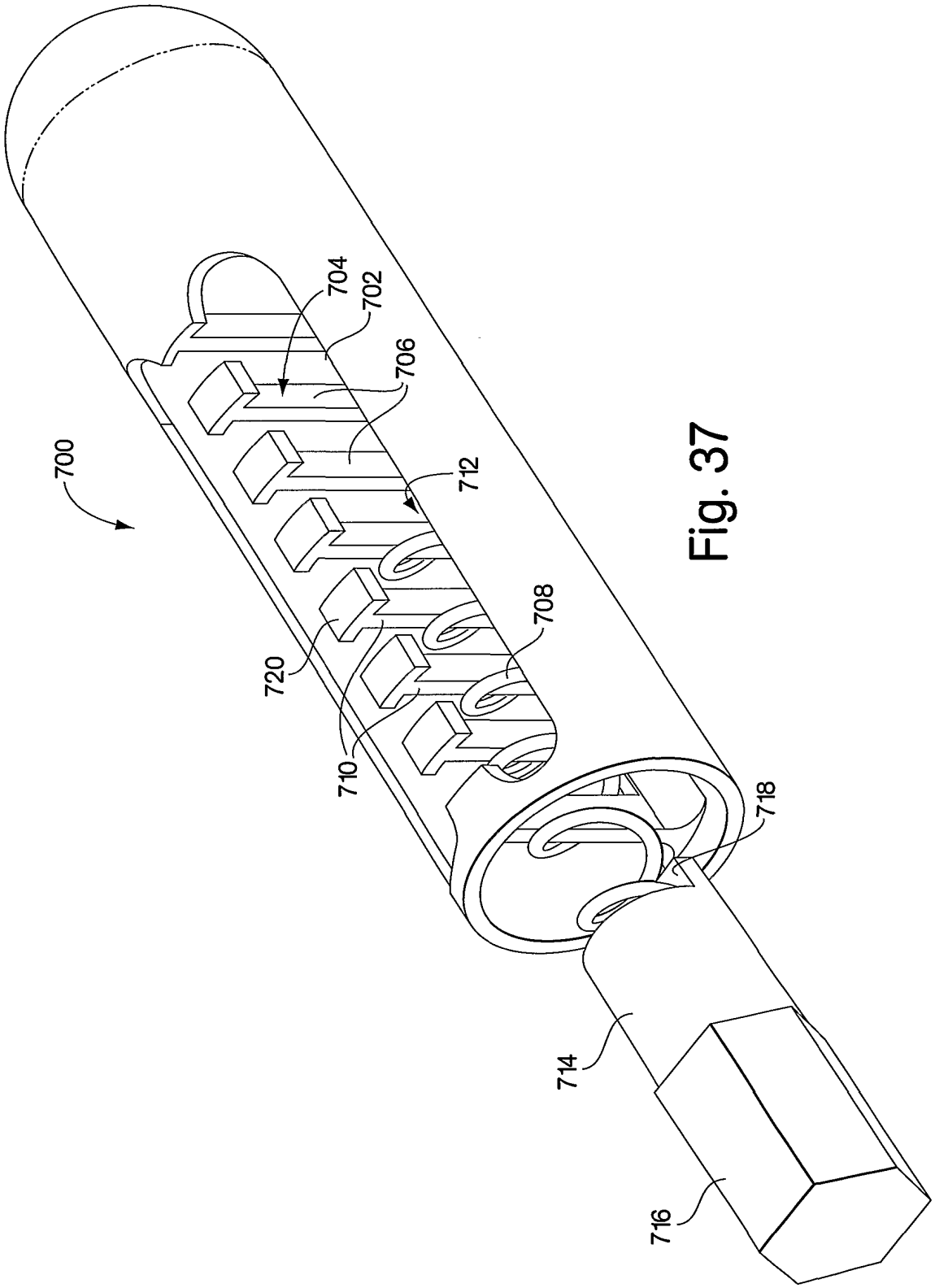

Fig. 37

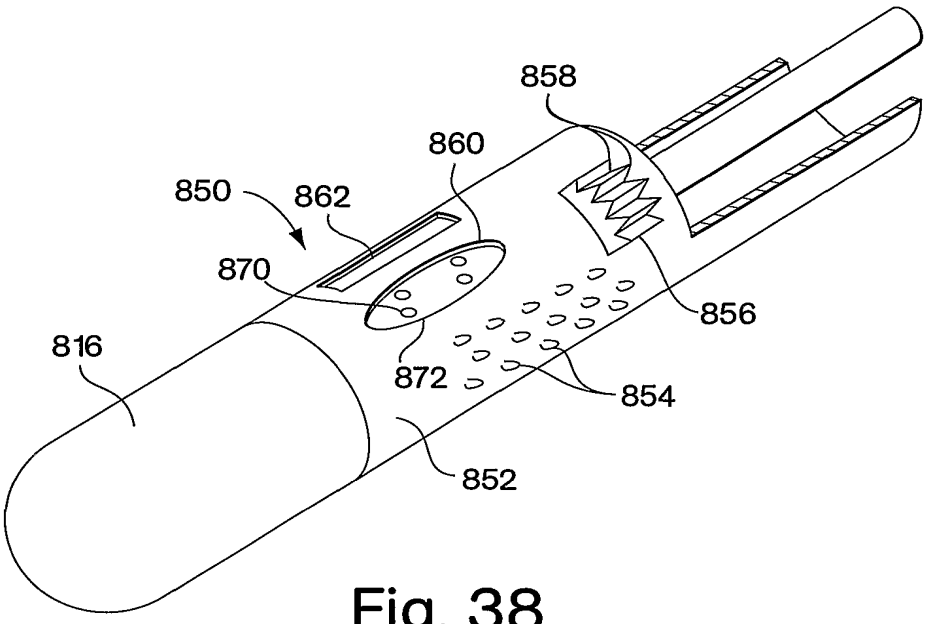

Fig. 38

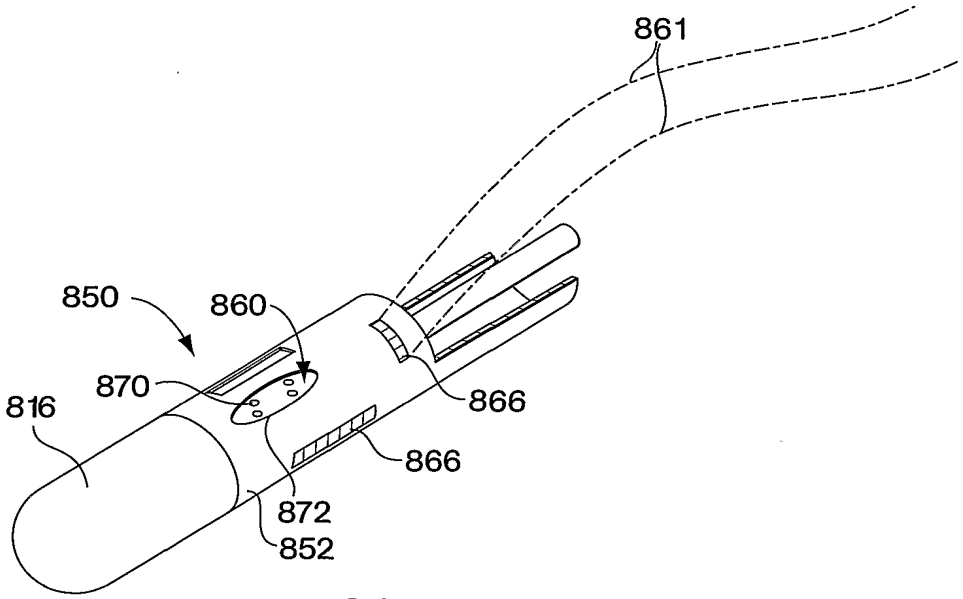

Fig. 39

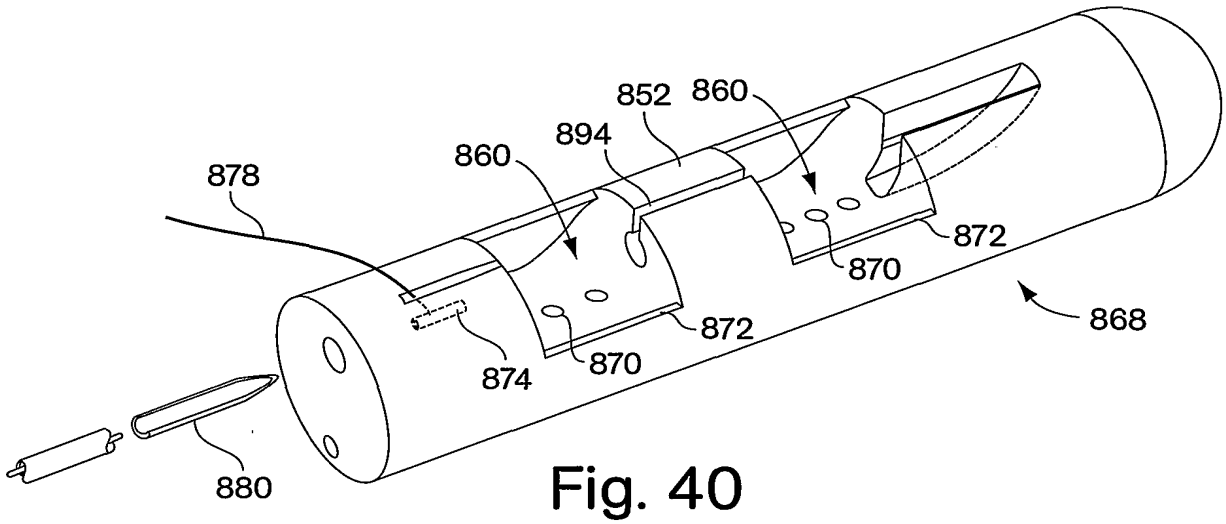

Fig. 40

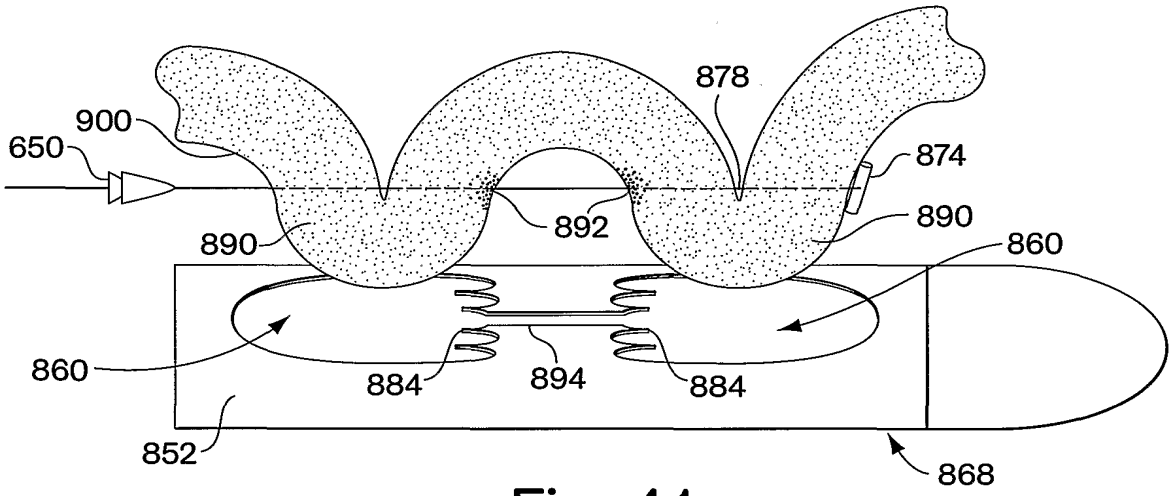

Fig. 41

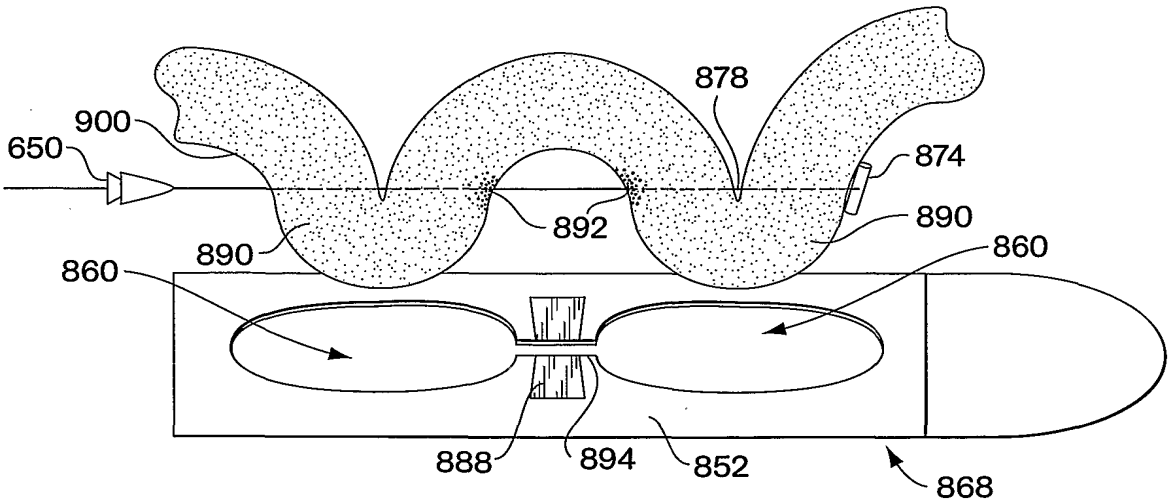

Fig. 42

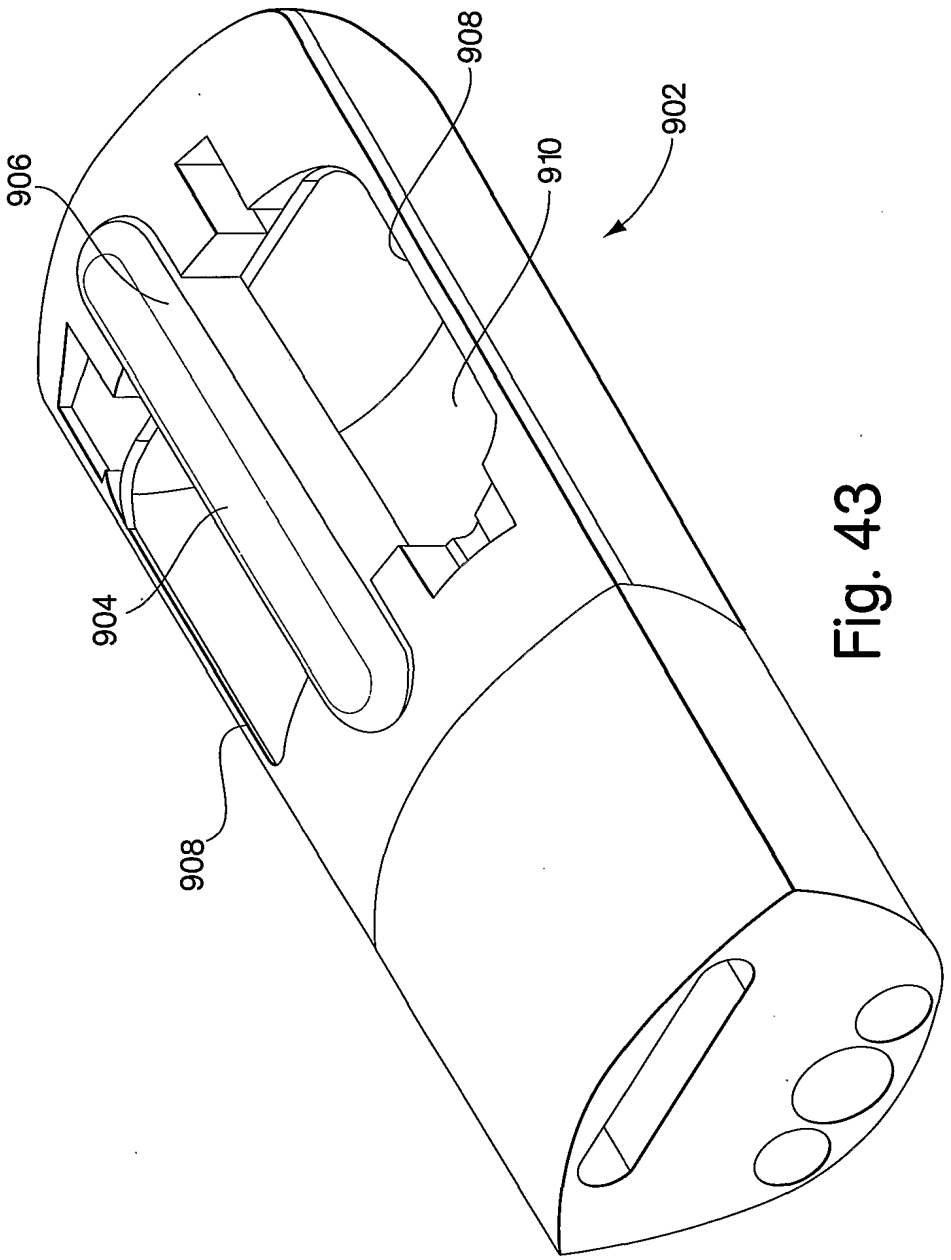

Fig. 43

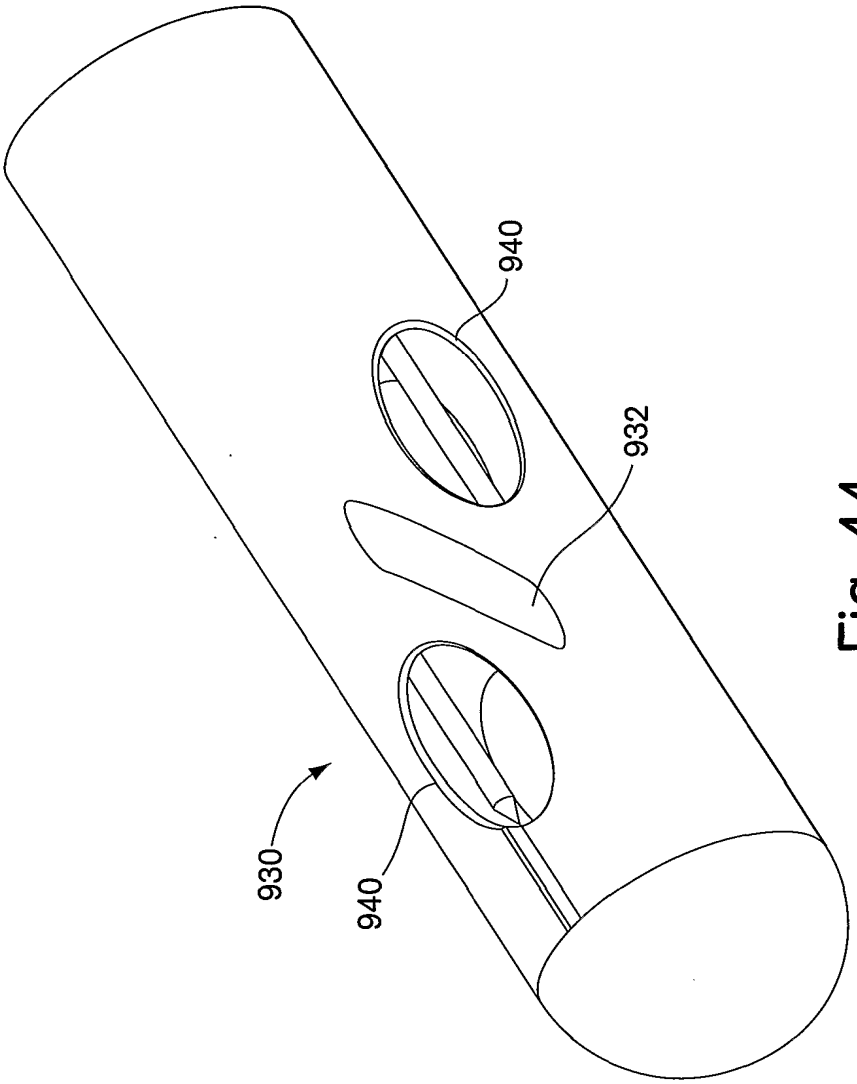

Fig. 44

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/06835

A. CLASSIFICATION OF SUBJECT MATTER

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US CL :606/144

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/139, 144, 148, 149, 150, 153, 159, 213, 216; 112/169

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

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

EAST BRS:
search terms: vacuum, suction, needle, apposition, abrade

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4,927,428 A (RICHARDS) 22 May 1990, see entire document.	1-70
X ---- Y	US 5,080,663 A (MILLS et al.) 14 January 1992, see entire document.	1,9,13,14,16-19,26, 28,29,31, 47,65 ----- 2,12
A	US 5,947,983 A (SOLAR et al.) 07 September 1999, see entire document.	1-70

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"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
"A"	document defining the general state of the art which is not considered to be of particular relevance	"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
"E"	earlier document published on or after the international filing date	"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
"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)	"&"	document member of the same patent family
"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		

Date of the actual completion of the international search
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Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231
Facsimile No. (703) 305-3230

Authorized officer
JULIAN W. WOO
Telephone No. (703) 308-0421

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(71) Applicant *(for all designated States except US)*: **STERILIS, INC.** [US/US]; 3520 Warner Avenue, Santa Ana, CA 92704 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **NOBLES, Anthony, A.** [US/US]; 8686 Tern Avenue, Fountain Valley, CA 92708 (US). **DECKER, Steven, E.** [US/US]; 6220 Hartford Road, Yorba Linda, CA 92887 (US). **PETERSON, Rod** [US/US]; 3520 Warner Avenue, Santa Ana, CA 92704 (US). **TREMBATH, Chad** [US/US]; 3520 Warner Avenue, Santa Ana, CA 92704 (US).

(74) Agent: **DELANEY, Karoline, A.**; Knobbe, Martens, Olson and Bear, LLP, 16th Floor, 620 Newport Center Drive, Newport Beach, CA 92660 (US).

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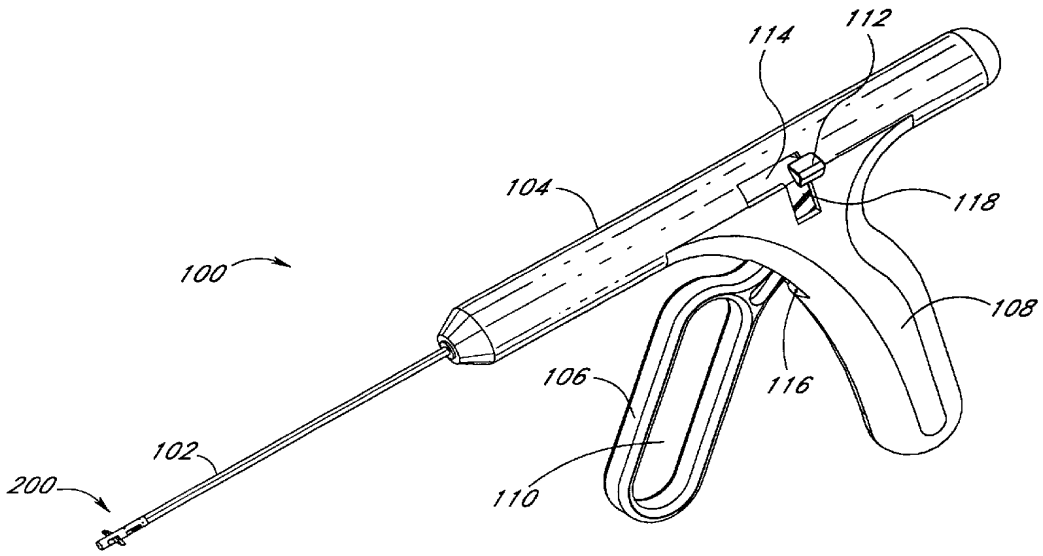
[Continued on next page]

(54) Title: SUTURING METHOD AND APPARATUS



(57) Abstract: A suturing apparatus (100) comprises an elongated body (102), at least one arms (204) movable relative to the elongated body (102) and at least one needle (216) movable relative to the elongated body (102). The arm (204) releasably holds an end portion of a length of suture (234). The arm (204) has a sharp end portion (208) adapted to pierce an inner surface of a wall of a biological structure and pass an end portion of the suture (234) through the inner surface. The needle (216) is adapted to pierce the inner surface of such biological structure at a location proximal to the location where the end portion of the suture (234) was inserted. The needle (216) captures an end portion of the suture (234) from the arm and (234) draws the end portion of the suture (234) back through the inner surface. The end of the suture (234) is then drawn out of the biological structure by removing the elongated body (102).

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IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, 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.

SUTURING METHOD AND APPARATUS

Background of the Invention

Field of the Invention

The present invention relates generally to medical devices, and more specifically to suturing devices and methods for applying suture to internal biological structures. The suturing devices and methods are well-suited for passing suture through the wall of a tubular biological structure from a location within the lumen or around the ostium for the purpose of closing the tubular biological structure. The suturing devices and methods are particularly well-suited for tubal sterilization.

Description of the Related Art

Each year, many thousands of women undergo some form of tubal sterilization in the United States and around the world. Tubal sterilization involves the blocking or removal of a segment from each of the fallopian tubes to prevent the fertilization of ovulated eggs. The various surgical methods used to accomplish tubal sterilization include: the laparoscopy method, the abdominal method, and the vaginal method.

In the laparoscopy method, one or two tiny incisions are made in the abdomen, in or near the navel. The laparoscope, a slim, lighted viewing tube, is inserted and a cauterizing instrument is passed through the laparoscope or through a second incision. The tubes are visualized so the surgeon can cauterize and seal each tube in turn.

In the abdominal method, a 3 to 4 inch incision is made just above the pubic hairline. The fallopian tubes are cut, sealed, and a section of each tube is removed. The ends of the tubes may be sealed or tied into the surrounding tissue.

In the vaginal method, the procedure is similar to the abdominal method. However, in this method the incision is made at the top of the vagina to avoid leaving a visible scar.

Unfortunately, these tubal sterilization procedures are quite invasive and involve the formation of one or more incisions. Because the incisions leave scars and can be damaging to the surrounding tissue, a need exists for an improved method for accomplishing tubal sterilization in a less invasive manner.

Hysterectomy is a common medical procedure in which the uterus is surgically removed from the body. Surgical removal of the uterus is widely accepted both by medical professionals and the public as an appropriate treatment for uterine cancer, and for various common non-cancerous uterine conditions that can produce often disabling levels of pain, discomfort, uterine bleeding, emotional distress, and related symptoms. A hysterectomy first requires cutting and tying the fallopian tubes to detach the uterus from the fallopian tubes. Accessing the fallopian tubes typically involves the formation of one or more incisions in the patient's skin as described above with respect to tubal sterilization procedures.

There are two traditional methods for removing the uterus from the body. The first method involves removing the uterus through a cut in the lower abdomen. The second method involves removing the uterus through a cut in the top of the vagina. The top of vagina is then sutured shut. Because these traditional hysterectomy methods

involve the formation of one or more large incisions in the patient's abdomen or vagina in order to remove the uterus, a less invasive method is desired.

One less invasive method of hysterectomy has recently been developed and is known as laparoscopically-assisted vaginal hysterectomy (LAVH). In this procedure, a few small abdominal incisions are made which allow for the insertion of a laparoscope and specially designed instruments designed for detaching and removing the uterus. The procedure is referred to as "vaginal" because the uterus is then removed through the vagina. While this procedure has become quite popular with patients because of the shortened recovery time and reduced scarring, this method has been shown to have a higher complication rate than traditional vaginal or abdominal techniques. Therefore, an improved method for performing a hysterectomy is needed.

Vasectomy is a medical procedure in which the vas deferentia are surgically interrupted so that the sperm can no longer enter the ejaculatory ducts and fertilization cannot take place. In a conventional vasectomy, the surgeon makes one or two small incisions in the scrotum to gain access to the vas deferens. One vas deferens is isolated, drawn through the incision, and clamped at two sites close to each other. The segment between the clamps is then removed. The surgeon seals either one or two of the cut ends with sutures, clips, or cauterization using an electric needle. The vas deferens is gently placed back into the scrotum and the procedure is then repeated on the other vas deferens.

No-scalpel vasectomy (NSV) is a less invasive procedure in which the vas deferens are accessed without making any incisions in the scrotum. In this procedure, the surgeon makes only one tiny puncture in the scrotum using a special instrument. The instrument is then used to gently stretch the opening until the vas deferens can be pulled through it. The vas is then blocked using any of the same methods as conventional vasectomy.

A wide variety of other surgical procedures may involve the application of suture to biological structures, such as, for example, soft tissue approximation and the treatment of bladder or uterine prolapse. These procedures typically require the formation of one or more large incisions through the patient's skin in order to access the target site. Once the target site is accessed, the application of suture to the biological structure is often cumbersome and time consuming due to the anatomy of the biological structure or the consistency of the tissue.

Thus, there has been a long-felt need for new and improved devices and methods for applying suture to internal biological structures that are difficult to treat with existing suturing devices.

Summary of the Invention

The preferred embodiments of the present invention describe devices and methods for applying suture to internal biological structures. The suturing devices provide means for quickly and easily applying suture to areas of the body that are often difficult to access with existing suturing devices and methods. The suturing mechanism of these devices can be operated remotely from outside the body, thereby making it possible to perform a wide variety of surgical procedures in a minimally invasive or non-invasive manner.

One aspect of the invention relates to a suturing device for closing an opening in a tubular biological structure having an inner surface, such as, for example, a fallopian tube, a common bile duct, or an arterial-venous fistula. One

embodiment comprises a suturing device for applying a suture, comprising an elongated body, at least one arm having a suture mounting portion, and at least one needle having a distal end. The suture mounting portion of the arm releasably holds a portion of the suture. The arm is mounted to cause an end portion of the arm to move (i) away from the elongated body from a first position to a second position and (ii) towards the elongated body from the second position to the first position. The end portion of the arm is adapted to penetrate tissue as the arm moves away from the elongated body to the second portion while holding the portion of the suture during such movement. The needle is mounted to move relative to the elongated body, the distal end of the needle movable from a first position adjacent to the elongated body to a second position adjacent the suture mounting portion of the arm when the arm is in the second position. The distal end of the needle is adapted to capture the portion of the suture from the suture mounting portion of the arm and draws the portion of the suture toward the elongated body.

The suturing device in one preferred embodiment is particularly adapted for closing a conical or funnel-shaped biological structure such as, for example, an ostium or an infundibulum where the uterine cavity narrows into the fallopian tube. However, this embodiment is not limited to such applications, and can be used for other biological structures as well. This embodiment is formed with one or more arms that extend distally and radially at an angle ideally positioned for insertion into the tissue of the funnel-shaped biological structure. This embodiment is also well suited for soft-tissue approximation procedures and can be used to facilitate various steps in a hysterectomy procedure, as described below.

In another embodiment, the arms of the suturing device can be operated independently, thereby allowing each end portion of the suture length to be applied separately. This modification is ideally suited for closing a gap between a first body structure and a second body structure or for attaching tissue to an adjacent body structure, such as, in the treatment of bladder or uterine prolapse. This modification is also ideally suited for use in achieving male sterilization wherein the suturing device is used to loop suture around a vas deferens.

In another embodiment, the suturing device is adapted for closing wounds or surgical incisions from the surface of the skin or other biological structure. This modification includes arms that extend beyond the distal end of the elongated body for insertion into the surface from an external location. The distal end of the elongated body is placed against the surface and the arms are extended distally to penetrate the tissue on both sides of the wound. The needles are deployed to capture and withdraw the suture ends from the tissue. After the suture ends have been withdrawn, they are tied together to close the wound.

Another aspect of the present invention relates to a method of placing a suture. The method comprises positioning a distal portion of an elongated member adjacent a location to be sutured. At least one arm is deployed which releasably holds a portion of a suture. A sharp end portion of the arm penetrates tissue. A needle also penetrates tissue and is driven toward the suture portion. The suture portion is captured from the arm with the needle and drawn through the tissue and toward the elongated body.

Brief Description of the Drawings

FIG. 1 is a perspective view of one embodiment of the suturing device of the present invention.

FIG. 2 is a perspective view of a distal portion of the device of FIG. 1.

FIG. 3 is a perspective view of the distal portion of the device of FIG. 1 with a pair of arms in the deployed position.

FIG. 4 is a perspective view of an arm of FIG. 3.

FIG. 5 is a side view of the distal portion of the device of FIG. 1 inserted in a tubular biological structure, with the tubular biological structure shown partially cut-away.

FIG. 6 is a side view of the distal portion of the device of FIG. 5 with a pair of arms opening.

FIG. 7 is a side view of the distal portion of the device of FIG. 5 with the arms piercing the walls of the tubular biological structure.

FIG. 8 is a side view of the distal portion of the device of FIG. 5 with a pair of needles engaging the arms.

FIG. 9 is a side view of the distal portion of the device of FIG. 5 with a suture placed in the walls of the tubular biological structure by the arms and needles of the distal portion of the device of FIG. 1.

FIG. 10 is a side view of the distal portion of the device of FIG. 5, the suture of FIG. 9 pulling the walls of the tubular biological structure together.

FIG. 11 is a side view of the distal portion of the device of FIG. 1, with a pair of needles engaging a pair of arms beyond the walls of a tubular biological structure shown partially cut-away.

FIG. 12 is a side view of the distal portion of the device of FIG. 1 with a pair of needles engaging a pair of arms in the walls surrounding a rupture or tear of a biological structure, shown partially cut-away.

FIG. 13 is a partial cross-sectional view of a first suture placed in a tubular biological structure by the distal portion of the device of FIG. 1 and a cutting device severing the tubular biological structure into a distal end and a proximal end.

FIG. 14 is a partial cross-sectional view of the distal portion of the device of FIG. 1 placing a second suture in a proximal end of a severed tubular biological structure.

FIG. 15 is a partial cross-sectional view of a first suture in the distal end of the severed biological structure of FIG. 14 and a second suture in a proximal end of the severed tubular biological structure.

FIG. 16 is a partial cross-sectional view of a first securement in the first suture and a second securement in the second suture of FIG. 15.

FIG. 17 is a perspective view of a second preferred embodiment of the suturing device of the present invention.

FIG. 18 is a side view of the distal portion of the device of FIG. 17.

FIGS. 19A-19D are partial cross-sectional views of the distal portion of FIG. 17 as the arms and needles are deployed.

FIGS. 20A-20F are side views of the distal portion of the device of FIG. 17 as used to apply suture to an ostium, with the ostium shown partially cut-away.

FIG. 21 is a perspective view of the distal portion of another embodiment of a suturing device, wherein the suturing mechanism comprises two arms and two needles per arm in a side-by-side configuration.

FIG. 22 is a side view of the distal portion of another embodiment of a suturing device, wherein the suturing mechanism comprises two arms and two needles per arm in an inner-outer configuration.

FIG. 23 is a side view of the distal portion of another embodiment of a suturing device, wherein the suturing mechanism comprises four arms and four needles.

FIG. 24 is a side view of the distal portion of another embodiment of a suturing device, wherein the distal portion of the device is formed with a flat surface.

FIG. 25A-25C are side views of the device of FIG. 24 used to close an incision from an external location, with the incision shown partially cut-away.

FIG. 26A is a perspective view of another embodiment of a suturing device, wherein the arms and needles of the suturing mechanism can be operated independently.

FIG. 26B is a side view of the distal portion of the device of FIG. 26A.

FIG. 27A is a side view of the distal portion of the device of FIG. 26A, shown attaching two biological structures.

FIG. 27B is a cross-sectional view of the biological structures of FIG. 27A attached together.

FIG. 28A is a perspective view of another embodiment of a suturing device, wherein the arms and needles can be deployed asymmetrically.

FIG. 28B is a side view of the distal portion of the device of FIG. 28A.

Detailed Description of the Preferred Embodiments

The application of suture to an internal biological structure can often be difficult due to the location of the target site in the body. Therefore, a suturing procedure often requires the formation of one or more large incisions through the patient's skin simply to access the target site. Because of the highly invasive nature of such procedures and other difficulties associated with suturing internal biological structures, there is an urgent need for improved suturing devices and methods that can be used in a less invasive manner. Various forms of improved suturing devices are disclosed in U.S. Patent No. 5,860,990 to Nobles et al., and U.S. Patent No. 6,117,144 to Nobles et al., both of which are incorporated herein by reference in their entirety.

FIG. 1 illustrates a suturing device 100 in accordance with one embodiment of the present invention. The apparatus includes, generally, a shaft 102 for insertion into an internal biological structure, a main body 104, a trigger actuator 106 for actuating the suturing mechanism, and a handle 108 for gripping and manipulating the device. The shaft 102 is preferably flexible to allow it to bend when advanced through an internal biological structure, such as a body lumen. The length of the shaft 102 may be modified to accommodate various suturing applications. The trigger 106 is formed with a finger aperture 110 to ensure secure engagement with the physician's hand. A lever 112 is provided for controlling the deployment of the distal suturing components and is contained within a horizontal slot 114 and a vertical slot 118 on the handle 104. The trigger 106 and lever 112 are operatively connected to the distal

portion 200 of the suturing device 100 and may be used to remotely manipulate the components of the distal portion 200.

FIGS. 2 and 3 illustrate the distal portion 200 of the device 100 in greater detail. The distal portion 200 comprises a suture introducer head 202, a pair of arms 204, 204', a pair of arm apertures 210, 210', a pair of curved or slanted upper arm guides 282, 282', a pair of lower arm guides 280, 280', a pair of needle apertures 214, 214', a pair of needles 216, 216', a pair of curved needle guides 215, 215' and an actuating rod 226. When the arms 204, 204′ are retracted into the arm apertures 210, 210′, the arms are recessed within the introducer head 202 so that the arms do not cause tissue damage upon insertion and retraction of the distal portion 200 from a biological structure.

FIG. 3 illustrates the distal portion 200 of the device 100 of FIG. 1 with the arms 204, 204' deployed outwardly from their recessed position. Such deployment is achieved by moving the lever actuator 112 upwardly. In FIG. 3, the shaft 102 is preferably a multi-lumen tube with a center lumen 224, two needle lumens 220, 222 and two other lumens 221, 223. The needles 216, 216′ may be advanced from a recessed position within the main body 104 to a distally extended position by squeezing the trigger actuator 106. When the two needles 216, 216' are moved distally, the needle guides 215, 215' (FIG. 2) guide the needles 216, 216' out of the needle apertures 214, 214' at an angle relative to the axis of the actuating rod 226.

FIG. 4 shows details of the arm 204. The other arm 204' (FIG. 3) is identical to the arm 204 shown in FIG. 4. The arm 204 comprises a sharp end 208, a needle receiving aperture 218, a suture end support 206, a suture support 212, a hinge 228, a pin slot 230 and a hinge receiving portion 232. The hinge receiving portion 232 receives a hinge portion of the other arm 204'. Except for the configuration of the arms 204, 204′, the structural components are similar to those shown and described in U.S. Patent No. 6,117,144 and U.S. Patent Application Serial No. 09/524,211, filed March 13, 2000, both of which are incorporated herein by reference in their entirety. The distal end of the actuating rod 226 (the end furthest from the main body 104 of FIG. 1) is attached to the hinge portions of the arms 204, 204' via a pin (not shown). Actuation of the actuating rod 226 controls the movement of the arms 204, 204'.

Before operation, the arms 204, 204' are pre-loaded with the ends of a suture, such as a polypropylene suture. Specifically, each end of a suture has a capture portion comprised of a loop, a sphere or a ferrule. In one embodiment, the loop, sphere or ferrule may be formed (e.g., by heat molding) with the same suture material as the length of suture. In another embodiment, the loop, sphere or ferrule may be a separate piece attached (e.g., molded, glued, etc.) onto each end of the length of suture. The loop, sphere or ferrule is loaded in each suture end support 206 (FIG. 4) of the arms 204, 204'. The suture support 212 receives a portion of the suture which adjoins the loop, sphere or ferrule. The remaining length of the suture is loaded into the distal end of the introducer head 202 and into one of the lumens 221, 223 shown in FIG. 3.

When the lever actuator is moved upwardly, the actuating rod 226 translates proximally. As the actuating rod 226 translates proximally, the ends 208, 208' of the arms 204, 204' come in contact with the curved, upper arm

guides 282, 282' and cause the arms 204, 204' to deploy radially. In one embodiment, the arms 204, 204' continue to deploy radially until the arms 204, 204' are substantially parallel to each other and perpendicular to the axis of the main body, as shown in FIG. 3. In other embodiments, the arms 204, 204' are considered fully deployed when they reach an acute or obtuse angle relative to each other. When the arms 204, 204' are fully deployed, either parallel to each other or at an angle, the physician may squeeze the trigger actuator 106 to move the needles 216, 216' distally. In one embodiment, the needles 216, 216' may be moved distally at substantially the same time. In another embodiment, the needles 216, 216´ are actuated separately so that one needle 216 moves before the other needle 216'.

The needles 216, 216' move distally at an angle or along a curved path until the tips of the needles 216, 216' engage the capture portion of the suture ends (e.g., loop, sphere or ferrule) lying within the suture end supports 206, 206'. Such engagement causes the suture capture portions to become attached to the ends of the needles 216, 216', respectively. The physician then returns the trigger actuator to its original position to cause the needles 216, 216', with the ends of the suture attached to the ends of the needle 216, 216', to retract proximally back into the introducer head 202 and the shaft 102. The physician then moves the lever actuator such that the actuating rod 226 translates distally. As the actuating rod 226 translates distally, the arms 204, 204' come in contact with the lower arm guides 280, 280', which causes the arms 204, 204' to return to their retracted position as shown in FIG. 2. The physician then removes the distal portion 200 from the patient. As tension is applied to the suture ends, the length of the suture in the distal end of the head 202 is pulled out of the distal portion 200.

The suturing device 100 of FIG. 1 may be used to suture a variety of biological structures. In general, the physician inserts the distal portion 200 into a cavernous or tubular structure within a patient to place a suture through two tissue portions. The distal portion 200 is then withdrawn from the patient to draw the two suture ends outside of the patient. The physician ties a knot with the suture ends, slides the knot down to the suture site, and cuts the lengths of suture that are unused. One preferred method involves use of the device 100 to close a fallopian tube. Other methods may, for example, involve closing a common bile duct, or an arterial-venous fistula.

In one application, shown in FIG. 5, the physician inserts the distal portion 200, preferably with a thin sheath (not shown) covering the distal portion 200, into a patient's vagina and into a fallopian tube 232. The sheath protects the distal portion 200 from a non-sterile environment, such as the vagina. Although the shaft 102 can be inserted directly into the fallopian tube, it may be desirable to use a guidewire to guide the placement of the distal portion 200. After the guidewire is inserted into the fallopian tube, the shaft 102 is advanced along the guidewire with the guidewire within a lumen extending through the distal portion 200. The physician positions the introducer head at a desired suture location within the fallopian tube. During insertion and positioning, the arms 204, 204' are in a retracted position, with each arm 204, 204' holding one end (loop, sphere or ferrule) of a suture. The length of the suture between the end portions is stored within the introducer head 202 and/or the shaft 102 and may extend outside the handle body (104 of Figure 1).

Referring to FIG. 5, after the distal portion 200 is positioned at the desired location, the sheath is withdrawn to expose the arms 204, 204′. The lever 112 is then moved to actuate the arms 204, 204′. FIG. 6 illustrates the distal portion 200 with the pair of arms 204, 204' beginning to open radially outwardly.

As shown in FIG. 7, as the arms 204, 204′ pivot outwardly, the sharp ends 208, 208' of the arms 204, 204' pierce the interior surface of the walls 230 of the fallopian tube 232. Additionally, although the arms 204, 204′ are shown as being substantially planar with the sharp ends 208, 208′ pointed in the direction of the longitudinal axis of the arms 204, 204′, other configurations may be used. For example, in some situations, it may be desirable to orient the sharp ends 208, 208′ at an angle relative to the longitudinal axis of the arms 204, 204′ so that the sharp ends 208, 208′ will be pointed more or less perpendicular to the inner surface of the walls 230 when it contacts such walls 230.

In one variation, the arms 204, 204' are deployed until the arms 204, 204' are parallel to each other as shown in FIG. 8. The length of the arms 204, 204' and/or the diameter of the introducer head 202 are selected such that the needle receiving apertures of the arms 204, 204′ are well beyond the inner wall surface of the fallopian tube 232 when the arms are fully extended radially outwardly in a deployed position. Preferably, the arms 204, 204' penetrate approximately 1.0 mm into the walls 230 of the biological structure 232 on each side of the distal portion 200. However, the depth of penetration may be varied without departing from the spirit of the invention.

As shown in FIG. 8, after the arms have been extended to pierce the fallopian tube, the trigger 106 is moved to advance the needles 216, 216' towards the needle receiving portions of the arms. As the needles 216, 216′ are advanced, they pierce the walls 230 of the fallopian tube 232 at a location proximal to the location where the arms 204, 204' pierced the walls 230. The needles 216, 216' continue to advance through tissue until they engage the capture portion (e.g., loops, spheres or ferrules) at the ends of the suture held by the arms 204, 204', as described above.

When the needles 216, 216' are withdrawn back into the introducer head 202, the ends of the suture are also drawn into the distal portion 200, as shown in FIG. 9. The suture 234 thus passes through opposing sides of the walls 230 of the fallopian tube 232 with the ends of the suture captured by the needles 216, 216'. In FIG. 9, the physician has retracted both the needles 216, 216' and the arms 204, 204'. The physician removes the distal portion 200 from the patient, and the length of suture 234 between the end portions is released from the distal end of the introducer head 202. Once the distal portion 200 is outside the patient, the physician detaches the ends of the suture 234 from the distal portion 200.

FIG. 10 illustrates tension being applied to the suture 234 during withdrawal of the distal portion 200. Such tension pulls the walls 230 of the fallopian tube 232 inwardly. Such pulling also causes the fallopian tube 232 to constrict longitudinally. After the distal portion 200 is removed from the patient and the suture end portions detached therefrom, the physician forms a self-cinching knot, such as a clinch knot or a half hitch, with the suture end portions that extend outside of the patient and slides the knot down the fallopian tube to the suture site. The knots may be advanced to the suture site using, for example, any of the devices disclosed in co-pending U.S. Application Serial No.

09/571,759, filed May 15, 2000, which is incorporated herein by reference in its entirety. As the knot reaches the suture site, it will apply tension to the portion of the suture extending through the walls 230 and draws the walls together as well as longitudinally shorten the fallopian tube. Additional self-cinching knots may be pushed down on top of the first knot to lock the first knot in place, and the lengths of the suture 234 extending from the knot are cut by the physician. The suture 234 is preferably made of a biocompatible material.

Although the above-discussed procedure passed the suture through walls of the fallopian tube without penetrating the exterior surface of the fallopian tube, it will be understood that the suturing device 200 may also be configured to pass the suture completely through the walls so as to penetrate the exterior surface of the fallopian tube. FIG. 11 illustrates the distal portion 200 of the device 100 of FIG. 1 with both the needles 216, 216' and the arms 204, 204' extending through exterior surface of the walls 250, 252 of a tubular biological structure 251, such as a fallopian tube. The arms 204, 204´ fold outwardly and puncture the walls 250, 252 such that the capture portion of the suture is exterior to the tube 251. As the unfolding arms engage the tissue to begin such penetration, the physician preferably pulls the distal portion 200 proximally to cause the pointed ends of the arms to be driven into the tissue and through the walls 250, 252. The needles 216, 216´ pass through the tissue at a location proximal to the arms 204, 204´ and engage the capture portions of the suture that are within the suture end supports 206, 206´. The physician then withdraws the needles 216, 216' and the ends of the suture 234 into the introducer head 202, retracts the arms 204, 204', and removes the introducer head 202 from the patient. The physician then secures the suture 234 with a securement, such as a knot, as described above with reference to FIGS. 9 and 10.

FIG. 12 illustrates the distal portion 200 of the device 100 of FIG. 1 with the needles 216, 216' engaging the arms 204, 204' in the walls of another type of biological structure 240. In FIG. 12, the distal portion 200 is used to close a suture site 242, such as an incision, rupture or tear, within the biological structure 240. For example, the rupture or tear can be an aneurysm. In operation, the physician inserts the introducer head 202 into a cavity 244 and deploys the arms 204, 204'. The physician manipulates the arms 204, 204' to pierce the walls of the structure 240. The physician then moves the needles 216, 216' distally until they engage the arms 204, 204' in the walls of the biological structure 240. The physician retracts the needles 216, 216' and the suture ends into the introducer head 202. The physician removes the introducer head 202 from the suture site and then removes the ends of the suture from the introducer head 202. The physician secures the suture with a securement such as a knot or clip. The physician then cuts the remaining, unused ends of the suture.

FIGS. 13-16 illustrate a method of using the device 100 of FIG. 1 to suture a tubular structure, such as a fallopian tube, at proximal and distal locations that are spaced from each other. In reference to FIG. 13, the physician initially uses the distal portion 200 to place a first suture 234 in the tubular structure as described above with reference to FIG. 11. The physician removes the introducer head 202 from the tubular structure, pulls the suture ends taut, and secures the first suture 234 with a first knot 270 or clip near the first suture site. The physician cuts and removes the remaining, unused ends of the suture 234.

As illustrated in FIG. 13, the physician then inserts a shaft 260 into the tubular biological structure. Preferably, the shaft 260 is flexible or bendable such that the physician can insert and position the shaft 260 at a desired location within the tubular structure. A cutter 264 is attached to the distal end of the shaft 260 by a pivot pin 262. In another embodiment, the cutter 264 and the shaft 260 are integrated as a single piece. In one embodiment, more than one cutter may be attached to the shaft 260 by one or more pivot pins. In one embodiment, the cutter is a fan-shaped blade.

During insertion of the shaft 260 into the tubular biological structure, the cutter 264 retracted. Once the shaft 260 and cutter 264 are positioned at a desired location near the first suture knot 270, the physician deploys the cutter 264. In one embodiment, the cutter 264 may be attached to an actuating rod or a spring that is attached to a lever or actuating rod at the proximal end of the shaft 260 outside of the tubular structure. The physician deploys the cutter 264 by pushing or pulling the lever or actuating rod outside of the tubular biological structure.

When the cutter 264 is deployed, the cutter 264 pierces the walls of the tubular biological structure. The physician rotates the cutter 264 to completely sever the tubular structure and thereby create a distal end 266 and a proximal end 268. The physician then retracts the cutter 264 and removes the shaft 260.

As shown in FIGS. 14-15, the physician then inserts the distal portion 200 of the device 100 of FIG. 1 (either the same device 100 loaded with another suture or another pre-loaded device 100) into the tubular structure and advances the portion 200 to a position near the second end 268. In one embodiment, a flexible, hollow tube with an inflation lumen and an inflatable balloon is inserted over the shaft 102. The physician causes the balloon to inflate and come in contact with the inner walls of the second end 268 of the severed tubular biological structure. Thus, the inflated balloon supports the second end 268 of the severed tubular biological structure as the distal portion 200 of the device 100 is used to place a second suture 274.

After the suture 274 has been passed through the tissue at the end 268, the physician removes the introducer head 202 from the tubular structure, pulls the second suture ends taut, and secures the second suture 274 with a second knot 272 or clip, as illustrated in FIGS. 15-16. The physician cuts and removes the remaining, unused ends of the suture 274.

The order of the acts described above with reference to FIGS. 13-16 may be rearranged in other embodiments of the suture method. For example, in one embodiment, the physician places the first suture 234 in the tubular biological structure, pulls the first suture 234 taut, forms a first securement 270 with ends of the first suture 234, cuts the remaining, unused ends of the first suture 234, places the second suture 274 but does not form a securement yet, inserts the flexible, hollow tube with the balloon, inflates the balloon for support, inserts the cutter 264 to cut the tubular biological structure into a first end 266 and a second end 268, pulls the second suture 274 taut, forms a second securement 272 with ends of the second suture 274 and finally cuts the remaining, unused ends of the second suture 274.

It will also be appreciated that the suturing device described in FIGS. 1-4 may incorporate more or less than two arms and needles in order to close the fallopian tube or other biological structure. Suturing devices with multiple

arms and needles are described below and in U.S. Patent No. 6,117,144 and U.S. Patent Application Serial No. 09/524,211, filed March 13, 2000, referenced above. By providing more than two arms and two needles around the circumference of the shaft 102, suture can be applied to more effectively close the body lumen.

FIG. 17 illustrates a suturing device 300 in accordance with a second preferred embodiment of the present invention. One preferred use of this embodiment is to close an infundibulum, particularly the conical or funnel-shaped cavity where the uterine cavity narrows into the fallopian tube. Other uses of this embodiment include soft tissue approximation in general surgical applications (such as laparoscopy), post-hysterectomy closure of a vagina (e.g., vaginal closure at the junction between the vagina and the uterus/cervix), treatment of prolapse by attachment of a bladder or uterus to an adjacent or distant body structure, closure of blood vessels, and closure of wounds or surgical incisions in the skin.

Still referring to FIG. 17, the suturing device 300 includes, generally, an elongated shaft 302 for insertion into an internal biological structure, a main body 304, a plunger 306 and a handle 308 for gripping the suturing device. The plunger 306 is located at the proximal end of the main body 304 and is operatively connected to the distal portion 400 of the suturing device 300. Actuation of the plunger provides a means for remotely manipulating the suturing components, as described below. The suturing device includes a distal annular mechanism 310 that can be turned to articulate or bend the distal end of the elongated shaft. Furthermore, the suturing device also includes a proximal annular mechanism 312 that can be turned to rotate the entire elongated shaft. The articulation and rotation of the elongated shaft are advantageous for advancing the device through or around biological structures, and for placement of the device in difficult to reach locations.

FIG. 18 illustrates the distal portion 400 of the suturing device 300 of FIG. 17 in greater detail. The distal portion 400 includes a conically-shaped nose portion 402, a pair of arms 404, 404', a pair of arm apertures 406, 406', a pair of needles 416, 416' and a pair of needle apertures 414, 414'. The nose portion 402 is adapted for insertion into an ostium, infindibulum or similarly shaped structure and provides a means to enable access into narrow passageways or openings. The nose portion may also be used to place the suturing device in optimum position of contact within the surrounding tissue. The arms 404, 404' extend through the arm apertures 406, 406' for penetrating the surrounding tissue in, for example, a conical or funnel-shaped biological structure such as an ostium. The needles 416, 416' extend through the needle apertures 414, 414' for capturing the end portions of the suture from the arms and withdrawing them back toward the device. An opening 428 is provided near or on the nose portion 402 to provide a location for the suture material to extend out of the device 300, as shown in FIG. 20A below.

FIGS. 19A-19D sequentially illustrate the movement of the arms and needles of the suturing device shown in FIGS. 17-18. FIG. 19A shows the arms 404, 404' in the recessed position within the apertures 406, 406' in the distal portion 400 of the suturing device. In the recessed position, the arms are fully contained within the suturing device and are configured in a substantially parallel arrangement. The proximal ends of the arms are coupled together by a hinge 408. In FIG. 19B, the arms are shown partially advanced such that the distal end of each arm contacts a spreader mechanism 412 thereby causing the arms 404, 404' to separate. As the arms are extended farther, they are

guided outward through the arm apertures 406, 406'. In FIG. 19C, the arms 404, 404' are shown in the fully deployed position, such that each arm extends outward distally and radially away from the distal end of the device. In FIG. 19D, the suturing device is shown with the needles 416, 416' in the extended position, such that the distal end of the needles engage the needle receiving portions 418, 418' of the arms 404, 404'.

A method of using the device of FIG. 17 on a tapered or narrowing body structure, such as the opening of a fallopian tube, is illustrated sequentially in FIGS. 20A through 20F. The physician initially advances the distal portion 400 of the elongated shaft of the suturing device through the patient's body toward the desired body structure 420, such as an ostium. The body structure may be accessed by various methods including: transcervically, transvaginally, percutaneously, laparoscopically, or through an incision in general open surgery. During the insertion of the suturing device, the elongated shaft may be articulated and rotated relative to the main body in order to steer the distal portion through the body structure.

Once the physician places the distal portion 400 of the suturing device at the desired location within the body structure 420, the plunger 306 (shown in FIG. 17) is rotated to advance the arms 404, 404' out of the arm apertures 406, 406' as shown in FIG. 20A. The plunger may be used to advance the arms through a variety of mechanisms. For example, the plunger may be coupled to a threaded screw in the main body and the arms may be coupled to a threaded nut. By rotating the plunger, the nut is advanced or retracted longitudinally along the length of the screw. Further mechanisms for operating the plunger are described in the above-referenced U.S. Patent No. 6,117,144 and U.S. Patent Application Serial No. 09/524,211, filed March 13, 2000, the entirety of which are incorporated by reference. As the arms are advanced outward and become fully deployed, the distal portion of each arm penetrates the tissue of the body structure 420. As the arms penetrate the tissue, the end portions of the suture 422 are inserted into the tissue as shown in FIG. 20B.

After the arms are fully deployed, the physician pushes the plunger distally relative to the main body to advance the needles 416, 416' through the needle apertures and out toward the needle receiving portion of each arm as shown in FIG. 20C. As each needle is advanced, it pierces the tissue of the body structure 420 at a location proximal to the location where the arm pierced the tissue. The needles continue to advance through the tissue until they engage the capture portion 424, 424' (e.g. loops, spheres or ferrules as described above) at the ends of the suture. The needles are then retracted by pulling the plunger proximally relative to the main body thereby removing the suture from the needle receiving portion of each arm and drawing the suture ends back toward the suturing device as shown in FIG. 20D. It should be noted that each suture end portion is inserted into the tissue by an arm along a first path and then retracted from the tissue by a needle along a second path. Therefore, the suture captures a portion of tissue denoted as 426, 426' in FIG. 20D.

After the suture has been applied through the tissue of the biological structure, the arms are retracted by rotation of the plunger in the other direction. The arms are retracted so that the suturing device can be removed from the biological structure without damaging the surrounding tissue. The physician removes the suturing device from the biological structure 420 with the capture portions of the suture ends still held by the needles as shown in FIG. 20E. If

necessary, this procedure may be repeated to insert multiple sutures through the walls of the ostium. After the suture(s) are in place, the end portions of each suture are drawn together to create tension and pull the walls of the biological structure into contact with each other as shown in FIG. 20F. The suture ends are secured together with a securement, such as a knot, as described above and to close the biological structure.

The second preferred embodiment described above in FIGS. 17 through 20F advantageously incorporates arms that penetrate the walls of a biological structure at an acute angle relative to the shaft 302. When the arms are in their fully extended position, they form an angle relative to each other that is less than 180°, more preferably, about 90°. The "forward-firing" arms of the second preferred embodiment are particularly advantageous for penetrating ostium-shaped tissue structures. The angle of the arms enables the needles to penetrate deeply into tissue, thereby allowing the suture to grab more tissue and form a stronger connection. The angle also enables the arms to penetrate difficult to reach locations.

FIGS. 21 through 23 show modifications of the second preferred embodiment of the suturing device whereby multiple sutures can be applied simultaneously. FIG. 21 illustrates the distal portion 500 of a suturing device having widened arms 504, 504' that are each formed with two suture end supports 520, 520' and 522, 522' in a side-by-side arrangement. Two pairs of needles 516, 518 and 516', 518' are provided, one pair of needles on each side. On each side, a first needle 516 cooperates with a first end support 520 and a second needle 518 cooperates with a second end support 522. Needles 516 and 516' work together to apply a first suture and needles 518 and 518' work together to apply a second suture. By advancing and retracting both sets of needles at the same time, this embodiment can be used to simultaneously apply two parallel sutures.

FIG. 22 illustrates another modification of the second preferred embodiment in which multiple sutures can be applied simultaneously in a colinear arrangement. The distal portion 600 of a suturing device in accordance with this embodiment includes a pair of arms 604, 604' that are each formed with two suture end supports 620, 622 and 620', 622'. In this modification, the end supports on each arm are arranged such that one of the end supports is distal to the other along the length of the arm. Two needles 616, 618 and 616', 618' are provided on each side arranged in an inner-outer configuration. The first needle 616 advances into the outer suture end support 620 and the second needle 618 advances into the inner suture end support 622. Needles 616 and 616' work together to apply a first suture and needles 618 and 618' work together to apply a second suture. By advancing and retracting both sets of needles at the same time, this embodiment can be used to simultaneously apply two colinear sutures. The colinear sutures are configured with one on top of the other such that a top suture extends into the tissue at locations proximal and distal to the bottom suture.

FIG. 23 illustrates yet another modification to the second preferred embodiment of the suturing device whereby multiple sutures can be applied simultaneously. The distal portion 700 of a suturing device in accordance with this modification comprises four arms 704, 704', 704", 704"' and four needles 716, 716', 716", 716"' equally spaced about the distal portion 700 of the suturing device. This embodiment is designed for simultaneously applying two perpendicular sutures to a conical or funnel-shaped biological structure, such as an ostium. In further

modifications, the suturing device can be formed with any even number of arms and needles, such as, for example, six or eight.

FIG. 24 illustrates yet another embodiment of a suturing device of the present invention. The distal portion 800 of this suturing device is formed with a flat distal surface 802 such that the arms 804, 804' and needles 816, 816' extend distally beyond the flat distal surface 802 of the elongated shaft when fully deployed. In this embodiment, the suture is provided to the arms through an opening in the distal end of the device. This embodiment may be advantageously used to apply suture to a substantially flat body structure from an external location and is particularly advantageous for closing wounds or surgical incisions.

A method of using the device of FIG. 24 for closing an incision in the skin or surface of another biological structure is illustrated sequentially in FIGS. 25A through 25C. As shown in FIG. 25A, the flat distal surface 802 of the suturing device 800 is placed against a substantially flat region of tissue 820 such that the longitudinal axis of the device 800 is substantially perpendicular to the plane of the tissue 820. The plunger mechanism (not shown) is rotated to deploy the arms 804, 804' thereby inserting the end portions of the suture 822 into the tissue 820, one end portion on each side of the incision. The plunger mechanism is then advanced distally to extend the needles 816, 816' into the tissue 820 and capture the end portions of the suture 822. By moving the plunger proximally, the needles are withdrawn thereby pulling the end portions of the suture 822 out of the tissue 820 as shown in FIG. 25B. The end portions of the suture 822 are then pulled to close the incision as shown in FIG. 25C.

It will be appreciated that for each of the embodiments described above, the arms and/or needles can be deployed simultaneously or sequentially. FIGS. 26A and 26B illustrate one embodiment which enables independent deployment of the arms. The suturing device 900 includes, generally, an elongated shaft 902 for insertion into an internal biological structure, a main body 904, two actuation mechanisms 906, 906' and a handle 908 for gripping the suturing device. The actuation mechanisms 906, 906' are located at the proximal end of the main body 904 and are operatively connected to the distal portion 1000 of the suturing device 900. In this modification, each of the arms 1004, 1004' can be actuated independently through independent manipulation of the actuation mechanisms 906, 906'. In such applications, the first needle/arm pair 1004, 1016 would be actuated independently of the second needle arm pair 1004', 1016' (shown in FIG. 27A).

The use of independently deployable arms allows for suturing across large gaps in tissue by first placing a first end of a suture in one area of tissue and then moving the device and placing a second end of the suture in a different area or tissue. In operation, one end of the suture is passed through tissue on one side of a cavity using the first needle arm pair 1004, 1016. The other end of the suture is passed through tissue using the second needle/arm pair 1004', 1016' on the other side of the cavity. This feature may also be advantageous for moving a body structure and attaching it to a new location such as in the treatment of bladder or uterine prolapse.

Independent actuation of the arms can also be advantageously used to attach or suspend a first body structure to a second body structure. The body structures used in this method can be any implantable or biological structures, including bones, ligaments, muscle tissue and body organs. In operation, one end of a suture is looped

around a first body structure 1050 for use as an anchor as illustrated in FIG. 27A. One of the arms 1004' is deployed on one side of the body structure 1050 and the corresponding needle 1016' is deployed on the other side of the first body structure, such that the arm 1004', the needle 1016' and the elongated body surround the body structure. One end portion of the suture 1022 is passed from the arm 1004' to the needle 1016' to form a loop around the first body structure.

The other end portion of the suture can then be threaded through a second body structure or tissue 1020 that is adjacent to, or distanced from, the first body structure. A penetrating arm 1004 penetrates the tissue 1020, and a deploying needle 1016 is moved relative to the arm 1004 to retrieve the suture end held in the arm 1004. Alternatively, the second arm and needle can be used to loop a suture around a second body structure, as with the first arm and needle. The ends of the suture 1022 are then pulled tight to bring the body structure 1050 and the tissue 1020 together as illustrated in FIG 27B.

It will be appreciated that the arms 1004 and 1004' can be deployed in any preferred sequence, and thus, arm 1004 can be used to penetrate tissue before arm 1004' is used to loop a body structure. It will also be appreciated that the arms 1004 and 1004' can be deployed simultaneously. In one embodiment of the device of FIG. 27A, the arm 1004' that is positioned around the body structure has a blunt tip, while the arm 1004 that penetrates tissue has a sharp tip.

The embodiment of FIG. 27A may also be used for suspending an organ from an adjacent or distant body structure, such as, for example, in the treatment of bladder or uterine prolapse. Organ suspension may be accomplished with this embodiment by penetrating an arm and firing an needle into an organ to place a first end of a suture, moving the suturing device to traverse a space, and then positioning a second arm and firing a second needle around a ligament to loop the second end of the suture around the ligament. By tightening the suture, the organ is suspended by using the ligament.

The ability of the suturing device to loop suture around a body structure may also be advantageously applied to an improved method for performing male sterilization. The vas deferens are first accessed using either a conventional approach (through scrotal incisions) or through a tiny puncture (similar to the no-scalpel vasectomy approach). After accessing the vas deferens, one arm of the suturing device is then deployed on one side of the vas deferens and one needle is deployed on the other side. The needle picks up the suture to loop suture around the vas deferens. The suture is then pulled tight and tied off to block the lumen in the vas deferens thereby blocking the flow of sperm into the ejaculatory ducts.

Other devices, including those described above, may also be used for looping suture around a body structure or for suspending a first body structure to a second body structure. For example, suturing devices may be used in which the arms are not moveable from within the elongated body to outside the elongated body. Rather, in these embodiments, the arm or arms may be fixed relative to the elongated body, and may simply be placed around the body structure to be suspended before the needles are deployed. Furthermore, once a first body structure is suspended to a

second body structure, it will be appreciated that the distance between the two structures can be adjustable using an adjustment feature, such as a turnbuckle, that can be utilized to draw up an organ, or draw to an organ.

It will also be appreciated that a suturing device with one or more fixed arms extending from the elongated body can be used in other applications as well. For example, this device can be used to place suture into tissue simply by manipulating the device such that the arm or arms punctures the desired tissue location. The needles then deploy in the manner described above to grab the suture ends mounted on the arms of the device.

FIGS. 28A and 28B illustrate yet another embodiment of a suturing device of the present invention. The suturing device 1100 includes, generally, an elongated shaft 1102 for insertion into an internal biological structure, a main body 1104, a plunger 1106 and a handle 1108 for gripping the suturing device. The plunger 1106 is located at the proximal end of the main body 1104 and is operatively connected to the distal portion 1200 of the suturing device 1100. In this modification, the arms 1204, 1204' are simultaneously deployed into an asymmetrical configuration using a single plunger 1106. This modification can be advantageously used to simultaneously penetrate different types of tissue that require different angles of entry or different tissue capture geometries. This modification can also be used for surrounding a body structure with a first arm/needle pair and applying suture through tissue with the other arm/needle pair. With this embodiment, the needle 1216, 1216' have trajectories that are preferably adjusted to find the proper placement in the arms 1204, 1204'. This embodiment can also be combined with independent arm actuation, as described above with reference to FIGS. 26A-27B, thereby providing independent arm actuation and asymmetric arm deployment in the same unit.

In variations of the preferred embodiments described above, each of the suturing devices described above may be formed with a guidewire lumen extending lengthwise through the elongated body for slidably receiving a guidewire. Such a lumen preferably terminates at an opening located on the distal portion of the device. Such an opening may be similar to the opening 428 shown in FIG. 18. The suturing device may be advanced over the guidewire to facilitate the placement of the device in the patient's body. In other variations, each of the suturing devices described above may be formed with an additional lumen for receiving an endoscope for viewing the target site within the body.

In another aspect of the present invention, various devices and methods are provided for performing a hysterectomy. In a first preferred method for performing a hysterectomy, a suturing device is inserted into each fallopian tube as described above and suture is applied to each fallopian tube to close the lumen. A cutting tool is then inserted into each fallopian tube and each fallopian tube is severed thereby disconnecting the tubes from the uterus. After the fallopian tubes have been severed, the uterus is inverted through the cervix. The uterus is cut away from the cervix and is removed from the body. A suturing device as described above can then be used to apply suture to the cervix to close the distal portion of the vagina. For closure of the cervix, it may be preferable to use a suturing device with multiple arms and needles, for example, 6 or 8.

In a second method for performing a hysterectomy, a suturing device is inserted into each fallopian tube as described above and suture is applied to each fallopian tube to close the lumen. A cutting tool is then inserted into

each fallopian tube and each fallopian tube is severed thereby disconnecting the tubes from the uterus. After the fallopian tubes have been severed, the uterus is cut away from the cervix and is removed from the body. A suturing device as described above is then used to apply suture to the cervix to close the distal portion of the vagina.

In a third preferred method for performing a hysterectomy, a suturing device is inserted into each fallopian tube as described above and suture is applied to each fallopian tube to close the lumen. A cutting tool is then inserted into each fallopian tube and each fallopian tube is severed thereby disconnecting the tubes from the uterus. After the fallopian tubes have been severed, a suturing device such as described is inserted into the cervical opening, and suture ends are placed loosely applied around the opening of the cervix in a purse-string arrangement. The uterus is cut around the cervix at a location distal to the placed sutures and is removed from the body. The ends of the sutures are then pulled together and tied to close the distal portion of the vagina.

In a fourth preferred method for performing a hysterectomy, a suturing device is inserted into each fallopian tube as described above and suture is applied to each fallopian tube to close the lumen. A cutting tool is then inserted into each fallopian tube and each fallopian tube is severed thereby disconnecting the tubes from the uterus. After the fallopian tubes have been severed, suture is loosely applied around the cervical opening as described in the third method above. After the suture has been applied, the uterus is inverted through the cervix. The uterus is then cut at a location distal of the placed sutures and the uterus is removed from the body. The ends of the sutures are then pulled together and tied to close the distal portion of the vagina.

While embodiments and applications of this invention have been shown and described, it will be apparent to those skilled in the art that various modifications are possible without departing from the scope of the invention. It is, therefore, to be understood that within the scope of the appended claims, this invention may be practiced otherwise than as specifically described.

WHAT IS CLAIMED IS:

1. A suturing device for applying a suture, comprising:

an elongated body;

at least one arm having a suture mounting portion to releasably hold a portion of said suture, said arm being mounted to cause an end portion of said arm to move (i) away from said elongated body from a first position to a second position and (ii) towards said elongated body from the second position to the first position, said end portion of said arm being adapted to penetrate tissue as the arm moves away from said elongated body to said second portion while holding said portion of the suture during such movement; and

at least one needle having a distal end, said needle mounted to move relative to said elongated body, said distal end of said needle movable from a first position adjacent to said elongated body to a second position adjacent said suture mounting portion of said arm when said arm is in said second position;

wherein said distal end of said needle is adapted to capture said portion of the suture from the suture mounting portion of the arm and draws said portion of said suture toward said elongated body.

2. The suturing device of Claim 1, wherein said second position of said needle is spaced away from said elongated body.

3. The suturing device of Claim 1, wherein the arm is hingedly mounted to an actuating rod, said actuating rod being movable within a lumen of the elongated body.

4. The suturing device of Claim 1, wherein the end portion of the arm includes a pointed tip.

5. The suturing device of Claim 1, comprising:

first and second arms each having a suture mounting portion to releasably hold an end portion of a suture; and

first and second needles adapted to capture the end portions of the suture from the suture mounting portions of the first and second arms and draw the end portions of the suture proximally.

6. The suturing device of Claim 5, wherein the first and second arms when in their second position are substantially parallel to one another.

7. The suturing device of Claim 5, wherein the first and second arms when in their second position form an angle that is less than 180 degrees.

8. The suturing device of Claim 5, wherein the first and second arms each have two suture mounting portions.

9. The suturing device of Claim 8, wherein the two suture mounting portions on each arm are side-by-side.

10. The suturing device of Claim 8, wherein one of the two suture mounting portions on each arm is distal to the other.

11. The suturing device of Claim 5, wherein the first and second arms are separately moveable.

12. The suturing device of Claim 5, wherein the first and second needles are separately moveable.

13. The suturing device of Claim 1, wherein the end portions of the suture are loops.

14. The suturing device of Claim 1, wherein the end portions of the suture are substantially spherical in shape.

15. The suturing device of Claim 1, wherein the end portions of the suture comprise a ferrule.

16. The suturing device of Claim 1, wherein the end portion of the at least one arm, when the arm is in its second position, is distal to a distal end of the elongated body.

17. A suturing device for applying a suture, comprising:

an elongated body;

at least one arm connected to said elongated body having a suture mounting portion and an end portion, said suture mounting portion being formed to releasably hold an end portion of said suture, said end portion of said arm being adapted to penetrate tissue; and

at least one needle having a distal end, said needle being extendable and retractable relative to said elongated body, said distal end of said needle being adapted for cooperation with said suture mounting portion of said arm;

whereby said needle can be extended such that said distal end of said needle captures said end portion of said suture from said suture mounting portion of said arm and said needle can be retracted to draw said end portion of said suture back toward said elongated body.

18. The suturing device of Claim 17, wherein said arm is capable of being advanced and retracted from said elongated body.

19. The suturing device of Claim 18, wherein said arm further comprises a proximal end, said proximal end of said arm being coupled to an actuating rod, said actuating rod being movable within a lumen of the elongated body to advance and retract said arm.

20. A suturing device for applying a suture, comprising:

an elongated body;

two arms located on opposite sides of said elongated body, each of said arms having a suture mounting portion and an end portion, said suture mounting portions being formed to releasably hold an end portion of said suture, said arms being extendable and retractable relative to said elongated body, said arms having sharp end portions adapted to penetrate tissue when said arms are extended; and

two needles located on opposite sides of said elongated body, each needle having a distal end, said needles being extendable and retractable relative to said elongated body, said distal ends of said needles being adapted for cooperation with said suture mounting portions of said arms when said needles and said arms are extended;

whereby said arms are advanced outward from said elongated body, said needles are advanced distally from said elongated body such that said distal ends of said needles engage and capture said end

portions of said sutures from said suture mounting portions of said arms, and said needles are retracted to draw said end portions of said sutures back toward said elongated body.

