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(54) Title: CONTROLLED TISSUE ANCHOR SPACING

(57) Abstract: An anchor guide includes an elongate shaft, an atraumatic tip, a channel defined at least in part by the elongate shaft and configured to retain a suture associated with an anchor, and a spacing feature configured to provide a spacing distance between the channel and a device disposed in physical contact with the spacing feature.

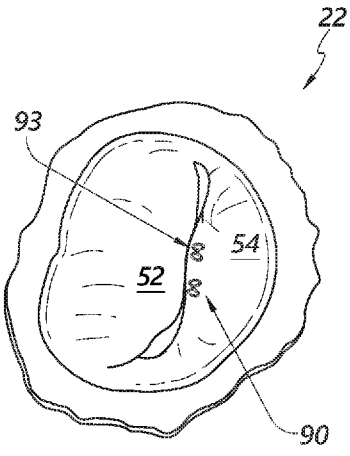

FIG. 12-3

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CONTROLLED TISSUE ANCHOR SPACING

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Patent Application No. 62/804,710, filed February 12, 2019, entitled "CONTROLLED TISSUE ANCHOR SPACING", the disclosure of which is hereby expressly incorporated by reference herein in its entirety for all purposes.

BACKGROUND

Technical Field

[0002] The disclosure herein relates to cardiac valve repairs, and more particularly to surgical suture placement in connection with minimally invasive valve repair operations.

Description of Related Art

[0003] Various surgical operations involve the placement of suture anchors or knots. Improper placement of such suture anchors or knots can result in adverse health complications.

SUMMARY

[0004] Described herein are one or more methods and/or devices to facilitate controlled spacing of adjacent tissue anchors deployed onto a heart valve leaflet, such as the mitral valve leaflet, during a minimally invasive heart valve repair procedure performed while the heart is beating.

[0005] In some implementations, the present disclosure relates to an anchor guide comprising an elongate shaft, an atraumatic tip, a channel defined at least in part by the elongate shaft and configured to retain a suture associated with an anchor, and a spacing feature configured to provide a spacing distance between the channel and a device disposed in physical contact with the spacing feature.

[0006] The device can comprise a lumen member of an anchor delivery system. In some embodiments, the spacing feature comprises one or more flanges. The elongate shaft can have a circular segment cross-section. The spacing feature can be associated with the atraumatic tip. In some embodiments, the atraumatic tip is C-shaped. The elongate shaft can comprise echogenic material. For example, the echogenic material can be grit-blasted stainless steel. In some embodiments, the anchor guide comprises a hemostasis valve.

[0007] In some implementations, the present disclosure relates to a tissue-anchoring system comprising an anchor delivery device configured to anchor a first anchor at a first location in a heart valve leaflet, the anchor delivery device comprising an elongate lumen member configured to allow the first anchor to be advanced therethrough, and an anchor guide comprising an elongate shaft including one or more engagement features configured to provide sliding engagement between the elongate shaft of the anchor guide and the elongate lumen member of the anchor delivery device, the elongate shaft defining a space configured to receive a suture associated with a second anchor anchored in the heart valve leaflet. A dimension of the anchor guide controls a distance between the first anchor and the second anchor when the anchor guide is disposed against the leaflet and aligned with the second anchor and the anchor delivery device is disposed against the leaflet against the one or more engagement features of the elongate shaft.

[0008] In some embodiments, the elongate shaft has a semi-circle shape and the one or more engagement features comprise a plurality of flange features associated with a diametrical barrier of the elongate shaft. The distance between the first anchor and the second anchor can be approximately 5 millimeters (mm). In some embodiments, the engagement features comprise a pair of opposing flanges extending from at least a portion of a length of the elongate shaft and the elongate lumen member of the anchor delivery device is shaped to be positioned between and in contact with the pair of opposing flanges. The elongate lumen member of the anchor delivery device can comprise a corresponding pair of opposing grooves configured to engage with the pair of opposing flanges. The elongate shaft can be extendable and retractable. In some embodiments, the space defined by the elongate shaft extends along an entire length of the elongate shaft. The anchor guide can comprise an echogenic material.

[0009] In some implementations, the present disclosure relates to a method of deploying a tissue anchor in a heart valve leaflet. The method comprises disposing one or more suture tails associated with a tissue anchor anchored in a heart valve leaflet of a heart within a channel of an anchor guide, the one or more suture tails passing through an access opening in a wall of a ventricle of the heart, inserting the anchor guide through the access opening at least partially into the ventricle, advancing the anchor guide to contact a first location on a proximal side of the heart valve leaflet, the first location being aligned with a first anchor associated with the one or more suture tails, inserting an anchor delivery device at least partially into the ventricle, advancing the anchor delivery device to contact a second location on the of the heart valve leaflet

while engaging the anchor delivery device with one or more engagement features of the anchor guide, and deploying a second tissue anchor at the second location using the anchor delivery device, wherein a distance between the first location and the second location is based on a dimension of the one or more engagement features.

[0010] Inserting the anchor delivery device can be done through the access opening. In some embodiments, advancing the anchor delivery device to contact the second location of the heart valve leaflet comprises maintaining a sliding engagement between the anchor delivery device and the one or more engagement features of the anchor guide. Advancing the anchor guide to contact the first location can comprise contacting the heart valve leaflet with a floating distal tip of the anchor guide and maintaining contact with the heart valve leaflet while extending the anchor delivery device. In some embodiments, the ventricle is a left ventricle and the heart valve leaflet is a mitral valve leaflet.

[0011] For purposes of summarizing the disclosure, certain aspects, advantages and novel features have been described herein. It is to be understood that not necessarily all such advantages may be achieved in accordance with any particular embodiment. Thus, the disclosed 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 advantages as may be taught or suggested herein.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] Various embodiments are depicted in the accompanying drawings for illustrative purposes, and should in no way be interpreted as limiting the scope of the disclosure. 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. However, it should be understood that the use of similar reference numbers in connection with multiple drawings does not necessarily imply similarity between respective embodiments associated therewith. Furthermore, it should be understood that the features of the respective drawings are not necessarily drawn to scale, and the illustrated sizes thereof are presented for the purpose of illustration of inventive aspects thereof. Generally, certain of the illustrated features may be relatively smaller than as illustrated in some embodiments or configurations.

[0013] Figure 1 is a cut-away anterior view of a heart.

[0014] Figure 2 is a top perspective view of a healthy mitral valve with the mitral leaflets closed.

[0015] Figure 3 is a top perspective view of a dysfunctional mitral valve with a visible gap between the mitral leaflets.

[0016] Figure 4 shows an example of an anchor delivery device inserted into a left ventricle of a heart for repairing a mitral valve in accordance with one or more embodiments.

[0017] Figure 5 is a top perspective view of a mitral valve comprising a plurality of suture knots deployed thereon in accordance with one or more embodiments.

[0018] Figure 6 is a perspective view of an example of an anchor guide in accordance with one or m–ore embodiments.

[0019] Figure 7 shows an example of an anchor guide positioned adjacent to an anchor delivery device in accordance with one or more embodiments.

[0020] Figures 8-1 through 8-3 illustrate a suture placement system and associated cardiac anatomy at one or more stages of an anchor deployment process in accordance with one or more embodiments.

[0021] Figures 9-1 through 9-3 illustrate a suture placement system and associated cardiac anatomy at one or more stages of an anchor deployment process in accordance with one or more embodiments.

[0022] Figures 10-1 through 10-3 illustrate a suture placement system and associated cardiac anatomy at one or more stages of an anchor deployment process in accordance with one or more embodiments.

[0023] Figures 11-1 through 11-3 illustrate a suture placement system and associated cardiac anatomy at one or more stages of an anchor deployment process in accordance with one or more embodiments.

[0024] Figures 12-1 through 12-3 illustrate a suture placement system and associated cardiac anatomy at one or more stages of an anchor deployment process in accordance with one or more embodiments.

[0025] Figures 13-1 through 13-3 illustrate a suture placement system and associated cardiac anatomy at one or more stages of an anchor deployment process in accordance with one or more embodiments.

[0026] Figure 14 is a perspective view of a surgical introducer device in accordance with one or more embodiments.

[0027] Figure 15 is a perspective view of a surgical introducer device in accordance with one or more embodiments.

[0028] Figure 16 is a perspective view of a surgical introducer device in accordance with one or more embodiments.

[0029] Figure 17 is a perspective view of a surgical introducer device in accordance with one or more embodiments.

[0030] Figure 18 is a close-up view of a suture spacing system in accordance with one or more embodiments.

[0031] Figure 19 is a top view of a suture spacing system in accordance with one or more embodiments.

[0032] Figure 20 is a side view of a suture spacing system and associated anatomy in accordance with one or more embodiments.

DETAILED DESCRIPTION

[0033] The headings provided herein are for convenience only and do not necessarily affect the scope or meaning of the claims.

[0034] 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.

Overview

[0035] Embodiments of the present disclosure provide solutions relating to the treatment of certain structural heart conditions with valve leaflet anchors having controlled spacing. Various disease processes can impair the proper functioning of one or more of the valves of the heart. These disease processes include degenerative processes (*e.g.*, Barlow's Disease, fibroelastic deficiency), inflammatory processes (*e.g.*, Rheumatic Heart Disease), and infectious processes (*e.g.*, endocarditis). Additionally, damage to the ventricle from prior heart attacks (*e.g.*, myocardial infarction secondary to coronary artery disease) or other heart diseases (*e.g.*, cardiomyopathy) can distort the geometry of the heart causing valves in the heart to dysfunction. Many patients undergoing valve surgery, such as mitral valve surgery, suffer from a degenerative disease that causes a malfunction in a leaflet of the valve, which results in prolapse and regurgitation.

[0036] Valve regurgitation occurs when the leaflets of the valve do not close completely, thereby allowing blood to leak back into the prior chamber when the heart contracts. There are generally three mechanisms by which a valve becomes regurgitant or incompetent, including Carpentier's type I, type II and type III malfunctions. A Carpentier type I malfunction involves the dilation of the annulus such that the area of the valve orifice increases. The otherwise normally functioning leaflets do not have enough surface area to cover the enlarged orifice and fail to form a tight seal (*e.g.*, do not coapt properly) causing regurgitation. Included in a type I mechanism malfunction are perforations of the valve leaflets, as in endocarditis. A Carpentier's type II malfunction involves prolapse of a segment of one or both leaflets above the plane of coaptation. This is the most commonly treated cause of mitral regurgitation, and is often caused by the stretching or rupturing of chordae tendineae normally connected to the leaflet. A Carpentier's type III malfunction involves restriction of the motion of one or more leaflets such that the leaflets are abnormally constrained below the level of the plane of the annulus. Leaflet restriction can be caused by rheumatic heart disease (IIIa) or dilation of the ventricle (IIIb).

[0037] Mitral valve disease is the most common valvular heart disorder, with nearly 4 million Americans estimated to have moderate to severe mitral valve regurgitation ("MR"), with similar numbers of individuals impacted outside of the United States. MR

can result in a volume overload on the left ventricle which in turn progresses to ventricular dilation, decreased ejection performance, pulmonary hypertension, symptomatic congestive heart failure, atrial fibrillation, right ventricular dysfunction, and/or death. Successful surgical mitral valve repair can at least partially restore mitral valve competence, abolish the volume overload on the left ventricle, improves symptom status, and/or prevents adverse left ventricular remodeling. While generally safe and effective, conventional open-heart operations are invasive, result in significant disability, and require extended post-procedure recovery. Patients routinely spend five to seven days in the hospital and often are not able to return to normal daily activities for a month or more.

[0038] In many instances of mitral valve regurgitation, repair may be preferable to valve replacement. There are a variety of advantages to performing heart valve repair (*e.g.*, mitral valve repair) using less invasive procedures while the heart is still beating, as described in detail herein. Mitral valve repair procedures may rely upon use of visualization technology, such as sonic guidance, which may have limitations that can reduce the effectiveness of such repairs. Accordingly, there is a continuing need for new procedures and devices for performing less invasive mitral valve repairs which do not require cardiac arrest and are less technologically challenging.

[0039] In some implementations, the present disclosure relates to an anchor guide for controlling placement of one or more suture knots or other tissue anchors. In some embodiments, the anchor guide comprises a relatively thin shaft having a central lumen, atraumatic tip, and proximal hemostasis valve(s). The anchor guide may include mechanical features for allowing the anchor guide to slide over an existing pair of suture portions (*e.g.*, polytetrafluoroethylene (PTFE, or ePTFE)) to facilitate consistent/controlled spacing with the next adjacent anchor to be deployed on the valve leaflet, and lessens the dependence on echo imaging for proper targeting. The term "suture" is used herein according to its plain and ordinary meaning and may refer to any elongate cord strip, strand, line, tie, string, ribbon, strap, or portion thereof, or other type of material used in medical procedures. One having ordinary skill in the art will understand that a wire or other similar material may be used in place of a suture. Furthermore, in some contexts herein, the terms "cord" and "suture" may be used substantially interchangeably. In addition, use of the singular form of any of the suture-related terms listed above, including the terms "suture" and "cord," may be used to refer to a single suture/cord, or to a portion thereof. For example, where a suture knot or

anchor is deployed on a distal side of a tissue portion, and where two suture portions extend from the knot/anchor on a proximal side of the tissue, either of the suture portions may be referred to as a "suture" or a "cord," regardless of whether both portions are part of a unitary suture or cord. Anchor guides in accordance with aspects of the present disclosure may be utilized in methods for controlling spacing of surgical sutures deployed in a ventricle and/or atrium of a heart. Such sutures and/or associated anchors may be introduced to the target implantation site using a minimally invasive incision and may be implanted/deployed while the patient's heart is beating.

[0040] Figure 1 is a cutaway view of a heart 10. The heart 10 has four chambers, the left atrium 12, left ventricle 14, right atrium 16, or right ventricle 18. The left atrioventricular valve, the mitral valve 22, controls the passage of oxygenated blood from the left atrium 12 to the left ventricle 14. Access into a chamber 12, 14, 16, 18 in the heart 10 may be made at any suitable site of entry. Certain embodiments disclosed herein related to process for accessing a chamber of the heart using a trans-apical access at or near the apex region (AR) of the heart slightly above the apex 20 at the level of the papillary muscles 19. For example, access into the left ventricle 14 to perform a mitral valve repair may be gained through a process performed in the apical region, close to, or slightly skewed toward the left of, the median axis of the heart 10. Generally, an apex region (AR) of the heart is a bottom region of the heart that is within the left or right ventricular region and is below the mitral valve 22 and tricuspid valve 24 and toward the tip or apex 20 of the heart 10. More specifically, an apex region (AR) of the heart may be considered to be within a few centimeters to the right or to the left of the ventricular septum of the heart 10 at or near the level of the papillary muscles 19. Accordingly, the ventricle can be accessed directly via the apex 20, or via an off-apex location that is in the apical or apex region (AR), but slightly removed from the apex 20, such as via a lateral ventricular wall, a region between the apex 20 and the base of a papillary muscle 19, or even directly at the base of a papillary muscle 19 or above. The incision made to access the appropriate ventricle of the heart may be no longer than about, for example, about 0.5 cm. Alternatively, access can be obtained using the Seldinger technique.

[0041] Figure 2 is a top perspective view of a mitral valve 22 with the mitral leaflets 52, 54 closed. The mitral valve 22 generally includes two leaflets, the anterior leaflet 52 and the posterior leaflet 54, and a diaphanous incomplete ring around the valve, called the annulus 53. Referring back to Figure 1, the mitral valve 22 generally is attached to

two papillary muscles 19, the anteromedial and the posterolateral papillary muscles, which attach the leaflets 52, 54 to the walls of the left ventricle 14 via the chordae tendineae 17. In Figure 2, the leaflets 52, 54 achieve proper coaptation when closed, thereby substantially preventing regurgitation back into the atrium when the valve 22 is closed.

[0042] Figure 3 is a top perspective view of a mitral valve 22 in a defective state, wherein a gap 55 between the mitral leaflets 52, 54 is present when the valve 22 is in a closed state. When the leaflets of a valve do not coapt properly, as in the image of Figure 3, such defect may be the result of one or more of the leaflets being in a prolapsed state. Leaflet prolapse occurs when a prolapsed segment of a leaflet 52, 54 of a valve (*e.g.*, the mitral valve 22) is displaced above the plane of the valve annulus into the associated atrium (*e.g.*, the left atrium 12), preventing the leaflets from properly sealing together to form the natural plane or line of coaptation between the valve leaflets during the relevant cardiac phase (*e.g.*, systole with respect to the mitral valve). With respect to the particular mitral valve 22 of Figure 3, because one or more of the leaflets 52, 54 malfunctions, the mitral valve 22 does not close properly, and, therefore, the leaflets 52, 54 fail to coapt. This failure to coapt causes the gap 55 between the leaflets 52, 54 that allows blood to flow back into the left atrium, during systole, while it is being ejected by the left ventricle into the aorta. As set forth above, there are several different ways a leaflet may malfunction, which can thereby lead to regurgitation.

[0043] Mitral valve regurgitation generally increases the workload on the heart and may lead to various serious health conditions if left untreated, such as decreased ventricular function, pulmonary hypertension, congestive heart failure, permanent heart damage, cardiac arrest, and ultimately death. Since the left heart is primarily responsible for circulating the flow of blood throughout the body, malfunction of the mitral valve 22 is particularly problematic and can be life threatening.

