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POST-IMPLANT ADJUSTABLE ANNULOPLASTY RING

Abstract

Annuloplasty rings that are size-adjustable after implant and which facilitate deployment and reduce long-term complications. The rings each have a hollow circumference with a cinching element extending therethrough whose length is controlled remotely via a deployment system handle. The ring may be anchored to the annulus and then the size adjusted while the heart beats and under visualization to minimize regurgitation. The cinching element may be a loop of metal which is clamped to size within a junction housing to which the deployment system attaches. The rings are especially beneficial for repairing the mitral annulus, and may be saddle shaped with the junction housing located on an anterior side.

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Background/Summary

CROSS REFERENCE TO RELATED APPLICATION [0001] This application is a U.S. National Stage of International Patent Application No. PCT/US2023/014440, filed Mar. 3, 2023, which claims the benefit of U.S. Application No. 63/268,906, filed Mar. 4, 2022, the entire disclosures all of which is incorporated by reference for all purposes.

TECHNICAL FIELD
[0002] The present disclosure relates generally to annuloplasty rings, and in particular to an adjustable mitral annuloplasty ring and deployment system.
BACKGROUND
[0003] In vertebrate animals, the heart is a hollow muscular organ having four pumping chambers: the left and right atria and the left and right ventricles, each provided with its own one-way valve. The natural heart valves are identified as the aortic, mitral (or bicuspid), tricuspid and pulmonary, and each has flexible leaflets that coapt against each other to prevent reverse flow.
[0004] Various surgical techniques may be used to repair a diseased or damaged valve. A commonly used repair technique effective in treating incompetence is annuloplasty, which often involves reshaping or remodeling the annulus by attaching a prosthetic annuloplasty repair segment or ring thereto. The procedure is done with the heart stopped and the patient on cardiopulmonary bypass (“on pump”). For instance, the goal of a posterior mitral annulus repair is to bring the posterior mitral leaflet forward toward to the anterior leaflet to improve leaflet coaptation. Annuloplasty rings may be stiff, flexible or semi-rigid, and a “remodeling” annuloplasty ring typically has an inner core that is “generally rigid” or “semi-rigid” in that it will flex to a small extent but resist distortion when subjected to the stress imparted thereon by the mitral valve annulus of an operating human heart.
[0005] Currently, during a mitral valve repair procedure, the size of the annuloplasty ring is determined by comparing different sizer templates to the patient's anatomy until the surgeon determines which one looks correct based on, for example, anterior leaflet area or length, intercommissural distance, and so on. However, unlike for an aortic valve replacement, where the goal is to implant the largest valve that will safely fit the patient's anatomy, mitral repair procedures implant a repair device that is somewhat smaller than the annulus to reduce the perimeter, or, more importantly, the anterior-posterior (AP) diameter, of the valve and restore leaflet coaptation. The surgeon must make an “educated guess” as to how much reduction in size is appropriate for any given patient and their specific disease state. If the wrong size repair product is chosen, the result may be a poor outcome manifested by residual mitral regurgitation (MR), insufficient coaptation length, high pressure gradients, or systolic anterior motion (SAM). If any of these conditions are found once the patient is weaned off-pump, the surgeon must make the difficult decision of going back on pump, with its associated morbidity and mortality, or leaving the patient with a sub-optimal repair, and its associated sequalae.

[0006] Given the above challenges, it would be desirable to have an annuloplasty device that could be adjusted once the patient was weaned off-pump in order to fine-tune the AP diameter (short axis) or AL-PM diameter (long axis) of the mitral valve in order to correct for small errors in the inherently imprecise sizing process. Such a ring would have the potential to reduce poor mitral valve repair outcomes and the need to go back on-pump in many cases to address them. Once adjustments were made and desired outcome achieved, the deployment system attachments could be disengaged, leaving the patient with a customized annuloplasty device that was tailored to their specific anatomy.

