

## DEVICES FOR TRANSCATHETER CHORDAL IMPLANTATION AND METHODS OF IMPLANTATION

### Cross Reference to Related Applications

- 5   **[0001]**        This application claims priority to US Provisional Patent App. No. 62/914,357 filed October 11, 2019, the disclosure of which is herein incorporated by reference.

### Field of the Invention

- 10   **[0002]**        The present invention relates generally to a medical assembly for restoring chordal support of a heart valve by implanting artificial chordae tendinae in the heart; one or more chords attach one or both mitral leaflets to at least one anchor device, which is implanted in any wall or papillary muscle of the left ventricle. The present invention also relates to methods of implantation of components of the medical assembly. More specifically, the invention pertains to a trans-septal guide  
15   catheter, anchor delivery system, anchor device, anchor line swivel, anchor lines, leaflet grasper, chords, reversible locks, and anchor line/chord crimper, as well as methods related to such assembly for endovascularly implanting the artificial chords in the heart and attaching them to the mitral valve, thereby restoring the function of the native mitral valve.

- 20   Background of the Invention

- [0003]**        Mitral valve disease, primarily causing mitral regurgitation (MR), results from either a primary degeneration of the valve (e.g. myxomatous degeneration, endocarditis, rheumatic disease, congenital disease, or other causes), or from incomplete leaflet coaptation (secondary or “functional” mitral regurgitation).  
25   MR increases left atrial pressure, causing pulmonary congestion, thereby leading to signs and symptoms of congestive heart failure, namely peripheral edema, orthopnea, paroxysmal nocturnal dyspnea, and progressive dyspnea on exertion. Additionally, MR exacerbates left ventricular dysfunction, decreasing survival. Because many patients suffering MR have significant comorbidities and have high surgical risk,  
30   developing minimally invasive (i.e. transcatheter) methods to treat MR is important.

[0004] For mitral regurgitation resulting from primary degeneration of the mitral valve, surgical mitral valve repair remains the gold standard. An important component of repair is the implantation of neo chordae into the heart with fixation to one or both mitral leaflets to support native chordae that are either elongated or  
5 ruptured. Developing transcatheter approaches for neo chordae implantation is important, not only for patients with co-morbidities that render them intermediate or high risk for open heart surgery, but also for patients that are low risk for surgery who may benefit from a quicker recovery time.

[0005] The current transcatheter devices being developed have important  
10 limitations such as inability to adjust chordal length easily during implantation, difficulty in being able to implant multiple chords, inability to adjust chordal length after implantation (i.e. inability to adjust chordal length after multiple chords have been implanted), or need for surgical access. For example, both the NeoChord (NeoChord, Inc., St. Louis Park, Minnesota, USA) and Harpoon devices (Edwards  
15 LifeSciences, Irvine, CA, USA) require a lateral thoracotomy and trans-apical incision of left ventricle.

[0006] Percutaneous devices avoid this risk by being delivered via a trans-septal approach. For example, the ChordArt system (CoreMedic, Biel/Bienne, Switzerland), allows trans-septal implantation of neo-chordae. The system, however,  
20 requires the operator to select the length of the chord prior to implantation, because chordal length cannot be changed during implantation.

[0007] Unlike the ChordArt system, the Pipeline Medical (W.L. Gore and Associates, Inc., Newark, Delaware, USA) and the CardioMech (CardioMech, Trondheim, Norway) systems allow chordal adjustment during implantation.  
25 Although all three systems allow multiple chords to be implanted, the ChordArt and CardioMech systems require a separate anchor for each chord, which requires hunting for multiple anchoring sites, which can be technically challenging, and which increases the risk of anchor dislodgement. Finally, in all three systems once an individual chord is implanted and adjusted, it cannot be readjusted after the placement  
30 of another chord.

[0008] Accordingly, it remains desirable in the pertinent art to provide a system for transcatheter chordal implantation that is fully percutaneous (i.e. trans-septal), facilitates multiple chord placement with low risk of anchor dislodgement, allows chordal length adjustment during implantation, and allows chordal length  
5 adjustment even after implantation. Thus, after the implantation of multiple chords, length of any chord can be re-adjusted before final release.

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### **Summary of the Invention**

[0009] Presented herein is a medical assembly that is implanted minimally invasively across the mitral valve for implantation of artificial chords to restore the function of the native mitral valve. The method disclosed herein implants the chords via trans-septal access, and the chords connect one or both mitral leaflets to at least  
15 one anchor, which is attached to any intraventricular wall and/or papillary muscle of the left ventricle. Accordingly, and beneficially, no portion of the system requires surgical thoracotomy or trans-apical access for implantation.

[0010] In one aspect, the system comprises a steerable trans-septal guide that allows delivery of an anchor delivery system into the left ventricle, with delivery of at  
20 least one anchor into any wall and/or papillary muscle of the left ventricle.

[0011] The system further comprises an anchor line swivel that allows rotational freedom of one or more anchor lines about the central access of the anchor. The anchor lines may consist of single lines attached to the end of anchor line rods of the anchor line swivel, or may consist of loops of lines running through a channel in  
25 each of the anchor line rods. The anchor line swivel may be delivered over a guidewire connected to the anchor until it docks onto the anchor, or the anchor line swivel may be pre-attached to the anchor and both are delivered as a unit to the desired intraventricular wall and/or papillary muscle of the left ventricle.

[0012] The system further comprises a leaflet grasper that advances over one  
30 of the anchor lines and grasps a mitral leaflet. Inside the leaflet grasper, a chord is

contained within the central channel of the puncturing rod. “Proximal end” of the chord is defined as the portion of the chord that will abut the superior (or atrial) surface of the leaflet. The “proximal end” of the channel or puncturing rod is the portion closest to the leaflet grasper control handle, which is outside the body.

5 Therefore, the proximal end of the chord has a preformed knot or pledget and is contained inside the proximal end of the channel within the puncturing rod. The distal end of the chord is immediately outside the distal end of the puncturing rod and is attached to a puncturing element, which abuts the distal end of puncturing rod, but is not attached to it. Once the leaflet is grasped, the puncturing rod drives the  
10 puncturing element and attached chord through the superior (or atrial) surface of leaflet into the receiving chamber in the inferior portion of the leaflet grasper. The puncturing element couples to a receiving cap within the receiving chamber, and the puncturing rod is retracted from the receiving chamber, leaving a preformed knot or pledget of the chord above the superior (or atrial) surface of the leaflet, with the rest  
15 of the chord passing through the leaflet and coupled to the receiving cap in the receiving chamber.

[0013] After coupling, the receiving cap is withdrawn by a retracting rod back up the shaft of the leaflet grasper out of the body, thereby withdrawing the puncturing element and the attached end of the chord out of the body. The proximal end of the  
20 chord is restrained on the superior (atrial) side of the grasped leaflet by a preformed knot, or by a pledget.

[0014] The system further comprises a chord release tube, integrated within the leaflet grasper, which advances over the chord out the bottom of the leaflet grasper, thereby allowing the chord to move out of a split seam that wraps around the side of  
25 the grasper arm to the bottom of the leaflet grasper. Once the chord is freed from the grasper arm, the leaflet grasper can translate freely over both the anchor line and chord, and can be retracted out of the body. The anchor line and chord remain attached to the anchor and leaflet, respectively, and are accessible outside the body.

[0015] The system further comprises chord locking tubes that consist of  
30 proximal positioning rods, and distal detachable and reversible locks. Over any anchor line and associated chord, a proximal positioning rod pushes a detachable lock over each anchor line and associated chord, which run through a central lumen of the

positioning rod, until the lock meets the end of an anchor line rod of the anchor line swivel. At this point, while the positioning rod provides counter-force, the chord may be pulled through the lumen of the lock and positioning rod until appropriate tension of the leaflet is obtained. Then, the lock may be deployed by pulling a hypotube  
5 within the positioning rod, thereby engaging a collet within the lock, which clamps onto the anchor line and chord. The positioning rod may then be unscrewed from the lock and withdrawn into the left atrium, and the anchor line and chord proximal to the lock can slacken. Therefore, the rod and the anchor line or chord do not interfere with the mitral valve coaptation, and one can assess the true residual mitral regurgitation. If  
10 re-adjustment of chord tension needs to occur, the positioning rod is re-advanced and screwed into the distal lock. Pushing the internal hypotube disengages the collet within the lock, which allows free movement of the chord again. Because this entire process can be repeated with other chords, multiple chords can be attached to one or more leaflets and secured to the ends of the anchor line rods of the anchor line swivel  
15 by reversible locks, and any or all of the chords can be re-adjusted multiple times after implantation.

