

TRANSCATHETER ANCHOR SUPPORT, SYSTEMS AND METHODS OF
IMPLANTATION

Cross Reference to Related Applications

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[0001] This application claims the priority of U.S. App. Nos. 63/122,934 (filed Dec. 8, 2020), 63/058,763 (filed July 30, 2020), 62/964,371 (filed Jan. 22, 2020) the disclosure of each are incorporated herein by reference.

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FIELD OF INVENTION

[0002] The present invention relates generally to medical devices and systems for minimally invasively being implanted into the heart and methods of implantation of these devices and systems. More specifically, the invention pertains to medical devices and systems which are implanted minimally invasively into any wall of the heart, using one or more anchor supports.

SUMMARY OF INVENTION

[0003] Presented herein are medical devices and systems which are implanted minimally invasively into any wall of the heart, using one or more anchor supports. The valve anchoring system presented herein includes a single-stage anchor support or a two-stage anchor support, each consisting of a distal flange, and an anchor. The two-stage anchor support additionally includes a proximal flange. The anchor cooperates with an appropriate heart wall to implant the anchor support to the heart wall. The distal flange is introduced with a distal flange sheath through the anchoring member, such as the anchor coil, and through to the opposing side of the heart wall and expands within the cardiac space to secure the anchor support. Regarding the two-stage anchor support, a proximal flange delivery catheter delivers the proximal flange, to the proximal end of the distal flange and cooperates therewith to conform to the heart wall opposing the distal flange.

[0004] The anchor support including the anchor is configured to cooperate with an anchor support delivery cable, which can be used for delivery of a tether assembly; this system may connect to any type of intracardiac prosthesis including, but not limited to, a transcatheter

valve replacement (complete or hemi-valve replacement), valve repair system (chordal replacement, coaptation element, leaflet augmentation device, or annuloplasty ring), myocardial remodeling device, or ventricular assist device, securely anchoring any of these devices to a respective intracardiac wall. In one aspect, the anchoring system is delivered completely
5 endovascularly, using a support delivery system, without the need for chest or cardiac incisions.

[0005] With regard to the two-stage anchor support, the distance between the distal and proximal flanges is not fixed and is variable depending on the heart wall thickness or application. Additionally, the physical properties of the distal and proximal flanges may selectively differ. The flexible compression element of the proximal flange allows it to be positioned securely at a
10 variable distance from the distal flange depending on the thickness of the intracardiac wall. Additionally, as the flex connector of the distal flange is pulled in tension by the tethering system, the flexible compression element pushes the proximal flange away from flex connector base towards the intracardiac tissue. This system of forces increases mechanical stability of the anchor support and replicates the effect of a cantilevered beam, enabling redirection of the
15 tensile force as displaced from the intracardiac wall anchoring site.

[0006] The system including the anchor support comprises a trans-septal guide catheter, anchor delivery guide, and an anchor support delivery system. The anchor support delivery system comprises an anchor, anchor torque driver, microcatheter with screw tip dilator, support delivery control handle, and anchor support.

[0007] According to the single-stage anchor support, the anchor support is composed of a distal flange and according to the two-stage anchor support, the anchor support is composed of a distal and proximal flange. According to both aspects, the distal flange may take various geometric forms, including, but not limited to, a generally disc-like form or a three-dimensional form. The distal flange includes an anchor restraint (shown as a disk and other configurations),
20 support rod, flex connector (in the form of a wire or flexible coil), and flex connector base. In the single-stage anchor support, the distal flange connects, via the support rod, to the flex connector, which connects to the flex connector cap, which serves as a docking element for the tether assembly. The two-stage anchor support incorporates all the elements of the distal flange, but also has a proximal flange, which is composed of an anchor restraint (for example, disk)
25 flexible compression element, and docking element to secure the proximal portion of the flexible compression element to the flex connector of the distal flange, just under the flex connector cap
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The distal flange has a cap at its terminal end, and the cap may take the shape of a portion of a sphere or of any polyhedron. Each face of the disk comprises a variable thickness or diameter, and may be shaped like a circle, ellipse, any polygon. In either the one or two-stage anchor support, attached to the distal flange is a rod, which can be of variable thickness and length, taking the shape of a circular or elliptical cylinder, or taking the shape of a prism with any polygonal cross-sectional shape. The distal flange selectively includes additional metal or plastic fixation elements that lock the position of the anchor support relative to the anchor. The proximal end of the rod connects to the flex connector.

[0008] The flex connector is selectively composed of any metal alloy such as a flexible nitinol wire or a variably pitched nitinol spring with variable thickness and length has variable flexibility along its length. The flex connector optionally is also covered by any biological or synthetic membrane as described above. The flex connector base is composed of a preselected material including any metal alloy and be of any shape. Further, the proximal end of the tether cap may define an internal “female” thread, which can accept “male” threads of a distal end of an anchor support delivery cable, although other means of attaching the anchor support delivery cable to the flex connector base are not excluded. Finally, the flex connector base can serve as a docking member for a tether assembly to connect the tether swivel to an intracardiac prosthesis such as a valve replacement.

[0009] The proximal flange is distal to the flex connector base and extends around the flex connector and the connector rod of the distal flange. The proximal flange has a restraint, abutting the anchor base of the anchor and around the proximal portion of support rod and distal portion of the flex connector of the distal flange, has a restraint face that may be of variable thickness or diameter, and may be shaped like a circle, ellipse, or any polygon. Also, the proximal flange restraint may take the same or different shape and may bend in a concave or convex fashion towards the intracardiac wall. The proximal flange restraint has a central lumen of any shape or diameter such that the it can be advanced over the flex connector and support rod. Extending from this lumen on the proximal side of the proximal flange restraint is a flexible compression element, which may be a helical coil or conical coil of any thickness, radius, pitch, helix angle, or cone angle. Alternatively, the flexible compression element may take the shape of any spring with an alternative cross-sectional shape, such as a square, rectangle, or any polygon, or take the form of any compression element designed to handle an axial load. Attached to the

proximal portion of the compression element is a docking element in the shape of a circular or elliptical cylinder or taking the shape of a prism with any polygonal cross-sectional shape. The docking element may have, anywhere along its length or radius, one or more extension members of any shape, and the element has a lumen of any diameter or shape that allows the element to go
5 over the flex connector base. Once the element has advanced over the flex connector base, either the shape of the element or extension members external or internal to the element's lumen prevent the element from moving proximal to the base of the flex connector base.

[0010] The anchor support or portions thereof may be formed of an appropriate material including any metal alloy, such as, but no limited to, nitinol, stainless steel, titanium, or cobalt
10 chromium, and any portion of the anchor support is optionally covered with biological tissue, such as bovine, ovine, porcine, or equine pericardium, or synthetic membranes such as, but not limited to, polytetrafluoroethylene (PTFE) or polyethylene terephthalate (PET).

[0011] According to various aspects, the anchor comprises an anchor coil and an anchor base. The anchor coil may comprise any appropriate helical device, or the anchor coil may be an
15 inclined plane wrapped around a nail-like head, or a type of Archimedes-type screw, and be "right-handed" or "left-handed". The anchor coil is composed of any appropriate material including a metal alloy, such as, but not limited to, nitinol, stainless steel, titanium, or cobalt-chromium, and is optionally covered by any biological or synthetic membranes as is possible for anchor support described above. To facilitate penetration of the tissue, the tip of the anchor coil
20 has, according to one aspect, a different diameter or cross-sectional shape as the rest of the coil; for example, the tip is, but is not limited to, the shape of a barb, hook, prong, or the like.

[0012] According to various aspects, the tether assembly consists of a tether swivel, composed of any metal or metallic alloy, and tethers, composed of, but without limitation, expanded polytetrafluoroethylene (ePTFE), ultra-high molecular-weight polyethylene
25 (UHMWPE or UHMW), nitinol wire, or any known surgical suture. The tether swivel further consists of a tether ring, one or more locking arms, with or without one or more tether arms. The locking arms and tether arms have a variable length and thickness and are spaced equally or at variable distances along the circumference of the tether ring. The tether arms have distal coupling members, in the shape of eyelets, but without limitation in shape, that attach to tethers.

[0013] In one aspect, prior to docking of the tether system, the anchor torque driver
30 remains attached to the anchor coil during fixation of the anchor coil to the cardiac wall. Fixation

occurs by rotation of the anchor coil knob of the anchor support delivery control handle, thereby rotating the torque driver, which rotates the anchor coil via engagement with the anchor base. In another aspect, after fixation of the anchor coil to the wall, rotation of the microcatheter delivery knob of the anchor support delivery control handle rotates the microcatheter with screw tip
5 dilator, driving the screw tip dilator and associated microcatheter across the interventricular septum (or another cardiac wall). Once microcatheter has traversed the septum (or other cardiac wall), the screw tip dilator is removed. In a further aspect, the distal flange of either the single or two-stage anchor support is pushed by the support delivery cable through the microcatheter until the anchor restraint exits the end of the microcatheter and is deployed. After deployment, the
10 microcatheter is removed, allowing the anchor torque driver to be disengaged from the anchor base of the anchor coil, which remains fixed into the cardiac wall.

[0014] In another aspect, the anchor support delivery cable is used as a guidewire for delivery of the proximal flange. Over the guidewire, the proximal flange delivery sheath, attached to the docking element of the proximal flange, pushes the proximal flange to the end of
15 anchor delivery guide. Once the proximal flange exits the distal end of the anchor delivery guide, the proximal flange restraint expands, and is pushed by the proximal flange delivery sheath (attached to disk via the flex coil and docking element) until the proximal flange restraint abuts the intracardiac wall near the anchor base. Continued pushing of the proximal flange advances the docking element and flexible compression element over the flex connector until the docking
20 element goes past the flex connector base, at which point the element cannot be retracted past the flex connector base. The proximal flange delivery sheath is disengaged from the docking element, leaving the proximal flange and anchor support delivery cable in place.

[0015] In another aspect, the anchor support delivery cable is used as a guidewire for the docking of the tether assembly onto the flex connector base of the flex connector. After docking
25 of the tether assembly and associated intracardiac device, the anchor support delivery cable is unscrewed or otherwise disengaged from the flex connector base, thereby fully deploying anchor support system.

[0016] In another aspect, before deployment of distal flange according to one aspect of the invention, the anchor is retrieved and redeployed if an alternative anchoring site is desired.
30 Specifically, the anchor torque driver is rotated in opposite direction, thereby turning the anchor base and attached anchor coil so that the anchor coil disengages from the tissue. After anchor and

anchor support delivery, the anchor support is capable of being retrieved and redeployed if it is interfering with intracardiac structures such as papillary muscles, chordal or valvular apparatus. Alternatively, the anchor support may be removed, leaving the anchor in position, and another anchor and support may be deployed at an alternative site.