[0044] Methods for repairing a target organ tissue, such as repair of mitral valve leaflets to address mitral valve regurgitation, include inserting a delivery device, such as a delivery device described in PCT Application No. PCT/US2012/043761, (published as WO 2013/003228, and referred to herein as "the '761 PCT Application") and/or in PCT Application No. PCT/US2016/055170 (published as WO 2017/059426 and referred to herein as "the '170 PCT Application"), the entire disclosure of each of which are incorporated herein by reference, into a body and extending a distal end of the delivery device to a proximal side of the tissue. Advancement of the delivery device may be

performed in conjunction with sonography or direct visualization (*e.g.*, direct transblood visualization), and/or any other suitable remote visualization technique. With respect to cardiac procedures, for example, the delivery device may be advanced in conjunction with transesophageal (TEE) guidance and/or intracardiac echocardiography (ICE) guidance to facilitate and to direct the movement and proper positioning of the device for contacting the appropriate target cardiac region and/or target cardiac tissue (*e.g.*, a valve leaflet, a valve annulus, or any other suitable cardiac tissue). Typical procedures for use of echo guidance are set forth in Suematsu, Y., *J. Thorac. Cardiovasc. Surg.* **2005**; *130*:1348–56 ("Suematsu"), the entire disclosure of which is incorporated herein by reference.

[0045] The '761 PCT Application and the '170 PCT Application describe in detail methods and devices for performing non-invasive procedures to repair a cardiac valve, such as a mitral valve. Such procedures include procedures to repair regurgitation that occurs when the leaflets of the mitral valve do not coapt properly at peak contraction pressures, resulting in an undesired backflow of blood from the ventricle into the atrium. As described in the '761 PCT Application and the '170 PCT Application, after the malfunctioning cardiac valve has been assessed and the source of the malfunction verified, a corrective procedure can be performed. Various procedures can be performed in accordance with the methods described therein to effectuate a cardiac valve repair, which may depend on the specific abnormality and the tissues involved.

[0046] After prepping and placing the subject under anesthesia, a transesophageal echocardiogram (TEE) (two-dimensional, 2D, and/or three-dimensional, 3D), a transthoracic echocardiogram (TTE), intracardiac echo (ICE), and/or cardio-optic direct visualization (*e.g.*, via infrared vision from the tip of a 7.5 F catheter) may be performed to assess the heart and its valves.

[0047] After a minimally invasive approach is determined to be advisable, one or more incisions are made proximate to the thoracic cavity to provide a surgical field of access. The total number and length of the incisions to be made depend on the number and types of the instruments to be used as well as the procedure(s) to be performed. The incision(s) should be made in such a manner to be minimally invasive. As referred to herein, the term minimally invasive means in a manner by which an interior organ or tissue may be accessed with as little as possible damage being done to the anatomical structure through which entry is sought. Typically, a minimally invasive procedure is one that involves accessing a body cavity by a small incision of, for example, about

5 centimeters (cm) or less made in the skin of the body. The incision may be vertical, horizontal, or slightly curved. If the incision is placed along one or more ribs, it should follow the outline of the rib. The opening should extend deep enough to allow access to the thoracic cavity between the ribs or under the sternum and is preferably set close to the rib cage and/or diaphragm, dependent on the entry point chosen.

[0048] In one example method, the heart may be accessed through one or more openings made by one or more small incisions in a portion of the body proximal to the thoracic cavity, such as between one or more of the ribs of the rib cage of a patient, proximate to the xyphoid appendage, or via the abdomen and diaphragm. Access to the thoracic cavity may be sought so as to allow the insertion and use of one or more thorascopic instruments, while access to the abdomen may be sought to allow the insertion and use of one or more laparoscopic instruments. Insertion of one or more visualizing instruments may then be followed by transdiaphragmatic access to the heart. Additionally, access to the heart may be gained by direct puncture (*e.g.*, via an appropriately sized needle, for instance an 18-gauge needle) of the heart from the xyphoid region. Accordingly, the one or more incisions should be made in such a manner as to provide an appropriate surgical field and access site to the heart in the least invasive manner possible. Access may also be achieved using percutaneous methods further reducing the invasiveness of the procedure. *See, e.g.,* "Full-Spectrum Cardiac Surgery Through a Minimal Incision Mini-Sternotomy (Lower Half) Technique," Doty *et al., Annals of Thoracic Surgery* **1998**; *65(2)*: 573–7 and "Transxiphoid Approach Without Median Sternotomy for the Repair of Atrial Septal Defects," Barbero-Marcial *et al., Annals of Thoracic Surgery* **1998**; *65(3)*: 771–4, the entire disclosures of each of which are incorporated herein by reference.

[0049] Once a suitable entry point has been established, the surgeon can use one or more sutures to make a series of stiches in one or more concentric circles in the myocardium at the desired location to create a "purse string" closure. The Seldinger technique can be used to access the left ventricle in the area surrounded by the purse string suture by puncturing the myocardium with a small sharp hollow needle (a "trocar") with a guidewire in the lumen of the trocar. In some contexts, trocar-type access devices are referred to as "introducers;" such devices may be used to provide a portal for placement or introduction of one or more instruments into a ventricle of the heart through a lumen thereof. In some embodiments, a trocar and a separate introducer device are employed to provide access to the heart ventricle.

[0050] Once the ventricle has been accessed, the guidewire can be advanced, and the trocar removed. A valved-introducer with a dilator device extending through the lumen of the valved-introducer can be advanced over the guidewire to gain access to the left ventricle. The guidewire and dilator can be removed and the valved-introducer can serve to maintain hemostasis, with or without a suitable delivery device inserted therein, throughout the procedure. Alternatively, the surgeon can make a small incision in the myocardium and insert the valved-introducer into the heart via the incision. Once the valved-introducer is properly placed the purse string suture is tightened to reduce bleeding around the shaft of the valved-introducer.

[0051] A suitable device, such as a delivery device described in the '761 PCT Application and/or the '170 PCT Application, may be advanced into the body and through the valved-introducer in a manner so as to access the left ventricle. The advancement of the device may be performed in conjunction with sonography or direct visualization (*e.g.*, direct transblood visualization). For example, the delivery device may be advanced in conjunction with TEE guidance and/or ICE to facilitate and direct the movement and proper positioning of the device for contacting the appropriate apical region of the heart. Some procedures for use of echo guidance are set forth in Suematsu.

[0052] Certain delivery devices described in the in the '761 PCT Application and/or the '170 PCT Application can be used to deliver a plurality of sutures and/or associated anchors (*e.g.*, suture knots) onto a mitral valve leaflet using minimally invasive techniques. A suture can be delivered into the left ventricle and a suture knot can be formed or configured on a distal/atrial side of the mitral valve leaflet using the suture, thereby coupling the suture to the mitral valve leaflet. One or more proximal portions of the suture can be secured to the outer ventricular wall of the heart. The length/tension of the suture or pair of sutures (*e.g.*, suture portions) within the ventricle can be adjusted prior to securing the proximal portion to the outer ventricular wall of the heart.

[0053] Reliable spacing between adjacent suture knots/anchors deployed onto a heart valve leaflet, such as a mitral valve leaflet, can promote desired repair of heart valve regurgitation. For example, in repair procedures to address mitral valve regurgitation, sonic guidance, such as transesophageal echocardiogram (TEE) (2D and/or 3D), transthoracic echocardiogram (TTE), and/or intracardiac echo (ICE), can be used to guide positioning of tissue anchors (*e.g.*, suture knots) onto the valve leaflets. However, deployment of a plurality of anchors onto a mitral valve leaflet at desired spacing(s)/position(s) performed under sonic guidance can be difficult due, for example,

to the level of resolution of the sonic guidance technology, and/or equipment and/or software limitations. Furthermore, use of sonic guidance can be relatively cumbersome. For example, reliance upon continuous tracking of images in multiple planes can be typical in 2D visualization. Clear and constant communication between a surgeon and echocardiographer can often be needed for desired positioning of the anchors. Such challenges can render positioning of the second, third, and/or final anchor even more difficult, for example due in part to the number of elements tracked by the sonic guidance. As certain mitral valve leaflet repair procedures using tissue anchors, as described herein, can be performed on a beating heart, motion of the beating heart, such as the mitral valve leaflets, may also interfere with desired visualization using sonic guidance.

[0054] One or more devices and/or methods described herein can provide controlled spacing/positioning of adjacent suture knots or other anchors while reducing or eliminating reliance upon sonic guidance to position the suture knots onto a mitral valve leaflet. Although certain embodiments are described herein in the context of suture knots, it should be understood that references to suture knots herein are applicable to other types of suture anchors comprising any suitable or desirable material and/or configuration. Therefore, references herein to suture knots may be interpreted as references to any other type(s) of anchors. Furthermore, although certain embodiments are described herein in the context of mitral valves, mitral valve leaflets, and/or mitral valve repair, it should be understood that the principles disclosed herein are applicable to any type of valve, valve repair, tissue, or other types of suture anchoring, such as for purposes other than valve repair. Furthermore, principles and embodiments disclosed herein may be applicable to certain non-biological applications as well.

[0055] In some embodiments, an anchor guide can be used in combination with an anchor delivery device to provide reliable spacing of adjacent suture knots/anchors. The anchor guide can have an elongate member or shaft that defines a space configured to receive and/or at least partially contain, house, or capture one or more suture portions associated with a suture anchor previously deployed onto a first location on a mitral valve leaflet (or other valve leaflet, such as for a tricuspid valve, or other biological tissue). In some embodiments, a suture associated with the suture portion(s) can be used to form a first suture knot at the first location, the suture knot representing the suture anchor referenced above. The elongate shaft of the anchor guide can be inserted into the left ventricle (or right ventricle) through an access opening on the heart wall.

[0056] With the previously deployed suture portion(s) captured or received within the space defined by the elongate shaft of the anchor guide, the elongate shaft of the anchor guide can be extended so as to contact the first anchor location of the mitral valve leaflet. Subsequently, an elongate lumen member of an anchor delivery device or introducer can be inserted through the access opening. An elongate lumen member of an anchor delivery device, which may or may not be the same anchor delivery device used to place the first or previous suture anchor, can be configured to be extended to contact a second portion or location of the proximal side of the target mitral valve leaflet, the elongate lumen member of the anchor delivery device being configured to be positioned in at least partial physical contact with the elongate shaft of the anchor guide while being extended to contact the second portion or location of the proximal side of the target mitral valve leaflet. The elongate shaft of the anchor guide can comprise one or more engagement features configured to provide sliding engagement with the elongate lumen member of the anchor delivery device. The anchor delivery device used for placement of the second suture can be configured such that the second suture can be deployed to the second location on the valve leaflet using the anchor delivery device, wherein a distance between the first and second locations can depend at least in part on the width or dimension of the elongate shaft, or spacer feature thereof, of the anchor guide. The anchor guide and the anchor delivery device can be used in a minimally invasive mitral valve repair procedure, with or without sonic guidance, to sequentially deploy suture knots/anchors at controlled distances from one another.

[0057] The methods, operations, steps, etc. described herein can be performed on a living animal or on a non-living cadaver, cadaver heart, simulator (e.g. with the body parts, tissue, etc. being simulated), etc.

Valve Repair Using Controlled Leaflet Anchor Spacing

[0058] Figure 4 shows an anchor delivery device 100 inserted into a ventricle 14 (*e.g.*, left ventricle) of a heart 10 in connection with a valve repair procedure in accordance with one or more embodiments of the present disclosure. For example, the valve 22 may be a mitral valve. The anchor delivery device 100 can be configured to deliver a tissue anchor 90 (*e.g.*, suture knot) to the valve leaflet 52. As an example, Figure 4 shows a valve leaflet 52, which may represent a posterolateral leaflet of a mitral valve. It will be understood that the anchor delivery device 100 can also deliver the suture anchor 90 to the anteromedial mitral valve leaflet. Although the description of Figure 4 below is presented in the context of a mitral valve, it should be understood that the principles

disclosed herein are applicable to other valves or biological tissues, such as a tricuspid valve.

[0059] The anchor delivery device 100 can comprise an elongate lumen member 101 configured to allow delivery of the anchor 90 to the valve leaflet 52. The lumen member 101 can comprise a functional distal end portion 104 configured to perform one or more selected functions, such as grasping, suctioning, irrigating, cutting, suturing, or otherwise engaging a valve leaflet. The functional distal portion 104 can be configured to contact the mitral valve leaflet 52 to effect repair of the mitral valve 22.

[0060] The anchor delivery device 100 can be inserted into a heart chamber, such as the left ventricle 14, through an introducer device 200, which includes a body portion 210 and a lumen member portion 220. The lumen member portion 220 of the introducer device 200 may be passed through the ventricular wall 11 via an incision/access at or proximate to the apex 20 of the heart 10. The lumen member 101 of the delivery device 100 can be passed through the lumen member portion 220 of the introducer device 200 and out of a distal tip thereof into the ventricle 14 to contact the valve leaflet 52 for delivery of the suture anchor 90 to a target site on the valve leaflet 52. Sonic guidance, such as transesophageal echocardiogram (TEE) (2D and/or 3D), transthoracic echocardiogram (TTE), and/or intracardiac echo (ICE), may be used to assist in the advancement and desired positioning of the anchor delivery device 100 within the ventricle 14. The distal end 104 of the delivery device 100 can contact a proximal surface (*e.g.*, underside surface with respect to the illustrated orientation of Figure 4) of the mitral valve leaflet 52, without or substantially without damaging the leaflet 52. For example, the distal end 104 in contact with the leaflet 52 can have a blunt form or configuration. The distal end 104 can be configured to maintain contact with the proximal side of the valve leaflet 52, for example, to facilitate reliable delivery of the anchor 90 to the target site on the leaflet 52.

[0061] In some embodiments, one or more perforation devices (*e.g.*, needle(s)) can be delivered through the lumen member 101 of the delivery device 100 to the valve leaflet 52 to puncture the valve leaflet 52 and project a sutureform into the atrium, wherein the sutureform is deployed to form the anchor 90. For example, in some embodiments, a slotted needle (not shown) is deployed from the distal end 104 of the delivery device 100, thereby puncturing the leaflet 52 and projecting into the atrium 12, wherein the slotted needle is wrapped with a suture (*e.g.*, PTFE suture) in a particular configuration (*See* the '761 PCT Application for further detail regarding example suture wrapping

configurations and needles for use in suture anchor deployment devices and methods). In some embodiments, a pusher or hollow guide wire (not shown) is provided on or at least partially around the needle, such that the needle may be withdrawn, leaving the pusher and wound sutureform. When a withdrawal force is applied to the sutureform using the pusher, the sutureform may form a bulky-knot-type anchor (*e.g.*, the anchor 90), after which the pusher may be withdrawn, leaving the permanent knot to anchor the suture 92 to the leaflet 52.

[0062] As described herein, the anchor delivery device 100 can be used in beating heart mitral valve repair procedures. In some embodiments, the elongate lumen member 101 of the delivery device 100 can be configured to extend and contract or retract with the beat of the heart 10. During systolic contraction, the median axis of the heart 10 generally shortens. For example, the distance from the apex 20 of the heart to the valve leaflets 52, 54 can vary by about 1 centimeter (cm) to about 2 centimeters (cm) with each heartbeat in some patients. In some embodiments, the length of the elongate lumen member 101 can change with the length of the median axis of the heart 10. The distal end 104 of the elongate lumen member 101 can be configured to be floating such that the distal end 104 can extend and retract with the beat of the heart 10 so as to maintain contact with the mitral valve leaflet 52.

[0063] Figure 5 shows a top view of a mitral valve leaflet 54 having a plurality of suture anchors (*e.g.*, knots) 99 formed thereon. An anchor delivery device as described herein can be used to deliver the plurality of suture knots 99 onto the atrial/distal side of the mitral valve leaflet 54. The anchor delivery device can be used to sequentially deploy the suture knots 99 onto the mitral valve leaflet 54. Although Figure 5 shows three suture knots 99 deployed onto the mitral valve leaflet 54, it should be understood that more or fewer suture knots can be formed/deployed on the mitral valve leaflet 54 to provide desired mitral valve repair. A distance "*d*" between adjacent suture knots can be selected to provide desired mitral valve repair functionality. In some embodiments, the distance *d* between adjacent suture knots can be about 1 millimeter (mm) to about 10 millimeters (mm), about 2 millimeters (mm) to about 8 millimeters (mm), about 3 millimeters (mm) to about 7 millimeters (mm), or about 4 millimeters (mm) to about 6 millimeters (mm), for example about 5 millimeters (mm). One or more anchor guides described herein can be used in combination with an anchor delivery device to facilitate reliable spacing between adjacent suture knots 99.

[0064] As referenced above, proper/desirable positioning and spacing of knots or other leaflet anchors can be difficult to achieve for various reasons. For example, delivery devices for deploying leaflet anchors, as described herein, can be relatively difficult to precisely control. Furthermore, where echocardiographic imaging is utilized to assist with positioning/spacing, inaccurate configuration of the echocardiograph tool(s) such that the desired image plane(s) are not presented can impede the surgeon's ability to achieve the proper/desired placement and/or spacing. In addition, the anchor delivery system may move or shift after the surgeon has positioned the anchor deliver system in the desired position.

[0065] Figure 6 is a perspective view of the distal portion of an example anchor guide/spacer 300 in accordance with one or more embodiments of the present disclosure. The anchor guide 300 can comprise an elongate shaft 302 having a space or channel 304 configured to receive one or more suture portions connected to, or otherwise associated with, an anchor (*e.g.*, suture knot) 90 previously deployed on a valve leaflet (*e.g.*, mitral valve leaflet; not shown for illustration purposes). For example, the anchor 90 can be formed on the mitral valve leaflet using a suture comprising the one or more suture portions 92, such that the anchor 90 and the suture portion(s) are part of a unitary length of suture. The shaft 302 can comprise a distal atraumatic tip portion 306 configured to contact the valve leaflet. The shaft 302 can be inserted through the access incision/opening made in the heart wall and extended from the access opening into the left (or right) ventricle until the distal tip portion 306 contacts the valve leaflet, while positioned over at least a portion of the suture(s) 92. For example, the suture(s) 92 can be received or disposed in the channel 304 defined by shaft 302 as the shaft 302 is extended to the mitral valve leaflet. The channel 304 can be defined at least in part by the elongate shaft 302 to retain the suture 92. The distal tip portion 306 can be configured to maintain contact with the valve leaflet after the shaft 302 is extended to the desired position so as to facilitate stable positioning of the anchor guide 300 against the mitral valve leaflet. The anchor guide 300 comprises one or more spacing features configured to provide a spacing distance between the channel 304 and a device disposed in physical contact with the spacing feature(s), such as a delivery system distal tip or lumen member. For example, the one or more spacing features may comprise the illustrated flanges 308 and/or tip surfaces 309.

