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(54) SYSTEMS AND METHODS FOR SEPARATING NATIVE HEART VALVE LEAFLETS ATTACHED TOGETHER BY A FIXATION DEVICE

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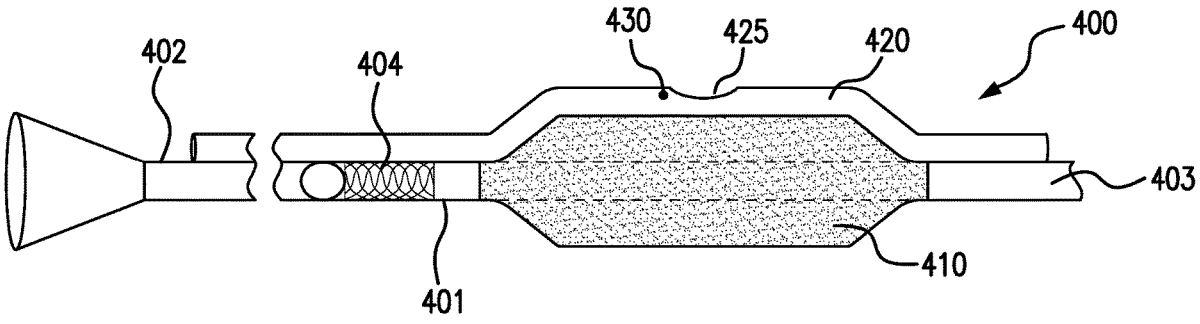
(52) **U.S. Cl.**

CPC ***A61B 17/32002*** (2013.01); ***A61F 2/2454*** (2013.01); ***A61M 29/02*** (2013.01); *A61B 2017/00358* (2013.01)

(57) **ABSTRACT**

Systems and methods for separating native heart valve leaflets attached together by a fixation device. The system has elongate shaft including a proximal end portion, a distal end portion and a longitudinal axis extending therebetween. The elongate shaft is configured for transvascular delivery of the distal end portion to a native heart valve. A balloon is disposed at the distal end portion of the elongate shaft, and the balloon is inflatable from a collapsed condition to an inflated condition. At least one snare lumen extends along at least a portion of the balloon, the at least one snare lumen having an exit port defined therein. A snare is deployable through the exit port from a delivery position within the at least one snare lumen to an extended position extending beyond the exit port. The snare in the extended position is configured to capture the fixation device.