5 **[0017]** Presented herein are anchor supports for supporting medical devices and systems which are implanted minimally invasively into any wall of the heart, such as a heart valve to replace a native heart valve. The anchoring devices includes an anchor support, with or without an anchor, and a tether assembly. According to one aspect, the distal end of the anchor support cooperates with an anchor and the proximal end of the anchor support cooperates with a tether
10 assembly. According to another aspect, the distal end of the anchor support connects to a cardiac wall directly and connects to the tether assembly. The anchor support thus connects to a tether assembly that connects to the intracardiac device or implant, such as a transcatheter valves, and securely anchors the to a respective intracardiac wall. In one aspect, the anchor support is delivered completely endovascularly, using a support delivery system, followed by delivery of
15 the tether assembly without the need for chest or cardiac incisions. In one aspect, the system comprises a trans-septal guide catheter, anchor delivery sheath, and an anchor support delivery system. The anchor support delivery system comprises an anchor, anchor torque driver, microcatheter with screw tip dilator, support delivery control handle, and anchor support. In another aspect, the system comprises a trans-septal guide catheter, anchor delivery sheath, and
20 anchor support delivery system without an anchor. In this aspect, instead of being secured to the wall with an anchor, the anchor delivery sheath is secured to the cardiac wall by protrusions, spikes, barbs, claws, microneedles, or suction mechanisms. In another aspect, the anchor support delivery system comprises a microcatheter that functions without a screw tip dilator, but with an alternative dilator. In this aspect, the microcatheter is coupled with either a radiofrequency tip
25 dilator, helical coil tip dilator, needle tip dilator, rotating tip drill dilator, oscillating tip dilator, or laser tip dilator.

30 **[0018]** Related methods of operation are also provided. Other apparatuses, methods, systems, features, and advantages of the medical devices and systems that are implanted minimally invasively in the heart will be or become apparent to one with skill in the art upon examination of the following Figures and detailed description. It is intended that all such additional apparatuses, methods, systems, features, and advantages be included within this

description, be within the scope of the medical devices and systems that are implanted minimally invasively in the heart and be protected by the accompanying claims.

BRIEF DESCRIPTION OF THE FIGURES

5 **[0019]** Figure 1A is a cut-away perspective view of a heart showing a transcatheter heart valve positioned across the mitral valve in the heart and secured to the interventricular septum by the two-stage anchor support according to one aspect of the present invention;

[0020] Figure 1B is a cut-away perspective view of a heart showing a transcatheter heart valve positioned across the mitral valve in the heart and secured to the interventricular septum by
10 the single-stage anchor support according to another aspect of the present invention

[0021] Figure 2A is a cut-away perspective view of a heart showing the transcatheter heart valve positioned across the tricuspid valve in the heart and secured to the interventricular septum by the single-stage anchor support;

[0022] Figure 2B is a cut-away perspective view of a heart showing the transcatheter heart
15 valve positioned across the tricuspid valve in the heart and secured to the interventricular septum by the two-stage anchor support;

[0023] Figure 3 is a cut-away perspective view of a heart showing a transcatheter chordal replacement system for a mitral valve in the heart and secured to the interventricular septum by the anchor support of Figure 1A;

20 **[0024]** Figure 4 is a cut-away perspective view of a heart showing a transcatheter coaptation element for a tricuspid valve in the heart and secured to the interventricular septum by the anchor support of Figure 1A;

[0025] Figure 5 is a cut-away perspective view of a heart showing a transcatheter hemi-valve replacement or leaflet augmentation element for a mitral valve in the heart and secured to
25 the interventricular septum by the anchor support of Figure 1A;

[0026] Figure 6 is a cut-away perspective view of a heart showing a transcatheter left ventricular assist device in the heart secured to the interventricular septum by the anchor support of Figure 1A;

30 **[0027]** Figure 7 is a cut-away perspective view of a heart showing a transcatheter left ventricular remodeling device with both cardiac wall implants secured to the interventricular septum and cardiac wall by the two-stage anchor support;

- [0028] Figure 8 is a side-elevational view of an anchoring member according to one aspect of the present invention;
- [0029] Figure 9 is a side-elevational view of an anchor torque driver;
- [0030] Figure 10 is a cross-sectional view of the anchor torque driver of Figure 9;
- 5 [0031] Figure 11 is a side-elevational view of the anchor attached to the anchor torque driver;
- [0032] Figure 12 is a cross-section view of Figure 11;
- [0033] Figure 13A is a schematically represented, cross-sectional view of a microcatheter for piercing the heart wall and for inserting the distal flange;
- 10 [0034] Figure 13B is a schematically represented view of the microcatheter of Figure 13A and including a screw tip dilator within its lumen;
- [0035] Figure 14A is a perspective view of a distal flange having an anchor restraint according to the present invention;
- [0036] Figure 14B is a side elevational view of a distal flange having an anchor restraint
15 according to another aspect of the invention and having a wire flex connector;
- [0037] Figure 14C is a side elevational view of a distal flange having the anchor restraint shown in Figure 14B with a spring flex connector;
- [0038] Figure 15 is a perspective view of a hollow support delivery cable for delivery the distal flange;
- 20 [0039] Figure 16A is a side elevational view of a tether swivel used at least in connection with the single-stage anchor of Figures 20A-20C;
- [0040] Figure 16B is a side elevational view of the tether swivel of Figure 16A attached to chords;
- [0041] Figure 16C is a side elevational view of the tether delivery system for docking the
25 tether swivel on the flex connector base of the distal flange at least in connection with the single-stage anchor.
- [0042] Figure 17 is a schematic view of a distal flange loader for facilitating distal flange introduction;
- [0043] Figure 18 is a side elevational view, partially schematic, of the anchor support
30 collapsed inside the support loader and connected to the support delivery cable;

- [0044] Figure 19A is a side elevational view of a distal flange having one configuration with support rod through the associated anchor and the wire flex connector extending from the support rod;
- 5 [0045] Figure 19B is a side elevational view of the distal flange of Figure 19A having another configuration;
- [0046] Figure 19C is a side elevational view of a distal flange having one configuration with support rod through the associated anchor and the coil flex connector extending from the support rod;
- 10 [0047] Figure 20A is a perspective view of a distal flange with support rod through the associated anchor with the flex connector of distal flange attached to the support delivery cable;
- [0048] Figure 20B is a side elevational view of the distal flange with the wire flex connector and associated anchor with the delivery cable attached;
- [0049] Figure 20C is a side elevational view of the distal flange with the spring flex connector and associated anchor with the delivery cable attached;
- 15 [0050] Figure 21A is a perspective view of a proximal flange with the docking element comprised of a base and docking arms according to one aspect of the present invention;
- [0051] Figure 21B is a perspective view of a proximal flange with the docking element according to another aspect of the present invention;
- 20 [0052] Figure 22 is a side elevational view of the distal flange of the single-stage anchor support deployed and coupled to the anchor with tether assembly coupled to the flex connector base, which is attached to the delivery cable;
- [0053] Figure 23 is a side elevational view of the proximal flange delivery catheter;
- [0054] Figure 24 is a cross-sectional view of proximal flange delivery catheter;
- [0055] Figure 25 is a perspective view of a proximal flange delivery catheter connected
25 to a proximal flange;
- [0056] Figure 26 is a side elevational view, partially schematic, of the proximal flange collapsed inside the proximal flange loader;
- [0057] Figure 27 is a perspective view of a proximal flange delivery catheter docking a proximal flange onto a distal flange;
- 30 [0058] Figure 28 is a cross-sectional view of Figure 27;

- [0059] Figure 29 is a perspective view of a distal flange coupled to a proximal flange of with the flex connector of the distal flange attached to the support delivery cable;
- [0060] Figure 30 is a perspective view of a distal flange coupled to a proximal flange with the flex connector of the distal flange attached to the support delivery cable;
- 5 [0061] Figure 31 is a perspective view of a distal flange with support rod through the associated anchor, coupled to a proximal flange, with the flex connector of distal flange attached to the support delivery cable, demonstrating the restraints of the two flanges separated to accommodate an intracardiac wall;
- [0062] Figure 32 is a perspective view of Figure 31 with the proximal flange more
10 advanced toward the distal flange than in Figure 31, demonstrating the restraints of the two flanges configured to accommodate a thinner intracardiac wall;
- [0063] Figure 33 is a perspective view of a distal flange with support rod through the associated anchor, coupled to the proximal flange, with the flex connector of the distal flange attached to the support delivery cable;
- 15 [0064] Figure 34 is a perspective view of Figure 33 with the proximal flange more advanced toward the distal flange than in Figure 33, demonstrating the restraints of two flanges configured to accommodate a thinner intracardiac wall;
- [0065] Figure 35 is a schematic illustration of an anchor delivery guide according to the present invention;
- 20 [0066] Figure 36 is a side-elevational view of the anchor support delivery system;
- [0067] Figure 37 is a cross-sectional view of the anchor support delivery system;
- [0068] Figure 38A is a cross-sectional view of the anchor support delivery system;
- [0069] Figure 38B is an enlarged, cross-sectional view of the distal end of the support
25 delivery system of Figure 38A, showing the anchor attached to the anchor torque driver and the microcatheter with screw tip dilator;
- [0070] Figure 39 is a cut-away perspective view of a heart with a trans-septal introducer sheath in delivery position;
- [0071] Figure 40 is a cut-away perspective view of a heart with an anchor delivery sheath advancing into the left ventricle over a guidewire;
- 30 [0072] Figure 41 is a cut-away perspective view of a heart with the anchor delivery sheath positioned next to the interventricular septum;

- [0073] Figure 42A is a cut-away perspective view of a heart with the anchor positioned within the anchor delivery sheath next to the interventricular septum and the anchor support delivery system being introduced;
- 5 [0074] Figure 42B is a magnified cut-away perspective view of a heart with the anchor positioned within the anchor delivery sheath next to the interventricular septum;
- [0075] Figure 43A is a cut-away perspective view of a heart with the anchor coil being screwed into the interventricular septum by the torque driver;
- [0076] Figure 43B is a magnified cut-away perspective view of a heart with the anchor coil being screwed into the interventricular septum by the torque driver;
- 10 [0077] Figure 44A is a cut-away perspective view of a heart with the anchor coil screwed into the interventricular septum and microcatheter with screw dilator being advanced;
- [0078] Figure 44B is a magnified cut-away perspective of a heart with the anchor coil screwed into the interventricular septum and microcatheter with screw dilator being advanced;
- [0079] Figure 45A is a cut-away perspective view of a heart with the anchor coil screwed
15 into the interventricular septum and the microcatheter screw dilator penetrating the septum;
- [0080] Figure 45B is a magnified cut-away perspective view of a heart with the anchor coil screwed into the interventricular septum and the microcatheter screw dilator penetrating the septum;
- [0081] Figure 46A is a cut-away perspective view of a heart with the anchor coil screwed
20 into the interventricular septum and the microcatheter across the septum with the screw dilator removed;
- [0082] Figure 46B is a magnified cut-away perspective view of a heart with the anchor coil screwed into the interventricular septum and the microcatheter across the septum with the screw dilator removed;
- 25 [0083] Figure 47A is a cut-away perspective view of a heart with a microcatheter across the interventricular septum and the distal flange of the two-stage anchor support being inserted into a microcatheter;
- [0084] Figure 47B is a magnified side-elevational view of the distal flange of the two-stage anchor support being inserted into the microcatheter;

