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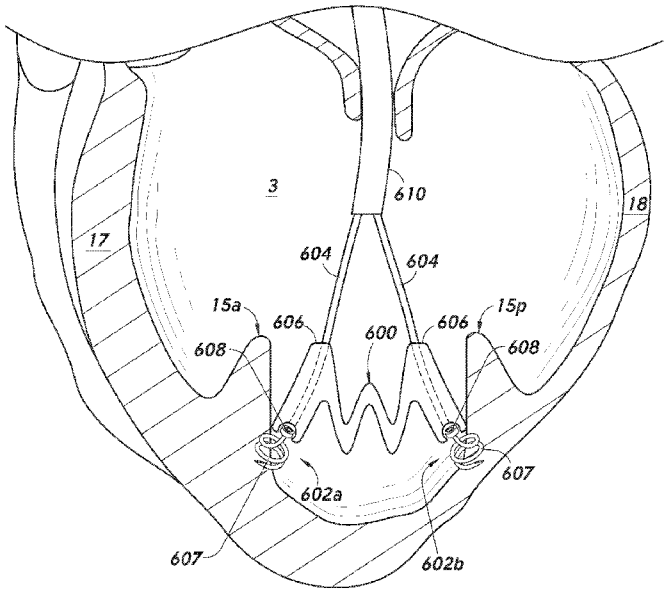


FIG. 6

(57) Abstract: A cardiac device comprises a first anchoring element configured to anchor to a first area of tissue, a second anchoring element configured to anchor to a second area of tissue, and a tension member configured to couple to the first anchoring element and the second anchoring element. The tension member is configured to expand and contract in response to applied pressure from the first anchoring element and the second anchoring element.

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TENSION DEVICE FOR VENTRICULAR REMODELING AND TREATMENT OF HEART FAILURE

BACKGROUND

[0001] The present disclosure generally relates to the field of improving heart performance.

[0002] Heart Failure with reduced Ejection Fraction (HFrEF), also known as systolic heart failure, is characterized by an inability of the heart to contract adequately, resulting in less oxygen-rich blood being expelled into the body. Functional mitral valve regurgitation (FMR) is a disease that occurs when the left ventricle of the heart is distorted or dilated, displacing the papillary muscles that support the two valve leaflets. When the valve leaflets can no longer come together to close the annulus, blood may flow back into the atrium.

SUMMARY

[0003] In some implementations, the present disclosure relates to a cardiac device. The cardiac device comprises a first anchoring element configured to anchor to a first area of tissue, a second anchoring element configured to anchor to a second area of tissue, and a tension member configured to couple to the first anchoring element and the second anchoring element, wherein the tension member is configured to expand and contract in response to applied pressure from the first anchoring element and the second anchoring element.

[0004] The tension member may be configured to apply force to the first anchoring element to move the first anchoring element towards the second anchoring element and apply force to the second anchoring element to move the second anchoring element towards the first anchoring element. In some embodiments, the tension member is configured to apply force to the first anchoring element to move the first anchoring element away from the second anchoring element and apply force to the second anchoring element to move the second anchoring element away from the first anchoring element. The tension member may be at least partially composed of a shape-memory alloy.

[0005] In some embodiments, the tension member has a tubular shape with an at least partially hollow interior. The tension member may have wavelike curves and comprise at least one crest. The first anchoring element may be configured to fit into the at least partially hollow interior of the tension member at a first end of the tension member. In some embodiments, the tension member comprises one or more connection mechanisms configured

to hold the first anchoring element at least partially inside the tension member. Each of the one or more connection mechanisms may comprise one of a group consisting of a peg, a notch, a cavity, a groove, and a hook.

[0006] The tension member may have a substantially flat shape in which a width of the tension member is greater than a thickness of the tension member. In some embodiments, the tension member may have wavelike curves and comprise at least one crest. The tension member may comprise one or more connection mechanisms configured to attach to the first anchoring element. Each of the one or more connection mechanisms may comprise, at a first end of the tension member, one of a group consisting of a peg, a notch, a cavity, a groove, and a hook.

[0007] In some embodiments, the tension member has a coiled shape and comprises one or more connection mechanisms configured to attach to the first anchoring element. Each of the one or more connection mechanisms may comprise, at a first end of the tension member, one of a group consisting of a peg, a notch, a cavity, a groove, and a hook. In some embodiments, the first area of tissue is a posterior wall and the second area of tissue is a septum.

[0008] Some implementations of the present disclosure relate to a method comprising anchoring a first anchoring element to a first area of tissue, anchoring a second anchoring element to a second area of tissue, and coupling a tension member to the first anchoring element and the second anchoring element. The tension member is configured to expand and contract in response to applied pressure from the first anchoring element and the second anchoring element.

[0009] The tension member may be configured to apply force to the first anchoring element to move the first anchoring element towards the second anchoring element and apply force to the second anchoring element to move the second anchoring element towards the first anchoring element. In some embodiments, the tension member is configured to apply force to the first anchoring element to move the first anchoring element away from the second anchoring element and apply force to the second anchoring element to move the second anchoring element away from the first anchoring element. The tension member may be at least partially composed of a shape-memory alloy.

[0010] In some embodiments, the tension member has a tubular shape with an at least partially hollow interior and has wavelike curves and comprises at least one crest. Coupling the tension member to the first anchoring element may involve inserting the first anchoring element at least partially into the at least partially hollow interior of the tension member at a

first end of the tension member. The tension member may comprise one or more connection mechanisms configured to hold the first anchoring element at least partially inside the tension member. In some embodiments, each of the one or more connection mechanisms comprises one of a group consisting of a peg, a notch, a cavity, a groove, and a hook.

[0011] The tension member may have a substantially flat shape in which a width of the tension member is greater than a thickness of the tension member and may have wavelike curves and comprises at least one crest. The tension member may comprise one or more connection mechanisms configured to attach to the first anchoring element. Each of the one or more connection mechanisms may comprise, at a first end of the tension member, one of a group consisting of a peg, a notch, a cavity, a groove, and a hook.

[0012] In some embodiments, the tension member has a coiled shape and comprises one or more connection mechanisms configured to attach to the first anchoring element. Each of the one or more connection mechanisms may comprise, at a first end of the tension member, one of a group consisting of a peg, a notch, a cavity, a groove, and a hook. The first area of tissue may be a posterior wall and the second area of tissue is a septum.

[0013] Some implementations of the present disclosure relate to an apparatus comprising first means for anchoring configured to anchor to a first area of tissue, second means for anchoring configured to anchor to a second area of tissue, and means for tensioning configured to couple to the first means for anchoring and the second means for anchoring. The means for tensioning is configured to expand and contract in response to applied pressure from the first means for anchoring and the second means for anchoring.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] Various embodiments are depicted in the accompanying drawings for illustrative purposes, and should in no way be interpreted as limiting the scope of the inventions. In addition, various features of different disclosed embodiments can be combined to form additional embodiments, which are part of this disclosure. Throughout the drawings, reference numbers may be reused to indicate correspondence between reference elements.

[0015] Figure 1 provides a cross-sectional view of a human heart.

[0016] Figure 2 provides a cross-sectional view of the left ventricle and left atrium of an example heart.

[0017] Figure 3 provides a cross-sectional view of a heart experiencing mitral regurgitation.

[0018] Figure 4 shows a view of the heart including a remodeling device implanted in the left ventricle in accordance with one or more embodiments.

[0019] Figure 5A illustrates a tension member having a tubular structure in accordance with one or more embodiments.

[0020] Figure 5B illustrates a tension member having a substantially flat shape in accordance with one or more embodiments.

[0021] Figure 5C illustrates a tension member having a helical coil shape in accordance with one or more embodiments.

[0022] Figure 6 is a cross-section view of the heart showing an implanted ventricle remodeling device having two anchoring points in accordance with one or more embodiments.

[0023] Figure 7 is a flow diagram representing a process for remodeling a ventricle of the heart in accordance with one or more embodiments.

DETAILED DESCRIPTION

[0024] The headings provided herein are for convenience only and do not necessarily affect the scope or meaning of the claimed invention.

[0025] Although certain preferred embodiments and examples are disclosed below, inventive subject matter extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses and to modifications and equivalents thereof. Thus, the scope of the claims that may arise herefrom is not limited by any of the particular embodiments described below. For example, in any method or process disclosed herein, the acts or operations of the method or process may be performed in any suitable sequence and are not necessarily limited to any particular disclosed sequence. Various operations may be described as multiple discrete operations in turn, in a manner that may be helpful in understanding certain embodiments; however, the order of description should not be construed to imply that these operations are order dependent. Additionally, the structures, systems, and/or devices described herein may be embodied as integrated components or as separate components. For purposes of comparing various embodiments, certain aspects and advantages of these embodiments are described. Not necessarily all such aspects or advantages are achieved by any particular embodiment. Thus, for example, various embodiments may be carried out in a manner that achieves or optimizes one advantage or

group of advantages as taught herein without necessarily achieving other aspects or advantages as may also be taught or suggested herein.

[0026] In humans and other vertebrate animals, the heart generally comprises a muscular organ having four pumping chambers, wherein the flow thereof is at least partially controlled by various heart valves, namely, the aortic, mitral (or bicuspid), tricuspid, and pulmonary valves. The valves may be configured to open and close in response to a pressure gradient present during various stages of the cardiac cycle (e.g., relaxation and contraction) to at least partially control the flow of blood to a respective region of the heart and/or to blood vessels (e.g., pulmonary, aorta, etc.).

[0027] Figure 1 illustrates an example representation of a heart 1 having various features relevant to certain embodiments of the present inventive disclosure. The heart 1 includes four chambers, namely the left atrium 2, the left ventricle 3, the right ventricle 4, and the right atrium 5. A wall of muscle 17, referred to as the septum, separates the left 2 and right 5 atria and the left 3 and right 4 ventricles. The heart 1 further includes four valves for aiding the circulation of blood therein, including the tricuspid valve 8, which separates the right atrium 5 from the right ventricle 4. The tricuspid valve 8 may generally have three cusps or leaflets and may generally close during ventricular contraction (i.e., systole) and open during ventricular expansion (i.e., diastole). The valves of the heart 1 further include the pulmonary valve 9, which separates the right ventricle 4 from the pulmonary artery 11 and may be configured to open during systole so that blood may be pumped toward the lungs, and close during diastole to prevent blood from leaking back into the heart from the pulmonary artery. The pulmonary valve 9 generally has three cusps/leaflets, wherein each one may have a crescent-type shape. The heart 1 further includes the mitral valve 6, which generally has two cusps/leaflets and separates the left atrium 2 from the left ventricle 3. The mitral valve 6 may generally be configured to open during diastole so that blood in the left atrium 2 can flow into the left ventricle 3, and advantageously close during diastole to prevent blood from leaking back into the left atrium 2. The aortic valve 7 separates the left ventricle 3 from the aorta 12. The aortic valve 7 is configured to open during systole to allow blood leaving the left ventricle 3 to enter the aorta 12, and close during diastole to prevent blood from leaking back into the left ventricle 3.