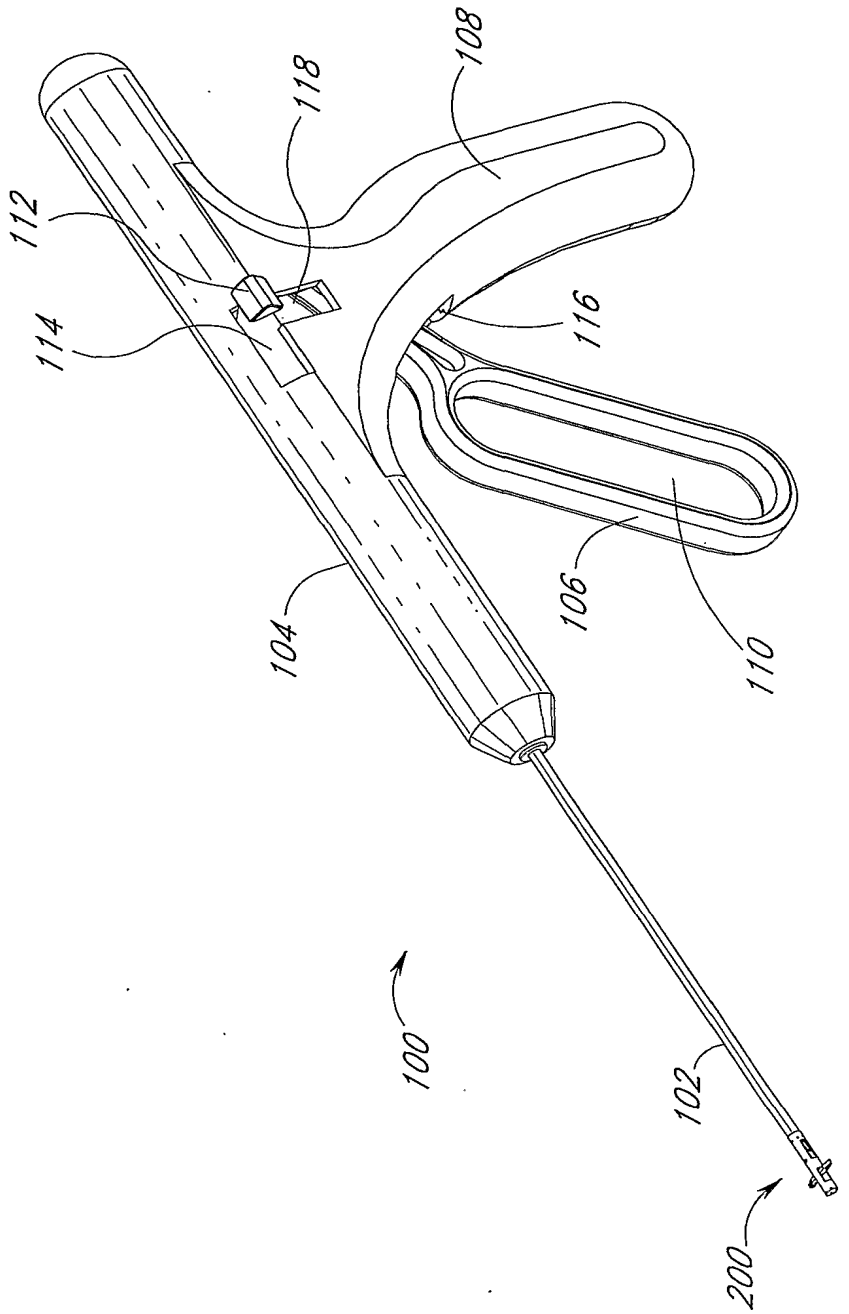


FIG. 1

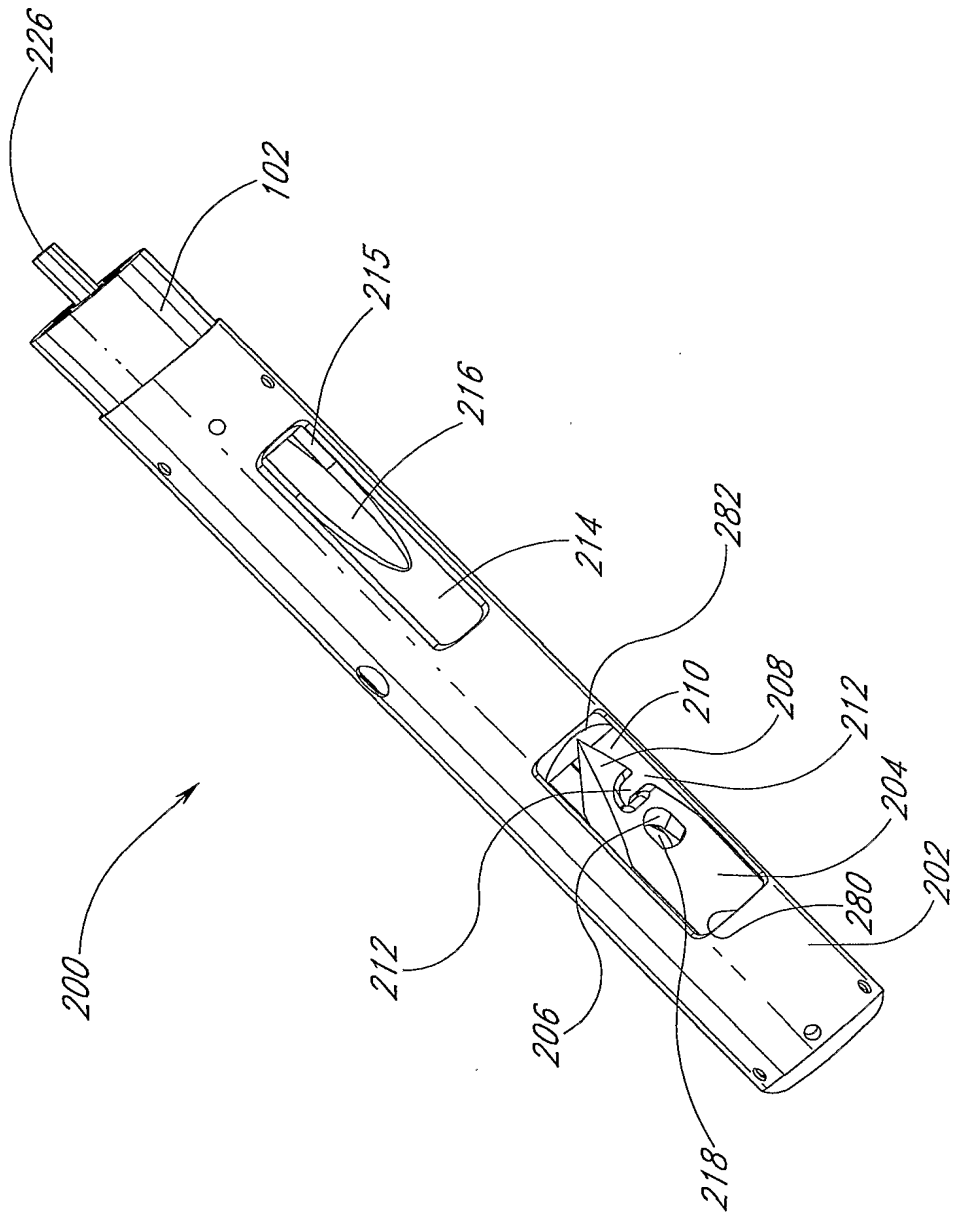


FIG. 2

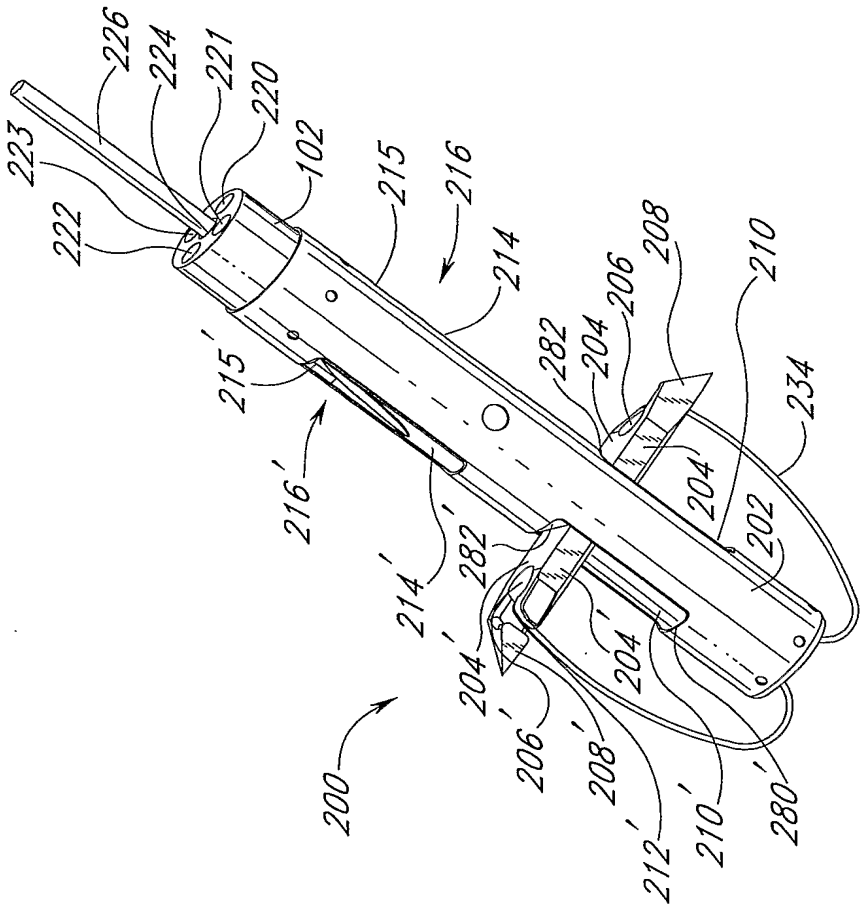


FIG. 3

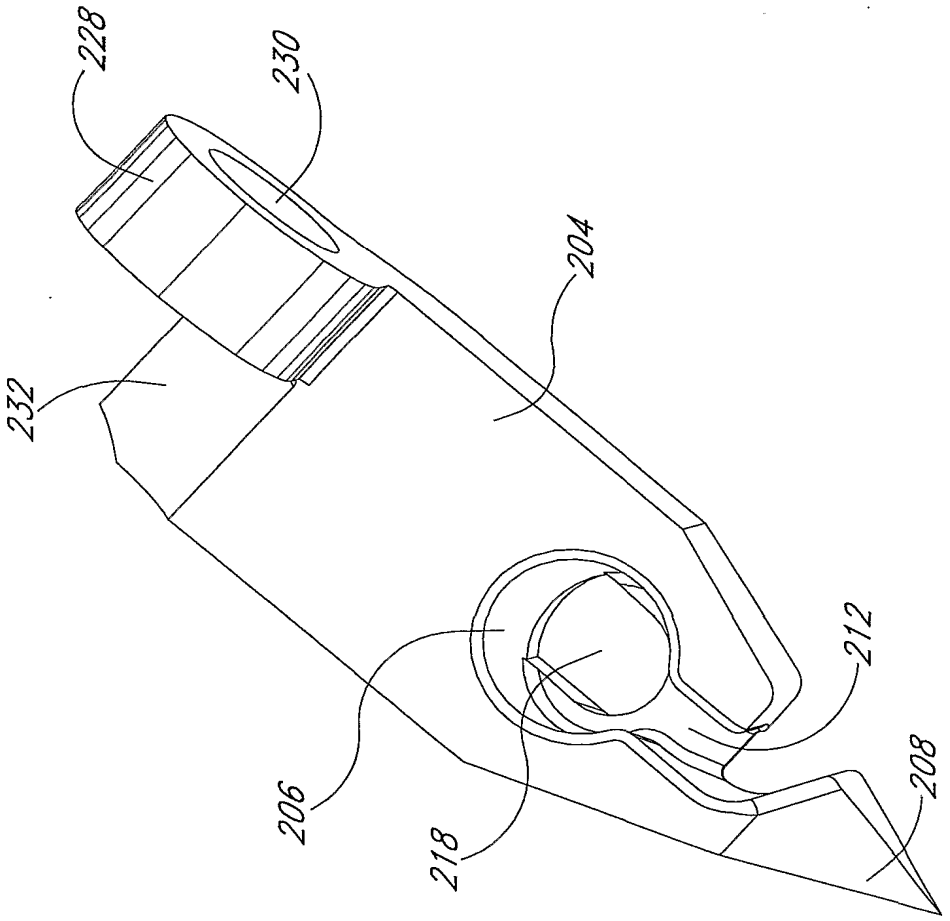


FIG. 4

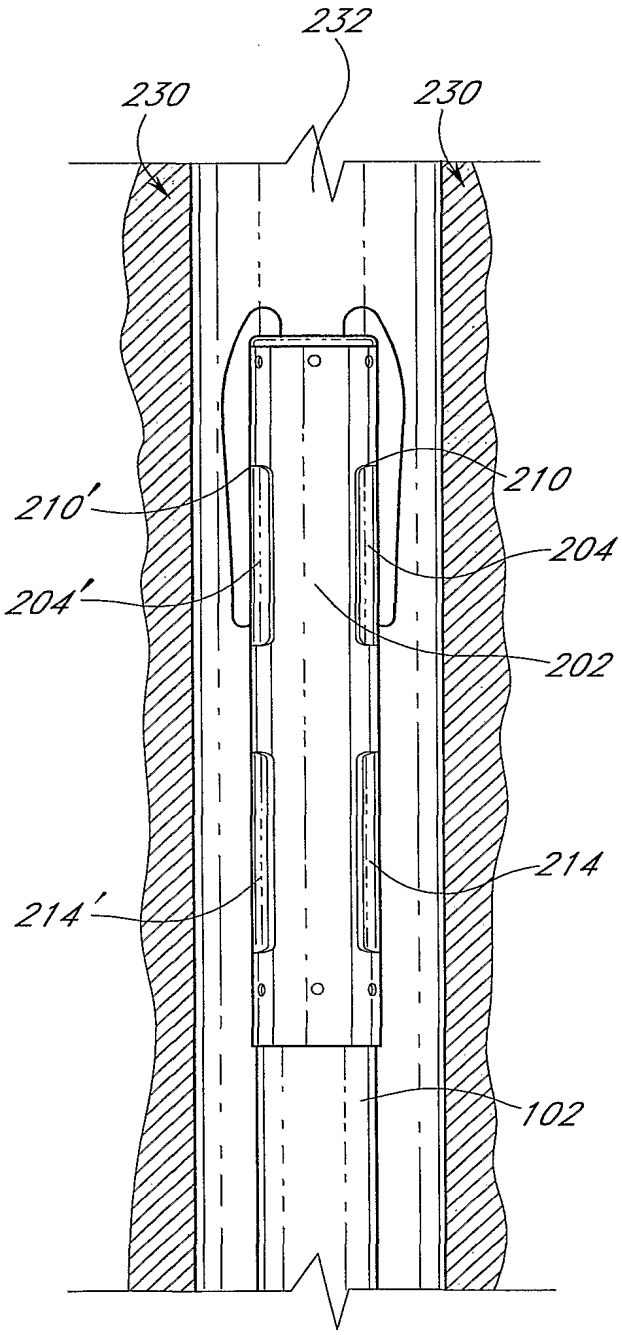


FIG. 5

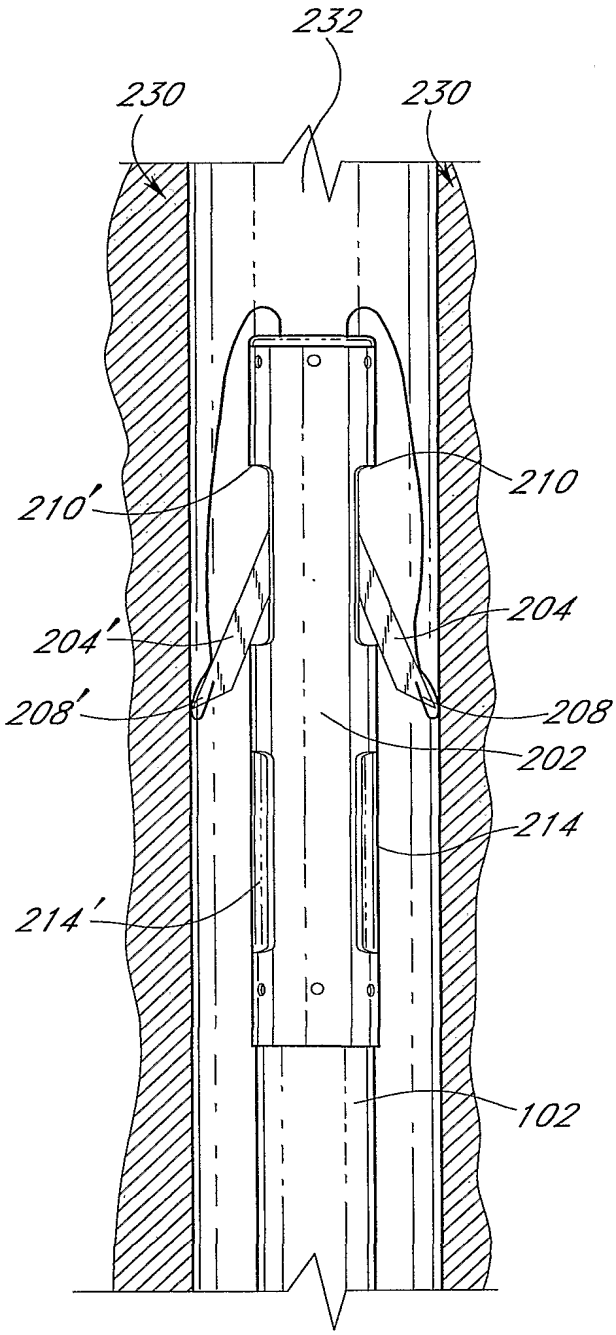


FIG. 6

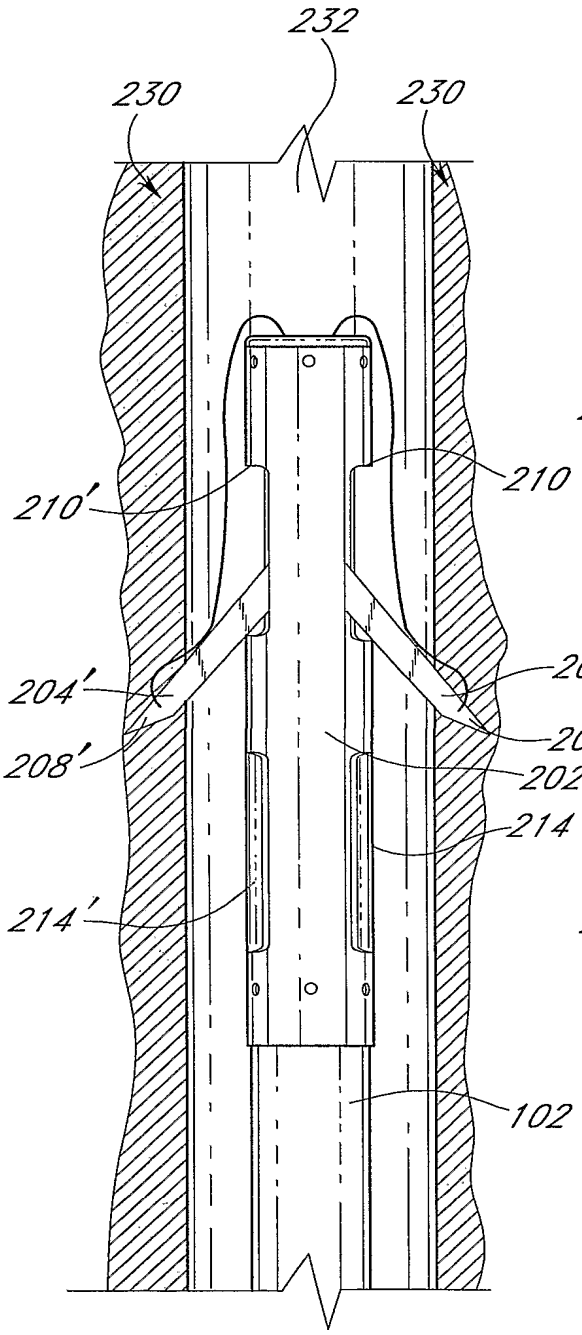


FIG.7

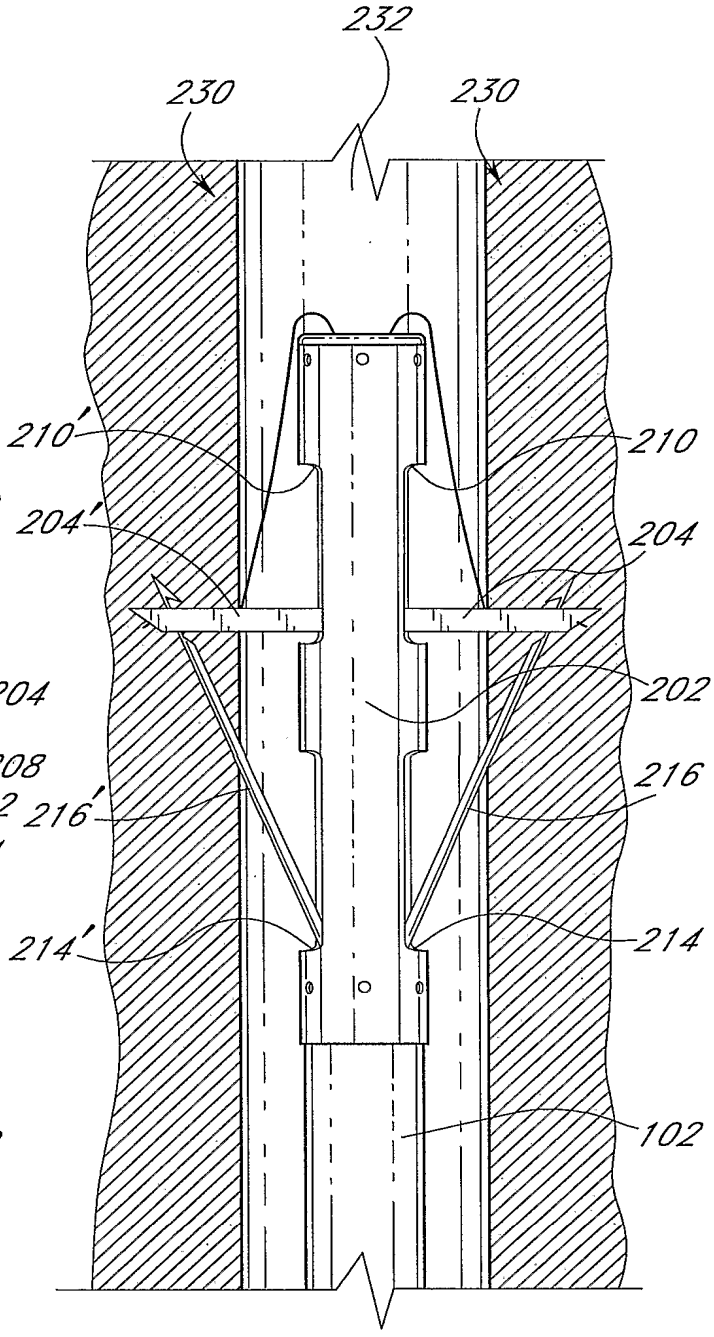


FIG.8

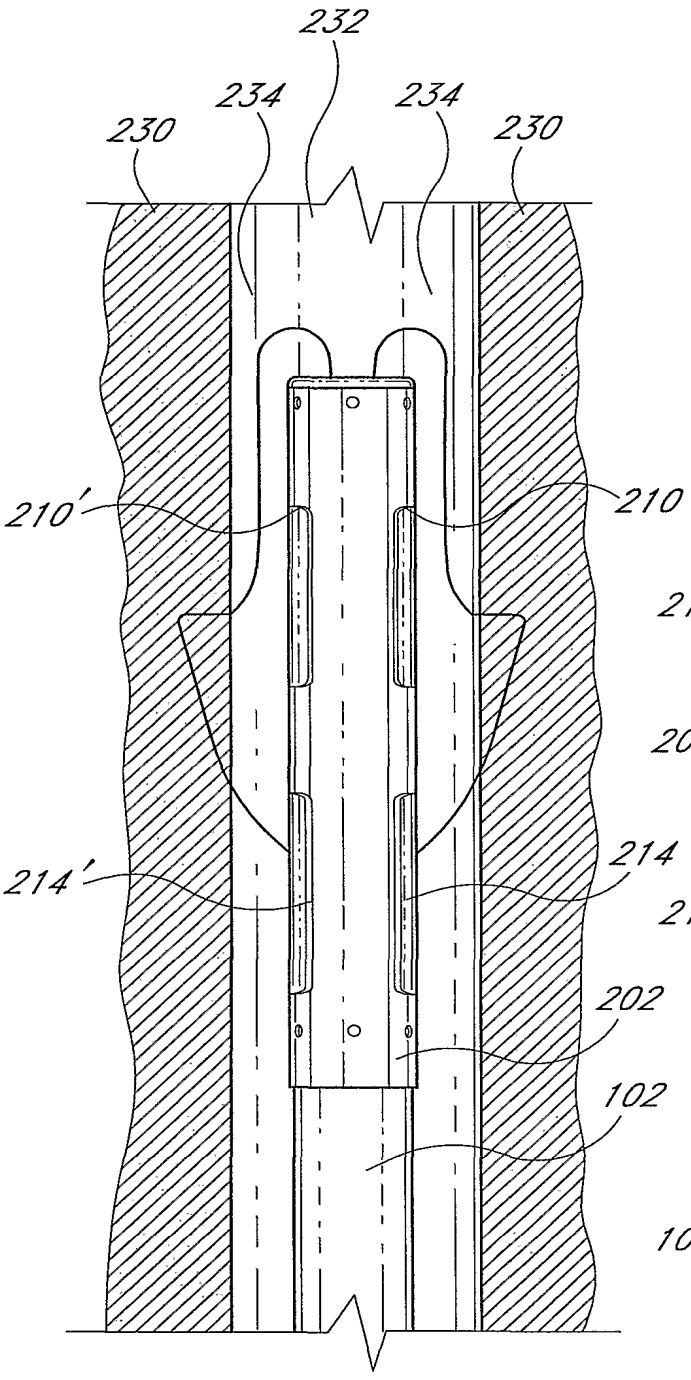


FIG. 9

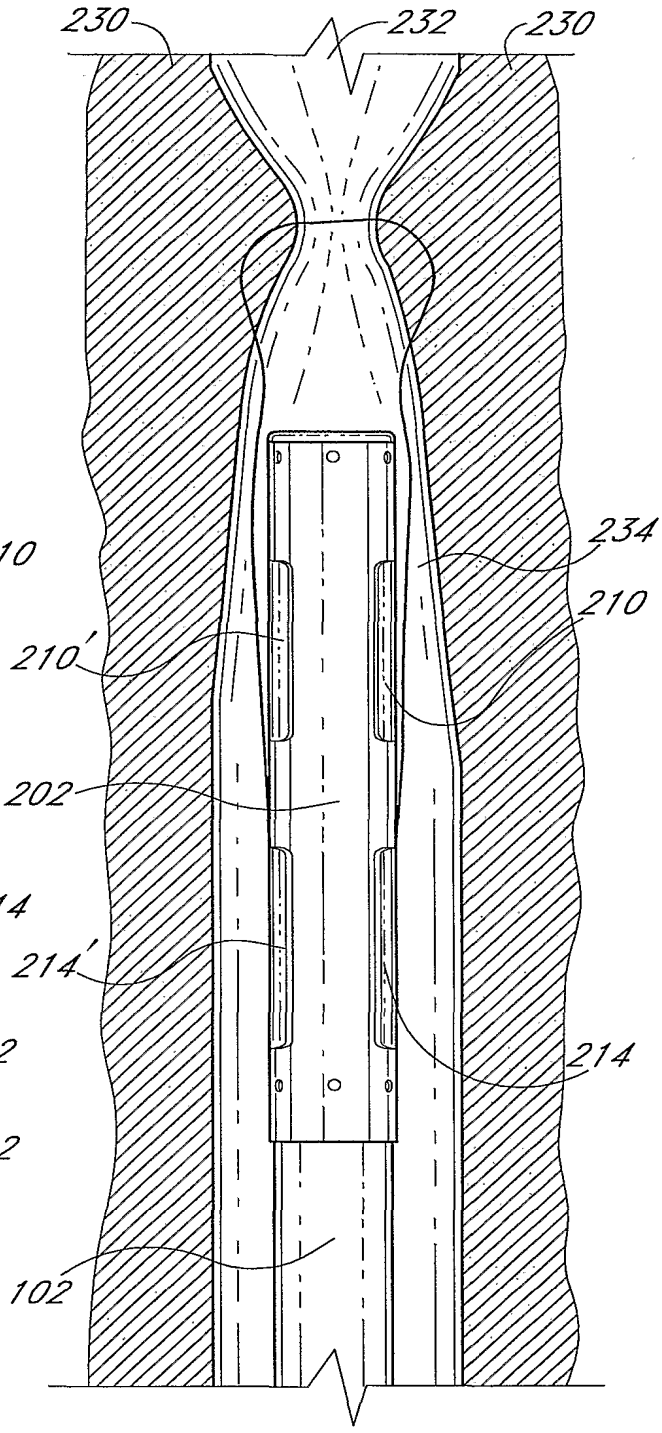


FIG. 10

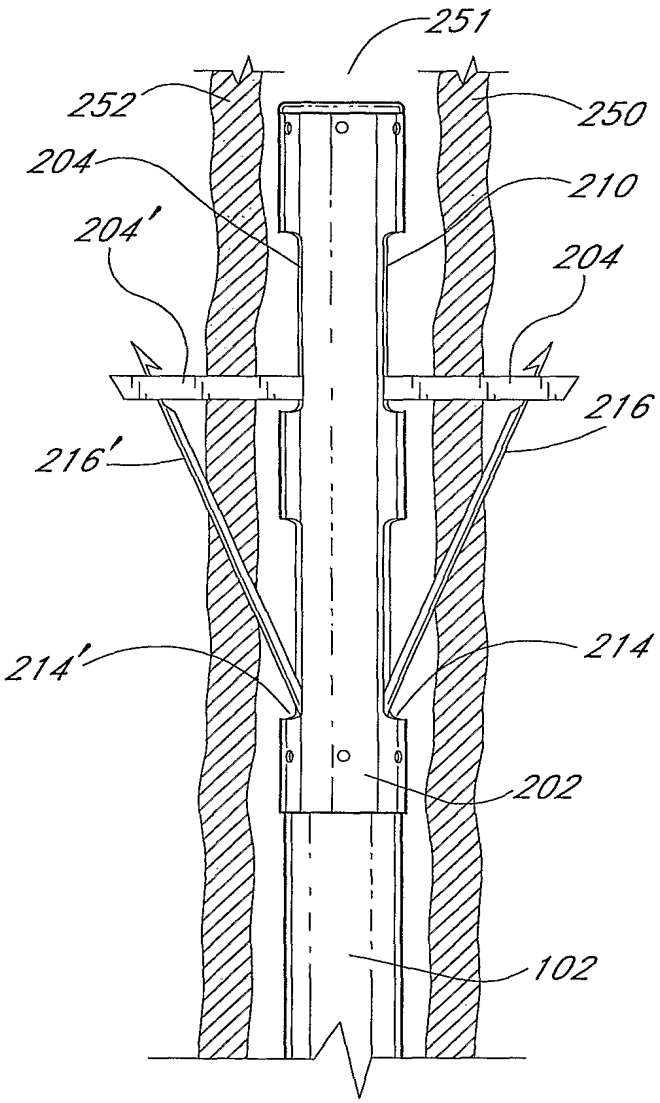


FIG. 11

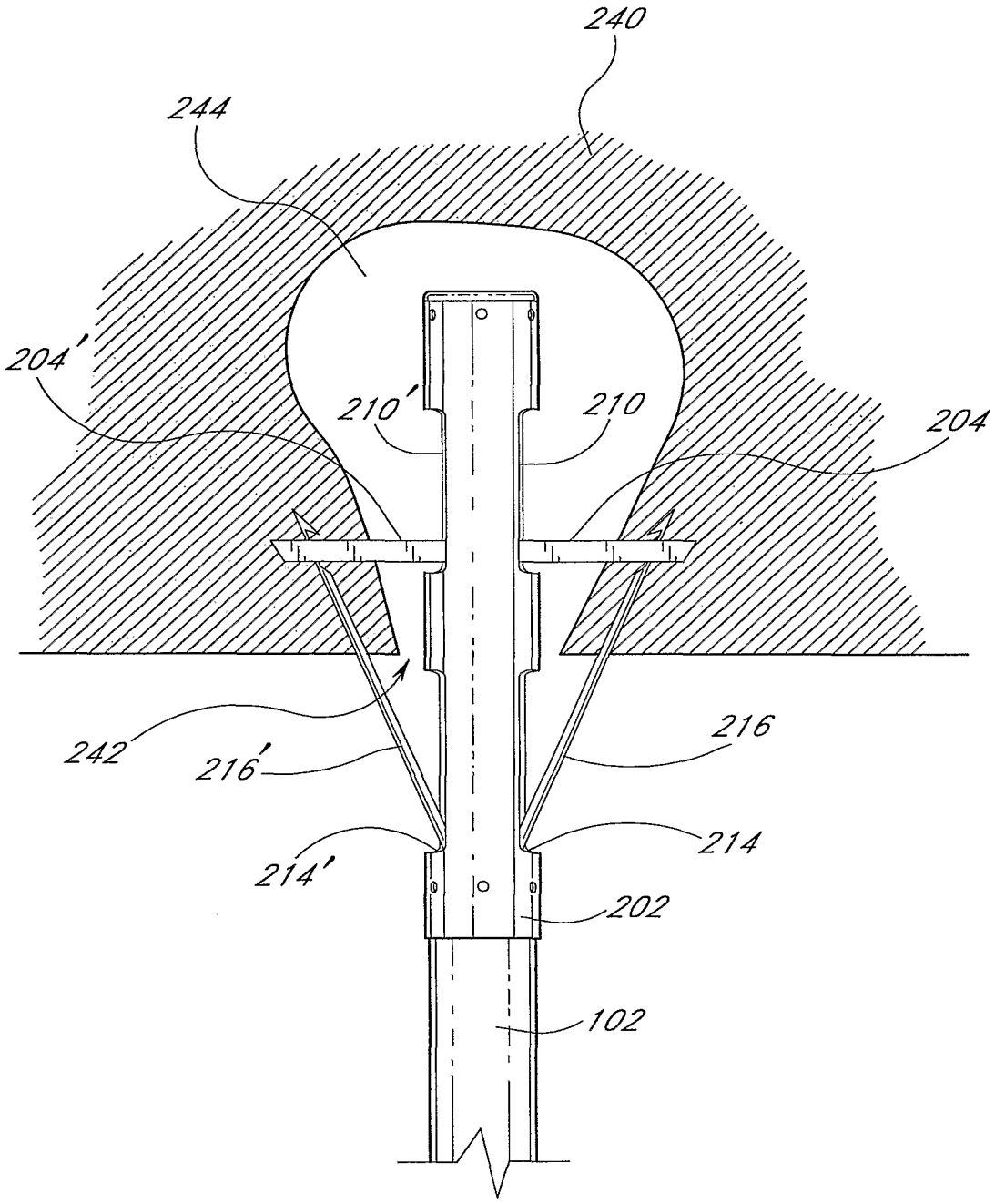
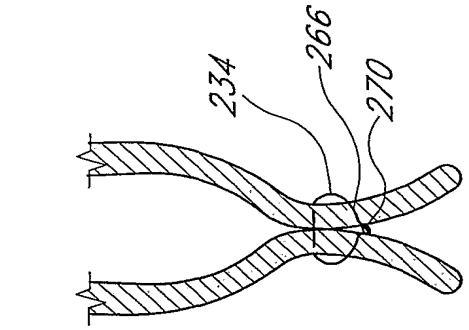


FIG. 12



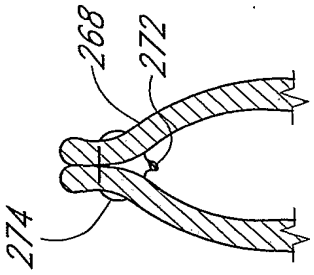
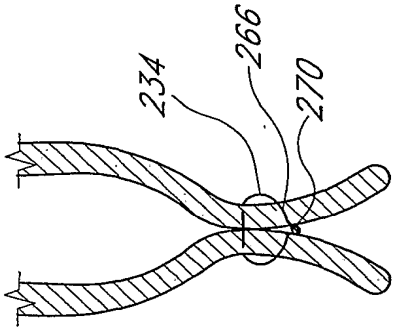


FIG. 16



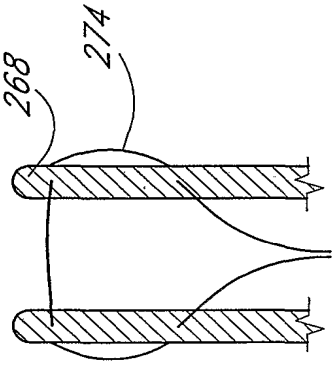
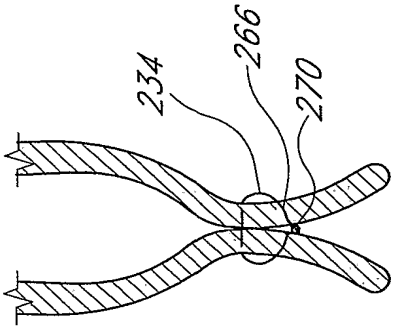
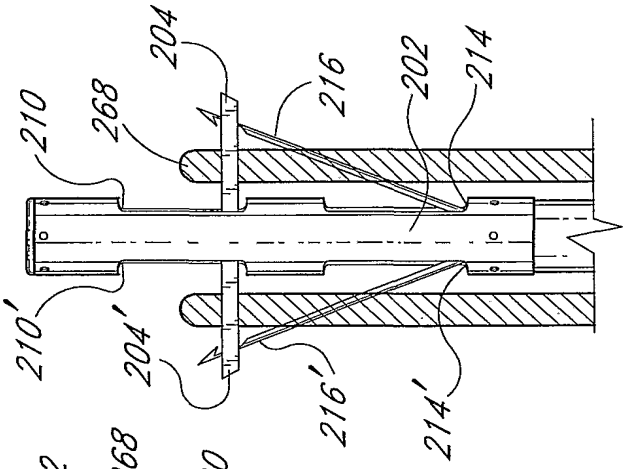
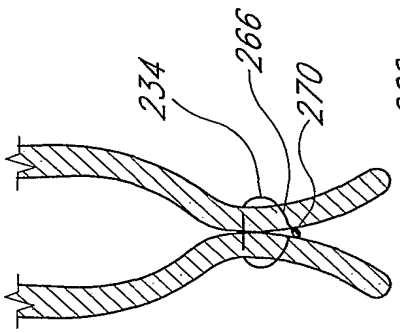


FIG. 15







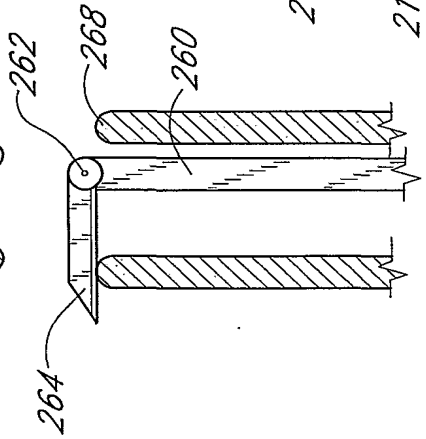


FIG. 13

FIG. 14

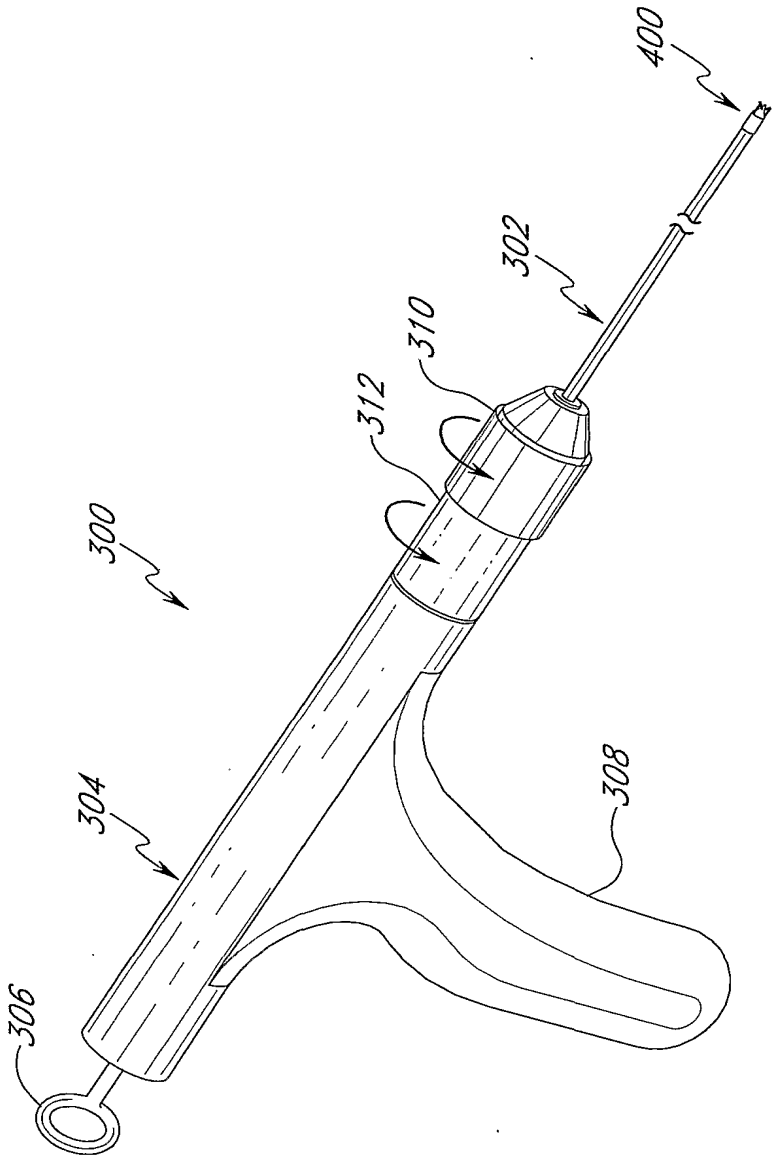


FIG. 17

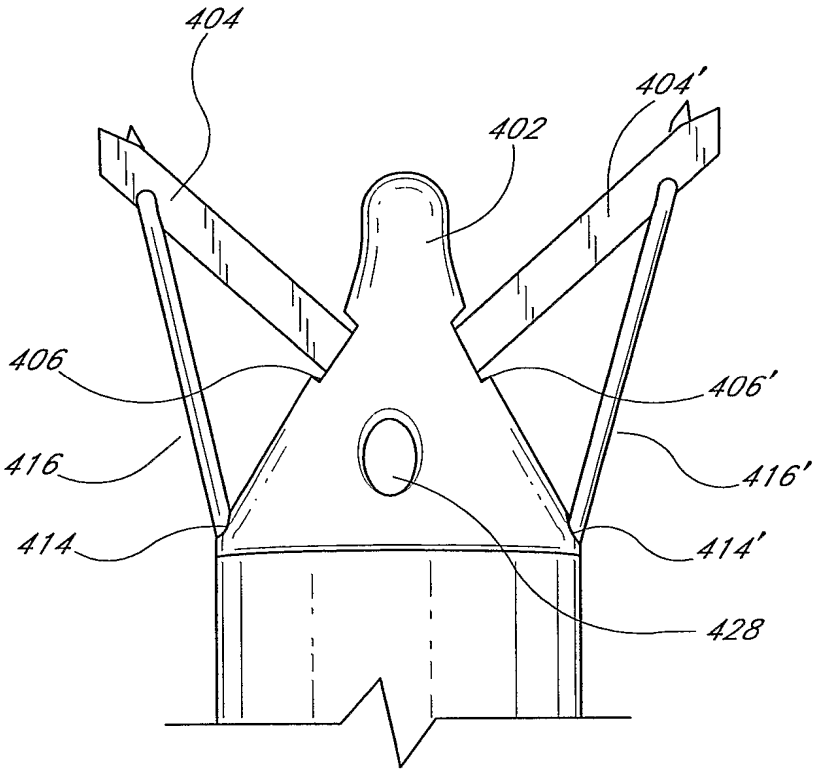


FIG. 18

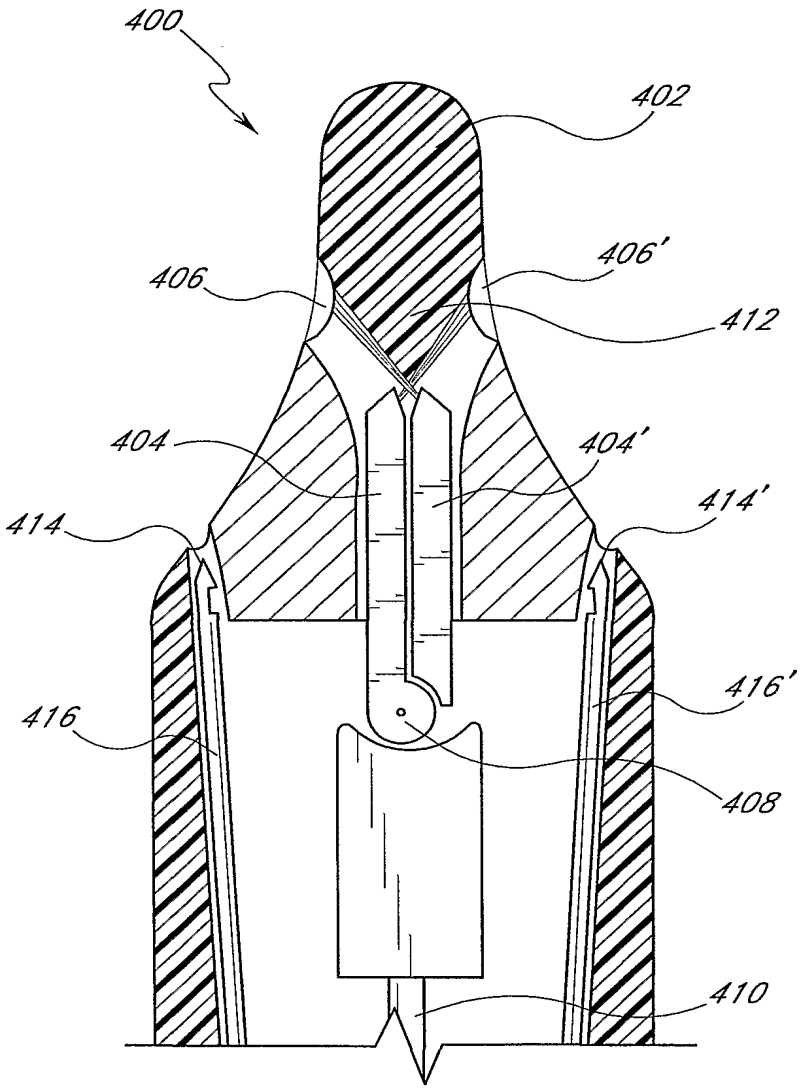


FIG. 19A

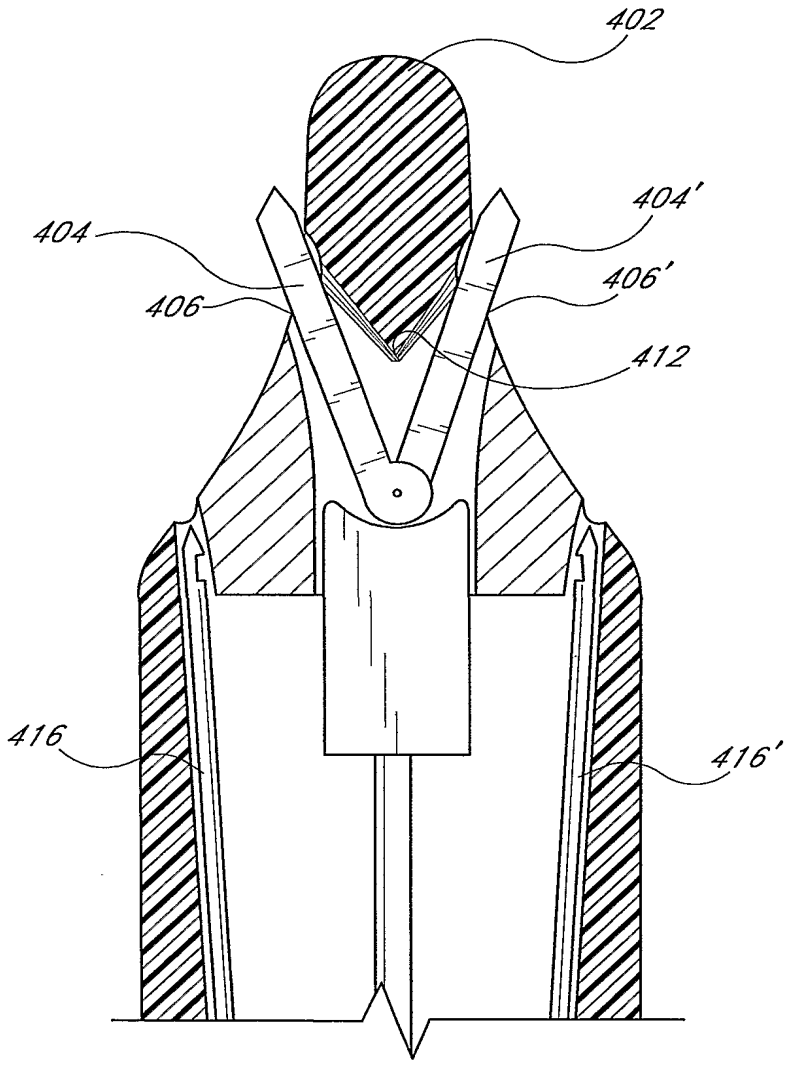


FIG. 19B

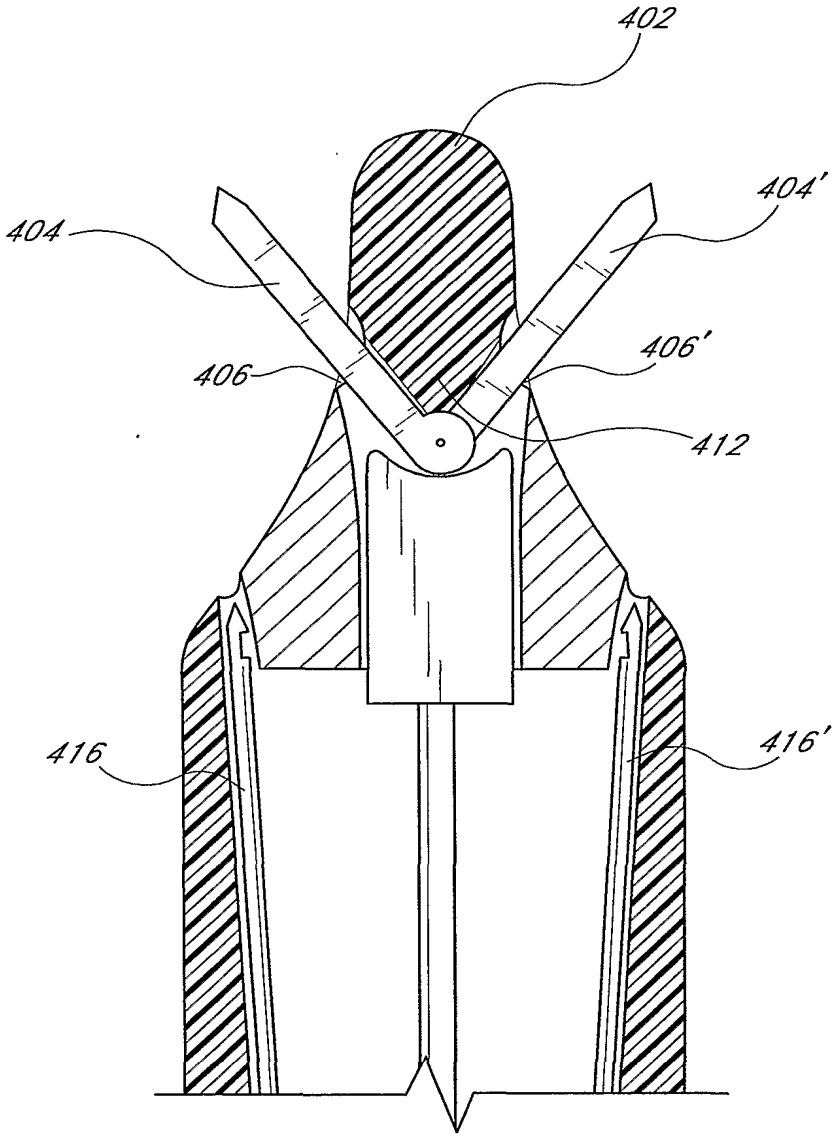


FIG. 19C

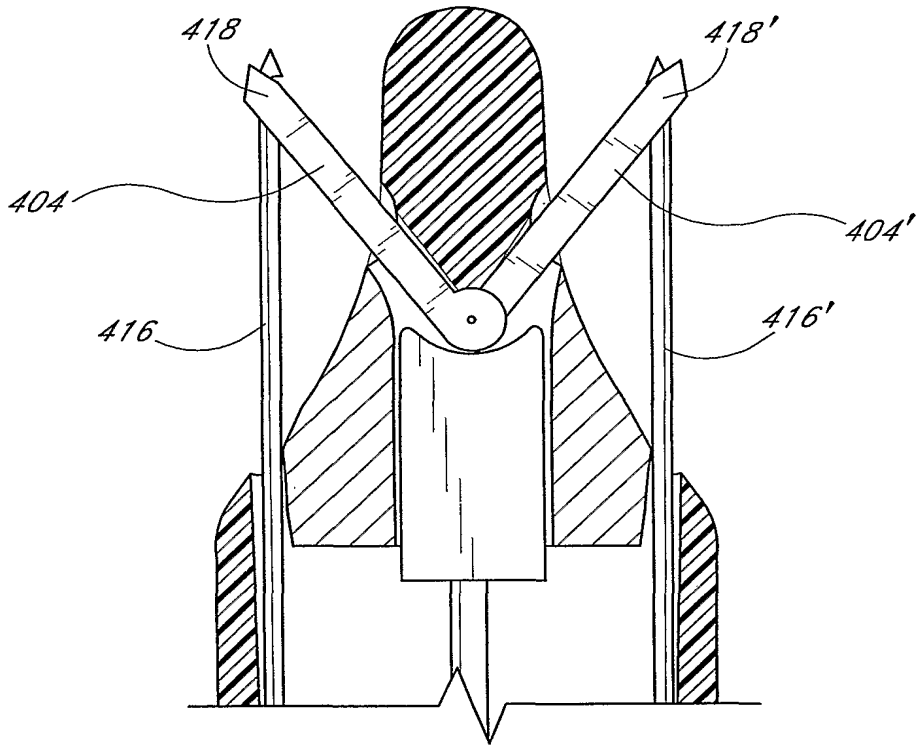


FIG. 19D

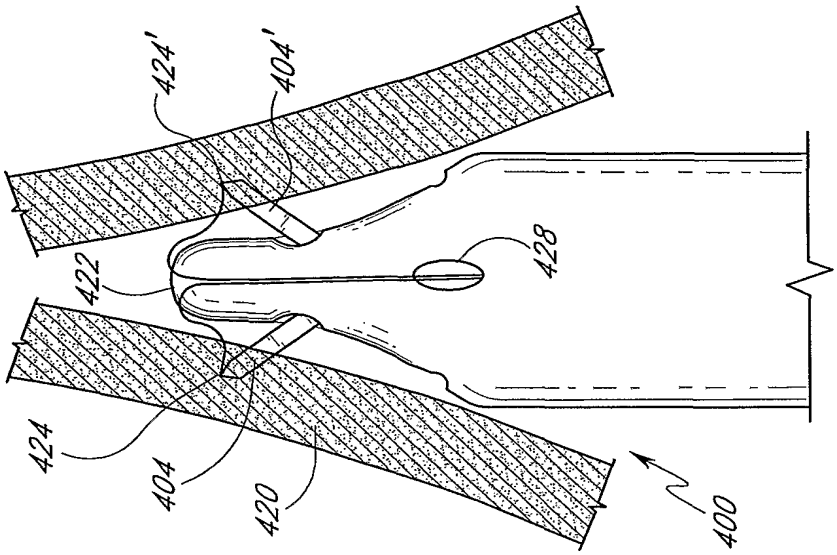


FIG.20B

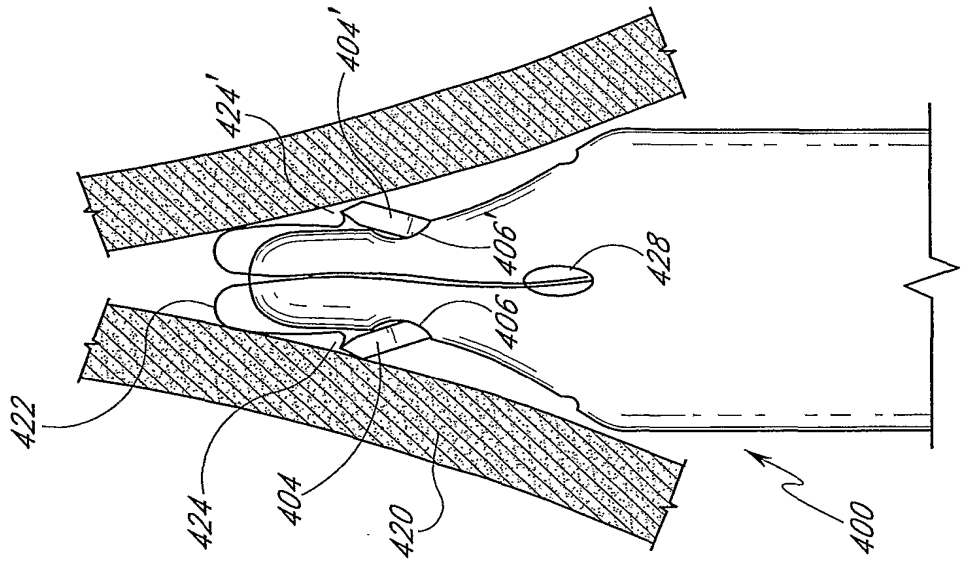


FIG.20A

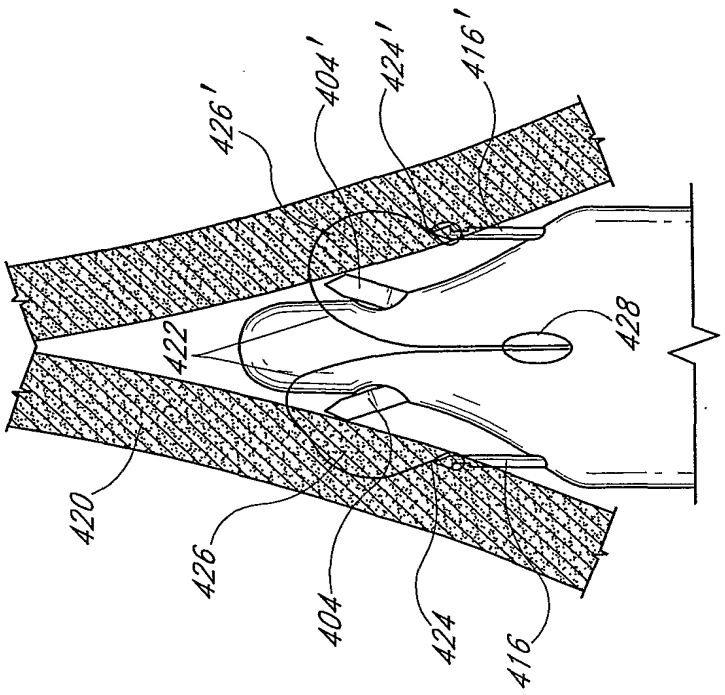


FIG.20D

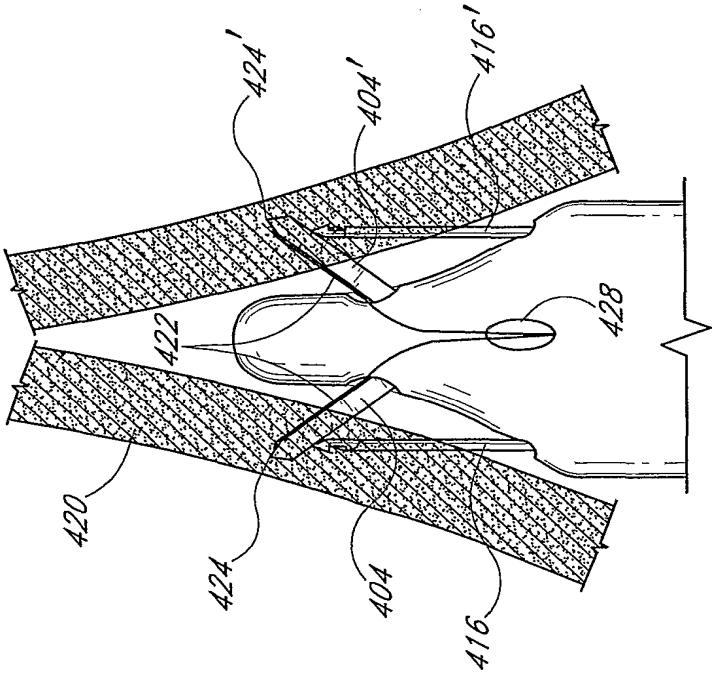


FIG.20C

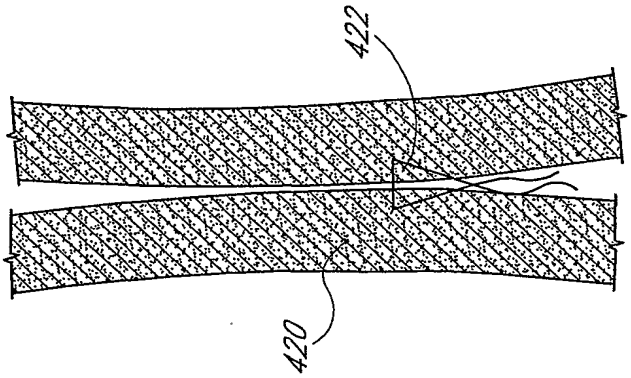


FIG.20F

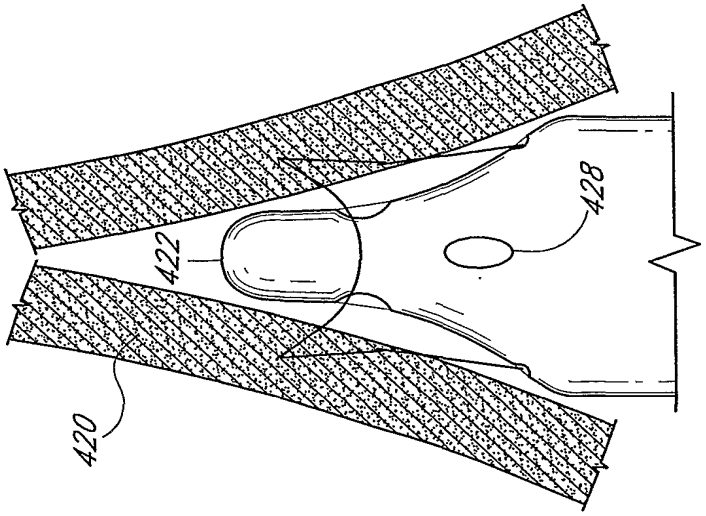


FIG.20E

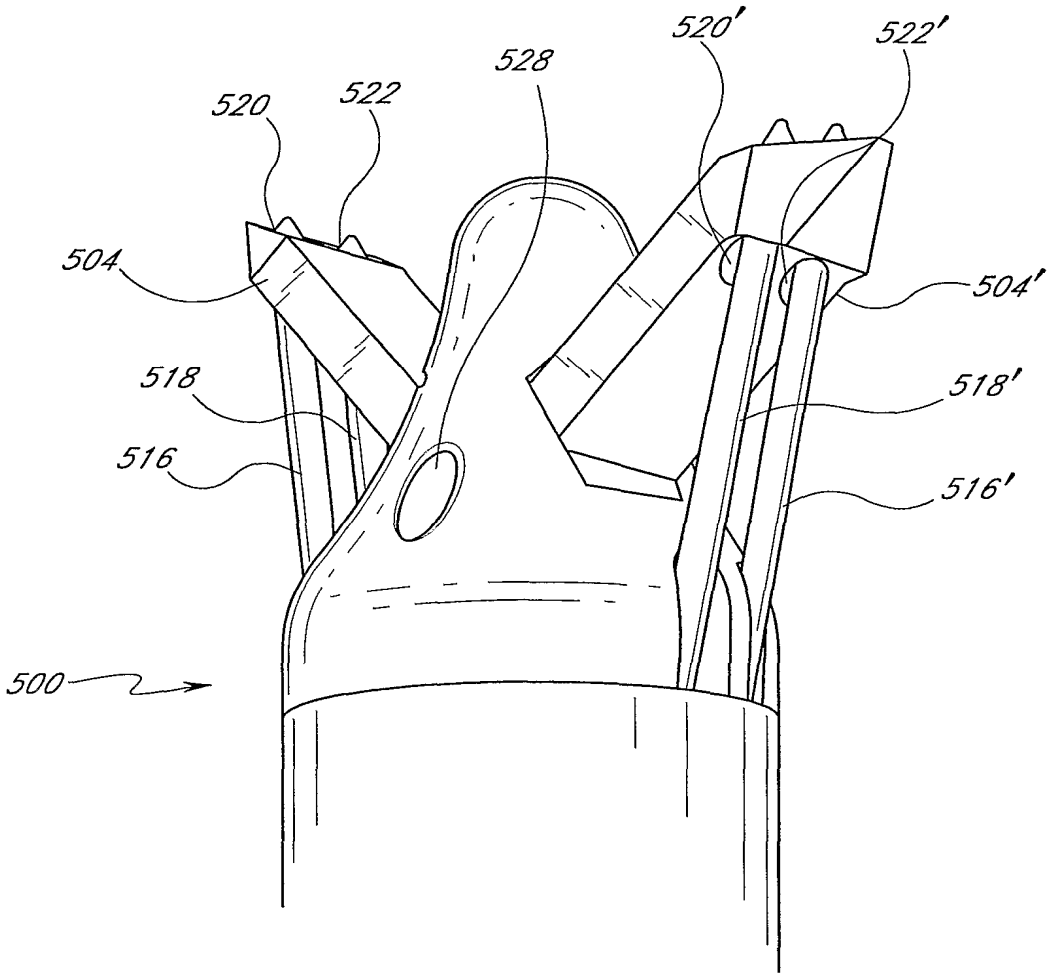


FIG. 21

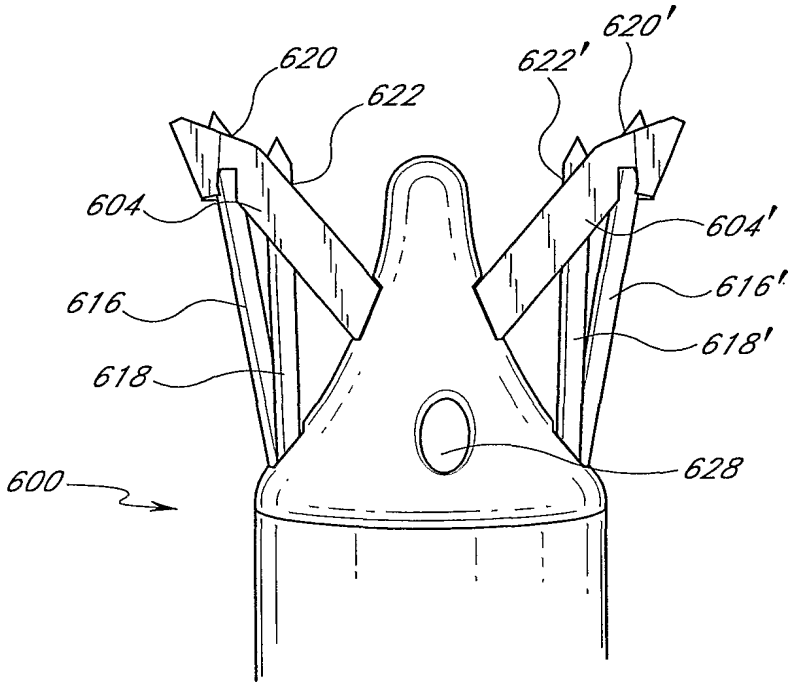


FIG. 22

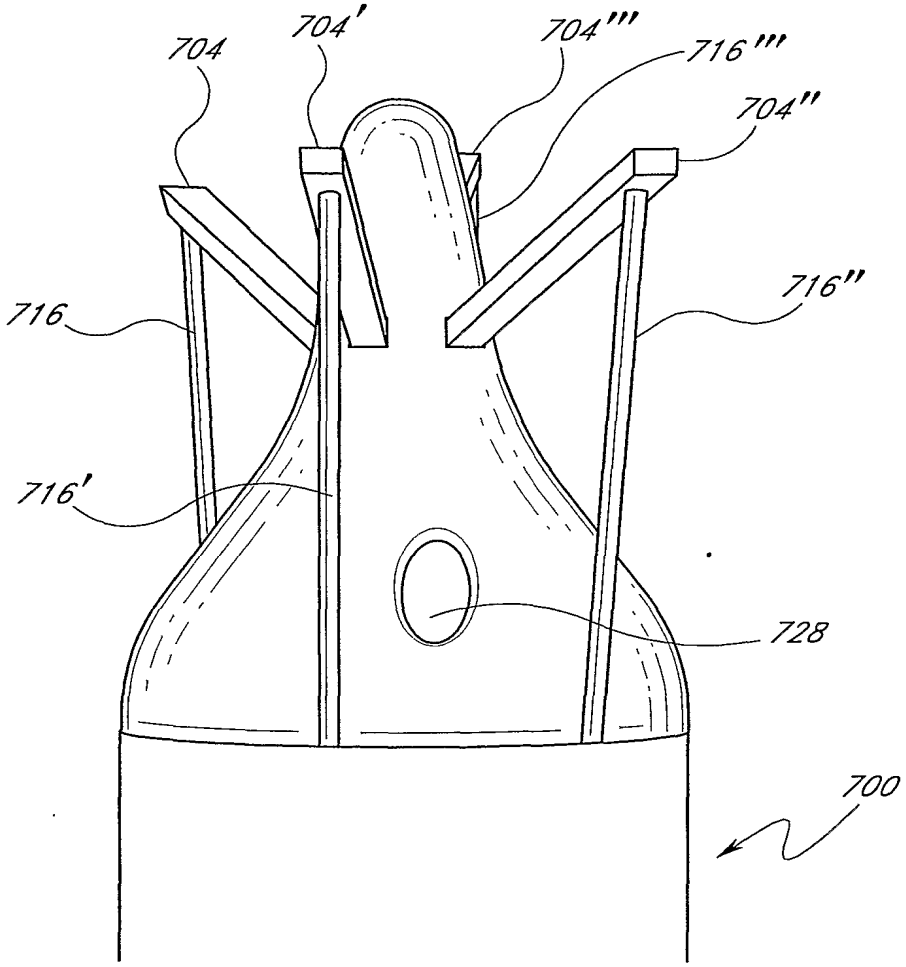


FIG.23

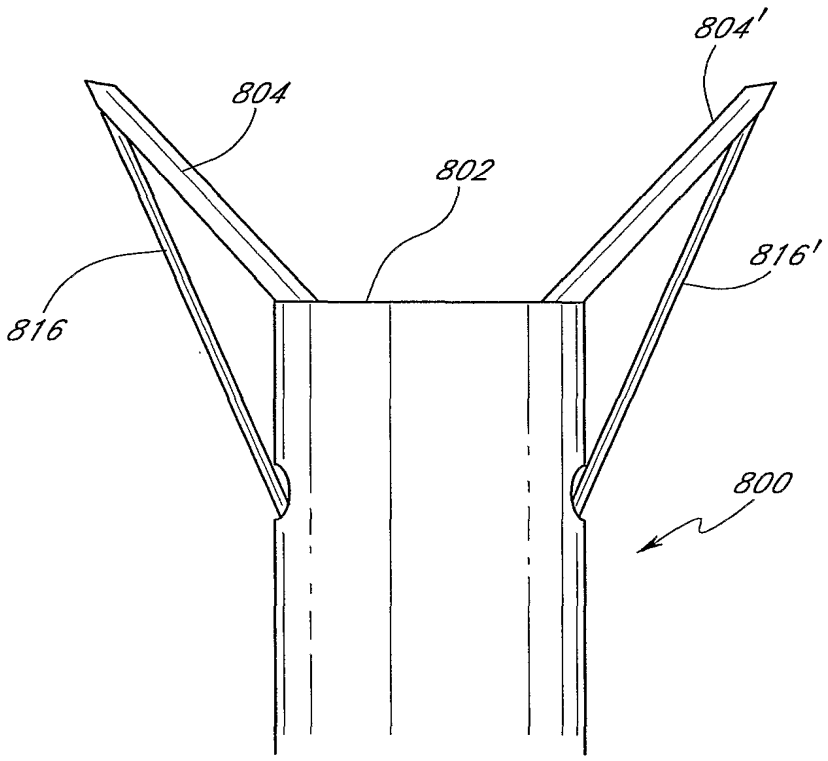


FIG. 24

FIG. 25A

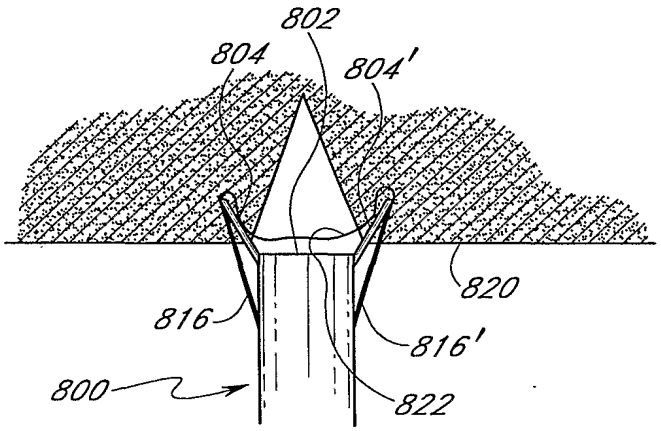


FIG. 25B

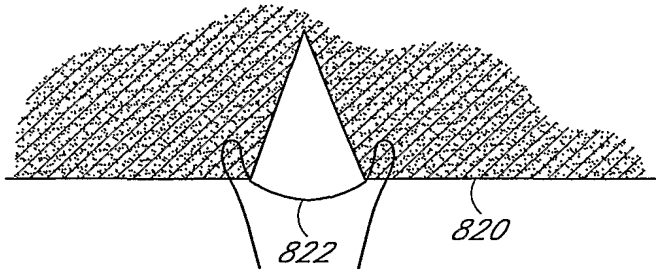
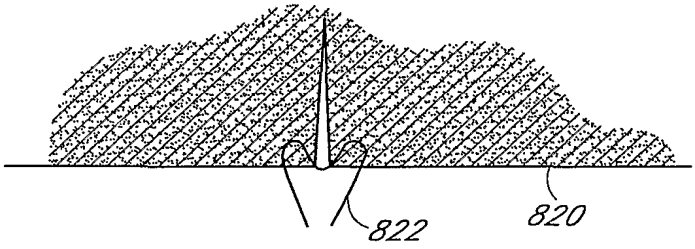