- [0085] Figure 48A is a cut-away perspective view of a heart with the microcatheter across the interventricular septum and the anchor restraint of the distal flange of the two-stage anchor support deployed against the interventricular septum;
- 5 [0086] Figure 48B is a magnified cut-away perspective view of a heart with the microcatheter across the interventricular septum and the anchor restraint of the distal flange of the two-stage anchor support deployed against the interventricular septum;
- [0087] Figure 48C is a cut-away perspective of a heart with the microcatheter across the interventricular septum and the anchor restraint of the single-stage anchor support deployed against the interventricular septum;
- 10 [0088] Figure 48D is a cut-away perspective of a heart with the microcatheter across the interventricular septum and the anchor restraint of the single-stage anchor support deployed and expanded against the interventricular septum;
- [0089] Figure 49A is a cut-away perspective view of a heart with the distal flange of the two-stage anchor support deployed and microcatheter being retracted;
- 15 [0090] Figure 49B is a magnified cut-away perspective view of a heart with the distal flange of the two-stage anchor support deployed and microcatheter being retracted;
- [0091] Figure 49C is a cut-away perspective of a heart with the single-stage anchor support deployed and microcatheter being retracted;
- [0092] Figure 49D is a magnified cut-away perspective of a heart with the single stage anchor support deployed and microcatheter being retracted;
- 20 [0093] Figure 50 is a magnified cut-away perspective of the anchor with microcatheter being retracted;
- [0094] Figure 51 is a magnified cut-away perspective of the anchor with microcatheter being retracted and end of torque driver bending inwards;
- 25 [0095] Figure 52 is a perspective view of the torque driver being disengaged and retracted from the anchor;
- [0096] Figure 53A is a cut-away perspective view of a heart with the single-stage anchor support delivered across the septum and connected to the delivery cable;
- [0097] Figure 53B is a magnified cut-away perspective view of a heart with the single-stage anchor support delivered across the septum and connected to the delivery cable;
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- [0098] Figure 53C is a cut-away perspective view of a tether delivery system advancing to the flex connector of the anchor support;
- [0099] Figure 53D is a magnified cut-away perspective view of the tether delivery system advancing to the flex connector of the anchor support;
- 5 [00100] Figure 53E is a cut-away perspective view of a tether assembly docked onto the flex connector base and tether delivery system retracting to expose tethers
- [00101] Figure 53F is a magnified cut-away perspective view a tether assembly docked onto the flex connector base and tether delivery system retracting to expose tethers
- [00102] Figure 54A is a cut-away perspective view of a heart with the distal flange of the
10 two-stage anchor support delivered across the septum and connected to the delivery cable
- [00103] Figure 54B is a magnified cut-away perspective view of a heart with the distal of the two-stage anchor support flange delivered across the septum and connected to the delivery cable;
- [00104] Figure 54C is a cut-away perspective view of a heart with a distal flange of the
15 two-stage anchor support across the interventricular septum and a proximal flange being inserted into the anchor delivery guide;
- [00105] Figure 54D is a magnified side-elevational view of the proximal flange being inserted into the anchor delivery guide;
- [00106] Figure 55A is a cut-away perspective view of a heart with a restraint of a proximal
20 flange exiting the anchor delivery guide;
- [00107] Figure 55B is a magnified cut-away perspective view of a heart with a restraint of a proximal flange exiting the anchor delivery guide;
- [00108] Figure 56A is a cut-away perspective view of a heart with a proximal flange being advanced over the flex connector of the distal flange;
- 25 [00109] Figure 56B is a magnified cut-away perspective view of a heart with a proximal flange being advanced over the flex connector of the distal flange;
- [00110] Figure 57A is a magnified view of Figure 56B;
- [00111] Figure 57B is a magnified perspective view of the proximal flange delivery catheter tip outside of the anchor delivery guide;
- 30 [00112] Figure 57C is a cut-away view of Figure 57B;

- [00113] Figure 58A is a cut-away perspective view of a heart with the distal and proximal flanges deployed against the interventricular septum, with the distal flange connected to the anchor delivery cable;
- 5 [00114] Figure 58B is a magnified cut-away perspective view of a heart with the distal and proximal flanges deployed against the interventricular septum, with the distal flange connected to the anchor delivery cable;
- [00115] Figure 59 is a perspective view of a tapered anchor according to another aspect of the present invention;
- 10 [00116] Figure 60 is a side elevational view of an anchor support with distal inflatable element;
- [00117] Figure 61 is a side elevational view of an anchor support with both distal and proximal inflatable elements;
- [00118] Figure 62 is a side elevational view of an anchor support with radially extending elements with concave bend, in its undeployed form;
- 15 [00119] Figure 63 is a side elevational view of an anchor support with radially extending elements with concave bend, in its deployed form;
- [00120] Figure 64 is a side elevational view of an anchor support with radially extending elements with convex bend, in its undeployed form;
- [00121] Figure 65 is a side elevational view of an anchor support with radially extending
20 elements with convex bend, in its deployed form;
- [00122] Figure 66 is a side elevational view of an anchor support with a helical coil, in its undeployed form;
- [00123] Figure 67 is a side elevational view of an anchor support with a helical coil, in its deployed form;
- 25 [00124] Figure 68 is a side elevational view of an anchor coil ending in a trowel-like element;
- [00125] Figure 69 is a magnified perspective of the trowel-like element;
- [00126] Figure 70 is a side elevational view of an anchor support with a helical coil in a conical shape, in its undeployed form;

- [00127] Figure 71 is a side elevational view of an anchor support with a helical coil in a conical shape, in its deployed form;
- [00128] Figure 72A is a side elevational view of an anchor support with a helical coil shaped like coil in FIG. 56, before it has been pushed through proximal segment;
- 5 [00129] Figure 72B is a side elevational view of an anchor support with helical coil partially pushed through proximal segment;
- [00130] Figure 72C is a side elevational view an anchor support with helical coil pushed through proximal segment and fully deployed;
- [00131] Figure 73 is a side elevational view of an anchor support with covered helix, in its
10 undeployed form;
- [00132] Figure 74 is a side elevational view of an anchor support with covered helix, it is deployed form;
- [00133] Figure 75 is a side elevational view of an anchor support with umbrella-like petals;
- [00134] Figure 76 is a side elevational view of an anchor support with umbrella-like
15 member;
- [00135] Figure 77 is a side elevational view of an anchor support with star-like element in the its undeployed form;
- [00136] Figure 78 is a side elevational view of an anchor support with star-like element in its deployed form;
- 20 [00137] Figure 79 is a side elevational view of an anchor support with pivoting bar in undeployed position;
- [00138] Figure 80 is a side elevational view of an anchor support with pivoting bar in deployed position;
- [00139] Figure 81 is a side elevational view of a fixation element with protrusions,
25 attached to the anchor torque driver;
- [00140] Figure 82 is a cross sectional view of FIG. 81;

- [00141] Figure 83 is a side elevational view of a fixation element with extension members, attached to the anchor torque driver;
- [00142] Figure 84 is a cross sectional view of FIG. 83;
- [00143] Figure 85 is a side elevational view of a fixation element with suction cup,
5 attached to the anchor torque driver;
- [00144] Figure 86 is a cross sectional view of FIG. 85;
- [00145] Figure 87A is a cut-away perspective view of a heart with the fixation element with protrusions of Figure 81 positioned outside tip of the anchor delivery sheath next to the interventricular septum;
- 10 [00146] Figure 87B is a magnified cut-away perspective view of a heart with the fixation element with protrusions of Figure 81 positioned outside tip the anchor delivery sheath next to the interventricular septum;
- [00147] Figure 88A is a cut-away perspective view of a heart with the fixation element with extension members of Figure 83 positioned outside tip of the anchor delivery sheath next to
15 the interventricular septum;
- [00148] Figure 88B is a magnified cut-away perspective view of a heart with the fixation element with extension members of Figure 81 positioned outside tip of the anchor delivery sheath next to the interventricular septum;
- [00149] Figure 89A is a cut-away perspective view of a heart with the fixation element with suction cup of Figure 85 positioned outside tip of the anchor delivery sheath next to the
20 interventricular septum;
- [00150] Figure 89B is a magnified cut-away perspective view of a heart with the fixation element with suction cup of Figure 85 positioned outside tip of the anchor delivery sheath next to the interventricular septum;
- 25 [00151] Figure 90A is a cut-away perspective of a heart with the fixation element secured to the interventricular septum and microcatheter with screw dilator being advanced; Figure 90B is a magnified cut-away perspective of a heart with the fixation element secured to the interventricular septum and microcatheter with screw dilator being advanced;

[00152] Figure 91A is a cut-away perspective view of a heart with the fixation element secured to the interventricular septum and the microcatheter screw dilator penetrating septum;

[00153] Figure 91B is a magnified cut-away perspective view of a heart with the fixation element secured to the interventricular septum and the microcatheter screw dilator penetrating septum;

[00154] Figure 92A is a cut-away perspective of a heart with the fixation element secured to the interventricular septum and the microcatheter across the septum with the screw dilator removed;

[00155] Figure 92B is a magnified cut-away perspective of a heart with the fixation element secured to the interventricular septum and the microcatheter across the septum with the screw dilator removed;

[00156] Figure 93 is a schematically represented view of a microcatheter having a needle tip dilator;

[00157] Figure 94 is a schematically represented view of a microcatheter having a radiofrequency tip dilator;

[00158] Figure 95 is a schematically represented view of a microcatheter having a laser tip dilator;

[00159] Figure 96 is a schematically represented view of a microcatheter having a rotating burr dilator;

[00160] Figure 97 is a schematically represented view of a microcatheter having a helical coil dilator;

[00161] Figure 98 is a schematically represented view of a microcatheter having an oscillating tip dilator;

[00162] Figure 99 is a cut-away perspective view of the anchor support with distal inflatable element of Figure 60 with an anchor, connected to the tethering system;

[00163] Figure 100 is a cut-away perspective view of the anchor support of Figure 60 not associated with an anchor, connected to the tethering system;