[0028] Heart valves may generally comprise a relatively dense fibrous ring, referred to herein as the annulus, as well as a plurality of leaflets or cusps attached to the annulus. Generally, the size of the leaflets or cusps may be such that when the heart contracts the resulting increased blood pressure produced within the corresponding heart chamber forces

the leaflets at least partially open to allow flow from the heart chamber. As the pressure in the heart chamber subsides, the pressure in the subsequent chamber or blood vessel may become dominant, and press back against the leaflets. As a result, the leaflets/cusps come in apposition to each other, thereby closing the flow passage.

[0029] The atrioventricular (i.e., mitral and tricuspid) heart valves may further comprise a collection of chordae tendineae and papillary muscles for securing the leaflets of the respective valves to promote and/or facilitate proper coaptation of the valve leaflets and prevent prolapse thereof. The papillary muscles, for example, may generally comprise finger-like projections from the ventricle wall. With respect to the tricuspid valve 8, the normal tricuspid valve may comprise three leaflets (two shown in Figure 1) and three corresponding papillary muscles 10 (two shown in Figure 1). The leaflets of the tricuspid valve may be referred to as the anterior, posterior and septal leaflets, respectively. The valve leaflets are connected to the papillary muscles 10 by the chordae tendineae 13, which are disposed in the right ventricle 4 along with the papillary muscles 10. Although tricuspid valves are described herein as comprising three leaflets, it should be understood that tricuspid valves may occur with two or four leaflets in certain patients and/or conditions; the principles relating to papillary muscle repositioning disclosed herein are applicable to atrioventricular valves having any number of leaflets and/or papillary muscles associated therewith.

[0030] The right ventricular papillary muscles 10 originate in the right ventricle wall, and attach to the anterior, posterior and septal leaflets of the tricuspid valve, respectively, via the chordae tendineae 13. The papillary muscles 10 of the right ventricle 4 may have variable anatomy; the anterior papillary may generally be the most prominent of the papillary muscles. The papillary muscles 10 may serve to secure the leaflets of the tricuspid valve 8 to prevent prolapsing of the leaflets into the right atrium 5 during ventricular systole. Tricuspid regurgitation can be the result of papillary dysfunction or chordae rupture.

[0031] With respect to the mitral valve 6, a normal mitral valve may comprise two leaflets (anterior and posterior) and two corresponding papillary muscles 15. The papillary muscles 15 originate in the left ventricle wall and project into the left ventricle 3. Generally, the anterior leaflet may cover approximately two-thirds of the valve annulus. Although the anterior leaflet covers a greater portion of the annulus, the posterior leaflet may comprise a larger surface area in certain anatomies.

[0032] The valve leaflets of the mitral valve 6 may be prevented from prolapsing into the left atrium 2 by the action of the chordae tendineae 16 tendons connecting the valve leaflets to the papillary muscles 15. The relatively inelastic chordae tendineae 16 are attached

at one end to the papillary muscles 15 and at the other to the valve leaflets; chordae tendineae from each of the papillary muscles 15 are attached to a respective leaflet of the mitral valve 6. Thus, when the left ventricle 3 contracts, the intraventricular pressure forces the valve to close, while the chordae tendineae 16 keep the leaflets coapting together and prevent the valve from opening in the wrong direction, thereby preventing blood to flow back to the left atrium 2. The various chords of the chordae tendineae may have different thicknesses, wherein relatively thinner chords are attached to the free leaflet margin, while relatively thicker chords (e.g., strut chords) are attached farther away from the free margin.

[0033] Figure 2 provides a cross-sectional view of the left ventricle 3 and left atrium 2 of an example heart 1. The diagram of Figure 2 shows the mitral valve 6, wherein the disposition of the valve 6, papillary muscles 15 and/or chordae tendineae 16 may be illustrative as providing for proper coapting of the valve leaflets to advantageously at least partially prevent regurgitation and/or undesirable flow into the left atrium from the left ventricle 3 and vice versa. Although a mitral valve 6 is shown in Figure 2 and various other figures provided herewith and described herein in the context of certain embodiments of the present disclosure, it should be understood that papillary muscle repositioning principles disclosed herein may be applicable with respect to any atrioventricular valve and associated anatomy (e.g., papillary muscles, chordae tendineae, ventricle wall, etc.), such as the tricuspid valve.

[0034] As described above, with respect to a healthy heart valve as shown in Figure 2, the valve leaflets 61 may extend inward from the valve annulus and come together in the flow orifice to permit flow in the outflow direction (e.g., the downward direction in Figure 2) and prevent backflow or regurgitation toward the inflow direction (e.g., the upward direction in Figure 2). For example, during atrial systole, blood flows from the atria 2 to the ventricle 3 down the pressure gradient, resulting in the chordae tendineae 16 being relaxed due to the atrioventricular valve 6 being forced open. When the ventricle 3 contracts during ventricular systole, the increased blood pressures in both chambers may push the valve 6 closed, preventing backflow of blood into the atria 2. Due to the lower blood pressure in the atria compared to the ventricles, the valve leaflets may tend to be drawn toward the atria. The chordae tendineae 16 can serve to tether the leaflets and hold them in a closed position when they become tense during ventricular systole. The papillary muscles 15 provide structures in the ventricles for securing the chordae tendineae 16 and therefore allowing the chordae tendineae 16 to hold the leaflets in a closed position. The papillary muscles 15 may include a first papillary muscle 15a (e.g., an anterolateral papillary muscle, which may be primarily

tethered to the anterior leaflet, for example) and a second papillary muscle 15p (e.g., the posteromedial papillary muscle, which may be primarily tethered to the posterior leaflet, for example). Each of the first papillary muscle 15a and second papillary muscle 15p may provide chordae tendineae 16 to each valve leaflet (e.g., the anterior and posterior leaflets). With respect to the state of the heart 1 shown in Figure 2, the proper coaptation of the valve leaflets, which may be due in part to proper position of the papillary muscles 15, may advantageously result in mitral valve operation substantially free of leakage.

[0035] Heart valve disease represents a condition in which one or more of the valves of the heart fails to function properly. Diseased heart valves may be categorized as stenotic, wherein the valve does not open sufficiently to allow adequate forward flow of blood through the valve, and/or incompetent, wherein the valve does not close completely, causing excessive backward flow of blood through the valve when the valve is closed. In certain conditions, valve disease can be severely debilitating and even fatal if left untreated. With regard to incompetent heart valves, over time and/or due to various physiological conditions, the position of papillary muscles may become altered, thereby potentially contributing to valve regurgitation. For example, as shown in Figure 3, which illustrates a cross-sectional view of a heart 1 experiencing mitral regurgitation flow 21, dilation of the left ventricle may cause changes in the position of the papillary muscles 15 that allow flow 21 back from the ventricle 3 to the atrium 2. Dilation of the left ventricle can be caused by any number of conditions, such as focal myocardial infarction, global ischemia of the myocardial tissue, or idiopathic dilated cardiomyopathy, resulting in alterations in the geometric relationship between papillary muscles and other components associated with the valve(s) that can cause valve regurgitation. Functional regurgitation may further be present even where the valve components may be normal pathologically, yet may be unable to function properly due to changes in the surrounding environment. Examples of such changes include geometric alterations of one or more heart chambers and/or decreases in myocardial contractility. In any case, the resultant volume overload that exists as a result of an insufficient valve may increase chamber wall stress, which may eventually result in a dilatory effect that causes papillary muscle alteration resulting in valve dysfunction and degraded cardiac efficiency.

[0036] With further reference to Figure 3, the heart 1 is shown in a state where functional mitral valve regurgitation (FMR) is present. FMR may be considered a disease of the left ventricle 3, rather than of the mitral valve 6. For example, mitral valve regurgitation may occur when the left ventricle 3 of the heart 1 is distorted or dilated, displacing the papillary muscles 15 that support the two valve leaflets 61. The valve leaflets 61 therefore

may no longer come together sufficiently to close the annulus and prevent blood flow back into the atrium 2. If left untreated, the FMR experienced in the state shown in Figure 3 may overload the heart 1 and can possibly lead to or accelerate heart failure. Solutions presented herein provide devices and methods for moving the papillary muscles 15 closer to their previous position, which may advantageously reduce the occurrence of mitral regurgitation.

[0037] As shown in Figure 3, the leaflets 61 of the mitral valve (or tricuspid valve) are not in a state of coaptation, resulting in an opening between the mitral valve leaflets 61 during the systolic phase of the cardiac cycle, which allows the leakage flow 21 of fluid back up into the atrium 2. The papillary muscles 15 may be displaced due to dilation of the left ventricle 3, or due to one or more other conditions, as described above, which may contribute to the failure of the valve 6 to close properly. The failure of the valve leaflets 61 to coapt properly may result in unwanted flow in the outflow direction (e.g., the upward direction in Figure 3) and/or unwanted backflow or regurgitation toward the inflow direction (e.g., the downward direction in Figure 2).

[0038] Some embodiments disclosed herein provide solutions for treating FMR and/or heart failure with reduced ejection fraction (HFrEF) and/or heart failure with preserved ejection fraction (HFpEF) without the need for surgical procedures or destroying cardiac tissue. In particular, passive techniques to improve valve performance are disclosed for improving cardiac function. Further, various embodiments disclosed herein provide for the treatment of FMR, HFpEF, and/or HFrEF that can be executed on a beating heart, thereby allowing for the ability to assess the efficacy of the treatment and potentially implement modification thereto without the need for bypass support.