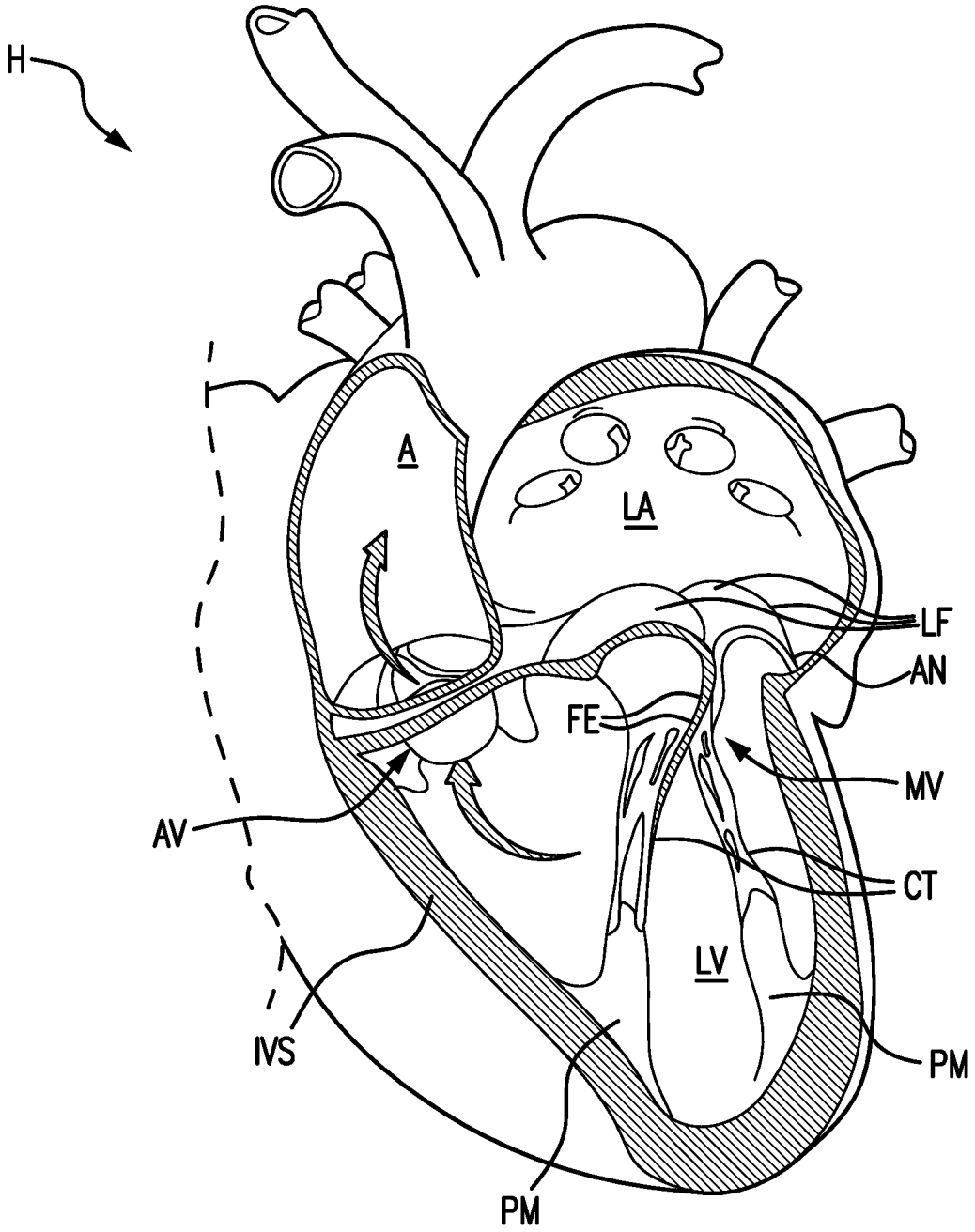


FIG. 1

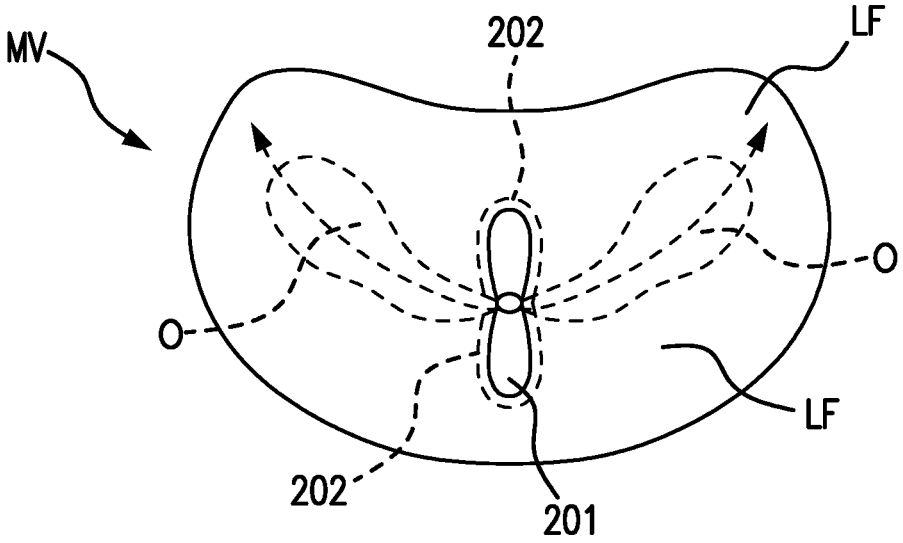


FIG. 2

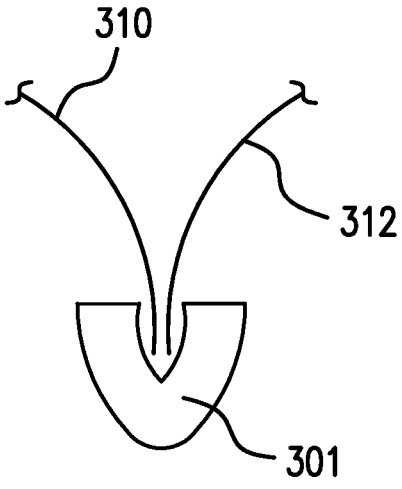


FIG. 3A

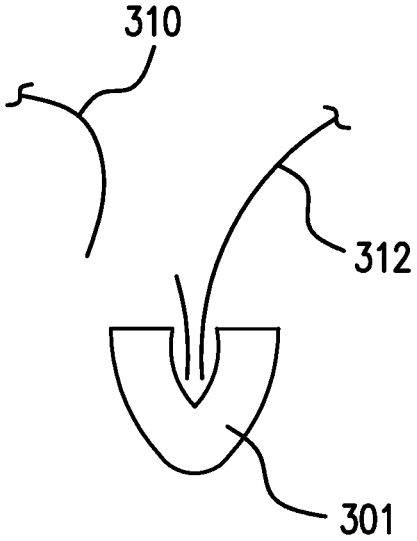


FIG. 3B

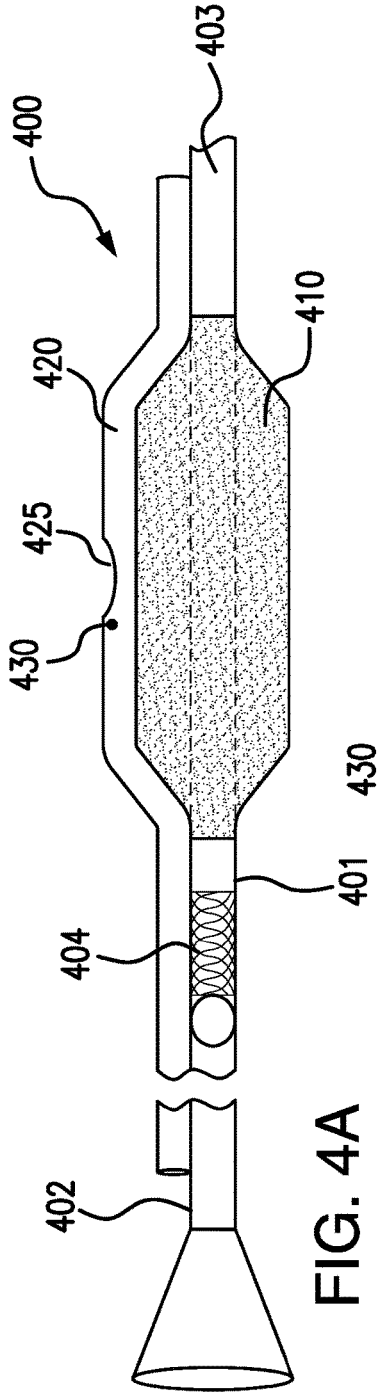


FIG. 4A

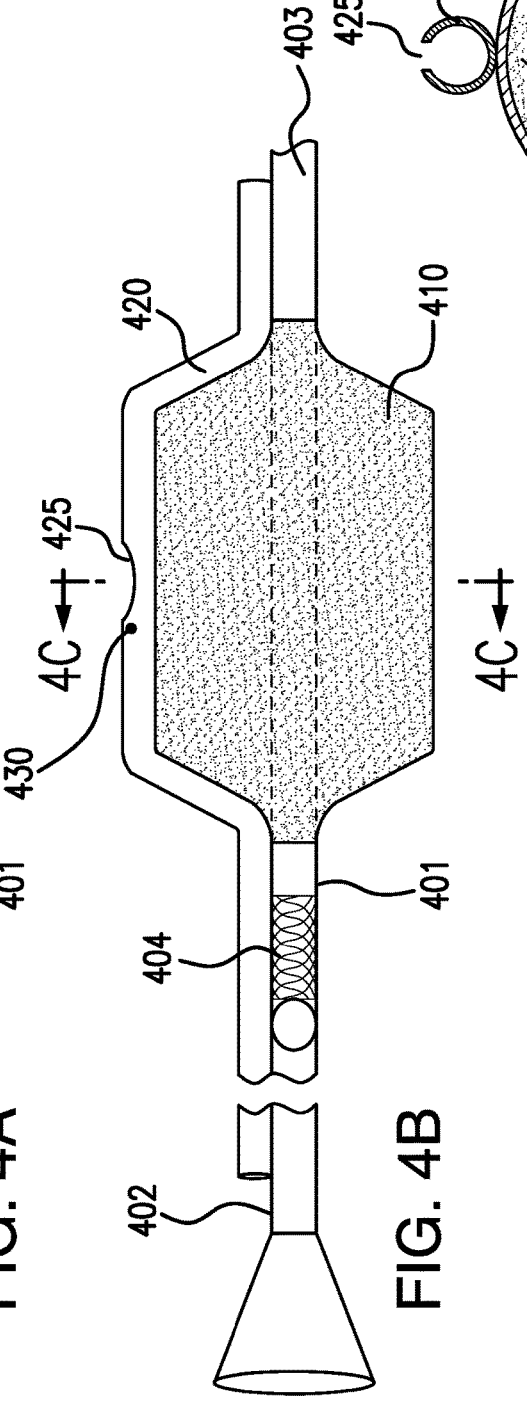


FIG. 4B

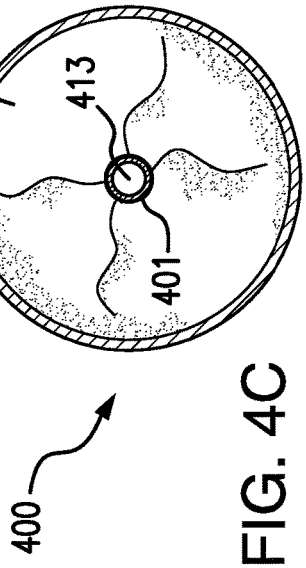


FIG. 4C