**[0016]** In another embodiment, the reversible locks are advanced by the positioning rods but are not activated by them. Instead of having one central lumen, these locks have one lumen through which the chord runs ("chord lumen"), and a  
20 second lumen through which the anchor line runs ("anchor line lumen"). The positioning rod pushes the lock over both the anchor line and chord until the lock docks onto the anchor line rod of the anchor line swivel. At this point the positioning rod disengages from the lock, and is retracted into the left atrium. Through the chord lumen, the chord can be pulled to tension the leaflet and this tension is retained within  
25 the lock ("self-locking"). To release tension, the anchor line is pulled, which brings an unlocking element attached to the anchor line into the anchor line lumen. The unlocking element pushes a plate that releases the lock and allows free movement of the chord through the chord lumen. The anchor line is allowed to translate relative to the anchor line rod by being attached to the rod with a spring internal or external to  
30 rod. When the anchor line is released and pulled back down by the spring, the unlocking element leaves the anchor line lumen, and the lock re-engages. Alternatively, a loop of anchor line goes through a channel running through the side

of the rod, which allows the line to be pulled by either end, thereby translating up or down relative to the rod. In this case, to unlock the chord lumen, the unlocking element attached to one side of the line is pulled into the anchor line lumen, thereby pushing a plate to release the lock. To allow the self-locking mechanism to re-engage, the line can be pulled from the other side, thereby pulling the unlocking element out of the anchor line lumen, which allows the plate to spring back to the locked position.

[0017] In another embodiment, the reversible lock is not “self-locking” but is locked/unlocked by pulling the anchor line. A “push button” element, attached to the anchor line, is pulled into the anchor line lumen, engaging the lock, and then is automatically retracted down by a spring attaching the anchor line to the anchor line rod. To unlock the lock, the push button element is retracted back again into the anchor line lumen, thereby unlocking the lock. Alternatively, a loop of anchor line goes through a channel running through the side of the rod; pulling one end of the line brings a push button element into the anchor line lumen, thereby locking the lock. Retracting the other end of the line pulls the push button element out of the anchor line lumen, and pulling the anchor line attached to the push button a second time brings the push button element back into the anchor line lumen, thereby unlocking the lock. To maintain tension on the chord during chord adjustment and unlocking/locking, the end of the chord (outside the body) is connected to a chord adjustment control of a chord tension board. Pulling or pushing the chord adjustment control increases or decreases the tension, respectively, and maintains that degree of tension until re-adjusted. To facilitate ease of locking or unlocking, the anchor line is placed in an anchor line lock/unlock control. Pulling the anchor line lock/unlock control pulls on the anchor line, locking the lock, and springing back to initial position. Pulling the anchor line lock/unlock control a second time pulls the anchor line, unlocking the lock. Alternatively, if a loop of anchor line is used to lock or unlock the lock, the push button end of the anchor line loop can be placed in an anchor line lock/unlock control, and the unlocking end of the anchor line loop can be placed in an anchor line release control.

[0018] In another embodiment, instead of deploying a reversible lock, the positioning rod deploys a chord tension regulator. The chord tension regulator has a

chord lumen and an anchor line lumen. The positioning rod pushes the chord tension regulator until it docks onto the anchor line rod, and then the positioning rod is unscrewed from the chord tension regulator and retracted into the left atrium. The proximal chord is attached to a chord adjustment control of a chord tension board and pulling or pushing the chord adjustment control pulls or pushes the chord through the chord lumen of the chord tension regulator, thereby increasing or decreasing tension on the leaflet, respectively, and maintains that degree of tension until readjusted. These steps can be repeated with other implanted chords. Therefore, multiple chords can be adjusted simultaneously. To lock any particular chord in place, an anchor line/chord crimper wraps around the proximal anchor line/chord outside the body, advances over both until it reaches the chord tension regulator, then crimps the line and chord together with a metallic clip and simultaneously cuts the line and chord, thereby fully releasing them. According to any alternative, including a removeable self locking or non-self locking or chord tension regulator, a line gathering member is provided to encompass the chord and anchor line.

**[0019]** In another aspect, the anchor line/chord crimper is used in either of the two reversible lock embodiments. Specifically, the anchor line/chord crimper wraps around the proximal anchor line/chord outside the body, advances over both until it reaches the reversible lock, then crimps the line and chord together with a metallic clip and simultaneously cuts the line and chord, thereby fully releasing them.

**[0020]** Related methods of implantation 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 assembly that is implanted minimally invasively in the heart, and be protected by the accompanying claims.

### DESCRIPTION OF THE FIGURES

- [0021] FIG. 1 is a cross-sectional perspective view of a heart showing the transcatheter chordal system of the present application positioned in the heart, according to one aspect;
- 5 [0022] FIG. 2 is a magnified cross-sectional perspective view of a left atrium and left ventricle of a heart showing the transcatheter chordal system of the present application positioned in the heart, according to one aspect;
- [0023] FIG. 3A is a perspective view of the delivery cable of the anchor for anchoring chords to a cardiac wall or papillary muscle;
- 10 [0024] FIG. 3B is a perspective view of an anchor for anchoring chords to a cardiac wall or papillary muscle;
- [0025] FIG. 4A is a perspective view of an anchor line swivel for connecting single anchor lines to the anchor;
- [0026] FIG. 4B is a perspective view of an anchor line swivel for connecting  
15 loops of anchor lines to the anchor;
- [0027] FIG. 5A is a perspective view of the anchor/chord assembly, comprised of the anchor line swivel for connecting single anchor lines to anchor, coupled to the anchor, for anchoring chords to a cardiac wall or papillary muscle;
- [0028] FIG. 5B is a perspective view of the anchor/chord assembly, comprised  
20 of the anchor line swivel for connecting loops of anchor lines to anchor, coupled to the anchor, for anchoring chords to a cardiac wall or papillary muscle;
- [0029] FIGS. 6A - 6F are perspective views of an anchor according to another aspect having an anchor screw and anchor cap configured for receipt of connecting ring and a tethering system illustrated in sequential steps.
- 25 [0030] FIG. 7 is an exploded view of an anchor having an anchor screw and anchor cap configured for receipt of connecting ring and a tethering system according to another aspect of the invention; and
- [0031] FIG. 8 is a perspective view and plan view of the anchor of Figure 7 with stabilizers according to another aspect of the invention;

- [0032] FIG. 9A is a side elevational view of the anchor delivery system, housing anchor assembly of FIG. 5A, according to one aspect;
- [0033] FIG. 9B is a magnified side elevational view of the anchor delivery system of FIG. 9A;
- 5 [0034] FIG. 9C is a plan view of the anchor delivery system of FIG. 9A;
- [0035] FIG. 10A is a side elevational view of the anchor delivery system, housing anchor assembly of FIGS. 6A-F, according to one aspect;
- [0036] FIG. 10B is a magnified side elevational view of the anchor delivery system of FIG. 10A;
- 10 [0037] FIG. 11A is a perspective view of the anchor delivery system of system of FIG. 9A or 10A, in which a portion of the device is positioned in the left ventricle;
- [0038] FIG. 11B is a perspective view of the anchor delivery system of FIG. 10A, in which the anchor delivery system is delivering a portion of the anchor,
- 15 connected to the anchor assembly of FIGS. 6A-F, into the left ventricle;
- [0039] FIG. 11C is a magnified side elevational view of the anchor, connected to anchor assembly of FIGS. 6A-F, being delivered into the left ventricle;
- [0040] FIG. 12A is a perspective view of the anchor delivery system of FIG. 10A in which the anchor delivery system is exposing a portion of the anchor lines,
- 20 connected via the anchor line swivel to the anchor assembly of FIGS. 6A-F, which is affixed to the left ventricle;
- [0041] FIG. 12B is a perspective view of the anchor lines, connected to the anchor assembly of FIGS. 6A-F, positioned in the left ventricle;
- [0042] FIG. 13A is a side elevational view of the leaflet grasper with grasper arm closed;
- 25 [0043] FIG. 13B is a side elevational view of the leaflet grasper with the grasper arm open;
- [0044] FIG. 14A is a magnified side elevational view of the distal end of the leaflet grasper when the grasper arm is open;