[0066] The anchor guide 300 can be sized/dimensioned so as to facilitate providing desired spacing between adjacent suture knot(s). For example, the shaft 302 can be

sized/dimensioned to facilitate providing the desired spacing between adjacent suture knots when a lumen member of an anchor delivery device is brought into appropriate physical contact with at least a portion of the anchor guide 300. For example, the shaft 302 can have radius and/or diameter dimension selected to provide the desired spacing *'x'* between a central shaft axis 303 and a central anchor axis 305 (*see* Figure 7) associated with an anchor delivery lumen member 702 physically coupled or contacting a side portion 307 of the shaft 302 and/or tip portion 306. In some embodiments, the shaft 302 can be sized such that adjacent sutures can be placed about 5 millimeters (mm) apart (*see* dimension *x* in Figure 7) on a mitral valve leaflet.

[0067] In some embodiments, the shaft 302 and/or tip 306 can have an arcuate shape, wherein a delivery lumen member can fit with and/or be secured by concave or inclined surface, face, or feature (*e.g.*, surface 309, guide feature(s) 308). In some embodiments, a longitudinal cross-section of the shaft 302 can have a semi-circle, crescent, or like shape. For example, the radius or other dimension of the semi-circle can be selected so as to provide desired spacing between the location on the valve leaflet at which the anchor 90 associated with the suture(s) 92 received within the space 304 of the shaft 302 is deployed and a location on the valve leaflet at which a subsequent suture is deployed. It will be understood that other longitudinal cross-sectional shapes can also be used, including, for example, a partial or full oval or circle shape.

[0068] The shaft 302 may include a side portion 307, such as a wall, bar, strap, or other barrier, that serves to retain and/or restrain the suture(s) 92 within the space 304. By restraining the suture(s) 92 within the space 304, the spacing of the anchor guide 300 can advantageously control the spacing between the restrained suture(s) 92, and therefore the associated anchor 90, and guide feature(s) (*e.g.*, 308, 309) of the anchor guide 300. In some embodiments, the space 304 can comprise at least a portion of which that is enclosed by the barrier feature 307. For example, the shaft 302 can comprise an enclosed lumen extending along at least a portion of its length to receive or hold at least a portion of the suture(s) 92. In some embodiments, an enclosed lumen can extend along substantially an entire length of the shaft 302. In some embodiments, an enclosed lumen can extend along only a portion of the length of the shaft 302.

[0069] In some embodiments, the shaft 302 can have an opening extending along at least a portion of its length such that the space 304 is not fully enclosed. The space 304 defined by shaft 302 can have a semi-circle/semi-cylinder shape. In some embodiments, the space 304 can comprise another shape, such as another arcuate shape, including a

partial oval shape. In some embodiments, the space 304 can extend along an entire or substantially an entire length of the shaft 302. In some embodiments, the space can extend along only a portion of the length of the shaft 302.

[0070] As referenced above, the shaft 302 can comprise a pair of guide/engagement features 308 extending along at least a portion of its length configured to engage with an anchor delivery device (*e.g.*, an embodiment of the delivery device 100 as described with reference to Figure 4). The anchor guide 300 can be used in combination with the anchor delivery device to facilitate reliable/controlled spacing between adjacent anchors (*e.g.*, suture knots). As described herein, the shaft 302 can be slid over a previously deployed suture 92. The anchor delivery device can be deployed to subsequently deliver one or more additional anchors to the target valve leaflet. For such purpose, the anchor delivery device can be deployed adjacent to and in physical contact with the anchor guide 300. For example, the engagement feature(s) 308 can have a sliding engagement with the anchor delivery device, such as with an elongate lumen member and/or distal tip of the anchor delivery device. The engagement features 308 can allow secure positioning of the anchor guide 300 against the anchor delivery device such that reliable spacing can be provided between the subsequently deployed anchor(s).

[0071] As shown in Figure 6, the engagement feature(s) 308 can comprise a pair of opposing extensions, such as a pair of opposing flanges, extending along at least a portion of a length of the shaft 302. The engagement feature(s) 308 can extend from opposing edges of the shaft 302. In some embodiments, a corresponding portion of an anchor delivery device elongate lumen member can be received at least partially between or against opposing flange features of the anchor guide 300. The delivery device, such as a lumen member thereof, may be in contact with the opposing flanges as the lumen member is slid relative to the shaft 302 during positioning of the distal end of the lumen member of the delivery device.

[0072] The engagement feature(s) 308 can have a variety of features configured to allow a reliable sliding engagement between the anchor guide 300 and an anchor delivery device. The engagement feature(s) 308 can provide reliable positioning of the anchor guide 300 relative to the anchor delivery device while the anchor delivery device is moved relative to the anchor guide 300. In some embodiments, the engagement feature(s) 308 can extend along an entire or substantially an entire length of the shaft 302. In some embodiments, the engagement feature(s) 308 extends along only one or more portions of the shaft 302. For example, the engagement feature(s) 308 can extend

along at least a portion of a length of the shaft 302 that is below the distal tip portion 306. In some embodiments, the engagement feature(s) 308 can be positioned at regular or irregular intervals along a portion of a length of the shaft 302.

[0073] As described herein, the distal tip portion 306 can be configured to contact the mitral valve leaflet to facilitate reliable positioning of the anchor guide 300 and anchor delivery device (not shown; *see* Figure 7). The distal tip portion 306 can contact the underside of the mitral valve leaflet, substantially without damaging the leaflet. For example, the distal tip portion 306 in contact with the leaflet can have a blunt configuration. The distal tip portion 306 can be configured to maintain reliable contact with the underside of the mitral valve leaflet to facilitate stable positioning of the anchor guide 300 such that reliable spacing can be achieved between consecutively deployed sutures. In some embodiments, the distal tip portion 306 can comprise a flexible flat surface 312 which can be positioned against the underside of the valve leaflet.

[0074] The anchor guide 300 can be used in beating-heart valve repair (*e.g.*, mitral valve repair) procedures. The shaft 302 can be configured to extend and contract with the beat of the heart. For example, the position of the shaft 302 with respect to a longitudinal axis thereof can change with the length of the median axis of the heart. In some embodiments, the distal tip portion 306 of the shaft 302 can be configured to be floating such that the distal tip portion 306 can extend and retract with the beat of the heart. The distal tip portion 306 can extend and retract during systole and diastole phases so as to maintain contact with the mitral valve leaflet (*e.g.*, extend outwardly about 1 centimeter (cm) to about 3 cm during the systolic phase). In some embodiments, the distal tip portion 306 can extend and retract so as to maintain a constant or substantially constant force/contact on the valve leaflet during the systolic and diastolic phases. The distal tip portion 306 can be configured to maintain contact with the mitral valve leaflet during movement of an anchor delivery device into position and/or during deployment of a subsequent suture using the anchor delivery device.

[0075] In some embodiments, the anchor guide 300 can comprise or be associated with a hemostasis valve (not shown) to prevent or reduce backflow of blood or other fluid during surgery. For example, the shaft 302 can comprise a proximal portion (not shown) including the homeostasis valve. The proximal portion may be a hub form, or the like.

[0076] The anchor guide in accordance with one or more embodiments of the present disclosure can be used with or without sonic guidance. In some embodiments, one or

more portions of the anchor guide 300 can comprise echogenic material (*e.g.*, hyperechogenic material). For example, at least an outer surface of the shaft 302 may comprise stainless steel (*e.g.*, bead-blasted), or other material. Sonic guidance, including transesophageal echocardiogram (TEE) (2D and/or 3D), transthoracic echocardiogram (TTE), and/or intracardiac echo (ICE), may be used to assist in the advancement and desired positioning of the anchor guide 300.

[0077] In some embodiments, the anchor guide 300 can comprise one or more external markings to facilitate desired orientation of the anchor guide 300 during its use. The external markings can be on any portion of the anchor guide 300 viewable by an operator while operating the anchor guide 300. For example, one or more labels and/or shape(s) of the anchor guide 300 can provide guidance to the operator as to the orientation of the anchor guide 300. In some embodiments, the external markings can facilitate use of the anchor guide 300 without sonic guidance. For example, knowledge of the orientation of the anchor guide 300 can aide the operator in engaging an anchor delivery device with the anchor guide 300 so as to provide desired positioning of the anchor delivery device.

[0078] The anchor guide 300 can comprise any number of suitable materials. In some embodiments, the anchor guide 300 can comprise a rigid material, a semi-rigid material, or combination thereof. In some embodiments, the anchor guide 300 can comprise a metallic material, such as stainless steel. In some embodiments, the anchor guide 300 can comprise a polymeric material, such as polyethylene.

[0079] Figure 7 shows an example of an anchor guide 300 positioned adjacent to an anchor delivery device 700. As described herein, the anchor guide 300 can be used in combination with the anchor delivery device 700 to facilitate reliable spacing between adjacent leaflet anchors (*e.g.*, suture knots). As described herein, the shaft 302 of the anchor guide 300 can be slid over a previously-deployed suture (*e.g.*, pair of suture tails) 92 associated with a previously-deployed anchor (*e.g.*, suture knot) 90. The anchor delivery device 700 can be deployed to deliver a subsequent anchor 708 to a valve leaflet. For example, the anchor 708 can be delivered via an elongate lumen member 702 of the anchor delivery device 700 to the valve leaflet. The anchor 708 may be formed on a distal/atrial side of the valve leaflet as a suture knot, as described herein. The elongate lumen member 702 can be deployed adjacent to and in contact with the shaft 302 of the anchor guide 300. For example, engagement feature(s) 308 of the anchor guide 300 can be configured to engage with the elongate lumen member 702 of the delivery device 700.

The engagement feature(s) 308 can allow secure positioning of the anchor guide 300 against the anchor delivery device 700 such that reliable spacing can be provided between the consecutively deployed sutures.

[0080] The engagement feature(s) 308 can be positioned against the anchor delivery device 700, such as against at least a portion of a length of the elongate lumen member 702 of the anchor delivery device 700, to securely position the anchor guide 300 relative to the anchor delivery device 700. The anchor delivery device 700 can have a pair of corresponding features (not shown) to engage with the engagement feature(s) 308. For example, an elongate lumen member 702 of the delivery device 700 can comprise a pair of corresponding recesses configured to receive the engagement feature(s) 308. The shaft 302 of the anchor guide 300 and the elongate lumen member 702 of the anchor delivery device 700 can be engaged with one another as the elongate lumen member 702 is slid relative to the shaft 302 of the anchor guide 300 to extend the anchor delivery device 700 to the subsequent target location on the mitral valve leaflet. For example, the anchor delivery device 700 can comprise a corresponding pair of grooves to receive the engagement feature(s) 308 such that the engagement feature(s) 308 can slide within the grooves as the anchor delivery device 700 is extended relative to the anchor guide 300. As described herein, the engagement features 308 can comprise a pair of opposing flanges. In some embodiments, the anchor delivery device 700 may not have corresponding engagement features to engage with the engagement feature(s) 308. For example, secure positioning of the elongate lumen member 702 of the anchor delivery device 700 relative to the shaft 302 of the anchor guide 300 may be achieved by positioning the elongate lumen member 702 of the delivery device 700 between the engagement feature(s) 308. The distal tip 706 of the delivery device 700 may further fit or engage or fit with a recess, or cut-out, feature of the distal tip 306 of the anchor guide 300, which may further serve to position the delivery device 700 in the desired spacing. In some embodiments, one or more magnets may be used to draw the distal tip 706 of the delivery device 700 to the distal tip 306 of the anchor guide 300. For example, each of the distal tip 706 of the delivery device 700 and the distal tip portion 306 of the anchor guide 300 may have attached thereto or embedded therein one or more magnets.

[0081] In some embodiments, an anchor delivery device can be used in combination with an anchor guide of a selected width, radius, diameter, or other spacing feature or dimension to provide the desired distance between adjacent tissue anchors (*e.g.*, suture knots). In some embodiments, an anchor guide of a predetermined width/dimension can

be selected based on the distance desired between anchors. For example, a kit configured for heart valve repair can comprise a plurality of anchor guides, each anchor guide comprising a different width or other dimension. In some embodiments, a kit can comprise one or more anchor delivery devices and a plurality of anchor guides, each anchor guide comprising a different width or other spacing dimension.

Controlled Anchor Spacing Processes

[0082] As described in detail above, in some implementations, the present disclosure relates to anchor guide systems and devices comprising a relatively thin shaft having a central lumen, an atraumatic tip, and/or one or more proximal hemostasis valves. The anchor guide may be advantageously configured to slide or otherwise be advanced/positioned over an existing pair of sutures, such as suture tails/portions associated with a deployed anchor. The anchor guide may be configured and/or dimensioned to facilitate more consistent spacing between adjacent anchors (*e.g.*, ePTFE knots) deployed on, for example, a mitral leaflet. Furthermore, processes associated with anchor guides in accordance with the present disclosure may allow for reduced dependence on echo imaging for proper anchor targeting.

[0083] Figures 8 through 13 illustrate stages and aspects of a process for deploying tissue anchors in a heart in accordance with one or more embodiments. The various images in Figure 8 through 13 relate to deployment of adjacent tissue anchors at desired distances from one another on a heart valve leaflet, such as a mitral valve leaflet. The process illustrated in Figure 8 through 13 may be performed using an anchor guide and an anchor delivery device, as described herein.

[0084] Figures 8-1 through 8-3, collectively referred to as Figure 8, illustrate a suture placement system and associated cardiac anatomy at one or more stages of an anchor deployment process in accordance with one or more embodiments. Figure 8-1 shows the deployment of a tissue anchor 90, such as a suture knot, on a valve leaflet 54, such as a mitral valve leaflet. Figure 8-3 shows an atrial view of the deployed knot 90.

[0085] As described in detail above, certain systems, devices, and processes can be employed to reduce valve regurgitation caused by mid-segment prolapse, which may result from valve disease (*e.g.*, mitral valve disease). For example, in certain valve repair procedures, a series of ePTFE cords are delivered and anchored on the P2 mitral valve leaflet in a beating heart under transesophageal echocardiography (TEE) guidance. Figures 8-1 through 8-3 show the delivery of a leaflet anchor 90 using an introducer 820 and a delivery system 800. The delivery system 800 may be used to deploy the anchor 90

via access to the target valve leaflet 54 through the introducer 820, which may be inserted into the ventricle 14 of the heart 10 at or near the apex 20 of the heart through, for example, a small left thoracotomy or other procedure. Generally, deployment of multiple anchors in a single leaflet may be desirable to establish effective coaptation between the valve leaflets (*e.g.*, posterior and anterior mitral valve leaflets) and/or to better distribute the loads across the deployed anchors.

[0086] Echo imaging may be desirable or critical to successful placement/deployment of leaflet anchors with respect to valve repair procedures related to the present disclosure. However, use of echo/sonic imaging guidance can present certain challenges due to various factors. For example, echo images can be undesirably unclear due to errors or inadequacies of equipment and/or associated software. Furthermore, visualization using 2D echo technology may require continuous tracking of images in two planes, which can be difficult to effectively achieve in some instances. Additional complications with echo imaging include difficulties with performing the procedure on a beating heart in view of relatively constant leaflet and heart motion and maintaining clear and/or constant communication between the surgeon and the echocardiographer during the procedure. In addition, spacing and/or proper targeting of anchors can become relatively more difficult as additional anchors (*e.g.*, knots) are deployed. For example, in some instances, the deployment of the final anchor of a procedure requires a greater amount of time due to targeting challenges.

[0087] The embodiments associated with Figures 8 through 13 provide solutions that advantageously lessen the dependence on echo imaging during the targeting of leaflet anchors and increase the consistency of anchor spacing after deployment of the first anchor of the procedure. Figure 8-1 shows deployment of the anchor 90 in the leaflet 54. In deploying the anchor 90, it may be desirable or necessary to apply substantially constant pressure on the leaflet during positioning and/or puncturing of the leaflet. In positioning the anchor 90, the process may involve assessing positioning using echo imaging, as described herein.

[0088] The anchor 90 is delivered through a lumen in the delivery system 800, which is inserted in, and passes through, an access of a hub portion 821 and a lumen member 822 of the introducer 820. Figure 8-2 shows a schematic view of the delivery system positioned against the valve leaflet 54 for deployment of the anchor 90. The view of the leaflet 54 in Figure 8-2 may correspond to a cross-sectional medial-lateral view, wherein

the leaflet 54 is a posterior leaflet of a mitral valve, as shown in the atrial view of Figure 8-3.

[0089] Figures 9-1 through 9-3, collectively referred to as Figure 9, illustrate stages of the anchor deployment process after deployment of a first anchor in accordance with one or more embodiments. In the images of Figures 9-1 through 9-3, the introducer 820 has been removed from the heart 10, and the delivery system 800 has been withdrawn from the introducer 820. In some embodiments, the delivery system 800 is withdrawn from the introducer 820 prior to removal of the introducer 820. Although Figures 8 through 13 and the accompanying text show and describe the removal of the introducer 820 after deployment of the anchor 90, in some embodiments, the introducer is not removed prior to deployment of a second anchor (93, *see* Figures 15 and 16). The introducer 820 may be removed from the heart 10 and the suture tails 97 may be withdrawn from the introducer 820, as shown. The suture(s) 92, 97 may be pulled to reduce slack for tensioning and/or to allow for an anchor guide to be passed over the suture(s), as described in detail below.