[0039] Some embodiments involve remodeling one or more ventricles (e.g., reducing ventricular volume) to restore valve function and/or improve ejection fraction. Ventricular remodeling (e.g., reducing and/or increasing left ventricle volume) can potentially treat FMR, HFpEF and/or HFrEF by, for example, repositioning the papillary muscles to improve coaptation of valve leaflets. Some embodiments described herein involve reducing and/or increasing ventricle volume by inserting one or more tension members, which may include one or more stents, wires, bands, cords, strings, tubes, sutures, sheets, struts, springs, and/or other lengths of material (referred to herein collectively as "tension members," or "means for tensioning") into a ventricle and anchoring the tension member(s) to anchoring elements at ventricle walls and/or papillary muscles. By compressing the tension member(s), the walls of the ventricle may be repositioned inward to decrease ventricle volume, whereas by expanding

the tension member(s), the walls of the ventricle may be repositioned outward to increase ventricle volume.

[0040] In some embodiments, a tension member may comprise one or more compressible, expandable, and/or bendable components to allow for compression and/or expansion of the tension member. For example, the tension member may comprise a bendable tube and/or wire, a substantially flat sheet configured to hold a waveform shape, and/or a spring. In some embodiments, the tension member may comprise a portion of a tube. The tension member may be composed of a shape-memory alloy or other material to allow the tension member to hold and/or assume a pre-determined shape when no force is applied to the tension member. When force is applied to the tension member, the tension member may expand and/or compress in response to the force.

[0041] When the tension member expands and/or compresses, potential energy may be created in the tension member such that the tension member may attempt to return to a pre-determined shape and may apply force at anchoring elements and/or surfaces holding the tension member in the expanded and/or compressed form. For example, a tension member may be attached to two or more anchoring elements, and a first anchoring element may be anchored to a first ventricle wall (e.g., the septum) and a second anchoring element may be anchored to a second ventricle wall (e.g., a posterior wall). If a distance between the first ventricle wall and the second ventricle exceeds a length of the tension member in the pre-determined shape of the tension member, the tension member may be configured to expand to approximately equal to and/or slightly less than the distance between the ventricle walls. While in the expanded shape, the tension member may be configured to apply pressure at each of the anchoring elements as the tension member naturally moves back to the pre-determined shape. Similarly, if the distance between the ventricle walls is smaller than the natural length of the tension member, the tension member may be configured to apply pressure at the anchoring elements to move the anchoring element further apart. In some embodiments, an elasticity of the tension member may be sufficiently low that an amount of resistance created by the ventricle tissue may prevent the tension member from returning completely to the pre-determined shape. Moreover, the tension member may cause gradual remodeling of the ventricle over time, rather than causing maximal remodeling when the tension member is first inserted. In this way, the remodeling device may be configured to create a reduced risk of damaging the ventricle tissue. Moreover, delivery of the remodeling device may be simplified by the expandable and/or compressible structure of the tension member as the remodeling device may be adjusted in length during delivery.

[0042] A tension member may be composed of metal, plastic, polymer, or other suitable material. Tension members may be substantially rigid in form in order to build up a desired amount of potential energy in response to expansion and/or compression forces. In some embodiments, a tension member may be composed of Nitinol or other shape-memory alloy. The tension member may be composed of a solid material (e.g., metal or solid plastic). In some embodiments, the material of the tension member itself may not be elastic, springy, and/or flexible. However, the tension member may have elastic, springy, and/or flexible characteristics due at least in part to the structure of the tension member. For example, the tension member may have a coiled (e.g., a spring) and/or wave-like form such that the structure of the tension member may be compressed (e.g., by bringing portions of the tension member closer together) and/or expanded (e.g., by increasing a separation between portions of the tension member). The tension member may be configured to be delivered into the heart with a relatively small profile to allow the tension member to fit through a catheter and/or other delivery systems. After delivery into the heart, the tension member may assume a pre-determined shape.

[0043] A tension member may be configured to be anchored through use of means for anchoring, which may include anchoring elements such as corkscrews, threaded screws, nails, buttons, needles, barbs, hooks, and other devices. Anchoring elements may be configured to directly contact and/or anchor the tension member to one or more ventricle walls and/or papillary muscles. In some embodiments, the tension member may be configured to be compressed (e.g., to reduce a distance between anchoring elements at the multiple walls, thereby reducing ventricle volume) and/or expanded (e.g., to increase the distance between anchoring elements, thereby increasing ventricle volume).

[0044] The term "ventricle wall" is used herein according to its broad and ordinary meaning and may refer to any area of tissue separating a ventricle of the heart from another chamber of the heart or an area outside the heart and may include, for example, the septum, posterior walls, and the region of the ventricle near the apex of the heart, among others. In some embodiments, one or more anchoring elements and/or tension members may be configured to pass through a ventricle wall and/or papillary muscle and extend at least partially outside of the heart and/or into another chamber of the heart.

[0045] In some embodiments, anchoring elements may comprise one or more connected/connectable components and/or may be configured to puncture and/or secure to a ventricle wall. One or more components of an anchoring element may have a threaded exterior and/or may include corkscrews, needles, barbs, hooks, and/or other devices to

facilitate puncturing and/or passing through the ventricle wall. When a tension member is allowed to compress and/or expand, pressure may be applied to each of the anchoring elements in order to reduce strain at any one individual anchor.

[0046] In some embodiments, a remodeling device may comprise anchoring elements at either side of a ventricle coupled by one or more tension members. For example, a first anchoring element may be configured to be inserted into a first ventricle wall (e.g., a posterior wall) and a second anchoring element may be configured to be inserted into a second ventricle wall (e.g., a septum). In some embodiments, a third anchoring element may be configured to be inserted at the first ventricle wall, second ventricle wall, a third ventricle wall (e.g., the apex region of the heart), and/or one or more papillary muscles. One or more tension members may couple to the first anchoring element, the second anchoring element, and/or the third anchoring element and may be configured to be activated (e.g., released from delivery systems) to reduce a distance between the first ventricle wall, the second ventricle wall, and/or any other area of tissue.

[0047] In some embodiments, a mechanical device for treating FMR, HFrEF, and/or other diseases may be configured to be delivered to an affected area of tissue via a transcatheter procedure. Each of the anchoring elements and/or tension member(s) may be configured to be delivered and/or adjusted using a transfemoral (artery), transapical, or transseptal procedure. Once in place, the anchoring elements and/or tension member(s) may be configured to be detached from the delivery system and left in the heart as an implant. The tension member(s) may be activated to apply pressure to the anchoring elements, thereby reducing and/or increasing a distance between a plurality of ventricle walls to reduce and/or increase ventricle volume and treat FMR, HFpEF, and/or HFrEF.

[0048] Due to the compressible, expandable, and/or bendable form of the tension member, the tension member may be configured to create an elastic, springy, and/or flexible connection between multiple anchoring elements and/or between an anchoring element and another device. In this way, the tension member may be configured to advantageously allow for a simplified delivery process which may reduce the risk of damage to the ventricle tissue. The flexible nature of the tension member may be configured to cause more gradual ventricle remodeling than other methods of remodeling ventricle which are not capable of expanding and/or compressing. Moreover, the tension member may be configured to create less risk of tearing at the tissue around the anchoring elements and may further reduce the risk of anchoring elements becoming dislodged from tissue by compressing and/or expanding in response to tension at the tissue walls.

[0049] Figure 4 shows a view of the heart 1 including a remodeling device implanted in the left ventricle 3. While Figure 4 shows the remodeling device anchored to ventricle walls, the remodeling device may also and/or alternatively be anchored to papillary muscles and/or other areas of tissue. Moreover, while Figure 4 shows a remodeling device comprising two ends, each anchored by an anchoring element, remodeling devices may comprise a third end and/or additional ends to more symmetrically remodel a ventricle and/or other chamber. For example, the tension member 401 may have a branching form in which three or more ends of the tension member 401 extend from a common joining point. The remodeling device may comprise one or more anchoring elements (e.g., a first anchoring element 402a and a second anchoring element 402b) and a tension member 401. Any additional ends of the remodeling device (e.g., a third end) may be configured to be anchored to an area of tissue through use of an additional anchoring element. An anchoring element 402a, 402b may comprise any of a variety of components, which may include a corkscrew, hook, threaded screw, and/or a barb or similar device. In some embodiments, the anchoring elements 402a, 402b may be at least partially threaded and/or may comprise coils and may be twisted into the ventricle wall to minimize bleeding.

[0050] The tension member 401 may be coupled to multiple anchoring elements 402a, 402b or may couple to a single anchoring element. In some embodiments, the tension member 401 may be configured to attach at a base portion of an anchoring element 402a, 402b. The tension member 401 may be configured to be activated (e.g., allowed to move towards a pre-determined shape) to apply pressure to the anchoring elements 402a, 402b and reposition the ventricle walls inward (i.e., closer together) and/or outward (i.e., further apart).

[0051] In some embodiments, the remodeling device may be delivered to the heart 1 percutaneously. For example, a catheter may be inserted into the right ventricle 4 and may be passed through the septum 17 into the left ventricle 3. Additionally or alternatively, a catheter may be inserted into the left ventricle 3. In some embodiments, a catheter may be inserted through the tricuspid valve, aortic valve, mitral valve, apex region (transapical), or through any other valve and/or ventricle wall. In the example shown in Figure 4, the remodeling device may be configured to reduce volume of the left ventricle 3, however some embodiments may involve reducing volume of the right ventricle 4 or other heart chamber, or may be implanted outside the heart. By passing the device through the septum 17, there may be a reduced risk of bleeding and open-heart surgery may not be required for implanting the device.

[0052] While figures herein may be described with reference to the heart and ventricle remodeling, some embodiments may be configured for delivery to parts of the body other than the heart and may be used for purposes other than ventricle remodeling. Moreover, while remodeling devices are shown as being implanted at ventricle walls, some embodiments may involve delivering one or more anchoring elements 402a, 402b to one or more papillary muscles. For example, a first anchoring element (e.g., 402a) may be configured to be inserted into a first papillary muscle and a second anchoring element (e.g., 402b) may be configured to be inserted into a second papillary muscle and the tension member 401, when activated, may be configured to create pressure at the first and second anchoring elements 402a, 402b to move the first and second papillary muscles closer together and/or further apart.

[0053] In some embodiments, the tension member 401 may comprise one or more lengths of material and/or may be configured to be attached to the anchoring elements 402a, 402b, or the anchoring elements 402a, 402b may extend from the tension member 401. Each of the one or more lengths of material may comprise a cord, string, wire, band, tube, or other similar device. In some embodiments, the tension member 401 may comprise one or more flexible or rigid materials and may be capable of compressing and/or expanding to decrease and/or increase a distance between one or more anchoring elements (e.g., 402a) at a first ventricle wall (e.g., the posterior wall 18) and one or more anchoring elements (e.g., 402b) at a second ventricle wall (e.g., the septum 17). The tension member 401 may be configured to be coupled to any of the one or more anchoring elements 402a, 402b. In optional embodiments, the tension member 401 and the anchoring elements 402a, 402b may comprise one continuous device. In some embodiments, the tension member 401 may be configured to be activated and locked into place through use of a locking element or otherwise.