- [0045] FIG. 14B is a perspective view of the distal end of the leaflet grasper when the grasper arm is open;
- [0046] FIG. 14C is a side elevational view of the puncturing rod and puncturing element;
- 5 [0047] FIG. 14D is a side elevational view of the receiving cap and retracting rod;
- [0048] FIG. 15A is a magnified side elevational view of the puncturing rod and puncturing element housing a chord attached to a pledget;
- [0049] FIG. 15B is a magnified side elevational view of the puncturing rod and  
10 puncturing element housing a chord attached to a knot;
- [0050] FIG. 16A is a perspective view of the leaflet grasper of FIG. 13A advancing over an anchor line into the transseptal sheath;
- [0051] FIG. 16B is a perspective view of the leaflet grasper of FIG. 13A advancing over anchor line across the mitral valve;
- 15 [0052] FIG. 17A is a perspective view of the leaflet grasper of FIG. 13A advancing separately from the anchor lines into the transseptal sheath;
- [0053] FIG. 17B is a perspective view of the leaflet grasper of FIG. 13A advancing separately from the anchor lines across the mitral valve;
- [0054] FIG. 18A is a magnified perspective view of the leaflet grasper going  
20 over an anchor line, with the leaflet grasper arm open and being retracted to grab the leaflet;
- [0055] FIG. 18B is a magnified perspective view of the leaflet grasper going over an anchor line, with the leaflet grasper arm closing on a leaflet;
- [0056] FIG. 18C is a magnified perspective view of the leaflet grasper going  
25 over an anchor line, with the leaflet grasper arm fully closed on the grasped leaflet;
- [0057] FIG. 19A is a magnified perspective view of the leaflet grasper advancing freely (not over an anchor line), with the leaflet grasper arm open and being retracted to grab the leaflet;

- [0058] FIG. 19B is a magnified perspective view of the leaflet grasper advancing freely (not over an anchor line), with the leaflet grasper arm closing on a leaflet;
- 5 [0059] FIG. 19C is a magnified perspective view of the leaflet grasper advancing freely (not over an anchor line), with the leaflet grasper arm fully closed on the grasped leaflet;
- [0060] FIG. 20A is a magnified side elevational view of the leaflet grasper with its grasper arm fully closed on the grasped leaflet;
- 10 [0061] FIG. 20B is a highly magnified side elevational view of the leaflet grasper with its grasper arm fully closed on the grasped leaflet;
- [0062] FIG. 21A is a magnified side elevational view of the leaflet grasper after leaflet has been grasped and punctured by puncturing rod and element
- [0063] FIG. 21B is a highly magnified side elevational view of the leaflet grasper after leaflet has been grasped and punctured by puncturing rod and element;
- 15 [0064] FIG. 21C is a highly magnified side elevational view of the puncturing rod and element coupling with the receiving cap and attached retracting rod;
- [0065] FIG. 22A is a magnified side elevational view of the leaflet grasper after chord has passed through leaflet and with the puncturing rod retracted above the leaflet;
- 20 [0066] FIG. 22B is a highly magnified side elevational view of the leaflet grasper after chord has passed through leaflet and with the puncturing rod retracted above the leaflet;
- [0067] FIG. 23 is a side elevational view of the handle of the leaflet grasper;
- [0068] FIG. 24A is a magnified side elevational view of the leaflet grasper after the puncturing element has been attached to the receiving cap, and the retracting rod has pulled the captured element and chord up the shaft;
- 25 [0069] FIG. 24B is a highly magnified side elevational view of the leaflet grasper after the puncturing element has been attached to the receiving cap, and the retracting rod has pulled the captured element and chord up the shaft;

- [0070] FIG. 25 is a side elevational view of the captured chord being pulled out of the handle of the leaflet grasper;
- [0071] FIG. 26A is a magnified side elevational view with the end of the chord (pledget pictured) pulled against the atrial side of the leaflet;
- 5 [0072] FIG. 26B is a highly magnified side elevational view with the end of the chord (pledget pictured) pulled against the atrial side of the leaflet;'
- [0073] FIG. 27A is a side elevational view of the leaflet grasper arm releasing the leaflet after chord delivery;
- [0074] FIG. 27B is a side elevational view of the leaflet grasper free from the  
10 leaflet;
- [0075] FIG. 27C is a side elevational view of the leaflet grasper free from the leaflet and being retracted up and away from the leaflet;
- [0076] FIG. 28A is a cross-sectional perspective view with the anchor and anchor lines in place, along with one chord delivered through one leaflet;
- 15 [0077] FIG. 28B is a magnified cross-sectional perspective view with the anchor and anchor lines in place, along with one chord delivered through one leaflet;
- [0078] FIG. 29A is a side elevational view of the collet locking system
- [0079] FIG. 29B is a magnified side elevational view of the collet locking system;
- 20 [0080] FIG. 30 is a perspective view of the collet locking system;
- [0081] FIG. 31A is a cross-sectional perspective view of the collet locking system in the unlocked position;
- [0082] FIG. 31B is a cross-sectional perspective view of the collet locking system in the locked position;
- 25 [0083] FIG. 32A is a cross-sectional perspective view of the collet locking system locked and released;
- [0084] FIG. 32B is an intact perspective view of the collet locking system locked and released;

- [0085] FIG. 33A is a cross-sectional perspective view of the collet locking system entering the transseptal sheath over the anchor line and chord;
- [0086] FIG. 33B is a cross-sectional perspective view of the collet locking system advancing over the anchor line and chord to the anchor line rod;
- 5 [0087] FIG. 34A is a cross-sectional perspective view of the collet locking system in place to be locked;
- [0088] FIG. 34B is a cross-sectional perspective view of the collet locking system locked in place;
- [0089] FIG. 35A is a cross-sectional side elevational view of the self-locking  
10 lock in the locked position;
- [0090] FIG. 35B is a cross-sectional side elevational view of the self-locking lock in the unlocked position;
- [0091] FIG. 36A is a cross-sectional perspective view of the self-locking lock abutting the anchor line rod;
- 15 [0092] FIG. 36B is a magnified cross-sectional perspective view of the self-locking lock abutting the anchor line rod;
- [0093] FIG. 37 is a cross-sectional side elevational view the chord tension regulator;
- [0094] FIG. 38A is a cross-sectional perspective view of the chord tension  
20 regulator in place, and the chord attached to the chord tension control board but not tensioned yet;
- [0095] FIG. 38B is a cross-sectional perspective view of the chord tension regulator in place, and the chord attached to the chord tension control board, and the chord has been tensioned;
- 25 [0096] FIG. 39A is a cross-sectional side elevational view of the locking/unlocking lock in the unlocked position;
- [0097] FIG. 39B is a cross-sectional side elevational view of the locking/unlocking lock in the locked position;

- [0098] FIG. 40A is a side elevational view of the anchor line/chord crimper with grasper hook pushed out;
- [0099] FIG. 40B is a side elevational view of the anchor line/chord crimper with the grasper hook pulled in;
- 5 [00100] FIG. 41A is a cross-sectional perspective view of the anchor line/chord crimper with the grasper hook ready for anchor line/chord insertion;
- [00101] FIG. 41B is a cross-sectional perspective view of the anchor line/chord crimper with the anchor line/chord inserted into the grasper hook;
- [00102] FIG. 41C is an enlarged perspective from FIG. 41A;
- 10 [00103] FIG. 42A is a cross-sectional perspective view of the anchor line/chord crimper advanced down to the chord tension regulator;
- [00104] FIG. 42B is a magnified cross-sectional perspective view of the anchor line/chord crimper advanced down to the chord tension regulator;
- [00105] FIG. 43A is a cross-sectional perspective view of the anchor lock
- 15 secured to anchor line and chord;
- [00106] FIG. 43B is a magnified cross-sectional perspective view of the anchor lock secured to the anchor line and chord;

### DESCRIPTION OF THE INVENTION

[00107] The present invention is understood more readily by reference to the

20 following detailed description, examples, and claims, and their previous and following description. Before 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

25 is for the purpose of describing particular aspects only and is not intended to be limiting.

[00108] 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 are 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 is 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 [00109] 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.

[00110] Ranges is 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, 15 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.

20 [00111] 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 25 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.

