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(71) **Applicant:** STANFORD SURGICAL TECHNOLOGIES, INC. [US/US]; 200 Chesapeake Drive, Redwood City, CA 94063 (US).

(72) **Inventors:** STERMAN, Wesley, D.; 2121 Sacramento Street #604, San Francisco, CA 94109 (US). GARRISON, Michi, E.; 2325 Casa Bona Avenue, Belmont, CA 94002 (US). GIFFORD, Hanson, S., III; 3180 Woodside Road, Woodside, CA 94062 (US). STEVENS, John, H.; 727 East Loma Verde Avenue, Palo Alto, CA 94303 (US).

(74) **Agents:** HESLIN, James, M. et al.; Townsend and Townsend Khourie and Crew, 20th floor, One Market Plaza, Steuart Street Tower, San Francisco, CA 94105 (US).

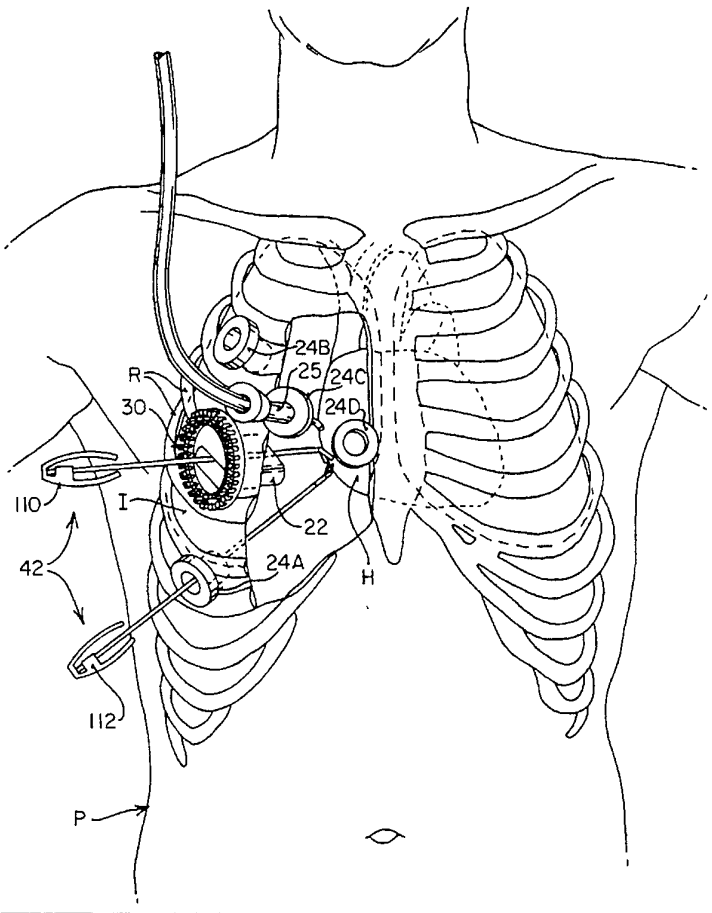
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(54) **Title:** DEVICES AND METHODS FOR INTRACARDIAC PROCEDURES

(57) **Abstract**

The invention provides devices and methods for performing less invasive surgical procedures with an organ or vessel. One embodiment provides a method of closed chest surgical intervention within an internal cavity of a patient's heart. The patient's heart is arrested and cardiopulmonary by-pass is established. A scope (25) extending through a percutaneous intercostal penetration in the patient's chest is used to view an internal portion of the patient's chest. The penetration is formed in a wall of the heart using a cutter (110) introduced through the percutaneous penetration. An interventional tool is then introduced through a cannula (22) positioned in the penetration. The interventional tool is inserted through the penetration to perform a surgical procedure within the internal cavity under visualization by a scope (25). A cutting tool is introduced into the patient's left atrium from a right portion of the patient's chest to remove the patient's mitral valve. A replacement valve (36) is then introduced through the intercostal space and through the penetration in the heart, and the replacement valve is attached in the mitral valve position.



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DEVICES AND METHODS FOR INTRACARDIAC PROCEDURES

FIELD OF THE INVENTION

This invention relates generally to instruments and techniques for performing less-invasive surgical procedures, and more specifically, to instruments and techniques for less-invasive surgery within the heart and great vessels.

BACKGROUND OF THE INVENTION

Various types of surgical procedures are currently performed to investigate, diagnose, and treat diseases of the heart and the great vessels of the thorax. Such procedures include repair and replacement of mitral, aortic, and other heart valves, repair of atrial and ventricular septal defects, pulmonary thrombectomy, treatment of aneurysms, electrophysiological mapping and ablation of the myocardium, and other procedures in which interventional devices are introduced into the interior of the heart or a great vessel.

Using current techniques, many of these procedures require a gross thoracotomy, usually in the form of a median sternotomy, to gain access into the patient's thoracic cavity. A saw or other cutting instrument is used to cut the sternum longitudinally, allowing two opposing halves of the anterior or ventral portion of the rib cage to be spread apart. A large opening into the thoracic cavity is thus created, through which the

surgical team may directly visualize and operate upon the heart and other thoracic contents.

Surgical intervention within the heart generally requires isolation of the heart and coronary blood vessels from the remainder of the arterial system, and arrest of cardiac function. Usually, the heart is isolated from the arterial system by introducing an external aortic cross-clamp through a sternotomy and applying it to the aorta between the brachiocephalic artery and the coronary ostia. Cardioplegic fluid is then injected into the coronary arteries, either directly into the coronary ostia or through a puncture in the aortic root, so as to arrest cardiac function. In some cases, cardioplegic fluid is injected into the coronary sinus for retrograde perfusion of the myocardium. The patient is placed on cardiopulmonary bypass to maintain peripheral circulation of oxygenated blood.

Of particular interest to the present invention are intracardiac procedures for surgical treatment of heart valves, especially the mitral and aortic valves. According to recent estimates, more than 79,000 patients are diagnosed with aortic and mitral valve disease in U.S. hospitals each year. More than 49,000 mitral valve or aortic valve replacement procedures are performed annually in the U.S., along with a significant number of heart valve repair procedures.

Various surgical techniques may be used to repair a diseased or damaged valve, including annuloplasty (contracting the valve annulus), quadrangular resection (narrowing the valve leaflets), commissurotomy (cutting the valve commissures to separate the valve leaflets), shortening mitral or tricuspid valve chordae tendonae, reattachment of severed mitral or tricuspid valve chordae tendonae or papillary muscle tissue, and decalcification of valve and annulus tissue. Alternatively, the valve may be replaced, by excising the valve leaflets of the natural valve, and securing a replacement valve in the

valve position, usually by suturing the replacement valve to the natural valve annulus. Various types of replacement valves are in current use, including mechanical and biological prostheses, homografts, and allografts, as described in Bodnar and Frater, *Replacement Cardiac Valves* 1-357 (1991), which is incorporated herein by reference. A comprehensive discussion of heart valve diseases and the surgical treatment thereof is found in Kirklin and Barratt-Boyes, *Cardiac Surgery* 323-459 (1986), the complete disclosure of which is incorporated herein by reference.

The mitral valve, located between the left atrium and left ventricle of the heart, is most easily reached through the wall of the left atrium, which normally resides on the posterior side of the heart, opposite the side of the heart that is exposed by a median sternotomy. Therefore, to access the mitral valve via a sternotomy, the heart is rotated to bring the left atrium into an anterior position accessible through the sternotomy. An opening, or atriotomy, is then made in the right side of the left atrium, anterior to the right pulmonary veins. The atriotomy is retracted by means of sutures or a retraction device, exposing the mitral valve directly posterior to the atriotomy. One of the forementioned techniques may then be used to repair or replace the valve.

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

in the wall of the left atrium, through which the mitral valve may be accessed for repair or replacement.

Using such open-chest techniques, the large opening provided by a median sternotomy or right thoracotomy enables the surgeon to see the mitral valve directly through the left atriotomy, and to position his or her hands within the thoracic cavity in close proximity to the exterior of the heart for manipulation of surgical instruments, removal of excised tissue, and/or introduction of a replacement valve through the atriotomy for attachment within the heart. However, these invasive, open-chest procedures produce a high degree of trauma, a significant risk of complications, an extended hospital stay, and a painful recovery period for the patient. Moreover, while heart valve surgery produces beneficial results for many patients, numerous others who might benefit from such surgery are unable or unwilling to undergo the trauma and risks of current techniques.

What is needed, therefore, are devices and methods for carrying out heart valve repair and replacement as well as other procedures within the heart and great vessels that reduce the trauma, risks, recovery time and pain that accompany current techniques. The devices and methods should facilitate surgical intervention within the heart or great vessels without the need for a gross thoracotomy, preferably through small incisions within intercostal spaces of the rib cage, without cutting, removing, or significantly deflecting the patient's ribs or sternum. In particular, the devices and methods should allow for removal of tissue from the thoracic cavity, as well as for introduction of surgical instruments, visualization devices, replacement valves and the like into the thoracic cavity, to facilitate heart valve repair and replacement. Preferably, the devices and methods should facilitate replacement of a heart valve with various types of prostheses, including

mechanical and biological prostheses, homografts, and allografts.

SUMMARY OF THE INVENTION

The invention provides devices and methods for performing less-invasive surgical procedures within an organ or vessel, and particularly, within the heart and great vessels of the thoracic cavity. The devices and methods of the invention facilitate intervention within the heart or great vessels without the need for a median sternotomy or other form of gross thoracotomy, substantially reducing trauma, risk of complication, recovery time, and pain for the patient. Using the devices and methods of the invention, surgical procedures may be performed through percutaneous penetrations within intercostal spaces of the patient's rib cage, without cutting, removing, or significantly displacing any of the patient's ribs or sternum. The devices and methods are particularly well-adapted for heart valve repair and replacement, facilitating visualization within the patient's thoracic cavity, repair or removal of the patient's natural valve, and, if necessary, attachment of a replacement valve in the natural valve position. The invention facilitates valve replacement with any of a variety of commercially-available replacement valves, including mechanical prostheses, bioprostheses, homografts, and allografts.

In a first preferred embodiment, the invention provides a method of closed-chest surgical intervention within an internal cavity of the patient's heart or great vessel. Utilizing the method of the invention, the patient's heart is arrested and cardiopulmonary bypass is established. An internal portion of the patient's chest is viewed by means of a scope extending through a percutaneous intercostal penetration in the patient's chest. A cutting means is introduced through a percutaneous intercostal penetration in the patient's

chest, and the cutting means is used to form an internal penetration in a wall of the heart or great vessel. An interventional tool is then introduced through a percutaneous intercostal penetration and through the internal penetration in the heart or great vessel to perform a surgical procedure within the internal cavity under visualization by means of the scope. One or more percutaneous cannulae may be positioned within an intercostal space of the chest wall through which the interventional tool may be introduced into the chest cavity. The surgical procedures which may be performed within the heart or great vessel include repair or replacement of heart valves, repair of atrial and ventricular septal defects, pulmonary thrombectomy, treatment of aneurysms, electrophysiological mapping and ablation of the myocardium, myocardial drilling, correction of congenital defects, coronary artery bypass grafting, and other procedures.

The patient's heart is preferably arrested by occluding the patient's aorta between the patient's coronary arteries and the patient's brachiocephalic artery with an expandable member on a distal end of an endovascular catheter. Cardioplegic fluid is then introduced through a lumen in the catheter into the patient's aorta upstream of the expandable member to arrest cardiac function. Alternatively, or in addition to such antegrade cardioplegic fluid delivery, cardioplegic fluid may be delivered in a retrograde manner by means of a catheter positioned in the coronary sinus of the patient's heart. In an alternative approach, an external cross-clamp may be placed thoracoscopically on the aorta through a small incision or cannula in the patient's chest. Cardioplegic fluid may be delivered through either a thoracoscopically introduced cannula or an endovascular catheter extending into the ascending aorta upstream of the cross-clamp.

In a preferred embodiment, the surgical procedure comprises surgically treating a heart valve. Such surgical treatment may involve repairing the valve by introducing instruments through an intercostal penetration and through the internal penetration in the heart to perform, for example, annuloplasty, quadrangular resection of valve leaflets, commissurotomy, reattachment of chordae tendonae or papillary muscle tissue, shortening of chordae tendonae, decalcification, and the like.

The heart valve may also be replaced with a replacement valve. In this embodiment, the method may further comprise the step of removing all or part of the patient's natural heart valve by means of a cutting tool introduced through a percutaneous intercostal penetration and through the internal penetration in the heart. The method further comprises the step of introducing a replacement valve through a percutaneous intercostal penetration and through the internal penetration into the internal cavity within the heart. The replacement valve is then fastened within the heart, usually by means of an instrument introduced through a percutaneous intercostal penetration and through the internal penetration in the heart wall.

The method may further include the step of sizing the patient's heart valve before the replacement valve is introduced. In an exemplary embodiment, a sizing instrument is introduced through a percutaneous intercostal penetration and through the internal penetration in the heart to measure the size of the valve annulus and to determine the size of the replacement valve.

The replacement valve may be fastened in position in various ways, including suturing the replacement valve to an annulus at the natural valve position in the heart. In one embodiment, the sutures are applied to the annulus at the valve position, drawn out of the patient's body

through the internal penetration and through a percutaneous intercostal penetration, and then applied to the replacement valve. The sutures may further be radially arranged in spaced-apart locations about an organizer ring disposed outside of the patient's body. The sutures are then held in tension as the replacement valve is introduced into the interior of the heart and positioned in the natural valve position. The replacement valve may be introduced by means of a valve holder attached to an elongated handle, or simply pushed along the sutures by means of the surgeon's hands or conventional tools such as forceps or needle drivers.

In a particular preferred embodiment, the heart valve comprises a mitral valve which is disposed between the left atrium and left ventricle of the patient's heart. A percutaneous penetration is made within an intercostal space in a right lateral portion of the patient's chest, usually within the fourth, fifth, or sixth intercostal space. From this penetration, an internal penetration may be formed in the wall of the left atrium at a location which is in a generally straight line drawn from the penetration in the right lateral portion of the chest to the patient's mitral valve. In this way, surgical instruments may be introduced from the penetration in the right chest to form the internal penetration in the heart wall, repair or excise the patient's natural valve, and introduce and attach a replacement valve.

In a further aspect of the invention, a prosthesis assembly is provided for closed-chest replacement of a heart valve. The prosthesis assembly comprises a replacement valve having an annular attachment portion and a movable valve portion coupled to the attachment portion. The prosthesis assembly further includes holder means releasably mounted to the attachment portion, wherein the holder means is configured to allow

introduction of the replacement valve through an intercostal space in the patient's chest.

In a preferred embodiment, the replacement valve and the holder means together have a profile with a width which is less than the width of the intercostal space. Preferably, the intercostal space is less than about 20 mm in width. The attachment portion of the replacement valve will usually have an outer diameter which is greater than the intercostal width.

The holder means of the device preferably comprises an elongated handle having a distal end mounted to the replacement valve and a proximal end opposite the distal end. The handle is configured to introduce the replacement valve into the patient's heart through the intercostal space. Preferably, the handle is at least about 20 cm in length to allow positioning the replacement valve in the heart from a right lateral portion of the patient's chest. The handle may further include means for releasing the replacement valve, the releasing means being configured for actuation from the proximal end of the handle.

The handle may also include means for pivoting the replacement valve from a first orientation for introduction through the intercostal space to a second orientation for attachment in the patient's heart. The pivoting means is configured for actuation from a proximal end of the handle. In this way, the replacement valve may be introduced edge-first through the intercostal space, then pivoted about an axis generally perpendicular to the handle into an orientation suitable for attachment within the patient's heart. Alternatively, the valve prosthesis may be collapsible or compressible to permit introduction through an intercostal space into the thoracic cavity.

Preferably, the replacement valve is premounted to the holder means and the two are sterilized and packaged together in a sterile pack. In this way, the pack may be

opened in the sterile operating room environment with the valve and holder ready for immediate surgical use.

In a further embodiment, the invention provides a thoracoscopic device for placement of a replacement valve in a valve position of a patient's heart. In a preferred embodiment, the thoracoscopic device comprises an elongated handle configured for positioning through an intercostal space in the patient's chest, as described above. The device includes means at a distal end of the handle for releasably holding a replacement valve in an orientation for introduction through the intercostal space, and may further include means for pivoting the replacement valve relative to the handle from a first orientation for introduction through the intercostal space, to a second orientation for placement in the valve position. The thoracoscopic device further includes, in a preferred embodiment, means at the proximal end of the handle for releasing the replacement valve from the holding means once the prosthesis has been positioned and secured within the heart.

In a further aspect of the invention, a percutaneous access cannula is provided to facilitate closed-chest replacement of a heart valve in a patient's heart. The access cannula comprises a cannula body configured for placement in an intercostal space in the patient's chest, the cannula having a distal end, a proximal end, and a lumen extending therebetween. The lumen is configured to allow passage of a replacement valve therethrough. An obturator is positionable in the lumen to facilitate introduction of the cannula body. The obturator has a cross-sectional width that is equal to or less than the width of the intercostal space, and a cross-sectional height that is greater than the cross-sectional width.

The replacement valve has an annular attachment portion with an outer diameter, and the obturator as well as the lumen in the cannula have a cross-sectional height at least equal to the outer diameter, allowing the

replacement valve to be introduced through the lumen of the cannula. In one embodiment, the cross-sectional height of the lumen in the cannula is about two to six times the cross-sectional width. The lumen and obturator may have a rectangular cross-section, oval cross-section, or other shape. The cannula body may be rigid or deformable, while the obturator is usually rigid to facilitate introduction.

The access cannula may further be provided with suture retaining means on its proximal end configured to retain a plurality of sutures in a spaced-apart relationship. The suture retaining means may have various configurations, such as a plurality of slots in a proximal end of the cannula body in circumferentially spaced positions around the lumen. The slots in the access cannula may further include means such as slitted, elastomeric inserts, for frictionally engaging the sutures to maintain tension thereon while the prosthesis is introduced into the heart.

A second organizing ring may also be provided in a position spaced-apart from the access cannula outside of the patient's body. The second organizing ring has an interior passage through which the sutures may extend and a plurality of means circumferentially spaced around the passage for frictionally engaging the sutures. In this way, sutures may be applied to the valve annulus in the patient's heart, drawn through the lumen in the cannula and retained in the suture organizing means on the access cannula's proximal end. The sutures may then be applied to the replacement valve and retained in the second organizing ring. Once all of the sutures have been applied to the prosthesis, the prosthesis may be introduced into the heart by sliding it along the sutures, which are held in tension by the second organizing ring. Alternatively, the sutures may be held in tension by individual clamps, tape, commercially-available suture organizers, or other means

for exerting traction on the free ends of each individual suture.

The invention further provides a system for closed-chest replacement of a heart valve in a patient's heart. The system includes means for forming a percutaneous intercostal penetration in the patient's chest, and a visualization scope configured to pass through an intercostal space in the patient's chest for viewing an internal chest cavity. Means are also provided for arresting the patient's heart from a location outside of the chest cavity. A cardiopulmonary bypass system, including means for delivering oxygenated blood to the patient's arterial system, is provided for maintaining peripheral circulation of oxygenated blood. Cutting means positionable through a percutaneous intercostal penetration into the chest cavity are provided for forming an internal penetration in a wall of the patient's heart or great vessel. The system further provides interventional means positionable through a percutaneous intercostal penetration and through the internal penetration for performing a surgical procedure within the heart or great vessel.