[0090] Figure 9-2 shows a schematic view of the deployed anchor 90 and associated suture portion(s) 92, which pass through the heart wall 11 (*e.g.*, left ventricular wall) and are associated with the suture tail(s) 97 that are accessible external to the heart and/or chest cavity of the patient. Figure 9-3 shows an atrial view of the valve 22, showing the anchor 90 deployed on the leaflet 54.

[0091] Figures 10-1 through 10-3, collectively referred to as Figure 10, illustrate stages of the anchor deployment process after deployment of the first anchor 90 in accordance with one or more embodiments. In the images of Figures 10-1 through 10-3, an anchor guide 810 has been introduced into the heart chamber 14 and approximated or advanced to the target leaflet 54. The anchor guide 810 can be advanced over one or more of the suture portion(s) 92, 97 to a position on a proximal side of the leaflet 54 under the anchor 90 and/or substantially axially centered therewith. The anchor guide 810 comprises an elongate shaft 802, which may be inserted into the heart ventricle 14 through the access opening 27 in the heart wall 11. The access opening 27 may be the same access opening through which the introducer 820 and/or suture(s) 92 were passed in the stages shown in Figures 8 and 9 and described above, or the access opening 27 shown in Figure 10 may be a separate access opening in the heart wall 11. The shaft 802 of the anchor guide 810 can be extended to contact or approximate a first location on the proximal side (*e.g.*, underside according to the illustrated orientation of Figure 10) of the

heart valve leaflet 54, wherein at least a portion of the anchor 90 is deployed on a distal side of the leaflet 54 at or near the first location. At least a portion of the suture(s) 92 are received or disposed within a lumen or space/channel defined by the shaft 802. In some embodiments, the heart ventricle 14 can be a left ventricle. In some embodiments, the access opening 27 can be formed in the heart wall at or proximate to the apex 20 of the heart 10.

[0092] In some embodiments, the shaft 802 is placed or passed along the suture tail(s) 97, 92 that are associated with the previously-deployed anchor 90. The term "associated with" is used herein according to its broad and ordinary meaning. With respect to a suture or suture or structure being "associated with" an anchor, such terminology may refer to a suture or other component or structure being physically coupled, attached, or connected to, or integrated with, the anchor. The anchor guide 810 can maintain hemostasis through the ventricular wall 11 after insertion thereof. In some embodiments, once the anchor guide 802 is properly placed, a purse string suture may be tightened to reduce bleeding around the shaft 802 of the anchor guide.

[0093] In some embodiments, the shaft 802 of the anchor guide 810 comprises a relatively thin shaft having a central lumen, as described above in connection with Figure 6. The shaft 802 may further comprise a substantially atraumatic tip portion 806 and/or a hub portion 803, which may comprise one or more hemostasis valves, and may be associated with a proximal end of the anchor guide 810. The atraumatic tip and/or other lumen/shaft tip or end portions disclosed herein may be at least partially flexible and/or may be configured to collapse down to fit through a lumen, such as the lumen of an introducer, wherein the tip expands after deployment from the introducer. In some embodiments, the anchor guide 810 does not include a hub portion, but rather one or more hemostasis valves are integrated with or part of the shaft 802 or other portion of the anchor guide 810 having any suitable or desirable shape. The anchor guide 810 and/or shaft 802 can comprise any rigid or semi-rigid material or combination of materials, such as stainless steel, polyethylene, or the like.

[0094] The shaft 802 may have a circular, partial-circular, semi-circular, oval, or semi-oval cross-sectional shape. The shaft 802 may be formed at least in part by shaping a sheet into a curved or circular form, or the lumen or channel thereof may be may be skived or cut-out to create the lumen or channel. In some embodiments, a separate semi-circle component can be assembled to the shaft 802 in the area intended to engage with the suture(s). The atraumatic tip 806 may be similar in certain respects to the tip/end

portion of the delivery system lumen member 801 shown in Figure 8. In some embodiments, one or more external indicators, such as geometrical or visual marker features, help facilitate orientation of the guide 810 from outside the heart and/or chest cavity.

[0095] The anchor guide 810 may be used to facilitate placement of a subsequently-deployed anchor in order to prevent undesirable clustering of anchors. For example, the guide 810 may advantageously guide the placement of anchors approximately 5 mm apart. Generally, the guide 810 may be lined-up and advanced over the first, or most-recently, deployed anchor/suture(s). In some embodiments, the process of Figures 8 through 13 involves selecting a desired anchor guide from among a plurality of available guides, which may be part of a common kit of anchor guides provided in a single packaging, or the like. Selection of the appropriate suture guide may be based on the relevant procedure, the target location or leaflet, or the like.

[0096] The use of an anchor guide in accordance with certain embodiments of the present disclosure may require one or more additional steps to deploy multiple leaflet anchors compared to procedures not utilizing such an anchor guide. Furthermore, for transapical leaflet access, use of an anchor guide in accordance with embodiments of the present disclosure may require a relatively wider/larger incision in the heart wall to allow access for a delivery system lumen and the anchor guide simultaneously through a single access channel. Therefore, anchor guides in accordance with embodiments of the present disclosure may be used selectively in cases in which targeting becomes difficult, such as for a final knot to be deployed where spacing is uncertain. Alternatively, a physician may choose to use an anchor guide for all anchors that are placed for a procedure, or may selectively choose to use an anchor guide for one or more sutures as needed or desired.

[0097] Figures 11-1 through 11-3, collectively referred to as Figure 11, illustrate stages of the anchor deployment process after insertion of an introducer 820 alongside the anchor guide 810 in accordance with one or more embodiments. The introducer 820 may be advanced adjacent to anchor guide 810, whether through a common incision with the anchor guide 810 or through another incision.

[0098] As described above, after deployment of the prior anchor 90 (*e.g.*, suture knot), the introducer 820 may be withdrawn from the associated suture portion(s) (*e.g.*, ePTFE cord(s)). The introducer 820 may be flushed and reintroduced into the same incision. Alternatively, a different introducer device may be used in connection with the

stages of Figure 11. As shown in Figure 11-1, the anchor guide 810 is slid over the suture(s) associated with the existing anchor 90. In embodiments in which the introducer is not previously withdrawn, the anchor guide 810 can be advanced next to the introducer lumen member 822 and to the target valve leaflet.

[0099] In some embodiments, the shaft 802 of the anchor guide 810 and/or portion(s) thereof comprise echogenic material/finish, such as grit-blasted stainless steel or the like, in order to allow for improved visualization of the location of the previously-deployed anchor 90 and/or its associated suture(s). The atraumatic tip 806 of the anchor guide 810 may be designed or configured to help ensure that the leaflet tissue is not damaged by the anchor guide 810. Generally, pushing the anchor guide against the leaflet 54 can provide additional support during the subsequent anchor deployment and improved centering of the suture(s) 92 within the channel/lumen of the shaft 802. The hemostasis valve(s) associated with the proximal end 803 of the anchor guide 810 may serve to reduce incidences of back-bleeding through the shaft 802. Furthermore, the proximal end 803 may advantageously have a wider width/thickness dimension relative to the shaft 802 and/or associated incision channel in the heart wall 11 such that when it protrudes from the heart, the end 803 at least partially prevents accidental implantation or insertion into the heart chamber 14.

[0100] In some embodiments, the initial introducer (*see* Figure 8) remains implanted from the initial insertion, wherein the anchor guide shaft 802 can be inserted through the introducer, as described in detail below in connection with Figures 15 and 16. In some embodiments, the anchor guide 810 comprises memory metal (*e.g.*, nitinol), wherein the guide shaft 802 can be inserted into the same aperture/channel in the introducer as the lumen member of the delivery system such that both may be present therein concurrently.

[0101] Figures 12-1 through 12-3, collectively referred to as Figure 12, illustrate stages of the anchor deployment process after insertion of a delivery system lumen member 804 through the introducer 820 alongside or adjacent to the anchor guide shaft 802 in accordance with one or more embodiments.

[0102] A second anchor 93 may be deployed using the delivery system lumen member 804 adjacent to the anchor guide shaft 802, which may comprise one or more geometrical and/or dimensional features configured such that when the delivery system lumen member 804 and/or tip 809 is/are positioned in physical contact with the anchor guide shaft 802 and/or tip 806, the center of the lumen member 804 is positioned at a

desired and/or pre-selected distance from the center axis of the previously-deployed anchor 90. For example, at the target leaflet, the delivery system lumen member 804/tip 809 may advantageously be in contact with a partial-/semi-circle portion of the guide shaft 802/tip 806, which may control the spacing based on the cross-sectional width or configuration of the guide shaft 802 and/or tip 806.

[0103] Once the delivery system lumen member 804 has been positioned, the anchor 93 can be deployed with desired and/or consistent spacing relative to the prior anchor 90. The anchor guide 810 may then be removed. It may be desirable for the anchor guide 810 to be relatively narrow at the base 803 and/or along a portion of the shaft 802 relative to the distal end and/or tip of the shaft 802 so as to take up minimal room in the incision or introducer channel when the anchor guide is deployed.

[0104] As described in detail herein, the lumen member 804 of the delivery system can comprise an elongate member configured to be inserted through the access opening of the introducer 820. The lumen member 804 may be extended to contact the proximal side (*e.g.*, underside) of the heart valve leaflet 54 while contacting engagement features of the shaft 802. For example, a sliding engagement between the lumen member 804 of the anchor delivery device and the shaft 802 of the anchor guide can be maintained while the lumen member 804 of the anchor delivery device is extended toward the leaflet 54. For example, as described above in connection with Figures 6 and 7, the shaft 802 may comprise one or more features for the lumen member 804 to sit on or be placed against to help guide the delivery system lumen member 804 as it is advancing towards the target leaflet 54. The engagement feature(s) of the shaft 802 may comprise one or more grooves, concave or convex surfaces, notches, projections, or the like. In some embodiments, engagement feature(s) of the shaft 802 are associated with only part of the shaft, such as the end portion of the shaft. The dimensions/features of the shaft 802 of the anchor guide may provide for controlled spacing between the anchors 90, 93, such as about a 5 mm spacing, or other distance. In some embodiments, the anchor guide is used in combination with sonic imaging to provide improved precision, efficiency, and/or convenience.

[0105] The tip 806 may be a floating distal portion, wherein contact can be maintained between the distal tip 806 portion and the underside of the heart valve leaflet 54 at the location of the first anchor 90 while the lumen member 804 of the anchor delivery device is extended to contact the location of the second anchor 93. In some embodiments, contact can be maintained between the distal tip portion 806 and

the underside of the heart valve leaflet 54 at the first location while the second anchor 93 is deployed. Having the distal tip portion 806 maintain contact with the heart valve leaflet 54 while extending the lumen member 804 of the anchor delivery device can facilitate maintaining a position of the leaflet, thereby improving accuracy/precision in positioning of the anchor delivery device relative to the leaflet. Having the distal tip portion 806 maintain contact with the heart valve leaflet 54 while deploying the second anchor 93 can thereby facilitate improved accuracy in deploying the second anchor 93 onto the target location on the leaflet.

[0106] Figures 13-1 through 13-3, collectively referred to as Figure 13, illustrate stages of the anchor deployment process after withdrawal of the introducer 820 and delivery system lumen member 804 from the heart chamber 14 in accordance with one or more embodiments. The introducer 820 and delivery system may be removed following deployment of the anchor 93. Furthermore, as shown, the suture tails 98 associated with the anchor 93 may be withdrawn from the delivery system.

[0107] As described above, the second anchor 93 can be deployed using the anchor delivery device, wherein a distance between the location of the first anchor 90 and the location of the second anchor 93 can be dependent on a width of at least a portion of the elongate shaft 802 and/or tip 806 of the anchor guide 810. In some embodiments, the elongate shaft 802 of the anchor guide 810 can have a semi-circle shape. For example, the width of the shaft 802 can be a diameter of the semi-circle shape.

[0108] The anchors deployed onto the heart valve leaflet can be suture knot anchors formed from suture windings. The suture tails associated with such suture knots may be used to tether the heart valve leaflet to the heart wall. Use of the anchor guide in combination with the anchor delivery device can facilitate reliable spacing between adjacent suture knots deployed onto a mitral valve leaflet so as to achieve desired mitral valve repair to address mitral valve regurgitation. For example, adjacent suture knots can be at a distance of about 5 mm apart.

[0109] As described, the anchor guide 810 can be used in combination with the anchor delivery device to consecutively deploy one or more additional anchors onto a valve leaflet after deployment of the first anchor 90. In some embodiments, such deployment is performed without sonic guidance. In some embodiments, the anchor guide 810 may be used in combination with the anchor delivery device to deploy only a last anchor of a plurality of anchors deployed onto the valve leaflet. For example, previously-deployed anchors can be positioned using traditional techniques without an

anchor guide as described herein, wherein only the last suture is deployed using an anchor guide.

[0110] The above-described procedures can be performed manually (*e.g.*, by a physician) or can alternatively be performed fully or in part using robotic or machine assistance. For example, in some embodiments, an anchor delivery device and/or anchor guide can be configured to be delivered and deployed automatically using one or more robotic mechanisms/devices.

[0111] Figure 14 is a perspective view of a surgical introducer device 150 in accordance with one or more embodiments. The introducer device 150 provides a conduit into a target surgical area or chamber. In some embodiments, the introducer 150 comprises one or more hemostasis valves associated with a channel port 153. Such hemostasis valve may comprise silicone or other flexible material configured to keep blood from flowing out of the channel port 153.

[0112] In some embodiments, the introducer 150 comprises a hub body 151, which may include a port 152 used to de-air the introducer 150 prior to use and/or connect a fluid flush during medical procedures. The hub body 151 may be used to secure the introducer 150 to the pericardium for stable entry of a delivery system (not shown) and/or to control the amount of bleed-back during a medical procedure. The channel port 153 may serve as a delivery system lumen member insertion port, wherein an inserted delivery system lumen member may pass through a lumen member 155 of the introducer 150 and out a distal end 156 thereof for access to the target chamber. The channel port 153 may further be dimensioned to accommodate insertion of a dilator device (not shown) used to guide the introducer into the target chamber (*e.g.*, left ventricle, off-apex). The distal end 156 of the introducer may have a tapered shape to seal against the delivery system lumen.

[0113] Figure 15 is a perspective view of a surgical introducer device 160 in accordance with one or more embodiments. In some embodiments, the introducer 160 comprises a hub body 161, which may include a port 162 used to de-air the introducer 150 prior to use and/or connect a fluid flush during medical procedures. The introducer 160 comprises a first channel insertion port 163 associated with a lumen member 165 of the introducer 160 for insertion of a lumen member of a delivery system and/or a dilator device, as well as a second insertion port 167 for insertion of an anchor guide shaft in accordance with embodiments of the present disclosure. An inserted delivery system lumen member may pass through the lumen member 165 of the introducer 160 and out

a distal end 166 thereof for access to the target chamber. The distal end 166 of the introducer may have a tapered shape to seal against the delivery system lumen. In some embodiments, the anchor guide is introduced using the same introducer lumen member 165, or the anchor guide may come out separately from hub 161 and have its own hemostasis valve within its lumen. Therefore, in some embodiments, a separate hemostasis valve for the anchor guide may be unnecessary and/or omitted. Each of the insertion ports 163, 167 may be associated with a separate hemostasis valve. The introducer 160 may have a generally oval-shaped hub body 161, wherein such shape may be leveraged to include the multiple insertion ports.

[0114] By using an introducer device with multiple insertion ports, including an insertion port dimensioned for insertion of an anchor guide shaft in accordance with embodiments of the present disclosure, it may be possible to perform controlled-spacing anchor deployment processes as described herein without requiring withdrawal of the originally-inserted introducer device. For example, in some embodiments, the anchor guide is at least partially flexible to allow insertion thereof without requiring withdrawal of the originally-inserted introducer.

[0115] Figure 16 is a perspective view of the surgical introducer device 160 in accordance with one or more embodiments. Figure 16 shows a shaft 172 of an anchor guide 170 in accordance with embodiments of the present disclosure inserted through the separate insertion port 167. The shaft 172 can comprise a distal tip 173 comprising one or more features as described herein. Although Figure 16 shows the insertion port 167 and lumen member 165 configured such that an inserted guide shaft 172 does not pass through the lumen member 165, in some embodiments, the lumen member 165 is large enough and configured to allow for passage of a delivery system lumen member and anchor guide shaft therethrough.

[0116] Figure 17 is a perspective view of a surgical introducer device 190 in accordance with one or more embodiments. In some embodiments, the introducer 190 comprises a hub body 191, which may include a port 192 used to de-air the introducer 190 prior to use and/or connect a fluid flush during medical procedures. The introducer 190 comprises a first channel insertion port 193 associated with a lumen member 195 of the introducer 190 for insertion of a lumen member of a delivery system, an anchor guide shaft, and/or a dilator device, as well as a second insertion port 197 for insertion of a lumen member of a delivery system, an anchor guide shaft, and/or a dilator device in accordance with embodiments of the present disclosure. In the embodiment of Figure 17,

the insertion port 197 is also associated with the lumen member 195, such that a shaft or lumen member inserted into the port 197 is channeled within the lumen member 195 in a sub-channel thereof. Each of the insertion ports 193, 197 may advantageously have or be associated with a separate hemostasis valve. The introducer 190 may have a generally oval-shaped hub body 191, wherein such shape may be leveraged to include the multiple insertion ports.

[0117] By using an introducer device with multiple insertion ports, including an insertion port dimensioned for insertion of an anchor guide shaft in accordance with embodiments of the present disclosure, it may be possible to perform controlled-spacing anchor deployment processes as described herein without requiring withdrawal of the originally-inserted introducer device. For example, in some embodiments, the anchor guide is at least partially flexible to allow insertion thereof without requiring withdrawal of the originally-inserted introducer.

