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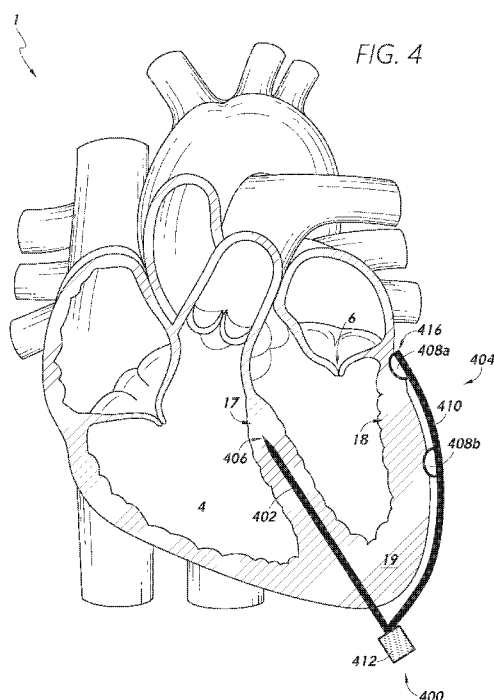
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(54) Title: DEVICE FOR RESHAPING HEART ANATOMY



(57) Abstract: A cardiac device comprises a first elongate member configured to contact a first area of tissue of a heart and a second elongate member configured to apply pressure to a second area of tissue of the heart. At least a portion of a ventricle is between the first area of tissue and the second area of tissue. The cardiac device further comprises a delivery mechanism configured to press the second elongate member towards the first elongate member to reduce a distance between the first area of tissue and the second area of tissue.

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DEVICE FOR RESHAPING HEART ANATOMY

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 comprising a first elongate member configured to contact a first area of tissue of a heart and a second elongate member configured to apply pressure to a second area of tissue of the heart. At least a portion of a ventricle is between the first area of tissue and the second area of tissue. The cardiac device further comprises a delivery mechanism configured to press the second elongate member towards the first elongate member to reduce a distance between the first area of tissue and the second area of tissue.

[0004] The first elongate member may be coupled to the second elongate member. In some embodiments, the first elongate member has a linear shape. The second elongate member may have a non-linear shape. In some embodiments, the second elongate member has a curved shape that approximates a curvature of the heart. The delivery mechanism may be at least partially hollow, and each of the first elongate member and the second elongate member may be configured to at least partially fit into the delivery mechanism. In some embodiments, the delivery mechanism is configured to twist and move along the first elongate member and the second elongate member.

[0005] In some embodiments, the second elongate member comprises one or more pads configured to press against an exterior portion of the second area of tissue. Each of the one or more pads may be configured to at least partially compress in response to pressure from the second area of tissue. In some embodiments, each of the one or more pads has a half-sphere, half-ovoid, or half-capsule shape. The first area of tissue may be a septum and the second area of tissue may be a posterior wall. In some embodiments, the first elongate

member has a threaded exterior. The first elongate member may be a coiled wire. In some embodiments, the first elongate member is configured to penetrate the first area of tissue. The first elongate member may be configured to contact an exterior portion of the first area of tissue.

[0006] In some implementations, the present disclosure relates to a method comprising contacting a first area of tissue of a heart with a first elongate member and contacting a second area of tissue of the heart with a second elongate member. At least a portion of a ventricle of the heart is between the first area of tissue and the second area of tissue. The method further comprises activating a delivery mechanism to press the second elongate member towards the first elongate member to reduce a distance between the first area of tissue and the second area of tissue.

[0007] The first elongate member may be coupled to the second elongate member. In some embodiments, the delivery mechanism is at least partially hollow and each of the first elongate member and the second elongate member is configured to at least partially fit into the delivery mechanism. The second elongate member may comprise one or more pads configured to press against an exterior portion of the second area of tissue. In some embodiments, each of the one or more pads is configured to at least partially compress in response to pressure from the second area of tissue.

[0008] In some embodiments, the first area of tissue is a septum and the second area of tissue is a posterior wall. The first elongate member may have a threaded exterior. In some embodiments, the first elongate member is a coiled wire. The first elongate member may be configured to penetrate the first area of tissue. In some embodiments, the method further comprises percutaneously delivering the first elongate member to the first area of tissue, the second elongate member to the second area of tissue, and the delivery mechanism to the ventricle.

[0009] In some implementations, the present disclosure relates to a cardiac device comprising a first means for anchoring configured to contact a first area of tissue of a heart and a second means for anchoring configured to apply pressure to a second area of tissue of the heart. At least a portion of a ventricle is between the first area of tissue and the second area of tissue. The cardiac device further comprises means for tensioning configured to press the second means for anchoring towards the first means for anchoring to reduce a distance between the first area of tissue and the second area of tissue.

[0010] The first means for anchoring may be coupled to the second means for anchoring. In some embodiments, the means for tensioning is at least partially hollow and

each of the first means for anchoring and the second means for anchoring is configured to at least partially fit into the means for tensioning. The second means for anchoring may comprise one or more pads configured to press against an exterior portion of the second area of tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] 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.

[0012] Figure 1 provides a cross-sectional view of a human heart.

[0013] Figure 2 provides a cross-sectional view of a heart experiencing heart failure with reduced ejection fraction.

[0014] Figure 3 provides a cross-sectional view of a heart experiencing heart failure with preserved ejection fraction.

[0015] Figure 4 shows a view of the heart including a minimally-invasive remodeling device for remodeling the left ventricle in accordance with one or more embodiments.

[0016] Figure 5 shows a view of the heart showing a percutaneous ventricle remodeling device in accordance with one or more embodiments.

[0017] Figure 6 provides a flow diagram representing a minimally-invasive process for remodeling a ventricle of the heart according to one or more embodiments.

[0018] Figure 7 provides a flow diagram representing a percutaneous process for remodeling a ventricle of the heart according to one or more embodiments disclosed herein.

DETAILED DESCRIPTION

[0019] The headings provided herein are for convenience only and do not necessarily affect the scope or meaning of the claimed invention.

[0020] 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.

[0021] 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.).

[0022] 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 inferior tip 19 of the heart 1 is referred to as the apex (or apex region) and is located on the midclavicular line, in the fifth intercostal space.

[0023] 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.

[0024] 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.

[0025] 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.

[0026] 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.

[0027] 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.

[0028] 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.

[0029] Figure 2 provides a cross-sectional view of a heart 1 experiencing Heart Failure with reduced Ejection Fraction (HFrEF), also known as systolic dysfunction. As shown in Figure 2, HFrEF may be characterized by a dilated left ventricle 3 and/or right ventricle 4, which may result in impaired ejection of blood from the ventricles. The ventricle walls, including the septum 17 and posterior wall 18, may be thinned and/or weakened as a result of the dilation of the left ventricle 3 and/or right ventricle 4. Normal ejection fraction of a human heart is typically defined as 55-70 percent of the heart's volume of blood with each beat. A heart experiencing HFrEF may provide an ejection fraction of less than 40 percent. A dilated ventricle (e.g., the left ventricle 3) may become overloaded with blood. As a result, the fraction of blood the ventricle is capable of pumping may decrease as the size/volume of the ventricle increases. Moreover, the resultant volume overload that exists as a result of HFrEF 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.

[0030] In Figure 3, the heart 1 is shown in a state where Heart Failure with preserved Ejection Fraction (HFpEF), also known as diastolic dysfunction, is present. HFpEF is characterized by thickened and/or stiffened heart muscle at the ventricle walls, which may include the septum 17 and/or posterior walls 18. While the left ventricle 3 and/or right ventricle 4 may be “normal” in size when HFpEF is present, the ventricles may lose the ability to fill before contraction due to the thickened and/or stiffened heart muscle, which may cause reduced output of the ventricles. A heart experiencing HFpEF may provide an ejection fraction of over 50 percent; however, the volume of ejected blood may be significantly reduced in comparison to a heart that is not experiencing HFpEF.

