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(54) Title: FIXED LENGTH ANCHOR AND PULL MITRAL VALVE DEVICE AND METHOD

(57) Abstract: A device (30) effects the mitral valve annulus geometry of a heart. The device comprises a first anchor (32) and a proximal second anchor (36), both anchors configured to be positioned within the coronary sinus adjacent the mitral valve annulus. The second anchor, when deployed, anchors against distal movement and is moveable proximally. The device further comprises a fixed length connecting member (34) permanently attached to the first and second anchors. When the both anchors are within the coronary sinus and the first anchor is anchored, the second anchor may be displaced proximally, effecting the mitral valve geometry, and then released, maintaining the new geometry.

FIXED LENGTH ANCHOR AND PULL MITRAL VALVE DEVICE AND METHOD

Field of the Invention:

[1] The present invention generally relates to a device and method for treating dilated cardiomyopathy of a heart. The present invention more particularly relates to a device and method for reshaping the mitral valve annulus.

Background of the Invention:

[2] The human heart generally includes four valves. Of these valves, a most critical one is known as the mitral valve. The mitral valve is located in the left atrial ventricular opening between the left atrium and left ventricle. The mitral valve is intended to prevent regurgitation of blood from the left ventricle into the left atrium when the left ventricle contracts. In preventing blood regurgitation the mitral valve must be able to withstand considerable back pressure as the left ventricle contracts.

[3] The valve cusps of the mitral valve are anchored to muscular wall of the heart by delicate but strong fibrous cords in order to support the cusps during left ventricular contraction. In a healthy mitral valve, the geometry of the mitral valve ensures that the cusps overlie each other to preclude regurgitation of the blood during left ventricular contraction.

[4] The normal functioning of the mitral valve in preventing regurgitation can be impaired by dilated cardiomyopathy caused by disease or certain natural defects. For example, certain diseases may cause dilation of the mitral valve annulus. This can result in deformation of the mitral valve geometry to cause ineffective closure of the mitral valve during left ventricular contraction. Such ineffective closure results in leakage through the mitral valve and regurgitation.

Diseases such as bacterial inflammations of the heart or heart failure can cause the aforementioned distortion or dilation of the mitral valve annulus. Needless to say, mitral valve regurgitation must not go uncorrected.

[5] One method of repairing a mitral valve having impaired function is to completely replace the valve. This method has been found to be particularly suitable for replacing a mitral valve when one of the cusps has been severely damaged or deformed. While the replacement of the entire valve eliminates the immediate problem associated with a dilated mitral valve annulus, presently available prosthetic heart valves do not possess the same durability as natural heart valves.

[6] Various other surgical procedures have been developed to correct the deformation of the mitral valve annulus and thus retain the intact natural heart valve function. These surgical techniques involve repairing the shape of the dilated or deformed valve annulus. Such techniques, generally known as annuloplasty, require surgically restricting the valve annulus to minimize dilation. Here, a prosthesis is typically sutured about the base of the valve leaflets to reshape the valve annulus and restrict the movement of the valve annulus during the opening and closing of the mitral valve.

[7] Many different types of prostheses have been developed for use in such surgery. In general, prostheses are annular or partially annular shaped members which fit about the base of the valve annulus. The annular or partially annular shaped members may be formed from a rigid material, such as a metal, or from a flexible material.

[8] While the prior art methods mentioned above have been able to achieve some success in treating mitral regurgitation, they have not been without problems and potential adverse consequences. For example, these procedures require open heart surgery. Such procedures are expensive, are extremely invasive requiring considerable recovery time, and pose the concomitant mortality risks associated with such procedures. Moreover, such open heart procedures are particularly stressful on patients with a comprised cardiac condition. Given these factors, such procedures are often reserved as a last resort and hence are employed late in the mitral regurgitation progression. Further, the effectiveness of such procedures is difficult to assess during the procedure and may not be known until a much later time. Hence, the ability to make adjustments to or changes in the prostheses to obtain optimum effectiveness is extremely limited. Later corrections, if made at all, require still another open heart surgery.

[9] An improved therapy to treat mitral regurgitation without resorting to open heart surgery has recently been proposed. This is rendered possible by the realization that the coronary sinus of a heart is near to and at least partially encircles the mitral valve annulus and then extends into a venous system including the great cardiac vein. As used herein, the term "coronary sinus" is meant to refer to not only the coronary sinus itself but in addition, the venous system associated with the coronary sinus including the great cardiac vein. The therapy contemplates the use of a device introduced into the coronary sinus to reshape and advantageously effect the geometry of the mitral valve annulus.

[10] The device includes a resilient member having a cross sectional dimension for being received within the coronary sinus of the heart and a longitudinal dimension having an unstressed arched configuration when placed in the coronary sinus. The device partially encircles and exerts an inward pressure on the mitral valve. The inward pressure constricts the mitral valve annulus, or at least a portion of it, to essentially restore the mitral valve geometry. This promotes effective valve sealing action and eliminates mitral regurgitation.

