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(54) **METHOD AND APPARATUS FOR IMPROVING MITRAL VALVE FUNCTION**

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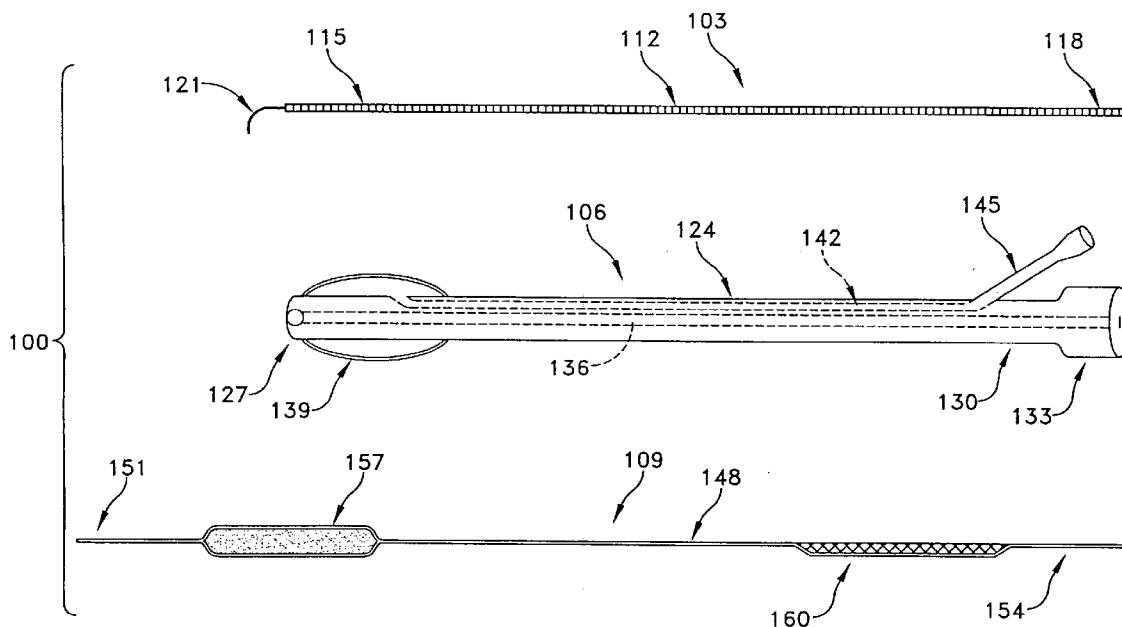
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(63) Continuation of application No. 10/068,264, filed on Feb. 5, 2002, now Pat. No. 6,656,221.

(57) **ABSTRACT**

A method and apparatus for reducing mitral regurgitation. The apparatus is inserted into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the apparatus being adapted to straighten the natural curvature of at least a portion of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation and reduce mitral regurgitation.