- [00164] Figure 101 is a cut-away perspective view of the anchor support with distal and proximal inflatable elements of Figure 61 associated with an anchor, connected to the tethering system
- 5 [00165] Figure 102 is a cut-away perspective view of the anchor support of Figure 61 not associated with an anchor, connected to the tethering system;
- [00166] Figure 103 is a cut-away perspective view of the anchor support of Figure 63 associated with an anchor, connected to the tethering system;
- [00167] Figure 104 is a cut-away perspective view of the anchor support of Figure 63 not associated with an anchor, connected to the tethering system;
- 10 [00168] Figure 105 is a cut-away perspective view of the anchor support of Figure 65 associated with an anchor, connected to the tethering system;
- [00169] Figure 106 is a cut-away perspective view of the anchor support of Figure 65 not associated with an anchor, connected to the tethering system;
- [00170] Figure 107 is a cut-away perspective view of the anchor support of Figure 67
15 associated with an anchor, connected to the tethering system;
- [00171] Figure 108 is a cut-away perspective view of the anchor support of Figure 67 not associated with an anchor, connected to the tethering system;
- [00172] Figure 109 is a cut-away perspective view of the anchor support of Figure 71 associated with an anchor, connected to the tethering system;
- 20 [00173] Figure 110 is a cut-away perspective view of the anchor support of Figure 71 not associated with an anchor, connected to the tethering system;
- [00174] Figure 111 is a cut-away perspective view of the anchor support of Figure 74 associated with an anchor, connected to the tethering system;
- [00175] Figure 112 is a cut-away perspective view of the anchor support of Figure 74 not
25 associated with an anchor, connected to the tethering system;
- [00176] Figure 113 is a cut-away perspective view of the anchor support of Figure 75 associated with an anchor, connected to the tethering system;

[00177] Figure 114 is a cut-away perspective view of the anchor support of Figure 75 not associated with an anchor, connected to the tethering system;

[00178] Figure 115 is a cut-away perspective view of the anchor support of Figure 76 associated with an anchor, connected to the tethering system;

5 [00179] Figure 116 is a cut-away perspective view of the anchor support of Figure 76 not associated with an anchor, connected to the tethering system;

[00180] Figure 117 is a cut-away perspective view of the anchor support of Figure 78 associated with an anchor, connected to the tethering system;

[00181] Figure 118 is a cut-away perspective view of the anchor support of Figure 78 not
10 associated with an anchor, connected to the tethering system;

[00182] Figure 119 is a cut-away perspective view of the anchor support of Figure 80 associated with an anchor, connected to the tethering system; and

[00183] Figure 120 is a cut-away perspective view of the anchor support of Figure 80 not associated with an anchor, connected to the tethering system.

15

DETAILED DESCRIPTION OF THE INVENTION

[00184] The present invention is understood more readily by reference to the following detailed description, examples, and claims, and their previous and following description. Before
20 the present system, devices, and/or methods are disclosed and described, it is to be understood that this invention is not limited to the specific systems, devices, and/or methods disclosed unless otherwise specified, as such can, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular aspects only and is not intended to be limiting.

25 [00185] The following description of the invention is provided as an enabling teaching of the invention in its best, currently known aspect. Those skilled in the relevant art will recognize that many changes can be made to the aspects described, while still obtaining the beneficial results of the present invention. It will also be apparent that some of the desired benefits of the present invention can be obtained by selecting some of the features of the present invention

without utilizing other features. Accordingly, those who work in the art will recognize that many modifications and adaptations to the present invention are possible and can even be desirable in certain circumstances and are a part of the present invention. Thus, the following description is provided as illustrative of the principles of the present invention and not in limitation thereof.

5 **[00186]** As used herein, the singular forms “a,” “an” and “the” include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to a “tether” includes aspects having two or more tethers unless the context clearly indicates otherwise.

10 **[00187]** Ranges can be expressed herein as from “about” one particular value, and/or to “about” another particular value. When such a range is expressed, another aspect includes from the one particular value and/or to the other particular value. Similarly, when values are expressed as approximations, by use of the antecedent “about,” it will be understood that the particular value forms another aspect. It will be further understood that the endpoints of each of the ranges are significant both in relation to the other endpoint, and independently of the other endpoint.

15 **[00188]** As used herein, the terms “optional” or “optionally” mean that the subsequently described event or circumstance may or may not occur, and that the description includes instances where said event or circumstance occurs and instances where it does not. For the purposes of describing and defining the present invention it is noted that the use of relative terms, such as “substantially”, “generally”, “approximately”, and the like, are utilized herein to represent an inherent degree of uncertainty that is attributed to any quantitative comparison, value, measurement, or other representation. These terms are also utilized herein to represent the degree by which a quantitative representation may vary from a stated reference without resulting in a change in the basic function of the subject matter at issue.

20 **[00189]** As used herein, “distal” refers generally to the operative end of a member or facing the direction of implantation and “proximal” refers generally to the end of a member facing direction of introduction or facing the user performing the implantation. As used herein, a “restraint” in terms of the anchor restraint **43** of the distal flange **41** and the anchor restraint of the proximal flange **210** may be of various geometric configurations, planar or multi-dimensional, without departing from the scope of the application. Particularly with regard to the

distal flange **41**, for the sake of discussion, a distal anchor restraint in the form of a disk is often shown and described.

[00190] The anchor support **40**, and medical systems and methods including the anchor support **40**, comprises either a single-stage anchor support **45** or a two-stage anchor support **245**.
5 The anchor support **40**, either a single-stage **45** or two-stage **245**, includes a distal flange **41** which is implanted with a single-stage flange delivery step. The anchor support **40** having a two-stage anchor support **245**, also includes a proximal flange **210** and a second-stage delivery step for its implantation. The anchor support **40** thus includes at least a distal flange **41** and an anchor securing member **21** such as coil **21** extending distally from an anchor cap **23**. The distal
10 flange **41** is implanted into the heart wall through the center lumen of the anchor coil **21** as explained below. Extending proximally from the distal flange **41** is a flex connector **47** which may be either a wire **47** or a coil **48**. With regards to the two-stage anchor support **245**, the flex connector **47** extends between the distal **41** and proximal **210** flanges and a flexible compression element **204** extends proximally from the proximal flange **210** and a docking element **206/211** is
15 positioned on its proximal end. The proximal flange **210** is introduced over the flexible connector **47** and the flex connector base **49** wherein the docking element **206/211** is pushed over the flex connector base **49** and the docking arms **208/213** spring inward to secure the proximal flange **210**. In all aspects, the system including the anchor support **40** is minimally invasively endovascularly implanted in the heart **1**. The distal flange **41** and proximal flange **210**
20 possesses different configurations as represented in the various Figures and discussed below. The anchor support **40** may also be secured with means of a any distal flange shown in Figures 60-80 as explained below, with or without an anchor coil **21**.

[00191] Tethering systems **110** and locking systems **300** are provided for use with the anchor supports **40**. Additionally, methods and systems for endovascularly introducing and
25 implanting anchors **20** and anchor support **40** to a cardiac wall using anchor delivery sheath **130**, anchor support delivery system **140**, and proximal flange delivery catheter **220** are described. The anchor support **45** or **245** is connected to a tethering system **110** and may be secured by locking system **300**, to anchor an intracardiac implant, such as a valve **100** in the heart. The intracardiac implant may be connected to another intracardiac implant with or without an
30 extension member in between. This application also relates to use of this system for the implantation of other intracardiac implants, such as valve repair devices (e.g. chordal repair

systems **400**, valve coaptation devices **500**, leaflet augmentation systems **600**, or annuloplasty rings), ventricular remodeling devices **800**, or other cardiac implants such as transcatheter ventricular assist devices **700**. FIGS. 1A and 1B illustrates the transcatheter valve **100** which has been implanted to the replace the native mitral valve (for example) according the medical assembly disclosed herein. FIG. 2A and 2B illustrate the valve **100** implanted to replace the native tricuspid valve. FIG. **3** illustrates the transcatheter chordal system **400** implanted to provide chordal support to the native mitral valve. FIG. **4** illustrates the coaptation element **500** implanted to facilitate coaptation of the native tricuspid leaflets. FIG. **5** illustrates the hemi-valve or leaflet augmentation device **600** implanted to improve function of the native mitral valve. FIG. **6** illustrates the transcatheter left ventricular assist device **700** implanted to improve function of the left ventricle. FIG. **7** illustrates the transcatheter left ventricular remodeling system **800**. The heart, of course, includes the left atrium **5**, mitral valve **6**, left ventricle **7**, interventricular septum **8**, right ventricle **9**, tricuspid valve **10**, and right atrium **11**. The replacement valve **100** is positioned either to replace the mitral valve **6** or the tricuspid valve **10**, or other intracardiac implants are positioned as shown in the various Figures. As shown and described in FIGS. 1A, 1B, 2A, 2B, by way of example, the anchor support **40** is used to secure a transcatheter valve to a tethering system **110** and locking system **300**.

The Anchor

[00192] Referring now to FIG. **8**, the anchor support **40** includes an anchoring member, which as shown in numerous figures, is an anchor coil **21** and anchor cap **23**. The description which immediately follows refers to the an anchor coil **21** but it is to be appreciated that other anchoring members such as shown in other figures may replace the coil **21** without departing from the scope of the present invention. In one aspect, the anchor coil **21** is coupled to and extends from the distal end **27** of anchor cap **23**. The anchor cap **23** has coupling recesses **24** configured to attach to an anchor torque driver **143**. The anchor coil **21** of anchor **20** is configured to securely attach to an intracardiac wall such as the interventricular septum **8** of the heart **1**. The anchor coil **21**, as shown, is sized and configured as a helix to fix to an intracardiac wall and has an open central lumen. Optionally, however, the anchor coil **21** may be differentially sized (longer or shorter depending on patient-specific anatomy of the cardiac wall to which it attaches) and configured as an inclined plane, nail-like head, or as any other type of screw that would be known to those skilled in the art. In one aspect, the coil is composed of any known metal alloy,

including, but not limited to, nitinol, titanium, or cobalt-chromium. In another aspect, the coil **21** may be covered in synthetic membranes such as polytetrafluoroethylene (PTFE), expanded polytetrafluoroethylene (ePTFE) or polyethylene terephthalate (PET). In another aspect, the coil **21** may be covered in biological tissue, such as bovine, ovine, porcine, or equine pericardium, or with any combination of anti-inflammatory drugs or other natural or synthetic compounds that might promote healing and limit inflammation. A tip(s) **22** of the anchor coil **21** optionally is constructed and/or coated with the same or different materials as the anchor screw **21** and may be fashioned as a blunt or sharp tip.

[00193] In use, the anchor **20** is secured to the cardiac wall by rotating anchor coil **21** until tip(s) **22** is at a desired depth in the cardiac wall. The depth to which anchor coil **21** is screwed in an adjustable manner according to not only the location within the heart but also the specific anatomy of a patient. For example, the anchor coil **22** may be implanted more deeply into the thicker portion of the interventricular septum, or more deeply into a patient with a thicker interventricular septum. By reversing the rotation of the anchor coil **21**, the anchor **20** is removed safely from the cardiac wall, either to be repositioned, or to be removed entirely.