[11] The device may be implanted in the coronary sinus using only percutaneous techniques similar to the techniques used to implant cardiac leads such as pacemaker leads. One proposed system for implanting the device includes an elongated introducer configured for being releasably coupled to the device. The introducer is preferably flexible to permit it to advance the device into the heart and into the coronary sinus through the coronary sinus ostium. To promote guidance, an elongated sheath is first advanced into the coronary sinus. Then, the device and introducer are moved through a lumen of the sheath until the device is in position within the coronary sinus. Because the device is formed of resilient material, it conforms to the curvatures of the lumen as it is advanced through the sheath. The sheath is then partially retracted to permit the device to assume its unstressed arched configuration. Once the device is properly positioned, the introducer is then decoupled from the device and retracted through the sheath. The procedure is then completed by the retraction of the sheath. As a result, the device is left within the coronary sinus to exert the inward pressure on the mitral valve to restore mitral valve geometry.

[12] The foregoing therapy has many advantages over the traditional open heart surgery approach. Since the device, system and method may be employed in a comparatively noninvasive procedure, mitral valve regurgitation may be treated at an early stage in the mitral regurgitation progression. Further, the device may be placed with relative ease by any minimally invasive cardiologist. Still further, since the heart remains completely intact throughout the procedure, the effectiveness of the procedure may be readily determined. Moreover, should adjustments be deemed desirable, such adjustments may be made during the procedure and before the patient is sent to recovery.

[13] Another approach to treat mitral regurgitation with a device in the coronary sinus is based upon the observation that the application of a localized force against a discrete portion of the mitral valve annulus can terminate mitral regurgitation. This suggests that mitral valve dilation may be localized and nonuniform. Hence, the device applies a force to one or more discrete portions of the atrial wall of the coronary sinus to provide localized mitral valve annulus reshaping instead of generalized reshaping of the mitral valve annulus. Such localized therapy would have all the benefits of the generalized therapy. In addition, a localized therapy device may be easier to implant and adjust.

[14] A still further approach to treat mitral regurgitation from the coronary sinus of the heart contemplates a device having a first anchor configured to be positioned within and fixed to the coronary sinus of the heart adjacent the mitral valve annulus within the heart, a cable fixed to the first anchor and extending proximally from the first anchor within the heart, a second anchor configured to be positioned in and fixed in the heart proximal to the first anchor and arranged to slidingly receive the cable, and a lock that locks the cable on the second anchor. When the first and second anchors are fixed within the heart, the cable may be drawn proximally and locked on the second anchor. The geometry of the mitral valve is thereby effected. This approach provides flexibility in that the second anchor may be positioned and fixed in the coronary sinus or alternatively, the second anchor may be positioned and fixed in the right atrium. This approach further allows adjustments in the cable tension after implant. The present invention provides a still further alternative for treating mitral regurgitation with a device placed in the coronary sinus adjacent to the mitral valve annulus.

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[14A] A reference herein to a patent document or other matter which is given as prior art is not to be taken as an admission or a suggestion that that document or matter was known or that the information it contains was part of the common general knowledge as at the priority date of any of the claims.

SUMMARY OF THE INVENTION

[15] The present invention provides a device that effects mitral valve annulus geometry of a heart. The device includes a first anchor configured to be positioned within and anchored to the coronary sinus of the heart adjacent the mitral valve annulus within the heart, and a second anchor configured to be positioned within the heart proximal to the first anchor and adjacent the mitral valve annulus within the heart. The device further includes a connecting member having a fixed length permanently attached to the first and second anchors. As a result, when the first and second anchors are within the heart with the first anchor anchored in the coronary sinus, the second anchor may be displaced proximally to effect the geometry of the mitral valve annulus and released to maintain the effect on the mitral valve geometry. The second anchor may be configured, when deployed, to anchor against distal movement but be moveable proximally to permit the second anchor to be displaced proximally within the coronary sinus.

[16] The first anchor and the second anchor are preferably self-deploying upon release in the coronary sinus or may be deployable after placement. Further, the connecting member, in being of fixed length, has a maximum extended length and as such may be a rigid member, have an initial arcuate configuration, include a spring, having a maximum length or be flexible but not stretchable.

[17] The present invention further provides a device for effecting mitral valve annulus geometry of a heart. The device includes first anchor means for anchoring in the coronary sinus of the heart adjacent the mitral valve annulus, and second anchor means for being deployed within the heart proximal to the first anchor means and adjacent the mitral valve annulus, and connecting means having a fixed length and permanently connecting the first anchor means to the second anchor means.

As a result, when the first and second anchor means are within the heart with the first anchor means anchored in the coronary sinus, the second anchor means may be displaced proximally for cooperating with the first anchor means and the connecting means for effecting the geometry of the mitral valve annulus and released for maintaining the effect on the mitral valve geometry.

[18] The invention further provides a system that effects mitral valve annulus geometry of a heart. The system includes a mitral valve device including a first anchor configured to be positioned within and anchored to the coronary sinus of the heart adjacent the mitral valve annulus within the heart, a second anchor configured to be positioned within the heart proximal to the first anchor and adjacent the mitral valve annulus within the heart, and a connecting member having a fixed length permanently attached to the first and second anchors.