[0054] The tension member 401 and/or one or more anchoring elements 402a, 402b may be configured to be passed through a catheter. Each of the one or more anchoring elements 402a, 402b may be configured to be passed at least partially through a ventricle wall. As shown in Figure 4, a first anchoring element 402a may be configured to be embedded into the posterior wall 18 of the left ventricle 3. The first anchoring element 402a may be composed of metal, plastic, polymer, Teflon, Nitinol, felt, or other material. Each of the anchoring elements 402a, 402b may be composed of a material that is sufficiently rigid in structure to maintain a desired level of pressure at the posterior wall 18, septum 17, or other tissue area.

[0055] As shown in Figure 4, a first anchoring element 402a may be configured to be embedded into a posterior wall 18 and a second anchoring element 402b may be configured to be embedded in the septum 17. In some embodiments, the second anchoring element 402b can be anchored to the septum 17 and at least a portion of the tension member 401 can pass through the septum 17. The tension member 401 can be pushed/pulled at and/or locked in place at and/or by the second anchoring element 402b.

[0056] In some embodiments, the tension member 401 may be configured to contract/compress and/or stretch/expand to increase and/or decrease a distance between the first anchoring element 402a and the second anchoring element 402b. The tension member 401 may have a pre-defined shape such that when the tension member 401 is expanded and/or contracted, it may naturally return (or attempt to return) to the pre-defined shape. For example, if a distance between the first anchoring element 402a and the second anchoring element 402b is greater than the length of the tension member 401 in the pre-defined shape, the tension member 401 may be configured to apply pressure to the anchoring elements 402a, 402b to move the anchoring elements 402, 402b closer together. Due at least in part to the ability of the tension member 401 to expand and/or contract, the tension member 401 may be configured to provide a flexible connection between the anchoring elements 402a, 402b that may cause reduced and/or minimal stress to the ventricle tissue.

[0057] In some embodiments, a delivery mechanism (e.g., a catheter) may be used for attaching the anchoring elements 402a, 402b to the ventricle walls. For example, the mechanism may be suitable for pressing against and/or twisting an anchoring element 402a, 402b to insert and/or screw the anchoring element 402a, 402b into a ventricle wall. In some embodiments, the mechanism may be used to detect infarctions in the tissue and/or to avoid portions of tissue that are more fibrous than other portions.

[0058] The tension member 401 may be configured to pass between multiple papillary muscles and/or may be configured to attach to one or more papillary muscles. In some embodiments, the remodeling device may be configured to be positioned to avoid contact with the papillary muscles and/or chordae tendineae in the ventricle.

[0059] While only two anchoring elements 402a, 402b are shown in Figure 4, any number of anchoring elements may be used (e.g., to anchor a third end and/or additional ends of the tension member 401). Moreover, anchoring elements may be anchored to more than two ventricle walls. In this way, the tension member 401 may be configured to cause radial remodeling of the ventricle in multiple directions.

[0060] Figures 5A, 5B, and 5C illustrate example tension members 500. As shown in Figure 5A, a tension member 500 may have a tubular structure and/or may have an at least partially hollow interior. While the tension member 500 is illustrated in Figure 5A as having a circular/cylindrical shape, the tension member 500 may alternatively have an oval, tri-oval, or other shape.

[0061] In some embodiments, a tension member 500 may have an at least partially bent form and/or may have wavelike curves (e.g., a wavy and/or zig-zag form) including one or more crests 502, as shown in Figures 5A and 5B. A crest 502 may comprise a point of changing direction of the tension member 500 and may create an angle 504 between multiple sections of the tension member 500 (e.g., a first section 506 and a second section 508) of the tension member 500. The tension member 500 may be configured to be stretched/expanded to increase the angle 504 and/or collapsed/contracted to decrease the angle 504. In some embodiments, the tension member 500 may have a pre-defined shape (including a pre-defined angle 504) such that when the tension member 500 is expanded and/or contracted, it may be configured to naturally return (or attempt to return) to the pre-defined shape and/or angle 504.

[0062] Each of one or more ends (e.g., a first end 510, second end 512, and/or additional ends not shown) of a tension member 500 may be configured to attach/couple to anchoring elements. In the example shown in Figure 5A, an anchoring element may be configured to at least partially fit inside a hollow interior of the tension member 500 at the first end 510 and/or the second end 512. For example, an anchoring element (e.g., a corkscrew anchor) may have a head portion that may fit into an end 510, 512 of the tension member 500. The first end 510 and/or second end 512 may comprise an opening into a hollow interior of the tension member 500 and/or a lip 514 configured to at least partially extend over the opening to hold an anchoring element in contact with the tension member 500. For example, an anchoring element may be configured to be at least partially inserted through an opening at the first end 510 and the lip 514 may prevent the anchoring element from exiting the first end 510. In optional embodiments, the lip 514 may comprise one or more protrusions (i.e., "teeth") configured to extend at least partially over the opening.

[0063] In some embodiments, a tension member 500 may comprise a substantially straight tube form with one or more struts extending from the tension member 500 to form the crests 502 of the tension member 500. For example, the tension member 500 may comprise a substantially straight tube and one or more struts may be configured to pass through a wall of the tube and extend out of the tube to create the wave-like crests 502.

[0064] In some embodiments, a delivery system may involve passing an anchoring element through an opening in the tension member 500 that is not at the first end 510 or second end 512. For example, the tension member 500 may have an opening at or near a crest 502 of the tension member. The opening may be sized to fit an anchoring element and/or a guidewire and/or delivery catheter such that the anchoring element may be delivered through the opening.

[0065] In the example shown in Figure 5B, a tension member 500 may have a substantially flat shape, in which a width 516 of the tension member 500 is greater (e.g., at least 5x greater) than a thickness 517 of the tension member 500. In this way, the tension member 500 may be capable of being significantly contracted by reducing an angle of separation and/or distance between multiple sections (e.g., a first section 520 and a second section 522) to significantly reduce a distance between the first end 510 and the second end 512. Similarly, the tension member 500 may be capable of being significantly expanded by increasing an angle and/or distance of separation between multiple sections (e.g., the first section 520 and the second section 522) to significantly increase the distance between the first end 510 and the second end 512.

[0066] As shown in Figure 5B, the first end 510 and/or second end 512 may comprise one or more notches 518 which may be configured to receive and/or hold in place an anchoring element. A notch 518 may include a cavity, groove, indentation, and/or other feature cut into the tension member 500. An anchoring element may be configured to at least partially fit into the notch 518 and/or may be held in place by the tension member 500. For example, an anchoring element may comprise a penetrating portion (e.g., a nail, needle, corkscrew, threaded screw, or similar device) configured to penetrate tissue and a base portion, in which at least part of a base portion diameter exceeds a puncturing portion diameter. In this way, the penetrating portion may fit into the notch 518 and the anchoring element may be restricted from exiting the notch 518 due to the base portion diameter exceeding a size of the notch 518. In optional embodiments, the notch 518 may be replaced with a peg, pin, clip, screw, or other mechanism for attaching to an anchoring element.

[0067] In the example shown in Figure 5C, the tension member 500 may have a helical coil shape including one or more coils 526. Each of multiple ends (including first end 510 and second end 512) may comprise a loop 524 or other mechanism configured to couple to and/or fit around at least a portion of an anchoring element. While the loops 524 are illustrated in Figure 5C as having a circular shape, the loops 524 may have any shape (e.g., oval, rectangle, etc.). An anchoring element may be configured to be passed at least partially

through a loop 524 and may hook onto or otherwise engage the loop 524 to create a connection between the anchoring element and the tension member 500. For example, a penetrating portion of an anchoring element may be configured to be passed through the loop 524 and a base portion of the anchoring element may prevent the anchoring element from passing entirely through the loop 524.

[0068] When the tension member 500 is expanded to increase a distance between the first end 510 and the second end 512, the tension member 500 may be configured to decrease in diameter as the coils 526 expand longitudinally. Similarly, when the tension member 500 is contracted to decrease a distance between the first end 510 and the second end 512, a diameter of the tension member 500c may increase as the coils 526 expand laterally.

[0069] Figure 6 is a cross-section view of the heart showing an implanted ventricle remodeling device having two anchoring points. While the device is illustrated as being implanted in the left ventricle 3, the device may alternatively be implanted in the right ventricle or other chamber. The device comprises a tension member 600 connecting a first anchoring element 602a and a second anchoring element 602b. The first anchoring element 602a and/or second anchoring element 602b may be separate or extend from the tension member 600. In some embodiments, the first anchoring element 602a and/or second anchoring element 602b may be pre-attached to the tension member 600. For example, prior to delivery into the heart 1, the first anchoring element 602a and/or second anchoring element 602b may be attached to the tension member 600. In some embodiments, the first anchoring element 602a and/or second anchoring element 602b may be configured to be attached to the tension member 600 after delivery into the heart 1.

[0070] As shown in Figure 6, the tension member 600, first anchoring element 602a, and/or second anchoring element 602b may be delivered to the heart 1 via a catheter 610 and/or other delivery systems. In some embodiments, one or more anchor drivers 604 may be delivered via the catheter 610 and may be used to drive the first anchoring element 602a and/or second anchoring element 602b into ventricle tissue.

[0071] The anchoring elements 602a, 602b may each comprise a penetrating portion 607 and/or a base portion 608. The penetrating portion 607 may comprise a helical coil (as in the example shown in Figure 6), a threaded screw, a needle, a nail, and/or or other devices/features. If the penetrating portion 607 comprises a helical coil (as in the example shown in Figure 6) and/or threaded screw, the anchor drivers 604 may be configured to twist the first anchoring element 602a and/or second anchoring element 602b. Each of the first anchoring element 602a and/or second anchoring element 602b may be configured to be

implanted at any point of the ventricle 3. In some embodiments, the anchoring elements 602a, 602b may be implanted at opposing (e.g., facing) ventricle walls. For example, the first anchoring element 602a may be configured to be implanted at the septum 17 or a first papillary muscle 15a and the second anchoring element 602b may be implanted at a posterior wall 18 or a second papillary muscle 15p. In the example shown in Figure 6, the anchor drivers 604, 604b pass through openings 606 in the tension member to access base portions 608 of the anchoring elements 602a, 602b.