In a preferred embodiment, the means for arresting the heart comprises an endovascular catheter having expandable means near its distal end for occluding the patient's ascending aorta between the patient's coronary arteries and the patient's brachiocephalic artery. The catheter further includes an internal lumen for delivering cardioplegic fluid into the aorta upstream of the expandable means to perfuse the myocardium through the coronary arteries.

The interventional means preferably comprises means for securing a replacement valve in a valve position within the patient's heart. Usually, the replacement valve securing means comprises an elongated handle like that described above, having means at its distal end for releasably holding a replacement valve. The handle may

also facilitate pivoting the replacement valve for introduction through an intercostal space.

Preferably, the system also includes at least one cannula positionable in a percutaneous intercostal penetration, through which surgical instruments or a replacement valve may be introduced into the thoracic cavity. The cannula may have a lumen with a cross-sectional height greater than its width to allow edge-first introduction of a replacement valve that has an outer diameter larger than the intercostal space, as described above.

The system may further include cutting means positionable through a percutaneous intercostal penetration and through the internal penetration in the patient's heart for removing at least a portion of the patient's heart valve. The cutting means for removing the heart valve may comprise scissors, retractable knife, biters, or the like.

The system preferably includes means positionable through a percutaneous intercostal penetration and through the internal penetration for sizing an annulus of the patient's heart valve. In one embodiment, the sizing means comprises an elongated shaft and a plurality of interchangeable sizing disks of various sizes attachable to a distal end of the shaft. The shaft and sizing disk may be introduced through a percutaneous intercostal penetration and through the internal penetration to position the sizing disk adjacent to the annulus of the patient's heart valve, allowing a comparison of the annulus diameter to the disk diameter. The sizing disk may be pivotable relative to the shaft to allow introduction into the thoracic cavity through an intercostal space. Alternative means for sizing may also be used, such as expandable baskets, balloons, endoscopic or endovascular visualization, fluoroscopy, or transesophageal echocardiography.

The system may further include means for attaching the replacement valve to the patient's heart, which comprises, in one embodiment, means for suturing the replacement valve to a valve annulus in the patient's heart. The system preferably includes organizing means for maintaining the sutures in spaced-apart positions outside of the chest cavity after the sutures have been applied to the valve annulus within the heart. The organizing means is preferably fixed to a proximal end of a cannula disposed in a percutaneous intercostal penetration, as described above. In this way, the sutures may be applied to the natural valve annulus within the patient's heart, drawn out of the chest cavity through the cannula lumen, and positioned in spaced-apart positions about the circumference of the proximal end of the cannula. Means may also be provided for maintaining tension on the ends of the sutures after they have been applied to the replacement valve. This facilitates advancing the replacement valve along the sutures, through the lumen in the cannula, and into the chest cavity.

The system may further include retraction means positionable through an intercostal space in the patient's chest for opening the internal penetration in the wall of the heart or great vessel. The retraction means may comprise a collapsible rake, tethered clamp, retraction sutures, or the like.

A further understanding of the nature and advantages of the invention may be realized by reference to the remaining portions of the specification and the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a system for closed-chest mitral valve replacement constructed in accordance with the principles of the present invention, showing the use of the system in a patient.

Figure 2 is a front view of the system of Figure 1, showing the positioning of the system in the patient's chest.

Figure 3 is a front view of a patient's cardiovascular system illustrating the positioning of a system for arresting the heart and establishing cardiopulmonary bypass in accordance with the principles of the present invention.

Figure 4 is a top view looking into the patient's thoracic cavity through a passage of an access cannula in the system of Figure 1, showing the creation of an atriotomy in the patient's left atrium.

Figure 5 is a top view looking into the patient's thoracic cavity through a passage of an access cannula in the system of Figure 1, showing the removal of the mitral valve leaflets.

Figure 6 is a top view looking into the patient's thoracic cavity through a passage of an access cannula in the system of Figure 1, showing the application of sutures to the mitral valve annulus.

Figure 7 is a perspective view of the system of Figure 1 positioned in the patient, showing the application of sutures to a replacement valve.

Figures 8A-8B are transverse cross-sectional views of the system and patient of Figure 1 taken through the patient's thorax, showing the introduction of the replacement valve into the left atrium and the tying of knots in the sutures to secure the prosthesis in the patient's heart.

Figure 9 is a top view looking into the patient's thoracic cavity through a passage of an access cannula in the system of Figure 1, showing pushing the knots toward the replacement valve and trimming the free ends of the sutures.

Figure 10 is a top view looking into the patient's thoracic cavity through a passage of an access cannula in

the system of Figure 1, showing the closure of the patient's left atrium.

Figures 11A-11C are perspective, front, and top views respectively of the access cannula in the system of Figure 1.

Figure 11D is a partial cut-away view taken along line 11D-11D in Figure 11C.

Figure 12A is a side view of angled scissors in the system of Figure 1.

Figures 12B-12D are side views of a distal portion of the scissors of Figure 12A showing alternative embodiments thereof.

Figure 13 is a side view of a retractable knife in the system of Figure 1.

Figures 14A-14B are side and top views, respectively, of grasping forceps in the system of Figure 1.

Figure 15 is a perspective view of a left atrial retractor in the system of Figure 1.

Figures 16A-16B are side and top views, respectively, of needle drivers in the system of Figure 1.

Figures 17A-17B are top and side views, respectively, of a replacement valve in the system of Figure 1.

Figure 17C is an end view of the replacement valve of Figures 17A-17B positioned in a passage of an access cannula in the system of Figure 1.

Figure 18 is a perspective view of a prosthesis introducer in the system of Figure 1.

Figure 19A is a side view of the prosthesis introducer of Figure 18.

Figures 19B-19C are bottom and side views, respectively, of a distal portion of the prosthesis introducer of Figure 18.

Figures 19D-19E are top and side views, respectively, of a stationary arm of the prosthesis introducer of Figure 18.

Figures 19F-19G are top and side views, respectively, of a movable arm of the prosthesis introducer of Figure 18.

Figure 20A is a side partial cut-away view of the prosthesis introducer of Figure 18.

Figure 20B is a top partial cut-away view of a distal portion of the prosthesis introducer of Figure 18.

Figure 21 is a perspective view of a sizing disk in the system of Figure 1, positioned on the introducer of Figure 18.

Figures 22, 23A and 23B are top and side views, respectively, of the sizing disk of Figure 21.

Figures 23A-23B are top and side views, respectively, of the sizing disk of Figure 21.

Figures 24A-24C are front, top, and side views, respectively of a suture organizing ring in the system of Figure 1.

Figures 25A-25B are side and top views, respectively of a knot-pushing device in the system of Figure 1.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

The invention provides methods and devices for performing surgical interventions within the heart or a great vessel such as the aorta, superior vena cava, inferior vena cava, pulmonary artery, pulmonary vein, coronary arteries, and coronary veins, among other vessels. While the specific embodiments of the invention described herein will refer to mitral valve repair and replacement, it should be understood that the invention will be useful in performing a great variety of surgical procedures, including repair and replacement of aortic, tricuspid, or pulmonary valves, repair of atrial and ventricular septal defects, pulmonary thrombectomy, removal of atrial myxoma, patent foramen ovale closure,

treatment of aneurysms, electrophysiological mapping and ablation of the myocardium, myocardial drilling, coronary artery bypass grafting, angioplasty, atherectomy, correction of congenital defects, and other procedures in which interventional devices are introduced into the interior of the heart, coronary arteries, or great vessels. Advantageously, the invention facilitates the performance of such procedures through percutaneous penetrations within intercostal spaces of the rib cage, obviating the need for a median sternotomy or other form of gross thoracotomy.

The terms "percutaneous intercostal penetration" and "intercostal penetration" as used herein refer to a penetration, in the form or a small cut, incision, hole, cannula, trocar sleeve, or the like, through the chest wall between two adjacent ribs, wherein the patient's rib cage and sternum remain substantially intact, without cutting, removing, or significantly displacing the ribs or sternum. These terms are intended to distinguish a gross thoracotomy such as a median sternotomy, wherein the sternum and/or one or more ribs are cut or removed from the rib cage, or one or more ribs are retracted significantly, to create a large opening into the thoracic cavity. A "percutaneous intercostal penetration" may abut or overlap the adjacent ribs between which it is formed, but the maximum width of the penetration which is available for introduction of instruments, prostheses and the like into the thoracic cavity will be the width of the intercostal space, bounded by two adjacent ribs in their natural, substantially undeflected positions. It should be understood that one or more ribs may be retracted or deflected a small amount without departing from the scope of the invention; however, the invention specifically seeks to avoid the pain, trauma, and complications which result from the large deflection or cutting of the ribs in conventional, open-chest techniques.

A first preferred embodiment of a system and method of closed-chest mitral valve replacement according to the invention will be described with reference to Figures 1-10. Figure 1 illustrates a system 20 for closed-chest valve replacement positioned in a patient **P** on an operating table **T**. Preferably, a wedge or block **W** having a top surface angled at approximately 20° to 45° is positioned under the right side of patient **P** so that the right side of the patient's body is somewhat higher than the left side. The patient's right arm **A** is allowed to rotate downward to rest on table **T**, exposing the right lateral side of the patient's chest.

The valve replacement system 20 includes an access cannula 22 positioned percutaneously within an intercostal space between two ribs (shown in phantom) in a right lateral side of the patient's chest. Additional thoracoscopic trocar sleeves 24 of conventional construction are positioned within intercostal spaces in the right lateral chest inferior and superior to access cannula 22, as well as in the right anterior (or ventral) portion of the chest. An endoscope 25 of conventional construction is positioned through a percutaneous intercostal penetration into the patient's chest, usually through one of trocar sleeves 24. The distal end of endoscope 25 (shown in phantom) is preferably configured to view at an angle between about 30° and 90° relative to the shaft of endoscope 25, to facilitate visualization of the heart from the right portion of the thoracic cavity. A light source (not shown) is also provided on endoscope 25 to illuminate the thoracic cavity. A video camera 26 is mounted to the proximal end of endoscope 25, and is connected to a video monitor 28 for viewing the interior of the thoracic cavity. A first suture organizing ring 30 is mounted to a proximal end of access cannula 22. A second organizing ring 32 is mounted to a support stand 34 fixed to table **T**. A replacement valve 36 is held at the distal end of an introducer 38 between first

organizing ring 30 and second organizing ring 32. Introducer 38 extends through second organizing ring 32 and is supported by support stand 34. Additional instruments to be used in a procedure such as a retractor 40, as well as cutting, suturing, stapling, aspirating, irrigating and other devices, may be introduced through access cannula 22, trocar sleeves 24, and/or small, percutaneous incisions within intercostal spaces of the rib cage.

Referring now to Figure 2, access cannula 22 is positioned within an intercostal space **I** in the right lateral side of the chest, preferably in the third, fourth, fifth, or sixth intercostal space between adjacent ribs **R**. Additional trocar sleeves 24A, 24B are positioned within intercostal spaces superior and inferior to access cannula 22 in the right lateral side of the chest. Access cannula 22 and trocar sleeves 24A, 24B are positioned so that instruments 42 introduced through them may be directed toward the right side of the left atrium of the heart **H**. A trocar sleeve 24C is positioned in an intercostal space in the right anterior side of the chest such that endoscope 25 may be introduced to view the thoracic cavity and heart **H** without interfering with instruments introduced through access cannula 22 or trocar sleeves 24A, 24B. An additional trocar sleeve 24D is positioned in an intercostal space in the anterior side of the chest just to the right of the sternum and anterior to the right lateral side of the heart **H**.

It will be understood to those of ordinary skill in the art that, in some cases, it may desirable to eliminate some or all of trocar sleeves 24 and/or access cannula 22, and introduce instruments directly through small, percutaneous intercostal incisions in the chest. Advantageously, unlike laparoscopic, arthroscopic, and other endoscopic procedures, no distension of the chest is required using the method of the invention, so that

leakage of distension fluid through percutaneous penetrations is not of concern. Thus, either thoracoscopic trocar sleeves without fluid seals or percutaneous incisions may be utilized for instrument introduction into the thoracic cavity. Trocar sleeves are generally preferred, however, in order to provide an open passage into the thoracic cavity, to protect adjacent tissue from injury resulting from contact with instruments, and to avoid damaging instruments, endoscopes, replacement valves, and the like when introduced into the thoracic cavity.

Referring now to Figures 11A-11D, access cannula 22 will be described in greater detail. Access cannula 22 comprises a body 44 having a proximal end 46, a distal end 48, and a passage 50 extending therebetween. Body 44 is configured to fit within an intercostal space **I** without significant deflection of adjacent ribs **R**, usually having a width of less than about 20 mm. Passage 50 is configured to facilitate passage of replacement valve 36 therethrough. Replacement valve 36 may have a variety of configurations, but must have a diameter at least equal to that of the patient's natural heart valve, a diameter which commonly exceeds the width of the intercostal spaces in the rib cage. Therefore, in order to avoid cutting or retracting the patient's ribs, replacement valve 36 is introduced edge-first through passage 50 of access cannula 22, as described more fully below. To accommodate such introduction of replacement valve 36, passage 50 usually has a cross-sectional width **w** of about 12 mm to 20 mm, and a cross-sectional height **h** that is somewhat greater than cross-sectional width **w**, usually 2-6 times cross-sectional width **w**, and preferably in the range of 25 mm to 50 mm. Passage 50 may have various cross-sectional shapes, including oval, rectangular, race-track, and the like. This accommodates a variety of replacement heart valves, including mechanical and biological prostheses, as well as

homograft and allograft tissue valves. It will be understood, however, that certain replacement valves may be collapsible or sufficiently small in size so that passage 50 in access cannula 22 may have a round or square cross-section and still allow passage of the replacement valve therethrough. However, a cross-sectional shape in which the height is greater than the width may still be advantageous to allow greater freedom of movement in manipulating the replacement valve and other instruments introduced through passage 50.

As shown in Figure 11B, an obturator 52 is positionable in passage 50 to facilitate introduction of access cannula 22 through the chest wall. Obturator 52 has a tapered distal end 54, a proximal end 56, and a rim 58 near proximal end 56 for engaging proximal end 46 of cannula body 44. Usually, obturator 52 is positioned in passage 50 of access cannula 22, and the two are introduced through a small incision formed in an intercostal space in the chest wall. Obturator 52 is then removed from passage 50.

As described briefly above, access cannula 22 may further include a suture organizing ring 30 mounted to its proximal end 46. Suture organizing ring 30 has a ring-shaped body 60 and a plurality of slots 62 circumferentially spaced about body 60. Usually, between 16 and 32 of slots 62 are provided, depending upon the type of replacement valve and suturing technique to be utilized in the procedure. An elastomeric retaining ring 64 is disposed in a circumferential channel in ring body 60, and has a plurality of slits 66, best seen in Figure 11D, aligned with each slot 62. Slits 66 are provided with chamfers 68 along the top surface of retaining ring 64 to facilitate positioning sutures within slits 66 for retention therein. The function of suture organizing ring 30 will be described in greater detail below.

Referring again to Figure 2, once access cannula 22 and trocar sleeves 24 have been positioned in the

patient's chest, endoscope 25 is introduced through trocar sleeve 24D and camera 26 is connected to video monitor 28 (Figure 1). Endoscope 25 is manipulated so as to provide a view of the right side of the heart, and particularly, a right side view of the left atrium. Usually, an endoscope of the type having an articulated distal end, or a distal end disposed at an angle between 30° and 90° will be used, which is commercially available from, for example, Olympus Corp., Medical Instruments Division, Lake Success, NY.

At this point in the procedure, if not previously accomplished, the patient is placed on cardiopulmonary bypass (CPB), the patient's right lung is at least partially collapsed, and the patient's heart is arrested. Suitable techniques for arresting cardiac function and establishing CPB without a thoracotomy are described in commonly-assigned, co-pending applications Serial No. 07/991,188, filed December 15, 1992, and Serial No. 08/123,411, Attorney Docket No. 14635-4/93002-1, filed September 17, 1993, both of which are incorporated herein by reference.

As illustrated in Figure 3, CPB is established by introducing a venous cannula 70 into a femoral vein 72 in patient **P** and advancing venous cannula 72 into the inferior vena cava 74 and/or into the interior of heart **H** to withdraw deoxygenated blood therefrom. Venous cannula 70 is connected to a cardiopulmonary bypass system 76 which receives the withdrawn blood, oxygenates the blood, and returns the oxygenated blood to an arterial return cannula 78 positioned in a femoral artery 80.

A pulmonary venting catheter 79 may also be utilized to withdraw blood from the pulmonary trunk 77. Pulmonary venting catheter 79 may be introduced from the neck through the interior jugular vein 106 and superior vena cava 108, or from the groin through femoral vein 72 and inferior vena cava 74. Usually, a Swan-Ganz catheter (not shown) is first introduced and positioned in

pulmonary artery 77 using well-known techniques, and pulmonary venting catheter 79 is then introduced over the Swan-Ganz catheter. Blood is withdrawn from pulmonary trunk 77 through a port at the distal end of pulmonary venting catheter 79 and an inner lumen extending through the catheter outside of the patient's body. Pulmonary venting catheter 79 may further have one or more balloons 81 at its distal end proximal to the distal port for occluding pulmonary trunk 77.

An alternative method of venting blood from pulmonary trunk 77 is described in U.S. Patent No. 4,889,137, which is incorporated herein by reference. In the technique described therein, a catheter is positioned from the interior jugular vein in the neck through the right atrium, right ventricle, and pulmonary valve into the pulmonary artery 77. The catheter has a coil about its periphery which holds the pulmonary valve open so as to drain blood from pulmonary trunk 77, thereby decompressing the left side of the heart.

For purposes of arresting cardiac function, an aortic occlusion catheter 82 is positioned in a femoral artery 84 by a percutaneous technique such as the Seldinger technique, or through a surgical cut-down 86. The aortic occlusion catheter 82 is advanced, usually over a guidewire (not shown), until an occlusion balloon 88 at its distal end is disposed in the ascending aorta 90 between the coronary ostia 92 and the brachiocephalic artery 94. Blood may be vented from ascending aorta 90 through a port 95 at the distal end of the aortic occlusion catheter 82 in communication with an inner lumen in aortic occlusion catheter 82, through which blood may flow to proximal end 96 of catheter 82. The blood may then be directed to a blood filter/recovery system 98 to remove emboli, and then returned to the patient's arterial system via CPB system 76.

When it is desired to arrest cardiac function, occlusion balloon 88 is inflated by injecting inflation

fluid, usually a mixture of saline and a radiographic contrast agent, from a syringe 100 connected to proximal end 96 of catheter 82, through an inflation lumen in catheter 82 to the interior of occlusion balloon 88. Occlusion balloon 88 is expanded until it completely occludes ascending aorta 92, blocking blood flow therethrough. A cardioplegic fluid such as potassium chloride (KCl) is then delivered to the myocardium in one or both of two ways. Cardioplegic fluid may be delivered in an anterograde manner from a cardioplegia pump 101 through an inner lumen in aortic occlusion catheter 82 and a port distal to occlusion balloon 88 into the ascending aorta upstream of occlusion balloon 88. The cardioplegic fluid is then infused into the coronary arteries and paralyzes the myocardium.

