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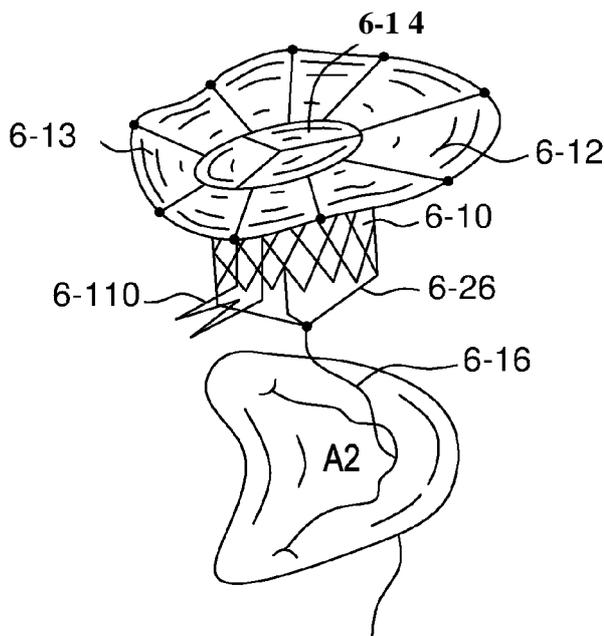
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(54) Title: IMPROVED DEVICES AND METHODS FOR TRANSCATHETER PROSTHETIC HEART VALVES

FIG. 31



(57) Abstract: This invention relates to relates to devices and methods for deploying prosthetic heart valves into a patient, and in particular to inventions relating to repositioning and retrieving deployed valves, anterior leaflet clips, deployment compensators, alignment devices, annular sealing devices, and related systems and methods for deploying a transcatheter valve in a patient in need thereof.

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TITLE

[004] Improved Devices and Methods for Transcatheter Prosthetic Heart Valves

CROSS REFERENCE TO RELATED APPLICATIONS

[005] Not applicable

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[006] No federal government funds were used in researching or developing this invention.

NAMES OF PARTIES TO A JOINT RESEARCH AGREEMENT

[007] Not applicable.

SEQUENCE LISTING INCLUDED AND INCORPORATED BY REFERENCE HEREIN

[008] Not applicable.

BACKGROUND

Field of the Invention.

[009] Retrieval and Repositioning System

[0010] This invention relates to a novel device and method for retrieval of a transcatheter heart valve replacement or for capture and repositioning of a deployed transcatheter heart valve replacement

[0011] Positioning Tool

[0012] This invention relates to a positioning device for delivery of a transcatheter prosthetic heart valve that comprises a ratchet rod with reference scale for accurate positioning a valve

during deployment.

[0013] Alignment Device

[0014] This invention relates to a alignment device for providing the correct valve alignment during deployment of an asymmetrical transcatheter valve while it is being deployed in a patient in need thereof, and methods of use thereof.

[0015] Deployment Compensator

[0016] This invention relates to a deployment compensator for reducing the expelling force of a compressed transcatheter valve while it is being deployed in a patient in need thereof, and methods of use thereof.

[0017] Inflatable Annular Sealing

[0018] This invention relates to an improved transcatheter prosthetic heart valve that comprises an inflatable annular sealing device for reducing or preventing leaking around an implanted self-expanding stent and valve assembly that is anchored within the mitral valve or tricuspid valve of the heart using an optional integral cuff to anchor the valve and using one or more tethers anchored to the heart, and a delivery system therefor.

[0019] Anterior Leaflet Clip

[0020] This invention relates to an improved transcatheter prosthetic heart valve that comprises an anterior leaflet clip device for reducing or preventing leaking around an implanted self-expanding stent and valve assembly that is anchored within the mitral valve or tricuspid valve of the heart using an optional integral cuff to anchor the valve and using one or more tethers anchored to the heart, and a delivery system therefor.

#### Background of the Invention

[0021] Valvular heart disease and specifically aortic and mitral valve disease is a significant health issue in the US. Annually approximately 90,000 valve replacements are conducted in the US. Traditional valve replacement surgery, the orthotopic replacement of a heart valve, is an "open heart" surgical procedure. Briefly, the procedure necessitates surgical opening of the thorax, the initiation of extra-corporeal circulation with a heart-lung machine, stopping and opening the heart, excision and replacement of the diseased valve, and re-starting of the heart. While valve replacement surgery typically carries a 1-4% mortality risk in otherwise healthy persons, a significantly higher morbidity is associated to the procedure largely due to the

necessity for extra-corporeal circulation. Further, open heart surgery is often poorly tolerated in elderly patients.

[0022] Thus if the extra-corporeal component of the procedure could be eliminated, morbidities and cost of valve replacement therapies would be significantly reduced.

[0023] While replacement of the aortic valve in a transcatheter manner is the subject of intense investigation, lesser attention has been focused on the mitral valve. This is in part reflective of the greater level of complexity associated to the native mitral valve apparatus and thus a greater level of difficulty with regards to inserting and anchoring the replacement prosthesis.

[0024] Several designs for catheter-deployed (transcatheter) aortic valve replacement are under various stages of development. The Edwards SAPIEN transcatheter heart valve is currently undergoing clinical trial in patients with calcific aortic valve disease who are considered high-risk for conventional open-heart valve surgery. This valve is deployable via a retrograde transarterial (transfemoral) approach or an antegrade transapical (transventricular) approach. A key aspect of the Edwards SAPIEN and other transcatheter aortic valve replacement designs is their dependence on lateral fixation (e.g. tines) that engages the valve tissues as the primary anchoring mechanism. Such a design basically relies on circumferential friction around the valve housing or stent to prevent dislodgement during the cardiac cycle. This anchoring mechanism is facilitated by, and may somewhat depend on, a calcified aortic valve annulus. This design also requires that the valve housing or stent have a certain degree of rigidity.

[0025] At least one transcatheter mitral valve design is currently in development. The Endovalve uses a folding tripod-like design that delivers a tri-leaflet bioprosthetic valve. It is designed to be deployed from a minimally invasive transatrial approach, and could eventually be adapted to a transvenous atrial septotomy delivery. This design uses "proprietary gripping features" designed to engage the valve annulus and leaflets tissues. Thus the anchoring mechanism of this device is essentially equivalent to that used by transcatheter aortic valve replacement designs.

[0026] Various problems continue to exist in this field, including problems with insufficient articulation and sealing of the valve within the native annulus, pulmonary edema due to poor atrial drainage, perivalvular leaking around the installed prosthetic valve, lack of a good fit for the prosthetic valve within the native mitral annulus, atrial tissue erosion, excess wear on the nitinol structures, interference with the aorta at the posterior side of the mitral annulus, and lack of customization, to name a few.

[0027] Accordingly, there is still a need for an improved prosthetic mitral valve having a commissural sealing structure, along with a means of positioning such prosthetic valve.

[0028] Accordingly, there is still a need for an improved valve having a commissural sealing structure for a prosthetic mitral valve.

[0029] Accordingly, there is a need for an improved device and method for retrieval when such valves need to be replaced.

[0030] Accordingly, there is still a need for an improved valve having a deployment compensator for a prosthetic mitral valve.

[0031] Accordingly, there is still a need for an inflatable annular sealing device.

[0032] Accordingly, there is still a need for an anterior leaflet clip for a prosthetic heart valve, especially a transcatheter delivered prosthetic mitral valve.

#### BRIEF SUMMARY OF THE INVENTION

[0033] Retrieval and Repositioning

[0034] In one embodiment, there is provided a prosthetic heart valve retrieval device, comprising: a dilator tip with a radio band, said dilator tip mounted at distal end of a dilator sheath, said dilator sheath having a lumen therethrough and said dilator sheath mounted on a distal side of dilator base, said dilator base having a sheath lock for operatively engaging the dilator sheath, said dilator base having a slidably removable luer-lock introducer disposed within the lumen, said dilator base having a guide rod aperture for engaging a guide rod that is connected to a guide rod handle mount that is attached on top of a handle apparatus, said dilator base having a traveller strap affixed on a proximal side and said traveller strap extending proximally to engage a tensioning unit on the handle apparatus, said handle apparatus having an actuator and a spring operatively connected to the traveller strap, wherein when the actuator is engaged the traveller strap is pulled proximally through the tensioning unit and the dilator base slides along guide rod towards the handle apparatus.

[0035] In another preferred embodiment, there is provided a device wherein the dilator tip is bullet-shaped, cone-shaped, hooded, or otherwise shaped to guide the valve tether into the lumen of the dilator sheath.

[0036] In another preferred embodiment, there is provided a method of using the retrieval device

for capturing a tethered expandable prosthetic heart valve to re-position or remove said valve, comprising the steps of: (i) inserting said retrieval device, containing a tethered and expandable prosthetic heart valve, into a patient, and (ii) capturing and retracting the tether into the retrieval device.

[0037] In another preferred embodiment, there is provided wherein the method may further include the step of inserting the retrieval device by directly accessing the heart through the intercostal space, or using an apical approach to enter a heart ventricle.

[0038] In another preferred embodiment, there is provided wherein the method may further include the step of inserting the retrieval device by directly accessing the heart through a thoracotomy, sternotomy, or minimally-invasive thoracic, thorascopic, or trans-diaphragmatic approach to enter the left ventricle.

[0039] In another preferred embodiment, there is provided wherein the method may further include the step of (iii) removing the tethered expandable prosthetic heart valve from the patient by collapsing the expandable prosthetic heart valve apparatus into the dilator sheath catheter and retracting the dilator sheath.

[0040] Positioning Tool

[0041] The present invention relates to a positioning device for delivery of a transcatheter prosthetic heart valve that comprises a ratchet rod with reference scale for accurate positioning a valve during deployment.

[0042] In a preferred embodiment, there is provided a positioning device for deploying a transcatheter prosthetic cardiovascular valve in a patient, which comprises a ratchet rod having a built-in collet at a distal end for attachment to the valve, a transparent sheath having a reference scale, the ratchet rod slidably disposed within the transparent sheath and said ratchet rod having one or more markings operatively associated with reference scale, a tensioning collar attached to the transparent sheath and positioned around the slidable ratchet rod, a tensioning-release level on the tensioning collar, and a removable epicardial attachment pad attached to a proximal end of the ratchet rod.

[0043] In another embodiment, there is provided a feature wherein the transparent sheath reference scale and ratchet rod markings provide a step resolution of between about 0.5mm and about 2.0mm.

[0044] In another embodiment, there is provided a feature wherein the ratchet rod and pawl mechanism provide an audible feedback to a user.

[0045] In another embodiment, there is provided a feature wherein the device has one or more radio-opaque markers thereon to facilitate positioning.

[0046] In another embodiment, there is provided a feature wherein the device fits within a surgical catheter sheath having a diameter of between about 10 Fr (3.3mm) to about 42 Fr (14mm).

[0047] In another embodiment, there is provided a method of tensioning a deployed transcatheter prosthetic cardiovascular valve in a patient, which comprises the step of pulling the ratchet rod to tighten a tether that extends from the valve that is surgically deployed into the mitral annulus of the patient and extends through an apical epicardial attachment point.

[0048] In another embodiment, there is provided a feature wherein the prosthetic heart valve is deployed by directly accessing the heart through an intercostal space, using an apical approach to enter the left (or right) ventricle, and deploying the prosthetic heart valve into the valvular annulus using the catheter delivery system.

[0049] In another embodiment, there is provided a feature wherein the prosthetic heart valve is deployed by directly accessing the heart through a thoracotomy, sternotomy, or minimally-invasive thoracic, thorascopic, or transdiaphragmatic approach to enter the left (or right) ventricle, and deploying the prosthetic heart valve into the valvular annulus using the catheter delivery system.

[0050] In another embodiment, there is provided a feature wherein the prosthetic heart valve is deployed by directly accessing the heart through the intercostal space, using a lateral approach to enter the left or right ventricle, and deploying the prosthetic heart valve into the valvular annulus using the catheter delivery system

[0051] Alignment Device

[0052] This invention relates to relates to a alignment device for providing the correct valve alignment during deployment of an asymmetrical transcatheter valve while it is being deployed in a patient in need thereof, and methods of use thereof.

[0053] In a preferred embodiment, there is provided an alignment device for deploying an asymmetric transcatheter prosthetic cardiovascular mitral valve in a patient, which comprises a

prosthetic mitral valve loading tube having a lateral radio-opaque marker and a longitudinal radio-opaque marker, and an asymmetric transcatheter prosthetic mitral valve disposed within the valve loading tube, wherein the asymmetric transcatheter prosthetic mitral valve comprises an expandable stent body having valve leaflets disposed therein and an asymmetric atrial collar attached to the stent, the asymmetric atrial collar having a flattened A2 segment to reduce LVOT obstruction and the asymmetric transcatheter prosthetic mitral valve is compressed within the valve loading tube having the A2 segment of the valve aligned with the lateral radio-opaque marker and a longitudinal radio-opaque marker of the tube, wherein the lateral radio-opaque marker provides a commissure-to-commissure alignment, and wherein the longitudinal radio-opaque marker provides an A2-anterior leaflet alignment.

[0054] In another preferred embodiment, there is provided a feature wherein the valve has one or more radio-opaque markers thereon to facilitate positioning.

[0055] In another preferred embodiment, there is provided a feature where the device fits within a surgical catheter sheath having a diameter of between about 10 Fr (3.3mm) to about 42 Fr (14mm).

[0056] In yet another preferred embodiment, there is provided a method of providing the correct valve alignment during deployment of an asymmetrical transcatheter valve while it is being deployed in a patient in need thereof, which comprises the step of deploying an alignment device as in claim 1 from a delivery catheter being used to surgically deploy the valve into the patient in need thereof.

[0057] Deployment Compensator

[0058] The present invention relates to a deployment compensator for reducing the expelling force of a compressed transcatheter valve while it is being deployed in a patient.

[0059] In a preferred embodiment, there is provided a deployment compensator for deploying a transcatheter prosthetic cardiovascular valve in a patient, which comprises an extension spring connecting an end block to a spring head, the end block sized to remain outside of a valve deployment catheter sheath and having a sheath guide block connected thereto for inserting into an end portion of a valve deployment catheter sheath, said end block and sheath guide block having a push rod aperture for mounting a push rod, the spring head having a spring barrel connected thereto, the spring barrel disposed within the extension spring, and said spring head

and spring barrel having a push rod aperture for mounting a push rod.

[0060] In another preferred embodiment, there is provided a deployment compensator for reducing the expelling force of a compressed transcatheter valve while it is being deployed in a patient in combination a push rod having a collet at a distal end and a removable epicardial attachment pad attached to a proximal end of the push rod.

[0061] In another preferred embodiment, there is provided a deployment compensator wherein the device has one or more radio-opaque markers thereon to facilitate positioning.

[0062] In another preferred embodiment, there is provided a deployment compensator where the device fits within a surgical catheter sheath having a diameter of between about 10 Fr (3.3mm) to about 42 Fr (14mm).