[0007] In attempts to vary the shape of the repair device, adjustable annuloplasty devices such as the Cardinal mitral annuloplasty system originally from Valtech Ltd. of Israel, now a part of Edwards Lifesciences of Irvine, CA. The Cardinal system has a semi-rigid annuloplasty ring enabled for ring diameter fine tuning and optimization of leaflet coaptation on a beating heart under real-time echocardiographic guidance. The Cardinal system is disclosed in U.S. Pat. Nos. 8,241,351 and 10,363,136 which are expressly incorporated herein by reference for all purposes.

[0008] Despite past attempts, there is a need for an annuloplasty ring that may be shaped adjusted to effect repair of a malfunctioning valve while avoiding negative outcomes.

SUMMARY

[0009] Disclosed here are adjustable annuloplasty rings and deployment systems. The annuloplasty rings are size-adjustable after implant and facilitate delivery and reduce long-term complications. The rings each have a hollow circumference with a cinching element extending therethrough whose length is controlled remotely via a deployment system handle. The ring may be anchored to the annulus and then the size adjusted while the heart beats and under visualization to minimize regurgitation. The cinching element may be a loop of metal which is clamped to size within a junction housing to which the deployment system attaches.

[0010] The rings are especially beneficial for repairing the mitral annulus, and may be saddle shaped with the junction housing located on an anterior side or posterior side. Each ring is advanced down to the mitral annulus along anchoring sutures. A distal end of a delivery or deployment system attaches to a junction housing at a midpoint of an anterior segment of the annuloplasty ring and in conjunction with a semi-rigid ring holder handle is used to parachute the ring down the array of sutures. The deployment system has a shaft long enough to extend from outside the body to the surgical site, and is connected to a proximal control handle. The length of the shaft allows for partial/full sternotomy and right lateral thoracotomy procedures.

[0011] A first exemplary annuloplasty ring and shape adjustment system disclosed herein, comprises an annuloplasty ring defining a continuous peripheral shape around a central aperture and central axis. The annuloplasty ring has a contractible inner body defining a lumen extending therethrough, wherein the inner body extends around the peripheral shape and has two ends connected to each other by a junction housing. The annuloplasty ring further includes a flexible non-extensible cinching element formed in a complete loop, the cinching element passing through the inner body lumen and into the junction housing. The junction housing has an inner cavity with three openings-first and second aligned openings in communication with the inner body lumen at the two ends of the inner body, and a third opening at an upper port facing axially up from the housing. The cinching element has a main portion generally in a plane of the inner body and a subloop that projects perpendicular to the main portion through the upper port. Finally, the inner body has a relaxed implant shape when the cinching element is under no tension and a smaller, contracted shape when the cinching element is placed under tension.

[0012] The first system junction housing may have external threads for attachment of a delivery shaft thereto. The annuloplasty ring may further include a locking member within the junction housing configured to clamp onto the cinching element and maintain the cinching element under tension around the inner body. For instance, the locking member comprises a locking screw positioned in a vertical channel of the junction housing aligned with the upper port and having