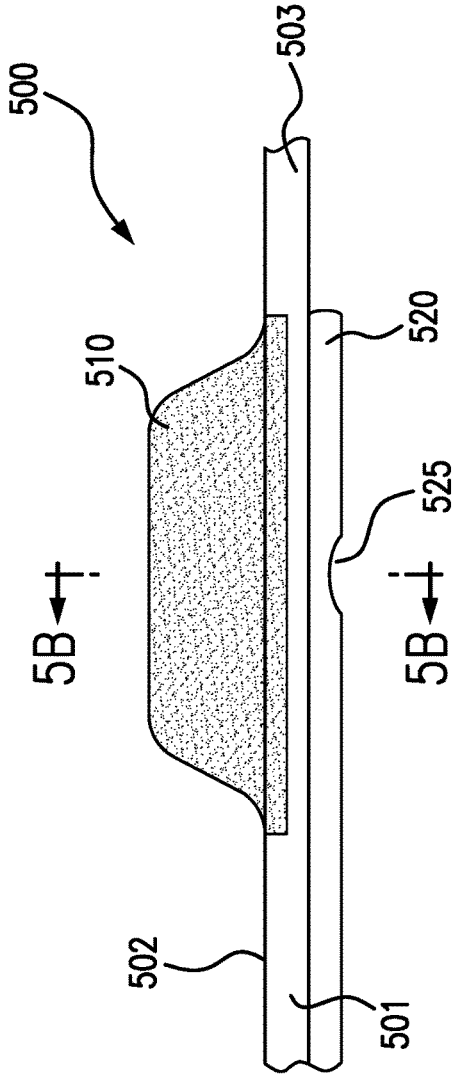


FIG. 5A

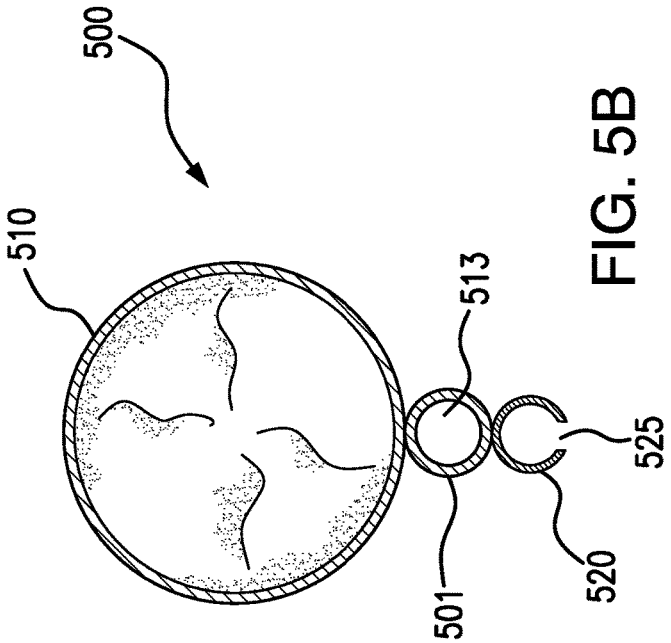


FIG. 5B

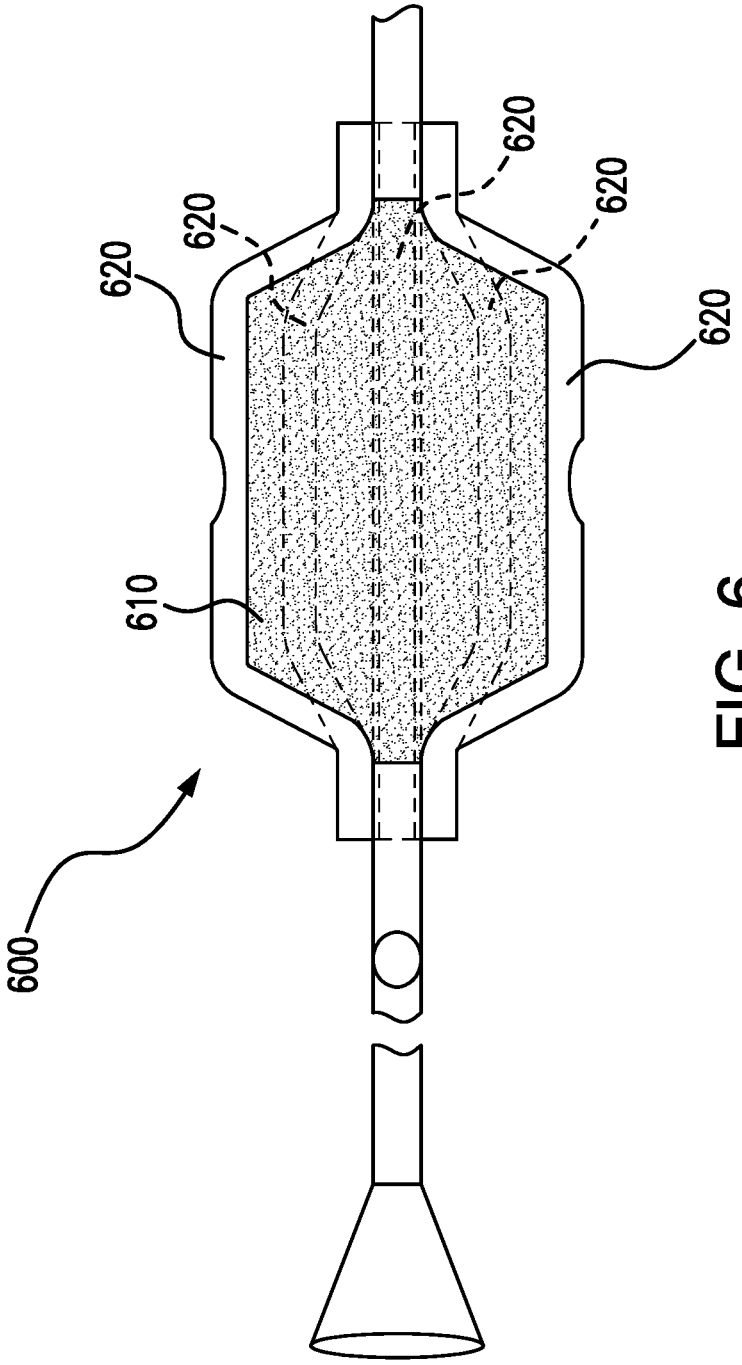


FIG. 6

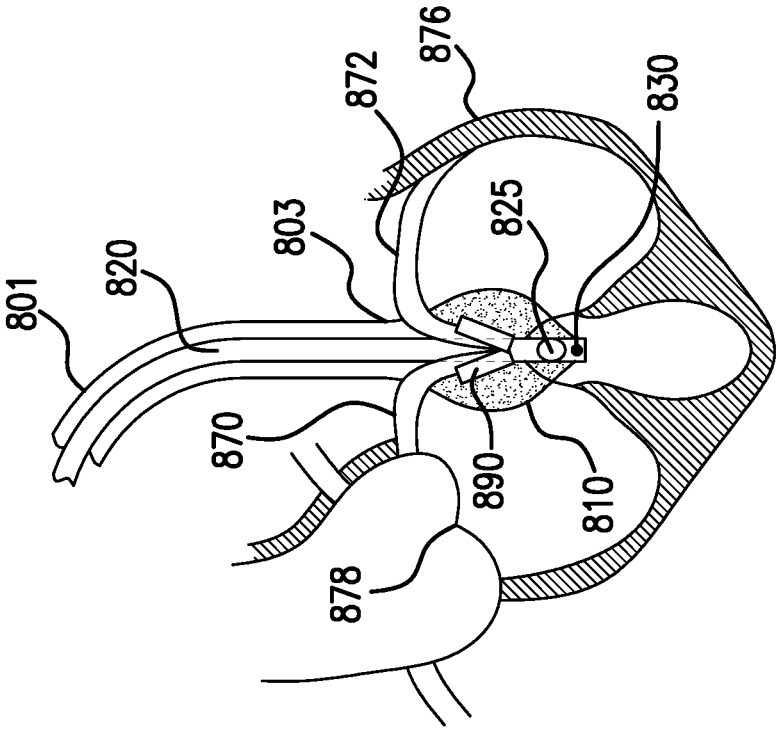

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FIG. 7B

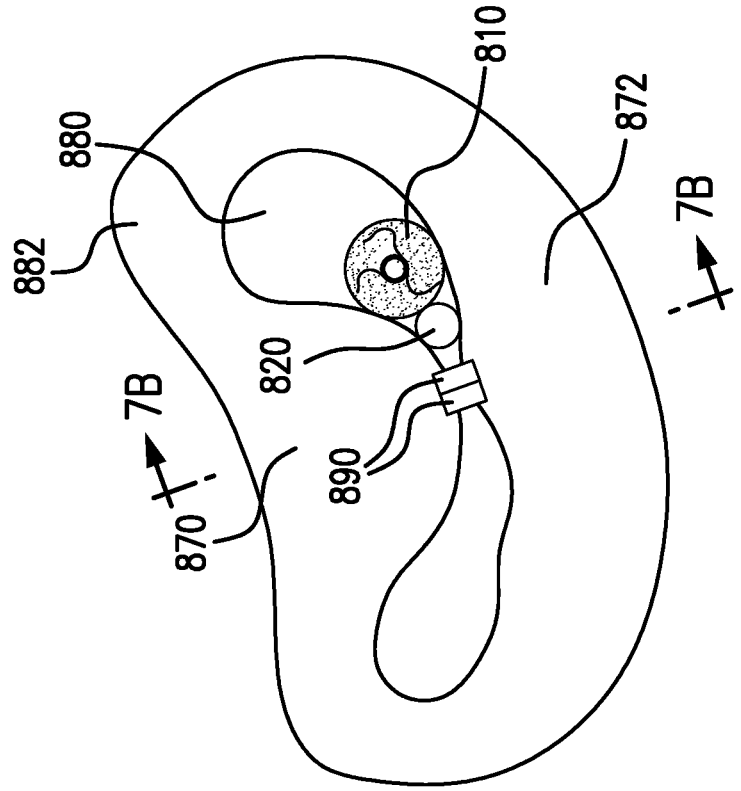
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FIG. 7A