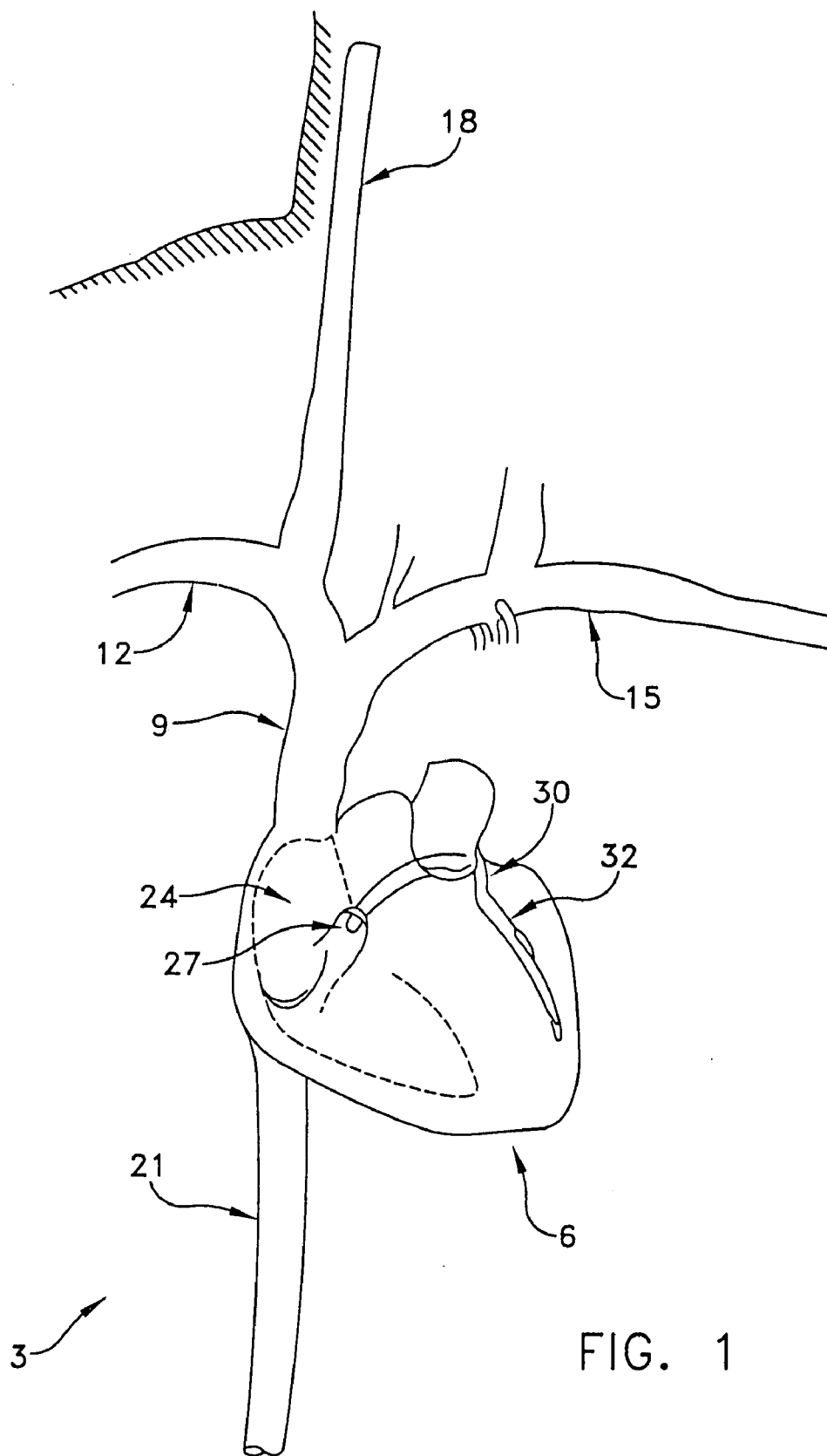


FIG. 1

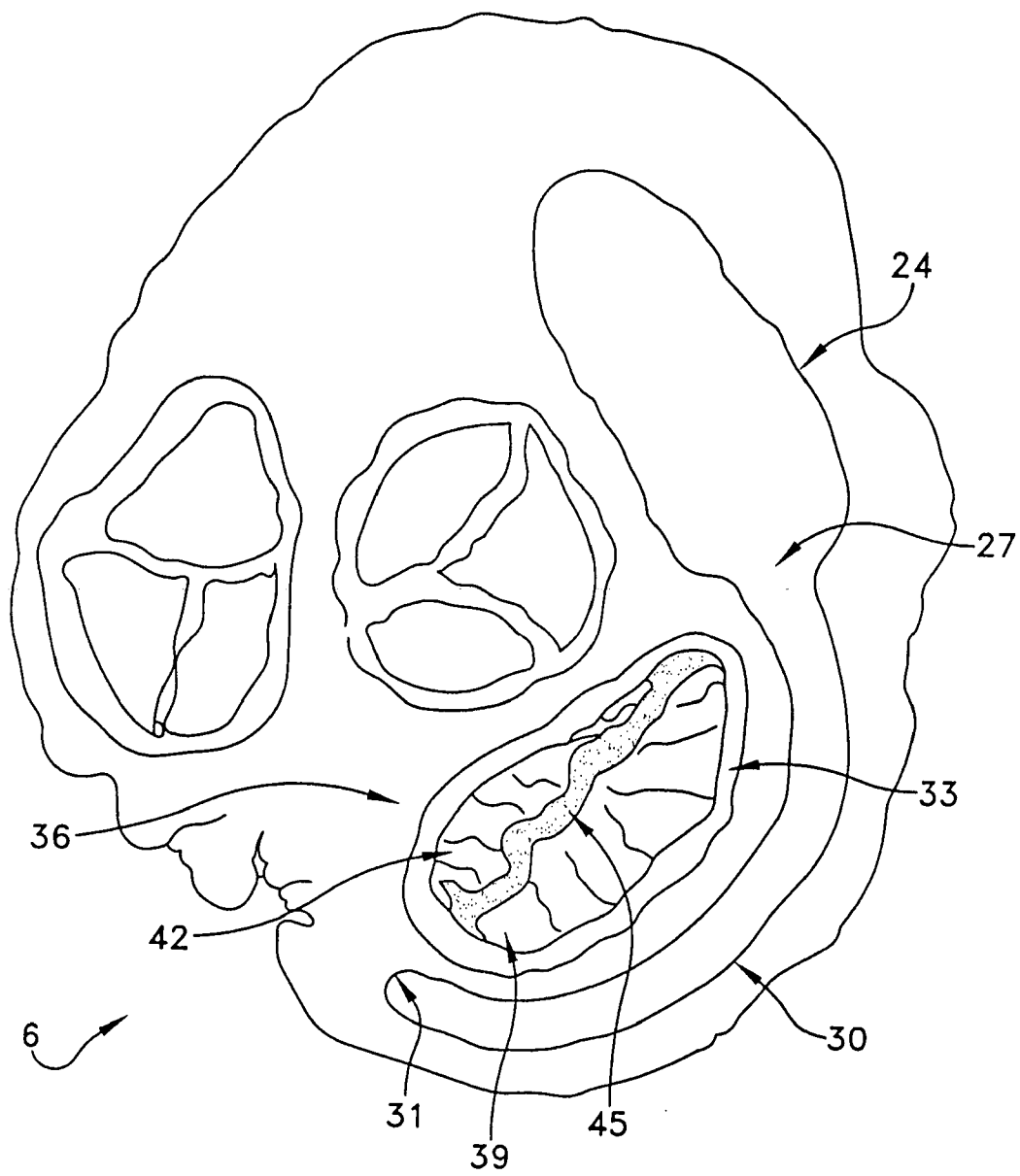


FIG. 2

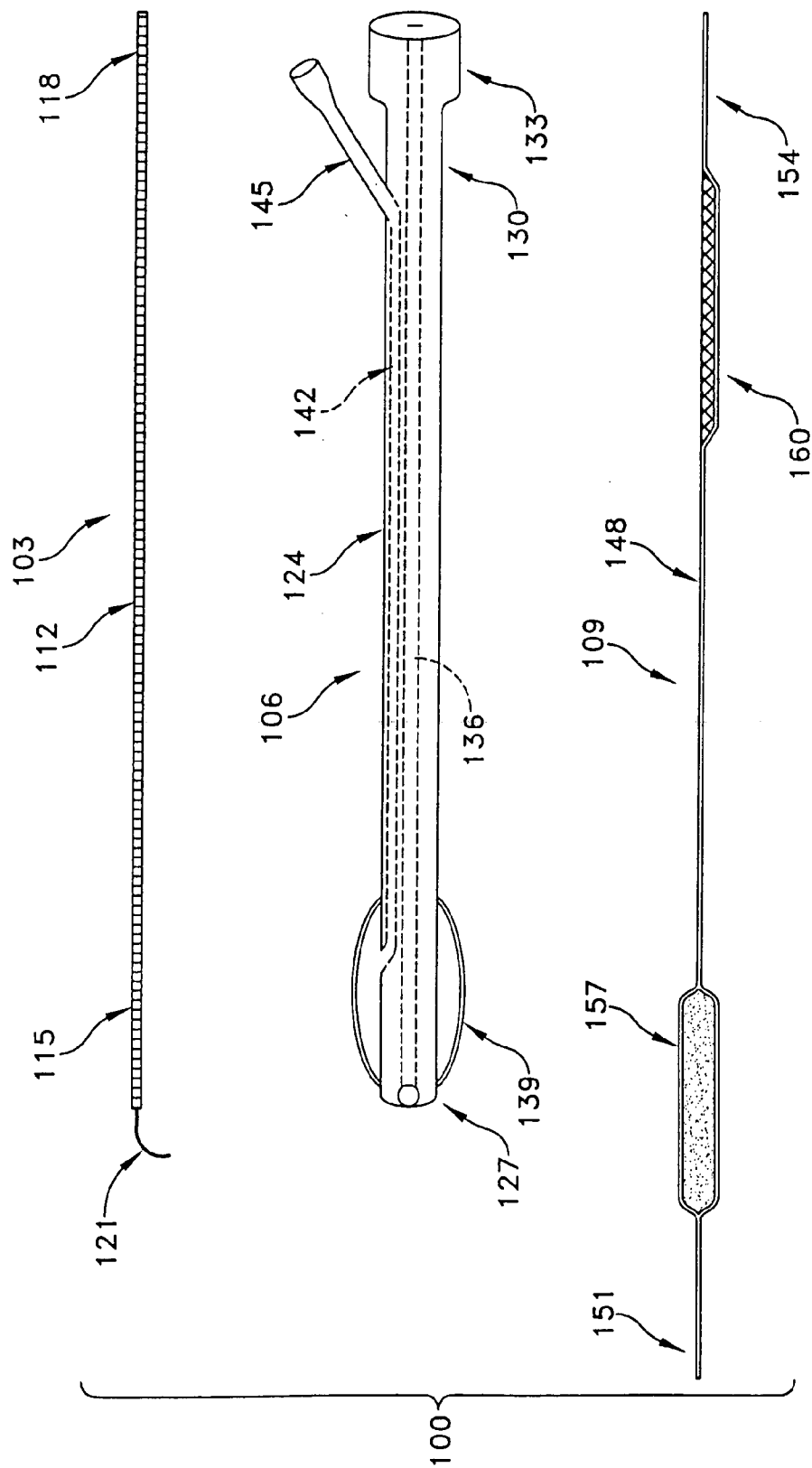


