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(71) Applicant: **EDWARDS LIFESCIENCES CORPORATION** [US/US]; One Edwards Way, Irvine, CA 92614 (US).

(72) Inventor: **RABITO, Glen, T.**; 22832 Maza Ct., Lake Forest, CA 92630 (US).

(74) Agent: **CRAPENHOFT, Michael** et al.; Edwards Lifesciences, One Edwards Way, Irvine, CA 92614 (US).

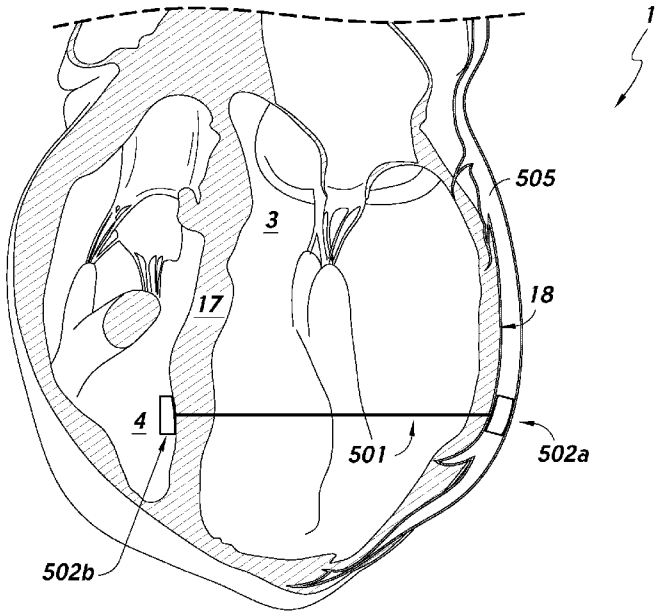
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(54) Title: CORONARY ANCHORING FOR VENTRICULAR REMODELING AND TREATMENT OF HEART FAILURE

FIG. 5



(57) **Abstract:** A cardiac device comprises a first anchoring element configured to be delivered into a coronary blood vessel of a heart. The coronary blood vessel is in proximity to a ventricle wall of a ventricle of the heart. The cardiac device further comprises a first tension member configured to couple to the first anchoring element and apply pressure to press the first anchoring element against the ventricle wall.

[Continued on next page]

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CORONARY ANCHORING 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 be delivered into a coronary blood vessel of a heart. The coronary blood vessel is in proximity to a ventricle wall of a ventricle of the heart. The cardiac device further comprises a first tension member configured to couple to the first anchoring element and apply pressure to press the first anchoring element against the ventricle wall.

[0004] The cardiac device may further comprise a second anchoring element configured to anchor to a first area of tissue. In some embodiments, the first tension member is further configured to couple to the second anchoring element. The cardiac device may further comprise a second tension member configured to couple to the second anchoring element. In some embodiments, the first tension member is configured to couple to the second tension member.

[0005] In some embodiments, the first anchoring element comprises a coupling mechanism configured to couple to the first tension member. The coupling mechanism may be configured to extend through a wall of the coronary blood vessel and the ventricle wall and into a ventricle of the heart. The coupling mechanism may be a hook.

[0006] The first tension member may be pre-coupled to the first anchoring element prior to delivery into the heart. In some embodiments, the first anchoring element is at least partially composed of metal. The first anchoring element may be at least partially

coated in radiopaque material. In some embodiments, the first tension member is configured to pass through the ventricle wall and into the coronary blood vessel.

[0007] In some implementations, the present disclosure relates to a method comprising delivering a first anchoring element, a first tension member, and a needle to a coronary blood vessel. A first end of the first tension member is coupled to the first anchoring element and a second end of the first tension member is coupled to the needle. The method further comprises passing the needle through a wall of the coronary blood vessel and through a ventricle wall in proximity to the coronary blood vessel and into a ventricle of a heart and tensioning the first tension member to press the first anchoring element against the ventricle wall.

[0008] The method may further comprise delivering a second anchoring element and a second tension member to the ventricle, anchoring the second anchoring element to an area of tissue, and coupling the second tension member to the second end of the first tension member. In some embodiments, the method comprises tensioning the first tension member and the second tension member to press the first anchoring element against the ventricle wall. The method may further comprise locking the first tension member and the second tension member in place to maintain pressure at the ventricle wall.

[0009] In some embodiments, the method further comprises delivering a snare, via a catheter, into the ventricle, snaring the needle using the snare, and pulling the needle through the catheter and out of the heart using the snare. The method may further comprise delivering a second anchoring element to the ventricle, anchoring the second anchoring element to an area of tissue, and coupling the second end of the first tension member to the second anchoring element.

[0010] In some implementations, the present disclosure relates to an apparatus comprising means for anchoring configured to be delivered into a coronary blood vessel of a heart. The coronary blood vessel is in proximity to a ventricle wall of a ventricle of the heart. The apparatus further comprises means for tensioning configured to couple to the first means for anchoring and apply pressure to press the means for anchoring against the ventricle wall.

[0011] The apparatus may further comprise second means for anchoring configured to anchor to a first area of tissue. In some embodiments, the first means for tensioning is further configured to couple to the second means for anchoring. The apparatus may further comprise second means for tensioning configured to couple to the second means for anchoring. The first means for tensioning may be configured to couple to the second means for tensioning.

[0012] In some embodiments, the first means for anchoring comprises a coupling mechanism configured to couple to the first means for tensioning. The coupling mechanism may be configured to extend through a wall of the coronary blood vessel and the ventricle wall and into a ventricle of the heart. The coupling mechanism may be a hook.

[0013] The first means for tensioning may be pre-coupled to the first means for anchoring prior to delivery into the heart. In some embodiments, the first means for anchoring is at least partially composed of metal. The first means for anchoring may be at least partially coated in radiopaque material. In some embodiments, the first means for tensioning is configured to pass through the ventricle wall and into the coronary blood vessel. The first means for anchoring may comprise a magnetic portion. In some embodiments, the first means for tensioning comprises a magnetic portion.

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 provides a view of a heart and a network of veins surrounding and supplying the heart.

[0019] Figure 5 shows a view of the heart including a remodeling device implanted for remodeling the left ventricle in accordance with one or more embodiments.

[0020] Figure 6 shows a remodeling device including a coronary anchoring element comprising an attachment mechanism in accordance with one or more embodiments.

[0021] Figure 7 (7-1 and 7-2) provides a flow diagram representing a process for remodeling a ventricle of the heart in accordance with one or more embodiments.

[0022] Figure 8 (8-1, 8-2, 8-3, and 8-4) shows examples of various stages of the process for remodeling a ventricle shown in Figure 7 in accordance with one or more embodiments.

DETAILED DESCRIPTION

[0023] The headings provided herein are for convenience only and do not necessarily affect the scope or meaning of the claimed invention.

[0024] 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.

[0025] 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.).

[0026] 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.

[0027] 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.

[0028] 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.

[0029] 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.

[0030] 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.

[0031] 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.

[0032] 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.

[0033] 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.

[0034] 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.

[0035] 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.

[0036] 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).

[0037] Figure 4 provides a view of the heart 1 and a network of veins surrounding and supplying the heart. The network of veins includes a venous channel called the coronary sinus 31 that receives blood from various coronary veins and empties into the right atrium of the heart. The coronary veins feeding into the coronary sinus 31 include the oblique vein 32, great cardiac vein 33, left marginal vein 34, left posterior ventricular vein 35, middle cardiac vein 36, and small cardiac vein 37.

[0038] As is described in detail below, some embodiments of the present disclosure involve implanting anchoring devices into coronary veins and/or arteries for purposes of ventricle remodeling. A catheter may be passed through, for example, the jugular vein and into the coronary sinus 31 to access a variety of the blood vessels surrounding the heart. When a catheter is delivered to the coronary sinus 31, a surgeon may have multiple options of blood vessels, including those shown in Figure 4, for passing the catheter into and delivering ventricle remodeling devices. Devices may be implanted in the veins shown in Figure 4 and/or in other veins and/or arteries surrounding the heart.