[19] The system further includes a catheter having a distal end, a proximal end and a lumen that receives the device, the catheter being guidable into the coronary sinus adjacent to the mitral valve annulus and deploying the first and second anchors of the device within the coronary sinus adjacent to the mitral valve annulus, and a tether releasably coupled to the second anchor and extending proximally through the lumen and out of the catheter proximal end. As a result, when the first anchor is deployed by the catheter in the coronary sinus, the second anchor may be displaced proximally by proximally pulling on the tether to effect the geometry of the mitral valve annulus and thereafter released for deployment to maintain the effect on the mitral valve geometry.

[20] The present invention further provides a method of effecting mitral valve annulus geometry in a heart. The method includes the steps of fixing a first anchor within the coronary sinus of the heart adjacent to the mitral valve annulus, positioning a second anchor within the coronary sinus adjacent to the mitral valve annulus and proximal to the first anchor, fixing a fixed length connecting member between the first anchor and the second anchor, displacing the second anchor proximally to effect the geometry of the mitral valve annulus, and releasing the second anchor from further proximal displacement to maintain the effect on the mitral valve geometry.

[20A] The present invention further provides a method of treating mitral valve regurgitation in a patient's heart, the method comprising delivering a mitral valve device to a coronary sinus of the patient, the mitral valve device comprising a distal anchor, a proximal anchor, and a connecting member attached to and connecting the distal and proximal anchors; expanding the distal anchor in the coronary sinus; moving the proximal anchor proximally with respect to the coronary sinus while preventing proximal movement of the distal anchor relative to the coronary sinus, wherein moving the proximal anchor proximally with respect to the coronary sinus affects the geometry of the mitral valve annulus.

[21] The present invention further provides a device that effects mitral valve annulus geometry of a heart. The device includes a first expandable anchor configured to be positioned within and anchored to the coronary sinus of the heart adjacent the mitral valve annulus within the heart, a second expandable anchor configured to be positioned within the heart proximal to the first anchor and adjacent the mitral valve annulus within the heart, and a connecting member attached between the first and second anchors. At least one of the first and second anchors anchoring against movement in a first direction and being moveable in a second direction opposite the first direction.

[22] The at least one anchor may be the first anchor wherein the first direction is a proximal direction and wherein the second direction is a distal direction. The at

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least one anchor may be the second anchor wherein the first direction is a distal direction and wherein the second direction is a proximal direction. In a preferred embodiment, the first anchor anchors against movement in a proximal direction and is moveable in a distal direction and the second anchor anchors against movement in the distal direction and is moveable in the proximal direction.

[23] The invention still further provides a device that effects mitral valve annulus geometry of a heart and which permits a cardiac lead to be implanted in the left side of the heart. The device includes a first anchor configured to be positioned within and anchored to the coronary sinus of the heart adjacent the mitral valve annulus within the heart, a second anchor configured to be positioned within the heart proximal to the first anchor and adjacent the mitral valve annulus within the heart, and a connecting member attached between the first and second anchors. The first anchor is configured to occupy less than all of the coronary sinus to permit a cardiac lead to be passed by the first anchor.

[24] The first anchor may include a loop through which the cardiac lead may be passed. The second anchor may be positionable within the coronary sinus and be configured to occupy less than all of the coronary sinus to permit the cardiac lead to be passed by the second anchor. The second anchor may also include a loop through which the cardiac lead may be passed.

BRIEF DESCRIPTION OF THE DRAWINGS

[25] The features of the present invention which are believed to be novel are set forth with particularity in the appended claims. The invention, together with further aspects and advantages thereof, may best be understood by making reference to the following description taken in conjunction with the accompanying drawings, in the several figures of which like reference numerals identify identical elements, and wherein:

[26] **FIG. 1** is a superior view of a human heart with the atria removed;

[27] **FIG. 2** is a superior view of a human heart similar to **FIG. 1** illustrating a deployed mitral valve device embodying the present invention;

[28] **FIG. 3** is a superior view of a human heart similar to **FIG. 2** illustrating a first step in the deployment of the mitral valve device of **FIG. 2** embodying the present invention;

[29] **FIG. 4** is a view similar to **FIG. 3** illustrating a further step in the deployment of the device of **FIG. 2**;

[30] **FIG. 5** is a view similar to **FIG. 3** illustrating a final step in the deployment of the device of **FIG. 2**;

[31] **FIG. 6** is a superior view of a human heart similar to **FIG. 1** illustrating another deployed mitral valve device embodying the present invention; and

[32] **FIG. 7** is a side view with a portion broken away illustrating further details of device anchors and the manner in which they permit an implantable lead to pass thereby.

DETAILED DESCRIPTION OF THE INVENTION

[33] Referring now to **FIG. 1**, it is a superior view of a human heart 10 with the atria removed to expose the mitral valve 12, the coronary sinus 14, the coronary artery 15, and the circumflex artery 17 of the heart 10 to lend a better understanding of the present invention. Also generally shown in **FIG. 1** are the pulmonary valve 22, the aortic valve 24, and the tricuspid valve 26 of the heart 10.

[34] The mitral valve 12 includes an anterior cusp 16, a posterior cusp 18 and an annulus 20. The annulus encircles the cusps 16 and 18 and maintains their spacing to provide a complete closure during a left ventricular contraction. As is well known, the coronary sinus 14 partially encircles the mitral valve 12 adjacent to the mitral valve annulus 20. As is also known, the coronary sinus is part of the venus system of the heart and extends along the AV groove between the left atrium and the left ventricle. This places the coronary sinus essentially within the same plane as the mitral valve annulus making the coronary sinus available for placement of the mitral valve therapy device of the present invention therein.