FIG. 3

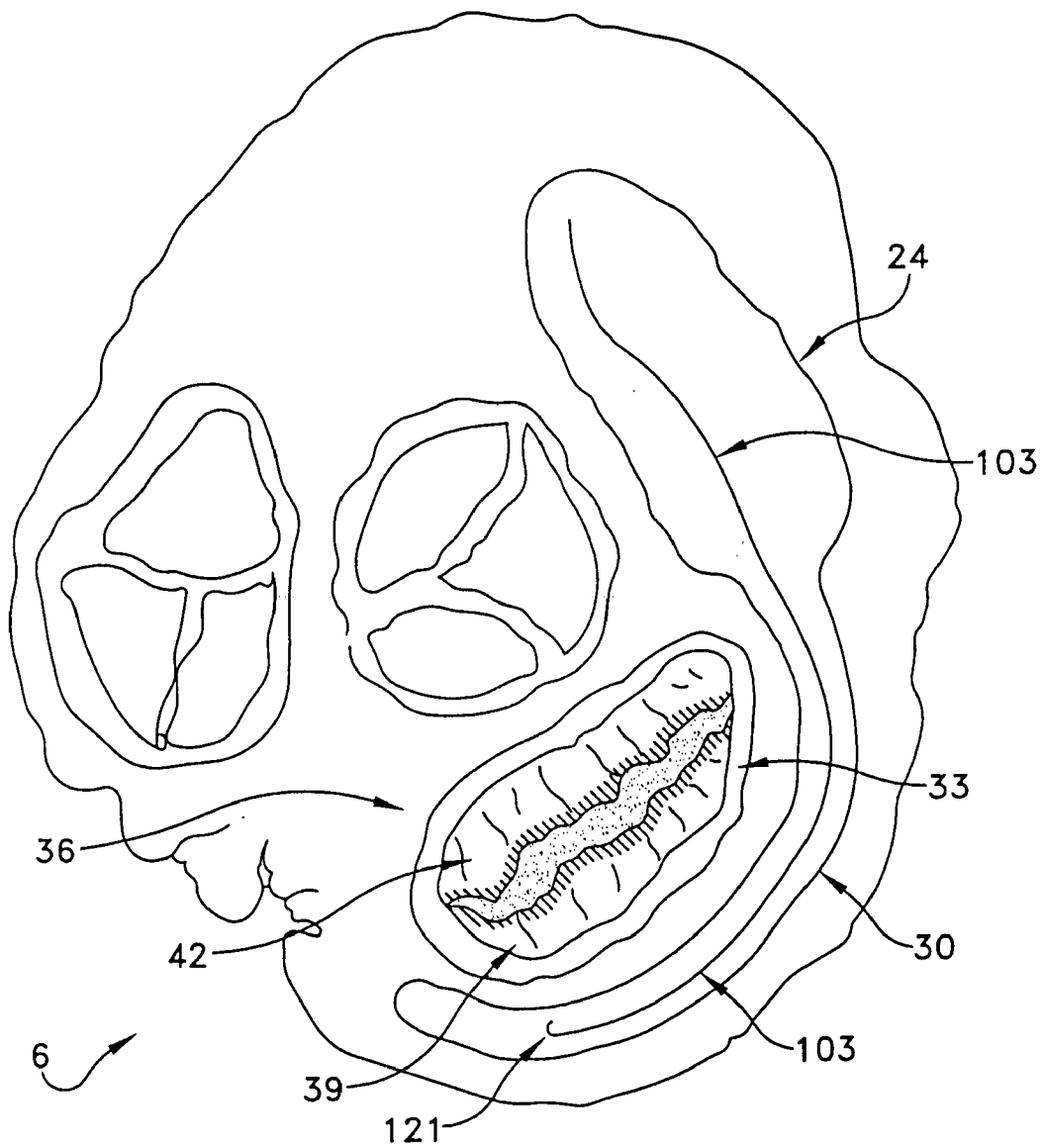


FIG. 4

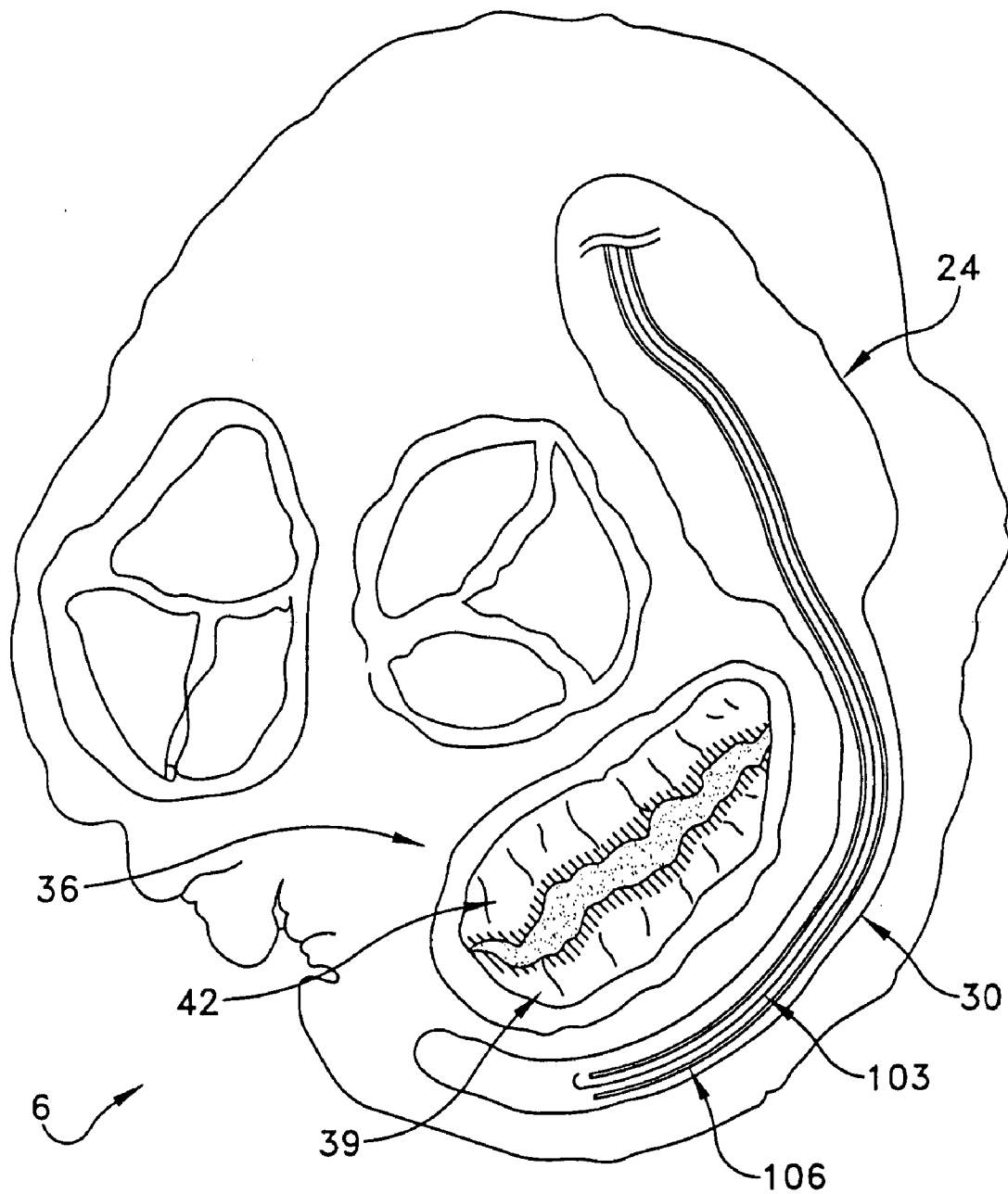


FIG. 5

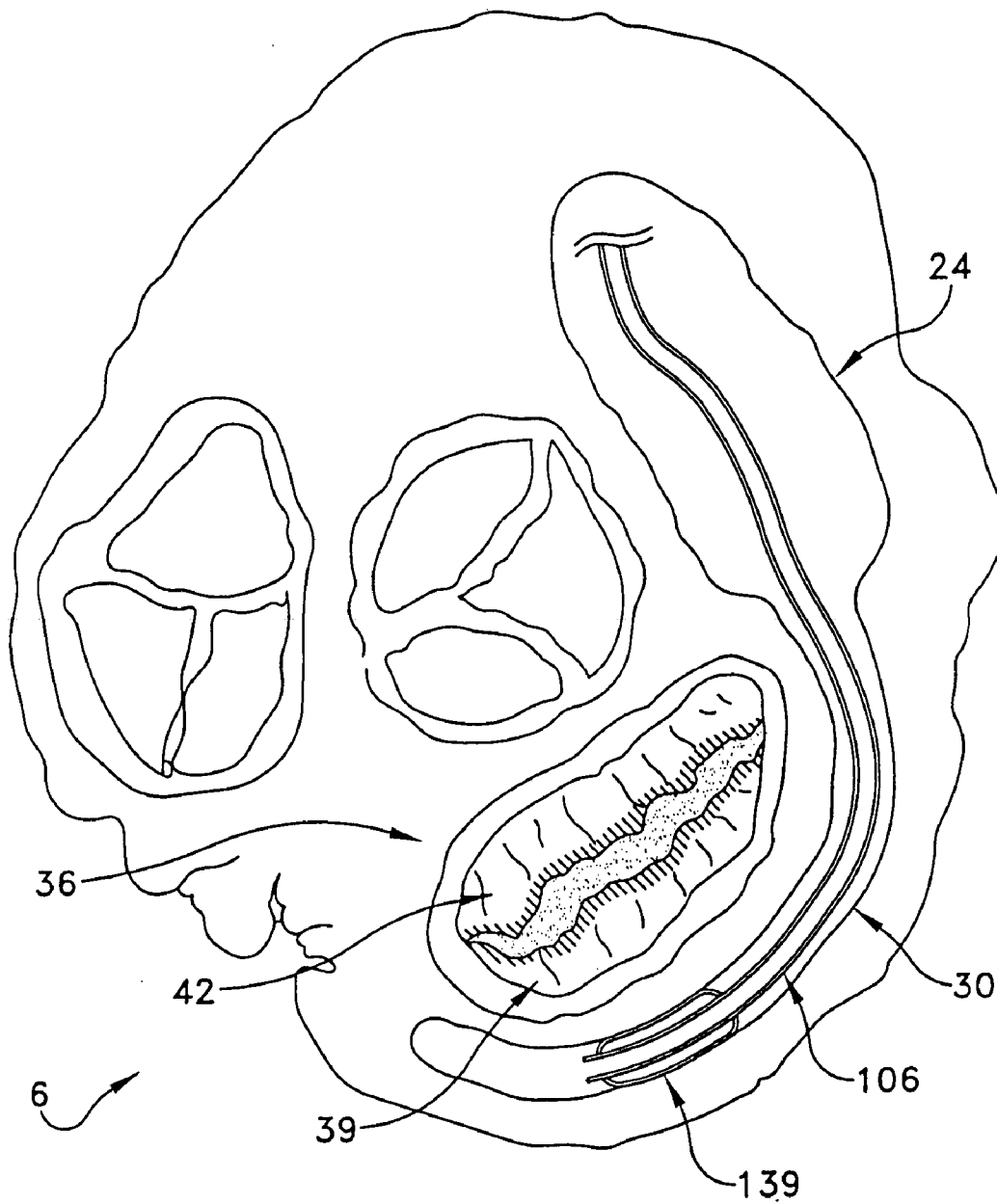