Alternatively, or in conjunction with such anterograde delivery, cardioplegic fluid may be delivered in a retrograde manner through a retroperfusion catheter 102 positioned in the coronary sinus 104. Retroperfusion catheter 102 may be positioned, usually over a guidewire (not shown), from the neck through the interior jugular vein 106 and superior vena cava 108, or from the groin through a femoral vein 72 and the inferior vena cava 74. Retroperfusion catheter 102 may have one or more balloons (not shown) at its distal end to enhance positioning and infusion of cardioplegia into the coronary sinus. Cardioplegic fluid may thus be infused through the coronary veins into the capillary beds, paralyzing the myocardium.

The right lung may be collapsed using known techniques. Usually, a tube is introduced through the trachea into the right main stem bronchus, and a vacuum is applied through the tube to collapse the lung.

With cardiopulmonary bypass established, cardiac function arrested, and the right lung collapsed, the patient is prepared for surgical intervention within the heart H. Referring again to Figure 2, a surgical cutting

instrument such as angled scissors 110, as well as a grasping instrument such as grasping forceps 112, are introduced through access cannula 22 or through trocar sleeves 24A, 24B. Angled scissors 110 and forceps 112 are used to form an opening in the pericardium, providing access to the right side of the left atrium.

Angled scissors 110 are illustrated more clearly in Figures 12A-12D. Angled scissors 110 include a shaft 114 having a distal end 116, a proximal end 118, and an actuator 120 attached to proximal end 118. Shaft 114 of angled scissors 110 has a length selected to allow intervention within left atrium **LA** of heart **H**, and is usually at least about 15 cm in length and preferably 20 cm to 35 cm in length. Actuator 120 includes a movable arm 122 pivotally coupled to a stationary arm 124. A linkage 126 connects movable arm 122 to a push rod 128 extending slidably through shaft 110. By pivoting movable arm 122 toward shaft 114, push rod 128 is translated distally. A stationary blade 130 is mounted to distal end 116 of shaft 114, and a movable blade 132 is pivotally mounted to stationary blade 130. Push rod 128 is linked to movable blade 132 such that distal movement of push rod 128 pivots movable blade 132 toward stationary blade 130. Blades 130, 132 may be mounted at various angles relative to shaft 114, as illustrated in Figures 12B-12D. A flush port (not shown) may also be provided in shaft 114 for delivering a flushing solution such as saline to distal end 116 to remove fluid and/or debris from blades 130, 132 or from the surgical site.

In addition to angled scissors 110, a retractable knife 134, illustrated in Figure 13, may be used for various cutting purposes. Retractable knife 134 comprises a shaft 136 having a distal end 138 and a proximal end 140. A handle 142 is attached to proximal end 140, to which an actuator 144 is slidably mounted. A push rod (not shown) is coupled to actuator 144 and extends slidably through shaft 136. A knife blade 146 is

slidably mounted at distal end 138 of shaft 136 and is linked to the push rod, such that sliding actuator 144 proximally retracts knife blade 146 within a sheath 148 mounted to distal end 138. Alternatively, knife blade 146 may be fixed to shaft 136, and sheath 148 slidably mounted to shaft 136 and linked to the push rod, such that sheath 148 may be retracted and extended over knife blade 146 by sliding actuator 144.

Grasping forceps 112 are illustrated in Figures 14A-14B. Grasping forceps 112 have a construction much the same as that of angled scissors 110, with an actuator 150 translating a push rod 152 slidably disposed in a shaft 154. A stationary jaw 158 is fixed to a distal end 156 of shaft 154, and a movable jaw 160 is slidably mounted to shaft 154. Push rod 152 is linked to movable jaw 160, such that translation of push rod 152 by actuator 150 closes movable jaw 160 against stationary jaw 158. Grooves or other textural features may be provided on the inner surfaces of jaw 158 and/or jaw 160 to improve grip upon tissue.

Figure 4 illustrates the view into the thoracic cavity through passage 50 of access cannula 22. Angled scissors 110 aided by grasping forceps 112 are shown cutting through the right side of left atrium **LA** to form an atriotomy 162. Atriotomy 162 is formed along dotted line 164 anterior to right pulmonary veins **PV**. A completed description of techniques for forming such an atriotomy is found in Kirklin and Barratt-Boyes, *Cardiac Surgery*, pp. 329-340, the disclosure of which has been incorporated herein by reference. Usually, atriotomy 162 will be formed under visualization by means of endoscope 25 (Figures 1 and 2), although direct viewing is possible through passage 50 of access cannula 22, or through a trocar sleeve 24.

Upon completion of atriotomy 162, the wall of left atrium **LA** on the anterior side of atriotomy 162 is retracted anteriorly by means of thoracoscopic retractor

40, as illustrated Figures 1 and 5. Thoracoscopic retractor 40, illustrated more clearly in Figure 15, includes a shaft 166 having a distal end 168, a proximal end 170, and an inner lumen 172 therebetween. A pair of finger rings 174 is mounted to proximal end 170 of shaft 166. A guide 175 is also mounted to proximal end 170 having a channel 176 extending therethrough. A sliding rod 178 extends through channel 176 and has a plurality of teeth 180 on a lateral surface thereof which are engaged by a pawl 182 pivotally mounted to guide 175 and biased by a spring (not shown) against teeth 180. Sliding rod 178 has a proximal end 184 to which a thumb ring 186 is attached, allowing thumb ring 186 to be drawn toward finger rings 174. A push rod 188 is slidably disposed in lumen 172 of shaft 166 and is attached at its proximal end 190 to sliding rod 178. Three rake arms 192 are pivotally coupled to shaft 166 within a transverse slot 194 at distal end 168. Rake arms 192 each have a hooked distal end 193 for engaging and retracting tissue. The distal end of push rod 188 slidably engages rake arms 192 within a slot 196 in each rake arm. In this way, by sliding push rod 188 distally, rake arms 192 collapse in an overlapping configuration suitable for introduction through one of trocar sleeves 24. Once rake arms 192 are introduced into the thoracic cavity, they may be expanded by pulling thumb ring 186 relative to finger rings 174.

Referring again to Figure 5, retractor 40 is introduced into the thoracic cavity through trocar sleeve 24 and rake arms 192 are deployed into their expanded configuration. Retractor 40 is manipulated so that hooked ends 193 of rake arms 192 engage the wall of left atrium **LA** on the anterior side of atriotomy 162. Retractor 40 is then pulled in the anterior direction to retract the wall of left atrium **LA**, opening atriotomy 162 and exposing the patient's mitral valve **MV** within the left atrium **LA**. A conventional stopcock, cam lock, or other clamping device (not shown) may be provided on

trocar sleeve 24 to lock retractor 40 in position, or shaft 166 may be provided with an adjustable collar (not shown) for engaging trocar sleeve 24 to maintain retractor 40 in position.

It will be understood that retractor 40 illustrated in Figures 1, 5 and 15 is merely exemplary of the various means that may be used for retraction of left atrium **LA**. Another suitable means of retraction is described in published European patent application number PCT/US92/06186, the complete disclosure of which is incorporated herein by reference. That application describes a clip which may be applied to tissue by means of an introducer, and a flexible cable assembly attached to the clip which may be used to apply traction to the clip from outside of the patient's body. The clip may be applied to the wall of the left atrium **LA** on the anterior side of atriotomy 162 with the cable extending through a trocar sleeve 24, whereby atriotomy 162 is retracted open by applying traction to the cable. The cable may be attached to the patient's body, to the surgical drapes, or to another support structure outside of the body to maintain the atriotomy open during the procedure. Alternatively, one or more sutures (not shown) may be applied to the wall of left atrium **LA** anterior to atriotomy 162. The free ends of the sutures may be applied to an internal structure in the thoracic cavity, or withdrawn from the thoracic cavity through a puncture or a trocar sleeve 24 and attached to the patient's body or to the surgical drapes, thereby opening atriotomy 162. Other suitable means of retraction include devices having a collapsible and expandable frame (not pictured) which is insertable within atriotomy 162. When deployed, the frame urges the opposing sides of atriotomy 162 away from each other, and maintains the atriotomy open throughout the procedure until the device is removed.

With atriotomy 162 retracted open, the interior of heart **H** is accessible for the performance of an

interventional procedure therein. Instruments may be introduced through access cannula 22 or trocar sleeves 24 and through atriotomy 162 to perform a procedure within left atrium **LA**. Additionally, such instruments may be extended through mitral valve **MV** into the left ventricle, or from the left ventricle through the aortic valve into the ascending aorta for inspection or intervention therein. In this way, the aortic valve may be repaired or replaced using techniques much like the mitral valve repair and replacement techniques described below.

When replacing mitral valve **MV**, it is often desirable to cut or remove all or a portion of the mitral valve leaflets **VL**. For this purpose, grasping forceps 112 may be used to grasp valve leaflet **VL** while angled scissors 110 and/or knife 134 are used to excise valve leaflet **VL** from the valve annulus **VA**. All or part of one or both valve leaflets **VL** may be cut or removed in this way. When removing valve leaflets **VL**, however, it is generally desirable to avoid permanently cutting or removing the chordae tendonae and papillary muscles (not shown) attached to the left ventricle. It has been found that a patient's chordae tendonae and papillary muscles may contribute to proper cardiac function even when a patient's natural valve has been replaced with a replacement valve.

At this point, it is usually necessary to size valve annulus **VA** so as to select a replacement valve 36 of the proper size for patient **P**. Various means may be used for sizing, but in one embodiment a sizing disk is introduced through access cannula 22, and the diameter of the sizing disk is compared to that of valve annulus **VA**. Preferred devices and methods for sizing valve annulus **VA** are described more fully below.

Various types of replacement valves are available for replacement of the mitral valve, and there are various ways of securing these replacement valves within the patient's heart. One common means of replacement

valve attachment is suturing the prosthesis to the patient's natural valve annulus. Referring to Figure 6, after valve leaflets **VL** have been removed, a plurality of sutures 198 are applied to valve annulus **VA**, under visualization by means of endoscope 25 (Figures 1-2) and/or by direct vision through passage 50 of access cannula 22. Each end of each suture 198 is attached to a curved needle 200. At least one and usually two needle drivers 202 are introduced into the thoracic cavity through trocar sleeves 24 and/or access cannula 22. A first of needle drivers 202 is used to drive a tip of needle 200 through valve annulus **VA**, while a second of needle drivers 202 is used to grasp the tip of needle 200 and pull it completely through valve annulus **VA**. After being applied to valve annulus **VA**, each suture 198 is withdrawn from the thoracic cavity through passage 50 of access cannula 22, and placed in one of slots 62 in organizing ring 30. Because a needle 200 is attached to both ends of each suture 198, each needle 200 may be driven through valve annulus **VA** in a single direction, then withdrawn from the thoracic cavity through passage 50 of access cannula 22. Preferably, each suture 198 is positioned within a slit 66 in retaining ring 64 (Figures 11A-11D) to frictionally engage the suture and keep it within slot 62.

Various types of stitches may be used in applying sutures 198 to valve annulus **VA**. In an exemplary embodiment, a "mattress" suture technique is used, wherein each needle 200 is driven through valve annulus **VA** from the ventricular side toward the atrial side of valve annulus **VA**. Alternatively, an "everting mattress" suture technique is used, wherein each needle 200 is driven through valve annulus **VA** from the atrial side toward the ventricular side of valve annulus **VA**. Various other types of stitches may also be used, depending upon the type of replacement valve to be utilized and the

position in which it is to be mounted to valve annulus **VA.**

Figures 16A-16B illustrate the construction of needle drivers 202 in greater detail. Needle drivers 202 include a shaft 204 having a distal end 206 and a proximal end 208. An actuator 210 is attached to proximal end 208, and is constructed as described above in connection with Figure 12A. Actuator 210 translates a push rod 212 extending through shaft 204. A stationary jaw 214 is fixed to distal end 206 of shaft 204, and a movable jaw 216 is pivotally mounted to stationary jaw 214. Movable jaw 216 is linked to push rod 212, whereby distal movement of push rod 212 closes movable jaw 216 against stationary jaw 214. Carbide surfaces as well as grooves or other textural features may be provided on the inner surfaces of jaws 214, 216 to enhance gripping of needles 200. Further, a locking mechanism (not shown) may be included on actuator 210 to lock jaws 214, 216 in the closed position.

Referring to Figure 7, once all of sutures 198 have been withdrawn from the thoracic cavity and placed in slots 62 of organizing ring 30, the sutures are applied to replacement valve 36, held in position by introducer 38. Replacement valve 36 may be any of a variety of commercially available prostheses, including mechanical and bioprosthetic, stented and unstented, as described in Bodnar and Frater, *Replacement Cardiac Valves*, pp. 4-7, which has been incorporated herein by reference, and in Jamieson, "Modern Cardiac Valve Devices--Bioprostheses and Mechanical Prostheses: State of the Art," *J. Card. Surg.* 8:89-98 (1993). Mechanical valves may be of the caged ball type such as the Starr-Edwards valve (Baxter Healthcare Corp., Edwards CVS Div., Irvine, CA), the tilting disk type such as the Medtronic Hall valve (Medtronic, Inc., Minneapolis, MN), the Bjork-Shiley Monostrut valve (Shiley, Inc., Irvine, CA), the Omniscience® valve (Omniscience Medical Inc., Grove

Heights, MN), as well as the bileaflet type such as the St. Jude Medical valve (St. Jude Medical, Inc., St. Paul, MN), the Baxter Duromedics valve (Baxter Healthcare Corp., Edwards CVS Div., Irvine, CA), the Carbomedics valve (Carbomedics, Inc., Austin, TX), or the Sorin valve (Sorin Biomedica, Saluggia, Italy). Bioprosthetic valves may be porcine aortic valves such as the Hancock II bioprosthesis (Medtronic, Inc., Minneapolis, MN), the Carpentier-Edwards supraannular bioprosthesis (Baxter Healthcare Corp., Edwards CVS Div., Irvine, CA), the Carpentier-Edwards stentless bioprosthesis (Baxter Healthcare Corp., Edwards CVS Div., Irvine, CA), the St. Jude-Bioimplant bioprosthesis (St. Jude Medical, Inc., St. Paul, MN), or the Medtronic Intact® bioprosthesis (Medtronic, Inc., Minneapolis, MN), as well as pericardial valves such as the Mitroflow bioprosthesis (Mitroflow International, Inc., Richmond, British Columbia, Canada), or the Carpentier-Edwards pericardial bioprostheses (Baxter Healthcare Corp., Edwards CVS Div., Irvine, CA). The invention also facilitates valve replacement with homografts and allografts, as well as with a variety of replacement valves not specifically listed here.

In an exemplary embodiment, the invention facilitates replacement of a patient's mitral valve with a mechanical bileaflet replacement valve such as the St. Jude Medical valve, illustrated in Figures 17A-17C. In this embodiment, replacement valve 36 comprises a ring-shaped frame 218 and a pair of leaflets 220 pivotally mounted to frame 218. In the open configuration illustrated in Figures 17A-17B, leaflets 220 are nearly parallel to each other, providing a flow passage 222 through which blood may flow in the direction of arrows 224. In the event of fluid pressure against the inner faces 226 of leaflets 220, leaflets 220 pivot into a closed configuration, blocking flow passage 222. A sewing ring 228 is attached to frame 218 to which

sutures 198 may be applied for securing replacement valve 36 in the heart.

As illustrated in Figures 17B-17C, replacement valve 36 may be mounted to introducer 38 for introduction into the heart through passage 50 of access cannula 22. Replacement valve 36 may have various sizes according to the size of the mitral valve being replaced. However, the outer diameter of sewing ring 228 is usually about 19 mm to 35 mm, which, for most adult patients, is larger than the width of the third, fourth, fifth or sixth intercostal spaces, which range from 15 mm to 20 mm in width. The height of replacement valve 36, on the other hand, is smaller than the width of these intercostal spaces, usually being about 8 mm to 15 mm. Therefore, passage 50 is configured to allow replacement valve 36 to pass through it in an edge-first orientation, as illustrated in Figure 17C.

Introducer 38 will now be described with reference to Figures 18-20. Introducer 38 includes a shaft 230 having a distal end 232, a proximal end 234, and an inner lumen 236 therebetween. Shaft 230 has a length selected to allow placement of replacement valve 36 in the mitral valve position within the patient's heart from outside of the patient's thoracic cavity, and is usually at least about 20 cm in length, and preferably about 25 cm to 35 cm in length. A handle 238 is attached to proximal end 234, and a rotatable knob 240 is mounted to handle 238 for pivoting the replacement valve 36 relative to shaft 230. A pull ring 242 extends proximally from pivot knob 240 for releasing replacement valve 36 from introducer 38. As best seen in Figures 20A-20B, push rod 244 extends through inner lumen 236, and is coupled at its distal end 248 to a pivot 250 which is pivotally mounted within a slot 252 at distal end 232 of shaft 230. A shank 254 extends distally from pivot 250 and has threads or other means for attachment to a valve holder 255 for replacement valve 36. Knob 240 is

fixed to a threaded shaft 256 received within a threaded bore 258 in handle 238, whereby rotation of knob 240 translates threaded shaft 256 distally or proximally, depending upon the direction of rotation. Push rod 244 has a proximal end 260 which engages a distal end 262 of threaded shaft 256. A spring 264 biases push rod 244 in a proximal direction against distal end 262. In this way, rotation of knob 240 pulls or pushes push rod 244, thereby pivoting pivot 250 such that shank 254 extends either distally or laterally.

Referring to Figures 19A-19G, valve holder 255 includes a stationary arm 266 attached to shank 254, and a movable arm 268 pivotally mounted to stationary arm 266. Each of arms 266, 268 has an annular channel 270 configured to engage frame 218 of replacement valve 36 within flow channel 222 (Figure 17A). Arms 266, 268 are further dimensioned and configured for introduction through passage 50 of access cannula 22 when replacement valve 36 is held in channels 270. As illustrated in Figure 19A, when attached to shank 254 on introducer 38, valve holder 255 may be pivoted in the direction of arrow 272 by rotation of knob 240. In this way, the replacement valve 36 held by holder 255 may be introduced edge-first through passage 50 in access cannula 22, then pivoted approximately 90° to an orientation suitable for attachment in the mitral valve position within heart **H**.

To facilitate releasing replacement valve 36 from holder 55 from a location outside of the patient's body, a pull wire 274 is coupled to movable arm 268 by, for example, an anchor ball 276 disposed within an aperture 278 (see Figure 20A). Pull wire 274 extends through an inner lumen (not shown) in push rod 244, and is attached at its proximal end 280 to pull ring 242. A spring 282 within an aperture 284 in knob 240 biases pull ring 242 in a distal direction. In this way, pulling on pull ring 242 pivots movable arm 268 as shown in Figure 19C, allowing replacement valve 36 to be removed from channels

270. Anchor ball 276 and/or pull ring 242 may be configured so as to be removable from pull wire 244, allowing valve holder 255 to be removed from introducer 38 by decoupling arm 266 from shank 254.

In order to keep replacement valve 36 on holder 255 when holder 255 is not attached to introducer 38, a pair of holes 286 are provided in arm 266 in alignment with a corresponding pair of holes 288 in arm 268. When replacement valve 36 has been placed on holder 255, a suture (not shown) may be tied through holes 286, 288 to prevent pivoting of arm 268, thereby retaining replacement valve 36 on holder 255. Once holder 255 has been attached to introducer 38, the suture may be removed, allowing arm 268 to pivot in response to rotation of knob 240.