[0063] In another preferred embodiment, there is provided a method of reducing the expelling force of a compressed transcatheter prosthetic cardiovascular valve out of a delivery catheter during deployment in a patient, which comprises the step of connecting a valve tether to a deployment compensator as in claim 1 while the valve is being expelled from the delivery catheter being used to surgically deploy the valve into the patient in need thereof.

[0064] Inflatable Annular Sealing

[0065] The present invention relates to the improved design and function of novel pre-configured compressible transcatheter prosthetic cardiovascular valves having an inflatable annular sealing device for reducing or preventing leaking around an implanted self-expanding stent and valve assembly that is anchored within the mitral valve or tricuspid valve of the heart.

[0066] In a preferred embodiment, there is provided a pre-configured compressible transcatheter prosthetic cardiovascular valve having an improved anterior leaflet sealing component, which comprises an expandable leaflet assembly comprised of stabilized tissue or synthetic material, said leaflet assembly disposed within an expandable stent having at a distal end a plurality of articulating collar support structures having a tissue covering to form an atrial collar, said expandable stent having a proximal end comprised of an integral tether connection apparatus, said anterior leaflet sealing component comprising an inflatable annular sealing device made of a shell of elastomeric material, stabilized tissue or synthetic material, said an inflatable annular sealing device attached to the stent, wherein during deployment of the valve the shell is filled to form a subvalvular seal.

[0067] In a preferred embodiment, the shell is comprised of an elastomer silicone and may be filled with surgical cement, a two-part epoxy, silicone gel or other biocompatible gel, saline, or a coiled material, spring-like material, or elastic material.

[0068] The design as provided focuses on the deployment of a device via a minimally invasive fashion and by way of example considers a minimally invasive surgical procedure utilizing the intercostal or subxyphoid space for valve introduction, but may also include standard retrograde, or antegrade transcatheter approaches. In order to accomplish this, the valve is formed in such a manner that it can be compressed to fit within a delivery system and secondarily ejected from the delivery system into the target location, for example the mitral or tricuspid valve annulus.

[0069] Anterior Leaflet Clip

[0070] The present invention relates to the improved design and function of novel pre-configured compressible transcatheter prosthetic cardiovascular valves having an anterior leaflet clip device for reducing or preventing leaking around an implanted self-expanding stent and valve assembly that is anchored within the mitral valve of the heart.

[0071] In a preferred embodiment, there is provided a pre-configured compressible transcatheter prosthetic cardiovascular valve having an anterior leaflet clip device, which comprises an expandable leaflet assembly comprised of stabilized tissue or synthetic material disposed within an expandable stent having at a distal end a plurality of articulating collar support structures having a tissue covering to form an atrial collar, said expandable stent having a proximal end comprised of an integral tether connection apparatus, said anterior leaflet clip device comprising a folding component that is mounted on the expandable stent, said folding component having a hinge segment and a leaflet capture and attachment segment.

[0072] In a preferred embodiment, the anterior leaflet clip device is an integrated component of the expandable stent.

[0073] In another preferred embodiment, the anterior leaflet clip device is a separate component that is sutured to the expanded stent before deployment of the valve, the device having a mounting segment connected to the hinge segment which is connected to the leaflet capture and attachment segment.

[0074] In a preferred embodiment, the anterior leaflet clip further comprises a plurality of pre-aligned suture holes in the leaflet capture and attachment segment.

[0075] In a preferred embodiment, the pre-aligned suture holes in the mounting segment and the leaflet capture and attachment segment wherein the suture holes line up in a substantially adjacent manner after the leaflet capture and attachment segment is folded over.

[0076] The design as provided focuses on the deployment of a device via a minimally invasive fashion and by way of example considers a minimally invasive surgical procedure utilizing the intercostal or subxyphoid space for valve introduction, but may also include standard retrograde, or antegrade transcatheter approaches. In order to accomplish this, the valve is formed in such a manner that it can be compressed to fit within a delivery system and secondarily ejected from the delivery system into the target location, for example the mitral or tricuspid valve annulus.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0077] Retrieval and Repositioning

[0078] FIGURE 1 is a side view of one embodiment of the prosthetic valve retrieval system provided herein.

[0079] FIGURE 2 is a side view of the dilator and tip components with handle and tapered connector (luer + tuohy borst).

[0080] FIGURE 3 is a side view of one embodiment of a dilator tip.

[0081] FIGURE 4 is a side view of another embodiment of a dilator tip.

[0082] FIGURE 5 is a side view of yet another embodiment of a dilator tip.

[0083] FIGURE 6 is a side view of the retrieval system in operation and connected to a tether of a prosthetic mitral valve.

[0084] Positioning Tool

[0085] FIGURE 7 is a side view of a positioning tool according to the present inventive subject matter.

[0086] FIGURE 8 is a view showing the ratchet rod separated from the sheath to illustrate the reference scale markings.

[0087] FIGURE 9 is a side view showing the tool within a catheter and used for expelling a compressed transcatheter valve.

[0088] FIGURE 10 is a side view showing the tool attached to a valve during the expelling process.

[0089] FIGURE 11 is a side view of the positioning tool attached to the valve tether and where the tool is used for pulling the valve into position and the reference scale used to establish the correct tension on the tether between the valve and the apical attachment.

[0090] Alignment Device

[0091] FIGURE 12 is a side view of a alignment device for deploying an asymmetric transcatheter prosthetic cardiovascular mitral valve in a patient according to the present inventive subject matter.

[0092] FIGURE 13 is a graphic representation of an apical transcatheter delivery of a compressed prosthetic mitral valve through a catheter to a mitral valve.

[0093] FIGURE 14 is a perspective view of a loading tube being aligned with an A2 segment of a mitral valve.

[0094] FIGURE 15 is perspective view of a loading tube that was successfully aligned with an A2 segment of a mitral valve and the asymmetric prosthetic mitral valve is shown as being expelled from the loading tube in the proper orientation wherein the valve's flattened A2 segment is in proper alignment with native A2 mitral valve leaflet, and the asymmetrical valve's commissural features are in proper alignment with native mitral commissures, thus reducing leaking of the deployed valve. Fig. 15 illustrates A2 and commissural alignment, but in a more anatomically correct depiction, the delivery tube would deliver the valve into the left atrium, the tube would be partially withdrawn or completely withdrawn, and the tether attached to the bottom of the valve would be used to seat the valve into the mitral annulus.

[0095] Deployment Compensator

[0096] FIGURE 16 is a side view of a deployment compensator according to the present inventive subject matter.

[0097] FIGURE 17 are end views showing each end, proximal and distal, of the deployment compensator.

[0098] FIGURE 18 is a side view showing a standard push rod.

[0099] FIGURE 19 is a side view showing the deployment compensator attached to a

valve/valve tether during the expelling process.

[00100] FIGURE 20 is a side view of the deployment compensator attached to the valve/valve tether and where the deployment compensator is shown being stretched into an elongated (extended) position and used to reduce the force of the valve as it is expelled from the delivery catheter, thus limiting the distance that the valve travels from the end of the delivery sheath/catheter.

[00101] Inflatable Annular Sealing

[00102] FIGURE 21 is a side-view of a valve and shows a filled shell at an A2 position.

[00103] FIGURE 22 is a top view of an expandable prosthetic valve and shows a filled shell at an A2 position.

[00104] FIGURE 23 is a perspective subvalvular view of one embodiment showing a laser cut stent with valve leaflets mounted therein and with tissue-covered articulating collar structure attached, and the inflatable sealing device attached to the stent and/or collar and providing a subvalvular seal against retrograde hemodynamic forces.

[00105] FIGURE 24 is a perspective subvalvular view of one embodiment showing laser cut stent with valve leaflets mounted therein and with tissue-covered articulating collar structure attached, and the inflatable sealing device/filled shell attached to the stent and/or collar extending the entire circumference of the stent-collar junction, and providing a subvalvular seal against retrograde hemodynamic forces.

[00106] Anterior Leaflet Clip

[00107] FIGURE 25 is a side-view of one preferred type of anterior leaflet clip device.

[00108] FIGURE 26 is a side view of the anterior leaflet clip device of Figure 25 clipped onto a native anterior leaflet.

[00109] FIGURE 27 is a side-view of another preferred type of anterior leaflet clip device.

[00110] FIGURE 28 is a side view of the anterior leaflet clip device of Figure 27 clipped onto a native anterior leaflet.

[00111] FIGURE 29 is a side-view of another preferred type of anterior leaflet clip device.

[00112] FIGURE 30 is a side view of the anterior leaflet clip device of Figure 29 clipped onto a native anterior leaflet.

[001 13] FIGURE 31 is a perspective anterolateral view of one embodiment showing laser cut stent with valve leaflets mounted therein and with tissue-covered articulating collar structure attached, and the anterior leaflet clip device attached to the stent and/or collar, and providing an attachment mechanism to secure the anterior leaflet and provide a subvalvular seal against retrograde hemodynamic forces.

[001 14] FIGURE 32a is a side view of one embodiment showing laser cut stent with valve leaflets mounted therein (not shown) and with tissue-covered articulating collar structure attached, and the anterior leaflet clip device attached to the stent, and providing an attachment mechanism to secure the anterior leaflet and provide a subvalvular seal against retrograde hemodynamic forces.

[001 15] FIGURE 32b is a side view of one embodiment showing the leaflet clip sutured across the anterior leaflet and securing it to the laser cut stent body, providing an attachment mechanism to secure the anterior leaflet and provide a subvalvular seal against retrograde hemodynamic forces.

[001 16] FIGURE 33 is a side view of one embodiment showing the leaflet clip manufactured as an integral component of the laser-cut stent body. FIGURE 33 shows how the clip moves from the first deployment position to the second leaflet capture position.

## DETAILED DESCRIPTION OF THE INVENTION

### Functions of the Retrievable Stented Prosthetic Mitral Valve

[001 17] The present invention provides in one embodiment a retrieval system for a previously deployed prosthetic heart valve wherein a valve tether is attached to the valve or to a collapsible stent containing the valve.

[001 18] The invention allows for the capture of the single retrieval tether by a catheter-based extraction device, and for the re-positioning or removing the entire deployed valve apparatus via the retrieval device.

[001 19] The prosthetic heart valve contemplated for retrieval using the retrieval device comprises a self-expanding tubular stent having a cuff at one end and tether loops for attaching tether(s) at the other end, and disposed within the tubular stent is a leaflet assembly that contains the valve leaflets, the valve leaflets being formed from stabilized tissue or other suitable

biological or synthetic material. In one embodiment, the leaflet assembly comprises a wire form where a formed wire structure is used in conjunction with stabilized tissue to create a leaflet support structure which can have anywhere from 1, 2, 3 or 4 leaflets, or valve cusps disposed therein. In another embodiment, the leaflet assembly is wireless and uses only the stabilized tissue and stent body to provide the leaflet support structure, without using wire, and which can also have anywhere from 1, 2, 3 or 4 leaflets, or valve cusps disposed therein.

[00120] The tether anchors the valve to an anchoring location within the ventricle. Preferably, the location is the apex of the heart and uses an epicardial attachment pad. However, other tether attachment locations may be used in the deployment of the valve and also therefore, for the retrieval.

[00121] The cuff of the valve functions to counter the forces that act to displace the prosthesis toward/into the ventricle (i.e., atrial pressure and flow-generated shear stress) during ventricular filling. Accordingly, the stent containing the valve is positioned and pulled between the ventricular tether and the atrial cuff.

#### Deployment of the Retrieval Device

[00122] The retrieval device is, in one embodiment, delivered through the apex of the left ventricle of the heart. In one aspect of the apical delivery, the retrieval device accesses the heart and pericardial space by intercostal delivery.

#### [00123] Description of the Retrieval System Figures

[00124] Referring now to the FIGURES, FIGURE 1 is a side view of one embodiment of the prosthetic valve retrieval system provided herein. Fig. 1 shows valve retrieval system 110 having dilator tip 10 with radio band 26 mounted at the distal end of dilator sheath 12. Dilator base 14 has sheath lock 16 and luer-lock introducer 18. Guide rod 20 connects dilator base 14 to guide rod handle mount 38. Guide rod handle mount 38 sits atop tensioning unit 32 which has tensioning unit top 34 and tensioning unit bottom 36, and the tensioning unit 32 provides segmented advancement of the traveller strap 22 that is affixed to dilator base 14 and extends proximally through the tensioning unit 32 towards handle apparatus 24. Handle apparatus 24 has the tensioning unit 32 affixed at a distal end and the proximal end of handle apparatus is composed of handle 28 and actuator 40 with actuator spring 30 providing a longitudinal

tensioning force on traveller strap 22. An important feature is the placement of the guide rod 20 and related assemblies on top of the handle which alleviates interference of the guide rod 20 during the retrieval process.

[00125] FIGURE 2 is a side view of the dilator and tip components with handle and tapered connector (luer + tuohy borst). Fig. 2 shows dilator tip 10 with radio band 26 to assist in roentgenographic imaging. Dilator sheath 12 is connected to dilator base 14 with luer-lock introducer 18 maintaining a seal to prevent intracardiac fluid/blood loss.

[00126] FIGURE 3 is a side view of one embodiment of a dilator tip 210, and shows lumen 213 that is used to extend the capture wire and pull the valve tether down into the lumen 213.

[00127] FIGURE 4 is a side view of another embodiment of a dilator tip 310 with tether capture lumen 313, and Fig. 4 also shows capture recess 311, which facilitates capture of a valve tether that may have a beaded or enlarged feature at the tether connection point where the tether connects to the valve.

[00128] FIGURE 5 is a side view of yet another embodiment of a dilator tip 410, and shows lumen 413 that is used to extend the capture wire and pull the valve tether down into the lumen 413. Fig. 5 also shows extended tip 411 which can be used to facilitate access and/or capture/repositioning in certain circumstances.

[00129] FIGURE 6 is a side view of the retrieval system 110 in operation and connected to a tether 42 of a prosthetic mitral valve 46. Fig. 6 shows dilator tip 310 with bead capture recess 311 for capturing tether connection bead 44 and captured tether 42 extending down into lumen 313 through dilator shaft 312. Radio band 326 is shown marking the dilator tip 310. Dilator shaft 312 is connected to dilator base 314 and vertically-slidable sheath lock 316 in an up, or locked position. Guide rod 320 is shown connected to dilator base 314 and traveller strap 322 is shown affixed to the dilator base. Luer-lock introducer sleeve 319 is shown with valve tether 42 exiting from lumen 313.

#### Functions of the Positioning Tool

[00130] When a transcatheter valve is delivered, the compressed valve is expelled from the delivery catheter and the valve expands to its functional structure. In the case of a prosthetic mitral valve that uses an atrial cuff in combination with a ventricular tether to seat itself within the mitral annulus, when the valve is deployed into the left atrium, the valve then needs to be

pulled toward the left ventricular apex to be seated within the mitral annulus, and it is then tethered to a suitable ventricular location (e.g., ventricular apex). The positioning tool is used to pull the valve down into the mitral annulus and to impart tension into the ventricular tether. The amount of tensioning force can range from that of a positioning tether (low) to that of a tensioning tether (high).