external threads which engage internal threads defined within the vertical channel. The locking screw has a non-circular internal throughbore that receives the subloop of the cinching element, wherein rotational advancement of the locking screw down into the vertical channel eventually clamps divergent portions of the cinching element against the inner cavity of the junction housing.
[0013] A second annuloplasty ring and shape adjustment system disclosed herein comprises an annuloplasty ring defining a continuous peripheral shape around a central aperture and a central axis. The annuloplasty ring has a contractible inner body defining a lumen extending therethrough, wherein the inner body extends around the peripheral shape and has two ends connected to each other by a junction housing. The annuloplasty ring further includes a flexible cinching element formed in a continuous loop, the cinching element passing through the inner body lumen and into the junction housing. The cinching element forms a subloop through a port formed in the junction housing, and the inner body has a relaxed implant shape when the cinching element is under no tension and a smaller, contracted shape when the cinching element is placed under tension. The second system further includes a deployment system including an elongated deployment shaft having a distal end configured to attach to the port of the junction housing, and a proximal control handle. The control handle has an adjustment cable connected to a tension actuator configured to pull the adjustment cable in a proximal direction. The adjustment cable has a length sufficient to extend through a lumen in the elongated shaft and loop through the subloop. Actuation of the tension actuator pulls the adjustment cable and in turn places the cinching element under tension to convert the inner body from the relaxed implant shape toward the smaller, contracted shape.
[0014] In the second system, the annuloplasty ring further may include a locking member within the junction housing configured to clamp onto the cinching element and maintain the cinching element under tension around the inner body. Further, the control handle may have a locking actuator connected to an elongated torque shaft configured to slide axially and rotate concentrically within the deployment shaft. The torque shaft has a distal non-circular torque driver shaped to mate with a similarly-sized and shaped opening in the locking member, wherein rotation of the torque shaft causes the locking member to clamp onto the cinching element.
[0015] In the second system, the locking member may comprise a locking screw positioned in a vertical channel of the junction housing aligned with the port. The locking screw may have external threads which engage internal threads defined within the vertical channel. The locking screw also has a throughbore that receives the subloop of the cinching element. The torque shaft and torque driver are hollow to receive the subloop and the adjustment cable passes through the torque shaft to loop through the subloop. Consequently, rotational advancement of the locking screw down into the vertical channel eventually clamps divergent portions of the cinching element against the inner cavity of the junction housing.
[0016] The second system tension actuator and locking actuator may be wheels positioned within a housing of the control handle and mounted to rotate about a longitudinal axis of the housing. The wheels may be exposed through windows formed in the housing with each having a locking collar associated therewith with a tab extending to the exterior of the housing, the tabs being arranged to toggle between permitting and preventing rotation of a respective wheel. The wheels may each have a scalloped or uneven outer surface to facilitate rotation.
[0017] In the second system, the junction housing may have external threads for attachment of the delivery system thereto, and the control handle has an attachment actuator connected to an elongated attachment shaft configured to slide axially and rotate concentrically within the deployment shaft. The attachment shaft also has a distal end with internal threads for mating with the external threads on the junction housing, wherein rotation of the attachment shaft enables attachment and detachment of the delivery system from the annuloplasty ring.
[0018] Alternatively, the second system delivery system may have a quick-release harness in the form of a loop of flexible material that extends from the control handle and around the junction housing, wherein one end of the loop of flexible material is severable within the control handle to