[00194] Rotation of anchor coil **21** occurs when the anchor torque driver **143**, shown in Figures 9-13B, rotates the anchor cap **23** via the coupling of the anchor cap to the anchor torque driver distal end **146**. The distal end **146** the anchor torque driver **143** comprises coupling arms **147**, which have coupling tabs **148** that connect to the anchor cap **23** via the coupling recesses **24**. The coupling tabs **148** remain outwardly expanded and attached to the coupling recesses **24** as long as the microcatheter **161** remains within this junction. Once the microcatheter **161** is retracted, the coupling tabs **148** may move inwards and away from the coupling recesses **24**, allowing the anchor torque driver **143** to disengage from the anchor cap **23** of the anchor **20**. The recesses **24** possesses any length, width, or polygonal shape to be complementary to coupling tabs **148**.

The Distal Flange of the Anchor Support

[00195] Referring to Figures 14A-C, the distal flange **41** consists of a cap **42**, disk **43**, proximal portion **44** of disk **43**, rod **46** ending in flex connector **47**, attached to flex connector base **49**. The cap **42** may take the shape of a portion of a sphere or any polyhedron. The disk **43** may be of any thickness or diameter, and may be circular, ellipsoid, polygonal, or be composed of one or more interconnecting polygonal shapes. In one aspect, the disk **43** or rod **46** are

preferably composed of nitinol, but may composed of any known metal alloy, including, but not limited to titanium, or cobalt-chromium. In another aspect, the disk **43** or rod **46** can have additional fixation members (not shown) extending from any portion of surface to provide further engagement with tissue. Distal flange **41** includes a rod **46** attached to a flex connector **47**
5 composed of a nitinol wire in Figures 14A and 14B and a flex connector **48** composed of a nitinol spring in Figure 14C.

[00196] Flex connector **47/48** may have variable diameter, length, coil pitch and be composed of additional metallic alloys or polymeric plastics. In another aspect, any portion of the distal flange **41** may be covered in synthetic membranes such as polytetrafluoroethylene (PTFE), expanded polytetrafluoroethylene (ePTFE) or polyethylene terephthalate (PET), or
10 covered in biological tissue, tissue, such as bovine, ovine, porcine, or equine pericardium, or with any combination of anti-inflammatory drugs or other natural or synthetic compounds that might promote healing and limit inflammation.

[00197] Referring to FIG. **15**, the distal flange delivery cable **60** includes a flexible
15 delivery wire **62** having a distal threaded end portion **61** positioned on or formed in the distal end of the delivery wire **62**. The delivery wire **62** is constructed of, but not limited to, stainless steel, nitinol or other metal alloys, with or without hydrophilic coatings, or with or without a polymer coating such as polytetrafluoroethylene (PTFE), expanded polytetrafluoroethylene (ePTFE) or polyethylene terephthalate (PET). The distal threaded end portion **61** is sized and configured to
20 selective engage complementary threads formed in a cavity defined in the end **50** of the flex connector base **49**. In use, before distal flange delivery, the distal threaded end portion **61** has been screwed into the end **50** of the flex connector base **49** of the flex connector **47** of distal flange **41**, forming the distal flange delivery cable assembly which has been loaded in the distal flange support loader **80** (Figure **17**) and the distal flange support holder/loaded flange **90** is used
25 to introduce the anchor support into microcatheter **161**. As described more fully below, at the end of procedure after distal flange **41** delivery, with or without proximal flange docking, the distal threaded end portion **61** is unscrewed from the end **50** of the flex connector base **49**, thereby detaching the flexible delivery wire **62** of the distal flange delivery cable **60** from the distal flange **41**.

30

The Proximal Flange of the Anchor Support

[00198] Referring to Figures 21A-B, the proximal flange **210** consists of disk **201**, lumen **202**, proximal connector **203**, and flexible compression element **204**. Proximal flange **210** has docking element **206** (Figure 21A) or **211** (Figure 21B). Figure 21A shows a docking element **206** comprising distal end **207**, at least one docking arms **208**, and at least one external arm **209**.
5 Figure 21B depicts a proximal flange **210** has docking element **211** comprised of distal end **212**, and docking arms **213**. The disk **201** may take the shape of like a circle, ellipse, or any polygon, be of variable thickness or diameter, and may take the same or different shape as the distal flange disk. Also, the disk and may bend in a concave or convex fashion towards the intracardiac wall, or take a frustoconical or any polyhedral shape towards the intracardiac wall. Connected to the
10 proximal side of the disk **201** is the proximal connector, which may take the shape of a column, cylinder, or prism with any polygonal cross-section, and is connected to a flexible compression element **204**, which may be a helical coil or conical coil of any thickness, radius, pitch, helix angle, or cone angle. Alternatively, the flexible compression element may take the shape of any spring with an alternative cross-sectional shape, such as a square, rectangle, or any polygon, or
15 take the form of any compression element designed to handle an axial load. Attached to the proximal portion of the compression element **204** in proximal flange **210** is a docking element **206** in the shape of a circular or elliptical cylinder, or taking the shape of a prism with any polygonal cross-sectional shape. Docking element **206** has one or more docking arms **208** of any shape, thickness, width, height, that bend towards the center at same or different angles, and may
20 be found anywhere around the perimeter of the docking element. The docking element **206** has one or more external arms **209**, and an end **207**. Docking element **211** may have any of the shape properties of docking element **206**, without the external arms **209**, and has docking arms **213**. The lumen **202** starts at the end of disk **201** and continues through the proximal connector **203**, is in continuity with the internal channel of the flexible compression element **204**, which is
25 continuity with the internal channels and ends **207** and **212** of docking elements **206** or **211**, respectively. Any of the components of proximal flange **210** are preferably composed of nitinol, but may composed of any known metal alloy, including, but not limited to titanium, or cobalt-chromium. In another aspect, any portion of the proximal flange **210** may be covered in synthetic membranes such as polytetrafluoroethylene (PTFE), expanded polytetrafluoroethylene (ePTFE) or polyethylene terephthalate (PET), or covered in biological tissue, tissue, such as
30 bovine, ovine, porcine, or equine pericardium, or with any combination of anti-inflammatory

drugs or other natural or synthetic compounds that might promote healing and limit inflammation.

The Proximal Portion of the Anchor Support and Tethering System

5 [00199] As shown in Figures 16A-B, a tether swivel base **112** having at least one tether swivel locking arm **113** and at least one tether swivel chord arm **114** is provided. As shown, a distal end of the swivel locking arm **113** and tether swivel chord arm **114** are securely coupled to or formed monolithically with the tether swivel base **112**. As shown, the plurality of tether swivel locking arms **113** and tether swivel chord arms **114** are spaced equally around the circumference
10 of the tether swivel base **112**, though it is contemplated that the locking arms **113** and chord arm **114** need not be spaced equally. An eyelet **116** is defined by the tether swivel chord arm **114**. The eyelet **116** is coupled to one or more chords **117**.

[00200] In one aspect, when tether assembly **110** is coupled to anchor support **45** and anchor **21**, the tether assembly **110** has freedom to rotate about a longitudinal axis of the anchor
15 support **45** a full 360 degrees. Optionally, in another aspect, the tether assembly **110** may be constrained to lesser degrees of rotation by interaction of a portion of the tether assembly **110** with the flex connector base **49**.

[00201] As shown, in another aspect, coupling occurs when the tether assembly **110** is advanced over the flexible delivery wire **62** of the anchor support delivery cable **60**. As the tether
20 swivel base **112** advances over the proximal end **50** of flex connector base **49**, the proximal end **50** pushes the tether swivel locking arms **113** outward, until the arms advance underneath the proximal end **50**, when they spring back into original position thereby locking the tether assembly **110** to the flex connector base **49** and therefore to the rest of the anchor support **45** and associated anchor support **45**. Any portion of the tether assembly may be composed of any metal
25 or metal alloy, and the chords may be composed of any combination of nitinol wire, any surgical suture, expanded polytetrafluoroethylene (ePTFE) or ultra-high-molecular-weight polyethylene (UHMPWE or UHMW).

The Anchor Support Assemblies

[00202] As shown in Figures 28A-28C, after anchor support **40** delivery to the
30 interventricular wall, distal flange delivery cable assembly is delivered through the anchor coil

21. Once fully deployed, the anchor support disk **43** is past the tip of **22** of anchor coil **21**, with the anchor support rod **46** extending through the center of the anchor coil **21** and anchor cap **23**, and the flex connector **47** extending proximally from the anchor cap **23**, and remains connected to the distal flange delivery cable **60** via the attachment of the distal threaded end **61** to the end
5 **50** of the flex connector base **49**. The anchor support delivery cable **60** serves as a guide wire for the proximal flange **210**. In anchor support **245**, as shown in Figures 29-34, the proximal flange **210** has been advanced over the flex connector **47** of distal flange delivery cable assembly with the flex connector **47** extending through lumen **202**, through flexible compression element **204**, and through docking element **211**. The end **212** of docking element **211** is below end **50** of flex
10 connector base **49**, and the locking arms **213** are flexed toward the segment of flex connector **47** just below the flex connector base **49** so that the docking element **211** prevents the proximal flange **210** from moving proximally relative to the flex connector **47**. Because the docking element **211** or **206** is fixed relative to the flex connector base **49**, the flexible compression element **204**, connected via the proximal connector **203**, urges the disk **201** forward. The disks
15 of the distal and proximal flanges can be at variable distances depending on the thickness of the intracardiac wall between the flanges as illustrated in Figures 31-34. After docking of the proximal flange, then anchor support delivery cable **60** serves as a guide wire for delivery of tethering system and locking system.

The Anchor Delivery Sheath

20 [00203] Referring now to Figure 35, the anchor delivery sheath **130** is illustrated. The sheath **130** has a shaft **131**, and a distal end **132**. In another aspect, at least a portion of the shaft **131** is flexible so that the distal end **132** is flexed and positioned at or adjacent to an intracardiac wall such as the interventricular septum **8**. Flexion occurs when the deflection knob **134** of the anchor delivery sheath handle **133** is rotated. The anchor support delivery system **140** is inserted
25 into the lumen **136**, extending from the proximal portion of anchor delivery sheath handle **133** to the distal end **132**.

The Proximal Flange Delivery Catheter

[00204] Referring now to Figures 23-24, shown is the proximal flange delivery catheter **220** with distal end **221**, lumen **222**, and shaft **223**. In one aspect, the distal end **221** reversibly
30 mates with the proximal flange **210** because the docking element **206** or **211** is reversibly

coupled inside the lumen **222** of the distal end **221**. In another aspect, at least a portion of the shaft **223** is flexible so that it can track the curve of the anchor support delivery system **140** and the anchor delivery sheath **130**.