FIG. 6

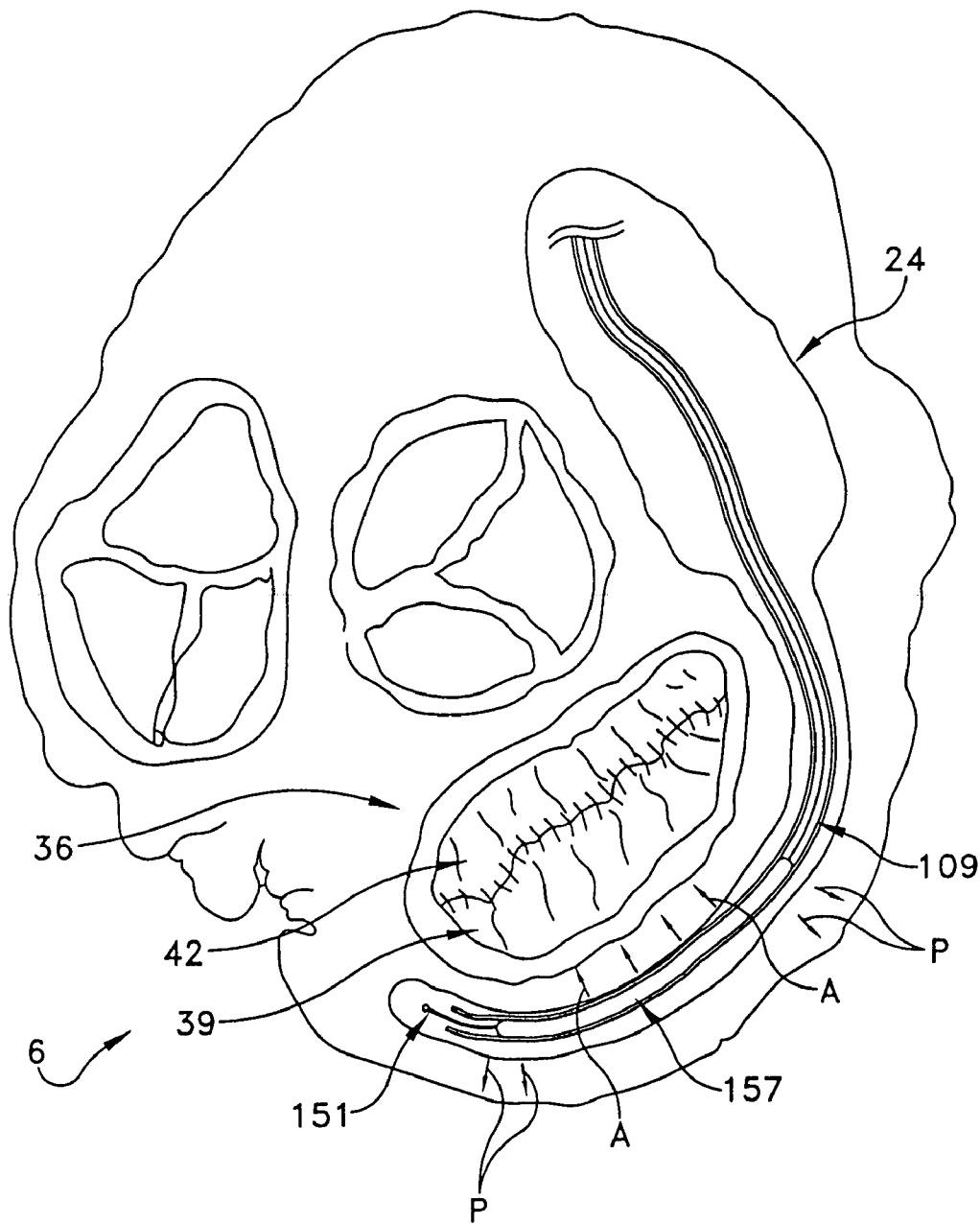
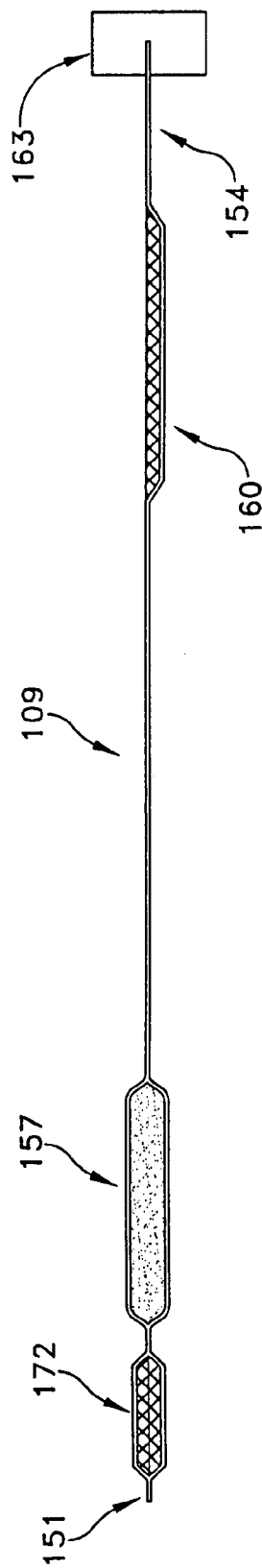
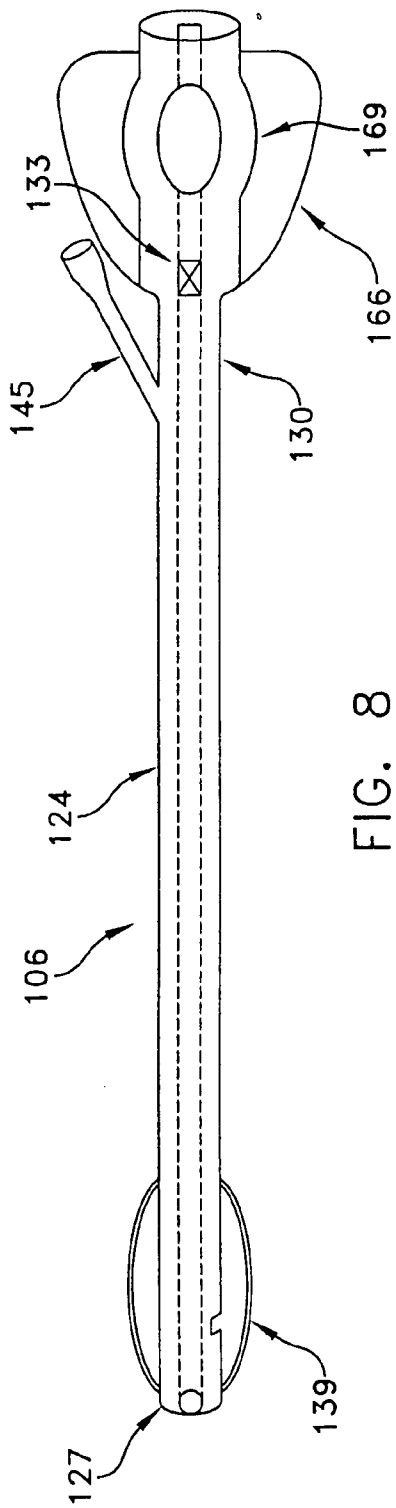