[0072] As in the examples shown in Figures 5A-5C, the tension member 600 may have any of a variety of shapes/structures, including an at least partially hollow tube, substantially flat (i.e., planar) surface, and/or a helical coil. As the tension member 600 is contracted, the tension member 600 may be configured to apply force to the first anchoring element 602a and/or the second anchoring element 602b to cause the first anchoring elements 602a to move towards the second anchoring element 602b and/or to cause the second anchoring elements 602b to move towards the first anchoring elements 602a. Accordingly, contracting the tension member 600 may be configured to cause the papillary muscles 15a, 15p and/or the septum 17 and posterior wall 18 to move closer together, thereby reducing the volume of the left ventricle 3.

[0073] Similarly, as the tension member 600 is expanded, the tension member 600 may be configured to apply force to the first anchoring element 602a and the second anchoring element 602b to cause the first anchoring elements 602a to move away from the second anchoring element 602b and/or to cause the second anchoring elements 602b to move away from the first anchoring elements 602a. Accordingly, expanding the tension member 600 may be configured to cause the papillary muscles 15a, 15p and/or the septum 17 and posterior wall 18 to move further apart, thereby increasing the volume of the left ventricle 3.

[0074] Figure 7 is a flow diagram representing a process 700 for remodeling a ventricle of the heart according to one or more embodiments disclosed herein. While some steps of the process 700 may be directed to the left ventricle, such steps may also be applied to the right ventricle.

[0075] At step 702, the process 700 involves inserting a remodeling device comprising a tension member and one or more anchoring elements into a ventricle of the heart using a transcatheter procedure. For example, the remodeling device may be delivered using a transfemoral, transendocardial, transcoronary, transseptal, transapical, or other approach. In optional embodiments, the remodeling device may be introduced into the

desired location during an open-chest surgical procedure, or using other surgical or non-surgical techniques known in the art.

[0076] In some embodiments, the remodeling device may be inserted into the right ventricle (e.g., through the pulmonary valve or tricuspid valve) where it can remodel the right ventricle or may be passed through the septum into the left ventricle. Alternatively, the remodeling device may be inserted into the left ventricle (e.g., through the aortic valve or mitral valve) where it can remodel the left ventricle or may be passed through the septum into the right ventricle. For a transapical procedure, the remodeling device may be inserted through the apex via a catheter.

[0077] The remodeling device may comprise one or more connected and/or connectable elements. In some embodiments, the remodeling device comprises a tension member (e.g., the tension members 500 in Figure 5A-5C) and one or more anchoring elements for anchoring the tension member to one or more tissue walls. The tension member may be configured to pull the anchoring elements closer together and/or press the anchoring elements further apart. In some embodiments, one or more anchor drivers and/or guidewires may be inserted into the ventricle to facilitate delivery of the tension member and/or anchoring elements.

[0078] In some embodiments, the remodeling device may be fed through a catheter (e.g., a transfemoral catheter) that may be inserted into the left ventricle or right ventricle. Needles and/or other devices may be passed through the catheter to penetrate the septum and/or other ventricle walls. For example, a transseptal needle may be introduced to pass through the septum from the right ventricle to the left ventricle. The catheter may be sized to accommodate the various elements of the remodeling device. For example, the catheter may have a diameter of at least 12 French to fit anchoring elements having a diameter equal to or less than 12 French.

[0079] The anchoring elements may be any kind of mechanical devices configured to penetrate or otherwise connect to a tissue wall. For example, the anchoring elements may comprise a Nitinol wire and/or mesh that may be shape-set in a pre-defined shape (e.g., a corkscrew). In some embodiments, the anchoring elements may be compressed to pass through a catheter and, after passing through the catheter, may reshape to the pre-defined shape. In some embodiments, the anchoring element may be configured to be twisted, pressed, or otherwise engaged via a catheter or other mechanism to force the anchoring element into a tissue wall.

[0080] The remodeling device may be positioned to cause remodeling of a ventricle while avoiding damage to the papillary muscles, chordae tendineae, and/or other heart anatomy. For example, the tension member and anchoring elements may be positioned to avoid contacting the papillary muscles during delivery and after delivery of the remodeling device.

[0081] At step 704, the process 700 involves anchoring a first end of the tension member to a first area of tissue within the ventricle. The first area of tissue may be a ventricle wall (e.g., a septum, posterior wall, or apex region), papillary muscle, or other area of tissue. The tension member may be attached to an anchoring element that was previously anchored to the first area of tissue or the tension member may be attached to an anchoring element before the anchoring element is anchored to the first area of tissue. In some embodiments, the tension member may comprise one or more anchoring mechanisms which may allow the tension member to anchor to the first area of tissue without requiring a separate anchoring element. For example, the tension member may comprise one or more corkscrews, pegs, needles, threaded screws, nails, or other mechanisms which may be used to penetrate and/or secure to an area of tissue.

[0082] At step 706, the process 700 involves anchoring a second end of the tension member to a second area of tissue within the ventricle. The second area of tissue may be a ventricle wall (e.g., a septum, posterior wall, or apex region), papillary muscle, or other area of tissue. The tension member may be attached to an anchoring element that was previously anchored to the second area of tissue or the tension member may be attached to an anchoring element before the anchoring element is anchored to the second area of tissue. In some embodiments, the tension member may comprise one or more anchoring mechanisms which may allow the tension member to anchor to the second area of tissue without requiring a separate anchoring element.

[0083] At step 708, the process 700 involves activating the tension member to apply pressure at the first area of tissue and/or at the second area of tissue. In some embodiments, the tension member may be configured to apply inward pressure to the first area of tissue and/or the second area of tissue to reduce ventricle volume. The tension member may be composed of a shape-memory alloy or similar material that causes the tension member to naturally return (or attempt to return) to a pre-determined shape when it is stretched and/or contracted. For example, the tension member may have a pre-determined length between the first end and the second end that is smaller than a length between the first area of tissue and the second area of tissue. After the tension member is stretched and anchored to the first area

of tissue and the second area of tissue, the tension member may apply inward force to the first area of tissue and the second area of tissue as the tension member naturally returns to the pre-determined length. When the tension member is anchored at each area of tissue, delivery systems may release the tension member to apply force at the areas of tissue.

[0084] In some embodiments, the tension member may be configured to apply outward pressure to the first area of tissue and/or the second area of tissue to increase ventricle volume. For example, the tension member may have a pre-determined length between the first end and the second end that is greater than a length between the first area of tissue and the second area of tissue. After the tension member is compressed and anchored to the first area of tissue and the second area of tissue, the tension member may apply outward force to the first area of tissue and the second area of tissue as the tension member naturally returns to the pre-determined length. When the tension member is anchored at each area of tissue, delivery systems may release the tension member to apply force at the areas of tissue.

[0085] In some embodiments, an elasticity of the tension member may be relatively low, such that when the tension member is activated (e.g., allowed to apply force at the first area of tissue and the second area of tissue), the tension member may be configured to not return completely to the pre-determined length and/or shape. Rather, a resistive force from the first area of tissue and/or the second area of tissue may be sufficient to prevent the tension member from immediately or quickly returning to the pre-determined length and/or shape. In this way, the tension member may be configured to apply a reduced amount of force to the ventricle to cause gradual ventricle remodeling which may create a reduced risk of damage to the ventricle tissue. Over a period of time, the first area of tissue and the second area of tissue may gradually move closer together or further apart as a result of the force applied by the tension member. In some embodiments, the elasticity of the tension member may be such that the length of the tension member reduces or increase upon activation, but the tension member never fully returns to the pre-determined length and/or shape.

[0086] The process 700 and/or other processes, devices, and systems disclosed herein may advantageously provide mechanisms for implementing ventricular remodeling using a fully transcatheter procedure on a beating heart. In certain embodiments, valve leaflets may not be substantially touched or damaged during the process 700. Furthermore, in certain embodiments, the remodeling device may be designed to be retrievable.

[0087] Depending on the embodiment, certain acts, events, or functions of any of the processes or algorithms described herein can be performed in a different sequence, may be

added, merged, or left out altogether. Thus, in certain embodiments, not all described acts or events are necessary for the practice of the processes.

[0088] Conditional language used herein, such as, among others, "can," "could," "might," "may," "e.g.," and the like, unless specifically stated otherwise, or otherwise understood within the context as used, is intended in its ordinary sense and is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or steps. Thus, such conditional language is not generally intended to imply that features, elements and/or steps are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without author input or prompting, whether these features, elements and/or steps are included or are to be performed in any particular embodiment. The terms "comprising," "including," "having," and the like are synonymous, are used in their ordinary sense, and are used inclusively, in an open-ended fashion, and do not exclude additional elements, features, acts, operations, and so forth. Also, the term "or" is used in its inclusive sense (and not in its exclusive sense) so that when used, for example, to connect a list of elements, the term "or" means one, some, or all of the elements in the list. Conjunctive language such as the phrase "at least one of X, Y and Z," unless specifically stated otherwise, is understood with the context as used in general to convey that an item, term, element, etc. may be either X, Y or Z. Thus, such conjunctive language is not generally intended to imply that certain embodiments require at least one of X, at least one of Y and at least one of Z to each be present.

[0089] It should be appreciated that in the above description of embodiments, various features are sometimes grouped together in a single embodiment, figure, or description thereof for the purpose of streamlining the disclosure and aiding in the understanding of one or more of the various inventive aspects. This method of disclosure, however, is not to be interpreted as reflecting an intention that any claim require more features than are expressly recited in that claim. Moreover, any components, features, or steps illustrated and/or described in a particular embodiment herein can be applied to or used with any other embodiment(s). Further, no component, feature, step, or group of components, features, or steps are necessary or indispensable for each embodiment. Thus, it is intended that the scope of the inventions herein disclosed and claimed below should not be limited by the particular embodiments described above, but should be determined only by a fair reading of the claims that follow.

WHAT IS CLAIMED IS:

1. A cardiac device comprising:

a first anchoring element configured to anchor to a first area of tissue;

a second anchoring element configured to anchor to a second area of tissue; and

a tension member configured to couple to the first anchoring element and the second anchoring element;

wherein the tension member is further configured to expand and contract in response to applied pressure from the first anchoring element and the second anchoring element.

2. The cardiac device of claim 1, wherein the tension member is configured to apply force to the first anchoring element to move the first anchoring element towards the second anchoring element, and to apply force to the second anchoring element to move the second anchoring element towards the first anchoring element.