FIG. 25C



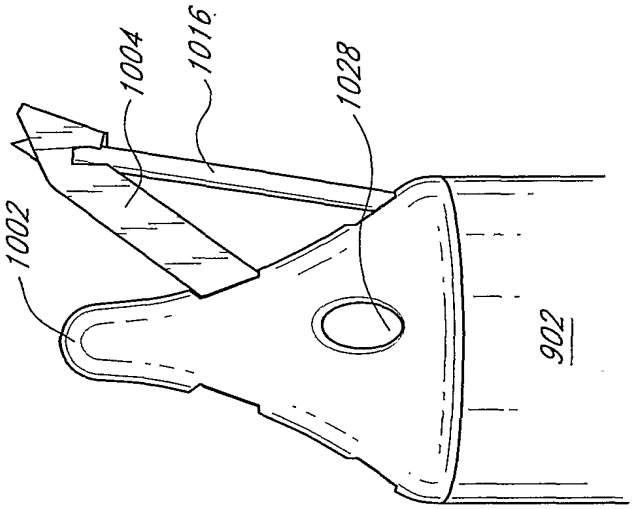


FIG.26B

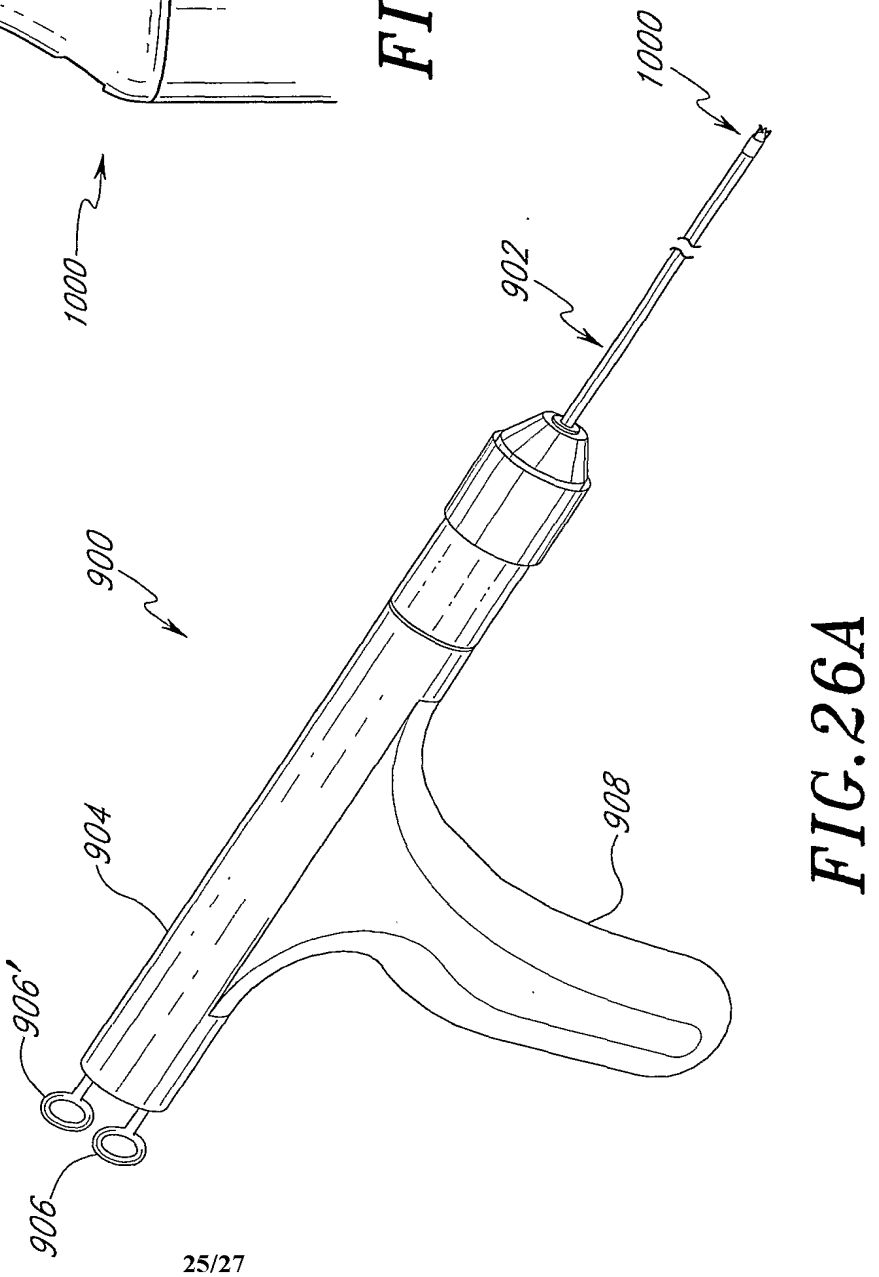


FIG.26A

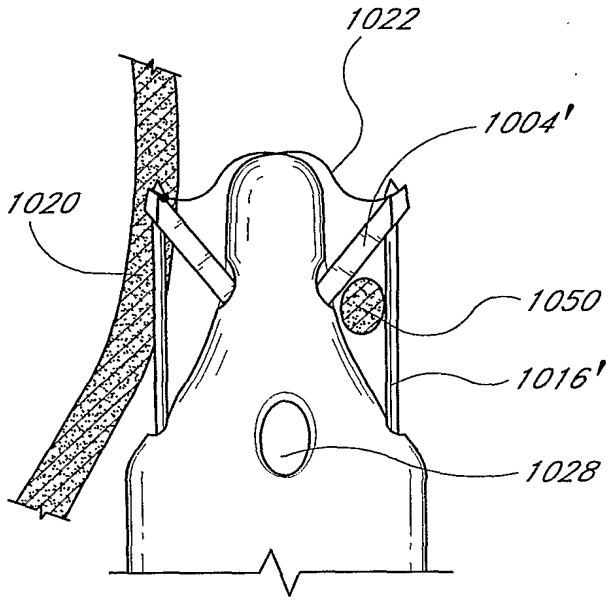


FIG.27A

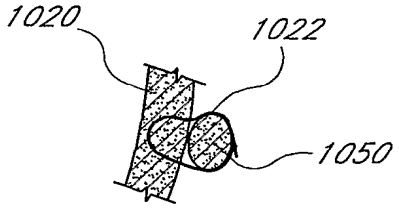


FIG.27B

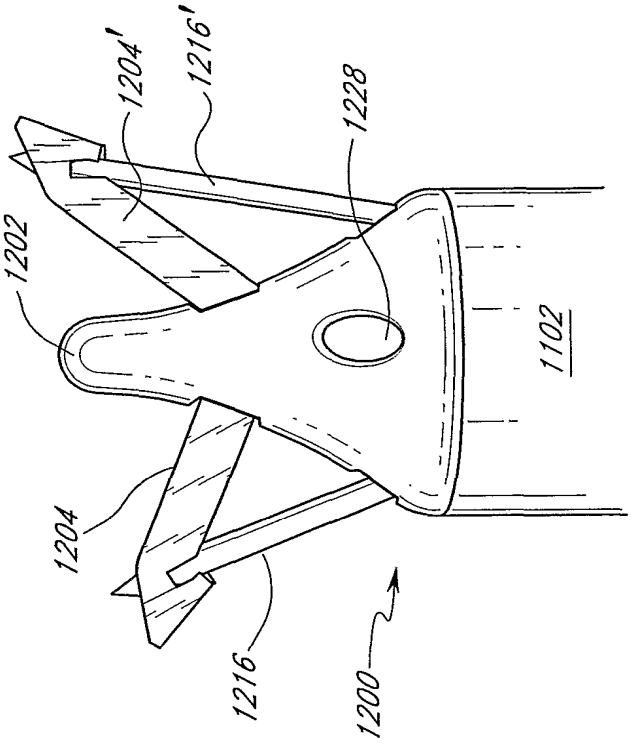


FIG.28B

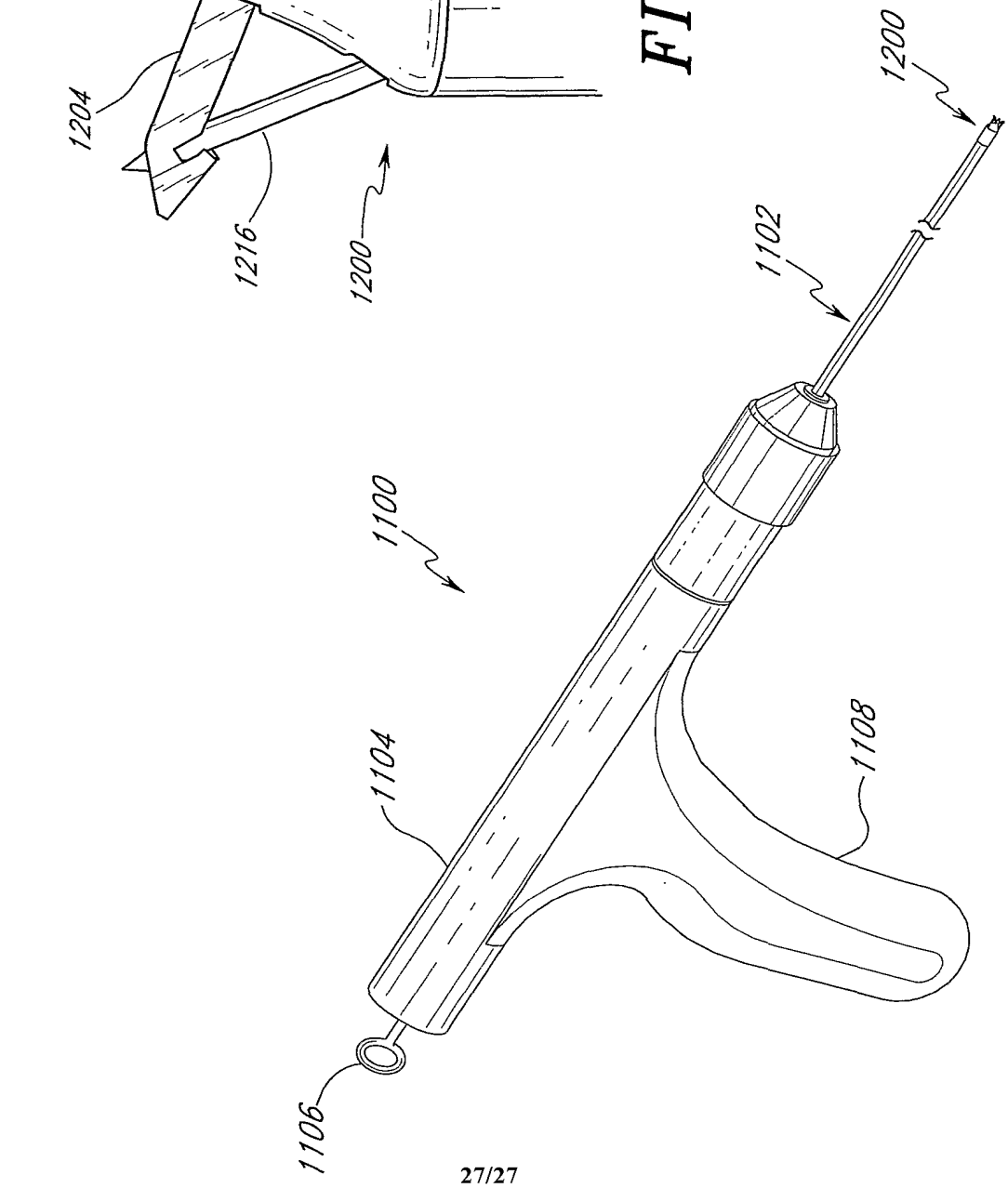


FIG.28A

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 01/19141

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

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0 941 698 A (NOBLES) 15 September 1999 (1999-09-15) column 5, line 51 -column 8, line 48; figures 2-8	1-20
Y	US 5 868 762 A (CRAGG) 9 February 1999 (1999-02-09) column 3, line 66 -column 4, line 9; figures 1-14	1-20
A	US 5 320 632 A (HEIDMUELLER) 14 June 1994 (1994-06-14) column 3, line 4 -column 4, line 58; figures 1-5	1-10,13, 17,20

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

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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(71) Applicant *(for all designated States except US)*: MYOCOR, INC. [US/US]; Suite 200W–B, 1380 Energy Lane, St. Paul, MN 55108 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: MORTIER, Todd, J. [US/US]; 3008 Colfax Avenue South, Minneapolis, MN 55408 (US). SCHWEICH, Cyril, J., Jr. [US/US]; 1685 Hillcrest Avenue, St. Paul, MN 55116 (US). VIDLUND, Robert, M. [US/US]; 1811 Kennard Street, Maplewood, MN 55109 (US).

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

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(54) Title: STRESS REDUCTION APPARATUS AND METHOD

(57) Abstract

The device and method for reducing heart wall stress. The device can be one which reduces wall stress throughout the cardiac cycle or only a portion of the cardiac cycle. The device can be configured to begin to engage, to reduce wall stress during diastolic filling, or begin to engage to reduce wall stress during systolic contraction. Furthermore, the device can be configured to include at least two elements, one of which engages full cycle and the other which engages only during a portion of the cardiac cycle.

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STRESS REDUCTION APPARATUS AND METHOD

Related Applications

This application is related to U.S. Application Serial No. 09/123,977, filed on date even herewith and entitled "Transventricular Implant Tools and Devices" and U.S. Application Serial No. 09/124,286, filed on date even herewith and entitled "Heart Wall Tension Reduction Apparatus and Method", both of which are incorporated herein by reference

Field of the Invention

The present invention pertains to the field of apparatus for treatment of a failing heart. In particular, the apparatus of the present invention is directed toward reducing the wall stress in the failing heart.

Background of the Invention

The syndrome of heart failure is a common course for the progression of many forms of heart disease. Heart failure may be considered to be the condition in which an abnormality of cardiac function is responsible for the inability of the heart to pump blood at a rate commensurate with the requirements of the metabolizing tissues, or can do so only at an abnormally elevated filling pressure. There are many specific disease processes that can lead to heart failure with a resulting difference in pathophysiology of the failing heart, such as the dilatation of the left ventricular chamber. Etiologies that can lead to this form of failure include idiopathic cardiomyopathy, viral cardiomyopathy, and ischemic cardiomyopathy.

The process of ventricular dilatation is generally the result of chronic volume overload or specific damage to the myocardium. In a normal heart that is exposed to long term increased cardiac output requirements, for example, that of an athlete, there is an adaptive process of ventricular dilation and myocyte hypertrophy. In this way, the heart fully compensates for the increased cardiac output requirements. With damage to the myocardium or chronic volume overload, however, there are increased requirements put on the contracting myocardium to such a level that this compensated state is never achieved and the heart continues to dilate.

The basic problem with a large dilated left ventricle is that there is a significant increase in wall tension and/or stress both during diastolic filling and during systolic contraction. In a normal heart, the adaptation of muscle hypertrophy (thickening) and ventricular dilatation maintain a fairly constant wall tension for systolic contraction. However, in a failing heart, the ongoing dilatation is greater than the hypertrophy and the result is a rising wall tension requirement for systolic contraction. This is felt to be an ongoing insult to the muscle myocyte resulting in further muscle damage. The increase in wall stress is also true for diastolic filling. Additionally, because of the lack of cardiac output, there is generally a rise in ventricular filling pressure from several physiologic mechanisms. Moreover, in diastole there is both a diameter increase and a pressure increase over normal, both contributing to higher wall stress levels. The increase in diastolic wall stress is felt to be the primary contributor to ongoing dilatation of the chamber.

Prior art treatments for heart failure fall into three generally categories. The first being pharmacological, for example, diuretics. The second being assist systems, for

example, pumps. Finally, surgical treatments have been experimented with, which are described in more detail below.

With respect to pharmacological treatments, diuretics have been used to reduce the workload of the heart by reducing blood volume and preload. Clinically, preload is defined in several ways including left ventricular end diastolic pressure (LVEDP), or left ventricular end diastolic volume (LVEDV). Physiologically, the preferred definition is the length of stretch of the sarcomere at end diastole. Diuretics reduce extra cellular fluid which builds in congestive heart failure patients increasing preload conditions. Nitrates, arteriolar vasodilators, angiotensin converting enzyme inhibitors have been used to treat heart failure through the reduction of cardiac workload through the reduction of afterload. Afterload may be defined as the tension or stress required in the wall of the ventricle during ejection. Inotropes such as digoxin are cardiac glycosides and function to increase cardiac output by increasing the force and speed of cardiac muscle contraction. These drug therapies offer some beneficial effects but do not stop the progression of the disease.

Assist devices include, for example, mechanical pumps. Mechanical pumps reduce the load on the heart by performing all or part of the pumping function normally done by the heart. Currently, mechanical pumps are used to sustain the patient while a donor heart for transplantation becomes available for the patient.

There are at least three surgical procedures for treatment of heart failure: 1) heart transplant; 2) dynamic cardiomyoplasty; and 3) the Batista partial left ventriculectomy. Heart transplantation has serious limitations including restricted availability of organs and adverse effects of immunosuppressive therapies required following heart transplantation. Cardiomyoplasty includes wrapping the heart with skeletal muscle and

electrically stimulating the muscle to contract synchronously with the heart in order to help the pumping function of the heart. The Batista partial left ventriculectomy includes surgically remodeling the left ventricle by removing a segment of the muscular wall. This procedure reduces the diameter of the dilated heart, which in turn reduces the loading of the heart. However, this extremely invasive procedure reduces muscle mass of the heart.

Summary of the Invention

The present invention pertains to a device and method for reducing mechanical heart wall muscle stress. Heart muscle stress is a stimulus for the initiation and progressive enlargement of the left ventricle in heart failure. Reduction of heart wall stress with the devices and methods disclosed herein is anticipated to substantially slow, stop or reverse the heart failure disease process. Although the primary focus of the discussion of the devices and methods of the present invention herein relates to heart failure and the left ventricle, these devices and method could be used to reduce stress in the heart's other chambers.

The devices and methods of the present invention can reduce heart wall stress throughout the cardiac cycle including end diastole and end systole. Alternatively, they can be used to reduce wall stress during the portions of the cardiac cycle not including end systole. Those devices which operate throughout the cardiac cycle are referred to herein as "full cycle splints". Those devices which do not operate to reduce wall stress during end stage systole are referred to as "restrictive devices". Restrictive devices include both "restrictive splints" which alter the geometric shape of the left ventricle, and

"wraps" which merely limit the magnitude of the expansion of the left ventricle during diastolic filling without a substantial shape change.

While it is desirable to reduce wall stress for the treatment of heart failure, to slow or reverse the disease process and to increase heart wall muscle shortening and pumping efficiency, it is also desirable to maintain or improve stroke volume and allow for variable preload.

Improving muscle shortening both total length change and extent at end systole, is particularly important in symptomatic heart failure wherein the heart has decreased left ventricle function and has enlarged. Full cycle splinting can be used to obtain a substantial increase in muscle shortening. Improved shortening will lead to an increase in pump function, and chronically may result in muscle strengthening and reversal of the disease because of increased pumping efficiency. The increase in shortening should be balanced against a reduction in chamber volume.

In asymtomatic, early stage heart failure, it may be possible to use only a restrictive device or method as elevated wall stress is considered to be an initiator of muscle damage and chamber enlargement. Restrictive devices and methods acting during diastole will reduce the maximum wall stress experience during end diastole and early systole. It should be understood that restrictive devices and methods can be used in combination with full cycle splinting to more precisely control or manipulate stress reduction throughout the cardiac cycle.

Brief Description of the Drawings

Figure 1 is a vertical side view of a heart including a transventricular splint and band splint;

Figure 2 is a horizontal cross section of the heart, splint and band splint of Figure 1;

Figure 3 is a graph showing the relationship between stress and strain for the sarcomeres of the left ventricle for a normal and failing heart throughout the cardiac cycle;

Figure 4 is an idealized horizontal cross section of a left ventricle splinted to form two lobes;

Figure 5 is an idealized horizontal cross sectional left ventricle splinted to form three lobes;

Figure 6 is a vertical view of a heart including two transventricular splints and two band splints;

Figure 7 is a cross sectional view of the heart, a band splint and a splint of Figure 6;

Figure 8 is a vertical view of a heart including a transventricular splint and a partial band splint;

Figure 9 is a horizontal cross sectional view of the heart, splint and band splint of Figure 8;

Figure 10 is a horizontal cross section of a heart including a splint having full cycle and restrictive elements at the beginning of diastolic filling;

Figure 11 is a view of the splint of Figure 10 at end diastole;

Figure 12 is a horizontal cross section of the left ventricle including a full cycle transventricular splint and a restrictive transventricular splint at the beginning of diastolic filling;

Figure 13 is a view of the splints of Figure 12 at end diastole;

Figure 14 is a horizontal cross sectional view of the left ventricle including a restrictive splint at the beginning of diastolic filling;

Figure 15 is a view of the splint of Figure 14 at end diastole;

Figure 16 is a vertical view of the heart in phantom line including a band splint;

Figure 17 is an alternate embodiment of the band splint of Figure 16;

Figure 18 is an alternate embodiment of the band splint of Figure 16;

Figure 19 is an alternate embodiment of the band splint of Figure 16;

Figure 20 is a vertical view of a heart including a partial circumferential strap;

Figure 21 is a horizontal cross sectional view of the heart and strap of Figure 20;

Figure 22 is a vertical view of a heart including a vertical partial strap;

Figure 23 is a horizontal cross sectional view of a heart including a transventricular splint passing through the papillary muscles;

Figure 24 is a horizontal cross sectional view of a heart including a transventricular splint passing through the left ventricle to lateral the papillary muscles;

Figure 25 is a horizontal cross sectional view of the left ventricle including a plurality of transventricular splints;

Figure 26 is a vertical view of a heart in phantom line including a single element wrap including longitudinal axis securing points;

Figure 27 is an alternate embodiment of the wrap of Figure 26;

Figure 28 is an alternate embodiment of the wrap of Figure 26;

Figure 29 is an alternate embodiment of the wrap of Figure 26;

Figure 30 is a vertical view of the heart including a mesh wrap;

Figure 31 is a cross sectional view of a patient's torso and heart showing a band splint anchored to the patient's ribs;

Figure 32 is a partial vertical view of the heart and band splint of Figure 31;

Figure 33 is a partial vertical view of a failing heart;

Figure 34 is a cross sectional view of the heart of Figure 33;

Figure 35 is a vertical view of the heart for decreasing the horizontal radius of the ventricles and increasing their vertical length;

Figure 36 is an exaggerated vertical view of the heart of Figure 33 elongated by the device of Figure 35;

Figure 37 is a view of the cross section of Figure 34 showing the decrease in radius of the ventricles;

Figure 38 is a horizontal cross sectional view of the heart showing the left and right ventricles and a splint disposed within the myocardium;

Figure 39 is a vertical cross section of the left ventricle showing a splint within the myocardium;

Figure 40 is a partial cross section of the left ventricle showing a splint extending through a portion of the myocardium;

Figure 41 is a partial vertical view of a heart showing the splint of Figure 40 extending horizontally through the myocardium;

Figure 42 is a horizontal cross sectional view of the left and right ventricles including reinforcement loops;

Figure 43 is an alternate embodiment of the reinforcing loops of Figure 43;

Figure 44 shows a vertical view of the heart including the reinforcement loops of Figure 43 and a rigid shape changing member; and

Figure 45 is a vertical cross sectional view of a heart showing a ring around the chordae.

Detailed Description of the Preferred Embodiments

The present invention is directed at reducing wall stress in a failing heart. Diastolic wall stress is considered to be an initiator of muscle damage and chamber enlargement. For this reason, it is desirable to reduce diastolic wall stress to prevent the progression of the disease. The significant impact of stress occurs at all stages and functional levels of heart failure, however, independent of the original causes. For example, in asymtomatic early stages of heart failure mechanical stress can lead to symptomatic heart failure marked by an enlarged heart with decreased left ventricle function. As the heart enlarges, mechanical stress on the heart wall increases proportionally to the increasing radius of the heart in accordance with LaPlace's Law. It can thus be appreciated that as stress increases in symptomatic heart failure, those factors that contributed to increasing stress also increase. Thus, the progression of the disease accelerates to late stage heart failure, end stage heart failure and death unless the disease is treated.

Three parameters influence mechanical stress on the muscle. These are: (1) muscle mass, i.e., as reflected by the thickness of the muscle; (2) pressure in the chamber which is a function of the resistance to blood flow of the patient's vasculature and the volume of blood within the patient; and (3) chamber of geometry. The present invention pertains to devices and methods for directly and passively changing chamber geometry to lower wall stress. In addition to treatment of heart failure, the devices and methods of the present invention also lend themselves to application in the case of a decrease in cardiac function caused by, for example, acute myocardial infarction.

The device's disclosed herein for changing chamber geometry are referred to as "splints". In addition to splints, wraps which can be placed around the heart can limit muscle stress without the chamber shape change. When a wrap is used, wall stress is merely transferred to the wrap, while the generally globular shape of the heart is maintained. A wrap could be used in conjunction with a splint to modulate heart wall stress reduction at various stages of the cardiac cycle.

The present invention includes a number of splint embodiments. Splints and wraps can be classified by where in the cardiac cycle they engage the heart wall, i.e., mechanically limit the size of the left ventricle in the case of wraps and change the geometry of the ventricle in the case of splints. If a splint or wrap only begins to engage during diastolic filling, the splint can be termed a "restrictive splint". If the splint or wrap is engaged throughout the cardiac cycle, both during diastolic filling and systolic contraction and ejection, the splint can be termed a "full cycle splint". The wrap will generally be a restrictive device which begins to engage during diastolic filling to increase the elastance (reduces compliance) of the chamber. If a wrap is made from

elastic material it may engage full cycle, but the force required to elongate the wrap will increase as diastolic filling progresses, preload strain will be reduced without an improvement in systolic contraction.

Figure 1 is a view of a heart A in a normal, generally vertical orientation. A wrap 11 surrounds heart A and a transventricular splint 12 extends through the heart and includes an anchor or anchor pad 13 disposed on opposite sides of the heart. Figure 2 is a horizontal cross sectional view of heart A taken through wrap 11 and splint 12. Splint 12 includes a tension member 15 extending through left ventricle B. Anchor pads 13 are disposed at each end of tension member 15. Right ventricle C is to the left of left ventricle B.

In Figure 1, wrap 11 and splint 12 are shown engaged with heart A. In Figure 2, heart A is shown spaced from wrap 11 except at anchor pads 13. In Figure 2, heart A is thus at a point in the cardiac cycle where the muscles are shortening during systole, or have yet to stretch sufficiently during diastolic expansion to reach wrap 11. Accordingly, wrap 11 can be considered a restrictive device as it does not engage the heart full cycle. Although wrap 11 is in contact with heart A at pads 13, only the splint is providing a compressive force to change the shape of the heart and limiting the stress of the heart in Figure 2.

If heart A, as shown in Figure 2 is at end systole, transventricular splint 12 is a full cycle device as the cross section of left ventricle B does not have the generally circular unsplinted shape. It can be appreciated that transventricular splint 12 can be used without wrap 11. Alternately, wrap 11 could be secured to heart A by sutures or other means than splint 12, in which case wrap 11 would be merely a restrictive device. It

should be noted that unless wrap 11 extends vertically along heart A a sufficient amount, as heart A expands and engages wrap 11, the portion of left ventricle B disposed above or below wrap 11 could expand substantially further than that portion of the left ventricle wall restrained by wrap 11. In such a case, left ventricle B could have a bi-lobed shape in a vertical cross section. As such, the wrap 11 would not be merely limiting the size of the left ventricle, but rather inducing a shape change in the left ventricle. In such a case, the element 11 would not be a wrap, but rather a splint which could be referred to as a "band splint".

Each of the splints, wraps and other devices disclosed in this application preferably do not substantially deform during the cardiac cycle such that the magnitude of the resistance to the expansion or contraction of the heart provided by these devices is reduced by substantial deflection. It is, however, contemplated that devices which deflect or elongate elastically under load are within the scope of the present invention, though not preferred. The materials from which each device are formed must be biocompatible and are preferably configured to be substantially atraumatic.

The distinction between restrictive devices, such as restrictive splints and wraps, and full cycle splints and wraps, can be better understood by reference to Figure 3. Figure 3 is a plot of sarcomere, i.e., heart wall muscle, stress in (g/cm^2) versus strain throughout a normal cardiac cycle N, and a failing heart cardiac cycle F. The cardiac cycles or loops shown on Figure 3 are bounded by the normal contractility curve N_c and failing heart contractility curve F_c above and to the left, and the diastolic filling curve 12 toward the bottom and right. Contractility is a measure of muscle stress at an attainable systolic stress at a given elongation or strain. It can be appreciated that the muscle

contractility N_c of normal muscle tissue is greater than the contractility F_c of the muscle tissue of a failing heart. The diastolic filling curve 12 is a plot of the stress in the muscle tissue at a given elongation or strain when the muscle is at rest.

An arbitrary beginning of the normal cardiac cycle N can be chosen at end diastole 14, where the left ventricle is full, the aortic valve is closed. Just after end diastole 14, systole begins, the sarcomere muscles become active and the mitral valve closes, increasing muscle stress without substantially shortening (sometimes referred to as "isovolumic contraction"). Stress increases until the aortic valve opens at 16. Isotonic shortening begins and stress decreases and the muscles shorten until end systole 18, where the blood has been ejected from the left ventricle and the aortic valve closes. After end systole 18, diastole begins, the muscles relax without elongating until diastolic filling begins when the mitral valve opens at 20. The muscles then elongate while the mitral valve remains open during diastolic filling until end diastole 14. The total muscle shortening and lengthening during the normal cycle N is N_s.

An analogous cycle F also occurs in a failing heart. As the left ventricle has dilated, in accordance with LaPlace's Law, the larger radius of a dilated left ventricle causes stress to increase at a given blood pressure. Consequently, a failing heart must compensate to maintain the blood pressure. The compensation for the increased stress is reflected in the shift to the right of failing heart cardiac cycle F relative to the normal cycle N. The stress at end diastole 22 is elevated over the stress at end diastole 14 of the normal heart. A similar increase can be seen for the point at which the aortic valve opens 24, end systole 26 and the beginning of diastolic filling 28 relative to the analogous points for the normal cycle N. Muscle shortening and elongation F_s throughout the cycle

is also reduced in view of the relative steepening of the diastolic curve 12 to the right and the flatter contractility curve F_c relative to the normal contractility N_c.

By reference to the heart cycle stress strain graph of Figure 3, the effect on mechanical muscle stress and strain caused by the use of the devices and methods of the present invention can be illustrated. Restrictive devices begin to engage during diastolic filling, which in the case of a failing heart occurs along diastolic filling curve 12 between point 28 and 22. Restrictive devices do not engage at end systole 26. Thus, the acute effect of placement of a restrictive device is to reduce muscle stress at end diastole relative to the stress at point 22, and shift the line 22-24 to the left reducing muscle shortening and elongation F_s. Acutely, the cardiac cycle will still operate between the failing heart contractility curve F_c and the diastolic filling curve 12. If chronic muscle contractility increases such that the muscle contractility curve F_c shifts back toward the normal heart contractility curve N_c as a consequence of the stress reduction, the stress/strain curve F of the cardiac cycle will shift to the left reducing mechanical stress still further.

The effect on the stress/strain relationship of a full cycle splint will acutely shift the entire stress/strain curve F for the cycle to the left. That is, stress is reduced at both end diastole 22 and end systole 26. Muscle shortening and elongation F_s will increase acutely. If, as in the case of a restrictive splint, muscle contractility F_c improves, the entire cardiac cycle curve F will shift further to the left reducing mechanical stress still further.

The type and magnitude of shape change are important factors in determining the effectiveness of splinting. There are several types of lower stress cardiac geometries that

can be created from an enlarged globular left ventricular chamber typically associate with heart failure. They include lobed, disc-like, narrowed elongate, and multiple vertically stacked bulbs.

Figure 4 shows an idealized horizontal cross section of a left ventricle 30 subdivided into two symmetrical lobes 32 and 34 having an arc passing through an angle $\theta > \pi$, and a radius R. Lobes 32 and 34 can be formed using a splint, such as transventricular splint 12 shown in Figures 1 and 2. Lobes 32 and 34 are joined at points 36 and 38. Points 36 and 38 are separated by a distance ℓ.

Figure 5 is an idealized horizontal cross section of a left ventricle 40 subdivided into three generally equal sized lobes 42, 44 and 46. Each lobe has an equal radius and has an arc passing through an angle less than π. Adjacent ends of the lobes 48, 50 and 52 are separated by a distance ℓ. A plurality of transventricular splints such as splint 12 as shown in Figures 1 and 2 could be extended between adjacent ends 48, 50 and 52 to form lobes 42, 44 and 46.

For a restrictive splint, the horizontal cross sections 30 and 40 will have a generally circular shape, i.e., a non-splinted shape at end systole. As diastolic filling proceeds, the radius of the circular shape will continue to increase until the splint engages. At the point the splint engages, the lobed shape will begin to form. In the case of the two lobe splinting of Figure 4, the radius will continue to increase as diastolic filling proceeds. In the case of the three or more lobed shape, such as the three lobed configuration of Figure 5, radius R will decrease as diastolic filling proceeds. The radius will continue to decrease unless or until the pressure in the heart causes the heart to expand such that the arc of the lobe passes through an angle θ greater than π.

In the case of a full cycle splint, at end systole, the splint will already be engaged. Thus, for a full cycle splint at end systole, the horizontal cross section of the chamber will not have the normal generally circular shape. Rather, at end systole, the horizontal cross sections 30 and 40 will have a lobed shape such as shown in Figures 4 and 5. Subsequent shape change during diastolic filling for a full cycle splint will be similar to that described with respect to restrictive splints.

In view of LaPlace's Law which states that stress is directly proportional to radius of curvature, it can be appreciated that whether the radius is increasing or decreasing during diastolic filling, will have an impact on heart pumping performance. Where R is increasing during diastolic filling, wall stress will increase more rapidly than where R is decreasing. The number of lobes that are created can significantly influence the level of end diastolic muscle stress reduction achieved through splinting. Eventually adding additional lobes forms a configuration which approaches a behavior similar to a wrap. If a wrap is substantially inelastic, or of sufficient size, a wrap will only engage the heart wall at some stage of diastolic filling. If the wrap is substantially inelastic, as pressure increases in the chamber during diastolic filling, stress in the heart wall muscle will increase until the wrap fully engages and substantially all additional muscle elongating load created by increased chamber pressure will be shifted to the wrap. No further elongation of the chamber muscles disposed in a horizontal cross section through the wrap and the chamber will occur. Thus, inelastic wraps will halt additional preload muscle strain (end diastolic muscle stretch).

The type of shape change illustrated in Figures 4 and 5 is of substantial significance for restrictive splints. It is undesirable in the case of restrictive splints, to

excessively limit preload muscle strain. The Frank-Starling Curve demonstrates the dependence and need for variable preload muscle strain on overall heart pumping performance. During a person's normal activities, their body may need increased blood perfusion, for example, during exertion. In response to increased blood perfusion through a person's tissue, the heart will compensate for the additional demand by increasing stroke volume and/or heart rate. When stroke volume is increased, the patient's normal preload strain is also increased. That is, the lines 14-16 and 22-24 of the normal and failing hearts, respectively, will shift to the right. An inelastic wrap will, at engagement, substantially stop this shift. In the case of the bi-load shape change of Figure 4 or a multiple lobed change having a small number of lobes of Figure 5, significant stress reduction can be achieved while allowing for variable preload strain. If the number of lobes is increased substantially, however, variable preload will decrease as the multi-lobed configuration approaches the performance of an inelastic wrap.

The magnitude of shape change in the case of full cycle splinting becomes very important as full cycle splinting generally reduces chamber volume more than restrictive splinting. Although as with restrictive devices, the type of shape change is also important to allow for variable preload strain. Both restrictive device and full cycle splints reduce chamber volume as they reduce the cross sectional area of the chamber during the cardiac cycle. The magnitude of the shape change can vary from very slight at end diastole, such that chamber volume is only slightly reduced from the unsplinted end diastolic volume, to an extreme reduction in volume, for example, complete bifurcation by transventricular splint. The magnitude of the shape change, for example, as measured by the ratio of splint length to non-splinted ventricular diameter, is preferably modulated to reduce

muscle stress while not overly reducing chamber volume. For full cycle splint, the reduction of chamber volume is compensated for by increased contractile shortening, which in turn leads to an increased ejection fraction, i.e., the ratio of the stroke volume to chamber volume. For given stress/volume and stress/shortening relationships, there will be a theoretical optimum maximal stroke volume. Clinically, 20% to 30% stress reduction is expected to be attainable through full cycle bi-lobe splinting. See U.S. Patent Application Serial No. 08/933,456, filed September 18, 1997 for calculation of stress reduction for idealized bi-lobe splinting.

When using the full cycle and restrictive devices described herein, caution should be exercised to limit the pressure on the coronary vasculature. In the case of transventricular splints, valve structure, electrical pathways and coronary vasculature should be avoided.

Figure 6 is a vertical view of a heart A similar to that shown in Figure 1. Rather than having a single band splints surrounding heart A, there are two band splints 51 affixed to the heart by two transventricular splints 52. Splints 52 include oppositely disposed anchors or anchor pads 53. Figure 7 is a horizontal cross sectional view of heart A of Figure 6, wraps 51 and splint 52. Splints 52 include a tension member 54 disposed through left ventricle B. Pads 53 are disposed on the opposite ends of tension members 54. Right ventricle C is shown to the left of left ventricle B.

Splints 52 can be restrictive or full cycle splints. Band Splints 51 are shown as restrictive band splints as in Figure 6, heart A is shown engaged with the band splints 51, where as in Figure 7, heart A has contracted to move away from band splints 51. Wraps 51 and splints 52 should be made from biocompatible materials. Band Splints 51 are

preferably made from a pliable fabric or other material which resists elongation under normal operating loads. Band splints 51 can, however, be made from an elastic material which elongates during the cardiac cycle. Tension members 54 also preferably resist elongation under normal operating loads. Tension members 54 can, however, be made from an elastic material which elongates during the cardiac cycle.

Figure 8 is a vertical view of heart A, partial wrap 61 and transventricular splint 62. Transventricular splint 62 includes anchor pads 63. Figure 9 is a horizontal cross sectional view of heart A, partial band splint 61 and splint 62. Splint 62 is essentially similar to wrap or band splint 12 shown in Figure 1 and 2. Partial band splint 61 is also essentially similar to wrap or band splint 11 shown in Figures 1 and 2 except that band splint 61 only surrounds a portion of heart A. This portion is shown in Figures 8 and 9 to the left including a portion of left ventricle B.

Figure 10 is a horizontal cross sectional view of left ventricle B and right ventricle C of heart A taken at a similar elevation as that shown in Figure 2. A splint 70 is shown disposed on heart A. Splint 70 includes a frame having two heart engaging anchors or pads 72 disposed at its opposite ends. A third heart engaging pad 73 is disposed along frame 70 approximately midway between pads 72.

Pads 72 are shown engaged with heart A to change the shape of ventricle B in Figure 10. Pads 73 are not engaged with heart A in Figure 10. Figure 11 is the same horizontal cross sectional view as Figure 10 except that heart A has to contact pad 73 to create a further shape change of left ventricle B.

Frame 70 is preferably rigid enough that pads 72 could be disposed on the heart for full cycle splinting and sufficiently adjustable that pads 72 could be spaced further

apart for restrictive splinting. Pad 73 accomplishes restrictive splinting. Frame 71, pads 72 and 73 of splint 70 are made of a biocompatible material. Pads 72 and 73 are preferably substantially atraumatic.

Figure 12 is a horizontal cross sectional view of the left ventricle B of heart A. A transventricular splint 80 having a tension member 81 and oppositely disposed anchor pads 82 is shown extending across left ventricle B. Another transventricular splint 83 having a tension member 84 and oppositely disposed anchor pads 85 extends generally perpendicularly to splint 80, across left ventricle B.

It can be appreciated that in Figure 12 splint 83 is engaging heart A to deform left ventricle B. Splint 80, however, includes a tension member 81 made of a flexible filament, line or the like which is shown in a relaxed state in Figure 12. In Figure 13, tension member 81 is shown in an elongated, taunt configuration as heart A has expanded into engagement with pads 82.

Transventricular splints 80 and 83 can be made as described above with respect to the transventricular splint of Figures 1 and 2. Tension member 81 may be elastic or inelastic.

Figure 14 is a horizontal cross section of left ventricle B of heart A including a transventricular splint 90. Splint 90 includes a tension member 91 including three branches extending to atraumatic anchors or anchor pads 92. Similarly to tension member 81 of Figure 12, tension member 90 is shown in a relaxed state. Splint 90 can be made in a similar way as splint 80 of Figures 12 and 13.

Figure 15 is the same horizontal cross section of heart A as shown in Figure 14 except that heart A has expanded to engage atraumatic pads 92 of splint 90. Tension

member 91 is now drawn taunt to form a three lobed cross sectional configuration of left ventricle B.

Figure 16 is a vertical view of heart A shown in phantom line. Shown disposed about the ventricles of heart A is a basket-like band splint 100. Band splint 100 includes a horizontal encircling band 101 around an upper region of the ventricles and four bands 102 which extend downward toward the apex of heart A. It can be appreciated that bands 102 can act as splints to form four lobes in heart A in a horizontal plane. Depending on the placement of bands 102 around heart A, lobes could be created only in the left ventricle or in the left ventricle and/or other chambers of the heart. Band 102 is joined at the apex Band 101 and band 102 can be made from a webbing, fabric or other biocompatible material.

If band splint 100 substantially elongated elastically under normal operating loads, it could be friction fit to heart A and act full cycle, limiting muscle stress at end diastole as well end systole. Band splint 100 could be sutured into place or otherwise held on heart A and act as a restrictive device. If band 101 were securely fastened to heart A, bands 102 could limit the vertical elongation of heart A during diastolic filling.

Figure 17 is an alternate embodiment 110 of the band splint of Figure 16. Band splint 110 includes a horizontally heart encircling band 111 and four bands 113 extending downward from band 111. Bands 113, however, unlike bands 102 of band splint 100 do not extend to the apex of heart A, but rather to a second horizontally heart encircling band 112.

Band splint 110 could be made of the same materials as band splint 100. Band splint 110 can also be used in a manner similar to band splint 100 except that band splint 110 would limit the vertical elongation of the ventricles less than band splint 100.

Figure 18 is yet another alternate embodiment 120 of the wrap of Figure 16. Band splint 120 closely resembles alternate embodiment 110 of Figure 17, except that rather than having four vertically extending web members, band splint 120 includes two substantially rigid members 123 interconnecting two horizontally encircling web members 121 and 122.

Figure 19 is yet another alternate embodiment 130 of the band splint of Figure 16. Like the wrap of Figure 16, band splint 130 includes a horizontally encircling member 131 and four downwardly extending members 132. At a location proximate of the apex of heart A, members 132 are joined by a ring 133. Members 132 extend through ring 133. Ring 133 can be used to adjust the length of members 132 between band 131 and ring 133. Ring 133 can be formed from metallic material and crimped inwardly to fix its position along members 132. Other means of holding ring 133 in position would be readily apparent to those skilled in the art.

Figure 20 is a vertical view of heart A including a partial band splint 140 secured around a substantial portion of left ventricle B. Band splint 140 includes a vertically elongating anchor member 141 which sutures 142 can encircle to anchor member 141 to heart A. A band 143 extends generally horizontally from anchor member 141 to an opposite anchor 141.

The length of band 143 can be seen in its entirety in Figure 21 which is a horizontal cross sectional view of heart A through band 143, left ventricle B and right

ventricle C. In Figure 20, heart A is shown engaged with band 143, however, in Figure 21, band 143 is shown spaced from heart A. Thus, in this configuration, wrap 140 would be acting as a restrictive device. If band splint 140 were made from a material that substantially deforms elastically under normal loads, band splint 140 could also be secured sufficiently snuggly to heart A to act as a full cycle device. Preferably, however, band 143 of band splint 140 is formed from a webbing or substantially inelastic fabric.

Figure 22 is a vertical view of heart A including band splint 140 disposed vertically on left ventricle B. In this position, band splint 140 can limit the vertical elongation of left ventricle B during diastolic filling.

Figure 23 is a horizontal cross section of heart A through left ventricle B, right ventricle C and the papillary muscles D of left ventricle B. A transventricular splint 150 including an elongate tension member 151 and oppositely disposed anchor pads 152 extends through left ventricle B and papillary muscles D. Splint 150 could be similar to splint 12 of Figure 1 and 2. Figure 24 is a horizontal cross section similar to that of Figure 23. In Figure 24, however, transventricular splint 150 is shown avoiding papillary muscles D.

Figure 25 is a horizontal cross section of left ventricle B of heart A. Here three splints 150 have been placed to form six lobes. Three of the lobes 153 have an arc length which passes through an angle greater than π. Disposed between each lobe 153 are three lobes 154 which have an arc length which passes through an angle less than π. Consequently, during diastolic filling, the effective radius of lobes 153 will be increasing while the radius of lobes 154 will be decreasing.

Figure 26 is a vertical view of heart A including a wrap 160. Wrap 160 can include a single thread or line 161 encircling the heart several times. After line 161 encircles heart A, line 161 can be threaded through a bar 162, including a plurality of eyelets 163 spaced along its length in pairs. Bar 162 is preferably rigid enough to substantially maintain the distance between eyelets 163 under normal operating loads.

When line 161 is placed in heart A, one end of line 161 can be tied to bar 162 at 164. Line 161 can then encircle the heart and be drawn through eyelet 162 adjacent the beginning of line 161 at 164. Line 161 can then be drawn through one eyelet 163 of a lower pair of eyelets to encircle the heart again. This process continues until line 161 is tied to an eyelet 163 at 165. It can be appreciated that wrap 160 could be used as a restrictive or full cycle device depending on the diameter of loop formed by line 161.

Figure 27 is an alternate embodiment 170 of the wrap of Figure 26. Wrap 170, however, includes two vertically extending bars 172 having eyelets 173 through which line 171 is threaded. Line 171 can be tied to one of the bars 172 at 174 and 175.

Figure 28 is a vertical view of heart A including yet another embodiment 180 of the wrap of Figure 26. Wrap 180 includes a line 181 encircling heart A a plurality of times. Rather than having a single vertically extending bar 162 to position line 180 on heart A, wrap 180 includes a plurality of horizontal bars 182 including a pair of eyelets 183. One end of line 181 is tied to an upper bar 182 at 184 and the opposite end of line 181 is tied to a lower bar 182 at 185. Between 184 and 185, line 181 is threaded through eyelets 182 to form the heart encircling pattern shown in Figure 28.

Figure 29 is a vertical view of heart A including yet another alternate embodiment 190 of the wrap of Figure 26. Wrap 190 closely resembles 180 of Figure 28. Line 181

has, however, been threaded through eyelets 183 of bars 182 in a pattern which, unlike that of Figure 28, bars 182 are disposed at various selected locations around the circumference of heart A.

Figure 30 is a vertical view of heart A including a wrap 200. Wrap 200 is substantially similar to wrap 11 of Figures 1 and 2, except that wrap 200 extends vertically a greater distance than wrap 11. Wrap 200 is not shown with a transventricular splint. It can be appreciated that wrap 200 could be used as restrictive or full cycle device.

Figure 31 is a horizontal cross section of a human torso including heart A, left ventricle B, right ventricle C, lungs E and ribs G. A wrap 210 is shown partially encircling heart A. Opposite ends of wrap 210 are anchored at 211 to ribs G. At 211, wrap 210 can be anchored to ribs G by bone screw, knot or other means of fastening. It can be appreciated that band splint 210 could be used as a restrictive or full cycle device.

Figure 33 is a vertical view of heart A having a W_1. Figure 34 is an idealized horizontal cross sectional view of heart A of Figure 33. Heart A includes left ventricle B and right ventricle C. Left ventricle B has a radius R_1.

Figure 35 is a view of a device 220. Device 220 includes a horizontally encircling band 222 which can be affixed to heart A by sutures, other attachment means or friction fit. Extending from band 222 is a substantially rigid elongate member 224. Member 224 extends to the apex of heart A. Pin 226 extends into left ventricle B of the apex. An anchor or pad 228 is disposed within left ventricle B to anchor the apex of heart A to elongate member 224. Elongate member 224 can be made of sufficient length such that heart A is vertically elongate full cycle, or alternately not at end diastole.

Figure 36 is a vertical view of an elongate heart A having a horizontal width W_2 less than W_1. Figure 37 is a horizontal cross section of the heart A of Figure 36 including left ventricle B and right ventricle C. In Figure 37, the radius R_2 of left ventricle B is less than R_1 of Figure 34. Assuming that the hearts of Figures 33 and 36 are at the same point in the cardiac cycle, it can be appreciated that the wall stress in heart A is less in Figure 37 as R_2 is shorter R.

If elongate bar 224 is sized such that device 220 does not engage at end diastole, but rather anchor pad 228 first engages during systolic contraction, device 220 can fall into a third class of device neither full cycle nor restrictive. Such a device would reduce wall stress during a portion of systolic contraction including end systole, but not reduce wall stress during end diastole, thus maintaining maximum preload.

Band 222 of device 220 is preferably formed from a web material or other fabric. Band 220 is preferably does not elongate substantially during diastolic filling. Members 224, 226 and 228 are formed from materials which remain substantially rigid under the influences of the forces encountered during the cardiac cycle.

Figure 38 is a horizontal cross section of heart A including left ventricle B and right ventricle C. Advanced through the myocardium of heart A is a device including a tubular member 231 and thread or line 232 disposed within tubular member 231. In Figure 38, the free ends of thread 232 are disposed outside of heart A. The free ends of thread 232 could be drawn toward each other to reduce the diameter of device 230 in heart A. After a desired reduction in diameter, the free ends could be tied together.

Tube 231 is preferably highly flexible, yet durable enough to prevent thread 232 from "cheese cutting" through the myocardium of heart A. Tube 231 and line 232 are

preferably formed from biocompatible atraumatic materials which do not substantially elongate under the influence of forces encountered during expansion and contraction of heart A. In an alternate embodiment, tube 231 and line 232 could be made from materials which readily elongate under the influence of the forces encountered during the cardiac cycle. It can be appreciated that device 230 could be used as a full cycle device or restrictive device.

Figure 39 is a vertical cross sectional view of heart A including left ventricle B. A substantially V-shaped or U-shaped member having arms 241 is shown substantially advanced into the myocardium of heart A. Device 240 includes an apex 242 disposed adjacent the apex of heart A. The spacing of arms 241 from each other is preferably such that device 240 can form lobes in horizontal cross sections of left ventricle B.

Device 240 is preferably formed from biocompatible materials which preferably do not deform substantially under the influence of the forces encountered during the cardiac cycle. It can be appreciated that device 240 could be used as a restrictive or full cycle device.

Figure 40 is a partial cross section of heart A and left ventricle B. A device 250 extends through a portion of the myocardium of heart A. Device 250 can be configured similarly to splint 12 of Figures 1 and 2. Device 250 accordingly includes two tension members 251 and oppositely disposed anchors pad 252. Tension members 251, however, do not extend transventricularly.

Figure 41 is a vertical view of heart A including device 250. Splint 250 can act as a full cycle device or a restrictive device, to shorten a portion of the left ventricle heart wall.

Figure 42 is a horizontal cross sectional view of heart A including left ventricle B and C. A device 260 including a thread or line 261 is disposed transventricularly and transmyocardially through heart A. A portion of line 261 is disposed outside of heart A. Opposite ends of line 261 are connected at 262. Those portions of line 261 outside heart A form loops 263. The size of loops 263 are exaggerated for purposes of illustration. It is assumed that heart A in the process of diastolic filling in Figure 42, and loops 263 are sufficiently small, eventually heart A will engage loops 263. In such a configuration, device 260 is used as a restrictive device. Loops 263 could be sized, however, such that they engage full cycle.

Line 261 is preferably made from atraumatic biocompatible material. The diameter of line 261 is preferably sufficiently great that cutting of heart A does not occur during diastolic filling.

Figure 43 is a horizontal cross sectional view of heart A including left ventricle B and right ventricle C and an alternate embodiment 270 of the device of Figure 42. Device 270 includes a line 271 which does not extend transventricularly but extends through the myocardium of heart A to form four loops 273.

Device 270 can be formed from material similar to that used to form device 260. Additionally, device 270 can be made to function as a restrictive device or full cycle device in a manner similar to that of device 260.

Line 261 and line 267 could be disposed within a tube such as tube 231 of Figure 38 to avoid cheese cutting of the myocardium. Devices 260 and 270 could extend through the septum or right ventricle to avoid forming lobes in right ventricle C.

Figure 44 is a vertical view of heart A including three devices 270 disposed at three spaced elevations. An elongate generally rigid bar 274 is disposed through loops 273 to distribute the load on heart A from loops 273 across a larger area than lines 271 can alone.

Figure 45 is a vertical cross section of heart A showing left ventricle B including papillary muscles D and chordae H. Joining chordae H is a ring 290. Ring 290 is preferably strong and rigid enough to hold chordae H, papillary muscles D and consequently the wall of left ventricle B inward during diastolic expansion. It can be appreciated that loop 290 could be configured to operate as a full cycle or a restrictive device. Preferably loop 229 is formed from an atraumatic biocompatible material.

Numerous characteristics and advantages of the invention covered by this document have been set forth in the foregoing description. It will be understood, however, that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size and ordering of steps without exceeding the scope of the invention. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A device for reducing heart wall stress, comprising:

a first means for reducing heart wall stress which engages throughout the cardiac cycle; and

second means for reducing heart wall stress which begins to engage the heart wall during diastolic filling.

2. The device in accordance with claim 1, wherein the first means includes a splint having an elongate tension member, the elongate tension member having a first end and a second end, the splint having a first anchor member connected at the first end of the tension member and a second anchor member connected at the second end of the tension member.

3. The device in accordance with claim 1, wherein the second means includes a splint having an elongate tension member, the elongate tension member having a first end and a second end, the splint having a first anchor member connected at the first end of the tension member and a second anchor member connected at the second end of the tension member.

4. The device in accordance with claim 1, wherein the second means includes an elongate member sized to surround the heart and begin to engage a portion of the left ventricle wall during diastolic filling.

5. The device in accordance with claim 1, wherein the first means includes a frame including at least two means for engaging the wall of the left ventricle.

6. The device in accordance with claim 5, wherein the means for engaging include pads.

7. The device in accordance with claim 5, wherein the second means for reducing heart wall stress includes a means for engaging connected to the frame.

8. The device in accordance with claim 7, wherein the means for engaging of the second means includes a pad.

9. A method of reducing heart wall stress, comprising the steps of:

providing a device having at least one heart engaging member;

placing the heart engaging member on the heart such that the shape of a cross section of the left ventricle is changed throughout the cardiac cycle;

providing a second device having at least one heart engaging member; and

placing the heart engaging member of the second device on the heart such that a second device begins to engage the heart during diastolic filling.

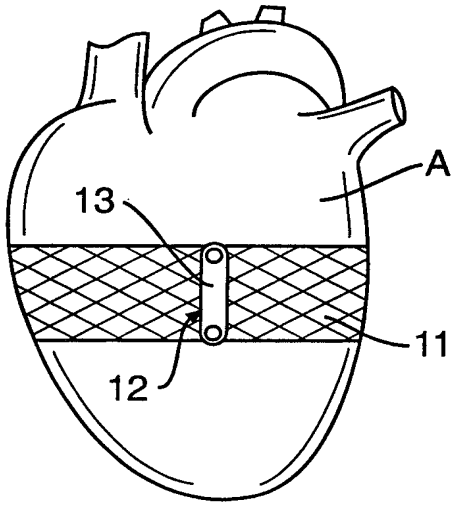

FIG. 1

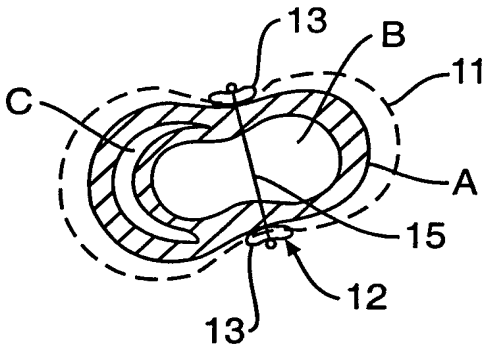

FIG. 2

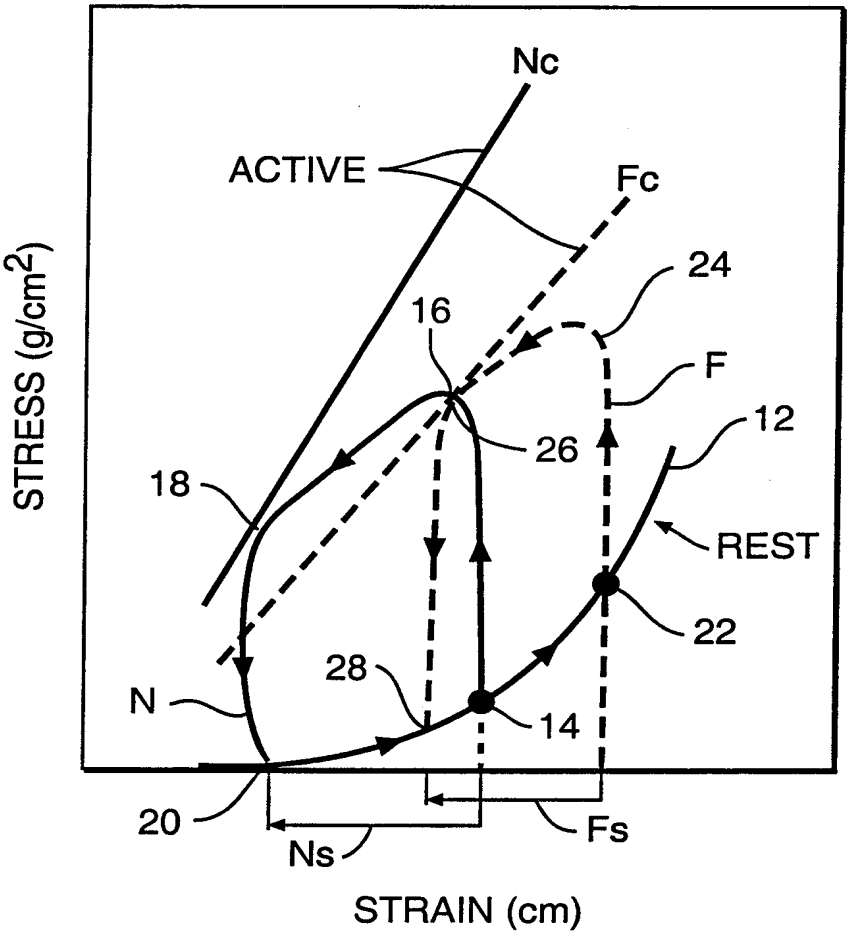
Nc
ACTIVE
Fc
24
16
F
12
26
18
REST
22
28
N
14
20
Fs
Ns
STRESS (g/cm2)
STRAIN (cm)

