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(54) **Deployable surgical platform and system for the removal and delivery of a medical device comprising such deployable surgical platform**

Chirurgische Plattform und System für das minimalinvasive Einführen einer bio-prothetischen Herzklappe

Plateforme chirurgicale et système minimal invasif pour l'introduction d'une valvule bio-prothétique

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(73) Proprietor: **THE CLEVELAND CLINIC**

FOUNDATION

Cleveland, OH 44195 (US)

(72) Inventor: **Vesely, Ivan**

Larkspur, CO 80118 (US)

(74) Representative: **Reitstötter - Kinzebach**

Patentanwälte

Sternwartstrasse 4

81679 München (DE)

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EP 2 258 312 B9

Description

Background of the Invention

[0001] The current practice of inserting artificial heart valves involves cutting the chest open, placing the patient on cardiopulmonary bypass, and surgically inserting the valve into an aorta. This process can take several hours and subjects the patient to significant operative mortality. While the mortality during first valve replacement surgery can be very low (less than 5%), the second surgery carries much greater operative mortality, and the third is even more risky (> 15%). Consequently, first and second re-operations to replace a worn out bioprosthetic heart valve are avoided. Since a typical bioprosthesis, or tissue valve, can wear out in 10 years, these valves are typically implanted into patients 60 years old, or older. Younger patients are often recommended a mechanical valve that does not wear out, and typically does not need replacement.

[0002] Tissue valves, however, are often preferred over mechanical valves because of their better biocompatibility. Mechanical valves cause blood to clot on their components, and the patient must therefore be chronically treated with anticoagulants to eliminate the risk of major blood clots. Anticoagulant themselves, however, carry a measurable risk of bleeding and thromboembolism and are not an ideal solution. Because tissue valves do not need to be anticoagulated, they are potentially the ideal valve prosthesis, if only their durability were to be improved.

[0003] Accordingly, the goal of most tissue valve research and development, has been the improvement in valve durability so that these tissue valves can be put into patients younger than 60 or 65. Because of the operative mortality and morbidity, the objectives of all valve research and development, has been to increase the functional life span of the bioprosthesis so that it can be put into patients only once, and will last the life of the patient. This has thus far been an extremely difficult goal to reach.

[0004] There may be another option, however, for the use of tissue heart valves in the younger population. Rather than building valves that last longer, it may be more appropriate to build valves that can be routinely replaced in a way that induces negligible patient morbidity. The objectives would therefore be not to have extremely durable valves, but rather valves that can be easily removed when they begin to fail and new ones inserted. The technologies that make this possible already exist with the advances made in the field of catheter-based endovascular procedures, and the more broad field of Minimally Invasive Surgery (MIS).

[0005] The field of MIS is growing at an accelerating pace. The approach involves the use of small surgical probes, cannulas, video cameras and remote staplers and suture drivers that enable surgery to be done without requiring large incisions. Most MIS is done with several

small incisions, simply to allow the passage of these instruments into the patients body. The principal advantages of MIS is that the patient is subjected to less surgical trauma and has a dramatically reduced hospital stay, which in turn significantly reduces the operating costs of the clinical center. Current generation minimally invasive procedures are being carried out using endoscopes and long-reaching surgical tools. Typically, the patient's abdomen is inflated with carbon dioxide and the instruments are inserted through small incisions. The surgeons then perform the procedures using endoscopic visualization. For cardiothoracic surgery, similar small incisions are created between the ribs and the heart is placed on bypass using multiple cannulas with balloons that can selectively shut off blood flow through the heart, and direct it through oxygenators.

[0006] Other technologies are being developed to do surgery on beating hearts, as to completely avoid placing the heart on bypass. Many of these procedures involve the use of specialized catheters that deploy devices or tools that perform a wide range of procedures on the beating heart. Typical beating heart procedures are endovascular balloon dilatation of arteries and stent placement. Deployment of stents and other permanent devices has become commonplace, but to date, no successful, catheter deployable valve has been developed.

[0007] While U.S. Patent No. 5,545,214 discloses a balloon-deployable tissue valve, the technology is similar to that of stents, and is not ideal for tissue heart valves. The material that anchors the valve in the patient's aortic root is permanently deformed through the bending of metal components, and is not intended to be re-collapsed into its original configuration. Practically the same approach is disclosed in U.S. Patent No. 5,411,552. U.S. Patent No. 5,554,185 discloses a means of deploying the valve by inflating of a hollow valve frame with a liquid that hardens. U.S. Patent No. 5,545,209 describes the use of balloon technology to permanently distend and deploy an endoprosthesis, typically a vascular segment for treating abdominal aneurysm. This patent makes reference to "a tubular prosthesis disposed on said catheter over at least a portion of said balloon." The major concepts disclosed by all of these patents are similar: the permanent deployment of a bioprosthetic heart valve. A permanently deployed tissue heart valve, whether it is done using MIS technology or not, is subject to the same requirements as conventional tissue valves: it must be very durable. Good durability, however, is not easily attained. The manufacturing process of tissue heart valves is very mature and complex from the quality control point of view, and only minimal improvements in valve durability have been achieved in recent years. Major improvements in valve durability are therefore not expected in the near future.

[0008] The present invention addresses the drawbacks discussed above, as well as other problems encountered with the prior art, to provide a system for minimally invasive removal and re-insertion of a bioprosthetic

heart valve. One feature is a valve that can be collapsed after many years of use in the patient. The collapsing or expanding process does not involve any permanent deformation of components, as has been required for the systems disclosed in the preceding patents. A properly collapsible valve is first removed from the patient using catheters, when it has failed to provide proper function to the patient, and a new version of the same temporary collapsible valve is inserted using the same catheter technology.

Summary of the Invention

[0009] According to the present invention there is provided a deployable surgical platform comprising the features of claim 1. Further aspects of the invention are described in the features of the dependent claims, including a system for the removal and delivery of a medical device comprising such deployable surgical platform. Furthermore, according to the present invention there is provided a system for minimally invasive removal and re-insertion of a bioprosthetic heart valve. Broadly stated, the device is sufficiently collapsible so as to be able to pass through the lumen of a catheter inserted into the femoral artery, or other large vessel. The collapsed valve is re-expanded when in place in order to fit into a permanent housing in the patients heart and assumes a fully functioning state. Integral to this system of removal and replacement of a prosthetic heart valve is an expandable "operative platform" that is deployed near the site of the valve so that it stabilizes the catheters and other instruments during the valve removal and reinsertion process.

[0010] Further there is provided a two component valve system comprised of a permanent housing which remains in the patient, and a collapsible valve which is replaced when it becomes necessary,

[0011] Further there is provided a permanent housing with an integrated sewing ring which is affixed to the patient aorta or other tissue by means of sutures or staples.

[0012] Further there is provided a collapsible inner frame onto which several leaflets or flexible occluders are affixed, comprised of several articulating or hinged components which have a substantially smaller perimeter when fully collapsed, than when fully expanded.

[0013] In accordance with the present invention, there is provided an inflatable or distensible "surgical platform" which can be delivered to a site near the heart in a collapsed state and distended at that site such that it anchors the numerous catheters and devices in space thereby ensuring proper controlled manipulation of their distal ends, when acted upon by controls at their proximal ends.

[0014] In accordance with another aspect of the present invention, there is provided an integrated check valve within the surgical platform that enables controlled ejection of blood from the ventricle during the process of collapsible valve removal and replacement.

[0015] In accordance with yet another aspect of the present invention, there is provided a split wall or "mon-

orail" catheter system which can guide larger instruments and devices between the outside of the patient and the surgical platform during the course of a valve replacement procedure.

[0016] In accordance with yet another aspect of the present invention, there is provided a tracking and visualization system that can generate accurate images or graphical representation of the catheters and other components on a computer screen so as to accurately represent the position of the real components inside the body of the patient.

[0017] Although the prosthetic collapsible valve may incorporate various number of leaflets, a preferred embodiment of the valve incorporates three (3) valve leaflets.

[0018] Although the collapsible valve may incorporate a wide range of leaflet materials, such as synthetic leaflets or those constructed from animal tissues, a preferred embodiment of the valve incorporates three (3) valve leaflets constructed from sheets of chemically preserved bovine pericardium.