[0031] Both HFrEF and HFpEF are characterized by an inability of the heart to pump enough blood for the body’s needs. Heart failure may cause various symptoms, including dyspnea, fatigue, swelling, and increased heart and breathing rates. In certain conditions, heart failure can be severely debilitating and even fatal if left untreated.

[0032] Some embodiments disclosed herein provide solutions for treating HFrEF, HFpEF, and/or functional mitral valve regurgitation (FMR) using minimally invasive procedures and/or without the need for surgical procedures or destroying cardiac tissue. In particular, minimally invasive and/or passive techniques to improve valve performance are disclosed for improving cardiac function. Further, various embodiments disclosed herein provide for the treatment of HFrEF, HFpEF, and/or FMR 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.

[0033] 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 (e.g., by reducing a distance between multiple ventricle walls) by delivering an adjustable remodeling device comprising one or more means for anchoring to the heart via a subclavian, transapical, transseptal, transfemoral, or other minimally invasive and/or percutaneous approach. The means for anchoring may include various elongate members which may be composed of metal (e.g., Nitinol or other shape-memory alloy, cobalt-chromium, and/or stainless steel), plastic, and/or a combination of materials. The elongate members may be configured to anchor to one or more areas of tissue by penetrating, contacting, pressing against, or otherwise engaging the tissue. In some embodiments, the elongate members may

have any shape and/or size/length and may be configured to contact a means for tensioning and/or extend various distances along and/or through areas of tissue. Multiple elongate members may be coupled at a joint and/or may extend from a common base and/or length of material. The means for tensioning may comprise a delivery mechanism configured to apply pressure to and/or otherwise move the elongate members to a desired orientation and/or to cause a desired level of remodeling. For example, the delivery mechanism may be used to press two or more members of the remodeling device closer together to apply pressure to ventricle walls.

[0034] The elongate members may be positioned at various points in and/or around the heart using various delivery procedures. In a minimally invasive procedure, the apex or other region of the heart may be made accessible through an incision at or near the ribs. The elongate members may be placed along or within various ventricle walls. 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, different elongate members may be positioned at or near different ventricle walls. For example, a first elongate member may be positioned within a ventricle and against an exterior of the septum and/or at least partially within the septum. A second elongate member may be positioned at an exterior of the heart and/or at an exterior of the posterior wall or other ventricle wall.

[0035] In some embodiments, remodeling devices may comprise one or more connected/connectable components and may be configured to apply pressure to one or more ventricle walls. Remodeling devices may comprise delivery mechanisms configured to move and/or cause movement of various elongate members of the remodeling devices to desired orientations within and/or near the heart. In some embodiments, the delivery mechanism may be configured to cause a “pinching” motion of the elongate members, in which the elongate members and/or ends of the elongate members move closer together.

[0036] A sheath may be used to at least partially cover elongate members during delivery into the heart. As used herein, the term “sheath” is used according to its broad and ordinary meaning and may refer to any covering, sleeve, shell, and/or casing configured to at least partially cover an outer portion of an elongate member. Sheaths may be composed of any material, including various metals and/or plastics. In some embodiments, a sheath may entirely surround at least a portion of an elongate member. In some embodiments, a sheath

may prevent movement and/or expansion of an elongate member. For example, a sheath may at least partially cover a portion of an elongate member that is composed of shape-memory alloy (e.g., Nitinol) and has a pre-defined shape. In some embodiments, a remodeling device may comprise multiple elongate members, wherein one or more elongate members may be positioned at two or more sides of a ventricle.

[0037] In some embodiments, a mechanical device for treating FMR, HFrEF, and/or other diseases may be delivered to an affected area of tissue via a minimally-invasive and/or transcatheter/percutaneous procedure. Various components of the mechanical device may be delivered and adjusted using a transfemoral (artery), transapical, or transseptal procedure. Once in place, components of the mechanical device may be detached from the delivery system and left in the heart as an implant.

[0038] Figure 4 shows a view of the heart 1 including a minimally-invasive remodeling device 400 for remodeling the left ventricle 3. In some embodiments, the remodeling device 400 may be delivered to the heart 1 via a minimally-invasive and/or percutaneous procedure. For example, an incision may be made in a patient's body at or near the ribs to allow access to the apex 19 region of the heart 1.

[0039] The remodeling device 400 comprises a first elongate member 402 and a second elongate member 404. In optional embodiments, the remodeling device may comprise more than two elongate members. For example, the second elongate member 404 may be delivered to and/or near a posterior wall 18 of the left ventricle, the first elongate member 402 may be delivered at or near a septum 17, and a third elongate member may be delivered at or near a posterior wall of the right ventricle 4.

[0040] In the example shown in Figure 4, the first elongate member 402 may be configured to be delivered to and/or near the septum 17. In one use case, a first end 406 of the first elongate member 402 may be configured to be delivered to the apex 19 of the heart and/or may be configured to penetrate the apex 19 and/or pass through the apex 19 and into the septum 17, the left ventricle 3, and/or the right ventricle 4. In some embodiments, the first end 406 of the first elongate member 402 may have a pointed tip and/or other feature to facilitate puncturing heart tissue (e.g., at the apex 19) by the first elongate member 402. In some embodiments, the first elongate member 402 may have an at least partially threaded exterior and/or may comprise a coiled wire such that the first elongate member 402 may be twisted into the ventricle tissue. The first elongate member 402 may have a substantially linear shape and/or may be configured to fit within the septum 17 or other area of tissue. For

example, the first elongate member 402 may be configured to pass linearly upward through an interior of the septum 17 without exiting the septum 17 into a ventricle or other chamber.

[0041] While the first elongate member 402 is shown in Figure 4 as being implanted at least partially within ventricle tissue (i.e., the septum 17 and/or apex 19 tissue), the first elongate member 402 may also or alternatively be situated at least partially outside the ventricle tissue and/or may be situated within the left ventricle 3 and/or right ventricle 4. In some embodiments, the first elongate member 402 may be configured to press against an exterior of one or more ventricle walls. For example, the first elongate member 402 may extend out of the apex 19 into the right ventricle 4 and may be configured to press against an exterior portion of the septum 17 from the right ventricle 4 side.

[0042] The first elongate member 402 and/or the second elongate member 404 may be configured to extend any distance into the heart 1 and/or around/along the heart. As shown in Figure 4, the first elongate member 402 may be configured to extend upward from the apex 19 into the septum 17, such that at least a portion of the first elongate member 402 is situated between the right ventricle 4 and the left ventricle 3. In some embodiments, the first elongate member 402 and/or the second elongate member 404 may be configured to extend a sufficient distance that at least a portion of the left ventricle 3 or the right ventricle 4 is between the first elongate member 402 and the second elongate member 404. For example, as shown in Figure 4, the second elongate member 404 may be configured to extend along the posterior wall 18 of the left ventricle 3 while the first elongate member 402 may extend into the septum 17 such that a portion of the left ventricle 3 may be configured to be situated between the first elongate member 402 and the second elongate member 404. In some embodiments, the second elongate member 404 may be configured to extend from a point of the heart 1 near the apex 19 to a point of the heart 1 near the mitral valve 6.