30 [00112] The disclosure herein relates to a medical assembly 10 for implanting one or more chords minimally invasively in the heart 11 to restore chordal support to

either the anterior mitral leaflet **13**, the posterior mitral leaflet **14**, or to both. FIG. 1 illustrates the chords **160** which have been implanted to support the anterior mitral leaflet **13** and the posterior mitral leaflet **14** to prevent either leaflet from prolapsing from the left ventricle **16** into the left atrium **12**. The assembly comprises chords **160** which anchor the mitral leaflets to the anchor assembly **40** or **41**, consisting of the anchor line swivel **50** or **51** (see FIGS. 4A and 4B), and anchor **20**, which has affixed to an intracardiac wall **17**. FIG. 2 is a magnified view of heart **11**, showing only the left atrium **12** and the left ventricle **16**. This figure further shows that each chord **160** has a proximal end **161** restrained on the atrial side of either leaflet by knot or pledget **162**. The distal end **163** of the chords **160** are attached to the anchor line rods **54** of the anchor assembly **40** or **41**, by reversible locks **176**, **190** or **220** or chord tension regulator **210**. The anchor line **52** or **53** has been crimped together to the distal end **163** of chord **160** by the anchor line/chord crimper **260** (Fig. 40A). The medical assembly **10** includes an anchor delivery system **92**, leaflet grasper **130**, reversible locks [**176**, **190**, or **220**] or chord tension regulator **210**, and anchor line/chord crimper **260**. The method for implanting the chord and anchoring the mitral leaflets to the intracardiac wall as herein shown and described includes, generally, the method of steps of: using the anchor delivery system **92** to deliver the anchor assembly **40** or **41** to an intracardiac wall **17**; using the leaflet grasper **130** to grasp one mitral leaflet at a time to pass a chord **160** through the leaflet; delivering the reversible locks or chord tension regulator over the anchor line **52** or **53** and chord **160** until the reversible locks or chord tension regulator reaches the anchor line rod **54** or **78**; tensioning the chord **160**; assessment residual mitral regurgitation on echocardiography and leaving chord **160** as is, or re-adjusting tension, with the possibility of implanting one or more additional chords and re-adjusting tension of one or all of them; advancing the anchor line/chord crimper and cutter over the externalized anchor line (s) **52** or **53** and chord (s) **160** to the reversible locks or chord tension regulator; crimping the anchor line **63** and distal end(s) **163** of chord(s) **160** together and cutting both proximal to the reversible locks or chord tension regulator, thereby leaving the implanted chord (s) **160** in place to support the function of the mitral leaflets.

Anchor Assembly (Anchor and Anchor Line Swivel)

[00113] The components of anchor assembly **40** or **41** shown in FIGS. **3-5** include an anchor **20**, which consists of an anchor in the form of an anchor screw **21** as shown and an anchor cap **22**, and an anchor line swivel **50** or **51**, which is either pre-attached to anchor **20** or delivered over delivery cable **30**, which maintains control of anchor assembly **40** or **41** during placement. In one aspect, the anchor screw is coupled to and extends from the distal end **26** of the anchor cap **22**. At the proximal end **27** of anchor cap **22**, the flexible wire **31** of the delivery cable **30** is removably connected by its distal end **32** to the proximal end **27** of the anchor cap **22**. The flexible wire **31** is constructed of, but not limited to, stainless steel, nitinol, or other metal alloys, with or without hydrophilic coatings, or with or with a polymer coating as a polytetrafluoroethylene (PTFE). The distal threaded end **32** is sized and configured to selectively engage complementary threads formed in a cavity defined in the proximal end **27** of the anchor cap **22**. In use, the distal threaded portion **32** has been pre-attached into the proximal end **27**, coupling the anchor cap **22** to the distal end of the flexible wire **31**. As described later, once the anchor assembly **40** or **41** has been implanted, the distal threaded end **32** is unscrewed from the proximal end **27** of the anchor **20**, detaching the flexible wire **31** from the anchor assembly **40** or **41**.

[00114] Attached to the end of the anchor assembly **40** or **41**, the anchor screw **21**, as shown, is sized and configured as a helical screw to affix to an intracardiac wall. Optionally, however, the anchor screw **21** may be differentially sized (longer or shorter depending on the cardiac wall to which it attaches) and configured as an inclined plane (such as an Archimedes-type screw), nail-like head, or as any other type of screw that would be known to those skilled in the art, and can be “right handed” or “left handed”. In one aspect, the screw is composed of any know metal alloy, including, but not limited to, nitinol, titanium, or cobalt-chromium. In another aspect, the metal alloy of the anchor screw **21** may be coated with biological tissue, such as bovine, ovine, porcine, or equine pericardium, or with any combination of anti-inflammatory drugs that might promote healing and limit inflammation. A tip **23** of the anchor screw **21** optionally is constructed of and/or coated with the same or different materials as the anchor screw **21**, and may be fashioned as a blunt or sharp tip. In a further aspect (not shown), rather than the anchor screw **21**, a fixation mechanism composed of, but not limited to, nitinol, stainless steel, cobalt-chromium,

or titanium alloys, the in the shape of barbs, hooks, prongs, and like is positioned at the distal end **26** of anchor cap **22** to securely attached the anchor assembly **40** or **41** to intracardiac wall **17**.

**[00115]** In use, the anchor **20** is secured to the intracardiac wall by rotating the anchor screw **21** until tip **23** is at the desired depth in the cardiac wall. The depth to which the anchor screw **21** is screwed in is adjustable according to the location within the heart. For example, the anchor screw **21** may be implanted more deploy into the interventricular septum, for greater fixation, as opposed to the ventricular free wall (i.e. epicardial wall), where a shallower implantation is safer. By reversing the rotation of anchor screw **21**, the anchor **20** is removed safely from the cardiac wall, either to be repositioned, or removed entirely.

**[00116]** The anchor **20**, via anchor cap **22**, is configured to accept an anchor line swivel **50** or **51**, which is either pre-attached before anchor delivery, or may be delivered separately over delivery cable **30** after anchor delivery. To allow this, the anchor cap **22** comprises at least one locking arm **24**. The locking arm **24** is sized and configured for releasably securing a portion of the anchor line swivel **50** or **51** (described below) to the anchor cap **22**. The at least one locking arm **24** moves between a first locked position, in which the locking arm **24** extends a first distance away from the body of the anchor cap **22**, and a second unlocked position in which the locking arm **24** extends a second distance away from the anchor cap **22** that is less than the first distance. The anchor cap **22** comprises at least one biasing member (not shown), such as a spring, configured to urge each locking arm **24** to the first locked position. As shown, a plurality of locking arms **24** are provided and are spaced equally around the circumference of the anchor cap **22**, though it is contemplated that the locking arms **24** need not be equally spaced.

**[00117]** Over these locking arms **24** the anchor line swivel **50** or **51** is configured to attach to the anchor cap **22**, either pre-attached before delivery of anchor to the interventricular wall (preferred embodiment), or delivered separately after anchor is delivered over flexible wire **31** of delivery cable **30**.

**[00118]** As shown in FIG. **4A** or **4B**, in one aspect, the anchor line swivel **50** or **51** comprises a docking ring **59** coupled to or formed monolithically to one or more

docking ring arms **58**. As shown, the plurality of docking ring arms **58** are spaced equally around the circumference of the docking ring, though it is contemplated that the docking ring arms **58** need not be spaced equally. Each docking ring arm **58** has a terminal eyelet **57** that is configured to operate with an anchor rod hook **56** defined by the end of each anchor line rod **54** as shown, and the anchor rod hook **56** is either coupled to or formed monolithically with the distal end of each anchor line rod **54**.

[00119] In another aspect the anchor rod hook **56** and eyelet **57** are sized and configured so that the anchor rod hook **56** is inserted into the eyelet **57** to securely, rotatably couple the distal end of an anchor line rod **54** to a respective proximal end of each docking ring arm **58** of the docking ring **59**. In use, each anchor rod hook **56** rotates about the circumference of the eyelet **57**. As shown in FIG. 4A and 4B, the proximal end of either anchor line rod is coupled to an anchor line, which may be a single anchor line **52** with or without connection to the anchor line rod by an external or internal spring (not shown), or may be a loop of anchor line **53** running through a side channel **55** of the anchor line rod **54**. Each anchor line can consist of, but not be limited to, expanded polytetrafluoroethylene (ePTFE) or ultra-high-molecular-weight polyethylene (UHMWPE or UHMW).

[00120] FIG. 5A and 5B show the final configuration of anchor assembly **40** or **41**. The anchor assembly is either formed prior to anchor delivery (pre-attached) or created after anchor **20** delivery. In either case, the anchor line swivel **50** or **51** is advanced over flexible **31** of delivery cable **30** (during manufacturing if pre-attached), and the docking ring **59** of the anchor line swivel **50** or **51** depresses the at least one locking arm **24** of the anchor cap **22** to the second unlocked position. With the locking arm **24** in the second position, the anchor line swivel **50** or **51** advances over the locking arm **24** on the anchor cap **22** until the docking ring **59** abuts and/or is adjacent to a distal end **26** of the anchor cap **22**. At this point, the biasing member of the anchor cap **22** urges the at least one locking arm **24** to the first locked position, thereby releasably coupling the docking ring **59**, and the rest of the anchor line swivel **50** or **51**, to the anchor **20**.