FIG. 3

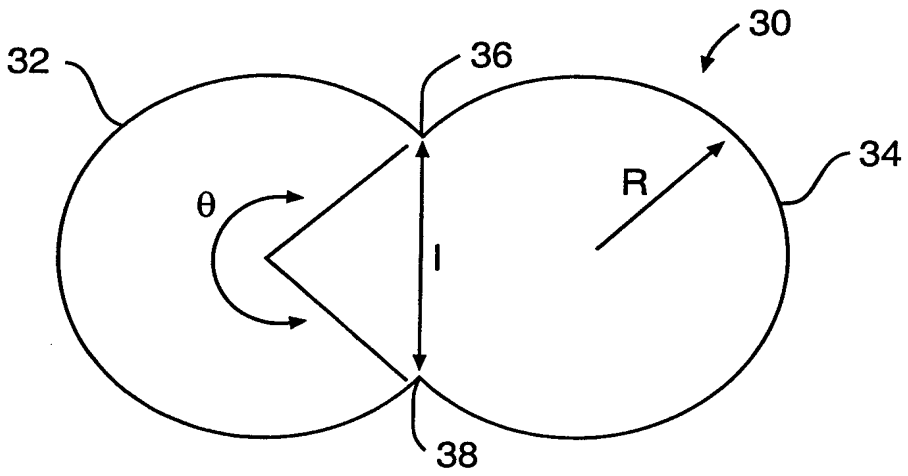

FIG. 4

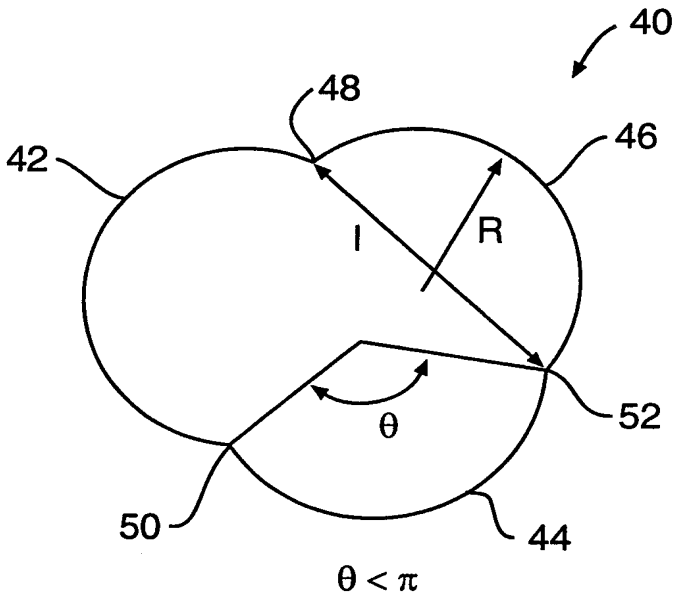

FIG. 5

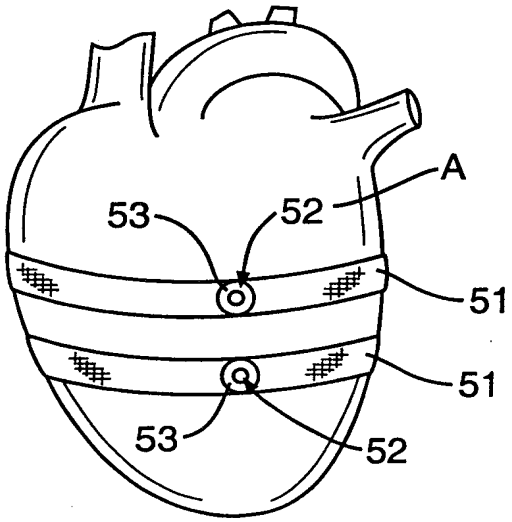

FIG. 6

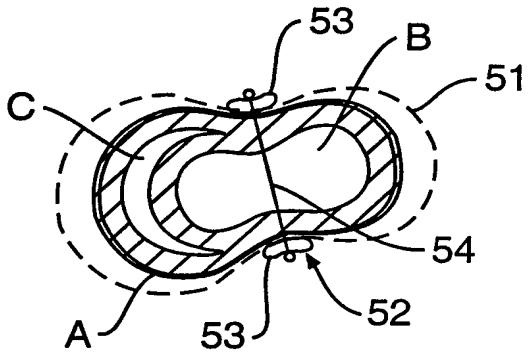

FIG. 7

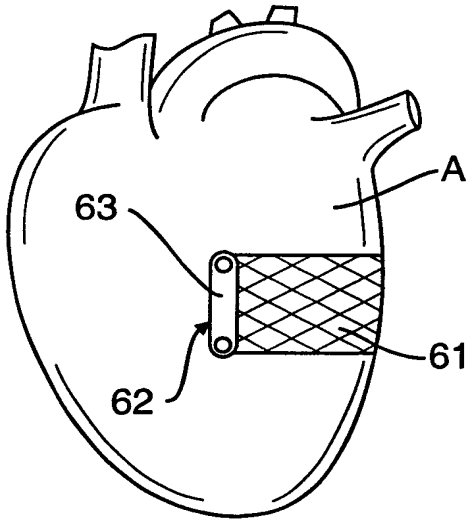

FIG. 8

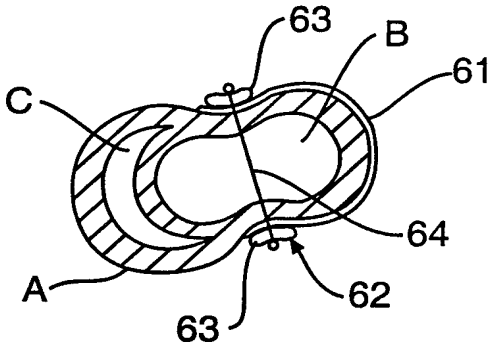

FIG. 9

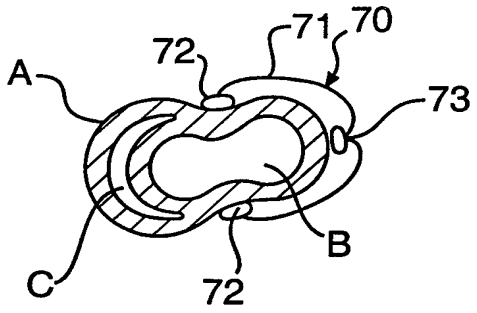

FIG. 10

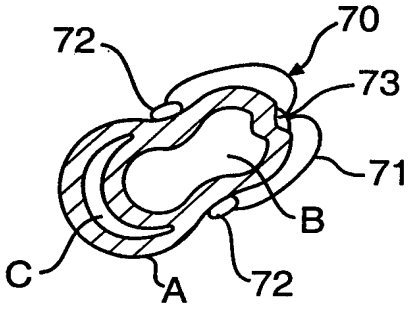

FIG. 11

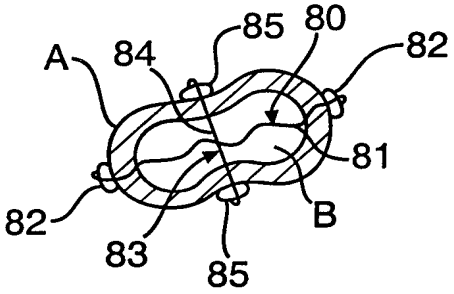

FIG. 12

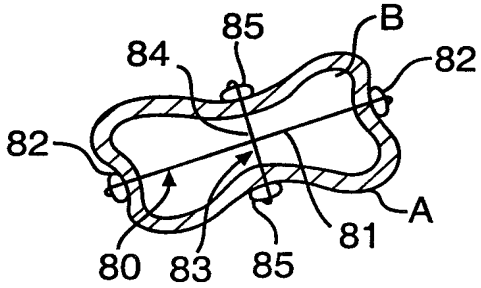

FIG. 13

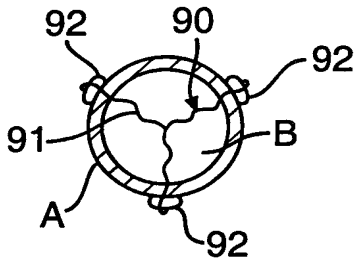

FIG. 14

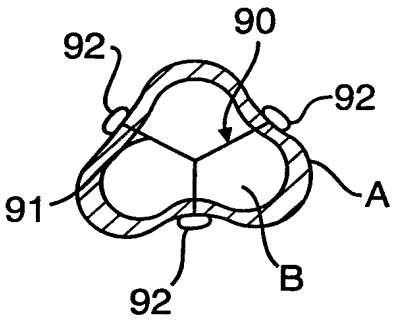

FIG. 15

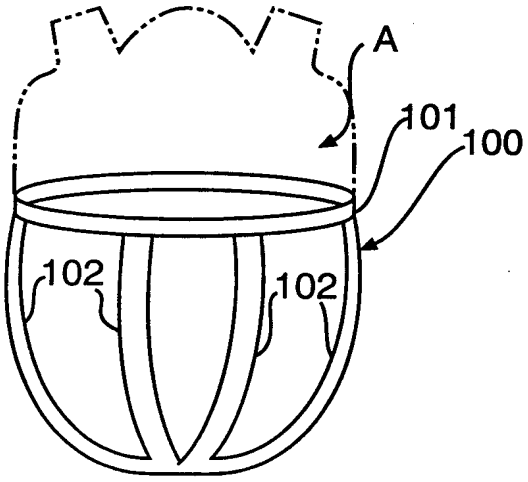

FIG. 16

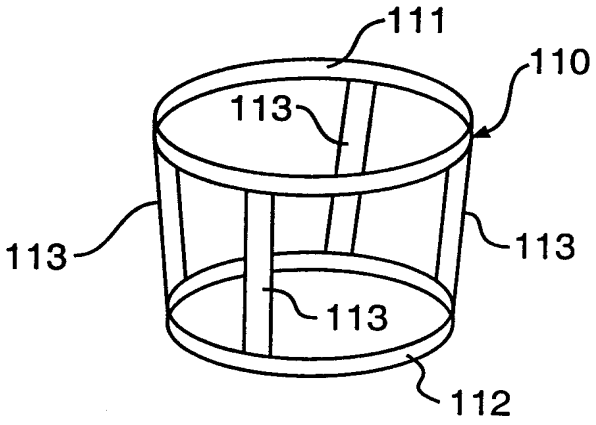

FIG. 17

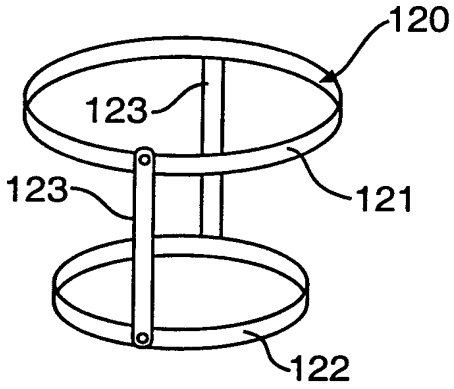

FIG. 18

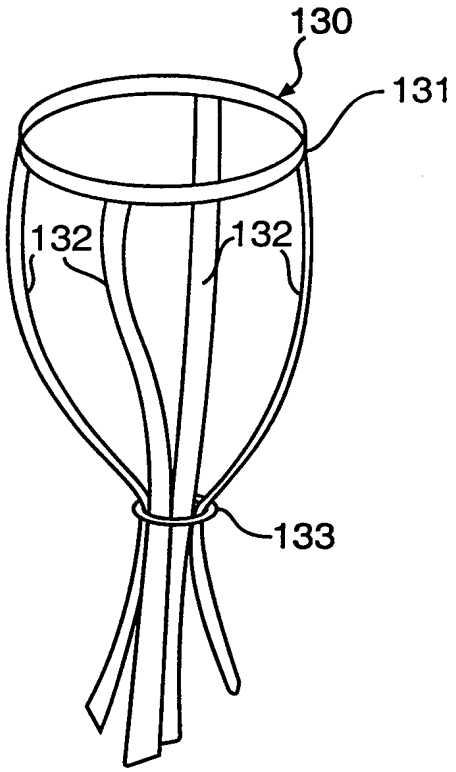

FIG. 19

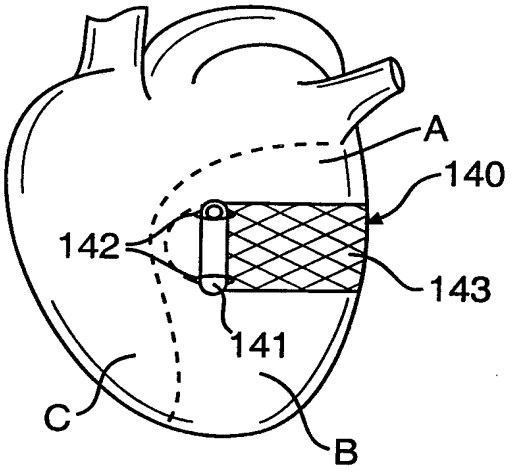

FIG. 20

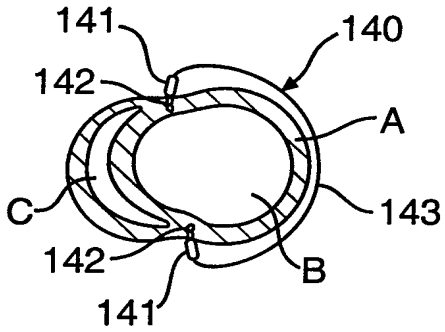

FIG. 21

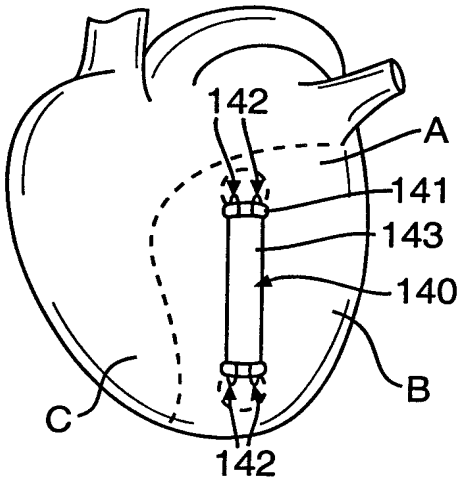

FIG. 22

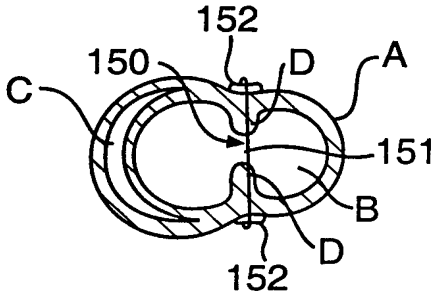

FIG. 23

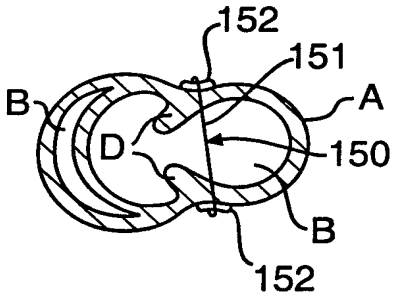

FIG. 24

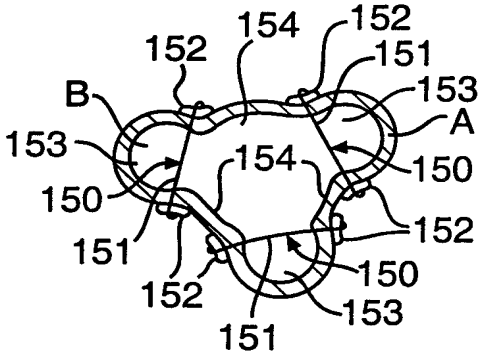

FIG. 25

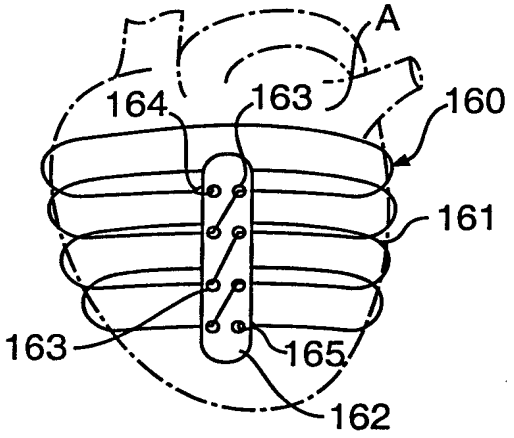

FIG. 26

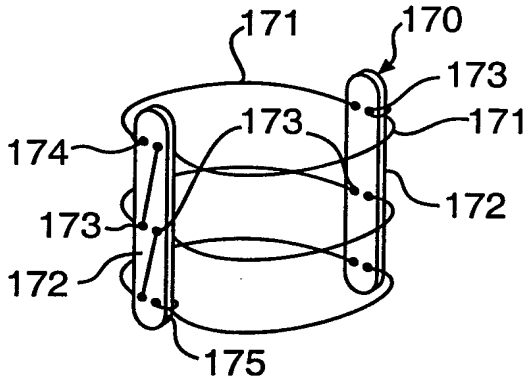

FIG. 27

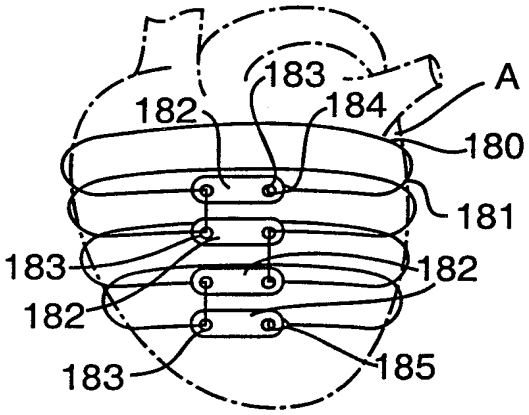

FIG. 28

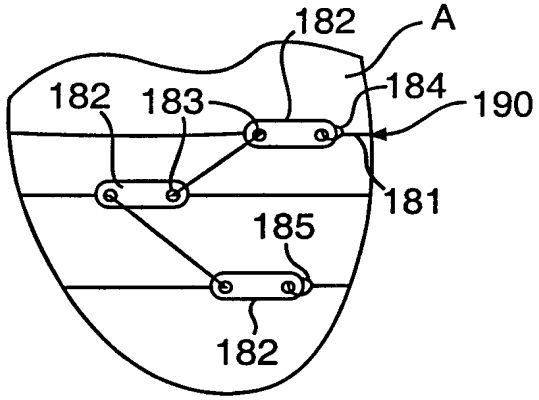

FIG. 29

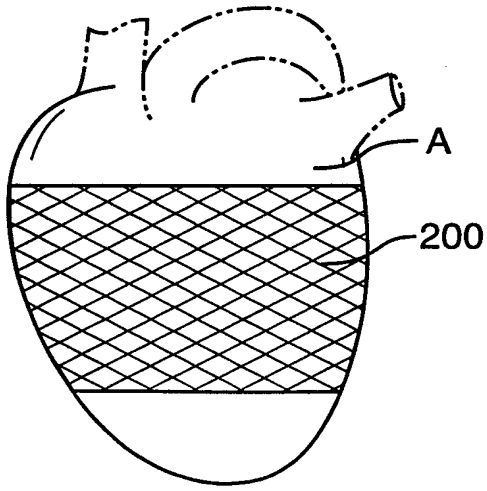

FIG. 30

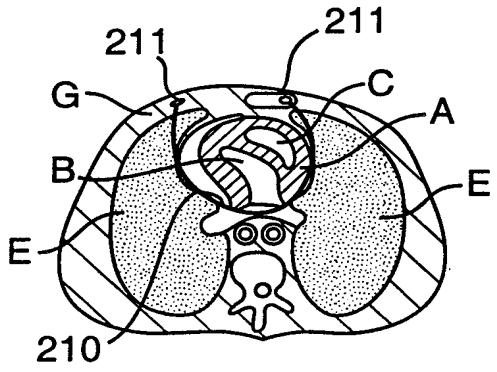

FIG. 31

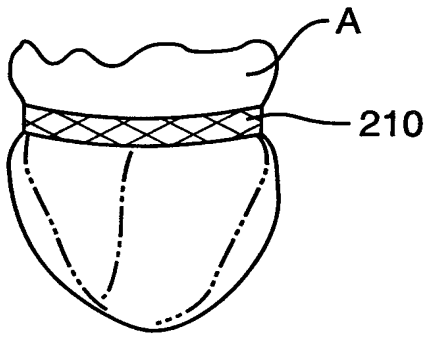

FIG. 32

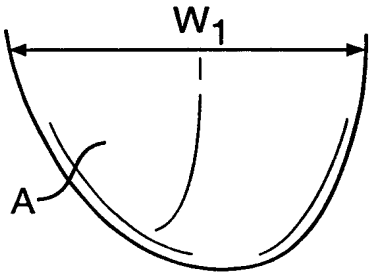

FIG. 33

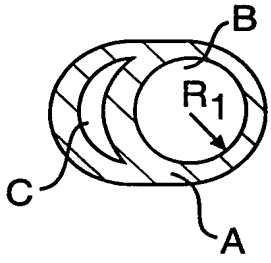

FIG. 34

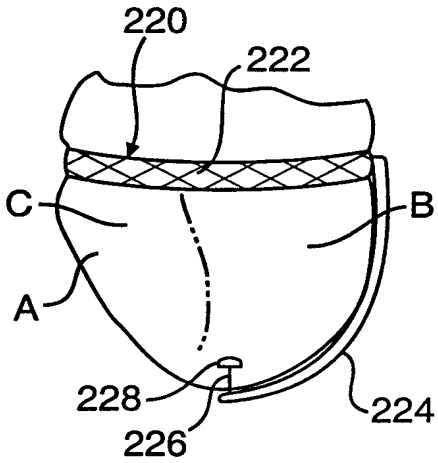

FIG. 35

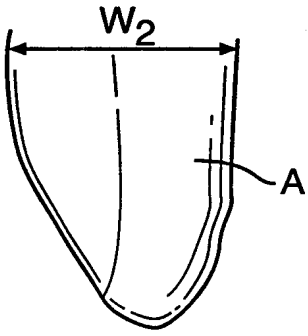

FIG. 36

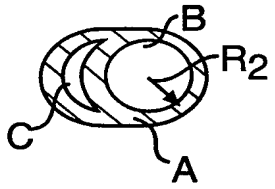

FIG. 37

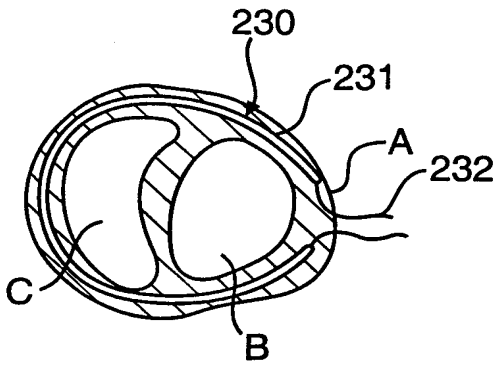

FIG. 38

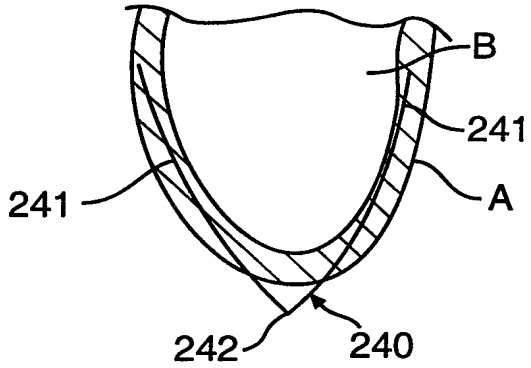

FIG. 39

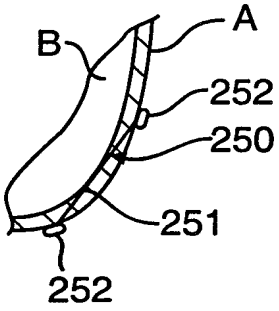

FIG. 40

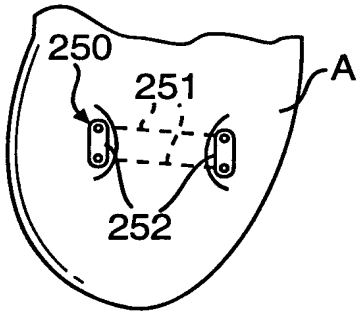

FIG. 41

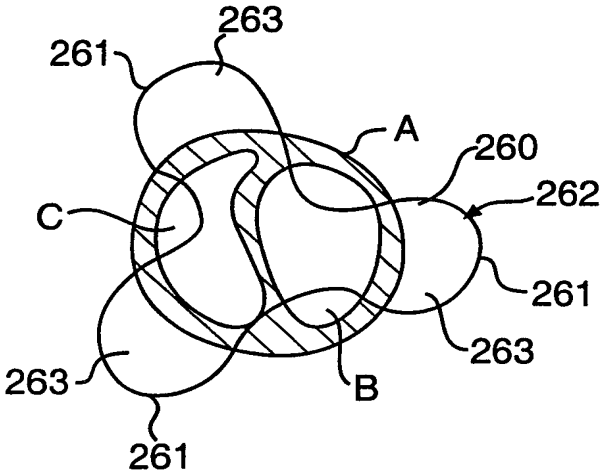

FIG. 42

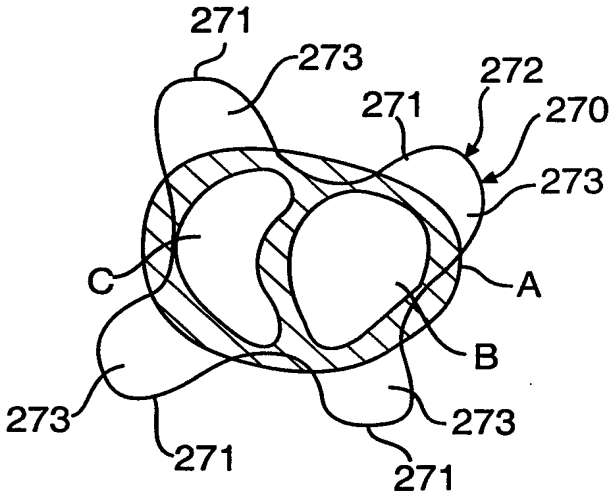

FIG. 43

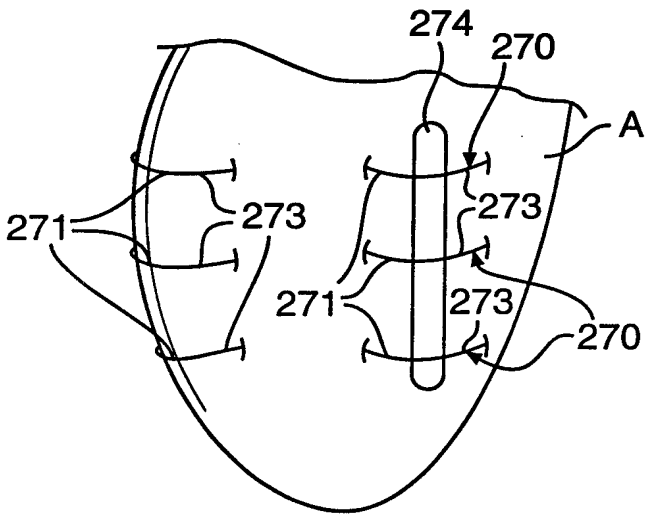

FIG. 44

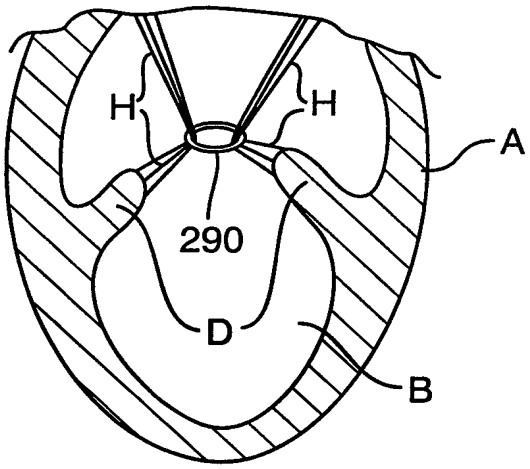

FIG. 45

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(71) Applicant *(for all designated States except US)*: **MYOCOR, INC.** [US/US]; 13300 67th Avenue North, Maple Grove, MN 55311 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **VIDLUND, Robert, M.** [US/US]; 1811 Kennard Street, Maplewood, MN 55109 (US). **KALGREEN, Jason, E.** [US/US]; 14820 39th Avenue North, Plymouth, MN 55446 (US). **MORTIER, Todd, J.** [US/US]; 3008 Colfax Avenue South, Minneapolis, MN 55408 (US). **SCHWEICH, Cyril, J., Jr.** [US/US]; 8936 Willowby Crossing, Maple Grove, MN 55311 (US). **SCHROEDER, Richard** [US/US]; 5497 East Danube Road, N.E., Fridley, MN 55432 (US). **KUSZ, David** [US/US]; 3229 39th Avenue South, Minneapolis, MN 55406 (US).

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

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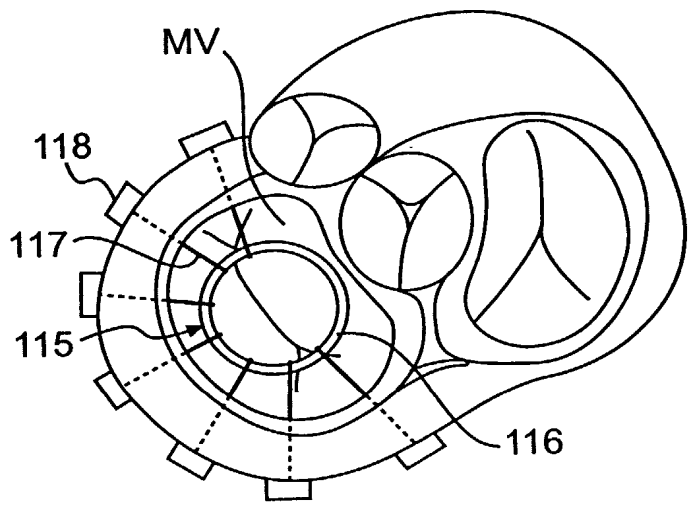
(54) Title: DEVICES AND METHODS FOR HEART VALVE TREATMENT



(57) Abstract: Devices and methods for treating heart valves include members that assist the valve in closing during at least a portion of the cardiac cycle. Such devices include members configured to alter the shape of a valve annulus, reposition at least one papillary muscle, and/or plug an orifice of the valve so as to provide a coaptation surface for the valve leaflets.

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Devices and Methods for Heart Valve Treatment

BACKGROUND OF THE INVENTION

Field of the Invention

[001] The present invention relates to devices and related methods for treating and improving the function of dysfunctional heart valves. More particularly, the invention relates to devices and related methods that passively assist to close a heart valve to improve valve function of poorly functioning valves.

Description of the Related Art

[002] Various etiologies may result in heart valve insufficiency depending upon both the particular valve as well as the underlying disease state of the patient. For instance, a congenital defect may be present resulting in poor coaptation of the valve leaflets, such as in the case of a monocusp aortic valve, for example. Valve insufficiency also may result from an infection, such as rheumatic fever, for example, which may cause a degradation of the valve leaflets. Functional regurgitation also may be present. In such cases, the valve components may be normal pathologically, yet may be unable to function properly due to changes in the surrounding environment. Examples of such changes include geometric alterations of one or more heart chambers and/or decreases in myocardial contractility. In any case, the resultant volume overload that exists as a result of an insufficient valve may increase chamber wall stress. Such an increase in stress may eventually result in a dilatory process that further exacerbates valve dysfunction and degrades cardiac efficiency.

[003] Mitral valve regurgitation often may be driven by the functional changes described above. Alterations in the geometric relationship between valvular components may occur for numerous reasons, including events ranging from focal myocardial infarction to global ischemia of the myocardial tissue.

Idiopathic dilated cardiomyopathy also may drive the evolution of functional mitral regurgitation. These disease states often lead to dilatation of the left ventricle. Such dilatation may cause papillary muscle displacement and/or dilatation of the valve annulus. As the papillary muscles move away from the valve annulus, the chordae connecting the muscles to the leaflets may become tethered. Such tethering may restrict the leaflets from closing together, either symmetrically or asymmetrically, depending on the relative degree of displacement between the papillary muscles. Moreover, as the annulus dilates in response to chamber enlargement and increased wall stress, increases in annular area and changes in annular shape may increase the degree of valve insufficiency. Annular dilatation is typically concentrated on the posterior aspect, since this aspect is directly associated with the expanding left ventricular free wall and not directly attached to the fibrous skeleton of the heart. Annular dilatation also may result in a flattening of the valve annulus from its normal saddle shape.

[004] Alterations in functional capacity also may cause valve insufficiency. In a normally functioning heart, the mitral valve annulus contracts during systole to assist in leaflet coaptation. Reductions in annular contractility commonly observed in ischemic or idiopathic cardiomyopathy patients therefore hamper the closure of the valve. Further, in a normal heart, the papillary muscles contract during the heart cycle to assist in maintaining proper valve function. Reductions in or failure of the papillary muscle function also may contribute to valve regurgitation. This may be caused by infarction at or near the papillary muscle, ischemia, or other causes, such as idiopathic dilated cardiomyopathy, for example.

[005] The degree of valve regurgitation may vary, especially in the case of functional insufficiency. In earlier stages of the disease, the valve may be able to compensate for geometric and/or functional changes in a resting state.

However, under higher loading resulting from an increase in output requirement, the valve may become incompetent. Such incompetence may only appear during intense exercise, or alternatively may be induced by far less of an exertion, such as walking up a flight of stairs, for example.

[006] Conventional techniques for managing mitral valve dysfunction include either surgical repair or replacement of the valve or medical management of the patient. Medical management typically applies only to early stages of mitral valve dysfunction, during which levels of regurgitation are relatively low. Such medical management tends to focus on volume reductions, such as diuresis, for example, or afterload reducers, such as vasodilators, for example.

[007] Early attempts to surgically treat mitral valve dysfunction focused on replacement technologies. In many of these cases, the importance of preserving the native subvalvular apparatus was not fully appreciated and many patients often acquired ventricular dysfunction or failure following the surgery. Though later experience was more successful, significant limitations to valve replacement still exist. For instance, in the case of mechanical prostheses, lifelong therapy with powerful anticoagulants may be required to mitigate the thromboembolic potential of these devices. In the case of biologically derived devices, in particular those used as mitral valve replacements, the long-term durability may be limited. Mineralization induced valve failure is common within ten years, even in older patients. Thus, the use of such devices in younger patient groups is impractical.

[008] Another commonly employed repair technique involves the use of annuloplasty rings. These rings originally were used to stabilize a complex valve repair. Now, they are more often used alone to improve mitral valve function. An annuloplasty ring has a diameter that is less than the diameter of the enlarged valve annulus. The ring is placed in the valve annulus and the tissue of the annulus sewn or otherwise secured to the ring. This causes a reduction in

the annular circumference and an increase in the leaflet coaptation area. Such rings, however, generally flatten the natural saddle shape of the valve and hinder the natural contractility of the valve annulus. This may be true even when the rings have relatively high flexibility.

[009] To further reduce the limitations of the therapies described above, purely surgical techniques for treating valve dysfunction have evolved. Among these surgical techniques is the Alfiere stitch or so-called bowtie repair. In this surgery, a suture is placed substantially centrally across the valve orifice between the posterior and anterior leaflets to create leaflet apposition. Another surgical technique includes plication of the posterior annular space to reduce the cross-sectional area of the valve annulus. A limitation of each of these techniques is that they typically require opening the heart to gain direct access to the valve and the valve annulus. This generally necessitates the use of cardiopulmonary bypass, which may introduce additional morbidity and mortality to the surgical procedures. Additionally, for each of these procedures, it is very difficult, if not impossible, to evaluate the efficacy of the repair prior to the conclusion of the operation.

[010] Due to these drawbacks, devising effective techniques that could improve valve function without the need for cardiopulmonary bypass and without requiring major remodeling of the valve may be advantageous. In particular, passive techniques to change the shape of the heart chamber and associated valve and/or reduce regurgitation while maintaining substantially normal leaflet motion may be desirable. Further, advantages may be obtained by a technique that reduces the overall time a patient is in surgery and under the influence of anesthesia. It also may be desirable to provide a technique for treating valve insufficiency that reduces the risk of bleeding associated with anticoagulation requirements of cardiopulmonary bypass. In addition, a technique that can be employed on a beating heart would allow the practitioner an opportunity to

assess the efficacy of the treatment and potentially address any inadequacies without the need for additional bypass support.

SUMMARY OF THE INVENTION

[011] A recently developed passive technique that addresses at least some of the drawbacks discussed above includes applying passive devices to the heart, for example the left ventricle, to change the shape of the ventricle and concomitantly to improve coaptation of the mitral valve leaflets. In one embodiment, the technique involves implanting splints across the left ventricle. Examples of various splinting approaches are disclosed in U.S. Application No. 09/680,435, filed October 6, 2000, entitled "Methods and Devices for the Improvement of Mitral Valve Function," which is assigned to the same assignee as the present application and which is incorporated by reference in its entirety herein.

[012] The devices and related methods which will be disclosed herein also operate passively to treat valve insufficiency, by altering the shape of the valve annulus and/or repositioning the papillary muscles, for example. Some of the devices of the present invention may be used in combination with the splinting treatments disclosed in U.S. Application No. 09/680,435, incorporated by reference herein.

[013] It should be understood that the invention disclosed herein could be practiced without performing one or more of the objects and/or advantages described above. Other aspects will become apparent from the detailed description which follows. As embodied and broadly described herein, the invention includes a method for treating a heart valve comprising providing a device having an arcuate portion and at least one elongate portion configured to extend from the arcuate portion. The method may further comprise encircling at least a portion of an annulus of a heart valve with the arcuate portion and adjusting a size of at least one of the arcuate portion and the elongate portion so

as to alter a shape of the portion of the annulus. The method also may include securing the at least one elongate portion to an exterior surface of the heart.

[014] According to another aspect, a method of treating a heart valve comprises providing a device having an arcuate portion and at least one elongate member configured to extend from the arcuate portion. The method further comprises placing the arcuate portion proximate an annulus of a heart valve and extending the at least one elongate member from the arcuate portion. The method also may comprise securing the at least one elongate member to an exterior surface of the heart, wherein the at least one elongate member extends from the arcuate portion to the heart wall in substantially the same plane as the arcuate portion.

[015] Yet another aspect includes a device for treating a heart valve comprising an arcuate portion configured to at least partly encircle an annulus of the heart valve and at least one elongate portion extending from the arcuate portion and configured to be secured to an exterior surface of a heart wall surrounding a heart chamber associated with the valve. At least one of the arcuate portion and the elongate portion is configured to be adjusted in size so as to alter a shape of at least a portion of the annulus.

[016] In yet another aspect, a device for treating a heart valve comprises an arcuate portion configured to be positioned proximate an annulus of the heart valve and at least one elongate member extending from the arcuate portion and configured to be secured to an exterior surface of the heart wall. The at least one elongate member extends from the arcuate portion to the heart wall in substantially the same plane as the arcuate portion.

[017] According to yet another aspect, the invention includes a device for treating a heart valve comprising at least one substantially elongate member configured to be implanted in a lumen of a coronary vessel so as to encircle at least a portion of an annulus of the heart valve and alter a shape of at least the

portion of the annulus. The device may further comprise a shape change element associated with the elongate member and configured to impart a local shape change to a portion of the valve annulus at a location corresponding to the shape change element.

[018] Yet another aspect includes a device for treating a heart valve comprising at least one substantially elongate member configured to be implanted in a lumen of a coronary vessel so as to encircle at least a portion of an annulus of the heart valve and alter a shape of at least the portion of the valve annulus. The shape of at least a portion of the elongate member may be configured to be adjustable so as to impart a local shape change to a portion of the valve annulus at a location corresponding to at least the adjustable portion.

[019] Yet another aspect of the invention includes a method for treating a heart valve comprising providing at least one substantially elongate member and extending at least a portion of the elongate member within a heart wall surrounding a chamber of the heart associated with the heart valve so as to encircle at least a portion of the heart chamber. The method may further comprise securing the elongate member in place with respect to the heart and compressing at least a portion of a heart wall surrounding at least the portion of the heart chamber so as to move leaflets of the valve toward each other so as to assist the valve in closing during at least a portion of the cardiac cycle.

[020] In yet another aspect, a method for treating a heart valve comprises providing at least one substantially elongate member and extending at least a portion of the elongate member within a lumen of a coronary sinus so as to encircle at least a portion of a heart chamber. The method further comprises securing the elongate member in place with respect to the heart via securement mechanisms and compressing at least a portion of a heart wall surrounding the portion of the heart chamber so as to move leaflets of the valve toward each

other so as to assist the valve in closing during at least a portion of the cardiac cycle.

[021] Yet another aspect of the invention includes a device for treating a heart valve comprising an elongate member having first and second oppositely disposed ends, with the elongate member being relatively rigid, a first anchoring member configured to be attached to the first end of the elongate member, and a second anchoring member configured to be attached to the second end of the elongate member. The first anchoring member may be configured to engage a first exterior surface of a wall of the heart and the second anchoring member may be configured to engage a second exterior surface of the wall of the heart to maintain a position of the elongate member transverse a heart chamber associated with the valve and substantially along a line of coaptation of the valve. The length of the elongate member may be such that the elongate member is capable of maintaining a substantially normal distance between trigones of the valve.

[022] In yet another aspect, a method for treating a heart valve comprises providing a relatively rigid elongate member having first and second oppositely disposed ends, securing the first end of the elongate member to a first exterior heart wall surface, and securing the second end of the elongate member to a second exterior heart wall surface, the second exterior surface being located substantially opposite to the first exterior surface such that the elongate member extends substantially transverse a heart chamber associated with the valve and substantially along a line of coaptation of the valve. The method also may comprise maintaining a substantially normal distance between the trigones of the valve via the elongate member.

[023] Yet another aspect of the invention includes a device for treating leakage of a heart valve comprising an expandable plug member having an external surface, with at least a portion of the plug member being configured to

be positioned proximate leaflets of the heart valve. The device also may comprise a securement mechanism attached to the plug member and configured to secure the plug member with respect to the heart such that during at least a portion of the cardiac cycle, the leaflets abut the external surface of the plug member to restrict bloodflow through the valve.

[024] According to another aspect, a device for treating leakage of a heart valve comprises a plug member having a piston-like configuration and an external surface being configured to abut free ends of leaflets of the valve to restrict bloodflow through the valve during at least the portion of the cardiac cycle. The device may further comprise a securement mechanism attached to the plug member and configured to secure the plug member with respect to the heart.

[025] Yet another aspect of the invention includes a method of preventing leakage in a heart valve comprising providing an expandable plug member having an external surface, delivering the plug member to a heart chamber containing a valve, and positioning the plug member proximate leaflets of the valve such that the leaflets contact the external surface of the plug member during at least a portion of the cardiac cycle so as to restrict bloodflow through the valve.

BRIEF DESCRIPTION OF THE DRAWINGS

[026] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate several embodiments of the invention and together with the description, serve to explain certain principles. In the drawings,

[027] Fig. 1a is a short-axis cross-sectional view of the heart;

[028] Fig. 1b is a partial short axis cross-sectional view of the heart;

[029] Fig. 2a is a top view of a properly functioning mitral valve in an open position;

[030] Fig. 2b is a top view of a properly functioning mitral valve in a closed position;

[031] Fig. 2c is a top view of an improperly functioning mitral valve in a "closed" position;

[032] Fig. 3a is a side view of a properly functioning mitral valve shown with its connection to the papillary muscles;

[033] Fig. 3b is a side view of an improperly functioning mitral valve shown with its connection to the papillary muscles;

[034] Fig. 4a is a cross-sectional view of a mitral valve and a coronary sinus with an exemplary embodiment of a curved frame member implanted in the coronary sinus according to an aspect of the invention;

[035] Fig. 4b is a cross-sectional view of another exemplary embodiment of a curved frame member implanted in a coronary sinus according to an aspect of the invention;

[036] Fig. 4c is a perspective view of yet another exemplary embodiment of a curved frame member implanted in a coronary sinus according to an aspect of the invention;

[037] Fig. 4d is a perspective view of yet another exemplary embodiment of a curved frame member for implantation in a coronary sinus according to an optional aspect of the invention;

[038] Fig. 4e is a perspective view of yet another exemplary embodiment of a curved frame member for implantation in a coronary sinus according to an aspect of the invention;

[039] Fig. 4f is a perspective view of yet another embodiment of a curved frame member for implantation in a coronary sinus according to an aspect of the invention;

[040] Fig. 4g is a perspective view of the curved frame member of Fig. 4f in a curved configuration;

[041] Fig. 4h is a perspective view of yet another exemplary embodiment of a curved frame member according to an aspect of the invention;

[042] Fig. 4i is a perspective view of the curved frame member of Fig. 4h in a curved configuration;

[043] Fig. 5a is a long axis, partial, cross-sectional view of a heart with a snare device delivered to the mitral valve according to an exemplary embodiment of the invention;

[044] Fig. 5b is a short axis, cross-sectional view of a heart with filaments delivered to the mitral valve and captured by the snare device of Fig. 5a according to an exemplary embodiment of the invention;

[045] Fig. 5c is a long axis, partial, cross-sectional view of a heart with the filaments of Fig. 5b drawn through the left atrium by the snare device according to an exemplary embodiment of the invention;

[046] Fig. 5d is a short axis, cross-sectional view of a heart showing an embodiment of a floating ring device implanted to treat the mitral valve according to an optional aspect of the invention;

[047] Fig. 5e is a perspective view of an exemplary embodiment of a floating ring device according to an aspect of the invention;

[048] Fig. 6a is a short axis cross-sectional view of a heart showing an exemplary embodiment of an annular noose implanted to treat the mitral valve according to an aspect of the invention;

[049] Fig. 6b is a cross-sectional view of a mitral valve with another exemplary embodiment of an annular noose implanted to treat the mitral valve according to an aspect of the invention;

[050] Fig. 6c is a cross-sectional view of a mitral valve with yet another exemplary embodiment of an annular noose implanted to treat the mitral valve according to an aspect of the invention;

[051] Fig. 6d is a short axis cross-sectional view of a heart with another exemplary embodiment of an annular noose implanted to treat the mitral valve according to an aspect of the invention;

[052] Fig. 6e is a short axis cross-sectional view of a heart with another exemplary embodiment of an annular noose according to an aspect of the invention;

[053] Fig. 7a is a short axis, cross-sectional view of a heart showing an exemplary embodiment of an elongate bar and a snare device around the elongate bar implanted to treat the mitral valve according to an aspect of the invention;

[054] Fig. 7b is a short axis, cross-sectional view of a heart showing an embodiment of an internal strut device implanted to treat the mitral valve according to an optional aspect of the present invention;

[055] Fig. 8 is a short axis, cross-sectional view of a heart implanted with an exemplary embodiment of an intrawall splint according to an aspect of the invention;

[056] Fig. 9 is a partial perspective view of a heart implanted with an exemplary embodiment of an external plication device according to an aspect of the invention;

[057] Fig. 10a is a schematic side view of an improperly functioning mitral valve during systole;

[058] Fig. 10b is a schematic side view of the valve of Fig. 10a with an exemplary embodiment of a plug device implanted in the valve orifice according to an aspect of the invention;

[059] Fig. 11a is an exemplary embodiment of a spherical plug device implanted in the valve orifice between the valve leaflets according to an aspect of the invention;

[060] Fig. 11b is an exemplary embodiment of an ellipsoidal plug device implanted in the valve orifice between the valve leaflets according to an aspect of the invention;

[061] Fig. 11c is an exemplary embodiment of a disk-shaped plug device implanted in the valve orifice between the valve leaflets according to an aspect of the invention;

[062] Fig. 11d is an exemplary embodiment of a wing-shaped plug device implanted in the valve orifice between the valve leaflets according to an aspect of the invention;

[063] Fig. 11e is an exemplary embodiment of a sheet-like plug device implanted in the valve orifice between the valve leaflets according to an aspect of the invention;

[064] Fig. 11f is an exemplary embodiment of an inflatable sheet-like plug device configured to be implanted in the valve orifice between the valve leaflets according to an aspect of the invention;

[065] Fig. 11g(i) is a perspective view of an exemplary embodiment of collapsible tube plug device in its expanded configuration according to an aspect of the invention;

[066] Fig. 11g(ii) is a perspective view of the collapsible tube plug device of Fig. 11g(i) in its collapsed configuration according to an aspect of the invention;

[067] Fig. 11h(i) is another exemplary embodiment of a collapsible plug device in its expanded configuration implanted in the valve according to an aspect of the invention;

[068] Fig. 11h(ii) shows the collapsible plug device of Fig. 11h(i) in its collapsed configuration implanted in the valve according to an aspect of the invention;

[069] Fig. 11i(i) is yet another exemplary embodiment of a collapsible plug device in its expanded configuration implanted in the valve according to an aspect of the invention;

[070] Fig. 11i(ii) shows the collapsible plug device of Fig. 11i(i) in its collapsed configuration implanted in the valve according to an aspect of the invention;

[071] Fig. 11j(i) is yet another exemplary embodiment of a collapsible plug device in its expanded configuration implanted in the valve according to an aspect of the invention;

[072] Fig. 11j(ii) shows the collapsible plug device of Fig. 11j(i) in its collapsed configuration implanted in the valve according to an aspect of the invention;

[073] Fig. 11k is an exemplary embodiment of a piston-like plug device implanted in the valve according to an aspect of the invention;

[074] Fig. 11l(i) is another exemplary embodiment of a piston-like plug device shown in a collapsed configuration implanted in the valve according to an aspect of the invention;

[075] Fig. 11l(ii) shows the piston-like plug device of Fig. 11l(i) shown in an expanded configuration implanted in the valve according to an aspect of the invention;

[076] Fig. 11m(i) is yet another exemplary embodiment of a plug device shown implanted in the heart during systole according to an aspect of the invention;

[077] Fig. 11m(ii) shows the plug device of Fig. 11m(i) shown implanted in the heart during diastole according to an aspect of the invention;

[078] Fig. 12 is a partial perspective view of the heart showing a plug device implanted in the heart according to an optional aspect of the invention;

[079] Fig. 13a is a long axis cross-sectional view of the left ventricle and left atrium of a heart showing schematically various exemplary positions for a plug device according to an optional aspect of the invention;

[080] Fig. 13b is a long axis cross-sectional view of the left ventricle and left atrium of a heart showing schematically various exemplary positions for a plug device according to an aspect of the invention;

[081] Fig. 13c is a basal cut away cross-sectional view of the heart showing schematically various exemplary positions for a plug device according to an aspect of the invention;

[082] Fig. 13d is a long axis cross-sectional view of the left ventricle and left atrium of a heart showing schematically an exemplary position for a plug device according to an aspect of the invention;

[083] Fig. 14a is a partial perspective view of the left ventricle and left atrium of a heart showing an exemplary embodiment of a needle and stylet assembly for delivering a plug device according to an aspect of the invention;

[084] Fig. 14b is a long axis cross-sectional view of the heart showing the placement of the needle and stylet assembly of Fig. 14a relative to the mitral valve leaflets according to an aspect of the invention;

[085] Fig. 14c is a partial perspective view of the left ventricle and left atrium with a leader assembly and sheath retaining a plug device being advanced through the needle of Fig. 14a according to an aspect of the invention;

[086] Fig. 14d is a partial perspective view of the left ventricle and left atrium showing an exemplary embodiment of a sheath retaining a plug device being advanced through the heart according to an aspect of the invention;

[087] Fig. 14e is a partial short axis cross-sectional view of the heart during systole viewed from the top and showing an exemplary embodiment of a plug device implanted in the valve according to an aspect of the invention;

[088] Fig. 14f is a partial short axis cross-sectional view of the heart during diastole viewed from the top and showing an exemplary embodiment of a plug device implanted in the valve according to an aspect of the invention;

[089] Fig. 15a is a perspective view of an exemplary embodiment of a trocar and needle assembly for delivery of a plug device according to an aspect of the invention;

[090] Fig. 15b is a perspective view of the trocar and needle assembly of Fig. 15a with an exemplary embodiment of a pusher assembly used to advance an anchor of a plug device out of the trocar and needle assembly according to an aspect of the invention;

[091] Fig. 15c is a perspective view of the trocar and needle assembly of Fig. 15a with an exemplary embodiment of plug member advanced out of the trocar and needle assembly according to an aspect of the invention;

[092] Fig. 16a is a perspective view of an exemplary embodiment of a plug device with a plug member in a folded configuration according to an aspect of the invention;

[093] Fig. 16b is a partial perspective view of a left ventricle and left atrium with the plug device of Fig. 16a delivered to the heart in a folded configuration according to an aspect of the invention;

[094] Fig. 16c is a partial perspective view of a left ventricle and left atrium showing an exemplary embodiment for unfolding the plug member of Fig. 16a according to an aspect of the invention;

[095] Fig. 16d is a partial perspective view of a left ventricle and left atrium showing the plug device of Fig. 16a implanted in the heart in an unfolded configuration according to an aspect of the invention;

[096] Fig. 17a is a cross-sectional view of the heart showing an exemplary embodiment of an endovascular delivery path for delivering a plug device according to an aspect of the invention;

[097] Fig. 17b is a cross-sectional view of the heart showing another exemplary embodiment of an endovascular delivery path for delivering a plug device according to an aspect of the invention;

[098] Fig. 17c is a cross-sectional view of the heart showing yet another exemplary embodiment of an endovascular delivery path for delivering a plug device according to an aspect of the invention;

[099] Fig. 18a is a perspective view of an exemplary embodiment of a plug device and anchoring frame according to an aspect of the invention;

[0100] Fig. 18b is a long axis partial cross-sectional view of the heart showing an exemplary embodiment of the implantation of the plug device and anchoring frame of Fig. 18a according to an aspect of the invention;

[0101] Fig. 19 is a long axis partial cross-sectional view of the heart showing an exemplary embodiment of an inflation device and a plug device having an inflatable plug member and anchors according to an aspect of the invention; and

[0102] Fig. 20 is a perspective view of an exemplary embodiment of an inflatable plug device according to an aspect of the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0103] Certain aspects of the invention that will be discussed herein generally pertain to devices and methods for treating valve insufficiency arising from heart conditions, including, for example, ventricle dilatation, valve incompetencies, congenital defects, and other conditions. The various devices to be described may operate passively in that, once implanted in the heart, they do not require an active stimulus, either mechanical, electrical, or otherwise, to function. Implanting one or more of the devices of the present invention may assist in closing a valve to prevent regurgitation by, for example, assisting in the proper coaptation of the heart valve leaflets, either against one another or independently against another surface. Assisting this coaptation may be

accomplished by directly geometrically altering the shape of the dysfunctional mitral valve annulus, by repositioning one or both of the papillary muscles to a more normal state, and/or by otherwise facilitating annular contraction during systole. In addition, these devices may be placed in conjunction with other devices that, or may themselves function to, alter the shape or geometry of one or more heart ventricles, locally and/or globally, and thereby further increase the heart's efficiency. That is, the heart may experience an increased pumping efficiency and concomitant reduction in stress on the heart walls through an alteration in the shape or geometry of one or more of the ventricles and through an improvement in valve function.

[0104] The inventive devices and related methods may offer numerous advantages over the existing treatments for various valve insufficiencies. The devices are relatively easy to manufacture and use, and the surgical techniques and tools for implanting the devices of the present invention do not require the invasive procedures of current surgical techniques. For instance, the surgical techniques do not require removing portions of the heart tissue, nor do they necessarily require opening the heart chamber or stopping the heart during operation. All of the techniques described may be performed without placing the patient on cardiopulmonary bypass, which, as discussed above, is routinely required for conventional procedures to repair and/or replace the mitral valve. Avoiding placing the patient on cardiopulmonary bypass may permit the inventive devices and related methods to be adjusted "real time" so as to optimize the performance of the valve. Furthermore, the inventive devices and related methods may avoid the need to place the patient on long-term anticoagulation, which currently is required for many current valve repair techniques. For these reasons, the surgical techniques for implanting the devices of the present invention also are less risky to the patient than other techniques. The less invasive nature of the surgical techniques and tools of the present invention may

also allow for earlier intervention in patients with heart failure and/or valve incompetencies.

[0105] Although many of the methods and devices are discussed below in connection with their use in the left ventricle and for the mitral valve of the heart, these methods and devices may be used in other chambers and for other valves of the heart for similar purposes. The left ventricle and the mitral valve have been selected for illustrative purposes because a large number of the disorders that the present invention treats occur in connection with the mitral valve. Furthermore, as will be shown, certain devices disclosed herein for improving valve function can be used either as stand-alone devices (i.e., solely for treatment of valve insufficiency) or in conjunction with other devices for changing the shape of a heart chamber or otherwise reducing heart wall stress.

[0106] Reference will now be made in detail to some optional embodiments of the invention, examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

[0107] Fig. 1a is a short-axis cross-sectional view of the heart illustrating the mitral valve MV in relation to the other valves of the heart, namely, the aortic valve AO, the tricuspid valve TV, and the pulmonary valve PV. The mitral valve has two leaflets, an anterior leaflet A and a posterior leaflet P. The anterior leaflet A is adjacent the aorta, AO, and the posterior leaflet P is opposite the aorta AO. An annulus AN surrounds the mitral valve leaflets. Fig. 1b is a partial short-axis cross-sectional view showing the mitral valve MV in relation to the coronary sinus CS. The coronary sinus CS wraps around a significant portion of the posterior aspect of the mitral valve annulus AN. The ostium OS of the coronary sinus CS drains into the right atrium RA.

[0108] In Figs. 2a and 2b, a top view of a properly functioning mitral valve MV is shown. Fig. 2a shows the valve MV in its open position during diastole in

which the posterior leaflet P is separated from the anterior leaflet A. Portions of the chordae C also can be seen in Fig. 2a. Fig. 2b shows the properly functioning mitral valve MV in the closed position during systole. In this figure, the anterior leaflet A and the posterior leaflet P contact one another along a line of coaptation to close the mitral valve MV and prevent blood from flowing through the valve MV from the left atrium to the left ventricle.

[0109] Fig. 2c shows a top view of an improperly functioning mitral valve MV in the "closed" position (i.e., during systole). In Fig. 2c, the anterior leaflet A and the posterior leaflet P do not properly co-apt when the valve MV is in the closed position. This may be caused by, for example, a dilatation of the annulus AN caused by an enlargement of the left ventricle, or other similar mechanisms discussed above. As shown in Fig. 2c, this improper coaptation prevents the complete closure of the orifice O between the valve leaflets, thereby permitting blood to leak through the valve from the left ventricle to the left atrium during systole. In other words, although the mitral valve is in a contracted state, it is not actually closed so as to prevent blood flow therethrough since the leaflets are prevented from completely coming together.

[0110] Fig. 3a shows a side view of a properly functioning mitral valve in the closed position with the valve leaflets L properly coapted so as to prevent blood flow through the valve. Fig. 3b shows a side view of an improperly functioning mitral valve in which the valve leaflets L are not properly coapted due to, for example, dislocation of the papillary muscles PM. Such dislocation of the papillary muscles also may be caused by enlargement of the left ventricle, for example. The arrows in Fig. 3a show the movement of the papillary muscles PM down and to the right resulting from such ventricle dilatation.

[0111] Such dysfunctioning valves, as shown in Figs. 2c and 3b, may cause a reduction in forward stroke volume from the left ventricle. Also, a blood flow reversal into the pulmonary veins may occur. Mitral valve regurgitation may

also arise from a combination of valve annulus dilation and papillary muscle dislocation.

[0112] It should be noted that dilatation of the left ventricle represents an example of a condition that can lead to improper valve function. Other conditions, discussed above, also may cause such valve dysfunction, and the devices and techniques discussed herein can be used to treat valve insufficiencies caused by these conditions.

[0113] Exemplary embodiments of a device for treating the mitral valve via a change in shape of the valve annulus, which may include a reduction in the effective circumference of the valve annulus, are shown in Figs 4a-4i. The devices of Figs. 4a-4i may be implanted on a beating heart, without the need for cardiopulmonary bypass. The devices of Figs. 4a-4i comprise curved frame members configured to be inserted into the coronary sinus to effect a shape change of the posterior aspect of the mitral valve annulus. In certain embodiments, as will be discussed, the frame members include mechanisms that allow for creating a focused shape change at selected locations along a portion of the mitral valve annulus adjacent the frame members. That is, the frame members may allow for differing shape change effects along the length of the frame member. The ability to selectively alter the shape in one region of the annulus differently than another region may be particularly advantageous when treating patients whose mitral valve insufficiency has arisen from local myocardial ischemia or infarction, since such patients may experience relatively localized geometrical alterations of the mitral valve annulus, as opposed to an overall radial increase of the annulus.

[0114] As shown in Fig. 4a, a curved frame member 110a is configured to be delivered endovascularly to and implanted in the coronary sinus CS. The origin of the coronary sinus CS is located in the wall of the right atrium (not shown), and may be accessed by, for example, catheterization of the femoral,

jugular, or subclavian veins, so as to endovascularly implant the frame member 110a. Alternatively, the frame member 110a could be implanted via a surgical approach. In any case, the frame member 110a may be positioned in the coronary sinus CS proximate the posterior aspect of the mitral valve annulus, as shown in Fig. 4a. In this position, the frame 110a may be used to alter the shape of the posterior aspect of the valve annulus, creating a configuration that effectively reduces the annular circumference and/or creates a greater degree of coaptation between the anterior and posterior leaflets A, P. Alternatively, the frame member 110a may be used to stabilize the shape of the posterior aspect of the valve annulus, thereby substantially preventing continued dilation or deformation of the valve annulus.

[0115] The frame member 110a may be made of a substantially rigid material such that the frame member 110a can be bent or otherwise formed into the desired shape and placed within the coronary sinus CS, causing the annulus of the mitral valve MV, or portions thereof, to change shape. The frame member 110a may engage within the coronary sinus CS via a friction fit to maintain its position within the coronary sinus CS. A further alternative is to fabricate the frame member 110a of a shape memory material, such as nickel-titanium alloy, for example. In this manner, the frame member 110a may be chilled prior to implantation such that it has some flexibility. This may permit the frame member 110a to be introduced into the coronary sinus CS in a relatively atraumatic manner. Once in place, the blood may warm the frame member 110a, causing a shape change to a preformed initial shape. This shape change of the frame member 110a may in turn alter the shape of the coronary sinus CS and thus the valve annulus.

[0116] As shown in Fig. 4b, one or both ends of the frame member 110a may exit the coronary sinus CS and anchor assemblies 105 may be provided on the ends of the frame member 110a. This may allow the frame member 110a to

impart a shape change to the valve annulus beyond the somewhat limited extent of the coronary sinus CS around the posterior aspect of the valve. The frame member 110a may be anchored to an exterior surface of the heart wall via the anchor assemblies 105. The ends of the frame member 110a may puncture through the coronary sinus CS to pass externally and allow connection of the anchor assemblies 105 to the exterior surface of the heart. The anchor assemblies 105 may be in the form of anchor pads. Some examples of such anchor pads are described in U.S. Application No. 09/680,435, incorporated above. The anchor assemblies 105 may be sutured, or secured by other similar attachment mechanisms, such as by providing a surface of the anchor assemblies 105 with a tissue ingrowth promoting material, to an exterior surface of the heart wall to hold the frame 110a in place with respect thereto. To further facilitate obtaining the desired shape change of the mitral valve annulus, the anchor assemblies 105 may be positionable along the length of the frame member 110 prior to fixation of the frame member 110 with respect to the heart or the frame member 110 may have a variable length. For example, the frame member 110a may be provided with a telescoping mechanism or the like.

[0117] In yet another exemplary embodiment, as shown in Fig. 4c, the frame member 110c may be configured to anchor itself into the vessel wall in order to maintain its position. For example, in the optional configuration shown in Fig. 4c, the frame member 110c is provided with barbs 111 along its length. The frame member 110c may be delivered endovascularly such that the barbs 111 do not engage the wall of the coronary sinus CS. Once the frame member 110c is placed within the coronary sinus CS in the desired position, it may be manipulated, for example, by rotation or by moving the frame member 110c in a direction opposite to the direction of advancement through the coronary sinus CS, so as to engage the barbs 111 with the coronary sinus wall. This engagement helps to maintain the position of the frame member 110c.

[0118] Fig. 4d shows another embodiment of a curved frame member 110d configured to be implanted in the coronary sinus CS for treating the mitral valve. In this embodiment, the frame member 110d may support a shape change element 106 configured to move along a length of the frame member 110d. The shape change element 106 may be configured to protrude radially with respect to the frame 110d, thereby providing a more localized shape change in an area along the posterior aspect of the mitral valve. A desired location for the shape change may be determined by moving the shape change element 106 along the length of the frame member 110d to a particular position and viewing the effects on mitral valve function through real-time imaging techniques. The shape change element 106 also may be detachable from the frame member 110d for easy removal from the frame member 110d if the localized shape change is no longer desired. The shape change element 101 may be mechanically detachable or it may be detached electrolytically in a manner similar to the detachment mechanism of the Guglielmi detachable coil. A delivery tool, which may be in the form of a delivery wire 106', may be used to deliver the shape change element 101 over the frame member 110d.

[0119] Fig. 4e shows another exemplary embodiment of a curved frame for insertion into the coronary sinus proximate the posterior aspect of the mitral valve. In this embodiment, the frame member 110e serves as a support for an adjustable shape change member 107. As an example, the curved frame 110e may define at least one slot 108 extending along at least part of the length of the frame 110e. A moveable pin 109 may engage with the slot 108 so as to slide along the length of the slot 108. A wire 112 may extend along the portion of the curved frame 110e that lies adjacent the posterior aspect of the mitral valve annulus. The wire 112 may have one end attached to the pin 109 and an opposite end attached at an end of the frame 110e substantially opposite to the moveable pin 109. For example, as shown in Fig. 4e, the wire 112 may be

attached to a fixed pin 109'. Alternatively, the wire may attach directly to the frame member 110e. Upon movement of the pin 109 toward a center of the frame member 110e, the wire 112 curves, forming a bulge that causes the mitral valve annulus to change shape.

[0120] The frame member 110e optionally may have two pins disposed at opposite ends of the frame in either a single slot running substantially the entire length of the frame 110e or two different slots disposed at substantially opposite ends of the frame 110e. In an exemplary embodiment, both of the pins 109, 109' shown in Fig. 4e, may be moveable. In either case, the movement of one pin or both pins may cause the wire 112 to bulge outward, thereby imparting a variable degree of shape change to the mitral valve annulus. Preferably, the wire 112 is sufficiently flexible so as to permit bending of the wire due to the movement of the pin 109 within the slot 108. However, the wire 112 also should be sufficiently rigid so as to maintain its bulged configuration and cause the desired shape change and/or repositioning of the valve annulus and/or papillary muscles.

[0121] Figs. 4f and 4g illustrate yet another exemplary embodiment of a curved frame member 110f for implanting in the coronary sinus to alter the shape of the mitral valve annulus. Fig. 4f is a perspective view of the frame member 110f, which is formed from segments 113 configured to rotate relative to each other. Rotating the segments 113 about their respective longitudinal axes and relative to each other may alter the curvature of the frame 110f along its length so as to produce various degrees of curvature in particular locations as desired. Such curvature of the frame member 110f is illustrated in Fig. 4g. As a direct surgical implant, the curved frame member 110f can have its segments 113 individually manipulated via direct rotation to achieve a desired final shape prior to insertion into the coronary sinus CS. A wire (not shown) extending down the

center of the segments 113 may hold the segments 113 in their final desired configuration, for example, due to frictional engagement.

[0122] In another contemplated embodiment, shown in Figs. 4h and 4i, a curved frame member 110h may comprise an actuation mechanism 90 attached to a portion of the frame member 110h. For example, the actuation mechanism 90 may be attached to a distal end of the frame member 110h. The frame member 110h may be formed of a plurality of substantially wedge-shaped segments 95. Actuating the actuation mechanism 90, by, for example, pulling mechanism 90 proximally, causes the distal end to retract so as to change the shape of the frame member 110h, as shown in Fig. 4i. This in turn may alter the shape of the mitral valve annulus when the frame member 110h is implanted in the coronary sinus CS. The actuation mechanism 90 may comprise a pull-actuated wire attached to a distal end of the frame member, as shown in Figs. 4h and 4i, or alternatively to an anchor assembly provided on the distal end of the frame member. The desired final shape of the frame member 110h may reduce or enlarge a radius of curvature of the valve annulus, or a combination of both, i.e., increasing the curvature in some regions and decreasing the curvature in other regions.

[0123] The various curved frame devices of Figs. 4a-4i may be configured to be implanted on a beating heart. Optionally, the frame devices may be implanted during an open chest or minimally invasive thoracic surgical procedure. For example, the frame member may be directly inserted into the coronary sinus through an incision in either the right atrium or the coronary sinus. In an alternative exemplary embodiment, the frame devices could be implanted endovascularly into the coronary sinus using catheter-based delivery techniques. For example, a catheter may be inserted into either the jugular vein or the vena cava and into the right atrium and then the coronary sinus.

[0124] Figs. 5a-5e show an exemplary embodiment of a floating ring device for treating mitral valve dysfunction by altering the shape of the mitral valve annulus. The floating ring device according to the invention may be implanted into the region of the mitral valve annulus itself (either above, at, or below the annulus) in order to effect the desired shape change of the mitral valve annulus.

[0125] A short axis cross-sectional view of the heart implanted with an exemplary embodiment of a floating ring device 115 is shown in Fig. 5d. The device comprises a semi-flexible ring 116 configured to be placed in the left atrium LA, proximate the mitral valve annulus. A plurality of tightening members 117, which may have the form of tension members, are secured to the ring 116. An anchor mechanism, for example in the form of a pad 118, attaches to the free end of each tightening member 117 opposite to the ring 116. The anchor pads 118 are adapted to be secured to the tightening members 117 and placed externally of the heart wall, for example on the posterior wall of the left atrium LA, to secure the floating ring device 115 in place with respect to the heart. Prior to securing the anchor pads 118 to the tightening members 117, the tightening members 117 may be tightened (i.e., their lengths between the valve annulus and heart wall altered) until the desired annular shape of the mitral valve is obtained. The tightening members 117 may be individually tightened to produce differing effects on the shape of the mitral valve annulus depending on the position around the annulus. The flexibility of the ring 116 also may assist in producing a varying effect on the mitral valve annulus geometry. It is contemplated that sutures or other attachment mechanisms may be employed instead of the anchor pads 118 to secure the tightening members 117 to the heart wall once the desired tensioning of the tightening members 117 has been achieved.

[0126] Referring to Figs. 5a-5d, an exemplary delivery technique for implanting a floating ring device will be described. The technique described preferably is performed on a beating heart. As shown in Fig. 5a, a snare 119 is first delivered through a relatively small incision in the wall of the appendage of the left atrium LA. As an example, the incision may be made at a location superior to the mitral valve MV. A trocar (not shown) also may assist in the delivery of the snare 119 through the incision. The snare 119 comprises a loop portion 119a at a distal end of the device and a handling portion 119b extending from the loop portion 119a. The handling portion 119b forms a proximal end of the snare 119. The handling portion 119b may extend out of the left atrium upon deployment of the snare 119 within the heart. According to an alternative aspect, the snare 119 may be delivered through the venous system to the right atrium (not shown) and then into the left atrium LA via the atrial septum. In either case, once the snare 119 is delivered into the left atrium LA, the loop portion 119a may be positioned with its perimeter resting on substantially the outermost edges of the mitral valve annulus AN.

[0127] After appropriately positioning the snare 119 with respect to the mitral valve annulus AN, a plurality of tightening members 117, which may have a substantially filament-like structure, may be inserted from external the heart, through the wall of the left atrium LA, and into the left atrial chamber. For example, as shown in Fig. 5b, a hollow, needle-like delivery tool 300 may be used to insert the tightening members 117 through the heart wall by inserting the delivery tool 300 carrying the tightening members 117 through the heart wall and ejecting the members 117 out of the delivery tool 300.

[0128] As shown in Fig. 5b, the tightening members 117 may be positioned along the posterior aspect of the mitral valve MV approximately at the level of the mitral valve annulus AN. As the tightening members 117 are inserted into the atrial chamber, they may be carried through the snare loop 119a via the

blood flowing from the left atrium LA through the mitral valve MV and to the left ventricle LV. To facilitate delivery of the tightening members 117, especially with regard to their insertion through the heart wall, the tightening members 117 optionally may be attached to needles which penetrate the heart wall first. In this case, the bloodflow would carry the needles with the tightening members 117 attached from the left atrium LA and through the snare loop portion 119a.

[0129] Once the tightening members 117 have been drawn through the snare loop portion 119a, the snare 119 may then be retracted and the tightening members 117 captured within the loop portion 119a. By pulling proximally on the handling member 119b, the snare 119 with the captured tightening members 117 may be retrieved from the left atrium LA. As shown in Fig. 5c, the free ends of the tightening members 117 may be pulled out of the left atrium appendage through the incision previously made to insert the snare device 119. The snare device 119 may be removed from the tightening members 117 once they are pulled out of the left atrium LA.

[0130] The free ends of the tightening members 117 may then be secured to the flexible ring 116, for example, by tying the ends to the ring. The flexible ring 116 may then be reinserted into the left atrium LA by pulling on the tightening members 117 at their respective insertion points in the left atrial wall. Thus, the flexible ring 116 may be inserted through the same delivery path that was used to insert the snare 119.

[0131] The flexible ring 116 preferably has enough flexibility so as to permit insertion of the ring 116 into a trocar and/or an incision made in the left atrial appendage and through the left atrium LA. Furthermore, the ring 116 and the tightening members 117 preferably are covered with a hemocompatible material, such as expanded PTFE, for example. This covering may facilitate the endothelialization of any portion of the ring 116 and tightening members 117 residing in the blood flow path near the mitral valve.

[0132] After tightening each tightening member 117 to a desired amount, a securing mechanism, such as the anchor pads 118 shown in Fig. 5d, may secure the tightening members 117 externally to the heart wall. Depending on the position and number of tightening members 117, and the relative degree of tightening of each, various annular geometries of the mitral valve may be obtained. Echocardiographic visualization may be employed to assist in adjusting the floating ring device. For example, the device can be selectively tightened in various locations and/or to various degrees until minimal or no mitral valve regurgitation is observed using the echocardiographic visualization.

[0133] A further exemplary embodiment of a floating ring device is illustrated in Fig. 5e. In this embodiment, the anterior-most pairs of tightening members 117e are relatively rigid. A single elongate anchor pad 118e connects to the ends of each of the pairs of tightening members 117e. In this manner, the position of the ring 116 over the central portion of the mitral valve may be maintained, even as the posterior-oriented tightening members 117e are tightened.

[0134] Yet another optional embodiment of a device for treating the mitral valve is illustrated in Figs. 6a-6d. The device shown in these figures is referred to herein as an "annular noose," so-named due to its noose-like configuration. The annular noose 120 is formed from a flexible rope-like member 121. The member 121 may be made of a braided polyester, or other similar material, that allows the member 121 to flex without forming kinks and/or permanent bends. The rope-like member 121 is shaped into a loop portion 122 that is placed around the exterior of the left atrium (not shown), as close as possible to the atrioventricular groove (not shown), and in substantially the same plane as the mitral valve annulus AN. It may be necessary for the portion between the anterior leaflet and the aorta to be passed through the tissue of the left atrium. An adjusting mechanism manipulable from external the heart, such as a cinch

ring 125, for example, may be used to adjust the size of the loop portion 122 and secure the free ends 123a, 123b of the member 121 that extend from the loop portion 122. After the loop portion 122 has been properly positioned with respect to the mitral valve annulus AN, the cinch ring 125 may be tightened, thereby permitting a reduction in the circumference of the mitral valve annulus AN.

[0135] Figs. 6b and 6c show various elements that may be used in conjunction with the annular noose 120 of Fig. 6a so as to provide a more focused geometrical shape change in selected regions of the mitral valve. For example, as shown in both Figs. 6b and 6c, a relatively rigid member 126 may be placed over the flexible member 121. In the optional embodiment shown in Figs. 6b and 6c, the relatively rigid member 126 has a tubular configuration that may be advanced over either of the free ends of the flexible member 121 and positioned as desired along the loop portion 122. Alternatively, the relatively rigid member 126 may be permanently secured to the loop portion 122 of the flexible member 121. In the embodiment of Figs. 6b, the annular noose 120, with the relatively rigid member 126 disposed thereon, is positioned with respect to the mitral valve MV such that the relatively rigid member 126 rests by the anterior leaflet side of the mitral valve MV. This placement may permit a more focused circumferential reduction to take place at a location proximate the posterior leaflet, since this portion is more flexible and will tend to draw the noose down as it is tightened.

[0136] Fig. 6c shows another embodiment of an element for use in conjunction with the annular noose 120. A shape change securing pad 127 may be used for adjusting the size of the loop portion 122 and for securing the free ends 123a, 123b. As shown in Fig. 6c, the shape change pad 127 may have a substantially disk-like configuration with a central, substantially longitudinal passage through which the ends 123a, 123b of the flexible member 121 extend. A securing pin 128 may operate to move toward and away from the center of the

pad to pass through the flexible members ends 123a, 123b and secure the annular noose 120 into position. A surface 129 of the pad 127 that faces the mitral valve annulus may have a substantially non-concave profile, for example the surface 129 may be either convex or flat. When the pad 127 is moved so as to tighten the annular noose 120, the pad 127 may press against the mitral valve annulus and thereby cause a relatively focused shape change in the region of the pad 127.

[0137] As shown in Fig. 6d, a plurality of pads 127 may be used to change the shape of the mitral valve in the regions of the mitral valve proximate the pads. Such a focused change may permit increased co-aptation of the valve leaflets in the various regions of the focused shape change. The shape change pad 127 and the relatively rigid member 126 may be used either in combination, as shown in Fig. 6c, or individually to create a focused shape change of the mitral valve. Such a focused shape change is in addition to the overall circumferential reduction achieved by the annular noose 120 alone.

[0138] Fig. 6e illustrates an alternative exemplary embodiment of a noose device. The noose device in Fig. 6e comprises a relatively rigid member 126e, similar to the relatively rigid member 126 of Fig. 6b. The member 126e is positioned on the posterior side of the mitral valve MV. Preferably, the rigid member 126e, which is placed on the loop portion 122, may be formed by bending or the like to a desired shape so as to impart a desired shape change to the posterior annulus. The rigid member 126e can be of any desired shape, and may include one or more local regions of indentations.

[0139] Another aspect of the present invention includes an internal strut device that operates to treat mitral valve dysfunction by causing a shape change to the mitral valve annulus while maintaining or restoring the normal distance between the trigones of the valve. The device also may move the posterior leaflet face closer to the anterior leaflet face. Combined, these movements tend

to increase the coaptation area of the mitral valve leaflets and improve mitral valve function. An exemplary embodiment of an internal strut device is shown in Figs. 7a and 7b.

[0140] The embodiment of the internal strut device shown in Figs. 7a and 7b generally comprises a relatively rigid elongate member 130 positioned so as to extend substantially along the line of leaflet coaptation of the mitral valve. The relatively rigid elongate member 130 may be positioned in close proximity to the valve annulus AN, either slightly above or slightly below the annulus AN, so as to appropriately affect the valve leaflets and move them into a desired position. A second elongate member 136 may be provided so as to extend substantially perpendicular to the relatively rigid elongate member 130 and to the line of leaflet coaptation. The relatively rigid elongate member 130 may be fixed to the outer walls of the left atrium or the left ventricle, depending on the positioning of the member 130 with respect to the mitral valve MV. Sutures, anchor pads, or other similar mechanisms may secure the member 130 with respect to the leaf. Figs. 7a and 7b illustrate the use of anchor pads 132 for securing the relatively rigid, elongate member 130.

[0141] Providing a relatively rigid elongate member 130 may substantially prevent the member from bending or buckling, which may in turn help to maintain the desired trigonal distance. The member 130 may be a rigid bar made from biocompatible metals, such as nitinol, titanium, chrome-alloys, MP-35N, and other similar metals, or from biocompatible polymers, such as PEEK, acetyl, or other similar materials. Optionally, the bar may be an extendable, telescoping bar (not shown). This may permit the length of the bar to be adjusted as necessary to optimize the trigonal distance.

[0142] The second elongate member 136 may optionally be in the form of a snare having a loop portion 136a that is secured around the relatively rigid member 130. The snare may be tightened as desired and the free end 136b

may be secured via an anchor pad 134 placed adjacent an exterior surface of the heart wall. Once secured, the snare essentially forms a tension member anchored at one end to the relatively rigid member 130 and at the opposite end to the heart wall. Together, the relatively rigid member 130 and the second elongate member 136 impart a shape change to the mitral valve annulus, while maintaining the distance between the valve trigones T. Alternatively, the distance between the valve trigones also may be altered to achieve a more normal distance between them if necessary.

[0143] An exemplary embodiment for the delivery and implantation of the internal strut device of Figs. 7a and 7b will now be explained. An introducer 138, such as a trocar or other suitable introducer mechanism, may be inserted through the heart wall proximate the level of the mitral valve annulus AN. As shown in Fig. 7a, the introducer 138 may be inserted in a substantially perpendicular direction relative to the line of coaptation of the mitral valve leaflets. Once the introducer is inserted, the second elongate member 136, in the form of a snare in Figs. 7a and 7b, may be inserted through the introducer 138 and positioned with the loop portion 136a substantially in the middle of the mitral valve annulus AN. The relatively rigid elongate member 130 may then be inserted through the left atrial wall (not shown) at approximately the same annular level as the snare 136. However, the member 130 is advanced in a direction along the line of coaptation of the mitral valve leaflets and substantially perpendicular to the snare 136. The member 130 may be passed through the loop portion 136a of the snare 136 and through the wall surrounding the left atrium located substantially opposite to the wall through which the member 130 was inserted. Once extended transverse the left atrium LA, securing mechanisms, such as anchor pads 132, for example, may fix the member 130 with respect to the heart. Prior to securing the member 130, its length between

the chamber walls may be adjusted, as described above, in order to alter the distance between the valve trigones as desired.

[0144] Once the relatively rigid elongate member 130 is secured into position, the snare loop portion 136a may be tightened around it and the snare 136 secured on the external surface of the atrial wall by a securing mechanism, such as anchor pad 134 as shown in Fig. 7b. Thus, the snare 136 also may induce a shape change to the mitral valve annulus AN, as shown by the indented region of the mitral valve annulus in Fig. 7b. Both the relatively rigid elongate member 130 and the snare 136 may have their lengths adjusted as necessary to provide the overall desired shape change of the mitral valve annulus. The snare 136 may optionally be secured using a securing mechanism that extends from the annular level of the left atrium LA down the epicardial surface to a region proximate the left ventricle LV. This would allow the strut device to change the shape of the mitral valve both at a level of the valve annulus and at a subvalvular level.

[0145] In an alternate embodiment (not shown), the relatively rigid bar may be replaced by a splint assembly similar to the splint assemblies disclosed in U.S. Application No. 09/680,435, incorporated by reference herein. Such a splint assembly would be relatively flexible and capable of adjusting in length by adjusting the position of the anchor members with respect to the tension member of the splint assembly. The splint assembly may extend along the line of coaptation of the valve leaflets. In this case, the length of the tension member between the heart walls may be adjusted in order to maintain or achieve a more desirable trigonal distance.

[0146] Yet another exemplary embodiment for treating a heart valve includes an intrawall splint comprising an elongate member configured to be implanted within the heart wall so as to extend around a portion of the chamber. The elongate member may optionally be either wire-like, similar to the braided

tension members used with the splint assemblies of U.S. Application No. 09/680,435, incorporated by reference herein, or tubular. Because the device of this optional embodiment is implanted within and exterior to the heart wall, there is substantially no blood contact with the device, reducing the risk of thrombus formation.

[0147] An example of an intrawall splint 140 according to an exemplary embodiment of the invention is shown in Fig. 8. The intrawall splint 140 comprises an elongate member 141 that may be implanted within the lateral myocardial wall of the heart, optionally near the atrio-ventricular groove, in an area substantially coinciding with or slightly offset from the annular edge of the posterior leaflet. In the embodiment shown in Fig. 8, the elongate member 141 is secured to the heart using anchor assemblies 148, which may have configurations similar to those discussed with reference to Figs. 4b, 5d, 7a, and 7b, for example. The anchor assemblies 148 attach to the end portions of the elongate member 141 at an exterior surface of the heart wall. The anchor assemblies 148 may move along the length of the elongate member 141 to adjust the degree of compression on the heart wall. By appropriately positioning the anchor assemblies 148 on the elongate member 141, the arc length of the mitral valve annulus along the posterior side of the valve may be reduced. This may increase the coaptation area between the valve leaflets and decrease the annular cross-section. Once a suitable degree of shape change of the valve annulus occurs, which may be determined by observing the mitral valve regurgitation through the use of echocardiagraphic or other similar visualization techniques, the anchor assemblies 148 may be fixed to the elongate member 141 to hold the elongate member 141 in place with respect to the heart. The elongate member 141 and the anchor assemblies 148 shown in Fig. 8 may be implanted in a manner similar to the implantation techniques for the splint

assemblies of U.S. Application No. 09/680,435, incorporated by reference herein.

[0148] The elongate member 141 may be made of bio-inert, bio-stable, and/or bio-resorbable materials. In each of these cases, the implantation of the elongate member 141 within the heart wall may provoke a healing response by the heart wall. This healing response may elicit a chronic process that results in the shrinkage of the tissue in a direction along the axis of the elongate member. In another exemplary configuration, the elongate member 141 may be configured so as to deliver heat to the heart wall during delivery. Such heat also may initiate a healing response in the heart wall tissue, resulting in tissue shrinkage along the elongate member. For example, the member 141 may be made of a conductive metal and be heated, such as by temporarily exposing it to an electrical current, preferably in the RF range. In an exemplary embodiment, the RF range will be chosen so as to minimize electrical interference with the heart's conduction system.

[0149] Another exemplary embodiment of the invention includes an external plication device that may be positioned on an exterior surface of the heart wall near the posterior mitral valve annulus in substantially the same plane as the annulus. As with other devices discussed herein, such an external plication device may be placed so as to reduce the valve annulus cross-section and increase the valve leaflet coaptation area. Fig. 9 shows an example of an external plication device 150 according to an aspect of the invention. The external plication device 150 comprises a curved rod 151 anchored on an exterior surface of the heart wall by a series of sutures 152. A series of tissue anchors may be used instead of sutures. The rod 151 may be shortened, for example, by telescoping, to a fixed length to provide a reduction of the lateral heart wall and/or posterior annular space. Alternatively, the external plication

device may be implanted so as to reposition the papillary muscles, such as by reducing the intrapapillary distance, for example.

[0150] The rod 151 may be either relatively rigid or relatively flexible. A relatively flexible rod 151 may take the form of a tension member, such as the tension members used with the splint assemblies of U.S. Application No. 09/680,435, incorporated by reference herein. A relatively rigid rod may be preferable to provide a local shape change, while a relatively flexible rod may be preferable for changing the arc length of at least a portion of the valve annulus. The external plication device may be made of biocompatible materials. Alternatively, the external plication device may be made of bioresorbable materials that provoke a chronic healing response of the heart wall tissue. This healing response may result in a scarring, causing the tissue to shrink in a particular direction, thereby reducing the posterior annular arc length.

[0151] As with the intrawall splint device of Fig. 8, the external plication device is implanted so as to substantially avoid blood contact within the heart chamber, which reduces the risk of thrombus formation.

[0152] The devices of Figs. 8 and 9 are shown in position on the lateral wall of the heart proximate the posterior aspect of the mitral valve annulus. It is contemplated, however, that these devices may be implanted in other positions with respect to the heart while still helping to reduce mitral valve regurgitation or to treat other heart valves altogether.

[0153] Yet another aspect of the invention includes the use of so-called "plug" devices, for treating incompetent heart valves. These plug devices are intended assist in closing the mitral valve to prevent regurgitation by increasing the coaptation area of the mitral valve leaflets and/or decreasing the coaptation depth of the mitral valve leaflets. This generally may be accomplished by placing a plug device in the "hole" between the valve leaflets (i.e., the valve orifice), thereby providing a surface against which the valve leaflets may abut (i.e, coapt),

in order to close the mitral valve during systole. The plug devices described herein assist in closing the mitral valve substantially without altering the shape of the valve annulus and/or repositioning the papillary muscles. To further understand how the plug devices according to optional aspects of the invention operate to improve mitral valve function, reference is made to the various optional embodiments of the device shown in Figs. 10b-11m(ii).

[0154] Fig. 10a illustrates a schematic side view of the leaflets L of a dysfunctional mitral valve during systole. As seen in this figure, the leaflets L do not coapt so as to close the mitral valve orifice. Therefore, regurgitant flow will occur through the valve during systole. Fig. 10b illustrates the valve of Fig. 10a during systole with an exemplary embodiment of a plug member 160 of the present invention implanted in the valve leaflet coaptation space. As can be seen, the presence of the plug member 160 will block the regurgitant flow through the valve during systole as the leaflets L abut against the outer surface of the plug member 160. In other words, the plug member 160 "plugs" the valve orifice during systole to hinder or prevent blood from leaking through the valve.

[0155] In the exemplary embodiments of Figs. 11a–11f, a plug member is suspended in the coaptation space substantially in the area where regurgitant blood flow occurs. The suspended plug member may have a variety of shapes depending on factors such as the mitral valve geometry, the alignment of the valve leaflets, and the size and shape of the regurgitant opening during systole. For example, the suspended plug member may have a spherical configuration (160a in Fig. 11a), an ellipsoidal configuration (160b in Fig. 11b), a disk-shaped configuration (160c in Fig. 11c), a wing-like configuration (160d in Fig. 11d), or a sheet-like configuration (160e in Fig. 11e, 160f in Fig. 11f). Figs. 11a-11e show schematically a partial cross-sectional view of the mitral valve with the various plug members disposed between the valve leaflets L and within the valve orifice.