#### Tethers

[00131] The tethers that are attached to the prosthetic heart valve may extend to one or more tissue anchor locations within the heart. In one preferred embodiment, the tethers extend downward through the left ventricle, exiting the left ventricle at the apex of the heart to be fastened on the epicardial surface outside of the heart. Similar anchoring is contemplated herein as it regards the tricuspid, or other valve structure requiring a prosthetic. There may be from 1 to 8 tethers which are preferably attached to the body of the valve. The positioning tool may be used for adjustment of each tether.

[00132] In another preferred embodiment, the tethers may optionally be attached to the atrial cuff to provide additional control over position, adjustment, and compliance. In this preferred embodiment, one or more tethers are optionally attached to the flared end or cuff, in addition to, or optionally, in place of, the tethers attached to the stent. By attaching to the flared end or cuff and/or the stent, an even higher degree of control over positioning, adjustment, and compliance is provided to the operator during deployment. The positioning tool may be used for adjustment of each atrial or positioning tether.

[00133] In another preferred embodiment, the tethers are optionally anchored to other tissue locations depending on the particular application of the prosthetic heart valve. In the case of a mitral valve, or the tricuspid valve, there are optionally one or more tethers anchored to one or both papillary muscles, the septum, and/or the ventricular wall.

[00134] Upon being drawn to and through the apex of the heart, the tethers may be fastened by a suitable mechanism such as tying off to a pledget or similar adjustable button-type anchoring device to inhibit retraction of the tether back into the ventricle. In a preferred embodiment, an epicardial pledget or attachment pad may be integrated directly into the tool, for instance on the ratchet rod so that once proper tension is achieved, the pad may be slid into place and surgically secured.

[00135] Further, it is contemplated that the prosthetic heart valve may optionally be deployed with a combination of installation tethers and permanent tethers, attached to either the stent or flared end or cuff, or both, the installation tethers being removed after the valve is successfully deployed. It is also contemplated that combinations of inelastic and elastic tethers may optionally be used for deployment and to provide structural and positional compliance of the valve during the cardiac cycle. The positioning tool may be used for adjustment of these tethers as well.

#### Description of Positioning Tool Figures

[00136] Referring now to the FIGURES, FIGURE 7 is a side view of a positioning tool according to the present inventive subject matter. Fig. 7 shows tool 2-110 having collet 2-112, tensioner 2-124, transparent sheath 2-120 with reference markings 2-122, ratchet rod 2-114, and sheath support 2-118. Fig. 7 also shows attachment pad 2-116.

[00137] FIGURE 8 is a view showing the ratchet rod 2-114 separated from the sheath 2-120 to illustrate the reference scale 2-122 and rod markings 2-126. Fig. 8 also shows collet 2-112 having aperture 2-128 which functions as a through-hole for an apical tether that has been attached to a valve being held by the collet 2-112. Fig. 8 also shows tensioner 2-124 having tensioner aperture 2-130 and sheath support 2-118 having sheath support aperture 2-132. Fig. 8 also shows attachment pad 2-116 attached to ratchet rod 2-114.

[00138] FIGURE 9 is a side view showing the tool within a catheter 2-138 and used for expelling a compressed transcatheter valve 2-136. Fig. 9 shows collet 2-112, catheter opening 2-140 with tensioner/reference sheath unit 2-134 outside the intracardiac catheter 2-138. Fig. 9 also shows tension release lever 2-125 for releasing the tension on ratchet rod 2-114 for re-adjustment of tether 2-142.

[00139] FIGURE 10 is a side view showing the tool attached to a valve during the expelling process. Valve 2-136 is being expelled from catheter 2-138 through distal catheter aperture 2-144 and shows how the positioning tool can be used to view reference scale 2-122 on sheath 2-120 connected to tensioner 2-124 having tensioner aperture 2-130, and the movement compared to ratchet rod 2-114 and the rod markings 2-126. Collet 2-112, tether 2-142 are also shown.

[00140] FIGURE 11 is a side view of the positioning tool attached to the valve tether 2-142 and where the tool is used for pulling the valve 2-136 into position using the ratchet rod 2-114 within sheath 2-138 and the reference scale 2-122 with rod markings 2-126 (not shown) being used to

establish the correct tension on the tether 2-142 between the valve 2-136 and the apical attachment 2-116.

#### Functions of the Alignment Device

[00141] When a transcatheter valve is delivered, the compressed valve is expelled from the delivery catheter and the valve expands to its functional structure. In the case of a prosthetic mitral valve that uses an atrial cuff in combination with a ventricular tether to seat itself within the mitral annulus, when the valve is deployed into the left atrium, the valve is expelled from the end of the delivery catheter without regard to proper alignment. This becomes especially important when using an asymmetric valve. The alignment device is used to seat the valve into the native mitral annulus in order to take advantage of the engineered anti-leakage structures developed into such asymmetric valve.

#### Description of Alignment Device Figures

[00142] Referring now to the FIGURES, FIGURE 12 is a side view of a alignment device for deploying an asymmetric transcatheter prosthetic cardiovascular mitral valve in a patient according to the present inventive subject matter. Fig. 12 shows alignment device 3-110 comprised of loading tube 3-112 and asymmetric valve 3-122. Fig. 12 shows longitudinal marker 3-114 and lateral marker 3-116. Longitudinal marker 3-114 provides A2 alignment and lateral marker 3-116 provides commissure-to-commissure alignment.

[00143] FIGURE 13 is a graphic representation of an apical transcatheter delivery of a compressed prosthetic mitral valve 3-118 through a catheter 3-120 to a native mitral valve in need of a prosthetic.

[00144] FIGURE 14 is a perspective view of a loading tube 3-112 being aligned 3-114 with an A2 segment of a mitral valve. Fig. 14 also shows lateral marker 3-116 and illustrates how it provides commissure-to-commissure alignment.

[00145] FIGURE 15 is perspective view of a loading tube 3-112 that was successfully aligned with an A2 segment of a mitral valve and the asymmetric prosthetic mitral valve 3-122 (expanded) is shown as being expelled from the loading tube 3-112 in the proper orientation wherein the valve's flattened A2 segment 3-126 is in proper alignment with native A2 mitral valve leaflet, and the asymmetrical valve's commissural features 3-124 are in proper alignment

with native mitral commissures, thus reducing leaking of the deployed valve 3-122. Fig. 15 illustrates A2 and commissural alignment, but in a more anatomically correct depiction, the delivery tube 3-112 would deliver the valve 3-122 into the left atrium, the tube would be partially withdrawn or completely withdrawn, and the tether(s) 3-128 attached to the bottom of the valve would be used to seat the valve into the mitral annulus by pulling on it. The tether may then be secured at an appropriate location, e.g. ventricular apex.

#### Functions of the Deployment Compensator

[00146] When a transcatheter valve is delivered, the compressed valve is expelled from the delivery catheter and the valve expands to its functional structure. In the case of a prosthetic mitral valve that uses an atrial cuff in combination with a ventricular tether to seat itself within the mitral annulus, when the valve is deployed into the left atrium, the valve shoots with great force from the end of the delivery catheter due to the strong compressive force that had been keeping the valve in the delivery catheter. This force is so large that it can cause significant damage to tissue, e.g. left atrium. The deployment compensator is used to pull the valve back towards the delivery catheter using an extension spring and counter-act the expelling force, this avoiding tissue damage.

#### Pledget/Attachment Pad

[00147] In a preferred embodiment, an epicardial pledget or attachment pad may be integrated directly into the deployment compensator, for instance on the push rod so that once proper deployment is achieved, the pad may be slid into place and surgically secured.

[00148] In one embodiment, to control the potential tearing of tissue at the apical entry point of the delivery system, a circular, semi-circular, or multi-part pledget is employed. The pledget may be constructed from a semi-rigid material such as PTFE felt. Prior to puncturing of the apex by the delivery system, the felt is firmly attached to the heart such that the apex is centrally located. Secondly, the delivery system is introduced through the central area, or orifice as it may be, of the pledget. Positioned and attached in this manner, the pledget acts to control any potential tearing at the apex.

#### Description of Deployment Compensator Figures

[00149] Referring now to the FIGURES, FIGURE 16 is a side view of a deployment compensator according to the present inventive subject matter. Fig. 16 shows deployment compensator 4-110 having extension spring 4-140 connecting end block 4-120 and spring head 4-130. Fig. 16 shows end block 4-120 having end block push rod aperture 4-122 and sheath guide 4-124. Sheath guide 4-124 fits within the deployment catheter, but end block 4-120 does not, this providing a stabilizing catheter plug at a proximal end of the delivery catheter. Spring head 4-130 has spring head aperture 4-132 and is also connect to barrel 4-150, which also has barrel push-rod aperture 4-152, for receiving the push rod (not shown). Spring head aperture 4-132 operates, in one embodiment, as a tensioning device to allow the valve tether (not shown) to advance through the aperture slowly, but to engage and reduce the travel speed of the tether through the aperture if a large longitudinal force is applied. This allows transference of the force to the extension spring and allows the spring to provide a counter-acting force in the opposite direction.

[00150] FIGURE 17 are end views showing each end, proximal and distal, of the deployment compensator. Fig. 17 shows end block 4-120 and end block push-rod aperture 4-122, and spring head 4-130, with cooperative surface 4-132, and spring head push-rod aperture 4-134.

[00151] FIGURE 18 is a side view showing a standard push rod. Fig. 18 shows rod 4-164, collet 4-160 and rod tether aperture 4-162.

[00152] FIGURE 19 and 20 are side views showing the deployment compensator attached to a valve/valve tether 4-172 during the expelling process. Fig. 19 and 20 shows end block 4-120 and sheath guide 4-124 having tether 4-172 extending through them. Spring 4-140 is shown compressed in Fig. 19 and then travels to an extended state in Fig. 20, shown by the spring head moving 4-130 and barrel 4-150 moving from left to right, as the push rod 4-164 and collet 4-160 move from left to right, expelling the valve 4-170 from the end of the delivery catheter 4-180.

[00153] FIGURE 20 is a side view of the deployment compensator attached to the valve/valve tether 4-172 and where the deployment compensator is shown being stretched into an elongated (extended) position and used to reduce the force of the valve as it is expelled from the delivery catheter 4-180, thus limiting the distance that the valve 4-170 travels from the end of the delivery sheath/catheter 4-180.

[00154] Inflatable Annular Sealing

### Functions of the Inflatable Annular Sealing Device

[00155] The inflatable annular sealing device, aka filled shell, functions by forming a filled shell or pouch of elastomeric silicone, stabilized tissue or synthetic material attached to the underside of the collar or cuff structure, wherein during systole the subvalvular space between the collar and native leaflet(s) are filled to form an additional seal against retrograde hemodynamic forces. During ventricular contraction or systole, the blood is ejected towards the prosthetic mitral valve. Retrograde blood hitting the prosthetic valve leaflets cause the leaflets to close, preventing regurgitation into the left atrium. Retrograde blood will then fill the subannular space around the chordae tendinae, which is frequently the cause and location of leakage around prosthetic valves which have been deployed into and through the native valve and annulus. However, the inflatable annular sealing device is constructed with a size and/or type of material so as to cause the retrograde blood to be blocked and avoid retrograde leaks.

### Description of Inflatable Annular Seal Figures

[00156] Referring now to the FIGURES, FIGURE 21 is a side-view of a valve and shows a filled shell at an A2 position. FIG. 21 shows inflatable annular sealing device (shell) 5-110 attached to the stent body 5-120. The collar at A2 5-124 is shown at a steeper angle to account for LVOT and tissue-covered atrial collar at 5-122 show a flatter angle for better atrial-floor contact. Tether 5-128 is connected to tether connection apparatus 5-126, which may be connected to the stent body 5-120.

[00157] FIGURE 22 is a top view of an expandable prosthetic valve and shows a filled shell at an A2 position. FIG. 22 shows inflatable annular sealing device (shell) 5-110 with commissural sealing portions 5-114 and 5-116 and A2 sealing portion 5-112. The tissue-covered atrial collar 5-122 is shown with articulating collar support(s) 5-132, and shows leaflet(s) 5-130.

[00158] FIGURE 23 is a perspective subvalvular view of one embodiment showing stent body 5-120 with valve leaflets 5-130 mounted therein and with tissue-covered atrial collar structure 5-122 attached. The inflatable sealing device (shell) 5-110 is attached to the stent body 5-120 and/or tissue-covered atrial collar 5-122 along edge 5-118 and provides a subvalvular seal against retrograde hemodynamic forces. FIGURE 23 also shows commissural sealing portions 5-114 and 5-116 and A2 sealing portion 5-112. Articulating collar support(s) 5-132 and tether connection apparatus 5-126 are also shown.

[00159] FIGURE 24 is a perspective subvalvular view of another non-limiting embodiment showing laser cut stent with valve leaflets mounted therein and with tissue-covered articulating collar structure attached. The inflatable sealing device 5-1 19 is attached to the stent and/or collar and provides a subvalvular seal against retrograde hemodynamic forces around the entire circumference of the stent/collar junction. FIGURE 24 also shows commissural sealing portions 5-1 14 and 5-116 and A2 sealing portion 5-1 12. Articulating collar support and tether connection apparatus are also shown.

#### [00160] Anterior Leaflet Clip

[00161] During systole the anterior leaflet of the mitral valve forms a semilunar seal with the posterior leaflet, and during diastole the anterior leaflet separates from the posterior leaflet to accommodate the emptying flow of the left atrium into the left ventricle. When the mitral valve is insufficient, regurgitant jets are directed back into the left atrium during systole. Deployment of a prosthetic mitral valve is one suitable solution to address this problem. Where a prosthetic mitral valve is deployed directly into the native annulus, the anterior and posterior leaflets are separated and form a partial seal around the circumference of the valve body. However, complete or nearly complete sealing is very difficult due to the complex shapes and structures formed when a prosthetic mitral valve body is deployed between the anterior leaflet and the posterior leaflet. This complexity is increased when the prosthetic valve has been engineered with features to accommodate LVOT problems and commissural leakage issues. Anterior leaflet prolapse, dislocations, pressure folds, leaflet eversion, leaflet inversion, and so forth are some of the problems that can arise with a prosthetic valve solution.

#### [00162] Functions of the Anterior Leaflet Clip Device

[00163] The anterior leaflet clip device functions by forming a pinched clip for attaching the native anterior leaflet to a prosthetic mitral valve. The clip device is attached to the prosthetic mitral valve body portion, either as an integral component of the valve body structure or as a separate device that is sutured in place. The clip device is constructed to bend or conform such that it can compress the native anterior leaflet against the side wall of the valve body. The clip device is also constructed with a plurality of suture holes to facilitate a permanent joining of the anterior leaflet to the valve body. Attachment mechanisms other than sutures are also contemplated.