[35] **FIG. 2** shows a mitral valve therapy device 30 embodying the present invention. As may be noted in **FIG. 2**, the device 30 includes a first anchor 32, a connecting member 34, and a second anchor 36. The anchors 32 and 36 and the connecting member 34 may be formed from the same material to provide an integral structure.

[36] The first anchor 32 is located at the distal end of the device 30. The anchor 32 is hook-shaped so as to be self-deployable when released in the coronary sinus 14. More specifically, the device 30 may be formed of most any biocompatible material such as stainless steel, Nitinol, a nickel/titanium alloy of the type well known in the art having shape memory or plastic. The hook-shaped configuration of the anchor 32 thus expands when released to wedge against the inner wall of the coronary sinus 14 for anchoring or fixing the anchor 32 against at least proximal movement. The anchor 32 may however allow distal movement. Preferably, the anchor 32 is positioned just proximally to the crossover point 19 of the coronary sinus 14 and a circumflex artery 17.

[37] The connecting member 34, by being formed of Nitinol, is relatively rigid and is predisposed to have an arcuate configuration to generally correspond to the shape of the mitral valve annulus 20. The connecting member 34 is of a fixed length and is permanently attached to the first and second anchors 32 and 36. Here it will be noted that the second anchor is positioned within the coronary sinus just distal to the ostium 21 of the coronary sinus 14. The second anchor 36 may have a similar hook-shaped configuration and is also preferably self-expanding to be self-deployable. The hook-shape of the anchor 36 anchors or fixes the anchor 36 against distal movement but permits the anchor to be pulled proximally. This is a particularly significant aspect of the device 30 because it permits the device to be adjusted after the anchors 32 and 36 are first deployed.

[38] When the device 30 is deployed as shown in **FIG. 2**, the first anchor 32 is fixed against proximal movement within the coronary sinus 14. The connecting member 34 then extends proximally from the first anchor 32 to the second anchor 36. The second anchor 36 is then positioned in its desired location within the coronary sinus 14 proximal to the first anchor 32 and permitted to self-expand for being anchored against distal movement. Then, the second anchor 36 is pulled proximally while the first anchor 32 is held in its fixed position. This creates tension in the connecting member 34 to effect the geometry of the mitral valve annulus 20. Once a desired amount of tension is applied to the connecting member 34, the second anchor 36 is released from further movement and is redeployed against distal movement. With the connecting member 34 now under maintained tension, the advantageously effected geometry of the mitral valve annulus 20 is now preserved. The tension in the cable is preferably adjusted by the pulling on the second anchor 26 while monitoring a parameter indicative of mitral regurgitation, such as Doppler echo.

[39] The connecting member 34 may be provided with a covering (not shown). The covering may preferably be formed of a compressible material to serve to cushion the forces of the connecting member applied against the inner wall of the coronary sinus 14.

[40] **FIGS. 3** through **5** show a manner in which the device 30 may be deployed by a deployment assembly 50. As will be noted in **FIG. 3**, the deployment assembly 50 includes a catheter 52 and a tether 54. The catheter 52 has a lumen 56 dimensioned for slidably receiving the device 30 in its predeployed state with the tether 54 looped around the second anchor 36 and extending out the proximal end of the catheter 52.

[41] As will be noted in **FIG. 3**, the first anchor 32 has been deployed while the second anchor remains in the catheter lumen 56. This may be accompanied by feeding the catheter 52 into the coronary sinus until the first anchor is in a desired position. Now, the catheter 52 may be moved proximally while maintaining the first anchor 32 against movement. Proximal movement of the catheter 52 will release the anchor 32. When the anchor is released, it will self-expand to self-deploy and be fixed against proximal movement.

[42] As shown in **FIG. 4**, the catheter 52 is further retracted to release the second anchor 36 to permit it to self-expand and to self-deploy. The second anchor 36 is now fixed against distal movement but permitted to move proximally. The tether 54 continues to extend out the proximal end of the catheter 52.

[43] As may now be further seen in **FIG. 5**, tension is then applied to the connecting member 34 by proximally pulling on the tether 54, and hence the second anchor 36, while the first anchor 32 resists proximal movement. When the desired tension is placed on the connecting member 34, the second anchor 36 is released for re-self-deployment. When this is completed, the first anchor 32 and the second anchor 36 are fixed in position with a tension in the connecting member 34. The catheter 52 and the tether 54 may then be removed to complete the deployment process. Although the proximal anchor 36 is shown to be finally deployed in the coronary sinus, it will be appreciated by those skilled in the art that the proximal anchor 36, after being displaced proximally, may finally be deployed within the right atrium just proximal to the ostium 21 of the coronary sinus 14. Hence, any final position of the proximal anchor 36 proximal to the distal anchor 32 and within the heart is contemplated in accordance with the present invention.

[44] In accordance with the present invention, the device 30 may be deployed in a slightly different manner as described above. Here, the first anchor 32 may be deployed as described above and the second anchor 36 left in the catheter 52 as it is moved proximally. When the second anchor 36 reaches a desired position, the catheter 52 may then be pulled back to release and deploy the second anchor 36. As a result, in accordance with this alternative embodiment, the second anchor, when deployed, may anchor against both distal and proximal movement.