[0039] When a heart becomes ischemic due to coronary blockage in a blood vessel (e.g., a vein or artery), a stent or similar device may be introduced into the blocked vessel to treat the blockage. The blood vessels surrounding the heart may provide advantageous positions for anchoring ventricle remodeling devices, as discussed herein. Moreover, a heart experiencing coronary blockage may be susceptible to distortion and/or dilation of the heart chambers, which may cause FMR. Accordingly, it may be advantageous in some cases to implant devices that may be used for performing ventricle remodeling as well as coronary blockage.

[0040] In some embodiments, coronary anchors may be pre-attached to sutures having attached needles and/or other devices configured to puncture and/or pass through blood vessel walls and enter one or more ventricles. The needles and/or sutures may be configured to be snared and gathered outside the body through use of a transcatheter procedure. In this way, coronary anchors delivered to a blood vessel may be advantageously accessible from a ventricle. Moreover, sutures attached to coronary blood vessels may be configured to be tied and/or otherwise attached to other anchoring devices and/or other sutures outside the body and/or inside the ventricle.

[0041] Some embodiments disclosed herein provide solutions for treating FMR, coronary blockage, and/or heart failure with reduced ejection fraction (HFrEF) 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, coronary blockage, 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.

[0042] 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 left ventricle volume) can potentially treat FMR and/or HFrEF by, for example, repositioning the papillary muscles to improve coaptation of valve leaflets. Some embodiments described herein involve reducing ventricle volume by implanting a stent-like anchoring element in a cardiac blood vessel. The anchoring element may be used as an anchoring point for one or more tension members, which may include sutures, wires, bands, cords, strings, tubes, or other lengths of material (referred to herein collectively as "sutures," "tension members," and/or "means for tensioning"). The anchoring element may be configured to attach to the tension member(s). Tension applied to the anchoring element from the tension member(s) may be configured to cause remodeling of ventricle tissue. For example, by tightening/tensioning the tension member(s), the walls of the ventricle may be repositioned inward to decrease ventricle volume.

[0043] Because of the position of the cardiac vessels around the outside of the heart, anchoring within the vessels may provide increased leverage on the ventricle walls. For example, a stent-like anchoring element within a blood vessel may be attached to a tension member having an end configured to be passed through a ventricle wall and/or into a ventricle. When the tension member is tightened (e.g., the end is pulled), the anchoring element within the blood vessel may be configured to press against the outside of the ventricle wall to move the ventricle wall inward. Because the anchoring element can be secured within the blood vessel, risk of the anchoring element becoming dislodged and/or the anchoring element and/or one or more sutures tearing through a ventricle wall during the ventricle remodeling process may be minimized or eliminated. Moreover, the position of the anchoring element within the blood vessel can potentially reduce the wall stress associated with anchoring to a ventricle wall.

[0044] An anchoring element may be composed of metal, plastic, polymer, or other suitable material. In some embodiments, anchoring elements may have one or more features configured to facilitate identifying and/or engaging the anchoring elements after the anchoring elements have been delivered to a patient's heart. In one use case, an anchoring element may have a coupling mechanism, which may include one or more of a protruding

hook, a notch, a loop, or similar mechanism configured for coupling to a suture. In another use case, an anchoring element may be at least partially composed of a metallic and/or magnetic material. Similarly, a suture may be at least partially composed of a metallic and/or magnetic material or may include a metallic and/or magnetic portion at an end of the suture that, once introduced into a patient's heart, may be magnetically drawn towards the anchoring element previously delivered to the heart. In some embodiments, an anchoring element may be at least partially composed of and/or have a coating of a material that is clearly visible through x-ray imaging. For example, a radiopaque marker may be used to improve visibility of an anchoring element. In this way, an anchoring element placed in a blood vessel may be easily located by surgeons for attachment of a tension member to remodel a ventricle.

[0045] As used herein, the term "ventricle wall" is used 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, into a blood vessel, and/or into another chamber of the heart.

[0046] In some embodiments, anchoring elements may comprise one or more connected/connectable components and may be configured to puncture and/or secure to a blood vessel and/or 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 blood vessels and/or ventricle walls.

[0047] In some embodiments, a remodeling device may comprise anchoring elements at multiple sides of a ventricle coupled by one or more tension members. For example, a first anchoring element may be configured to be delivered to a blood vessel outside a first ventricle wall (e.g., a posterior wall) and a second anchoring element may be configured to be anchored into a second ventricle wall (e.g., a septum). One or more tension members may be configured to couple to the first anchoring element and the second anchoring element and may be configured to be tensioned to reduce a distance between the first ventricle wall and the second ventricle wall.

[0048] In some embodiments, devices for treating FMR, HFrEF, and/or other diseases may 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/or left in the heart as implants. The tension member(s) may be tensioned to apply pressure to the anchoring elements, thereby reducing a distance between a plurality of ventricle walls to reduce ventricle volume and treat FMR and/or HFrEF.

[0049] Figure 5 shows a view of the heart 1 including a remodeling device implanted for remodeling the left ventricle 3. In some embodiments, remodeling devices may be implemented for remodeling other chambers of the heart, including the right ventricle 4, and/or other organs of the body. A first anchoring element 502a may be configured to be delivered (e.g., a via a transcatheter procedure) into a blood vessel 505 at the exterior of the posterior wall 18 of the left ventricle 3 and a second anchoring element 502b may be configured to be delivered to the right ventricle 4 and may be anchored against the septum 17. Alternatively, the second anchoring element 502b may be configured to be implanted within the septum 17, against the septum 17 on the left ventricle 3 side, at a papillary muscle, or at a different area of tissue. In some embodiments, more than two anchoring elements may be used. For example, in addition to the second anchoring element 502b at the septum 17, a third anchoring element may be configured to be anchored to a ventricle wall, papillary muscle, and/or other area of tissue. In some embodiments, additional anchoring elements (e.g., more than two) may be used to create symmetric volume reduction across an increased area of the left ventricle and/or other chamber. Each of the anchoring elements 502a, 502b (and/or a third anchoring element and/or additional anchoring elements not shown in Figure 5) may be configured to be coupled to a tension member 501 and/or may be coupled to different tension members. Each of the anchoring elements 502a, 502b may comprise any of a variety of components, which may include a corkscrew, a hook, a threaded screw, an Amplatzer device, and/or a barb or similar device.

[0050] The tension member 501 may be configured to couple to multiple anchoring elements 502a, 502b and/or may be configured to couple to a single anchoring element. In some embodiments, the tension member 501 may be configured to pass through one or more ventricle walls to couple to anchoring elements 502a, 502b within or on a distal side of the one or more ventricle walls (relative to the inside of the ventricle). The tension member 501 may be configured to be tensioned to apply pressure to the anchoring elements 502a, 502b and/or reposition the ventricle walls inward (e.g., closer together).

[0051] In some embodiments, components of the remodeling device may be configured to be delivered to the heart 1 percutaneously. For example, a catheter may be configured to be inserted into the coronary sinus to deliver the first anchoring element 502a

into a blood vessel feeding into the coronary sinus. The second anchoring element 502b may be configured to be delivered into the right ventricle 4 and/or may be configured to be passed through the septum 17 into the left ventricle 3. Additionally or alternatively, a catheter may be configured to 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 5, 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 delivering the anchoring elements into blood vessels and/or through ventricle walls, there may be a reduced risk of bleeding and open-heart surgery may not be required for implanting the remodeling 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 the second anchoring element 502b is shown as being implanted at a ventricle wall, some embodiments may involve delivering one or more anchoring elements to one or more papillary muscles. For example, the second anchoring element 502b may be configured to be inserted into a papillary muscle and the tension member 501, when tensioned, may be configured to create pressure at the first and second anchoring elements 502a, 502b to move the papillary muscle closer to the first anchoring element 502a.

[0053] In some embodiments, the tension member 501 may comprise one or more lengths of material and/or may be attached to the anchoring elements 502a, 502b, or the anchoring elements may extend from the tension member 501. Each of the one or more lengths of material may be a cord, string, wire, band, tube, or other similar device. The tension member 501 may be configured to be coupled to any of the one or more anchoring elements 502a, 502b. In optional embodiments, the tension member 501 and the first anchoring element 502a and/or second anchoring element 502b may comprise one continuous device. In some embodiments, the tension member 501 may be configured to be tensioned and locked into place through use of a locking element or otherwise.