[0156] In Figs. 11a-11d, the valve is shown in an open position, with a space between the valve leaflets L and the outer surface of the plug member 160a-160d to allow blood flow therethrough. During closure of the valve, the leaflets L abut against the outer surface of the plug member 160a-160d, thereby preventing regurgitation through the valve orifice, which may otherwise occur if the leaflets are unable to properly coapt against one another. Fig. 11e shows schematically a partial cross-sectional view of a mitral valve during systole with a plug member 160e disposed between the valve leaflets L. The presence of the plug member 160e permits the valve to close during systole as a result of the valve leaflets L coapting against the surface of the plug member 160e. This coaptation will substantially prevent regurgitant blood flow from occurring during systole.

[0157] A suspended member 160d having a wing-like configuration, as shown in Fig. 11d, may provide an advantageous surface for the valve leaflets L to close against due to its tapered configuration. The tapered configuration substantially mutually corresponds to the profile of the valve leaflets surfaces themselves. Such a tapered and mutually corresponding shape may help to reduce thrombus formation at the blood-surface contact points with the suspended member 160d. Moreover, this shape may reduce insult to the valve leaflets L as they close against the surface of the suspended member 160d.

[0158] A suspended member 160e having a substantially sheet-like configuration may be particularly suitable for use as a plug device in patients having misaligned leaflets. In this case, as shown in Fig. 11e, the ends of the valve leaflets L tend to reach the centerline of the valve as they come together during systole. However, the leaflets L are arranged such that the ends of the leaflets L are in different transverse planes upon closing of the valve, therefore hindering proper coaptation and valve closure. The substantially planar plug member 160e in Fig. 11e may be suspended substantially along the centerline of

the valve, providing the misaligned valve ends with a surface to abut against. Due to its substantially planar configuration, the plug member 160e may minimize the cross-sectional area of the blood flow path that is blocked by the device, while also providing the desired closure of the valve. In an alternative embodiment, shown in Fig. 11f, the sheet-like plug 160f may be constructed of two layers sealed along their perimeters. This embodiment therefore may form an inflatable structure. Such an inflatable plug member may permit the cross-section of the member to be selected and varied according to the size of the "hole" between the improperly coapting valve leaflets.

[0159] As shown in the Figs. 11a - 11f, the plug members 160 operate to reduce mitral valve regurgitation and improve valve function by providing a surface against which the mitral valve leaflets may coapt during systole, thereby closing the valve to blood flow therethrough. Thus, these plug members 160 may operate as plugs to close the hole otherwise left open due to the inability of the valve leaflets to properly coapt. Providing such a surface against which the mitral valve leaflets may coapt may benefit both patients having valve leaflets with a reduced range of motion, for example, due to chordal tethering, and/or patients having leaflets unable to coapt due to left ventricular dilatation. The plug devices of Figs 11a - 11f also may enhance coaptation in patients whose leaflets are misaligned, since each leaflet may coapt with the surface provided by the plug member independently of the other leaflet.

[0160] Materials suitable for construction of the various plug devices disclosed herein may be categorized generally into the following broad groups: synthetic polymers, biological polymers, metals, ceramics, and engineered tissues. Suitable synthetic polymers may include flouroethylenes, silicones, urethanes, poyamides, polyimides, polysulfone, poly-ether ketones, poly-methyl methacrylates, and other similar materials. Moreover, each of these

compositions potentially may be configured from a variety of molecular weights or physical conformations.

[0161] Suitable metals may be composed from a variety of biocompatible elements or alloys. Examples include titanium, Ti-6AL-4V, stainless steel alloys, chromium alloys, and cobalt alloys. The stainless steel alloys may include, for example, 304 and 316 stainless steel alloys. The cobalt alloys may include Elgiloy, MP35N, and Stellite, for example.

[0162] Suitable ceramic materials may be fashioned from pyrolytic carbon and other diamond-like materials, such as zirconium, for example. These materials may be applied to a variety of core materials, such as graphite, for example.

[0163] As for biological materials for manufacturing the devices, a variety of fixed tissues may be useful in the fabrication process. Base materials, such as pericardium, facia mater, dura mater, and vascular tissues may be fixed with a variety of chemical additives, such as aldehydes and epoxies, for example, so as to render them nonimmunogenic and biologically stable.

[0164] Tissues also may be engineered to meet the intended purpose. Substrates may be constructed from a variety of materials, such as resorbable polymers (e.g., polylactic acid, polyglycolic acid, or collagen). These materials may be coated with biologically active molecules to encourage cellular colonization. Additionally, these tissues may be constructed *in vitro,* for example using the patient's own cells or using universal cell lines. In this way, the tissue may maintain an ability to repair itself or grow with the patient. This may be particularly advantageous in the case of pediatric patients, for example.

[0165] Each of the previously mentioned materials also may be subjected to surface modification techniques, for example, to make them selectively bioreactive or nonreactive. Such modification may include physical modification, such as texturing; surface coatings, including hydrophilic polymers and ceramics

(e.g., pyrolytic carbon, zirconium nitrate, and aluminum oxide); electrical modification, such as ionic modification, for example; or coating or impregnation of biologically derived coatings, such as heparin, albumin, a variety of growth healing modification factors, such as, for example, vascular endothelial growth factors (VEGF), or other cytokines.

[0166] The tethers used to suspend the plug members, which will be described in more detail shortly, may be constructed of either monofilament or multifilament constructions, such as braids or cables, for example. Materials such as high strength polymers, including liquid crystal polymers (Vectran) and ultra high molecular weight polyethylene fibers (Spectra) may be suitable to provide desirable mechanical and fatigue properties. Suitable metals may include stainless steel, titanium alloys, and cobalt-chrome alloys, for example.

[0167] The materials discussed above are exemplary and not intended to limit the scope of the invention. Those skilled in the art would recognize that a variety of other similar suitable materials may be used for the plug devices and suspension members disclosed herein.

[0168] The suspended plug members 160a-160f of Figs. 11a - 11f may be anchored to the heart walls using anchoring members such as, for example, internal tissue anchors or anchor pads attached externally of the heart. An example of utilizing external anchor pads for suspending the plug members 160 within the valve orifice is illustrated in Fig. 12, which will be explained in more detail shortly.

[0169] Yet another exemplary embodiment of a plug device is illustrated in Figs. 11g(i), 11g(ii). The device of Figs. 11g(i), 11g(ii) comprises a tubular member 167 that may be at least partially collapsible and flexible. The top portion of the tubular member 167 may include a ring structure 168 that may be placed on the mitral valve annulus. The remaining portions of the tubular member 167 may be placed through the valve orifice between the valve leaflets

such that the tubular member 167 extends at least partially into the left ventricular chamber. When pressure in the left ventricle increases, such as during systole, for example, the mitral valve leaflets may begin to close. As the leaflets begin to close, the tubular member 167 collapses, as shown in Fig. 11g(ii), so as to close the tube 167 at its distal end. This closure closes the blood flow path between the left atrium and the left ventricle. Once the pressure in the left atrium again becomes higher than the pressure in the left ventricle, the tubular member 167 may open to allow bloodflow therethrough. The tubular plug member 167 itself therefore provides a type of valving mechanism without the need to remove the natural valve or provide other mechanical valve devices.

[0170] Other embodiments of expandable/collapsible plug devices that operate to perform valving functions are shown in Figs. 11h-11j. Figs. 11h(i), 11h(ii) illustrate a collapsible plug member 169 that has a hollow, tapered configuration. During diastole, as shown in Fig. 11h(i), the plug member 169 has an expanded configuration so that blood can flow through the plug member 169 and also between the leaflets L and the outer surface of the plug member 169. The plug member 169 is configured to collapse during systole, as shown in Fig. 11h(ii), so that the bottom portion 169B of the plug facing the left ventricle is closed off to prevent blood flow through the plug 169. In the collapsed configuration, the member 169 maintains a relatively wide profile at a top portion 169T and tapers toward the bottom portion 169B where the sides of the plug member 169 come together to close the plug member 169 to flow therethrough. The tapered sides also allow the valve leaflets to close against the plug member 169 during systole. In this manner, blood is substantially prevented from flowing through the mitral valve during systole.

[0171] Figs. 11i(i), 11i(ii) show yet another exemplary embodiment of a collapsible and expandable plug member 170. The plug member 170 includes two wing members 170a, 17b, and an articulation 171 connecting the two wing

members 170a, 170b at their top ends. During systole, as shown in Fig. 11i(i), the pressure in the left ventricle acts on the wing members 170a, 170b, causing them to pivot about the articulation 171 in an outward direction (i.e., the wing members 170a, 170b pivot away from each other). This pivoting outward of the wing members 170a, 170b allows the wing members 170a, 170b to abut with the valve leaflets L, thus closing the valve orifice to prevent bloodflow through the valve.

[0172] During diastole, as shown in Fig. 11i(ii), pressure from the left atrium causes the wing members 170a, 170b to pivot about the articulation 171 in an inward direction (i.e., the wing members 170a, 170b pivot toward each other). Thus, the wing members 170a, 170b separate from the leaflets L, allowing blood to flow through the valve from the left atrium into the left ventricle.

[0173] Yet another exemplary embodiment of an expandable and collapsible plug device is shown in Figs. 11j(i), 11j(ii). Fig. 11j(i) shows a collapsible plug member 172 during systole and Fig. 11j(ii) shows the collapsible plug device 172 during diastole. During systole, the plug member 172 essentially is in the form of a hollow cone with a base of the cone disposed proximate the free ends of the valve leaflets L. The sides 172a, 172b of the cone take on a concave configuration during systole, as shown in Fig. 11j(ii) so as to allow blood to flow between the sides 172a, 172b and the valve leaflets L. During diastole, the blood flow through the valve will cause the plug member 172 to expand, thereby billowing the side walls 172a, 172b outwardly such that they abut the valve leaflets L to restrict or prevent blood from flowing through the valve.

[0174] Another exemplary embodiment for a plug device may comprise a member that is suspended in place below the free edges of the valve leaflets in a plane substantially parallel to the valve annulus. Such a plug device is shown in Fig. 11k. In this embodiment, a piston-like plug device 173 having a disk member 174 suspended on the end of an elongate member 174' is movable

along the longitudinal axis of the valve. The disk member 174, which preferably has a circular or oval shape, is movable into and out of contact with the free ends of the valve leaflets L in accordance with the bloodflow through the heart. In this manner, the piston-like plug device 173 may operate similar to a one-way check valve, reducing regurgitation during systole by moving to seal the free ends of the valve leaflets L with the disk-like member 174, as shown in Fig. 11k, for example. During diastole, the piston-like plug device 173 may move in a direction toward the left ventricle such that the disk member 174 moves out of contact with the free ends of the valve leaflets L. Figs. 11l(i), 11l(ii) show an alternative arrangement of the piston-like plug device 173 of Fig. 11k. In this embodiment, the disk member 174l is made of a flexible or semi-flexible material. This material may allow the disk member 174l to obtain a reduced cross-sectional profile during diastole, as shown in Fig. 11l(i), allowing for a relatively normal size valve orifice blood flow area. During systole, the disk member 174l expands and inverts as pressure in the left ventricle increases causing blood to flow toward the valve. The disk member 174l envelops the ends of the valve leaflets L to substantially prevent regurgitant bloodflow through the valve, as shown in Fig. 11l(ii).

[0175] Yet another alternative arrangement of a plug device is shown in Figs. 11m(i), 11m(ii). In this exemplary embodiment, the device 175 is implanted such that a disk-like member 176 is situated substantially above the level of the valve leaflets L proximate the valve annulus AN. As shown in the Fig. 11m(i), the perimeter of the disk-like member 176 contacts the upper portions of the valve leaflets L proximate the valve annulus AN as the pressure in the left ventricle increases during systole, moving the valve leaflets L toward one another. This contact facilitates closure of the mitral valve orifice. On the other hand, during diastole, as shown in Fig. 11m(ii), the leaflets L move away from and out of contact with the disk-like member 176, allowing blood to flow between the disk-

like member 176 and the valve leaflets L from the left atrium LA in to the left ventricle LV.

[0176] The various devices shown in Figs. 11a-11m(ii) can be delivered and implanted in the heart using numerous approaches. Fig. 12 shows one example of an embodiment for implanting a plug device of the invention, indicated generally as 200, in the heart. In Fig. 12, the plug member 201 is suspended from at least one elongate member 202. The elongate member 202 optionally has a tether-like structure. Anchors 203 are provided on the ends of the elongate member 202 to secure the device to exterior portions of the heart wall HW. The anchors 203 optionally may be similar to the anchors discussed above with reference to Figs. 4b and 5d, for example. Fig. 12 shows an exemplary implantation position, namely a sub-annular position, for the plug device 200 with respect to the heart.

[0177] Numerous other implantation positions for the plug devices, discussed above with reference to Figs. 11a-11m, are envisioned and are considered within the scope of the invention. Some examples of these positions are shown in Figs. 13a-13d. The lines shown in these figures represent the extension of the elongate member (or members) 202, from which the plug member is suspended, between the anchors 203 secured to the exterior portions of the heart wall HW. Fig. 13a shows a long axis cross-sectional view (from the lateral side) of the left ventricle LV and left atrium LA. Each of the positions shown by lines A-D represents anterior-to-posterior positioning of a plug device. Line A represents a supra-annular, anterior-to-posterior position; line B represents a sub-annular, anterior-to-posterior position; line C represents a supra-annular, anterior to sub-annular, posterior position, and line D represents a supra-annular, posterior to sub-annular, anterior position. Fig. 13b shows various lateral-medial positions for a plug device. The various positions are indicated by lines E-H in Fig. 13b. Line E represents an intraventricular septum

S to sub-annular, lateral wall LW position; line F represents an intraventricular septum S to supra-annular, lateral wall LW position; line G represents an atrial septum AS to supra-annular, lateral wall LW position; and line H represents an atrial septum AS to sub-annular, lateral wall LW position. Fig. 13c shows a basal cut-away, cross-sectional view of the heart with the various positions corresponding to lines A-H in Figs. 13a and 13b represented. Fig. 13c also shows two additional optional positions, indicated by lines I and J, for the implantation of the plug devices. Line I represents an anterior-medial, supra-annular atrial wall AW to supra-annular atrial wall AW position and line J represents an anterior-medial, supra-annular atrial wall AW to sub-annular atrial wall AW position. Fig. 13d shows a long-axis cross-sectional view of the left ventricle LV and left atrium LA with an apical wall APW to atrial wall AW position, indicated by line K.

[0178] The particular position selected to implant a plug device may depend on a variety of factors, such as the condition of the patient's heart, including the heart valves, the delivery technique utilized to implant the device, the type of plug device utilized to treat the valve, and other similar factors. Each of the positions shown in Figs. 13a-13d, however, permits proper positioning of the plug device to prevent regurgitation and avoids damage to key coronary structure. Further, particular positions may be selected based on factors such as, for example, the geometry, including size and shape, of the valve orifice.

[0179] The plug devices of Figs. 11a-11m(ii) may be delivered to the heart in several ways, including ways that do not require placing the patient on bypass. Perhaps the most direct approach includes obtaining open chest access to the left ventricular and atrial walls. However, the devices also may be implanted using off-pump surgical techniques or endovascular techniques.

[0180] An example of an approach for delivery of the plug device of Fig. 12 is illustrated in Figs. 14a-14c. For exemplary purposes, the position of the

plug device resulting from the delivery shown in Figs. 14a-14c corresponds to position B, as shown in Figs. 13a and 13c. However, other positions for the plug device could be obtained using the delivery approach which will now be described. Moreover, plug devices other than that of Fig. 12 could be implanted via the delivery techniques to be described.

[0181] In Fig. 14a, a needle and stylet assembly 210 is passed through the left ventricle LV between the mitral valve leaflets L. The stylet 211 is then removed, as shown by the arrow in Fig. 14a, leaving only the hollow needle 212 in place. The position of the needle 212 between the leaflets L is represented by the label X in Fig. 14b. The plug device may then be delivered through the needle 212. Or, as shown in Fig. 14c, a leader assembly 213 may be attached to the elongate member 202 from which the plug member 201 is suspended. The plug member 201 may have a folded configuration or may be a collapsible and expandable member. A sheath 214 may retain the plug member 201 during delivery across the heart chamber. An anchor pad 203 may be attached to the proximal end of the elongate member 202 during delivery. The anchor pad may optionally be either fixed at a predetermined position on the elongate member 202 or it may be movable with respect to the elongate member 202 so that its position is adjustable. The leader assembly 213 may be advanced through the heart wall at the side opposite to the side the needle 212 entered, and the needle 212 may then be removed from the heart. The leader assembly 213 and the elongate member 202 may then be advanced further until the plug member 201 is extracted from the sheath 214. This extraction causes the plug member 201 to unfold. Once the plug member 201 is fully extracted from the sheath 214 and appropriately positioned between the mitral valve leaflets, retaining sheath 214 may be removed from the heart and the leader assembly removed from the elongate member 202. A second anchor pad 203 may be placed on the distal

end of the elongate member 202 to hold the plug device in place, as shown in Fig. 12.

[0182] An exemplary embodiment for delivering a plug device using a retaining sheath is illustrated in Fig. 14d. Elongate member 202 may be connected to a leader member (not shown), which may be in the form of a sharpened needle, or the like. The leader member is configured to pass through the heart wall and across the ventricle. As shown in Fig. 14d, removal of the plug member 201 from the retaining sheath 214 may occur by advancing the sheath 214 partially through the heart wall HW and pulling the elongate member 202 extending through the heart wall HW opposite to the retaining sheath 214. As the elongate member 202 is pulled, the plug member 201 advances out of the distal end of the sheath 214. Once the plug member 201 advances entirely out of the distal end of the sheath 214, it will have an unfolded or expanded configuration and may be positioned as desired between the mitral valve leaflets L by pulling on the elongate member (in the direction of the arrow shown in Fig. 14d).

[0183] Fig. 14e illustrates a top view of an implanted plug device, including plug member 201, during systole, according to an exemplary embodiment of the invention. The plug member 201 is disposed between the valve leaflets L and occupies the position of the valve opening O through which regurgitant flow would occur in the absence of valve treatment. Fig. 14f shows a top view of the implanted plug device during diastole, when the valve leaflets A, P are opened. As shown, flow through the valve O is permitted in the orifice space O between the leaflets A, P and the plug member 201.

[0184] Figs 15a-15c illustrate another delivery tool that may be used in lieu of those discussed with reference to Figs. 14a-14d. In this embodiment, the elongate member 202, the folded plug member 201, and a deployable anchor member 218 may be retained in a trocar and needle assembly 216, as shown in

Fig. 15a. The assembly 216 may be inserted across the heart such that it extends out of opposite heart walls and transverse the mitral valve in any of the positions discussed with reference to Figs. 13a-13d, or other suitable, desired positions. A pusher mechanism 217 may then be inserted through the proximal end of the trocar and needle assembly 216 to advance the plug device 200 from the distal end of the assembly 216. As shown in Fig. 15b, an anchor 218 attached to an elongate member 202 exits the assembly 216 first. The anchor 218 is attached to the elongate member 202 so as to extend substantially perpendicularly to the elongate member 202. However, when placed in the assembly 216, the anchor 218 is turned with respect to the elongate member 202 such that it lies substantially parallel to the elongate member 202.

[0185] Once the anchor 218 has advanced out of the assembly 216, the pusher mechanism may be removed and the assembly 216 and plug device 200 may be retracted back through the heart in a direction opposite to the direction of advancement of the assembly 216 into the heart. As the plug device 200 is retracted with the assembly 216, the anchor 218 will catch on the external surface of the heart wall, preventing the plug device 200 from being pulled back through the heart with the assembly 216. The assembly 216 may continue to be retracted out of the heart and off of the plug device 200 until the plug member 201 eventually exits the distal end of the assembly 216, as shown in Fig. 15c. Upon exiting the assembly 216, the plug member 201 unfolds. The plug member 201 may then be positioned appropriately with respect to the mitral valve and, once the assembly 216 has been entirely removed from the plug device 200, an anchor (not shown) may be placed on the free end of the elongate member opposite to the anchor 218 to secure the plug device 200 in position.

[0186] Yet another exemplary embodiment of a delivery technique for a folded plug member is illustrated in Figs. 16a-16d. In this embodiment, the plug

member 201 may have a folded configuration and be attached to a plurality of elongate members 202 (e.g., tethers) for suspending the plug member 201 in the mitral valve orifice between the leaflets, as described above. These elongate members 202 also assist in the unfolding of the plug member 201. Fig. 16a depicts the plug device 200 with the plug member 201 in a folded configuration and attached to four elongate members 202a-202d. The stylet and needle assembly, and the leader assembly described above with reference to Figs. 14a-14c may be used to deliver the plug device 200 to the valve. In this manner, the elongate members 202a and 202d may be advanced together through the needle assembly, for example, in a supra-annular position, as shown in Fig. 16b. Once advanced, the elongate members 202a and 202d exit one side of the left atrial wall and the elongate members 202b and 202c exit the left atrial wall at an opposite side. The plug member 201, still in a folded configuration, is suspended slightly above the annular level of the mitral valve MV adjacent the valve orifice.

[0187] To unfold the plug member 201, stylets 14 are attached to the free ends of the elongate members 202c and 202d. Using the needle stylets 14 to guide the free ends of the elongate members 202c, 202d, as shown in Fig. 16c, each member 202c, 202d is advanced back through the heart to an opposite side and to a sub-annular position, thus exiting through the left ventricular wall on a side opposite to its original exit through the left atrial wall. This action causes the plug member 201 to unfold and extend between the valve leaflets. The elongate members 202a-202d may then be secured with respect to the heart using external anchors 203, as shown in Fig. 16d. The plug device 200 in Fig. 16d thus has a supra-annular, sub-annular position.

[0188] Other techniques for delivery and implantation of the plug devices of the invention are envisioned and are considered to be within the scope of the invention. For example, the plug member and at least one of the anchor

members may be inflatable so that during delivery the members can be in a deflated configuration to facilitate passage through the heart wall or through a needle. As shown in Fig. 19, once the plug device 200 (i.e., at least one anchor and the plug member 202) is placed in the desired position relative to the mitral valve MV and heart wall HW, an inflator, which may optionally be in the form of a compressed air device or a needle 250 (as shown in Fig. 19) containing a fluid, such as PMMA (polymethylmethacrylate) P-HEMA (poly (2-hydroxyethyl methacrylate)), for example, may be connected to the elongate member and used to inflate the plug member 201 and the at least one anchor member 203. The elongate member in this case would be configured to allow passage of fluid therethrough to the plug member and at least one anchor member.

[0189] Fig. 20 illustrates an additional exemplary embodiment of an inflatable plug device 350. The plug device comprises plug member 351 made of two sheets 351a and 351b attached to each other along the edges. The plug device 350 also comprises tethers 352, for example, four tethers 352 attached to the plug member 351 proximate the corners of the sheets 351a, 351b. At least one of the tethers 352 may define a lumen configured for fluid flow therethrough. The lumen may be in flow communication with the plug member 351 so as to permit inflation of the plug member 351 via the lumen. In this manner, the plug member 351 may be filled to the desired shape and size as is needed to at least substantially prevent regurgitation through the valve.

[0190] Endovascular delivery techniques, including, for example, catheter-based delivery techniques, also are envisioned as within the scope of the invention. Such endovascular delivery techniques may be utilized in combination with the methods discussed with reference to Figs. 14a-19. For example, the plug devices may be delivered through a catheter advanced through the lumen of the aorta AO and across the left atrial chamber LA, as shown in Fig. 17a. Alternatively, as shown in Fig. 17b, the delivery path may be

through the lumen of the coronary sinus CS and the coronary vein CV, and from the coronary vein CV across the left atrial chamber LA. Yet another embodiment of an endovascular delivery path is shown in Fig. 17c. In this figure, the delivery path is through the lumen of the vena cava CV into the right atrial chamber RA and across the left atrial chamber LA.

[0191] The techniques for implanting the plug devices discussed above include extending elongate members, with the plug member suspended therefrom, substantially transversely from one wall of a heart chamber to an opposite wall of a heart chamber. In an alternative embodiment, shown in Figs. 18a and 18b. The plug member may be suspended from an elongate member that engages only on one side of the heart. Such a configuration may alleviate the need to traverse the entire heart chamber, thereby minimizing risk of damaging internal cardiac structure.

[0192] Fig. 18a shows an exemplary embodiment of a plug device 230 and anchoring frame 233 for engaging only one side of the heart to implant the plug device 230. The plug member 201, shown as an ellipsoid plug member in this figure, depends from a beam member 231 having a horizontally extending portion 231h and a shorter, vertically extending portion 231v. The plug member 201 is connected to the vertically extending portion 231v so that the plug member 201 is placed within the valve orifice between the valve leaflets, as shown in Fig 18b. Optionally, a intramuscular ingrowth sleeve 232, made of a Dacron velour, for example, may be placed around the horizontal portion 231h. The function of this sleeve 232 will be explained with reference to the discussion of the implantation of the device. The horizontal portion 231h connects to the anchoring frame 233 at an end opposite to the plug member 201. The anchoring frame 233 has a substantially I-shaped configuration and the horizontal portion 231h of the beam member 231 connects to the vertical leg 233v of the anchoring frame 233.

[0193] The horizontal legs 233h of the anchoring frame are placed on the external surfaces of the atrial wall and the ventricular wall, respectively, as shown in Fig 18b. The vertical leg 233v is thus spaced from the heart wall. The horizontal legs 233h may be secured to the heart walls by suturing or other suitable, similar attachment mechanisms. The horizontal portion 231h of the beam member 231 extends from the vertical leg 233v and through the atrial wall so as to suspend the plug member 201 in the appropriate position relative to the mitral valve MV. The sleeve 232 is positioned on the horizontal portion 231h, and optionally may be slidable relative thereto, such that the heart wall surrounds the sleeve 232. The sleeve 232 therefore provides a surface that permits ingrowth of the heart wall muscle to assist in stabilizing the device relative to the heart. The ingrowth of the heart wall into the sleeve 232 also may prevent damage to the heart wall which would otherwise occur as a result of relative motion between the heart wall and the horizontal portion 231h caused by the heart's beating.

[0194] It will be apparent to those skilled in the art that various modifications and variations can be made in the devices and related methods for improving mitral valve function of the present invention and in construction of such devices without departing from the scope or spirit of the invention. As an example, a combination of devices depicted above may be used for achieving improved mitral valve function. Moreover, although reference has been made to treating the mitral valve and to the bloodflow patterns relating to the mitral valve, it is envisioned that other heart valves may be treated using the devices and methods of the present invention. Those having skill in the art would recognize how the devices and methods could be employed and/or modified to treat valves other than the mitral valve, taking into consideration factors such as the desired blood flow patterns through the valve. Other optional embodiments of the invention will be apparent to those skilled in the art from consideration of the

specification and practice of the invention disclosed herein. The specification and examples are exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

WHAT IS CLAIMED IS:

1. A method for treating a heart valve, comprising:

providing a device having an arcuate portion and at least one elongate portion configured to extend from the arcuate portion;

encircling at least a portion of an annulus of a heart valve with the arcuate portion;

adjusting a size of at least one of the arcuate portion and the elongate portion so as to alter a shape of the portion of the annulus; and

securing the at least one elongate portion to an exterior surface of the heart.

2. The method of claim 1, wherein providing the arcuate portion and the at least one elongate portion includes providing an elongate member and forming a loop in the elongate member such that the elongate portion extends from the loop.

3. The method of claim 2, further comprising adjusting the size of the loop so as to alter the shape of at least the portion of the annulus.

4. The method of claim 3, further comprising an adjusting mechanism configured to slide along the elongate portion, wherein adjusting the size of the loop includes sliding the adjusting mechanism along the elongate portion.

5. The method of claim 3, further comprising extending the elongate portion from the arcuate portion through the heart wall.

6. The method of claim 5, wherein securing the elongate portion includes engaging an anchor assembly with the elongate portion adjacent the exterior surface of the heart wall.

7. The method of claim 6, wherein engaging the anchor assembly includes slidably engaging the anchor assembly with the elongate portion, and wherein the adjusting includes sliding the anchor assembly along the elongate portion to adjust the respective dimensions of the elongate portion and the loop.

8. The method of claim 7, further comprising compressing the exterior surface of the heart wall via the anchor assembly.

9. The method of claim 1, wherein providing the device includes providing a plurality of elongate portions extending from the arcuate portion.

10. The method of claim 2, wherein providing the device includes providing a tubular member disposed on at least a portion of the arcuate portion.

11. The method of claim 10, wherein the heart valve is a mitral valve and encircling at least the portion of the annulus includes positioning the tubular member adjacent a posterior aspect of the annulus.

12. The method of claim 11, wherein the tubular member is made of a substantially rigid material.

13. A method of treating a heart valve, comprising:

providing a device having an arcuate portion and at least one elongate member configured to extend from the arcuate portion;

placing the arcuate portion proximate an annulus of a heart valve;

extending the at least one elongate member from the arcuate portion; and

securing the at least one elongate member to an exterior surface of the heart,

wherein the at least one elongate member extends from the arcuate portion to the heart wall in substantially the same plane as the arcuate portion.

14. The method of claim 13, further comprising connecting the at least one elongate member to the arcuate portion.

15. The method of claim 13, wherein the at least one elongate member includes a tension member.

16. The method of claim 15, further comprising extending the at least one elongate member from the arcuate portion through a heart wall surrounding a heart chamber associated with the valve.

17. The method of claim 16, further comprising adjusting a length of the elongate member between the arcuate portion and the heart wall so as to alter the shape of at least the portion of the annulus.

18. The method of claim 16, wherein securing the at least one elongate member comprises engaging an anchor assembly with the at least one elongate member exterior to the heart.

19. The method of claim 18, further comprising sliding the anchor assembly along a length of the at least one elongate member and adjusting the length of the elongate member between the arcuate portion and the heart wall.

20. The method of claim 13, further comprising a plurality of elongate members extending from the arcuate portion at differing angular positions along the arcuate portion.

21. The method of claim 20, wherein securing the at least one elongate member includes securing each of the plurality of elongate members to an exterior surface of the heart wall at differing angular positions along the heart wall.

22. The method of claim 21, wherein adjusting the size includes adjusting a length of each of the elongate members between the arcuate portion and the heart wall.

23. A device for treating a heart valve, the device comprising:

an arcuate portion configured to at least partly encircle an annulus of the heart valve; and

at least one elongate portion extending from the arcuate portion and configured to be secured to an exterior surface of a heart wall surrounding a heart chamber associated with the valve,

wherein at least one of the arcuate portion and the elongate portion is configured to be adjusted in size so as to alter a shape of at least a portion of the annulus.

24. The device of claim 23, wherein the arcuate portion and the at least one elongate portion are made as a single piece.

25. The device of claim 24, wherein the arcuate portion and the elongate portion are formed by an elongate member having a portion formed into a loop.

26. The device of claim 25, wherein the loop is configured to be adjusted in size.

27. The device of claim 26, further comprising an adjusting mechanism configured to slide along the elongate portion to adjust the respective sizes of the loop and the elongate portion.

28. The device of claim 25, wherein the elongate portion is configured to extend through the heart wall.

29. The device of claim 28, further comprising an anchor assembly configured to engage with the elongate portion at the exterior surface of the heart wall.

30. The device of claim 29, wherein the anchor assembly is slidably engageable with the elongate portion.

31. The device of claim 29, wherein the anchor assembly is configured to compress the external surface of the heart wall.

32. The device of claim 23, further comprising a plurality of elongate portions extending from the arcuate portion.

33. The device of claim 23, further comprising a tubular member disposed on at least a portion of the arcuate portion.

34. The device of claim 33, wherein the heart valve is a mitral valve and the tubular member is configured to be positioned adjacent a posterior aspect of the valve annulus.

35. The device of claim 34, wherein the tubular member is made of a substantially rigid material.

36. A device for treating a heart valve, the device comprising:

an arcuate portion configured to be positioned proximate an annulus of the heart valve; and

at least one elongate member extending from the arcuate portion and configured to be secured to an exterior surface of the heart wall,

wherein the at least one elongate member extends from the arcuate portion to the heart wall in substantially the same plane as the arcuate portion.

37. The device of claim 36, wherein the at least one elongate member is configured to connect to the arcuate portion.

38. The device of claim 36, wherein the at least one elongate member includes a tension member.

39. The device of claim 36, wherein the at least one elongate member is configured to extend from the arcuate portion through the heart wall surrounding the chamber associated with the valve.

40. The device of claim 36, wherein a length of the elongate member between the arcuate portion and the heart wall is configured to be adjusted.

41. The device of claim 36, further comprising an anchor assembly configured to engage the at least one elongate member exterior to the heart to secure the device in place with respect to the heart.

42. The device of claim 41, wherein the anchor assembly is slidable along a length of the at least one elongate member.

43. The device of claim 36, further comprising a plurality of elongate members extending from the arcuate portion at differing angular positions along the arcuate portion.

44. The device of claim 43, wherein each of the elongate members is configured to be secured to an exterior surface of the heart wall at differing angular positions along the heart wall.

45. The device of claim 43, wherein each of the elongate members is configured to have an adjustable length between the arcuate portion and the heart wall.

46. The device of claim 36, wherein the arcuate portion is substantially ring-shaped.

47. A device for treating a heart valve, the device comprising:

at least one substantially elongate member configured to be implanted in a lumen of a coronary vessel so as to encircle at least a portion of an annulus of the heart valve and alter a shape of at least the portion of the annulus; and

a shape change element associated with the elongate member and configured to impart a local shape change to a portion of the valve annulus at a location corresponding to the shape change element.

48. The device of claim 47, wherein the heart valve is a mitral valve and at least a portion of the elongate member is configured to be positioned adjacent a posterior aspect of the valve.

49. The device of claim 47, further comprising at least one anchoring member configured to secure the elongate member in place within the lumen of the coronary vessel.

50. The device of claim 49, further comprising a plurality of anchoring members disposed along a length of the elongate member and configured to engage with a wall of the coronary vessel to secure the elongate member in place.

51. The device of claim 49, further comprising an anchoring member provided at each end of the elongate member.

52. The device of claim 51, wherein the anchoring members provided at each end of the elongate member are configured to engage a heart wall surrounding a heart chamber associated with the valve.

53. The device of claim 47, wherein the elongate member is configured to be friction fit within the lumen of the coronary sinus.

54. The device of claim 47, wherein the elongate member is heat-shrinkable.

55. The device of claim 47, wherein the shape change element includes a retractable wire disposed along a length of the elongate member.

56. The device of claim 55, wherein the wire is configured to form a bulge extending outward from the elongate member.

57. The device of claim 47, wherein the shape change element includes an annular shape change element disposed on the elongate member.

58. The device of claim 56, wherein the shape change element is slidably disposed on the elongate member.

59. A device for treating a heart valve, the device comprising:

at least one substantially elongate member comprising a plurality of rotatable elements, the elongate member being configured to be implanted in a lumen of a coronary vessel so as to encircle at least a portion of an annulus of the heart valve and alter a shape of at least the portion of the valve annulus,

wherein a shape of at least a portion of the elongate member is configured to be adjustable so as to impart a local shape change to a portion of the valve annulus at a location corresponding to at least the adjustable portion.

60. The device of claim 59, wherein the rotatable elements are configured to rotate about a longitudinal axis of the elongate member.

61. The device of claim 59, wherein the rotatable elements are independently rotatable.

62. The device of claim 59, wherein the rotatable elements are configured such that rotation of the rotatable elements alters the shape of at least the portion of the elongate member.

63. A method for treating a heart valve, comprising:

providing at least one substantially elongate member;

extending at least a portion of the elongate member within a heart wall surrounding a chamber of the heart associated with the heart valve so as to encircle at least a portion of the heart chamber;

securing the elongate member in place with respect to the heart; and

compressing at least a portion of a heart wall surrounding at least the portion of the heart chamber so as to move leaflets of the valve toward each other so as to assist the valve in closing during at least a portion of the cardiac cycle.

64. The method of claim 63, wherein the compressing includes compressing a portion of the heart wall proximate an annulus of the valve.

65. The method of claim 63, wherein the compressing includes compressing a portion of the heart wall proximate at least one papillary muscle associated with the valve.

66. The method of claim 63, further comprising engaging a pad with the at least one elongate member and compressing a portion of the heart wall proximate a location of the pad.

67. The method of claim 63, wherein moving the leaflets of the valve includes changing a shape of at least a portion of the valve annulus.

68. The method of claim 63, wherein moving the leaflets of the valve includes repositioning at least one papillary muscle to which at least one leaflet connects.

69. The method of claim 63, wherein the elongate member is made of a biocompatible material.

70. The method of claim 63, wherein providing the at least one elongate member includes providing at least one curved elongate member.

71. A method for treating a heart valve, comprising:

providing at least one substantially elongate member;

extending at least a portion of the elongate member within a lumen of a coronary sinus so as to encircle at least a portion of a heart chamber;

securing the elongate member in place with respect to the heart via at least one securement mechanism; and

compressing at least a portion of a heart wall surrounding at least the portion of the heart chamber so as to move leaflets of the valve toward each other so as to assist the valve in closing during at least a portion of the cardiac cycle.

72. The method of claim 71, further comprising delivering the elongate member endovascularly to the coronary sinus lumen.

73. The method of claim 71, wherein extending at least the portion of the elongate member includes extending at least the portion of the elongate member within the coronary sinus lumen adjacent a posterior aspect of a mitral valve.

74. The method of claim 71, wherein the valve is a mitral valve.

75. A device for treating a heart valve, the device comprising:

an elongate member having first and second oppositely disposed ends, the elongate member being relatively rigid;

a first anchoring member configured to be attached to the first end of the elongate member;

a second anchoring member configured to be attached to the second end of the elongate member,

wherein the first anchoring member is configured to engage a first exterior surface of a wall of the heart and the second anchoring member is configured to engage a second exterior surface of the wall of the heart to maintain a position of the elongate member transverse a heart chamber associated with the valve and substantially along a line of coaptation of the valve, and

wherein a length of the elongate member is such that the elongate member is capable of maintaining a substantially normal distance between trigones of the valve.

76. The device of claim 75, wherein the length of the elongate member is adjustable.

77. The device of claim 75, wherein the elongate member is a telescoping member.

78. The device of claim 75, wherein the elongate member is a bar.

79. The device of claim 75, wherein the elongate member is made of a material chosen from biocompatible metals and biocompatible polymers.

80. The device of claim 75, wherein the elongate member includes a first elongate member and the device further comprises a second elongate member having a first end portion configured to be connected to the first elongate member and a second opposite free end portion.

81. The device of claim 80, wherein the second elongate member is configured to extend substantially perpendicular to the first elongate member and is configured to be secured to a third exterior surface of the heart wall surrounding the chamber associate with the valve.

82. The device of claim 81, further comprising a third anchoring member configured to be attached to the free end portion of the second elongate member.

83. The device of claim 81, wherein the third anchoring member is configured to secure the second elongate member to the third exterior surface of the heart wall to thereby alter a shape of an annulus of the valve.

84. The device of claim 80, wherein the second elongate member is a tension member.

85. The device of claim 80, wherein the second elongate member is relatively flexible.

86. A method for treating a heart valve, the method comprising:

providing a relatively rigid elongate member having first and second oppositely disposed ends;

securing the first end of the elongate member to a first exterior heart wall surface; and

securing the second end of the elongate member to a second exterior heart wall surface, the second exterior surface being located substantially opposite to the first exterior surface such that the elongate member extends substantially transverse a heart chamber associated with the valve and substantially along a line of coaptation of the valve; and

maintaining a substantially normal distance between the trigones of the valve via the elongate member.

87. The method of claim 86, further comprising adjusting a length of the elongate member.

88. The method of claim 87, wherein adjusting the length of the elongate member includes telescoping the elongate member.

89. The method of claim 87, wherein the elongate member is a bar.

90. The method of claim 86, wherein the elongate member is made of a material chosen from biocompatible metals and biocompatible polymers.

91. The method of claim 86, wherein the elongate member is a first elongate member and the method further comprises providing a second elongate member and connecting a first end of the second elongate member to the first elongate member.

92. The method of claim 91, further comprising extending the second elongate member substantially perpendicular to the first elongate member and securing a second end of the second elongate member to a third exterior heart wall surface.

93. The method of claim 92, wherein securing the second end of the second elongate member to the third exterior heart wall surface includes altering a shape of an annulus of the valve.

94. The method of claim 91, wherein the second elongate member is a tension member.

95. The method of claim 91, wherein the second elongate member is relatively flexible.

96. The method of claim 86, further comprising providing a first anchoring member and a second anchoring member, and securing the first end of the elongate member to the first exterior surface via the first anchoring member and securing the second end of the elongate member to the second exterior surface via the second anchoring member

97. A device for treating leakage of a heart valve, the device comprising:

an expandable plug member having an external surface, at least a portion of the plug member being configured to be positioned proximate leaflets of the heart valve; and

a securement mechanism attached to the plug member and configured to secure the plug member with respect to the heart,

wherein during at least a portion of the cardiac cycle, the leaflets abut the external surface of the plug member to restrict bloodflow through the valve.

98. The device of claim 97, wherein the plug member is inflatable.

99. The device of claim 97, wherein the plug member is foldable.

100. The device of claim 97, wherein the securement mechanism includes at least one elongate member configured to suspend the plug member between the valve leaflets.

101. The device of claim 100, wherein the securement mechanism further comprises at least one anchoring member configured to secure the elongate member to a heart wall surrounding a chamber containing the valve.

102. The device of claim 101, wherein the elongate member is in the form of a tether.

103. The device of claim 97, wherein at least a portion of the plug member is configured to be positioned between the valve leaflets.

104. The device of claim 97, wherein at least a portion of the plug member is configured to be positioned below free ends of the valve leaflets.

105. The device of claim 97, wherein at least a portion of the plug member is configured to be positioned approximately at a level of an annulus of the valve.

106. The device of claim 97, wherein the plug member is configured to expand and collapse in response to pressure changes in the heart.

107. The device of claim 106, wherein the plug member is configured to collapse during systole.

108. The device of claim 106, wherein the plug member is configured to expand during diastole.

109. The device of claim 97, wherein the plug member defines at least one passage configured to permit bloodflow therethrough.

110. A device for treating leakage of a heart valve, the device comprising:

a plug member having a piston-like configuration and an external surface being configured to abut free ends of leaflets of the valve to restrict bloodflow through the valve during at least the portion of the cardiac cycle; and

a securement mechanism attached to the plug member and configured to secure the plug member with respect to the heart.

111. A method of preventing leakage in a heart valve comprising:

providing an expandable plug member having an external surface;

delivering the plug member to a heart chamber containing a valve; and

positioning the plug member proximate leaflets of the valve such that the leaflets contact the external surface of the plug member during at least a portion of the cardiac cycle so as to restrict bloodflow through the valve.

112. The method of claim 111, further comprising inflating the plug member during at least a portion of the cardiac cycle.

113. The method of claim 111, further comprising expanding the plug member during at least a portion of the cardiac cycle.

114. The method of claim 111, further comprising unfolding the plug member upon delivery of the plug member to the heart chamber.

115. The method of claim 111, wherein positioning the plug member includes suspending the plug member via at least one elongate member.

116. The method of claim 115, further comprising securing the elongate member to a heart wall surrounding the heart chamber.

117. The method of claim 116, wherein securing the elongate member includes securing the elongate member via an anchoring member configured to engage the heart wall.

118. The method of claim 115, wherein the elongate member is in the form of a tether.

119. The method of claim 111, wherein positioning the plug member includes positioning at least a portion of the plug member between the valve leaflets.

120. The method of claim 111, wherein positioning the plug member includes positioning at least a portion of the plug member below free ends of the valve leaflets.

121. The method of claim 111, further comprising, in response to pressure changes in the heart, respectively expanding and collapsing the plug member.

122. The method of claim 121, further comprising collapsing the plug member during systole.

123. The method of claim 121, further comprising expanding the plug member during diastole.

124. The method of claim 111, further comprising flowing blood through at least one passage defined in the plug member during at least another portion of the cardiac cycle.

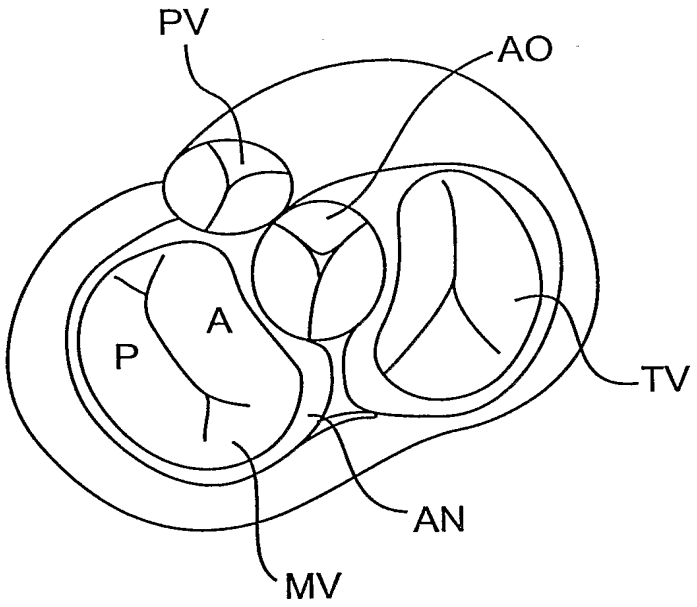


FIG. 1a

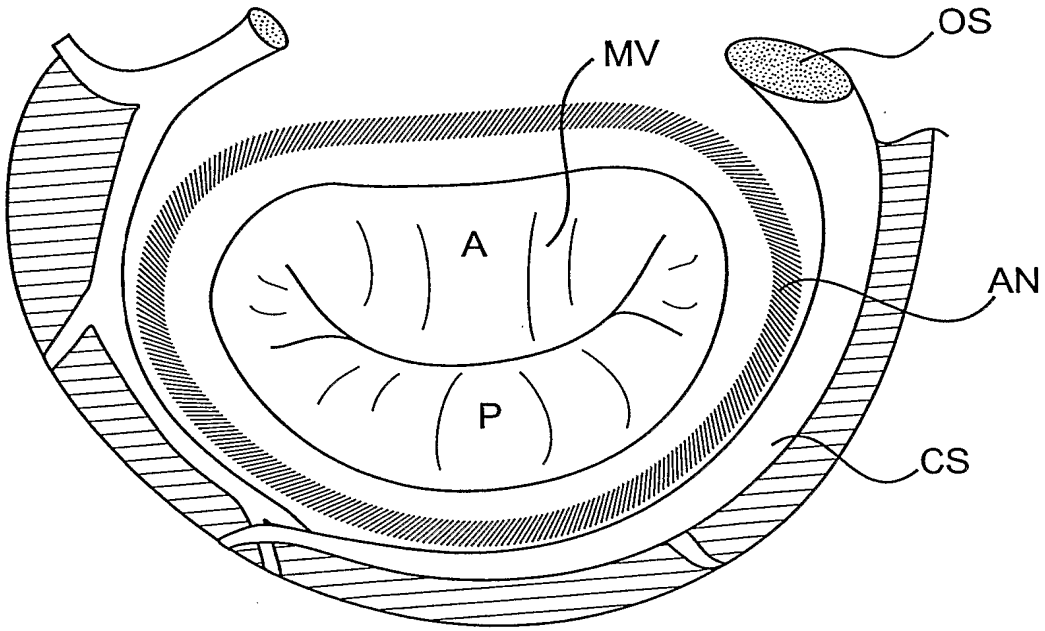


FIG. 1b

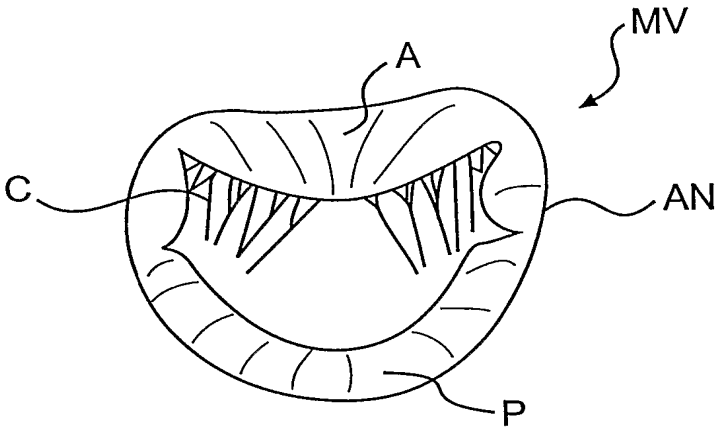


FIG. 2a

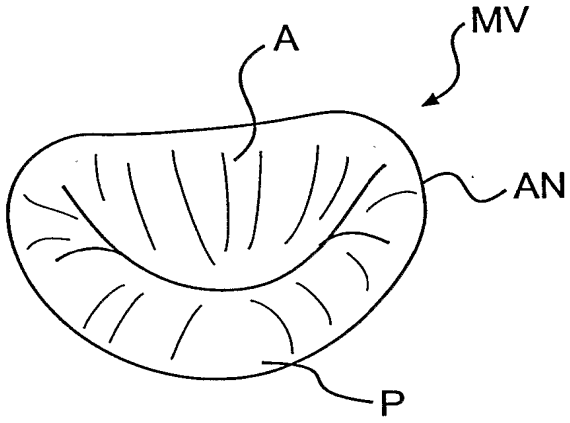


FIG. 2b

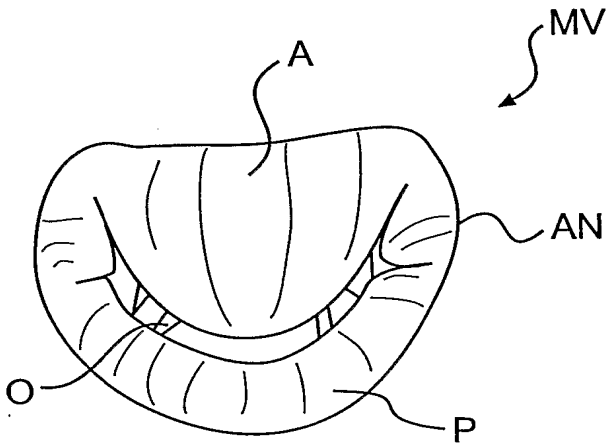


FIG. 2c

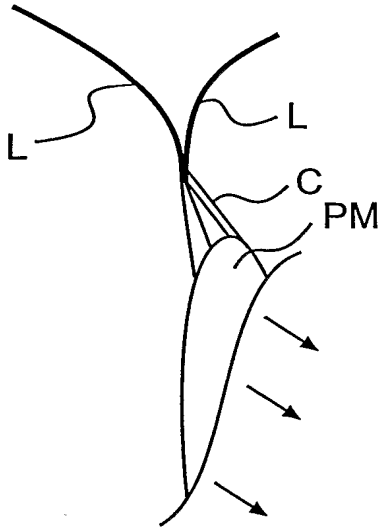


FIG. 3a

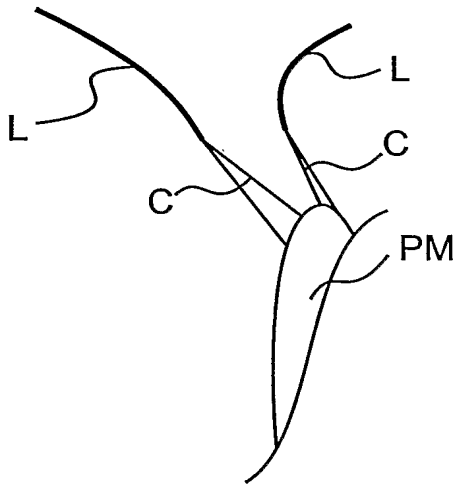


FIG. 3b

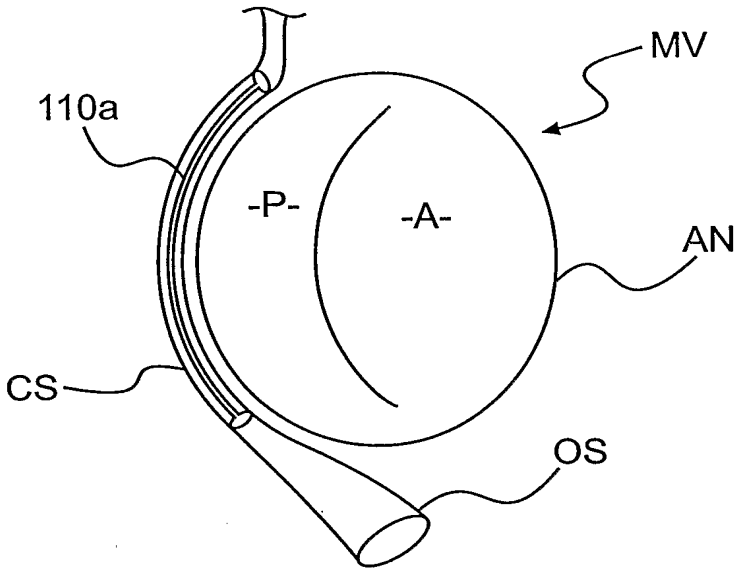


FIG. 4a

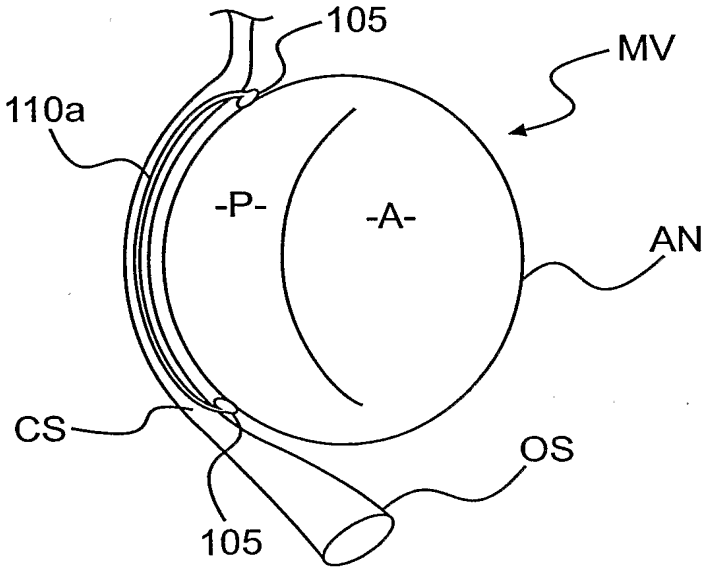


FIG. 4b

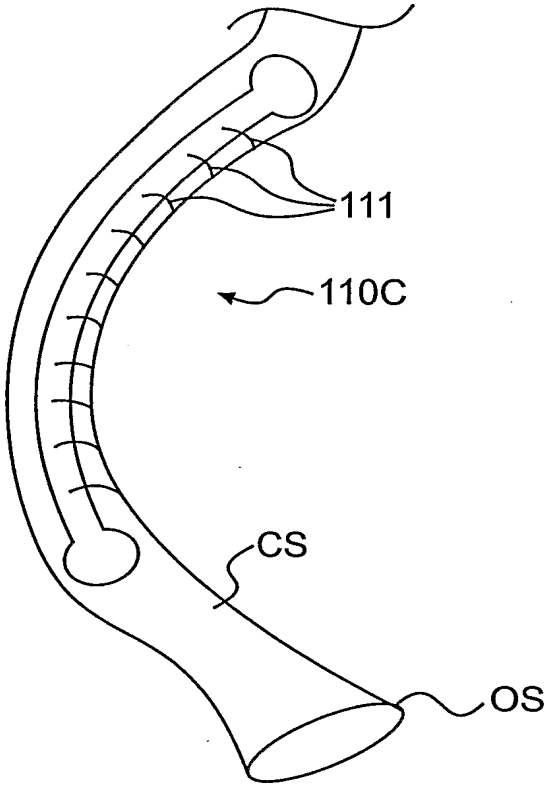


FIG. 4c

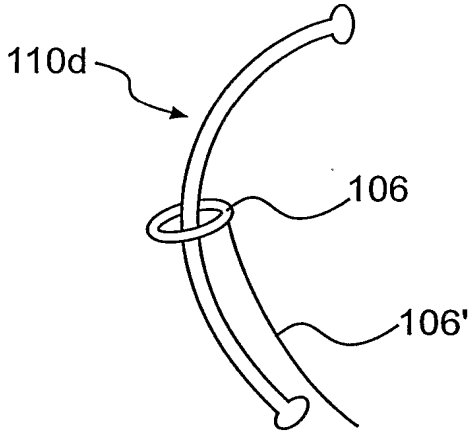


FIG. 4d

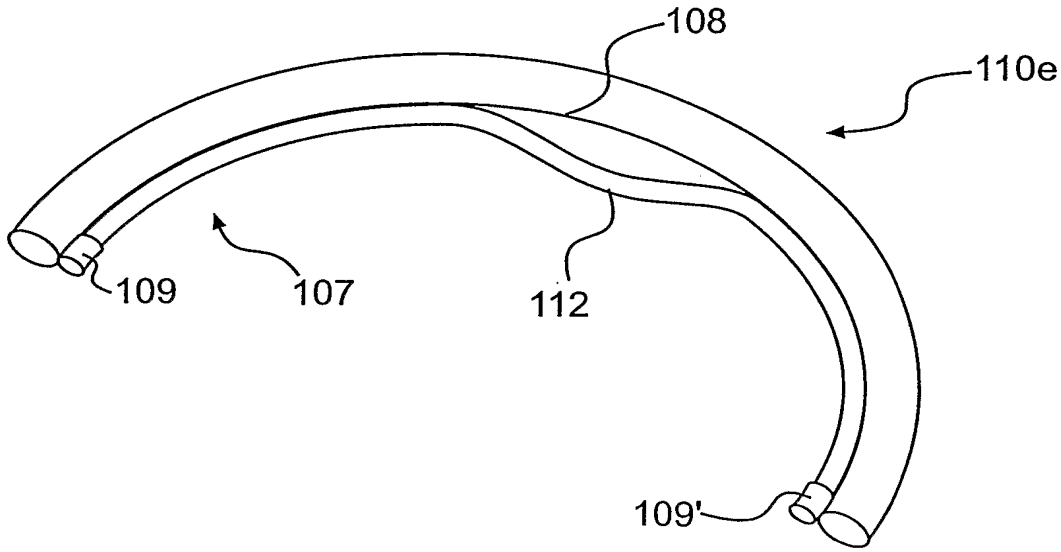


FIG. 4e

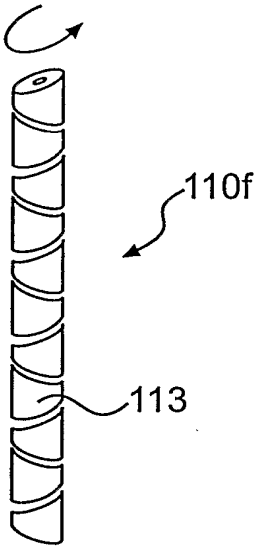


FIG. 4f

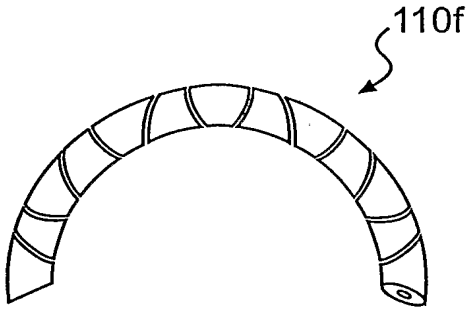


FIG. 4g

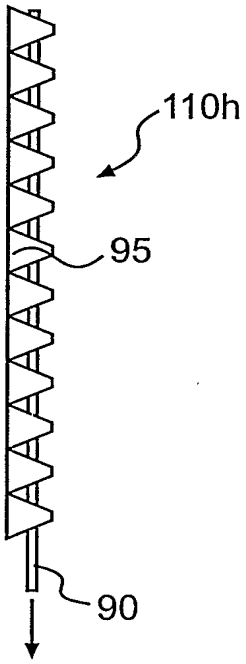


FIG. 4h

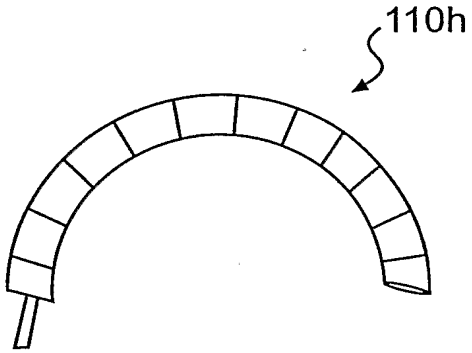


FIG. 4i

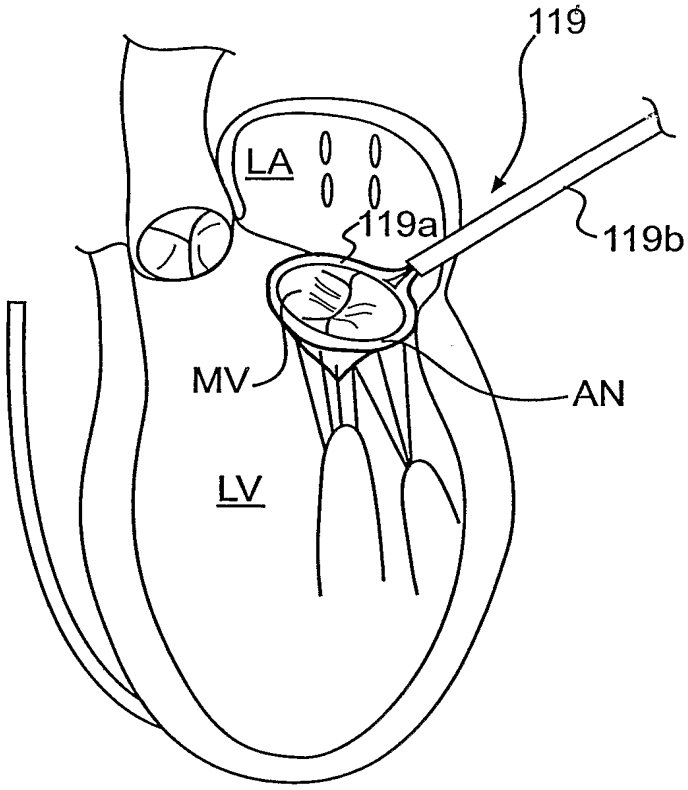


FIG. 5a

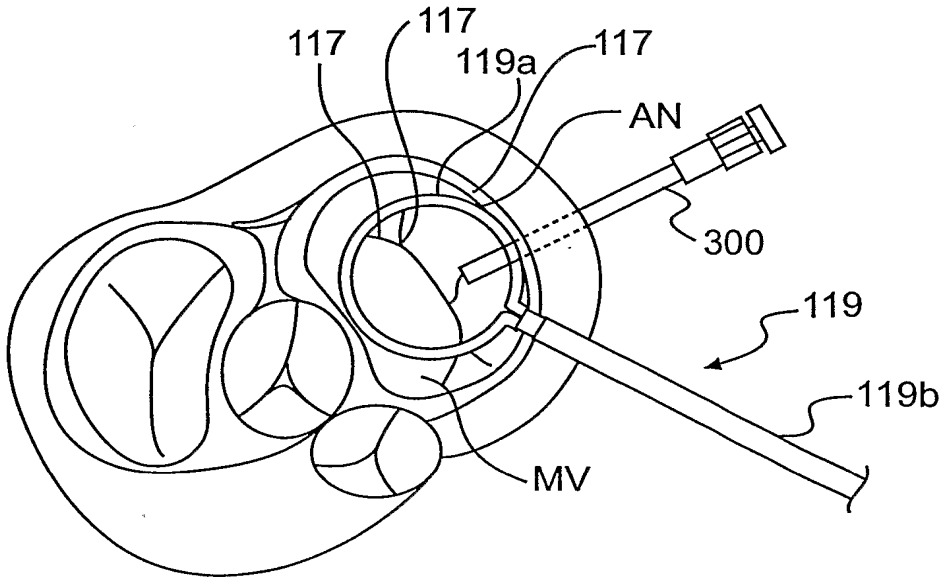


FIG. 5b

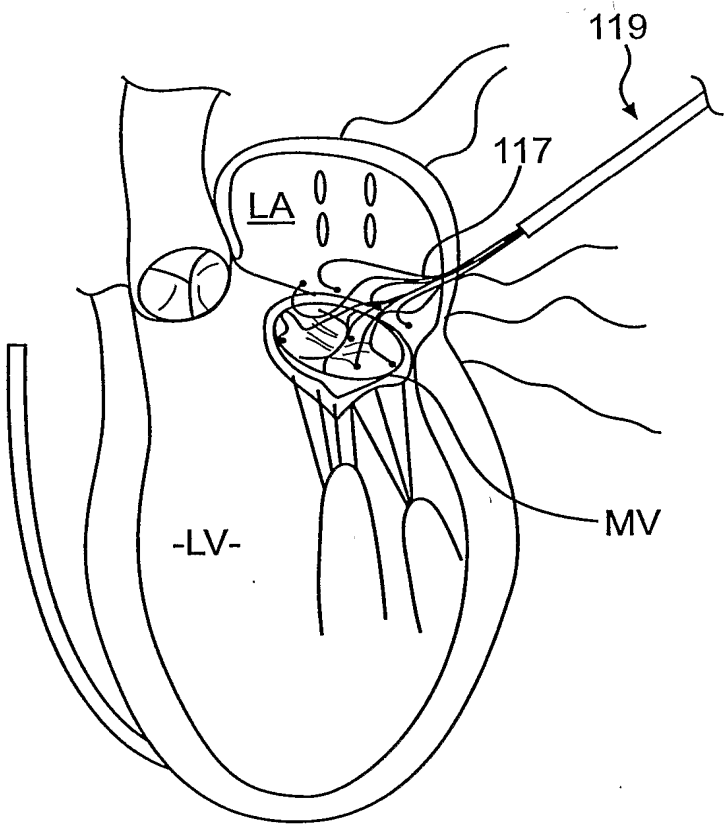


FIG. 5c

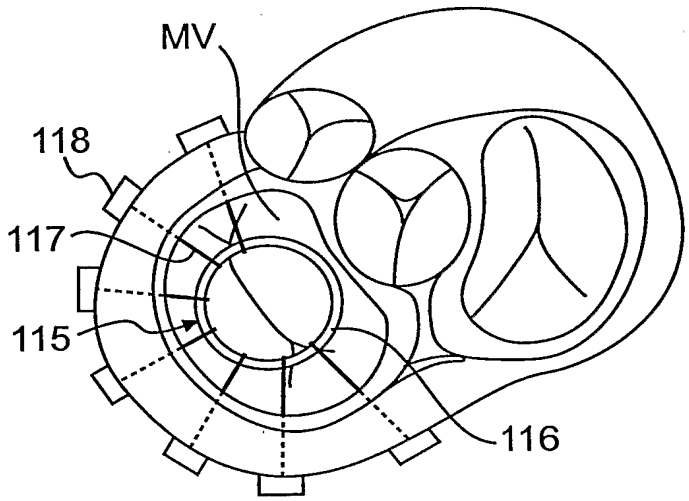


FIG. 5d

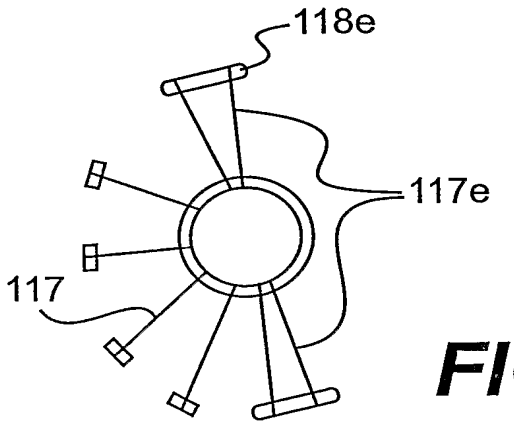


FIG. 5e

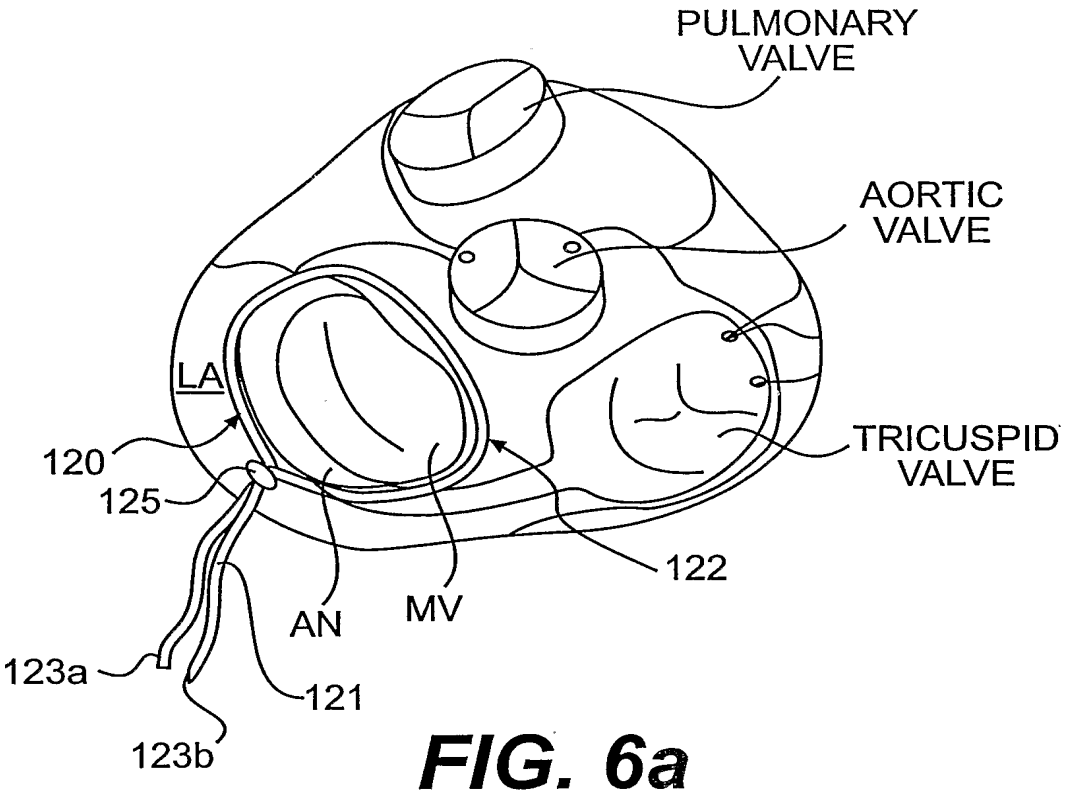


FIG. 6a

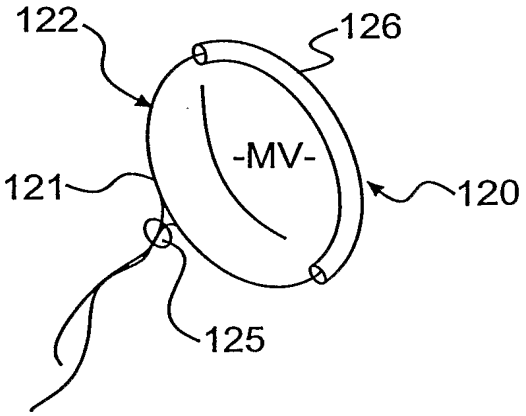


FIG. 6b

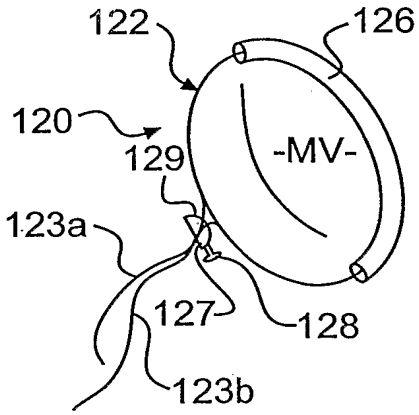


FIG. 6c

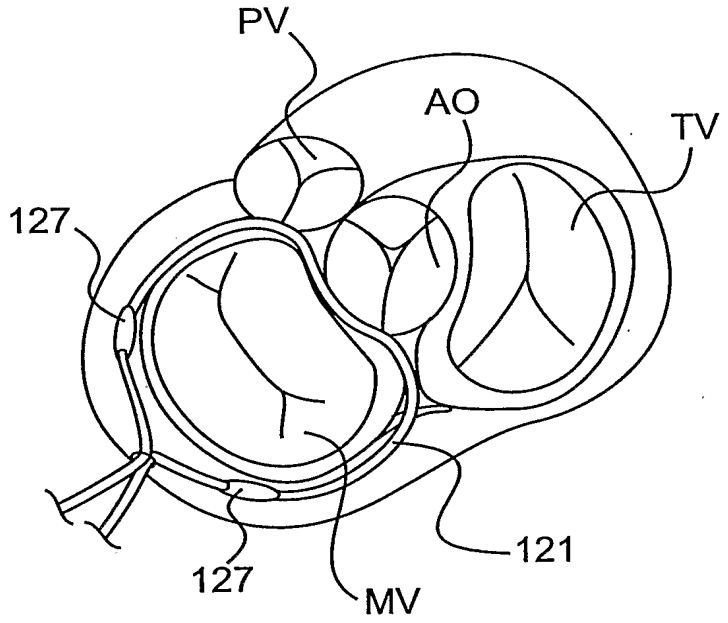


FIG. 6d

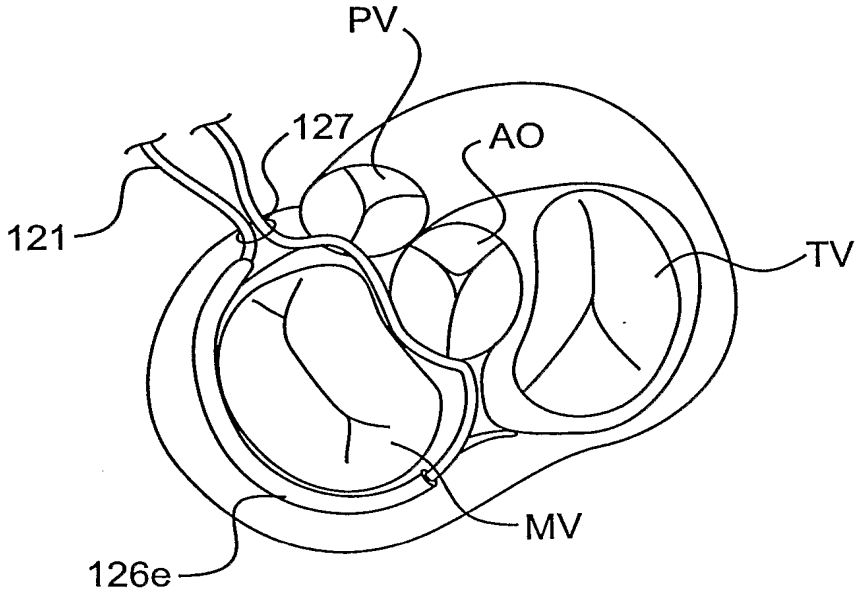
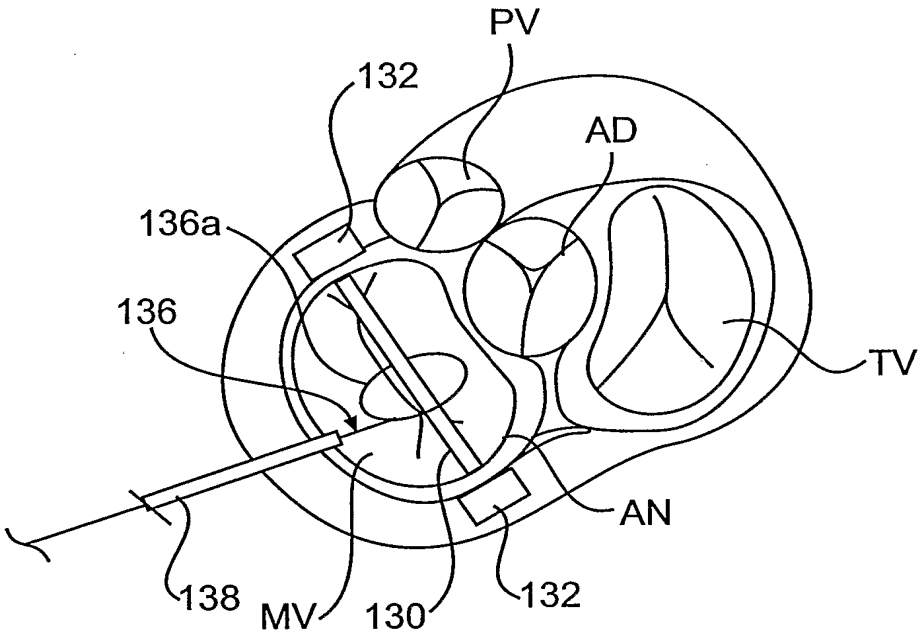