[45] **FIG. 6** shows another mitral valve device 70 embodying the present invention. The device 70 is similar to the device 30 previously described except that its connecting member 74 includes a spring configuration 75. The spring 75 has a maximum length and serves to more forcefully maintain the applied tension on the mitral valve annulus 20. To this end, the device 70 includes a first anchor 72, the connecting member 74, and a second anchor 76.

[46] The first and second anchors 72 and 76 are again configured so that when they are released, they self-expand, to wedge against the inner wall of the coronary sinus 14. Again, the first anchor resists proximal movement and the second anchor 76 resists distal movement. In all other respects, the device 70 may be identical to and deployed in the same manner as the device 30.

[47] Implantable cardiac stimulation devices are well known in the art. Such devices may include, for example, implantable cardiac pacemakers and defibrillators. The devices are generally implanted in a pectoral region of the chest beneath the skin of a patient within what is known as a subcutaneous pocket. The implantable devices generally function in association with one or more electrode carrying leads which are implanted within the heart. The electrodes are usually positioned within the right side of the heart, either within the right ventricle or right atrium, or both, for making electrical contact with their respective heart chamber. Conductors within the leads and a proximal connector carried by the leads couple the electrodes to the device to enable the device to sense cardiac electrical activity and deliver the desired therapy.

[48] Traditionally, therapy delivery had been limited to the venous, or right side of the heart. The reason for this is that implanted electrodes can cause blood clot formation in some patients. If a blood clot were released arterially from the left heart, as for example the left ventricle, it could pass directly to the brain potentially resulting in a paralyzing or fatal stroke. However, a blood clot released from the right heart, as from the right ventricle, would pass into the lungs where the filtering action of the lungs would prevent a fatal or debilitating embolism in the brain.

[49] Recently, new lead structures and methods have been proposed and even practiced for delivering cardiac rhythm management therapy to the left heart. These lead structures and methods avoid direct electrode placement within the left atrium and left ventricle of the heart by lead implantation within the coronary sinus of the heart. As previously mentioned, the phrase "coronary sinus" refers to not only the coronary sinus itself but in addition, the venous system associated with the coronary sinus including the great cardiac vein.

[50] It has been demonstrated that electrodes placed in the coronary sinus region of the heart may be used for left atrial pacing, left ventricular pacing, or cardioversion and defibrillation. These advancements enable implantable cardiac stimulation devices to address the needs of a patient population with left ventricular dysfunction and/or congestive heart failure which would benefit from left heart side pacing, either alone or in conjunction with right heart side pacing (bi-chamber pacing), and/or defibrillation.

[51] Even though the device of the present invention is implantable in the coronary sinus of the heart, it is configured in accordance with further aspects of the present invention to permit a cardiac lead to pass through the coronary sinus for functioning as described above. To that end, and as best seen in **FIG. 7**, the anchors 32 and 36 of the device 30 occupy only a small portion of and hence less than all of the interior space of the coronary sinus 14. This permits a cardiac lead 80 to be advanced into the coronary sinus 14 for implant in the left side of the heart.

[52] More specifically, the anchors 32 and 36 take the form of loops 33 and 35 respectively which are then bent backwards on the device to form the previously referred to hook-shapes for self-deployment. The loops 33 and 35 thus permit the cardiac lead 80 to be passed therethrough for implant in the left heart. This is particularly desirable because many patients suffering from mitral regurgitation may also be candidates for left heart cardiac rhythm management therapy.

[53] While particular embodiments of the present invention have been shown and described, modifications may be made, and it is therefore intended in the appended claims to cover all such changes and modifications which fall within the true spirit and scope of the invention as defined by the appended claims.

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THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A system that effects mitral valve annulus geometry of a heart, including:

a mitral valve device including a first anchor configured to be positioned within and anchored to the coronary sinus of the heart adjacent the mitral valve annulus within the heart, a second anchor configured to be positioned within the heart proximal to the first anchor and adjacent and mitral valve annulus within the heart, and a connecting member having a fixed length permanently attached to the first and second anchors;

a catheter having a distal end, a proximal end and a lumen that receives the device, the catheter being guidable into the coronary sinus adjacent to the mitral value annulus and deploying the first and second anchors of the device within the coronary sinus adjacent to the mitral valve annulus; and

a tether releasably coupled to the second anchor and extending proximally through the lumen and out of the catheter proximal end, whereby

when the first anchor is deployed by the catheter in the coronary sinus, the second anchor may be displaced proximally by proximally pulling on the tether to effect the geometry of the mitral valve annulus and thereafter released for deployment to maintain the effect on the mitral valve geometry.

2. The system of claim 1 wherein the second anchor, when deployed, is anchored against distal movement and moveable in a proximal direction.

3. The system of claim 1 or 2 wherein the first anchor is self-deploying upon release in the coronary sinus.

4. The system of any one of the preceding claims wherein the second anchor is self-deploying upon release in the coronary sinus.

5. The system of any one of the preceding claims wherein the connecting member is a rigid member.

6. The system of any one of the preceding claims wherein the connecting member includes a spring having a maximum length.