[0118] The lumen member 195 of the introducer 190 is advantageously large enough and configured/shaped to allow for passage of a delivery system lumen member and anchor guide shaft therethrough. In some embodiments, an inserted delivery system lumen member and/or guide shaft may pass through a lumen member 195 of the introducer 190 and out a distal end 196 thereof for access to the target chamber. The distal end 196 of the introducer may have a tapered shape to seal against the delivery system lumen. In some embodiments, a thin channel 199 between insertion ports 193 and 197 extends through the hub 191 and/or the length of the inside lumen member 195, thereby providing an opening/passage for suture tails to pass between the separate sub-lumens/channels associated with the ports 193, 197, respectively. For example, it may be desirable for the lumen member 195 to accommodate both the anchor guide and the delivery system in respective ones of the ports 193, 197. In implementations in which suture tails from a previously-deployed knot are disposed within, and run the length of, one of the insertion ports (*e.g.*, 193) and associated sub-channel, it may be desirable for the anchor guide to be inserted over the suture tail(s). For example, in some embodiments, a process for implementing suture anchoring using the introducer 190 involves inserting a delivery system lumen into the port 193 (or port 197) to deploy a first anchor, after which the delivery system may be withdrawn from the introducer 190. The process may further involve inserting an anchor guide shaft into the port 193 (or port 197) over the suture tail(s) associated with the previously-deployed anchor. The process may further involve subsequently inserting a new delivery system lumen (or re-

inserting the previously-used delivery system lumen) into the port 197 (or port 193) adjacent to the anchor guide shaft and deploying another suture anchor at a spacing and/or position against the distal end of the anchor guide shaft. After the second suture anchor has been deployed, the process may involve withdrawing the delivery system used to deploy the second suture, as well as the anchor guide shaft. The suture tail(s) may be guided through the channel 199 between the ports 193, 197, after which the anchor guide may be inserted into the port 193 (or port 197) over the suture tail(s) associated with the second suture anchor. These steps may be repeated until the desired number of knots have been deployed.

[0119] Figure 18 is a close-up view of a suture spacing system 1700 in accordance with one or more embodiments. The suture spacing system includes an anchor delivery device 180 having a wire (or suture) 185 attached thereto. In some embodiments, the wire includes a collar portion 186 and a loop portion 181. The wire 185 may be configured such that a tail portion 188 thereof may be manipulated (*e.g.*, pushed and/or pulled) in order to cause the loop 181 to be expanded and/or contracted. The wire tail portion 188 may be disposed at least partially within, and extend down, a lumen 182 of the delivery device 180. The loop 181 may be pre-formed and may be configured to be passed through a lumen of an introducer device in a collapsed, compressed, contracted, or other configuration, wherein the loop 181 may be expanded or extended once deployed from the introducer.

[0120] The loop 181 may advantageously provide spacing guidance for deployment of a leaflet anchor, as described in detail herein. For example, the loop 181 may be routed or threaded over previously-deployed suture tail(s) 183, wherein a dimension *'z'* of the loop determines a distance *'y'* between a central axis of the delivery device 180 and the deployed suture(s) 183. Although Figures 18–20 illustrate a single loop, it should be understood that the loop 181 may have one or more additional loops or spacing features. For example, an additional loop or feature configured to maintain the sutures 183 at or near a far side 184 of the loop 181 with respect to the anchor delivery device 180. In some embodiments, the loop 181 is comprised of a stiffener tab in addition to, or instead of, the illustrated loop. Such a stiffener tab may comprise an opening on the far side 184 to keep the sutures 183 in place.

[0121] Figure 19 is a top view of the suture spacing system 1700 in accordance with one or more embodiments. Figure 19 shows an example configuration of the loop 181 around and retaining/maintaining the suture(s) 183. Figure 20 is a side view of the

suture spacing system and associated anatomy (*e.g.*, heart valve leaflet 187) in accordance with one or more embodiments. An anchor (e.g., suture knot) 189 is shown as being associated with the sutures 183. Although the suture spacing system 1700 is shown as comprising a wire/suture loop, in some embodiments, the suture spacing system may implement another structure through which suture(s) may be routed to provide spacing therefrom, such as a tab or other structure having an opening therein. Such a feature may be configured with a hinge or other similar feature allowing the spacer to swing out once deployed and be passed through a lumen in a collapsed/contracted state. In some embodiments, suture/anchor spacing is achieved using a delivery system having an inflatable balloon feature. Alternatively, spacing may be achieved using a tether connected to a previously-deployed suture or anchor.

[0122] Although the above-described methods and/or devices are described primarily with reference to mitral valve repair, it will be understood that the methods and/or devices can be applicable to repair of other heart valves, such as the tricuspid valve.

Additional Embodiments and Terminology

[0123] Certain standard anatomical terms of location are used herein to refer to the anatomy of animals, and namely humans, with respect to the preferred embodiments. Although certain spatially relative terms, such as "outer," "inner," "upper," "lower," "below," "above," "vertical," "horizontal," "top," "bottom," and similar terms, are used herein to describe a spatial relationship of one device/element or anatomical structure to another device/element or anatomical structure, it is understood that these terms are used herein for ease of description to describe the positional relationship between element(s)/structures(s), as illustrated in the drawings. Spatially relative terms are intended to encompass different orientations of the element(s)/structures(s), in use or operation, in addition to the orientations depicted in the drawings. For example, an element/structure described as "above" another element/structure may represent a position that is below or beside such other element/structure with respect to alternate orientations of the subject patient or element/structure, and vice-versa.

[0124] Furthermore, references may be made herein to certain anatomical planes, such as the sagittal plane, or median plane, or longitudinal plane, referring to a plane parallel to the sagittal suture, and/or other sagittal planes (*e.g.*, parasagittal planes) parallel thereto. In addition, "frontal plane," or "coronal plane," may refer to an X-Y plane that is perpendicular to the ground when standing, which divides the body into back and front, or posterior and anterior, portions. Furthermore, a "transverse plane," or

"cross-sectional plane," or horizontal plane, may refer to an X-Z plane that is parallel to the ground when standing, that divides the body in upper and lower portions, such as superior and inferior. A "longitudinal plane" may refer to any plane perpendicular to the transverse plane. Furthermore, various axes may be described, such as a longitudinal axis, which may refer to an axis that is directed towards head of a human in the cranial direction and/or directed towards inferior of a human in caudal direction. A left-right or horizontal axis, which may refer to an axis that is directed towards the left-hand side and/or right-hand side of a patient. An anteroposterior axis which may refer to an axis that is directed towards the belly of a human in the anterior direction and/or directed towards the back of a human in the posterior direction. While various embodiments have been described above, it should be understood that they have been presented by way of example only, and not limitation. Where methods described above indicate certain events occurring in certain order, the ordering of certain events may be modified. Additionally, certain of the events may be performed concurrently in a parallel process when possible, as well as performed sequentially as described above.

[0125] Where schematics and/or embodiments described above indicate certain components arranged in certain orientations or positions, the arrangement of components may be modified. While the embodiments have been particularly shown and described, it will be understood that various changes in form and details may be made. Any portion of the apparatus and/or methods described herein may be combined in any combination, except mutually exclusive combinations. The embodiments described herein can include various combinations and/or sub-combinations of the functions, components and/or features of the different embodiments described.

[0126] The present disclosure describes various features, no single one of which is solely responsible for the benefits described herein. It will be understood that various features described herein may be combined, modified, or omitted, as would be apparent to one of ordinary skill. Other combinations and sub-combinations than those specifically described herein will be apparent to one of ordinary skill, and are intended to form a part of this disclosure. Various methods are described herein in connection with various flowchart steps and/or phases. It will be understood that in many cases, certain steps and/or phases may be combined together such that multiple steps and/or phases shown in the flowcharts can be performed as a single step and/or phase. Also, certain steps and/or phases can be broken into additional sub-components to be performed separately. In some instances, the order of the steps and/or phases can be

rearranged and certain steps and/or phases may be omitted entirely. Also, the methods described herein are to be understood to be open-ended, such that additional steps and/or phases to those shown and described herein can also be performed.

[0127] Unless the context clearly requires otherwise, throughout the description and the claims, the words "comprise," "comprising," and the like are to be construed in an inclusive sense, as opposed to an exclusive or exhaustive sense; that is to say, in the sense of "including, but not limited to." The word "coupled", as generally used herein, refers to two or more elements that may be either directly connected, or connected by way of one or more intermediate elements. Additionally, the words "herein," "above," "below," and words of similar import, when used in this application, shall refer to this application as a whole and not to any particular portions of this application. Where the context permits, words in the above Detailed Description using the singular or plural number may also include the plural or singular number respectively. The word "or" in reference to a list of two or more items, that word covers all of the following interpretations of the word: any of the items in the list, all of the items in the list, and any combination of the items in the list.

[0128] The disclosure is not intended to be limited to the implementations shown herein. Various modifications to the implementations described in this disclosure may be readily apparent to those skilled in the art, and the generic principles defined herein may be applied to other implementations without departing from the spirit or scope of this disclosure. The teachings provided herein can be applied to other methods and systems, and are not limited to the methods and systems described above, and elements and acts of the various embodiments described above can be combined to provide further embodiments. Accordingly, the novel methods and systems described herein may be embodied in a variety of other forms; furthermore, various omissions, substitutions and changes in the form of the methods and systems described herein may be made without departing from the spirit of the disclosure. The accompanying claims and their equivalents are intended to cover such forms or modifications as would fall within the scope and spirit of the disclosure.

WHAT IS CLAIMED IS:

1. An anchor guide comprising:

an elongate shaft;

an atraumatic tip;

a channel defined at least in part by the elongate shaft and configured to retain a suture associated with an anchor; and

a spacing feature configured to provide a spacing distance between the channel and a device disposed in physical contact with the spacing feature.

2. The anchor guide of claim 1, wherein the device comprises a lumen member of an anchor delivery system.

3. The anchor guide of claim 1 or claim 2, wherein the spacing feature comprises one or more flanges.

4. The anchor guide of any of claims 1–3, wherein the elongate shaft has a circular segment cross-section.

5. The anchor guide of any of claims 1–4, wherein the spacing feature is associated with the atraumatic tip.

6. The anchor guide of any of claims 1–5, wherein the atraumatic tip is C-shaped.

7. The anchor guide of any of claims 1–6, wherein the elongate shaft comprises echogenic material.

8. The anchor guide of claim 7, wherein the echogenic material is grit-blasted stainless steel.

9. The anchor guide of any of claims 1–8, wherein the anchor guide comprises a hemostasis valve.

10. A tissue-anchoring system comprising:

an anchor delivery device configured to anchor a first anchor at a first location in a heart valve leaflet, the anchor delivery device comprising an elongate lumen member configured to allow the first anchor to be advance therethrough; and

an anchor guide comprising an elongate shaft including one or more engagement features configured to provide sliding engagement between the elongate shaft of the anchor guide and the elongate lumen member of the anchor

delivery device, the elongate shaft defining a space configured to receive a suture associated with a second anchor anchored in the heart valve leaflet;

wherein a dimension of the anchor guide controls a distance between the first anchor and the second anchor when the anchor guide is disposed against the leaflet and aligned with the second anchor and the anchor delivery device is disposed against the leaflet against the one or more engagement features of the elongate shaft.

11. The system of claim 10, wherein:

the elongate shaft has a semi-circle shape; and

the one or more engagement features comprise a plurality of flange features associated with a diametrical barrier of the elongate shaft.

12. The system of claim 10 or 11, wherein the distance between the first anchor and the second anchor is approximately 5 millimeters (mm).

13. The system of any of claims 10–12, wherein:

the engagement features comprise a pair of opposing flanges extending from at least a portion of a length of the elongate shaft; and

the elongate lumen member of the anchor delivery device is shaped to be positioned between and in contact with the pair of opposing flanges.

14. The system of claim 13, wherein the elongate lumen member of the anchor delivery device comprises a corresponding pair of opposing grooves configured to engage with the pair of opposing flanges.

15. The system of any of claims 10–14, wherein the elongate shaft is extendable and retractable.

16. The system of any of claims 10–15, wherein the space defined by the elongate shaft extends along an entire length of the elongate shaft.

17. The system of any of claims 10–16, wherein the anchor guide comprises an echogenic material.

18. A method of deploying a tissue anchor in a heart valve leaflet, the method comprising:

disposing one or more suture tails associated with a tissue anchor anchored in a heart valve leaflet of a heart within a channel of an anchor guide, the one

or more suture tails passing through an access opening in a wall of a ventricle of the heart;

inserting the anchor guide through the access opening at least partially into the ventricle;

advancing the anchor guide to contact a first location on a proximal side of the heart valve leaflet, the first location being aligned with a first anchor associated with the one or more suture tails;

inserting an anchor delivery device at least partially into the ventricle;

advancing the anchor delivery device to contact a second location on the of the heart valve leaflet while engaging the anchor delivery device with one or more engagement features of the anchor guide; and

deploying a second tissue anchor at the second location using the anchor delivery device;

wherein a distance between the first location and the second location is based on a dimension of the one or more engagement features.

19. The method of claim 18, wherein said inserting the anchor delivery device is through the access opening.

20. The method of claim 18 or claim 19, wherein said advancing the anchor delivery device to contact the second location of the heart valve leaflet comprises maintaining a sliding engagement between the anchor delivery device and the one or more engagement features of the anchor guide.

21. The method of any of claims 18–20, wherein said advancing the anchor guide to contact the first location comprises contacting the heart valve leaflet with a floating distal tip of the anchor guide and maintaining contact with the heart valve leaflet while extending the anchor delivery device.

22. The method of any of claims 18–21, wherein the ventricle is a left ventricle and the heart valve leaflet is a mitral valve leaflet.