FIG. 6e


PV
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136
TV
AN
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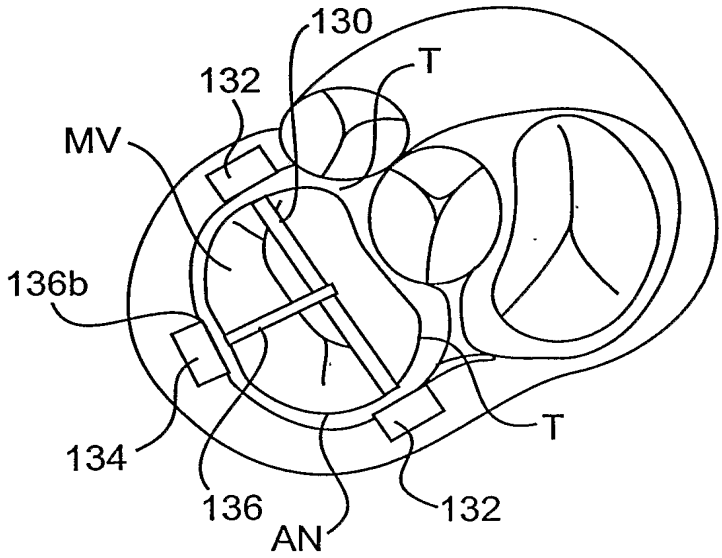
MV
130
132

FIG. 7a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136
AN
132

FIG. 7b

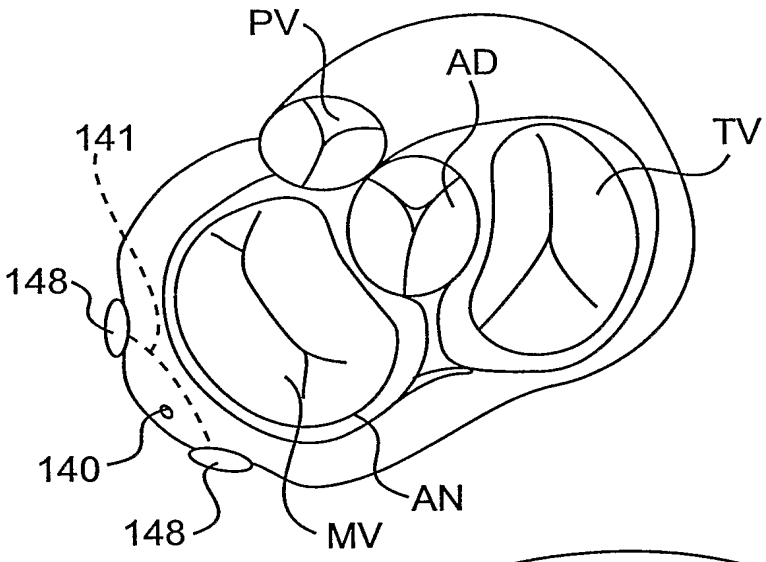

FIG. 8

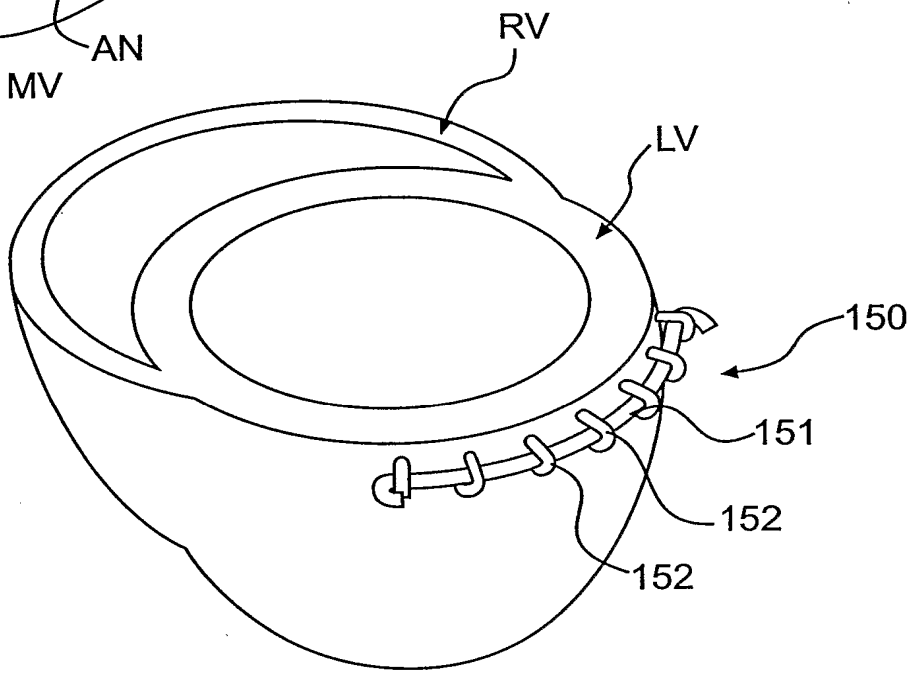

FIG. 9

FIG. 10a

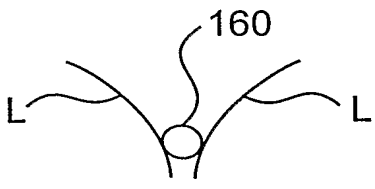

FIG. 10b

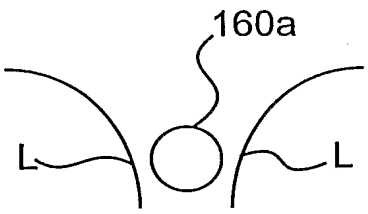

FIG. 11a

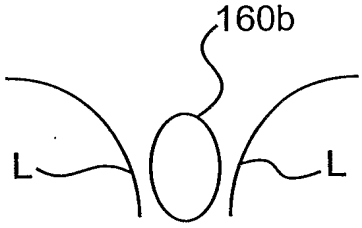

FIG. 11b

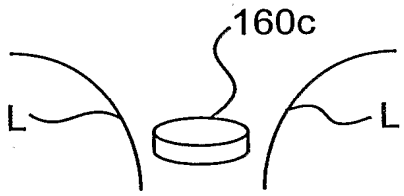

FIG. 11c

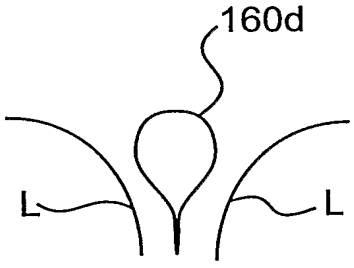

FIG. 11d

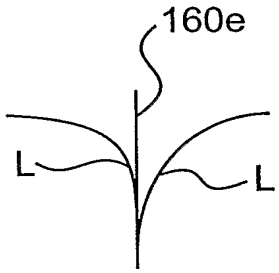

FIG. 11e

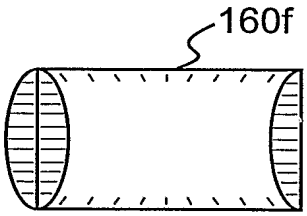

FIG. 11f

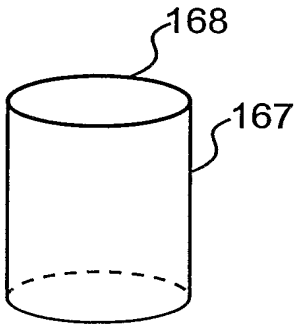

FIG. 11g(i)

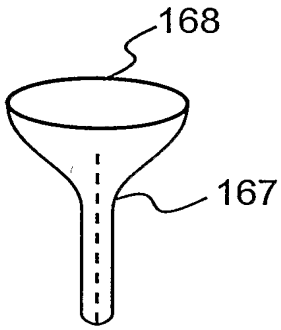

FIG. 11g(ii)

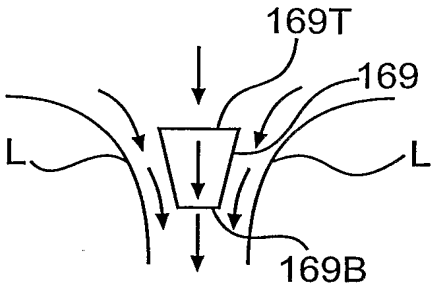

FIG. 11h(i)

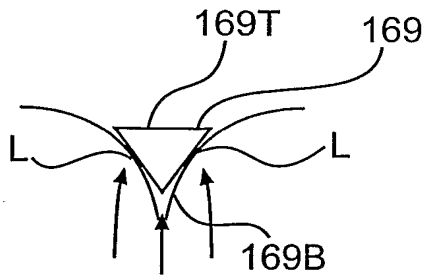

FIG. 11h(ii)

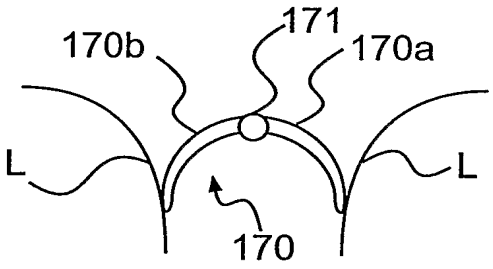

FIG. 11i(i)

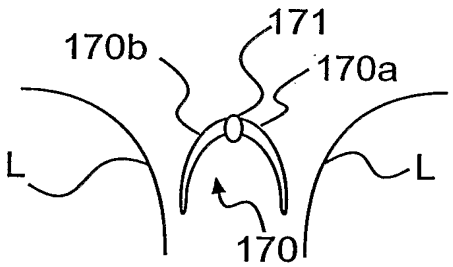

FIG. 11i(ii)

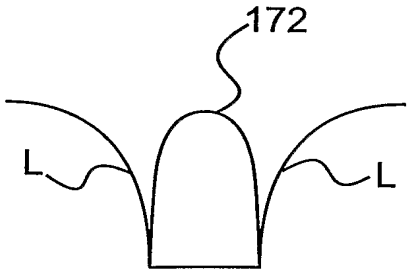

FIG. 11j(i)

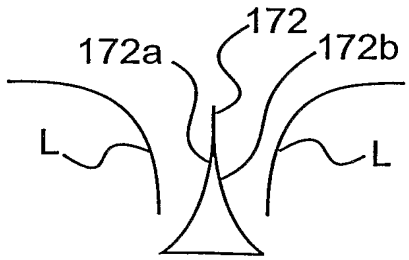

FIG. 11j(ii)

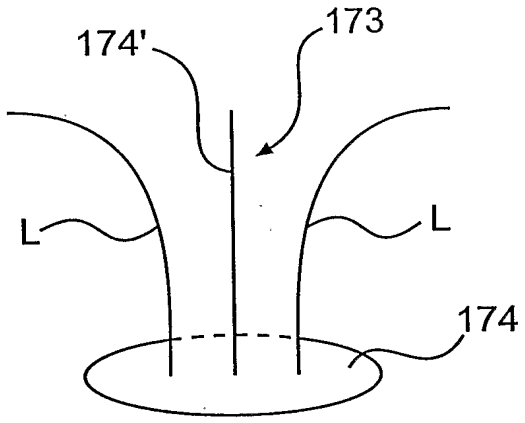

FIG. 11k

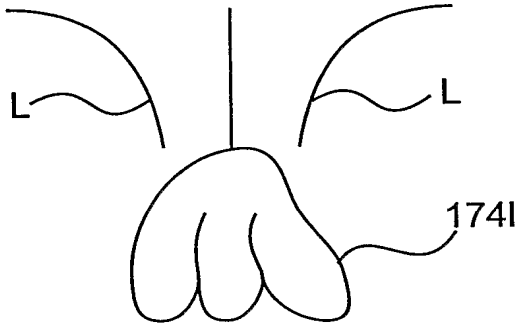

FIG. 11l(i)

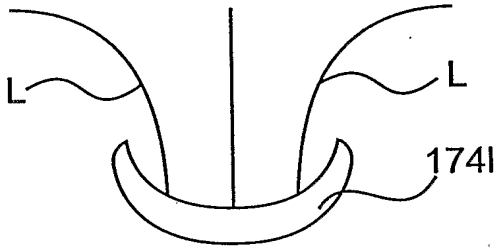

FIG. 11l(ii)

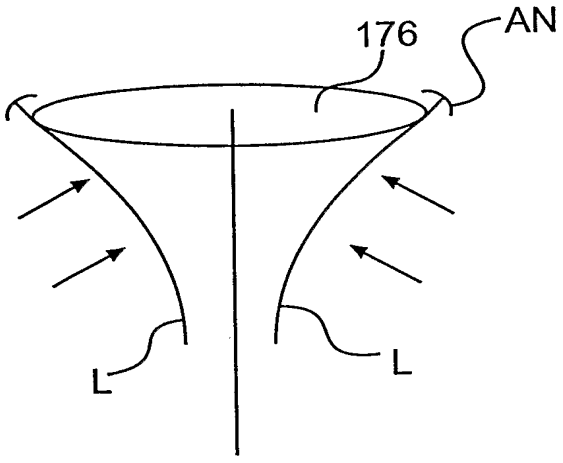

FIG. 11m(i)

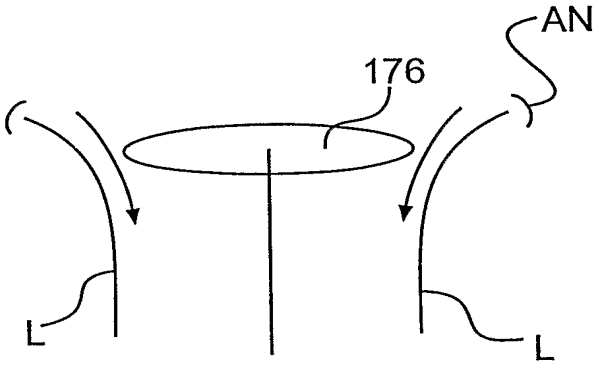

FIG. 11m(ii)

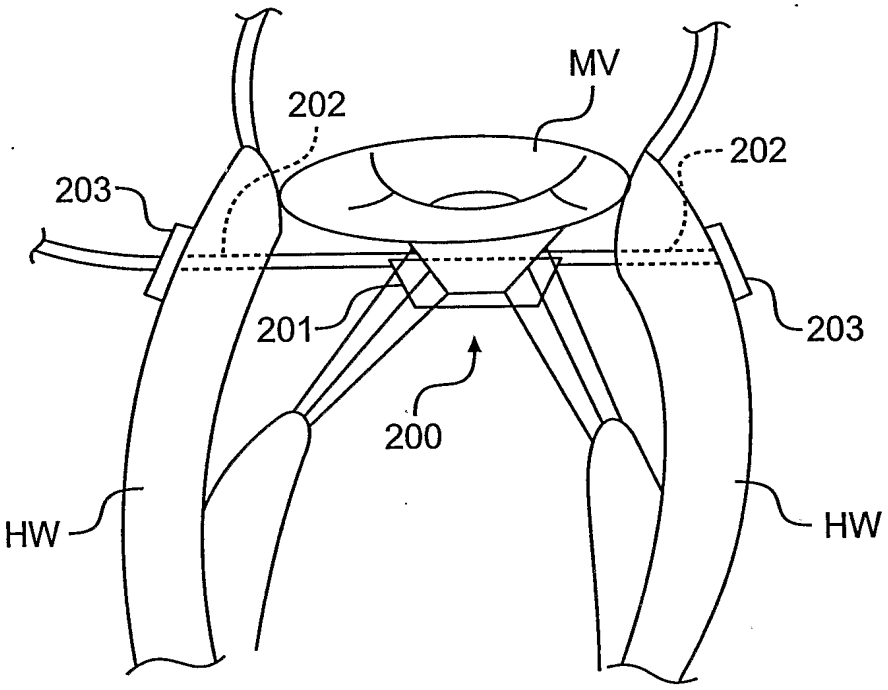

FIG. 12

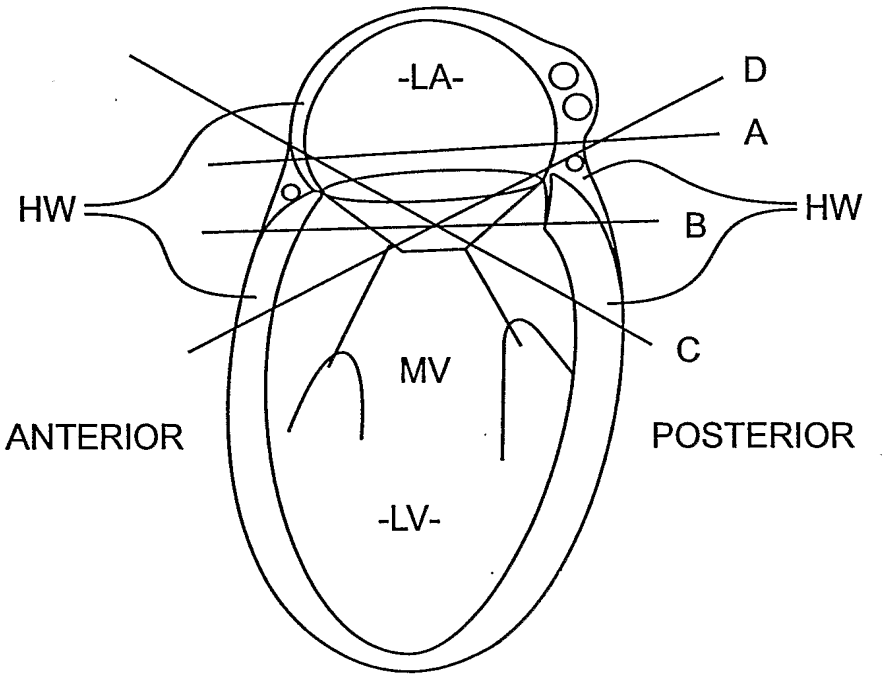

FIG. 13a

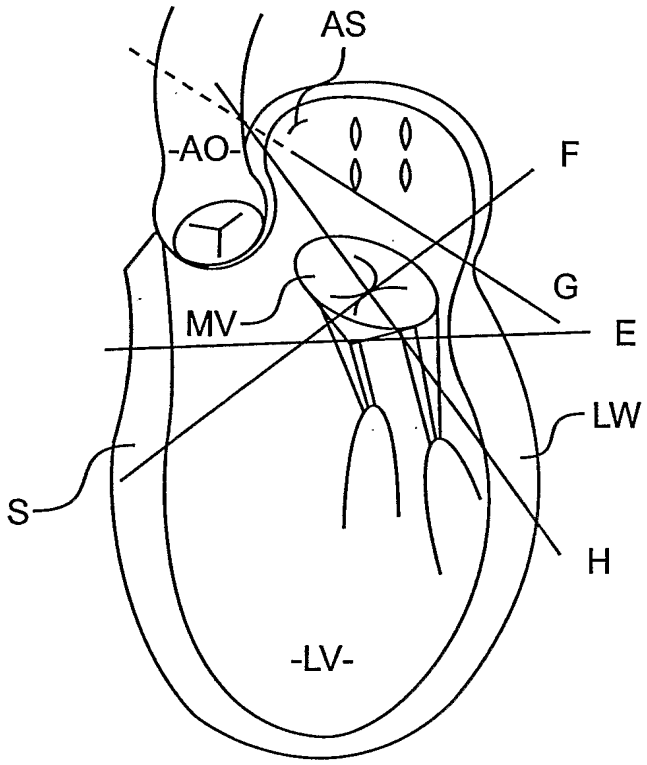

FIG. 13b

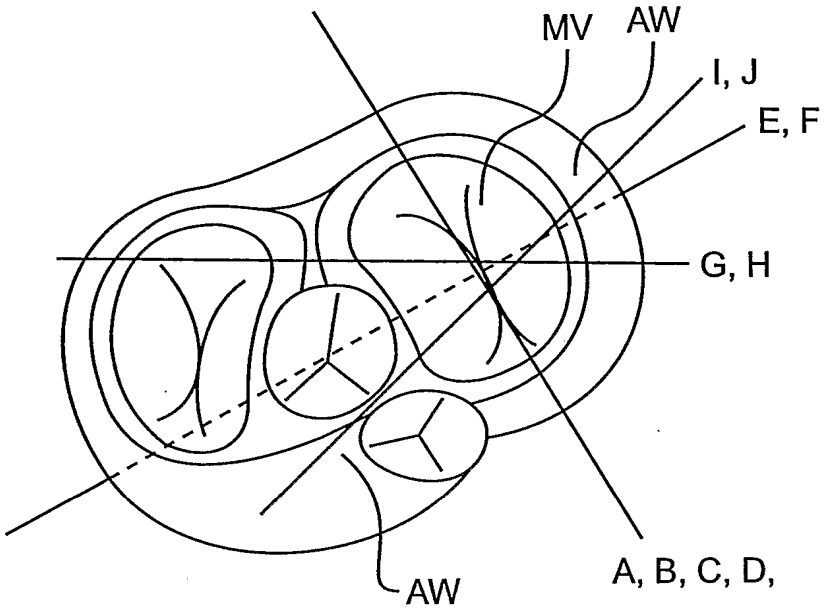

FIG. 13c

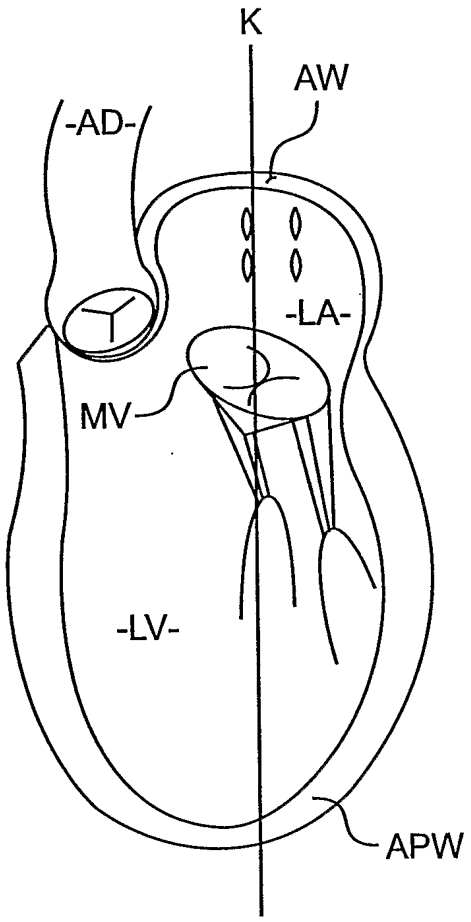

FIG. 13d

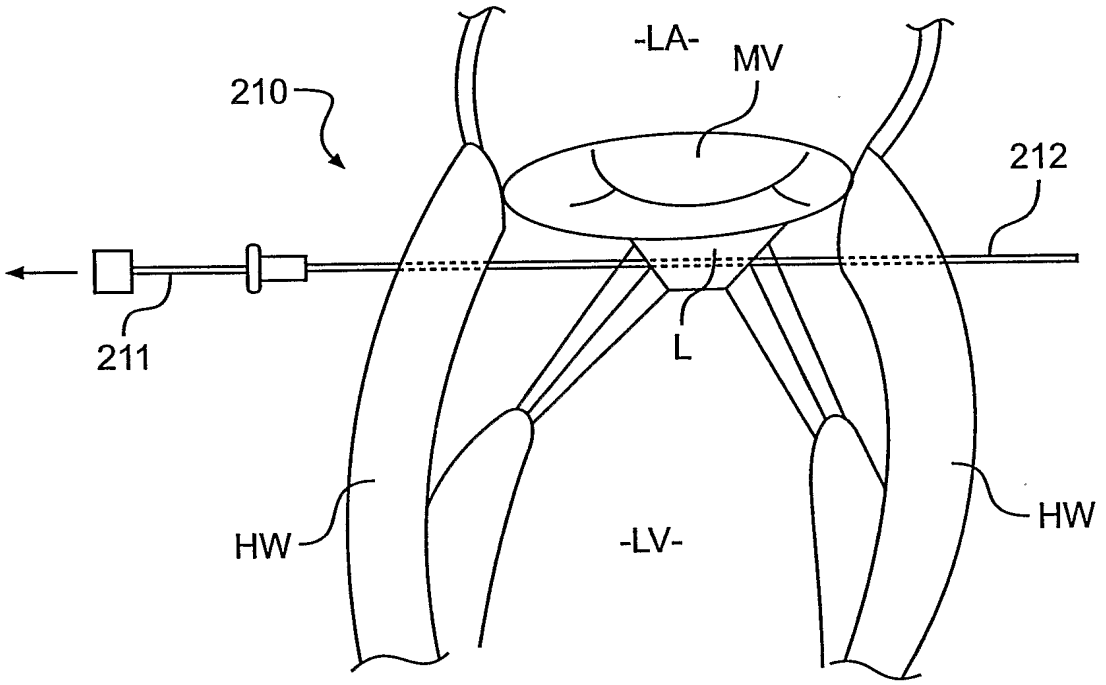

FIG. 14a

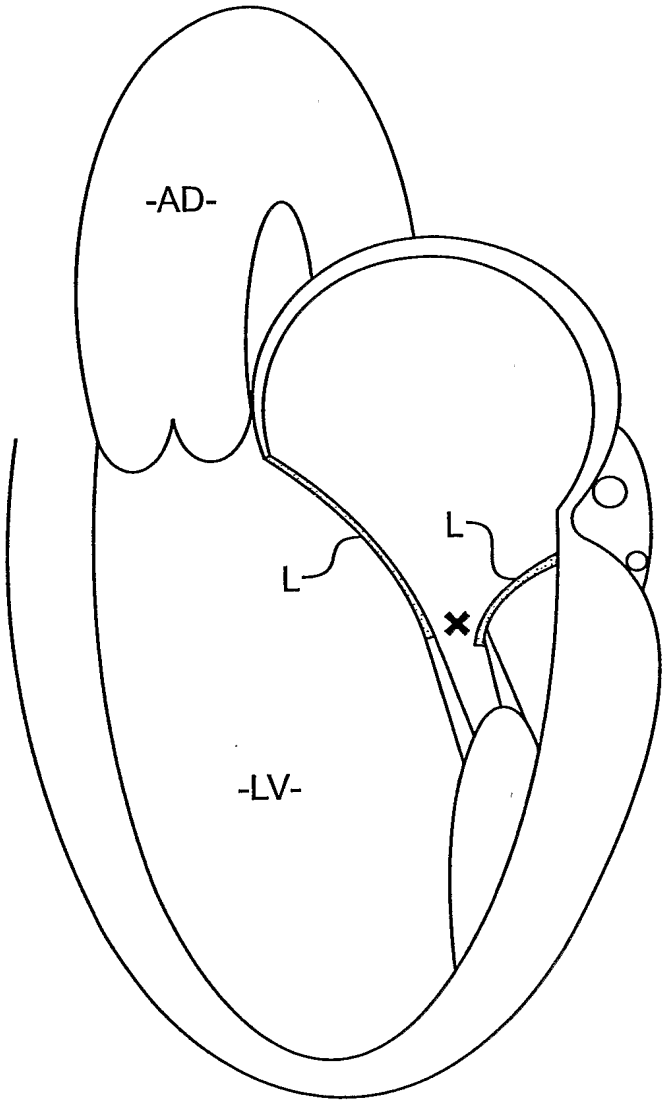

FIG. 14b

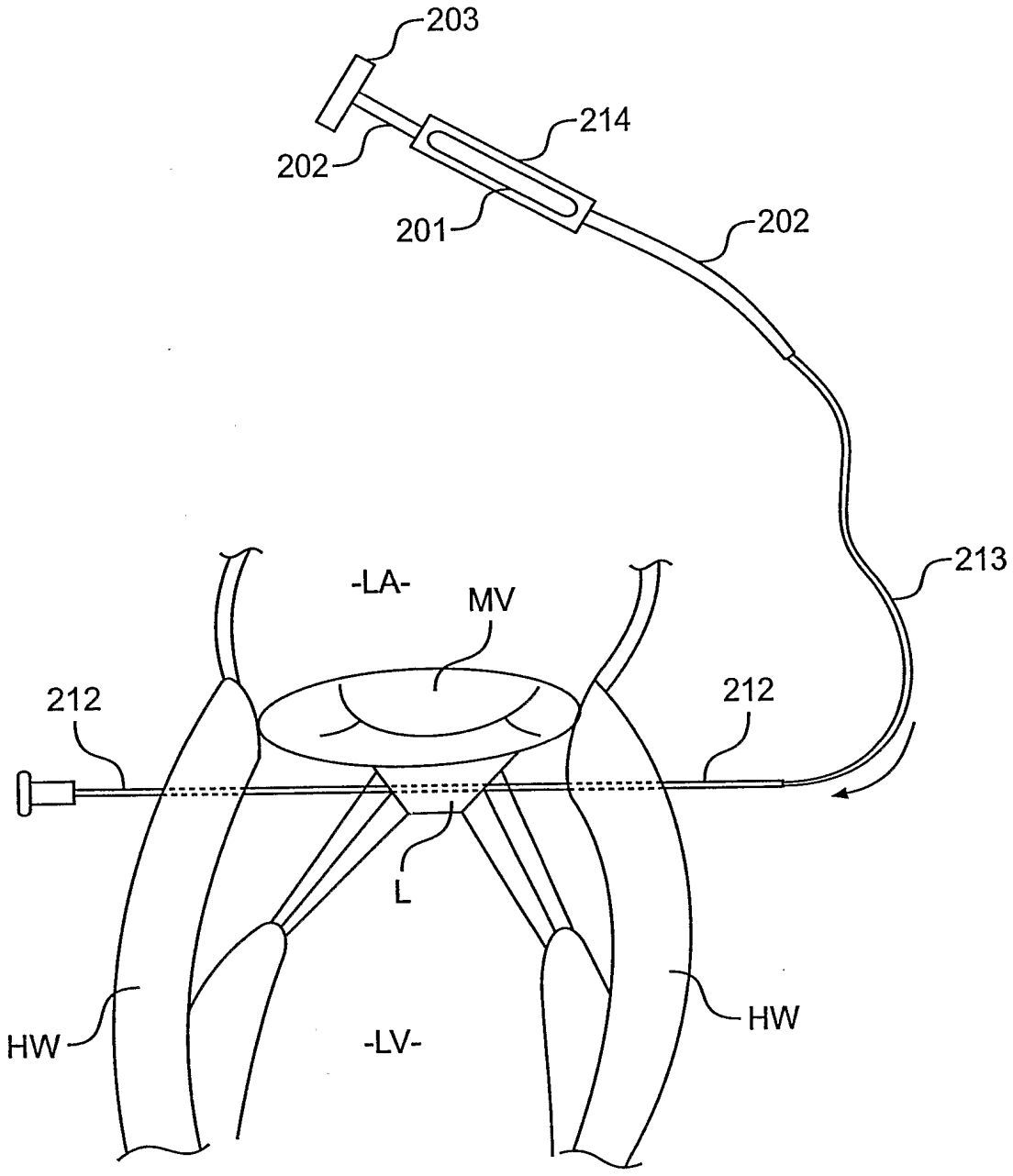

FIG. 14c

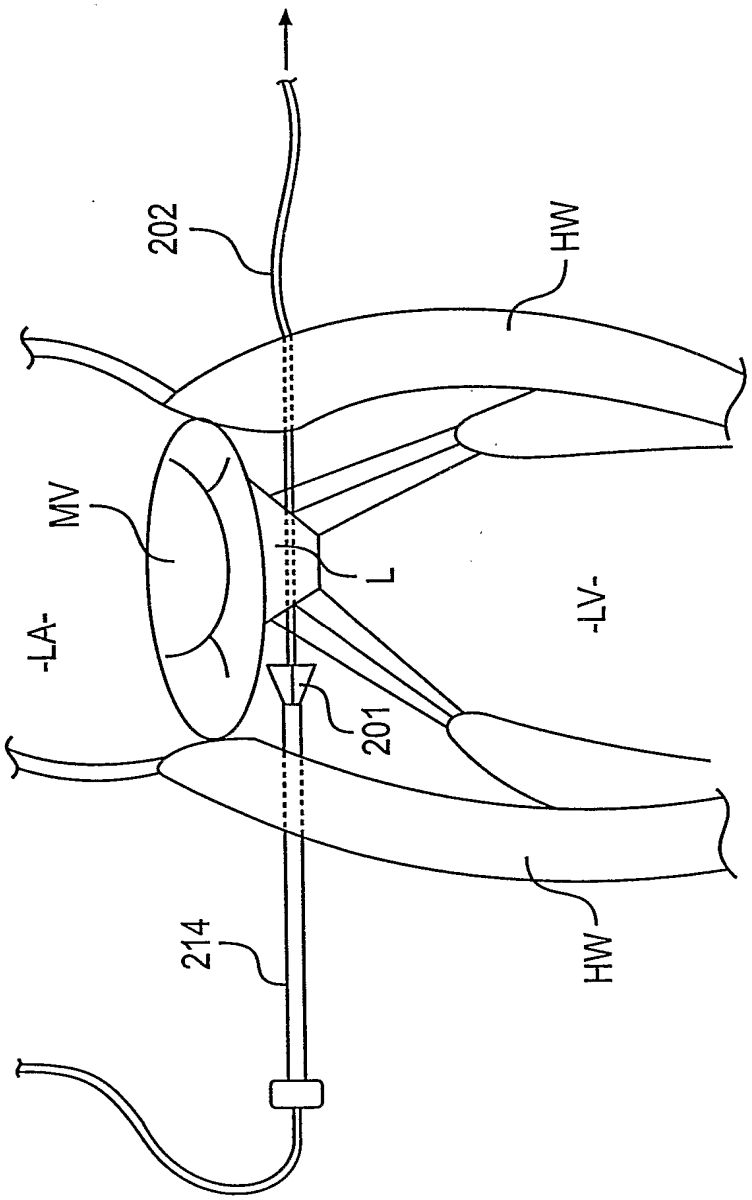

FIG. 14d

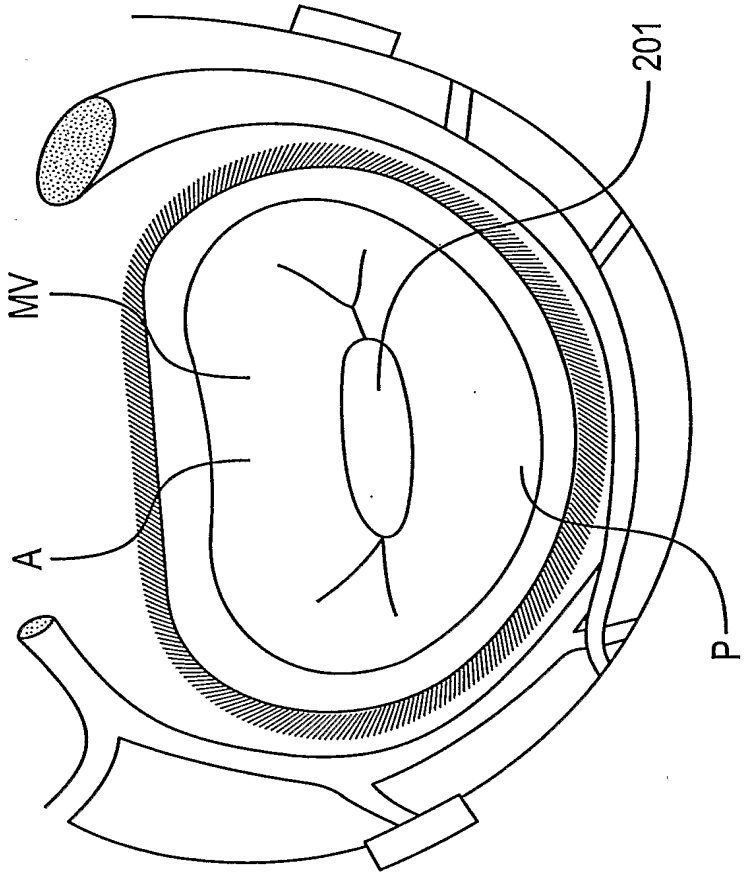

FIG. 14e

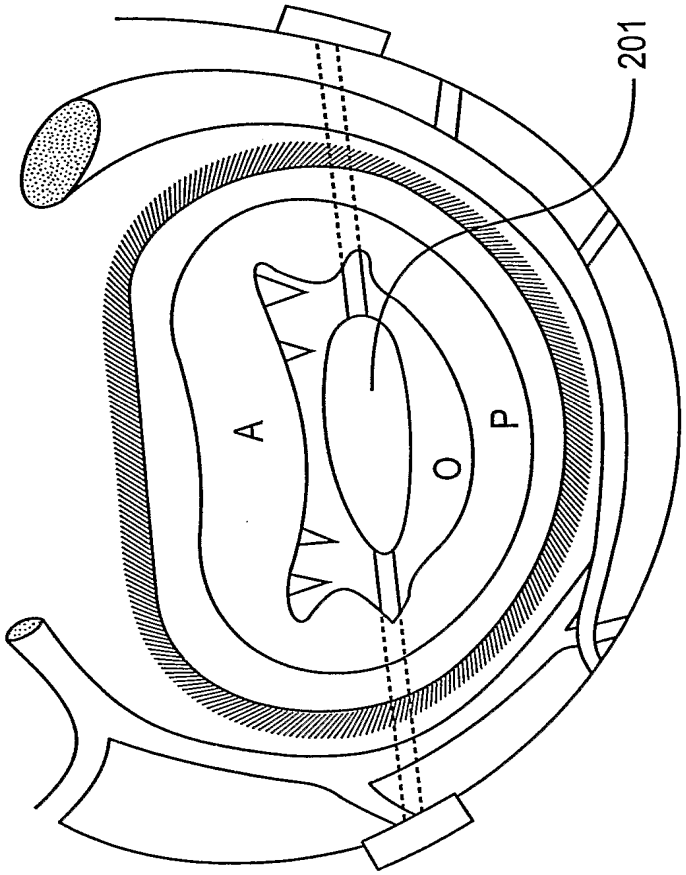

FIG. 14f

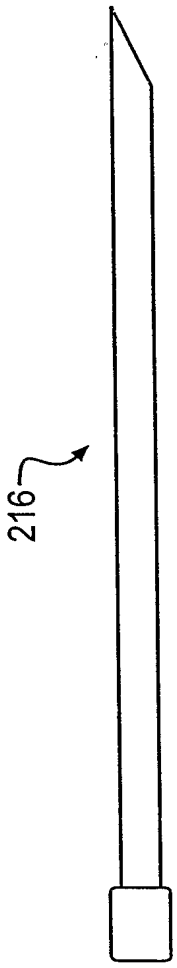

FIG. 15a

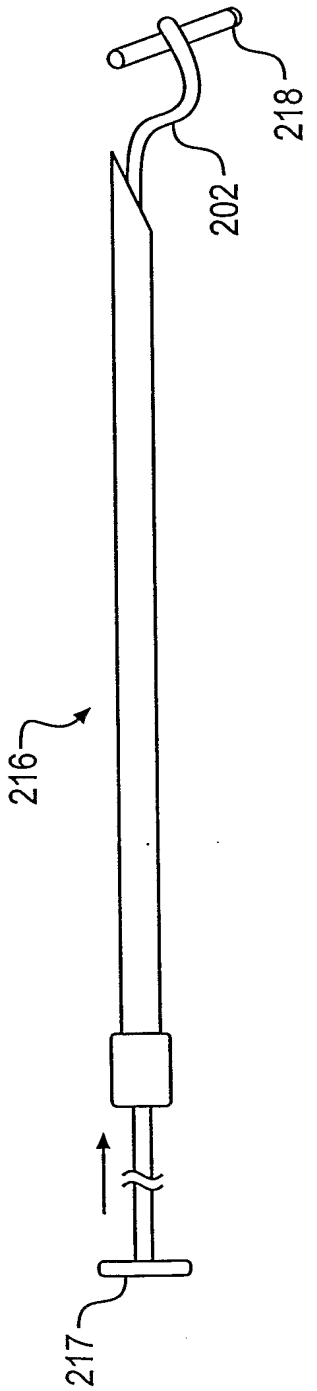

FIG. 15b

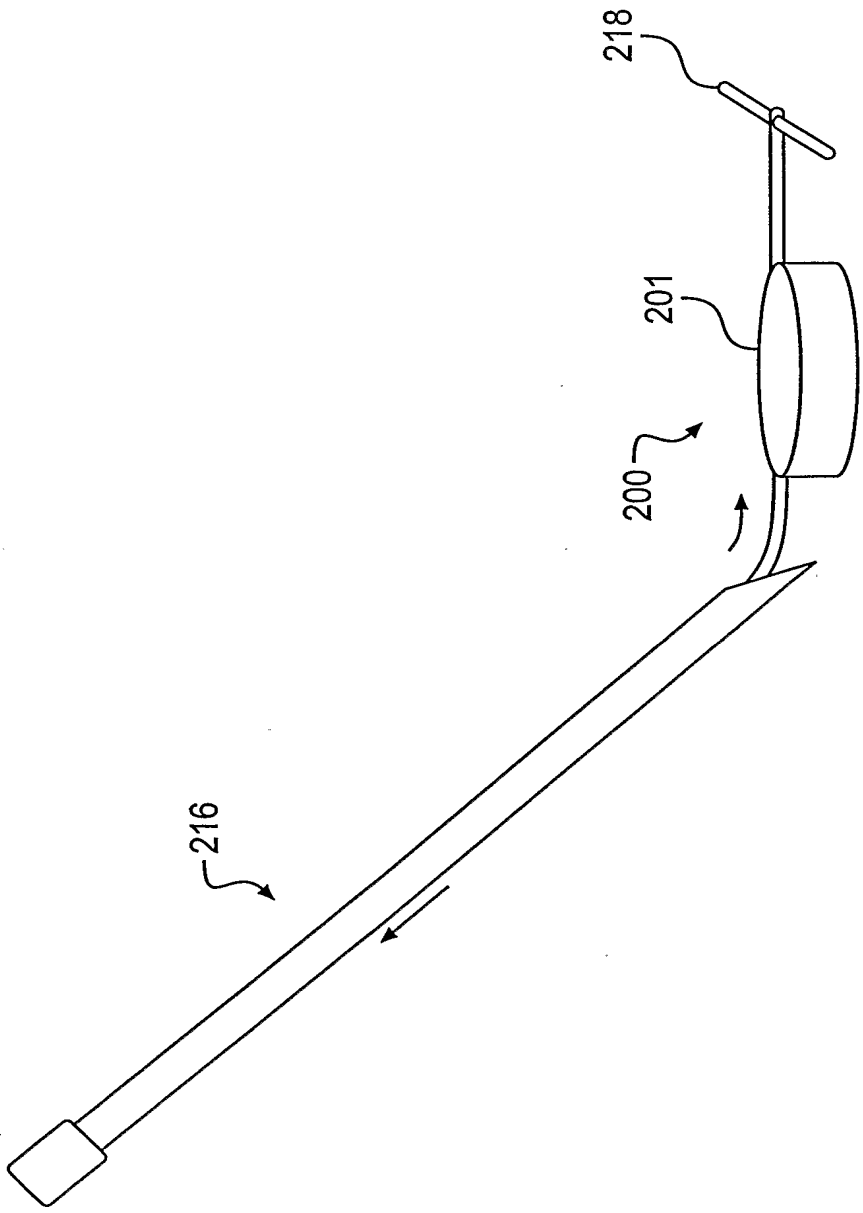

FIG. 15c

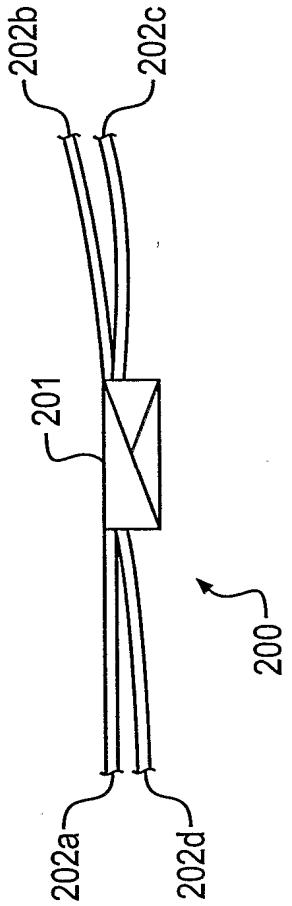

FIG. 16a

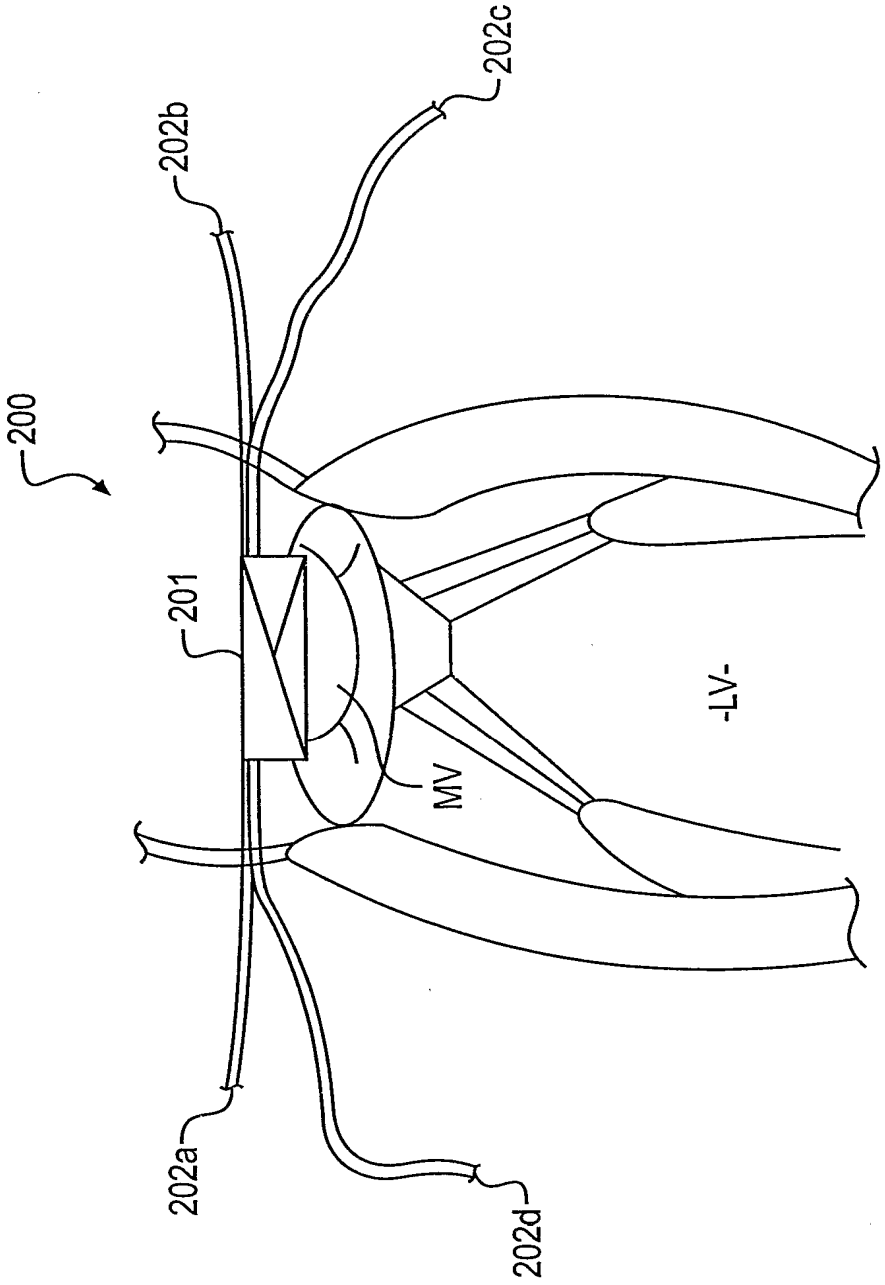

FIG. 16b

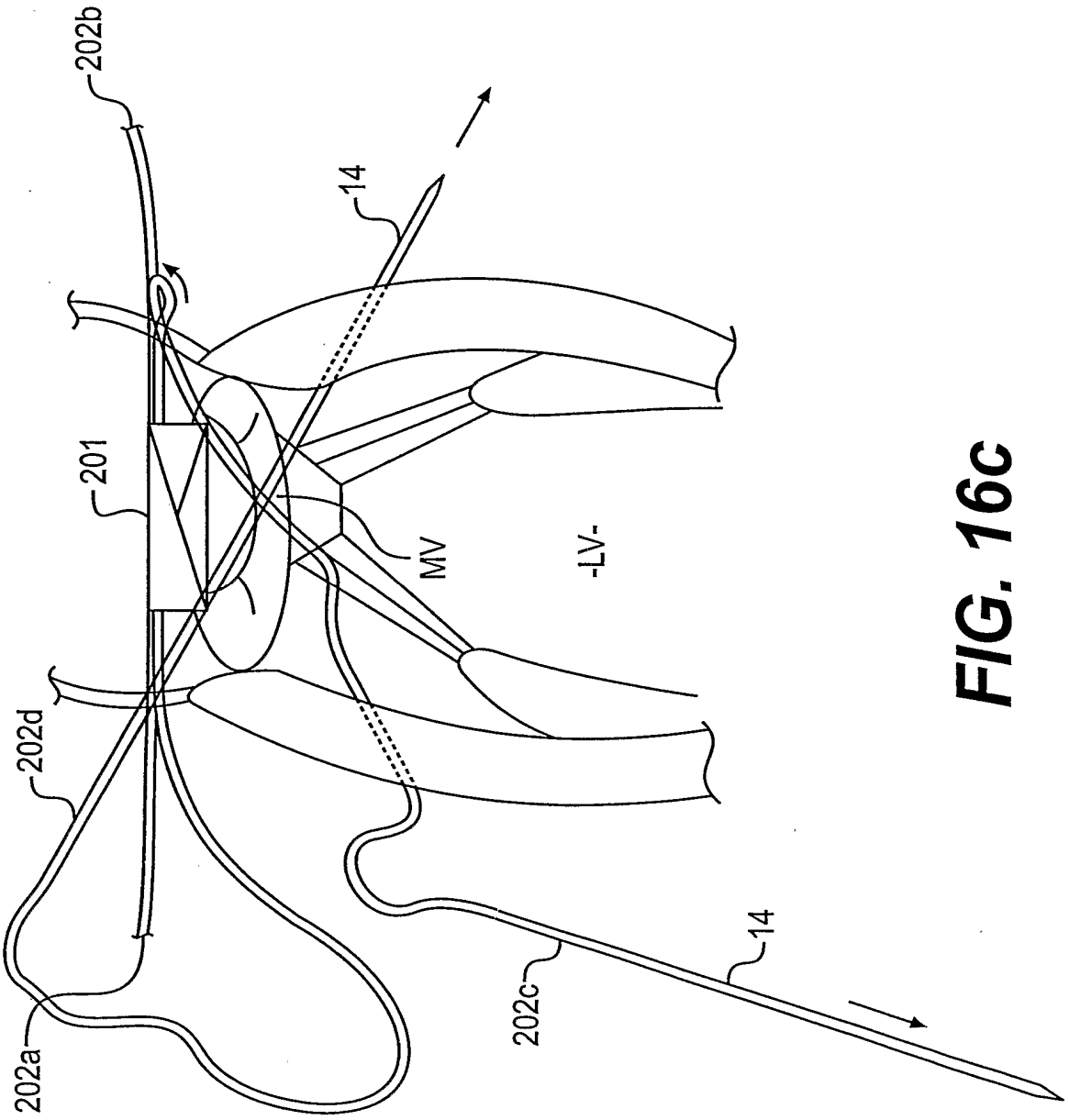

FIG. 16c

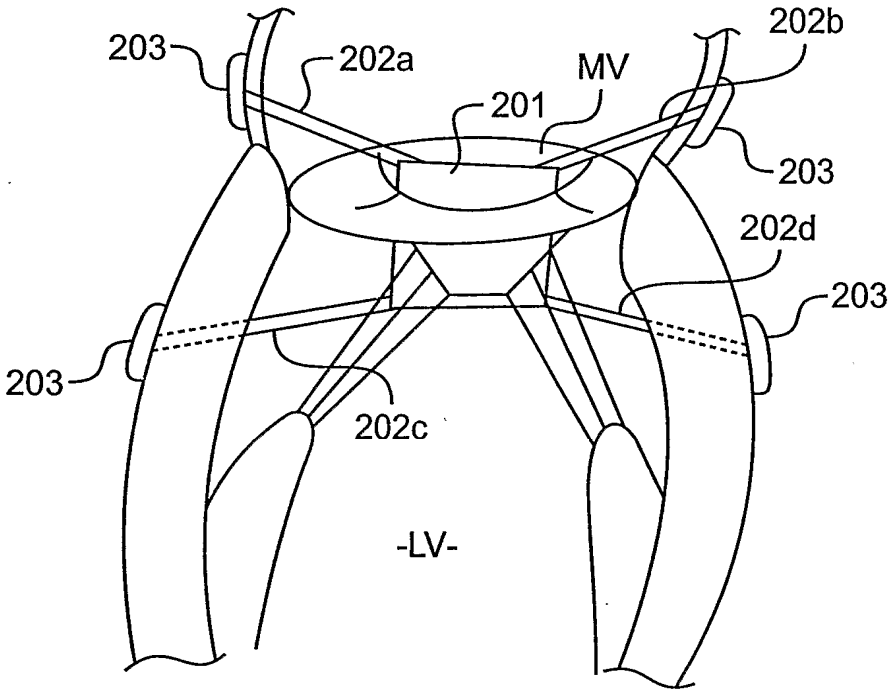

FIG. 16d

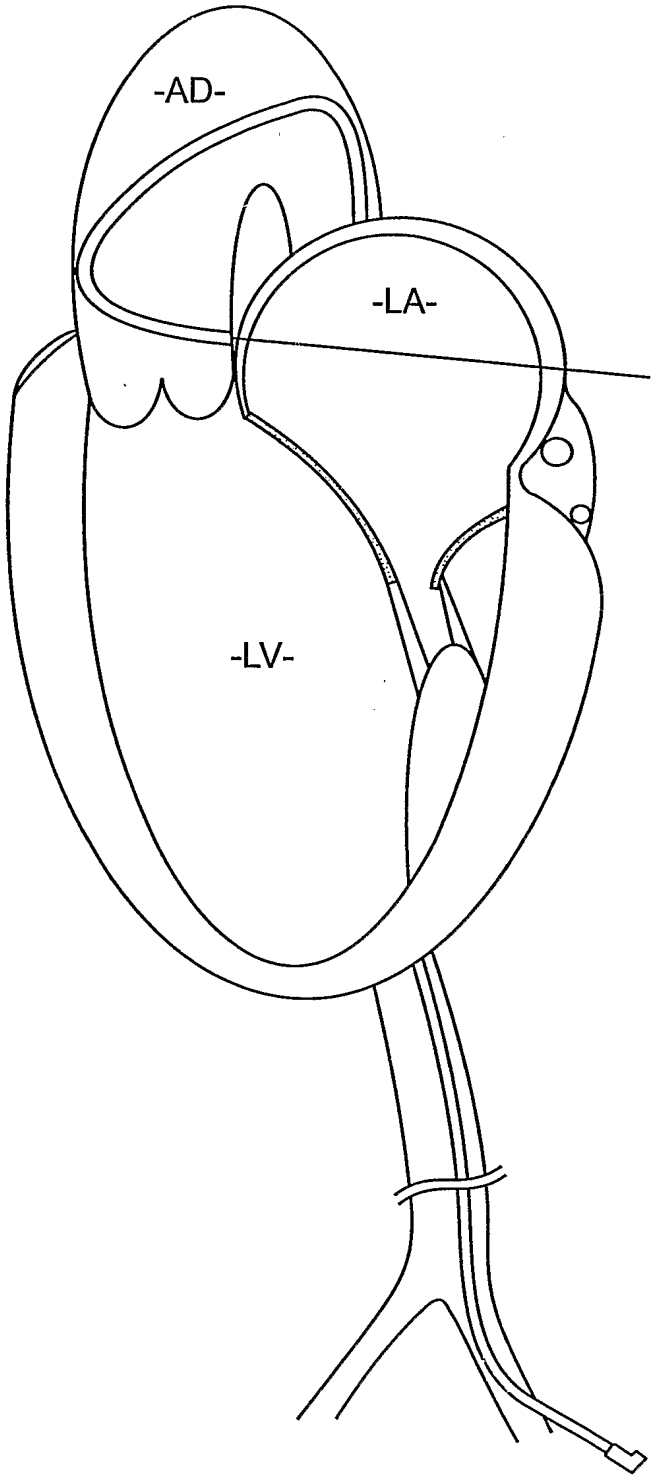

FIG. 17a

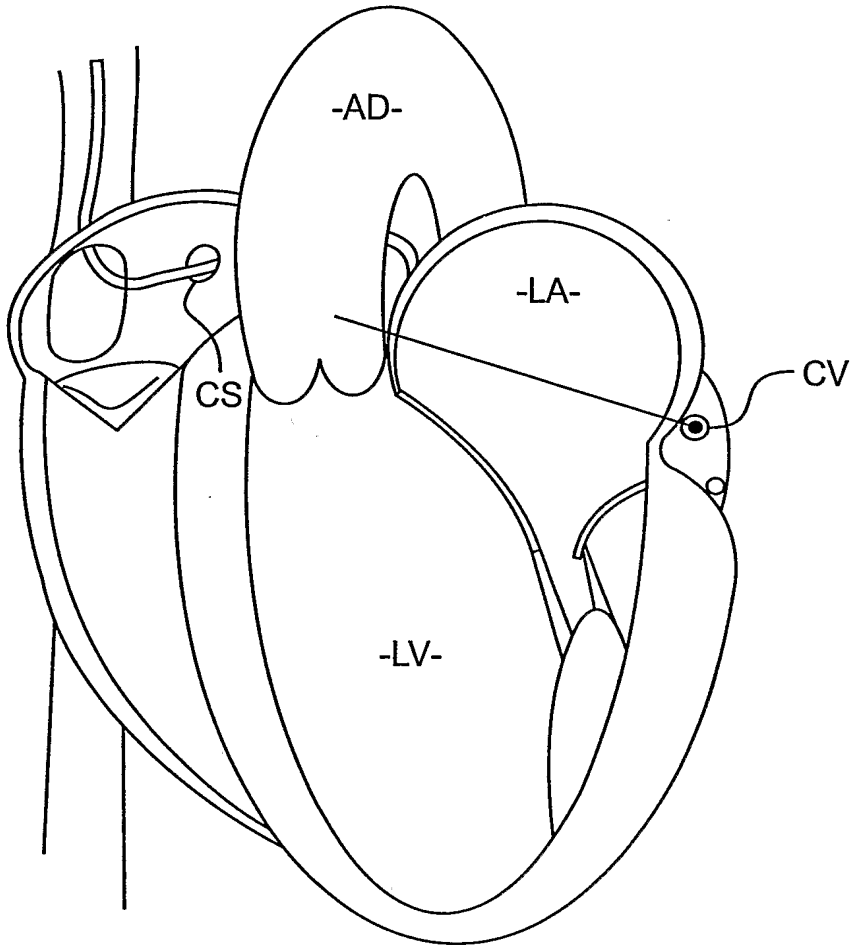

FIG. 17b

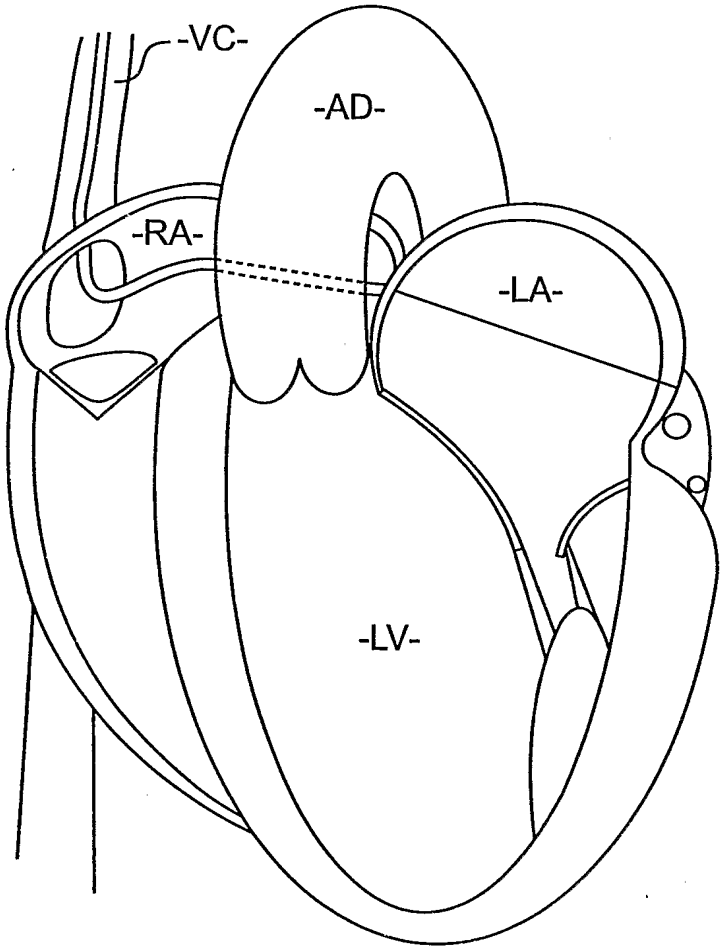

FIG. 17c

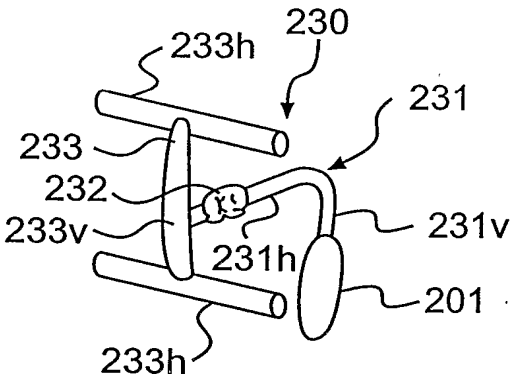

FIG. 18a

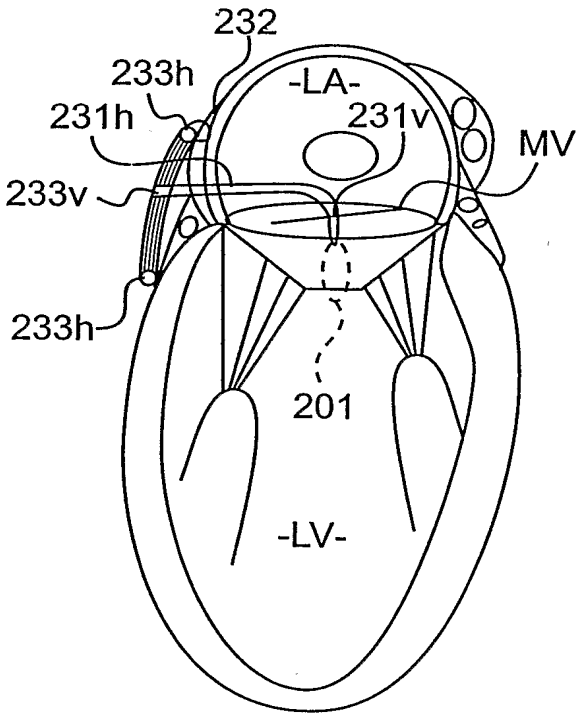

FIG. 18b

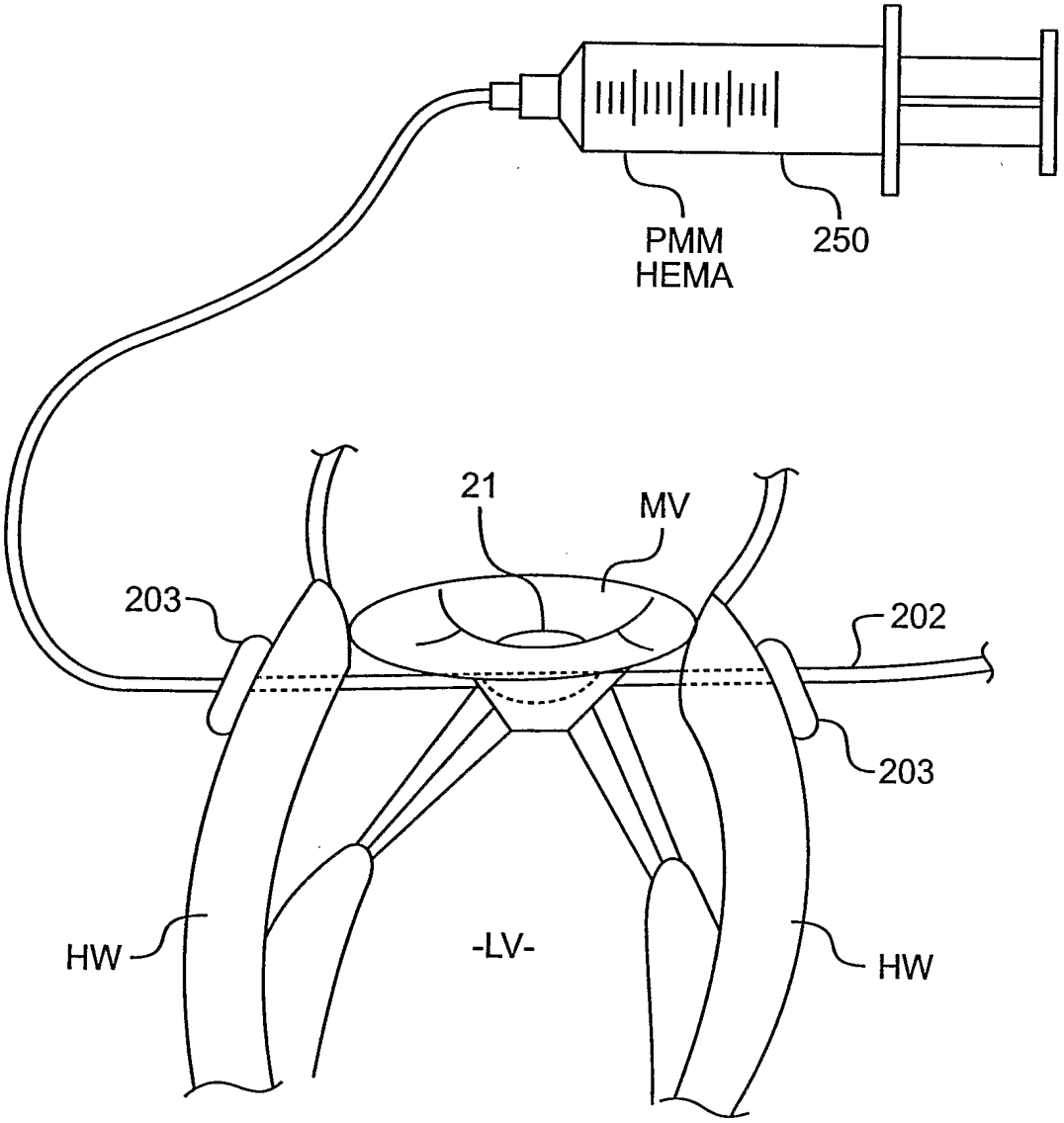

FIG. 19

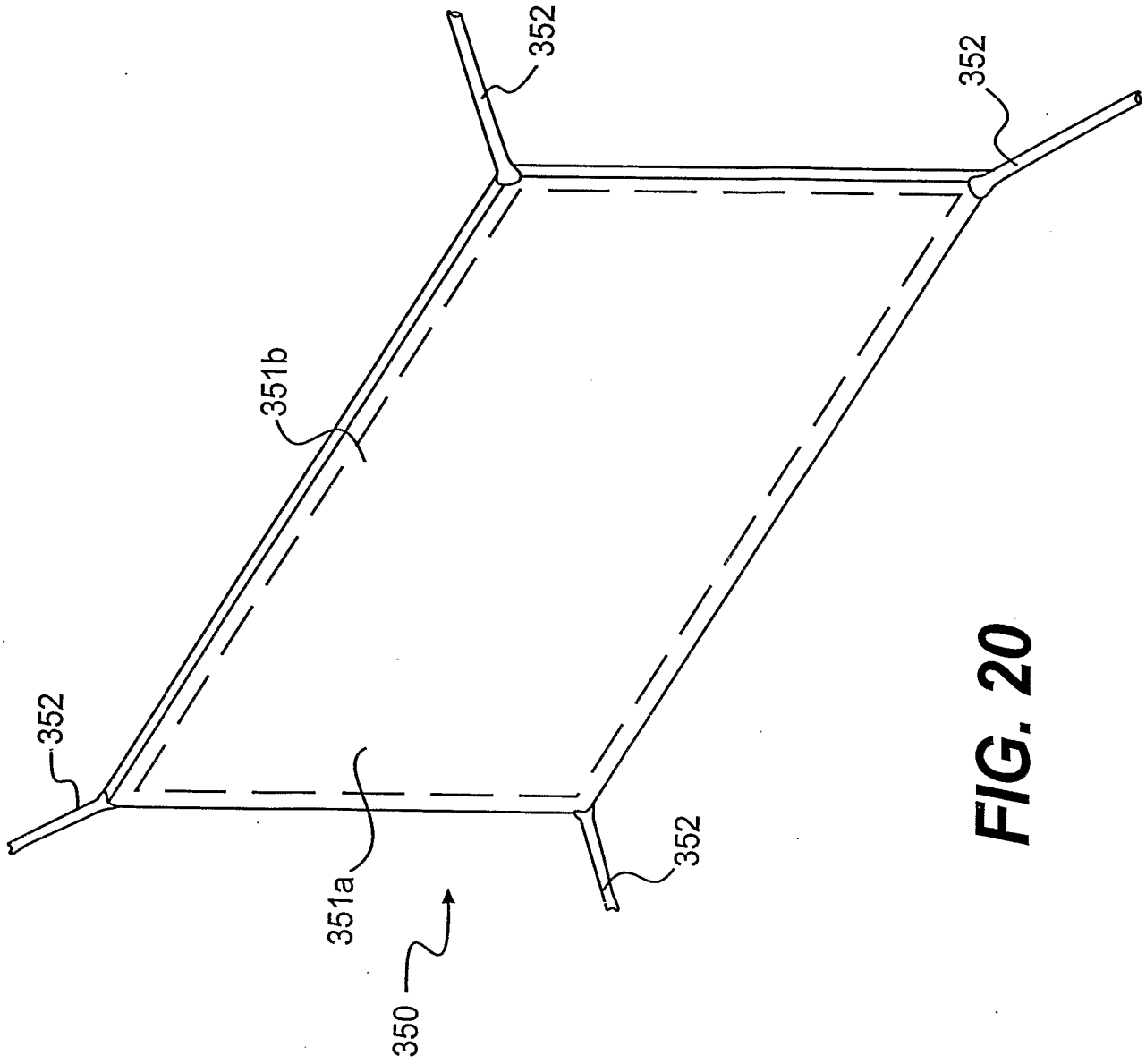

FIG. 20

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(71) Applicant *(for all designated States except US)*: **MYOCOR, INC.** [US/US]; 13300 67th Avenue North, Maple Grove, MN 55311 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **VIDLUND, Robert, M.** [US/US]; 1811 Kennard Street, Maplewood, MN 55109 (US). **KALGREEN, Jason, E.** [US/US]; 14820 39th Avenue North, Plymouth, MN 55446 (US). **MORTIER, Todd, J.** [US/US]; 3008 Colfax Avenue South, Minneapolis, MN 55408 (US). **SCHWEICH, Cyril, J., Jr.** [US/US]; 8936 Willowby Crossing, Maple Grove, MN 55311 (US). **SCHROEDER, Richard** [US/US]; 5497 East Danube Road, N.E., Fridley, MN 55432 (US). **KUSZ, David** [US/US]; 3229 39th Avenue South, Minneapolis, MN 55406 (US).

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

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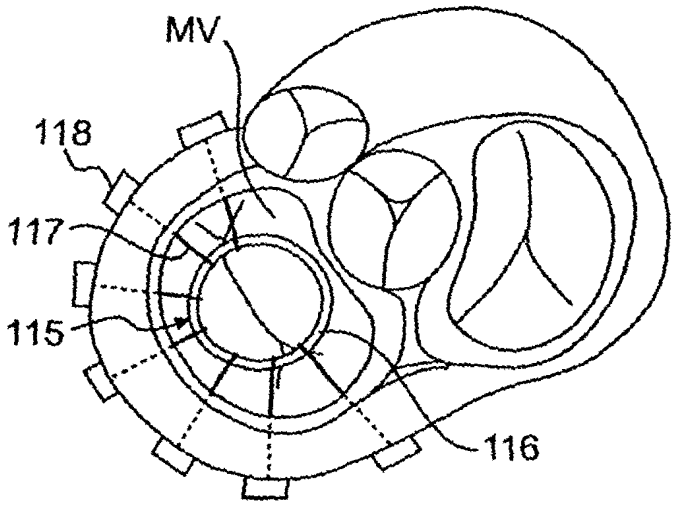
[Continued on next page]

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



(57) Abstract: Devices and methods for treating heart valves include members that assist the valve in closing during at least a portion of the cardiac cycle. Such devices include members configured to alter the shape of a valve annulus, reposition at least one papillary muscle, and/or plug an orifice of the valve so as to provide a coaptation surface for the valve leaflets.