[00121] In one aspect, when coupled to anchor **20**, the anchor line swivel **50** or **51** rotates about a longitudinal axis of the anchor a full 360 degrees. Optionally, in another respect, the anchor line swivel **50** or **51** may be constrained to lesser degrees

of rotation by interaction of a portion of the anchor line swivel **50** or **51** with the at least one locking arm **24**.

#### Halo Anchor Assembly

**[00122]** According to another aspect of the disclosure, as shown in FIGS. **6A-F**,  
5 an anchor assembly **60**, is illustrated. As is true for the anchor assembly described in **[0057-0064]**, the halo anchor assembly can have the anchor line swivel pre-attached to the anchor, or attached after anchor is delivered. The halo anchor assembly **60** includes an anchor shaft **66** and an anchor screw **61**. As shown, the anchor screw **61** has a helical configuration and extends distally from an anchor screw base **62**. The  
10 anchor screw base **62** defines at least one, or a plurality as shown, of anchor flanges **63** and recessed areas **64** therebetween. The anchor shaft **66** includes at least one or, as shown, a plurality of locking members **67** shown in FIG. **6B**. Locking members **67** are biased, such as by a spring (not shown), radially outwardly from the anchor shaft **66**. A delivery cable in the form of an anchor connector **69** and anchor rod **71**  
15 cooperate with the anchor shaft **66** to rotate the anchor screw **61**. The anchor connector **69** defines at least one or, as shown, a plurality of apertures **68** configured for receipt of the anchor flanges **63**. Accordingly, the anchor connector **69** and connector rod **71** are matingly connected to the anchor shaft **66**, thereby urging the locking members **67** inward. The cooperating of the apertures **68** and flanges **63**  
20 integrate the anchor connector **69** the anchor screw base **62**. Rotation of the connector rod **71** thereby rotates the anchor screw **61** for interventricular or epicardial implantation into the an intracardiac wall.

**[00123]** It is the preferred embodiment that the tether ring **72** has been pre-attached to the anchor screw **61**. If not, then after the anchor screw **62** has been  
25 implanted, a docking ring **72** is applied over the connector rod **71** and anchor connector **69** and abuts the proximal end of the anchor screw **61**. The docking ring **72** includes a generally cylindrical first distal portion **73** and a second proximal portion **74** having a diameter greater than the first portion **73**. The second portion **74** defines at least one or, as shown, a plurality of apertures **76** configured for receipt of anchor  
30 line rods **78** as shown in FIGS **6E** and **6F**. As in shown in FIG. **6D**, the anchor connector **69** and anchor connector rod **71** are removed. The locking members **67** are urged radially outward so as to engage the second portion **74** of the docking ring **72** to

lock the docking ring **72** on the anchor screw base **62**. The anchor line rods **78** are attached to either a single anchor line (not shown) via an internal or external spring (not shown), or to a loop of anchor line (not shown) via a side channel in the anchor line rods **78**.

5    **[00124]**       Another aspect of the halo anchor assembly is shown in FIGS. 7 and 8. The anchor assembly **79** additionally includes a flex connector **89** extending between anchor shaft **81** and the anchor base **83**. This permits anchor assembly **79** and chord to remain axially aligned with the mitral valve leaflets (such as, parallel to the interventricular septum), particularly when the anchor screw **82** is implanted in an  
10   intracardiac wall this is not directly perpendicular to the mitral valve annular plane. As shown, the flex connector **89** is a coiled configuration, but other configurations are envisioned. Flex connector **89** may be formed of a suitable material such as a metal or metal alloy.

**[00125]**       The anchor assembly **79** shown in these drawings also includes  
15   stabilizers **90** to stabilize the anchor and limit or prevent movement, such as rotational movement, from tension transferred from the tethers and to provide traction to limit or prevent the anchor screw **82** from inadvertently rotating so as to uncouple from the tissue in which it was implanted. At least one stabilizer **90** may be provided. As shown in FIG. 7, eight stabilizers **90** are illustrated and FIG. 8 illustrates three. As  
20   shown in FIG. 7, the stabilizers **90** extend radially outward from the longitudinal axis of the anchor. The stabilizers **90** are configured to have a non-linear configuration. Other configurations are envisioned. The stabilizers **90** shown in FIG. 8 also extend radially outwardly from the anchor longitudinal axis and extend at an acute angle, for example 45 degrees, along the horizontal axis. The angle is generally facing the  
25   opposite direction of the anchor screw **82**. The stabilizers are generally linear, but other configurations are envisioned. When inserted into any intracardiac wall, for example, the stabilizers **90** urge against perhaps into the tissue in a direction opposite the anchor screw **82** implantation to prevent unintentional withdrawal of the anchor screw **82**.

30   Anchor delivery system

[00126] Referring to FIGS. 9A-C, the anchor delivery system 92 for positioning and deploying the anchor cap 22 of anchor assembly 40 or 41 is illustrated. The anchor delivery system 92 comprises an anchor delivery guide 93 and an anchor delivery rod 94. In this aspect, the anchor delivery guide 93 has a distal end 96, an  
5 opposed proximal end 97 and an inner guide lumen 98, extending between the anchor delivery guide tip 99 and the opposed proximal end 97, and is configured so that at least a portion of the anchor delivery rod 94 along with the anchor assembly 40 or 41 extends therethrough. In another aspect, at least a portion of the anchor delivery guide 93 is flexible so that a tip 99 at the distal end of anchor delivery guide 93 is  
10 positioned at or adjacent to an intracardiac wall anchoring site 17.

[00127] The anchor delivery rod 94 is configured to securely attach anchor screw 21 to the anchoring site 17. The anchor delivery rod 94 has a distal end 101, an opposed proximal end 102 and an inner rod lumen 103 extending therebetween, the inner rod lumen 103 sized and configured so that at least a portion of the delivery  
15 cable 30 is inserted therethrough. In another aspect, at least a portion of the anchor delivery rod 94 is flexible so that a rod tip 104 at the distal end of the anchor delivery rod 94 is positioned at or adjacent to the intracardiac wall anchoring site 17.

[00128] As shown in FIG. 9B, a bore or socket 105 is defined in the anchor rod tip 104 of the anchor delivery rod 94. The socket is sized and configured to matingly  
20 engage the anchor cap 22 which includes a mating member such as an outer surface configuration which, as shown, is a hexagon. Other mating members or outer surface configurations may be employed. That is, at least a portion of the anchor cap is positioned in the socket 105 so that walls 107 of the socket engage the anchor cap. Thus, for example, when the anchor cap 22 is positioned in and engages the socket  
25 105, rotation of the anchor delivery rod 94 rotates the anchor cap 22. Accordingly, the socket engages the anchor cap 22, and the anchor screw 21 extends distally from the anchor delivery rod 94 illustrated in 9B.

[00129] Now referring to FIGS. 10A-B, same anchor delivery system 92 is being used to deploy the anchor screw 61 of the halo anchor assembly 60, and it is  
30 contemplated that same anchor delivery system can be used to deploy the anchor screw 82 of the halo anchor assembly with flex connector 79, at the desired implantation site. As described in [0070], at least a portion of the anchor delivery

guide **93** is flexible so that a tip **99** at the distal end of anchor delivery guide **93** is positioned at or adjacent to an intracardiac wall anchoring site **17**.

[00130] The anchor connector rod **71**, coupled to the anchor connector **69**, is configured to rotate anchor shaft **66** (not shown), which rotates the anchor screw base **62** and the attached anchor screw **61**.

[00131] The anchor delivery system **92** further comprises a guide handle **108** with a deflection knob **109** coupled to the anchor delivery guide **93**. The guide handle and the deflection knob are configured and used to help guide the tip **99** of the anchor delivery guide to the intracardiac wall anchoring site **17**. As shown in FIG. **9A**, the anchor delivery system **92** includes a rod handle **111** coupled to the anchor delivery rod **54**. In FIG. **10A**, rod handle **111** is coupled to anchor connector rod **71**. In use, described more fully below, rotation of the rod handle **111** correspondingly rotates the rod tip **104**, and the anchor cap **22** when the anchor cap **22** is received in the socket **105**. In another aspect, rotation for the rod handle **111** correspondingly rotates the anchor connector rod **71** and affixed anchor connector **69**, thereby rotating the anchor shaft base **62** and attached anchor screw **61**.