It will frequently be desirable for valve holder 255 and replacement valve 36 to be pre-assembled, sterilized, and packaged together in a single sterile pack. In this way, upon opening the sterile pack in the operating room, the replacement valve 36 and holder 255 are ready for immediate surgical use. Further, it may be desirable for introducer 38 to be sterilized with replacement valve 36 and included in the same sterile pack. In such cases, holder 255 may be integrated with and non-removable from introducer 38, with replacement valve 36 being mounted to arms 266, 268 at the distal end of introducer 38 within the sterile pack. Alternatively, introducer 38 may be a reusable device which is attached to holder 255 and replacement valve 36 in the operating room at the time of the procedure.

As mentioned above, in order to select a replacement valve 36 which is of the appropriate size for patient **P**, valve annulus **VA** is usually sized prior to applying sutures 198 to valve annulus **VA**. Sizing may be accomplished in various ways, but in an exemplary embodiment, is performed by means of a sizing disk 290, illustrated in Figures 21-23, pivotally attached to

introducer 38. Sizing disk 290 may be pivoted approximately 90° relative to shaft 230 of introducer 38, from an edge-first orientation suitable for introduction through access cannula 22, to a face-first orientation suitable for sizing valve annulus **VA**. As shown in Figures 22 and 23, sizing disk 290 is configured for attachment to shank 254 of introducer 38, preferably by means of a threaded hole 292. A notch 294 is provided in a proximal portion of disk 290 through which distal end 232 of shaft 230 may extend when disk 290 is in the edge-first orientation. An aperture 296 is disposed in the middle of disk 290 through which distal end 232 of shaft 230 may extend when disk 290 is in the face-first orientation. Preferably, a plurality of interchangeable sizing disks 290 of various diameters are provided for the procedure, allowing various sizing disks 290 to be introduced into heart **H** and compared with valve annulus **VA** until the diameter of the sizing disk corresponds to that of valve annulus **VA**.

In place of sizing disk 290, an expandable balloon or basket may be used for sizing valve annulus **VA**. Fluoroscopy, transesophageal echocardiography (TEE), epicardial or trans-thoracic ultra-sonography, or angiography may also be used to facilitate sizing valve annulus **VA**.

When the size of valve annulus **VA** has been identified, sizing disk 290 may be removed from introducer 38 and replaced by a replacement valve 36 of the appropriate size, mounted on holder 255. Introducer 38 may then be clamped to support stand 34 with replacement valve 36 positioned between first organizing ring 30 and second organizing ring 32, as illustrated in Figure 7.

Sutures 198 are applied to replacement valve 36 by passing needles 200 through sewing ring 228 using needle drivers 202. Sutures 198 are then positioned in circumferentially spaced positions on second organizing

ring 32. Second organizing ring 32 comprises, as illustrated in Figures 24A-24C, an inner ring 298 fixed to support stand 34, and an outer ring 300 rotatably mounted to inner ring 298. An elastomeric retaining ring 302 is disposed in an annular channel 304 in inner ring 298. Radial pins 303 are fixed to inner ring 298 and extend through slots 305 in outer ring 300, thereby limiting the rotation of outer ring 300 relative to inner ring 298. A plurality of slots 306 are disposed in circumferentially spaced positions about inner ring 298, and a corresponding number of slots 308 alignable with slots 306 are disposed in outer ring 300. Retaining ring 302 has a plurality of slits 310 which are aligned with slots 306 in inner ring 298. A clamp 312 for clamping shaft 230 of introducer 38 is disposed on an extension 314 fixed to support stand 34.

After being applied to replacement valve 36, sutures 198 may be positioned within inner slots 306, slits 310, and outer slots 308. Once all of sutures 298 have been applied to replacement valve 36 and positioned in organizing ring 32, outer ring 300 may be rotated relative to inner ring 298, thereby locking sutures 298 in position.

Referring now to Figure 8A, replacement valve 36 may then be introduced into the left atrium **LA** by advancing introducer 38 through passage 50 of access cannula 22. Replacement valve 36 is oriented on introducer 38 so as to be introduced edge-first through passage 50. As replacement valve 36 is advanced into the thoracic cavity, organizing ring 32 maintains tension on sutures 198, allowing replacement valve 36 to slide along sutures 198. Introducer 38 is advanced through atriotomy 162 so that replacement valve 36 is disposed within left atrium **LA**. Replacement valve 36 is then pivoted on introducer 38 by rotating knob 240, so that sewing ring 228 of replacement valve 36 (Figure 17A) may be aligned with valve annulus **VA**.

Introducer 38 is then advanced further into left atrium **LA** so as to position replacement valve 36 against or within valve annulus **VA**, as illustrated in Figure 8B. Square or overhand knots are then formed in sutures 198 outside of the patient's thoracic cavity, and the knots are pushed by a knot pusher 316 through passage 50 and atriotomy 162 toward sewing ring 228 of replacement valve 36.

While knot pusher 316 may have a variety of configurations, an exemplary embodiment is illustrated in Figures 25A-25B. Knot pusher 316 comprises a shaft 318 having a distal end 320 and a proximal end 322, to which is connected an actuator 324 constructed like actuator 120 described above in connection with Figure 12A. Actuator 324 translates a push rod 326 extending through shaft 318. A pair of movable jaws 328 are pivotally mounted to distal end 320 of shaft 318, and are coupled to push rod 326 such that proximal movement of push rod 326 opens jaws 328. A notch 330 at the distal end of each jaw 328 is configured to receive a suture 198.

In use, a first free end of a suture 198 is tied in a loop or slip knot over a second free end of suture 198, and jaws 328 are positioned just proximal to the knot. Jaws 328 are then opened such that each free end of suture 198 is positioned within a notch 330 at the distal end of jaws 328 and the slip knot is disposed centrally between jaws 328. While holding tension on the free ends of the sutures outside the thoracic cavity, knot pusher 316 is advanced distally, pushing the slip knot through passage 50 of access cannula 22 and atriotomy 162 until the slip knot engages sewing ring 228 of replacement valve 36.

Referring now to Figure 9, when a plurality of knots 332 (usually 5 to 8) have been tied and pushed against sewing ring 228 by knot pusher 316, knots 332 are cinched down tightly, and free ends 334 are trimmed using scissors 110 or other cutting device.

It will be understood to those of ordinary skill in the art that the thoracoscopic devices and methods disclosed above for tissue manipulation, retraction, cutting, suturing, and the like may be used to accomplish procedures such as annuloplasty, commissurotomy, quadrangular resection, shortening and reattachment of chordae tendonae, and various other valve repair procedures. To perform annuloplasty, valve annulus **VA** is contracted by suturing a portion of the valve annulus so as to overlap an adjacent portion, or by attaching a prosthetic annuloplasty device such as a Carpentier or Duran annuloplasty ring (not shown) to valve annulus **VA** to reduce its diameter. To perform commissurotomy, the valve leaflets **VL** are separated by cutting between them where they have fused together due to calcification or disease. To perform quandrangular resection, valve leaflets **VL** are shortened or narrowed by excising a portion of one or more leaflets **VL**, and reattaching the remaining portions of the leaflet by suturing. The chordae tendonae (not shown), which act as resilient springs between valve leaflets **VL** and the papillary muscles (not shown) attached to the heart wall in the left ventricle **LV**, may be shortened by excising a portion thereof and reattaching the ends of the remaining portions by suturing. Similarly, severed chordae tendonae may be restored by reattachment of the severed ends with sutures. Open-chest techniques for performing such procedures are described in detail in Kirklin and Barratt-Boyes, *Cardiac Surgery*, pp. 329-340, the disclosure of which has been incorporated herein by reference.

When the valve replacement or other surgical procedure in left atrium **LA** is completed, atriotomy 162 is closed. Sutures, thoracoscopic staples or other types of closure devices may be used for this purpose. In one embodiment, illustrated in Figure 10, atriotomy 162 is closed by suturing, wherein needle drivers 202 are

introduced through trocar sleeves 24 and/or access cannula 22, and a suture 336 having a needle 338 attached to an end thereof is used to sew up atriotomy 162 using conventional suturing techniques. Before and/or during closure, a suction/irrigation tube (not shown) is usually introduced through a trocar sleeve 24 and into left atrium **LA** or left ventricle **LV** to remove any air therein and to fill the heart chambers with a saline solution.

After atriotomy 162 has been closed, any remaining instruments are removed from the thoracic cavity. A chest tube may be introduced through one of trocar sleeves 24 to facilitate evacuation of the pleural cavity. Access cannula 22 and trocar sleeves 24 are then removed from the chest wall, and the incisions or penetrations through which they were introduced are closed, usually by suturing or stapling.

The patient's lung may then be reinflated, and cardiac function may be restarted. As described in copending application Serial No. 07/991,188, which has been incorporated herein by reference, infusion of cardioplegic fluid through aortic occlusion catheter 82 and/or retroperfusion catheter 102 is discontinued, and a saline solution is infused through one or both of these catheters to irrigate the heart and coronary arteries (see Figure 3). The saline solution, along with blood, other fluids, air, thrombus, and other emboli within the heart or coronary arteries are then aspirated through the inner lumen of aortic occlusion catheter 82, as well as through venous cannula 70 and/or pulmonary venting catheter 79. Occlusion balloon 88 on aortic occlusion catheter 82 is then deflated, allowing warm, oxygenated blood to flow into the coronary arteries to perfuse the myocardium. Cardiac contractions will usually begin soon thereafter. In some cases, electrical defibrillation may be necessary to help restore cardiac function. Aortic occlusion catheter 82 and retroperfusion catheter 102 may then be removed from the patient. Cardiopulmonary bypass

is then discontinued, and arterial cannula 78, venous cannula 70, and pulmonary venting catheter 79 are removed from the patient.

In addition to performing mitral valve repair and replacement, the techniques of the invention also facilitate surgical intervention into other regions of the heart and great vessels. The devices and methods described above may be used to form an opening directly into the left ventricle, right atrium, or right ventricle, or into a great vessel such as the aorta, superior vena cava, inferior vena cava, pulmonary artery, or pulmonary vein, for surgical intervention in such cavities. For example, a penetration may be made in the wall of the aorta, and the aortic valve may be repaired or replaced with a prosthesis, using techniques and devices like those described above for mitral valve replacement. Moreover, the devices and methods of the invention also facilitate intracardiac procedures such as repair of atrial or ventricular septal defects, electrophysiological mapping and ablation of the myocardium, myocardial drilling, and other procedures. Furthermore, devices may be introduced through an opening into the heart or great vessel and advanced therefrom into vessels such as the coronary arteries to perform procedures such as angioplasty, atherectomy, coronary artery bypass grafting, or treatment of aneurysms.

While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention, which is defined by the appended claims.

What Is Claimed Is:

1. A method of closed-chest surgical intervention within an internal cavity of a patient's heart or great vessel, the method comprising:

establishing cardiopulmonary bypass;

arresting the patient's heart;

viewing an internal portion of the patient's chest through a scope extending through a percutaneous intercostal penetration in the patient's chest;

forming an internal penetration in a wall of the heart or great vessel using cutting means introduced through a percutaneous intercostal penetration in the patient's chest; and

introducing an interventional tool through a percutaneous intercostal penetration and through the internal penetration to perform a surgical procedure within the internal cavity under visualization by means of said scope.

2. The method of claim 1 wherein the patient's heart is arrested by occluding the patient's aorta between the patient's coronary arteries and the patient's brachiocephalic artery with an expandable member on a distal end of an endovascular catheter, and perfusing the patient's myocardium with cardioplegic fluid.

3. The method of claim 1 wherein the interventional tool is introduced through a cannula positioned in a percutaneous intercostal penetration.

4. The method of claim 1 wherein the surgical procedure comprises surgically treating a heart valve.

5. The method of claim 4 further comprising the step of removing at least a portion of the heart valve by means of a cutting tool introduced through a percutaneous intercostal penetration and through the internal penetration.

6. The method of claim 4 further comprising the step of introducing a replacement valve through a percutaneous intercostal penetration and through the internal penetration into the internal cavity.

7. The method of claim 6 further comprising fastening the replacement valve within the internal cavity by means of an instrument introduced through a percutaneous intercostal penetration and through the internal penetration.

8. The method of claim 6 wherein the replacement valve is introduced through a cannula positioned in a percutaneous intercostal penetration.

9. The method of claim 4 wherein a percutaneous intercostal penetration is created in a right lateral portion of the patient's chest.

10. The method of claim 9 wherein the internal penetration is made in a wall of the patient's left atrium.

11. The method of claim 10 wherein the heart valve comprises a mitral valve.

12. The method of claim 10 wherein the heart valve comprises an aortic valve.

13. A method of closed-chest replacement of a heart valve in a patient's heart, the method comprising:

establishing cardiopulmonary bypass;

arresting the patient's heart;

viewing the patient's heart through a scope extending through a percutaneous intercostal penetration in the patient's chest;

forming an internal penetration through a wall of the patient's heart using a cutting tool introduced through a percutaneous intercostal penetration in the patient's chest;

positioning a replacement valve through a percutaneous intercostal penetration in the patient's chest and through the internal penetration into a chamber of the heart; and

securing the replacement valve in a valve position in the heart.

14. The method of claim 13 wherein the patient's heart is arrested by occluding the patient's aorta between the patient's coronary arteries and the patient's brachiocephalic artery with an expandable member on a distal end of an endovascular catheter, and perfusing the patient's myocardium with cardioplegic fluid.

15. The method of claim 13 wherein the heart valve comprises a mitral valve, the valve position comprising a mitral valve position.

16. The method of claim 15 wherein the chamber comprises a left atrium of the patient's heart.

17. The method of claim 13 wherein the percutaneous intercostal penetration is disposed in a right lateral portion of the patient's chest.

18. The method of claim 13 further comprising the step of removing at least a portion of the patient's heart valve using a cutting tool introduced through a percutaneous intercostal penetration and through the internal penetration.

19. The method of claim 13 further comprising sizing the patient's heart valve by means of a sizing instrument introduced through a percutaneous intercostal penetration and through the internal penetration.

20. The method of claim 13 wherein the replacement valve is positioned by means of an introducer, the introducer comprising an elongated shaft and means at a distal end of the shaft for holding the replacement valve.

21. The method of claim 13 wherein the step of fastening comprises suturing the replacement valve to an annulus at the valve position.

22. The method of claim 21 wherein the step of suturing comprises applying a plurality of sutures to an annulus at the valve position, drawing the sutures out of the patient's body through the internal penetration and through a percutaneous intercostal penetration, and applying the sutures to the replacement valve.

23. The method of claim 22 further comprising radially arranging the sutures in spaced-apart locations about an organizing ring disposed outside of the patient's body.

24. The method of claim 23 further comprising holding the sutures in tension in the organizing ring as the replacement valve is positioned in the valve position.

25. The method of claim 13 wherein the replacement valve is introduced through a cannula positioned in a percutaneous intercostal penetration.

26. A system for closed-chest surgical intervention within a patient's heart or great vessel, the system comprising:

means for forming a percutaneous penetration in an intercostal space in the patient's chest;

a visualization scope configured to pass through an intercostal space in the patient's chest for viewing an internal chest cavity;

means for arresting the patient's heart from a location outside of the chest cavity;

a cardiopulmonary bypass system, including means for delivering oxygenated blood to the patient's arterial system;

cutting means positionable through a percutaneous intercostal penetration into the chest cavity for forming an internal penetration in a wall of the patient's heart or great vessel; and

interventional means positionable through a percutaneous intercostal penetration and through the internal penetration for performing a surgical procedure within the heart or great vessel.

27. The system of claim 26 wherein the means for arresting the heart comprises an endovascular catheter having expandable means for occluding the patient's ascending aorta between the patient's coronary arteries and the patient's brachiocephalic artery, and an internal lumen for delivering cardioplegic fluid into the ascending aorta upstream of the expandable means.

28. The system of claim 26 wherein the interventional means comprises means for securing a replacement valve at a valve location within the patient's heart.

29. The system of claim 28 further comprising a cannula positionable in a percutaneous intercostal penetration, the cannula having a lumen therein through which the replacement valve may be introduced into the internal chest cavity.

30. The system of claim 28 wherein the replacement valve comprises an annular portion for attachment to a valve annulus in the heart, the annular portion having an outer diameter, wherein the lumen in the cannula has a cross-sectional height at least equal to the outer diameter, and a cross-sectional width less than the width of the intercostal space.

31. The system of claim 28 further comprising cutting means positionable through a percutaneous intercostal penetration and through the internal penetration for removing at least a portion of the patient's heart valve.

32. The system of claim 28 further comprising means positionable through a percutaneous intercostal penetration and through the internal penetration for sizing a valve annulus of the patient's heart valve.

33. The system of claim 32 wherein the sizing means comprises an elongated shaft and sizing means at a distal end of the shaft, wherein the shaft and sizing means may be introduced through a percutaneous intercostal penetration and through the internal penetration to position the sizing means near the valve annulus.

34. The system of claim 28 further comprising means for introducing the replacement valve into the patient's heart, the introducing means comprising an elongated shaft having means at a distal end thereof for releasably holding the replacement valve.

35. The system of claim 34 wherein the introducing means further comprises means actuated from a proximal end of the shaft for pivoting the replacement valve relative to the shaft from a first position for introduction through a percutaneous intercostal penetration to a second position for attachment at the valve location.

36. The system of claim 28 wherein the means for securing the replacement valve comprises means positionable through a percutaneous intercostal penetration for suturing the replacement valve to a valve annulus at the valve location.

37. The system of claim 36 further comprising organizing means for maintaining sutures in spaced-apart positions outside of the chest cavity after the sutures have been applied to the valve annulus.

38. The system of claim 37 wherein the organizing means is fixed to a proximal end of a cannula disposed in a percutaneous intercostal penetration, the cannula having a lumen through which the replacement valve may be introduced into the chest cavity.

39. The system of claim 37 further comprising means on the organizing means for maintaining tension on ends of the sutures to facilitate advancing the replacement valve along the sutures into the patient's heart.

40. The system of claim 26 further comprising retraction means positionable through an intercostal space in the patient's chest for opening the internal penetration in the wall of the heart or great vessel.

41. The system of claim 26 wherein the interventional means is configured to reach the interior of the heart or great vessel from a percutaneous penetration in a right lateral portion of the patient's chest.

42. The system of claim 41 wherein the interventional means is at least about 20 cm in length.

43. A percutaneous access cannula to facilitate closed-chest replacement of a heart valve in a patient's heart, the access cannula comprising:

a cannula body configured for placement in an intercostal space in the patient's chest, the cannula body having a distal end, a proximal end, and a lumen extending therebetween, the lumen being configured to allow passage of a replacement valve therethrough; and

an obturator positionable in the lumen, the obturator having a cross-sectional width less than the width of the intercostal space and a cross-sectional height greater than the cross-sectional width.

44. The access cannula of claim 43 wherein the valve prosthesis has an annular attachment portion with an outer diameter, the obturator having a cross-sectional height at least equal to the outer diameter.

45. The access cannula of claim 43 wherein the cross-sectional height is about 2 to 6 times the cross-sectional width.

46. The access cannula of claim 43 wherein the obturator has a generally rectangular cross-section.

47. The access cannula of claim 43 wherein the obturator has a generally oval cross-section.

48. The access cannula of claim 44 wherein the lumen in the cannula body has a cross-sectional shape in an unstressed condition with a width less than the width of the intercostal space and a height greater than the outer diameter of the valve prosthesis.

49. The access cannula of claim 48 wherein the lumen has a generally rectangular cross-section.

50. The access cannula of claim 48 wherein the lumen has a generally oval-shaped cross-section.

51. The access cannula of claim 48 wherein the cross-sectional height of the lumen is 2 to 6 times the cross-sectional width of the lumen.