[00164] During systole the subannular space is filled and the anterior leaflet clip forms an additional seal against retrograde hemodynamic forces. During ventricular contraction or systole, the blood is ejected towards the prosthetic mitral valve. Retrograde blood hitting the prosthetic valve leaflets cause the leaflets to close, preventing regurgitation into the left atrium. Retrograde blood will then fill the subannular space around the chordae tendinae, which is frequently the cause and location of leakage around prosthetic valves which have been deployed into and through the native valve and annulus. However, the anterior leaflet clip device is constructed with a size and/or type of material so as to cause the retrograde blood to be blocked and avoid retrograde leaks.

#### Description of Anterior Leaflet Clip Figures

[00165] Referring now to the FIGURES, FIGURE 25 is a side-view of one preferred type of anterior leaflet clip device 6-110 and shows an embodiment as a two-pronged hasp having a mounting segment 6-111, hinge segment 6-116, and leaflet capture and attachment segment 6-112. Fig. 25 shows stent mounting segment 6-114 with stent mounting suture holes 6-122. Fig. 25 also shows pre-aligned suture holes 6-120 in the mounting segment 6-111, and pre-aligned suture holes 6-118 in the leaflet capture and attachment segment 6-112. Fig. 25 shows valve tether aperture 6-124 as a mechanism to prevent an adjacent valve tether (not shown) from obstruct the clip device and to longitudinally traverse the clipping area while still providing for attachment of the anterior leaflet to the valve stent body.

[00166] FIGURE 26 is a side view of the anterior leaflet clip device of Fig. 25 clipped onto a native anterior leaflet and shows valve tether 6-126 traversing through valve tether aperture 6-124.

[00167] FIGURE 27 is a side-view of another preferred type of anterior leaflet clip device and shows an embodiment as a two-pronged hasp having a mounting segment 6-211, hinge segment 6-216, and leaflet capture and attachment segment 6-212. Fig. 27 shows stent mounting segment 6-214 with stent mounting suture holes 6-222. Fig. 27 also shows pre-aligned suture holes 6-220 in the mounting segment 6-211, and pre-aligned suture holes 6-218 in the leaflet capture and attachment segment 6-212. Fig. 27 shows valve tether aperture 6-224 as a mechanism to avoid obstructing and to accommodate the need of an adjacent valve tether (not shown) to not obstruct the clip device and to longitudinally traverse the clipping area while still providing for

attachment of the anterior leaflet to the valve stent body.

[00168] FIGURE 28 is a side view of the anterior leaflet clip device of Figure 27 clipped onto a native anterior leaflet and shows valve tether 6-226 traversing through valve tether aperture 6-224.

[00169] FIGURE 29 is a side-view of another preferred type of anterior leaflet clip device and shows an embodiment as a U-shaped hasp having a mounting segment 6-311, hinge segment 6-316, and leaflet capture and attachment segment 6-312. Fig. 29 shows stent mounting segments 6-311 and 6-313 with stent mounting suture holes 6-321 and 6-322. Fig. 29 also shows pre-aligned suture holes 6-320 in the mounting segment 6-311, and pre-aligned suture holes 6-318 in the leaflet capture and attachment segment 6-312. Fig. 29 shows valve tether aperture 6-324 as a mechanism to accommodate the need of an adjacent valve tether (not shown) to not obstruct the clip device and to longitudinally traverse the clipping area while still providing for attachment of the anterior leaflet to the valve stent body.

[00170] FIGURE 30 is a side view of the anterior leaflet clip device of Figure 29 clipped onto a native anterior leaflet and shows valve tether 6-326 traversing through valve tether aperture 6-324.

[00171] FIGURE 31 is a perspective anterolateral view of one embodiment showing laser cut stent 6-10 with valve leaflets 6-14 mounted therein and with tissue-covered articulating collar structure 6-12 attached, and the anterior leaflet clip device 6-110 attached to the stent 6-10 and/or anterior collar 6-13, and providing an attachment mechanism to secure the anterior leaflet and provide a subvalvular seal against retrograde hemodynamic forces. Fig. 31 shows valve tether 6-26 connecting to apical ventricular tether 6-16. Fig. 31 is an atrial view after the valve is ejected from the delivery catheter but prior to the valve being seated into the mitral annulus and the consequential prosthetic valve deformation of the anterior leaflet A2 of the mitral valve.

[00172] FIGURE 32A is a side of one embodiment showing laser cut stent 6-10 with valve leaflets mounted therein (not shown) and with tissue-covered articulating collar structure 6-12 attached, and the anterior leaflet clip device 6-110 attached to the stent 6-10, and providing an attachment mechanism to secure the anterior leaflet and provide a subvalvular seal against retrograde hemodynamic forces. Fig. 32A also shows the anterior collar segment 6-13 in the necessary angular geometry to avoid LVOT obstruction. Fig. 32A also shows valve tether 6-26 travelling unobstructed through the clip 6-110 and connecting with apical tether 6-16.

[00173] FIGURE 32B is a side of one embodiment showing the leaflet clip 6-110 and suture 6-128 across the anterior leaflet and securing it to the laser cut stent body 6-10, providing an attachment mechanism to secure the anterior leaflet and provide a subvalvular seal against retrograde hemodynamic forces. Fig. 32B also shows the anterior collar segment 6-13 in the necessary angular geometry to avoid LVOT obstruction. Fig. 32B also shows valve tether 6-26 travelling unobstructed through the clip 6-110 and connecting with apical tether 6-16.

[00174] FIGURE 33 is a side view of one embodiment showing the leaflet clip manufactured as an integral component of the laser-cut stent body 6-410. Fig. 33 shows how the hinge segment 6-416 and leaflet capture and attachment segment 6-412 move from the first deployment position to the second leaflet capture position.

#### Functions of the Flared End of the Stent to Effect Atrial Sealing

[00175] The flared collar-end, also known as a collar or cuff, functions in a variety of ways. The first function of the flared end or cuff is to inhibit perivalvular leak/regurgitation of blood around the prosthesis. By flexing and sealing across the irregular contours of the annulus and atrium, leakage is minimized or prevented.

[00176] The second function of the flared end or cuff is to provide an adjustable and/or compliant bioprosthetic valve. The heart and its structures undergo complex conformational changes during the cardiac cycle. For example, the mitral valve annulus has a complex geometric shape known as a hyperbolic paraboloid that is shaped like a saddle, with the horn being anterior, the seat back being posterior, and the left and right valleys located medially and laterally. Beyond this complexity, the area of the mitral annulus changes over the course of the cardiac cycle. Further, the geometry of the tricuspid valve and tricuspid annulus continues to be a topic of research, posing its own particular problems. Accordingly, compliance is a very important but unfortunately often overlooked requirement of cardiac devices. Compliance here refers to the ability of the valve to change conformation with the native annulus in order to maintain structural position and integrity throughout the cardiac cycle. Compliance with the motion of the heart is a particularly important feature, especially the ability to provide localized compliance where the underlying surfaces are acting differently from the adjacent surfaces. This ability to vary throughout the cardiac cycle allows the valve to remain seated and properly deployed in a manner not heretofore provided.

[00177] Additionally, compliance may be achieved through the use of the tethers where the tethers are preferably made from an elastic material. Tether-based compliance may be used alone, or in combination with the flared end or cuff-based compliance.

[00178] The third function of the flared end or cuff and valve is to provide a valve that, during implantation surgery, can contour to the irregular surfaces of the atrium. The use of independent tethers allows for side to side fitting of the valve within the annulus. For example, where three tethers are used, they are located circumferentially about 120 degrees relative to each other which allows the surgeon to observe whether or where perivalvular leaking might be occurring and to pull on one side or the other to create localized pressure and reduce or eliminate the leakage.

[00179] The fourth function of the flared end or cuff is to counter the forces that act to displace the prosthesis toward/into the ventricle (i.e. atrial pressure and flow-generated shear stress) during ventricular filling.

[00180] Additional features of the flared end or cuff include that it functions to strengthen the leaflet assembly/stent combination by providing additional structure. Further, during deployment, the flared end or cuff functions to guide the entire structure, the prosthetic valve, into place at the mitral annulus during deployment and to keep the valve in place once it is deployed. Another important function is to reduce pulmonary edema by improving atrial drainage.

#### Flared End or Cuff Structure

[00181] The flared end or cuff is a substantially flat plate that projects beyond the diameter of the tubular stent to form a rim or border. As used herein, the term flared end, cuff, flange, collar, bonnet, apron, or skirting are considered to be functionally equivalent. When the tubular stent is pulled through the mitral valve aperture, the mitral annulus, by the tether loops in the direction of the left ventricle, the flared end or cuff acts as a collar to stop the tubular stent from traveling any further through the mitral valve aperture. The entire prosthetic valve is held by longitudinal forces between the flared end or cuff which is seated in the left atrium and mitral annulus, and the ventricular tethers attached to the left ventricle.

[00182] The flared end or cuff is formed from a stiff, flexible shape-memory material such as the nickel-titanium alloy material Nitinol® wire that is covered by stabilized tissue or other

suitable biocompatible or synthetic material. In one embodiment, the flared end or cuff wire form is constructed from independent articulating radial tines or posts of wire extending axially around the circumference of the bend or seam where the flared end or cuff transitions to the tubular stent (in an integral flared end or cuff) or where the flared end or cuff is attached to the stent (where they are separate, but joined components).

[00183] Once covered by stabilized tissue or material, the articulating radial tines or posts of wire provide the flared end or cuff the ability to travel up and down, to articulate, along the longitudinal axis that runs through the center of the tubular stent. In other words, the individual articulating radial tines or posts of wire can independently move up and down, and can spring back to their original position due to the relative stiffness of the wire. The tissue or material that covers the flared end or cuff wire has a certain modulus of elasticity such that, when attached to the wire of the flared end or cuff, is able to allow the wire spindles to move. This flexibility gives the flared end or cuff, upon being deployed within a patient's heart, the ability to conform to the anatomical shape necessary for a particular application. In the example of a prosthetic mitral valve, the flared end or cuff is able to conform to the irregularities of the left atrium and shape of the mitral annulus, and to provide a tight seal against the atrial tissue adjacent the mitral annulus and the tissue within the mitral annulus. As stated previously, this feature importantly provides a degree of flexibility in sizing the a mitral valve and prevents blood from leaking around the implanted prosthetic heart valve.

[00184] An additional important aspect of the flared end or cuff dimension and shape is that, when fully seated and secured, the edge of the flared end or cuff preferably should not be oriented laterally into the atrial wall such that it can produce a penetrating or cutting action on the atrial wall.

[00185] In one preferred embodiment, the wire spindles of the flared end or cuff are substantially uniform in shape and size. In another preferred embodiment of the present invention, each loop or spindle may be of varying shapes and sizes. In this example, it is contemplated that the articulating radial tines or posts of wire may form a pattern of alternating large and small articulating radial tines or posts of wire, depending on where the valve is being deployed. In the case of a prosthetic mitral valve, pre-operative imaging may allow for customizing the structure of the flared end or cuff depending on a particular patient's anatomical geometry in the vicinity of the mitral annulus.

[00186] The flared end or cuff wire form is constructed so as to provide sufficient structural integrity to withstand the intracardiac forces without collapsing. The flared end or cuff wire form is preferably constructed of a superelastic metal, such as Nitinol® and is capable of maintaining its function as a sealing collar for the tubular stent while under longitudinal forces that might cause a structural deformation or valve displacement. It is contemplated as within the scope of the invention to optionally use other shape memory alloys such as Cu-Zn-Al-Ni alloys, and Cu-Al-Ni alloys. The heart is known to generate an average left atrial pressure between about 8 and 30 mm Hg (about 0.15 to 0.6 psi). This left atrial filling pressure is the expected approximate pressure that would be exerted in the direction of the left ventricle when the prosthesis is open against the outer face of the flared end or cuff as an anchoring force holding the flared end or cuff against the atrial tissue that is adjacent the mitral valve. The flared end or cuff counteracts this longitudinal pressure against the prosthesis in the direction of the left ventricle to keep the valve from being displaced or slipping into the ventricle. In contrast, left ventricular systolic pressure, normally about 120 mm Hg, exerts a force on the closed prosthesis in the direction of the left atrium. The tethers counteract this force and are used to maintain the valve position and withstand the ventricular force during ventricular contraction or systole. Accordingly, the flared end or cuff has sufficient structural integrity to provide the necessary tension against the tethers without being dislodged and pulled into the left ventricle. After a period of time, changes in the geometry of the heart and/or fibrous adhesion between prosthesis and surrounding cardiac tissues may assist or replace the function of the ventricular tethers in resisting longitudinal forces on the valve prosthesis during ventricular contraction.

#### Stent Structure

[00187] Preferably, superelastic metal wire, such as Nitinol® wire, is used for the stent, for the inner wire-based leaflet assembly that is disposed within the stent, and for the flared end or cuff wire form. As stated, it is contemplated as within the scope of the invention to optionally use other shape memory alloys such as Cu-Zn-Al-Ni alloys, and Cu-Al-Ni alloys. It is contemplated that the stent may be constructed as a braided stent or as a laser cut stent. Such stents are available from any number of commercial manufacturers, such as Pulse Systems. Laser cut stents are preferably made from Nickel-Titanium (Nitinol®), but also without limitation made from stainless steel, cobalt chromium, titanium, and other functionally equivalent metals and

alloys, or Pulse Systems braided stent that is shape-set by heat treating on a fixture or mandrel. [00188] One key aspect of the stent design is that it be compressible and when released have the stated property that it return to its original (uncompressed) shape. This requirement limits the potential material selections to metals and plastics that have shape memory properties. With regards to metals, Nitinol® has been found to be especially useful since it can be processed to be austenitic, martensitic or super elastic. Martensitic and super elastic alloys can be processed to demonstrate the required compression features.

#### Laser cut stent

[00189] One possible construction of the stent envisions the laser cutting of a thin, isodiametric Nitinol tube. The laser cuts form regular cutouts in the thin Nitinol® tube. Secondly the tube is placed on a mold of the desired shape, heated to the martensitic temperature and quenched. The treatment of the stent in this manner will form a stent or stent/flared end or cuff that has shape memory properties and will readily revert to the memory shape at the calibrated temperature.

#### Braided wire stent

[00190] A stent can be constructed utilizing simple braiding techniques. Using a Nitinol® wire - for example a 0.012" wire - and a simple braiding fixture, the wire is wound on the braiding fixture in a simple over-under braiding pattern until an isodiametric tube is formed from a single wire. The two loose ends of the wire are coupled using a stainless steel or Nitinol® coupling tube into which the loose ends are placed and crimped. Angular braids of approximately 60 degrees have been found to be particularly useful. Secondly, the braided stent is placed on a shaping fixture and placed in a muffle furnace at a specified temperature to set the stent to the desired shape and to develop the martensitic or super elastic properties desired.