[0019] Although the permanent outer frame of the prosthetic cardiac valve may be constructed from a wide range of materials including metals and plastics, a preferred embodiment of the outer frame is constructed from stiff, rigid metal such as stainless steel.

[0020] Although the collapsing mechanism of the collapsible valve may incorporate various means of remaining permanently expanded within the permanent outer frame, a preferred embodiment of maintaining the collapsible valve in its expanded state is by means of precision machining of the components of the inner frame so that a "snapping" action holds them in their expanded position by means of an interference fit between components.

[0021] Although the collapsible valve may be collapsed by various means, a preferred embodiment of the valve collapsing means incorporates one or more projections or "handles" that protrude from the collapsible frame so that they can be grabbed by a catheter-based snare means.

[0022] Although the collapsible valve may be expanded by various means, a preferred embodiment of the valve expanding means incorporates an articulating expanding means that does not require the use of balloon technology to expand the collapsible frame.

[0023] Although the system for minimally invasive insertion of a collapsible valve may make use of numerous means of stabilizing the proximal ends of the catheters, a preferred embodiment of the procedure is the use of a stabilizing surgical platform that can be anchored distal to the aortic valve. The surgical platform incorporates slots and fixtures for attaching and holding catheters in slots that stabilize the movement and position of the distal ends of the catheters so that deflection and manipulation of the catheter ends is done in a controlled way.

[0024] Although the system for minimally invasive insertion of a collapsible valve may make use of numerous

means of temporarily augmenting the action of the contracting heart by means of valves, a preferred embodiment of the procedure is the incorporation of an integrated check valve within the surgical platform that becomes functional once the platform is expanded in place. The integrated check valve can be fabricated out of polymer and have one or more occluding leaflets. The leaflets are soft and pliable and enable the passage of catheters and other devices past and through the leaflets.

[0025] Although the system for minimally invasive insertion of a collapsible valve may make use of numerous catheters to deliver the components of the collapsible valve system into the desired site, a preferred embodiment of the procedure is the use of a "monorail" or slotted catheter sheath that enables larger devices to be guided along the outside of the slotted catheter sheath to the operative site.

[0026] Although the system for minimally invasive insertion of a collapsible valve may make use of numerous imaging or visualization techniques, a preferred embodiment of the procedure is the use of a ultrasonic or electromagnetic sensors affixed to the catheters and components such that their position can be detected and tracked in 3-D space, in sufficient spatial and temporal resolution and precision, so as to make the procedure easy and accurate.

[0027] As can be seen by those skilled in the art, there is provided a valve system that allows for safe and convenient removal and replacement of a collapsible valve when it begins to fail,

an expandable, re-collapsible tissue-based heart valve, a catheter-based valve delivery system, a stable surgical platform within which catheter-based manipulators can be securely anchored so that intracardiac procedures can be properly executed, a synthetic valve integrated with the surgical platform to act as a temporary check valve while the expandable, re-collapsible tissue-based heart valve is being replaced, a slotted catheter sheath that can act as a "monorail" guide to shuttle components along the outside of the sheath between the exit/entry port of the patient and the surgical platform within the heart, and a ultrasound or electromagnetic catheter guidance system that can track the position and motion of the catheters and devices during the procedure and display images of the system components on a video display monitor, so as to make the procedure easy and accurate.

[0028] Further there is provided a bioprosthetic heart valve system comprising: first frame means attachable to tissue; and second frame means engageable with said first frame means, wherein said second frame means is movable between a collapsed position and an expanded position.

[0029] Said second frame means may support occluding means movable between an occluded position and an open position. Said occluding means may include at least one leaflet occluder. Said leaflet occluder may include biological tissue or bovine pericardium.

[0030] Said second frame means may be comprised of a plurality of articulated segments. At least one of said plurality of articulated segments may include a projection member for facilitating the movement of said second frame means between said collapsed position and said expanded position.

[0031] Furthermore, said plurality of articulated segments may define a first outer diameter when said second frame means is moved to said collapsed position, and may define a second outer diameter when said second frame means is moved to said expanded position, said first outer diameter being less than said second outer diameter.

[0032] Said plurality of articulated segments may articulate by pin joints or flexible strips or ball and socket joints.

[0033] Said first frame means may include a rigid member having interface means for reversibly engaging said second frame means therewith. Said interface means may include a groove member for receiving at least a portion of said second frame means when said second frame means is in the expanded position.

[0034] Said first frame means may include attachment means for attaching said first frame means to said tissue.

Said attachment means may include a sewing ring.

[0035] Further there is provided a remote manipulation system for remotely manipulating a medical device movable between a collapsed position and an expanded position, the manipulation system comprising: manipulation means for percutaneous insertion and withdrawal of the cardiovascular device means. Said manipulation means may include a catheter, said catheter including at least one connection means for connecting to the medical device and facilitating the movement of said medical device between the collapsed and expanded positions. Said connection means may include flexible snares. Said connection means may engage with one or more projection formed on said medical device.

[0036] Said medical device may be a prosthetic valve or an endoprosthesis.

[0037] According to an aspect of the invention there is provided a deployable surgical platform that is expandable for anchoring the platform at the site of a surgical procedure. The platform includes an inflatable balloon and anchoring means for anchoring one or more catheters within the surgical platform, said anchoring means comprises at least one slot formed in the inflatable balloon of the surgical platform.

[0038] Further there is provided a deployable surgical platform, wherein said expanding means includes multiple deformable projections that project from the distal end of a catheter.

[0039] Further there is provided a system for the removal and delivery of a medical device, the system comprising: a deployable surgical platform anchorable distal to the medical device, the surgical platform including: hollow expanding means anchorable at the site of the medical device; and anchoring means for anchoring at least

one catheter to the hollow expanding means.

[0040] Further there is provided a system for the removal and delivery of a medical device, wherein said medical device is a collapsible cardiovascular valve means, and said surgical platform further comprises first valve means for controlling the flow of blood traveling through said hollow expanding means.

[0041] Further there is provided a system for the removal and delivery of a medical device, wherein said first valve means includes a polymer.

[0042] Further there is provided a system for the removal and delivery of a medical device, wherein said first valve means includes a biological tissue.

[0043] Further there is provided a system for the removal and delivery of a medical device, wherein said anchoring means includes a twist connection.

[0044] Further there is provided a system for the removal and delivery of a medical device, wherein said anchoring means includes a snap connection.

[0045] According to an aspect of the invention there is provided a system for the removal and delivery of a medical device, wherein said system further comprises tracking means to locate the position of said medical device in 3-D space.

[0046] According to an aspect of the invention there is provided a system for the removal and delivery of a medical device, wherein said tracking means uses ultrasound signals.

[0047] According to an aspect of the invention there is provided a system for the removal and delivery of a medical device, wherein said tracking means uses electromagnetic fields.

[0048] According to an aspect of the invention there is provided a system for the removal and delivery of a medical device, wherein said tracking means uses sensors that are mounted to said medical device to locate said medical device in 3-D space.

[0049] According to an aspect of the invention there is provided a system for the removal and delivery of a medical device, wherein said at least one catheter has a longitudinally-extending slot, said slot dimensioned to allow a central sliding means to partially project therethrough and slide along said slot.

[0050] According to an aspect of the invention there is provided a system for the removal and delivery of a medical device, wherein said central sliding means includes gripping means for reversibly connecting said medical device to said central sliding means.

[0051] According to an aspect of the invention there is provided a system for the removal and delivery of a medical device, wherein said central sliding means is moved through a lumen of said at least one catheter by internal pull wire means.

[0052] Further there is provided a valve system comprising: first frame means attachable to bodily tissue; second frame means engageable with said first frame means, wherein said second frame means is movable between a collapsed position and an expanded position;

and valve means supported by said second frame means. Said valve means may include biological tissue.

[0053] Still other advantages of the invention will become apparent to those skilled in the art upon a reading and understanding of the following detailed description, and accompanying drawings.

Brief Description of the Drawings

[0054] The invention may take physical form in certain parts and arrangements of parts, a preferred embodiment and method of which will be described in detail in this specification and illustrated in the accompanying drawings which form a part hereof, and wherein:

Fig. 1 shows images of typical prior art bioprosthetic valve having leaflets made of bovine pericardium mounted on a supporting stent;

Fig. 2 shows a top plan view of the permanent outer frame;

Fig. 3A shows a perspective view of the collapsible inner frame in an expanded position;

Fig. 3B shows a top plan view of the collapsible inner frame shown in Fig. 3A;

Fig. 3C shows a top plan view of the collapsible inner frame shown in Fig. 3A, in a collapsed position.

