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# DESCRIPTION

Description

## FIELD OF THE INVENTION

**[0001]** The present disclosure is related to the field of interventional cardiology systems and, in particular, systems for heart valve repair

## BACKGROUND

**[0002]** Prosthetic devices are commonly used to replace or repair native heart valves that have become inefficient due to age, disease, or congenital reasons. Valve insufficiency, for example, is characterized by a loose or elastic valve structure. This often results in regurgitation wherein the valve leaflets fail to close property ("coapt") and guard against backflow of blood.

**[0003]** Transvascular techniques have enabled physicians to access the mitral and other valves for repair without open-heart surgery. Valves or annuloplasty rings may be delivered to the site of the valve by catheter and expanded once properly positioned.

**[0004]** A physician may have difficulty precisely positioning prosthetic devices between the mitral valve leaflets - especially when the mitral valve is insufficient. The prosthetic devices may slip upon expansion within the relatively elastic annulus of the insufficient mitral valve.

**[0005]** A physician may provide support for the annular ring of the valve during implantation to compensate for mitral valve insufficiency. But, positioning of such support devices in a safe and minimally invasive manner is technically challenging. For example, the chordae tendinae attached to the mitral valve leaflets can interfere with efforts to support the valve or its annulus.

**[0006]** It is therefore desirable to provide improved systems for supporting replacement valves, especially replacement valves implanted with minimally invasive procedures. US 2013/0090726 A1 discloses a support band configured to be positioned around native leaflets of the deficient mitral valve. The support band is preferably formed of a shape memory material and is configured to assume a curved shape upon advancement from the delivery catheter. While the support band is positioned around the native leaflets of the mitral valve, an expandable prosthetic heart valve is delivered through an apex of the left ventricle and into the mitral valve. The expandable prosthetic heart valve is then expanded within the mitral valve, thereby causing one or more of the native leaflets of the mitral valve to be frictionally secured between

the support band and the prosthetic heart valve.

**SUMMARY**

**[0007]** The present invention is defined in the appended claims. Disclosed herein are apparatuses for greatly simplifying and improving the outcome of minimally invasive valve procedures - making those procedures much more accessible to less experienced physicians or cardiologists. For example, implementations are applicable to full mitral valve replacement, or to mitral valve annuloplasty. The mitral valve can be accessed by femoral catheterization with a fluoroscopically guided, low-profile catheter. Once the right atrium is accessed and the interatrial septum is punctured, the mitral valve can be approached from the left atrium. This approach avoids contact with the left ventricular outflow tract and the chordae tendineae. Methods are disclosed for illustrative purposes only.

**[0008]** As part of the method, two leaflet braces circumnavigate the anterior and posterior mitral valve leaflets, forming a loop around each leaflet. Tension in the atrial direction from the catheter keeps the loops tightly wedged under the leaflets for the remainder of the procedure. A fastener joins the ends of each loop to form one annular ring circling the valve under the anterior and posterior leaflets.

**[0009]** The procedure can be performed with a sub-commissural catheter to assist in steering behind the leaflets. After bracing the individual leaflets, a transcatheter heart valve system can then be deployed between the native leaflets. Expansion of the heart valve traps and sandwiches the native mitral valve leaflets between the valve frame and the leaflet braces. The procedure can be performed in catheterization laboratories and by practitioners with varying levels of expertise.

**[0010]** A method of supporting a heart valve can include looping around a first leaflet of the heart valve. And, applying tension directed through the valve to the first leaflet. The method can also include performing a procedure on the heart valve.

**[0011]** The method can further comprise looping around a second leaflet of the heart valve and applying tension directed through the valve to the second leaflet.

**[0012]** The method can also include extending a guide catheter through the valve and advancing a first guide wire through the guide catheter. In this manner, looping around the leaflet includes extending the first guide wire around the first leaflet. Also, a second guide wire could be deployed through the guide catheter and looped around the second leaflet.

**[0013]** The guide wires can include snare loops and the method includes snaring the snare loop of the guide wires after extending them around the leaflets.

**[0014]** The method can also include forming first and second leaflet braces. A first leaflet brace

extends over the first guide wire and around the first leaflet. Also, a second leaflet brace is extended over the second guide wire and around the second leaflet.

**[0015]** The method can also include securing adjacent ends of the leaflet braces to each other to form a closed loop, such as a circle. For example, the physician can attach a first pair of adjacent ends using a first leaflet brace and a second pair of adjacent ends using a second leaflet brace. Then, as an exemplary procedure on the heart valve, a replacement heart valve can be expanded within the native heart valve. Expansion for example can include releasing a self-expanding heart valve within the (native) heart valve and against the leaflets (directly) and the leaflet braces (indirectly). The method can also include removing excess tubing from the leaflet braces.

**[0016]** Advantageously, all of these procedures can occur while the method applies tension to the leaflets for improved results. For example, the tension on the leaflets helps with accurate positioning (and slip avoidance) during expansion of the replacement heart valve.

**[0017]** The heart valve can be, for example, a mitral heart valve and the method can be used to avoid and preserve the chordae tendinae. Other heart valves might be aortic, tricuspid or pulmonic, or prior replacement heart valves in need of repair.

**DESCRIPTION OF DRAWINGS**

**[0018]**

Figure 1A is a cross-sectional schematic of a heart undergoing a minimally invasive mitral valve procedure including introduction of a catheter via a transseptal access point.

Figure 1B is a cross-sectional schematic of the heart from Figure 1A with introduction of a guide catheter.

Figure 1C is a cross-sectional schematic of the heart from Figure 1A with introduction of a snare catheter and formation of a loop around the posterior leaflet.

Figure 1D is a cross-sectional schematic of the heart from Figure 1A with introduction of a second guide catheter.

Figure 1E is a cross-sectional schematic of the heart from Figure 1A with introduction of a second snare catheter and formation of a loop around the anterior leaflet.

Figure 1F is a cross-sectional schematic of the heart from Figure 1A with introduction of first and second leaflet braces over the loops.

Figure 1G is a cross-sectional schematic of the heart from Figure 1A with introduction of fastening catheters to secure the loops at either end.

Figure 1H is a cross-sectional schematic of the heart from Figure 1A after introduction and expansion of a balloon inflatable stented heart valve within the native mitral valve.

Figure 1I is a cross-sectional schematic of the heart from Figure 1A after completion of the procedure.

Figure 2 shows a cross-section of a leaflet brace.

Figure 3A shows a perspective view of a distal end of a pair of fastening catheters.

Figures 3B and 3F show a cross section and perspective view of the fastening catheter and fastener of Figure 3A engaged with a leaflet brace.

Figure 3C shows a cross-section of the fastening catheter and fastener of Figure 3A after advancement of the fastening catheter down the leaflet brace.

Figure 3D shows a cross-section of the fastening catheter, fastener and leaflet brace of Figure 3C after removal of the leaflet brace ends.

Figures 3E and 3G shows a cross-section and perspective view of the fastener and leaflet brace of Figures 3A-3D after removal of the fastening catheter.

Figure 4A shows a perspective view of two fasteners having barbs.

Figure 4B shows a perspective view of one of the fasteners of Figure 4A bound to a fastening catheter.

Figure 4C is a cross-sectional schematic of a heart having a leaflet brace ring fastened by the fasteners of Figures 4A and 4B.

Figure 4D is a cross-sectional schematic of the heart of Figure 4C after expansion of a balloon inflatable stented heart valve within the native mitral valve.

Figure 4E is a cross-sectional schematic of a heart after completion of the procedure using the fasteners of Figures 4A-4B.

Figure 5A shows a top view of two fasteners mounted on a fastener hoop.

Figure 5B shows a perspective view of the fasteners and fastener hoop of Figure 5A in a transseptal introducer sheath.

Figure 5C is a cross-sectional schematic of the introduction of the fastening hoop of Figures 5A-5B during a mitral valve procedure.

Figure 5D is a cross-sectional schematic of the heart after expansion of the fastening hoop of Figure 5C.

Figure 5E is a cross-sectional schematic of the heart of Figure 5D after expansion of a balloon inflatable stented heart valve within the native mitral valve.

Figure 5F is a cross-sectional schematic of the heart after completion of the procedure using the fastening hoop of Figures 5A-5D.

Figure 6A is perspective view of a fastener stent.

Figure 6B is an enlarged top view of the boxed area of Figure 6A showing the detail of a fastener on the fastener stent.

Figure 6C is a cross-sectional schematic of a heart after undergoing a minimally invasive mitral valve procedure with the fastener stent of Figure 6A.

Figure 6D is a perspective view of the fastener stent of Figure 6A.

Figure 6E is a cross-sectional schematic of a heart with the leaflet brace, the fastener stent and an anchor.

Figure 7A is a perspective view of a sub-commissural catheter in a transseptal introducer sheath.

Figure 7B shows perspective views of the sub-commissural catheter of Figure 7A with sub-commissural extensions in both retracted and deployed states.

Figure 7C is a perspective view of the sub-commissural catheter of Figure 7B with right angle guide catheters deployed.

Figure 7D is a perspective view of the sub-commissural catheter of Figure 7C with ringed and snare guide wires deployed.

Figure 7E is a cross-sectional schematic of a heart undergoing a minimally invasive mitral valve procedure after introduction of the transseptal introducer sheath of Figure 7A-7D.

Figure 7F is a cross-sectional schematic of the heart of Figure 7E after introduction of a valve guide wire.

Figure 7G is a cross-sectional schematic of the heart of Figure 7F after introduction of a sub-commissural catheter over the valve guide wire.

Figure 7H is a cross-sectional schematic of the heart of Figure 7G with the commissural extensions deployed from the sub-commissural catheter.

Figure 7I is a cross-sectional schematic of the heart of Figure 7H after formation of a guide wire loop around the posterior leaflet.

Figure 7J is a cross-sectional schematic of the heart of Figure 7I after formation of a guide wire loop around the anterior leaflet.

Figure 7K is a cross-sectional schematic of the heart of Figure 7J after retraction of the sub-commissural catheter.

Figure 7L is a cross-sectional schematic of the heart of Figure 7K after deployment of the

leaflet braces around the guide wire loops.