enable the detachment of the delivery system from the annuloplasty ring.
[0019] In either the first or second system, the cinching element is metallic, such as a cobalt chromium alloy. The inner body may be formed of a metallic tube having V-shaped gaps formed therein to permit contraction. The inner body may be heat set into a saddle shape, and may be Nitinol. Further, the annuloplasty ring in either system may include a hollow compressible filler member extending within the inner body lumen and through which the cinching element extends. The ring may also have a tubular fabric cover surrounding the inner body and having a sewing cuff of a ring of fabric attached to an outer periphery of the fabric cover.
[0020] A third annuloplasty ring and shape adjustment system comprises an annuloplasty ring defining a continuous peripheral shape around a central aperture and a central axis. The annuloplasty ring has a contractible inner body defining a lumen extending therethrough, wherein the inner body extends around the peripheral shape and has two ends connected to each other by a junction housing. The annuloplasty ring further includes a flexible cinching element formed in a continuous loop, the cinching element passing through the inner body lumen and into the junction housing. The junction housing has an inner cavity opening to an upper port, wherein the cinching element forms a subloop through the upper port. The inner body has a relaxed implant shape when the cinching element is under no tension and a smaller, contracted shape when the cinching element is placed under tension. A deployment system includes an elongated deployment shaft having a distal end configured to attach to the upper port of the junction housing, the deployment system being configured to apply variable tension to the subloop of the cinching element. The annuloplasty ring further includes at least one finger spring-biased toward the junction housing, wherein the finger is positioned and sized to contact a portion of the subloop extending out of the junction housing and trap the portion against the junction housing.
[0021] A fourth annuloplasty ring and shape adjustment system comprises an annuloplasty ring defining a continuous peripheral shape around a central aperture and a central axis. The annuloplasty ring has a contractible inner body defining a lumen extending therethrough. The inner body extends around the peripheral shape and has two ends connected to each other by a junction housing. The annuloplasty ring further including a flexible cinching element formed in a continuous loop, the cinching element passing through the inner body lumen and into the junction housing. The junction housing has an inner cavity opening to an upper port, wherein the cinching element forms a subloop through the upper port. The inner body has a relaxed implant shape when the cinching element is under no tension and a smaller, contracted shape when the cinching element is placed under tension. A locking member within the junction housing is configured to clamp onto the cinching element and maintain the cinching element under tension around the inner body. Also, the locking member is adapted to apply a clamping force calibrated to resist expansion of the annuloplasty ring from natural cardiac cycling motion, but which enables the cinching element to slip through the locking member from expansion forces associated with balloon expansion from within the annuloplasty ring.
[0022] A still further fifth annuloplasty ring and shape adjustment system comprises an annuloplasty ring defining a continuous peripheral shape around a central aperture and a central axis. The annuloplasty ring having a contractible inner body defining a lumen extending therethrough, wherein the inner body extends around the peripheral shape and has two ends connected to each other by a junction housing. The annuloplasty ring further including a flexible cinching element formed in a continuous loop, the cinching element passing through the inner body lumen and into the junction housing. The junction housing has an inner cavity opening to an upper port, wherein the cinching element forms a subloop through the upper port. The inner body has a relaxed implant shape when the cinching element is under no tension and a smaller, contracted shape when the cinching element is placed under tension. Also, a locking member within the junction housing is configured to clamp onto the cinching element and maintain the cinching element under tension around the inner body. The cinching element is strong enough to resist

breakage from natural cardiac cycling motion, but is calibrated to break from expansion forces associated with balloon expansion from within the annuloplasty ring. Further, a secondary cord formed in a continuous loop passes through the inner body lumen. The secondary cord has a longer length than the circumference of the inner body and is strong enough to resist breakage from forces associated with balloon expansion from within the annuloplasty ring to enable limited post-implant expansion of the annuloplasty ring with a balloon.

[0023] A further understanding of the nature and advantages will become apparent by reference to the remaining portions of the specification and drawings.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] Features and advantages of the present disclosure will become appreciated as the same become better understood with reference to the specification, claims, and appended drawings wherein:

[0025] FIG. **1**A-**1**E are perspective views of an atrial side of a mitral annulus illustrating several steps of implanting and adjusting an annuloplasty ring of the present application;

[0026] FIG. **2** is a perspective view of an exemplary deployment system for the adjustable annuloplasty ring, and FIG. **2**A is an enlarged view of the distal end of a deployment shaft coupled to the annuloplasty ring;

[0027] FIG. **3** is a perspective view of the distal end of the deployment shaft shown in phantom engaged with a junction housing of the annuloplasty ring;

[0028] FIG. **4**A is a perspective view of an inner coupling member of the deployment shaft engaged with the ring junction housing, and FIG. **4**B shows disengagement of the coupling member from the junction housing;

[0029] FIG. **5**A is a vertical sectional view of the interaction between the distal end of the deployment shaft and the junction housing of the annuloplasty ring, FIG. **5**B is an exploded perspective view of the components thereof, and FIG. **5**C (sheet **12**) is a vertical sectional view showing tension being applied by a tension adjustment cable through the deployment shaft to a cinching element within the annuloplasty ring;

[0030] FIG. **6** is a perspective view of the exemplary adjustable annuloplasty ring, FIG. **6**A is an enlarged cutaway view of one portion thereof, and FIG. **6**B is a radial sectional view thereof;