3. The cardiac device of claim 1 or claim 2, wherein the tension member is configured to apply force to the first anchoring element to move the first anchoring element away from the second anchoring element, and to apply force to the second anchoring element to move the second anchoring element away from the first anchoring element.

4. The cardiac device of any of claims 1-3, wherein the tension member is at least partially composed of a shape-memory alloy.

5. The cardiac device of any of claims 1-4, wherein the tension member has a tubular shape with an at least partially hollow interior, and the first anchoring element is configured to fit into the at least partially hollow interior of the tension member at a first end of the tension member.

6. The cardiac device of claim 5, wherein the tension member has wavelike curves and comprises at least one crest.

7. The cardiac device of claim 5 or claim 6, wherein the tension member comprises one or more struts configured to pass through and extend from the tubular shape to form wavelike curves comprising at least one crest.

8. The cardiac device of any of claims 5-7, wherein the tension member comprises one or more connection mechanisms configured to hold the first anchoring element at least partially inside the tension member.

9. The cardiac device of claim 8, wherein each of the one or more connection mechanisms comprises one of a group consisting of a peg, a notch, a cavity, a groove, and a hook.

10. The cardiac device of any of claims 1-9, wherein the tension member has a substantially flat shape in which a width of the tension member is greater than a thickness of the tension member, has wavelike curves and comprises at least one crest, and comprises one or more connection mechanisms configured to attach to the first anchoring element.

11. The cardiac device of claim 10, wherein each of the one or more connection mechanisms comprises, at a first end of the tension member, one of a group consisting of a peg, a notch, a cavity, a groove, and a hook.

12. The cardiac device of any of claims 1-11, wherein the tension member has a coiled shape, and comprises one or more connection mechanisms configured to attach to the first anchoring element.

13. The cardiac device of claim 12, wherein each of the one or more connection mechanisms comprises, at a first end of the tension member, one of a group consisting of a peg, a notch, a cavity, a groove, and a hook.

14. The cardiac device of any of claims 1-13, wherein the first area of tissue is a posterior wall and the second area of tissue is a septum.

15. The cardiac device of any of claims 1-14, wherein the first anchoring element comprises one of a group consisting of a corkscrew, a threaded screw, a nail, a button, a needle, a barb, and a hook.

16. The cardiac device of any of claims 1-15, further comprising a third anchoring element configured to anchor to a third area of tissue, wherein the tension member is further configured to couple to the third anchoring element.

17. A method comprising:

anchoring a first anchoring element to a first area of tissue;

anchoring a second anchoring element to a second area of tissue; and

coupling a tension member to the first anchoring element and the second anchoring element, wherein the tension member is configured to expand and contract in response to applied pressure from the first anchoring element and the second anchoring element.

18. The method of claim 17, wherein the tension member is configured to apply force to the first anchoring element to move the first anchoring element towards the second anchoring element, and to apply force to the second anchoring element to move the second anchoring element towards the first anchoring element.

19. The method of claim 17 or claim 18, wherein the tension member is configured to apply force to the first anchoring element to move the first anchoring element away from the second anchoring element, and to apply force to the second anchoring element to move the second anchoring element away from the first anchoring element.

20. The method of any of claims 17-19, wherein the tension member is at least partially composed of a shape-memory alloy.

21. The method of any of claims 17-20, wherein the tension member has a tubular shape with an at least partially hollow interior, the tension member has wavelike curves and comprises at least one crest, and coupling the tension member to the first anchoring element involves inserting the first anchoring element at least partially into the at least partially hollow interior of the tension member at a first end of the tension member.

22. The method of claim 21, wherein the tension member comprises one or more connection mechanisms configured to hold the first anchoring element at least partially inside the tension member.

23. The method of claim 22, wherein each of the one or more connection mechanisms comprises one of a group consisting of a peg, a notch, a cavity, a groove, and a hook.

24. The method of any of claims 17-23, wherein the tension member has a substantially flat shape in which a width of the tension member is greater than a thickness of the tension member, has wavelike curves and comprises at least one crest; and comprises one or more connection mechanisms configured to attach to the first anchoring element.

25. The method of claim 24, wherein each of the one or more connection mechanisms comprises, at a first end of the tension member, one of a group consisting of a peg, a notch, a cavity, a groove, and a hook.

26. The method of any of claims 17-25, wherein the tension member has a coiled shape, and comprises one or more connection mechanisms configured to attach to the first anchoring element.

27. The method of claim 26, wherein each of the one or more connection mechanisms comprises, at a first end of the tension member, one of a group consisting of a peg, a notch, a cavity, a groove, and a hook.

28. The method of any of claims 17-27, wherein the first area of tissue is a posterior wall and the second area of tissue is a septum.

29. An apparatus comprising:

first means for anchoring configured to anchor to a first area of tissue;

second means for anchoring configured to anchor to a second area of tissue; and

means for tensioning configured to couple to the first means for anchoring and the second means for anchoring, wherein the means for tensioning is configured to expand and contract in response to applied pressure from the first means for anchoring and the second means for anchoring.

30 The apparatus of claim 29, wherein the means for tensioning is configured to apply force to the first means for anchoring to move the first means for anchoring towards the

second means for anchoring, and to apply force to the second means for anchoring to move the second means for anchoring towards the first means for anchoring.

31. The apparatus of claim 29 or claim 30, wherein the means for tensioning is configured to apply force to the first means for anchoring to move the first means for anchoring away from the second means for anchoring, and to apply force to the second means for anchoring to move the second means for anchoring away from the first means for anchoring.

32. The apparatus of any of claims 29-31, wherein the means for tensioning is at least partially composed of a shape-memory alloy.

33. The apparatus of any of claims 29-32, wherein the means for tensioning has a tubular shape with an at least partially hollow interior, and the first means for anchoring is configured to fit into the at least partially hollow interior of the means for tension at a first end of the means for tensioning.

34. The apparatus of claim 33, wherein the means for tensioning has wavelike curves and comprises at least one crest.

35. The apparatus of claim 33 or claim 34, wherein the means for tensioning comprises one or more struts configured to pass through and extend from the tubular shape to form wavelike curves comprising at least one crest.

36. The apparatus of any of claims 33-35, wherein the means for tensioning comprises one or more connection mechanisms configured to hold the first means for anchoring at least partially inside the means for tensioning.

37. The apparatus of claim 36, wherein each of the one or more connection mechanisms comprises one of a group consisting of a peg, a notch, a cavity, a groove, and a hook.

38. The apparatus of any of claims 29-37, wherein the means for tensioning has a substantially flat shape in which a width of the means for tensioning is greater than a

thickness of the means for tensioning, has wavelike curves and comprises at least one crest, and comprises one or more connection mechanisms configured to attach to the first means for anchoring.

39. The apparatus of claim 38, wherein each of the one or more connection mechanisms comprises, at a first end of the means for tensioning, one of a group consisting of a peg, a notch, a cavity, a groove, and a hook.

40. The apparatus of any of claims 29-39, wherein the means for tensioning has a coiled shape, and comprises one or more connection mechanisms configured to attach to the first means for anchoring.

41. The apparatus of claim 40, wherein each of the one or more connection mechanisms comprises, at a first end of the means for tensioning, one of a group consisting of a peg, a notch, a cavity, a groove, and a hook.

42. The apparatus of any of claims 29-41, wherein the first area of tissue is a posterior wall and the second area of tissue is a septum.

43. The apparatus of any of claims 29-42, wherein the first means for anchoring comprises one of a group consisting of a corkscrew, a threaded screw, a nail, a button, a needle, a barb, and a hook.