Fig. 4A illustrates a collapsible inner frame in an expanded position, in accordance with an alternative embodiment.

Fig. 4B illustrates the collapsible inner frame of Fig. 4A, in a collapsed position.

Fig. 5 shows an enlarged partial sectional view of the inner and outer frames, to illustrate the mating surfaces thereof;

Fig. 6A shows an exemplary embodiment of a valve collapsing catheter;

Figs. 6B and 6C show an exemplary embodiment of a valve expanding catheter;

Fig. 7A shows an exploded view of a catheter-based valve delivery system, including a surgical platform and numerous accessory devices and catheters, according to one preferred embodiment of the present invention;

Fig. 7B shows an enlarged partial sectional view of a slotted catheter sheath, according to a preferred embodiment of the present invention;

Fig. 7C shows an enlarged partial sectional view of an inner catheter, according to a preferred embodiment of the present invention;

Fig. 7D is a schematic representation illustrating the operation of gripping means, in accordance with a preferred embodiment of the present invention;

Fig. 7E illustrates a surgical platform having a check valve, in

accordance with a preferred embodiment of the present invention;

Fig. 8A illustrates a front view of the cardiac anatomic site;

Fig. 8B illustrates a top view of the cardiac anatomic site shown in Fig. 8A; and

Fig. 8C is a simplified enlarged front view of the cardiac anatomic site shown in Fig. 8A.

I. Construction of the Collapsible Cardiac Valve and Frame

[0055] One aspect of the present invention is directed to an expandable, re-collapsible tissue-based valve system. With reference to Fig. 1, a typical prior art tissue-based prosthetic valve includes three (3) leaflets 13 sewn to and supported on a metal or polymer frame or stent 11. One aspect of the present invention is directed to a collapsible valve system generally comprised of two components: (i) a permanent outer frame that is affixed to the patient using conventional sutures or staples (Fig. 2), and (ii) an inner collapsible valve (Figs. 3A-3C and 4A-4B) that mates with the outer frame and includes valve leaflets. The inner collapsible valve is normally collapsed, is delivered against the previously inserted outer frame, expanded, and locked in place. Importantly, the inner collapsible valve may be collapsed again and removed. A new inner collapsible valve is then inserted into the original outer frame, to resume the function of the prosthesis.

[0056] With reference to Fig. 2, there is shown a preferred embodiment of the outer frame 10. Outer frame 10 is generally comprised of a rigid ring 11, and a soft sewing ring 12 for attachment of the outer frame 10 to the wall of the aorta or other structure within the heart.

[0057] Referring now to Figs. 3A-3B and 4A-4B, there is shown a preferred embodiment of the collapsible valve 20. Collapsible valve 20 is generally comprised of an articulating inner frame 21 having a plurality of projections or stent posts 22, and a plurality of leaflets (not shown). It should be understood that the leaflets are mounted to the stent posts 22 in a manner similar to that shown in Fig. 1, and movable between an occluded position and an open position. The inner frame 21 that supports the plurality of leaflets is formed of a plurality of articulated segments 24 (typically 6 or more segments), that fold together in a way so that the total outer diameter of the inner frame is reduced for insertion, as best seen in Fig. 3C. The articulated segments 24 are typically rigid structures that snap into a locked position as they are completely unfolded during deployment. Articulated segments 24 articulate around pin hinges 25 (Figs. 3B-3C) or other flexible strips 28 (Figs. 4A-4B), means that can assure a flexible attachment between any adjacent segments. It will be appreciated that other means for articulating are also suitable, including ball and socket joints.

[0058] The process of collapse and expansion involves a "snapping" action that produces some elastic material deformation of the segments 24 and/or the hinges 25 and/or the strips 28, as the segments articulate between their fully expanded configuration and their partially collapsed configuration. This is achieved by means of an interference fit between opposing segments that

articulate near each other. The provision for the snapping process is so that once expanded, the inner frame remains expanded under its own internal tension, and does not collapse due to undue internal or external force applied to it during normal activity.

[0059] Referring now to Fig. 5, the inner frame 21 is held in tight opposition against the rigid ring 11 of the outer frame 10 by means of a generally annular groove 14 on the inner surface of the rigid ring 11, into which each of the articulating segments 24 fit when the inner frame 21 is expanded. Accordingly, annular groove 14 provides a means for interfacing and attaching outer frame 10 with inner frame 11. It will be appreciated that articulated segments 24 include a flange portion 23, which is dimensioned to be received into groove 14. The fit between flange portion 23 of inner frame 21 and groove 14 of rigid ring 11 is such that the collapsible valve 20 cannot be withdrawn from the outer frame 10 when the inner frame 21 is expanded, and can only be withdrawn when the inner frame 21 is collapsed. It should be appreciated that other means for interfacing inner frame 21 with outer frame 10 are also suitable.

II. Collapse and Expansion of the Collapsible Cardiac Valve

[0060] During most of its useable life span, the collapsible valve 20 remains in its expanded state. The collapse of the inner frame 21 may be carried out with a remote manipulating device, such as valve collapsing catheter 30 (Fig. 6A) that includes one or more snares that grab onto projections 26 or "handles" formed on the collapsible inner frame 21 (Figs. 3A-3C). The valve collapsing catheter 30 includes a catheter body 31 and a plurality of cables preformed to conveniently sized loops or snare means 32. The snare means 32 can be extended from the catheter body 31 to preformed shapes, such that they can grab onto the projections 26 of the collapsible inner frame 21. When the snare means 32 are pulled back into the lumen of the catheter body 31, an inward force is achieved, sufficiently strong to "snap" the collapsible inner frame 21 into its collapsed position.

[0061] The process of expansion of the inner frame 21 is opposite to the collapsing process. Referring now to Figs. 6B and 6C, there is shown a suitable remote manipulating device for expanding the inner frame 21. Valve expanding catheter 40 includes a catheter body 41 and an articulating system 43 at its end that pushes against the projections 26 or some convenient segments 24 in order to expand the inner frame 21 and properly seat it in the outer frame 10. Valve expanding catheter 40 includes an inner rod 42 that slides in when pulled or pushed upon at its proximal end. Articulating system 43 is located at the distal end of inner rod 42, and includes a number of articulating arms or levers that hinge such that they expand when the inner rod 42 is drawn inwards. This action generates an outward push upon the inner frame 21 so that it expands and snaps into place in the

rigid ring 11 of the outer frame 10. Because of the fit between the inner frame 21 and the rigid ring 11, the inner frame 21 cannot be separated from the outer frame 10 when expanded, and can only be separated when the inner frame 21 is in the collapsed position. Accordingly, the collapsible valve 20 safely operates when the inner frame 21 is in the expanded position.

III. Intra cardiac Removal and Delivery of Collapsible Cardiac Valve

[0062] The system for collapse, removal and delivery of a replacement collapsible valve makes use of novel catheter technologies. A catheter-based valve delivery system must itself be collapsible so that it can be inserted percutaneously, and deliverable by catheter to the appropriate site. In accordance with a preferred embodiment of the present invention, a catheter-based valve delivery system is generally comprised of several catheters or catheter sheaths, that can shuttle components in and out of the body to the desired spot with minimal repositioning.

[0063] Figs. 7A-7E illustrate components of a delivery system, according to a preferred embodiment of the present invention. The distal end of the delivery system is anchored in the ascending aorta, and is referred to herein as the surgical platform 50. All catheters C1, 53 and 57, and other valve manipulation devices have their distal ends anchored within the surgical platform 50, so that they can be stable at their distal end and perform their function with good control and accuracy. The catheters, themselves act as remote manipulators that can be controlled by pull wires, or by means of small actuators controlled electrically or hydraulically that deflect the catheters or in some way change their shape. Since the objectives of some of the catheters is to deliver the collapsible valve 20 and other components from the outside of the patient to the operative site inside the patient, these catheters have an inner lumen through which pull cables and other catheters can slide.