52. The access cannula of claim 43 further comprising means at the proximal end of the cannula body for retaining a plurality of sutures extending through the lumen in a spaced apart relationship.

53. The access cannula of claim 52 wherein the suture retaining means comprises a plurality of slots in the proximal end of the cannula body in circumferentially spaced positions around the lumen.

54. The access cannula of claim 52 further comprising means at the proximal end of the cannula body for maintaining tension on the sutures.

55. The access cannula of claim 54 wherein the means for maintaining tension comprises an organizing ring having an interior passage through which the sutures may extend and a plurality of means circumferentially spaced around the passage for frictionally engaging the sutures.

56. The access cannula of claim 55 wherein the organizing ring comprises an inner ring, an outer ring rotatably coupled to the inner ring, a first plurality of apertures circumferentially spaced about the inner ring, and a second plurality of apertures circumferentially spaced about the outer ring, the first and second plurality of apertures being aligned when the outer ring is in a first rotational position, and non-aligned when the outer ring is in a second rotational position.

57. A cannula system to facilitate surgical intervention in a patient's body cavity, the cannula system comprising:

a cannula body having a distal end, a proximal end, and a lumen therebetween, the lumen being configured for introduction of surgical instruments therethrough; and

organizer means at the proximal end of the cannula body for retaining a plurality of sutures extending through the lumen from the body cavity in spaced apart positions outside of the body cavity.

58. The cannula system of claim 57 wherein the cannula body is configured for positioning in an intercostal space in the patient's chest.

59. The cannula system of claim 57 wherein the organizer means comprises a first organizing ring having an interior passage and a plurality of suture retaining means circumferentially spaced about the interior passage.

60. The cannula system of claim 59 wherein the first organizing ring is fixed to the proximal end of the cannula body with the interior passage aligned with the lumen.

61. The cannula system of claim 59 wherein the suture retaining means comprise a plurality of slots in the first organizing ring circumferentially spaced about the interior passage.

62. The cannula system of claim 60 further comprising means at the proximal end of the cannula body for maintaining the sutures in tension.

63. The cannula system of claim 62 wherein the means for maintaining the sutures in tension comprises a second organizing ring spaced apart from the first organizing ring, the second organizing ring having an interior passage and a plurality of means circumferentially spaced about the interior passage for holding the sutures in tension.

64. The cannula system of claim 63 wherein the means for holding the sutures in tension comprise slits in the second organizing ring for frictionally engaging the sutures.

65. The cannula system of claim 62 wherein the means for maintaining the sutures in tension comprises slits in the first organizing ring for frictionally engaging the sutures.

66. The cannula system of claim 58 further comprising means for holding a replacement valve outside the chest in proximity to the organizer means, whereby a suture extending from the body cavity through the lumen

in the cannula may be applied to the replacement valve and secured in the organizer means.

67. The cannula system of claim 66 wherein the lumen is configured to facilitate introduction of the replacement valve therethrough into the body cavity.

68. A thoracoscopic device for placement of a replacement valve in a valve position of a patient's heart, the thoracoscopic device comprising:

an elongated handle having a distal end and a proximal end, the handle configured for positioning through an intercostal space in the patient's chest; and

means at the distal end of the handle for releasably holding a replacement valve in an orientation for introduction through the intercostal space.

69. The thoracoscopic device of claim 68 wherein the handle is at least about 20 cm in length.

70. The thoracoscopic device of claim 68 further comprising means for pivoting the replacement valve relative to the handle from a first orientation for introduction through the intercostal space, to a second orientation for placement in the valve position.

71. The thoracoscopic device of claim 68 wherein the pivoting means includes an actuator disposed at the proximal end of the handle.

72. The thoracoscopic device of claim 68 further comprising means at the proximal end of the handle for releasing the replacement valve from the holding means.

73. A prosthesis assembly for closed-chest replacement of a heart valve, the prosthesis assembly comprising:

a replacement valve having an annular attachment portion and a movable valve portion coupled to the attachment portion; and

holder means releasably mounted to the attachment portion, wherein the holder means is configured to allow introduction of the replacement valve through an intercostal space in the patient's chest.

74. The prosthesis assembly of claim 73 wherein the intercostal space has an intercostal width, the replacement valve and holder means together having a profile with a width less than the intercostal width.

75. The prosthesis assembly of claim 74 wherein the attachment portion of the replacement valve has an outer diameter which is greater than the intercostal width.

76. The prosthesis assembly of claim 73 wherein the holder means comprises an elongated handle having a distal end mounted to the replacement valve and a proximal end opposite the distal end, the handle being configured for introducing the replacement valve into the patient's heart through the intercostal space.

77. The prosthesis assembly of claim 76 wherein the handle is at least about 20 cm in length so as to allow positioning the replacement valve in the heart from a right lateral portion of the chest.

78. The prosthesis assembly of claim 76 wherein the handle comprises means for releasing the replacement valve, the releasing means being configured for actuation from a proximal end of the handle.

79. The prosthesis assembly of claim 76 wherein the handle comprises means for pivoting the replacement valve from a first orientation for introduction through the intercostal space to a second orientation for attachment within the patient's heart, the pivoting means being configured for actuation from a proximal end of the handle.

80. The prosthesis assembly of claim 73 wherein the intercostal space is less than about 20 mm in width.

81. The prosthesis assembly of claim 73 wherein the replacement valve and holding means are contained in a sterile pack.

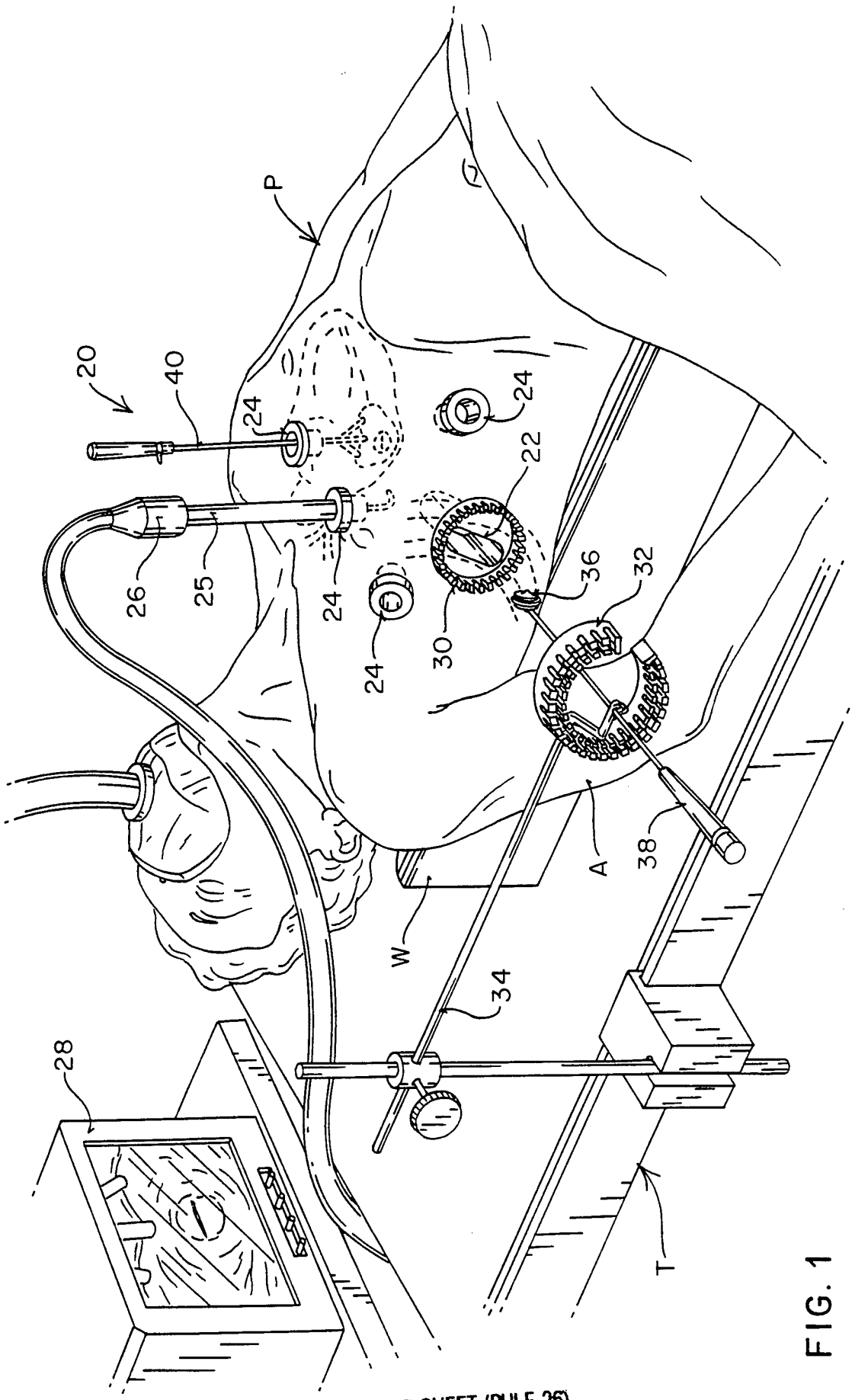


FIG. 1

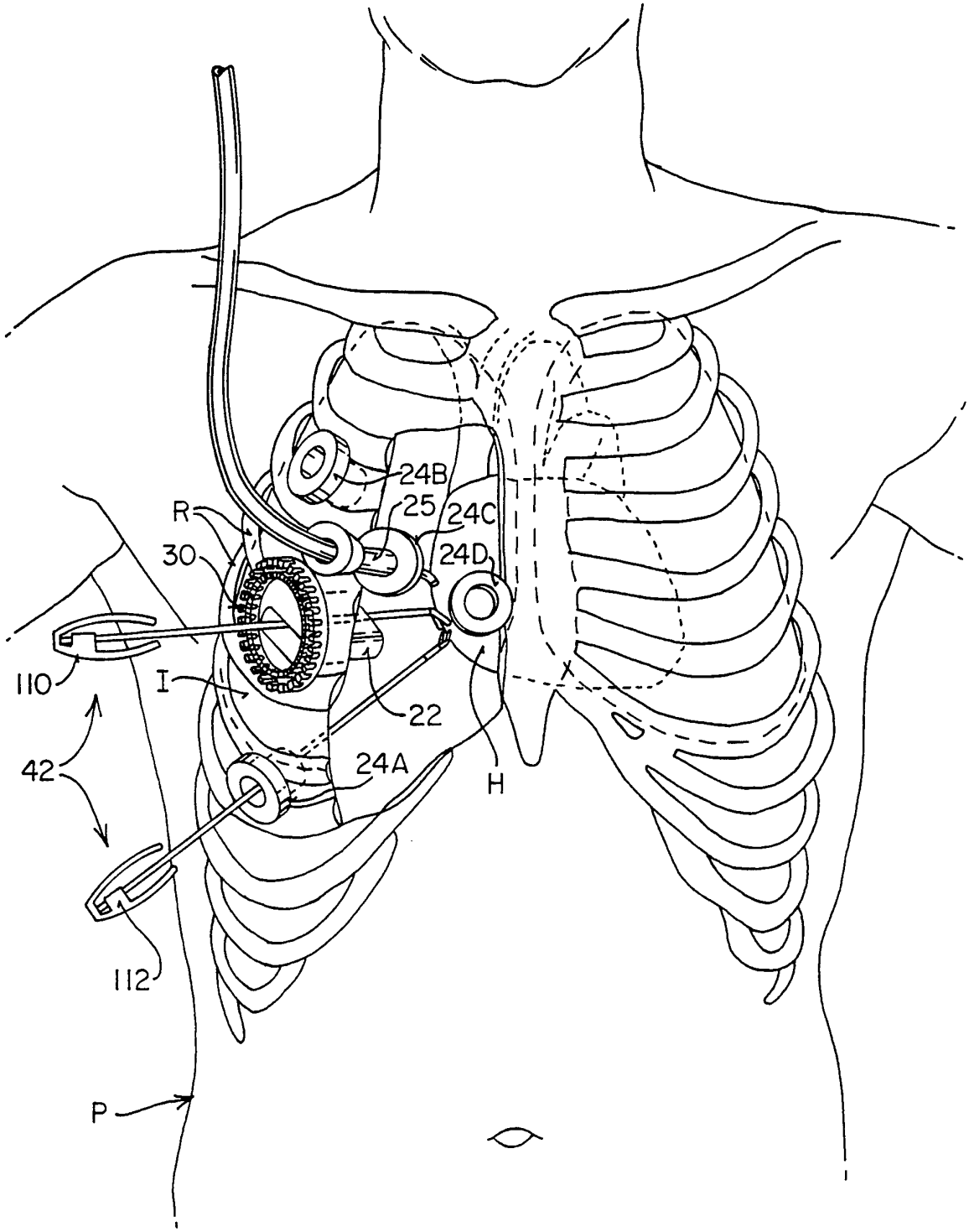


FIG. 2

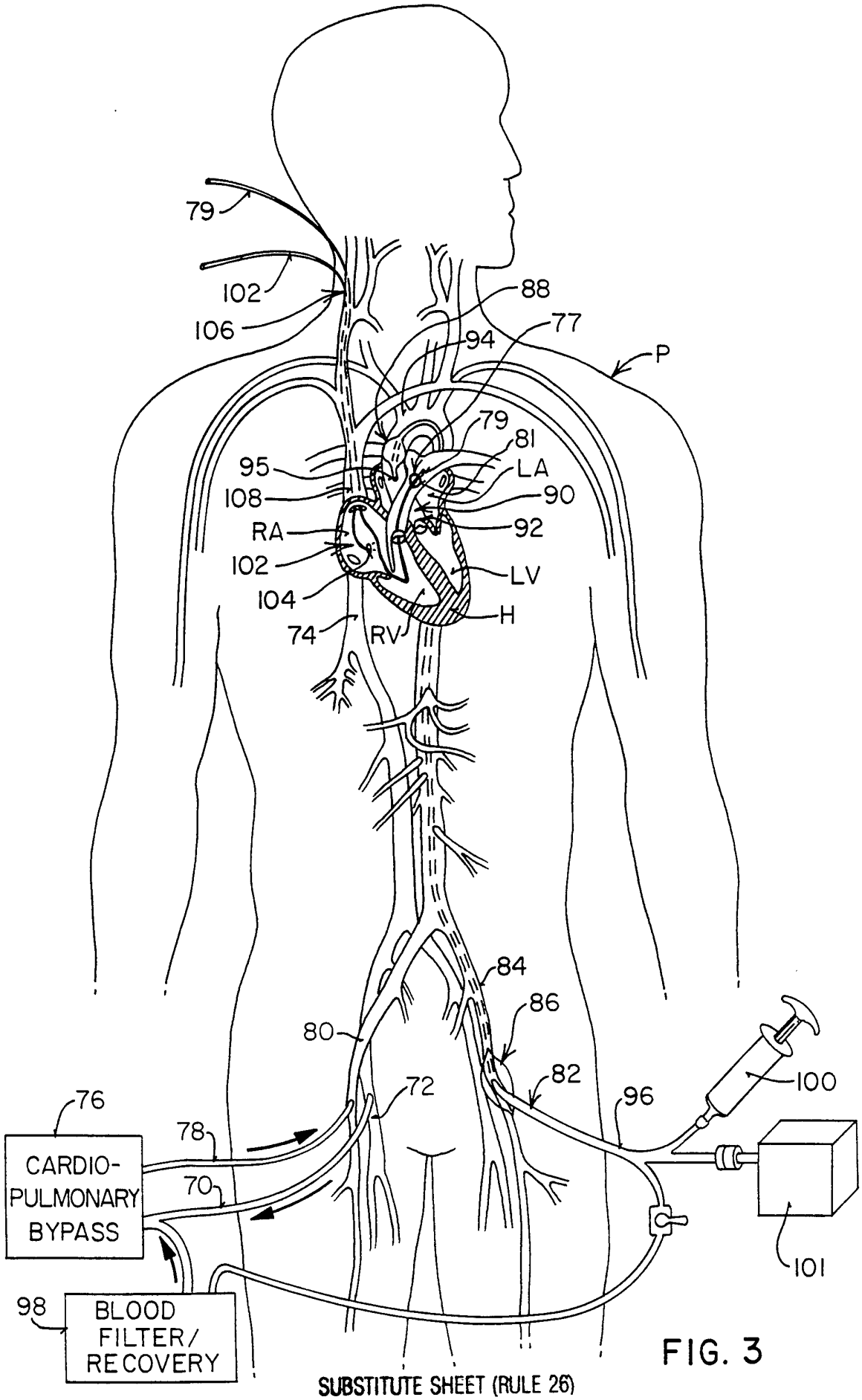

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86
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82
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PULMONARY
BYPASS
70
101
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BLOOD
FILTER/
RECOVERY