7. The system of any one of the preceding claims wherein the connecting member is flexible and nonstretchable.

8. A device that effects mitral valve annulus geometry of a heart, including:

a first expandable anchor, a second expandable anchor and a fixed length connecting member attached to the first and second anchors; said first anchor configured to be anchored in a coronary sinus; said second anchor configured to be deployed adjacent the mitral valve annulus; whereby the first anchor is positioned in the coronary sinus and the second anchor is deployed proximal of the first anchor.

9. The device of claim 8 wherein the first anchor is anchored proximal to a crossover point located between a coronary sinus and the cimcumflex artery.

10. The device of claim 9 wherein the proximal anchor is positioned in the coronary sinus distal to an ostium of the coronary sinus.

11. The device of claim 10 wherein the connecting member has an arcuate configuration.

12. The device of claim 11 wherein a tension applied to the connecting member affects the geometry of the mitral valve annulus.

13. The device of claim 12 wherein the tension is applied by applying a force on the second anchor.

14. The device of claim 13 wherein the device further includes a tension applying member releasably coupled to the second anchor.

15. The device of claim 13 or 14 wherein a desired level of tension is applied in order to affect a concomitant change in the geometry of the mitral valve annulus.

16. The device of claim 14 or 15 wherein the second member is decoupled from the second anchor after the desired change in mitral valve geometry is achieved.

17. The device of claim 15 or 16 wherein the desired change in the geometry of the mitral valve annulus is monitored.

18. The device of any one of claims 15 to 17 wherein the desired change in the geometry of the mitral valve annulus is indicated by a change in a patient's mitral valve regurgitation.

19. The device of any one of claims 15 to 18 wherein change in the geometry of the mitral valve annulus reduces mitral valve regurgitation.

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20. The device of any one of claims 15 to 19 wherein the device further includes a covering.

21. The device of any one of claims 8 to 20 wherein the connecting member is configured to be atraumatic.

22. The device of any one of claims 8 to 21 wherein the first anchor, the second anchor and connecting members are integral.

23. The device of any one of claims 8 to 22, wherein the first and second anchors are each configured and arranged to have a collapsed delivery configuration and an expanded deployed configuration.

24. The device of any one of claims 8 to 23, wherein the fixed length connecting member comprises a spring.

25. A method of treating mitral valve regurgitation in a patient's heart, the method comprising:

delivering a mitral valve device to a coronary sinus of the patient, the mitral valve device comprising a distal anchor, a proximal anchor, and a connecting member attached to and connecting the distal and proximal anchors;

expanding the distal anchor in the coronary sinus;

moving the proximal anchor proximally with respect to the coronary sinus while preventing proximal movement of the distal anchor relative to the coronary sinus, wherein moving the proximal anchor proximally with respect to the coronary sinus affects the geometry of the mitral valve annulus.

26. The method of claim 25 further comprising expanding the proximal anchor after the moving step, wherein expanding the

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proximal anchor maintains the effect on the mitral valve geometry.

27. The method of claim 25 or 26 wherein the step of expanding the distal anchor comprises releasing the distal anchor to permit the distal anchor to self-expand.

28. The method of any one of claims 25 to 27 further comprising expanding the proximal anchor after the moving step.

29. The method of any one of claims 25 to 28 wherein the step of expanding the proximal anchor comprises expanding the proximal anchor in the coronary sinus.

30. A system that effects mitral valve annulus geometry of a heart substantially as hereinbefore described with reference to any one of the embodiments illustrated in Figures 2 to 7.

31. A device that effects mitral valve annulus geometry of a heart substantially as hereinbefore described with reference to any one of the embodiments illustrated in Figures 2 to 7.

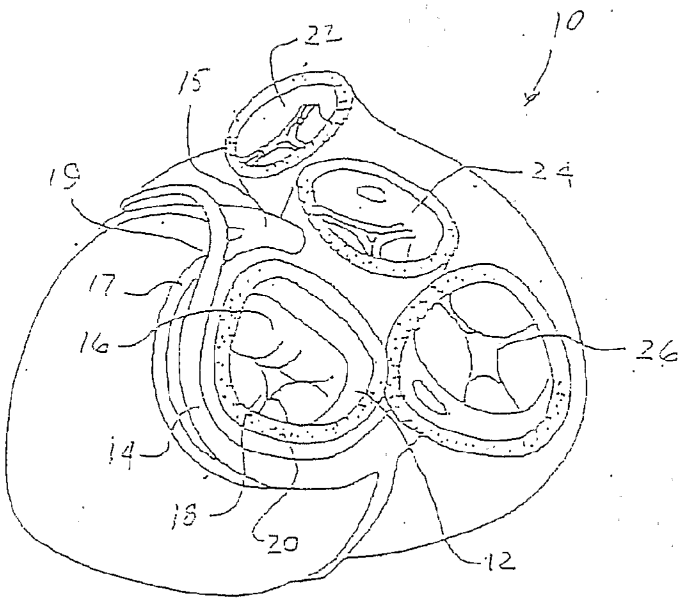
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FIG. 1