[00132] The anchor delivery system **92** includes a trans-septal sheath **115** reversibly coupled to anchor delivery guide **93**. The sheath **115** is in fluid communication with anchor delivery guide **93** so that fluids, such as heparinized saline and the like, surround the anchor delivery guide through the sheath. A central sheath channel **116** is defined by the sheath **115** that is in communication with the anchor delivery guide **93** so that the anchor delivery rod **94** or anchor connector rod **71**, and other system components, run through the central sheath channel **116**. In another aspect, the trans-septal sheath **115** has a trans-septal sheath deflector knob **117** which deflects the sheath tip **118** when rotated.

[00133] The anchor delivery system **92** includes a J-wire **119** as shown in FIG. **11A** that is guidable by the user to the anchoring site **17**. The J-wire is, for example and without limitation, a 0.025" or 0.0035" J-wire. Of course, J-wires having other diameters are contemplated. As in any over-the-wire system, the J-wire is introduced first via sheath **115** into the left atrium **12** and, directed by any known intracardiac catheters, advanced to the left ventricle **16** to the anchoring site **17**. By providing a

pathway for anchor delivery guide **93** to track over to its final target, a J-wire increases the efficiency and safety of this step.

The Method of Implanting the Anchor Assembly

**[00134]** To install the anchor assembly **60** (anchor assembly **40, 41** not shown) to anchoring site **17**, as shown in FIG. **11A**, access is 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 **12**. Over a wire in the left atrium **12**, the trans-septal sheath **115** is advanced into the left atrium **12**; the trans-septal sheath deflector knob **117** is rotated until the trans-septal sheath tip **118** is pointing to the mitral valve orifice **18**. The J-wire **119**, serving as a guidewire, is advanced to the anchor site **17**, and the anchor delivery system **92** is guided by the user over the J-wire **119** to anchoring site **17**.

**[00135]** As shown in FIG. **11A**, the anchor delivery guide tip **99** is deflected by deflection knob **109** of guide handle **108** so that the distal end **96** of the anchor delivery guide **93** is positioned at or adjacent the anchoring site **17**. The anchor connector rod **71** and anchor assembly **60** (anchor delivery rod **94** if anchor assembly **40** or **41** used) are initially positioned within the inner guide lumen **98** of the anchor delivery guide **93**, but as shown in FIG. **11B** when the anchor connector rod **71** has been advanced distally through the inner guide lumen **98**, the docking ring **72**, anchor screw base **62** and anchor screw **61** at or adjacent to the anchoring site **17**.

**[00136]** With the anchor screw **61** of anchor assembly **60** positioned adjacent to the anchoring site **17**, the rotating hand **111** of the anchor connector rod **71** is rotated to cause the corresponding rotation of the anchor screw base **62** as illustrated in FIG. **11B-C**. For example, the rotating handle **111** is rotated in a first direction to cause corresponding rotation of the anchor screw base **62**. The anchor screw **61** coupled the anchor screw base **62** also rotates and screws into the anchoring site **17**, until the distal end portion **73** of the docking ring **72** is adjacent to the anchoring site **17**. Note that in this position, the anchor screw **61** may or may not extend through this portion of the heart wall, but hemostatic membranes prevent bleeding from the anchoring site **17**.

[00137] Upon placement of the anchor assembly 60 in the desired position, the anchor connector rod 71 and the anchor delivery guide 93 of the anchor delivery system 92 are retracted from the heart 11 as illustrated in FIG. 12A. As such, in FIG. 12B, the anchor lines 63 of anchor assembly 60, coupled to the anchor line rods 78 of docking ring 72 (which is coupled to anchor screw base 62), are secured by the anchor screw 61 within the left ventricle 16.

[00138] As shown in FIG. 12B, after placement of the anchor assembly 60, the at least one anchor line extends from the anchor assembly 60 through the mitral annulus 18 into the left atrium 12 into the trans-septal sheath 115 and externalized outside the body.

#### The Leaflet Grasper

[00139] Referring to FIGS. 13A-B, the system also comprises a leaflet grasper 130. The leaflet grasper 130 consists of a control handle 131, grasper shaft 135, and grasper arm 136. The leaflet grasper 10 may be formed of any flexible material such as, composed of one or more metal or metal alloys and/or one or more plastics.

[00140] In one aspect the grasper arm 136 consists of a grasping plate 138 and articulating arm 137, and can be in the closed configuration (FIG. 13A) or the open configuration (FIG. 13B). The grasper arm 136 is located at the distal end 133 of the grasper shaft 135, and the tip of the distal end 133 ends in nosecone 134.

[00141] In another aspect, the control handle 131, fused to the proximal end 132 of the grasper shaft 135 has a trajectory knob 141, which controls the medial/lateral trajectory of the distal end 133 of grasper shaft 135, grasper control 142, which opens and closes the grasper arm 136, puncturing rod handle 143, which drives the puncturing rod 147 and attached chord 160 through the grasped leaflet, retraction handle 146 which pulls the retraction rod and captured chord 160 out of the control handle 131 of the leaflet grasper 130, and a chord release handle 144, which advances the chord release tube 156 out of the nosecone 134, allowing the chord to move out of the split seam of the grasper arm, thereby freeing the chord from the grasper arm.

[00142] Now referring to FIGS. 14A-D, the grasper shaft 135 contains puncturing rod 147, which houses the chord 160, which is fused to puncturing element 148, which rests outside, but is not connected to, puncturing rod 147. After

puncturing rod **147** has pushed puncturing element **148** and attached chord **160** through the leaflet (after leaflet has been captured by grasping plate **138** of grasping arm **136**), puncturing element **148** enters the lumen **151** of receiving cap **149**, which captures puncturing element **148**. Pulling retraction handle **146** (FIGS. **13A-B**) pulls  
5 on retracting rod **153** thereby retracting receiving cap **149**, which is attached to distal end **154** of retracting rod **153**. Therefore, receiving cap **149**, attached to chord **160** via puncturing element **148**, can be withdrawn through distal end **157** of chord release tube **156**, until it exits the grasper shaft **135** via the proximal end of the control handle **131** (FIGS. **13A-B**).

#### 10 The Chords

[00143] Referring to FIGS. **15A-B**, each chord **160** is housed inside the puncturing rod **147** before deployment. The proximal chord **162** rests in the proximal portion of the puncturing rod **147** close to the puncturing rod handle **143** and is attached to either a pledget **161** or a bulky knot **164**. The knot **164** may consist of one  
15 or more knots of any configuration and be composed of, but not limited to, expanded polytetrafluoroethylene (ePTFE), polyethylene terephthalate (PET), ultra-high-molecular-weight polyethylene, nylon, or nitinol wire. The pledget **161** may be of any dimension or polygonal shape and may be composed of any combination of PTFE, ePTFE, PET, or biological membranes such as, but not limited to, bovine or  
20 porcine pericardial tissue. The body of the chord **160** may be composed of any combination of PTFE, ePTFE, PET, nylon, ultra-high-molecular-weight polyethylene or nitinol wire. The end of the chord is fused to a puncturing element **148** that may be composed of any metallic alloy.

#### The Method of Grasping the Leaflet and Chord Implantation

##### 25 *Advancing the Leaflet Grasper to the Leaflet*

[00144] Referring to FIG. **16A**, anchor line **63** is advanced through nosecone **134** of leaflet grasper **130**, through chord release tube **156**, until anchor line **63** exits leaflet grasper through the end of chord release handle **144**. Then leaflet grasper **130** is introduced into lumen **116** of trans-septal sheath **115** and advanced until it exits end  
30 **118** of trans-septal sheath **115**. The length of leaflet grasper **130** is shown as abbreviated in FIG. **16A** by use of sinusoidal lines. Now referring to FIG. **16B**, after

exiting end **118** of trans-septal sheath **115**, trajectory knob **141**, located on the control handle **131**, is rotated until the end **133** of leaflet grasper **130** flexes in the left atrium **12** so that the end **133** can be perpendicular to the mitral valve orifice **18**, and then be able to advance into the left ventricle **16**. Referring to FIG. **17A**, the leaflet grasper **130** can be advanced through lumen **116** of trans-septal sheath **115** and exit end **118** of trans-septal sheath **115** *without* having to advance over anchor line **63**. Referring to **17B**, after exiting end **118** of trans-septal sheath **115**, trajectory knob **141**, located on the control handle **131**, is rotated until the end **133** of leaflet grasper **130** flexes in the left atrium **12** so that the end **133** can be perpendicular to the mitral valve orifice **18**, and then be able to advance into the left ventricle **16**.