Figure 7M is a cross-sectional schematic of the heart of Figure 7L after introduction of fastening catheters over the leaflet braces.

Figure 7N is a cross-sectional schematic of the heart of Figure 7M after expansion of a balloon inflatable stented heart valve.

Figure 7O is a cross-sectional schematic of the heart of Figure 7E-7N after completion of a minimally invasive mitral valve procedure with the sub-commissural catheter and transseptal introducer sheath of Figure 7A-D.

Figure 8 shows a schematic of a tool for cutting leaflet braces.

## DETAILED DESCRIPTION

**[0019]** The following description of certain examples of a medical system (e.g., catheters and implants) should not be used to limit the scope of the medical system. Accordingly, the drawings and descriptions should be regarded as illustrative in nature and not restrictive.

**[0020]** The invention is not restricted to the details of any foregoing embodiments.

**[0021]** Apparatuses for performing minimally invasive mitral valve procedures are disclosed herein. For example, these apparatuses can be applied to full mitral valve replacement, or to mitral valve annuloplasty. Although particularly suited for mitral valves, these apparatuses can also be applied to other valves. The procedures can be performed in catheterization laboratories and by practitioners with varying levels of expertise.

**[0022]** For illustrative purposes, certain systems are described as being used in connection with a trans-catheter heart valve (THV). For example, the systems and methods may be employed with the balloon-expandable THV described in U.S. Patent Application Publication No. 8,764,820. It should be understood, however, that the systems and methods should not be limited to use with balloon-expandable THVs. Instead, the disclosed systems can be used to secure a wide variety of THVs delivered through a variety of mechanisms (e.g., self-expanding heart valves, mechanically-expanding heart valves, other balloon-expanding heart valves, and the like). For instance, any of the embodiments described in U.S. Pat. No. 6,730,118 can be used with embodiments of the disclosed system.

**[0023]** Access to the mitral valve can be obtained using femoral catheterization with a fluoroscopically guided, low-profile catheter. For example, the right atrium is accessed and the interatrial septum punctured to get to the left atrium. Then the mitral valve is approached through the left atrium. Advantageously, this approach avoids contact with the left ventricular

outflow tract and the chordae tendineae.

**[0024]** Two leaflet braces are extended over guide wires to form semicircular loops that circumnavigate the anterior and posterior mitral valve leaflets. Tension is applied to the catheter from the atrial direction to keep the leaflet braces tightly wedged under the leaflets for the remainder of the procedure. A fastener joins the ends of each loop to create one annular ring encircling the valve under the anterior and posterior leaflets.

**[0025]** The procedure can be performed with a sub-commissural catheter to assist in steering behind the leaflets. The remaining catheters can be separated from the leaflet braces after implantation, leaving the annular ring in place behind the leaflets. The annular ring formed can serve as part of an annuloplasty device. Alternatively, a transcatheter heart valve system can then be deployed between the native leaflets. Expansion of the heart valve traps and sandwiches the native mitral valve leaflets between the valve frame and the leaflet braces.

**[0026]** To begin the transseptal procedure, a physician punctures the septum with a needle and advances a guide wire through the needle. The physician then retrieves the needle, leaving a guide wire across the septum. The physician then advances a dilator with a cone shaped distal end over the guide wire and across the septum. The physician then advances a transseptal introducer sheath 2 over the dilator, through the interatrial septum 4 and toward the anterior and posterior leaflets 6, 7 of a mitral valve as seen in FIG. 1A.

**[0027]** As in FIG. 1B, a first double bend guide catheter 8 extends from the introducer sheath 2 to cannulate the mitral valve at the posteromedial commissure. The physician then advances a first guide wire with a ringed end through guide catheter 8 and around the posterior leaflet 7 towards the anterolateral commissure. A first snare catheter 10 then cannulates the mitral valve at the anterolateral commissure. A first snare guide wire positioned at the distal end of the snare catheter 10 captures the first ringed guide wire and pulls it out, so that the guide wire circumvents the posterior leaflet 7 at the base of the mitral valve, as in FIG. 1C. This forms a posterior leaflet wire loop 12.

**[0028]** The process is repeated in FIGS. 1D and 1E around the anterior leaflet 6 using a second double bend guide catheter 13, a second ringed guide wire (not shown), a second snare catheter 15, and a second snare guide wire (not shown). This forms an anterior leaflet wire loop 17.

**[0029]** The physician retracts the guide and snare catheters, leaving the wire loops in place. The physician then slides two tubular leaflet braces 18, 20 over the loops such that they are positioned around the posterior and anterior wire leaflet loops 12, 17 as seen in FIG. 1F. The structure of the braces is shown in FIG. 2 and will be described in greater detail below.

**[0030]** The physician then slides anterolateral and a posteromedial fastening catheters 22, 24 along the guide wires and over portions of the leaflet braces 18, 20 as seen in FIG. 1G. In particular, the posteromedial fastening catheter 22 runs up the two ringed guide wires 9, 14

and over the leaflet brace ends located at the posteromedial side of the valve. The anterolateral fastening catheter 24 runs up the two snared guide wires 11, 15 and over the brace ends located at the anterolateral side of the valve.

**[0031]** Fasteners 26 located at the distal faces of the fastening catheters 22, 24 are used to join the two leaflet braces at both commissures. Examples of fastener structures are shown in FIGS. 3A, 4A, 5A, and 6A, and are described in greater detail below.

**[0032]** The physician then removes excess tubing from the leaflet braces and retracts the excess tubing back through the transseptal introducer sheath 2. The two braces now form one annular ring circling the valve under the anterior and posterior leaflets 6, 7, as shown in FIG. 1G. Both fastening catheters 22, 24 are kept under tension, which holds the annular ring close to the base of the mitral valve.

**[0033]** The physician can then guide a valve delivery catheter 28 through the transseptal introducer sheath 2 and into the space between mitral valve leaflets 6, 7. The transcatheter heart valve 38 can be mounted on a stent 32. It can be self-expandable, mechanically-expandable, or expanded by balloon 30 as shown in FIG. 1H. Expansion of the heart valve 38 traps and sandwiches the native mitral valve leaflets 6, 7 between the valve frame and the leaflet braces 18, 20. The physician then releases fasteners 26 from the fastening catheters 22, 24 by removing a suture 64 that binds them to the fastening catheter (see FIGS. 3A-3E). The physician then retracts the fastening catheters and balloon delivery catheter 28 back through the transseptal introducer sheath. Finally, the transseptal introducer sheath 2 is removed from the patient. FIG. 1I shows the heart after the procedure with the surgical devices in place.

**[0034]** As shown in FIG. 2, stacked layers of polymer tubing form the exemplary leaflet braces 18, 20. The leaflet braces 18, 20 can be formed using standard catheter extrusion and braiding techniques. The innermost tubing 40 can be made from an elastic polymer such as PTFE or PU, or other elastic polymers suitable for medical device tubing. The innermost tubing 40 can have 10-100% elongation at failure. For example, the innermost tubing 40 can have about 20% elongation at failure.

**[0035]** Two or more layers of radiopaque marker tubing 42 extend over a portion of the innermost tubing 40 of the leaflet braces seen in FIG. 2. These layers widen the diameter of the leaflet brace 18, 20 to form an abutment 43 along with tubing 44. Abutment 43 stops the fastening catheter 22, 24 from moving further along the leaflet brace during the fastening step. The radiopaque marker tubing 42 also allows practitioners to more easily fluoroscopically monitor the position of the leaflet braces as they are arranged behind the anterior and posterior leaflets 6, 7.

**[0036]** As shown in FIG. 2, one or more layers of tissue ingrowth tubing 44 can cover the radiopaque marker tubing 42 of the leaflet braces 18, 20. The tissue ingrowth tubing 44 extends in both directions past the radiopaque marker tubing 42. It can be a porous or

filamentous material that encourages fixation of the leaflet brace to the tissue behind the leaflets. For example, the tissue ingrowth tubing 44 can be a multi-filament PTFE yarn.

**[0037]** The leaflet braces 18, 20 can have a shortening mechanism to allow removal of excess tubing during the mitral valve procedure. For example, tear notches 48 can be provided as seen FIG. 2. These tear notches 48 create weak points that allow excess tubing to be pulled off of the leaflet braces and slid back up the transseptal introducer sheath 2. Shrink tubing 46 can extend over the tissue ingrowth tubing 44 anywhere that tissue ingrowth is not desired. This can, for example, prevent the yarn from fraying after the ends are torn.

**[0038]** FIGS. 3A-3E depict the structural details of exemplary fastening catheters 22, fasteners 26, and the process of fastening the leaflet braces 18, 20. The exemplary fastener 26 depicted in FIG. 3A has an elongate fastener body 50 with rounded ends, two locking tab rings 54 positioned inward from the edge of the fastener body, and locking tabs 56 arranged circumferentially inside each locking tab ring 54 and defining spaces through which the leaflet braces 18, 20 can move. The locking tabs taper slightly as they extend inward and away from the fastener body 50. In FIG. 3A, there are 4 locking tabs per locking tab ring. However, the fasteners 26 can have fewer - such as 2 - locking tabs or more - such as 16 - locking tabs. Alternatively, the fasteners can secure the leaflet braces 18, 20 using other mechanisms, such as screws, clips, latches or knots. The fastener 26 can be cut from sheet metal with a laser or other cutting techniques. The fastener 26 can be a shape-memory metal, such as Nitinol. Alternatively, the fastener 26 can be stainless steel or other metals acceptable for use in implantable medical devices.

**[0039]** As shown in FIG. 3A, the body 50 of the fastener 26 can be secured to the distal face 58 of the fastening catheter 22 using suture 64. Fastening catheter lumens 60 slide down over the leaflet braces 18, 20, as shown in FIG. 3B. The fastening catheter 22 continues to push the fastener 26 along the leaflet braces 18, 20 until it reaches the abutment 43, as in FIG. 3C. Locking tabs 56 catch on the wider section of leaflet braces 18, 22 and prevent it from slipping backward. A practitioner can remove the excess tubing from the leaflet braces by pulling at the ends. The polymers tear at the tear notches 48, and the excess can be retracted back up the transseptal introducer sheath 2, as shown in FIG. 3D.