[0054] The tension member 501 and/or one or more anchoring elements 502a, 502b may be configured to be delivered through a catheter. In some embodiments, one or more anchoring elements 502a, 502b may be configured to be passed at least partially through a ventricle wall. As shown in Figure 5, a first anchoring element 502a may be

configured to be situated within a blood vessel 505 outside the posterior wall 18 of the left ventricle 3.

[0055] In some embodiments, the first anchoring element 502a may have a mesh structure and/or may be configured to expand and/or contract to enlarge and/or relax the blood vessel 505 for purposes of treating coronary blockage. The first anchoring element 502a may be composed of one or more of metal, plastic, polymer, Teflon, Nitinol, felt, or other material. Each of the anchoring elements 502a, 502b 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.

[0056] As shown in Figure 5, the first anchoring element 502a may be situated outside the posterior wall 18 and the second anchoring element 502b may be embedded in the septum 17. In some embodiments, the second anchoring element 502b can be anchored to the septum 17 and at least a portion of the tension member 501 can pass through the septum 17. The tension member 501 can be pushed/pulled at and/or locked in place at and/or by the second anchoring element 502b.

[0057] In some embodiments, one or more delivery mechanisms (e.g., a catheter and/or anchor driver) may be used for delivering the anchoring elements 502a, 502b. For example, the delivery mechanism(s) may be suitable for pressing against and/or twisting the second anchoring element 502b to insert and/or screw the second anchoring element 502b into a ventricle wall. In some embodiments, the delivery mechanism(s) 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 501 may be configured to pass through a wall of the blood vessel 505 and/or one or more ventricle walls (e.g., the posterior wall 18). The tension member 501 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 positioned to avoid contact with the papillary muscles and/or chordae tendineae in the ventricle.

[0059] While only two anchoring elements 502a, 502b are shown in Figure 5, any number of anchoring elements may be used. Moreover, anchoring elements may be anchored within and/or to more than two blood vessels and/or areas of tissue. In this way, the tension member 501 may be configured to cause radial remodeling of the ventricle in multiple directions.

[0060] Figure 6 shows a remodeling device including a coronary anchoring element comprising an attachment mechanism. As shown in Figure 6, the coronary anchoring element 602 may be configured to be situated in a blood vessel 605. The coronary anchoring element 602 may be configured to be delivered to the blood vessel 605 through a transcatheter procedure (e.g., via the coronary sinus). In some embodiments, the coronary anchoring element 602 may be configured to improve blood flow in the blood vessel 605. The coronary anchoring element 602 may comprise a stent-like portion 604 configured to rest in the blood vessel 605 and/or treat a coronary blockage in the blood vessel 605. In some embodiments, the stent-like portion 604 may comprise a mesh form and/or may be configured to expand within the blood vessel 605. The stent-like portion 604 may be composed of metal (e.g., Nitinol), plastic, polymer, or other material.

[0061] The coronary anchoring element 602 may further comprise a coupling mechanism 603 configured to attach to a suture 601 or another device. In some embodiments, the suture 601 may also be coupled to a ventricle anchoring element 607 that may be anchored to heart and/or ventricle tissue. As shown in Figure 6, the ventricle anchoring element 607 may be configured to be implanted at or near the septum 17 of the heart. However, the ventricle anchoring element 607 may be configured to be implanted at other areas in the heart, including papillary muscles, the apex region of the left ventricle 3, the posterior wall 18, or other areas of tissue. Moreover, while Figure 6 only shows one ventricle anchoring element 607 (not including the coronary anchoring element 602), the remodeling device may include more than one ventricle anchoring element 607 and/or more than one suture 601 coupled to the coronary anchoring element 602. The ventricle anchoring element 607 may comprise one or more features, which may include a corkscrew, a pledget, a braid, and/or a harpoon knot, among others, for penetrating and/or securing to ventricular tissue.

[0062] The coupling mechanism 603 of the coronary anchoring element 602 may extend from the stent-like portion 604 or may be coupled to the stent-like portion 604. In some embodiments, the coupling mechanism 603 may be configured to pass at least partially through a ventricle wall (e.g., the posterior wall 18) and into a chamber of the heart (e.g., the left ventricle 3) to facilitate coupling with devices inside the chamber. The coupling mechanism 603 may comprise one or more prongs, hooks, ends, and/or other features to securely hold a suture 601 and prevent the suture 601 from disengaging after the suture 601 is coupled to the coupling mechanism 603. In some embodiments, a stent-like portion 604 may not include and/or be coupled to a coupling mechanism 603.

[0063] The coronary anchoring element 602 may include one or more identification features (e.g., fluoro or echo markers) that may allow for simplified identification and/or targeting of the coronary anchoring element 602. In some embodiments, the coronary anchoring element 602 may be at least partially composed of metal, plastic, and/or polymer. At least one material (e.g., platinum or gold) of the coronary anchoring element 602 may have a sufficient density to make the coronary anchoring element 602 clearly visible to an x-ray scan. In some embodiments, a radiopaque marker may be used to increase the visibility of the coronary anchoring element 602.

[0064] The suture 601 may be configured to be coupled to the coronary anchoring element 602 during a delivery process of the coronary anchoring element 602 or may be configured to be coupled to the coronary anchoring element 602 at a later stage. For example, the coronary anchoring element 602 may be delivered to a patient's heart during a first visit to treat a blockage at the blood vessel 605. If, during a follow-up visit, the patient's heart shows signs of ventricle dilation or FMR, the suture 601 and/or the ventricle anchoring element 607 may be delivered to the patient's heart and the suture 601 may be coupled to the coronary anchoring element 602 to remodel the ventricle. The ventricle anchoring element 607 may be configured to be delivered during the same process as the coronary anchoring element 602 or may be delivered with the suture 601.

[0065] While the device is illustrated as being implanted in the left ventricle 3, the device may additionally or alternatively be implanted in the right ventricle or other chamber. In some embodiments, the coronary anchoring element 602 and/or ventricle anchoring element 607 may be configured to be pre-attached to the tension member 600. For example, prior to delivery into the heart 1, the coronary anchoring element 602 and/or ventricle anchoring element 607 may be attached to the tension member 600. In some embodiments, the coronary anchoring element 602 and/or ventricle anchoring element 607 may be attached to the tension member 601 after delivery into the heart 1.

[0066] The tension member 601, coronary anchoring element 602, and/or ventricle anchoring element 607 may be configured to be delivered to the heart 1 via a catheter and/or other delivery systems. In some embodiments, one or more anchor drivers may be configured to be delivered via the catheter and/or may be used to drive the coronary anchoring element 602 and/or ventricle anchoring element 607 into a blood vessel and/or ventricle tissue.

[0067] In some embodiments, the anchoring elements 602, 607 may be configured to be implanted at opposing (e.g., facing) ventricle walls. For example, the coronary

anchoring element 602 may be implanted in a blood vessel 605 outside the posterior wall 18 and the ventricle anchoring element 607 may be implanted at the septum 17 such that when a distance between the coronary anchoring element 602 and the ventricle anchoring element 607 is reduced, ventricle volume may also be reduced.

[0068] Figure 7 (7-1 and 7-2) provides 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. Figure 8 (8-1, 8-2, 8-3, and 8-4) shows examples of various stages of the process 700 for remodeling a ventricle shown in Figure 7.

[0069] At step 702, the process 700 involves inserting one or more components of a remodeling device into a heart using a transcatheter procedure. For example, the remodeling device may be delivered using a transfemoral, transendocardial, transcoronary, transseptal, and/or transapical procedure, 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. The remodeling device may include one or more sutures and/or anchoring elements.

[0070] In some embodiments, at least some components of the remodeling device may be configured to be inserted into the right ventricle (e.g., through the pulmonary valve or tricuspid valve) for remodeling of the right ventricle or may be passed through the septum into the left ventricle. Alternatively, the at least some components of the remodeling device may be configured to be inserted into the left ventricle (e.g., through the aortic valve or mitral valve) for remodeling the left ventricle or may be passed through the septum into the right ventricle. For a transapical procedure, components of the remodeling device may be configured to be inserted through the apex via a catheter. In optional embodiments, components of the remodeling device may be delivered to a location outside of the heart for purposes other than remodeling ventricles.