[0043] In some embodiments, the remodeling device 400 may comprise a delivery mechanism 412. While the delivery mechanism 412 is shown in Figure 4 as having a rectangular shape, the delivery mechanism 412 may have any size and/or shape. The delivery mechanism 412 may comprise any of a variety of tensioning mechanisms configured to cause movement and/or pressure at the first elongate member 402 and/or second elongate member 404. For example, the first elongate member 402 and the second elongate member 404 may branch apart from a common point (e.g., a joint) and one or more sides of the delivery mechanism 412 may be configured to press the first elongate member 402 and/or second elongate member 404 closer together. Moreover, the delivery mechanism 412 may comprise a housing for the tensioning mechanisms and/or the housing may comprise a tensioning

mechanism. In some embodiments, the delivery mechanism may comprise any of a variety of coupling mechanisms configured to couple to the first elongate member 402 and/or the second elongate member 404. For example, the delivery mechanism 412 may comprise grooves configured to couple to a threaded surface of the first elongate member 402 and/or second elongate member and/or the delivery mechanism may comprise a latch, hook, or other device configured to securely couple to the first elongate member 402 and/or the second elongate member 404. The delivery mechanism 412 may be at least partially hollow and/or may be configured to receive at least a portion of the first elongate member 402 and/or second elongate member 404 into the delivery mechanism 412.

[0044] The first elongate member 402 and/or second elongate member 404 may pass at least partially through and/or into the delivery mechanism 412. In some embodiments, the delivery mechanism 412 may be configured to press and/or twist the first elongate member 402 into the heart 1 (e.g., at the apex). For example, the first elongate member 402 may comprise a coil and/or may have a threaded surface and may be configured to twist into cardiac tissue. In some embodiments, an anchor driver or similar mechanism may be used to drive the first elongate member 402 into the tissue. The delivery mechanism 412 may be at least partially hollow and the first elongate member 402 and/or second elongate member 404 may be configured to at least partially fit into a hollow interior of the delivery mechanism 412. An inner surface of the delivery mechanism 412 may comprise grooves to allow the delivery mechanism 412 to twist along a threaded surface of the first elongate member and/or the second elongate member 412. For example, the delivery mechanism 412 may be similar to a bolt and may twist along a threaded surface of one or more elongate members. Alternatively, the delivery mechanism 412 may comprise a threaded surface to twist along grooves of the first elongate member 402 and/or second elongate member 404.

[0045] The first elongate member 402 may be configured to be coupled to the second elongate member 404 and/or the first elongate member 402 and second elongate member 404 may extend from a common member. For example, the first elongate member 402 and/or the second elongate member 404 may branch and/or extend from a common joint and/or elongate member, such as a wire. A joint of the first elongate member 402 and the second elongate member 404 may fit inside the delivery mechanism 412 and the delivery mechanism 412 may be configured to increase and/or decrease an angle of separation and/or a distance between the first elongate member 402 and the second elongate member 404. As shown in Figure 4, the second elongate member 404 may be configured to extend laterally over a rim/edge of the delivery mechanism 412. Accordingly, as the delivery mechanism 412

moves upward (e.g., towards the apex), the delivery mechanism 412 may be configured to press against the second elongate member 404 and/or move at least a portion of the second elongate member 404 (e.g., at least a first end 416 of the second elongate member 404) towards the first elongate member 402. In some embodiments, the first elongate member 402 may be configured to be stationary after placement in the heart.

[0046] The second elongate member 404 may have a curved or otherwise non-linear shape. In some embodiments, a curvature of the second elongate member 404 may be configured to match and/or approximate a curvature of the heart 1. In this way, the second elongate member 404 may extend along an external/outside portion of the heart 1 and/or may contact the heart 1 at one or more points on the external/outside portion of the heart 1. In some embodiments, the first elongate member 402 and/or second elongate member 404 may comprise one or more pads 408a, 408b which may be configured to contact and/or apply pressure to walls of the heart. A pad 408a, 408b may be composed of any bio-compatible material and/or may be at least partially compressible such that the pad 408a, 408b may at least partially compress in response to pressure/resistance applied by cardiac tissue to the pad 408a, 408b. In some embodiments, the pads 408a, 408b may extend from and/or attach to a base portion 410 of the second elongate member 404 to contact the heart 1. The base portion 410 may not contact the heart 1 or may be configured to contact the heart 1 only minimally. The pads 408a, 408b may have any shape, which may include half-sphere, half-ovoid, and/or half-capsule shapes.

[0047] In some embodiments, different pads 408a, 408b may perform different functions and/or may be configured to cause different outcomes and/or a variety of outcomes. For example, a first pad 408a may be positioned at or near the first end 416 of the second elongate member 404, which may be placed/situated at or near a mitral valve 6, and the first pad 408a may be configured to cause ventricle remodeling and/or treat mitral regurgitation. A second pad 408b may be configured to be positioned further from the first end 416 than the first pad 408a (i.e., between the first pad 408a and the delivery mechanism 412) and/or at or near a ventricle (e.g., the left ventricle 3) and/or may be configured to cause ventricle remodeling.

[0048] The first elongate member 402, second elongate member 404, and/or delivery mechanism 412 may be composed of metal (e.g., Nitinol or other shape-memory alloy), plastic, and/or a bio-compatible polymer. In some embodiments, the first elongate member 402, second elongate member 404, and/or delivery mechanism 412 may be composed of a material and/or coated with a material that is visible under x-ray and/or other

viewing systems. For example, the first elongate member 402, second elongate member 404, and/or delivery mechanism 412 may be coated through use of a radiopaque marker or similar device.

[0049] Because the remodeling device 400 may be configured for delivery through the apex 19 region of the heart, the delivery process may be simplified for surgeons by only requiring access to the apex 19 region. As described above, a simple incision may be performed at or near the ribs. Each of the components of the remodeling device 400 may be inserted at a common incision point, without requiring multiple incisions and/or access points.

[0050] 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, optional embodiments may involve delivering one or more elongate members 402, 404 to contact and/or apply pressure to one or more papillary muscles.

[0051] Figure 5 shows a view of the heart 1 showing a percutaneous ventricle remodeling device. While the remodeling device 500 is illustrated as being implanted for remodeling the left ventricle 3, the remodeling device 500 may alternatively be implanted for remodeling the right ventricle 4 or other chamber.

[0052] In some embodiments, the remodeling device 500 may be delivered to the heart 1 percutaneously. For example, in a transcatheter procedure, a catheter may be delivered into the right ventricle 4 and the remodeling device 500 and may be passed through the catheter. 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 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 remodeling device 500 percutaneously, there may be a reduced risk of bleeding and open-heart surgery may not be required for implanting the device.

[0053] The remodeling device 500 may comprise a first elongate member 502, a second elongate member 504, and a delivery mechanism 512. The first elongate member 502 and/or second elongate member 504 may be composed of metal (e.g., Nitinol or other shape-memory alloy), plastic, and/or a polymer. In some embodiments, the first elongate member

502 may be configured to apply pressure to a first area of tissue, which may include a ventricle wall. For example, the first elongate member 502 may be configured to apply pressure to the septum 17 to move the septum 17 towards the posterior wall 18 or to maintain a position of the septum 17 (i.e., not allow the ventricle to further dilate). While the first elongate member 502 is shown in Figure 5 as being positioned outside the septum 17 and within the right ventricle 4, the first elongate member 502 may also or alternatively be configured to be at least partially positioned within the septum 17 and/or through the septum 17 and into the left ventricle 3 after delivery into the heart.

[0054] The second elongate member 504 may be configured to penetrate and/or pass through cardiac tissue. For example, the second elongate member 504 may be configured to be delivered into the right ventricle 4 via a catheter and/or may be configured to pass through the apex 19 region of the heart 1, as shown in Figure 5. In some embodiments, the second elongate member 504 may be housed within a sheath while passing through cardiac tissue. The sheath may be configured to prevent the second elongate member 504 from assuming a pre-determined shape.

[0055] In some embodiments, the second elongate member 504 may be composed of a shape-memory alloy (e.g., Nitinol) and/or may be configured to assume a pre-determined shape after delivery to the heart 1. As shown in Figure 5, the second elongate member 504 may comprise a bend 514 between a first portion 516 and a base portion 510. The bend 514 may represent a point of changing direction of the second elongate member 504. In some embodiments, the base portion 510 may have a curved shape to conform to and/or approximately match a curvature of the heart 1. In this way, the base portion 510 may be configured to extend away from the apex 19 and around a posterior wall 18 or other area of tissue.