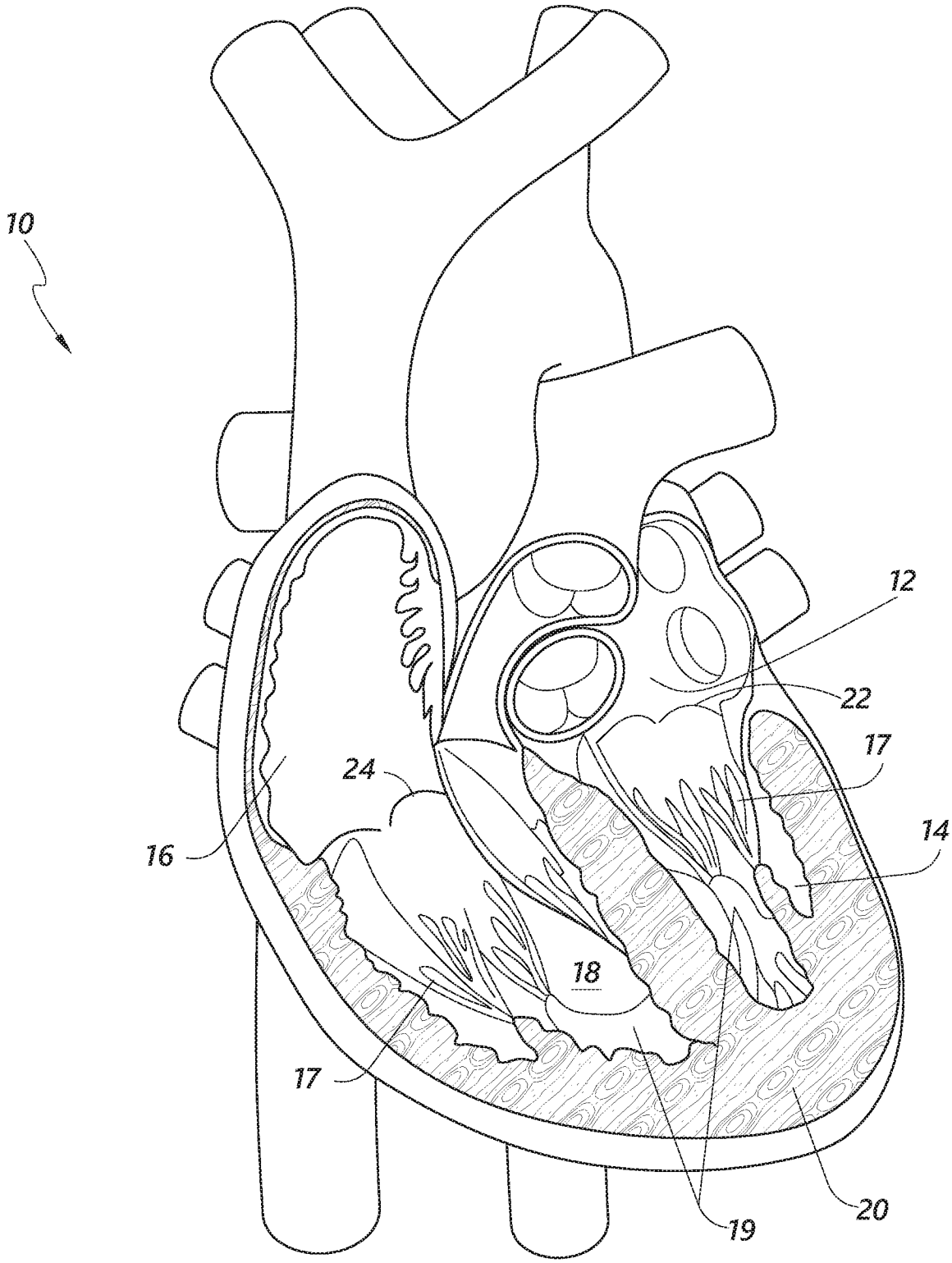


FIG. 1

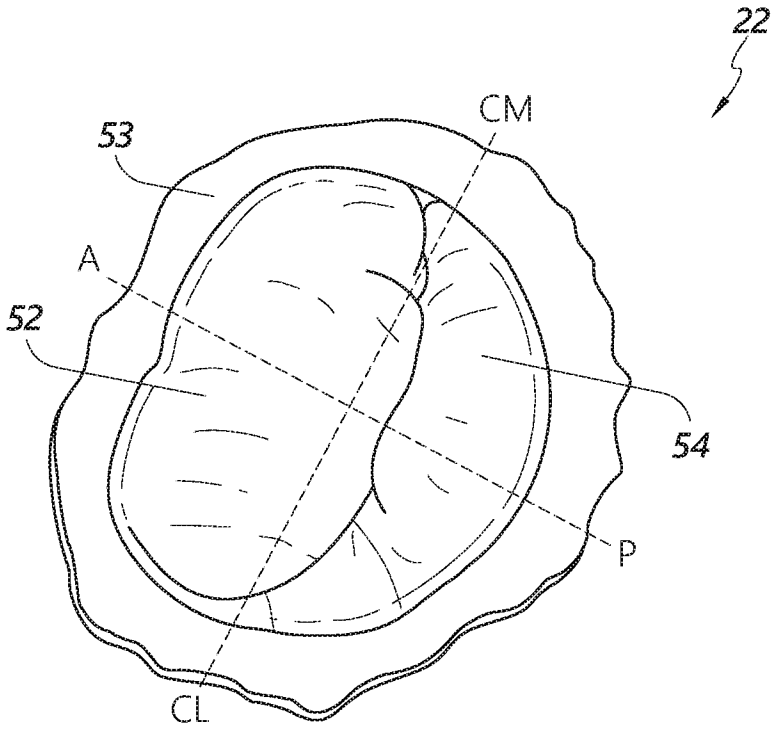


FIG. 2

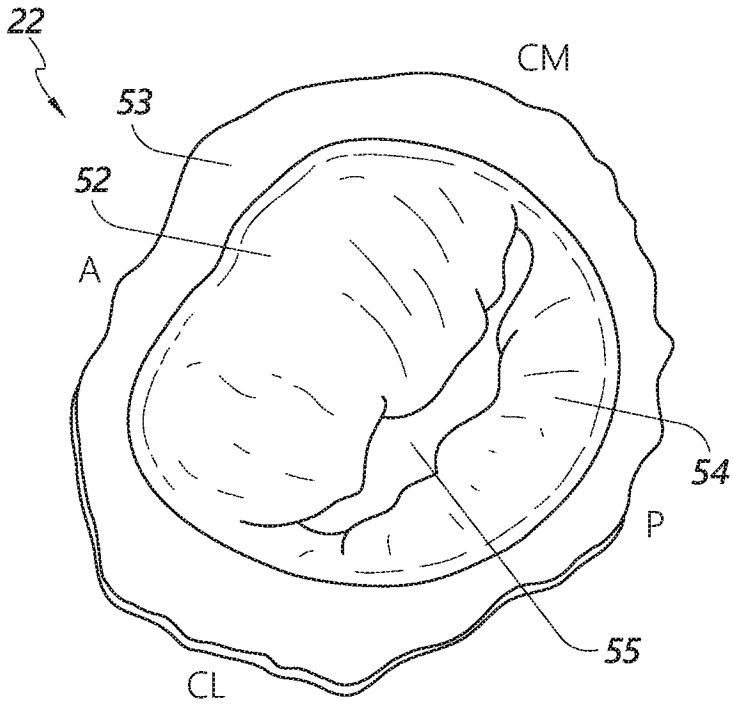


FIG. 3

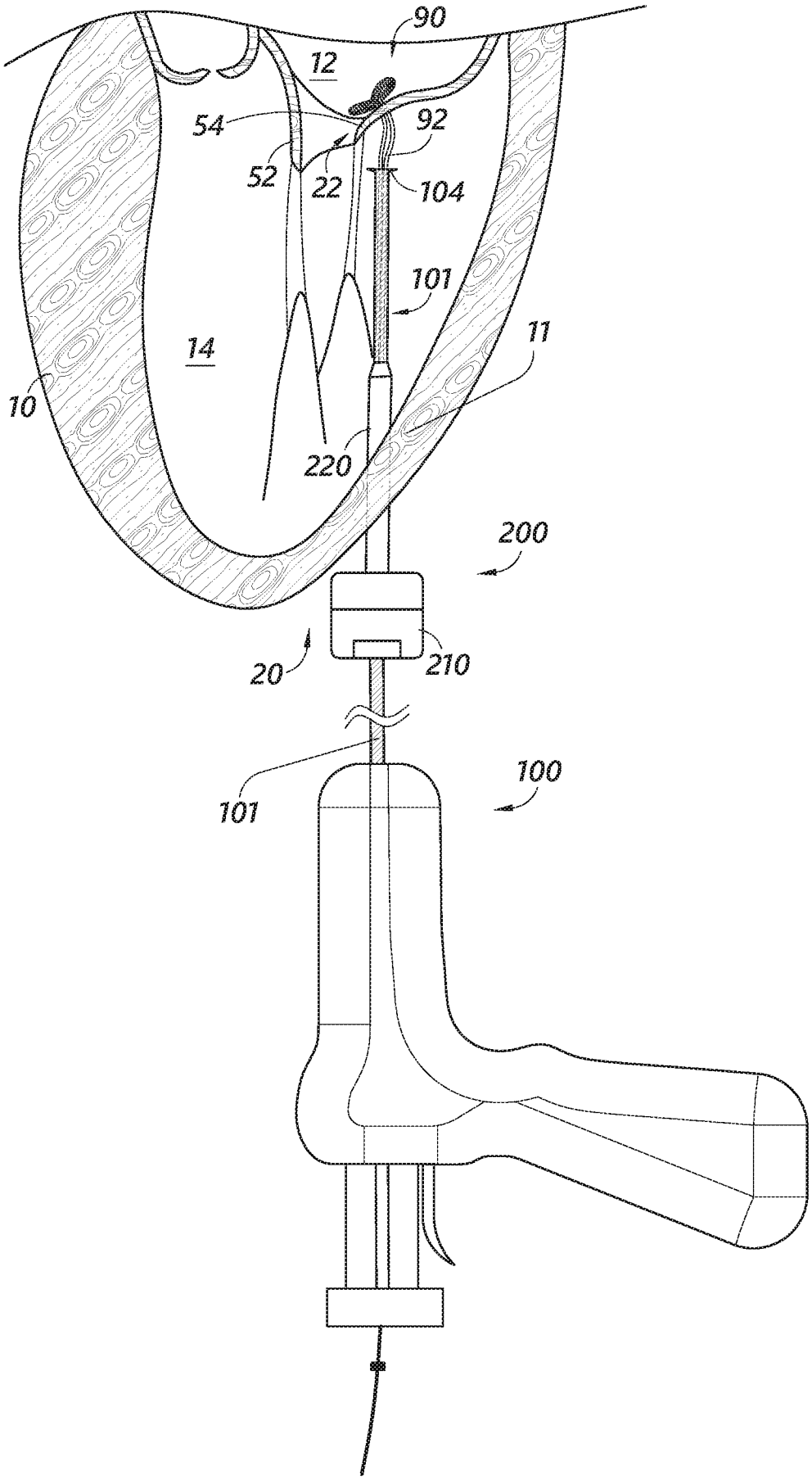


FIG. 4

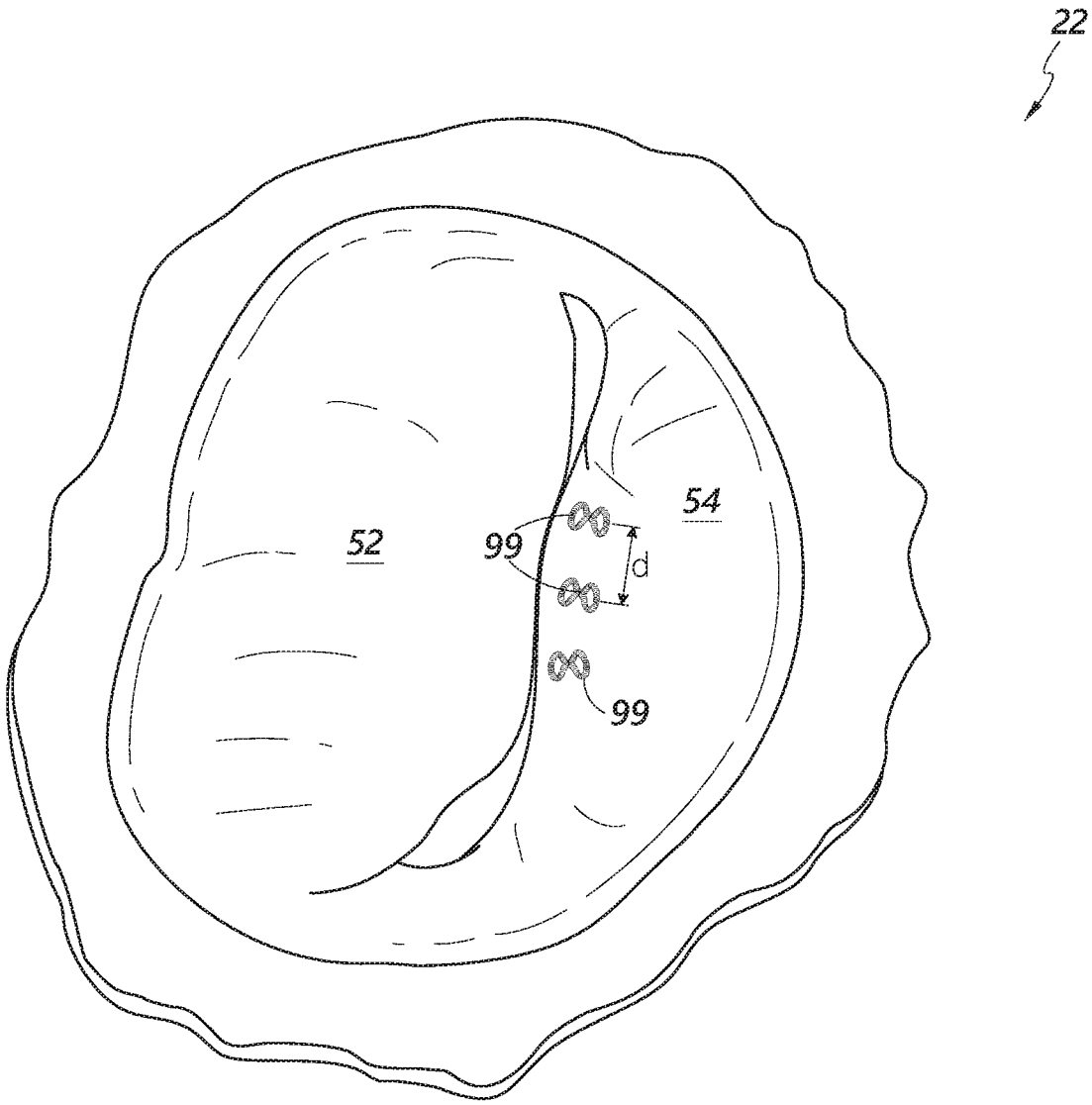


FIG. 5

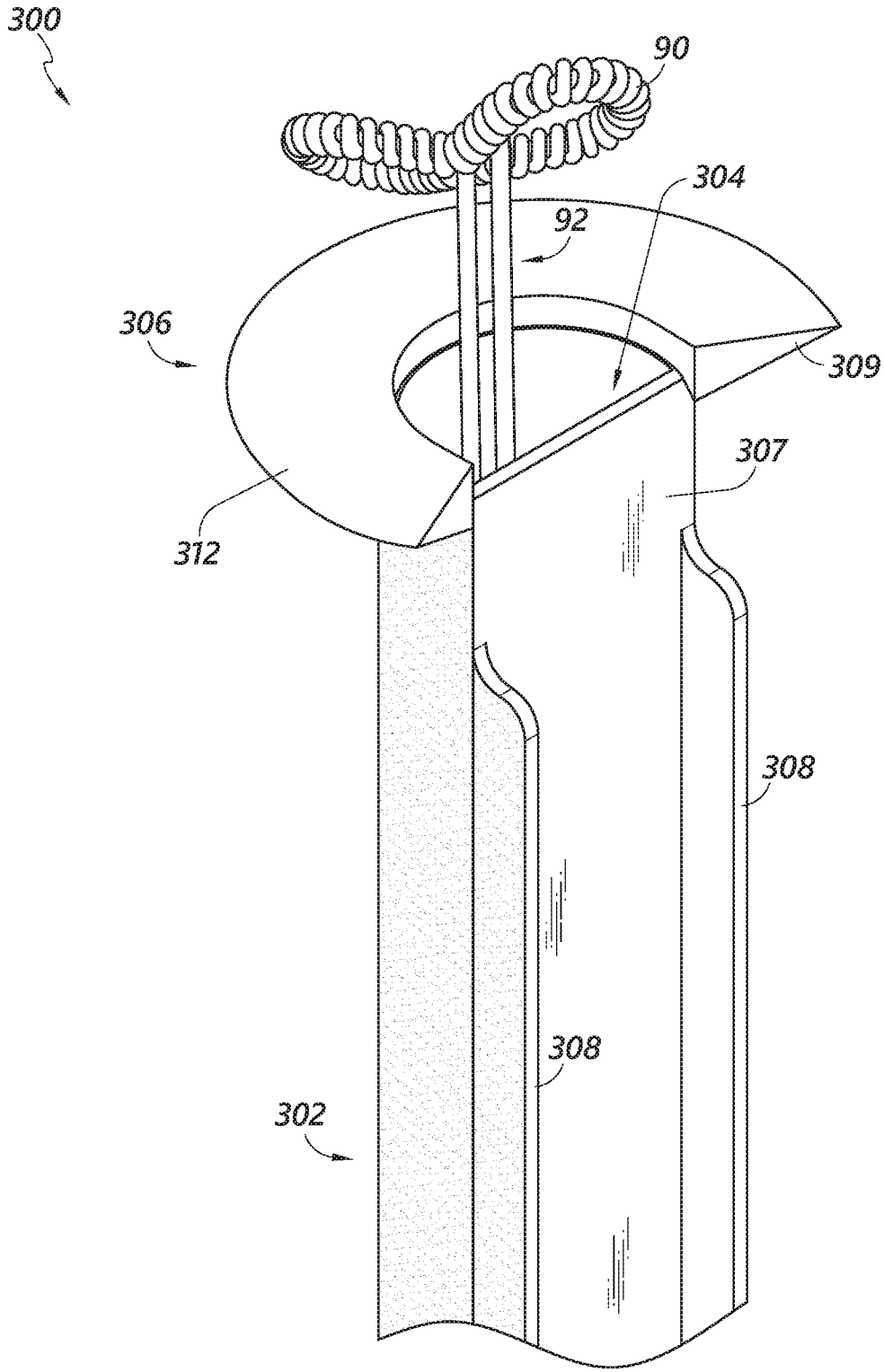