[0031] FIG. **7** is a perspective view of the distal end of the deployment shaft coupled to the adjustable annuloplasty ring having an outer cover removed, and FIG. **7**A is an exploded perspective view of the inner components of the annuloplasty ring;

[0032] FIG. **8**A is a perspective view of the adjustable annuloplasty ring with the outer cover and an inner filler tube removed, and FIG. **8**B is the same perspective view with a coiled body removed illustrating the cinching element;

[0033] FIG. **9**A is an enlarged perspective view of a junction housing of the adjustable annuloplasty ring, and FIG. **9**B is a cutaway view of the junction housing showing internal components thereof;

[0034] FIG. **10**A is a view similar to FIG. **9**B showing tension being applied by the adjustment cable to the cinching element, FIG. **10**B is a view of the junction housing being acted on by a locking driver of the deployment system, and FIG. **10**C shows the junction housing after the cinching element has been locked in place;

[0035] FIG. **11** is a perspective view of a proximal control handle of the deployment system with a front cover removed to illustrate certain internal components, including an enlarged, exploded view of a distal end of the deployment shaft and inner components;

[0036] FIG. **12** is an exploded perspective view of the proximal control handle of the deployment system, and FIG. **12**A is an enlarged view of the connection between the tension adjustment cable

and control handle;
[0037] FIG. **13**A-**13**C are perspective views of the proximal control handle during operation thereof, and FIG. **13**D is an enlarged view of an operation to sever the adjustment cable within the deployment system;
[0038] FIG. **14** is a schematic view of an anterior segment of the adjustable annuloplasty ring without a sewing cuff and with an outer cover partially removed and a suture being threaded through an outer periphery thereof, and FIG. **14**A is a sectional view through the annuloplasty ring indicating one possible path of the suture through the ring;
[0039] FIG. **15** is a sectional view through an annuloplasty ring of the present application having an outer sewing cuff and indicating one possible path of an anchoring suture through the ring;
[0040] FIGS. **16**A-**16**F are radial sectional views through alternative annuloplasty rings showing a variety of supplemental sewing cuffs that can be used;
[0041] FIG. **17** is a front elevational view of a saddle-shaped coiled body that may be used with the adjustable annuloplasty rings of the present application;
[0042] FIG. **18** is a front elevational view of an alternative saddle-shaped coiled body that may be used with the adjustable annuloplasty rings of the present application;
[0043] FIG. **19**A is a front elevational view of a still further saddle-shaped coiled body, and FIG. **19**B schematically illustrates expansion of the coil body during expansion of the annulus during the normal cardiac cycle;
[0044] FIG. **20** is a front elevational view of another saddle-shaped coiled body for an annuloplasty ring having a size adjustable remodeling core positioned therethrough, and
[0045] FIG. **21** is a front elevational view of the remodeling core;
[0046] FIG. **22** is a view of the inner components of the saddle-shaped annuloplasty ring similar of FIG. **20** with the addition of a cinching element, and
[0047] FIG. **23** is a sectional view through a junction housing thereof;
[0048] FIG. **24** is a front elevational view of inner components of a still further saddle-shaped annuloplasty ring having a shaped sleeve component surrounding a posterior segment to form an upward bow, and FIG. **24**A is a sectional view through the posterior segment thereof;
[0049] FIG. **25** is a front elevational view of inner components of another saddle-shaped annuloplasty ring having a shaped sleeve component surrounding an anterior segment to form an upward bow;
[0050] FIG. **26** is a front elevational view of a saddle-shaped support body for an annuloplasty ring formed by laser cutting a Nitinol tube and a junction housing;
[0051] FIG. **27** is a perspective view of a junction housing for the adjustable annuloplasty rings described herein illustrating one potential drawback of using an elongated cinching element;
[0052] FIG. **28**A is a perspective view of a junction housing with an inner coupling member of the deployment shaft attached and showing an exemplary spring-biased finger, and FIG. **28**B shows deployment of the spring-biased finger to fold the elongated cinching element against the junction housing once the inner coupling member is removed;
[0053] FIG. **29** is a side elevational view of an alternative configuration for folding the elongated cinching element through the use of two spring-biased fingers;
[0054] FIG. **30**A is a schematic view of an adjustable annuloplasty ring of the present application having a cinching element and junction housing that permit but limit expansion of the ring, and FIG. **30**B is a view of the annuloplasty ring after expansion showing the cinching element limiting further expansion;
[0055] FIG. **31**A is a schematic view of another adjustable annuloplasty ring having a cinching element and a secondary cord within the ring to limit expansion thereof, and FIG. **31**B shows the annuloplasty ring after expansion with the cinching element broken and the cord expanded taut;
[0056] FIG. **32** is a perspective view of an alternative junction housing for an adjustable annuloplasty ring;