**[0040]** FIG. 3E shows the leaflet brace 20 after the fasteners are released and the fastening catheter is withdrawn. To release the fastener from the fastening catheter, the physician releases one end of the suture 64 and pulls on the other end. The suture slides over the fastener body 50 and back up the transseptal introducer sheath 2. This releases the fastener 26 and the attached leaflet braces 18, 20 from the fastening catheter 22. The fastening catheter 22 is then withdrawn up the transseptal introducer sheath 2.

**[0041]** The sheath 2 can be between 3.33-16.67 mm (10-50 French), depending on the particular method being performed. For example, in FIGS. 1A-1I, the sheath 2 can contain both the fastening catheters and the valve delivery catheter simultaneously. In this case, the introducer sheath 2 can be between 8.33-16.67 mm (25-50 French). In FIGS. 4A-E, the

fastening catheter can be removed prior to entry of the valve delivery catheter. Thus, introducer sheath 2 can be narrower because it does not have to house multiple catheters simultaneously.

**[0042]** In FIGS. 4A-E, fasteners 126 can include one or more fastener barbs 166. FIG. 4A shows two exemplary fasteners 126 with barbs. FIG. 4B shows one of the exemplary fasteners 126 bound to a fastening catheter 22 by a suture 64. After removal of the fastening catheters 22, 24, the barbs protrude as shown in FIG. 4C. The physician can use a steerable catheter to push fastener barbs 166 into the myocardial wall, securing the annular ring formed by the leaflet braces 18, 20.

**[0043]** The physician can then deploy a transcatheter heart valve 38 via a valve delivery catheter 28. The expansion of the valve 38 secures barbs 166 within the myocardial tissue. Figure 4D is a cross-sectional schematic of the heart of FIG. 4C after expansion of a balloon inflatable stented heart valve within the native mitral valve. Figure 4E is a cross-sectional schematic of a heart after completion of the procedure using the fasteners of FIGS. 4A-4B. Because fastening catheters 22, 24 are removed prior to inserting the valve delivery catheter 28, the diameter of the transseptal introducer sheath 2 can be lower than depicted in FIGS. 1A-1I. For example, the diameter of the transseptal introducer sheath can be between 3.33-10 mm (10-30 French).

**[0044]** In FIGS. 5A-5F, fasteners 226 are mounted on a flexible fastener hoop 268. The fastener hoop 268 can be between about 50-65 millimeters in diameter. The fasteners 226 and hoop 268 can be one piece, as shown in FIG. 5A, or they can be separate pieces joined after forming. The fastening hoop 268 can be made of a shape memory material. For example, the shape memory material can be Nitinol.

**[0045]** During deployment, the fasteners 226 are secured by suture 64 at the distal face 58 of the fastening catheter 22 as shown in FIG. 5B. The fastener hoop 268 is folded outside of the fastening catheters but within the transseptal introducer sheath 2.

**[0046]** FIG. 5C depicts the fastening catheters advanced along the leaflet braces 18, 20 with the ends of the fastening hoop 268 still retained in the folded state by the introducer sheath 2. Once the fastening catheters 22, 24 are sufficiently spaced from the distal end of the introducer sheath 2, the ends of the fastening hoop 268 open above the mitral valve while the fasteners 226 secure the ends of the leaflet braces 18, 20. The physician then releases the fastening hoop 268 and removes the fastening catheters 22, 24.

**[0047]** FIG. 5D shows the fastening hoop 268 in an open position above the mitral valve, while the leaflet braces 18, 20 form an annular ring below the mitral valve. The combination of the fastener hoop 268 and the leaflet braces 18, 20 can be used as an annuloplasty device. Alternatively, the physician can then deploy a transcatheter heart valve via valve delivery catheter 28 as shown in FIG. 5E. As above, the transcatheter heart valve 38 can be mounted on a stent 32. It can be self-expandable, mechanically-expandable or expanded by balloon 30.

FIG. 5F shows the heart after completion of the procedure using fastener hoop 268.

**[0048]** Alternatively, such as shown in FIGS. 6A-6C, fasteners 326 can be mounted directly onto a fastening stent 132. FIGS. 6A and 6B illustrate the fastener stent 326. When deployed, the fasteners 326 are positioned on the atrial edge of the stent 132. The fasteners 326 and stent 132 can be one piece, or they can be separate pieces joined after forming. The fastening stent 132 can be made of a shape memory material. For example, the shape memory material can be Nitinol. The leaflet braces 18, 20 are not directly connected to one another, but instead are attached to the fastening stent 132 supporting the heart valve 38 as seen in FIG. 6C.

**[0049]** Securement of just one leaflet can be sufficient. FIG. 6D shows fasteners 326 mounted directly onto a fastening stent 132. This stent also includes an anchor 327. As described in the disclosure of U.S. Patent 8,926,691, the anchor 327 can be used to capture one of the leaflets of the mitral valve as the stent expands. The leaflet braces disclosed herein can be used to attach the other leaflet. FIG. 6E shows the heart after completion of the procedure using leaflet brace 18, the fastening stent 132, and the anchor 327. The anchor can have a petal-like shape, similar to those shown in the '691 patent used to attach to the anterior leaflet, whereas here they attach to the posterior leaflet.

**[0050]** As shown in FIGS. 7A-7O, other methods can use a sub-commissural catheter 470 to assist in steering the guide wires 9, 11, 14, 16 behind their respective leaflets. The sub-commisural catheter 470 as seen in FIG. 7A includes four lumens. The first and second lumens house first and second commissural extensions 408 and 410. A third lumen houses a valve guide wire 474 terminating in a nose cone 472. A fourth lumen houses an internal deflection wire, the anchor point 476 of which can be seen at the distal face of the sub-commissural catheter 470. Pulling on the proximal end of the internal deflection wire causes the sub-commissural catheter to bend.

**[0051]** FIG. 7B depicts the system in a bent state. The bending allows it to curve in the left atrium and enter the left ventricle. The physician pulls back on the transseptal introducer sheath 2 to release the commissural extensions 408, 410. The extensions extend in opposite directions, such that an end of each can be positioned beneath the two mitral valve commissures.

**[0052]** The extensions 408, 410 can house right angle guide catheters 413, 415, as shown in FIG. 7C. The physician can rotate the guide catheters to face either the anterior or posterior leaflets 6, 7. The physician can then deploy ringed guide wires 9, 14 and corresponding snare wires 11, 16 through the right angle guide catheters as shown in FIG. 7D.

**[0053]** FIGS. 7E-7O depict a procedure using the sub-commissural catheter 470. The physician first punctures the interatrial septum 4 using the transseptal introducer sheath 2 such that the distal end of the introducer sheath is within the left atrium, as shown in FIG. 7E. The physician then advances a valve delivery guidewire 474 through the introducer sheath, through the mitral valve, and into the left ventricle, as seen in FIG. 7F. The sub-commissural catheter

470 advances over the guide wire 474 to a point below the valve, as seen in FIG. 7G. The physician then pulls back on the transseptal introducer sheath 2 to deploy the commissural extensions 408, 410 as seen in FIG. 7H. The catheter 470 is twisted to position one extension end beneath each of the commissures of the mitral valve. The physician can position a guide wire in the coronary sinus to assist in the orientation of the commissural extensions.

**[0054]** The physician then deploys the first ringed guide wire 9 and first snare wire 11 and connects them behind the leaflet. The snared distal end of the ringed guide wire 9 is pulled back into the sub-commissural catheter 470 and all the way out of the proximal end of the catheter 470. This forms the posterior leaflet wire loop 12 shown in FIG. 7I. The physician can then rotate the right angle guide catheters 13, 15 to face the opposite leaflet. The physician can then deploy a second set of ring and snare guide wires to form an anterior leaflet wire loop 17, as seen in FIG 7J. The sub-commissural catheter 470 and extensions 408, 410 are then removed, leaving behind the wire loops as shown in FIG. 7K.

**[0055]** The physician then slides the radiopaque leaflet braces 18, 20 down the guide wires and positions them along posterior and anterior leaflet wire loops 12, 17, as seen in FIG. 7L. He or she then moves the anterolateral and a posteromedial fastening catheters 22, 24 along the guide wires and positions them over the leaflet braces 18, 20, as seen in FIG. 7M. Various fasteners, such as (but not limited to) those described herein, can be used to join the two leaflet braces. For example, fasteners including screws, latches, clips, or knots can be used to secure the leaflet braces 18, 20.

**[0056]** The physician can then tear away the excess tubing from the leaflet braces and retract it back through the transseptal introducer sheath 2. The two braces now form one annular ring circling the valve under the anterior and posterior leaflets 6, 7. The physician can then insert valve delivery catheter 28 and deploy a transcatheter heart valve 38. FIG. 7N depicts an inflated balloon 30 positioned between the mitral valve leaflets to open a transcatheter heart valve 38. Alternatively, or in addition, the valve can be mechanically-expandable or self-expanding. The transcatheter heart valve 38 can be mounted on a stent 32.

**[0057]** After delivering the valve, the physician releases the fasteners 26 from the fastening catheters 22, 24 and retracts the fastening catheters and balloon delivery catheter 28 back up the transseptal introducer sheath 2. The transseptal introducer sheath 2 is then removed from the patient, completing the procedure as shown in FIG. 7O.

**[0058]** In the event that the procedure must be prematurely aborted, the leaflet braces 18, 20 can be retrieved back through the transseptal introducer sheath 2. If the leaflet braces are attached to each other by a metal fastener 26 at only one commissure, the entire system can still be retrieved via the transseptal introducer sheath 2.

**[0059]** If the braces are attached to each other at both commissures and/or secured to the myocardium with barb, they can be cut to be retrieved. FIG. 8 depicts a tool for cutting the leaflet braces 18, 20. The tool includes a J-curved steel hook 78 with a curved blade 80. Using

a tube cutting catheter and fluoroscopic imaging techniques, the physician can advance the hook 78 and position the curved blade 80 over the leaflet brace 18, 20. The physician then pulls the hook 78 back into the catheter with force to sever the brace and abort the procedure.