FIG. 7



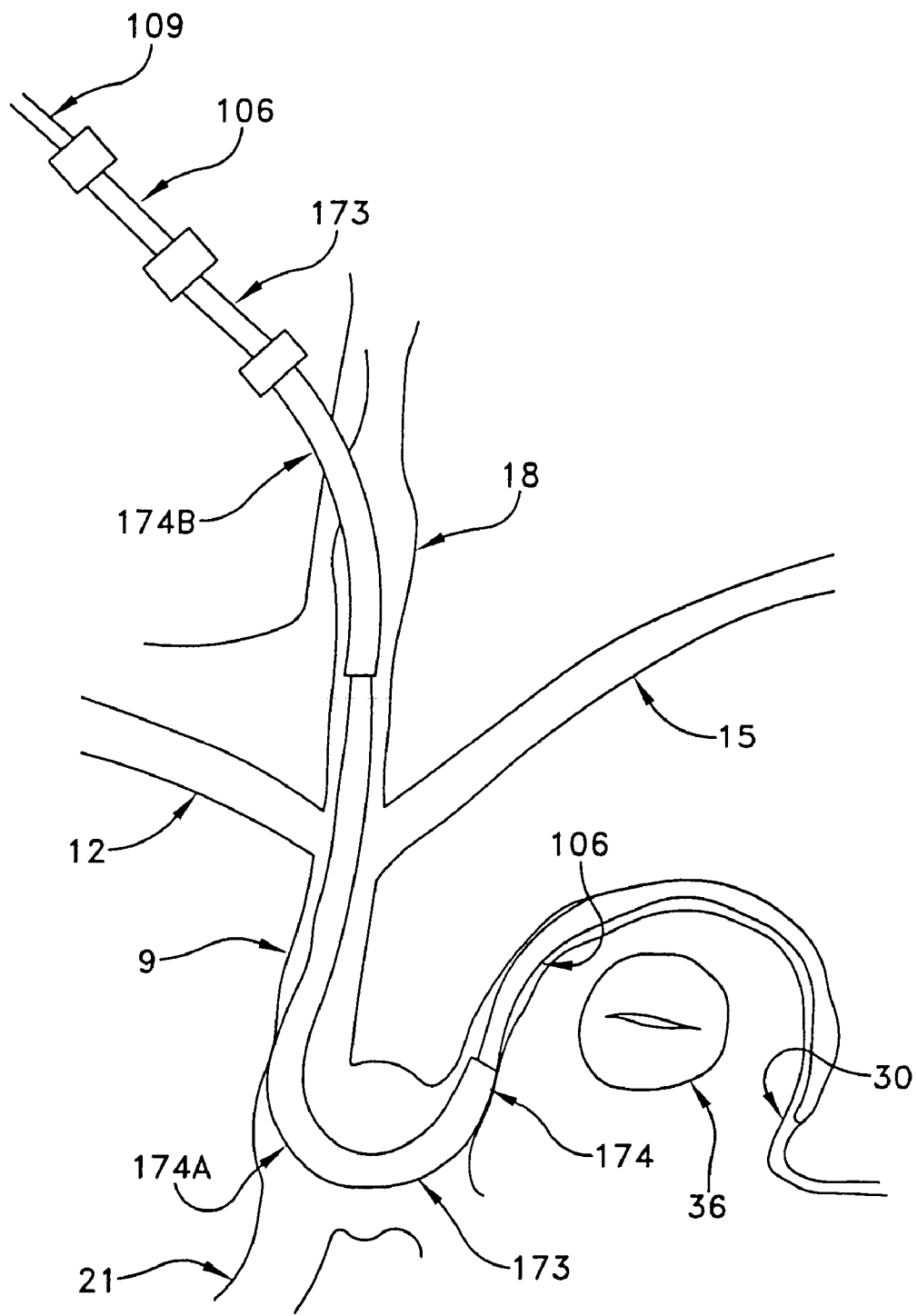


FIG. 9A

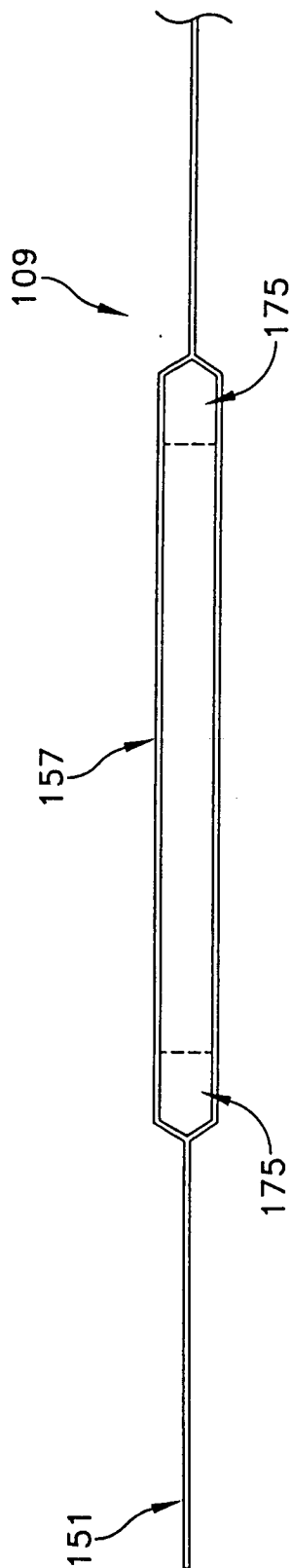


FIG. 10

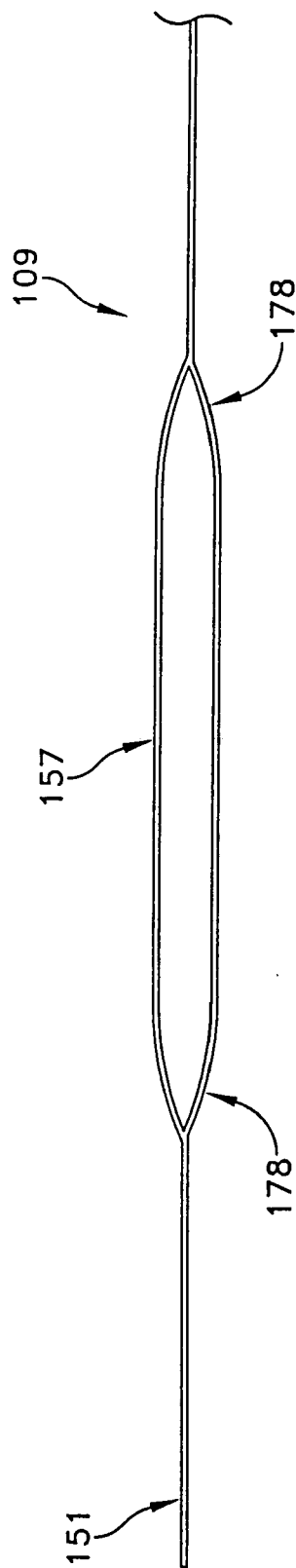


FIG. 11

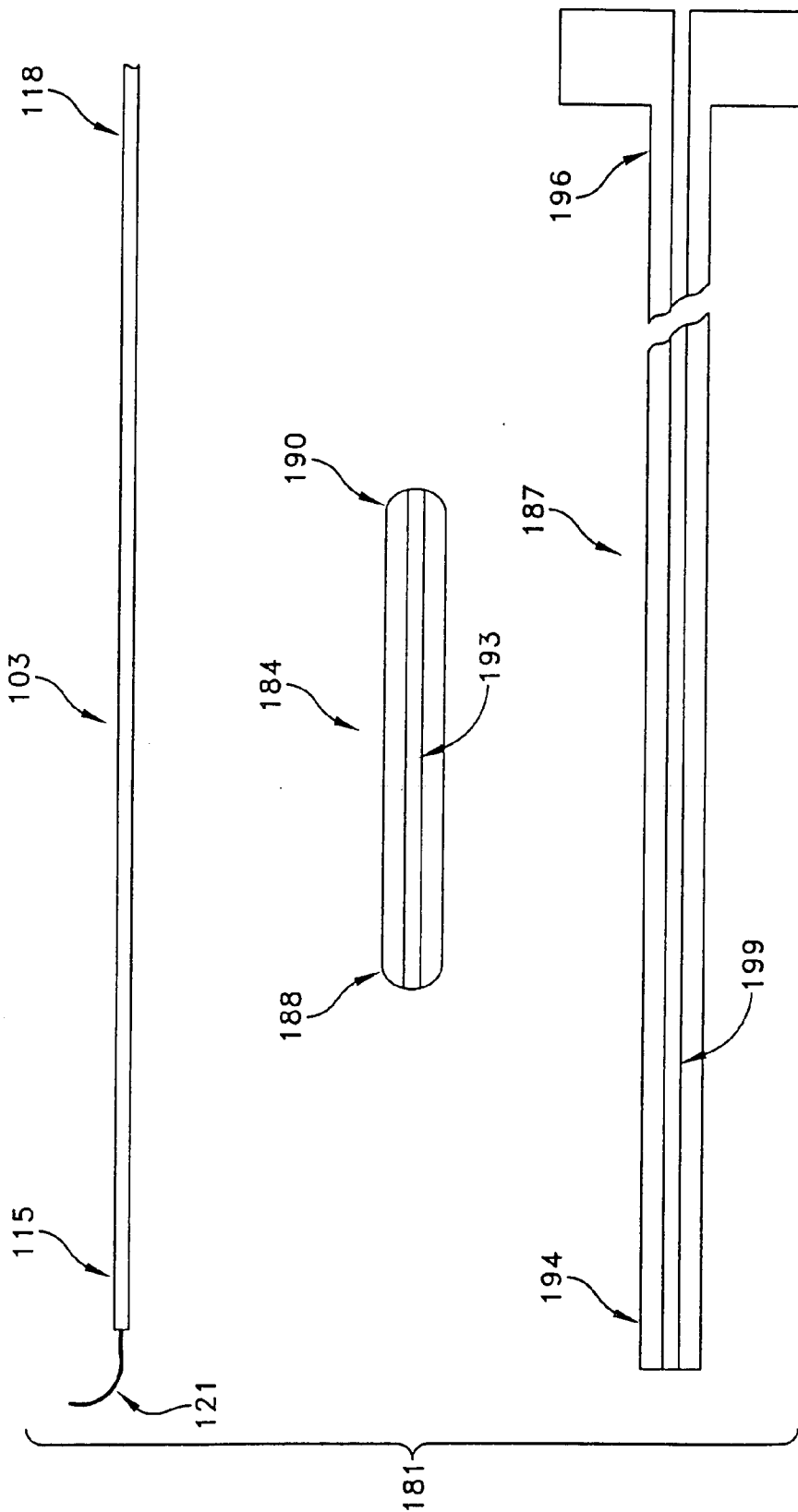


FIG. 12

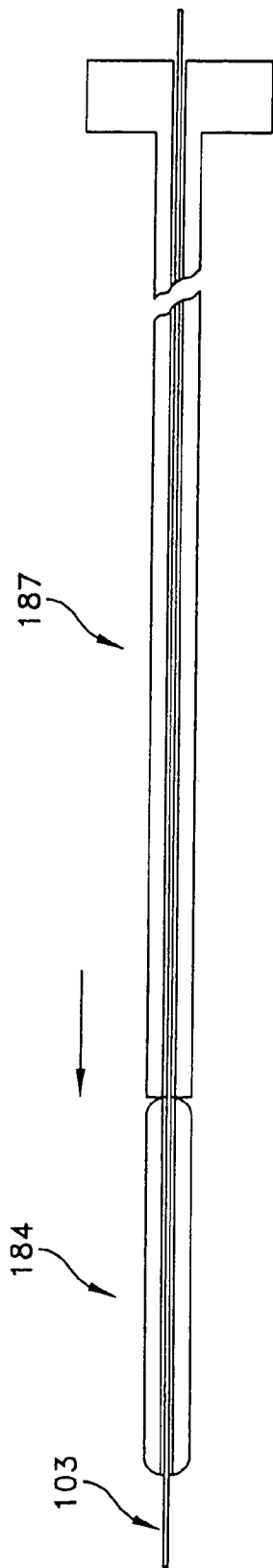


FIG. 13

METHOD AND APPARATUS FOR IMPROVING MITRAL VALVE FUNCTION

REFERENCE TO PENDING PRIOR PATENT APPLICATIONS

- [0001] This patent application claims benefit of:
- [0002] (1) pending prior U.S. Provisional Patent Application Ser. No. 60/266,766, filed Feb. 5, 2001 by William E. Cohn et al. for TRANSVASCULAR APPROACH TO MITRAL VALVE PROCEDURES (Attorney's Docket No. VIA-16 PROV);
- [0003] (2) pending prior U.S. Provisional Patent Application Ser. No. 60/273,893, filed Mar. 5, 2001 by William E. Cohn et al. for TRANSVASCULAR METHODS AND DEVICES FOR MITRAL VALVE PROCEDURES (Attorney's Docket No. VIA-17 PROV);
- [0004] (3) pending prior U.S. Provisional Patent Application Ser. No. 60/278,153, filed Mar. 23, 2001 by William E. Cohn et al. for METHOD AND APPARATUS TO IMPROVE MITRAL VALVE FUNCTION (Attorney's Docket No. VIA-18 PROV);
- [0005] (4) pending prior U.S. Provisional Patent Application Ser. No. 60/279,974, filed Mar. 29, 2001 by Daniel C. Taylor et al. for METHOD AND APPARATUS TO IMPROVE MITRAL VALVE FUNCTION (Attorney's Docket No. VIA-19 PROV);
- [0006] (5) pending prior U.S. Provisional Patent Application Ser. No. 60/280,038, filed Mar. 30, 2001 by William E. Cohn et al. for METHODS AND APPARATUS FOR TEMPORARY IMPROVEMENT IN MITRAL VALVE FUNCTION (Attorney's Docket No. VIA-20 PROV);
- [0007] (6) pending prior U.S. Provisional Patent Application Ser. No. 60/279,973, filed Mar. 29, 2001 by Daniel C. Taylor et al. for METHODS AND DEVICES TO IMPROVE MITRAL VALVE FUNCTION (Attorney's Docket No. VIA-21 PROV);
- [0008] (7) pending prior U.S. Provisional Patent Application Ser. No. 60/283,820, filed Apr. 13, 2001 by William E. Cohn et al. for METHOD AND APPARATUS FOR TEMPORARY IMPROVEMENT IN MITRAL VALVE FUNCTION (Attorney's Docket No. VIA-22 PROV);
- [0009] (8) pending prior U.S. Provisional Patent Application Ser. No. 60/312,217, filed Aug. 14, 2001 by Daniel C. Taylor et al. for METHOD AND APPARATUS FOR TEMPORARY IMPROVEMENT IN MITRAL VALVE FUNCTION (Attorney's Docket No. VIA-23 PROV);
- [0010] (9) pending prior U.S. Provisional Patent Application Ser. No. 60/339,481, filed Oct. 26, 2001 by William E. Cohn et al. for TRANSVASCULAR APPROACH TO MITRAL VALVE PROCEDURES (Attorney's Docket No. VIA-30 PROV); and
- [0011] (10) pending prior U.S. Provisional Patent Application Ser. No. 60/348,424, filed Jan. 14, 2002

by Daniel C. Taylor et al. for METHOD AND APPARATUS TO IMPROVE MITRAL VALVE FUNCTION (Attorney's Docket No. VIA-31 PROV).

[0012] The aforementioned ten (10) patent applications are hereby incorporated herein by reference.

FIELD OF THE INVENTION

[0013] This invention relates to surgical methods and apparatus in general, and more particularly to surgical methods and apparatus for improving mitral valve function.

BACKGROUND OF THE INVENTION

[0014] Mitral valve repair is the procedure of choice to correct mitral regurgitation of all etiologies. With the use of current surgical techniques, between 70% and 95% of regurgitant mitral valves can be repaired. The advantages of mitral valve repair over mitral valve replacement are well documented. These include better preservation of cardiac function and reduced risk of anticoagulant-related hemorrhage, thromboembolism and endocarditis.

[0015] In current practice, mitral valve surgery requires an extremely invasive approach that includes a chest wall incision, cardiopulmonary bypass, cardiac and pulmonary arrest, and an incision on the heart itself to gain access to the mitral valve. Such a procedure is associated with high morbidity and mortality. Due to the risk associated with this procedure, many of the sickest patients are denied the potential benefits of surgical correction of mitral regurgitation. In addition, patients with moderate, symptomatic mitral regurgitation are denied early intervention and undergo surgical correction only after the development of cardiac dysfunction.

[0016] Mitral regurgitation is a common occurrence in patients with heart failure and a source of important morbidity and mortality in these patients. Mitral regurgitation in patients with heart failure is caused by changes in the geometric configurations of the left ventricle, papillary muscles and mitral annulus. These geometric alterations result in incomplete coaptation of the mitral leaflets at systole. In this situation, mitral regurgitation is corrected by plicating the mitral valve annulus, either by sutures alone or by sutures in combination with a support ring, so as to reduce the circumference of the distended annulus and restore the original geometry of the mitral valve annulus.

[0017] More particularly, current surgical practice for mitral valve repair generally requires that the mitral valve annulus be reduced in radius by surgically opening the left atrium and then fixing sutures, or more commonly sutures in combination with a support ring, to the internal surface of the annulus; this structure is used to cinch the annulus, in a pursestring-like fashion, to a smaller radius, thereby reducing mitral regurgitation by improving leaflet coaptation.

[0018] This method of mitral valve repair, generally termed "annuloplasty", effectively reduces mitral regurgitation in heart failure patients. This, in turn, reduces symptoms of heart failure, improves quality of life and increases longevity. Unfortunately, however, the invasive nature of mitral valve surgery and the attendant risks render most heart failure patients poor surgical candidates. Thus, a less invasive means to increase leaflet coaptation and thereby

reduce mitral regurgitation in heart failure patients would make this therapy available to a much greater percentage of patients.

[0019] Mitral regurgitation also occurs in approximately 20% of patients suffering acute myocardial infarction. In addition, mitral regurgitation is the primary cause of cardiogenic shock in approximately 10% of patients who develop severe hemodynamic instability in the setting of acute myocardial infarction. Patients with mitral regurgitation and cardiogenic shock have about a 50% hospital mortality. Elimination of mitral regurgitation in these patients would be of significant benefit. Unfortunately, however, patients with acute mitral regurgitation complicating acute myocardial infarction are particularly high-risk surgical candidates, and are therefore not good candidates for a traditional annuloplasty procedure. Thus, a minimally invasive means to effect a temporary reduction or elimination of mitral regurgitation in these critically ill patients would afford them the time to recover from the myocardial infarction or other acute life-threatening events and make them better candidates for medical, interventional or surgical therapy.

SUMMARY OF THE INVENTION

[0020] As a result, one object of the present invention is to provide an improved method and apparatus for reducing mitral regurgitation.

[0021] Another object of the present invention is to provide a method and apparatus for reducing mitral regurgitation which is minimally invasive.

[0022] Another object of the present invention is to provide a method and apparatus for reducing mitral regurgitation which can be deployed either permanently (e.g., for patients suffering from heart failure) or temporarily (e.g., for patients suffering from mitral regurgitation with acute myocardial infarction).

[0023] These and other objects are addressed by the present invention, which comprises an improved method and apparatus for reducing mitral regurgitation.