#### *Grasping the Leaflet*

[00145] Now referring to FIGS. **18A-C**, first the grasper arm **136** is opened by the grasper control **142** (FIG. **13B**). Next the grasper shaft **135** of the leaflet grasper **130** is retracted until either the mitral leaflet (in FIGS. **18A-C**, it is posterior mitral leaflet **14**) is captured by the grasper arm **136**. Once the leaflet is securely in the grasper arm **136**, the grasper control **142** is used to close the grasper arm **136** so that the leaflet is trapped between the grasper arm **136** and the grasper shaft **135**. In the FIGS. **19A-C**, the process for grasping the leaflets is the same except the leaflet grasper, as in FIGS. **17A-B**, does not have anchor line running through it.

#### *Chord Implantation*

[00146] For FIGS. **20-27**, the leaflet grasper **135** is shown with anchor line **63** entering nosecone **134** and running through chord release tube **156**, but the same sequence of events can occur with the leaflet grasper **135** not having anchor line **63** run through it.

[00147] Now referring to FIGS. **20A-B**, the leaflet (for purposes of illustration leaflet **14**, although leaflet **13** can be similarly grasped) has been grasped by the grasper plate **138** of the grasper arm **136**. Within the grasper shaft **135**, the puncturing rod **147**, containing chord **160**, rests above puncturing element **148**, which is connected to chord **160**. Referring to FIGS. **21A-C**, puncturing rod **147**, containing chord **160**, is pushed down by puncturing rod handle **143** (FIGS. **13A-B**), thereby driving puncturing element **148** through the leaflet **14**. Puncturing element **148**

continues moving down until it enters receiving cap 149, which couples to puncturing element 148 and associated chord 160. Next, referring to FIGS. 22A-B, the puncturing rod 147 is retracted back up and above the leaflet 14 by retracting the puncturing rod handle 143, leaving behind leaflet chord 160, which remains through the leaflet 14, and is attached to puncturing element 148, which is coupled to receiving cap 149. Referring to FIG. 23, pulling retraction handle 146 pulls retracting rod 153 out of chord release handle 144 of control handle 131. As shown in FIGS. 24A-B, this motion is transmitted distally so that as retracting rod 153 moves up in grasper shaft 135, receiving cap 149 (attached to distal end of retracting rod 153) is pulled through the chord release tube 156, along with the puncturing element 148 (coupled to receiving cap 149) and attached chord 160. As shown in FIG. 25, the operator keeps pulling back the retraction handle 146 (connected to retracting rod 153), until the receiving cap 149 and coupled puncturing element 148 are pulled out of the chord release handle 144, thereby externalizing chord 160. Internally, as shown in FIGS. 26A-B, within grasper shaft 135, the pledget 161 (or knot 164), stops on the atrial surface of leaflet 14, with the rest of the chord 160 going through the leaflets 14, back out the chord release tube 156.

[00148] Referring to FIGS. 27A-C, to free the leaflet grasper 130 from leaflet 14, the grasper arm 136 is inverted by action of the grasper control 142. Then, the leaflet grasper 130 can be pushed away from the leaflet 14, and as the leaflet grasper 130 is removed out of the body, the chord 160 and anchor line 63 freely translate through chord release tube 156. In the situation that the leaflet grasper 130 does not run over an anchor line 63, only the chord 160 translates through chord release tube 156. After the leaflet grasper 135 has been removed, FIGS. 28A-B show the implanted chord 160, secured to leaflet by pledget 161, running along side anchor line 63, entering distal end 118 of trans-septal guide 115, and exiting lumen 116 to outside body.

#### Tensioning and Locking Chords

##### *Reversible Locks (Collet Mechanism)*

[00149] With reference to FIGS. 29A-B, the at least one lock positioning rod 170 has a distal end 171, a proximal end 172 and an inner rod lumen 173 sized and

configured so that a portion of a chord **160** and anchor line **63** are inserted therethrough. At least a portion of the lock positioning rod **170** is flexible so that the distal end **171** may be positioned at or adjacent anchor rod line **54** or **78**. The at least one lock positioning rod **170** is coupled to conduit **174**. As illustrated in FIGS. **29A-B** and **Figures 30-31**, each conduit **174** contains a detachable lock **176**, which is

5 configured to securely attach at least one chord **160** and anchor line **63**.

[00150] Referring to FIGS. **30, 31A-B**, an inner surface of lock **176** defines a first mating surface **186** which is shown as a threaded area. A distal end of the second hypotube **178** defines a second mating surface **187** configured to cooperate with the

10 first mating surface **186**. Accordingly, the second retracting hypotube **178** may be rotated so as to disengage the cooperating threaded areas **186** and **187**. The second hypotube **178** is then retracted. This is illustrated in FIG. **31B**. As the second hypotube (i.e. is withdrawn past) the tabs **183** of the first hypotube **177**, the tabs **183** are biased inwardly to release the first hypotube **177** from the lock **176** to enable it to

15 also be retracted. FIG. **32A** illustrated the lock **176** after the first **177** and second **178** hypotubes have been retracted. Moreover, pulling of the retracting hypotube **178** causes retraction of locking clip **179**, which pushes down on locking tabs **182**, engaging chord **160** and anchor line **63**. More specifically, the second hypotube **178** is retracted and due to its connection to locking clip **179**, it also retracts the locking

20 clip **179**. The locking clip **179**, upon retraction, contacts the tabs **183** of the first gateway hypotube **177**, disconnecting the clip **179** permitting the second hypotube **178** to be removed. Once retracting hypotube **178** is pulled, the inner arms of gateway hypotube **177** spring inward. The first gateway hypotube **177**, beneficially enables the chord **160** to be locked while the second hypotube **178** is being retracted.

25 Once the gateway hypotube **177** is removed, the clip **179** remains within conduit **174**. FIG. **32A** shows a cross-sectional view of a lock fully engaged. According to one aspect, the lock positioning rod **170** may be integrated with the gateway hypotube or removably connected thereto. FIG. **14B** shows an intact view of a fully engaged lock.

*Method of Implanting Reversible Locks (Collet Mechanism) and Tensioning Chords*

30 [00151] Now referring to FIGS. **33A-B**, a lock positioning rod **170**, of locking system **180**, is introduced over a chord **160** and anchor line **63** (for purposes of illustration only one chord and anchor line are illustrated) into lumen **116** of the trans-

septal guide **115**. The lock positioning rod **170** advances over chord **160** and anchor line **63** through the end **118** of trans-septal guide **115**, moving through left atrium **12**, across mitral annulus **18**, into left ventricle **16**, until the end of locking system **180** abuts the anchor line rod **54** or **78**. The locking system **180** according to one aspect  
5 abuts the anchor line rod **54** or **78**, alternatively engages therewith. At this point, chord **160** can be pulled backwards until the appropriate tension has been applied to leaflet **14**.

[00152] Now referring to FIGS. **34A**, chord **160** can be pulled backwards until appropriate tension has been applied to leaflet **14**, followed by lock deployment as  
10 illustrated in FIG. **34B**, and as detailed in [0093]. In one aspect, if the tension on the chord needs to be adjusted further, the lock may be unlocked so that the chord may freely translate again. Specifically, when the distal end **171** of the lock positioning rod is adjacent to or in contact with the detachable lock **176**, the first gateway  
hypotube **177** is advanced back into the lock **176**, followed by the second retracting  
15 hypotube **178**, whose second mating surface **187** can screw back into first mating surface **186**, allowing the second retracting hypotube **178** to push the first mating surface **186** (attached to locking clip **179**) down, thereby disengaging locking tabs **182** from chord **160** and anchor line **63**. With chord unlocked, more or less tension can be applied to the leaflet **14** by pulling or releasing chord. This process can be repeated as  
20 many times as necessary and even after multiple locks have been implanted.