FIG. 6

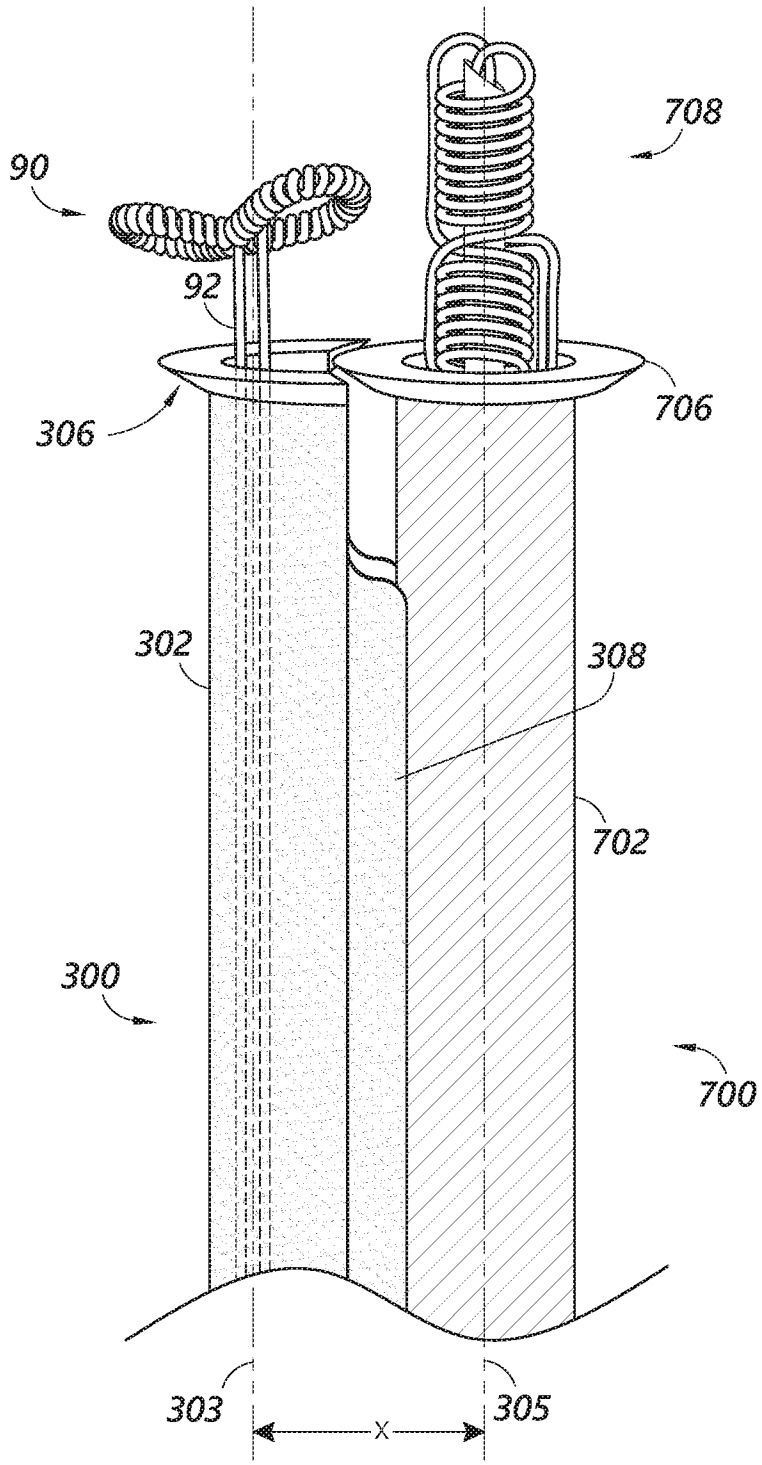


FIG. 7

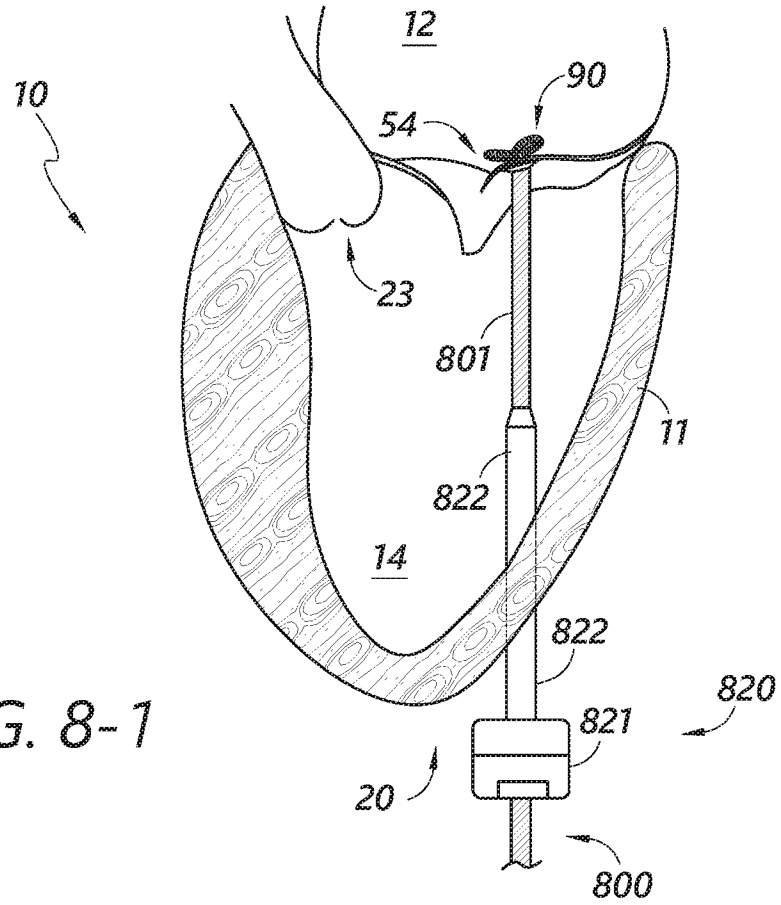


FIG. 8-1

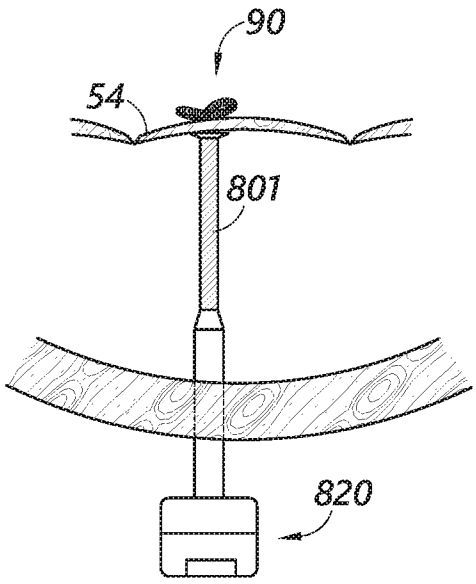


FIG. 8-2

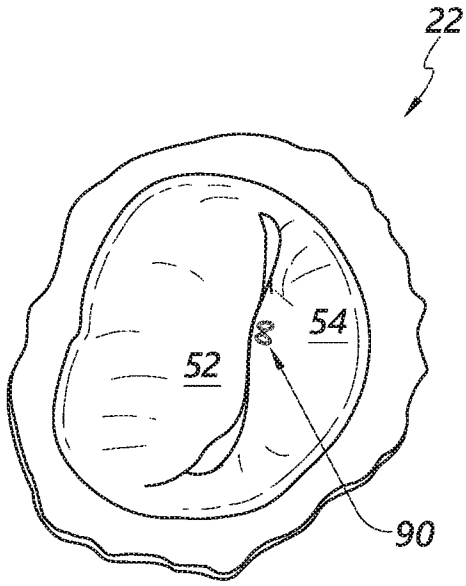


FIG. 8-3

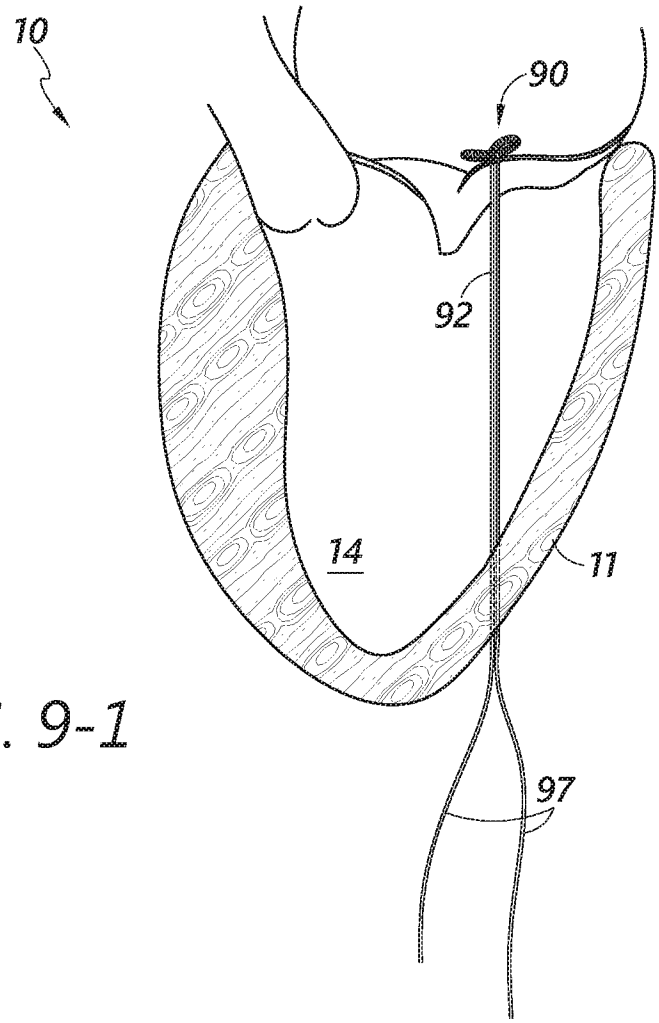
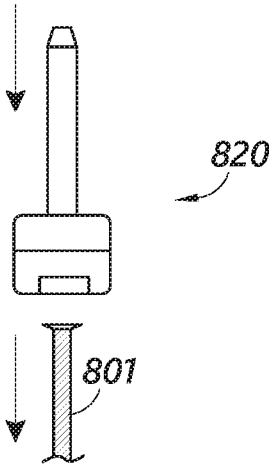