The Anchor and Distal Flange Delivery System

5 **[00205]** Referring now to Figures 35A-38B, the anchor support delivery system **140** for delivering the anchor **21** and deploying the distal flange delivery cable assembly **65** across the interventricular septum is illustrated. The delivery system **140** comprises the anchor **21**, anchor torque driver **143**, microcatheter **161** and screw dilator **162**, access valve **151**, and anchor support delivery handle **150**. As illustrated in Figures 9-10, the anchor torque driver **143** consists of a
10 shaft **144** with inner lumen **149**, ending in distal end **146**, with one or more coupling arms **147** ending in coupling tabs **148** which mate with the coupling recesses **24** of anchor cap **23** of anchor **20**. In another aspect, the anchor driver **143** is coupled to the delivery handle **150** by entering the valve **151**. Rotation of the anchor driver is controlled by the anchor coil knob **152** at distal end of the delivery handle **150**.

15 **[00206]** As illustrated in Figure 13A, the microcatheter **161** has a distal shaft **164** integrated with a proximal control hub **166**. In another aspect, the microcatheter screw dilator **162** with tip **163** resides inside the microcatheter **161**, as illustrated in FIGS. **13B** and **38B**. the microcatheter screw dilator tip **163**, like the anchor coil, may be differentially sized (longer or shorter depending on patient-specific anatomy of the cardiac wall to which it attaches) and
20 configured as an inclined plane, nail-like head, or as any other type of screw that would be known to those skilled in the art. Alternatively the dilator tip **163** may be a cone, sphere, cylinder, or any polyhedral shape for the purpose of penetrating tissue. In one aspect, the coil is composed of any known metal alloy, including, but not limited to, nitinol, titanium, or cobalt-chromium. The microcatheter may be of any diameter or length with lumen to
25 accommodate the microcatheter dilator, and the microcatheter may be composed of any metallic alloy or polymeric plastic.

[00207] As illustrated in Figure 38B, the dilator tip **163** of microcatheter screw dilator **162** and associated microcatheter **161** reside within the anchor cap **23** of the anchor **20**, and the proximal portion of each extend through the lumen of the anchor torque driver **143**. Inside the
30 anchor torque driver **143**, the microcatheter extends into the anchor support delivery handle **150** via the access valve **151**, and the proximal control hub **166** of the microcatheter **161** couples

inside the microcatheter holder **160** within the ground **153** of the anchor support delivery handle **150**.

The Method of Implanting the Anchor

[00208] To install anchor **20** to interventricular septum **8**, as shown in Figure **39**, access is
5 obtained to the femoral vein (not shown) using standard techniques, and a trans-septal crossing
system (not shown) is used to traverse the interatrial septum into the left atrium **5**. Over a wire in
the left atrium **5**, the trans-septal sheath **180** is advanced into the left atrium **5**; the trans-septal
sheath deflector knob **181** is rotated until the trans-septal sheath tip **182** is pointing to the mitral
valve **6**. As shown in Figures 40-41, a j-wire **190** is advanced over into the left ventricle **7**, and
10 the anchor delivery sheath **130** is advanced over the wire into the left ventricle **7**, followed by
removal of the j-wire **190** and the anchor delivery sheath dilator **136**. Next, rotation of the
deflector knob **134** bends the distal tip **132** of the anchor delivery sheath **130** toward the
interventricular septum **8**.

[00209] As shown in FIGS. **42A-B**, the delivery system **140** is inserted into the anchor
15 delivery sheath **130**, until the anchor coil **21** of the anchor **20** extends outside the distal tip **132** of
the anchor delivery sheath **130** and abuts the interventricular septum **8**. As shown in FIGS. **43A-**
B, rotation of the anchor coil knob **152** rotates the anchor driver **143**, which rotates the coupled
anchor cap **23**, thereby driving the anchor coil **21** across the interventricular septum.

The Method of Advancing the Microcatheter

[00210] As illustrated by FIGS. **44-46** once the anchor **20** is secured in the septum, the
20 microcatheter with screw dilator traverses the septum according to the following steps: 1) the
dilator knob **158** is pushed forward until the magnets **159** of the head **155** of the threaded rod **154**
secure the dilator knob **158**, so that the dilator tip **163** extends outside the end of the
microcatheter 2) rotation of the microcatheter control knob **156** rotates the threaded rod **154**,
25 which rotates the microcatheter holder **160**, thereby rotating the proximal control hub **166** of the
microcatheter **161**. This rotation causes the microcatheter **161** and screw tip dilator **162** to rotate
in unison, and both advance across tissue as the dilator tip **163** of the dilator **162** screws through
the tissue 3) Once the microcatheter and screw tip dilator have traversed the tissue, the
dilator knob **158** is pulled out, thereby pulling out screw tip dilator **162**, leaving microcatheter
30 **161** across the tissue for anchor support delivery.

The Method of Implanting the Distal Flange

[00211] As shown in Figures 47A-B, the distal flange **41** collapsed within the distal flange loader **80** is inserted into the proximal end of the anchor support delivery system **140** via the head **155** of the threaded rod **154**. As shown in FIGS. **48A-B**, the distal flange **41** is pushed inside the microcatheter **161** until the disk **43** exits the microcatheter and expands on the other side of the septum. Figures 48C and 48D show the same procedure with the flange **41** according to another aspect of the invention.

[00212] As shown in Figures. 49A-B, reverse rotation of the head **155** of the threaded rod **154** turns the microcatheter holder **160** (Figure 37), thereby turning the proximal control hub **166** of the microcatheter **161** (Figure 13A), so that the microcatheter **161** retracts back out of the junction of the anchor torque driver **143** and the anchor cap **23** of the anchor **20**. When this occurs, as shown in Figures **50-51**, the coupling tabs **148** of the coupling arms **147** of the anchor torque driver **143** are released from the coupling recesses **24** of the anchor cap **23**, thereby allowing the anchor torque driver **143** to be retracted from the anchor **20** as shown in Figure **52**. After the anchor torque driver **143** is disengaged the anchor support delivery system **140** is removed, leaving the distal flange delivery cable **60** in place. The same procedure is shown in Figures 53A and 53B in connection with the alternative distal flange **41**.

The Method of Implanting the Proximal Flange

[00213] As shown in Figures 54A-D, representing a two-stage anchor support **245** having a proximal flange **210**, the proximal flange **210**, attached to the proximal flange delivery catheter **220** and collapsed within the proximal flange loader **280** having lumen **28** in Figure 26, is threaded over the delivery cable **60** and is inserted into the proximal end of anchor delivery guide **130** in Figures 54C and 54D. Proximal flange delivery catheter **220** pushes the proximal flange **210** into the anchor delivery guide **130** when the proximal flange loader **280** is removed. As shown in Figures 55A-B, the proximal flange is pushed out of the anchor delivery guide **130** by the proximal flange delivery catheter **220**, allowing the disk **201** to advance over the flex connector **47** and rod **46** via lumen **202** of proximal flange **210**; once outside the tip of the anchor delivery guide **130**, the disk **201** expands. Continued pushing of the proximal flange delivery catheter **220** advances the disk **201** until it approaches the interventricular septum **8** (or other intracardiac wall) as shown in Figures 56A-56B. Once the disk **201** contacts tissue, the proximal flange delivery catheter pushes the docking element **211** or **206**, compressing the flexible compression element **204** until the docking element **211** or **206** goes over the end **50** flex

connector base **49** of the flex connector **47**. At this point the docking arms **208** or **213** bend inwards towards the flex connector base **49**, locking the docking element below the end **50** of the flex connector base **49**, preventing the docking element and associated proximal flange from moving proximally and the proximal flange is secured in its position. As tension is applied to the flex connector backwards via the tethering/locking systems associated with an intracardiac device, the flexible compression element, expanding against the secured docking element, urges the disk **201** forwards, providing a cantilever force to the anchor and distal flange.

The Method of Implanting the Tether System

[00214] As shown in Figure 53C-D, the tether delivery system **170** is advanced over delivery cable **60** into trans-septal sheath **180**, until the tether delivery system **170** exits the distal tip **182**. As shown in Figures 53E-F, the single stage anchor support **45** is shown. It is to be understood that this is by way of example and the same tether delivery system **170** may be employed with the two-stage anchor support **245**. Tracking over the delivery cable **60**, the distal end **172** of the tether delivery system **170** docks onto the flex connector base **49** of the flex connector **47** or **48**. After coupling of the tether assembly **110** to the flex connector base **49** occurs, the distal end **172** of the tether delivery system **170** may be retracted, leaving the tether assembly **110** connected to the anchor/anchor support assembly, as shown in Figure 53E-F. The tether assembly **110** may be pre-connected to a transcatheter valve **100** or other intracardiac device, and the delivery cable **60** may be detached from the end **50** of the flex connector base **49**, leaving behind, for example, a transcatheter valve connected via the tether assembly to the anchor/anchor support assembly.

The Tapered Anchor

[00215] Referring now to Figure 59, at least one tapered anchor **900** includes a penetrating coil **902**, stacked coil **903**, funneled coil **904**, and docking coil **906**. In one aspect, the penetrating coil **902** is continuous with the stacked coil **903**, which is continuous with the funneled coil **904**, which is continuous with the docking coil **206**. The docking coil **906** with distal end **907** is configured to reversibly attach to the anchor torque driver **143**. The penetrating coil **902** of anchor **900** is configured to securely attach to an intracardiac wall such as the interventricular septum **8** of the heart **1**. The tapered anchor **900**, as shown, is sized and configured as a helix to fix to an intracardiac wall. Optionally, each section of tapered anchor **900** may be differentially

sized by radius, length, or pitch of coil (e.g. wider/narrower radius and/or longer or shorter and/or coil density depending on patient-specific anatomy of the cardiac wall to which it attaches). In one aspect, any section of the tapered anchor **900** is composed of any known metal alloy, including, but not limited to, nitinol, titanium, or cobalt-chromium. In another aspect, any
5 section of the tapered anchor **200** may be covered in synthetic membranes such as polytetrafluoroethylene (PTFE), expanded polytetrafluoroethylene (ePTFE) or polyethylene terephthalate (PET). In another aspect, any section of the tapered anchor **200** may be covered in biological tissue, such as bovine, ovine, porcine, or equine pericardium, or with any combination of anti-inflammatory drugs or other natural or synthetic compounds that might promote healing
10 and limit inflammation. A tip(s) **901** at the end of the penetrating coil **902** of the tapered anchor **200** optionally is constructed and/or coated with the same or different materials as the rest of the tapered anchor **200** and may be fashioned as a blunt or sharp tip.

[00216] In use, the tapered anchor **900** is secured to the cardiac wall by rotating tapered anchor **900** until tip(s) **901** is at a desired depth in the cardiac wall. The depth to which the
15 tapered anchor **900** is screwed in an adjustable manner according to not only the location within the heart but also the specific anatomy of a patient. For example, the tapered anchor **900** may be implanted more deeply into the thicker portion of the interventricular septum, or more deeply into a patient with a thicker interventricular septum. In another aspect, the stacked coil **903** of the tapered anchor **900** has a smaller coil angle, creating a denser coil that prevents the tapered
20 anchor **900** from advancing further once the stacked coil **903** has contacted the cardiac wall. By reversing the rotation of the tapered anchor **900**, it is removed safely from the cardiac wall, either to be repositioned, or to be removed entirely.