**[0060]** Although the disclosure has been shown and described with respect to a certain embodiment or embodiments, it is obvious that equivalent alterations and modifications will occur to others skilled in the art upon the reading and understanding of this specification and the annexed drawings. In particular regard to the various functions performed by the above described elements (components, assemblies, devices, compositions, etc.), the terms (including a reference to a "means") used to describe such elements are intended to correspond, unless otherwise indicated, to any element which performs the specified function of the described element (i.e., that is functionally equivalent), even though not structurally equivalent to the disclosed structure which performs the function in the herein illustrated exemplary embodiment or embodiments.

# REFERENCES CITED IN THE DESCRIPTION

Cited references

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

**Patent documents cited in the description**


- US20130090726A1 **[0006]**
- US8764820 **[0022]**
- US6730118B **[0022]**
- US8926691B **[0049]**

## Patentkrav

**1.** System til reparation af en naturlig hjerteklap med mindst første og andet native blad (6, 7), hvor systemet omfatter:

en hjerteklapprotese (38);

en første bladstiver (18) med en første endedel og en anden endedel, og en anden bladstiver (20) med en første endedel og en anden endedel, hvor enhver af den første og anden bladstiver (18, 20) danner en langstrakt fleksibel struktur og er konfigureret til at strække sig delvis omkring det første og anden native blad (6, 7); og

et første fastgørelseselement (26), der er konfigureret til at forbinde den første endedel af den første bladstiver (18) og den første endedel af den anden bladstiver (20), og et andet fastgørelseselement (26), der er konfigureret til at forbinde den anden endedel af første bladstiver (18) og den anden endedel af den anden bladstiver (20), så den første og anden bladstiver (18, 20) omkranser det første og andet native blad (6, 7),

hvor hjerteklapprotesen (38) er konfigureret til at udvide sig inden i det i det mindste første og andet blad (6, 7) af den native hjerteklap og den første og anden bladstiver (18, 20) for at klemme det i det mindste første og andet blad (6, 7) mellem hjerteklapprotesen (38) og det første og andet blad (18, 20).

**2.** System ifølge krav 1, hvor det første fastgørelseselement (26) omfatter en første og anden åbning og er konfigureret til at modtage den første endedel af den første bladstiver (18) og den første endedel af den anden bladstiver (20).

**3.** System ifølge krav 2, hvor det andet fastgørelseselement (26) omfatter en første og anden åbning og er konfigureret til at modtage den anden endedel af den første bladstiver (18) og den anden endedel af den anden bladstiver (20).

**4.** System ifølge krav 2, hvor det første fastgørelseselement (26) omfatter en flerhed af låseflige (54, 56), der er anbragt inden i den første og anden åbning og konfigureret til at gå i indgreb med de udvendige overflader af den første og anden bladstiver (18, 20).

**5.** System ifølge krav 3, hvor det andet fastgørelseselement (26) omfatter en flerhed af låseflige (54, 56), der er anbragt inden i den første og anden åbning og konfigureret til at gå i indgreb med de udvendige overflader af den første og anden bladstiver (18, 20).

**6.** System ifølge krav 1 til 5, hvor det første fastgørelseselement (126) omfatter en eller flere fastgørelsesmodhager (166), der er konfigureret til at blive skubbet ind i tilstødende væv i hjertet.

**7.** System ifølge krav 1 til 6, hvor hjerteklapprotesen (38) er selvekspanderende.

**8.** System ifølge krav 1 til 7, hvor enhver af det første og andet bladstiver (18, 20) indbefatter et indvendigt elastisk lag og et udvendigt funktionelt lag.

**9.** System ifølge krav 8, hvor det udvendige funktionelle lag er et af et indvækstlag eller et røntgenfast lag eller et krympelag.

**10.** System ifølge krav 1 til 9, yderligere omfattende en fastgørelsesring (268), der er koblet til det første og andet fastgørelseselement (226).

**11.** System ifølge krav 10, hvor fastgørelsesringen (268) er cirkulær, og det første fastgørelseselement (226) er koblet til en modsat side af fastgørelsesringen (268) fra det anden fastgørelseselement (226).

**12.** System ifølge krav 1 til 11, yderligere omfattende mindst én modhage (166), der er koblet til enhver af den første og anden bladstiver (18, 20).