#### *Reversible Locks (self-locking)*

[00153] Now referring to FIGS. **35A-B**, the reversible and detachable self-locking locks **190** securely fix the chord **160** to the anchor line **63** and to the anchor line **78** rod of the anchor line swivel attached to the anchor. The locks **190** may be  
25 composed of any combination of metallic alloy or plastic, and be of any dimension, shaped as any type of polyhedron or as a cylinder whose cross-section area can be a circle or ellipse. Each lock **190** has a chord lumen **191** of any caliber through which the chord runs, and an anchor line lumen **192** of any caliber through which the anchor line **63** runs. As shown in FIG. **35A**, as the chord **160** is pulled through the chord  
30 lumen, a binding plate **193** allows the chord **160** to be pulled up, but does not allow the chord to move down, thereby maintaining any tension applied to chord. The binding plate **193** can be of any dimension and polygonal shape, and composed of any

metallic allow, plastic, or covered in silicon. As shown in FIG. 35B, to release tension, the anchor line 63 is pulled up, bring up an unlocking element 194, composed of any metallic allow or plastic polymer, and may be shaped as a sphere, cylinder, or any polyhedron. The unlocking element 194 pushes up the binding plate 193, allowing to the chord to translate up or down in the chord lumen. Because the unlocking element is fixed to the anchor line by a spring 196, releasing tension on anchor line allows the spring 196 to bring the anchor line 63 and attached unlocking element 194 down, thereby causing the binding plate 193 within the lock 190 to re-engage with the chord 160, re-locking chord tension by preventing the chord from slipping back down, as shown in FIG. 35A. The lumens 191 and 192 in FIGS. 35A and 35B are shown as representative. The lumens 191 and 192B define channels (not shown) for receipt of the respective member.

*Method of Implanting Reversible Locks (self-locking) and Tensioning Chords*

[00154] Now referring to FIGS. 36A-B, a lock positioning rod 200, pushes lock 190 over a chord 160 and anchor line 63, until lock 190 docks onto anchor line rod 78 of the anchor line swivel attached to the anchor. Lock positioning rod 200 may be retracted anytime after docking, and preferentially is removed before final chord tensioning to understand efficacy of chord without the rod being across the mitral coaptation plane. Final chord tensioning, as shown in FIGS. 35A-B, occurs when chord 160 can be pulled through chord lumen 191 until appropriate tension is placed on leaflet 14 (in FIG. 36A), and this tension is automatically maintained because binding plate 193 prevents chord 160 from slipping back though chord lumen 191. As stated in [0085], if chord tension needs to lessened, pulling on anchor line 63 brings the unlocking element 194 up, thereby pushing up binding plate 193 so that chord 160 can again freely translate through chord lumen 190.

*Chord Tension Regulator, Chord Tension Control Board, and Method of Chord Tensioning*

[00155] As shown in FIG. 37, the chord tension regulator 210 has a chord lumen 211 with chord lumen exit 212 through which the chord 160 runs. The chord tension regulator also has an anchor rod lumen 214 which snaps onto anchor rod 78, once the regulator 210 is pushed by a regulator rod (not shown) onto the base of the anchor rod

78. The top of the anchor rod 78 exits the anchor rod exit 213, and the anchor line 63 is attached to the top of the anchor rod 78.

[00156] FIGS. 38A-B show how the chord tension regulator functions with the chord tension control board 250 to adjust tension of the chord 160. The chord tension control board 250 houses one or more chord tension controls 251, each of which contains a chord tension lever 252. As shown in FIG. 38A, the chord 160 and anchor line 63 enter the distal end 118 of the transseptal sheath 115, both exiting out the sheath through the central sheath channel 116.

[00157] The operator may attach one or more chords 160 to one or more chord tension levers 252 of the chord tension control board 250. Initially, as shown in FIG. 38A, the chord tension lever 252 has not been retracted so the chord 160 is in the relaxed position, and has not tensioned the leaflet 14. As shown in FIG. 38B, as the chord tension lever 252 is retracted, the chord 160 is pulled backward through the chord tension regulator 210, until the chord 160 has adequate tension on leaflet 14. The chord tension lever 252 maintains its position, but at anytime may be readjusted to release or increase tension on the chord 160 and attached leaflet 14.

*Reversible Locks (locking/unlocking)*

[00158] Now referring to FIGS. 39A-B, the locking/unlocking reversible locks 220 securely fix the chord 160 to the anchor line 63 and to the anchor line 78 rod of the anchor line swivel attached to the anchor. The locks 220 may be composed of any combination of metallic alloy or plastic, and be of any dimension, shaped as any type of polyhedron or as a cylinder whose cross-section area can be a circle or ellipse. Each lock 220 has a chord lumen 221 of any caliber, with chord lumen exit 222, through which the chord runs, and the anchor line 63 runs through the push button element 226 (composed of any metallic alloy or plastic polymer), then through the locking chamber 227, through the binding plate pusher 228 until the anchor line 63 exits the anchor line exit 229, which abuts the binding plate 223. As shown in FIG. 39A, when the lock 220 is unlocked, the chord 160 can translate freely through chord lumen 221 and chord lumen exit 222.

[00159] In principle, the locking chamber 227, push button element 226, and binding plate pusher 228, function just like a standard retractable ballpoint pen.

Specifically, the push button element **226** can slide back and forth via internal grooves (not shown) of locking chamber **227** and is always urged backwards by internal spring (not shown). The push button element, itself, has distal slanted edges (not shown) that co-operate with a cam shaft (not shown) abutting binding plate pusher **228**. As  
5 in a retractable ballpoint pen, the push button element pushes the cam shaft forward past the internal grooves; once past the internal grooves, the cam shaft cooperates further with the push button element edges, consequently rotating. When the spring pushes the cam shaft back, because the shaft has rotated it settles in a “forward” position as it sets against the internal grooves. When the push button element pushes  
10 the cam shaft forward again, the cam shaft rotates again, and as it is pushed back by internal spring, settling in its baseline “backward” position.

[00160] Thus, as shown in FIG. **39A**, by retracting the anchor line **63**, attached to unlocking element **224** (composed of any metallic allow or plastic polymer, and may be shaped as a sphere, cylinder, or any polyhedron), the unlocking element **224**  
15 brings the push button element **226** into locking chamber **227**, which pushes binding plate pusher **228** into the anchor line exit **229**, thereby causing binding plate **223** to crimp the chord **160** as it exits the chord lumen exit **222**, thereby locking chord **160** in place. As shown in FIG. **39A**, because push button element **226** is attached to anchor line rod **78** by spring **231**, the push button element **226** is automatically retracted  
20 away from locking chamber **227** back down when anchor line **63** is released. By pulling the anchor line **63** a second time the push button element re-enters the locking chamber **227**, pushing on push button element **226**, which interacts with internal elements, as described in [0088], causing binding plate pusher **228** to retract back into locking chamber **227**, allowing binding plate **223** to move away from chord lumen  
25 exit **222**, allowing chord **160** to translate freely again.

#### The Anchor line/Chord Crimper

[00161] As shown in FIG. **40A-B**, the anchor line/chord crimper **260** has a control handle **263**, shaft **261**, distal end **262**, connected to grasping hook **268**. The control handle **263** contains a grasping lever **264**, lock knob **266**, and cutting lever  
30 **267**. FIG. **40A** shows grasping lever **264** pushed forward in control handle **263**, thereby pushing grasping hook **268** forward, allowing anchor line and chord to enter.

FIG. 40B shows grasping lever 264 retracted back in control handle 263, thereby retracting grasping hook 268 back to distal end 262 of the shaft 261.

#### The Method of Crimping/Cutting Chords

[00162] FIGS. 41A-C show the process of the anchor line/chord crimper 260  
5 grabbing the chord 160 and anchor line 63. For purpose of illustration, the anchor/line crimper 260 is shown with the chord tension regulator system, but may be used with other locking systems. In FIG. 41A, the distal end 262 of anchor line/chord crimper 260 is advanced toward chord 160 and anchor line 63. Because the grasping hook 268 is in the open position, the chord 160 and anchor line 63 may be inserted  
10 into the grasping hook 268. As illustrated in FIGS. 41B-C, the grasping hook 268 is retracted to the closed position (as described in [00149]), so that the anchor line/chord crimper 260 may be advanced over the chord 160 and anchor line 63 into trans-septal sheath 115.

#### Chord 160 vs anchor line 63

15 [00163] FIGS. 42A-B show the anchor line/chord crimper 260 that has advanced through trans-septal sheath 115 until the grasping hook 268 is next to the chord tension regulator 210. In FIGS. 43A-B, lock knob 266 (FIGS. 40A-B) has been rotated, thereby deploying lock 280 to fix chord 160 and anchor line 63 to chord tension regulator 210. At the same time, cutting lever 267 (FIGS. 40A-B) has been  
20 pushed, thereby cutting the end of chord 160 and anchor line 63 proximal to lock 280, allowing the proximal chord 160, anchor line 63, and anchor line/chord crimper 260 to be retracted back into trans-septal sheath 115.

[00164] Although several aspects of the invention have been disclosed in the foregoing specification, it is understood by those skilled in the art that many  
25 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 modifications and other aspects are intended to be included within the scope of the appended claims.  
30 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.

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