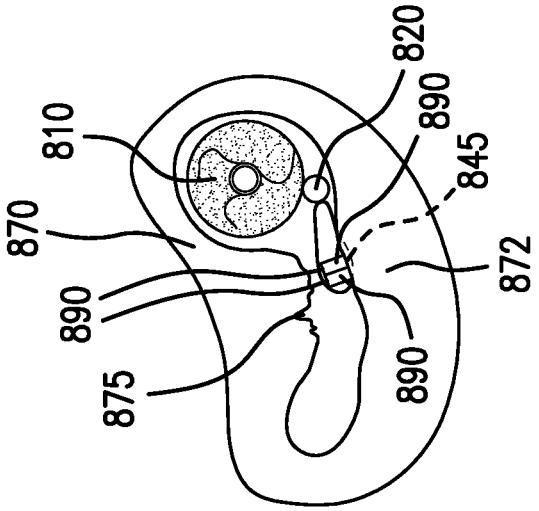

FIG. 8C

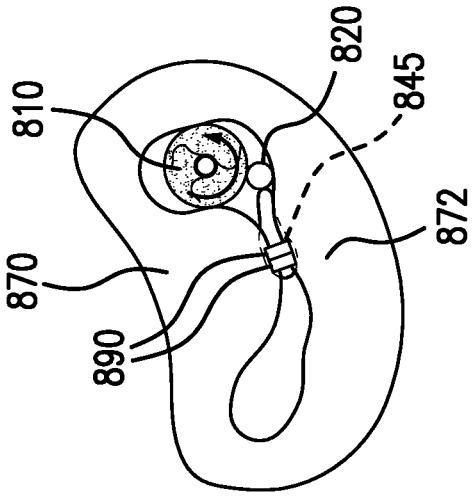

FIG. 8B

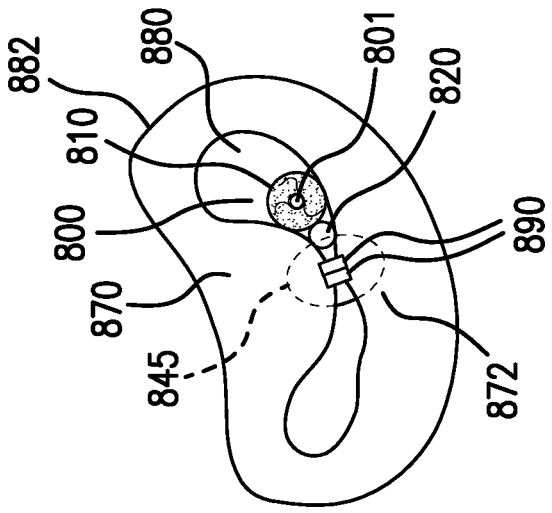

FIG. 8A

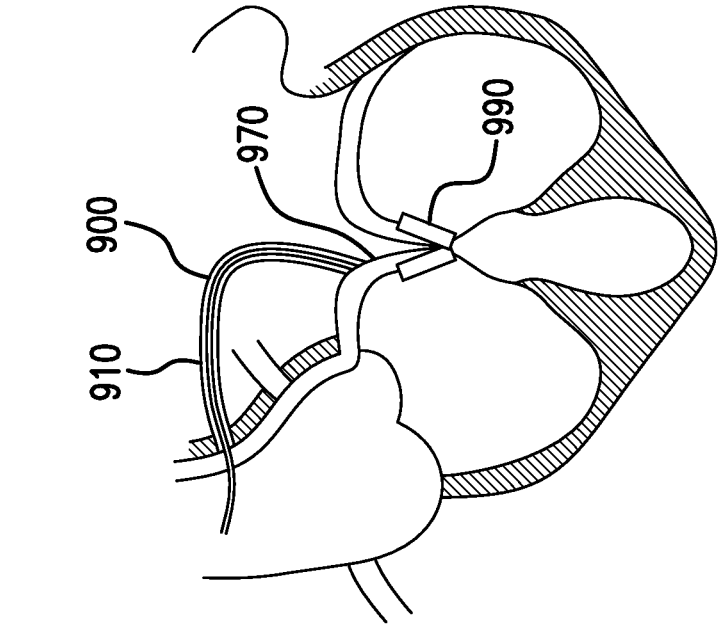

FIG. 9B

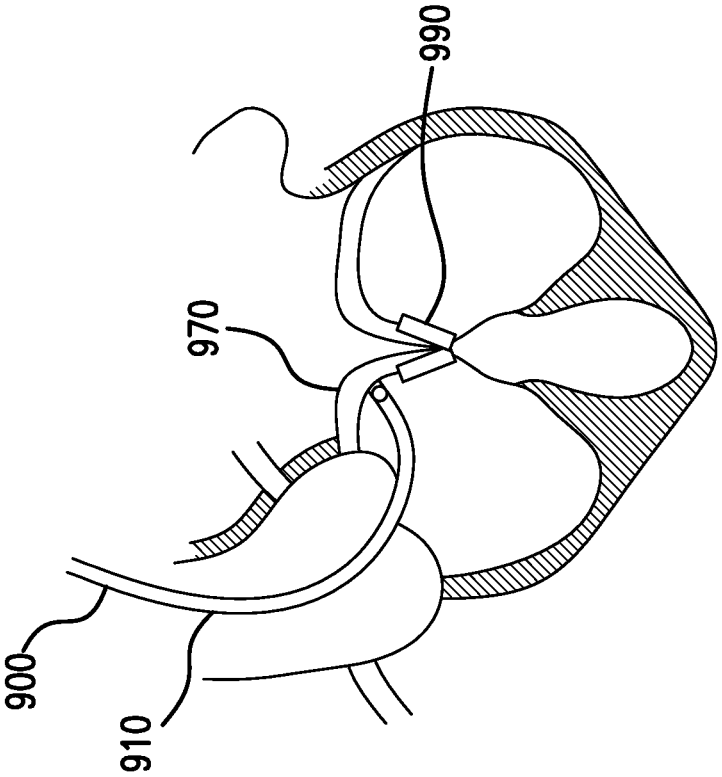

FIG. 9A

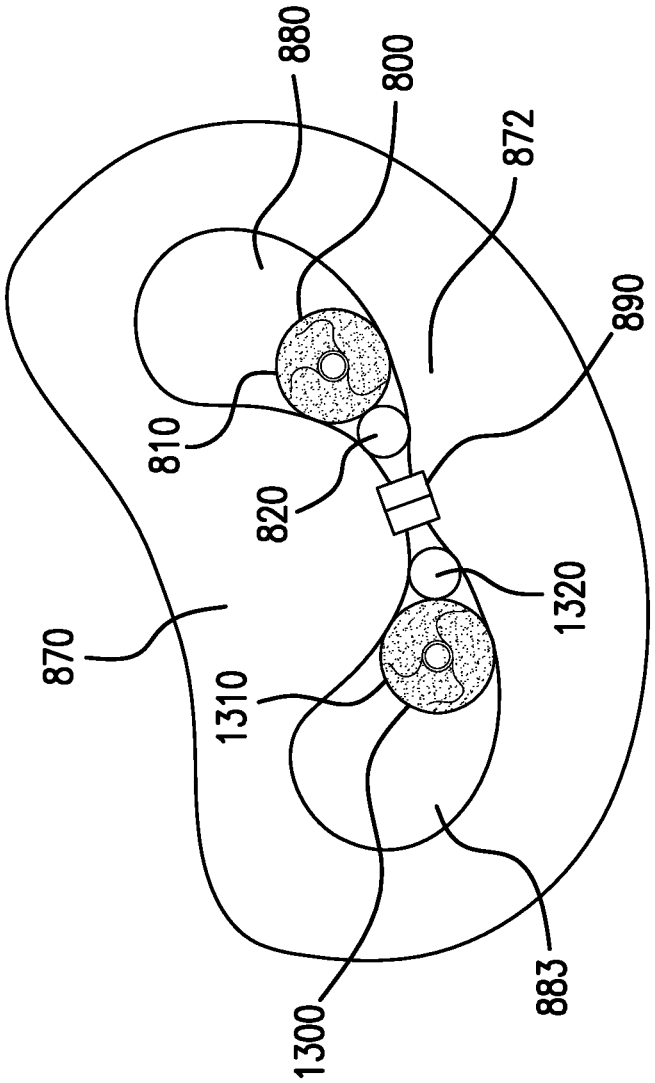

FIG. 10

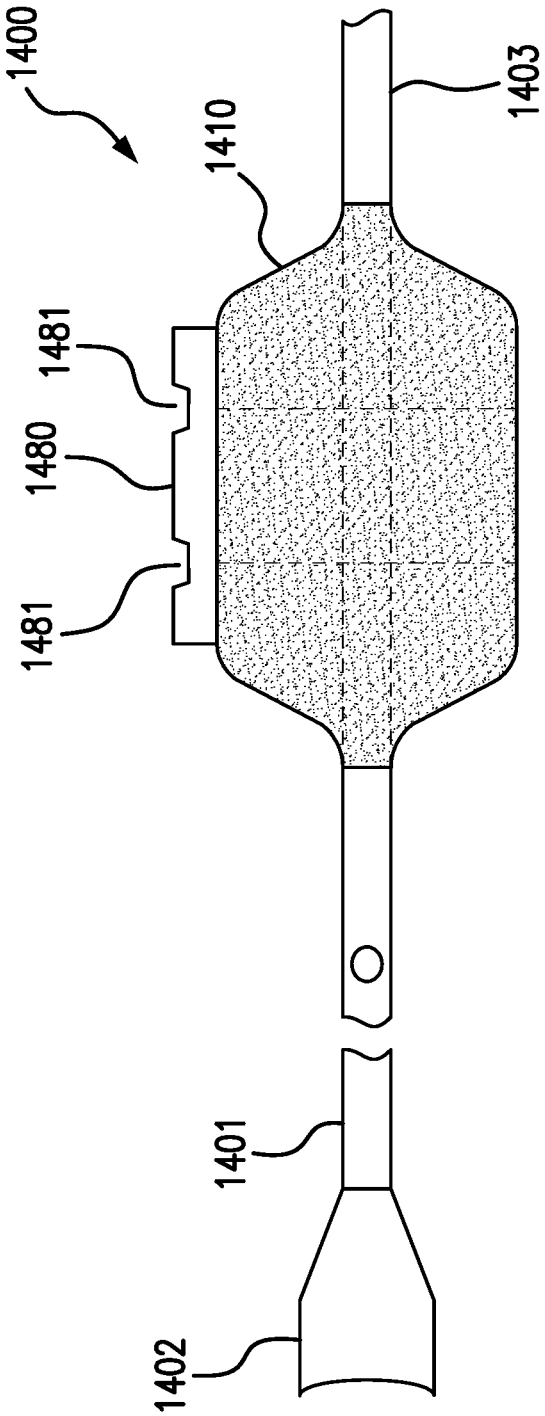

FIG. 11

SYSTEMS AND METHODS FOR SEPARATING NATIVE HEART VALVE LEAFLETS ATTACHED TOGETHER BY A FIXATION DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority under 35 U.S.C. § 119(e) to U.S. Provisional Application No. 63/188,614 filed May 14, 2021, the disclosures of which are hereby expressly incorporated by reference in their entirety.

BACKGROUND

[0002] Mitral valve regurgitation is characterized by retrograde flow from the left ventricle of a heart through an incompetent mitral valve into the left atrium. During a normal cycle of heart contraction (systole), the mitral valve acts as a check valve to prevent flow of oxygenated blood back into the left atrium. In this way, the oxygenated blood is pumped into the aorta through the aortic valve. Regurgitation of the valve can significantly decrease the pumping efficiency of the heart, placing the patient at risk of severe, progressive heart failure.

[0003] Mitral valve regurgitation can result from a number of different mechanical defects in the mitral valve or the left ventricular wall. The valve leaflets, the valve chordae which connect the leaflets to the papillary muscles, the papillary muscles themselves or the left ventricular wall may be damaged or otherwise dysfunctional. Commonly, the valve annulus can be damaged, dilated, or weakened, limiting the ability of the mitral valve to close adequately against the high pressures of the left ventricle.

[0004] The most common treatments for mitral valve regurgitation rely on valve replacement or repair including leaflet and annulus remodeling, the latter generally referred to as valve annuloplasty. One technique for mitral valve repair which relies on suturing adjacent segments of the opposed valve leaflets together is referred to as the "bow-tie" or "edge-to-edge" technique. While all these techniques can be effective, they often rely on open heart surgery where the patient's chest is opened, frequently via a sternotomy, with the patient placed on cardiopulmonary bypass. The need to both open the chest and place the patient on bypass can be traumatic.

[0005] In some patients, a fixation device can be installed into the heart using minimally invasive techniques. The fixation device can hold the adjacent segments of the opposed valve leaflets together and may reduce mitral valve regurgitation. One such device used to clip the anterior and posterior leaflets of the mitral valve together is the MitraClip® fixation device, sold by Abbott Vascular, Santa Clara, Calif., USA.

[0006] Sometimes after a fixation device is installed mitral valve regurgitation can still exist, or can arise again. Further, other problems with the heart may arise that can make it desirable for the fixation device to be disabled or removed. For example, it can be desirable to remove the fixation device to allow for implantation of a replacement heart valve. For at least these reasons, it is desirable to provide systems and methods for removing or disabling fixation devices that are already installed.

SUMMARY

[0007] The purpose and advantages of the disclosed subject matter will be set forth in and apparent from the description that follows, as well as will be learned by practice of the disclosed subject matter. For purpose of illustration and not limitation, the various embodiments described herein relate to systems and methods for separating native heart valve leaflets attached together by a fixation device. Additional advantages of the disclosed subject matter will be realized and attained by the systems and methods particularly pointed out in the written description and claims hereof, as well as from the appended drawings.

[0008] To achieve these and other advantages, and in accordance with the purpose of the disclosed subject matter, as embodied and broadly described, the disclosed subject matter includes systems for separating native heart valve leaflets attached together by a fixation device. Systems in accordance with the disclosed subject matter include an elongate shaft including a proximal end portion, a distal end portion and a longitudinal axis extending therebetween. The elongate shaft is configured for transvascular delivery of the distal end portion to a native heart valve. A balloon is disposed at the distal end portion of the elongate shaft, and the balloon is inflatable from a collapsed condition to an inflated condition. At least one snare lumen extends along at least a portion of the balloon, the at least one snare lumen having an exit port defined therein. A snare is deployable through the exit port from a delivery position within the at least one snare lumen to an extended position extending beyond the exit port. The snare in the extended position is configured to capture the fixation device.

[0009] For purpose of example, the elongate shaft can include a braided reinforcement. Additionally or alternatively, the elongate shaft can include a hypotube. Additionally or alternatively, the elongate shaft can include at least one of stainless steel, nitinol, mp35, polyimide, pebax, and braid reinforced polyimide. Additionally or alternatively, the elongate shaft can be configured to transmit torque along the longitudinal axis and the exit port of the at least one snare lumen can be moved circumferentially about the longitudinal axis by rotation of the proximal end portion.

[0010] For purpose of example and not limitation, the balloon can be rotatable about the longitudinal axis of the elongate shaft to move the exit port of the at least one snare lumen circumferentially about the longitudinal axis. Additionally or alternatively, the balloon can be configured to unfold upon inflation from the collapsed condition to the inflated condition.

[0011] For purpose of example and not limitation, the at least one snare lumen can extend along an exterior of the balloon and can be bonded to a portion of the balloon. Additionally or alternatively, a segment of the at least one snare lumen can be attached to at least one of the elongate shaft and the balloon, and the at least one snare lumen can extend along an exterior of the balloon and can be movable relative the exterior of the balloon as the balloon inflates from the collapsed condition to the inflated condition to accommodate an increased circumference of the balloon. Additionally or alternatively, the at least one snare lumen can be defined within a wall of the balloon. Additionally or alternatively, the at least one snare lumen can be configured to increase in length axially as the balloon inflates from the collapsed condition to the inflated condition to accommodate an increased circumference of the balloon. Additionally

or alternatively, the at least one snare lumen can include between one and four snare lumens spaced about an outer circumference of the balloon.

[0012] For example and not limitation, the exit port can be disposed at an intermediate location along a length of the balloon.

[0013] For example and not limitation, least one of the balloon and the at least one snare lumen can include a radiopaque marker proximate the exit port.

[0014] For example and not limitation, a guidewire lumen can extend along at least a length of the elongate shaft.

[0015] For example and not limitation, the balloon can be concentric with the longitudinal axis of the elongate shaft. Additionally or alternatively, the balloon can be acentric with the longitudinal axis of the elongate shaft.

[0016] For example and not limitation, the balloon can have an inflation diameter in the inflated condition and the inflation diameter can be larger than a maximum cross dimension of an orifice defined between the native heart valve leaflets to be separated.

[0017] For example and not limitation, at least one cutter can be disposed along at least a portion of the balloon. For example and not limitation, the at least one cutter can be disposed between about 30 degrees and 180 degrees about an outer circumference of the balloon from the at least one snare lumen.

[0018] The disclosed subject matter further includes methods for separating native heart valve leaflets attached together by a fixation device. Methods in accordance with the disclosed subject matter include delivering a distal end portion of a system for separating native heart valve leaflets attached together by a fixation device as described above to a native heart valve. Methods in accordance with the disclosed subject matter further include deploying a snare from a delivery position within the at least one snare lumen to an extended position extending beyond the exit port. Methods in accordance with the disclosed subject matter further include capturing the fixation device within the snare with the snare in the extended position, and inflating the balloon from a collapsed condition to an inflated condition to separate the native heart valve leaflets.

[0019] For example and not limitation, delivering the distal end portion can include positioning the balloon through an orifice defined between the native heart valve leaflets. For example and not limitation, the distal end can be delivered transapically. Additionally or alternatively, the distal end can be delivered transeptally.

[0020] For example and not limitation, deploying the snare can include rotating the balloon about the longitudinal axis of the elongate shaft to align the exit port towards the fixation device.