WO 03/059209 A3

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

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/00012

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/24

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 332 893 B1 (SCHWEICH JR CYRIL J ET AL) 25 December 2001 (2001-12-25) figure 4 column 3, line 3 - column 5, line 24	23-46
P,X	WO 02 076284 A (VIACOR INC) 3 October 2002 (2002-10-03) figures 8-12 page 15, line 6 - page 27, line 22	23-46
P,A	WO 02 062263 A (VIACOR INC) 15 August 2002 (2002-08-15) page 12, line 15 - page 20, line 19	23-46

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

☒ Patent family members are listed in annex.

° Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 April 2003	21 10. 2003

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	Mary, C.

1

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/00012

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

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

1. [X] Claims Nos.: 1-22,63-74,86-96,111-124
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 II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

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

see additional sheet

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

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

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

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

23-46

Remark on Protest

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

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

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Claims Nos.: 1-22,63-74,86-96,111-124

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

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 23-46

A device for treating a heart valve comprising an arcuate portion to encircle the annulus and an elongated member configured to be secured to an exterior surface of the heart wall.

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2. claims: 47-58

A device for treating a heart valve comprising an elongated member to be implanted in a lumen of a coronary vessel and a shape change element associated with the elongated member.

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3. claims: 59-62

A device for treating a heart valve comprising an elongated member with a plurality of rotatable elements.

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4. claims: 75-85

A device for treating a heart valve comprising an elongated member, two anchoring members configured to engage opposite walls of the heart, to maintain a position of the elongated member transerve a heart chamber.

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5. claims: 97-110

A device for treating leakage of a heart valve comprising a plug and a securement mechanism.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 03/00012

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6332893 B1	25-12-2001	AU 2199899 A	05-07-1999
		EP 1039851 A1	04-10-2000
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		US 2002029080 A1	07-03-2002
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		US 2002183835 A1	05-12-2002
		US 2002183837 A1	05-12-2002
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(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
9 October 2003 (09.10.2003)

PCT

(10) International Publication Number
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(51) International Patent Classification[7]: A61B 17/064

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PCT/US2003/009215

(22) International Filing Date: 25 March 2003 (25.03.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/106,583 26 March 2002 (26.03.2002) US

(71) Applicant: EDWARDS LIFESCIENCES CORPORATION [US/US]; One Edwards Way, Irvine, CA 92614 (US).

(72) Inventor: SCHRECK, Stefan; 2057 White Birch Drive, Vista, CA 92083 (US).

(74) Agents: JAMES, John, Christopher et al.; Edwards Lifesciences LLC, One Edwards Way, Irvine, CA 92614 (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, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.

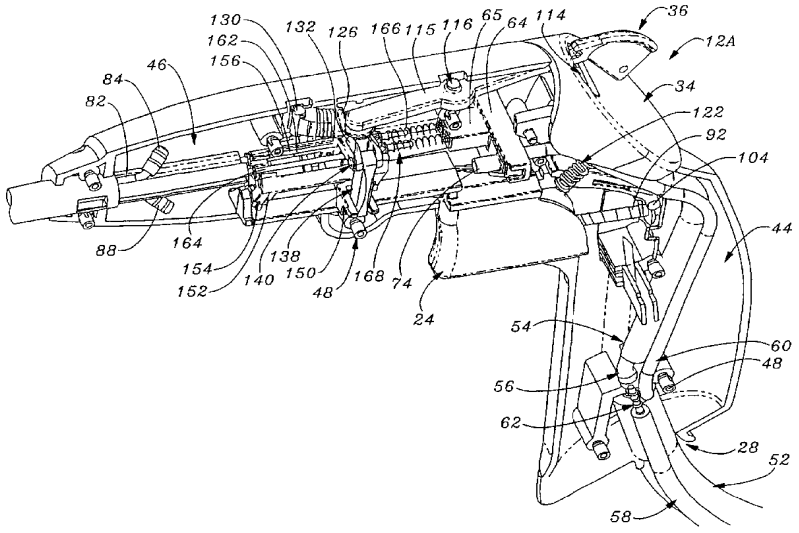
(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF,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

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*

(88) Date of publication of the international search report:
23 December 2004

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: DEVICE AND METHOD FOR HEART VALVE REPAIR



(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.

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INTERNATIONAL SEARCH REPORT

International Application No
/US 03/09215

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/064

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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 01/95809 A (TREMBATH CHAD ; DECKER STEVEN E (US); PETERSON ROD (US); STERILIS INC) 20 December 2001 (2001-12-20) cited in the application page 22, line 2 - line 14; figure 44 page 26, line 21 - line 36; figures 38-42 page 27, line 25; figures 22,23 page 17 - page 18 pages 13,16; figures 9,17	1-3,5,6, 10-15, 19,20, 22-27, 33-36
Y	WO 01/66018 A (GAMBALE RICHARD A ; LUKIN PETER J (US); PAGE EDWARD C (US); BARD INC C) 13 September 2001 (2001-09-13) the whole document page 18 - page 32; figure 26	1-3,5,6, 10-15, 19,20, 22-27, 33-36

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

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
"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
18 October 2004	25/10/2004

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

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

INTERNATIONAL SEARCH REPORT

International Application No
/US 03/09215

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 01/28432 A (EDWARDS LIFESCIENCES CORP) 26 April 2001 (2001-04-26) abstract figures 1-3	1,19,20, 25
A	US 5 741 277 A (GUNN GORDON C ET AL) 21 April 1998 (1998-04-21) the whole document abstract; figure 24 column 21, line 44 - line 48	1,19,20, 25
A	US 5 374 275 A (BRADLEY JAMES G ET AL) 20 December 1994 (1994-12-20) page 4, line 9 - line 16	1,19,20, 25

1

INTERNATIONAL SEARCH REPORT

nformation on patent family members

ıational Application No
/US 03/09215

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		EP 1303218 A1	23-04-2003
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		US 5575800 A	19-11-1996
US 5374275 A	20-12-1994	NONE	

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

(19) World Intellectual Property Organization
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(43) International Publication Date
27 May 2004 (27.05.2004)

PCT

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WO 2004/043265 A2

(51) International Patent Classification[7]: A61B 17/00, 17/04

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10/704,143	10 November 2003 (10.11.2003)	US
10/704,145	10 November 2003 (10.11.2003)	US

(71) Applicant *(for all designated States except US)*: **MYOCOR, INC.** [US/US]; 13300 67th Avenue North, Maple Grove, MN 55311 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **VIDLUND, Robert, M.** [US/US]; 1811 Kennard Street, Maplewood, MN 55109 (US). **KALGREEN, Jason, E.** [US/US]; 14820 39th Avenue North, Plymouth, MN 55446 (US). **MORTIER, Todd, J.** [US/US]; 3008 Colfax Ave South, Minneapolis, MN 55408 (US). **SCHWEICH, Cyril, J., Jr.** [US/US]; 8936 Willowby Crossing, Maple Grove, MN 55311 (US). **SCHROEDER, Richard** [US/US]; 5497 East Danube Road NE, Fridley, MN 55432 (US). **KUSZ, David** [US/US]; 3229 39th Avenue South, Minneapolis, MN 55406 (US). **EKVALL, Craig, A.** [US/US]; 15959 214th Avenue, N.W., Elk River, MN 55330 (US). **MATTHEES, Edward** [US/US]; 11-2nd Street S.E., Minneapolis, MN 55414 (US).

(74) Agents: **GARRETT, Arthur, S.** et al.; Finnegan, Henderson, Farabow, Garrett, & Dunner, L.L.P., 1300 I Street, NW, Washington, DC 20005-3315 (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, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

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

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

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

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

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

WO 2004/043265 A2

DEVICES AND METHODS FOR HEART VALVE TREATMENT

Field of the Invention

[001] The present invention relates to devices and associated methods for treating and improving the performance of dysfunctional heart valves. More particularly, the invention relates to devices and methods that passively assist to reshape a dysfunctional heart valve to improve its performance.

Background of the Invention

[002] Various etiologies may result in heart valve insufficiency depending upon both the particular valve as well as the underlying disease state of the patient. For instance, a congenital defect may be present resulting in poor coaptation of the valve leaflets, such as in the case of a monocusp aortic valve, for example. Valve insufficiency also may result from an infection, such as rheumatic fever, for example, which may cause a degradation of the valve leaflets. Functional regurgitation also may be present. In such cases, the valve components may be normal pathologically, yet may be unable to function properly due to changes in the surrounding environment. Examples of such changes include geometric alterations of one or more heart chambers and/or decreases in myocardial contractility. In any case, the resultant volume overload that exists as a result of an insufficient valve may increase chamber wall stress. Such an increase in stress may eventually result in a dilatory process that further exacerbates valve dysfunction and degrades cardiac efficiency.

[003] Mitral valve regurgitation often may be driven by the functional changes described above. Alterations in the geometric relationship between valvular components may occur for numerous reasons, including events ranging from focal

myocardial infarction to global ischemia of the myocardial tissue. Idiopathic dilated cardiomyopathy also may drive the evolution of functional mitral regurgitation. These disease states often lead to dilatation of the left ventricle. Such dilatation may cause papillary muscle displacement and/or dilatation of the valve annulus. As the papillary muscles move away from the valve annulus, the chordae connecting the muscles to the leaflets may become tethered. Such tethering may restrict the leaflets from closing together, either symmetrically or asymmetrically, depending on the relative degree of displacement between the papillary muscles. Moreover, as the annulus dilates in response to chamber enlargement and increased wall stress, increases in annular area and changes in annular shape may increase the degree of valve insufficiency. Annular dilatation is typically concentrated on the posterior aspect, since this aspect is directly associated with the dilating left ventricular free wall and not directly attached to the fibrous skeleton of the heart. Annular dilatation also may result in a flattening of the valve annulus from its normal saddle shape.

[004] Alterations in functional capacity also may cause valve insufficiency. In a normally functioning heart, the mitral valve annulus contracts during systole to assist in leaflet coaptation. Reductions in annular contractility commonly observed in ischemic or idiopathic cardiomyopathy patients therefore hamper the closure of the valve. Further, in a normal heart, the papillary muscles contract during the heart cycle to assist in maintaining proper valve function. Reductions in or failure of the papillary muscle function also may contribute to valve regurgitation. This may be caused by infarction at or near the papillary muscle, ischemia, or other causes, such as idiopathic dilated cardiomyopathy, for example.

[005] The degree of valve regurgitation may vary, especially in the case of functional insufficiency. In earlier stages of the disease, the valve may be able to compensate for geometric and/or functional changes in a resting state. However, under higher loading resulting from an increase in output requirement, the valve may become incompetent. Such incompetence may only appear during intense exercise, or alternatively may be induced by far less of an exertion, such as walking up a flight of stairs, for example.

[006] Conventional techniques for managing mitral valve dysfunction include either surgical repair or replacement of the valve or medical management of the patient. Medical management typically applies only to early stages of mitral valve dysfunction, during which levels of regurgitation are relatively low. Such medical management tends to focus on volume reductions, such as diuresis, for example, or afterload reducers, such as vasodilators, for example.

[007] Early attempts to surgically treat mitral valve dysfunction focused on replacement technologies. In many of these cases, the importance of preserving the native subvalvular apparatus was not fully appreciated and many patients often acquired ventricular dysfunction or failure following the surgery. Though later experience was more successful, significant limitations to valve replacement still exist. For instance, in the case of mechanical prostheses, lifelong therapy with powerful anticoagulants may be required to mitigate the thromboembolic potential of these devices. In the case of biologically derived devices, in particular those used as mitral valve replacements, the long-term durability may be limited. Mineralization

induced valve failure is common within ten years, even in younger patients. Thus, the use of such devices in younger patient groups is impractical.

[008] Another commonly employed repair technique involves the use of annuloplasty rings. These rings originally were used to stabilize a complex valve repair. Now, they are more often used alone to improve mitral valve function. An annuloplasty ring has a diameter that is less than the diameter of the enlarged valve annulus. The ring is placed in the valve annulus and the tissue of the annulus sewn or otherwise secured to the ring. This causes a reduction in the annular circumference and an increase in the leaflet coaptation area. Such rings, however, generally flatten the natural saddle shape of the valve and hinder the natural contractility of the valve annulus. This may be true even when the rings have relatively high flexibility.

[009] To further reduce the limitations of the therapies described above, purely surgical techniques for treating valve dysfunction have evolved. Among these surgical techniques is the Alfiere stitch or so-called bowtie repair. In this surgery, a suture is placed substantially centrally across the valve orifice joining the posterior and anterior leaflets to create leaflet apposition. Another surgical technique includes plication of the posterior annular space to reduce the cross-sectional area of the valve annulus. A limitation of each of these techniques is that they typically require opening the heart to gain direct access to the valve and the valve annulus. This generally necessitates the use of cardiopulmonary bypass, which may introduce additional morbidity and mortality to the surgical procedures. Additionally, for each of these procedures, it is very difficult to evaluate the efficacy of the repair prior to the conclusion of the operation.

[010] Due to these drawbacks, devising effective techniques that could improve valve function without the need for cardiopulmonary bypass and without requiring major remodeling of the valve may be advantageous. In particular, passive techniques to change the shape of the heart chamber and/or associated valve and reduce regurgitation while maintaining substantially normal leaflet motion may be desirable. Further, advantages may be obtained by a technique that reduces the overall time a patient is in surgery and under the influence of anesthesia. It also may be desirable to provide a technique for treating valve insufficiency that reduces the risk of bleeding associated with anticoagulation requirements of cardiopulmonary bypass. In addition, a technique that can be employed on a beating heart would allow the practitioner an opportunity to assess the efficacy of the treatment and potentially address any inadequacies without the need for additional bypass support.

Summary of the Invention

[011] To address these needs, the present invention provides, in exemplary non-limiting embodiments, devices and methods for improving the function of a valve (e.g., mitral valve) by positioning an implantable device outside and adjacent the heart wall such that the device alters the shape of the heart wall acting on the valve. The implantable device may include two anchor ends with a interconnecting member connected therebetween. The anchor ends and the interconnecting member may be positioned on the outside of the heart. Optionally, a protrusion may be connected to the interconnecting member between the anchor ends. The anchor ends may be connected to the heart wall around the dysfunctional valve, and the interconnecting member may be tightened or cinched therebetween. Because the heart wall is

generally curved, the act of cinching the interconnecting member between the attached anchor ends may cause the interconnecting member to apply an inward force against the heart wall acting on the dysfunctional valve, and/or may shorten the distance between the anchor ends and thus deform the heart wall inward to act on the dysfunctional valve. The inward force may act on any one of or any combination of valve structures (e.g., valve annulus, papillary muscles, etc.) and/or adjacent anatomical coronary structures. If a protrusion is utilized, it may be used to apply and focus additional force against the heart wall.

Brief Description of the Drawings

[012] Besides the structural and procedural arrangements set forth above, the invention could include a number of other arrangements, such as those explained hereinafter. It is to be understood that both the foregoing description and the following description are exemplary. The accompanying drawings are included to provide a further understanding of the invention and are incorporated in and constitute a part of this specification. The drawings illustrate exemplary embodiments of the invention and, together with the description, serve to explain certain principles. In the drawings,

[013] Figures 1A and 1B are bottom and side views, respectively, of an exemplary, non-limiting embodiment of an implantable device utilizing a protrusion;

[014] Figures 1C and 1D are bottom and side views, respectively, of an exemplary, non-limiting alternative embodiment of an implantable device without a protrusion;

[015] Figures 2A – 2C are sectional views of a patient's trunk at the level of the mitral valve of the heart, showing an example of where the implantable devices may be positioned in the short axis view, and showing the effects of the implantable devices on mitral valve function;

[016] Figure 3 is a sectional view of a patient's heart bisecting the mitral valve, showing an example of where the implantable devices may be positioned in the long axis view;

[017] Figure 4 is an angiographic illustration of a patient's heart, showing an example of where the implantable devices may be positioned relative to the coronary arteries;

[018] Figures 5A – 5D are perspective views of more specific embodiments of implantable devices of the present invention;

[019] Figure 5E is a schematic illustration of a cable locking mechanism for use in any of the implantable devices shown in Figures 5A – 5D;

[020] Figure 6A is a perspective plan view of a delivery system for implanting the implantable devices shown in Figures 5A – 5D;

[021] Figure 6B is a perspective bottom view of an anchor catheter for use in the delivery system shown in Figure 6A;

[022] Figure 7 is a perspective plan view of an alternative delivery system for implanting the implantable devices shown in Figures 5A – 5D;

[023] Figure 8 is a perspective view of a sizing device for use in adjusting the implantable devices shown in Figures 5A – 5D;

[024] Figure 9 is a perspective exploded view of an access system to facilitate pericardial access of the delivery systems;

[025] Figure 10 is a partially sectioned side view of a distal portion of the access device shown in Figure 9, illustrating engagement with the pericardial sac;

[026] Figure 11 is an illustration schematically showing a pericardial access approach for delivery of the implantable devices;

[027] Figure 12 is a schematic plan view of a catheter and guide wire for use in delivering implantable devices by transluminal techniques;

[028] Figures 13A and 13B are cross sectional views of the catheter shown in Figure 12 taken along line 13 – 13;

[029] Figure 14 is a cross sectional view of the catheter shown in Figure 12 taken along line 14 – 14;

[030] Figures 15A and 15B are schematic top and side views of a transdermal access port connected to an implantable device by a flexible tube;

[031] Figure 16 is a schematic plan view of a guide catheter for use in delivering implantable devices by transluminal techniques;

[032] Figure 17 is a schematic plan view of an isolation catheter for use in delivering implantable devices by transluminal techniques;

[033] Figures 18 – 30 are schematic illustrations of various design alternatives of implantable devices; and

[034] Figures 31A and 31B are schematic views of a catheter for use in delivering implantable devices by transthoracic techniques.

Detailed Description of Exemplary Embodiments

[035] The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention.

[036] The various aspects of the devices and methods described herein generally pertain to devices and methods for treating heart conditions, including, for example, dilatation, valve incompetencies, including mitral valve leakage, and other similar heart failure conditions. Each disclosed device may operate passively in that, once placed on the heart, it does not require an active stimulus, either mechanical, electrical, hydraulic, pneumatic, or otherwise, to function. Implanting one or more of the devices operates to assist in the apposition of heart valve leaflets to improve valve function.

[037] In addition, these devices may either be placed in conjunction with other devices that, or may themselves function to, alter the shape or geometry of the heart, locally and/or globally, and thereby further increase the heart's efficiency. That is, the heart experiences an increased pumping efficiency through an alteration in its shape or geometry and concomitant reduction in stress on the heart walls, and through an improvement in valve function.

[038] However, the devices disclosed herein for improving valve function can be "stand-alone" devices, that is, they do not necessarily have to be used in conjunction with additional devices for changing the shape of a heart chamber or otherwise reducing heart wall stress. It also is contemplated that a device for improving valve function may be placed relative to the heart without altering the

shape of the chamber, and only altering the shape of the valve itself. In other words, the devices and methods described herein involve geometric reshaping of portions of the heart and treating valve incompetencies.

[039] The devices and methods described herein offer numerous advantages over the existing treatments for various heart conditions, including valve incompetencies. The devices are relatively easy to manufacture and use, and the transluminal, transthoracic, and surgical techniques and tools for implanting the devices do not require the invasive procedures of current surgical techniques. For instance, these techniques do not require removing portions of the heart tissue, nor do they necessarily require opening the heart chamber or stopping the heart during operation. For these reasons, the techniques for implanting the devices disclosed herein also are less risky to the patient than other techniques. The less invasive nature of these techniques and tools may also allow for earlier intervention in patients with heart failure and/or valve incompetencies.

[040] Although the methods and devices are discussed hereinafter in connection with their use for the mitral valve of the heart, these methods and devices may be used for other valves of the heart for similar purposes. One of ordinary skill in the art would understand that the use of the devices and methods described herein also could be employed for other valves of the heart. The mitral valve has been selected for illustrative purposes because a large number of the disorders occur in connection with the mitral valve.

[041] The devices and methods described herein are discussed herein with reference to the human heart H, but may be equally applied to other animal hearts not

specifically mentioned herein. For purposes of discussion and illustration, several anatomical features may be labeled as follows: left ventricle LV; right ventricle RV; left atrium LA; ventricular septum VS; right ventricular free wall RVFW; left ventricular free wall LVFW; atrioventricular groove AVG; mitral valve MV; tricuspid valve TV; aortic valve AV; pulmonary valve PV; papillary muscle PM; chordae tendeneae CT (or simply chordae); anterior leaflet AL; posterior leaflet PL; coaptation line CL; annulus AN; ascending aorta AA; thoracic aorta TA; azygos vein AZV; coronary sinus CS; cardiac vein CV; right coronary artery RCA; left anterior descending artery LAD; obtuse marginal artery OM; circumflex artery CFX; left lung LL; right lung RL; dermal layer DL; sternum ST; xiphoid XPH; diaphragm DPH; and vertebrae VRT.

[042] **General Description of Exemplary Implant Devices**

[043] With reference to Figures 1A and 1B, a generic implantable device 10 is shown schematically. The implantable device 10 may generally include two or more anchor ends 12/14 with a interconnecting member 16 connected therebetween. The anchor ends 12/14 may be configured to permanently or releasably attach to the outside of the heart wall. The interconnecting member 16 may be selectively tightened or loosened to correspondingly affect the tension between the anchor ends 12/14. A protrusion 18 may be connected to the interconnecting member 16 between the anchor ends 12/14. Alternatively, as shown in Figures 1C and 1D, the implantable device 10 may utilize anchor ends 12/14 and interconnecting member 16 alone, without the use of a protrusion 18. With or without protrusion 18, the interconnecting member may be generally flexible to conform to the outer surface of the heart.

Protrusion 18 may alternatively be referred to as a space filling member or a focal member. Interconnecting member 16 may alternatively be referred to as an elongate member or as a tension member.

[044] The position of the protrusion 18 may be adjusted relative to the anchor ends 12/14. To accommodate such adjustment, the interconnecting member 16 may be fixedly connected to one or both of the anchor ends 12/14 and adjustably connected to the protrusion 18. Alternatively, the interconnecting member 16 may be fixedly connected to the protrusion 18 and adjustably connected to one or both of the anchor ends 12/14. In both instances, the length of the interconnecting member 16 between the protrusion 18 and the anchor ends 12/14 may be adjusted to change the position of the protrusion 18 relative to the anchor ends 12/14.

[045] The anchors 12/14 serve to secure the ends of the interconnecting member 16 to the heart wall. The anchors 12/14 may comprise vacuum cups with tissue piercing pins for securement as described in more detail with reference to Figures 5A – 5D. The anchors 12/14 may be remotely activated as described with reference to Figures 6 and 7. The anchors 12/14 may selectively connect to some tissue (e.g., epicardium, myocardium) while remaining free of other tissue (e.g. pericardium). Various alternative anchor embodiments are envisioned, such as tines, screws, sutures, adhesives, etc., and/or a tissue in-growth promoting material (e.g., Dacron fabric). For example, the anchors 12/14 may comprise tines that extend through the epicardium and into the myocardium, and optionally extend through the endocardium into a heart chamber. Additional alternative anchor embodiments are described by Vidlund et al., '519.

[046] The interconnecting member 16 may be fixed or selectively fixed (i.e., adjustable) to each of the anchors 12/14 and/or the protrusion 18 as described above. The interconnecting member may be made fixed or adjustable using, for example, a lock pin technique as described in more detail with reference to Figures 5A – 5D.

[047] As an alternative to interconnecting member 16, or in conjunction with interconnecting member 16, pericardial tissue may be used to connect the anchor ends 12/14 and protrusion 18 (if used). For example, a first anchor end 12 may be fixedly secured to both the epicardium and the pericardium using an anchor device with open top and bottom surfaces as described in Vidlund et al., '519. The second anchor end 14 may be secured to epicardium, and the protrusion 18 may be secured to the pericardium (by using an anchor device for the protrusion 18). The interconnecting member 16 may be fixedly connected to the protrusion 18 and adjustably connected to the second anchor end 14 (or visa-versa) such that the position of the protrusion 18 may be adjusted (e.g., cinched) relative to the second anchor end 14. By virtue of the common pericardial connection between the first anchor 12 and the protrusion 18, cinching the interconnecting member 16 between the protrusion 18 and the second anchor 14 also causes cinching between the protrusion 18 and the first anchor 12, without requiring the interconnecting member 16 to be connected to the first anchor 12.

[048] The interconnecting member 16 may be elongate and will normally be in tension when implanted. The interconnecting member may comprise a flexible and biocompatible multifilament braid in the form of a string or strap, for example. If a string or chord is used, for example, an atraumatic pad (as seen in Figure 5A) may be

disposed on the interconnecting member 16 to avoid stress concentration on the heart wall by the interconnecting member 16.

[049] The interconnecting member 16 may be formed as described in U.S. Patent No. 6,537,198 to Vidlund et al., the entire disclosure of which is incorporated herein by reference. In particular, the interconnecting member 16 may comprise a composite structure including an inner cable to provide mechanical integrity and an outer covering to provide biocompatibility. The inner cable of interconnecting member 16 may have a multifilament braided-cable of high performance polymeric fibers such as ultra high molecular weight polyethylene available under the trade names Spectra™ and Dyneema™, polyester available under the trade name Dacron™, or liquid crystal polymer available under the trade name Vectran™. The filaments forming the inner cable may be combined, for example, in yarn bundles of approximately 50 individual filaments, with each yarn bundle being approximately 180 denier, and two bundles may be paired together (referred to as 2-ply) and braided with approximately 16 total bundle pairs with approximately 20 to 50 picks per inch (number of linear yarn overlaps per inch).

[050] The outer covering surrounding the inner cable of the interconnecting member 16 may provide properties that facilitate sustained implantation, and may thus be formed of a material that is biocompatible and allows for tissue ingrowth. For example, the outer covering surrounding the inner cable of the interconnecting member 16 may be made of a polyester material such as Dacron or ePTFE. If an atraumatic pad is used, it may be formed of, coated with, or covered by the same or similar material as the outer covering of the interconnecting member to promote tissue

in-growth for additional anchoring effect. For example, the atraumatic pad may be formed of ePTFE which is biocompatible, promotes tissue in-growth, and conserves cross-sectional size and shape despite elongation.

[051] The protrusion 18 may comprise a balloon, plug, or other mechanical spacer or structure, and may be fixedly or adjustably connected to the interconnecting member 16. The protrusion 18 may be centered between the anchors 12/14, or may be eccentrically positioned therebetween. One or more protrusions 18 may be used, and the protrusions may have various geometries depending on the desired allocation of forces acting on the heart wall. The protrusion 18 may be coated or covered by a tissue in-growth promoting material to secure the protrusion to the heart wall in the desired position, and the material may be highly elastic or otherwise stretchable to permit expansion of the protrusion 18. Examples of suitable materials include ePTFE and polyester knits.

[052] **Description of Exemplary Implant Positions and Functions**

[053] With reference to Figure 2A – 2C, cross sectional views of a patient's trunk at the level of the mitral valve MV of the heart H show the effects of implantable device 10 on mitral valve MV function. As seen in Figure 2A, an incompetent mitral valve MV is shown during systole, as rendered incompetent by, for example, a dilated valve annulus AN, a displaced papillary muscle PM due to ventricular dilation or other mechanism. With reference to Figures 2B and 2C, the implantable device 10 may be positioned outside and adjacent the heart wall such that the device 10 acts on the mitral valve MV. As seen in Figures 2B and 2C, the formerly incompetent mitral valve MV is shown during systole as corrected with

implantable device 10. The implantable device 10 causes inward displacement of a specific portion of the heart wall adjacent the mitral valve MV resulting in re-configuration and re-shaping of the annulus AN and/or the papillary muscles PM, thus providing more complete closure of the mitral valve leaflets AL/PL during systole, as shown by closed coaptation line CL in Figures 2B and 2C.

[054] The implantable device 10 may affect MV function by acting on the adjacent heart wall in several different modes. For example, in one mode of operation, the protrusion 18 (or the interconnecting member 16 if no protrusion is used) of the implantable device 10 may apply or focus an inward force against the heart wall acting on the MV. The back-up force (i.e., the substantially equal and opposite force to the inward force) may be provided by the interconnecting member 16 as fixed to the heart wall by the anchor ends 12/14, the anatomical structure behind the protrusion 18, or a combination thereof. In an alternative mode of operation, the implantable device 10 may act to cinch, compress or otherwise deform the heart wall surrounding the posterior aspect of the mitral valve MV by shortening the circumferential length thereof. In another alternative mode of operation, the implantable device 10 acts to both apply an inward force and cause circumferential shortening. In each of these modes of operation, the inward force and/or circumferential shortening may be applied throughout the cardiac cycle, or may only act during a portion of the cardiac cycle such as during systole.

[055] The implantable device 10 may be implanted in a number of different positions, a select few of which are described herein for purposes of illustration, not necessarily limitation. Generally, the implantable device 10 may be positioned

outside the epicardium of the heart wall adjacent the mitral valve MV, such as between the epicardium and pericardium, or between the pericardium and the pleural sac. Also generally, to maximize the effectiveness of the inward force, the implantable device 10 may be positioned to create a normal force against the heart wall that is generally orthogonal to the coaptation line CL formed by the leaflets PL/AL. This may be achieved, for example, by positioning the device 10 in a posterior-lateral projection of the mitral valve MV generally orthogonal to the middle tangent of the coaptation line CL as shown in Figures 2B and 2C.

[056] A variety of long axis and short axis positions are contemplated and the particular combination may be selected to have the desired effect. In the short axis view as seen in Figures 2B and 2C, the implantable device 10 may extend along all of, a portion of, or beyond the posterior-lateral projection of the mitral valve MV. In the long axis view as seen in Figure 3, the implantable device 10 may extend along all of, a portion of, or beyond the posterior-lateral projection of the mitral valve MV structures, including the papillary muscles PM, the chordae CT, the leaflets PL/AL, and the annulus AN. For example, the implantable device 10 may be positioned adjacent the annulus AN (e.g., extending slightly above and below the annulus AN near the AV groove), or adjacent the papillary muscles PM (e.g., extending slightly above and below the papillary muscles PM).

[057] To avoid compression of the coronary arteries which typically reside near the surface of the heart wall, the implantable device 10 may have relatively small contact areas selected and positioned to establish contact with the heart wall while avoiding key anatomical structures. For example, as shown in Figure 4, the

implantable device 10 may be positioned with the first anchor 12 positioned between the proximal left anterior descending artery LAD and the proximal first obtuse marginal OM1, the protrusion positioned inferior of the circumflex artery CFX between the second obtuse marginal OM2 and third obtuse marginal OM3, and the second anchor 14 positioned adjacent the posterior descending artery PDA. Alternatively, the implantable device 10 may have a relatively large surface area in contact with the heart wall to distribute the applied forces and avoid force focal points, particularly on the cardiac vasculature.

[058] **Description of Exemplary Delivery Techniques and Approaches**

[059] The implantable device 10 may be implanted using one or a combination of various methods and approaches. Generally, these delivery methods may be utilized to implant the device 10 in the pericardial space adjacent the posterior projection of the mitral valve MV. There are a number of different approaches and techniques for positioning the implantable device 10 as such, and these generally include surgical, transluminal and transthoracic techniques. For purposes of illustration, not necessarily limitation, an anterior transthoracic (subxiphoid) approach is described in more detail with reference to Figure 11. Examples of other suitable approaches are described in more detail by Vidlund et al., '519.

[060] **Exemplary Embodiments of Implant Devices**

[061] With reference to Figures 5A – 5D, perspective views of implantable devices 110, 210, 610 and 710, respectively, are shown. Note that the side of the device 110/210/610 that faces the heart wall when implanted is the top side in the illustration. Devices 110, 210, 610 and 710 are further exemplary embodiments of the

generic embodiment of implantable device 10 described previously, in which similar components have similar nomenclature, and such may be made, used and function in the same or similar manner.

[062] As seen in Figure 5A, implantable device 110 includes a first anchor 112, a second anchor 114, a interconnecting member 116, and an optional protrusion 118. Each of the first anchor 112, second anchor 114, interconnecting member 116, and protrusion 110 may be loaded with a radiopaque material to render the visible under x-ray. In this embodiment, the interconnecting member 116 may comprise cables 132 and 134, and the anchors 112 and 114 may comprise vacuum cups 120 with tissue piercing pins 122, as will be described in more detail hereinafter. The anchor members 112 and 114 may be selectively attached, released and re-attached to the heart, and the protrusion 118 may be selectively adjusted relative to the anchor members 112 and 114 by adjusting the respective lengths of the interconnecting member 116. The ends of the interconnecting member 116 may be fixedly attached to the anchors 112 and 114, and adjustment of the length of the interconnecting member 116 is provided by a locking mechanism 160 as seen in and described with reference to Figure 6A.

[063] The anchors 112 and 114 may comprise a vacuum cup 120 with a tissue piercing pin 122 extending through the interior thereof. The cup 120 may be injection molded, for example, of a suitable biocompatible material such as PEEK, HDPE or PTFE, and the piercing pins 122 may be formed of stainless steel, for example. The piercing pins 122 are slidingly received in two bores disposed in the walls of the cup 120. A locking mechanism such as mating geometry between the

bores and the pins may be used to lock the pins in the pierced position as shown. A port 124 in communication with the interior of the cup 120 is provided for releasable connection to an anchor catheter 400 as shown and described with reference to Figures 6A and 6B.

[064] Each cup 120 has a rim that conforms to the epicardial surface of the heart wall such that vacuum applied to the cup 120 by the anchor catheter 400 via port 124 draws the epicardial surface of the heart into the interior of the cup. With the epicardial tissue drawn inside the cup by the vacuum, the tissue piercing pin 122 may be advanced to pierce through the heart tissue and lock in the pierced position as shown. A lock mechanism such as illustrated in Figure 5E may be used to secure pins 122. In this manner, the anchors 112 and 114 may be secured to the outside surface of the heart wall.

[065] The protrusion 118 includes a base 140, an inflatable balloon 142 mounted to the base 140, and an outer covering 144 (shown partially cut-away) extending over the balloon 142. The base 140 may be connected to a locking mechanism 160 (not visible) located on the opposite side of the balloon 142, which in turn is connected to the interconnecting member 116. The base 140 may comprise a flexible or semi rigid polymeric material, and the balloon 142 may comprise a compliant or non-complaint polymeric material conventionally used for implantable balloons. Outer covering 144 may comprise a material that promotes tissue in-growth to provide additional anchoring stability over time. The balloon 142 may be pre-filled, or may be filled during implantation, with a liquid that may solidify (cured) over time. To facilitate inflation of the balloon 142, the interior of the balloon 142

may be in fluid communication with an inflation catheter via a lumen (not visible) extending through the locking mechanism 160 and the base 140 as described with reference to Figure 6A.

[066] The interconnecting member 116 may comprise two multifilament braided cables 132 and 134. One end of each cable 132 and 134 may be fixedly connected to the anchors 112 and 114, respectively, and the other ends of the cables 132 and 134 may be adjustably connected together by a locking mechanism 160 (not visible) attached to the base 140 of the protrusion 118. The cables 132 and 134 may extend through a pair of atraumatic pads 130 that are secured to the base 140 of the protrusion 118.

[067] As seen in Figure 5B, implantable device 210 includes a first anchor 212, a second anchor 214, a interconnecting member 216, and a protrusion 218. In this embodiment, the interconnecting member 216 includes a cable 232 extending through a strap 230, with one end of the cable 232 fixedly connected to first anchor 212, and the other end extending through second anchor 214 to which the cable may be selectively locked to adjust the length of the interconnecting member 216. A locking mechanism 260, similar to the locking mechanism 160 discussed with reference to Figure 6A, may be connected to the second anchor 214 for selective tightening of and fixation to cable 232. Otherwise, anchors 212 and 214 may be the same as anchors 112 and 114 described previously.

[068] Strap 230 may vary in length as a function of the length of the cable 232, and includes a plurality of pockets 234 that may be selectively filled with one or more plugs 236 to serve as the protrusion 218, or the pockets 234 may remain empty.

For example, selection of the pockets 234 to fill with plugs 236 may be made apply an inward force against the heart wall while avoiding or jumping over coronary arteries residing near the surface of the heart wall. Strap 230 may comprise a woven polymeric material as polyester, and the plug 236 may comprise a solid polymeric material such as PEEK, silicone, HDPE, PTFE or ePTFE.

[069] As seen in Figure 5C, implantable device 610 includes a first anchor 612, a second anchor 614, a interconnecting member 616, and a protrusion 618. In this embodiment, the interconnecting member 616 includes cable 632 extending through protrusion 618, with one end of the cable 632 fixedly connected to first anchor 612, and the other end extending through second anchor 614 to which the cable may be selectively locked to adjust the length of the interconnecting member 616. A locking mechanism 660, similar to the locking mechanism 160 discussed with reference to Figures 6A and 5E, may be connected to the second anchor 614 for selective tightening of and fixation to cable 632. Anchors 612 and 614 include interior cavities 620 in fluid communication with a vacuum source to accommodate heart tissue for securement thereto by tissue piercing pins 622. A port 624 in communication with the interior of the cup 620 is provided for releasable connection to an anchor catheter 400 or 800 as shown and described with reference to Figures 6A/6B and Figure 7, respectively. Recesses may be provided in each of the anchors 612 and 614 and the protrusion 618 for attachment of tissue in-growth promoting material such as Dacron fabric attached by suture-like material to cover the top, bottom and side surfaces. Otherwise, anchors 612 and 614 may be the same as anchors 112 and 114 described previously.

[070] Protrusion 618 may include a center rotating member 642 coupled to cross member 644 by pivot connection 646. The rotating member 642 may be rotated 90 degrees relative to cross member 644 about pivot 646 as indicated by arrows 640. The rotating member 642 may be rotated as indicated by arrows 640 between a low profile delivery configuration wherein the rotating member 642 is generally aligned with the cross member 644, and a deployed configuration wherein the rotating member 642 is generally orthogonal to the cross member 644 as shown. The rotating member 642 may be rotationally biased to the deployed configuration and may be locked in the deployed configuration. A pair of protrusions 648 may be disposed at opposite ends of the cross member 644. The rotating member 642 in addition to the protrusions 648 may function as protrusions as described previously, while the gap therebetween may be used to avoid critical anatomical structures such as coronary vasculature.

[071] As seen in Figure 5D, implantable device 710 includes a first anchor 712, a second anchor 714, a interconnecting member 716, and a protrusion 718. In this embodiment, the interconnecting member 716 includes cable 732 fixedly attached to and extending through protrusion 718, with both ends of the cable 732 adjustably connected to the anchors 712 and 714 by pins 752 to selectively lock and adjust the length of the interconnecting member 716. Anchors 712 and 714 include interior cavities 720 in fluid communication with a vacuum source to accommodate heart tissue for securement thereto by tissue piercing pins 722. A port 724 in communication with the interior of the cup 720 is provided for releasable connection to an anchor catheter 400 or 800 as shown and described with reference to Figures

6A/6B or Figure 7, respectively. Recesses may be provided in each of the anchors 712 and 714 and the protrusion 718 for attachment of tissue in-growth promoting material such as Dacron fabric attached by suture-like material to cover the top, bottom (inside anchor) and side surfaces (away from heart surface). Otherwise, anchors 712 and 714 may be the substantially the same as anchors 112 and 114 described previously.

[072] Protrusion 718 may include a center rotating member 742 coupled to cross member 744 by pivot connection 746. The rotating member 742 may be connected to the cross member 744 by an elastic ring and may be rotated 90 degrees relative to cross member 744 about pivot 746 as indicated by arrows 740. The rotating member 742 may be rotated as indicated by arrows 740 between a low profile delivery configuration wherein the rotating member 742 is generally aligned with the cross member 744, and a deployed configuration wherein the rotating member 742 is generally orthogonal to the cross member 744 as shown. The rotating member 742 may be rotationally biased to the deployed configuration and may be locked in the deployed configuration. A pair of protrusions 748 may be disposed at opposite ends of the cross member 744. The rotating member 742 in addition to the protrusions 748 may function as protrusions as described previously, while the gap therebetween may be used to avoid critical anatomical structures such as coronary vasculature.

[073] As seen in Figure 5E, an example of a lock mechanism is shown to secure tissue piercing pins 722 and/or cable piercing pins 752. The pins 722/752 may include a cylindrical shaft 754 and a sharpened tip 756 with a recess 755 therebetween. A braided multifilament material 758 such as Spectra™ is provided

distal of the pins 722/752 in the anchor housing 712/714 to catch the recess 755 of the pins 722/752 when the tip 756 is advanced therethrough. This effectively locks the pins 722/752 in the advanced position to secure the interconnecting member 716 to the anchors 712 and 714 and/or to secure the anchors 712 and 714 to the heart tissue as will be described in more detail hereinafter.

[074] **Exemplary Embodiments of Delivery Devices**

[075] With reference to Figure 6A, an example of a delivery system for delivery and implanting device 110 is shown. The delivery system generally includes a delivery catheter 300 and two anchor catheters 400, all of which are releasably connected to the implantable device 110. The illustrated delivery system is particularly suitable for delivering implantable device 110, but may also be modified for delivery of implantable devices 210, 610 and 710. The delivery system may be configured in terms of size, length, flexibility, radiopacity, etc., to facilitate a transthoracic delivery approach such as the subxiphoid delivery approach described with reference to Figure 11.

[076] The delivery catheter 300 includes a tubular shaft 310 defining an inflation lumen and two cable lumens extending therethrough. A pair of push tubes 312 extend along side the tubular shaft 310 and slidably accommodate push rods 332 and 334. The distal ends of the tubular shaft 310 and push tubes 312 are coupled to the locking mechanism 160 by a release mechanism 326 such as a threaded, pinned or other releasable connection, such as the pin mechanism illustrated in Figure 5E. The push rods 332 and 334 may be advanced or retracted to selectively actuate individual pins 162 and 164 respectively in the lock mechanism 160 such that the pins 162 and

164 pass through the cables 132 and 134, respectively, and thus lock the cables relative thereto. Reference may be made to published U.S. Patent Application No. 2003/0050529 to Vidlund et al., the disclosure of which is incorporated herein by reference, for an example of a similar locking mechanism.

[077] The proximal end of the tubular shaft 310 is connected to a manifold including connectors 322 and 324 and inflation port 318. The inflation lumen of the tubular shaft 310 provides fluid communication between the interior of the balloon 142 and the inflation port 318 of the manifold 314 for connection to an inflation device (not shown) to facilitate inflation and deflation of the balloon 142. If no balloon 142 is used, the inflation lumen and associated parts may be eliminated. The cable lumens of the tubular shaft 310 accommodate the proximal portions of the cables 132 and 134 for connection to a sizing device 500 via connectors 322 and 324 as described with reference to Figure 8, and for positioning the implant 110 relative to the anchors 112 and 114.

[078] With additional reference to Figure 6B, the anchor catheters 400 are essentially mirror constructions of each other, and include a tubular shaft 410. A slit guide tube 412 extends along side a portion of the tubular shaft 410 to guide the cable 132/134 before the delivery catheter 300 is advanced as will be discussed in more detail hereinafter. A proximal end of the tubular shaft 410 is connected to a manifold 418 including a vacuum port 416 and a gasketed port 415 containing a push rod 414. A distal end of the tubular shaft 410 is releasably connected to the anchor 112/114 by a release mechanism 420 that may comprise a threaded, pinned or other releasable connection, for example. The tubular shaft 410 includes a vacuum lumen (not visible)

extending therethrough to provide a fluid path from the interior of the cup 120 to the vacuum port 416 to facilitate connection to a vacuum source. The push rod 414 is disposed in the vacuum lumen of the catheter shaft 410 and may be slid therethrough to selectively advance or retract the piercing pin 122 in the cup 120.

[079] With reference to Figure 7, an example of a delivery system for delivery and implanting device 710 is shown. The delivery system generally includes a two anchor catheters 800, both of which are releasably connected to the implantable device 710. The illustrated delivery system is particularly suitable for delivering implantable devices 210, 610 and 710, but may also be modified for delivery of implantable device 110. The delivery system may be configured in terms of size, length, flexibility, radiopacity, etc., to facilitate a transthoracic delivery approach such as the subxiphoid delivery approach described with reference to Figure 11.

[080] The anchor catheters 800 are essentially mirror constructions of each other (with the exception of split tube 813), and include a tubular shaft 810 comprising a directional catheter construction connected to a handle 850. The directional catheter shaft 810 and associated handle 850 are available from Medamicus, Inc. of Plymouth, Minnesota. Handle 850 generally includes a grip portion 852 and a thumb knob 854 which actuates control wires in the directional catheter shaft 810 to permit selective bi-directional lateral deflection of the distal end thereof. The directional catheter shaft 810 and associated handle 850 accommodate a push rod (not visible) extending therethrough for actuation of the tissue piercing pin 722. The push rod for the tissue piercing pin 722 may comprise a stainless steel mandrel, for example, with a distal end abutting the proximal end of the tissue

piercing pin 722, and a proximal end connected to a knob 814. The directional catheter shaft 810 and associated handle 850 also accommodate a vacuum lumen (not visible) extending therethrough to define a fluid path to the interior 720 of the anchor 712/714, such that a vacuum source (not shown) may be connected to vacuum port 816 on the handle 850 to provide suction at the anchor 712/714 to facilitate stabilization and securement to the outside of the heart wall.

[081] Each of the anchor catheters 800 also includes a side tube 812 coextending with the directional catheter shaft 810. Side tube 812 accommodates the interconnecting member 732, a push rod (not visible) for actuation of the interconnecting member piercing pin 752, and a pull wire (not visible) for release of the anchor 712/714 as described in more detail below. The interconnecting member 732 extends through the side tube 812 from a proximal port 822/824 through the anchor 712/714 to the protrusion 718. To accommodate the interconnecting member 732 during initial delivery of the implant 710, a slotted side tube 813 may be provided on one of the catheters 800.

[082] The push rod for the interconnecting member piercing pin 752 may comprise a stainless steel mandrel, for example, with a distal end abutting the proximal end of the interconnecting member piercing pin 752, and a proximal end connected to knob 832/834. A pair of guide loops 815 may be provided distal of the side tube to guide the interconnecting member 732, and a guide tube 862/864 may be provided distal of the side tube 812 to guide the push rod for the interconnecting member piercing pin 752.

[083] The distal end of the directional catheter shaft 810 is connected to anchor 712/714 by a releasable connection 820, which may comprise a threaded type connection or a cotter pin type connection, for example. In the illustrated embodiment, the releasable connection 820 comprises a cotter pin type connection, with the pull wire (not visible) proximally connected to pull knob 842/844, and distally extending through aligned holes (not visible) in the anchor 712/714 and in the fitting on the distal end of the directional catheter shaft 810. By pulling proximally on pull knob 842/844, the anchor 712/714 may be released from the distal end of the directional catheter shaft 810.

[084] With reference to Figure 8, a sizing device 500 is shown for adjusting the tension of interconnecting member 116, 216, 616, or 716 and in particular cable members 132/134, 232, 632 or 732. Sizing device 500 includes an elongate interconnecting member receiving tube 510 having a distal end including an engagement member 512 and a proximal end 516 connected to a preferably clear measuring tube 514 having a measuring scale 515 marked thereon. An inner tube 518 is disposed in the measuring tube 514 and is connected to a proximal end of the cable member to be tensioned. A lock mechanism 522 and release button 524 (biased in locked position) are connected to the proximal end of the measuring tube 514 to selectively lock the inner tube 518 relative to the measuring tube. A pin 522 protruding from inner tube 518 extends through a slot in measuring tube 514 to prevent relative rotation. An indicator (not visible) on the inner tube 518 adjacent the pin 522 is visible through transparent measuring tube 514 to facilitate linear measurement relative to scale 515.

[085] To connect the cable to the inner rod or tube 518, the cable 132/134, 232, 632 or 732 is threaded through receiving tube 510, through measuring tube 514, through the inner tube 518, and placed in a retaining mechanism 520 disposed on the inner tube 518. Engagement member 512 may be connected to one of the connectors 322/324 or 822/824 on the delivery catheter, or directly to the lock mechanism 160 of device 110 or lock mechanism of device 210. With this arrangement, the inner tube 518 may be pulled proximally relative to the measuring tube 514 to apply tension to the cable and thus selectively adjust the tightness or degree of cinching of the implantable device 110/210/610/710, and/or selectively adjust the position of the protrusion relative to the anchor ends.

[086] **Exemplary Embodiments of Access Devices**

[087] With reference to Figure 9, an exemplary embodiment of an access device 1000 is shown. Access device 1000 provides for less invasive surgical access from a point outside the patient's body, through a transthoracic port to the pericardial space around the patient's heart, as will be described in more detail with reference to Figure 11. A variety of pericardial access devices may be used to delivery the implantable device 10, and thus access device 1000 is shown by way of example not limitation. In this exemplary embodiment, access device 1000 includes an outer tube 1100, a securement tube 1200, and a cutter tube 1300. The securement tube 1200 is slidably and coaxially disposed in outer tube 1100, and similarly, the cutter tube 1300 is slidably and coaxially disposed in the securement tube 1200.

[088] Outer tube 1100 may comprise a rigid tubular shaft 1102 formed of stainless steel, for example, having a lumen extending therethrough. A cap 1104

having an interior recess (not visible) may be connected to the distal end of the shaft 1102. A handle 1106 may be connected to a proximal end of the tubular shaft 1102 to facilitate manual manipulation. A vacuum port 1108 may be incorporated into the handle 1106 to facilitate connection to a vacuum source (not shown) for establishing a vacuum in the lumen extending through the tubular shaft 1102.

[089] The securement tube 1200 may comprise a rigid tubular shaft 1202 formed of stainless steel, for example, having a lumen extending therethrough. An annular array of pericardium piercing pins 1204 may be disposed at the distal end of the tubular shaft 1202, and are sized to fit in the recess inside cap 1104 at the distal end of the outer tube 1100 as will be discussed in more detail with reference to Figure 10. A handle 1206 may be disposed at the proximal end of the tubular shaft 1202 to facilitate manual manipulation and to act as a stop to prevent the securement tube 1200 from advancing fully into outer tube 1100. A vacuum hole 1208 may be provided through the side of the tubular shaft 1202 to provide a fluid path from the interior of the outer tube 1100 to the interior of the securement tube 1200, thus permitting a vacuum to be established inside the tubular shaft 1202 of the securement tube 1200 by application of a vacuum to vacuum port 1108.

[090] The cutter tube 1300 may comprise a rigid tubular shaft 1302 formed of stainless steel, for example, having a lumen extending therethrough. An annular cutting edge 1304 may be disposed at the distal end of the tubular shaft 1302. An annular ring 1306 may be disposed adjacent the distal end of the tubular shaft 1302 to provide a slidable fluid seal with the inside surface of the tubular shaft 1202 of the securement tube 1200. A series of vacuum holes 1308 may be provided through the

side of the tubular shaft 1302 distal of the annular ring 1306 to provide a fluid path from the interior of the securement tube 1200 to the interior of the cutter tube 1300, thus permitting a vacuum to be established inside the tubular shaft 1302 of the cutter tube 1300 by application of a vacuum to vacuum port 1108. A handle 1310 may be disposed at the proximal end of the tubular shaft 1302 to facilitate manual manipulation and to act as a stop to prevent the cutter tube 1300 from advancing fully into securement tube 1200. A visualization device 1320 such as a camera or eye piece 1322 and light source 1324 may be connected to the proximal end of the tubular shaft 1302 to permit direct visualization down the lumen of the cutter tube 1300. Alternatively, an intracardiac echo device may be inserted therethrough, using vacuum for stability, to permit visualization and guidance on the epicardial surface.

[091] With reference to Figures 9 and 10, the operation of the distal portion of the access device 1000 may be appreciated. The cutter tube 1300 and the securement tube 1200 may be disposed in the outer tube 1100 with the distal ends thereof slightly retracted. The outer tube 1100 may be inserted through a transthoracic port until the distal cap 1104 engages the pericardium (PC) surrounding the heart. Vacuum is applied to port 1108 thus drawing the PC into the lumen of the outer tube 1100, the securement tube 1200, and the cutter tube 1300 to form inward protrusion. The vacuum also draws the PC into the interior recess of the cap 1104 to form an annular fold. The securement tube 1200 may then be advanced distally until the array of pins 1204 passes through the annular fold in the PC, thus mechanically securing and sealing the PC to the access device 1000. The cutter tube 1300 may then be advanced distally until the annular cutting edge 1304 cuts the inward protrusion of

the PC, leaving the annular fold of the PC secured to the access device 1000. With the annular fold of the PC mechanically and sealingly connected to the distal end of the access device 1000, and with the outside diameter of the access device 1000 sized to form a seal in the transthoracic port, a sealed access path is established to the pericardial space that is isolated from the pleural space.

[092] **Exemplary Embodiments of Access and Delivery Methods**

[093] In Figure 11, a transthoracic anterior approach is shown as a dashed line with a distal arrow. This anterior approach may comprise a subxiphoid approach to establish access to the pericardial space, similar to the technique described by Kaplan et al. in U.S. Patent No. 6,423,051 the entire disclosure of which is incorporated herein by reference. An alternative lateral or posterior approach may utilize similar tools and techniques to access the pericardial space from the side or back between the ribs (intercostal space), similar to the techniques described by Johnson in U.S. Patent No. 5,306,234 the entire disclosure of which is incorporated herein by reference.

[094] Generally speaking, once pericardial access is established with an access system as described with reference to Figures 9 and 10, a delivery system as described with reference to Figures 6 and 7 may be used to advance and manipulate the device 10 to the desired deployment position in the pericardial space adjacent the mitral valve MV or a specific part thereof. Assessment of the position and function of the device 10 relative to internal mitral valve MV structures such as leaflets AL/PL, papillary muscles PM, and regurgitant jet may be performed with ultrasonic imaging such as trans-esophageal, intracardiac or epicardial echocardiography, or x-ray

fluoroscopy. These techniques may also be used monitor the adjustment of the size and/or tension of the device 10 with an adjustment device as described with reference to Figure 8 until the desired acute effect is established. Once in the desired position, the device 10 may be detached or otherwise disengaged from the distal end of the delivery system, which is subsequently removed.

[095] The following detailed example of a delivery method using the delivery system and implant illustrated in Figure 7 is described by way of example, not limitation, and may be applied to other delivery systems and implants described herein. This method may be broken down into six general steps: (1) establish pericardial access; (2) deliver the first anchor (e.g., near the PDA); (3) deliver the protrusion; (4) deliver the second anchor (e.g., near the LAD); (5) adjust the implant to achieve the desired effect on MV function; and (6) remove the delivery system leaving the implant in place on the outside of the heart.

[096] To establish pericardial access, a needle may be inserted into the chest cavity below the xiphoid as generally shown in Figure 11. A guide wire (e.g., 0.035" diameter) may then be inserted into the needle and advanced toward the cardiac space. The needle may then be removed leaving the guide wire in place, and one or more dilators may then be advanced over the guide wire to dilate the percutaneous path. The dilator(s) may then be removed, and the access device illustrated in Figure 9 may be advanced over the wire adjacent the pericardium. Fluoroscopic visualization (e.g., AP and lateral views) may be used to confirm the desired pericardial access site.

[097] Using the access device illustrated in Figure 9, vacuum may be applied to cause the pericardium to be sucked into the distal end thereof, and the tissue

piercing pins may be actuated to mechanically secure the pericardium to the access device. The cutter tube may then be advanced to cut and remove a portion of the pericardium in the distal end of the access device, thus establishing a path from the exterior of the body to the pericardial space around the heart.

[098] Initially, the interconnecting member may be loaded into the first anchor and anchor catheter with one side of the interconnecting member extending through the side tube and the other side of the interconnecting member extending through the slotted side tube. Before delivering the anchor, angiographic visualization of the left and/or right coronary arteries may be performed to map the locations of the critical arteries. To deliver the first anchor near the PDA as shown in Figure 4, for example, the anchor catheter may be manipulated through the access device until the anchor is adjacent the PDA near the last obtuse marginal (OM3), using fluoroscopic visualization to aid navigation. After ascertaining that the first anchor is not positioned over any coronary arteries, vacuum may be applied to the first anchor to temporarily stabilize the anchor on the outside of the heart wall and to pull tissue into the interior of the anchor. The tissue piercing pins may then be actuated to secure the first anchor to the heart wall.

[099] The protrusion may then be advanced along the first anchor catheter by removing one end of the interconnecting member from the slotted tube on the anchor catheter, inserting it through the protrusion and fixing the protrusion midway on the interconnecting member. A delivery tube may be placed about the protrusion to retain it in the delivery configuration, and the delivery tube with the protrusion therein may then be inserted through the access device. By pulling on the opposite end of the

interconnecting member and by manipulating the delivery tube, the protrusion may be advanced until it is adjacent the first anchor.

[0100] Before delivering the second anchor near the LAD as shown in Figure 4, the interconnecting member may be inserted into the second anchor and through the side tube of the second anchor catheter. The second anchor may then be slid over the interconnecting member using the anchor catheter, passing through the access device and into the pericardial space. With the aid of fluoroscopic guidance, the second anchor may be positioned next to the junction of the LAD and CFX as seen in Figure 4, for example. After ascertaining that the second anchor is not positioned over any coronary arteries, vacuum may be applied to the second anchor to temporarily stabilize the anchor on the outside of the heart wall and to pull tissue into the interior of the anchor. The tissue piercing pins may then be actuated to secure the second anchor to the heart wall.

[0101] With the first and second anchors secured to the outside of the heart wall, and the protrusion extending therebetween, the interconnecting member may be tightened or cinched using the device illustrated in Figure 8, for example. MV function may be simultaneously observed using TEE or ICE, and the degree of cinching of the interconnecting member and/or the position of the protrusion may be adjusted to obtain the desired reduction in MV regurgitation (MVR).

[0102] With the aid of fluoroscopy, correct anchor positioning may be verified and adequate blood flow may be confirmed in the left coronary arteries. After confirming correct positioning and adequate reduction in MVR, the interconnecting members may be secured by actuating interconnecting member piercing pins with the

associated push rods, and the directional catheter shaft may be disconnected from the anchors by actuating the releasable connection with the associated pull wires.

[0103] The delivery system may then be removed, and the interconnecting members may be trimmed adjacent the anchors with a cutting device such as an elongate cautery tool. The access device may be removed and the sub-xiphoid access site may be closed using sutures.

[0104] **Alternative Delivery Approaches**

[0105] Various alternative approaches for delivering the implantable devices may be utilized. By way of example, not limitation, the implant may be positioned outside the wall of the heart H adjacent the mitral valve MV to improve valvular function as described previously. The implant may be positioned outside the epicardium, such as between the epicardium and pericardium, or between the pericardium and the pleural sac, for example. There are a number of different approaches and techniques for positioning the implant as such, and these approaches generally include surgical, transluminal and transthoracic techniques. An example of a suitable surgical technique is conventional open heart surgery similar to that which is performed for coronary artery bypass surgery (CABG) or valve repair, which may be performed on-pump or off-pump. Examples of transluminal and transthoracic approaches are described below.

[0106] An example of a transluminal approach is via the coronary sinus CS. The coronary sinus CS may be catheterized by, for example, using a guide catheter and guide wire navigated through the inferior vena cava IVC or superior vena cava SVC from a convenient venous access site such as a femoral, brachial or jugular

approach. A guide catheter may be navigated into the right atrium RA and the distal end of the guide catheter may be seated in the ostium of the coronary sinus CS. A delivery catheter may be navigated through the guide catheter into the coronary sinus CS, with its distal end positioned near the desired exit point into the pericardial space. A guide wire may be advanced through the delivery catheter, out the distal end of the delivery catheter, and penetrate through the wall of the coronary sinus CS at the exit point. The delivery catheter may be advanced over the guide wire and through the hole in the coronary sinus CS and manipulated to the desired deployment position in the pericardial space adjacent the mitral valve MV or a specific part thereof.

[0107] The implant, which may be predisposed at the distal end of the delivery catheter or advanced to the distal end thereof, is then manipulated into the desired position and actuated, if necessary. The position of the implant may be monitored and confirmed using medical imaging techniques such as radiographic techniques, for example, with radiopaque material incorporated into the implant and/or the distal end of the delivery catheter. Upon deployment and actuation of the implant, assessment of the position of the implant relative to internal mitral valve MV structures such as leaflets AL/PL, papillary muscles PM, and regurgitant jet may be performed with ultrasonic imaging such as trans-esophageal, epicardial or intracardiac echocardiography. These techniques may also be used to refine the position of the implantable device until the desired acute effect is established. Once in the desired position, the implantable device may be detached or otherwise disengaged from the distal end of the delivery catheter, and the delivery catheter, guide wire and guide catheter may be removed. If desired, a catheter or small tube may remain

permanently or temporarily attached to the implantable device to selectively adjust the tension of the interconnecting member or the size of the protrusion (e.g., by adding or removing material therefrom).

[0108] Another example of a transluminal approach is via a cardiac vein CV. This approach is similar to the coronary sinus CS approach described above except that the delivery catheter is navigated further through the coronary sinus CS and into a desirable cardiac vein CV near the desired implant site. The cardiac vein CV may be catheterized by, for example, using a guide catheter and guide wire navigated through the inferior vena cava IVC or superior vena cava SVC from a convenient venous access site such as a femoral, brachial or jugular approach. The guide catheter may be navigated into the right atrium RA and the distal end of the guide catheter may be seated in the ostium of the coronary sinus CS. The delivery catheter may be navigated through the guide catheter into the coronary sinus CS, into a cardiac vein CV, with its distal end positioned near the desired exit point into the pericardial space. The guide wire may be advanced through the delivery catheter, out the distal end of the delivery catheter, and penetrate through the wall of the cardiac vein CV at the exit point. The delivery catheter may be advanced over the guide wire and through the hole in the cardiac vein CV and manipulated to the desired deployment position in the pericardial space adjacent the mitral valve MV or a specific part thereof. Having established access to the desired implant position, the remaining steps for implantation may be the same or similar to those described above.

[0109] Yet another example of a transluminal approach is via the azygos vein AZV. The azygos vein AZV extends past the posterior aspect of the heart H near the

left-right midline. The azygos vein AZV may be catheterized by, for example, using a guide catheter and guide wire navigated through the venous system from a convenient venous access site such as a femoral vein. The guide catheter may be navigated up to and adjacent the desired exit point adjacent the mitral valve MV or a specific part thereof. The delivery catheter may be navigated through the guide catheter until the distal end of the delivery catheter exits the distal end of the guide catheter and is positioned near the desired exit point. The guide wire may be advanced through the delivery catheter, out the distal end of the delivery catheter, and penetrate through the wall of the azygos vein AZV at the exit point. The delivery catheter may be advanced over the guide wire and through the hole in the azygos vein AZV and manipulated to the desired deployment position in the pericardial space adjacent the mitral valve MV or a specific part thereof. Having established access to the desired implant position, the remaining steps for implantation may be the same or similar to those described above.

[0110] A further example of a transluminal approach is via the right atrium RA. The pericardial space may be accessed via the right atrium RA using a percutaneous transatrial technique wherein the right atrium or right atrial appendage is catheterized by, for example, using a guide catheter and guide wire navigated through the inferior vena cava IVC from a convenient venous access site such as a femoral approach. The guide catheter may be navigated into the right atrium or atrial appendage and the guide wire may be used to puncture through the atrial wall to gain access to the pericardial space. The delivery catheter may be advanced over the guide wire and through the hole in the atrial wall and manipulated to the desired deployment

position in the pericardial space adjacent the mitral valve MV or a specific part thereof. Having established access to the desired implant position, the remaining steps for implantation may be the same or similar to those described above.

[0111] Yet a further example of a transluminal approach is via the left ventricle LV. The pericardial space may be accessed via the left ventricle LV using a percutaneous transventricular technique wherein the left ventricle LV is catheterized by, for example, using a guide catheter and guide wire navigated through the ascending aorta AA from a convenient arterial access site such as a femoral approach. The guide catheter may be navigated into the left ventricle LV and the guide wire may be used to puncture through the ventricular wall to gain access to the pericardial space. The delivery catheter may be advanced over the guide wire and through the hole in the ventricular wall and manipulated to the desired deployment position in the pericardial space adjacent the mitral valve MV or a specific part thereof. Having established access to the desired implant position, the remaining steps for implantation may be the same or similar to those described above.

[0112] An alternative LV approach is across the atrial septum. The pericardial space may be accessed via the left ventricle LV using a percutaneous transventricular technique wherein the left ventricle LV is catheterized by, for example, using a guide catheter and guide wire navigated through the inferior vena cava IVC from a convenient venous access site. The guide wire may be navigated into the right atrium RA, through the atrial septum, into the left atrium LA, through the mitral valve MV, into the left ventricle LV, and punctured through the left ventricular wall to gain access to the pericardial space. The delivery catheter may be advanced over the guide

wire and through the hole in the ventricular wall and manipulated to the desired deployment position in the pericardial space adjacent the mitral valve MV or a specific part thereof. Having established access to the desired implant position, the remaining steps for implantation may be the same or similar to those described above.

[0113] Another transluminal approach is via the left atrium LA. The pericardial space may be accessed via the left atrium LA using a percutaneous transatrial technique wherein the left atrium LA is catheterized by, for example, using a guide catheter and guide wire navigated through the inferior vena cava IVC from a convenient venous access site. The guide wire may be navigated into the right atrium RA, through the atrial septum, into the left atrium LA, and punctured through the left atrial wall to gain access to the pericardial space. The delivery catheter may be advanced over the guide wire and through the hole in the atrial wall and manipulated to the desired deployment position in the pericardial space adjacent the mitral valve MV or a specific part thereof. Having established access to the desired implant position, the remaining steps for implantation may be the same or similar to those described above.

[0114] Yet another transluminal approach is via the esophagus ES. The esophagus ES extends past the heart H near the posterior aspect of the right atrium. Because the esophagus ES does not provide a sterile environment, as isolation catheter may be used to isolate a portion of the esophageal lumen and establish a sterile environment. The isolation catheter may be inserted through nasal passage, past the pharynx, and into the esophagus ES. Alternatively, the isolation catheter may be inserted into the esophagus ES via the mouth. The distal portion of the

isolation catheter may be positioned adjacent the heart H at the level of the mitral valve MV as confirmed by a suitable visualization techniques such as ultrasonic imaging (e.g., trans-esophageal, trans-thoracic, epicardial or intracardiac echocardiography). Once in the desired position, the isolation catheter may be actuated and the confined space may be flushed with a suitable sterilizing wash. Having established an isolated sterile environment, a guide wire may be advanced through the isolation catheter exiting near the isolated space and puncturing the esophageal wall at the desired exit point. The delivery catheter may be advanced over the guide wire and through the hole in the esophageal wall and manipulated to the desired deployment position in the pericardial space adjacent the mitral valve MV or a specific part thereof. Having established access to the desired implant position, the remaining steps for implantation may be the same or similar to those described above.

[0115] Examples of transthoracic approaches include anterior and posterior approaches. The anterior approach may comprise a subxiphoid approach to establish access to the pericardial space similar to the techniques described previously. The posterior approach may utilize similar tools and techniques to access the pericardial space from the back between the ribs and extending into the thoracic cavity. Once pericardial access is established with, for example, a thoracic guide catheter used in such techniques, a delivery catheter may be advanced over or together with a guide wire and manipulated to the desired deployment position in the pericardial space adjacent the mitral valve MV or a specific part thereof. Having established access to the desired implant position, the remaining steps for implantation may be the same or similar to those described above.

[0116] **Alternative Implants & Delivery Tools**

[0117] With reference to Figure 12, a schematic plan view of a delivery catheter 2020 and a guide wire 2040 is shown for use in delivering a implantable device 2010 by the transluminal techniques described above, for example. Delivery catheter 2020 includes an elongate shaft 2022 that is sized appropriately as a function of the delivery approach, both in terms of the size of the lumen and the distance from the access point to the deployment point. As seen in Figure 13A, the elongate shaft 2022 may comprise a coaxial over-the-wire design with an outer tube 2032 coaxially disposed about an inner tube 2034. The inner tube may define a guide wire lumen 2035 and the annular space between the outer tube 2032 and the inner tube 2034 may define an inflation lumen 2033. Alternatively, as seen in Figure 13B, the elongate shaft 2022 may comprise an innerless, semi-movable wire, or fixed-wire design with the outer tube 2032 coaxially disposed about the guide wire 2040, and a distal (movable, semi-movable or fixed) fluid seal provided between the distal end of the outer tube 2032 and a distal portion of the guide wire 2042. In this alternative design, the outer tube 2032 may define a combined guide wire lumen 2035 and inflation lumen 2033. In both designs, the outer tube 2032 includes an opening (not shown) to establish fluid communication with the interior 2012 of the implantable device 2010.

[0118] A manifold 2024 may be connected to the proximal end of the elongate shaft 2022 and may include an inflation lumen arm 2026 and a through lumen arm 2028. The inflation lumen arm 2026 is in fluid communication with the inflation lumen 2033 extending through the shaft 2022 and the interior 2012 of the implantable device 2010. The through lumen arm 2028 provides access for the guide wire 2040 to

extend into the guide wire lumen 2035 through the shaft 2022 and through the implantable device 2010. The inflation lumen arm 2026 may be connected to an inflation device or other source of filler material such that material may be selectively added to or removed from the interior 2012 defined by wall 2014 of the implantable device 2010.

[0119] The implantable device 2010 may be releasably connected to a distal portion of the shaft 2022 by a release mechanism 2030 (shown schematically). The release mechanism 2030 may comprise a wide variety of forms known in the art related to detachable balloons and detachable coils. The release mechanism 2030 may be actuated at the proximal end of the catheter 2020 by an appropriate means depending on the type of release mechanism utilized. The release mechanism 2030 operates to secure the implantable device 2010 to the distal portion of the shaft 2022 during delivery until the implantable device 2010 is the desired deployment position. Once the implantable device is in the desired position and expanded, the release mechanism 2030 may be actuated to sever the connection between the delivery catheter 2020 and the implantable device 2010.

[0120] The guide wire 2040 may have sufficient length to extend through the delivery catheter, and sufficient flexibility and column strength to facilitate manipulation, navigation and tissue puncture capabilities. The size and shape of the distal tip 2042 of the guide wire 2040 may be selected as a function of what lumen need to be navigated and what tissue needs to be penetrated. For example, the distal tip 2042 may comprise a rounded tip having a diameter similar to a coronary guide wire to enable navigation through the vasculature and pericardial space, but with

sufficient stiffness to puncture venous walls and atrial walls. Alternatively, the distal tip 2042 may have a smaller diameter or may be sharpened to puncture ventricular walls, esophageal walls, etc.

[0121] With reference to Figures 15A and 15B, schematic top and side views of a transdermal access port 2050 connected to a implantable device 2010 by a flexible catheter 2060. The transdermal access port 2050 may be used to selectively add or remove material to or from (e.g., inflate or deflate) the implantable device 2010 after the device 2010 has been deployed and the delivery procedure has been completed. For example, if the desired acute effect is achieved during deployment of the implantable device 2010, but thereafter the effect diminishes or otherwise changes in an undesirable way, it may be desirable to modify the size and/or shape of the implantable device 2010 by selectively adding or removing material form the device 2010 using the transdermal access port 2050.

[0122] The transdermal access port 2050 generally includes a base housing 2052 and a reservoir housing 2054 containing a reservoir (not visible) therein. A septum 2056 is disposed over the top of the reservoir in the housing 2054 and permits a needle to be inserted into the reservoir. The catheter 2060 is connected to the reservoir housing 2054 at strain relief 2058 and is in fluid communication with the reservoir therein. The transdermal access port 2050 may be implanted just below the dermal layer DL at a convenient access point such as in the pectoral region. The catheter 2060 extends from the subdermal location of the transdermal access port 2050 to the implantable device 2010 located adjacent the heart. With this arrangement, a needle may be used to inject fluid, for example, through the septum

2056 and into the reservoir of the transdermal access port 2050. From the reservoir of the transdermal access port 2050, the fluid passes through the flexible catheter 2060 and into the interior 2012 of the implantable device 2010 to increase its size and/or shape. In a similar manner, a needle may be used to withdraw fluid from the interior 2012 of the implantable device 2010 to decrease its size and/or shape. The catheter 2060 may be connected to the implantable device 2010 prior to deployment thereof and snaked to the transdermal access port 2050 via the delivery path defined by the delivery catheter or via an alternative route to the transdermal access port 2050, which may be surgically placed in a subdermal pocket. Alternatively, the catheter 2060 may be connected to the implantable device 2010 after deployment thereof.

[0123] With reference to Figure 16, a schematic plan view of a guide catheter 2070 is shown, for use in delivering a implantable device 2010 by transluminal techniques, for example. The guide catheter 2070 includes an elongate shaft 2072 that is sized appropriately as a function of the delivery approach, both in terms of the size of the lumen and the distance from the access point to the deployment point. A hub 2074 may be connected to the proximal end of the shaft 2072 to facilitate insertion of a delivery catheter and/or guide wire, and to permit connection to a syringe for infusion of fluids such as radiopaque media. The construction of the shaft 2072 may be conventional, such as a multilayered design with composite braid and polymeric layers. The distal portion 2076 of the shaft 2072 may be curved with one or more curves in two or three dimensions to facilitate navigation and seating in the luminal path chosen. By way of example, not limitation, the guide catheter 2070 may comprise a commercially available 8 French multipurpose guide catheter.

[0124] With reference to Figure 17, a schematic plan view of an isolation catheter 2080 is shown, for use in delivering a implantable device 2010 by transluminal techniques, such as a transesophageal approach. The isolation catheter 2080 includes an elongate shaft 2082 that is sized appropriately as a function of the delivery approach, both in terms of the size of the lumen and the distance from the access point to the deployment point. For example, for a transesophageal approach, the shaft 2082 may have a diameter sized to fit into the esophagus ES and a length sufficient to extend from the nose or mouth to a point adjacent the heart H. The shaft 2082 includes a through lumen (not visible) for passage of a delivery catheter and/or guide wire, and a distal window or opening 2083 through which the space filling member 2010, the delivery catheter and/or the guide wire may exit the catheter 2080 between two balloons 2084, and through which a sterilizing wash solution may be flushed to aspirate the region between the balloons 2084. The shaft 2082 also includes an inflation lumen (not visible) to selectively inflate and deflate the balloons 2084. Upon inflation in the luminal passage (e.g., esophageal lumen), the balloons 2084 define an isolation zone therebetween that may be sterilized and isolated from the remainder of the passage. A manifold 2086 may be connected to the proximal end of the shaft 2082, and may include an inflation lumen arm 2087 in fluid communication with the inflation lumen in the shaft 2082 and a through lumen arm 2085 to provide access to the through lumen in the shaft 2082 and window 2083.