# DRAWINGS

Drawing

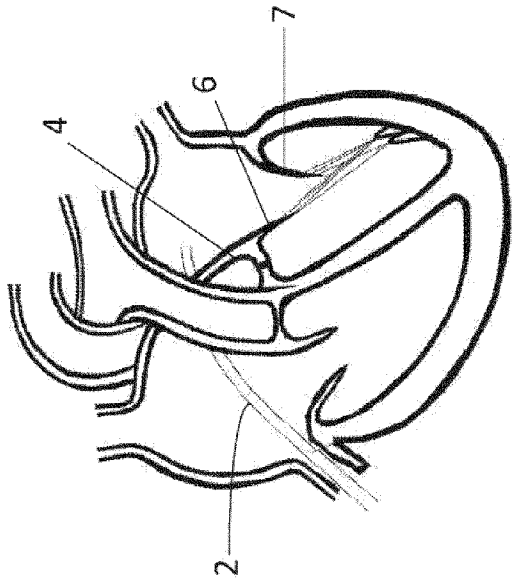



Figure 1A

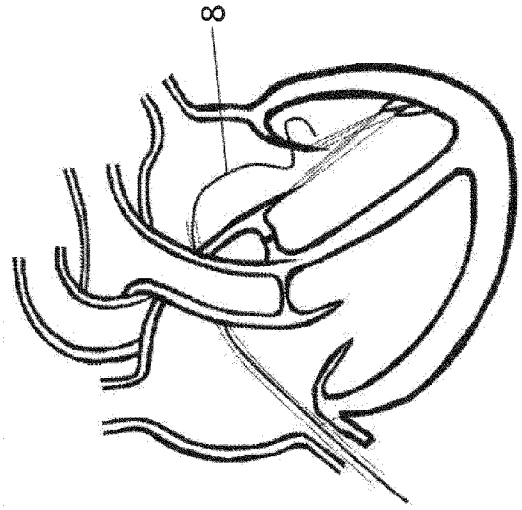



Figure 1B

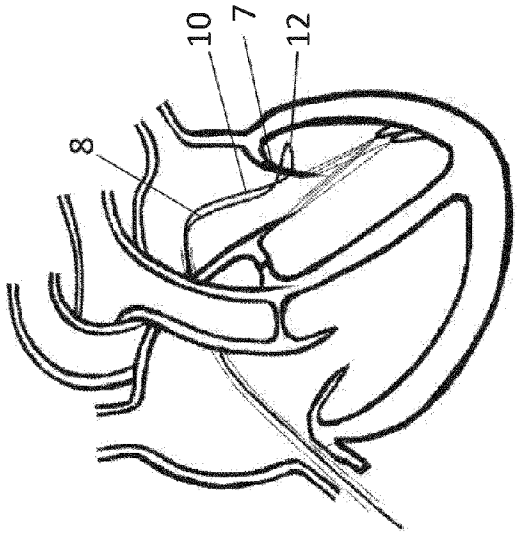



Figure 1C

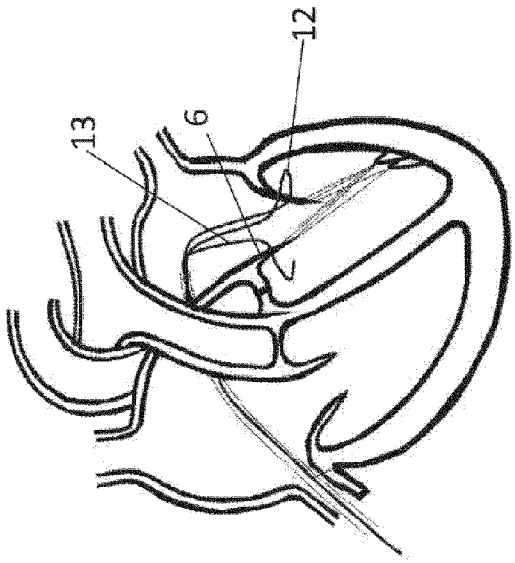



Figure 1D

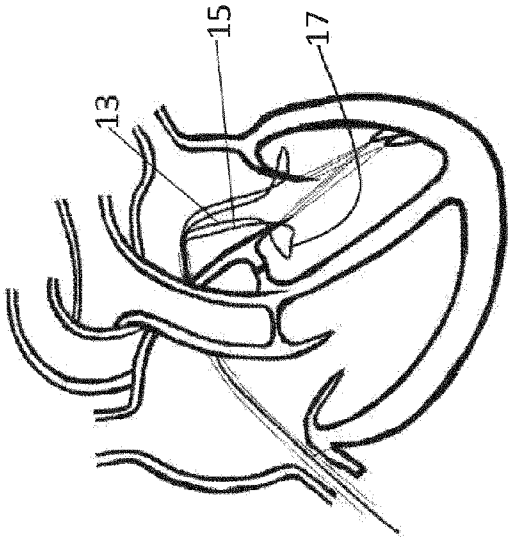



Figure 1E

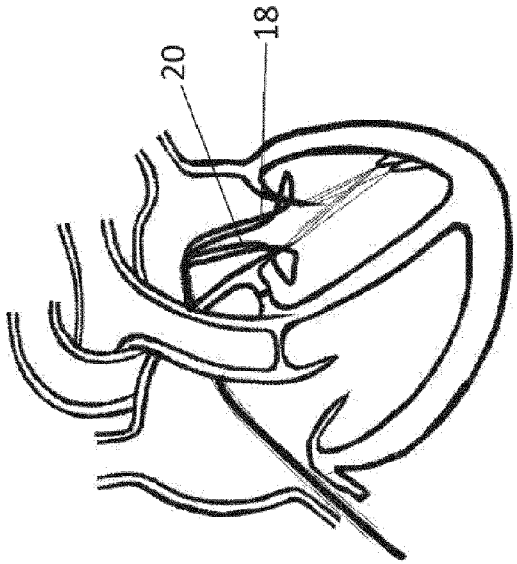



Figure 1F

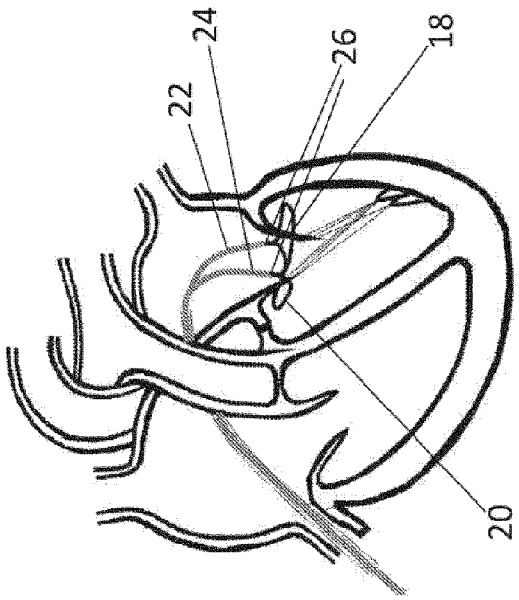



Figure 1G

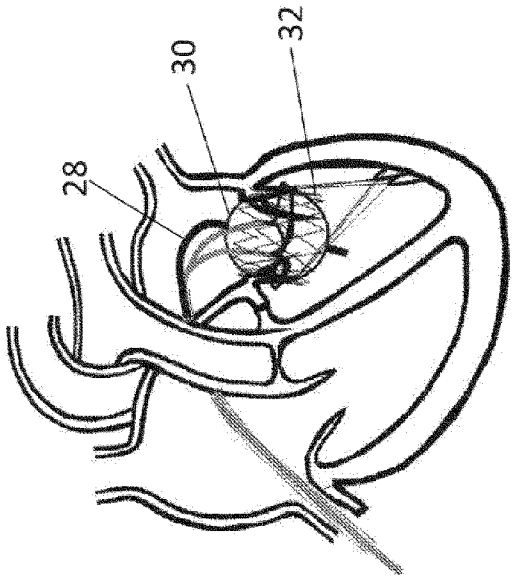



Figure 1H

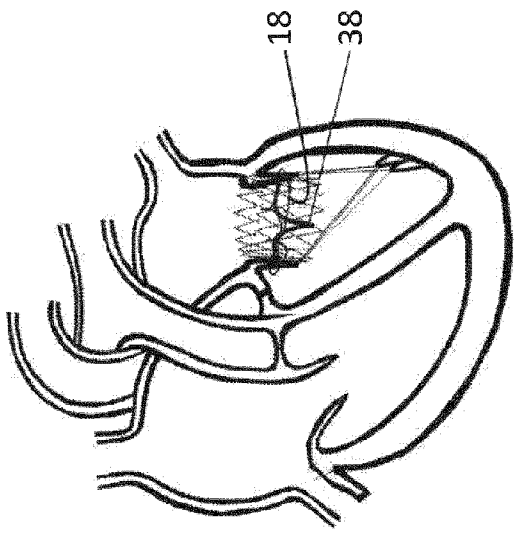



Figure 1I

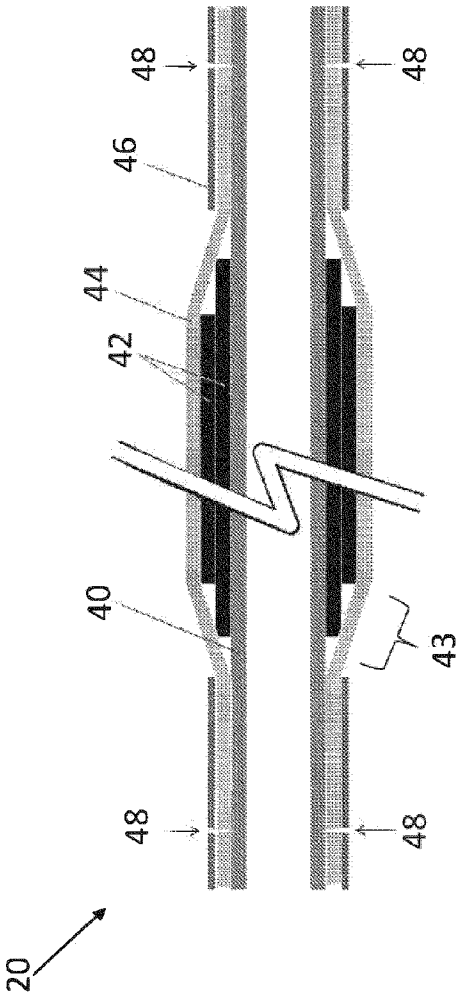



Figure 2

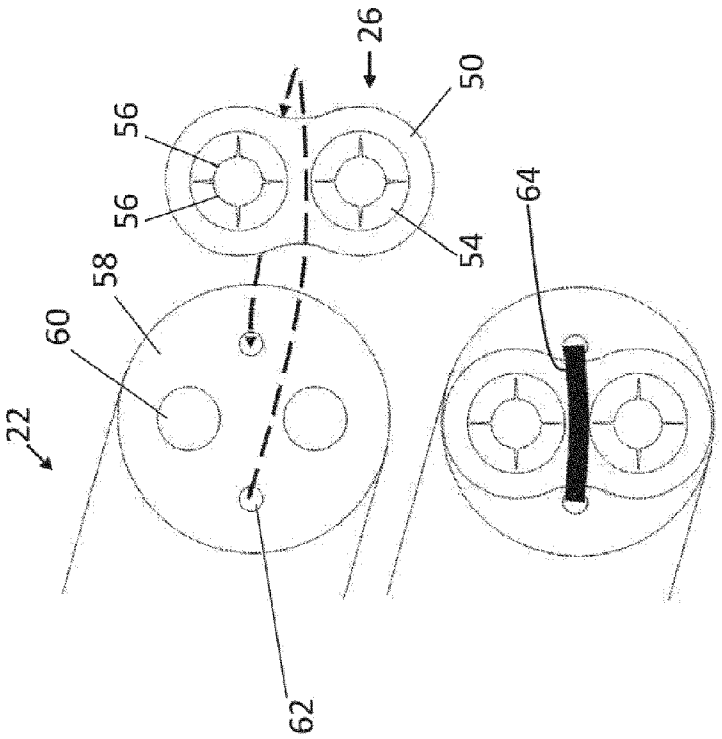



Figure 3A

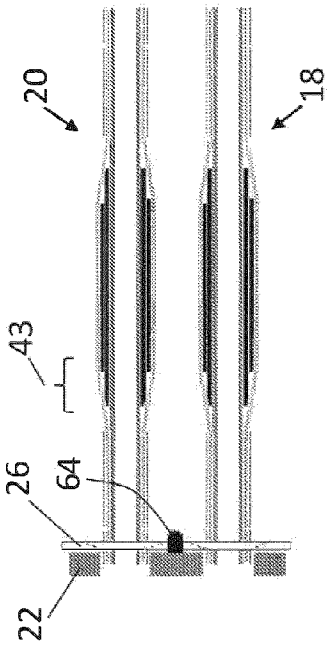



Figure 3B

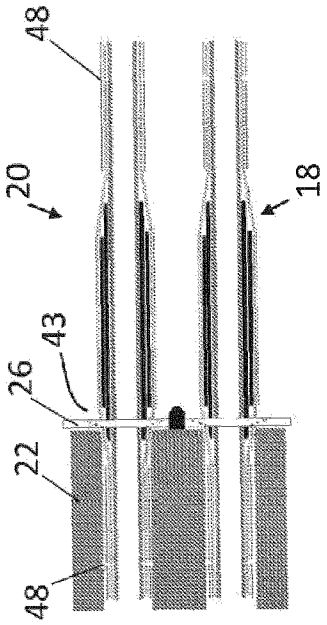



Figure 3C

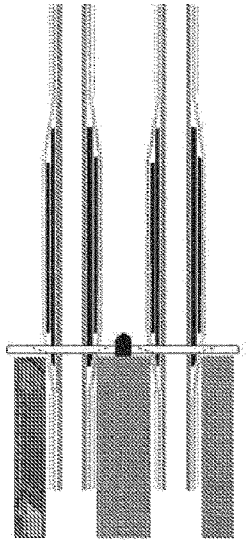


Figure 3D