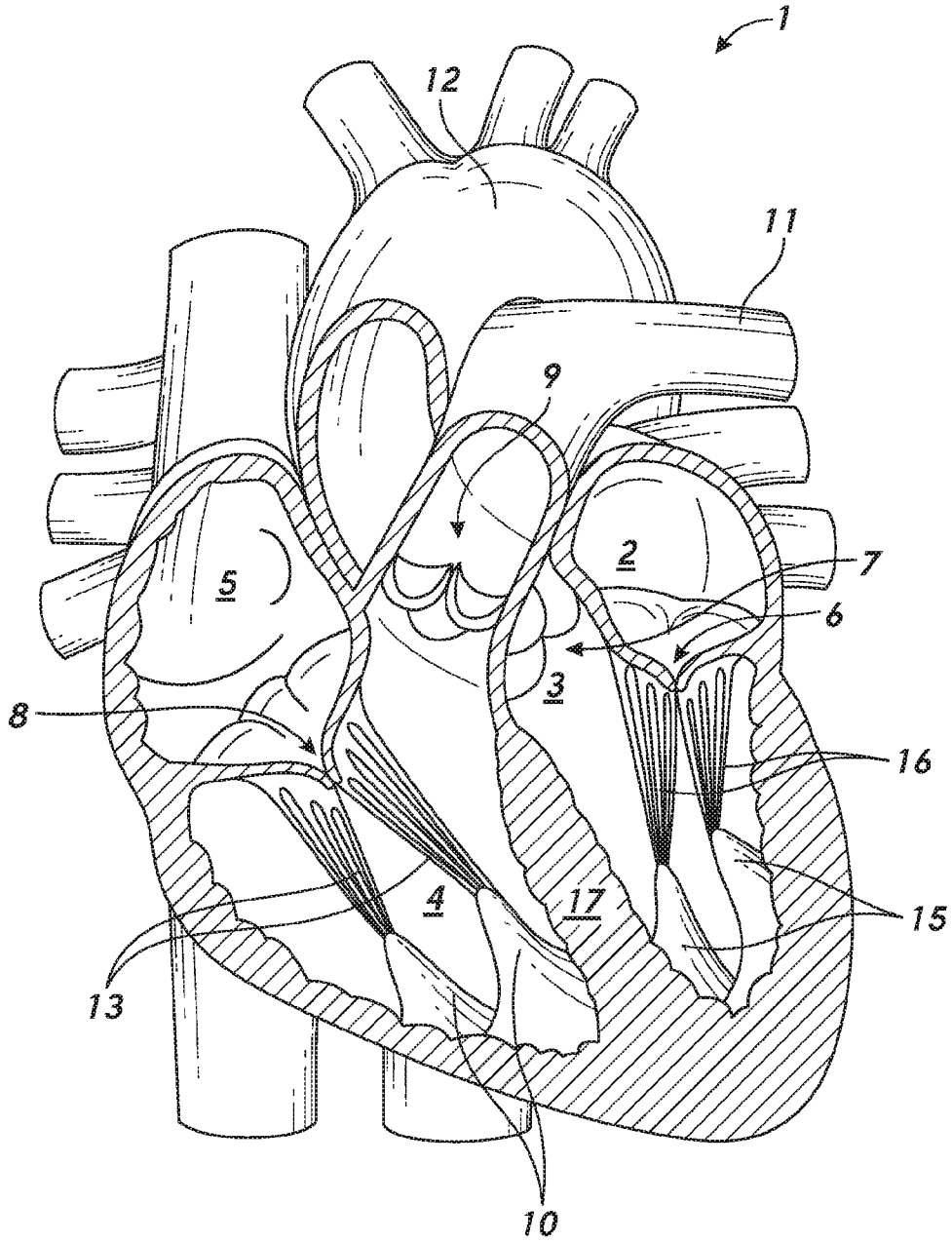


FIG. 1

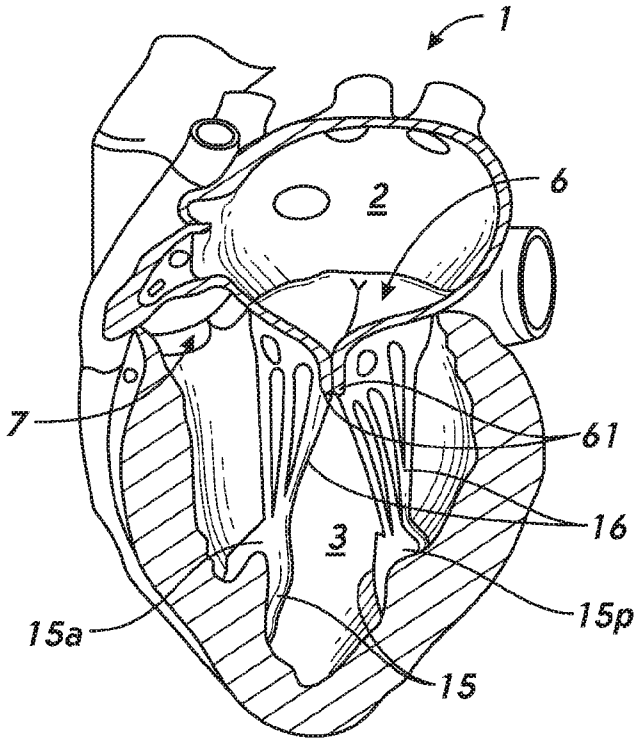


FIG. 2

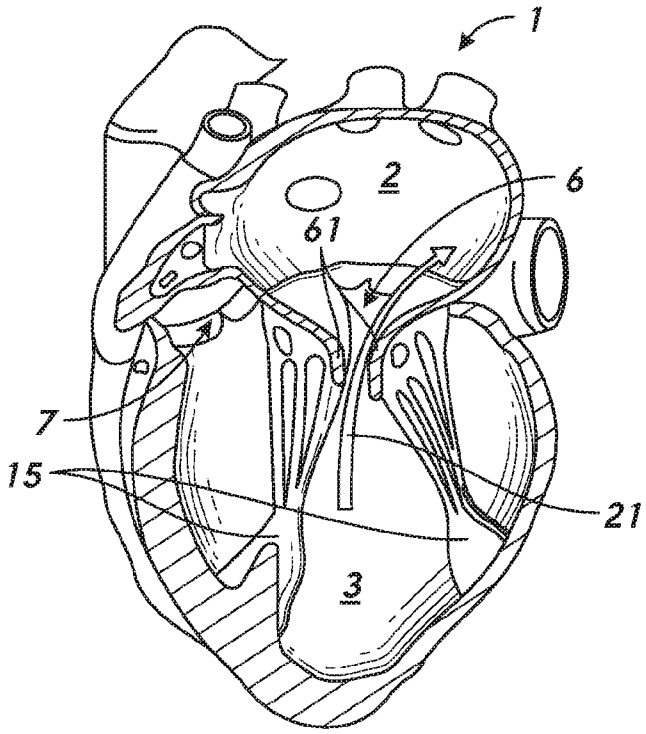


FIG. 3

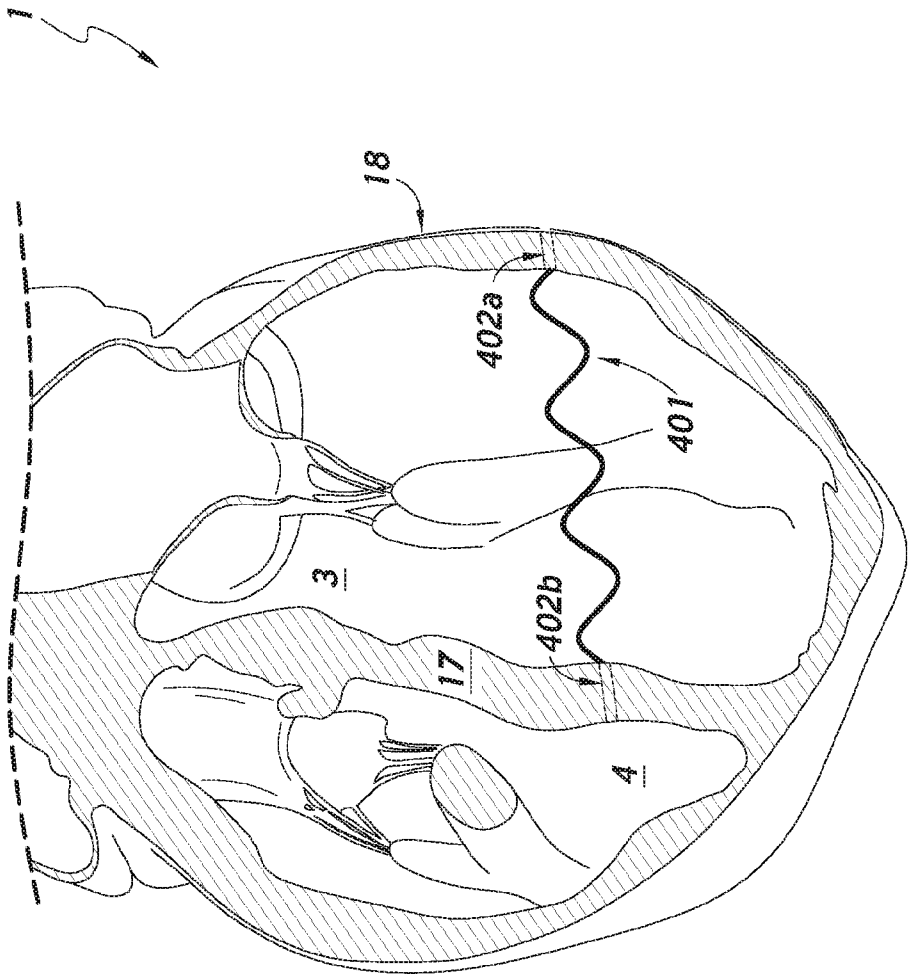


FIG. 4

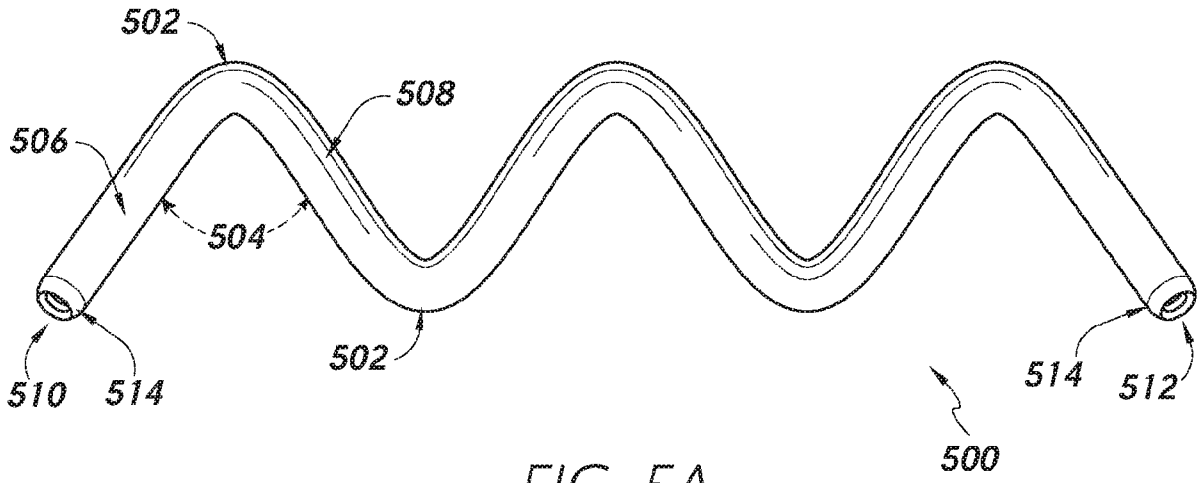


FIG. 5A

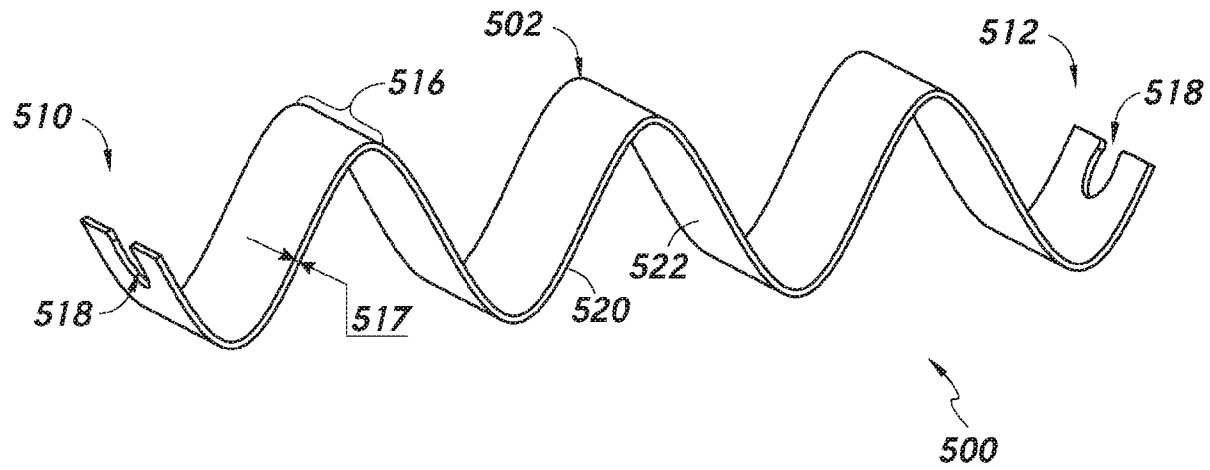


FIG. 5B

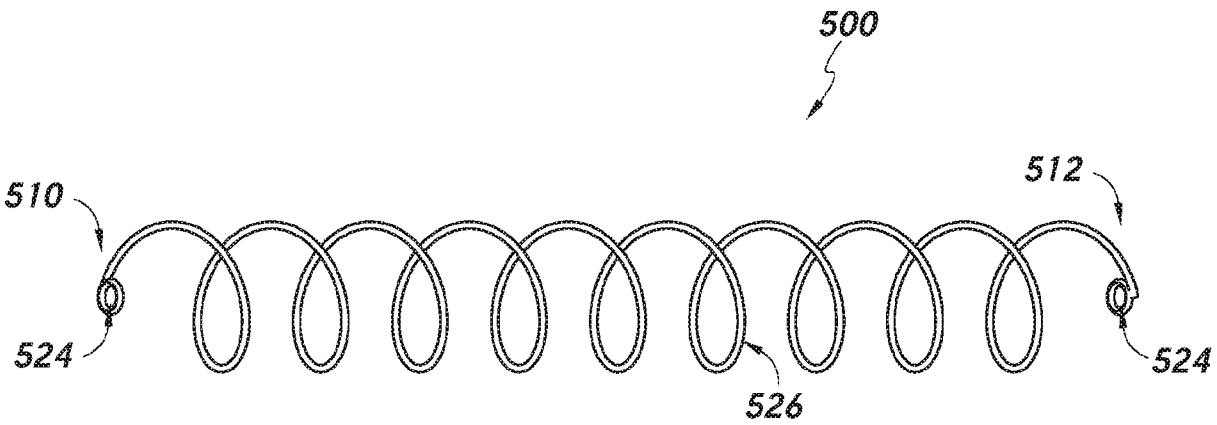


FIG. 5C

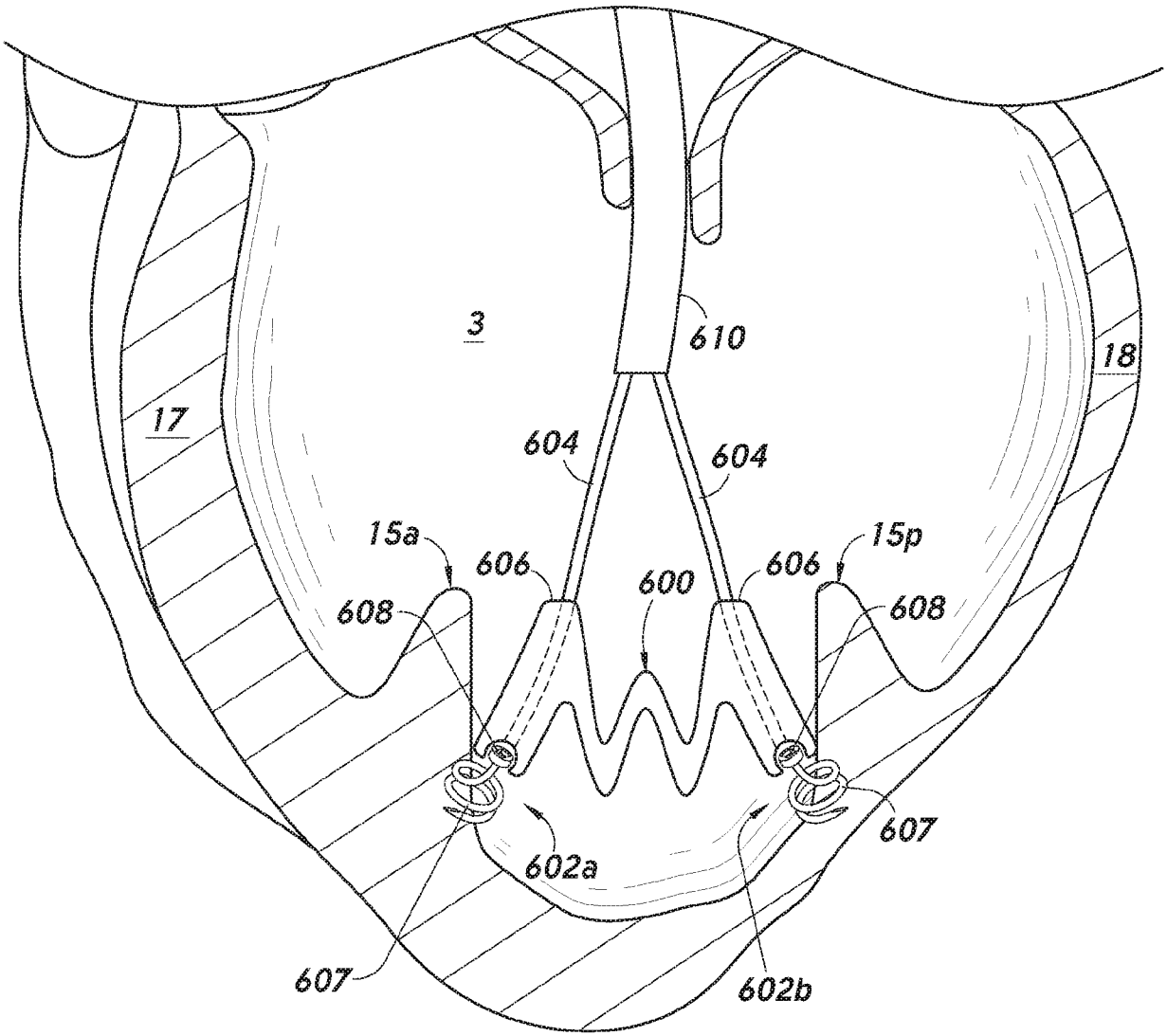


FIG. 6

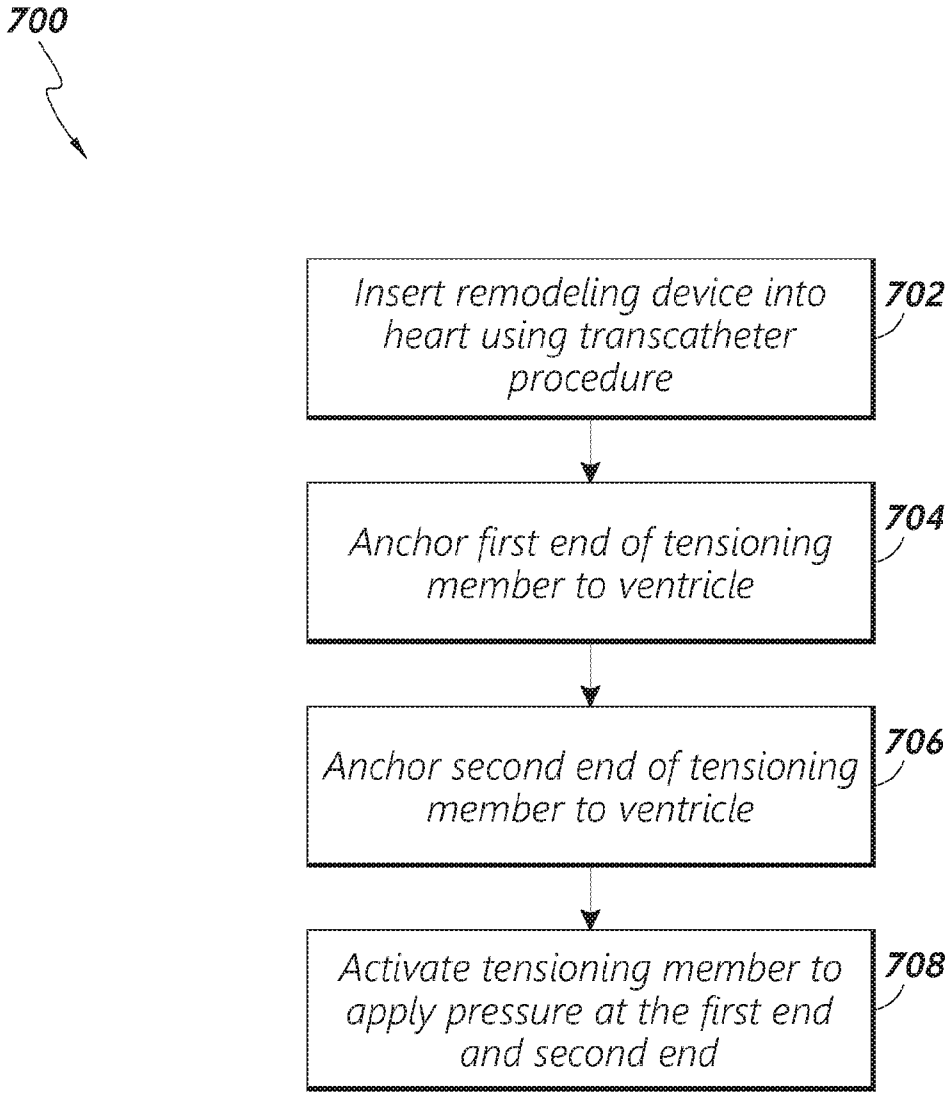

700
Insert remodeling device into heart using transcatheter procedure
702
Anchor first end of tensioning member to ventricle
704
Anchor second end of tensioning member to ventricle
706
Activate tensioning member to apply pressure at the first end and second end
708

FIG. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2020/014941

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/24
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F A61B

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007/066863 A1 (RAFIEE NASSER [US] ET AL) 22 March 2007 (2007-03-22) paragraphs [0034] - [0045]; figures 1-10	1-4, 10-15, 29-32, 38,40-43
X	US 2010/161041 A1 (MAISANO FRANCESCO [IT] ET AL) 24 June 2010 (2010-06-24) paragraphs [0364] - [0366]; figure 11	1-4, 12-15, 29-32, 40-43
X	US 2006/106278 A1 (MACHOLD TIMOTHY R [US] ET AL) 18 May 2006 (2006-05-18) paragraphs [0140] - [0150], [0159] - [0161]; figures 10A-12C	1-9, 12-16, 29-37, 39-43

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 April 2020	12/05/2020

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Geuer, Melanie

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/014941

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 17-28
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2020/014941

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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