[00191] The stent as envisioned in one preferred embodiment is designed such that the ventricular aspect of the stent comes to 2-5 points onto which anchoring sutures are affixed. The anchoring sutures (tethers) will traverse the ventricle and ultimately be anchored to the epicardial surface of the heart approximately at the level of the apex. The tethers when installed under slight tension will serve to hold the valve in place, i.e. inhibit paravalvular leakage during systole.

### Leaflet and Assembly Structure

[00192] The valve leaflets are held by, or within, a leaflet assembly. In one preferred embodiment of the invention, the leaflet assembly comprises a leaflet wire support structure to which the leaflets are attached and the entire leaflet assembly is housed within the stent body. In this embodiment, the assembly is constructed of wire and stabilized tissue to form a suitable platform for attaching the leaflets. In this aspect, the wire and stabilized tissue allow for the leaflet structure to be compressed when the prosthetic valve is compressed within the deployment catheter, and to spring open into the proper functional shape when the prosthetic valve is opened during deployment. In this embodiment, the leaflet assembly may optionally be attached to and housed within a separate cylindrical liner made of stabilized tissue or material, and the liner is then attached to line the interior of the stent body.

[00193] In this embodiment, the leaflet wire support structure is constructed to have a collapsible/expandable geometry. In a preferred embodiment, the structure is a single piece of wire. The wireform is, in one embodiment, constructed from a shape memory alloy such as Nitinol®. The structure may optionally be made of a plurality of wires, including between 2 to 10 wires. Further, the geometry of the wire form is without limitation, and may optionally be a series of parabolic inverted collapsible arches to mimic the saddle-like shape of the native annulus when the leaflets are attached. Alternatively, it may optionally be constructed as collapsible concentric rings, or other similar geometric forms, each of which is able to collapse or compress, then expand back to its functional shape. In certain preferred embodiments, there may be 2, 3 or 4 arches. In another embodiment, closed circular or ellipsoid structure designs are contemplated. In another embodiment, the wire form may be an umbrella-type structure, or other similar unfold-and-lock-open designs. A preferred embodiment utilizes super elastic Nitinol® wire approximately 0.015" in diameter. In this embodiment, the wire is wound around a shaping fixture in such a manner that 2-3 commissural posts are formed. The fixture containing the wrapped wire is placed in a muffle furnace at a pre-determined temperature to set the shape of the wire form and to impart its super elastic properties. Secondly, the loose ends of the wireform are joined with a stainless steel or Nitinol® tube and crimped to form a continuous shape. In another preferred embodiment, the commissural posts of the wireform are adjoined at their tips by a circular connecting ring, or halo, whose purpose is to minimize inward

deflection of the post(s).

[00194] In another preferred embodiment, the leaflet assembly is constructed solely of stabilized tissue or other suitable material without a separate wire support structure. The leaflet assembly in this embodiment is also disposed within the lumen of the stent and is attached to the stent to provide a sealed joint between the leaflet assembly and the inner wall of the stent. By definition, it is contemplated within the scope of the invention that any structure made from stabilized tissue and/or wire(s) related to supporting the leaflets within the stent constitute a leaflet assembly.

In this embodiment, stabilized tissue or suitable material may also optionally be used as a liner for the inner wall of the stent and is considered part of the leaflet assembly.

[00195] Liner tissue or biocompatible material may be processed to have the same or different mechanical qualities, such as thickness, durability, etc., from the leaflet tissue.

#### Deployment within the valvular annulus

[00196] The prosthetic heart valve is, in one embodiment, apically delivered through the apex of the left ventricle of the heart using a catheter system. In one aspect of the apical delivery, the catheter system accesses the heart and pericardial space by intercostal delivery. In another delivery approach, the catheter system delivers the prosthetic heart valve using either an antegrade or retrograde delivery approach using a flexible catheter system, and without requiring the rigid tube system commonly used. In another embodiment, the catheter system accesses the heart via a trans-septal approach.

[00197] In one non-limiting preferred embodiment, the stent body extends into the ventricle about to the edge of the open mitral valve leaflets (approximately 25% of the distance between the annulus and the ventricular apex). The open native leaflets lay against the outside stent wall and parallel to the long axis of the stent (i.e. the stent holds the native mitral valve open).

[00198] In one non-limiting preferred embodiment, the diameter should approximately match the diameter of the mitral annulus. Optionally, the valve may be positioned to sit in the mitral annulus at a slight angle directed away from the aortic valve such that it is not obstructing flow through the aortic valve. Optionally, the outflow portion (bottom) of the stent should not be too close to the lateral wall of the ventricle or papillary muscle as this position may interfere with flow through the prosthesis. As these options relate to the tricuspid, the position of the tricuspid valve may be very similar to that of the mitral valve.

[00199] In another embodiment, the prosthetic valve is sized and configured for use in areas other than the mitral annulus, including, without limitation, the tricuspid valve between the right atrium and right ventricle. Alternative embodiments may optionally include variations to the flared end or cuff structure to accommodate deployment to the pulmonary valve between the right ventricle and pulmonary artery, and the aortic valve between the left ventricle and the aorta. In one embodiment, the prosthetic valve is optionally used as a venous backflow valve for the venous system, including without limitation the vena cava, femoral, subclavian, pulmonary, hepatic, renal and cardiac. In this aspect, the flared end or cuff feature is utilized to provide additional protection against leaking.

#### Tethers

[00200] In one preferred embodiment, there are tethers attached to the prosthetic heart valve that extend to one or more tissue anchor locations within the heart. In one preferred embodiment, the tethers extend downward through the left ventricle, exiting the left ventricle at the apex of the heart to be fastened on the epicardial surface outside of the heart. Similar anchoring is contemplated herein as it regards the tricuspid, or other valve structure requiring a prosthetic. There may be from 1 to 8 tethers which are preferably attached to the stent.

[00201] In another preferred embodiment, the tethers may optionally be attached to the flared end or cuff to provide additional control over position, adjustment, and compliance. In this preferred embodiment, one or more tethers are optionally attached to the flared end or cuff, in addition to, or optionally, in place of, the tethers attached to the stent. By attaching to the flared end or cuff and/or the stent, an even higher degree of control over positioning, adjustment, and compliance is provided to the operator during deployment.

[00202] During deployment, the operator is able to adjust or customize the tethers to the correct length for a particular patient's anatomy. The tethers also allow the operator to tighten the flared end or cuff onto the tissue around the valvular annulus by pulling the tethers, which creates a leak-free seal.

[00203] In another preferred embodiment, the tethers are optionally anchored to other tissue locations depending on the particular application of the prosthetic heart valve. In the case of a mitral valve, or the tricuspid valve, there are optionally one or more tethers anchored to one or both papillary muscles, septum, and/or ventricular wall.

[00204] The tethers, in conjunction with the flared end or cuff, provide for a compliant valve which has heretofore not been available. The tethers are made from surgical-grade materials such as biocompatible polymer suture material. Non-limiting examples of such material include ultra high-molecular weight polyethylene (UHMWPE), 2-0 ePTFE (polytetrafluoroethylene) or 2-0 polypropylene. In one embodiment the tethers are inelastic. It is also contemplated that one or more of the tethers may optionally be elastic to provide an even further degree of compliance of the valve during the cardiac cycle. Upon being drawn to and through the apex of the heart, the tethers may be fastened by a suitable mechanism such as tying off to a pledget or similar adjustable button-type anchoring device to inhibit retraction of the tether back into the ventricle. It is also contemplated that the tethers might be bioresorbable/bioabsorbable and thereby provide temporary fixation until other types of fixation take hold such as a biological fibrous adhesion between the tissues and prosthesis and/or radial compression from a reduction in the degree of heart chamber dilation.

[00205] Further, it is contemplated that the prosthetic heart valve may optionally be deployed with a combination of installation tethers and permanent tethers, attached to either the stent or flared end or cuff, or both, the installation tethers being removed after the valve is successfully deployed. It is also contemplated that combinations of inelastic and elastic tethers may optionally be used for deployment and to provide structural and positional compliance of the valve during the cardiac cycle.

#### Pledget

[00206] In one embodiment, to control the potential tearing of tissue at the apical entry point of the delivery system, a circular, semi-circular, or multi-part pledget is employed. The pledget may be constructed from a semi-rigid material such as PTFE felt. Prior to puncturing of the apex by the delivery system, the felt is firmly attached to the heart such that the apex is centrally located. Secondly, the delivery system is introduced through the central area, or orifice as it may be, of the pledget. Positioned and attached in this manner, the pledget acts to control any potential tearing at the apex.

#### Tines / Barbs

[00207] In another embodiment the valve can be seated within the valvular annulus through the

use of tines or barbs. These may be used in conjunction with, or in place of one or more tethers. The tines or barbs are located to provide attachment to adjacent tissue. In one preferred embodiment, the tines are optionally circumferentially located around the bend/transition area between the stent and the flared end or cuff. Such tines are forced into the annular tissue by mechanical means such as using a balloon catheter. In one non-limiting embodiment, the tines may optionally be semi-circular hooks that upon expansion of the stent body, pierce, rotate into, and hold annular tissue securely.

#### Stabilized Tissue or Biocompatible Material

[00208] In one embodiment, it is contemplated that multiple types of tissue and biocompatible material may be used to cover the flared end or cuff, to form the valve leaflets, to form a wireless leaflet assembly, and/or to line both the inner and/or outer lateral walls of the stent. As stated previously, the leaflet component may be constructed solely from stabilized tissue, without using wire, to create a leaflet assembly and valve leaflets. In this aspect, the tissue-only leaflet component may be attached to the stent with or without the use of the wire form. In a preferred embodiment, there can be anywhere from 1, 2, 3 or 4 leaflets, or valve cusps.

[00209] It is contemplated that the tissue may be used to cover the inside of the stent body, the outside of the stent body, and the top and/or bottom side of the flared end or cuff wire form, or any combination thereof.

[00210] In one preferred embodiment, the tissue used herein is optionally a biological tissue and may be a chemically stabilized valve of an animal, such as a pig. In another preferred embodiment, the biological tissue is used to make leaflets that are sewn or attached to a metal frame. This tissue is chemically stabilized pericardial tissue of an animal, such as a cow (bovine pericardium) or sheep (ovine pericardium) or pig (porcine pericardium) or horse (equine pericardium).

[00211] Preferably, the tissue is bovine pericardial tissue. Examples of suitable tissue include that used in the products Duraguard®, Peri-Guard®, and Vascu-Guard®, all products currently used in surgical procedures, and which are marketed as being harvested generally from cattle less than 30 months old. Other patents and publications disclose the surgical use of harvested, biocompatible animal thin tissues suitable herein as biocompatible "jackets" or sleeves for implantable stents, including for example, U.S. Patent No. 5,554,185 to Block, U.S. Patent No.

7,108,717 to Design & Performance-Cyprus Limited disclosing a covered stent assembly, U.S. Patent No. 6,440,164 to Scimed Life Systems, Inc. disclosing a bioprosthetic valve for implantation, and U.S. Patent No. 5,336,616 to LifeCell Corporation discloses acellular collagen-based tissue matrix for transplantation.

[00212] In one preferred embodiment, the valve leaflets may optionally be made from a synthetic material such a polyurethane or polytetrafluoroethylene. Where a thin, durable synthetic material is contemplated, e.g. for covering the flared end or cuff, synthetic polymer materials such expanded polytetrafluoroethylene or polyester may optionally be used. Other suitable materials may optionally include thermoplastic polycarbonate urethane, polyether urethane, segmented polyether urethane, silicone polyether urethane, silicone-polycarbonate urethane, and ultra-high molecular weight polyethylene. Additional biocompatible polymers may optionally include polyolefins, elastomers, polyethylene-glycols, polyethersulphones, polysulphones, polyvinylpyrrolidones, polyvinylchlorides, other fluoropolymers, silicone polyesters, siloxane polymers and/or oligomers, and/or polylactones, and block co-polymers using the same.

[00213] In another embodiment, the valve leaflets may optionally have a surface that has been treated with (or reacted with) an anti-coagulant, such as, without limitation, immobilized heparin. Such currently available heparinized polymers are known and available to a person of ordinary skill in the art.

[00214] Alternatively, the valve leaflets may optionally be made from pericardial tissue or small intestine submucosal tissue.

#### Ultra-thin Stabilized Tissue

[00215] In a preferred embodiment, ultra-thin vapor-cross linked stabilized bioprosthetic or implant tissue material is contemplated. Tissue having a 0.003" (0.0762 mm) to about 0.010" (0.254 mm) may be made using a process comprising the steps of: (a) vapor cross-linking a pre-digested compressed tissue specimen by exposing the tissue specimen to a vapor of a cross-linking agent selected from the group consisting of aldehydes, epoxides, isocyanates, carbodiimides, isothiocyanates, glycidalethers, and acyl azides; and (b) chemically cross-linking the vapor-cross-linked tissue specimen by exposing the vapor-crosslinked tissue specimen to an aqueous crosslinking bath for a predetermined time, such crosslinking bath containing a liquid

phase of a crosslinking agent selected from the group consisting of aldehydes, epoxides, isocyanates, carbodiimides, isothiocyanates, glycidalethers, and acyl azides.

[00216] Such tissue may be porcine, ovine, equine or bovine in origin and preferably the initial material is taken from a bovine animal 30 days old or less, although tissue from older animals is contemplated as within the scope of the invention. In one preferred embodiment, the tissue specimen is subjected to chemical dehydration/compression and mechanical compression before cross-linking.

[00217] Pre-digestion is provided by digesting a harvested, cleaned pericardial tissue in a solution containing a surfactant, such as 1% sodium laurel sulfate. The chemical dehydration/compression step comprises subjecting the tissue specimen to hyperosmotic salt solution. And, the mechanical compression may be performed by subjecting the tissue specimen to a roller apparatus capable of compressing the tissue specimen to a thickness ranging from about 0.003" (0.0762 mm) to about 0.010" (0.254 mm).

[00218] The animal collagen tissue specimen is then chemically cross-linked first by exposing the tissue to formaldehyde vapor for approximately 10 minutes, and second by immersing the tissue in a glutaraldehyde solution for two consecutive sessions of approximately 24 hours each.

[00219] The references recited herein are incorporated herein in their entirety, particularly as they relate to teaching the level of ordinary skill in this art and for any disclosure necessary for the commoner understanding of the subject matter of the claimed invention. It will be clear to a person of ordinary skill in the art that the above embodiments may be altered or that insubstantial changes may be made without departing from the scope of the invention. Accordingly, the scope of the invention is determined by the scope of the following claims and their equitable Equivalents.