[0064] The shuttling of larger objects between the outside world and the surgical platform 50 is achieved by splitting the main guiding catheter 53 along its length to form an elongated slot 55. Accordingly, main guiding catheter 53 acts as a slotted catheter sheath for inner pull cables or an inner catheter 57. Inner catheter 57 has gripping means 54 that project through slot 55 spanning the wall of the main guiding catheter 53. Gripping means 54 attach collapsible valve 20 or other devices to inner catheter 57, and slide along slot 55, as will be explained in detail below. Accordingly, the slotted main guiding catheter 53 and inner catheter 57 provide a "monorail" system that conveniently transports devices in and out of the body by moving them along the length of the main guiding catheter 53.

[0065] Since the collapsible valve 20 and other devices may not fit inside a typical catheter, they must be delivered to the operative site along the outside of the main

guiding catheter 53. Moreover, the collapsible valve 20 needs to be passed through the surgical platform 50 to the operative site, the slots 55 need to be continuous through the surgical platform 50. Accordingly, the surgical platform 50 is fitted with appropriate similar slots 56 so that the surgical platform 50 does not interfere with the passage of objects along the main guiding catheter 53.

[0066] The main guiding catheter 53 is locked in place to the surgical platform 50 by means of a system, such as a twist or snap connector, that lines up the slot 55 of the main guiding catheter 53 with the slot 56 formed in the surgical platform 50. Objects that are passed through the vasculature to the operative site, can be anchored to the inner catheter 57. In this regard, gripping means 54 may include a simple, spring-loaded clamp 59 that is held closed by a conventional coil spring 51 (Fig. 7D). The spring 51 can be opened remotely simply by pushing the inner catheter 57 against the closed end 75 of the main guiding catheter 53. This generates a pushing force on the clamp 59 and allows one of the jaws to rotate, thus opening the clamp and releasing the device. It will be appreciated that gripping means 54 may take other suitable forms.

[0067] The surgical platform 50 can be fabricated from balloon technology, as shown in Fig. 7A.

[0068] It should be appreciated that the delivery system, and in particular the surgical platforms 50 may also contain an auxiliary synthetic check valve 70 (Fig. 7E) that cyclically opens and closes, replacing the function of the worn out collapsible valve while it is being removed and replaced with a new collapsible valve. The synthetic check valve 70 may be integrated into the lumen 58 defined by the annular wall of the surgical platform 50. The synthetic check valve 70 is comprised of a one or more flaps of polymer that seal the lumen 58 when the check valve 70 is closed, and move out of the way when the check valve 70 opens passively as blood is ejected from the heart. There is provision made for manually opening the check valve 70 by means of catheters and pull wires, so that larger objects can be passed by this check valve on the way to the operative site. Alternatively, the action of the one-way check valve 70 can be replaced by an occluding balloon that cyclically expands and collapses under external control, and occludes the aorta distal to the surgical platform.

IV. Imaging System for Implantation of Collapsible Cardiac Valve

[0069] Complex, remote surgery such as described above, requires a suitable device tracking and visualization system. Conventional MIS procedures can be performed only on organs that do not involve considerable bleeding since the surgeon is oriented and guided only with his own vision, using endoscopic video cameras. Using endoscopes in a bloody environment is not convenient because blood is opaque. Optical visualization

and localization inside the beating heart is simply impractical.

[0070] Such a system will therefore need real-time, high resolution ultrasound imaging, continuous X-ray fluoroscopy, or some combination of both. Real-time open magnet MRI is also an option, but the need for high strength metallic instruments in this system makes MRI unlikely. X-ray imaging is undesirable because of the harmful radiation, and ultrasound does not currently have sufficient spatial resolution when operated in 3-D mode and is unlikely to in the near future. Ultrasound imaging is also susceptible to shadowing from dense, metallic objects. Innovative imaging modalities alone, may not be sufficient for properly guiding the valve replacement procedure. A 3-D visualization system, that integrates multiple imaging modalities and real time device tracking, is therefore most suitable. For instance, an ultrasonic catheter and device tracking system, analogous to that described in U.S. Patent No. 5,515,853 (incorporated herein by reference), would be very appropriate, if linked to a powerful 3-D graphics engine that can simulate the position and movement of the various objects as they are manipulated inside the patient. Another device tracking system that could be used would employ electromagnetic localizer technology, such as that described in U.S. Patent No. 5,546,951 (incorporated herein by reference). Other electrical, magnetic or image based localizer system can be used with similar function. To provide additional information, numerous images obtained simultaneously using ultrasound, X-ray or other imaging modalities could be integrated into this viewing environment, as described in U.S. Patent No. 5,817,022 (incorporated herein by reference), to provide additional feedback regarding the true position of the objects.

V. Other uses of device delivery system.

[0071] There is a growing number of surgical and therapeutic procedures that involve the delivery of a device or multiple devices to the inside of a body to a site of surgery or device deployment. To date, all of these systems employed a conventional catheter without the longitudinal split, and without the use of a surgical platform. Use of the present invention: (i) enables the delivery of larger devices to the target site by the use of smaller catheters, and (ii) stabilizes the distal end of the catheter for much more precise, more controllable catheter-based procedures. Such a surgical platform can be used for ablation procedures within the ventricles and the atria by better stabilizing the catheters, for the delivery of larger endovascular prostheses or occluding devices to stop internal bleeding, such as in cirrhotic liver vessels or ventricular-septal defects. The surgical platforms for such applications do not need to incorporate internal valves and can therefore be simplified into baskets or cages or articulating structures that simply lodge themselves against the appropriate anatomy, as shown in Figs. 8A-C, in the case for atrial access. In this embodiment, the

surgical platform 80 includes forked projections 81 that slide out of a main catheter 82 and lodge themselves against appropriate cardiac anatomy, such as the commissures of the mitral valve 85. The "commissure" is an anatomic site, defined as the spot where the anterior leaflet 86 meets the posterior leaflet 87. These commissures are also located between the atrium 88 and the ventricle 89, which in themselves provide walls or surfaces against which the projections 81 can be anchored.

[0072] The present invention has been described with reference to a preferred embodiment. Obviously, it will be appreciated by those skilled in the art that various additions, modifications, deletions and alterations will occur to others upon a reading and understanding of this specification, and may be made to such preferred embodiments without departing from the spirit and scope of the invention. Accordingly, it is intended that all such modifications and alterations be included within the scope of the invention as defined in the following claims.

Claims

1. A deployable surgical platform (50) that is expandable for anchoring the platform (50) at the site of a surgical procedure, comprising:

anchoring means for anchoring one or more catheters (1, 53, 57) within the surgical platform (50),

characterized in that the platform includes an inflatable balloon and

said anchoring means comprises at least one slot (56) formed in the inflatable balloon of the surgical platform (50).

2. The deployable surgical platform (50) according to claim 1, wherein said platform (50) comprises an annular wall defining a lumen (58), the diameter of the annular wall being expandable to anchor the platform (50) at the site of the surgical procedure, and wherein said slot (56) is formed in the annular wall to receive the one or more catheters (53) and for anchoring distal ends of the one or more catheters (53) to the platform (50).
3. The deployable surgical platform (50) according to claim 2, wherein said platform (50) includes a synthetic check valve (70) integrated into the lumen (58) defined by the annular wall.
4. The deployable surgical platform (50) according to claim 2, wherein said platform (50) includes an occluding balloon integrated into the lumen (58) defined by the annular wall
5. A system for the removal and delivery of a medical device, the system comprising:

a deployable surgical platform (50) according to any one of claim 1 to 4, wherein said platform (50) is anchorable distal to the medical device.