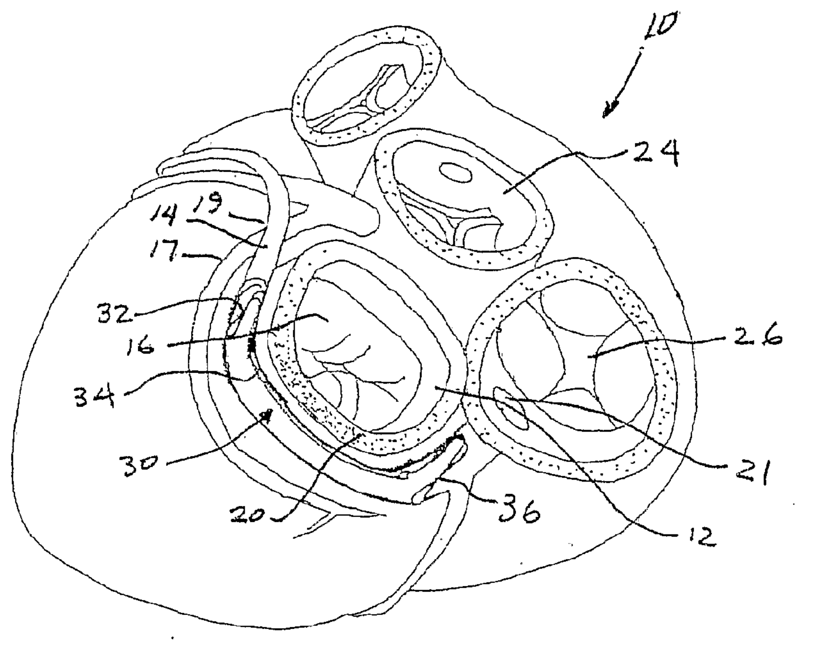
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FIG. 2

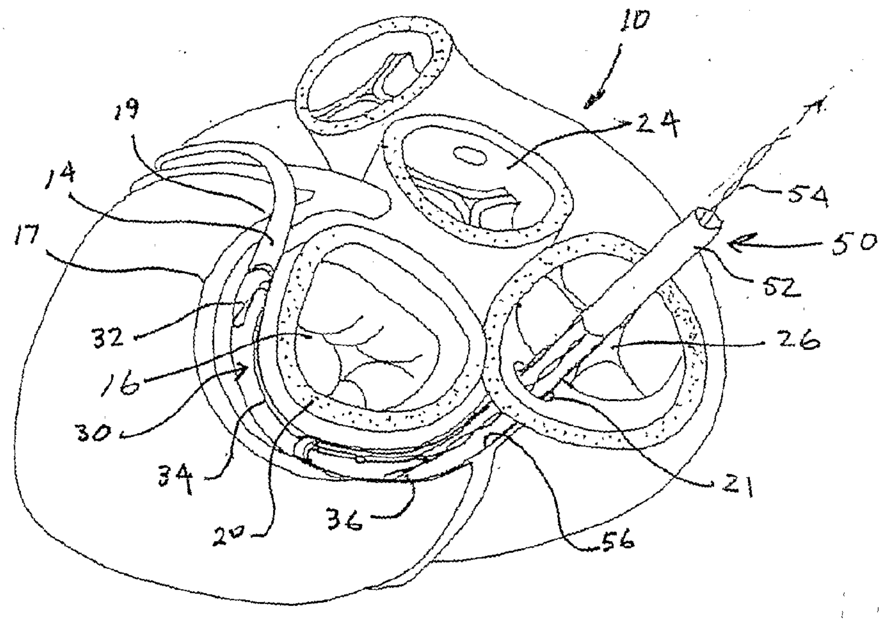
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FIG. 3

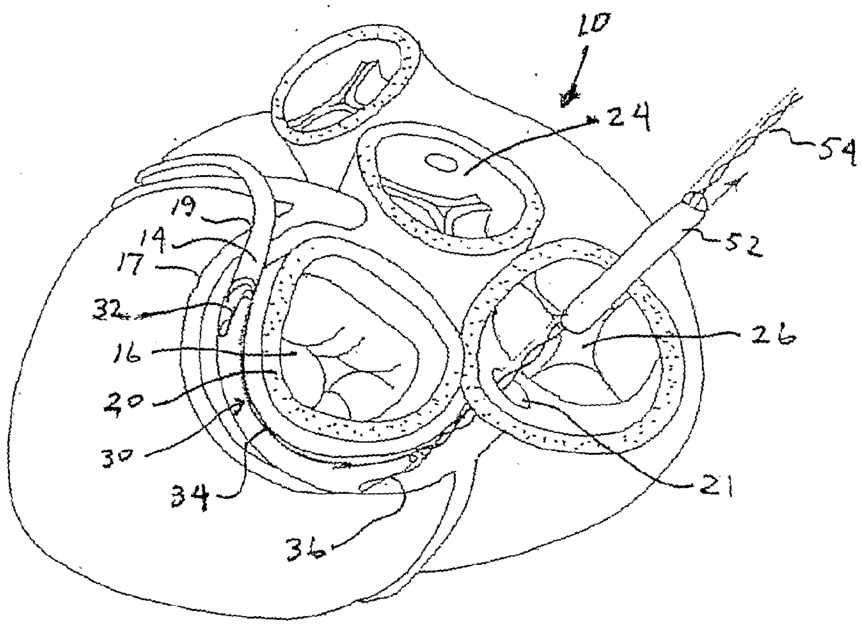
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FIG. 4