[0071] In some embodiments, anchoring elements and/or sutures may be fed through a catheter (e.g., a transfemoral catheter) that may be inserted into one or more blood vessels and/or ventricles. Needles and/or other devices may be passed through the catheter to penetrate the blood vessel and/or ventricle walls (e.g., the septum and/or posterior wall). 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.

[0072] Components of 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 sutures and anchoring elements may be positioned to avoid contacting the papillary muscles during delivery and after delivery of the remodeling device. In some embodiments, the remodeling device may comprise multiple anchoring elements which may each be anchored within blood vessels and/or to different areas of tissue in a ventricle of the heart.

[0073] As shown in Figure 8-1, the remodeling device may comprise at least a first anchoring element 802a that may be configured for delivery into a coronary blood vessel 805. The first anchoring element 802a may be configured to couple to a first suture 801a. The first suture 801a may be pre-coupled to the first anchoring element 802a prior to delivery into the heart or may be attached after the first anchoring element 802a is positioned in the blood vessel 805.

[0074] A first end of the first suture 801a may be configured to couple to the first anchoring element 802a and a second end of the first suture 801a may be configured to attach to a needle 806. The needle 806 may be any device configured to penetrate and/or pass through a blood vessel and/or ventricle wall. In some embodiments, the first suture 801a and/or the needle 806 may be delivered into the blood vessel 805 along with the first anchoring element 802.

[0075] At step 704, the process 700 involves passing at least a portion of the needle 806 and/or first suture 801a through the blood vessel 805 and/or a ventricle wall (e.g., the posterior wall 18 as shown in Figure 8-1) adjacent and/or in close proximity to the blood vessel 805. The needle 806 may first pass through a wall of the blood vessel 805 and may then pass through the ventricle wall. The first suture 801a may be configured to attach to the needle 806 and may also pass through the wall of the blood vessel 805 and/or the ventricle wall. In some embodiments, the needle 806 may be controlled using various delivery systems (e.g., anchor driver, guidewire, etc.) delivered to the blood vessel 805 via a catheter.

[0076] At step 706, the process 700 involves snaring the needle 806 from within the ventricle (e.g., the left ventricle 3 as shown in Figure 8-2). One or more snares 812 may be delivered into the ventricle via a catheter 810 and/or other delivery systems. The one or more snares 812 may be any devices configured to engage and/or securely hold the needle 806 for purposes of pulling the needle 806 through the catheter 810 and out of the body. As shown in Figure 8-2, a snare 812 may have a lasso shape to fit around and grasp the needle 806. However, the snare 812 may include a magnet, pincer, or other device configured to

engage and/or securely hold a needle 806. The catheter 810 may be delivered to the ventricle through any valve and/or ventricle wall. For example, as shown in Figure 8-2, the catheter 810 may be delivered through the aortic valve 7 into the left ventricle 3. In some embodiments, multiple snares 812 may be used to increase a likelihood of snaring the needle 806.

[0077] At step 708, the process 700 involves delivering a second anchoring element 802b, second suture 801b, and/or additional anchoring elements and/or sutures to the heart. The second anchoring element 802b and/or additional anchoring elements may be delivered into a ventricle (e.g., the left ventricle 3) and anchored to any areas of tissue. For example, the second anchoring element 802b may be anchored to the septum 17. While the second anchoring element 802b is shown in Figure 8-3 as passing entirely through the septum 17 and being positioned in the right ventricle 4, the second anchoring element 802 and/or additional anchoring elements may be embedded into a ventricle wall and/or papillary muscle and/or may be anchored to a proximal (e.g., left ventricle 3 side) of a ventricle wall and/or papillary muscle.

[0078] At step 710, the process 700 involves coupling the first suture 801a, second suture 801b, and/or additional sutures together. In some embodiments, the sutures may be coupled through use of a coupling mechanism 807, as shown in Figure 8-4. In optional embodiments, the sutures may be tied together or otherwise coupled without use of a coupling mechanism 807. The coupling mechanism 807 may be adjustable to create a desired amount of pressure at the first anchoring element 802a and/or second anchoring element 802b and/or to cause a desired distance between the anchoring elements.

[0079] At step 712, the process 700 involves cinching and/or locking the first suture 801a, second suture 801b, and/or additional sutures to apply pressure to the first anchoring element 802a, second anchoring element 802b, and/or additional anchoring elements. In some embodiments, one or more ends of the suture(s) 801a, 801b may be accessible to a surgeon, for example via a catheter. Cinching the suture(s) 801a, 801b may involve pulling one or more ends of the suture(s) 801a, 801b. The suture(s) 801a, 801b may be tightened as necessary to cause a desired amount of ventricle remodeling. Cinching the suture(s) 801a, 801b may reduce a distance between the first anchoring element 802a, the second anchoring element 802b, and/or additional anchoring elements, thereby applying force to move the ventricle walls and/or papillary muscles closer together.

[0080] The suture(s) may be locked to maintain pressure on the anchoring elements. In some embodiments, one or more locking mechanisms may be delivered (e.g., via

a catheter) for use in locking one or more ends of the suture(s) 801a, 801b in place. For example, a locking mechanism may be fitted around the suture(s) 801a, 801b and may be configured to slide along the suture(s) 801a, 801b and/or pinch or otherwise engage the suture(s) 801a, 801b at a desired position to prevent movement of the suture(s) or other anchoring elements. After the suture(s) 801a, 801b is/are locked in place, excess length of the suture(s) 801a, 801b may be cut off or otherwise removed.

[0081] 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.

[0082] 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.

[0083] 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.

[0084] 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 be delivered into a coronary blood vessel of a heart, wherein the coronary blood vessel is in proximity to a ventricle wall of a ventricle of the heart; and

a first tension member configured to couple to the first anchoring element and apply pressure to press the first anchoring element against the ventricle wall.

2. The cardiac device of claim 1, further comprising a second anchoring element configured to anchor to a first area of tissue.

3. The cardiac device of claim 2, wherein the first tension member is further configured to couple to the second anchoring element.

4. The cardiac device of claim 2 or claim 3, further comprising a second tension member configured to couple to the second anchoring element.

5. The cardiac device of claim 4, wherein the first tension member is configured to couple to the second tension member.

6. The cardiac device of any of claims 2-5, wherein the second anchoring element comprises one or more of a group consisting of a corkscrew, a hook, a threaded screw, an Amplatzer device, and a barb.

7. The cardiac device of any of claims 2-6, further comprising a third anchoring element configured to anchor to a second area of tissue.

8. The cardiac device of any of claims 1-7, wherein the first anchoring element comprises a coupling mechanism configured to couple to the first tension member.

9. The cardiac device of claim 8, wherein the coupling mechanism is configured to extend through a wall of the coronary blood vessel and the ventricle wall and into a ventricle of the heart.

10. The cardiac device of claim 8 or claim 9, wherein the coupling mechanism is a hook.

11. The cardiac device of any of claims 1-10, wherein the first tension member is pre-coupled to the first anchoring element prior to delivery into the heart.

12. The cardiac device of any of claims 1-11, wherein the first anchoring element is at least partially composed of metal.

13. The cardiac device of any of claims 1-12, wherein the first anchoring element is at least partially coated in radiopaque material.

14. The cardiac device of any of claims 1-13, wherein the first tension member is configured to pass through the ventricle wall and into the coronary blood vessel.

15. The cardiac device of any of claims 1-14, wherein the first anchoring element comprises a magnetic portion.

16. The cardiac device of any of claims 1-15, wherein the first tension member comprises a magnetic portion.

17. The cardiac device of any of claims 1-16, wherein the first anchoring element comprises one or more of a group consisting of a corkscrew, a hook, a threaded screw, an Amplatzer device, and a barb.

18. A method comprising:

delivering a first anchoring element, a first tension member, and a needle to a coronary blood vessel, a first end of the first tension member coupled to the first anchoring element and a second end of the first tension member coupled to the needle;

passing the needle through a wall of the coronary blood vessel and through a ventricle wall in proximity to the coronary blood vessel and into a ventricle of a heart; and

tensioning the first tension member to press the first anchoring element against the ventricle wall.