[0056] The second elongate member 504 may comprise one or more pads 508a, 508b which may be configured to contact and/or apply pressure to cardiac tissue. In some embodiments, the pads 508a, 508b may be at least partially soft and/or compressible to allow the pads 508a, 508b to fit into a catheter, sheath, and/or other device. The pads 508a, 508b may extend from and/or attach to the base portion 510 of the second elongate member. In some embodiments, the pads 508a, 508b may be sized and/or shaped (e.g., a capsule or half-capsule shape as shown in Figure 5) to have a minimal profile and/or may be compressible such that the pads 508a, 508b may fit through a catheter and/or other delivery device.

[0057] A delivery mechanism 512 may be delivered to the heart 1 percutaneously. For example, the delivery mechanism 512 may be implanted in the right ventricle 4 or left

ventricle 3 via a catheter. The delivery mechanism 512 may be configured to apply pressure to the first elongate member 502 and/or the second elongate member 504 to move at least portions of the first elongate member 502 and/or the second elongate member 504 closer together. For example, the delivery mechanism 512 may be configured to move the second elongate member 504 such that the base portion 510 may be configured to press against the posterior wall 18 and towards the first elongate member 502. The delivery mechanism 512 may be configured to cause movement of the first elongate member 502 and/or second elongate member 504 in one or more of a variety of ways. In one use case, the delivery mechanism 512 may be configured to cause lateral movement of the second elongate member 504 such that the first portion moves toward the left ventricle 3 and/or the base portion 510 moves upward along the heart 1 and/or increases pressure against the posterior wall 18 and/or other ventricle wall. In another use case, the delivery mechanism 512 may be configured to pull the second elongate member 504 further into the delivery mechanism 512 such that the joint 514 moves toward the delivery mechanism 512 and/or the base portion 510 moves toward the posterior wall 18 and/or other ventricle wall.

[0058] In some embodiments, the first elongate member 502 may be configured to attach to the second elongate member 504. In optional embodiments, the first elongate member 502 and the second elongate member 504 may comprise a single elongate member. The delivery mechanism 512 may fit over and/or attach to at least a portion of the first elongate member 502 and/or the second elongate member 504. For example, the delivery mechanism 512 may comprise one or more openings and the first elongate member 502 and/or second elongate member 504 may pass at least partially through the one or more openings. In some embodiments, a joint between the first elongate member 502 and the second elongate member 504 may be configured to be situated within the delivery mechanism 512.

[0059] The delivery mechanism may have any of a variety of features to allow the delivery mechanism 512 to move and/or control the first elongate member 502 and/or second elongate member 504. In one use case, the delivery mechanism 512 may comprise grooves and/or threads and the delivery mechanism 512 may be configured to screw over a grooved and/or threaded exterior of the first elongate member 502 and/or the second elongate member 504. In another use case, the delivery mechanism 512 may comprise screws, pegs, hook, pincers or similar mechanisms which may be configured to be activated to extend, rotate, twist, and/or otherwise move to press against the first elongate member 502 and/or second

elongate member 504 to cause movement of the first elongate member 502 and/or second elongate member 504.

[0060] In some embodiments, a first pad 508a of the second elongate member 504 may be situated at or near the mitral valve 6 or other valve. When the second elongate member is moved by the delivery mechanism 512, the first pad 508a may be configured to cause remodeling of the left ventricle 3 or other ventricle to correct valve regurgitation. In some embodiments, a second pad 508b of the second elongate member 504 may be configured to be situated at or near a ventricle and/or may be positioned lower than the first pad 508. When the second elongate member 504 is moved by the delivery mechanism 512, the second pad 508b may be configured to cause remodeling of the ventricle to treat HFrEF and/or other diseases.

[0061] Because the remodeling device 500 may be configured for percutaneous delivery, the remodeling device 500 may provide for simplified delivery and a very low risk of complications associated with delivery. The remodeling device 500 may be delivered via a transcatheter procedure without requiring open-heart surgery.

[0062] Figure 6 provides a flow diagram representing a minimally invasive process 600 for remodeling a ventricle of the heart according to one or more embodiments disclosed herein. While some steps of the process 600 may be directed to the left ventricle, such steps may also be applied to the right ventricle.

[0063] At step 602, the process 600 involves making an incision in a patient's body between the ribs to allow access to the patient's heart, for example the apex of the heart. In one use case, an incision may be made between the fourth and fifth intercostal ribs to provide access to the apex of the heart.

[0064] At step 604, the process 600 involves delivering a first elongate member through the apex into the heart. In some embodiments, the first elongate member may comprise a coiled wire and/or may have a threaded exterior and may be twisted into the cardiac tissue to minimize damage to the tissue and risk of bleeding. A first end of the elongate member may have a pointed tip to facilitate puncturing, penetrating, and/or passing through cardiac tissue. In some embodiments, the first elongate member may be configured to be pressed and/or twisted through the tissue at or near the apex and may pass into the septum or other ventricle wall. The first elongate member may be configured to extend any distance into the heart. For example, the first elongate member may be configured to extend from the apex to a point of the septum that is approximately level with the mitral valve. In some embodiments, a delivery mechanism (e.g., the delivery mechanism 412 of Figure 4

and/or an anchor driver) may be configured to be used to deliver the first elongate member into the heart.

[0065] At step 606, the process 600 may involve placing a second elongate member around an exterior portion of the heart, for example around an exterior of a ventricle. The second elongate member may be configured to be coupled to the first elongate member at a joint and/or the first elongate member and the second elongate member may extend from a common device.

[0066] The second elongate member may comprise one or more pads attached to and/or extending from a base portion of the second elongate member. The one or more pads may be composed of any bio-compatible polymer and may have a soft and/or compressible structure. In some embodiments, the one or more pads may be configured to contact and/or press against cardiac tissue to cause remodeling of the cardiac tissue. The base portion of the second elongate member may not contact cardiac tissue. In optional embodiments, the first elongate member may comprise one or more pads.

[0067] In some embodiments, the first elongate member and/or the second elongate member may be configured to be coupled to a delivery mechanism and/or the delivery mechanism may be configured to fit over at least a portion of the first elongate member and/or the second elongate member. The delivery mechanism may be delivered into the heart with the first elongate member and/or second elongate member or may be configured to be delivered after the first elongate member and/or second elongate member is/are in place.

[0068] At step 608, the process 600 involves activating the delivery mechanism to cause movement of the first elongate member and/or second elongate member to reduce a distance between the first elongate member and second elongate member. In some embodiments, only one of the first elongate member and the second elongate member may be configured to be moved by the delivery mechanism. In some embodiments, portions of the first elongate member and the second elongate member may not move closer together while other portions of the first elongate member and the second elongate member may move closer together. Movement of the first elongate member and/or second elongate member may be configured to cause pressure at the ventricle walls of the heart and/or may result in remodeling of the ventricles.

[0069] At step 610, the process 600 involves placing a locking mechanism at or near the delivery mechanism. The locking mechanism may comprise a nut, clip, pin, or similar device configured to prevent movement of the first elongate member and/or second

elongate member in one or more directions. For example, the locking mechanism may be configured to prevent the first elongate member and/or second elongate member from returning to a previous position (e.g., prior to activation of the delivery mechanism). In some embodiments, the locking mechanism may be configured to have a smaller profile than the delivery mechanism. The locking mechanisms may be composed of bio-compatible polymer or other material.

[0070] At step 612, the process 600 may involve removing the delivery mechanism from the patient's body when a desired amount of movement and/or ventricle remodeling is achieved. In some embodiments, the delivery mechanism may comprise a release mechanism (e.g., a pin, latch, hook, etc.) to couple and/or decouple the delivery mechanism from the first elongate member and/or second elongate member.

[0071] Figure 7 provides a flow diagram representing a percutaneous 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.