6. The system for the removal and delivery of a medical device according to claim 5, wherein said system further comprises tracking means to locate the position of said medical device in 3-D space. 5
7. The system for the removal and delivery of a medical device according to claim 6, wherein said tracking means uses ultrasound signals. 10
8. The system for the removal and delivery of a medical device according to claim 6, wherein said tracking means uses electromagnetic fields. 15
9. The system for the removal and delivery of a medical device according to claim 6, wherein said tracking means uses sensors that are mounted to said medical device to locate said medical device in 3-D space. 20
10. The system for the removal and delivery of a medical device according to any one of claims 5 to 9, comprising a guiding catheter (53) and an inner catheter (57) moveable relative to the guiding catheter (53), said inner catheter (57) including gripping means (54) to grip the medical device. 25
11. The system for the removal and delivery of a medical device according to claim 10, wherein said gripping means (54) comprises a spring-loaded clamp (59). 30
12. The system for the removal and delivery of a medical device according to claim 10 or 11, wherein said guiding catheter (53) is a sheath for said inner catheter (57). 35
13. The system for the removal and delivery of a medical device according to claim 12, wherein said sheath of said guiding catheter (53) includes a longitudinally-extending slot (55), said slot (55) dimensioned to allow said gripping means (54) to at least partially project therethrough. 40
14. The system for the removal and delivery of a medical device according to any one of claims 10 to 13, wherein said system includes pull wire means for moving said inner catheter (57) relative to the guiding catheter (53). 50

Patentansprüche

1. Einsetzbare chirurgische Plattform (50), welche zum Verankern der Plattform (50) an einem Ort eines chirurgischen Verfahrens expandierbar ist, umfassend:

Verankerungsmittel zum Verankern eines oder mehrerer Katheter (1, 53, 57) innerhalb der chirurgischen Plattform (50),

dadurch gekennzeichnet, dass

die Plattform einen aufblasbaren Ballon umfasst und die Verankerungsmittel wenigstens einen Schlitz (56) umfassen, der in dem aufblasbaren Ballon der chirurgischen Plattform (50) ausgebildet ist.

2. Einsetzbare chirurgische Plattform (50) gemäß Anspruch 1, wobei die Plattform (50) eine ein Lumen (58) definierende ringförmige Wand umfasst, dessen Durchmesser expandierbar ist, um die Plattform (50) an dem Ort des chirurgischen Verfahrens zu verankern, und wobei der Schlitz (56) in der ringförmigen Wand ausgebildet ist, um den einen oder die mehreren Katheter (53) aufzunehmen und um die distalen Enden von dem einen oder den mehreren Kathetern (53) an der Plattform (50) zu verankern.
3. Einsetzbare chirurgische Plattform (50) gemäß Anspruch 2, wobei die Plattform (50) ein synthetisches Rückschlagventil (70) umfasst, welches in das durch die ringförmige Wand definierte Lumen (58) integriert ist.
4. Einsetzbare chirurgische Plattform (50) gemäß Anspruch 2, wobei die Plattform (50) einen verschließenden Ballon umfasst, welcher in das durch die ringförmige Wand definierte Lumen (58) integriert ist.
5. System zum Entfernen und Zuführen eines Medizingeräts, wobei das System umfasst:

eine einsetzbare chirurgische Plattform (50) gemäß einem der Ansprüche 1 bis 4, wobei die Plattform (50) distal an dem Medizingerät verankerbar ist.
6. System zum Entfernen und Zuführen eines Medizingeräts gemäß Anspruch 5, wobei das System des Weiteren Nachverfolgungsmittel zum Lokalisieren der Position des Medizingeräts im 3D-Raum umfasst.
7. System zum Entfernen und Zuführen eines Medizingeräts gemäß Anspruch 6, wobei die Nachverfolgungsmittel Ultraschallsignale verwenden.
8. System zum Entfernen und Zuführen eines Medizingeräts gemäß Anspruch 6, wobei die Nachverfolgungsmittel elektromagnetische Felder verwenden.
9. System zum Entfernen und Zuführen eines Medizingeräts gemäß Anspruch 6, wobei die Nachverfolgungsmittel Sensoren verwenden, welche an dem

Medizingerät befestigt sind, um das Medizingerät im 3D-Raum zu lokalisieren.

10. System zum Entfernen und Zuführen eines Medizingeräts gemäß einem der Ansprüche 5 bis 9, umfassend einen Führungskatheter (53) und einen Innenkatheter (57), welcher relativ zum Führungskatheter (53) bewegbar ist, wobei der Innenkatheter (57) Greifmittel (54) umfasst, um das Medizingerät zu ergreifen.
11. System zum Entfernen und Zuführen eines Medizingeräts gemäß Anspruch 10, wobei die Greifmittel (54) eine federgespannte Klammer (59) umfassen.
12. System zum Entfernen und Zuführen eines Medizingeräts gemäß Anspruch 10 oder 11, wobei der Führungskatheter (53) ein Futteral für den Innenkatheter (57) ist.
13. System zum Entfernen und Zuführen eines Medizingeräts gemäß Anspruch 12, wobei das Futteral des Führungskatheters (53) einen sich longitudinal erstreckenden Schlitz (55) umfasst, wobei der Schlitz (55) so dimensioniert ist, dass ein wenigstens teilweises Durchdringen der Greifmittel (54) durch diesen hindurch ermöglicht wird.
14. System zum Entfernen und Zuführen eines Medizingeräts gemäß einem der Ansprüche 10 bis 13, wobei das System Zugdrahtmittel zum Bewegen des Innenkatheters (57) relativ zum Führungskatheter (53) umfasst.

Revendications

1. Plateforme chirurgicale déployable (50) qui est expansible pour ancrer la plateforme (50) sur le site d'une procédure chirurgicale, comprenant :

des moyens d'ancrage pour ancrer un ou plusieurs cathéters (1, 53, 57) à l'intérieur de la plateforme chirurgicale (50),
caractérisée en ce que la plateforme comprend un ballonnet gonflable et lesdits moyens d'ancrage comprennent au moins une fente (56) formée dans le ballonnet gonflable de la plateforme chirurgicale (50).
2. Plateforme chirurgicale déployable (50) selon la revendication 1, dans laquelle ladite plateforme (50) comprend une paroi annulaire définissant une lumière (58), le diamètre de la paroi annulaire étant expansible pour ancrer la plateforme (50) sur le site de la procédure chirurgicale, et dans laquelle ladite fente (56) est formée dans la paroi annulaire pour recevoir les un ou plusieurs cathéters (53) et pour an-

crer les extrémités distales des un ou plusieurs cathéters (53) à la plateforme (50).

3. Plateforme chirurgicale déployable (50) selon la revendication 2, dans laquelle ladite plateforme (50) comprend une soupape de non-retour synthétique (70) intégrée dans la lumière (58) définie par la paroi annulaire.
4. Plateforme chirurgicale déployable (50) selon la revendication 2, dans laquelle ladite plateforme (50) comprend un ballonnet d'occlusion intégré dans la lumière (58) définie par la paroi annulaire.
5. Système pour le retrait et la pose d'un dispositif médical, le système comprenant :

une plateforme chirurgicale déployable (50) selon l'une quelconque des revendications 1 à 4, dans laquelle ladite plateforme (50) peut être ancrée de manière distale audit dispositif médical.
6. Système pour le retrait et la pose d'un dispositif médical selon la revendication 5, dans lequel ledit système comprend en outre des moyens de traçage pour localiser la position dudit dispositif médical dans un espace tridimensionnel.
7. Système pour le retrait et la pose d'un dispositif médical selon la revendication 6, dans lequel lesdits moyens de traçage utilisent des signaux à ultrasons.
8. Système pour le retrait et la pose d'un dispositif médical selon la revendication 6, dans lequel lesdits moyens de traçage utilisent des champs électromagnétiques.
9. Système pour le retrait et la pose d'un dispositif médical selon la revendication 6, dans lequel lesdits moyens de traçage utilisent des capteurs qui sont montés sur ledit dispositif médical pour localiser ledit dispositif médical dans un espace tridimensionnel.
10. Système pour le retrait et la pose d'un dispositif médical selon l'une quelconque des revendications 5 à 9, comprenant un cathéter de guidage (53) et un cathéter interne (57) mobile par rapport au cathéter de guidage (53), ledit cathéter interne (57) comprenant des moyens de préhension (54) pour saisir le dispositif médical.
11. Système pour le retrait et la pose d'un dispositif médical selon la revendication 10, dans lequel lesdits moyens de préhension (54) comprennent une pince à ressort (59).
12. Système pour le retrait et la pose d'un dispositif mé-

dical selon la revendication 10 ou 11, dans lequel ledit cathéter de guidage (53) est une gaine pour ledit cathéter interne (57).