19. The method of claim 18, further comprising:

delivering a second anchoring element and a second tension member to the ventricle;

anchoring the second anchoring element to an area of tissue; and

coupling the second tension member to the second end of the first tension member.

20. The method of claim 19, further comprising tensioning the first tension member and the second tension member to press the first anchoring element against the ventricle wall.

21. The method of claim 20, further comprising locking the first tension member and the second tension member in place to maintain pressure at the ventricle wall.

22. The method of any of claims 18-21, further comprising:

delivering a snare, via a catheter, into the ventricle;

snaring the needle using the snare; and

pulling the needle through the catheter and out of the heart using the snare.

23. The method of any of claims 18-22, further comprising;

delivering a second anchoring element to the ventricle;

anchoring the second anchoring element to an area of tissue; and

coupling the second end of the first tension member to the second anchoring element.

24. An apparatus comprising:

first means for anchoring configured to be delivered into a coronary blood vessel of a heart, wherein the coronary blood vessel is in proximity to a ventricle wall of a ventricle of the heart; and

first means for tensioning configured to couple to the first means for anchoring and apply pressure to press the first means for anchoring against the ventricle wall.

25. The apparatus of claim 24, further comprising second means for anchoring configured to anchor to a first area of tissue.

26. The apparatus of claim 25, wherein the first means for tensioning is further configured to couple to the second means for anchoring.

27. The apparatus of claim 25 or claim 26, further comprising second means for tensioning configured to couple to the second means for anchoring.

28. The apparatus of claim 27, wherein the first means for tensioning is configured to couple to the second means for tensioning.

29. The apparatus of any of claims 24-28, wherein the first means for anchoring comprises a coupling mechanism configured to couple to the first means for tensioning.

30. The apparatus of claim 29, wherein the coupling mechanism is configured to extend through a wall of the coronary blood vessel and the ventricle wall and into a ventricle of the heart.

31. The apparatus of claim 29 or claim 30, wherein the coupling mechanism is a hook.

32. The apparatus of any of claims 24-31, wherein the first means for tensioning is pre-coupled to the first means for anchoring prior to delivery into the heart.

33. The apparatus of any of claims 24-32, wherein the first means for anchoring is at least partially composed of metal.

34. The apparatus of any of claims 24-33, wherein the first means for anchoring is at least partially coated in radiopaque material.

35. The apparatus of any of claims 24-34, wherein the first means for tensioning is configured to pass through the ventricle wall and into the coronary blood vessel.