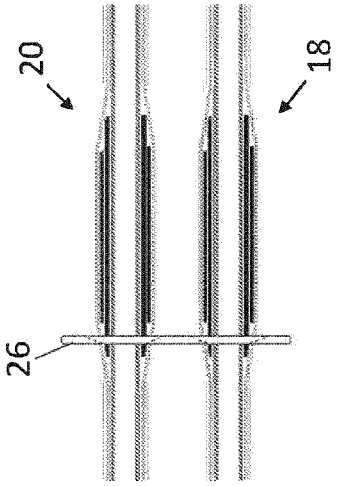



Figure 3E

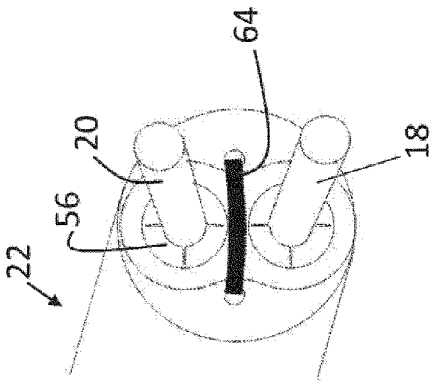



Figure 3F

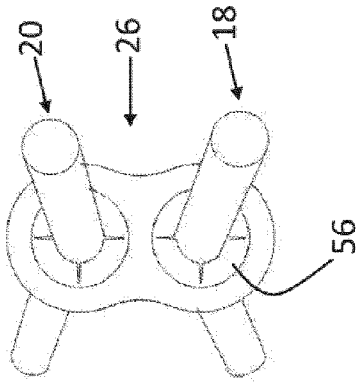



Figure 3G

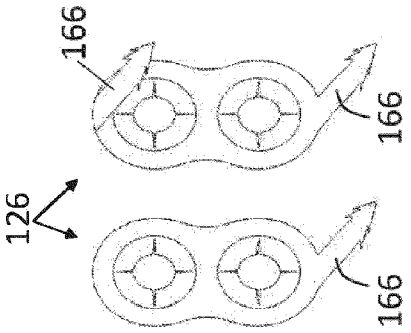



Figure 4A

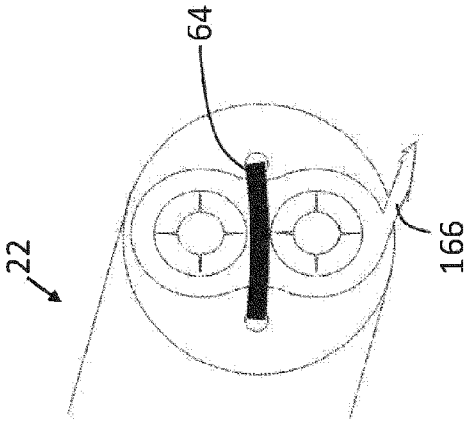



Figure 4B

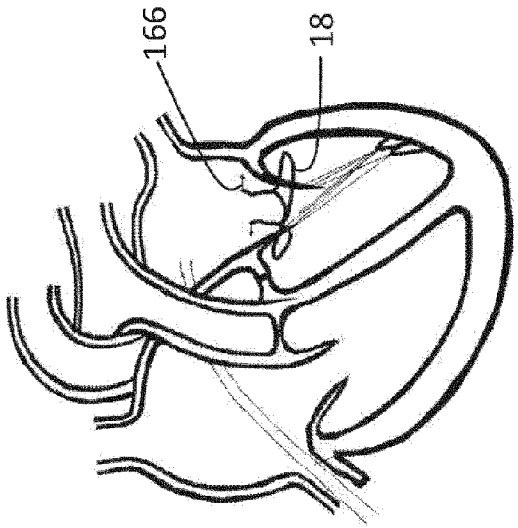



Figure 4C

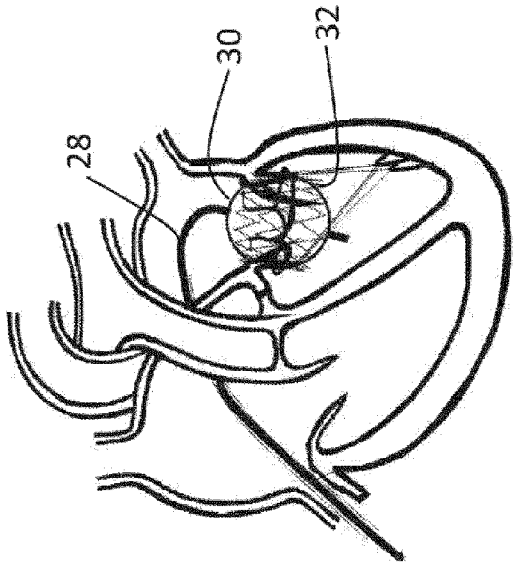



Figure 4D

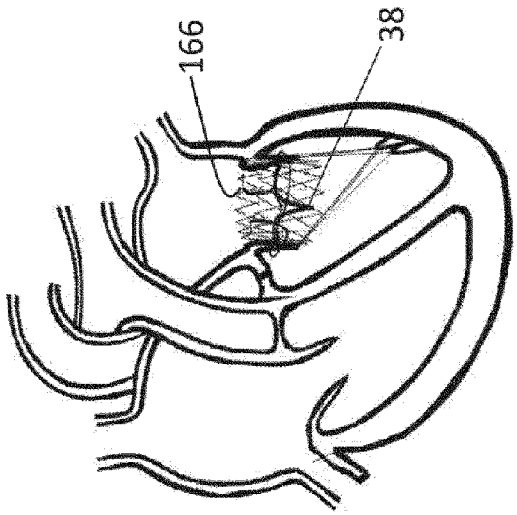



Figure 4E

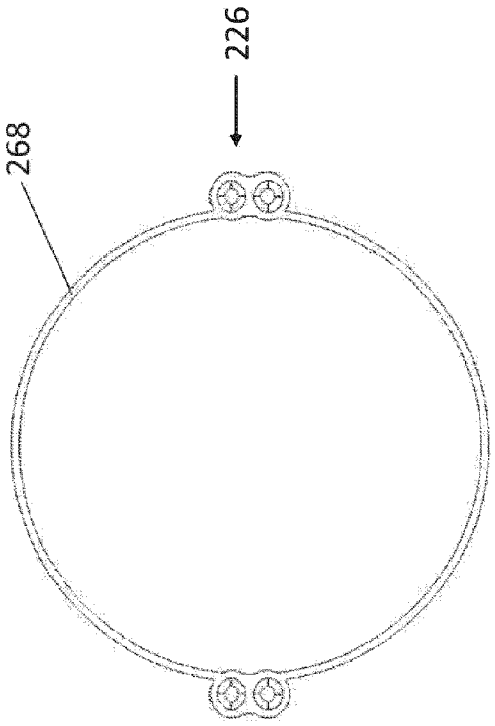



Figure 5A

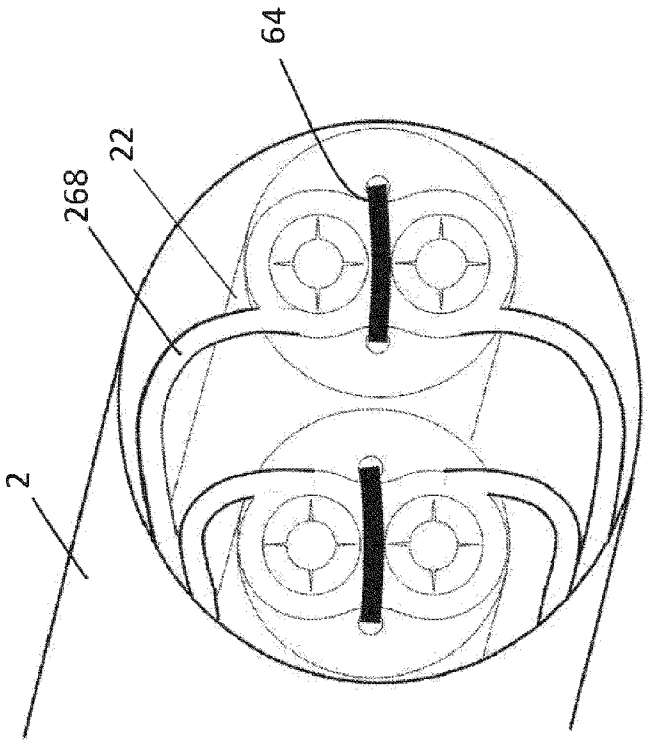



Figure 5B

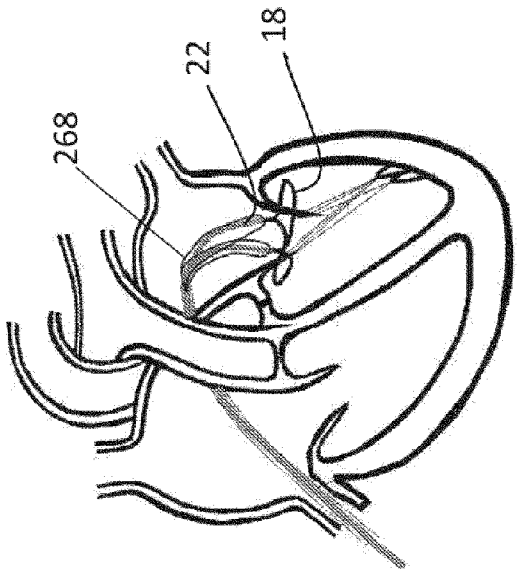



Figure 5C

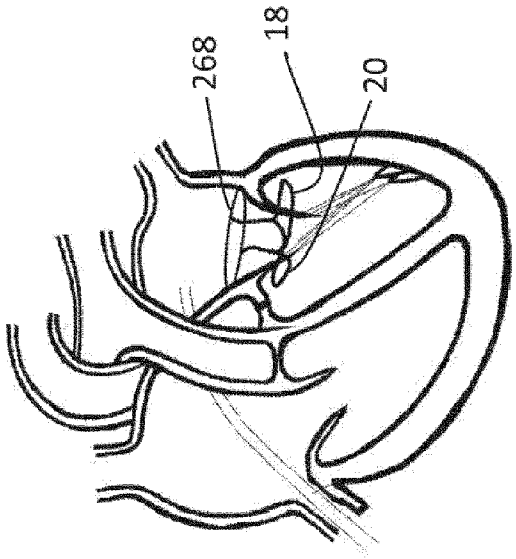



Figure 5D

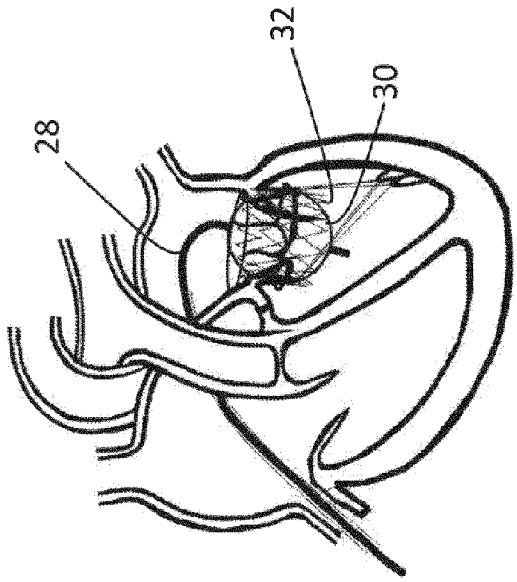



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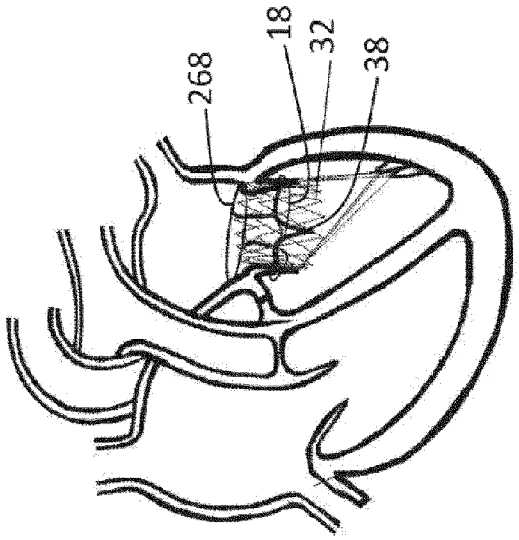