## CLAIMS

What is claimed is:

Retrieval and Repositioning

1. A prosthetic heart valve retrieval device, comprising: a dilator tip with a radio band, said dilator tip mounted at distal end of a dilator sheath, said dilator sheath having a lumen therethrough and said dilator sheath mounted on a distal side of dilator base, said dilator base having a sheath lock for operatively engaging the dilator sheath, said dilator base having a slidably removable luer-lock introducer disposed within the lumen, said dilator base having a guide rod aperture for engaging a guide rod that is connected to a guide rod handle mount that is attached on top of a handle apparatus, said dilator base having a traveller strap affixed on a proximal side and said traveller strap extending proximally to engage a tensioning unit on the handle apparatus, said handle apparatus having an actuator and a spring operatively connected to the traveller strap, wherein when the actuator is engaged the traveller strap is pulled proximally through the tensioning unit and the dilator base slides along guide rod towards the handle apparatus.
2. The prosthetic heart valve retrieval device of claim 1, further comprising wherein the dilator tip is bullet-shaped, cone-shaped, hooded, or otherwise shaped to guide the valve tether into the lumen of the dilator sheath.
3. A method of using the retrieval device of claim 1 for capturing a tethered expandable prosthetic heart valve to re-position or remove said valve, comprising the steps of: (i) inserting said retrieval device containing a tethered and expandable prosthetic heart valve into a patient, and (ii) capturing and retracting the tether into the retrieval device.
4. The method of claim 3, wherein the step of inserting the retrieval device by directly accessing the heart through the intercostal space, or using an apical approach to enter a heart ventricle.
5. The method of claim 3, wherein the step of inserting the retrieval device by directly accessing the heart through a thoracotomy, sternotomy, or minimally-invasive thoracic, thorascopic, or trans-diaphragmatic approach to enter the left ventricle.

6. The method of claim 3, further comprising the step of (iii) removing the tethered and expandable heart valve from the patient by collapsing the expandable prosthetic heart valve apparatus into the dilator sheath catheter and retracting the dilator sheath.

#### Positioning Tool

7. A positioning device for deploying a transcatheter prosthetic cardiovascular valve in a patient, which comprises a ratchet rod having a built-in collet at a distal end for attachment to the valve, a transparent sheath having a reference scale, the ratchet rod slidably disposed within the transparent sheath and said ratchet rod having one or more markings operatively associated with reference scale, a tensioning collar attached to the transparent sheath and positioned around the slidable ratchet rod, a tensioning-release lever on the tensioning collar to actuate a pawl mechanism within the tensioning collar, and a removable epicardial attachment pad attached to a proximal end of the ratchet rod.
8. The positioning device of claim 7, wherein the transparent sheath reference scale and ratchet rod markings provide a step resolution of between about 0.5mm and about 2.0mm.
9. The positioning device of claim 7, wherein the ratchet rod and pawl mechanism provide an audible feedback to a user.
10. The positioning device of claim 7, wherein the device has one or more radio-opaque markers thereon to facilitate positioning.
11. The positioning device of claim 7, where the device fits within a surgical catheter sheath having a diameter of between about 10 Fr (3.3mm) to about 42 Fr (14mm).
12. A method of tensioning a deployed transcatheter prosthetic cardiovascular valve in a patient, which comprises the step of pulling the ratchet rod to tighten a tether that extends from the valve that is surgically deployed into the mitral annulus of the patient and through an apical epicardial attachment point.

#### Alignment Device

13. An alignment device for deploying an asymmetric transcatheter prosthetic cardiovascular mitral valve in a patient, which comprises a prosthetic mitral valve loading tube having a

lateral radio-opaque marker and a longitudinal radio-opaque marker, and an asymmetric transcatheter prosthetic mitral valve disposed within the valve loading tube, wherein the asymmetric transcatheter prosthetic mitral valve comprises an expandable stent body having valve leaflets disposed therein and an asymmetric atrial collar attached to the stent, the asymmetric atrial collar having a flattened A2 segment to reduce LVOT obstruction and the asymmetric transcatheter prosthetic mitral valve is compressed within the valve loading tube having the A2 segment of the valve aligned with the lateral radio-opaque marker and a longitudinal radio-opaque marker of the tube, wherein the lateral radio-opaque marker provides a commissure-to-commissure alignment, and wherein the longitudinal radio-opaque marker provides an A2-anterior leaflet alignment.

14. The alignment device of claim 13, wherein the valve has one or more radio-opaque markers thereon to facilitate positioning.
15. The alignment device of claim 13, where the device fits within a surgical catheter sheath having a diameter of between about 10 Fr (3.3mm) to about 42 Fr (14mm).
16. A method of providing the correct valve alignment during deployment of an asymmetrical transcatheter valve while it is being deployed in a patient in need thereof, which comprises the step of deploying an alignment device as in claim 1 from a delivery catheter being used to surgically deploy the valve into the patient in need thereof.

#### Deployment Compensator

17. A deployment compensator for deploying a transcatheter prosthetic cardiovascular valve in a patient, which comprises an extension spring connecting an end block to a spring head, the end block sized to remain outside of a valve deployment catheter sheath and having a sheath guide block connected thereto for inserting into an end portion of a valve deployment catheter sheath, said end block and sheath guide block having a push rod aperture for mounting a push rod, the spring head having a spring barrel connected thereto, the spring barrel disposed within the extension spring, and said spring head and spring barrel having a push rod aperture for mounting a push rod.
18. The deployment compensator of claim 17, further comprising in combination a push rod having a collet at a distal end and a removable epicardial attachment pad attached to a

proximal end of the push rod.

19. The deployment compensator of claim 17, wherein the device has one or more radio-opaque markers thereon to facilitate positioning.
20. The deployment compensator of claim 17, where the device fits within a surgical catheter sheath having a diameter of between about 10 Fr (3.3mm) to about 42 Fr (14mm).
21. A method of reducing the expelling force of a compressed transcatheter prosthetic cardiovascular valve out of a delivery catheter during deployment in a patient, which comprises the step of connecting a valve tether to a deployment compensator as in claim 1 while the valve is being expelled from the delivery catheter being used to surgically deploy the valve into the patient in need thereof.

#### Anterior Leaflet Clip

22. Apre-configured compressible transcatheter prosthetic cardiovascular valve having an anterior leaflet clip device, which comprises an expandable leaflet assembly comprised of stabilized tissue or synthetic material disposed within an expandable stent having at a distal end a plurality of articulating collar support structures having a tissue covering to form an atrial collar, said expandable stent having a proximal end comprised of an integral tether connection apparatus, said anterior leaflet clip device comprising a folding component that is mounted on the expandable stent, said folding component having a hinge segment and a leaflet capture and attachment segment.
23. The prosthetic heart valve of claim 22, further comprising wherein the anterior leaflet clip device is an integrated component of the expandable stent.
24. The prosthetic heart valve of claim 22, further comprising wherein the anterior leaflet clip device is a separate component that is sutured to the expanded stent before deployment of the valve, the device having a mounting segment connected to the hinge segment which is connected to the leaflet capture and attachment segment.
25. The anterior leaflet clip of claim 22, further comprising a plurality of pre-aligned suture holes in the leaflet capture and attachment segment.
26. The anterior leaflet clip of claim 24, further comprising a plurality of pre-aligned suture

- holes in the mounting segment and the leaflet capture and attachment segment wherein the suture holes line up in a substantially adjacent manner after the leaflet capture and attachment segment is folded over.
27. The prosthetic heart valve of claim 22, further comprising wherein the expandable stent has a low height to width profile.
28. The prosthetic heart valve of claim 22, further comprising wherein the expandable stent is a half-round D-shape in cross-section.
29. The prosthetic heart valve of claim 22, wherein the expandable stent is made from superelastic metal.
30. The prosthetic heart valve of claim 26, further comprising wherein the superelastic metal is a nickel-titanium alloy.
31. The prosthetic heart valve of claim 26, wherein the stent and cuff are formed from the same piece of superelastic metal.
32. The prosthetic heart valve of claim 22, further comprising wherein the expandable stent and collar are covered with stabilized tissue is derived from adult, 90-day old, or 30-day old, bovine, ovine, equine or porcine pericardium, or from animal small intestine submucosa.
33. The prosthetic heart valve of claim 22, further comprising wherein the expandable stent and collar are covered with synthetic material selected from the group consisting of polyester, polyurethane, polytetrafluoroethylene or another elastomeric material.
34. The prosthetic heart valve of claim 22, wherein the elastomeric material, stabilized tissue or synthetic material is treated with anticoagulant.
35. The prosthetic heart valve of claim 22, wherein the elastomeric material, the stabilized tissue or synthetic material is heparinized.
36. The prosthetic heart valve of claim 22, wherein integral tether connection apparatus has a plurality of tether attachment structures with anchoring tethers attached for anchoring the prosthetic heart valve to tissue.
37. The prosthetic heart valve of claim 36, wherein at least one of the plurality of tethers is a positioning tether and at least one of the plurality of tethers is an anchoring tether.
38. The prosthetic heart valve of claim 36, further comprising wherein one of the plurality of tethers is attached to an epicardial tether securing device.

39. The prosthetic heart valve of claim 22, wherein the valve does not use an anchoring tether or a positioning tether at all, and instead is held in the mitral annulus by the wrapping forces of the native leaflets, and optionally one or more standard anchoring elements, including but not limited to barbs, pins, and/or hooks, or combinations thereof.
40. A method of treating mitral regurgitation in a patient, which comprises the step of surgically deploying the prosthetic heart valve of claim 22 into the mitral annulus of the patient.
41. The method of claim 40, wherein the prosthetic heart valve is deployed by directly accessing the heart through the intercostal space, using an apical approach to enter the left ventricle, and deploying the prosthetic heart valve into the mitral annulus using a catheter delivery system.
42. The method of claim 40, wherein the prosthetic heart valve is deployed by directly accessing the heart through a thoracotomy, sternotomy, or minimally-invasive thoracic, thoroscopic, or trans-diaphragmatic approach to enter the left ventricle.
43. The method of claim 40, wherein the prosthetic heart valve is deployed by directly accessing the heart through the intercostal space, using an approach through the lateral ventricular wall to enter the left ventricle.
44. The method of claim 40, wherein the prosthetic heart valve is deployed by accessing the left atrium of the heart using a transvenous atrial septostomy approach.
45. The method of claim 40, wherein the prosthetic heart valve is deployed by accessing the left ventricle of the heart using a transarterial retrograde aortic valve approach.
46. The method of claim 40, wherein the prosthetic heart valve is deployed by accessing the left ventricle of the heart using a transvenous ventricular septostomy approach.
47. The method of claim 40, further comprising tethering the prosthetic heart valve to tissue within the left ventricle.
48. The method of claim 40, wherein the prosthetic heart valve is tethered to the apex of the left ventricle using an epicardial tether securing device.