[0024] In one form of the invention, there is provided a method for reducing mitral regurgitation comprising:

[0025] inserting apparatus into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the apparatus being adapted to straighten the natural curvature of at least a portion of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

[0026] In another form of the invention, there is provided a method for reducing mitral regurgitation comprising:

[0027] inserting apparatus into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the apparatus being adapted to move at least a portion of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve anteriorly, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

[0028] In another form of the invention, there is provided a method for reducing mitral regurgitation comprising:

[0029] inserting apparatus into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the apparatus being adapted to reduce the degree of natural curvature of at least a portion of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

[0030] In another form of the invention, there is provided a method for reducing mitral regurgitation comprising:

[0031] inserting apparatus into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the apparatus being adapted to increase the natural radius of curvature of at least a portion of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

[0032] In another form of the invention, there is provided a method for reducing mitral regurgitation comprising:

[0033] inserting apparatus into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the apparatus having a distal end, a proximal end and an intermediate portion, the apparatus being configured so that when the apparatus is positioned in the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, the distal and proximal ends will apply a posteriorly-directed force to the walls of the coronary sinus and the intermediate portion will apply an anteriorly-directed force to the walls of the coronary sinus, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

[0034] In another form of the invention, there is provided a method for reducing mitral regurgitation comprising:

[0035] inserting a substantially straight elongated body into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the length of the substantially straight elongated body being sized relative to the natural curvature of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve so that when the substantially straight elongated body is positioned in the coronary sinus, it will cause at least a portion of the coronary sinus to assume a substantially straight configuration adjacent to the posterior leaflet of the mitral valve, whereby to increase the radius of curvature of the mitral annulus and thereby improve leaflet coaptation.

[0036] In another form of the invention, there is provided a method for reducing mitral regurgitation comprising:

[0037] inserting a substantially rigid elongated body into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the substantially rigid elongated body being configured relative to the natural curvature of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve so that when the substantially rigid elongated body is

positioned in the coronary sinus, it will cause at least a portion of the coronary sinus to assume a different configuration adjacent to the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

[0038] In another form of the invention, there is provided a method for reducing mitral regurgitation comprising:

[0039] inserting a straight, substantially rigid elongated body into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the length of the straight, substantially rigid elongated body being sized relative to the natural curvature of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve so that when the straight, substantially rigid elongated body is positioned in the coronary sinus, it will cause at least a portion of the coronary sinus to assume a substantially straight configuration adjacent to the posterior leaflet of the mitral valve, whereby to increase the radius of curvature of the mitral annulus and thereby improve leaflet coaptation.

[0040] In another form of the invention, there is provided an apparatus for reducing mitral regurgitation comprising:

[0041] a body having a distal end, a proximal end and an intermediate portion, the body being configured so that when the body is positioned in the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, the distal and proximal ends will apply a posteriorly-directed force to the walls of the coronary sinus, and the intermediate portion will apply an anteriorly-directed force to the walls of the coronary sinus, whereby to move the posterior annulus of the mitral valve anteriorly and thereby improve leaflet coaptation.

[0042] In another form of the invention, there is provided an apparatus for reducing mitral regurgitation comprising:

[0043] a substantially straight elongated body adapted to be inserted into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the length of the substantially straight elongated body being sized relative to the natural curvature of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve so that when the substantially straight elongated body is positioned in the coronary sinus, it will cause at least a portion of the coronary sinus to assume a substantially straight configuration adjacent to the posterior leaflet of the mitral valve, whereby to increase the radius of curvature of the mitral annulus, moving it anteriorly, and thereby improve leaflet coaptation.

[0044] In another form of the invention, there is provided an apparatus for reducing mitral regurgitation comprising:

[0045] a substantially rigid elongated body adapted to be inserted into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the length of the straight, substantially rigid elongated body being sized relative to the natural curvature of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve so that when the substantially rigid elongated body is positioned in

the coronary sinus, it will cause at least a portion of the coronary sinus to assume a different configuration adjacent to the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

[0046] In another form of the invention, there is provided an apparatus for reducing mitral regurgitation comprising:

[0047] a straight, substantially rigid elongated body adapted to be inserted into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the length of the straight, substantially rigid elongated body being sized relative to the natural curvature of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve so that when the straight, substantially rigid elongated body is positioned in the coronary sinus, it will cause at least a portion of the coronary sinus to assume a substantially straight configuration adjacent to the posterior leaflet of the mitral valve, whereby to increase the radius of curvature of the mitral annulus, moving it anteriorly, and thereby improve leaflet coaptation.

[0048] Significantly, the present invention may be practiced in a minimally invasive manner, either permanently or temporarily, so as to reduce mitral regurgitation.

BRIEF DESCRIPTION OF THE DRAWINGS

[0049] These and other objects and features of the present invention will be more fully disclosed or rendered obvious by the following detailed description of the preferred embodiments of the invention, which is to be considered together with the accompanying drawings wherein like numbers refer to like parts and further wherein:

[0050] **FIG. 1** is a schematic view of portions of the human vascular system;

[0051] **FIG. 2** is a schematic view of portions of the human heart;

[0052] **FIG. 3** is a schematic view of a preferred system formed in accordance with the present invention;

[0053] **FIGS. 4-7** are a series of views illustrating use of the system of **FIG. 3** to reduce mitral regurgitation;

[0054] **FIG. 8** shows an alternative form of delivery catheter;

[0055] **FIG. 9** shows an alternative form of flexible push rod;

[0056] **FIG. 9A** shows another alternative form of the present invention;

[0057] **FIGS. 10 and 11** show alternative constructions for the straight, substantially rigid elongated body;

[0058] **FIG. 12** shows an alternative system formed in accordance with the present invention; and

[0059] **FIG. 13** shows use of the system shown in **FIG. 12**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0060] The coronary sinus is the largest vein in the human heart. During a large portion of its course in the atrioven-

tricular groove, the coronary sinus typically extends adjacent to the left atrium of the heart for a distance of approximately 5 to 10 centimeters. Significantly, for a portion of its length, e.g., typically approximately 7-9 cm, the coronary sinus extends substantially adjacent to the posterior perimeter of the mitral annulus. The present invention takes advantage of this fact. More particularly, by deploying novel apparatus in the coronary sinus, adjacent to the posterior leaflet of the mitral valve, the natural curvature of the coronary sinus may be modified in the vicinity of the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly so as to improve leaflet coaptation and, as a result, reduce mitral regurgitation.

[0061] In one preferred embodiment of the invention, the novel apparatus comprises a straight, substantially rigid elongated body, the length of the straight, substantially rigid elongated body being sized so that when the straight, substantially rigid body is positioned in the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, the straight, substantially rigid elongated body will cause at least a portion of the coronary sinus to assume a substantially straight configuration adjacent to the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

[0062] And in one preferred embodiment of the invention, access to the coronary sinus is gained percutaneously, e.g., the straight, substantially rigid elongated body is introduced into the patient's vascular system via the jugular vein or via the left subclavian vein, passed down the superior vena cava, passed through the right atrium and then passed into the coronary sinus, where it is deployed. Alternatively, the straight, substantially rigid elongated body may be introduced into the coronary sinus through a small incision in the heart, or through some other incision into the patient's vascular system.

[0063] And in one preferred embodiment of the invention, the straight, substantially rigid elongated body is guided into position by (i) passing it through a pre-positioned catheter, or (ii) passing it over a pre-positioned guidewire, or (iii) passing it guide-free (e.g., on the end of a steerable delivery tool) to the surgical site.

[0064] Once deployed, the novel apparatus may be left in position permanently (e.g., in the case of patients suffering from mitral regurgitation associated with heart failure) or the novel apparatus may be left in position only temporarily (e.g., in the case of patients suffering from mitral regurgitation associated with acute myocardial infarction).

[0065] Visualization of the procedure may be obtained by fluoroscopy, echocardiography, intravascular ultrasound, angiography, real-time magnetic resonance imaging, etc. The efficacy of the procedure may be determined through echocardiography, although other imaging modalities may also be suitable.

[0066] Looking now at FIG. 1, there are shown aspects of the cardiovascular system 3 of a patient. More particularly, cardiovascular system 3 generally comprises the heart 6, the superior vena cava 9, the right subclavian vein 12, the left subclavian vein 15, the jugular vein 18, and the inferior vena cava 21. Superior vena cava 9 and inferior vena cava 21 communicate with the heart's right atrium 24. The coronary ostium 27 leads to coronary sinus 30. At the far end 31 (FIG.

2) of coronary sinus 30, the vascular structure turns into the vertically-descending anterior interventricular vein ("AIV") 32 (see FIG. 1). For purposes of the present invention, it can generally be convenient to consider the term "coronary sinus" to mean the vascular structure extending between coronary ostium 27 and AIV 32.

[0067] As seen in FIG. 2, between coronary ostium 27 and AIV 32, coronary sinus 30 generally extends substantially adjacent to the posterior perimeter of the annulus 33 of the mitral valve 36. Mitral valve 36 comprises a posterior leaflet 39 and an anterior leaflet 42. In the case of a regurgitant mitral valve, posterior leaflet 39 and anterior leaflet 42 will generally fail to properly coapt at systole, thereby leaving an intervening gap 45 which will permit regurgitation.

[0068] Looking next at FIG. 3, there is shown a system 100 which comprises one preferred embodiment of the present invention. More particularly, system 100 generally comprises a guidewire 103, a delivery catheter 106 and a push rod 109.

[0069] Guidewire 103 comprises a flexible body 112 having a distal end 115 and a proximal end 118. The distal end 115 of guidewire 103 preferably includes a spring tip 121 for allowing the distal end of guidewire 106 to atraumatically traverse vascular structures, i.e., while the guidewire is being passed through the vascular system of a patient.

[0070] Delivery catheter 106 comprises a flexible body 124 having a distal end 127 and a proximal end 130, preferably with an adjustable valve 133 attached. A central lumen 136 extends from distal end 127 to proximal end 130. In some circumstances it may be desirable to provide a securing mechanism for securing the distal end of the delivery catheter within a vascular structure. By way of example but not limitation, a balloon 139 may be positioned about the exterior of flexible body 124, just proximal to distal end 127, with an inflation lumen 142 extending between balloon 139 and an inflation fitting 145.

[0071] Push rod 109 comprises a flexible body 148 having a distal end 151 and a proximal end 154. A straight, substantially rigid elongated body 157, which may have a variety of different lengths, is formed on flexible body 148, proximal to distal end 151. A removable proximal stiffener or handle 160 may be placed between straight, substantially rigid elongated body 157 and proximal end 154.

[0072] System 100 may be used as follows to reduce mitral regurgitation.

[0073] First, distal end 115 of guidewire 103 is passed down the jugular vein 18 (or the left subclavian vein 15) of a patient, down superior vena cava 9, through right atrium 24 of the heart, and then into coronary sinus 30. See FIG. 4. It will be appreciated that as flexible guidewire 103 is passed down coronary sinus 30, the guidewire will tend to assume the natural curved shape of the coronary sinus, due to the flexible nature of the guidewire. The guidewire's atraumatic spring tip 121 will help ensure minimal damage to vascular structures as guidewire 103 is maneuvered into position.

[0074] Next, distal end 127 of delivery catheter 106 is placed over proximal end 118 of guidewire 103 and passed down the guidewire until the distal end of the delivery catheter is positioned in coronary sinus 30. See FIG. 5. Again, it will be appreciated that as the flexible delivery

catheter **106** passes down the coronary sinus, the delivery catheter will tend to assume the natural curved shape of the coronary sinus, due to the flexible nature of the delivery catheter.