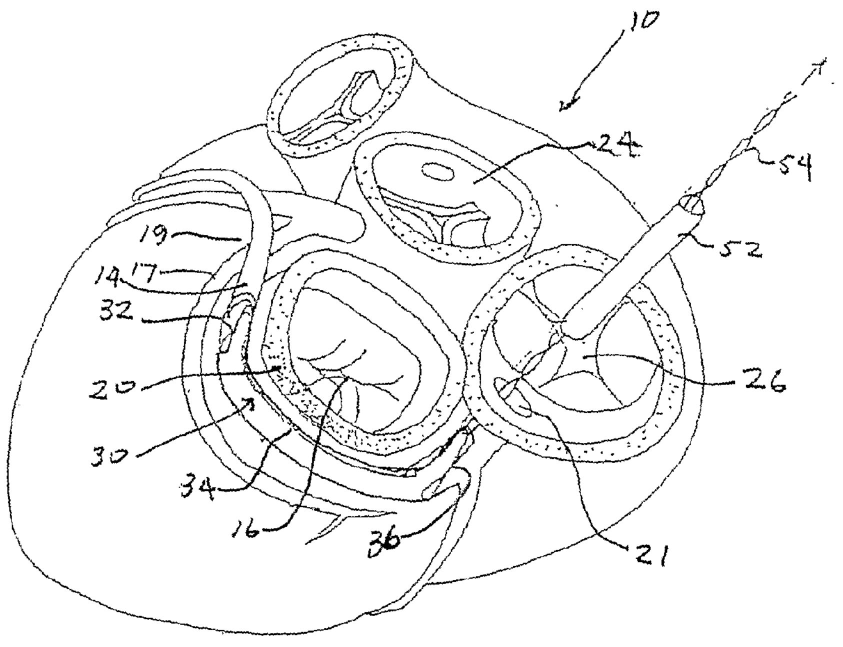
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FIG. 5

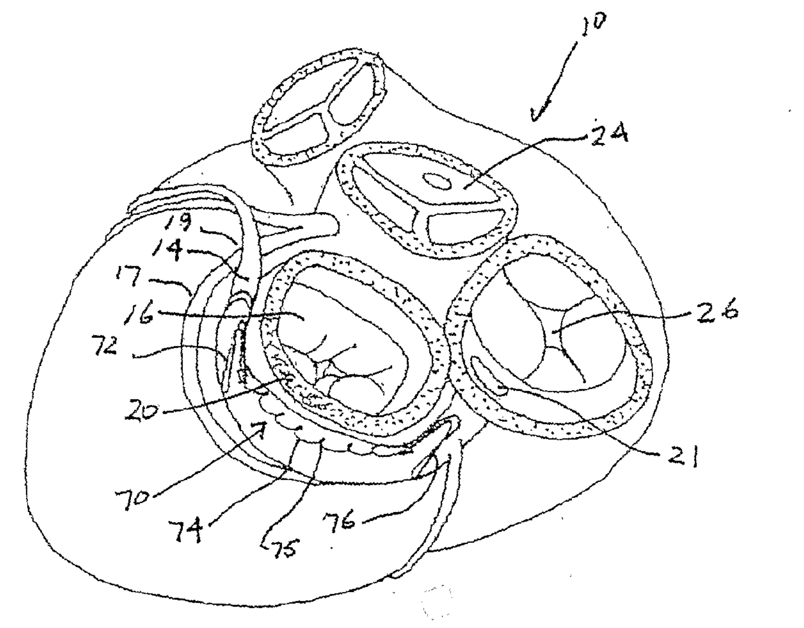
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FIG. 6

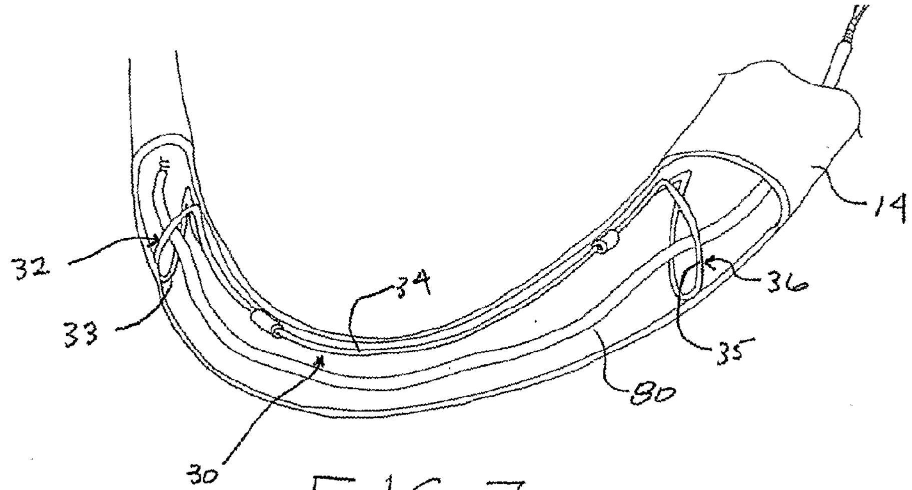

FIG. 7