FIG. 1

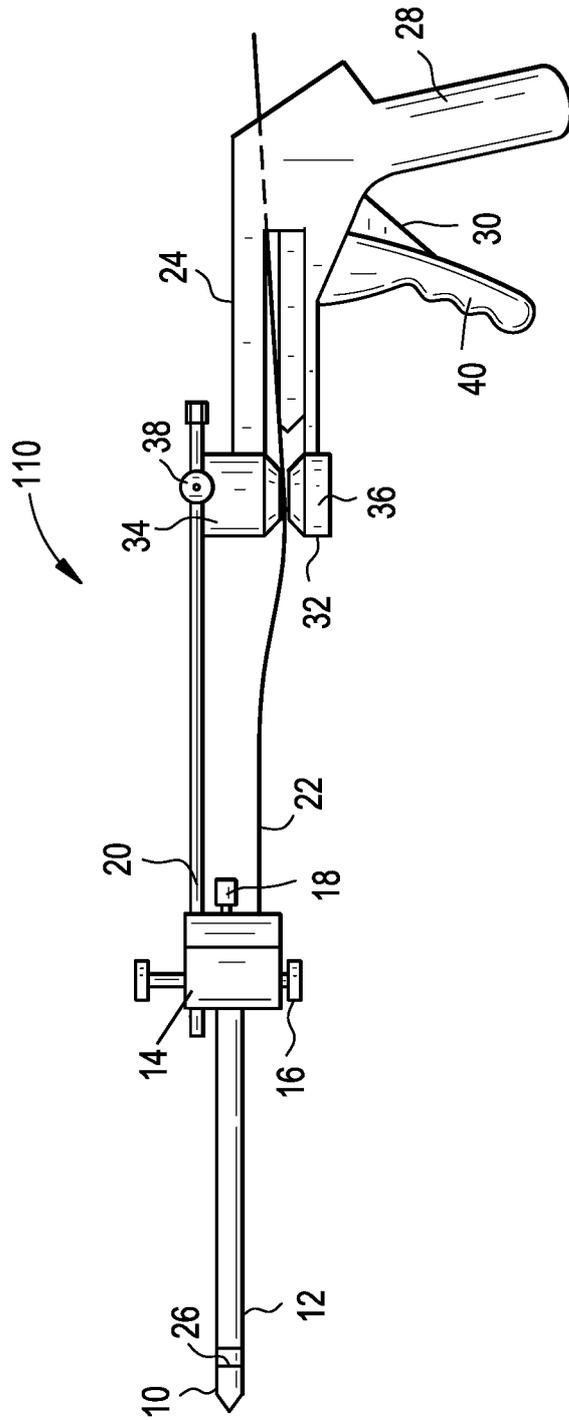


FIG. 2

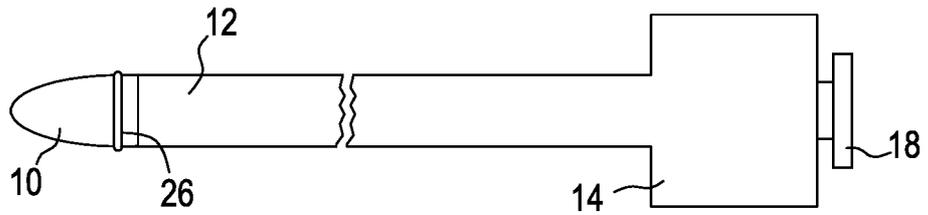


FIG. 3

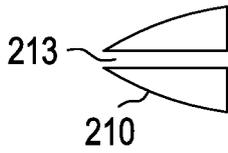


FIG. 4

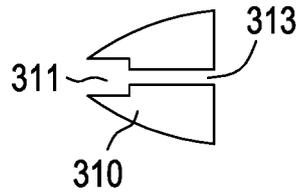


FIG. 5

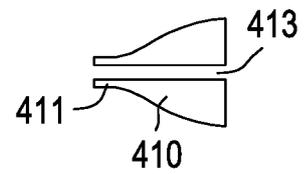


FIG. 6

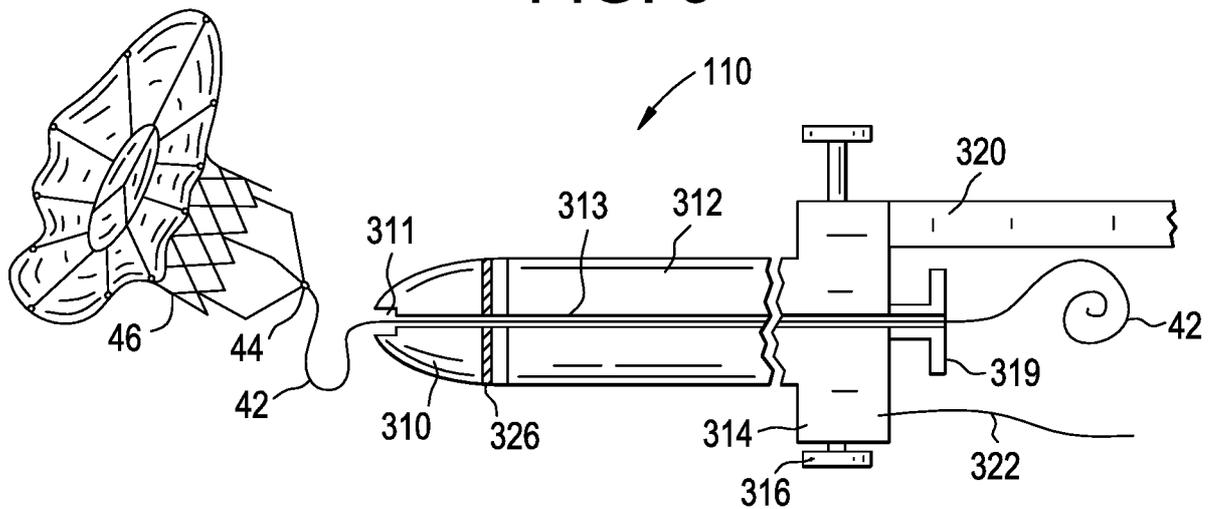


FIG. 7

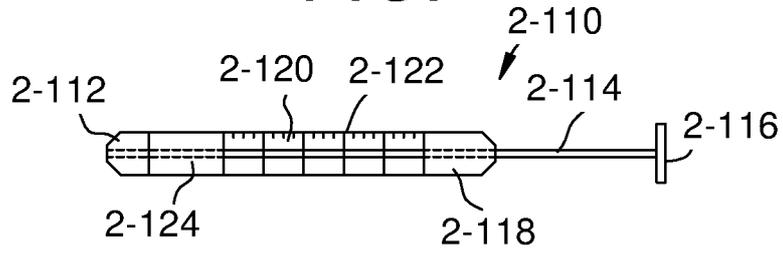


FIG. 8

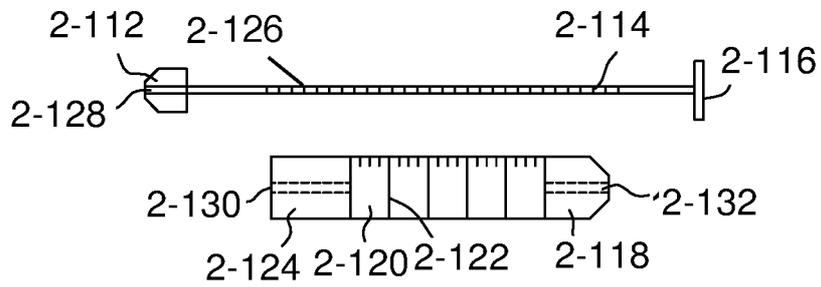


FIG. 9

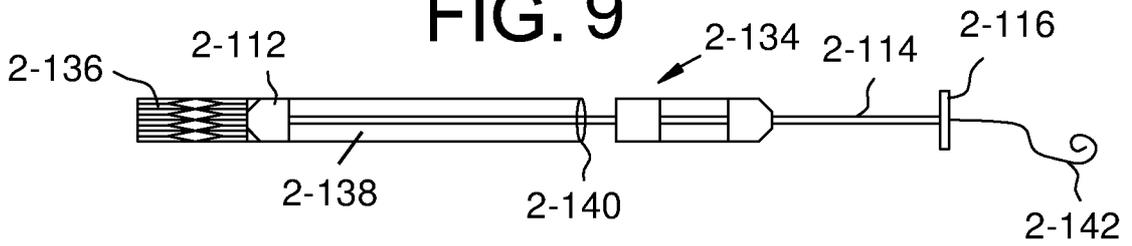


FIG. 10

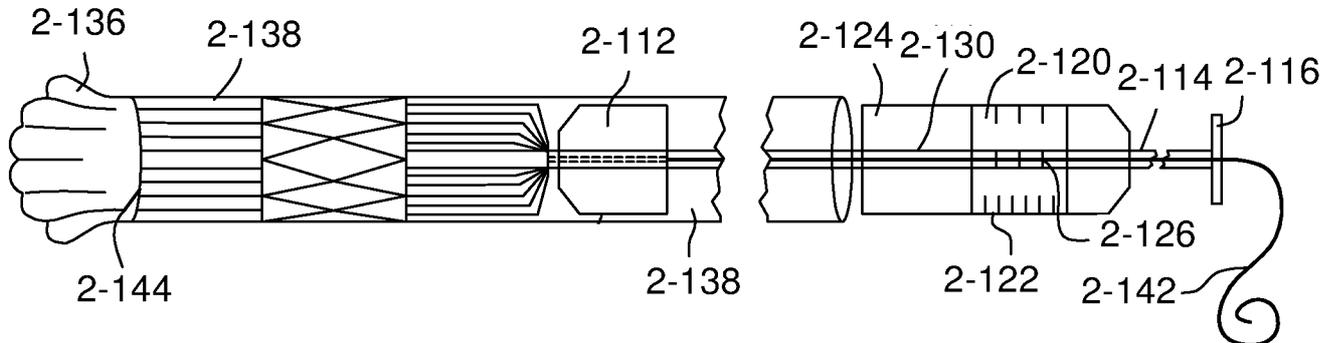


FIG. 11

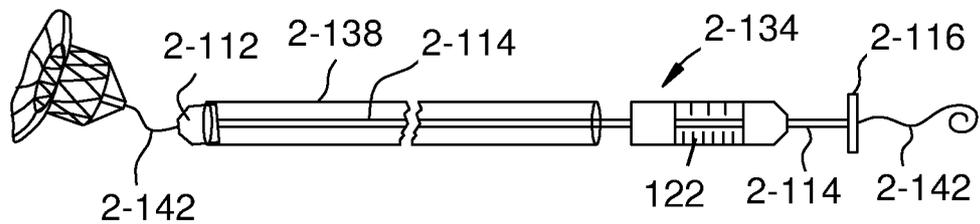


FIG. 12

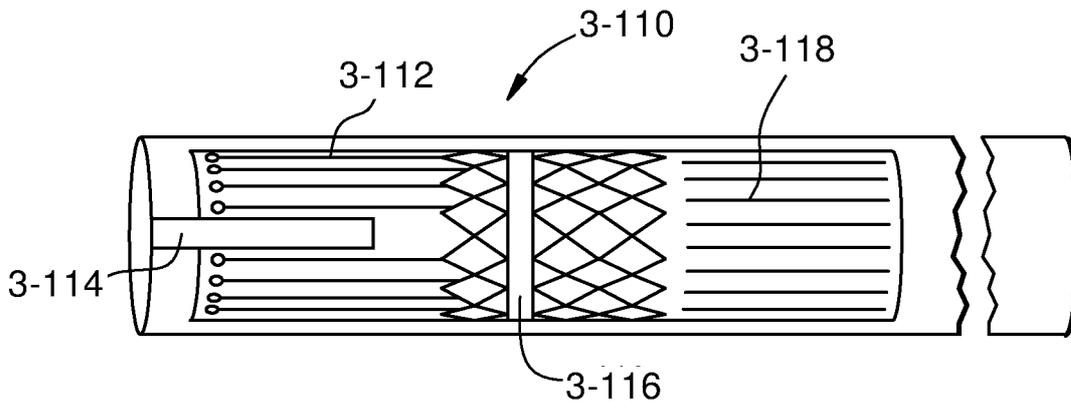


FIG. 13

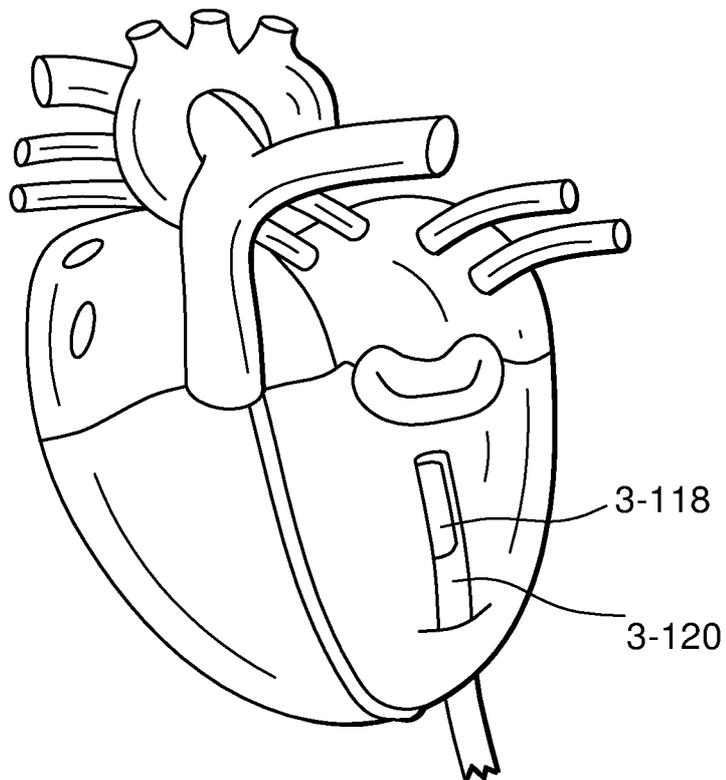


FIG. 14

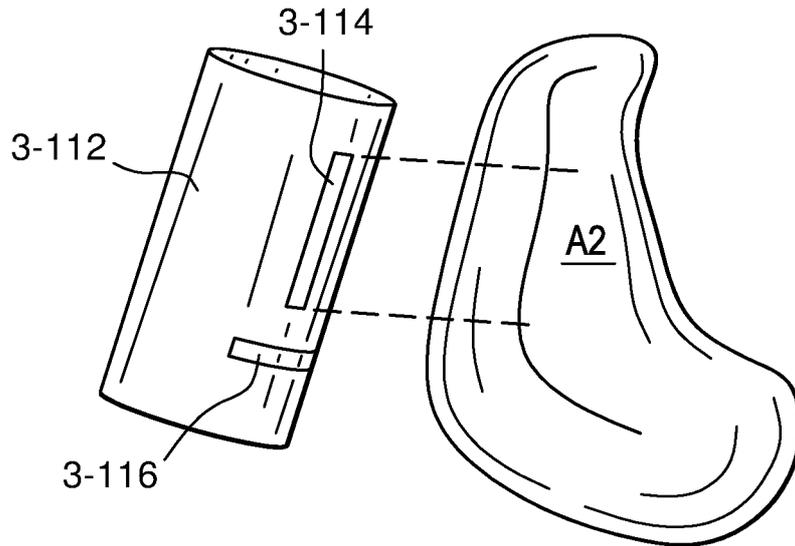


FIG. 15

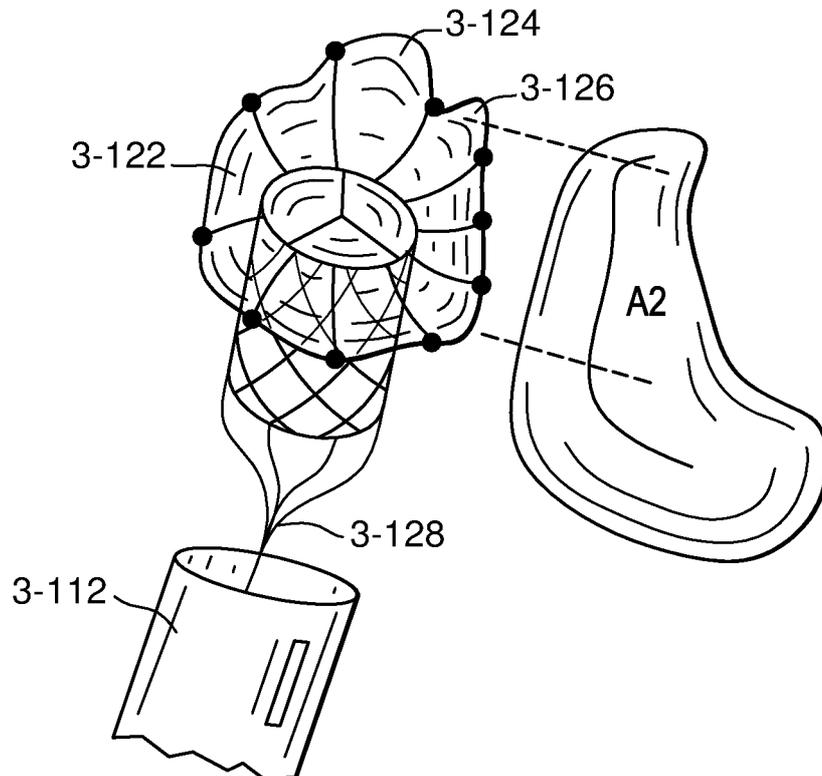


FIG. 16

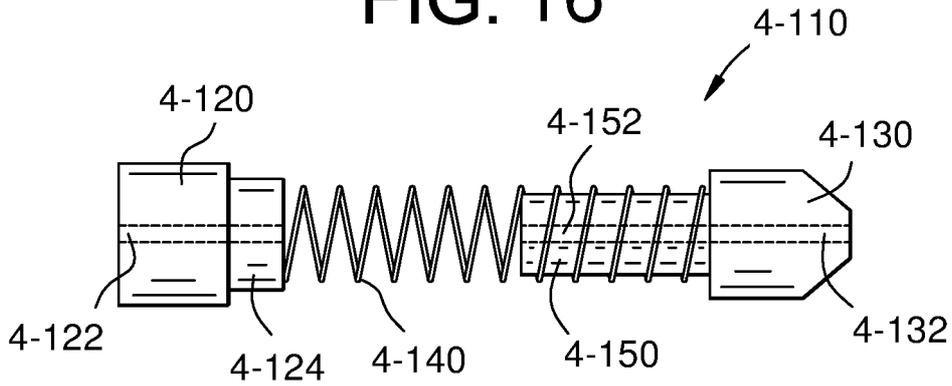


FIG. 17

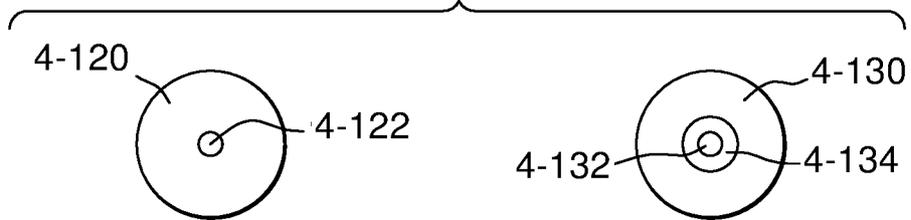