36. The apparatus of any of claims 24-35, wherein the first means for anchoring comprises a magnetic portion.

37. The apparatus of any of claims 24-36, wherein the first means for tensioning comprises a magnetic portion.

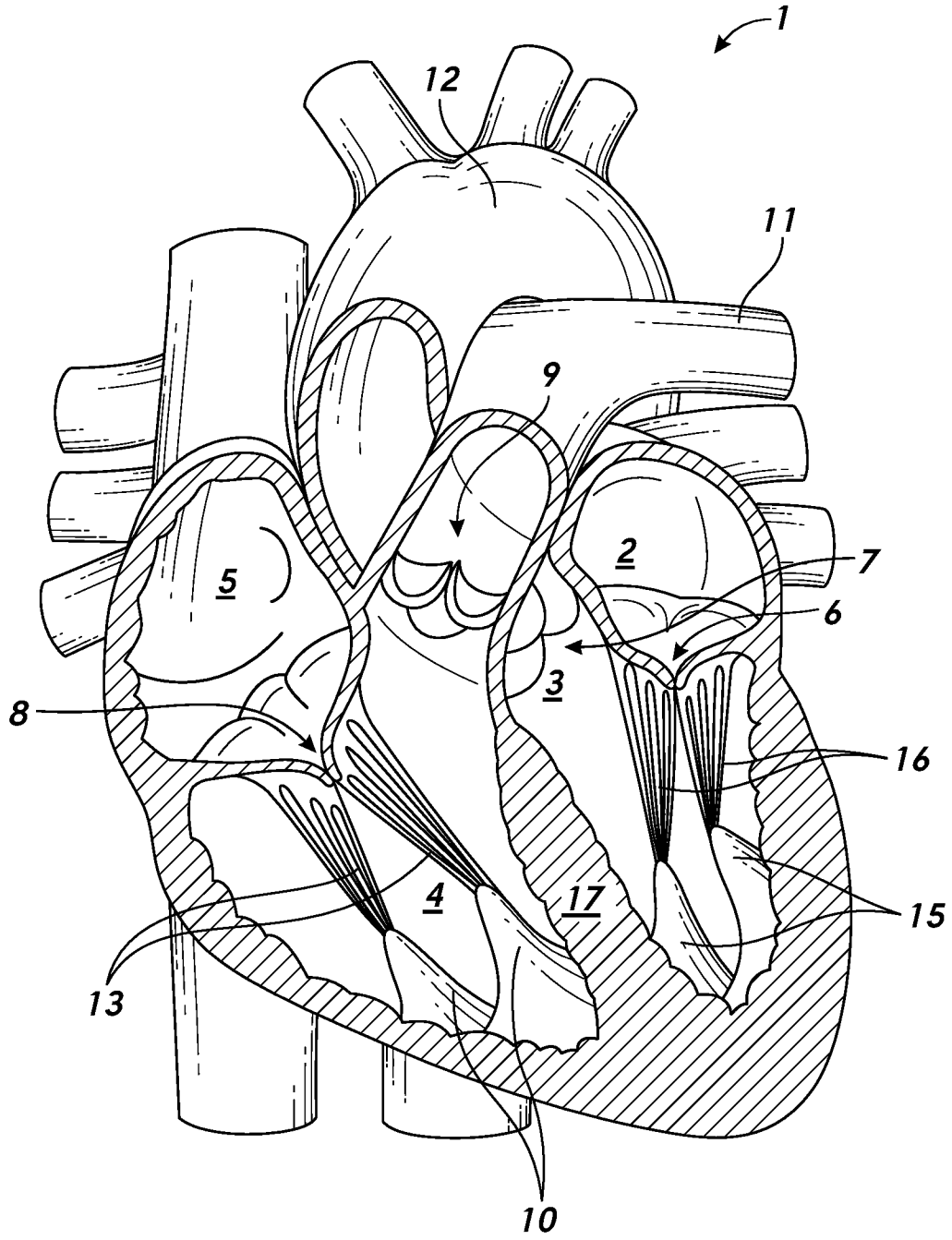


FIG. 1

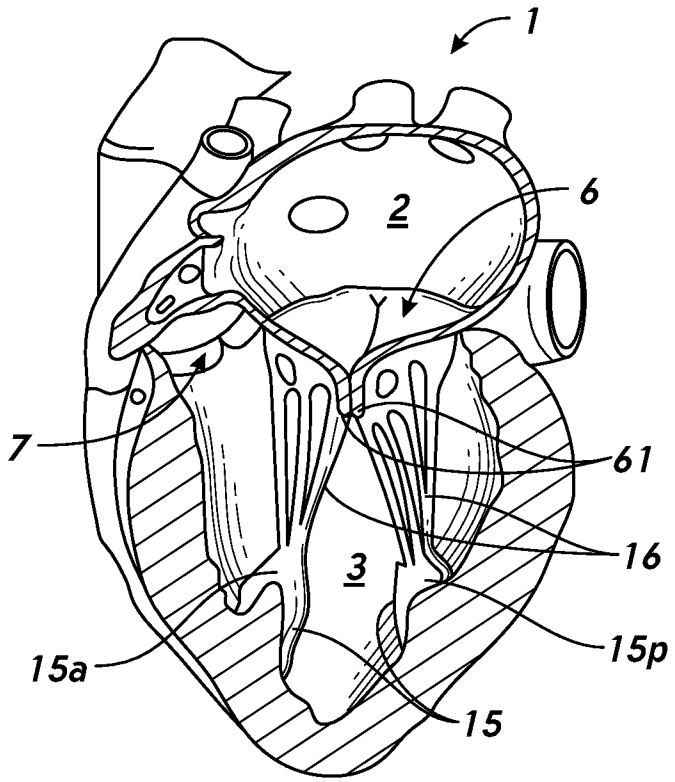


FIG. 2

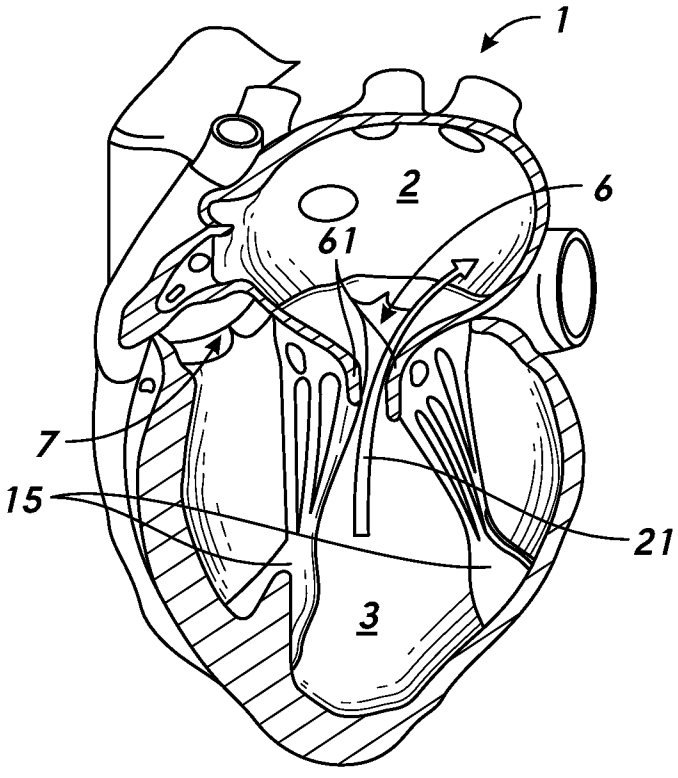


FIG. 3

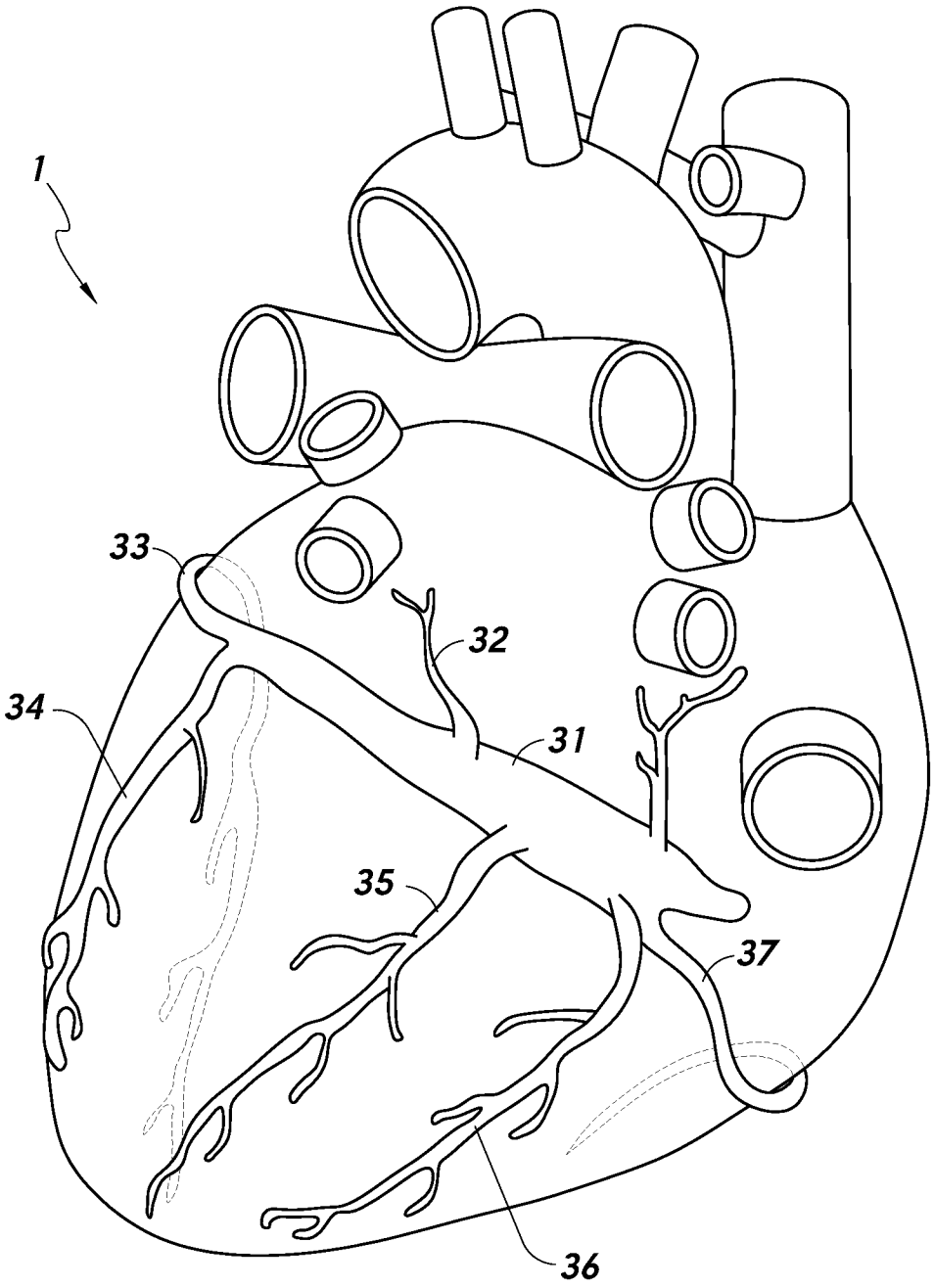


FIG. 4

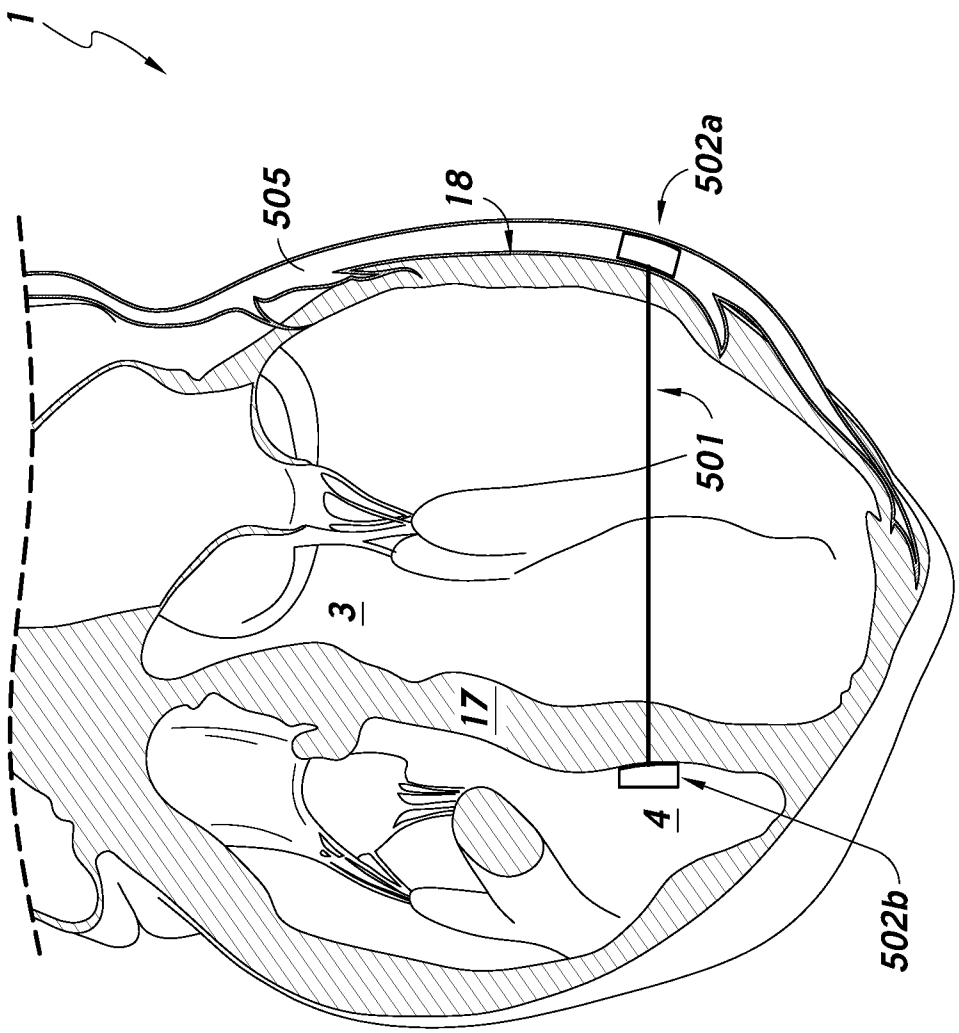


FIG. 5

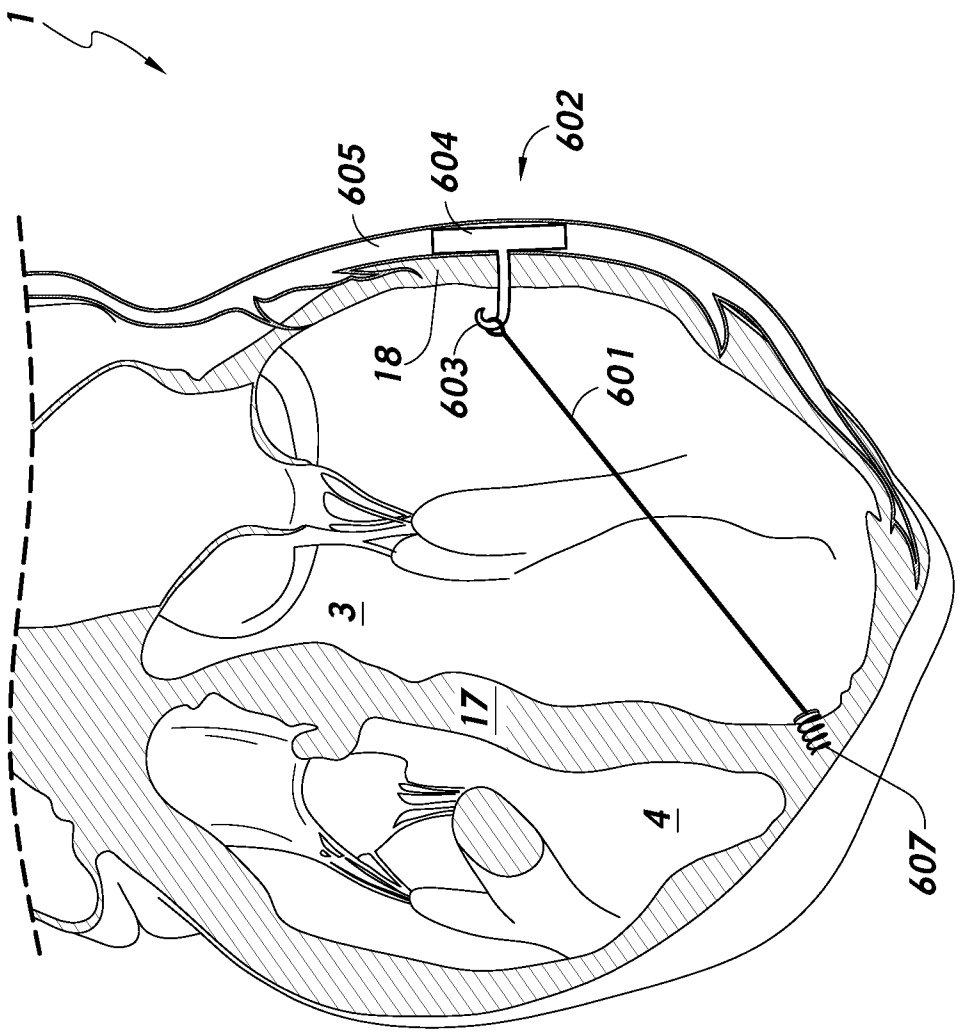


FIG. 6

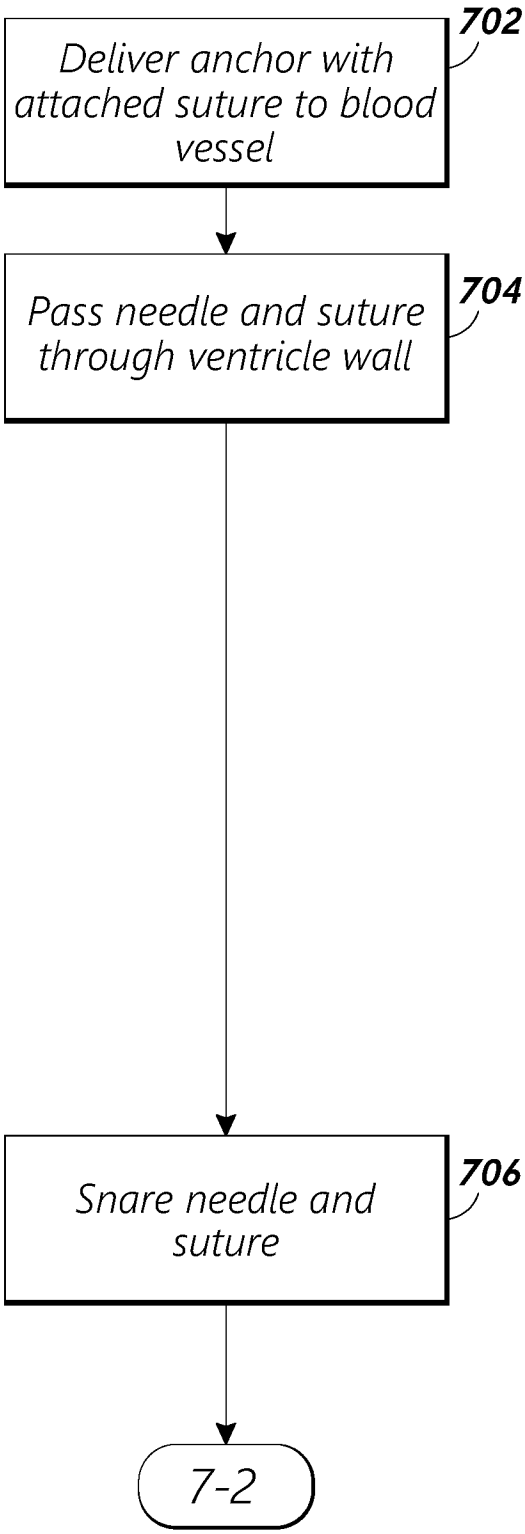


FIG. 7-1

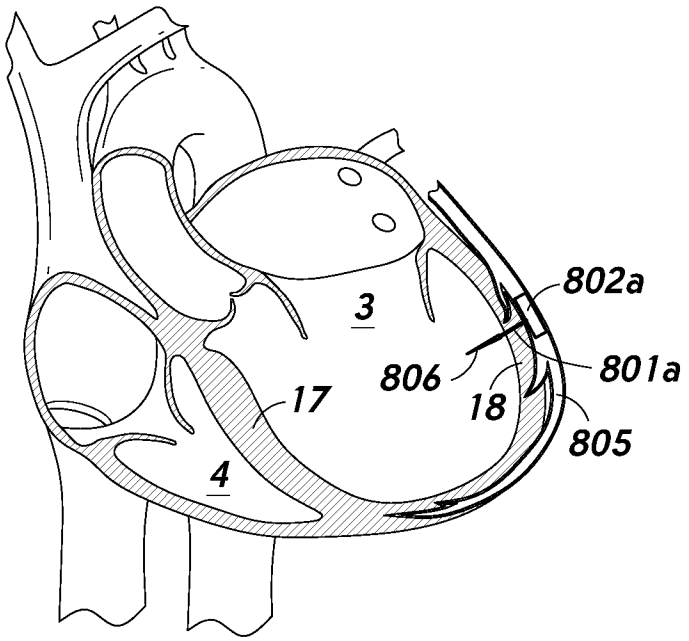