FIG. 3

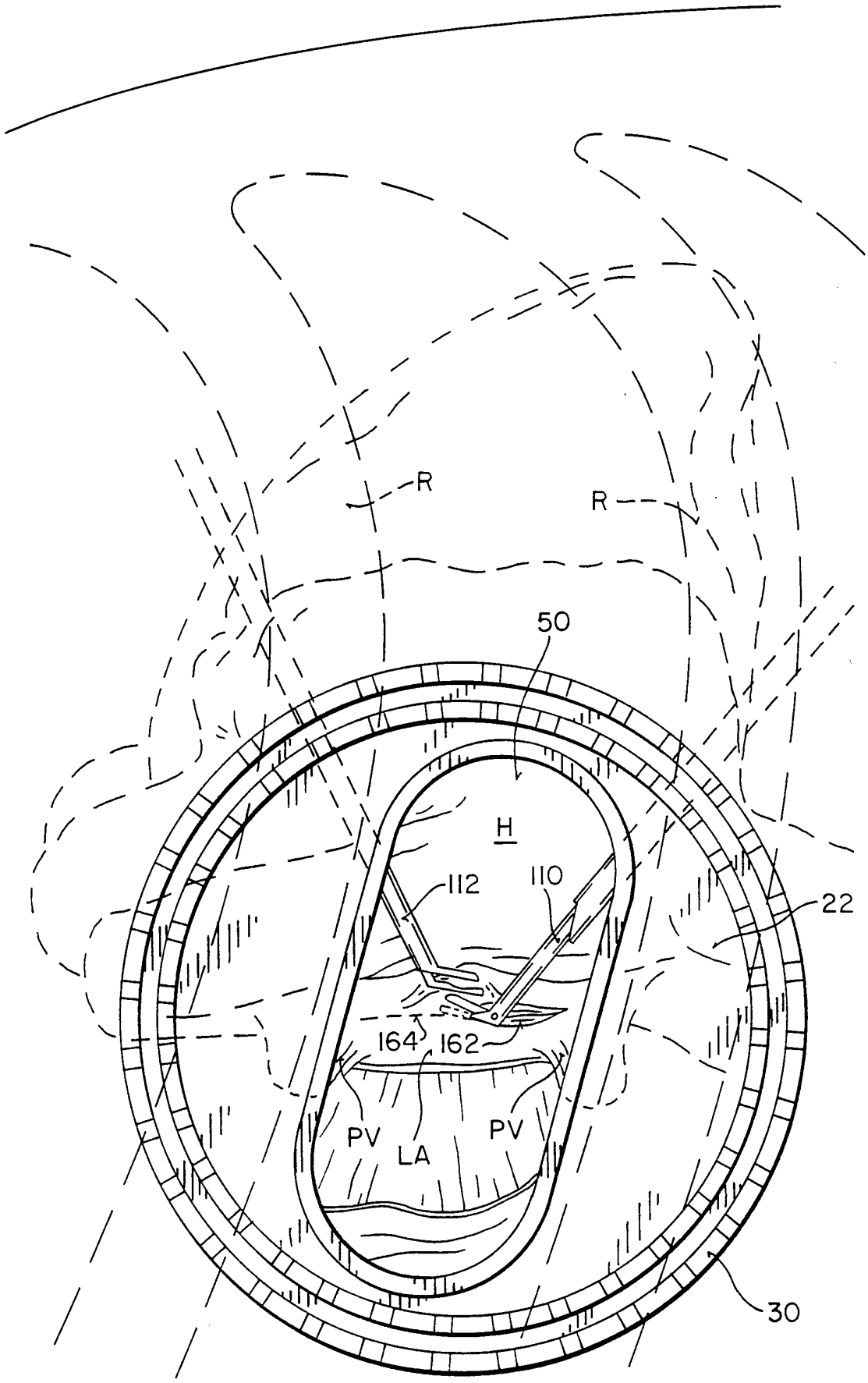


FIG. 4

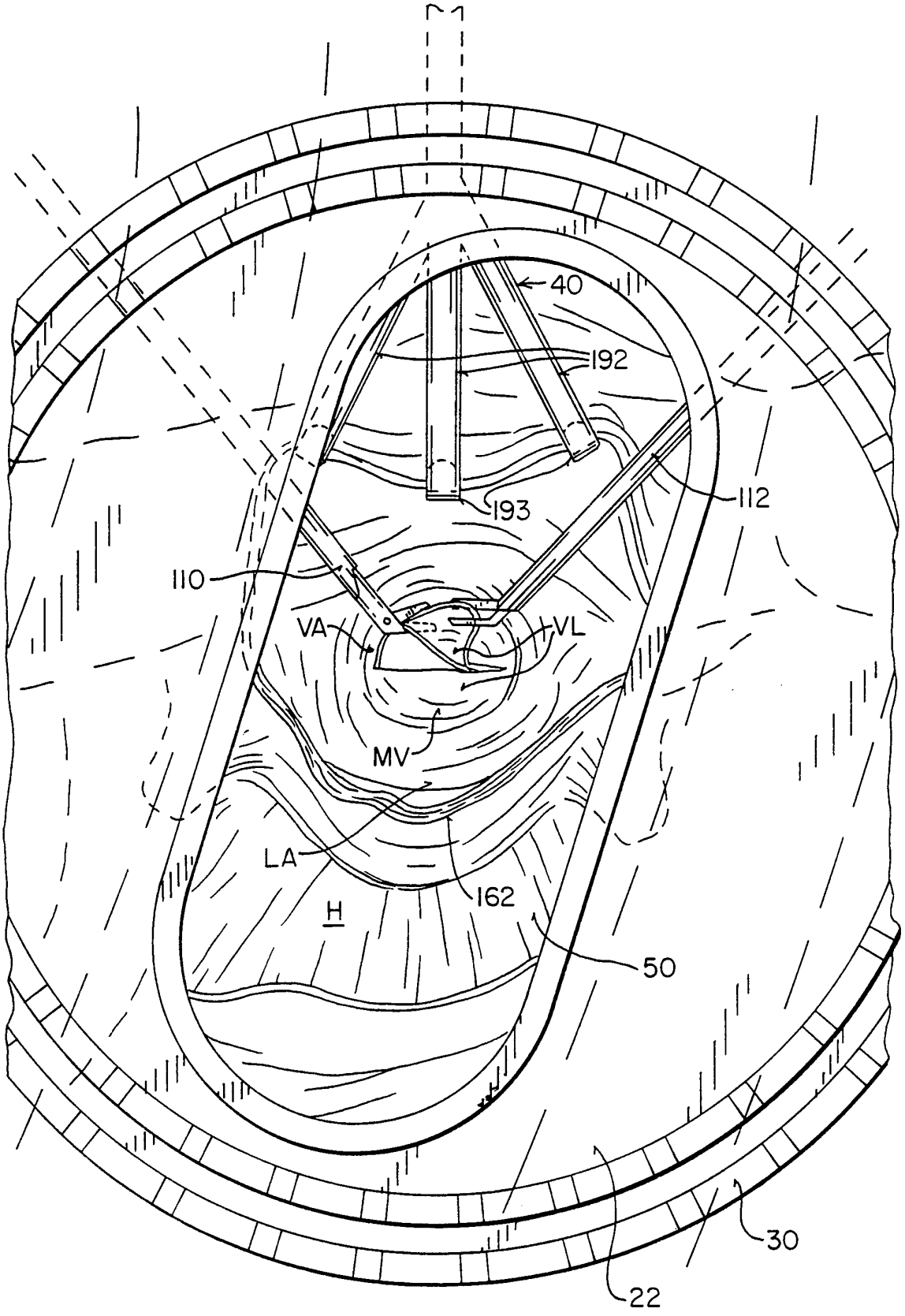


FIG. 5

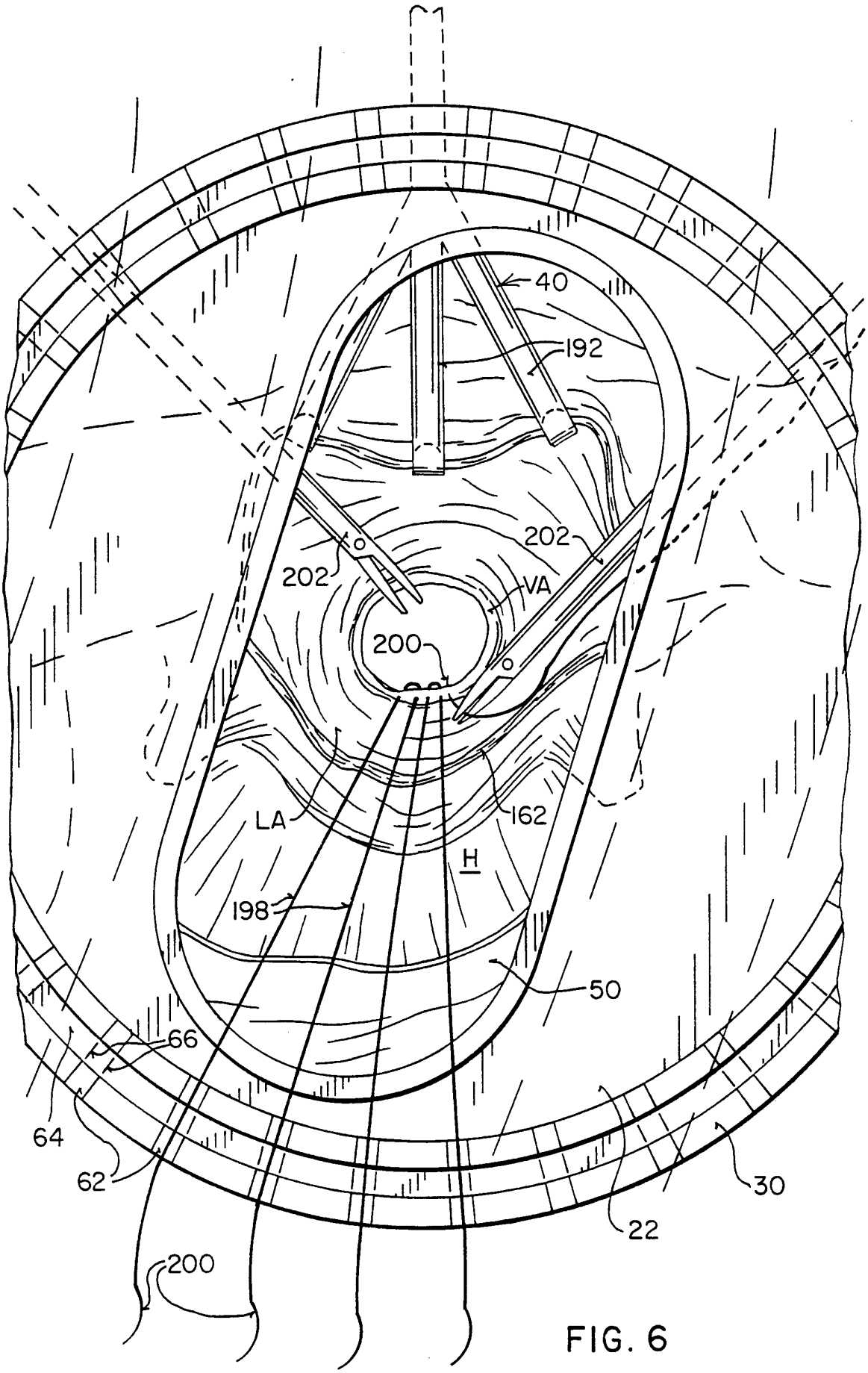


FIG. 6

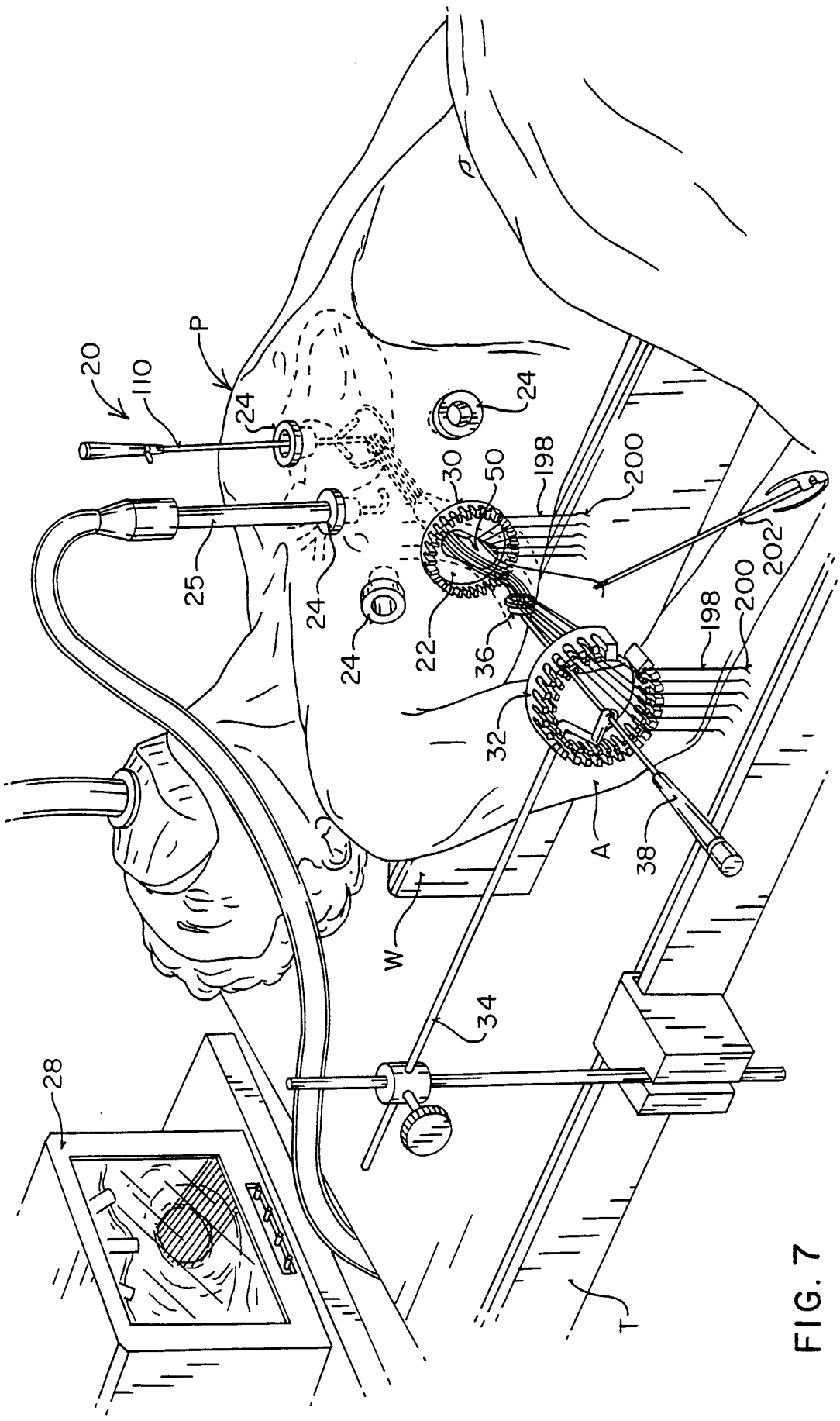

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FIG. 7

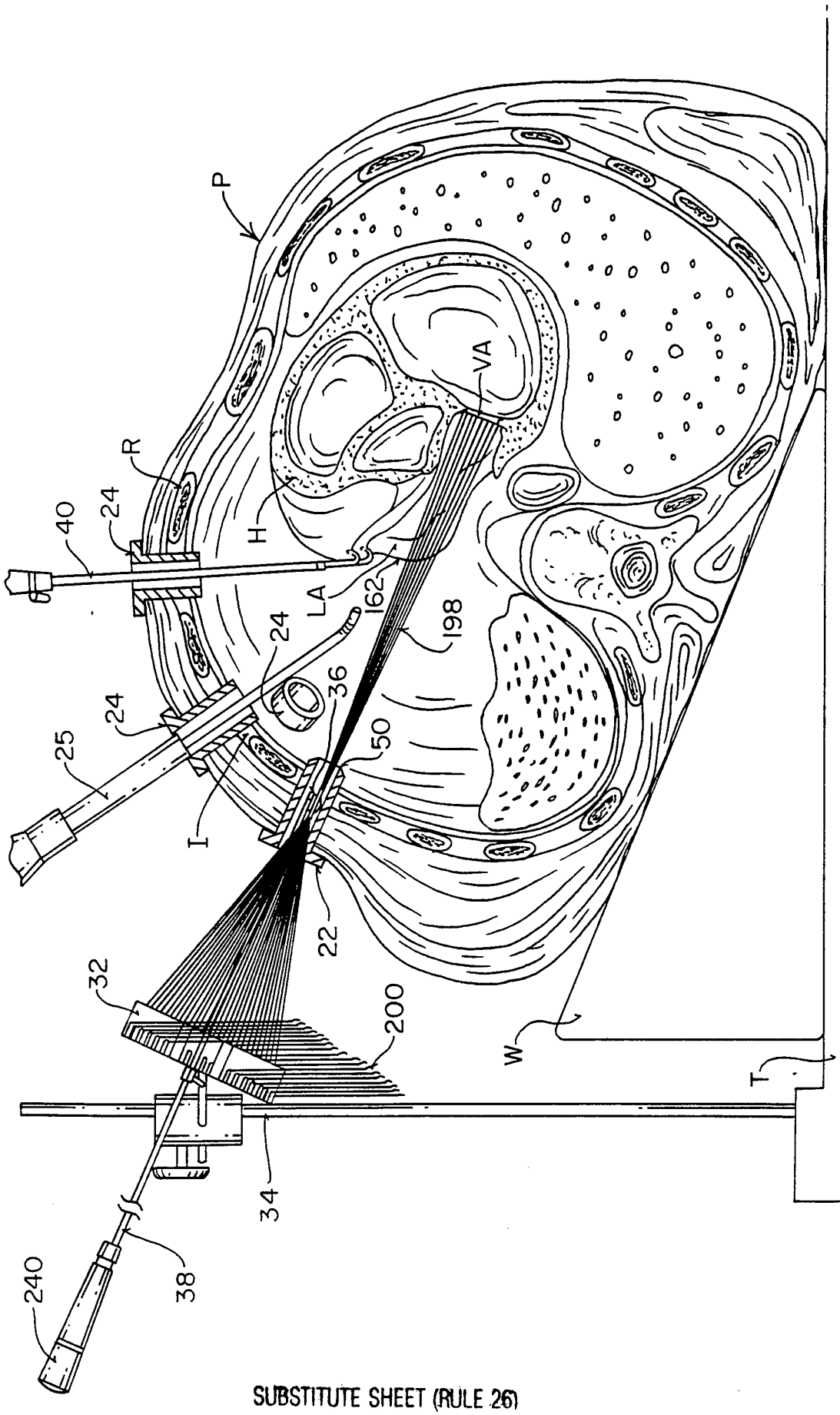


FIG. 8A

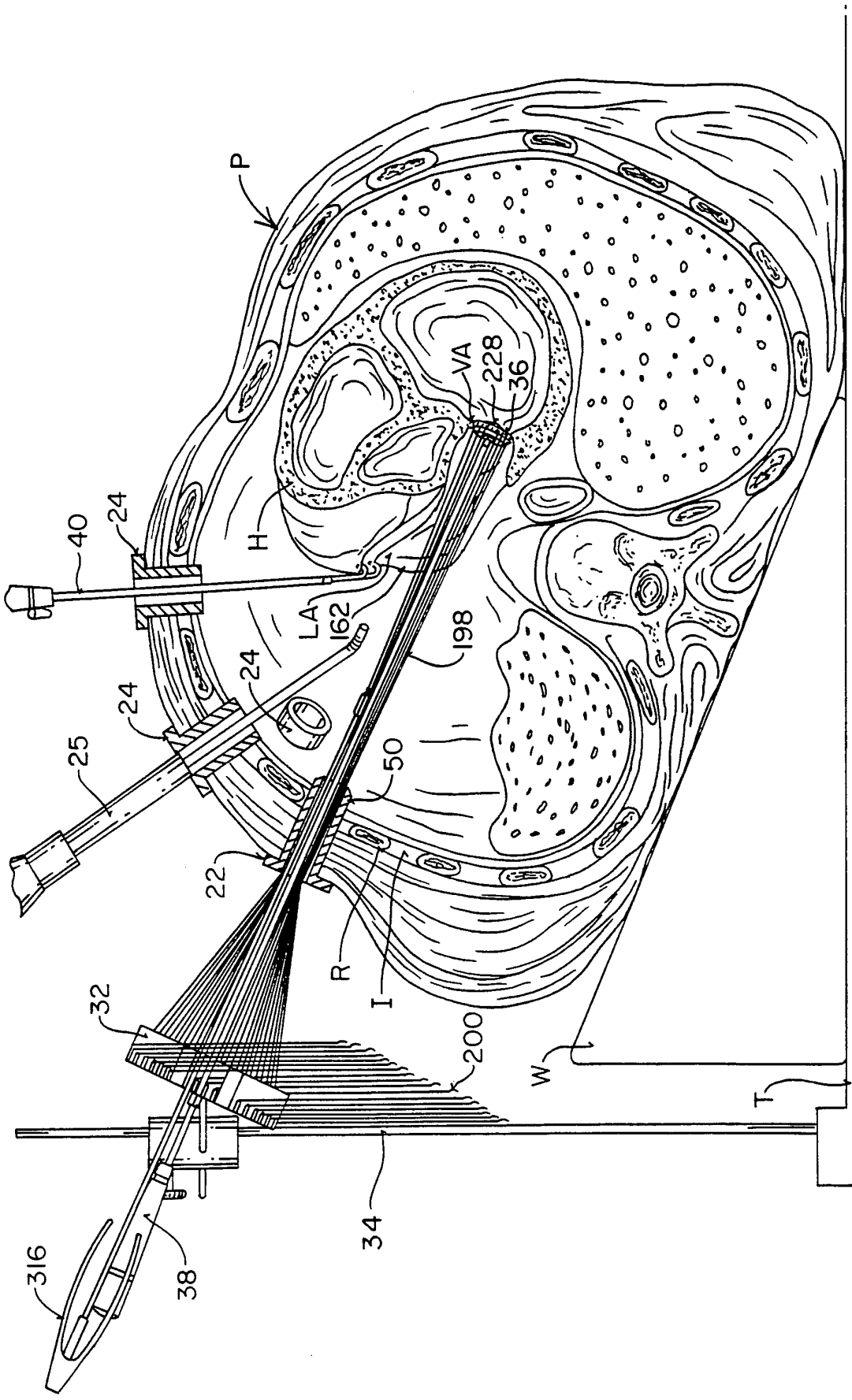


FIG. 8B

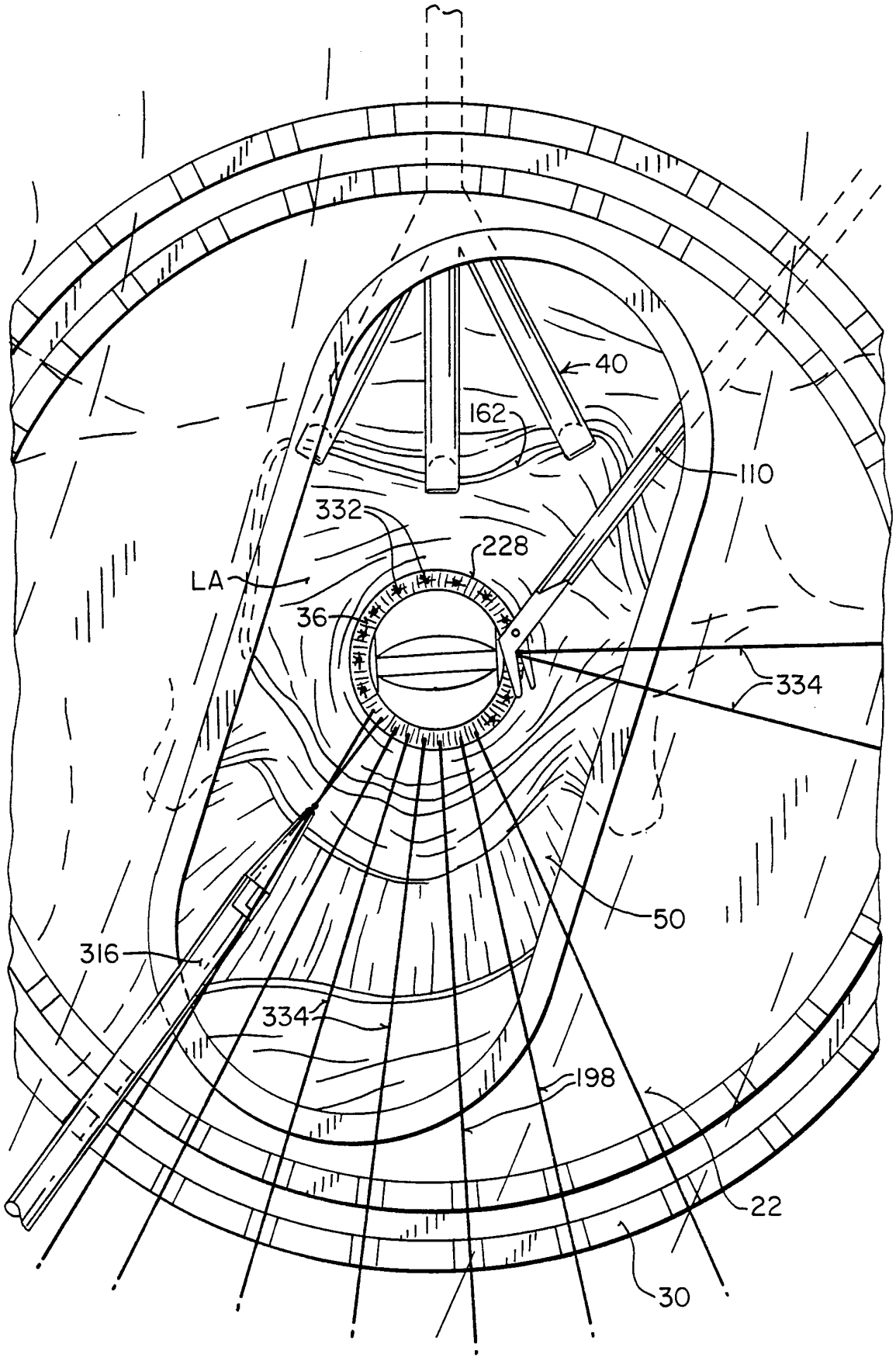


FIG. 9

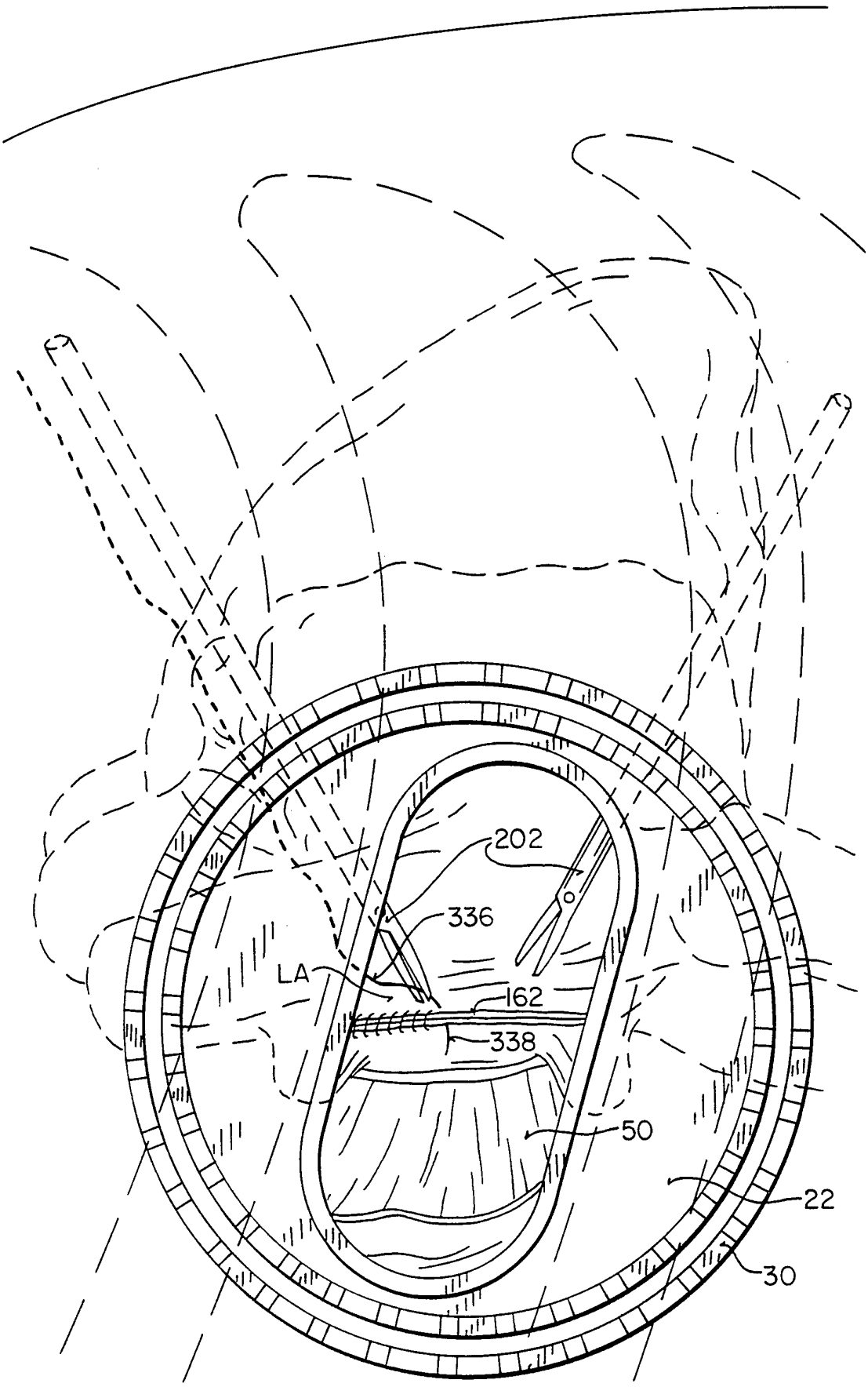