FIG. 18

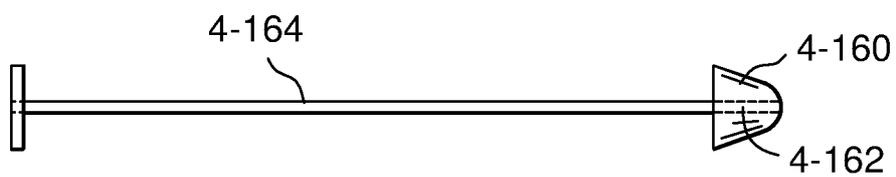


FIG. 19

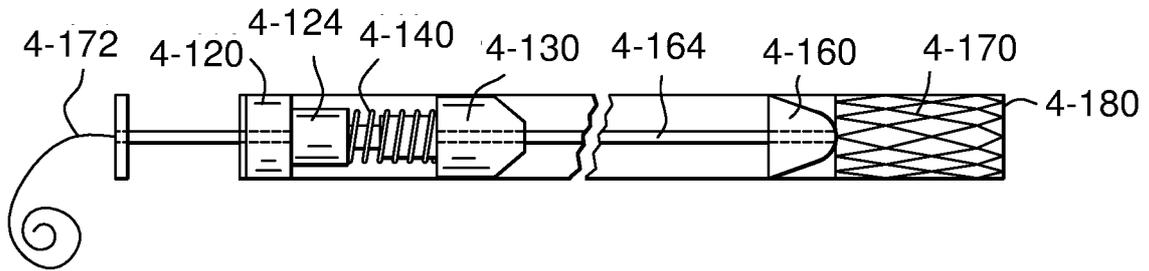


FIG. 20

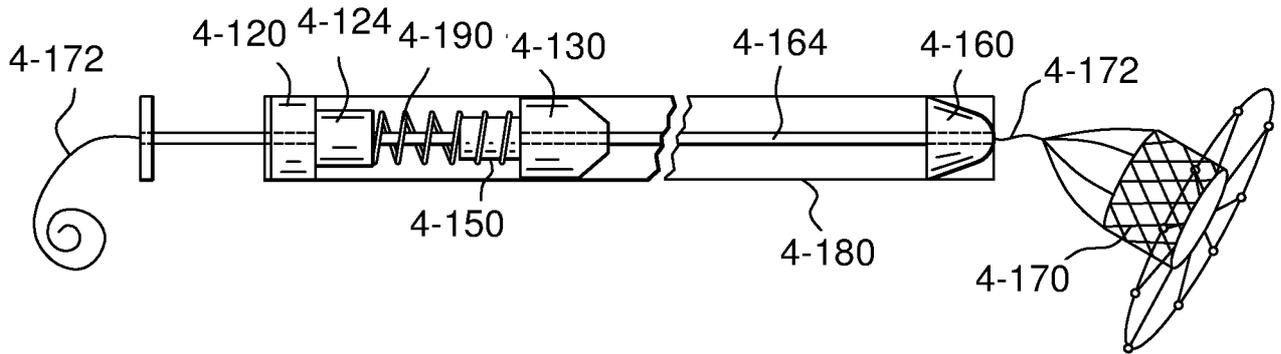


FIG. 21

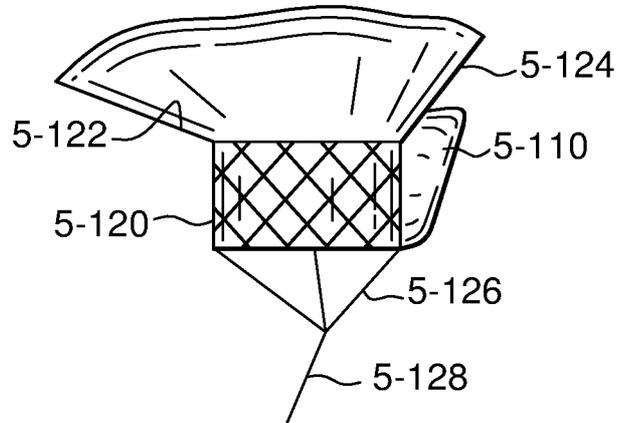


FIG. 22

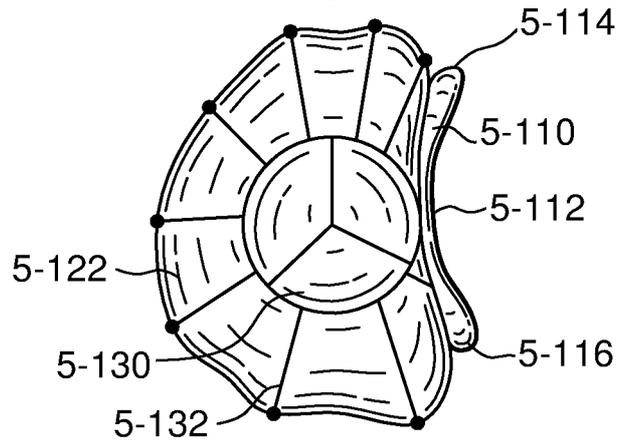


FIG. 23

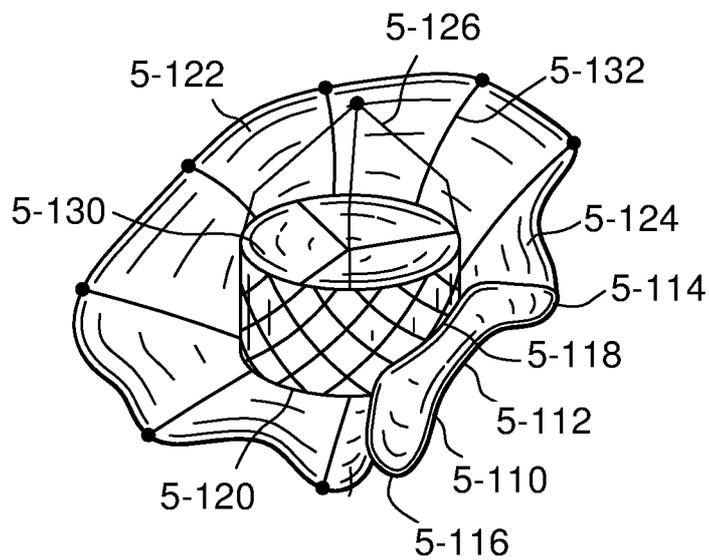


FIG. 24

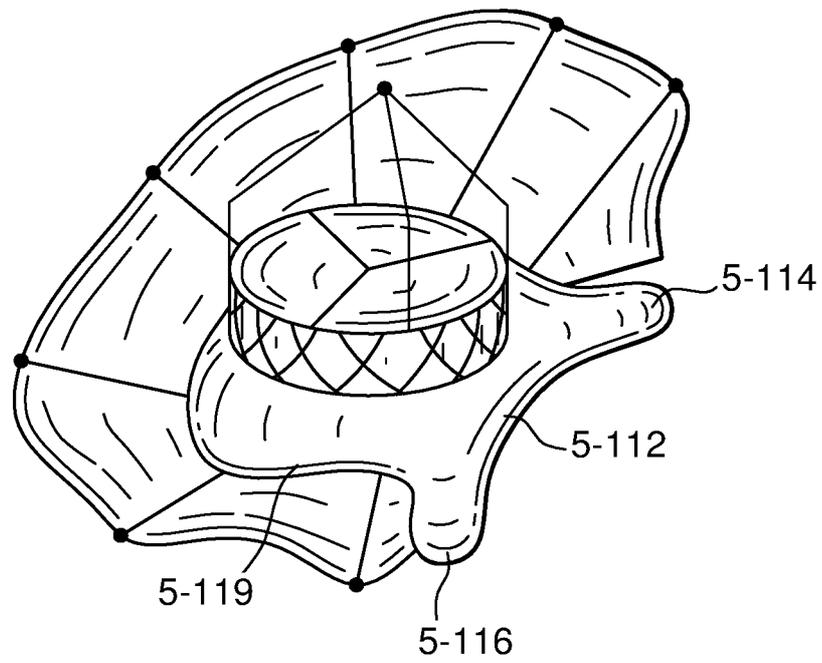


FIG. 25

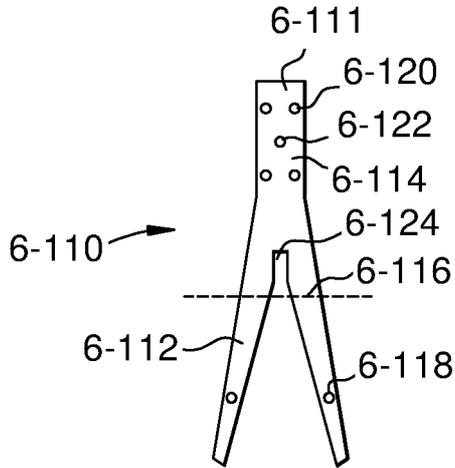


FIG. 26

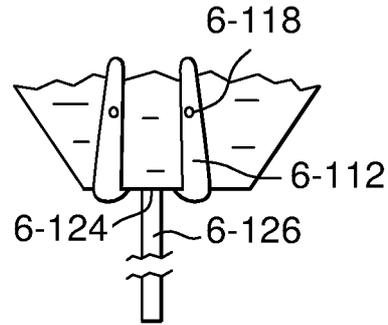


FIG. 27

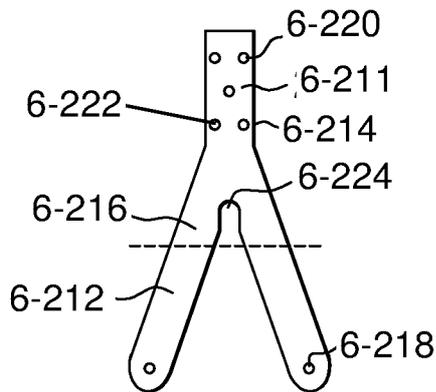


FIG. 28

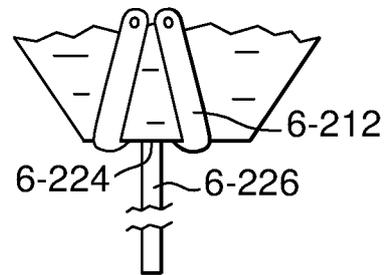


FIG. 29

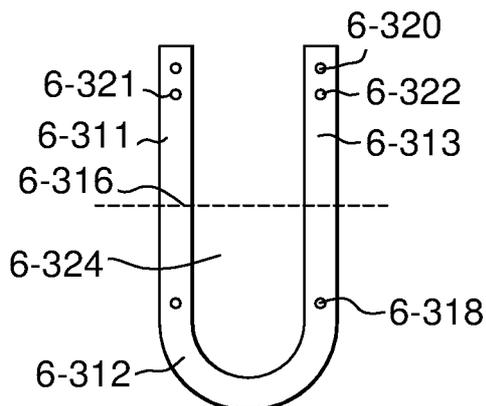


FIG. 30

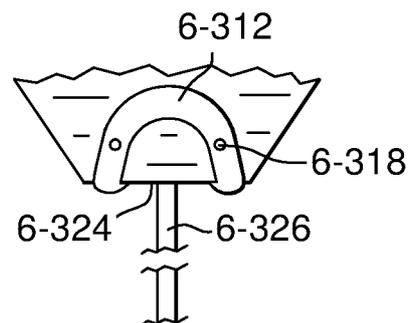


FIG. 31

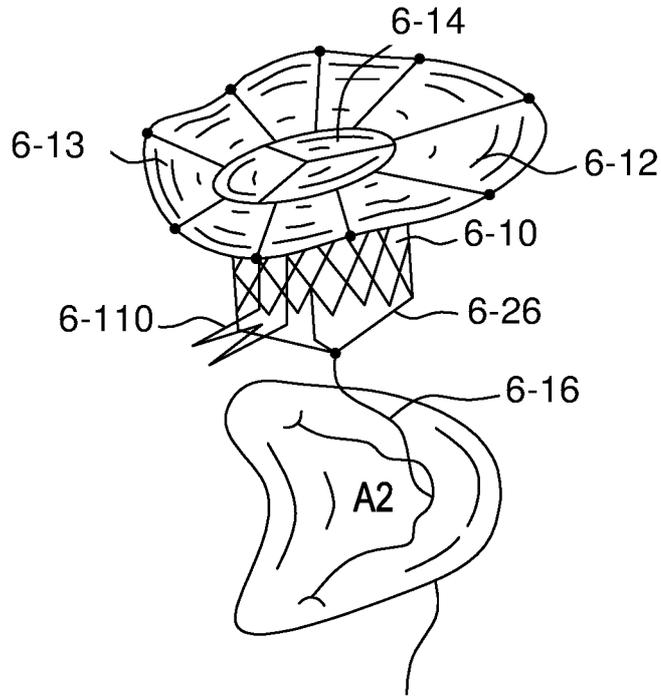


FIG. 32A

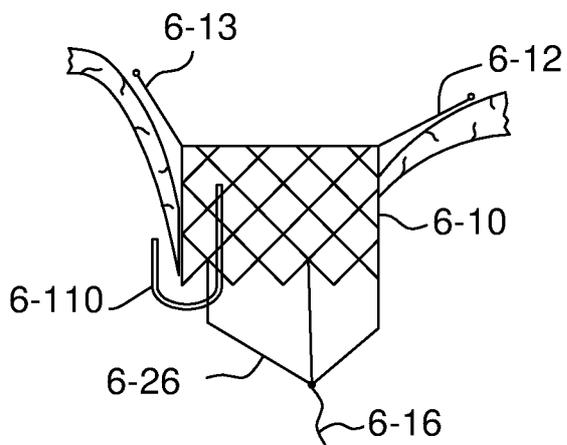


FIG. 32B

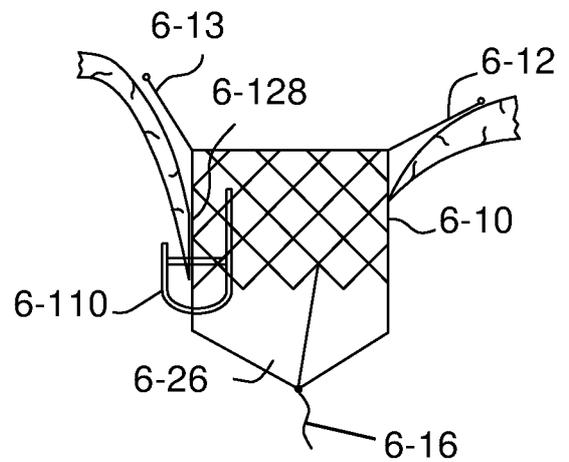


FIG. 33