- 13.** Système pour le retrait et la pose d'un dispositif médical selon la revendication 12, dans lequel ladite gaine dudit cathéter de guidage (53) comprend une fente (55) s'étendant longitudinalement, ladite fente (55) étant dimensionnée pour permettre auxdits moyens de préhension (54) de faire saillie au moins partiellement à travers cette dernière. 5 10
- 14.** Système pour le retrait et la pose d'un dispositif médical selon l'une quelconque des revendications 10 à 13, dans lequel ledit système comprend des moyens formant fil de traction pour déplacer ledit cathéter interne (57) par rapport au cathéter de guidage (53). 15

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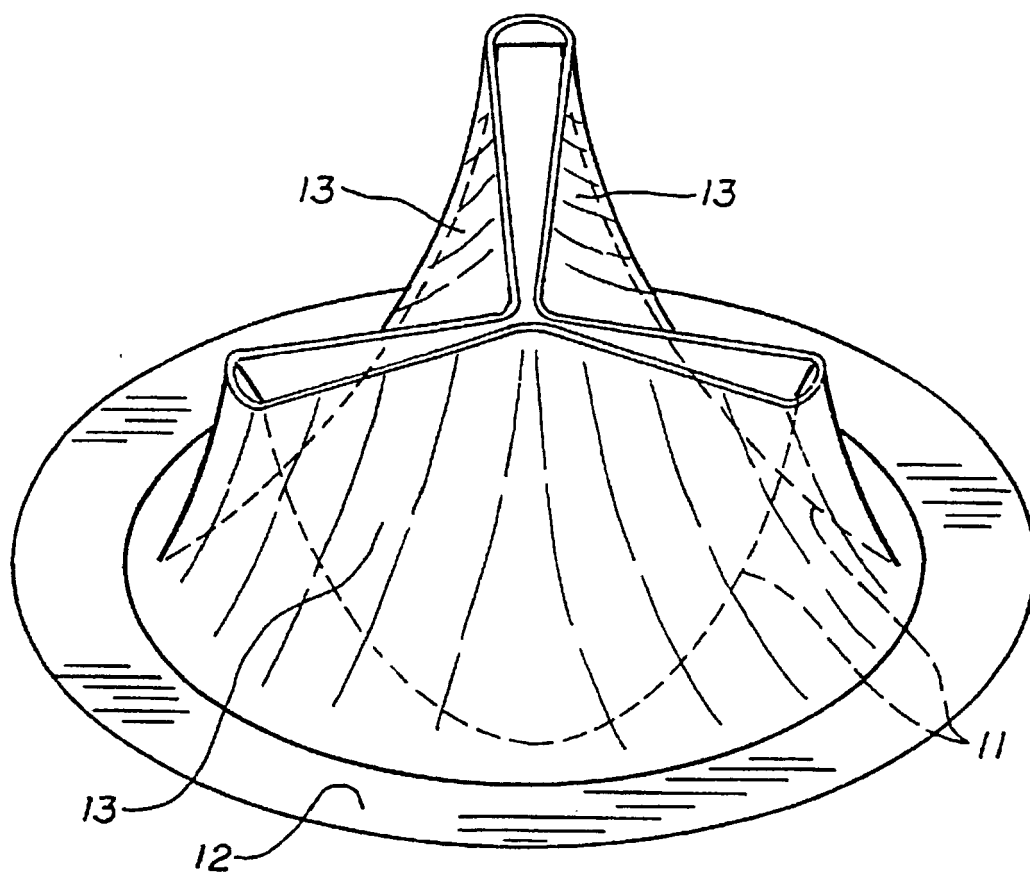


Fig. 1
(PRIOR ART)