[0021] For example and not limitation, the native heart valve can be a mitral valve. Additionally or alternatively, delivering the distal end portion can include positioning the balloon through a lateral orifice defined between the native mitral valve leaflets. Additionally or alternatively, methods can include rotating the balloon about the longitudinal axis of the elongate shaft to align the exit port away from the native mitral valve anterior leaflet after capturing the fixation device. Additionally or alternatively, inflating the balloon can tear the native mitral valve anterior leaflet. Additionally or alternatively, the fixation device can remain attached to the native mitral valve posterior leaflet.

[0022] Additionally or alternatively, methods can include weakening native mitral valve anterior leaflet tissue before inflating the balloon. For example and not limitation, at least one of a needle, blade, RF energy, and hydrogen peroxide can be applied to the native mitral valve anterior leaflet tissue in order to weaken it.

[0023] Additionally or alternatively, the balloon can include a cutter disposed along at least a portion thereof, and methods can include aligning the least one cutter with the native mitral valve anterior leaflet.

[0024] Additionally or alternatively, methods can include positioning a second balloon through a second orifice on an opposing side of the fixation device, and inflating the second balloon.

[0025] The disclosed subject matter further includes kits for treating a native heart valve having leaflets attached together by a fixation device. Kits in accordance with the disclosed subject matter include a system for separating native heart valve leaflets attached together by a fixation device having any of the features described above. Kits in accordance with the disclosed subject matter also include a prosthetic heart valve.

[0026] It is to be understood that both the foregoing general description and the following detailed description are exemplary and are intended to provide further explanation of the disclosed subject matter claimed.

[0027] The accompanying drawings, which are incorporated in and constitute part of this specification, are included to illustrate and provide a further understanding of the systems and methods of the disclosed subject matter. Together with the description, the drawings serve to explain the principles of the disclosed subject matter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0028] FIG. **1** illustrates the left ventricle and left atrium of the heart during systole.

[0029] FIG. **2**. illustrates an exemplary fixation device clipping together the anterior and posterior leaflets of a mitral valve.

[0030] FIG. **3**A illustrates a cross-sectional side view of a mitral valve having a fixation device clipping together the anterior and posterior leaflets of the mitral valve.

[0031] FIG. **3**B illustrates a cross-sectional side view of the mitral valve of FIG. **3**A after separation of the anterior and posterior leaflets with the fixation device remaining clipped to the posterior leaflet.

[0032] FIG. **4**A is a side view of an exemplary system for separating native heart valve leaflets in accordance with the disclosed subject matter with the balloon in the collapsed condition.

[0033] FIG. **4**B is a side view of the exemplary system of FIG. **4**A with the balloon in the inflated condition.

[0034] FIG. **4**C is a cross-sectional view of the exemplary system of FIG. **4**A with the balloon in the inflated condition taken along line **4**C-**4**C, as depicted in FIG. **4**B.

[0035] FIG. **5**A is a side view of another exemplary system for separating native heart valve leaflets in accordance with the disclosed subject matter with the balloon in the inflated condition.

[0036] FIG. **5**B is a cross-sectional view of the exemplary system of FIG. **5**A taken along line **5**B-**5**B, as depicted in FIG. **5**A.

[0037] FIG. **6** is a side view of another exemplary system for separating native heart valve leaflets in accordance with the disclosed subject matter with the balloon in the inflated condition.

[0038] FIG. **7**A is a cross-sectional view of a native mitral valve taken along the native mitral valve annulus looking down from the left atrium. The native mitral valve has fixation devices clipping together the native heart valve leaflets, and an exemplary system for separating native heart valve leaflets in accordance with the disclosed subject matter is positioned within the native mitral valve with the balloon in the collapsed condition.

[0039] FIG. **7**B is a front cross-sectional view of the heart valve and exemplary system of FIG. **7**A taken along line **7**B-**7**B, as depicted in FIG. **7**A.

[0040] FIG. **8**A is the cross-sectional view of the native mitral valve and exemplary system of FIG. **7**A with the snare deployed to capture the fixation devices.

[0041] FIG. **8**B is the cross-sectional view of the native mitral valve and exemplary system of FIG. **7**A with the balloon inflating from the collapsed condition to the inflated condition and the exit port of the at least one snare lumen moving circumferentially about the longitudinal axis of the elongate shaft.

[0042] FIG. **8**C is the cross-sectional view of the native mitral valve and exemplary system of FIG. **7**A with the balloon in the inflated condition and the leaflets of the native mitral valve separated.

[0043] FIG. **9**A is a front cross-sectional view of a native mitral valve and a transaortically delivered device for weakening tissue of the native mitral valve anterior leaflet tissue.

[0044] FIG. **9**B is a front cross-sectional view of a native mitral valve and a transeptally delivered device for weakening tissue of the native mitral valve anterior leaflet tissue.

[0045] FIG. **10** is the cross-sectional view of the native mitral valve and exemplary system of FIG. **7**A with a second balloon positioned within the native mitral valve.

[0046] FIG. **11** is a side view of another exemplary system for separating native heart valve leaflets in accordance with the disclosed subject matter with the balloon in the inflated condition.

DETAILED DESCRIPTION

[0047] Reference will now be made in detail to the various exemplary embodiments of the disclosed subject matter, which are illustrated in the accompanying drawings. The structure and corresponding method of operation of the disclosed subject matter will be described in conjunction with the detailed description of the system. The accompanying drawings, where like reference numerals refer to identical or functionally similar elements throughout the separate views, serve to further illustrate various embodiments and to explain various principles and advantages all in accordance with the disclosed subject matter.

[0048] The disclosed subject matter is directed to systems and methods for separating native heart valve leaflets attached together by a fixation device. Although embodiments described herein are directed to separating native mitral valve leaflets attached together by a fixation device, it will be understood that systems and methods in accordance with the disclosed subject matter can also be applied to separate leaflets of other heart valves attached together by a fixation device, such as the tricuspid valve, aortic valve, or pulmonary valve. Additionally, the term fixation device as used herein encompasses both the singular—fixation device—as well as a plurality of fixation devices. That is, it is understood that one or more fixation devices may be used to attach native heart valve leaflets together, and systems and methods in accordance with the disclosed subject matter can be used to separate the native heart valve leaflets attached together by the one or more fixation devices.

[0049] The left ventricle (LV) of a normal heart H in systole is illustrated in FIG. **1**. The left ventricle (LV) is contracting and blood flows outwardly through the tricuspid (aortic) valve (AV) in the direction of the arrows. Back flow of blood or "regurgitation" through the mitral valve (MV) is prevented since the mitral valve is configured as a "check valve" which prevents back flow when pressure in the left ventricle is higher than that in the left atrium (LA). The mitral valve (MV) comprises a pair of leaflets having free edges (FE) which meet evenly to close, as illustrated in FIG. **1**. The opposite ends of the leaflets (LF) are attached to the surrounding heart structure along an annular region referred to as the annulus (AN). The free edges (FE) of the leaflets (LF) are secured to the lower portions of the left ventricle LV through chordae tendinae (CT) which include a plurality of branching tendons secured over the lower surfaces of each of the valve leaflets (LF). The chordae (CT) in turn, are attached to the papillary muscles (PM) which extend upwardly from the lower portions of the left ventricle and intraventricular septum IVS.

[0050] A number of structural defects in the heart can cause mitral valve regurgitation. Regurgitation occurs when the valve leaflets do not close properly allowing leakage from the ventricle into the atrium. For example, enlargement of the heart can cause the mitral annulus to become enlarged such that the free edges (FE) of the mitral valve do not meet during systole. This can result in a gap which allows blood to leak through the valve during ventricular systole. Ruptured or elongated chordae tendinae can also cause one or more valve leaflets to prolapse such that the two valve leaflets do not properly meet and leakage occurs from the left ventricle into the left atrium. Such regurgitation can also occur in patients who have suffered ischemic heart disease where the left ventricle does not contract sufficiently to effect proper closure.

[0051] Fixation devices can be used for grasping, approximating and fixating tissues such as valve leaflets to treat cardiac valve regurgitation, particularly mitral valve regurgitation. Additional examples and details related to fixation devices, delivery devices for directing fixation devices to a targeted treatment area, handles, and deployment mechanisms, are described in U.S. Pat. Nos. 7,666,204, 7,563,267, and U.S. Patent Application Publication No. 2017/0100250, the disclosures of each of which are incorporated herein in their entirety by this reference. One such device used to clip the anterior and posterior leaflets of the mitral valve together is the MitraClip® fixation device, sold by Abbott Vascular, Santa Clara, Calif., USA.

[0052] FIG. **2** illustrates an exemplary fixation device clipping together the anterior and posterior leaflets of a mitral valve. FIG. **2** is a taken from the atrial side of the mitral valve (MV), and therefore, the atrial elements **201** of the fixation device are shown in solid line and the ventricular elements **202** are shown in dashed line. The leaflets LF are held in place so that during diastole, as shown in FIG. **2**, the leaflets LF remain in position between the atrial elements **201** and ventricular elements **202** surrounded by openings or

orifices O which result from the diastolic pressure gradient. As depicted in FIG. **2**, the leaflets LF can be coapted or attached together such that their upstream surfaces are facing each other in a vertical orientation, parallel to the direction of blood flow through mitral valve MV.

[0053] FIG. **3**A illustrates a side cross-sectional view of a mitral valve having native leaflets attached together by a fixation device **301**. As embodied herein, the fixation device **301** can be coupled to the anterior leaflet **310** and posterior leaflet **312**. As described further herein, separating the native leaflets may be desirable to facilitate further treatment of the native mitral valve, such as by installing a replacement heart valve, or to satisfy another clinical need. However, fixation devices can be embedded with the leaflet tissue and/or other surrounding tissues as a result of tissue ingrowth, making it difficult to extract the implant and/or separate the native leaflets. With reference to FIG. **3**B, separation of the native leaflets can be achieved by tearing, cutting, or severing the tissue of one or more of the leaflets. For example, and as embodied herein, separation can be achieved by tearing the native mitral valve anterior leaflet tissue with the fixation device **301** remaining attached to the posterior leaflet **312** after the leaflets are separated. As described further herein, tearing of the anterior leaflet tissue can be advantageous, as there is less risk that the fixation device will interfere with functioning of the left ventricular outflow tract when the fixation device remains attached to the posterior leaflet.

[0054] Systems for separating native heart valve leaflets attached together by a fixation device in accordance with the disclosed subject matter generally include an elongate shaft having a proximal end portion, a distal end portion and a longitudinal axis extending therebetween. The elongate shaft is configured for transvascular delivery of the distal end portion to a native heart valve. A balloon is disposed at the distal end portion of the elongate shaft, and the balloon is inflatable from a collapsed condition to an inflated condition. At least one snare lumen extends along at least a portion of the balloon, the at least one snare lumen having an exit port defined therein. A snare is deployable through the exit port from a delivery position within the at least one snare lumen to an extended position extending beyond the exit port. The snare in the extended position is configured to capture the fixation device.