[0075] Once delivery catheter **106** has been positioned within the coronary sinus, guidewire **103** is removed. See **FIG. 6**. Either before or after guidewire **103** is removed, balloon **139** may be inflated so as to secure distal end **127** of delivery catheter **106** in position within coronary sinus **30**.

[0076] Next, push rod **109** is passed down the central lumen **136** of delivery catheter **106**. As the push rod's straight, substantially rigid elongated body **157** is passed down central lumen **136** of delivery catheter **106**, it will force the delivery catheter to assume a straight configuration at the point where the straight, substantially rigid elongated body **157** currently resides. As push rod **109** is pushed down delivery catheter **106**, balloon **139** will hold the distal end of the delivery catheter in position within coronary sinus **30**.

[0077] Push rod **109** is pushed down delivery catheter **106**, utilizing removable proximal stiffener **160** as needed, until the straight, substantially rigid elongated body **157** is located adjacent to the posterior annulus of mitral valve **36**. See **FIG. 7**. As this occurs, the presence of the straight, substantially rigid elongated body **157** in delivery catheter **106** will cause at least a portion of coronary sinus **30** to assume a substantially straight configuration at this point, so that the posterior annulus of mitral valve **36** is forced anteriorly. This will cause the mitral valve's posterior leaflet **39** to also move anteriorly so as to improve mitral valve leaflet coaptation and thereby reduce (or completely eliminate) mitral valve regurgitation. In this respect it should be appreciated that the posterior annulus may be shifted anteriorly so as to achieve, or to attempt to achieve to the extent anatomically possible, leaflet-to-leaflet engagement or leaflet-to-annulus engagement (e.g., where a leaflet may be tethered due to left ventricular distortion). Both of these types of engagement, or targeted engagement, are intended to be encompassed by the terms "improved leaflet coaptation" and/or "increased leaflet coaptation" and the like. Using standard visualization means (e.g. echocardiography or fluoroscopy), the exact position of the straight, substantially rigid elongated body **157** is adjusted so as to reduce (or completely eliminate) regurgitation in mitral valve **36**.

[0078] In this respect it should be appreciated that the straight, substantially rigid elongated body **157** is preferably sized to be somewhat less than the length of the coronary sinus between coronary ostium **27** and AIV **32**. However, in some circumstances it may be desirable to size the straight, substantially rigid elongated body **157** so that it will extend out of the coronary sinus and into the right atrium.

[0079] Furthermore, it should also be appreciated that the system provides a degree of tactile feedback to the user during deployment. More particularly, substantial resistance will typically be encountered as the straight, substantially rigid elongated body **157** is pushed out of right atrium **24** and into coronary sinus **30**; then resistance will typically drop as body **157** is moved through the coronary sinus; and then resistance will typically increase significantly again as the distal tip of body **157** comes to the far end **31** of the coronary sinus. Thus, there is a sort of tactile "sweet spot" when the straight, substantially rigid elongated body **157** is located in the coronary sinus between coronary ostium **27**

and AIV **32**, and this tactile "sweet spot" can be helpful to the user in positioning the straight, substantially rigid elongated body **157** in coronary sinus **30**.

[0080] At this point the straight, substantially rigid elongated body **157** is locked in position, e.g., by closing adjustable valve **133**, and balloon **139** may be deflated.

[0081] System **100** is left in this position until it is no longer needed. In some cases this may mean that system **100** is left in position for a period of a few hours, days or weeks; in other cases system **100** may be substantially permanent. If and when system **100** is to be removed, push rod **109** is removed from delivery catheter **106**, and then delivery catheter **106** is removed from the patient.

[0082] Thus it will be seen that with the present invention, the straight, substantially rigid elongated body **157** is essentially force-fit into the normally curved portion of the coronary sinus adjacent to the mitral valve's posterior leaflet. By properly sizing the length of the straight, substantially rigid elongated body **157** relative to the natural curvature of the patient's anatomy, and by properly positioning the straight, substantially rigid elongated body **157** in the patient's coronary sinus, the straight, substantially rigid elongated body will cause at least a portion of the coronary sinus to assume a substantially straight configuration adjacent to the posterior leaflet of the mitral valve. This action will in turn drive the posterior annulus of the mitral valve anteriorly, so as to improve leaflet coaptation and thereby reduce mitral regurgitation. Thus, by inserting the straight, substantially rigid elongated body **157** into the coronary sinus adjacent to the posterior leaflet of the mitral valve, the annulus of the mitral valve is effectively manipulated so that it will assume an increased radius of curvature.

[0083] It has also been found that by inserting the straight, substantially rigid elongated body into the coronary sinus adjacent to the posterior leaflet of the mitral valve, the left ventricle may also be remodeled so as to help alleviate congestive heart failure.

[0084] It is significant to note that with the present invention, the distal and proximal ends of straight, substantially rigid elongated body **157** apply a posteriorly-directed force on the walls of coronary sinus **30** (e.g., as shown with arrows P in **FIG. 7**) while the intermediate portion of straight, substantially rigid elongated body **157** applies an anteriorly-directed force on the walls of coronary sinus **30** (e.g., as shown with arrows A in **FIG. 7**).

[0085] In some cases the proximal end **130** of delivery catheter **106** may be fixed to the patient's outer skin using standard patient care methods such as adhesive tape, purse-string sutures, skin staples, etc. In other cases proximal end **130** of delivery catheter **106** may include a sewing cuff whereby the delivery catheter may be secured to the patient's tissue by suturing. See, for example, **FIG. 8**, where a sewing cuff **166** is shown attached to the proximal end **130** of delivery catheter **106**. If desired, an element **169** may be provided proximal to adjustable valve **133**, whereby flexible push rod **109** may be made fast to delivery catheter **106**. By way of example, element **169** may comprise a crimpable element to secure flexible push rod **109** to delivery catheter **106**, which is in turn secured to the patient. If desired, the proximal end of the assembly may be embedded under the skin of the patient, e.g., in the case of a permanent implant.

[0086] As noted above, it can be helpful to anchor the distal end of delivery catheter **106** in position within the coronary sinus prior to pushing push rod **109** into the delivery catheter. Such an arrangement will keep the delivery catheter in place as the push rod makes the turn within the right atrium and enters the coronary sinus. In the absence of such anchoring, the push rod may drive the delivery catheter down the inferior vena cava **21**. By securing the distal end of delivery catheter **106** to the walls of coronary sinus **30**, the delivery catheter can be stabilized against diversion down the inferior vena cava **21** when the straight, substantially rigid elongate body **157** encounters initial resistance to making the turn into the coronary sinus.

[0087] The balloon **139** is one way of accomplishing such anchoring. However, it is also possible to utilize other types of securing mechanisms to anchor the distal end **127** of delivery catheter **106** in position within coronary sinus **30**, e.g., spring clips, ribs, etc.

[0088] Alternatively, and looking next at **FIG. 9**, the distal end **151** of push rod **109** may itself be provided with a distal anchor, e.g., such as the distal anchor **172** shown in **FIG. 9**.

[0089] It is also possible to prevent diversion of delivery catheter **106** down inferior vena cava **21** without anchoring the distal end of delivery catheter **106** or flexible push rod **109** to the walls of the coronary sinus. More particularly, and looking now at **FIG. 9A**, there is shown a support catheter **173** which is formed out of a more rigid material than delivery catheter **106**. Support catheter **173** is constructed so that its distal end **174** can be positioned in coronary ostium **27** and then its sidewall **174A** can support delivery catheter **106** adjacent to inferior vena cava **21** when push rod **109** is passed down delivery catheter **106**, whereby to prevent delivery catheter **106** from diverting down inferior vena cava **106**. **FIG. 9A** also shows an introducer catheter **174B** at the entrance to jugular vein **18**.

[0090] As noted above, as push rod **109** is advanced to the region adjacent to the posterior annulus of the mitral valve, the straight, substantially rigid elongated body **157** will distort the natural configuration of the coronary sinus so that it will assume a substantially straight configuration. While this action induces the desired valve remodeling, it can also induce a significant stress on the walls of the coronary sinus, particularly at the distal and proximal ends of the straight, substantially rigid elongated body **157**, where stress will be concentrated. To this end, the construction of the straight, substantially rigid elongated body **157** may be modified somewhat so as to better distribute this stress. More particularly, and looking next at **FIG. 10**, the distal and proximal ends of straight, substantially rigid elongated body **157** may include relatively flexible portions **175** to help better distribute the stress exerted on the walls of the coronary sinus. Additionally, and/or alternatively, any taper applied to the distal and proximal ends of straight, substantially rigid elongated body **157** may be elongated, e.g., such as shown at **178** in **FIG. 11**, so as to better distribute the stress imposed on the walls of the coronary sinus.

[0091] Looking next at **FIG. 12**, there is shown a system **181** which comprises another preferred embodiment of the present invention. More particularly, system **181** generally comprises the guidewire **103**, a straight, substantially rigid elongated body **184** and a push cannula **187**.

[0092] Guidewire **103** is as previously described.

[0093] Straight, substantially rigid elongated body **184**, which may have a variety of different lengths, comprises a distal end **188** and a proximal end **190**. A central lumen **193** extends between distal end **188** and proximal end **190**. Central lumen **193** accommodates guidewire **103**.

[0094] Push cannula **187** comprises a distal end **194** and a proximal end **196**. A central lumen **199** extends between distal end **194** and proximal end **196**. Central lumen **199** accommodates guidewire **103**.

[0095] System **181** may be used as follows to reduce mitral regurgitation.

[0096] First, distal end **115** of guidewire **103** is passed down jugular vein **18** (or the left subclavian vein **15**) of a patient, down superior vena cava **9**, through right atrium **24** of the heart, and into coronary sinus **30**. It will be appreciated that as flexible guidewire **103** is passed down coronary sinus **30**, the guidewire will tend to assume the natural curved shape of the coronary sinus, due to the flexible nature of the guidewire. The guidewire's atraumatic spring tip **121** will help minimize damage to vascular structures as the guidewire is advanced into position.

[0097] Next, distal end **188** of straight, substantially rigid elongated body **184** is placed over proximal end **118** of guidewire **103** and passed a short distance down the guidewire. Then the distal end **194** of push cannula **187** is placed over proximal end **118** of guidewire **103**, and then push cannula **187** is advanced down the guidewire. As push cannula **187** is advanced down the guidewire, its distal end **194** pushes the straight, substantially rigid elongated body **184** ahead of it. See **FIG. 13**.