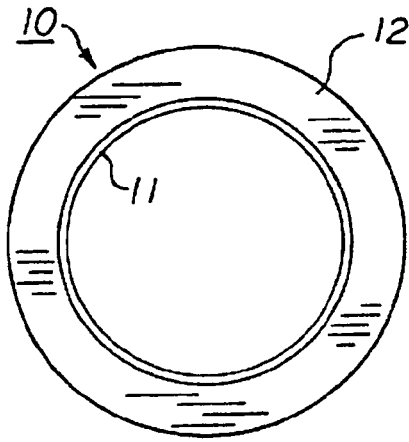


Fig. 2

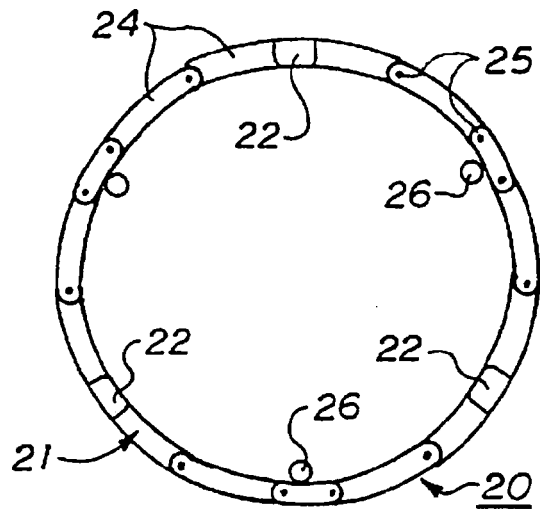


Fig. 3B

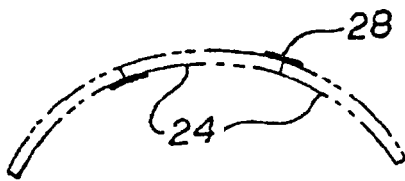


Fig. 4A

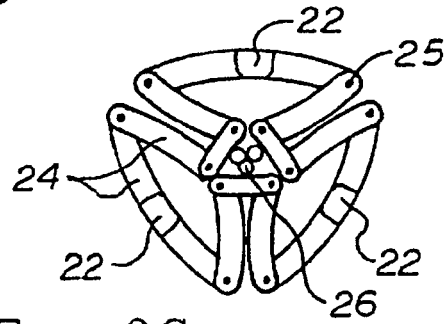


Fig. 3C

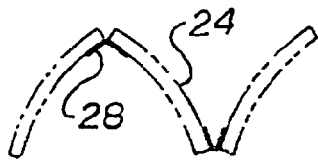


Fig. 4B

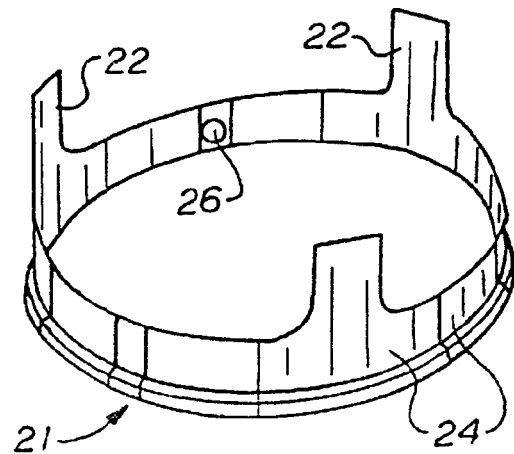


Fig. 3A

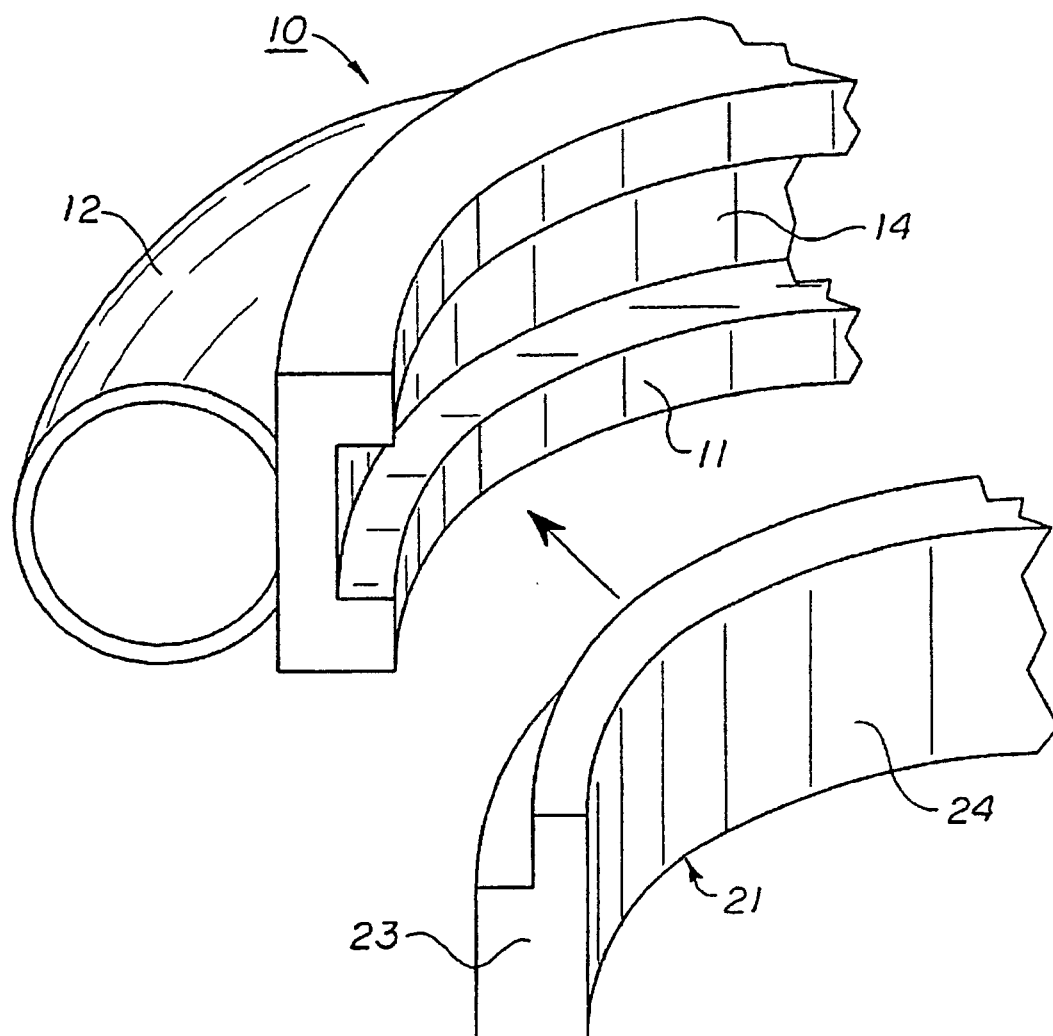


Fig. 5

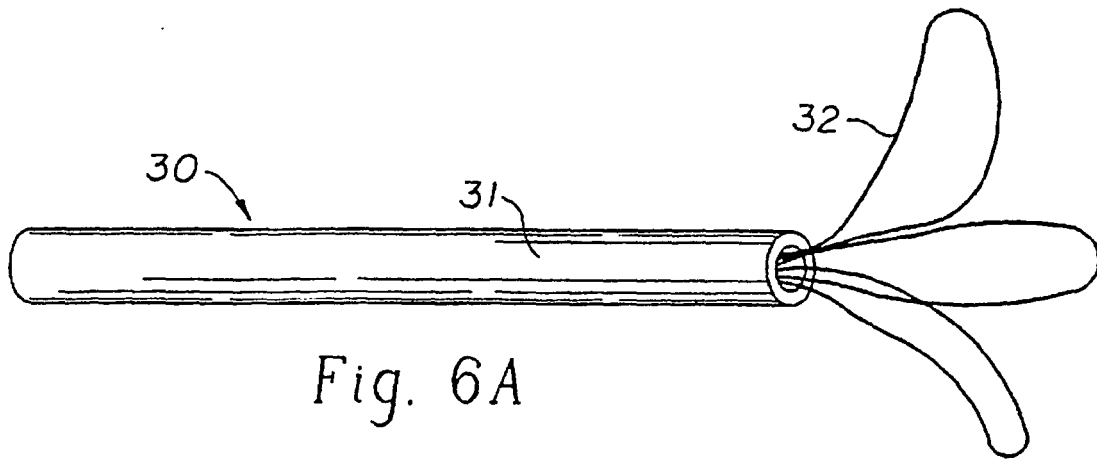


Fig. 6A

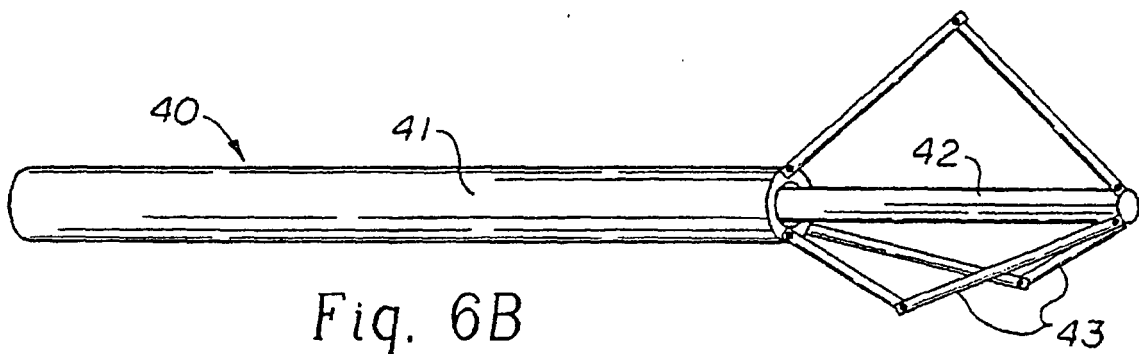


Fig. 6B