FIG. 9-1



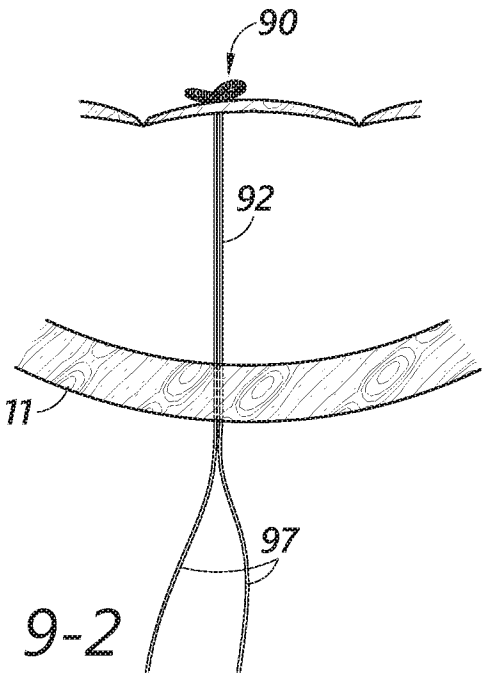


FIG. 9-2

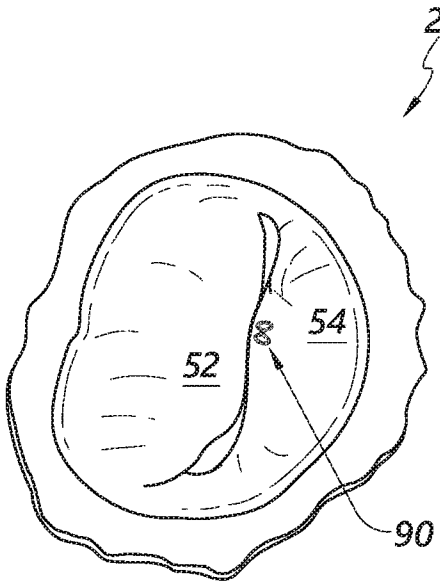


FIG. 9-3

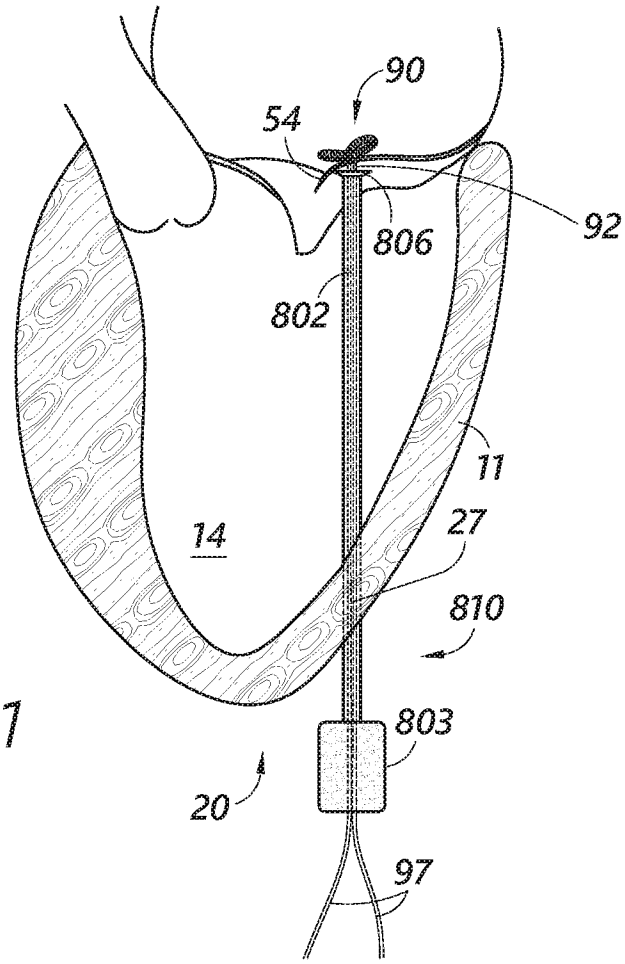


FIG. 10-1

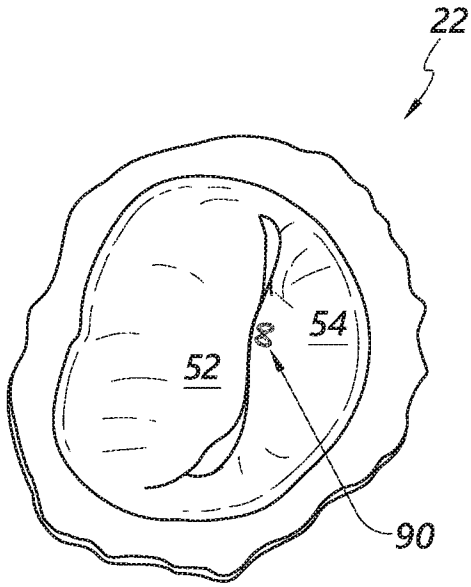


FIG. 10-3

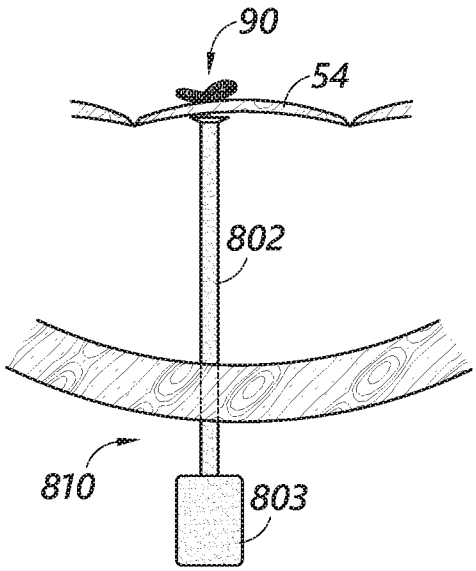


FIG. 10-2

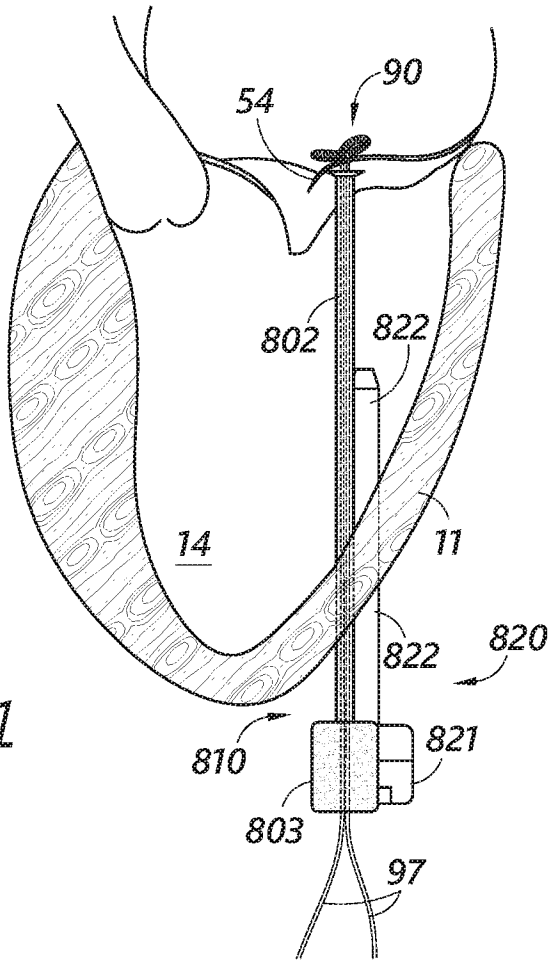


FIG. 11-1

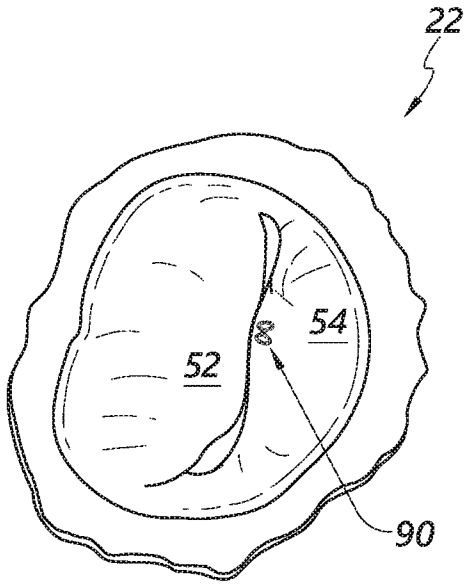


FIG. 11-3

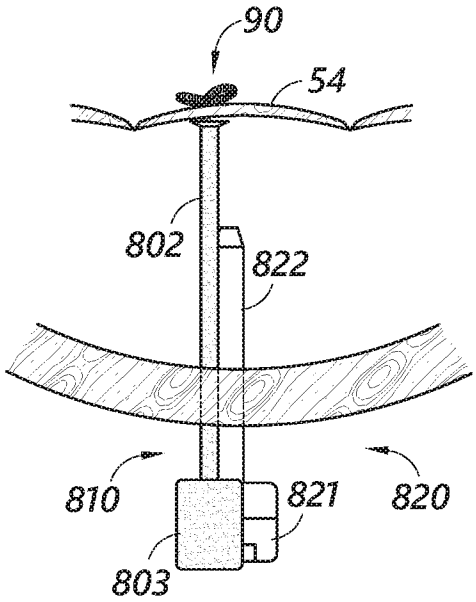


FIG. 11-2

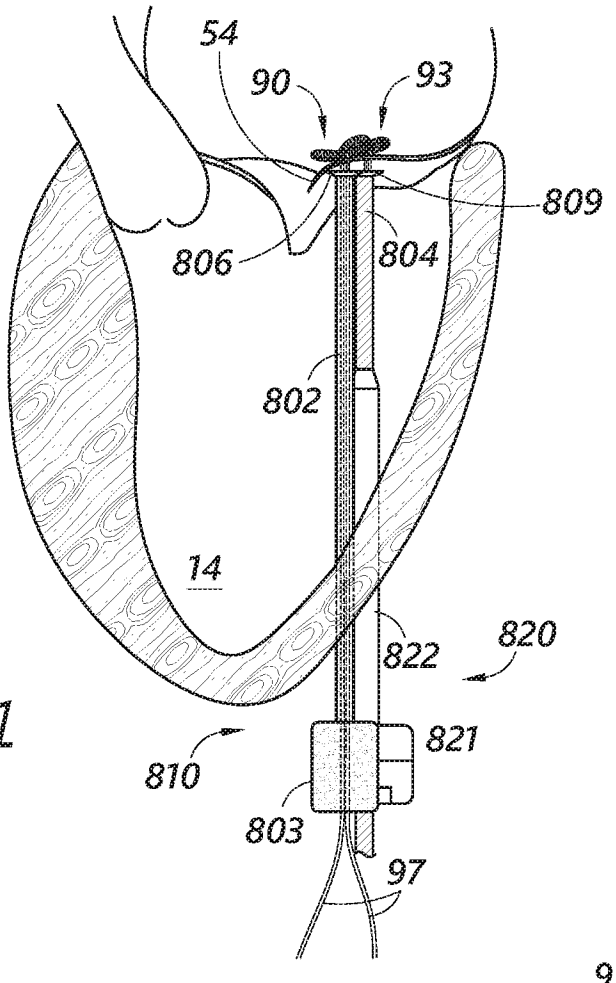


FIG. 12-1

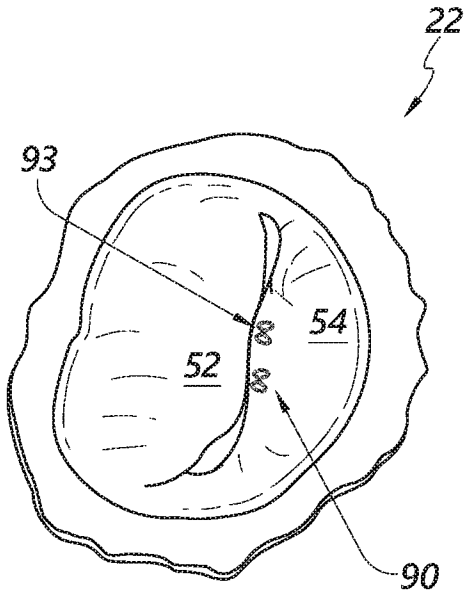


FIG. 12-3

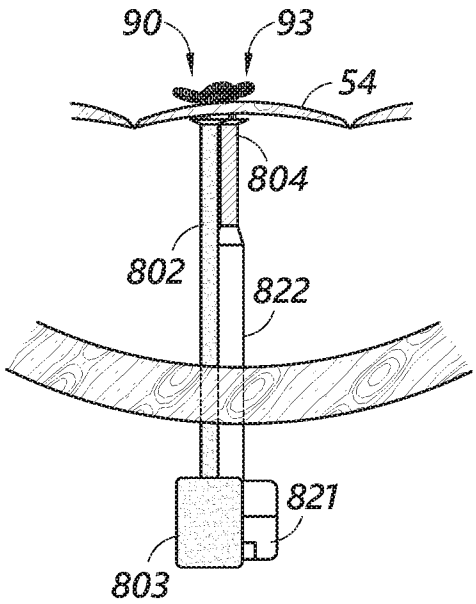


FIG. 12-2

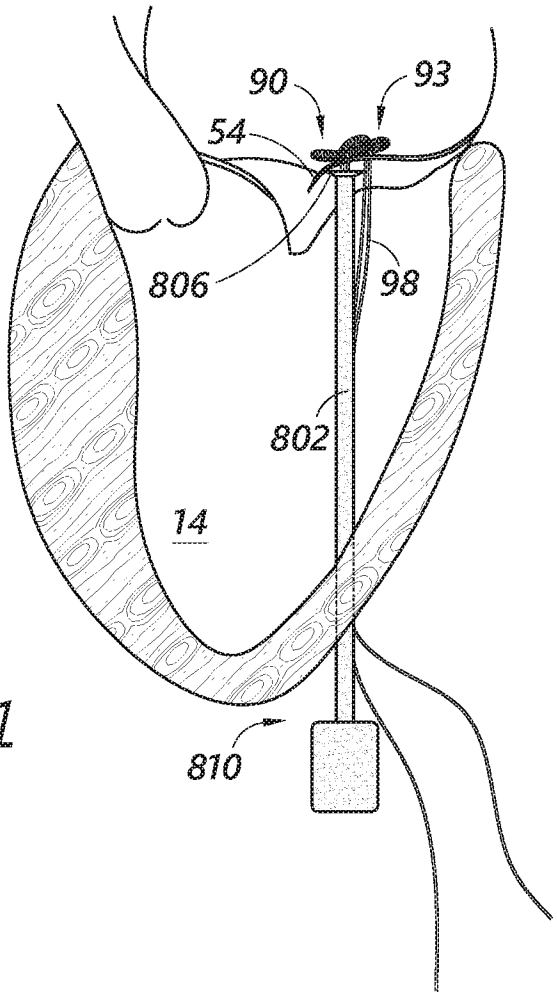
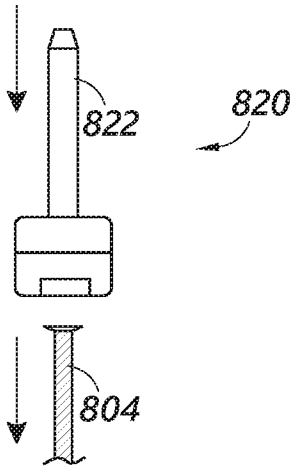


FIG. 13-1



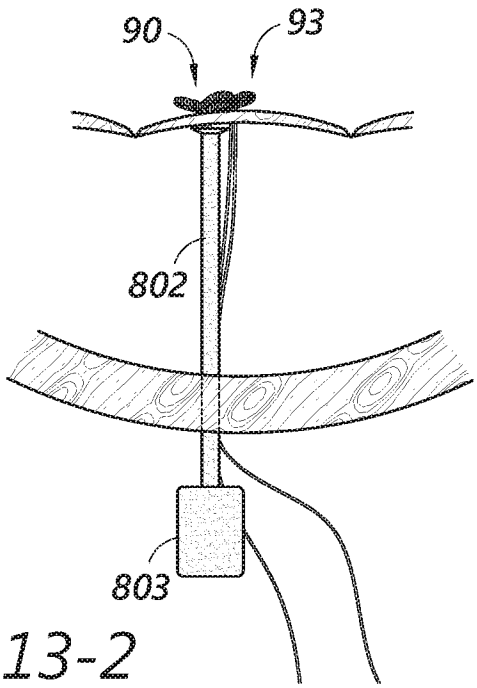


FIG. 13-2

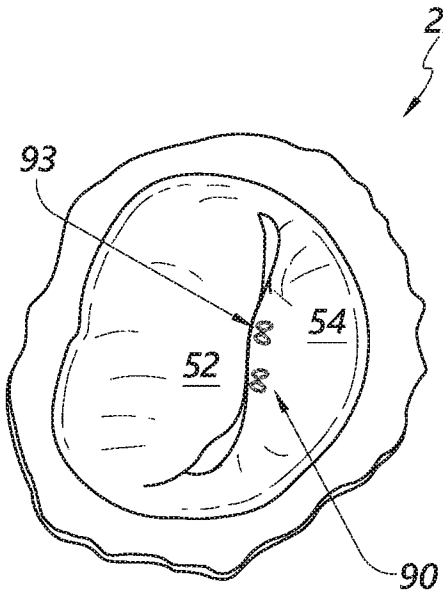


FIG. 13-3

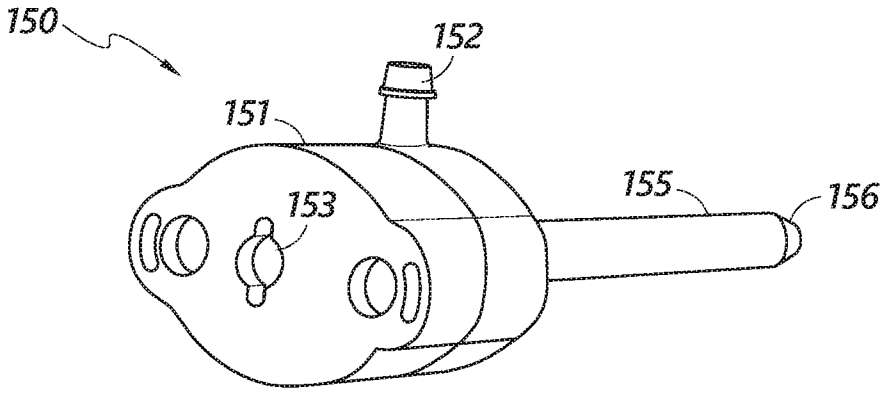


FIG. 14

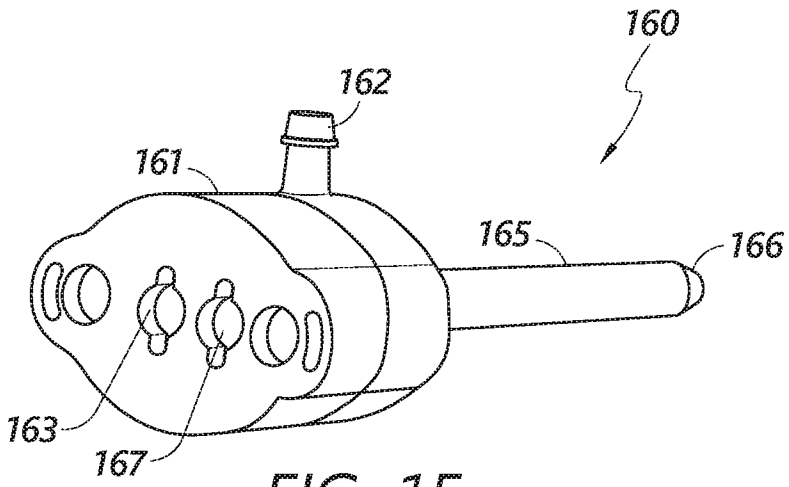


FIG. 15

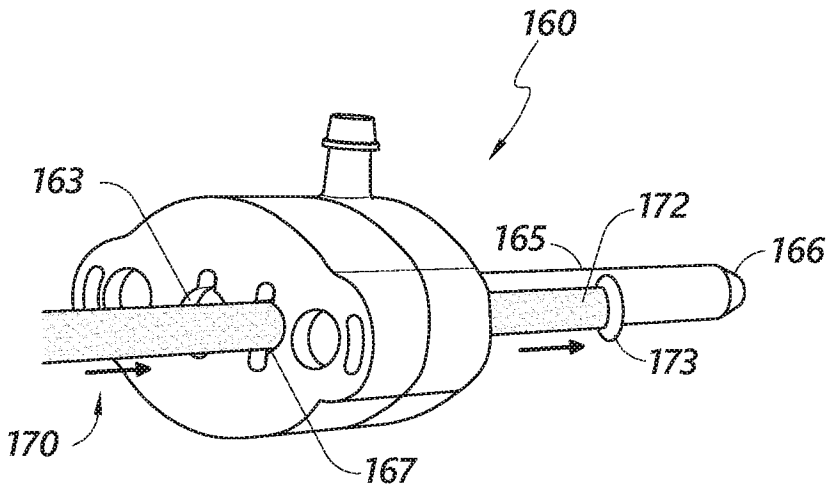


FIG. 16

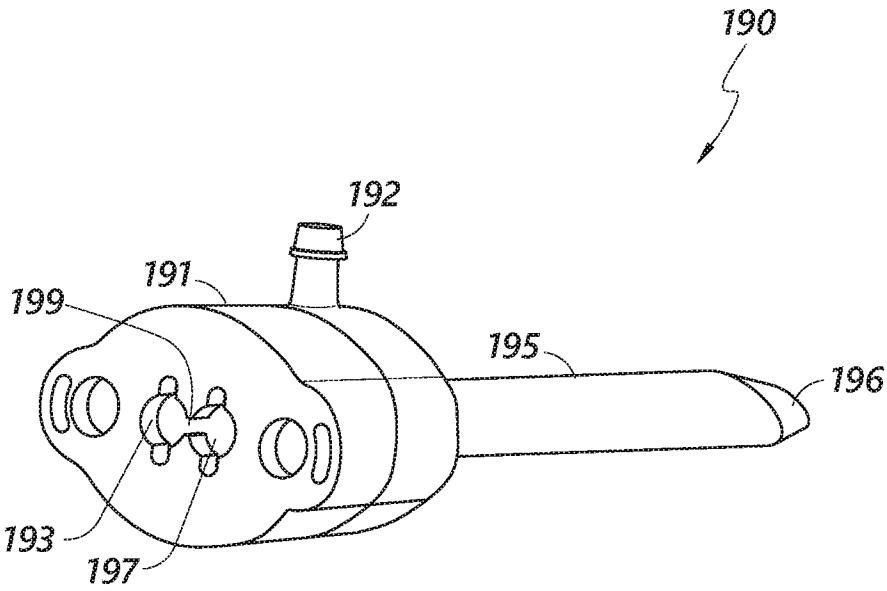


FIG. 17

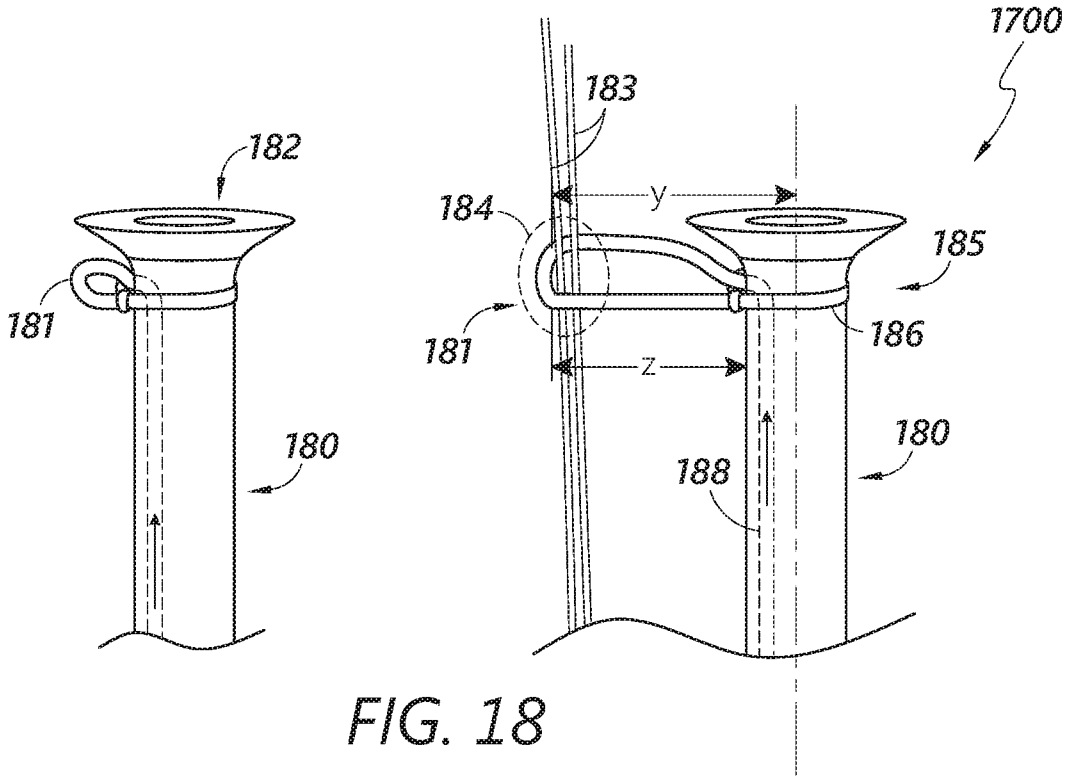
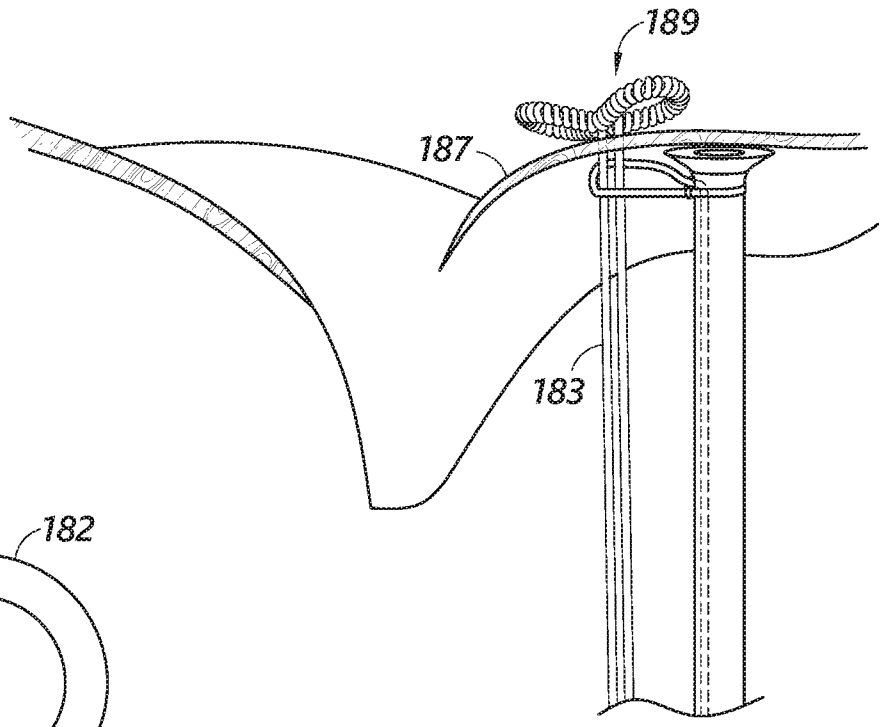


FIG. 18



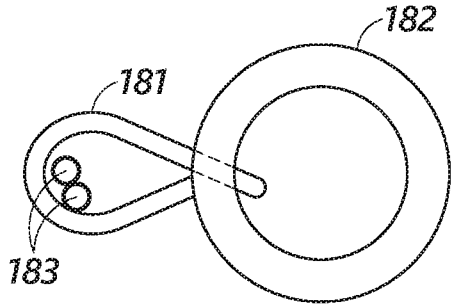


FIG. 19

FIG. 20