[0098] As the straight, substantially rigid elongated body **184** is passed down the coronary sinus, it will force the coronary sinus to assume a straight configuration at the point where the straight, substantially rigid elongated body **184** currently resides. Push cannula **187** is pushed down guidewire as needed, until the straight, substantially rigid elongated body **184** is located adjacent to the posterior annulus of the mitral valve. As this occurs, the presence of the straight, substantially rigid elongated body **184** in the coronary sinus will cause coronary sinus to assume a substantially straight configuration at this point, so that the posterior annulus of the mitral valve is forced anteriorly. This will cause the posterior mitral valve leaflet to also move anteriorly so as to improve leaflet coaptation and thereby reduce (or completely eliminate) mitral valve regurgitation. Using standard visualization means (e.g. echocardiography or fluoroscopy), the exact position of the straight, substantially rigid elongated body may be adjusted so as to reduce (or completely eliminate) regurgitation in the mitral valve.

[0099] If desired, the push cannula **187** may be provided with a releasably attachable interface (e.g., a grasper) so that it may releasably secure the proximal end **190** of the straight, substantially rigid elongated body **184**. Such a feature will permit the straight, substantially rigid elongated body to be pulled backward within the coronary sinus, either for positioning or removal purposes.

[0100] Alternatively, elongated body **184** or **157** may have any of a variety of non-straight shapes along its length. For example, the elongated body may be wavy, spiraled, or curved along all or a portion of its length. By way of example, elongated body **157** and/or **184** may have a curved

configuration so as to invert the natural curvature of the coronary sinus, i.e., so that it is bowed towards the anterior annulus. Or the elongated body may have a compound shape along its length, e.g., it may have a sort of "w" shape, with the center of the "w" being directed towards the anterior annulus. Any of these or other alternate shapes may effect the anterior displacement of the posterior annulus that results in reduction of the mitral valve regurgitation.

[0101] In other alternative embodiments, the elongated body may be flexible along at least a portion of its length. Regional flexibility and regional stiffness may allow for straightening of select locations of the coronary sinus and corresponding locations of the posterior mitral annulus. This can cause regions of the mitral annulus to move anteriorly, thus causing regional improvements in leaflet coaptation. In addition, the elongated body may be formed by two end segments connected together by a filament: by anchoring the two end segments relative to the anatomy and pulling the filament taught, the naturally curved wall of the coronary sinus can be straightened, whereby to move the posterior mitral annulus anteriorly and thereby reduce mitral regurgitation.

[0102] It is to be understood that the present invention is by no means limited to the particular constructions herein disclosed and/or shown in the drawings, but also comprises any modifications or equivalents within the scope of the claims.

What is claimed is:

1. A method for reducing mitral regurgitation comprising:

inserting apparatus into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the apparatus being adapted to straighten the natural curvature of at least a portion of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

2. A method for reducing mitral regurgitation comprising:

inserting apparatus into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the apparatus being adapted to move at least a portion of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve anteriorly, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

3. A method for reducing mitral regurgitation comprising:

inserting apparatus into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the apparatus being adapted to reduce the degree of natural curvature of at least a portion of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

4. A method for reducing mitral regurgitation comprising:

inserting apparatus into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the apparatus being adapted to increase the natural radius of curvature of at least a portion of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

5. A method for reducing mitral regurgitation comprising:

inserting apparatus into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the apparatus having a distal end, a proximal end and an intermediate portion, the apparatus being configured so that when the apparatus is positioned in the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, the distal and proximal ends will apply a posteriorly-directed force to the walls of the coronary sinus and the intermediate portion will apply an anteriorly-directed force to the walls of the coronary sinus, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

6. A method for reducing mitral regurgitation comprising:

inserting a substantially straight elongated body into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the length of the substantially straight elongated body being sized relative to the natural curvature of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve so that when the substantially straight elongated body is positioned in the coronary sinus, it will cause at least a portion of the coronary sinus to assume a substantially straight configuration adjacent to the posterior leaflet of the mitral valve, whereby to increase the radius of curvature of the mitral annulus and thereby improve leaflet coaptation.

7. A method for reducing mitral regurgitation comprising:

inserting a substantially rigid elongated body into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the substantially rigid elongated body being configured relative to the natural curvature of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve so that when the substantially rigid elongated body is positioned in the coronary sinus, it will cause at least a portion of the coronary sinus to assume a different configuration adjacent to the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

8. A method for reducing mitral regurgitation comprising:

inserting a straight, substantially rigid elongated body into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the length of the straight, substantially rigid elongated body being sized relative to the natural curvature of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve so that when the straight, substantially rigid elongated body is positioned in the coronary sinus, it will cause at least a portion of the coronary sinus to assume a substantially straight configuration adjacent to the posterior leaflet of the mitral valve, whereby to increase the radius of curvature of the mitral annulus and thereby improve leaflet coaptation.

9. A method according to claim 8 wherein the straight, substantially rigid elongated body is inserted into the coronary sinus percutaneously.

10. A method according to claim 9 wherein the straight, substantially rigid elongated body is inserted into the coronary sinus by introducing the straight, substantially rigid elongated body into the patient's jugular vein, passing it

down the superior vena cava, passing it through the right atrium and then passing it into the coronary sinus.

11. A method according to claim 9 wherein the straight, substantially rigid elongated body is inserted into the coronary sinus by introducing the straight, substantially rigid elongated body into the patient's left subclavian vein, passing it down the superior vena cava, passing it through the right atrium and then passing it into the coronary sinus.

12. A method according to claim 8 wherein the straight, substantially rigid elongated body is inserted into the coronary sinus through an incision in the patient's heart.

13. A method according to claim 8 wherein the straight, substantially rigid elongated body is guided into position by passing it through a pre-positioned delivery catheter.

14. A method according to claim 13 wherein the straight, substantially rigid elongated body is guided into position by inserting a guidewire into the coronary sinus, passing the delivery catheter over the guidewire and into the coronary sinus, removing the guidewire, and then passing the straight, substantially rigid elongated body down the delivery catheter.

15. A method according to claim 8 wherein the straight, substantially rigid elongated body is guided into position by passing it over a pre-positioned guidewire.

16. A method according to claim 15 wherein the straight, substantially rigid elongated body is guided into position by inserting a guidewire into the coronary sinus and then passing the straight, substantially rigid elongated body down the guidewire.

17. A method according to claim 8 further comprising the subsequent step of removing the straight, substantially rigid elongated body from the coronary sinus.

18. A method according to claim 8 wherein the straight, substantially rigid elongated body is inserted under visualization.

19. A method according to claim 18 wherein visualization is achieved by using a procedure chosen from the group consisting of fluoroscopy, echocardiography, intravascular ultrasound, angiography and real-time magnetic resonance imaging.

20. A method according to claim 8 including the additional step of assessing the efficacy of the procedure.

21. Apparatus for reducing mitral regurgitation comprising:

a body having a distal end, a proximal end and an intermediate portion, the body being configured so that when the body is positioned in the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, the distal and proximal ends will apply a posteriorly-directed force to the walls of the coronary sinus, and the intermediate portion will apply an anteriorly-directed force to the walls of the coronary sinus, whereby to move the posterior annulus of the mitral valve anteriorly and thereby improve leaflet coaptation.

22. Apparatus for reducing mitral regurgitation comprising:

a substantially straight elongated body adapted to be inserted into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the length of the substantially straight elongated body being sized relative to the natural curvature of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve so that when the substantially straight

elongated body is positioned in the coronary sinus, it will cause at least a portion of the coronary sinus to assume a substantially straight configuration adjacent to the posterior leaflet of the mitral valve, whereby to increase the radius of curvature of the mitral annulus, moving it anteriorly, and thereby improve leaflet coaptation.

23. Apparatus for reducing mitral regurgitation comprising:

a substantially rigid elongated body adapted to be inserted into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the length of the substantially rigid elongated body being sized relative to the natural curvature of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve so that when the substantially rigid elongated body is positioned in the coronary sinus, it will cause at least a portion of the coronary sinus to assume a different configuration adjacent to the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

24. Apparatus for reducing mitral regurgitation comprising:

a straight, substantially rigid elongated body adapted to be inserted into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the length of the straight, substantially rigid elongated body being sized relative to the natural curvature of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve so that when the straight, substantially rigid elongated body is positioned in the coronary sinus, it will cause at least a portion of the coronary sinus to assume a substantially straight configuration adjacent to the posterior leaflet of the mitral valve, whereby to increase the radius of curvature of the mitral annulus, moving it anteriorly, and thereby improve leaflet coaptation.

25. Apparatus according to claim 24 further comprising a delivery catheter adapted to be positioned within the coronary sinus of the patient, said flexible delivery catheter being formed out of a flexible material so that it will substantially assume the configuration of the coronary sinus, said delivery catheter being adapted to receive said straight, substantially rigid elongated body therein.

26. Apparatus according to claim 25 wherein said straight, substantially rigid elongated body is mounted to a rod, wherein said rod is formed out of a flexible material so that said rod will assume the configuration of the coronary sinus, and further wherein said rod is sized to fit within said delivery catheter.

27. Apparatus according to claim 24 further comprising a removable guidewire for positioning said delivery catheter in the coronary sinus.

28. Apparatus according to claim 24 further comprising a guidewire adapted to be positioned within the coronary sinus, said guidewire being formed out of a flexible material so that it will substantially assume the configuration of the coronary sinus, and further wherein the straight, substantially rigid elongated body is cannulated for riding along said guidewire.

29. Apparatus according to claim 24 wherein at least one of the distal and proximal ends of said straight, substantially rigid elongated body includes a flexible portion for relieving

the stress imposed on the coronary sinus when said straight, substantially rigid elongated body is disposed within the coronary sinus.

30. Apparatus according to claim 24 wherein at least one of the distal and proximal ends of said straight, substantially rigid elongated body is tapered for relieving the stress imposed on the coronary sinus when said straight, substantially rigid elongated body is disposed within the coronary sinus.

31. Apparatus according to claim 24 wherein said straight, substantially rigid elongated body has a length no longer than the segment of the coronary sinus located between the coronary ostium and the AIV.

32. Apparatus according to claim 25 wherein said apparatus further comprises a support catheter for preventing said delivery catheter from diverting into the inferior vena cava when said straight, substantially rigid elongated body is passed through said delivery catheter.

33. A method for reducing mitral regurgitation comprising:

inserting apparatus into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve,

the apparatus being adapted to invert the natural curvature of at least a portion of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

34. Apparatus for reducing mitral regurgitation comprising:

an elongated body adapted to be inserted into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the apparatus being adapted to invert the natural curvature of at least a portion of the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, whereby to move the posterior annulus anteriorly and thereby improve leaflet coaptation.

35. A method according to claim 8 wherein said straight, substantially rigid elongated body is guided into position without the use of a guide catheter and a guidewire.

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