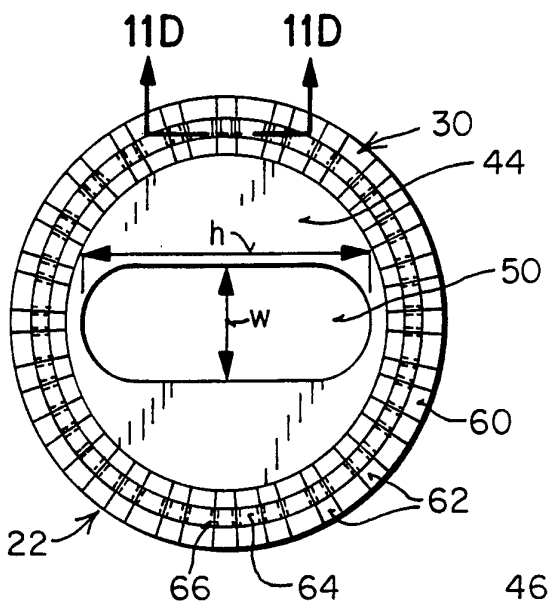


FIG. 10

FIG. 11C



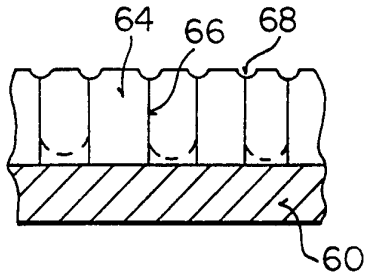


FIG. 11D

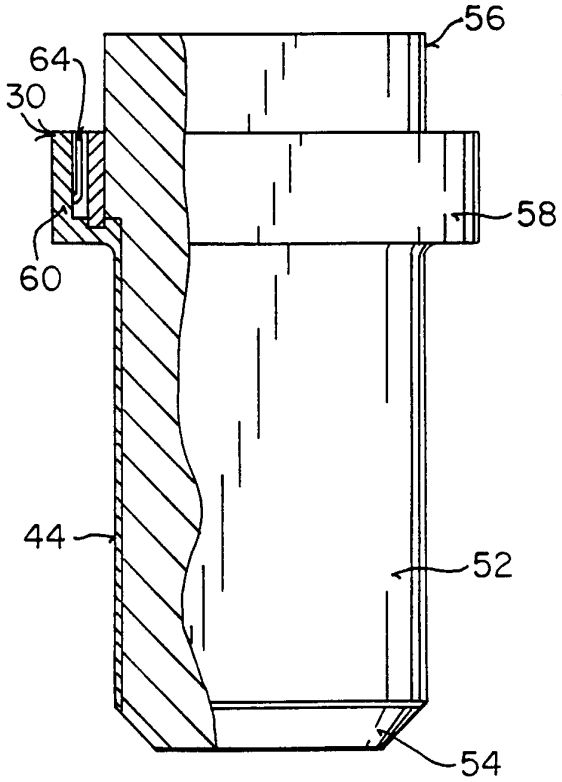


FIG. 11B

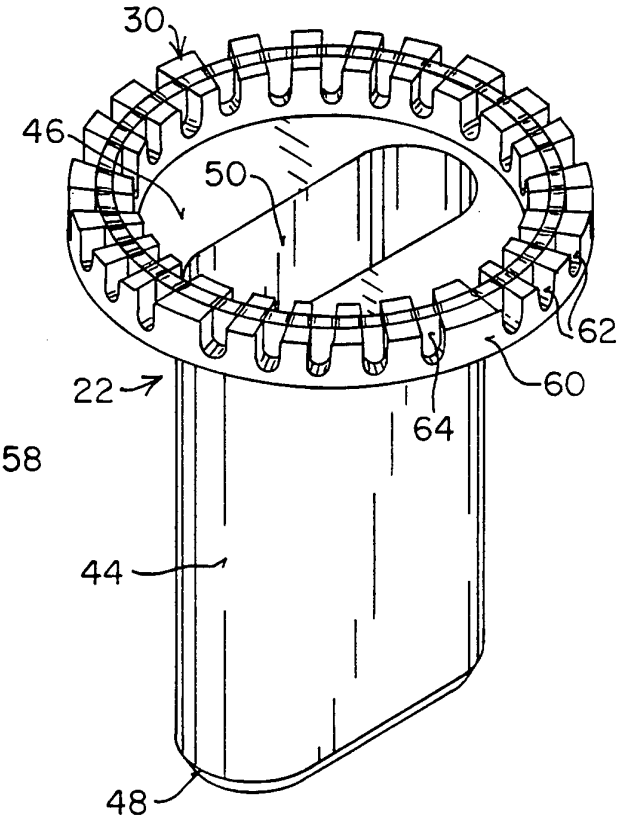
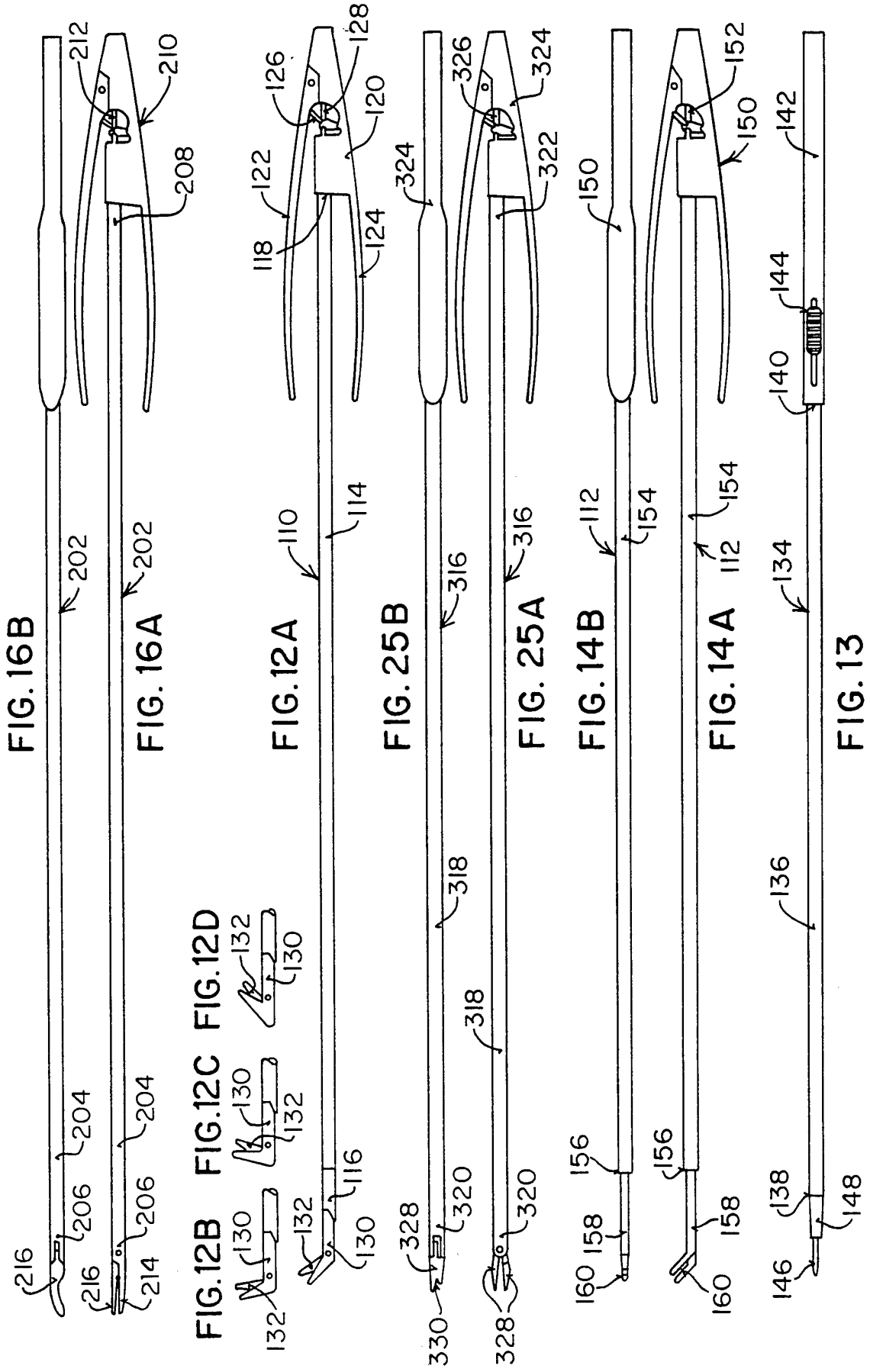


FIG. 11A


FIG. 16B
FIG. 16A
FIG. 12A
FIG. 25B
FIG. 25A
FIG. 14B
FIG. 14A
FIG. 13
FIG. 12B
FIG. 12C
FIG. 12D
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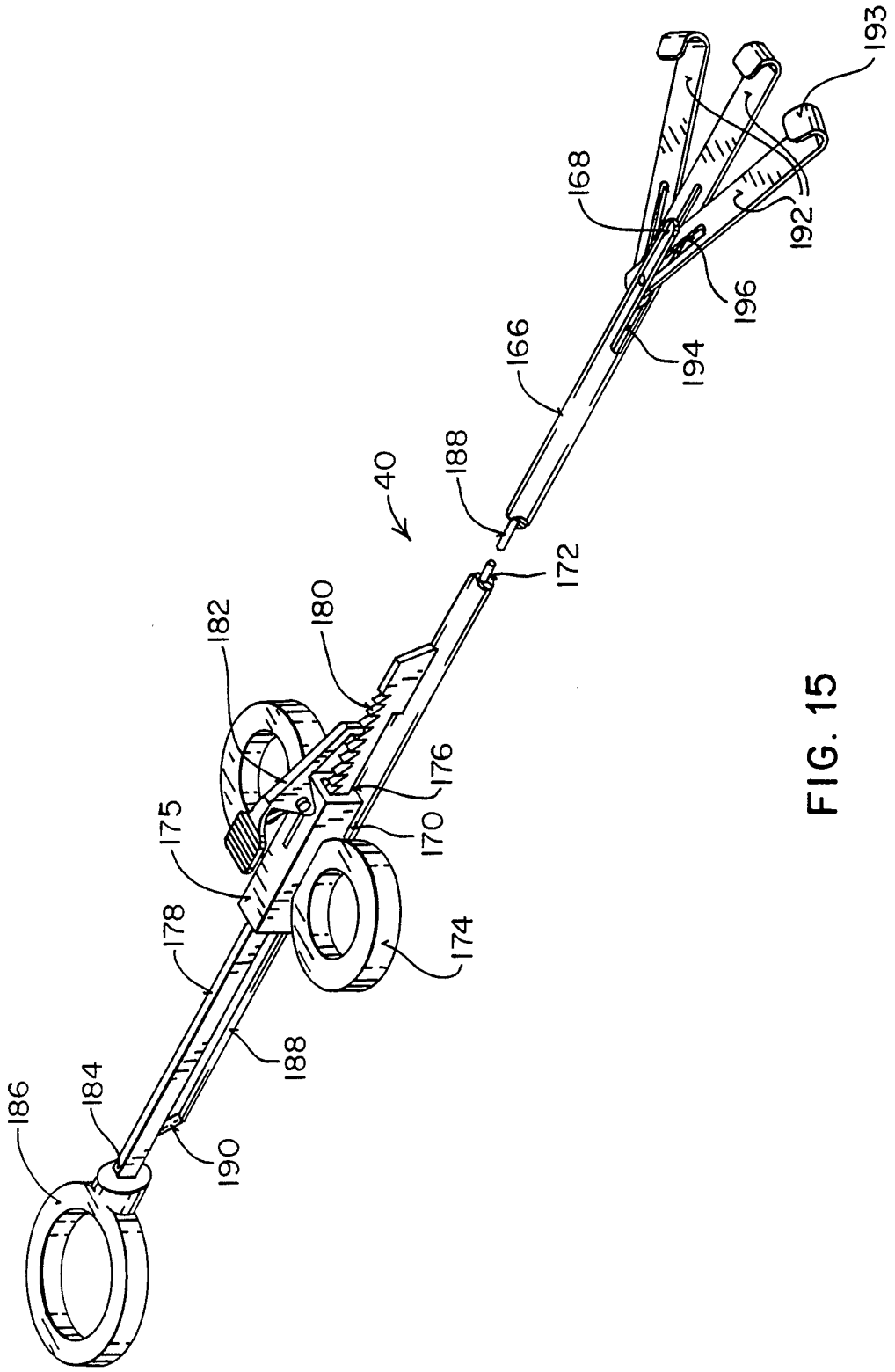