[0072] At step 702, the process 700 involves inserting a remodeling device into a heart using a transcatheter procedure. For example, the remodeling device may be delivered using a transfemoral, transendocardial, transc coronary, transseptal, and/or transapical procedure, or other approach. The remodeling device may be delivered via the superior vena cava, right atrium, and finally into the right ventricle. 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 elongate members and/or a delivery mechanism.

[0073] 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) where the remodeling device 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 configured to be inserted through the apex via a catheter. In optional embodiments, the remodeling device may be delivered to a location outside of the heart for purposes other than remodeling ventricles.

[0074] In some embodiments, the remodeling device may be configured to 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 configured to be passed through the catheter to penetrate the septum and/or other ventricle walls. For example, a transseptal needle may be configured to 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.

[0075] At step 704, the process 700 involves placing a first elongate member of the remodeling device against the septum or other ventricle wall. In some embodiments, the first elongate member may be configured to be situated within the right ventricle and/or left ventricle and may contact an exterior portion of the septum or other ventricle wall. In optional embodiments, the first elongate member may be configured to penetrate and/or at least partially pass through the septum or other ventricle wall. The first elongate member may comprise a first end that may be configured to fit into an opening in a delivery mechanism (e.g., the delivery mechanism 512 of Figure 5) and/or the first end may be configured to be coupled to a second elongate member.

[0076] At step 706, the process 700 involves passing the second elongate member through the apex region of the heart or other ventricle wall to exit the heart. In some embodiments, the second elongate member may be configured to be situated within a sheath or similar device while passing through cardiac tissue. A first end of the second elongate member may have a pointed tip configured to facilitate penetrating and/or passing through cardiac tissue.

[0077] At step 708, the process 700 involves placing the second elongate member along an exterior portion of the heart, for example an exterior of a ventricle. In some embodiments, the second elongate member may be composed of a shape-memory alloy (e.g., Nitinol) and/or may have an at least partially curved shape to approximate a curvature of the exterior of the heart. The second elongate member may comprise one or more pads configured to contact and/or apply pressure to the exterior of the heart.

[0078] At step 710, the process 700 involves activating the delivery mechanism to cause movement of the first elongate member towards the second elongate member and/or to cause movement of the second elongate member towards the first elongate member. For example, the delivery mechanism may be configured to cause the portion of the second elongate member along the exterior of the ventricle wall to press against the ventricle wall and towards the first elongate member and/or the septum. Activating the delivery mechanism may involve twisting the delivery mechanism along the first elongate member and/or second

elongate member and/or otherwise pressing against the first elongate member and/or second elongate member.

[0079] At step 712, the process 700 involves placing a locking mechanism at and/or near the delivery mechanism. The locking mechanism may be any device (e.g., a nut) configured to contact the first elongate member and/or second elongate member and prevent movement of the first elongate member and/or second elongate member in one or more directions. In some embodiments, the locking mechanism may have a smaller profile than the delivery mechanism.

[0080] At step 714, the process 700 involves removing the delivery mechanism from the heart and/or body. In some embodiments, removing the delivery mechanism may involve activating a release mechanism of the delivery mechanism.

[0081] The processes 600, 700 and/or other processes, devices, and systems disclosed herein may advantageously provide mechanisms for implementing ventricular remodeling using a minimally invasive and/or fully transcatheter procedure on a beating heart. In certain embodiments, valve leaflets may not be substantially touched or damaged during the processes 600, 700. Furthermore, in certain embodiments, at least portions of the remodeling devices 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 elongate member configured to contact a first area of tissue of a heart;
 - a second elongate member configured to apply pressure to a second area of tissue of the heart, wherein at least a portion of a ventricle is between the first area of tissue and the second area of tissue; and
 - a delivery mechanism configured to press the second elongate member towards the first elongate member to reduce a distance between the first area of tissue and the second area of tissue.
2. The cardiac device of claim 1, wherein the first elongate member is coupled to the second elongate member.
3. The cardiac device of claim 1 or claim 2, wherein the first elongate member has a linear shape.
4. The cardiac device of any of claims 1-3, wherein the second elongate member has a non-linear shape.
5. The cardiac device of claim 4, wherein the second elongate member has a curved shape that approximates a curvature of the heart.
6. The cardiac device of any of claims 1-5, wherein the delivery mechanism is at least partially hollow, and each of the first elongate member and the second elongate member is configured to at least partially fit into the delivery mechanism.
7. The cardiac device of claim 6, wherein the delivery mechanism is configured to twist and move along the first elongate member and the second elongate member.
8. The cardiac device of any of claims 1-7, wherein the second elongate member comprises one or more pads configured to press against an exterior portion of the second area of tissue.

9. The cardiac device of claim 8, wherein each of the one or more pads is configured to at least partially compress in response to pressure from the second area of tissue.

10. The cardiac device of claim 8 or claim 9, wherein each of the one or more pads has a half-sphere, half-ovoid, or half-capsule shape.

11. The cardiac device of any of claims 1-10, wherein the first area of tissue is a septum and the second area of tissue is a posterior wall.

12. The cardiac device of any of claims 1-11, wherein the first elongate member has a threaded exterior.

13. The cardiac device of any of claims 1-12, wherein the first elongate member is a coiled wire.

14. The cardiac device of any of claims 1-13, wherein the first elongate member is configured to penetrate the first area of tissue.

15. The cardiac device of any of claims 1-14, wherein the first elongate member is configured to contact an exterior portion of the first area of tissue.

16. A method comprising:
contacting a first area of tissue of a heart with a first elongate member;
contacting a second area of tissue of the heart with a second elongate member,
wherein at least a portion of a ventricle of the heart is between the first area of tissue and the second area of tissue; and
activating a delivery mechanism to press the second elongate member towards the first elongate member to reduce a distance between the first area of tissue and the second area of tissue.

17. The method of claim 16, wherein the first elongate member is coupled to the second elongate member.

18. The method of claim 16 or claim 17, wherein the delivery mechanism is at least partially hollow, and each of the first elongate member and the second elongate member is configured to at least partially fit into the delivery mechanism.

19. The method of any of claims 16-18, wherein the second elongate member comprises one or more pads configured to press against an exterior portion of the second area of tissue.

20. The method of claim 19, wherein each of the one or more pads is configured to at least partially compress in response to pressure from the second area of tissue.

21. The method of any of claims 16-20, wherein the first area of tissue is a septum and the second area of tissue is a posterior wall.

22. The method of any of claims 16-21, wherein the first elongate member has a threaded exterior.

23. The method of any of claims 16-22, wherein the first elongate member is a coiled wire.

24. The method of any of claims 16-23, wherein the first elongate member is configured to penetrate the first area of tissue.

25. The method of any of claims 16-24, further comprising percutaneously delivering the first elongate member to the first area of tissue, the second elongate member to the second area of tissue, and the delivery mechanism to the ventricle.

26. A cardiac device comprising:
a first means for anchoring configured to contact a first area of tissue of a heart;
a second means for anchoring configured to apply pressure to a second area of tissue of the heart, wherein at least a portion of a ventricle is between the first area of tissue and the second area of tissue; and

a means for tensioning configured to press the second means for anchoring towards the first means for anchoring to reduce a distance between the first area of tissue and the second area of tissue.

27. The cardiac device of claim 26, wherein the first means for anchoring is coupled to the second means for anchoring.

28. The cardiac device of claim 26 or claim 27, wherein the means for tensioning is at least partially hollow, and each of the first means for anchoring and the second means for anchoring is configured to at least partially fit into the means for tensioning.

29. The cardiac device of any of claims 26-28, wherein the second means for anchoring comprises one or more pads configured to press against an exterior portion of the second area of tissue.