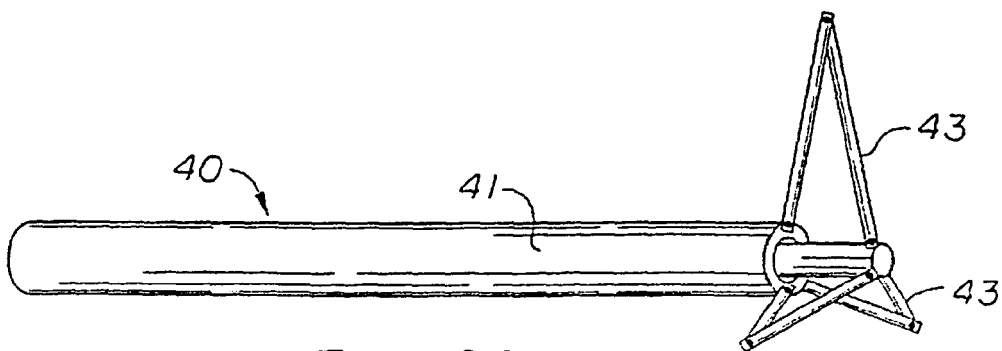
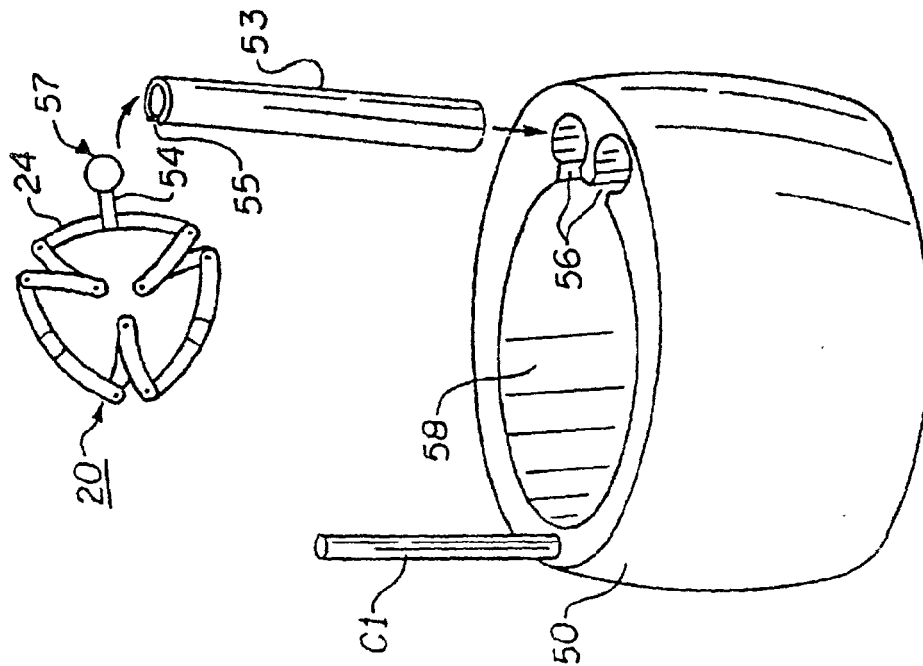
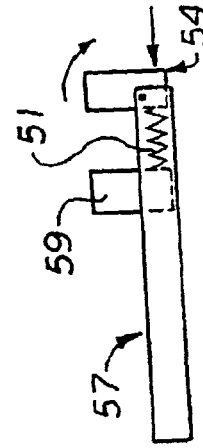
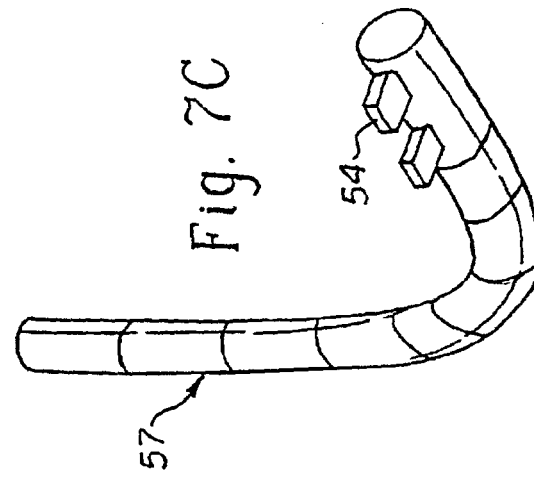
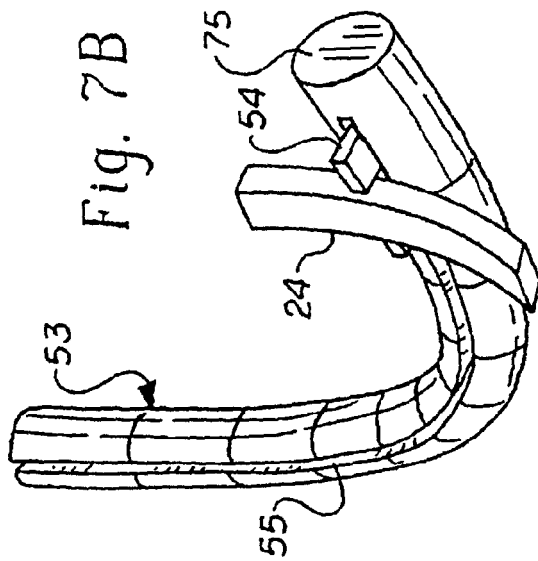
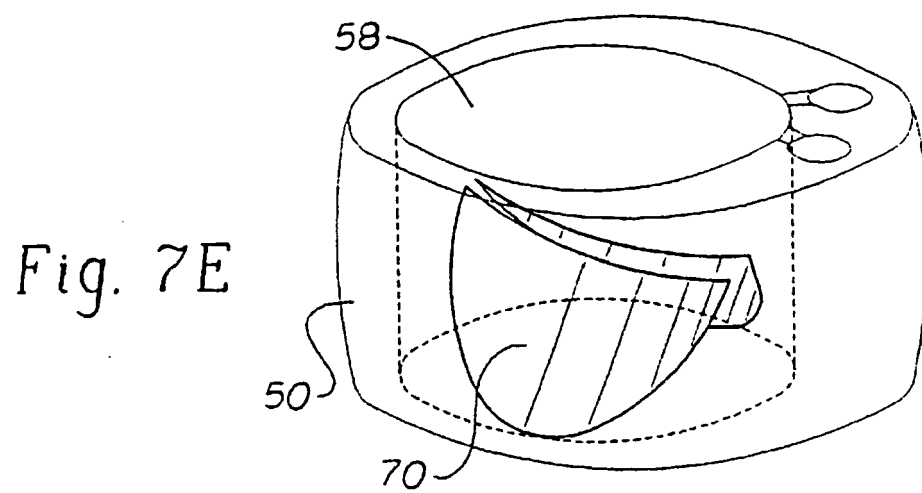


Fig. 6C





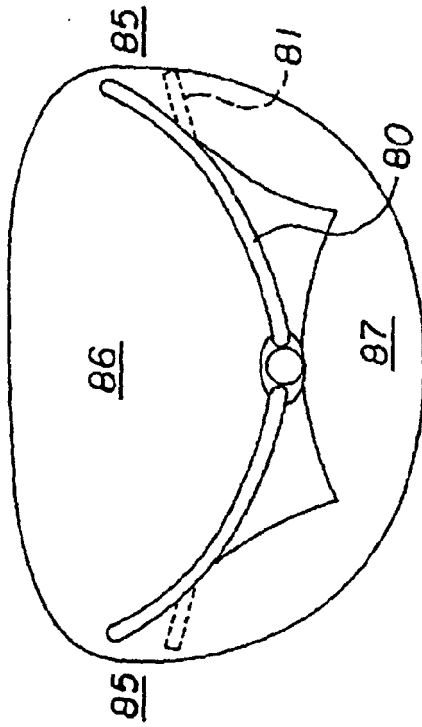


Fig. 8B

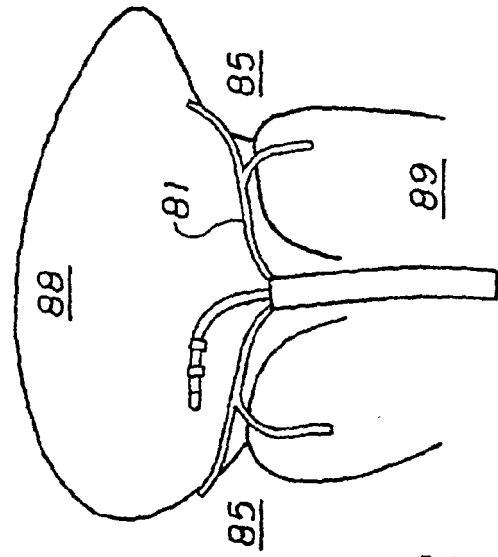


Fig. 8C

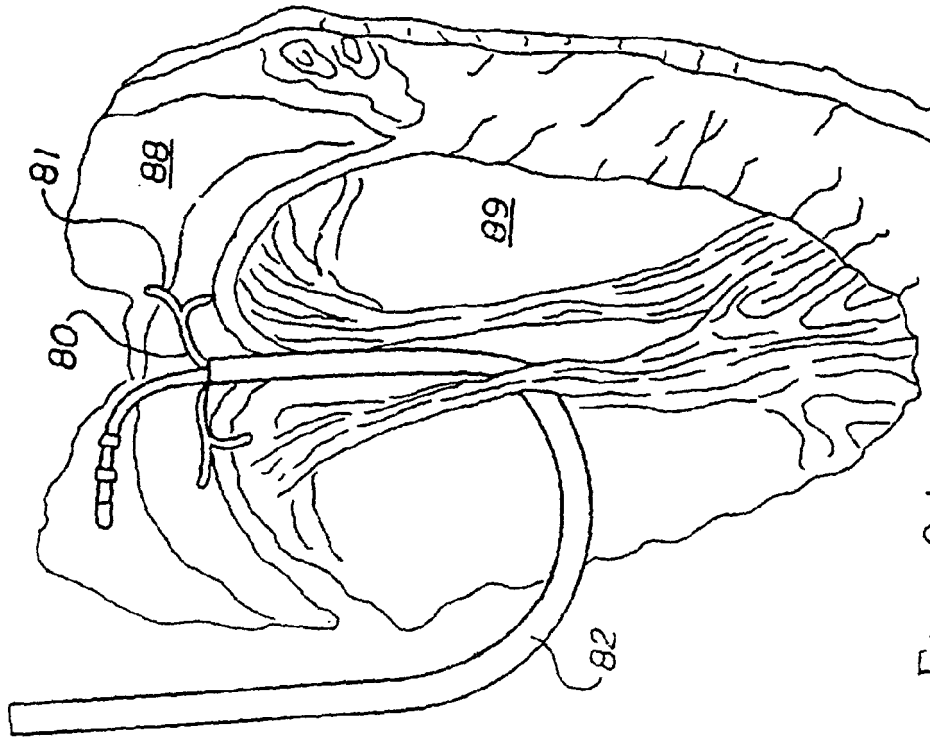


Fig. 8A

REFERENCES CITED IN THE DESCRIPTION

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