Figure 5F

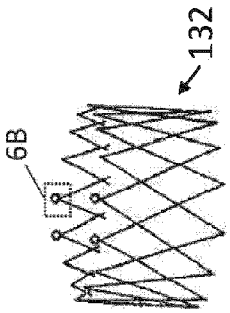



Figure 6A

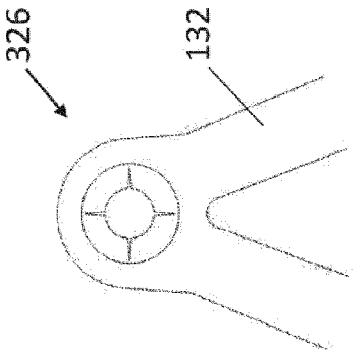



Figure 6B

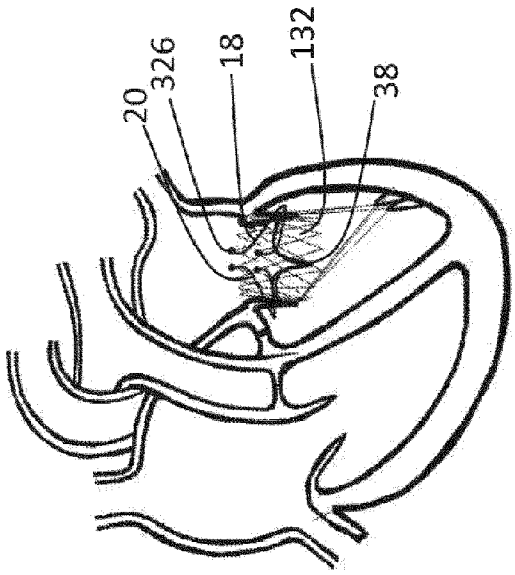



Figure 6C

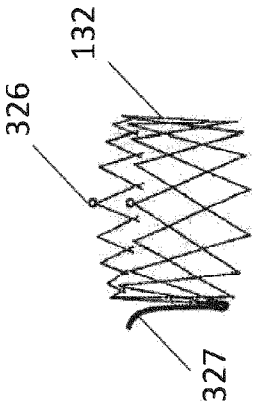



Figure 6D

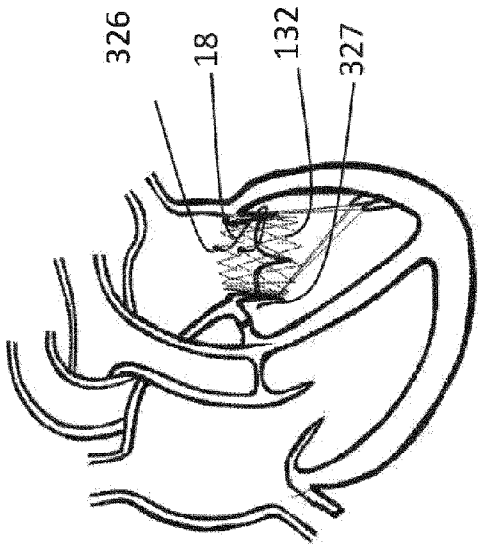



Figure 6E

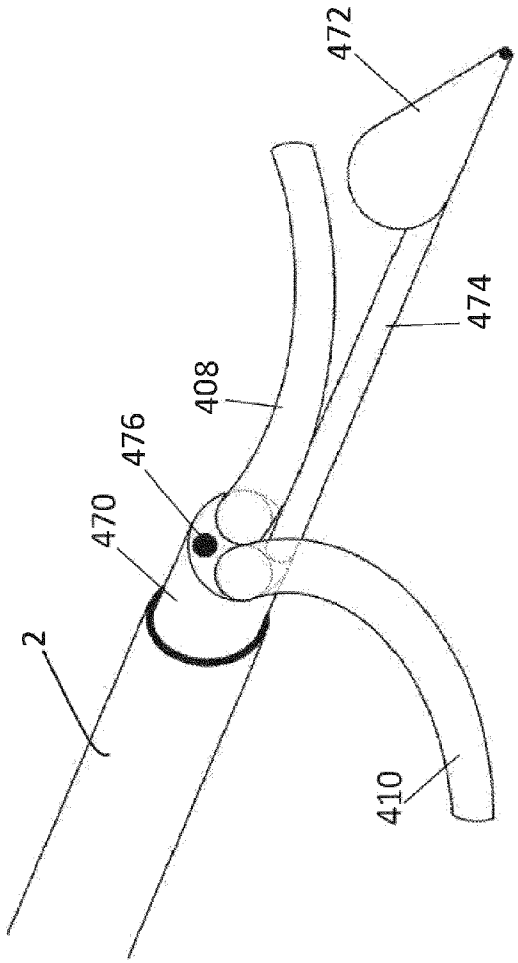



Figure 7A

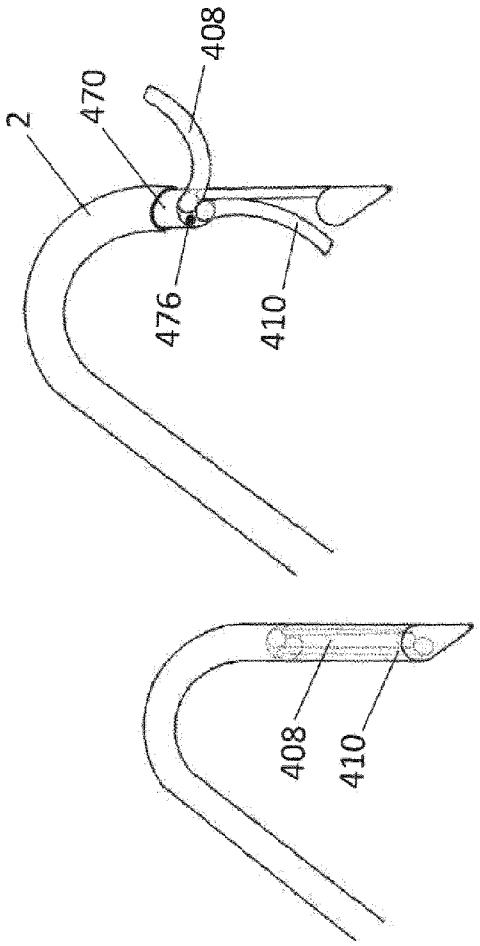



Figure 7B

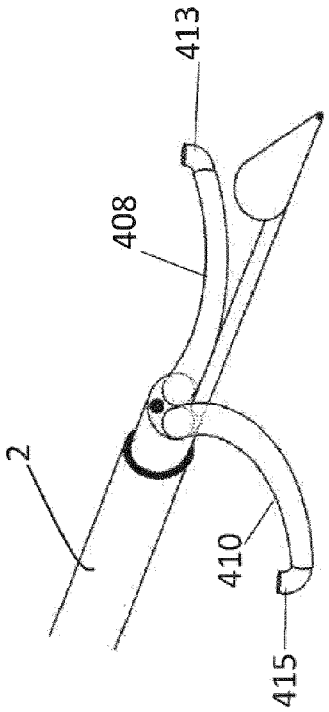



Figure 7C

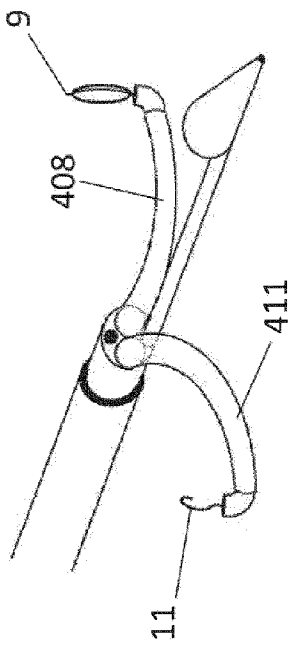



Figure 7D

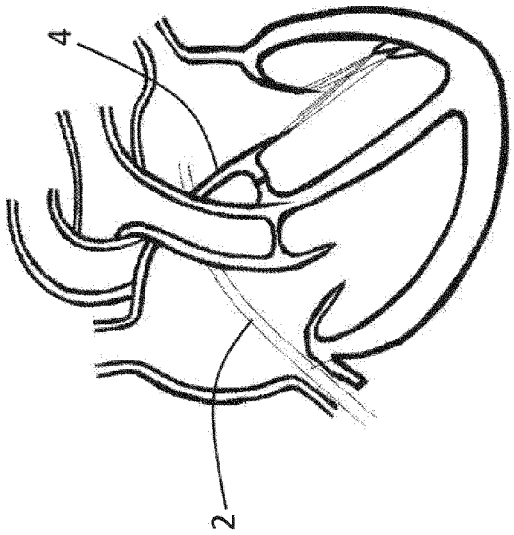



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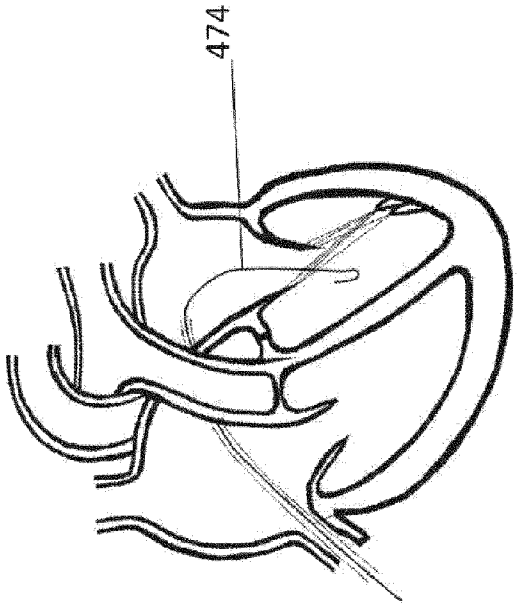