FIG. 8-1

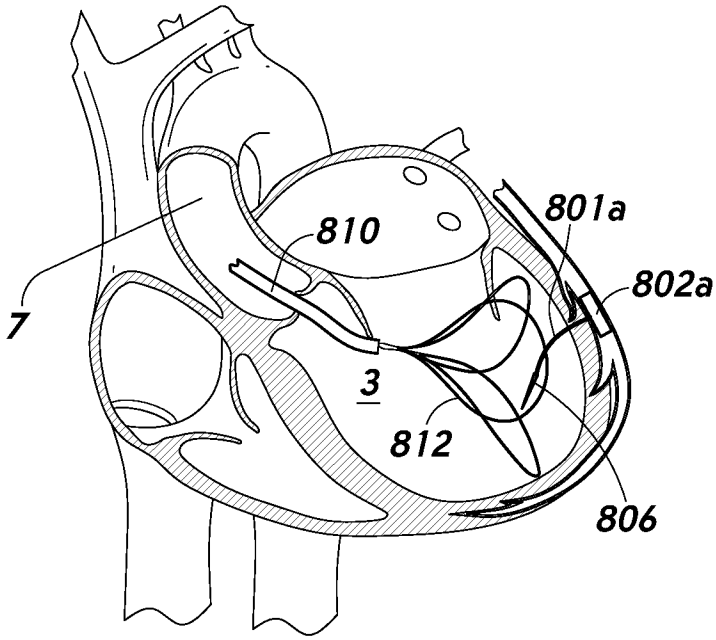


FIG. 8-2

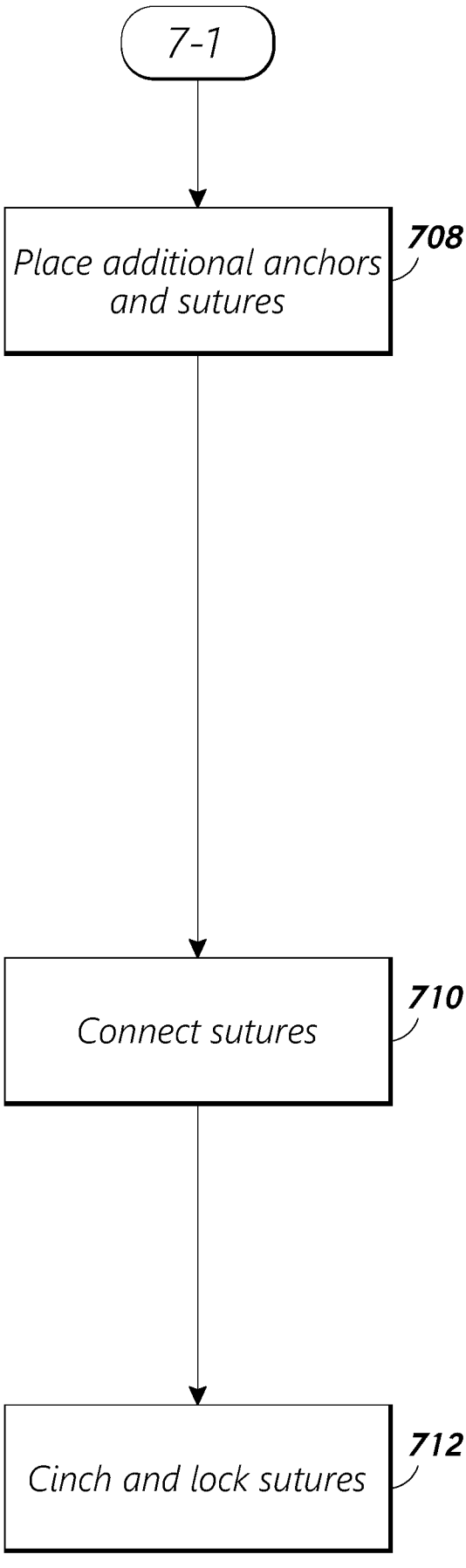


FIG. 7-2

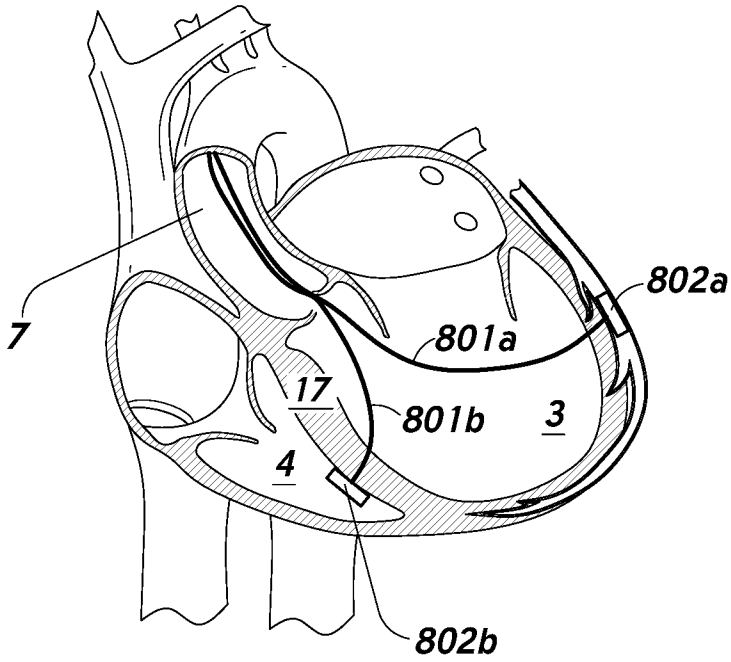


FIG. 8-3

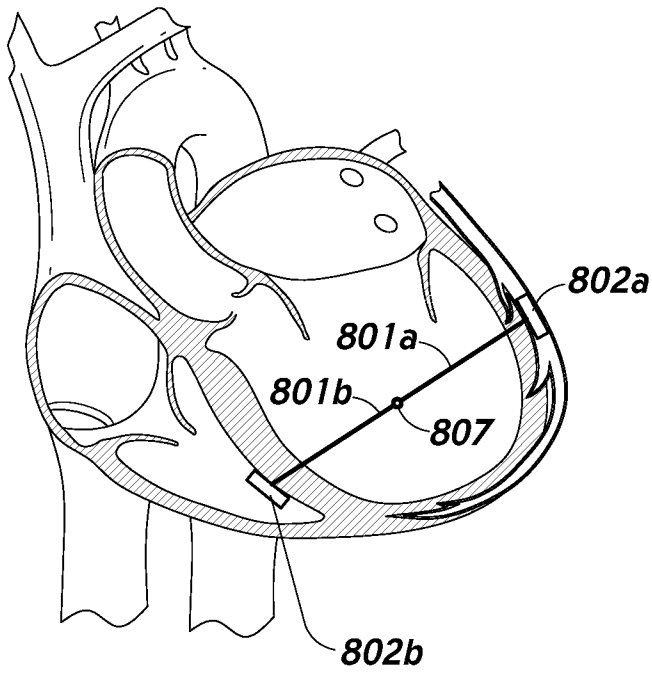


FIG. 8-4

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2020/014924

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 2006/106279 A1 (MACHOLD TIMOTHY R [US] ET AL) 18 May 2006 (2006-05-18) paragraphs [0140] - [0149], [0170] - [0173]; figures 10A-11C,19-21	1-17, 24-37
X,P	WO 2019/027507 A1 (MVRX INC [US]) 7 February 2019 (2019-02-07) paragraphs [0046] - [0071]; figures 3A-9B	1-3,6, 8-17, 24-26, 30-37
A	US 2018/318082 A1 (MANASH BOAZ [IL]) 8 November 2018 (2018-11-08) paragraph [0061]; figures 7-2	1-17, 24-37

☐ 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

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/014924

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.: 18-23
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/US2020/014924

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2006106279 A1	18-05-2006	US 2006106279 A1	18-05-2006
		US 2011295059 A1	01-12-2011
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		WO 2018204518 A1	08-11-2018