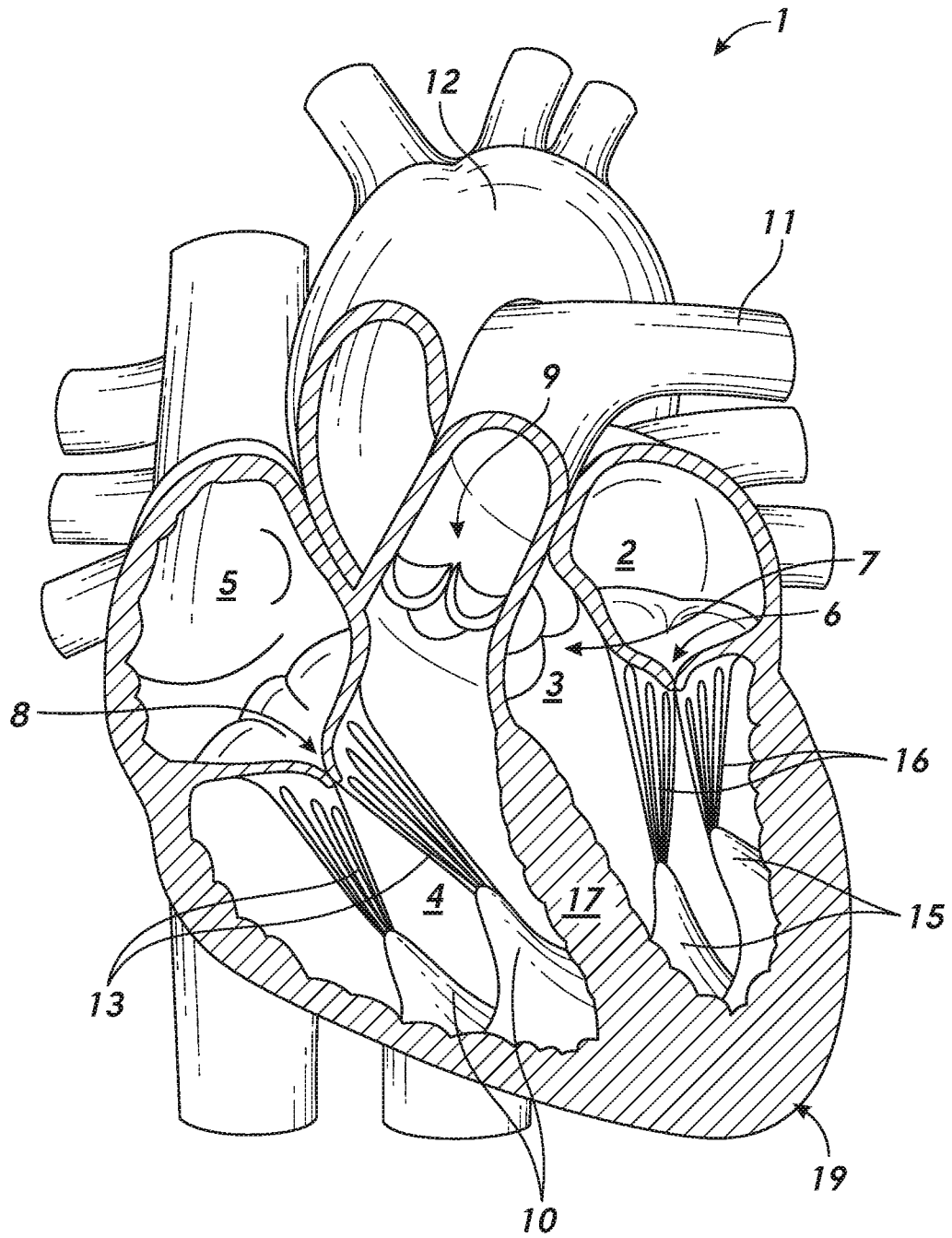


FIG. 1

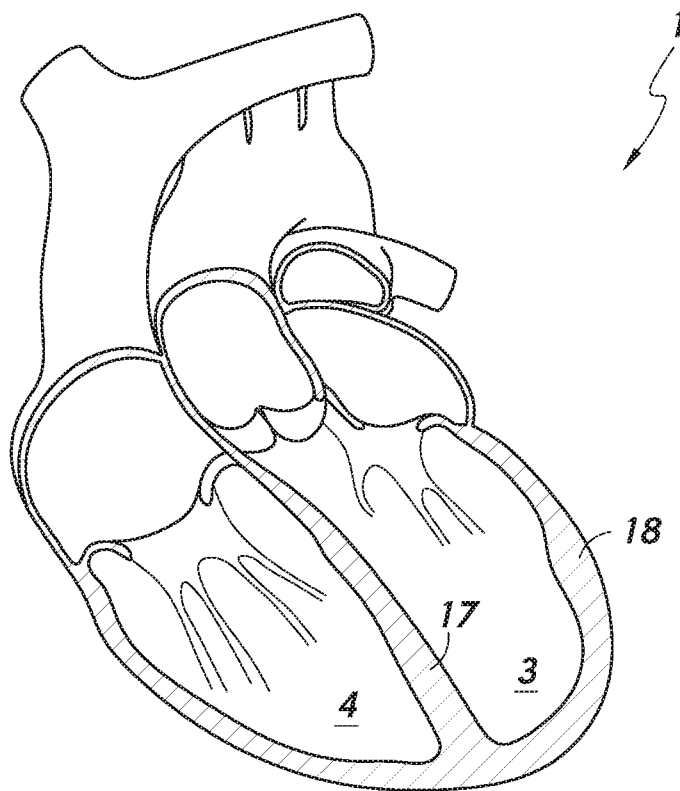


FIG. 2

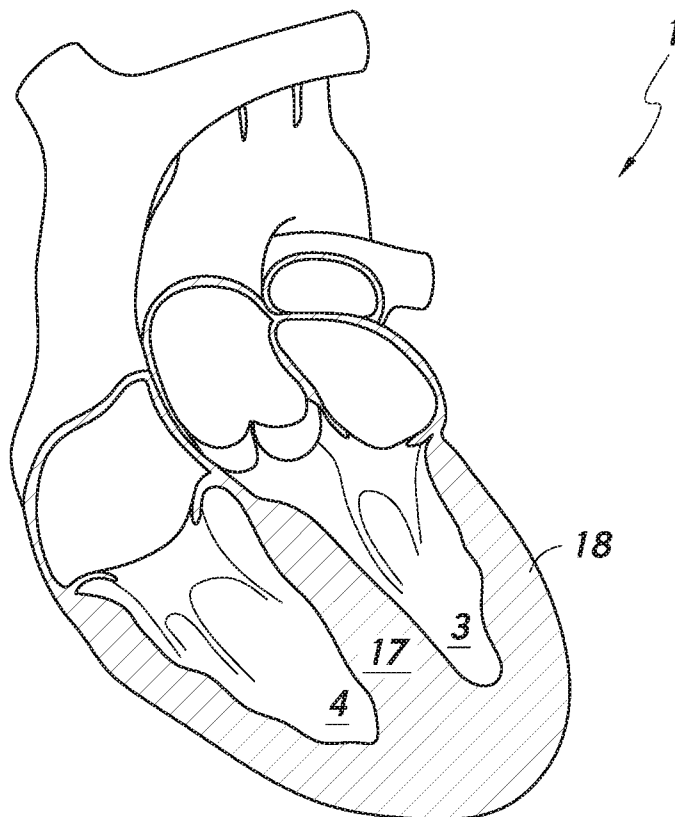


FIG. 3

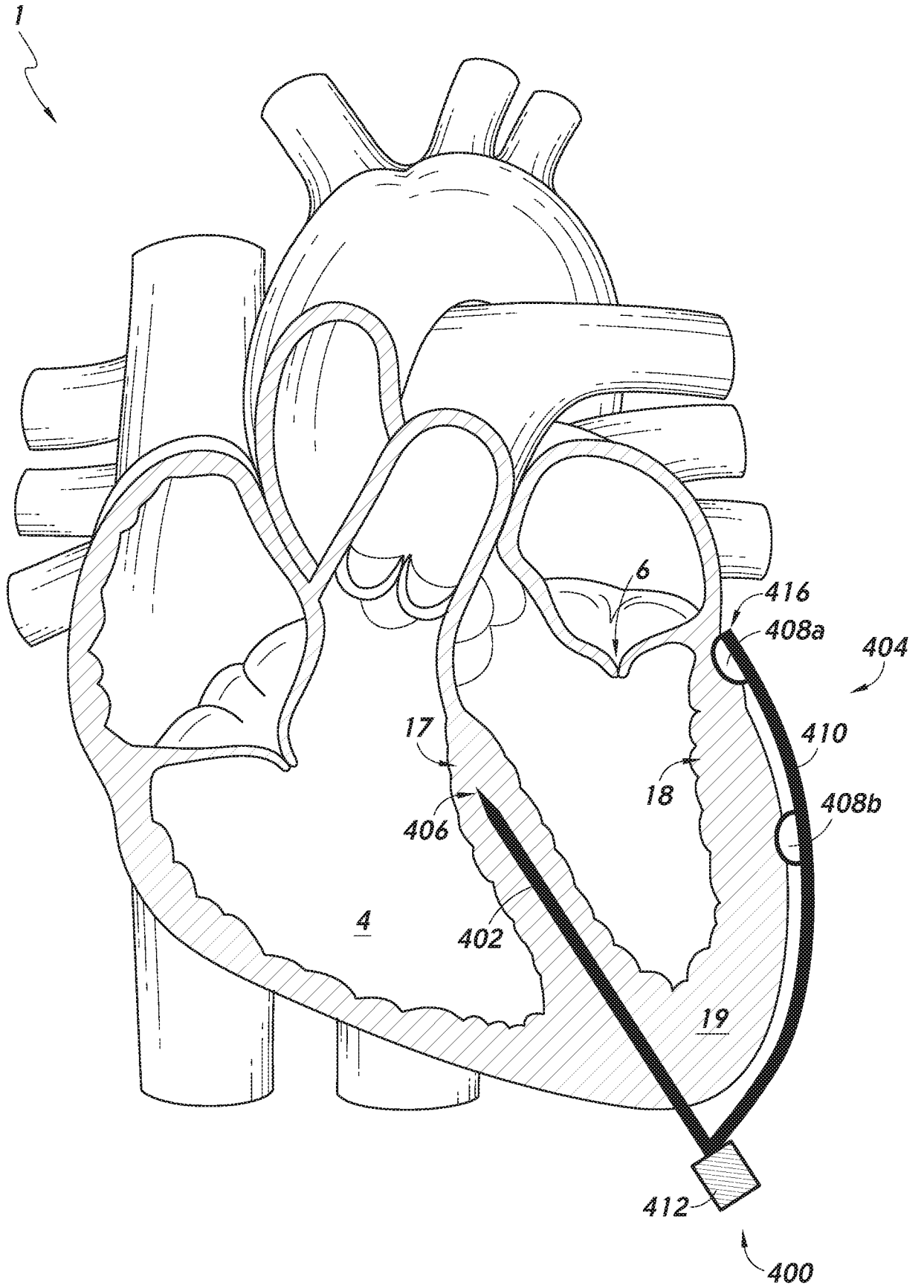


FIG. 4

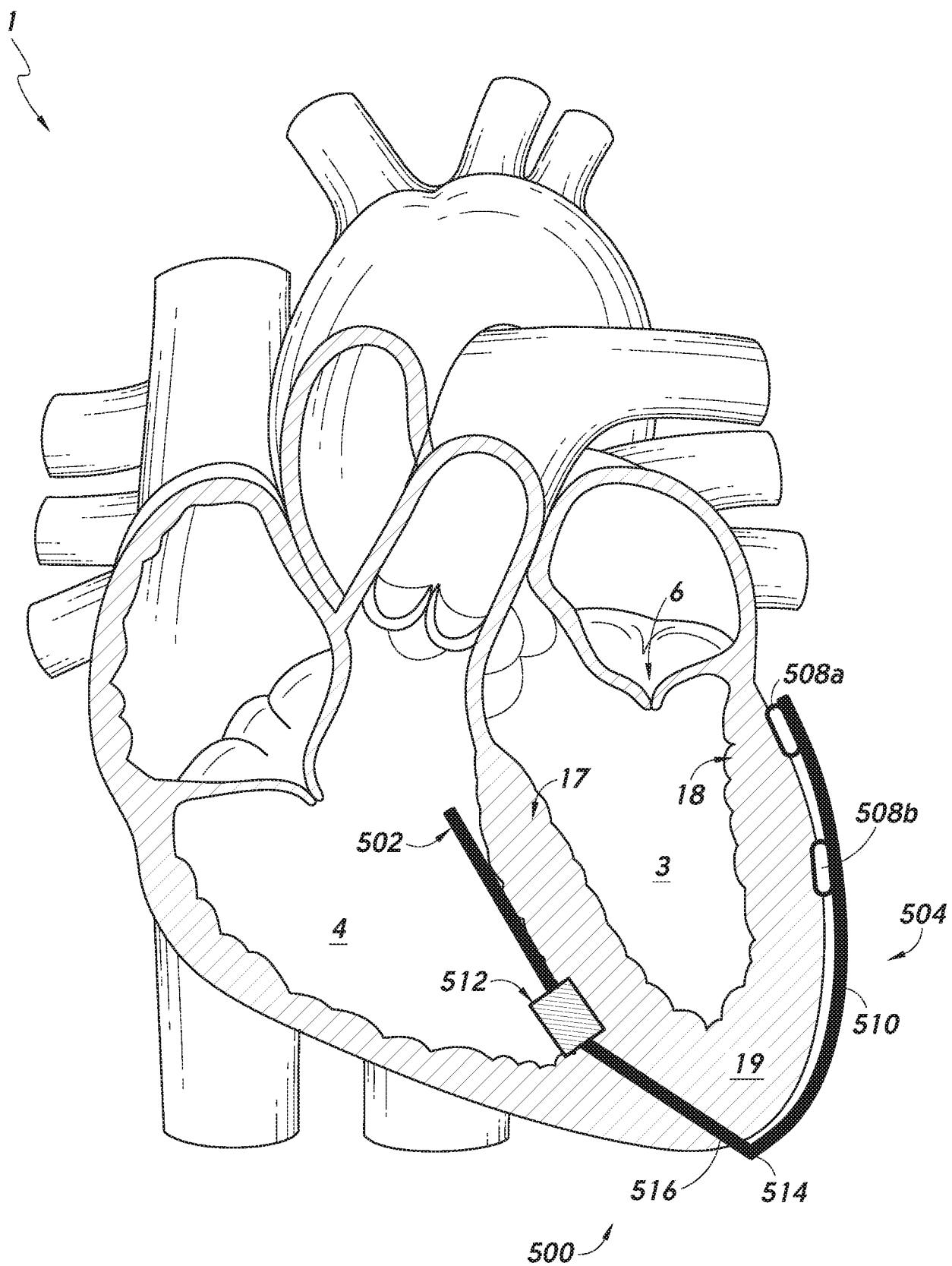


FIG. 5

600
↘

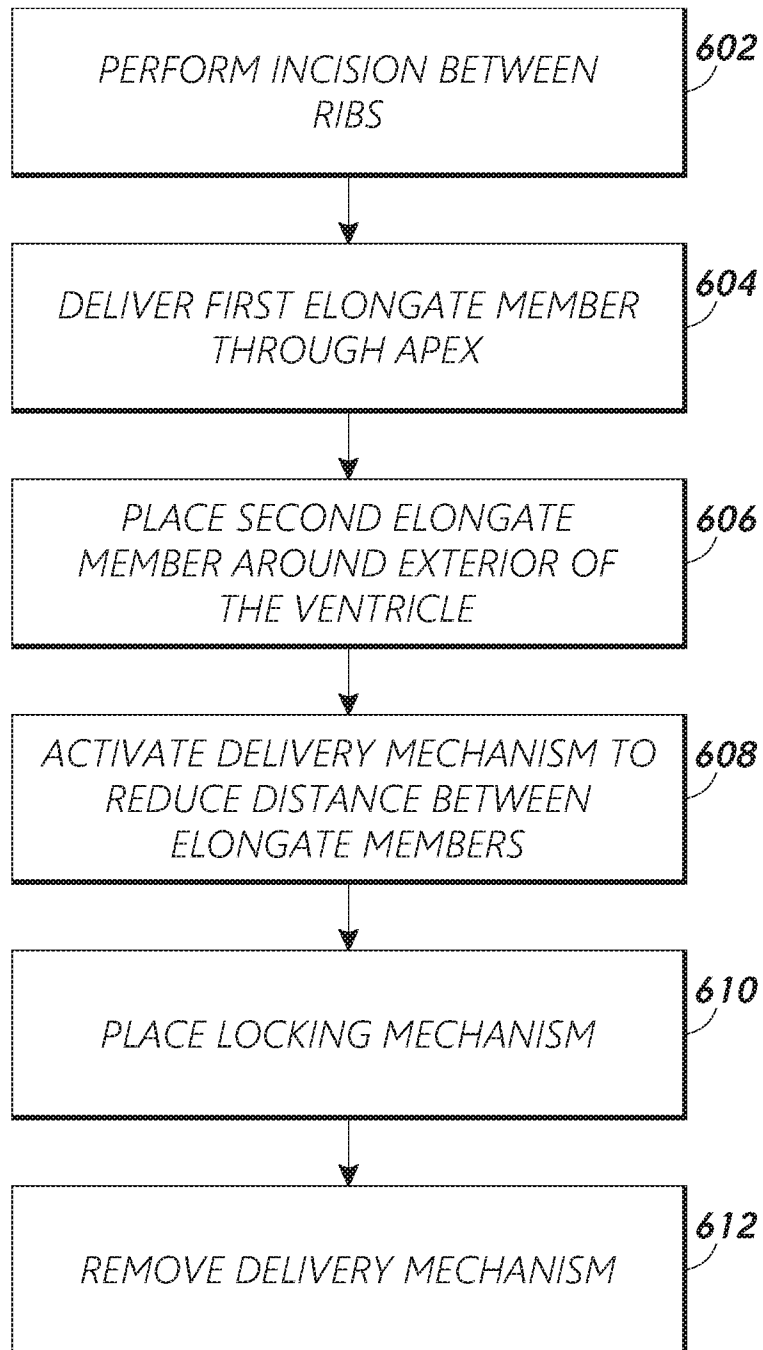


FIG. 6

700

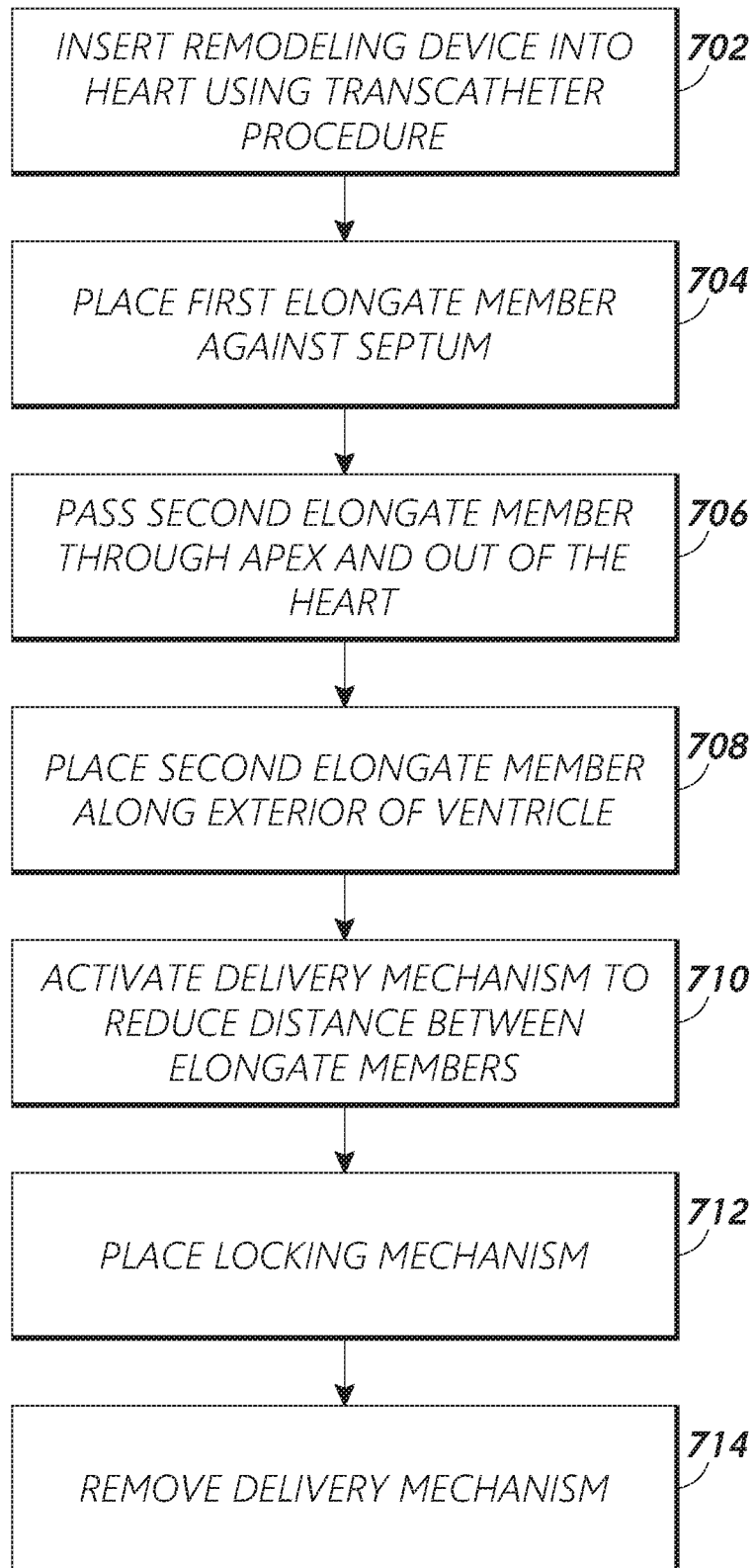


FIG. 7

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2020/016942

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

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 2010/004504 A1 (CALLAS PETER TACHI [US] ET AL) 7 January 2010 (2010-01-07) paragraphs [0076], [0092], [0093], [0101] - [0139]; claims; figures -----	1-10, 12-15, 26-29
X	US 2008/312493 A1 (MORTIER TODD J [US] ET AL) 18 December 2008 (2008-12-18) paragraphs [0086] - [0088]; figures 32-34 paragraphs [0056], [0069] - [0072]; figures 7,19-22 -----	1-15, 26-29
X	US 6 409 760 B1 (MELVIN DAVID B [US]) 25 June 2002 (2002-06-25) column 7, line 3 - column 8, line 57; figures 4,6 ----- -/--	1-5,15, 26-29



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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"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

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"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

7 May 2020

Date of mailing of the international search report

31/07/2020

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No

PCT/US2020/016942

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/28455 A1 (MYOCOR INC [US]; MCCARTHY PATRICK M [US] ET AL.) 26 April 2001 (2001-04-26) claims; figures -----	1-5, 8-11, 15, 26-29

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2020/016942

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/016942

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. ☒ Claims Nos.: 16-25
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.