[0125] With reference to Figures 31A and 31B, side and top views, respectively, of anchor catheter 2300 are illustrated. Anchor catheter 2300 is particularly useful for delivering implantable devices by transthoracic techniques.

Anchor catheter 2300 includes an elongate tubular shaft 2302 comprising a relatively rigid material such as stainless steel, NiTi, a braided composite. The elongate shaft 2302 may be straight or gently curved depending on the approach (subxiphoid or posterior). A suction cup 2304 may be connected to the distal end of the shaft 2302. The suction cup 2304 defines an interior 2308, and may have an open top and bottom, or an open bottom and closed top. For example, the suction cup 2304 may have an open top and bottom facing both the pericardium and epicardium, or an open bottom facing the epicardium and a closed top facing the pericardium.

[0126] The interior 2308 of the suction cup 2304 is in fluid communication with a vacuum lumen extending through the shaft 2302 to hub 2306, which may be connected to a vacuum source (not shown). A flexible guide wire 2320 extends alongside the shaft 2302, with its distal end connected to the suction cup 2304 and its proximal end free. A guide wire tube 2310 may extend through the suction cup 2304 to slidably accommodate pericardial space guide wire 2330 shown in phantom. A radiopaque marker 2312 may be disposed about the guide wire tube 2310 to facilitate visualization by radiography.

[0127] Pericardial space guide wire 2330 may be delivered into the pericardial space using a subxiphoid transthoracic cardiac access technique similar to that which is described by Schmidt et al. in U.S. Patent No. 6,206,004, the entire disclosure of which is incorporated herein by reference. The pericardial space guide wire 2330 provides access to the pericardial space, but typically has a free distal end and therefore may not be easily positioned or anchored in the desired location. Accordingly, the anchor catheter 2300 may be advanced over the pericardial space

guide wire 2330, manipulated to the desired implant location using semi-rigid shaft 2302, and anchored in place using vacuum. Application of vacuum to suction cup 2304 effectively anchors the distal end of the catheter 2300 to the heart wall and permits delivery catheter 1900 (described hereinafter) to be advanced thereover.

[0128] With reference to Figures 18 – 30, schematic illustrations of various design alternatives of implantable devices are shown. In Figures 18 – 23, a bottom view is shown in Figures labeled "A" and a side view (cross sectional in some) is shown in Figures labeled "B". The bottom view generally corresponds to the surface or surfaces facing the wall of the heart H and may lie directly against the epicardium, for example. The side view may represent a superior/inferior view, and/or a lateral view, depending on the selected orientation of the device. The size, shape and orientation of the implantable devices may be selected as a function of the implant site, such as the anatomical features associated with the implant site, and as a function of the desired effect(s) on valve function. The design alternatives schematically illustrated in Figures 18 – 25 are given by way of example, not limitation, and may be used individually or collectively.

[0129] Each implantable device described herein may have virtually any desired size, shape or configuration to meet the particular clinical requirements and to have the desired clinical effect(s) as described previously, some of which have been illustrated, and variations of which are described with reference to Figures 18 – 25. Generally, the implantable device may comprise a single large mass or single large protrusion to uniformly apply force to the heart wall and to avoid focused compression of the coronary arteries and cardiac veins. Alternatively, the implantable

device may have a relatively small contact area defined by one or a plurality of protrusions selected and positioned to establish localized contact with the heart wall while avoiding contact with and compression of the coronary arteries and cardiac veins.

[0130] In Figures 18A and 18B, the implantable device 3010 includes a base 2016 defining a wall 2014 and an interior 2012. A single circular protrusion 2018 extends from the base 2016, which may be in fluid communication therewith. The base 2016 and/or the protrusion 2018 may be expanded to the desired size and shape. The base 2016 may include a securement as described hereinafter, such as a tissue in-growth promoting surface 2017.

[0131] In Figures 19A and 19B, the implantable device 3110 is similar to device 3010 described above except that a plurality (e.g., two, three or more) of circular protrusions 2018 extend from the base 2016. This embodiment illustrates that any suitable number of protrusion(s) 2018 may be utilized.

[0132] In Figures 20A and 20B, the implantable device 3210 is similar to device 3010 except that a single oblong protrusion 2018 extends from the base 2016. This embodiment illustrates that the protrusion(s) 2018 may assume a wide variety of geometries, including circular and non-circular geometries.

[0133] In Figures 21A and 21B, the implantable device 3310 the implantable device 3210 is similar to device 3010 except that one or more elongate protrusions 2018 are integrally formed with and extend from both sides of the base 2016. In addition, reinforcement strips 2019 may be disposed at the apex of the protrusions 2018 to enhance rigidity thereof. This embodiment illustrates that the protrusions

2018 may be integrally formed with the base 2016, and/or may extend from both sides of the base 2016, and/or may be selectively reinforced.

[0134] In Figures 22A and 22B, the implantable device 3410 is similar to device 3310 except that the protrusion 2018 includes a reinforcement structure 2019 (e.g., 2-dimensional or 3-dimensional coil or stent) disposed in the interior 2012 thereof to enhance the hoop strength of the protrusion 2018. The reinforcement structure 2019 disposed in the elongate protrusion 18 illustrates that the hoop strength or holding power of the protrusion(s) 2018 may be increased by mechanical means.

[0135] In Figures 23A and 23B, the implantable device 3510 is similar to device 3010 except that the device 3510 comprises one or more discrete protrusions 2018. This embodiment illustrates that the implantable device 3510 may comprise one or more individual and separate protrusions 2018 used collectively, which may not define a discrete base portion and a discrete protrusion portion.

[0136] Each implantable device described herein may be expanded or filled by different materials and/or structures, each of which may dictate a different construction of the device as illustrated by the following discussion with reference to Figures 24A – 24F which schematically illustrate different embodiments of an implantable device 3610. The implantable device 3610 may include an interior 2012 defined by wall 2014, wherein the interior 2012 is filled by a fluid as shown in Figure 24A. The fluid may remain a liquid (e.g., saline) or a gas (e.g., carbon dioxide) as shown in Figure 24A, or may comprise or cure into a solid or semi-solid (e.g., gel, expandable foam, sponge, PVA, collagen) as shown in Figure 24B. In addition or in the alternative, a mechanical structure 2019 such as a stent or coil may be placed in

the interior 2012 as shown in Figure 24C. To the extent that the wall 2014 is not necessary to contain the solid filler material, the device 3610 may have dissolvable walls or may not have walls at all as shown in Figure 24D. Similarly, to the extent a mechanical structure 2019 such as a stent or coil is used, the device 3610 may not require walls as shown in Figure 24E, and the device 3610 may simply comprise the mechanical structure 2019 itself.

[0137] In addition, each of the implantable devices may include a means to secure itself to the heart H wall and/or other surrounding tissue. The securement may comprise tines, screws, sutures, or other structural anchors, and/or the securement may comprise a material (e.g., Dacron fabric) that promotes tissue in-growth. The securement may be remotely activated. For example, the securement may comprise curled wires disposed on either side of the implantable device, wherein the wires curl into the heart wall as they are advanced out of a catheter lumen. The securement may selectively anchor to some tissue while remaining free of other tissue. For example, the securement may anchor to the epicardium and/or myocardium, while remaining free of the pericardium. It has been observed that the epicardium is a relatively tough tissue, thus providing a good anatomical structure to secure the implantable device.

[0138] In the embodiments described with reference to Figures 18 – 25, the securement is shown as a tissue in-growth promoting surface on the bottom, and a smooth surface on the top, thus establishing, for example, a secure connection to the epicardium while remaining free of the pericardium. In the embodiment shown in Figure 24F, the device 3610 includes an transmyocardial securement 3602 having an intra-chamber anchor pad 3604 and a connection member 3606. The intra-chamber

pad 3604 resides within a chamber (e.g., left ventricle LV) of the heart H, and the connection member 3606 extends through the heart wall (endocardium, myocardium and epicardium) to the implantable device 3610 disposed outside the heart wall. The transmyocardial securement 3602 is particularly suited for the transventricular approach described previously.

[0139] Each implantable device described herein may be expandable between a relatively small delivery configuration and a relatively large deployed configuration. The smaller delivery configuration permits the device to be low profile to facilitate advancement through catheter lumens in the various transluminal approaches described herein. For example, the implantable device 3710 may be expanded radially as shown by arrows 3700A in Figure 25A, or unfurled as shown by arrow 3700B in Figure 25B. Radial expansion may be appropriate when the device 3710 is constructed of highly elastic materials (e.g., silicone rubber, latex, elastomeric polymers, etc.) and unfurling may be appropriate when the device 3710 is constructed of relatively inelastic materials (e.g., PET, HDPE, PTFE, SST, Nitinol, etc.).

[0140] In Figures 26A and 26B, side and bottom views, respectively, are shown of implantable device 1810. Implantable device 1810 includes a base 1812 which may comprise, for example, a flexible polymer sheet having resistance to elongation. Two or more suction cups 1814 are connected to opposite ends of the base 1812. The suction cups 1814 have an open bottom portion, with the top portion thereof sealing connected to the base 1812. One or more pins 1816 extend through and across each of the suction cups 1814. The pins 1816 may be inserted and locked in holes defined in the walls of the suction cups 1814. A inflatable and deflatable

balloon 1818 is connected to and extends from the bottom of the base 1812. The balloon 1818 may be filled with a variety of materials as described previously.

[0141] In Figure 27, a bottom view of a delivery catheter 1900 connected to the implantable device 1810 is shown. Delivery catheter 1900 includes an inflation tube 1902 releasably connected to and in fluid communication with the balloon 1818. Inflation tube 1902 includes an inflation lumen extending therethrough, and may include a guide wire lumen for advancement over guide wire 2320 as shown and described with reference to Figures 31A and 31B. The proximal end (not shown) of the inflation tube 1902 may be connected to an inflation device to selectively inflate and deflate the balloon 1818. Delivery catheter 1900 also includes vacuum tubes 1904 releasably connected to and in fluid communication with each of the suction cups 1814. The proximal ends (not shown) of the vacuum tubes 1904 may be connected to an vacuum source to selectively apply suction to the suction cups 1814. The pins 1816 are releasably connected to push/pull wires (not shown) extending through the vacuum tubes 1904 such that the pins may be remotely and selectively advanced and retracted by manipulating the proximal ands of the push/pull wires.

[0142] In Figures 28A – 28D, an example of a method of deploying the implantable device 1810 is schematically shown. The implantable device 1810 may be positioned adjacent the heart wall HW (e.g., between the epicardium and pericardium) as shown in Figure 28A, using delivery catheter 1900 (not shown) advanced over guide wire 2320 (shown in Figures 31A and 31B), by a transthoracic approach, for example. The balloon 1818 of implantable device 1810 may be positioned adjacent the MV or a specific part thereof (e.g., annulus AN or papillary

muscles PM) as confirmed using by echocardiography, with the suction cups 1814 avoiding coronary vasculature as confirmed by radiography. For example, the balloon 1818 may be positioned adjacent the annulus and/or posterior papillary muscle PPM, with the suction cups 1814 disposed on opposite sides of the second and third obtuse marginals, such that the device 1810 is inferior of the circumflex artery CFX and straddles the second and third obtuse marginals.

[0143] Suction is applied to the suction cups 1814 by vacuum tubes 1904 (not shown), causing a portion of the heart wall HW to be displaced into the interior of each suction cup 1814 as shown in Figure 28B. Pins 1816 may then be advanced through the vacuum tubes 1904 and into each of the suction cups 1814 by remotely pushing on the push/pull wires, thus causing the pins 1816 to pierce the portion of the heart wall HW displaced into the interior of the suction cups 1814 as shown in Figure 28C. The vacuum source may then be deactivated to release the vacuum applied to the suction cups 1814 via vacuum tubes 1904. Because the epicardium of the heart wall HW is a relatively tough tissue, the pins 1816 provide a secure connection to the heart wall HW. As an alternative, the pericardium may be suctioned into the suction cups 1814 such that the pins 1816 pierce the pericardium as well. The balloon 1818 may then be inflated as shown in Figure 28D, and the desired acute effect may be confirmed by echocardiography. The catheter 1900 may then be disconnected from the implantable device 1810, leaving the balloon 1818 inflated and the pins 1816 secured to the heart wall HW in suction cups 1814.

[0144] In Figure 29A, a bottom view is shown of an alternative implantable device 2110, which may be similar in design and substantially the same in use as

implantable device 1810 described previously. In this alternative embodiment, implantable device 2110 includes a base 2110 which may comprise, for example, a flexible polymer sheet having resistance to elongation. Two series of three suction cups 2114 each are uniformly distributed along and connected to opposite sides of the base 2112, and are interconnected by tubes 2115. A pin 2116 extends through and across each series of the suction cups 2114 and tubes 2115. A inflatable and deflatable balloon 2118 is connected to and extends from the bottom of the base 2112, and may be filled with a variety of materials as described previously.. As compared to the implantable device 1810 described with reference to Figures 26A and 26B, the implantable device 2110 illustrated in Figure 29A utilizes a balloon 2118 having a larger surface area and different geometry, and more suction cups 2114 interconnected by tubes 2115. As shown in Figure 29B, delivery catheter 1900 may be connected to implantable device 2110 in a similar manner as the connection to implantable device 1810 described previously. Further, the steps of deploying implantable device 2110 may be the same as described previously for implantable device 1810.

[0145] With reference to Figures 30A – 30C, various design alternatives for the suction cups 1814/2114 are shown as top views and side views. In Figure 30A, the suction cup 2200 includes a circular wall portion 2202 defining an interior with an open bottom and top. A pin 2204 extends through holes in the wall 2202 as well as the interior defined by circular wall 2202. With an open bottom and top, suction applied to the cup 2200 pulls both the heart wall (at least the epicardium) and the

pericardium into the interior allowing the pin 2204 to pierce through both tissue layers.

[0146] In Figure 30B, the suction cup 2210 includes a circular wall portion 2212 defining an interior. A cap 2216 covers the top portion of the wall 2212 to define a closed top portion and an open bottom potion of the cup 2210. A pin 2214 extends through holes in the wall 2212 as well as the interior defined by circular wall 2212. With an open bottom and a closed top, suction applied to the cup 2210 pulls the heart wall (at least the epicardium) into the interior while the cover 2216 prevents the pericardium from entering, thus allowing the pin 2214 to pierce through the heart wall but not the pericardium.

[0147] In Figure 30C, the suction cup 2220 includes a circular wall portion 2222 defining an interior. A series of crossing wires 2226 cover the top portion of the wall 2222 to define a screened top portion and an open bottom potion of the cup 2220. The wall 2222 may be formed of a tubular structure with a highly elastic wire (e.g., NiTi) running therethrough, and the wires 2226 may be formed of a highly elastic material (e.g., NiTi) such that the entire cup 2220 may be collapsed into a delivery configuration small enough to fit into a delivery catheter and subsequently deployed into an expanded configuration as shown. A pin 2224 extends through holes in the wall 2222 as well as the interior defined by the wall 2222. With an open bottom and a screened top, suction applied to the cup 2220 pulls the heart wall (at least the epicardium) into the interior. Depending on the density of wires 2226 and the amount of suction applied, the pericardium may be selectively pulled into the interior, thus allowing the pin 2224 to pierce through the heart wall and optionally the pericardium.

[0148] With reference to Figure 30D, an alternative implantation arrangement is shown. In this embodiment, three or more suction cups 2220 are attached to the heart wall and pericardium to isolate and hold the balloon 2218 therebetween. By connecting to both the epicardium and the heart wall in three or more locations, the balloon 2218 is constrained by the heart wall, the epicardium and the suction cup anchors 2220. This arrangement eliminates the need to interconnect the balloon 2218 and suction cups 2220 (e.g., by a base structure), and permits the suction cups and balloon to be separately delivered in a smaller profile enabling transluminal delivery through a catheter.

[0149] From the foregoing, it will be apparent to those skilled in the art that the present invention provides, in exemplary non-limiting embodiments, devices and methods for improving the function of a valve (e.g., mitral valve) by positioning an implantable device outside and adjacent the heart wall such that the device applies an inward force against the heart wall or otherwise deforms the heart wall thus acting on the valve to improve leaflet coaptation. Further, those skilled in the art will recognize that the present invention may be manifested in a variety of forms other than the specific embodiments described and contemplated herein. Accordingly, departures in form and detail may be made without departing from the scope and spirit of the present invention as described in the appended claims.

What is claimed is:

1. A device for improving heart valve function, the device comprising:

a first anchor configured to be secured to heart tissue;

a second anchor configured to be secured to heart tissue; and

an interconnecting member connecting the first anchor and the second anchor,

wherein the interconnecting member is configured to be selectively adjustable so as to alter a tension of the interconnecting member between the first anchor and the second anchor, and

wherein at least a portion of the interconnecting member is configured to be positioned in contact with an external surface of a heart wall proximate a valve such that the device exerts an inward force on the heart wall sufficient to alter the valve function.

2. The device of claim 1, wherein the interconnecting member is flexible.

3. The device of claim 1, wherein the interconnecting member is made of a plurality of filaments.

4. The device of claim 3, wherein the plurality of filaments form a braided structure.

5. The device of claim 1, further comprising a covering provided on the interconnecting member.

6. The device of claim 5, wherein the covering is biocompatible.

7. The device of claim 5, wherein the covering is configured to promote tissue ingrowth.

8. The device of claim 5, wherein the covering comprises an atraumatic pad.

9. The device of claim 1, wherein each of the first and second anchors defines vacuum chamber.

10. The device of claim 1, further comprising a tissue penetrating member associated with each of the first anchor and the second anchor.

11. The device of claim 10, wherein the tissue penetrating members comprise selectively actuatable pins.

12. The device of claim 1, wherein the first anchor and the second anchor are configured to be positioned to avoid coronary arteries and coronary veins when the device implanted relative to the heart.

13. The device of claim 1, wherein the interconnecting member is configured to be adjustably connected to at least one of the first and second anchors.

14. The device of claim 13, wherein the interconnecting member is configured t be selectively lockable relative to the at least one first and second anchor.

15. The device of claim 14, further comprising a pin configured to selectively penetrate the interconnecting member so as to selectively lock the interconnecting member to the at least one first and second anchor.

16. The device of claim 13, wherein the interconnecting member is configured t be adjustably connected to the first anchor and to the second anchor.

17. The device of claim 13, wherein the interconnecting member is configured t be adjustably connected to one of the first anchor and the second anchor and fixedly connected to the other of the first anchor and the second anchor.

18. The device of claim 1, wherein the device is configured to be delivered to th heart via a delivery catheter.

19. The device of claim 1, wherein the first anchor and the second anchor are configured to be secured to an epicardial layer of the heart.

20. The device of claim 19, wherein the first anchor and the second anchor are configured to be secured to the epicardial layer while the anchors remain free from a pericardial layer of the heart.

21. The device of claim 19, wherein at least one of the first anchor and the second anchor is configured to be secured to the pericardial layer of the heart.

22. The device of claim 1, further comprising least one protrusion connected to the interconnecting member and configured to be positioned between the first anchor and th second anchor.

23. A device for improving heart valve function, the device comprising:

a first anchor configured to be secured to heart tissue;

a second anchor configured to be secured to heart tissue;

a protrusion disposed between the first anchor and the second anchor; and

an interconnecting member connecting the first anchor, the protrusion, and the second anchor,

wherein the interconnecting member is configured to be selectively adjustable so as to alter relative positions between at least one of the first and second anchor and the protrusion, and

wherein the protrusion is configured to be positioned adjacent an external surface of a heart wall proximate a valve so as to exert an inward force on the heart wall and alter the valve function.

24. The device of claim 23, wherein the interconnecting member is made of a plurality of filaments.

25. The device of claim 24, wherein the plurality of filaments form a braided structure.

26. The device of claim 23, further comprising a covering provided on the interconnecting member.

27. The device of claim 26, wherein the covering is biocompatible.

28. The device of claim 26, wherein the covering is configured to promote tissu ingrowth.

29. The device of claim 26, wherein the covering comprises an atraumatic pad.

30. The device of claim 23, wherein the protrusion is one of fixedly and adjustably connected to the interconnecting member.

31. The device of claim 23, wherein the protrusion comprises an expandable structure.

32. The device of claim 31, wherein the expandable structure is configured to b selectively expandable after implantation of the device relative to the heart.

33. The device of claim 31, wherein the protrusion comprises an inflatable structure.

34. The device of claim 33, wherein the protrusion comprises a balloon.

35. The device of claim 23, wherein the protrusion comprises an outer surface configured to promote tissue ingrowth.

36. The device of claim 23, further comprising a plurality of protrusions connected to the interconnecting member and disposed between the first and second anchors.

37. The device of claim 23, wherein each of the first and second anchors define a vacuum chamber.

38. The device of claim 23, further comprising a tissue penetrating member associated with each of the first anchor and the second anchor.

39. The device of claim 38, wherein the tissue penetrating members comprise selectively actuatable pins.

40. The device of claim 23, wherein the interconnecting member defines a plurality of pockets.

41. The device of claim 40, wherein the pockets are configured to selectively receive a structure forming the protrusion.

42. The device of claim 23, wherein the first anchor, the second anchor, and the protrusion are configured to be positioned so as to avoid coronary arteries and coronary veins when the device is implanted relative to the heart.

43. The device of claim 23, wherein the protrusion is rotatably connected to the interconnecting member.

44. The device of claim 43, wherein the protrusion is rotatable relative to the interconnecting member between a relatively low profile delivery configuration and a large profile deployed configuration.

45. The device of claim 44, wherein the protrusion extends substantially along a axis of the interconnecting member in the delivery configuration and extends substantially perpendicular to the axis of the interconnecting member in the deployed configuration.

46. The device of claim 45, further comprising a pair of protrusions disposed on opposite sides of the rotatable protrusion.

47. The device of claim 23, wherein the interconnecting member is configured t be adjustably connected to at least one of the first and second anchors.

48. The device of claim 47, wherein the interconnecting member is configured t be selectively lockable relative to the at least one first and second anchor.

49. The device of claim 48, further comprising a pin configured to selectively penetrate the interconnecting member so as to selectively lock the interconnecting member to the at least one first and second anchor.

50. The device of claim 47, wherein the interconnecting member is configured t be adjustably connected to the first anchor and to the second anchor.

51. The device of claim 47, wherein the interconnecting member is configured t be adjustably connected to one of the first anchor and the second anchor and fixedly connected to the other of the first anchor and the second anchor.

52. The device of claim 23, wherein the interconnecting member is configured t be adjustably connected to the protrusion and fixedly connected to the first anchor and to tl second anchor.

53. The device of claim 23, wherein the device is configured to be delivered to the heart via a delivery catheter.

54. The device of claim 23, wherein the interconnecting member comprises a first interconnecting member connecting the protrusion to the first anchor and a second interconnecting member connecting the protrusion to the second anchor.

55. A device for improving valve function, the device comprising:

a first anchor, at least a portion of the first anchor being remotely actuatable so as to embed into heart tissue;

a second anchor, at least a portion of the second anchor being remotely actuatable so as to embed into heart tissue;

an interconnecting member connecting the first anchor and the second anchor,

wherein the interconnecting member is configured to be selectively adjustable so as to alter a tension of the interconnecting member between the first anchor and the second anchor, and

wherein the device is configured to be positioned adjacent an external surface of a heart wall proximate a valve so as to exert an inward force on the heart wall sufficient to alter the valve function.

56. The device of claim 55, wherein the portion of the first anchor and the portion of the second anchor comprise tissue penetrating members.

57. The device of claim 56, wherein the tissue penetrating members are pins.

58. The device of claim 55, wherein the portion of the first anchor and the portion of the second anchor are configured to be remotely actuable via push-pull member associated with a catheter.

59. The device of claim 55, wherein the first anchor and the second anchor defi vacuum chambers.

60. A securement device, the device comprising:

a pin configured to penetrate a structure to be secured, the pin comprising a shaft a a piercing tip, wherein a recess is defined between the shaft and the piercing tip; and

a multifilament material associated with the pin,

wherein the multifilament material and pin are configured to permit the piercing tip to pass through the material in a first direction and prevent the piercing tip from passing through the material in a second direction opposite to the first direction.

61. The device of claim 60, wherein the material is configured to be disposed i the recess so as to prevent the piercing tip from passing through the material in the second direction.

62. The device of claim 60, wherein the material has a braided configuration.

63. A delivery system for delivering an implant to a heart, the delivery system comprising:

at least one anchor catheter, the anchor catheter comprising:

a shaft defining a vacuum lumen;

at least one actuatable push rod configured to actuate a securing member associated with the implant;

a side tube extending alongside the shaft and configured to receive an elongate member for implanting relative to the heart; and

a releasable connection configured to be releasably connected to a portion the implant.

64. The delivery system of claim 63, further comprising two anchor catheters.

65. The delivery system of claim 63, wherein a distal end of the shaft is configured to be bi-directionally laterally deflectable.

66. A delivery system for delivering an implant to a heart, the delivery system comprising:

a delivery catheter configured to be releasably connected to the implant, the delive catheter comprising

a shaft defining an inflation lumen and two cable lumens, and

a pair of push tubes extending alongside the shaft and configured to slidably receive push rods configured to actuate an actuatable member associat with the implant; and

two anchor catheters each disposed on opposite sides of the delivery catheter and configured to be releasably connected to anchors associated with the implant, each anchor catheter comprising

a shaft defining a vacuum lumen,

a push rod configured to be slidably received in the vacuum lumen and configured to actuate an actuatable member associated with a respective anchor, and

a guide lumen extending alongside the shaft and configured to receive a cable.

67. A device for adjusting tension of an elongate member, the device comprisin

a receiving tube for receiving the elongate member, the receiving tube having a proximal end and a distal end;

an engagement mechanism on the distal end of the receiving tube;

a measuring tube having markings thereon connected to the proximal end of the receiving tube;

an inner tube disposed in the measuring tube and configured to be connected to a proximal end of the elongate member for tensioning; and

a lock mechanism connected to the proximal end of the measuring tube configured selectively lock the inner tube to the measuring tube,

wherein the inner tube is configured to be moved relative to the measuring tube so a to adjust the tension of the elongate member when the elongate member is connected to the inner tube.

68. A device for accessing pericardial space around a heart, the device comprising:

an outer tube defining a lumen and having a handle and a vacuum port;

a securement tube defining a lumen and comprising a plurality of piercing member disposed at a distal end of the securement tube, the securement tube being configured to b received in the lumen of the outer tube; and

a cutter tube defining a lumen and being configured to be received in the lumen of the securement tube, the cutter tube comprising a cutting edge on a distal end thereof and plurality of vacuum holes proximate the distal end, the cutter tube being advanceable with the securement tube.

69. The device of claim 68, further comprising a visualization device.

70. The device of claim 68, wherein the cutter tube further comprises an annu fluid seal so as to provide a seal between the securement tube and the cutter tube.

71. A device for improving heart valve function, the device comprising:

a first anchoring member;

a second anchoring member;

a flexible member configured to connect the first and second anchoring member, t flexible member being further configured to be positioned adjacent an external surface of heart wall; and

at least one protrusion configured to be positioned in contact with an external surf of the heart wall such that the at least one protrusion exerts an inward force against the he wall proximate a valve,

wherein the inward force is sufficient to alter valve function.

72. The device of claim 71, wherein the device is configured such that the dev exerts a force substantially opposite to the inward force by securing the device to the hear wall.

73. The device of claim 71, wherein the device is configured such that the dev exerts a force substantially opposite to the inward force against anatomical structure outsi the heart wall.

74. The device of claim 71, wherein the protrusion is expandable.

75. The device of claim 74, wherein the protrusion is inflatable.

76. The device of claim 75, wherein the protrusion includes a balloon.

77. The device of claim 74, wherein the protrusion defines an interior.

78. The device of claim 77, further comprising a coil disposed in the interior of the protrusion.

79. The device of claim 77, further comprising a foam disposed in the interior o the protrusion.

80. The device of claim 77, further comprising a sponge disposed in the interio of the protrusion.

81. The device of claim 77, further comprising a liquid disposed in the interior the protrusion.

82. The device of claim 81, wherein the liquid is a curable liquid.

83. The device of claim 77, further comprising a mechanical reinforcement member disposed in the interior of the protrusion.

84. The device of claim 77, further comprising means for selectively adding or removing material from the interior.

85. The device of claim 74, wherein the means is transdermally accessible.

86. The device of claim 71, wherein the at least one protrusion comprises a plurality of protrusions.

87. The device of claim 86, wherein the plurality of protrusions form an integral structure.

88. The device of claim 86, wherein the plurality of protrusions are separate from each other.

89. The device of claim 86, wherein the plurality of protrusions are arranged so as to avoid cardiac veins and coronary arteries when positioned in contact with the heart wall.

90. The device of claim 71, wherein the at least one protrusion protrudes from the flexible member.

91. The device of claim 71, wherein the at least one protrusion is expandable between a relatively small delivery configuration and a relatively large deployed configuration.

92. The device of claim 71, wherein the device is configured to be delivered to the heart via a delivery catheter.

93. The device of claim 92, wherein the device is configured to be releasably connected to the delivery catheter.

94. The device of claim 71, wherein the at least one protrusion is configured to exert an inward force sufficient to draw leaflets of the valve together.

95. The device of claim 71, wherein the anchoring members are configured to secure the device to the heart.

96. The device of claim 72, wherein the force exerted substantially opposite the inward force is substantially equal to the inward force.

97. The device of claim 73, wherein the force exerted substantially opposite the inward force is substantially equal to the inward force.

98. A device for improving heart valve function, the device comprising:

at least one protrusion configured to be placed in contact with an external surface o a heart wall and to exert an inward force against the heart wall proximate the valve,

wherein the device is configured to exert a force substantially opposite to the inwa force against an anatomical structure outside the heart wall.

99. The device of claim 98, wherein the at least one protrusion is configured to exert an inward force sufficient to alter valve function.

100. The device of claim 98, wherein the inward force is sufficient to draw leafl of the valve together.

101. The device of claim 98, wherein the force exerted substantially opposite the inward force is substantially equal to the inward force.

102. A device for improving heart valve function, the device comprising:

a substantially elongate member having a first end and a second end;

an anchoring member associated with each of the first end and the second end and configured to secure the device relative to the heart,

wherein each of the anchoring members includes

a vacuum chamber, and

a piercing member configured to pierce tissue.

103. The device of claim 102, wherein the piercing member includes a pin.

104. The device of claim 102, wherein the piercing member is remotely actuatable.

105. The device of claim 102, further comprising a protrusion disposed between the anchoring members and configured to be disposed adjacent an external surface of a hea wall when the device is secured with respect to the heart.

106. The device of claim 105, wherein the protrusion is configured to exert an inward force on the heart wall when the device is secured with respect to the heart.

107. The device of claim 106, wherein the protrusion is configured to exert an inward force on the heart wall proximate a valve, the inward force being sufficient to alter function of the valve.

108. The device of claim 105, wherein the protrusion is expandable.

109. The device of claim 108, wherein the protrusion is inflatable.

110. The device of claim 102, wherein the elongate member is configured to be positioned adjacent the external surface of the heart when the device is secured relative to the heart.

111. The device of claim 102, wherein the vacuum chambers are configured to selectively placed in fluid communication with vacuum tubes of a delivery catheter.

112. The device of claim 102, wherein the piercing members are configured to remotely actuatable.

113. The device of claim 112, wherein the piercing members are configured to releasably connectable to push-pull wires of a delivery catheter for remote actuation.

114. A catheter for transthoracic delivery of an implant to the heart, the catheter comprising:

an elongate shaft having a proximal end and a distal end;

a vacuum lumen extending through the elongate shaft;

a suction cup disposed proximate the distal end, the suction cup defining an interior configured to be in fluid communication with the vacuum lumen;

a guide wire tube extending through the suction cup and configured to slidably receive a first guide wire; and

a second guide wire extending alongside the elongate shaft and having an end connected to the suction cup.

115. A delivery catheter comprising:

an inflation tube defining an inflation lumen configured to be placed in fluid communication with an inflation source at a proximal end and with an inflatable structure a a distal end;

first and second vacuum tubes disposed on opposite sides of the inflation tube, each vacuum tube defining a vacuum lumen configured to be placed in fluid communication witl a vacuum source at a proximal end and with a vacuum chamber at a distal end; and

a wire extending through each vacuum tube, each wire being configured to be selectively advanced or retracted through the vacuum tube so as to actuate an actuatable member.

116. A device for improving heart valve function, the device comprising:

means for exerting an inward force on an external surface of a heart wall proximate valve, the inward force being sufficient to alter valve function; and

means for exerting a force substantially opposite the inward force on anatomical structure outside the heart wall.

117. The device of claim 116, wherein the means for exerting a force substantially opposite the inward force includes a means for exerting a force substantially equal to the inward force.

118. A device for improving heart valve function, the device comprising:

a substantially elongate member having a first end and a second end and configured to be positioned external to a heart chamber; and

an anchoring member associated with each of the first end and the second end and configured to secure the device relative to the heart,

wherein the anchoring members are configured to be remotely securable to a wall of heart.

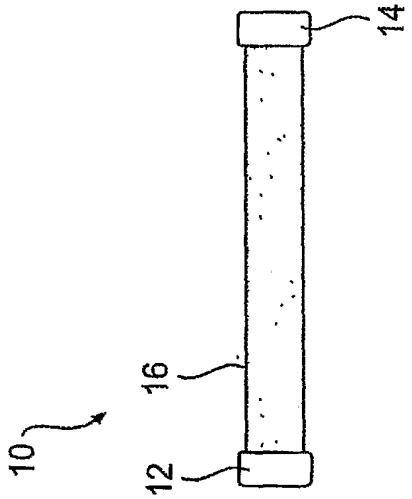

FIG. 1C

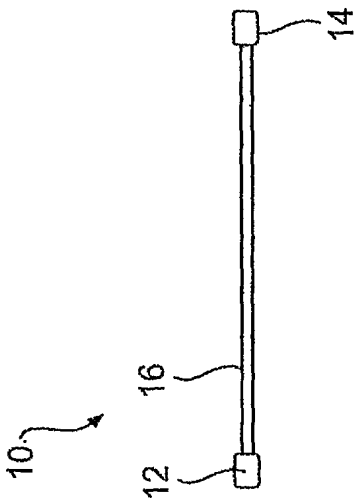

FIG. 1D

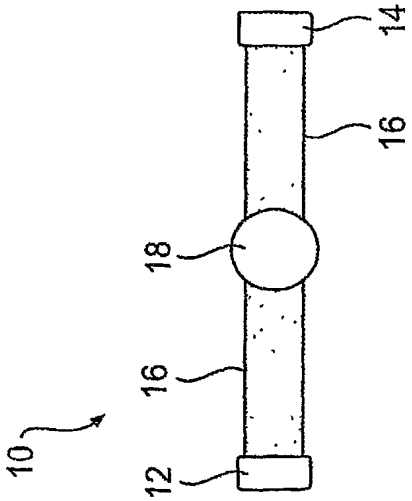

FIG. 1A

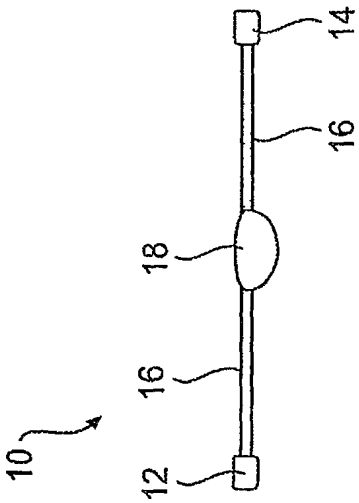

FIG. 1B

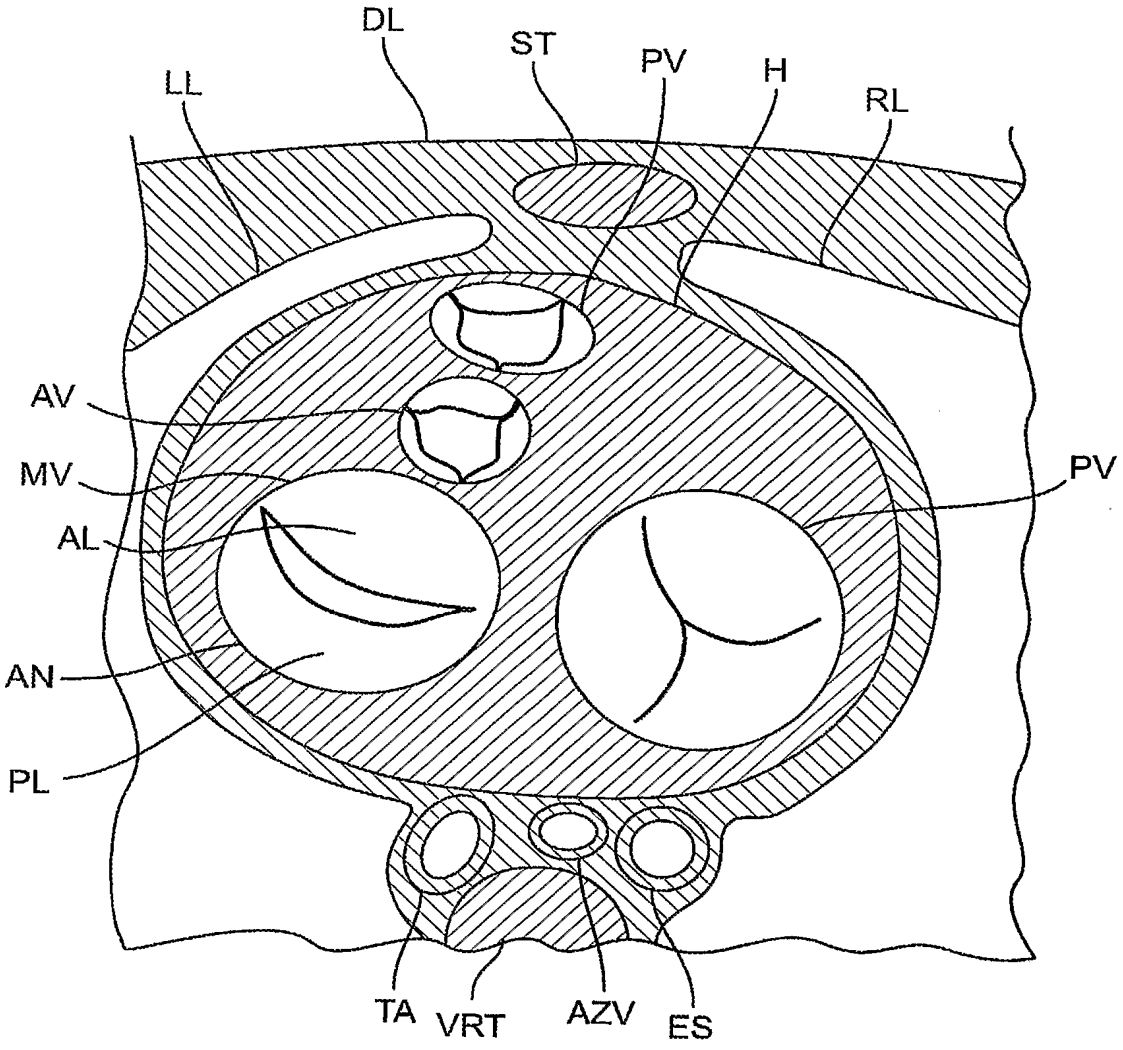

FIG. 2A

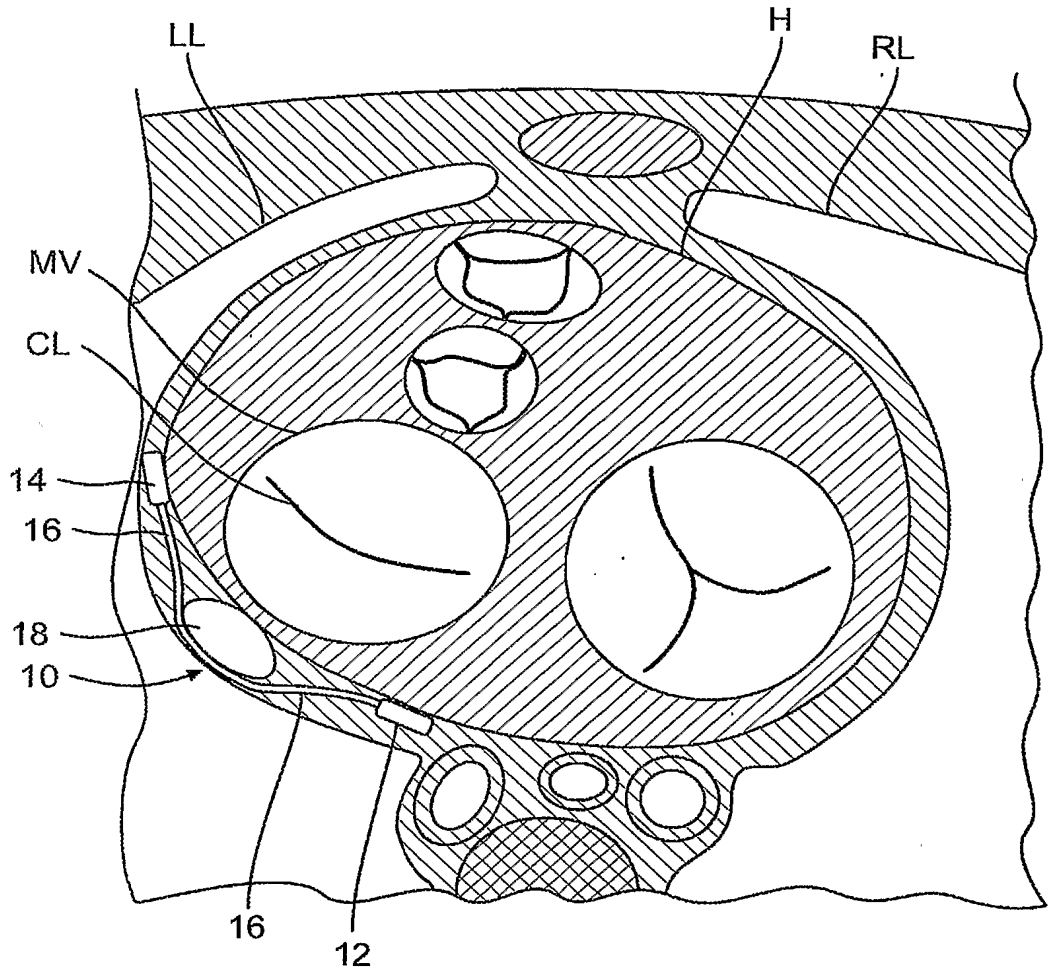

FIG. 2B

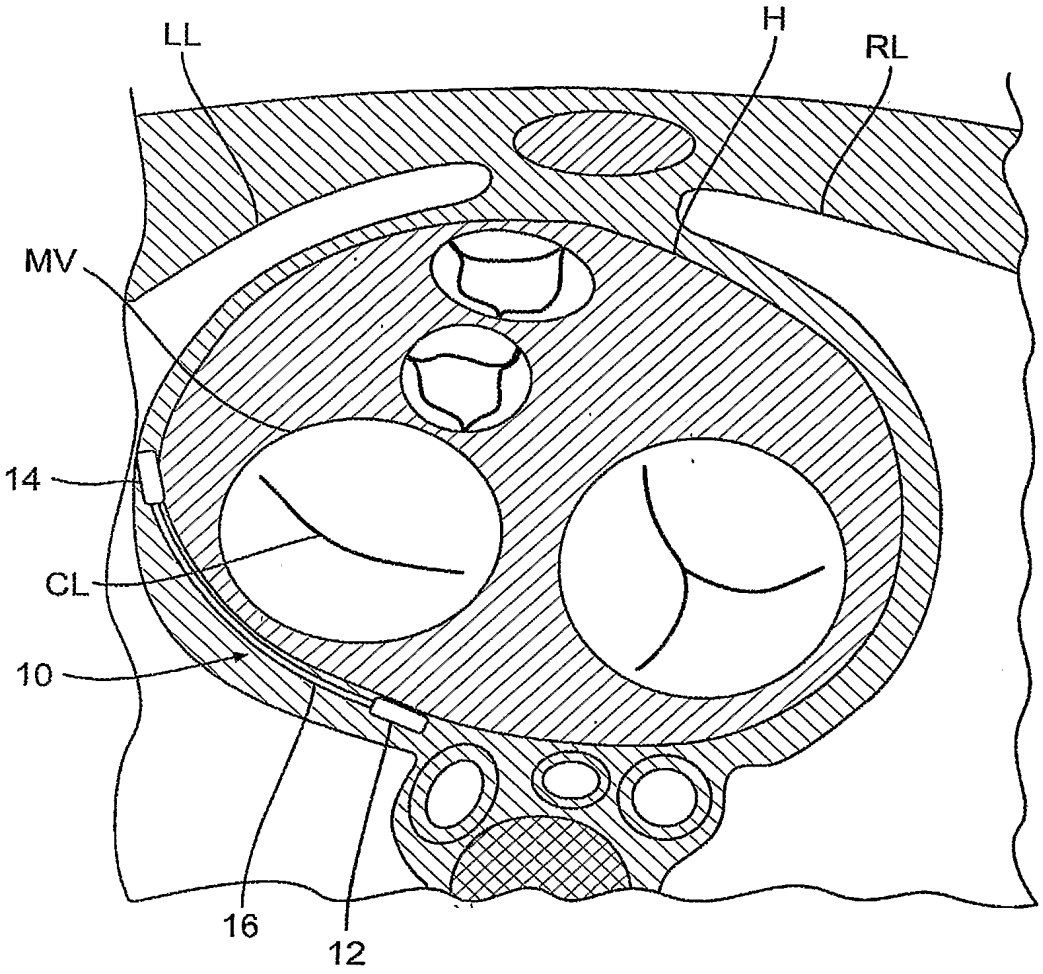

FIG. 2C

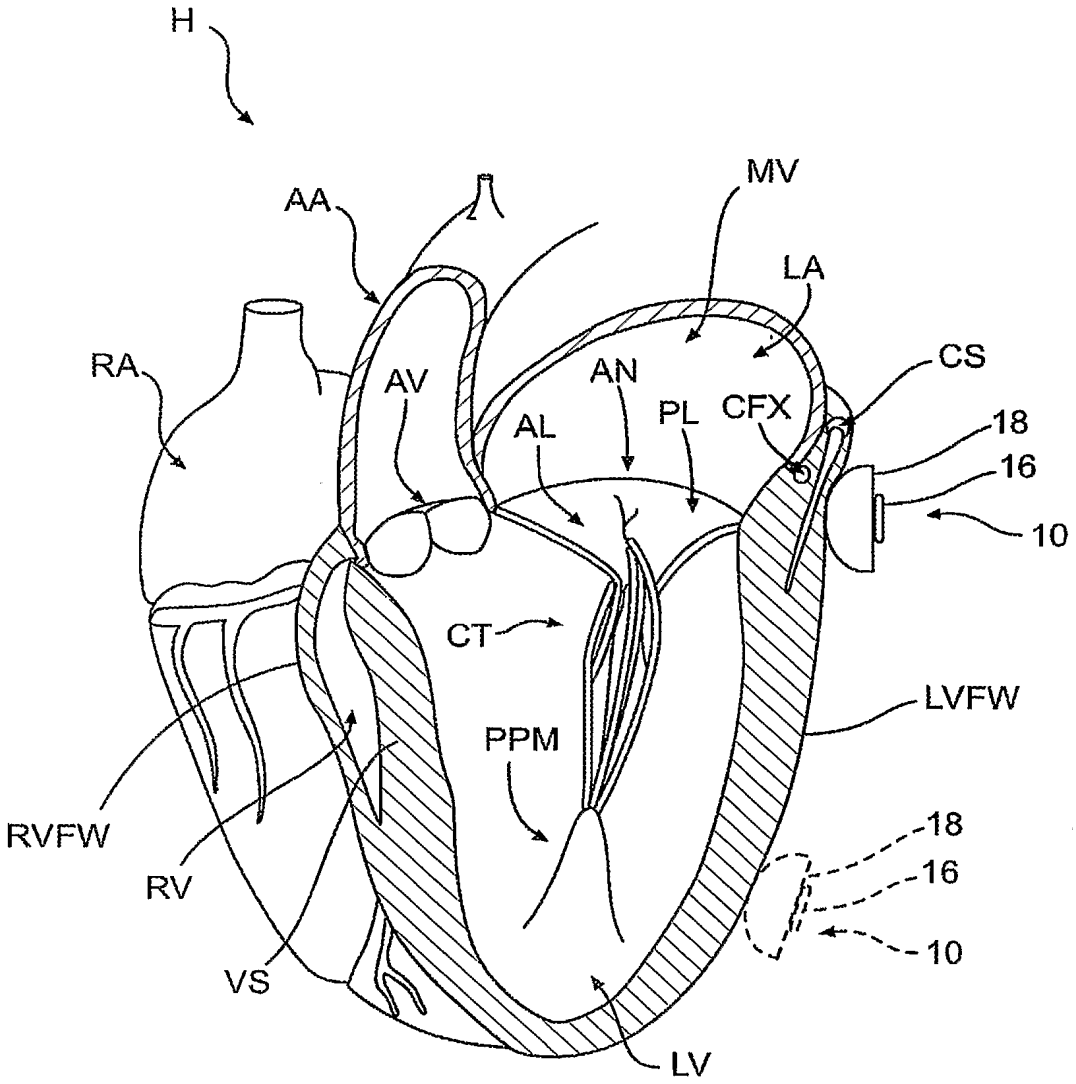

FIG. 3

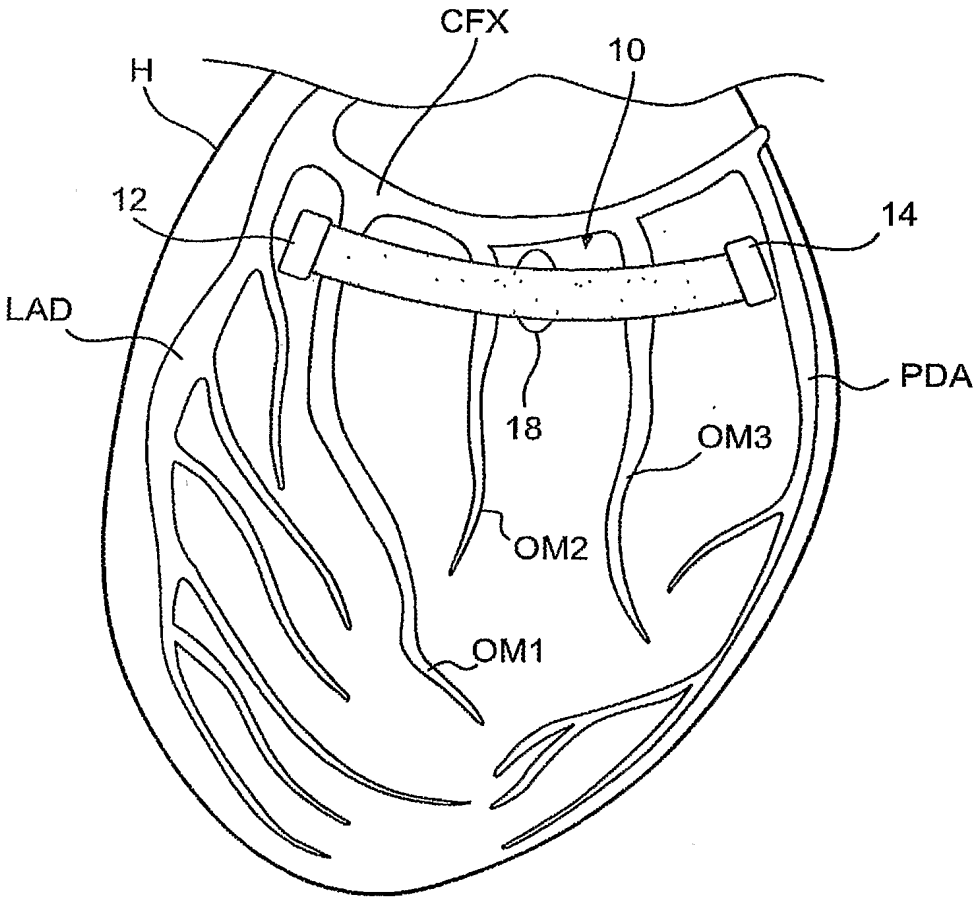

FIG. 4

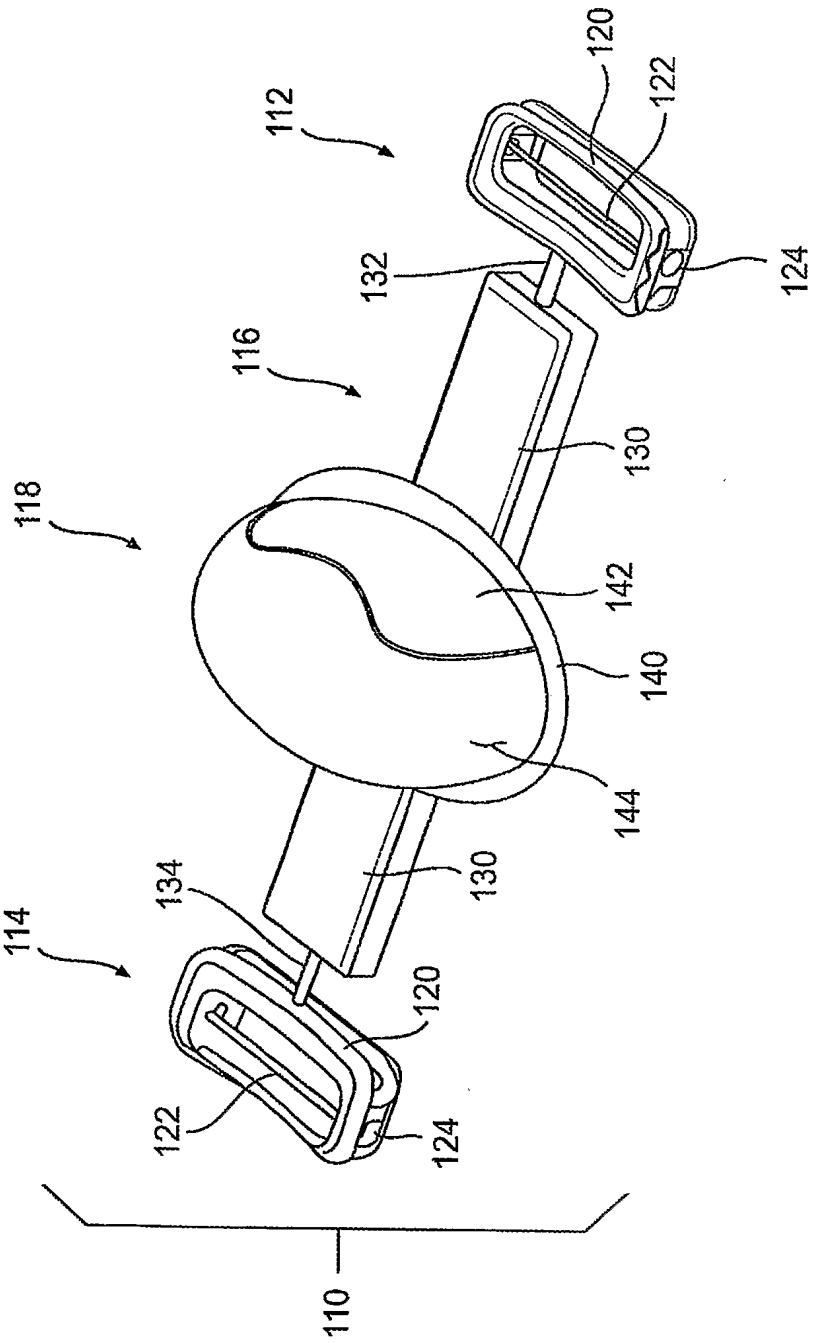

FIG. 5A

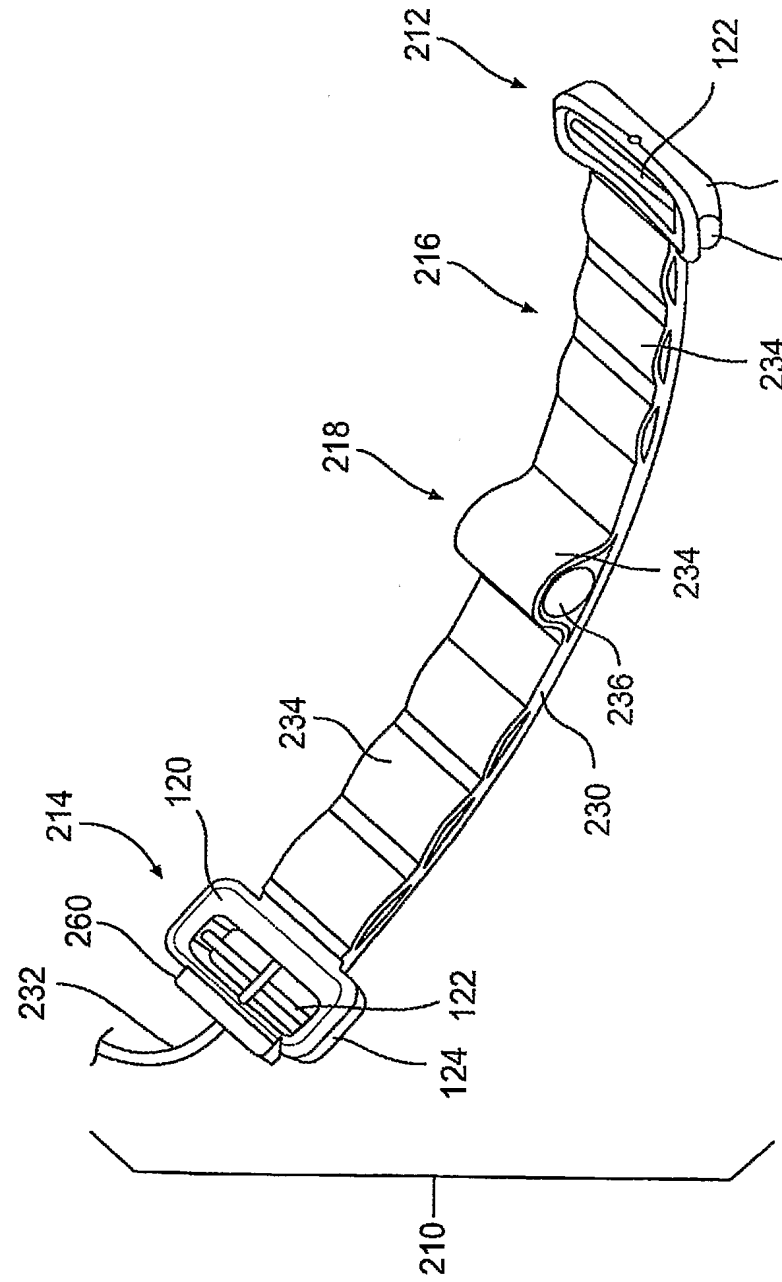

FIG. 5B

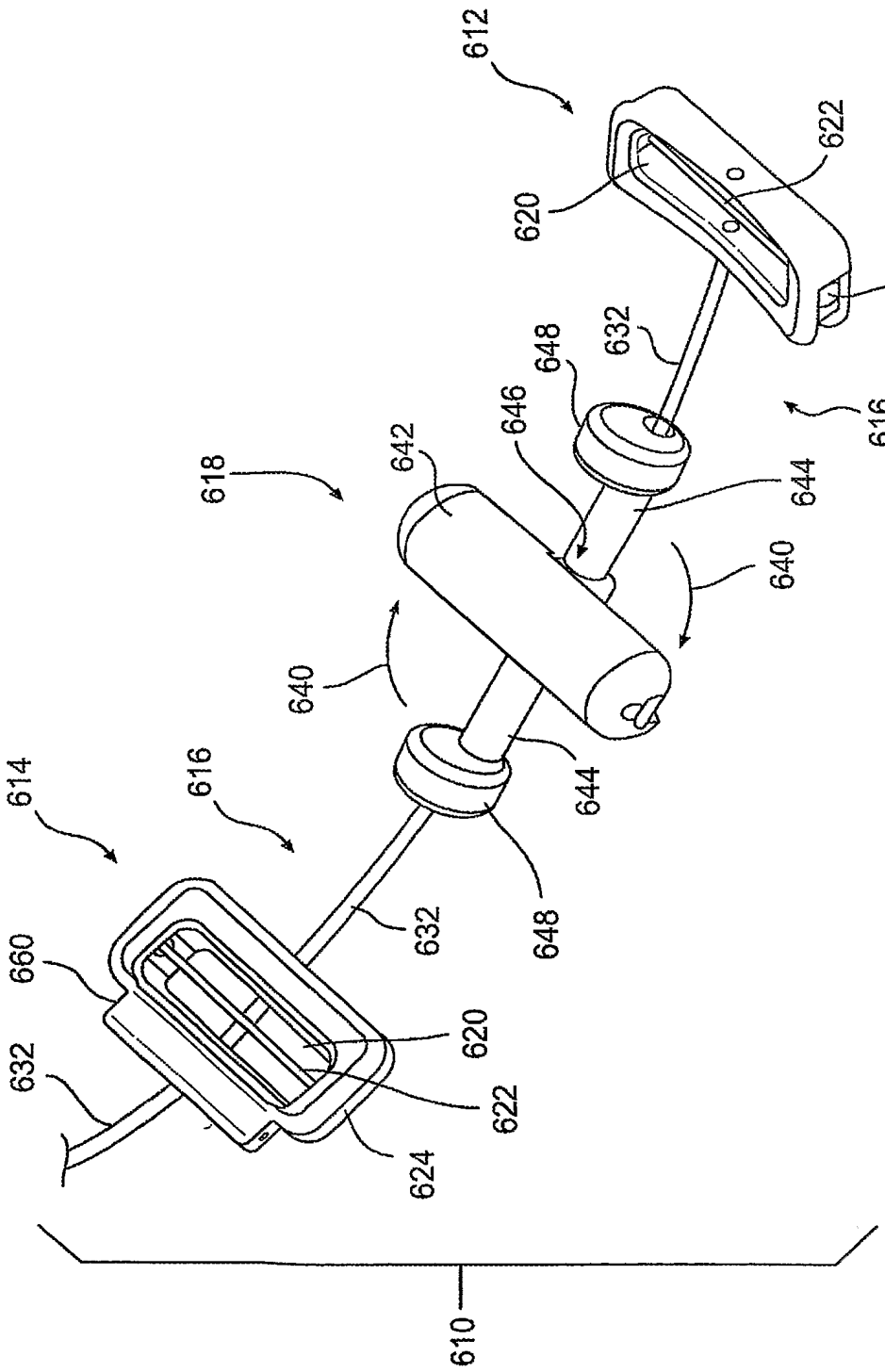

FIG. 5C

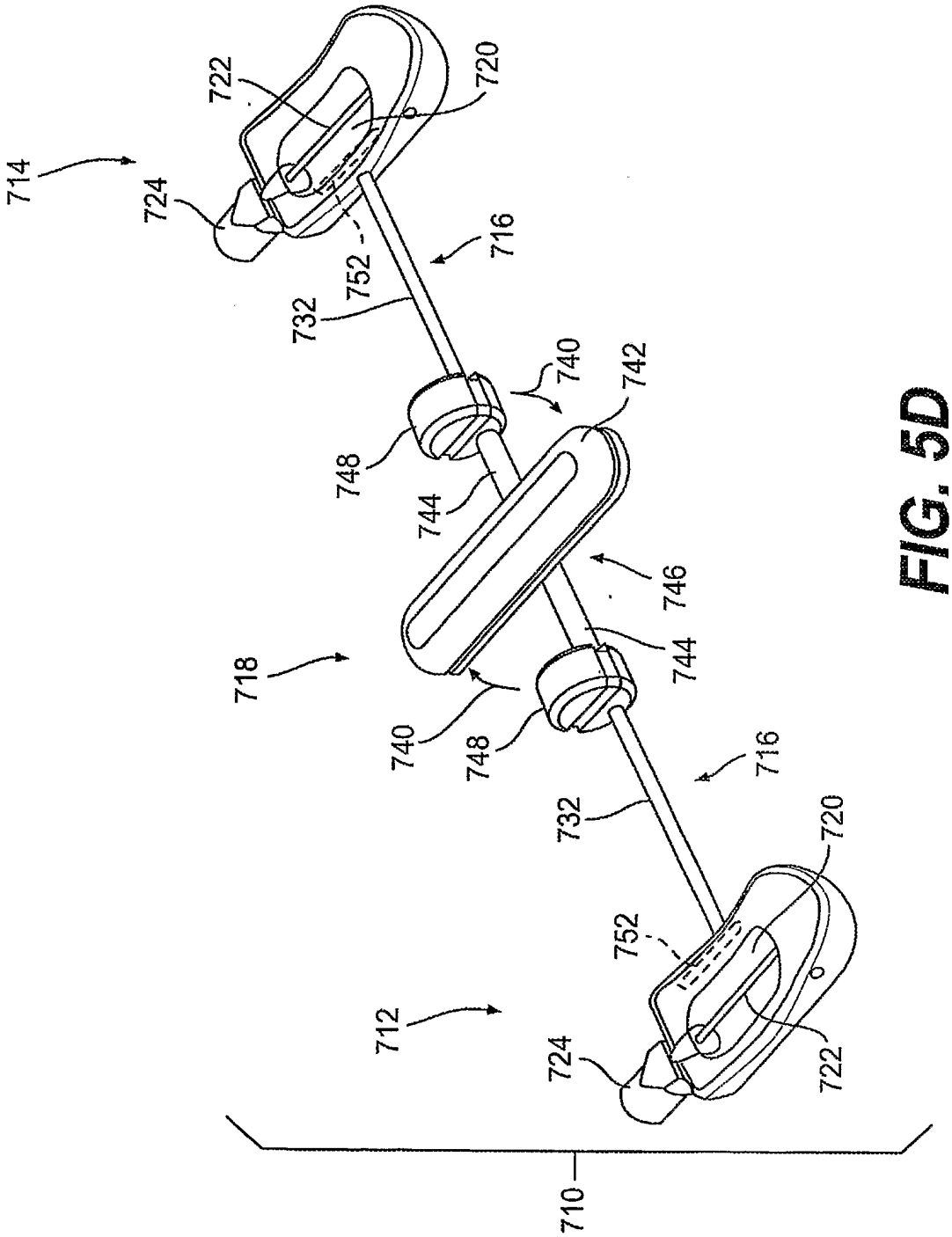

FIG. 5D

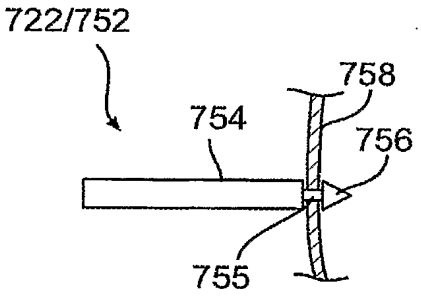

FIG. 5E

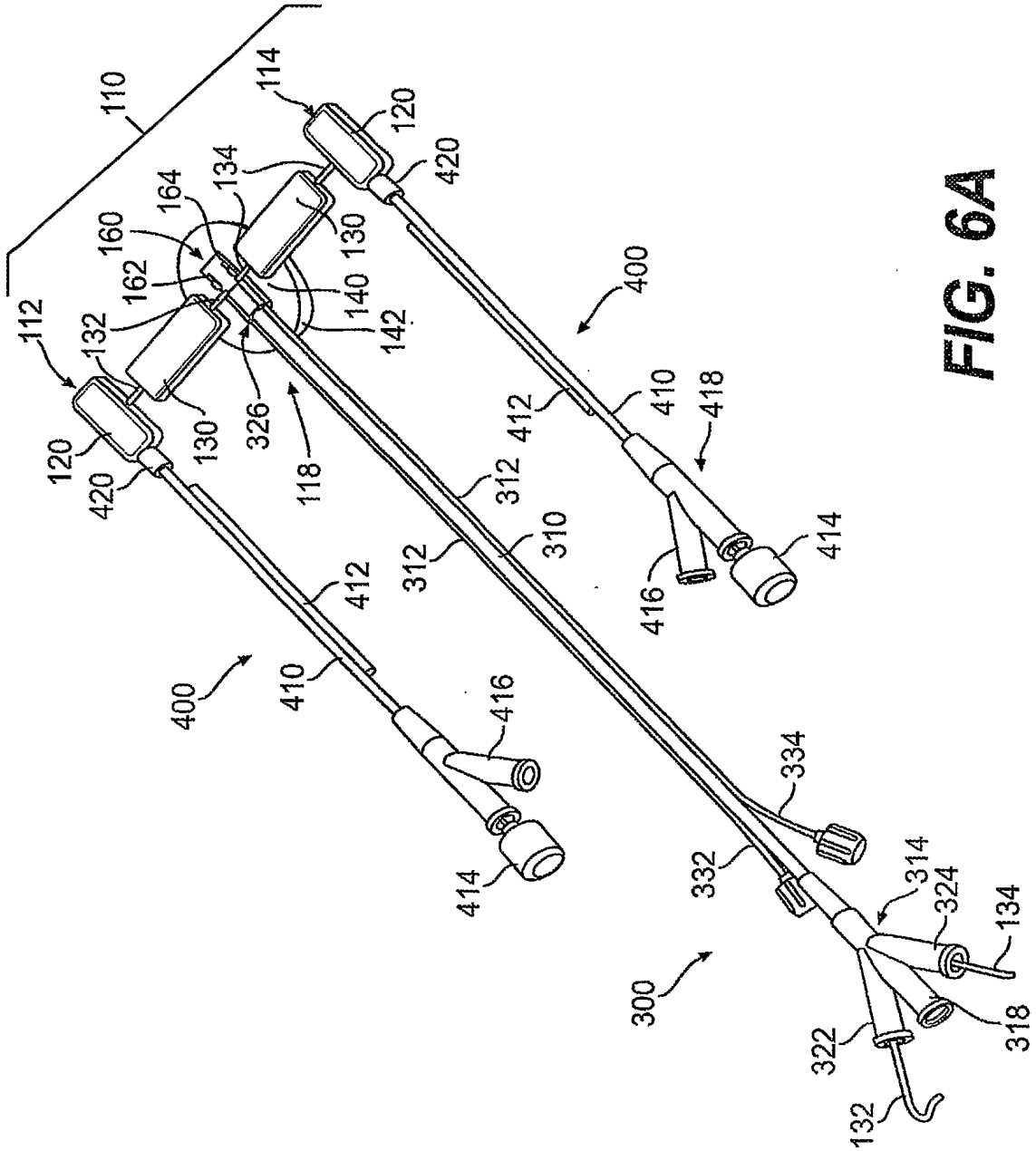

FIG. 6A

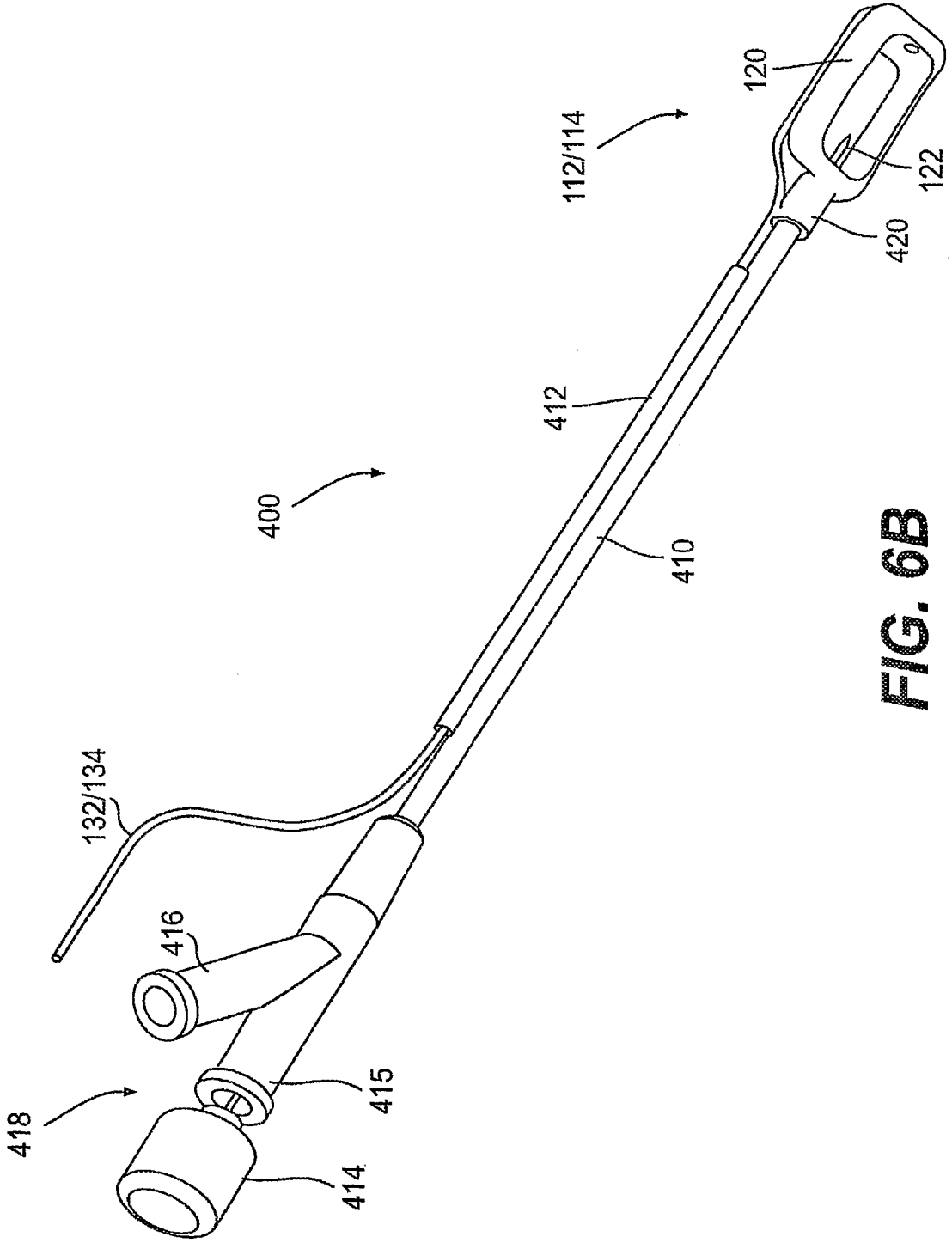

FIG. 6B