Figure 7F

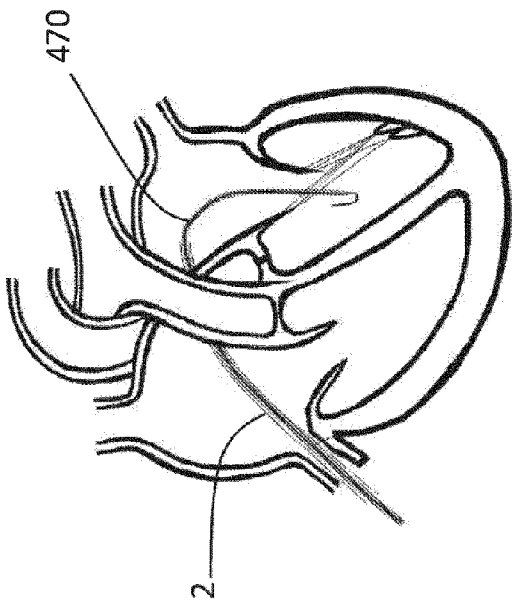



Figure 7G

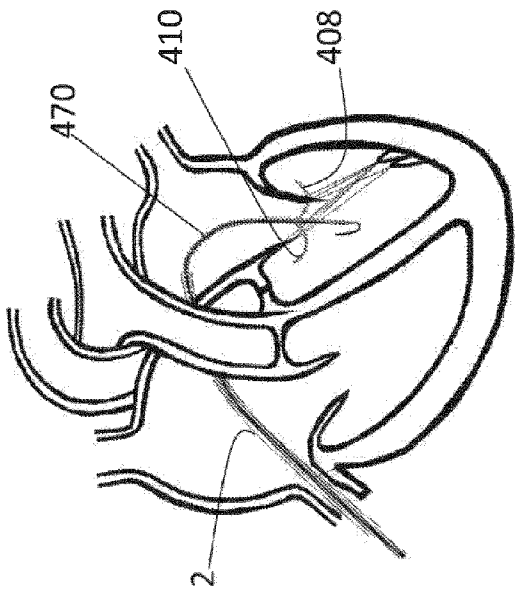



Figure 7H

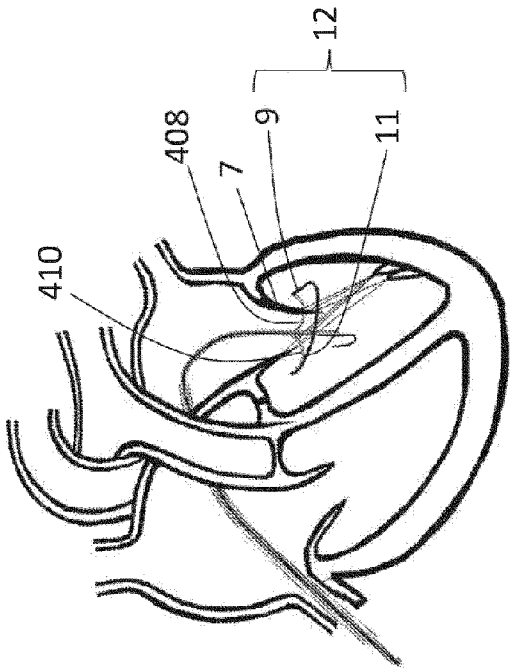



Figure 7I

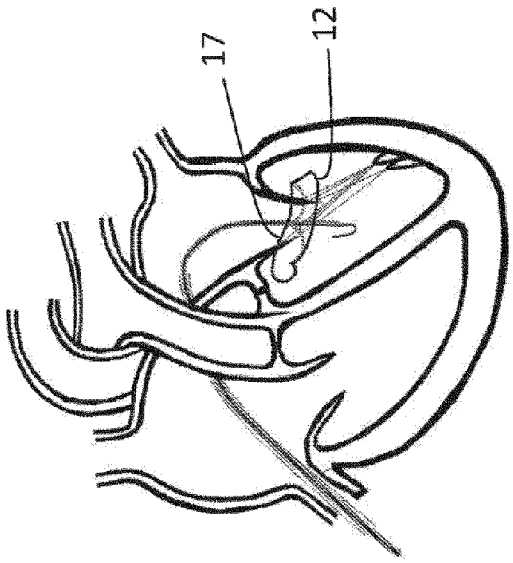



Figure 7J

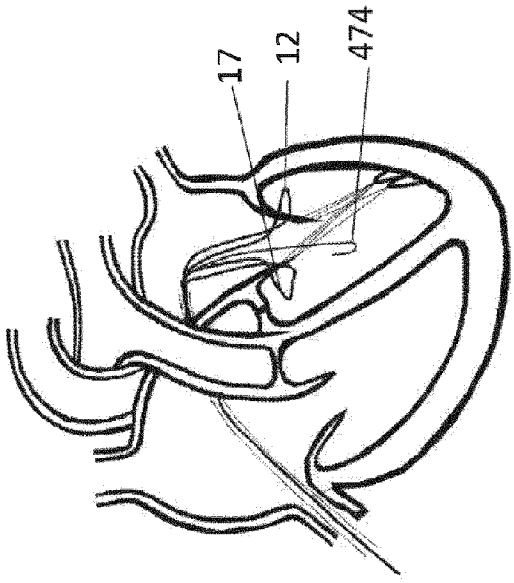



Figure 7K

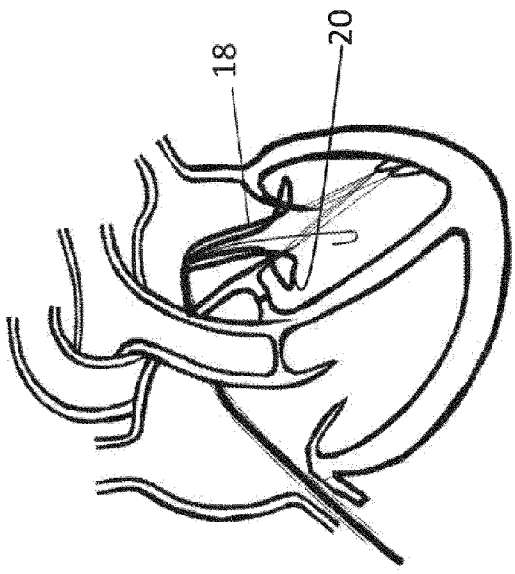



Figure 7L

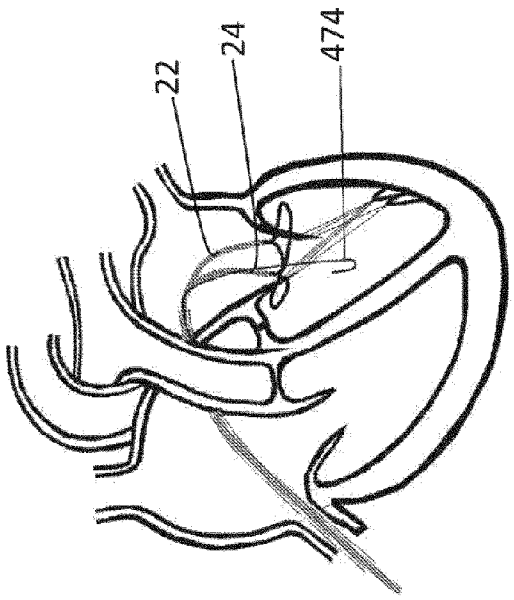



Figure 7M

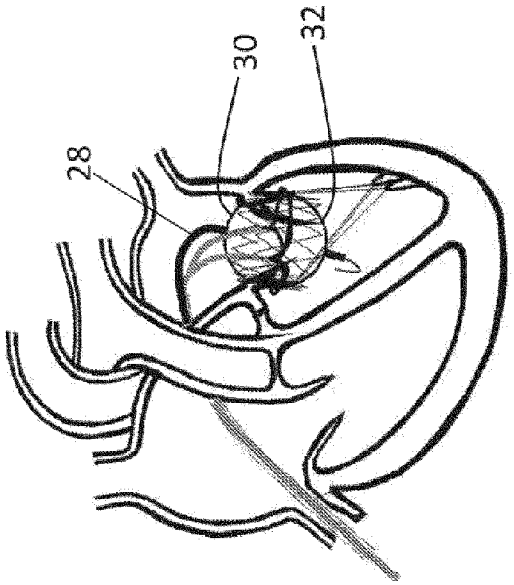



Figure 7N

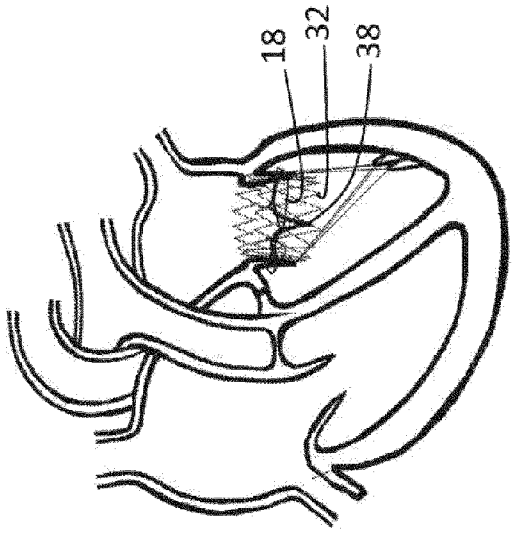



Figure 7O

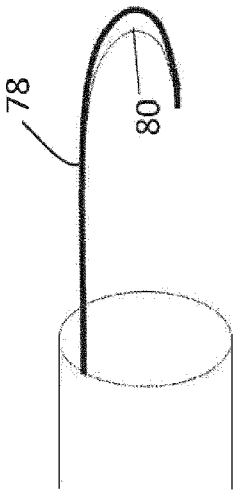



Figure 8