[0055] For purpose of illustration and not limitation, reference is made to the exemplary embodiment of a system **400** for separating native heart valve leaflets attached together by a fixation device shown in FIGS. **4**A-**4**C. The system **400** generally includes an elongate shaft **401** having a proximal end portion **402**, a distal end portion **403**, and a longitudinal axis extending therebetween. The elongate shaft **401** is configured for transvascular delivery of the distal end portion to a native heart valve. Techniques for delivering elongate shafts to a native heart valve are known in the art. For example, the elongate shaft can be delivered to the native heart valve transapically. Alternatively, and as embodied herein, the elongate shaft **401** can be delivered to the native heart valve transvascularly. For example, the elongate shaft **401** can be delivered to the native heart valve using a transseptal approach.

[0056] As embodied herein, the system **400** can include a guidewire lumen **413** extending along at least a length of the elongate shaft. As embodied herein, the elongate shaft can have a guidewire lumen **413** defined therein. Alternatively a guidewire lumen can extend along an outer wall of the elongate shaft. A guidewire can be used in combination with known surgical techniques to deliver the distal portion **403** of the system **400** to the native heart valve. For purpose of example, and as embodied herein, a guidewire can be transeptally delivered to the native mitral valve, and the distal portion **403** of the system **400** can be delivered to the native heart valve over the guidewire. Various guidewire configurations are known in the art and suitable for use with the disclosed subject matter. For example, both over-the-wire and monorail configurations can be used. For purpose of example and not limitation, the guidewire lumen can extend along at least 20 cm from the distal tip along the length of the elongate shaft **401**.

[0057] The elongate shaft **401** can define one or more lumens, as described above. The elongate shaft can have any suitable construction. The materials and method of construction for the elongate shaft **401** can be selected to provide desirable performance properties of the elongate shaft **401**. As described further herein, the configuration of the elongate shaft **401** can facilitate transmission of torque applied at the proximal end portion **402** of the elongate shaft to the distal end portion **403** of the elongate shaft. Further, the tensile or compressive properties of the elongate shaft **401** can impact the force transmission from the proximal end **402** to the distal end **403**. The elongate shaft can have a uniform construction, or a composite construction. A composite construction, including for example, using different materials and/or constructions along the length of the elongate shaft **401** can provide desired performance characteristics (e.g., bending or torque transmission) at desired sections along the length of the elongate shaft **401**. For purpose of example and not limitation, the elongate shaft construction can include polymer extrusions or assemblies of laminations such as Pebax. Additionally or alternatively, the elongate shaft construction can incorporate lumen liners such as PTFE or Polyimide.

[0058] For purpose of example, and as embodied herein, the elongate shaft **401** can include a braided reinforcement **404**. The braided reinforcement **404** can be included along a portion of the elongate shaft **401**, or can extend along substantially the length of the elongate shaft **401**. For purpose of example and not limitation, the braided reinforcement **404** can be included between laminations. The braided reinforcement **404** can provide increased torque transmission and force transmission between the proximal end **402** and distal end **403**, without compromising the integrity of the elongate shaft **401**.

[0059] Additionally or alternatively, the elongate shaft can comprise a hypotube. The hypotube can include cut out portions along its length. For example, cut outs can be included to provide the hypotube with flexibility and the desired torque transmission properties. The elongate shaft can include one or more materials, including stainless steel, nitinol, or other materials known in the art for surgical applications. Examples of additional elongate shaft configurations are described in U.S. Pat. Nos. 4,646,719, 4,998,917, and 6,540,719, the content of each of which is hereby incorporated by reference in its entirety.

[0060] In accordance with the disclosed subject matter, a balloon **410** is disposed at the distal end portion **403** of the elongate shaft **401**. The balloon **410** is inflatable from a collapsed condition to an inflated condition. For purpose of example and as embodied herein, the elongate shaft can include an outer lumen for admitting fluid and withdrawing

fluid from the balloon to inflate and collapse the balloon. The elongate shaft **401** can also include a guidewire lumen **413**, as described above. One or more of the outer lumen and the guidewire lumen **413** can include a braided reinforcement as described above. As embodied herein, inflation of the balloon **410** can be used to separate the native heart valve leaflets attached together by a fixation device. For example, and as described further herein with reference to FIGS. **8**A-**8**C, the balloon can have an inflation diameter in the inflated condition, the inflated balloon inflation diameter being larger than a maximum cross dimension of an orifice defined between the native heart valve leaflets to be separated.

[0061] FIG. **4**A depicts a balloon **410** disposed at the distal end portion **403** of the elongate shaft **401** with the balloon **410** in a collapsed condition. The system **400** can be delivered to the native heart valve with the balloon **410** in the collapsed condition. For example, the smaller diameter of the balloon in the collapsed condition can facilitate transvascular delivery of the system to, and positioning within, the native heart valve. FIG. **4**B depicts the balloon **410** in an inflated condition. With reference to FIG. **4**C, the balloon **410** can be concentric with the longitudinal axis of the elongate shaft **401**. Alternatively, and with reference to the exemplary system **500** depicted in FIGS. **5**A and **5**B, the balloon **510** can be acentric with the longitudinal axis of the elongate shaft **501**. As described further herein, an acentric balloon configuration can be used to control the application of forces to separate the native heart valve leaflets attached together by a fixation device.

[0062] In accordance with the disclosed subject matter, at least one snare lumen **420** extends along at least a portion of the balloon **410**. As embodied herein, the at least one snare lumen **420** can extend along an exterior of the balloon **410**. For purpose of example, at least one snare lumen **420** can be attached to at least one of the elongate shaft **401** and the balloon **410**, and the at least one snare lumen **420** can be moveable relative to the exterior of the balloon **410** to accommodate an increased circumference of the balloon **410** as the balloon **410** inflates from the collapsed condition to the inflated condition. As embodied herein, a portion of the at least one snare lumen **420** can be attached to a distal portion of the balloon **410** with a remaining portion of the at least one snare lumen **420** moveable relative to the exterior of the balloon **410** to accommodate changing circumference of the balloon **410** and prevent restriction of the balloon as it expands. For purpose of example, the at least one snare lumen **420** can be bonded to a portion of the balloon **410**. For purpose of example, the remaining portion of the at least one snare lumen **420** which remains moveable relative to the exterior of the balloon can be disposed within another lumen, which can maintain the radial position of the at least one snare lumen **420** relative to the balloon **410** while allowing the at least one snare lumen **420** to move longitudinally as the balloon expands.

[0063] In accordance with another aspect of the disclosed subject matter, the at least one snare lumen can be defined within a wall of the balloon. For example, polyimide tubing can be used to reinforce the at least one snare lumen defined within a wall of the balloon.

[0064] The configuration of the at least one snare lumen **420** can be selected based on the desired properties of the system. For example, and as described above, the construction of the at least one snare lumen **420** can be selected based on the desired torque transmission properties of the system. The at least one snare lumen **420** can have a uniform construction, or a composite construction. A composite construction, including for example, using different materials and/or constructions along the length of the at least one snare lumen **420** can provide desired performance characteristics (e.g., bending or torque transmission) at desired sections along the length of at least one snare lumen **420**. For purpose of example and not limitation, the snare lumen construction can include polymer extrusions or assemblies of laminations such as Pebax. Additionally or alternatively, the at least one snare lumen **420** can be configured to increase in length axially as the balloon **410** inflates from the collapsed condition to the inflated condition to accommodate an increased circumference of the balloon **410**. For example, the at least one snare lumen **420** can include elastic materials to facilitate changes in axial length of the at least one snare lumen **420** during inflation of the balloon **410**. Additionally or alternatively, the at least one snare lumen **420** can include a telescoping tube construction.

[0065] Systems in accordance with the disclosed subject matter can include any desirable number of snare lumens. For example, the at least one snare lumen can include between one and six snare lumens spaced about an outer circumference of the balloon. With reference to the exemplary system depicted in FIG. **6**, the system **600** can include five snare lumens **620** spaced about an outer perimeter of balloon **610**.

[0066] In accordance with the disclosed subject matter, the at least one snare lumen **420** has an exit port **425** defined therein. As embodied herein, the exit port **425** can be disposed at an intermediate location along the length of the balloon **410**. For example, the balloon **410** can have an inflation diameter as described above, and a maximum inflation diameter of the balloon **410** can be at the intermediate location along the length of the balloon. The balloon **410** can apply a greater tension to the snare when the exit port **425** is disposed at an intermediate location along the length of the balloon proximate the maximum inflation diameter of the balloon **410**, as described further herein. Additionally, the deployed snare can be more stable with respect to the fixation device when the snare lumen is located at a portion of the balloon **410** having the maximum inflation diameter.

[0067] As embodied herein, the system **400** can include a radiopaque marker **430** proximate the exit port. The radiopaque marker **430** can facilitate visualization and positioning of the system **400** during surgical procedures. For example, and as further described herein, the radiopaque marker **430** can facilitate orientation of the exit port **425** within the native heart valve using surgical visualization techniques known in the art.

[0068] As embodied herein, the system **400** can be configured with the balloon **410** rotatable about the longitudinal axis of the elongate shaft **401** to move the exit port **425** of the at least one snare lumen **420** circumferentially about the longitudinal axis. For example, and as described above, the elongate shaft **401** can include braided reinforcement **404** or a hypotube to facilitate transmission of torque applied at the proximal end portion **402** of the elongate shaft **401** to the distal end portion **403** of the elongate shaft **401**. Accordingly, rotation of the proximal end portion **402** of the elongate shaft **401** can cause corresponding rotation of the balloon **410** at the distal end portion **403** of the elongate

shaft **401**. Additionally or alternatively, and in accordance with another aspect of the disclosed subject matter, the balloon **410** can be wrapped around the elongate shaft **401** in the collapsed condition and configured to unfold upon inflation from the collapsed condition to the inflated condition. Unfolding of the balloon **410** can cause rotation of the balloon **410** about the longitudinal axis of the elongate shaft **401** and corresponding movement of the exit port **425** circumferentially about the longitudinal axis. As described further herein, controlling rotation of the balloon **410** and movement of the exit port **425** circumferentially about the longitudinal axis can be desirable for separating native heart valve leaflets. For example, rotation of the balloon **410** and corresponding movement of the exit port **425** can be used to control the application of forces to separate the native heart valve leaflets As embodied herein, rotation of the balloon **410** and corresponding movement of the exit port **425** can concentrate the forces generated by inflation of the balloon **410** on the anterior leaflet tissue to tear the native mitral valve anterior leaflet.