[00217] Rotation of the tapered anchor **900** occurs when the anchor torque driver **143** rotates the docking coil **906**, which has coupled to the anchor torque driver distal end **146**
25 (coupling mechanism not shown). The anchor torque driver distal end **146** remains coupled to the docking coil **906**, while the microcatheter **161** is advanced and the anchor support **40** is implanted. After anchor support **40** has been implanted, similar to anchor/anchor support assembly illustrated in 46A-B, the anchor disk **43** abuts the end of the penetrating coil **202** of the tapered anchor **900**, with the funneled coil **904** extending over the proximal portion **44** of the
30 disk **43** and over the rod **46** of anchor support **45**. In another aspect, the docking coil **906** is configured to couple around the flex connector **47** or **48** of anchor support **45**, respectively. The

flex connector base **49** abuts the end **207** of the docking coil **906** of the tapered coil **900**, ready to accept the tether **110** as described above.

Figures 60-120

[00218] Figures 60 -120 generally illustrate alternative configurations of the distal flange anchor restraint and alternative anchoring members other than a coil as shown in the preceding figures. It is to be understood that the distal flanges depicted therein may be employed with a single-stage anchor support or a two-stage anchor support having a proximal flange. The proximal flange anchor restraint may also assume any configurations shown with regard to the distal flange anchor restraint.

10 *The Anchor Support with Inflatable Elements*

[00219] Referring to Figures 60-61, the anchor support **40** may include the anchor support shown in Figure **60** or anchor support **301** shown in Figure **61**. Anchor support, both consist of a distal inflatable element **302**, proximal portion **303** of inflatable element **302**, rod **304** ending in flex connector **306**, attached to flex connector base **307**. The distal inflatable element **302** may take any shape, including a any portion of a (or complete) sphere, cylinder, polyhedron, or torus. The distal inflatable element **302** may contain one or more metallic components, including, but not limited to, nitinol, stainless steel, titanium, or cobalt-chromium, stainless steel, and any portion of the one or more inflatable elements is composed of biological tissue, such as bovine, ovine, porcine, or equine pericardium, or synthetic membranes such as, but not limited to, polytetrafluoroethylene (PTFE) or polyethylene terephthalate (PET). In practice the distal inflatable element **302** is in a collapsed form with low profile until anchor support is in position, at which time any gaseous or liquid element is infused via the distal end **308** of flex connector base **307** such that the gaseous or liquid element goes through a channel (not illustrated) in inner lumen **311**, until it exits proximal portion **303**, thereby inflating distal element **302** until desired shape and size is obtained. In another aspect, proximal portion **303** and rod **304** are preferably composed of nitinol, but may composed of any known metal alloy, including, but not limited to titanium, or cobalt-chromium. In another aspect, the distal inflatable element **302** or rod **304** have additional fixation members (not shown) extending from any portion of surface to provide further engagement with tissue. Flex connector **306** is a nitinol wire like flex connector **47** or maybe a nitinol spring like flex connector **48**. As either a nitinol wire or nitinol spring, flex

connector **306** is of variable diameter, length, coil pitch and be composed of additional metallic alloys or polymeric plastics. Figure 61 illustrates anchor support with all the characteristics of anchor support, but with a proximal inflatable element **309**, that may take any shape and contain any material that distal inflatable element **302** takes, but the shape and/or material of proximal inflatable element **309** may differ from distal inflatable element **302**. Like distal inflatable element **302**, proximal inflatable element **309** begins as a deflated low-profile element and is inflated, at the same or at a different time, via infusion of a gaseous or liquid element via the distal end **308** of flex connector base **307** through a channel (not illustrated) in lumen **311**. According to another aspect, the gaseous or liquid element infused into either inflatable element is exchanged for any type of polymeric resin. Like distal inflatable element **302**, proximal inflatable element **309** can have additional fixation members (not shown) extending from any portion of surface to provide further engagement with tissue. In another aspect, any portion of the anchor support is covered in synthetic membranes such as polytetrafluoroethylene (PTFE), expanded polytetrafluoroethylene (ePTFE) or polyethylene terephthalate (PET), or covered in biological tissue, tissue, such as bovine, ovine, porcine, or equine pericardium, or with any combination of anti-inflammatory drugs or other natural or synthetic compounds that might promote healing and limit inflammation.

The Anchor Support with Radially Extending Elements

[00220] Referring to FIGS. **62-63**, the anchor support **40** may include anchor support **320** which may convert from its undeployed form **321** to its deployed form **322**. Anchor support **320** has a distal securing element **323** in a collapsed form shown in FIG. **52** or in an expanded form shown in FIG. **53**. Distal securing element **323** is composed of one or more extension elements **324** generally bending backwards (concave). These extension elements **324** are connected via element base **325**, which connects to the proximal section **326** of anchor support **320**. The extension elements **324** are preferentially composed of nitinol metal, but any portion of them is composed of any metallic or plastic alloy and is covered anywhere along their length with biological or synthetic membranes. The extension elements **324** is spaced evenly or variably around the long axis of element base **325**. The extension elements **324** is the same or different in diameter and length, and the cross section of each is the cross section of any polygon, circle, or ellipse, and each extension element may generally bend backwards (concave) in the shape of a circle, ellipse, parabola, any sinusoidal curve, or is shaped as the edge of any polygon; it is also

understood that one of more extension elements **324** of distal securing element **323** may bend forwards (convex). The tip of each element is the same as each element, or is, but is not limited to, the shape of a barb, hook, prong, or the like. The components of proximal section **326** have the same structure and function as components **303, 304, 306-308**, in Figures 60-61 except
5 proximal section **326** does not have an inner lumen and does not serve to inflate any element.

[00221] Referring to Figures 64-65, the anchor support **40** includes anchor support **327** which converts from its undeployed form **328** to its deployed form **329**. Anchor support **327** has distal securing element **331** in its undeployed form in Figure 64, or in its deployed form in Figure 65, with extension elements. These extension elements connect via element base **333** to proximal
10 section **334**. Like extension elements **324**, extension elements **332** may have variability in location along the long axis of **333**, may have any variability in material or shape properties. Also, although these extension elements **332** are general bending forwards (convex), one or more of these elements may bend forwards (convex). Proximal section **334** has the same characteristics as proximal section **326**.

15 ***The Anchor Support with Helical Coil***

[00222] Referring to Figures 66-67, the anchor support **40** includes anchor support **340**, which converts from its undeployed form **341** to its deployed form **342**. Anchor support **340** has support coil **343**, shown in its undeployed form in Figure 66, and in its deployed form in Figure 67. Support coil **343** is formed by wire **344**, whose proximal end **347**, is fixed to the distal end
20 **349** of proximal element **348**, and wire **344** is preferentially constructed of nitinol although either one may have any metallic alloy or plastic element, and any portion of either support coil is covered by either synthetic or biological membranes. Support coil **343**, along its length, is differentially sized by radius, length, or pitch of coil (e.g. wider/narrower radius and/or longer or shorter and/or coil density depending on patient-specific anatomy of the cardiac wall to which it
25 attaches). The tip **346** of support coil **343** is the same as rest of the coil, or is, but is not limited to, the shape of a barb, hook, prong, or even a straight rod; for purpose of example, Figures 68-69 illustrate an anchor coil which ends in a trowel element **351**, composed of a trowel bar **352** and trowel head **353**. Finally, proximal element **348** has the same material and shape properties as proximal section **326** in Figure 63.

30 ***The Anchor Support with Helical Coil in Conical Shape***

[00223] Referring to Figures 70-71, anchor support 45 includes anchor support 355 and converts from its undeployed form 356 to its deployed form 357. Anchor support 355 has anchor coil 358, shown in its undeployed form in Figure 70, and shown in its deployed form in Figure 71. Except for the shape of the anchor coil 358, anchor support 355 has all the subcomponents, and material/shape possibilities as anchor support 340.

The Anchor Support with Helical Coil in Two-Stage Process

[00224] Referring to FIGS. 72A-C, anchor support 45 may include anchor support 360, where the anchor coil 361, is similar to anchor support 340 in FIGS. 66-67, but is not directly attached to the tip 367 of proximal section 366. Instead anchor coil 361 is in an elongated form as shown in FIG. 72A, and the proximal end 363 of anchor coil 361 is attached to delivery cable 364. Once proximal section 366 is in position, delivery cable 364 is pushed so that anchor coil 361 moves from the proximal tip 368 of proximal section 366, through channel 369, until the distal tip 362 of anchor coil 361, exits the distal tip 367 of proximal section 366. As the distal tip 362 of anchor coil exits 361, as shown in FIG. 62B, the anchor coil takes its preformed shape; as it exits fully, anchor coil 361 forms its fully preformed shape as shown in FIG. 72C. At this point, delivery cable 364 is disengaged from the proximal end 363 of anchor coil 361. Otherwise, the material and shape properties of anchor support 360 mirror those of anchor support 340 in FIGS. 66-67.

The Anchor Support with Covered Helix

[00225] Referring to FIGS. 73-74, the anchor support 45 includes anchor support 380, which may convert from its undeployed form 381 to its deployed form 382. Anchor support 380 as a distal covered helix 383, in its undeployed form in FIG. 73, and in its deployed form in FIG. 74. The distal covered helix 383 is formed by a support wire 384, which is preferentially constructed of nitinol although it may have any metallic alloy or plastic element, and along its length is differentially sized by radius, length, or pitch of coil. The support wire 384 is covered by synthetic and/or biological membrane 386 across the diameter of each loop, so that helical coil formed by support wire 384 is a covered helix much like a compressed Archimedes screw.

The Anchor Support with Umbrella/Parachute-like Element(s)

[00226] Now referring to FIGS. 75-76, the anchor support 40 includes anchor support 390 shown in FIG. 75, or anchor support 391 shown in FIG. 76. Anchor support 390 has distal

umbrella element **392**. Umbrella element **392** has one or more umbrella petals **393**. Each umbrella petal **393** has a wire frame **394**, preferentially composed of nitinol, although any portion of the frame is any metallic or plastic element and is covered by any synthetic or biological membrane. Spanning the wire frame **394** is a membrane **396**, which may be any synthetic or biological membrane. Each umbrella petal **393** may be the same or different from the other petal, and may take the shape of polygon, circle, ellipse, or sinusoidal curve in the X-Y plane, and any portion may curve in a convex/concave or sinusoidal fashion in the Z-plane toward the cardiac wall. Anchor support **391** has distal parachute element **398**. Parachute element **398** is formed by a wire frame **399**, also preferentially nitinol, although any portion of the frame may contain any metallic or plastic element and is covered by any synthetic or biological membrane. The parachute element **398** may take the shape of any parachute or sail-like shape, may have any number or shape of struts (not shown) spanning the element **398**, and is covered by any type of synthetic or biological membrane. Finally, proximal elements **397** and **402** have the same material and shape properties as proximal section **326** in FIG. **63**.