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FIG. 15

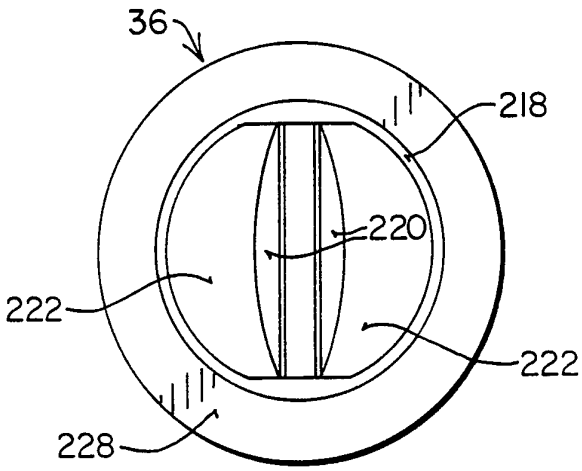


FIG. 17A

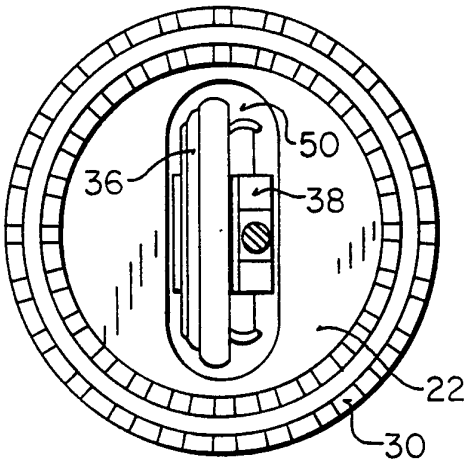


FIG. 17C

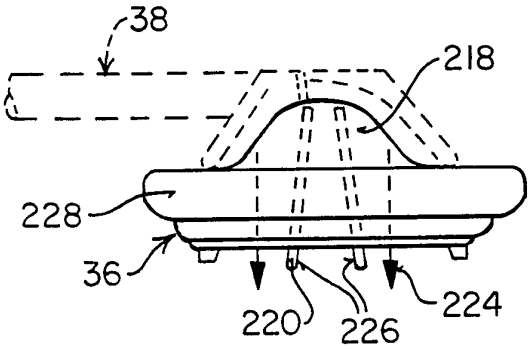


FIG. 17B

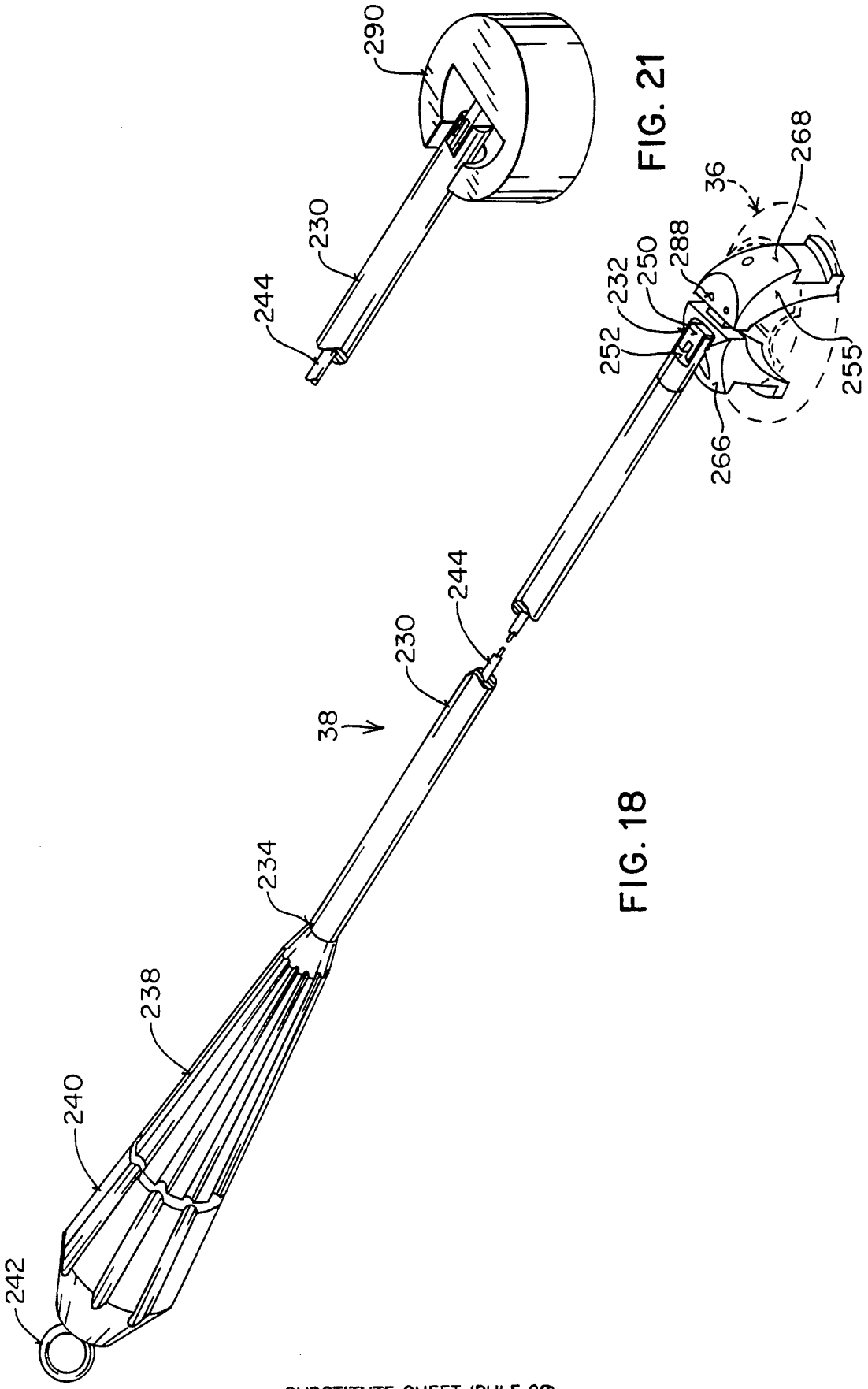

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FIG. 21

FIG. 18

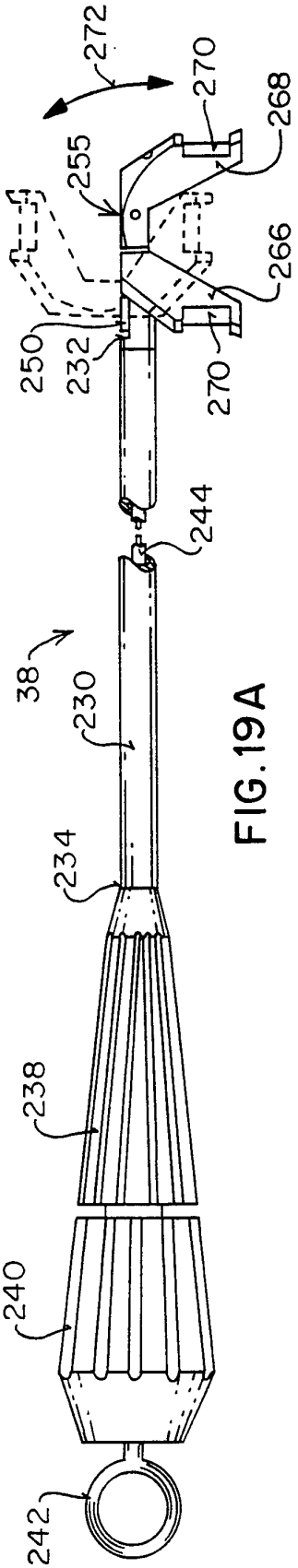


FIG.19A

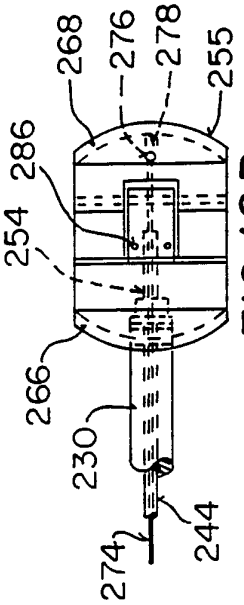


FIG.19B

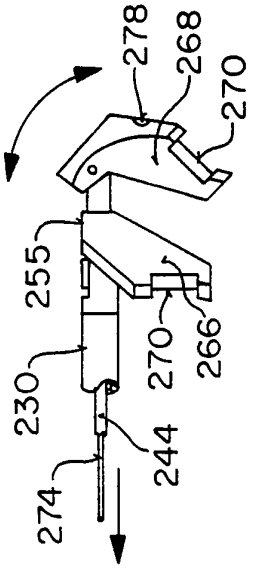


FIG.19C

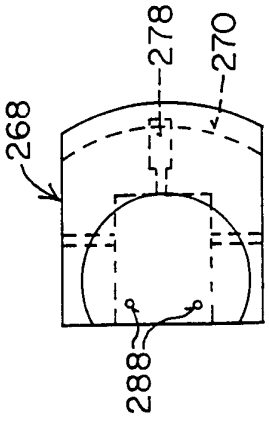


FIG.19F

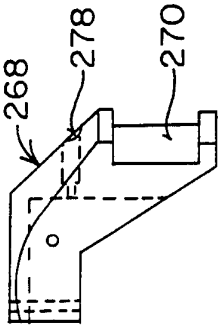


FIG.19G

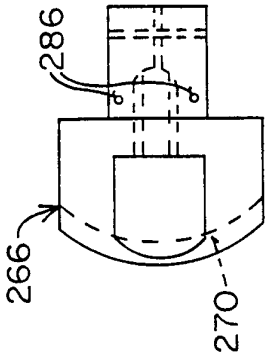


FIG.19D

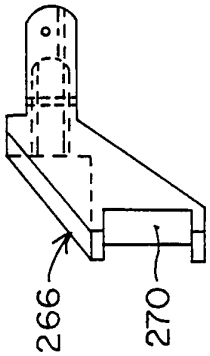


FIG.19E

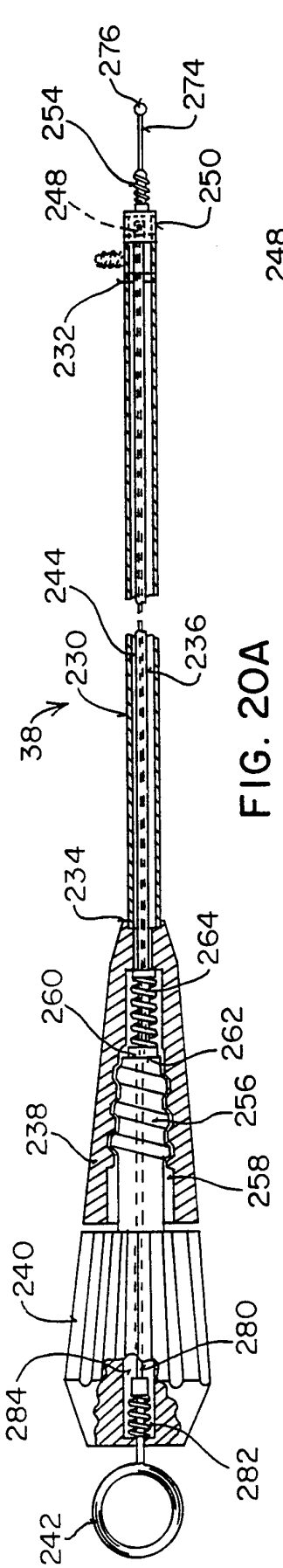


FIG. 20A

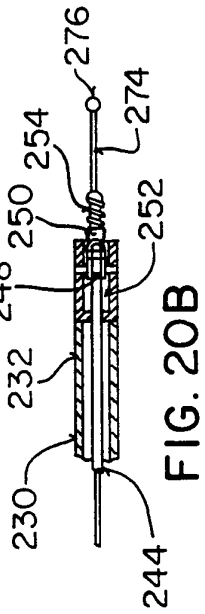


FIG. 20B

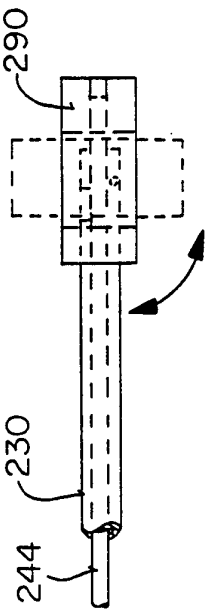


FIG. 22

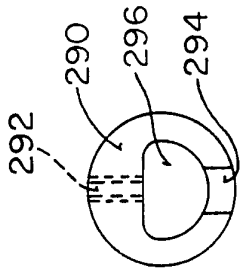


FIG. 23A

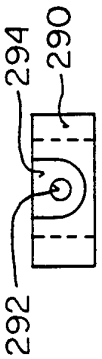


FIG. 23B

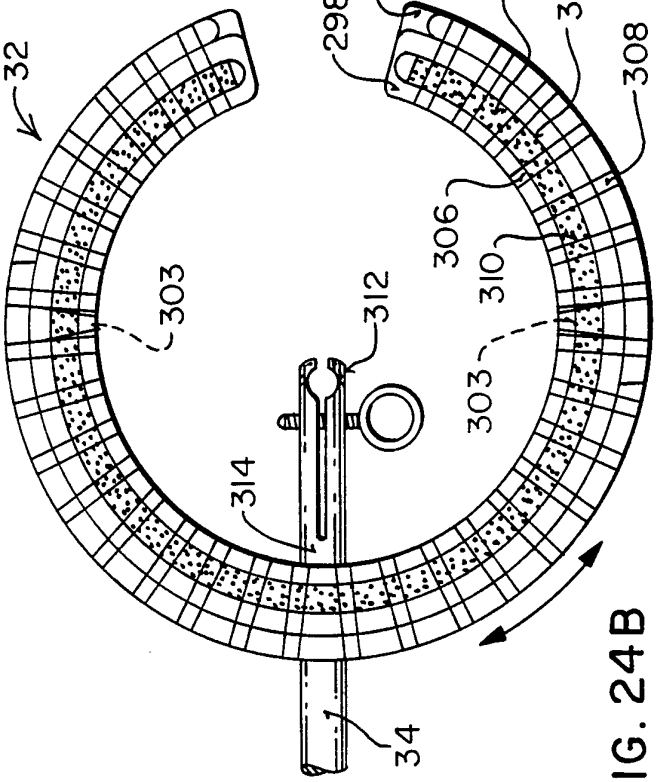


FIG. 24B

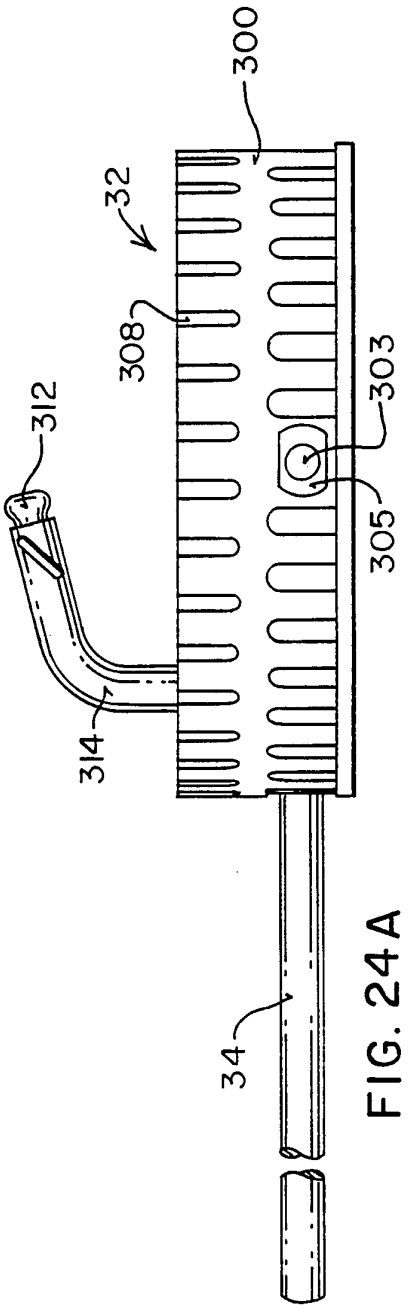


FIG. 24A

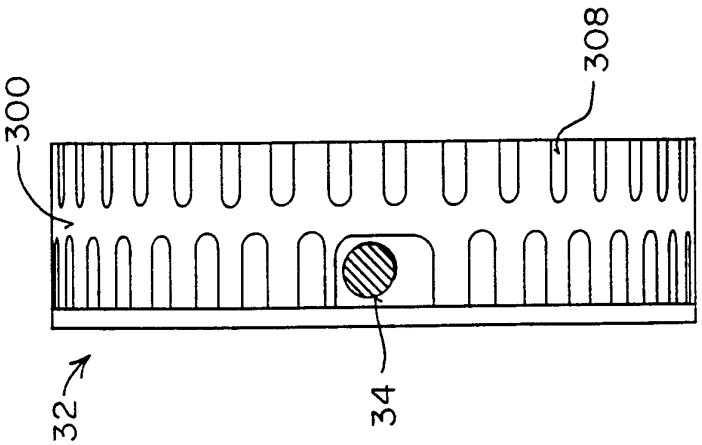


FIG. 24C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/13305

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 8/12; A61F 2/24; A61M 5/00
US CL :604/264; 623/2
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. : 604/264; 623/2

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

NONE

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

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	The AustralAsian Journal of Cardiac and Thoracic Surgery, VOL. 2, November 1993, "Minimally Invasive Cardiac Surgery By Cardioscopy", (WILLIAM S. PETERS), St. Vincent's Hospital Sydney, New South Wales, Australia.	1-3, 26, 27, 41, 42, 68, 69
Y	US, A, 5,041,130 (COSGROVE ET AL.) 20 August 1991. See entire document	57-81

☐ 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 part 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 21 MARCH 1995	Date of mailing of the international search report 27 MAR 1995
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 DAVID J. ISABELLA Telephone No. (703) 308-3060

Form PCT/ISA/210 (second sheet)(July 1992)*