[0069] With reference to FIGS. **7**B and **8**A-**8**C, and in accordance with the disclosed subject matter, a snare **845** is deployable through the exit port **825** from a delivery position within the at least one snare lumen **820** to an extended position extending beyond the exit port **825**. The snare **845** in the extended position is configured to capture the fixation devices **890**. With reference to FIG. **8**A, the snare **845** is depicted in an extended position extending beyond the exit port of the at least one snare lumen **820** to encircle the fixation devices **890**. As embodied herein, the snare **845** can be a loop of wire. The snare **845** can be made of any suitable material. For purpose of example and as embodied herein, the snare **845** can be made from stainless steel wire, mp35, or nitinol. The snare **845** can include a continuous wire having, for example, a monofilament or braided construction. Additionally or alternatively, the snare **845** can include a closed coil exterior and central wire looped at the distal end, which can prevent elongation. The snare **845** can include a loop defined along a portion of the snare **845**, for example at the snare distal end. Additionally or alternatively, the snare **845** can include a loop with both ends terminating at the proximal end. As embodied herein, the at least one snare lumen **820** and snare **845** can extend along the longitudinal axis of the elongate shaft **801** towards the proximal end portion **402** of the elongate shaft **401**, and deployment and retraction of the snare **845** can be controlled from the proximal end portion **402** of the elongate shaft **401**. For example, manipulation of the snare **845** from the proximal end portion **402** can result in the distal portion of the snare **845** responding in kind.

[0070] The disclosed subject matter also includes methods for separating native heart valve leaflets attached together by a fixation device. Methods in accordance with the disclosed subject matter include delivering a distal end portion of a system for separating native heart valve leaflets to a native heart valve. The system for separating native heart valve leaflets can include the features described herein. With reference to the exemplary system **800** depicted in FIG. **7**A-FIG. **8**C, delivering the distal end portion **803** can include positioning the balloon **810** through an orifice **880** defined between the native heart valve leaflets **870**, **872**. As embodied herein, the native heart valve can be a native mitral valve and the distal end portion **803** and balloon **810** of the system **800** can be positioned through a lateral orifice **880** of the native mitral valve defined between the attached native leaflets **870**, **872**. With reference to FIGS. **8**A-**8**C, the lateral orifice **880** is disposed opposite the septal wall **882**. As described above, the native leaflets can be attached by a previously implanted fixation device, such as a MitraClip® fixation device, sold by Abbott Vascular, Santa Clara, Calif., USA. Various surgical access routes can be used to access the native heart valve in accordance with the disclosed subject matter. For example, the distal end portion **803** can be delivered to the native heart valve transapically, or as embodied herein, the distal end portion **803** can be delivered transseptally. The system **800** can include a steerable catheter for transseptal delivery to and positioning within the native mitral valve.

[0071] Methods for separating native heart valve leaflets attached together by a fixation device in accordance with the disclosed subject matter further include deploying a snare **845** from a delivery position within the at least one snare lumen to an extended position extending beyond the exit port **825**. As embodied herein, deploying the snare can include rotating the balloon **810** about the longitudinal axis of the elongate shaft **801** to align the exit port **825** towards the fixation devices **890**. For example, and with reference to FIG. **7**B, the exemplary system **800** is depicted with the exit port **825** aligned towards the fixation devices **890**. As discussed above, the system can include one or more markers, such as a radiopaque marker **830**, which can be used to position the system for deployment of the snare using known visualization techniques.

[0072] Methods in accordance with the disclosed subject matter further include capturing the fixation devices **890** within the snare **845** with the snare **845** in the extended position. As described above, the snare **845** and snare lumen **820** can extend along the longitudinal axis of the elongate shaft **801**, and deployment and retraction of the snare **845** can be controlled from the proximal end portion **802** of the elongate shaft **801**. Additionally, and as further embodied herein, the balloon **810** and snare lumen **820** can be vertically and rotationally aligned within the native heart valve to deploy the snare **845** and capture the fixation devices **890** with the snare **845** in the extended position. For example, the system **800** can be positioned vertically within the native heart valve prior to snare deployment. For example, and as embodied herein, the system can be positioned with the exit port **825** underneath the native heart valve leaflets **870**, **872** and vertically aligned beneath a lower portion of the fixation devices **890** when the heart is viewed in cross section. As embodied herein, the snare **845** can be deployed with the exit port **825** rotationally aligned towards the fixation devices **890** and vertically aligned below a lower portion of the fixation devices **890**. With the snare **845** deployed, the system **800** can be retracted along the longitudinal axis of the elongate shaft **801** to adjust the vertical position of the system **800** within the native heart valve and place the snare **845** around the fixation devices **890**. With reference to FIG. **8**A, the exemplary system **800** is depicted with the snare **845** deployed in the extended position extending beyond the exit port **825** and encircling the fixation devices **890** to capture the fixation devices **890** within the snare **845**. FIG. **8**A is a taken from the atrial side of the mitral valve, and therefore, the snare **845** is depicted in broken line where the snare extends beneath the native leaflets **870**, **872** for purpose of explanation. As embodied herein, the snare **845** can be comprised of material that is visible using surgical imaging

techniques known in the art, and visualization techniques can be used during deployment of the snare **845** to facilitate capture of the fixation devices **890**. As embodied herein, the snare **845** can be deployed and positioned around the fixation devices **890** prior to inflation of the balloon **810**.

[0073] With reference to FIGS. **8**B & **8**C, methods in accordance with the disclosed subject matter include inflating the balloon **810** from a collapsed condition to an inflated condition to separate the native heart valve leaflets **870**, **872**. As embodied herein, the balloon **810** can be inflated after the fixation devices **890** are captured within the snare **845**. As described above, the balloon **810** can have an inflation diameter in the inflated condition, the balloon inflation diameter being larger than a maximum cross dimension of an orifice **880** defined between the native heart valve leaflets **870**, **872** to be separated. As embodied herein, the method can include rotating the balloon **810** about the longitudinal axis of the elongate shaft **801** to align the exit port **825** away from the native mitral valve anterior leaflet **870** after capturing the fixation devices **890** in the snare **845**. As described above, aligning the exit port **825** away from the anterior leaflet **870** after capturing the fixation devices **890** with the snare **845** can cause the balloon **810** to apply tension to the snare **845** and fixation devices **890** captured therein in a direction extending away from the anterior leaflet **870** as the balloon **810** inflates. Applying tension to the fixation devices **890** in a direction extending away from the anterior leaflet **870** during balloon inflation can separate the native valve leaflets by tearing the anterior mitral valve leaflet **870**. With reference to FIG. **8**C, the system **800** is depicted with the balloon **810** in the inflated condition and the native mitral valve leaflets separated by a tear **875** through the native mitral valve anterior leaflet tissue **870**.

[0074] The balloon **810** can be rotated prior to or during inflation of the balloon from the collapsed condition to the inflated condition. For example, and as described above, the balloon **810** can be configured to unfold as the balloon **810** inflates, and the unfolding can cause rotation of the balloon and corresponding rotation of the at least one snare lumen **820** and exit port **825** to align the exit port **825** away from the native mitral valve anterior leaflet **870**. Additionally or alternatively, the elongate shaft **801** can include a braided reinforcement and/or additional features to transmit torque from the proximal portion **802** of the elongate shaft **801** to the balloon **810**.

[0075] In accordance with another aspect of the disclosed subject matter, and as described above with reference to FIGS. **5**A and **5**B, the balloon **510** can be acentric with the longitudinal axis of the elongate shaft **501**. The exemplary system **500** includes an elongate shaft **501** having a proximal end portion **502**, a distal end portion **503** and a longitudinal axis extending therebetween. The elongate shaft **501** is configured for transvascular delivery of the distal end portion **503** to a native heart valve. A balloon **510** is disposed at the distal end portion **503** of the elongate shaft **501**, and the balloon **510** is inflatable from a collapsed condition to an inflated condition. At least one snare lumen **520** extends along the longitudinal axis along at least a portion of the balloon **510**, the at least one snare lumen **520** having an exit port **525** defined therein. A snare is deployable through the exit port **525** from a delivery position within the at least one snare lumen **520** to an extended position extending beyond the exit port **525**. The snare in the extended position is configured to capture the fixation device. As described above, the system **500** can include a guidewire lumen **513** extending along at least a length of the elongate shaft. As embodied herein, the balloon **510** can be configured to inflate away from the at least one snare lumen **520** and the exit port **525**. An acentric balloon configuration can concentrate forces generated by inflation of the balloon **510** on the anterior leaflet tissue to tear the anterior leaflet during inflation of the balloon **510**. As embodied herein, the exit port **525** can be aligned away from the anterior leaflet after capturing the fixation device in the snare, and inflation of the acentric balloon **510** can apply tension to the snare in a direction extending away from the anterior leaflet to tear the anterior leaflet during balloon inflation.

[0076] As described above, separation of native heart valve leaflets attached by a fixation device can be desirable for a number of clinical reasons. For example, sometimes after a fixation device is installed mitral valve regurgitation can still exist, or can arise again. In some cases, it can be desirable to remove the fixation device to allow for implantation of a replacement heart valve. Accordingly, and in accordance with another aspect of the disclosed subject matter, after separating the native heart valve leaflets as described herein, a prosthetic heart valve can be installed at the native heart valve. The prosthetic heart valve can be delivered to and installed at the native heart valve using techniques known in the art. For example, the prosthetic heart valve can be delivered transapically, or alternatively, can be delivered transvascularly, including transeptally. Examples of prosthetic heart valves and methods for delivering prosthetic heart valves are described in U.S. Pat. Nos. 10,470,881, 9,439,757, and 8,870,948, the content of each of which is hereby incorporated by reference in its entirety.

[0077] As embodied herein, the fixation devices **890** can remain attached to the native mitral valve posterior leaflet **872** after the native heart leaflets **870**, **872** are separated. Having the fixation devices **890** remain attached to the posterior leaflet **872** can be desirable, including for reducing the risk of left ventricular outflow tract obstruction ("LVOTO"). For example, installation of a prosthetic valve at the native mitral valve after separation of the native heart leaflets **870**, **872** can trap the fixation devices **890** and native posterior leaflet **872** against the ventricular wall **876** away from the aortic valve **878** and left ventricular outflow tract, which can reduce the risk of LVOTO.