The Anchor Support with Star-like Element(s)

[00227] Now referring to FIGS. **77-78**, the anchor support **40** includes anchor support **410**, which converts from its undeployed form **411** to its deployed form **412**. Anchor support **410** has a star element **413** that traverses the septum as a slotted hypotube with a distal end **414**, proximal end **416** and one or more deformable members **417** between the ends. The star element **413** is preferably composed of cobalt-chromium and nitinol, although any portion of it is constructed of any metallic alloy or plastic polymer and covered with either synthetic or biological membranes. The distal **414** and proximal **416** ends have the cross-sectional area of a circle, ellipse, or any polygon, and the deformable members **417** also have any cross-section shape and deform along one or more junctions to form any polygonal shape. As a matter of example, the deployed form **412** shows the deformable members **417** taking the shape of triangles. Also, any deformable member **417** may take the same or different shape as any other deformable member. The proximal element **418** have the same material and shape properties as proximal section **326** in FIG. **62**.

The Anchor Support with Pivoting Bar Element(s)

[00228] Now referring to FIGS. **79-80**, the anchor support **40** includes anchor support **430**, which convert from its undeployed form **431** to its deployed form **432**. Anchor support **430** has

a bar element **433**, which has a distal end **434**, pivot element **436**, and proximal end **437**. The bar element **433** have any diameter or length and have any straight or curved shape along its long axis, with its cross-sectional areal is any circle, ellipse, or polygon. The pivot element **436** is any shape and located anywhere along the long axis of bar element **433**. Both the bar and pivot
 5 elements are constructed of any metallic allow or plastic polymer, is covered by any synthetic or biological membrane and may or may not have additional fixation members on its surface (not shown). Deployment wire **438**, also constructed of any metallic alloy or plastic polymer, is attached to pivot element **436** and extends through lumen (not shown) of proximal element **439**, until wire **438** exits the proximal end **441** of proximal element **439**. Thus, deployment wire,
 10 through pushing or pulling can assist in deploying the bar element **433**. Alternatively, deployment wire **438** is a spring or coil and connects to distal end **442** of proximal element **439** such that when bar element **433** exits microcatheter and is in free space, the bar element **433** pivots and then is pulled taut against the distal end **442** of the proximal element **439**.

The Anchor Support Delivery System without Anchor Coil

15 **[00229]** When the anchor support delivery system **140** is be used to deliver an anchor support without using anchor **20**, the anchor support delivery system **140** is combined with an alternative embodiment of the anchor torque driver **143**, which does not have one or more coupling arms **147** and tabs **148**. Instead the end **146** of this alternative embodiment of anchor torque driver **143** is connected directly and irreversibly to fixation elements **450**, **460**, or **470**.
 20 Also, these fixation elements attached to anchor torque driver **143** are be used to stabilize the anchor delivery **130**, so that microcatheter **161** has a stable platform to traverse the cardiac wall. FIG. **81-82** shows a fixation element **450** that has one or more protrusions **451** attached to fixation element base **452**, which is attached to the distal end of anchor torque driver **143**. The one or more protrusions **451** are shaped as a needle, barb, hook, spear, circle, ellipse, or as any
 25 polyhedron. Any portion of the fixation element **450**, including the one or more protrusions **451**, is composed of any metallic alloy or plastic polymer and may be coated with any synthetic or biological membrane.

[00230] As shown in FIGS. **83-84**, is an alternative fixation element **460** attached to anchor torque driver **143**. Fixation element **460**, has one or more extension members **461**, with tip **462**
 30 and base **463**. The one or more extension members **461** may be of any length or diameter, have the cross-section of a circle, ellipse, or any polygon. Along the long axis, the extension member

is straight, be any type of curve, or any portion of the perimeter of a polygon. The tip **462** may or be the same shape as rest of the extension member **461**, or is shaped as needle, barb, hook, spear, circle, ellipse, or as any polyhedron. Base **463** of each extension member **461** is attached to fixation element base **464**, and each base **463** may or may not have a pivot element, joint, or spring to allow the extension member **461** to bend inwards or outwards to any degree. Any portion of fixation element **460** is composed of any metallic alloy or plastic polymer and may be coated with any synthetic or biological membrane.

[00231] As shown in FIGS. **85-86**, fixation element **470** is attached to anchor torque driver **143** via element base **474**. Fixation element **470** is in the shape of a suction cup with a frame **471**, inlet **472**, and covering surface **473**. Fixation element **470** may be frusto-conical in structure, or its base might be any type of circle, ellipse, or polygon, and the rest of the suction cup could also be in the shape of any part of a polygon. The frame **471** is constructed of any metallic alloy or plastic polymer, and the covering surface **473** may be any synthetic or biological membrane. Around the perimeter of the inlet **472**, additional fixation elements such as microneedles (not shown) may be provided. Finally, a lumen (not shown) within base **474** extending through anchor torque driver all the way to beginning of the anchor support delivery system is used to create negative pressure so that the fixation element **470** further adheres to the cardiac wall.

20

The Method of Stabilizing the Anchor Delivery Sheath without Anchor

[00232] As shown in FIGS. **87A-B**, the delivery system **140** attached to fixation element **450** is inserted into the anchor delivery sheath **130** until the fixation element **450** extends outside the distal tip **132** of the anchor delivery sheath **130** and engages the interventricular septum **8**. After microcatheter delivery and anchor support delivery, the fixation element **450** is disengaged from the intraventricular septum **8** with retraction of the delivery system **140**.

[00233] As shown in FIGS. **88A-B**, the delivery system **140** attached to fixation element **460** is inserted into the anchor delivery sheath **130**. While within the anchor delivery sheath **130**, fixation element **460** is constrained. Namely, extension members **461** may be closer together when the extension members pivot close together by the freedom of movement given by a pivot

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element at base **463** of each extension member **461**. Alternatively, the extension members **461** are constructed of nitinol so that the members are constrained with the sheath before exiting the tip of anchor delivery sheath **130**. Once the fixation element **460** exits distal tip **132** of anchor delivery sheath **130**, the extension members **461**, either through action of a pivot element at each base **463** or through the members forming pre-formed shape of nitinol, extend radially outward as they affix to the interventricular septum **8**. Additionally, the tip **462** of each extension member **461** is shaped (as a barb, spear, hook, needle, etc.) so as to engage tissue of the interventricular septum. After microcatheter delivery and anchor support delivery, the fixation element **460** is disengaged from the intraventricular septum **8** with retraction of the delivery system **140**. As the delivery system **140** retracts, the extension members **461** move inwards so that they are pulled inside the distal tip **132** of anchor delivery sheath **130**.

[00234] As shown in FIGS. **89A-B**, the delivery system **140** attached to fixation element **470** is inserted into anchor delivery sheath **130**. While in the sheath, element **470** is constrained by the diameter of the anchor delivery sheath **130**, but upon exit of distal tip **132**, element **470** expands to its pre-formed size. The suction cup adheres to the interventricular septum **8** through passive action, additional active fixation elements (not shown) and/or negative pressure exerted to element **470** through the delivery system **140**. After microcatheter delivery and anchor support delivery, the fixation element **470** is disengaged and retracted back into anchor delivery sheath **130** by retraction of the delivery system **140**.

20

The Method of Advancing Microcatheter without Anchor Coil

[00235] As illustrated in FIGS. **90-92**, the microcatheter with screw tip dilator traverses the septum without the anchor coil, using an alternative fixation element. For purposes of illustration, the fixation element **450** is being shown, although the same process can be used with fixation elements **460** or **470**. All the same steps described above are used as well.

25

Method of Advancing Microcatheters with Alternative Mechanisms

[00236] The methods of advancing the microcatheter also apply to microcatheters with alternative tip dilators. For example, FIG. **93** shows a microcatheter, but instead of screw tip dilator **162**, as needle tip dilator **480** penetrates tissue. Needle tip dilator **480** may be of any known shape in the art and may be composed of any metallic alloy or plastic polymer and

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covered with any biological or synthetic membrane. Also, needle tip dilator **480** may rotate as screw tip dilator does or may have a swivel mechanism to stay in same position as the body of the needle tip dilator advances forward.

5 [00237] FIG. **94** shows a radiofrequency tip dilator **490**. Radiofrequency tip dilator **490** is connected via a radiofrequency cable **491**, which connects to radiofrequency generator **492**. Radiofrequency tip dilator **490** delivers radiofrequency energy to the tissue while being advanced. It is also contemplated that the radiofrequency generator **492** and cable **491** could also connect to other tip dilators.

10 [00238] FIG. **95** shows a laser tip dilator **500**. Laser tip dilator might be any type of laser that administers laser light impulses as the laser tip dilator and microcatheter are being advanced through the tissue.

[00239] FIG. **96** shows a rotating burr tip dilator **510**. The rotating burr has any spherical, ellipsoid, or polyhedral shape, and is made of any metallic alloy and be covered by any cutting elements that may also be made of any metallic allow or gem, such as diamonds. The rotating
15 burr tip dilator **510** is connecting to rotating cable **511**, which is connected to power source **512**. The rotating burr tip dilator **510**, rotates clockwise or counterclockwise at any revolutions per minute. The rotating burr tip dilator **510**, like other tip dilators, is advanced as by rotation of the microcatheter control knob **156**.

[00240] FIG. **97** shows a helical tip dilator **520**. The helical tip dilator **520** may take any of
20 the shape or material properties as described for the anchor coil in [00142]. In practice, the helical tip dilator **520** traverses the interventricular septum in exactly the same way as the screw tip dilator as described above.

[00241] FIG. **98** shows an oscillating tip dilator **530**. The oscillating tip dilator **530** may take any shape and is composed of any metallic alloy or plastic polymer. Oscillating tip dilator
25 **530** is connected to oscillator rod **531** which is connected to oscillator motor **532**. Oscillator motor **532**, when activated, pushes the oscillator rod **531** to and fro, thereby moving the oscillator tip dilator **530** back and forth, at any hertz, along the long axis of the microcatheter.

Examples of Other Anchor Supports Connected via the Tether Assembly

[00242] As illustrated in FIGS. 99-120, any of the other anchor supports is connected to the tether assembly with or without the anchor, just as anchor support 40 is connected to the tether assembly with or without the anchor.

[00243] Although several aspects of the invention have been disclosed in the foregoing
5 specification, it is understood by those skilled in the art that many modifications and other aspects of the invention will come to mind to which the invention pertains, having the benefit of the teaching presented in the foregoing description and associated drawings. It is thus understood that the invention is not limited to the specific aspects disclosed hereinabove, and that many
10 modifications and other aspects are intended to be included within the scope of the appended claims. Moreover, although specific terms are employed herein, as well as in the claims that follow, they are used only in a generic and descriptive sense, and not for the purposes
of limiting the described invention.