[0078] Methods in accordance with the disclosed subject matter can include additional features. For example, methods can include weakening native mitral valve anterior leaflet tissue before inflating the balloon. As described above, it can be desirable to separate the native heart valve leaflets by tearing the native mitral valve anterior leaflet tissue. Weakening the native mitral valve anterior leaflet tissue can help ensure that the native mitral valve anterior leaflet tissue tears when the balloon is inflated. Any suitable means for weakening the native anterior leaflet tissue can be used. For example, one or more of a needle, blade, and hydrogen peroxide can be applied to the native mitral valve anterior leaflet tissue to weaken the tissue prior to balloon inflation. As embodied herein, RF energy can be used to weaken the native mitral valve anterior leaflet tissue adjacent to the fixation device. Weakening the anterior leaflet tissue adjacent to the fixation device can reduce the amount of anterior leaflet tissue that remains captured in the fixation device after the native leaflets are separated. With reference to FIGS. **9**A and **9**B, a device **900** can be delivered to the

native mitral valve anterior leaflet **970** coapted to the posterior leaflet by a fixation device **990**, as described above. The device **900** can be used to weaken the tissue of the anterior leaflet **970**. As embodied herein, the device **900** can be separate from the system for separating the native heart valve leaflets, and can be delivered to the native mitral valve anterior leaflet **970** transvascularly, using a transseptal approach or an aortic approach. As embodied herein, the device **900** can include a steerable catheter **910** to deliver and position the device **900**. In accordance with another aspect of the disclosed subject matter, the system for separating the native heart valve leaflets can include one or more of the features described herein for weakening the native mitral valve anterior leaflet prior to balloon inflation. For example, the system can include a lumen for applying hydrogen peroxide to the native anterior leaflet **970**.

[0079] In accordance with another aspect of the disclosed subject matter, a second balloon can be positioned through a second orifice on an opposing side of the fixation device. For purpose of example and as embodied herein, the first and second balloons can each be part of a system for separating native heart valve leaflets as described herein. With reference to FIG. **10**, system **800** having a balloon **810** and a snare lumen **820** can be positioned through lateral orifice **880**, and system **1300** having a balloon **1310** and a snare lumen **1320** can be positioned through medial orifice **883** on an opposing side of the fixation devices **890**. The first balloon **810** and the second balloon **1310** can be inflated to separate the native heart valve leaflets **870**, **872**.

[0080] Additionally or alternatively, and in accordance with another aspect of the disclosed subject matter, the system for separating native heart valve leaflets can include at least one cutter. With reference to FIG. **11**, the system **1400** includes an elongate shaft **1401** having a proximal end portion **1402**, a distal end portion **1403** and a longitudinal axis extending therebetween. The elongate shaft **1401** is configured for transvascular delivery of the distal end portion **1403** to a native heart valve. A balloon **1410** is disposed at the distal end portion **1403** of the elongate shaft **1401**, and the balloon **1410** is inflatable from a collapsed condition to an inflated condition. A cutter **1480** is disposed along at least a portion of the balloon **1410**. As embodied herein, the cutter **1480** can extend along a length of the balloon **1410** generally parallel to the longitudinal axis of the elongate shaft **1410**. In accordance with another aspect of the disclosed subject matter, the cutter can extend along the balloon in a spiral. Additionally, and as embodied herein, the cutter **1480** can include one or more serrations **1481**. The cutter **1410** can be used to cut or tear native heart valve leaflet tissue when the balloon **1410** is inflated to the inflated condition to separate native heart valve leaflets. For example, inflation of the balloon can force the cutter **1481** into contact with native heart valve leaflet tissue. As embodied herein, the at least one cutter **1481** can be aligned with the native mitral valve anterior leaflet prior to inflation of the balloon **1410** at the native mitral valve. Aligning the cutter **1481** with the native mitral valve anterior leaflet can cause the cutter **1481** to cut or tear the mitral valve anterior leaflet when the balloon **1410** is inflated.

[0081] As described above, the system **1410** can include at least one snare lumen extending along at least a portion of the balloon, the at least one snare lumen having an exit port defined therein. The cutter **1480** can be disposed between about 30 degrees and 180 degrees about an outer circumference of the balloon from the at least one snare lumen. For purpose of example and not limitation, the at least one snare lumen can be positioned at approximately the 9 o'clock position when the system **1410** is viewed in end view, and the cutter **1480** can be positioned at approximately the 10 o'clock or 11 o'clock position. Positioning the cutter **1480** between about 30 degrees and 180 degrees about an outer circumference of the balloon from the at least one snare lumen can align the cutter with the native mitral valve anterior leaflet once the system **1400** has been rotated about the longitudinal axis of the elongate shaft to align the exit port away from the native mitral valve anterior leaflet after capturing the fixation device.

[0082] The disclosed subject matter further includes a kit for treating a native heart valve having leaflets attached together by a fixation device. The kit includes a system for separating native heart valve leaflets attached together by a fixation device. The system can include the features described above. The kit also includes a prosthetic heart valve.

[0083] In addition to the specific embodiments claimed below, the disclosed subject matter is also directed to other embodiments having any other possible combination of the dependent features claimed below and those disclosed above. As such, the particular features presented in the dependent claims and disclosed above can be combined with each other in other manners within the scope of the disclosed subject matter such that the disclosed subject matter should be recognized as also specifically directed to other embodiments having any other possible combinations. Thus, the foregoing description of specific embodiments of the disclosed subject matter has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the disclosed subject matter to those embodiments disclosed.

[0084] It will be apparent to those skilled in the art that various modifications and variations can be made in the method and system of the disclosed subject matter without departing from the spirit or scope of the disclosed subject matter. Thus, it is intended that the disclosed subject matter include modifications and variations that are within the scope of the appended claims and their equivalents.

1. A system for separating native heart valve leaflets attached together by a fixation device, comprising:

an elongate shaft having a proximal end portion, a distal end portion and a longitudinal axis extending therebetween, the elongate shaft configured for transvascular delivery of the distal end portion to a native heart valve;

a balloon disposed at the distal end portion of the elongate shaft, the balloon inflatable from a collapsed condition to an inflated condition;

at least one snare lumen extending along at least a portion of the balloon, the at least one snare lumen having an exit port defined therein; and

a snare deployable through the exit port from a delivery position within the at least one snare lumen to an extended position extending beyond the exit port, the snare in the extended position configured to capture the fixation device.

2. The system of claim **1**, wherein the elongate shaft is configured to transmit torque along the longitudinal axis and wherein the exit port of the at least one snare lumen can be moved circumferentially about the longitudinal axis by rotation of the proximal end portion.

3. The system of claim 1, wherein the at least one snare lumen extends along an exterior of the balloon and is bonded to a portion of the balloon.

4. The system of claim 1, wherein a segment of the at least one snare lumen is attached to at least one of the elongate shaft and the balloon, and the at least one snare lumen extends along an exterior of the balloon and is movable relative the exterior of the balloon as the balloon inflates from the collapsed condition to the inflated condition to accommodate an increased circumference of the balloon.

5. The system of claim 1, wherein the at least one snare lumen is defined within a wall of the balloon.

6. The system of claim 1, wherein the at least one snare lumen is configured to increase in length axially as the balloon inflates from the collapsed condition to the inflated condition to accommodate an increased circumference of the balloon.

7. The system of claim 1, wherein the exit port is disposed at an intermediate location along a length of the balloon.

8. The system of claim 1, wherein at least one of the balloon and the at least one snare lumen includes a radiopaque marker proximate the exit port.

9. The system of claim 1, wherein the balloon is concentric with the longitudinal axis of the elongate shaft.

10. The system of claim 1, wherein the balloon has an inflation diameter in the inflated condition; the inflation diameter being larger than a maximum cross dimension of an orifice defined between the native heart valve leaflets to be separated.

11. The system of claim 1, wherein the balloon is acentric with the longitudinal axis of the elongate shaft.

12. The system of claim 1, wherein the at least one snare lumen includes between one and four snare lumens spaced about an outer circumference of the balloon.

13. The system of claim 1, further comprising at least one cutter disposed along at least a portion of the balloon.

14. The system of claim 13, wherein the cutter is disposed between about 30 degrees and 180 degrees about an outer circumference of the balloon from the at least one snare lumen.

15. A method for separating native heart valve leaflets attached together by a fixation device, the method comprising:

delivering a distal end portion of a system for separating native heart valve leaflets to a native heart valve, the system including:

an elongate shaft having a proximal end portion, the distal end portion, and a longitudinal axis extending therebetween;

a balloon disposed at the distal end portion; and

at least one snare lumen extending along at least a portion of the balloon, the at least one snare lumen having an exit port defined therein;

deploying a snare from a delivery position within the at least one snare lumen to an extended position extending beyond the exit port;

capturing the fixation device within the snare with the snare in the extended position; and

inflating the balloon from a collapsed condition to an inflated condition to separate the native heart valve leaflets.

16. The method of claim 15, wherein delivering the distal end portion includes positioning the balloon through an orifice defined between the native heart valve leaflets.

17. The method of claim 15, further comprising positioning a second balloon through a second orifice on an opposing side of the fixation device, and inflating the second balloon.

18. The method of claim 15, wherein the native heart valve is a mitral valve.

19. The method of claim 18, wherein delivering the distal end portion includes positioning the balloon through a lateral orifice defined between the native mitral valve leaflets.

20. The method of claim 18, wherein the balloon includes a cutter disposed along at least a portion thereof, the method comprising aligning the least one cutter with the native mitral valve anterior leaflet.

21. The method of claim 15, wherein deploying the snare includes rotating the balloon about the longitudinal axis of the elongate shaft to align the exit port towards the fixation device.

22. The method of claim 18, further comprising rotating the balloon about the longitudinal axis of the elongate shaft to align the exit port away from the native mitral valve anterior leaflet after capturing the fixation device.

23. The method of claim 18, wherein inflating the balloon tears the native mitral valve anterior leaflet.

24. The method of claim 18, wherein the fixation device remains attached to the native mitral valve posterior leaflet.

25. The method of claim 18, further comprising weakening native mitral valve anterior leaflet tissue before inflating the balloon.

26. The method of claim 25, wherein at least one of a needle, blade, RF energy, and hydrogen peroxide are applied to the native mitral valve anterior leaflet tissue in order to weaken it.

27. The method of claim 15, further comprising installing a prosthetic heart valve at the native heart valve.

28. A kit for treating a native heart valve having leaflets attached together by a fixation device, the kit comprising:

a system for separating native heart valve leaflets attached together by a fixation device, the system including:

an elongate shaft having a proximal end portion, a distal end portion and a longitudinal axis extending therebetween, the elongate shaft configured for transvascular delivery of the distal end portion to a native heart valve;

a balloon disposed at the distal end portion of the elongate shaft, the balloon inflatable from a collapsed condition to an inflated condition;

at least one snare lumen extending along at least a portion of the balloon, the at least one snare lumen having an exit port defined therein; and

a snare deployable through the exit port from a delivery position within the at least one snare lumen to an extended position extending beyond the exit port, the snare in the extended position configured to capture the fixation device; and

a prosthetic heart valve.

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