[0057] FIG. **33** is an exploded perspective view of the alternative junction housing of FIG. **32**;
[0058] FIG. **34** is an assembled perspective view of the alternative junction housing, and FIG. **34**A is a radial sectional view therethrough taken along line **34***a*-**34***a;*
[0059] FIG. **35** is a circumferential sectional view through the alternative junction housing of FIG. **32** and a portion of the connected annuloplasty ring;
[0060] FIG. **36** is a schematic view of an alternative cinching element utilizing tension sutures connected to a metallic wire;
[0061] FIG. **37**A is a perspective view of a junction housing of an alternative annuloplasty ring having a suture loop for a cinching element and shown a portion of a modified deployment system, and FIG. **37**B is a perspective view of the junction housing after cinching and severing the suture loop;
[0062] FIG. **38** is a schematic view of an alternative annuloplasty ring utilizing a suture loop for a cinching element and two pairs of tension suture loops attached to opposite ends of the cinching element; and
[0063] FIG. **39** is a perspective view of a junction housing for the annuloplasty ring of FIG. **38** after cinching and removal of the tension suture loops.

DETAILED DESCRIPTION

[0064] The right ventricle and left ventricle are separated from the right atrium and left atrium, respectively, by the tricuspid valve and mitral valve; e.g., the atrioventricular valves. Though correction of the mitral annulus is the primary focus of the present application, it should be understood that certain characteristics of the annuloplasty rings described herein may equally be used to treat the tricuspid valve, and thus the claims should not be constrained to the mitral ring unless expressly limited.
[0065] The term “axis” in reference to the illustrated annuloplasty rings, and other non-circular or non-planar rings, refers to a line generally through the centroid of the ring periphery when viewed in plan view. “Axial” or the direction of the “axis” can also be viewed as being parallel to the average direction of blood flow within the valve orifice and thus within the ring when implanted therein. Stated another way, an implanted mitral ring orients about a central flow axis aligned along an average direction of blood flow through the mitral annulus from the left atrium to the left ventricle. The plan views of the annuloplasty rings illustrated herein are as looking from the atrial side in the direction of blood flow. For the purpose of orientation, therefore, the atrial side of the ring is up and the ventricular side is down.
[0066] FIG. **1**A is a schematic perspective view from the atrial side of a mitral valve MV with posterior being down and anterior being up. The mitral valve MV primarily comprises a pair of floppy coapting leaflets—an anterior leaflet AL and a posterior leaflet PL—secured around their outer edges to a fibrous mitral annulus MA. The anterior leaflet AL attaches to a somewhat straighter anterior fibrous portion of the mitral annulus MA, which makes up about one-third of the total mitral annulus circumference. The anterior fibrous annulus forms part of the central fibrous skeleton of the heart, and the two ends are called the fibrous left and right trigones. The arcuate muscular portion of the mitral annulus MA constitutes the remaining two-thirds of the mitral annulus, and the posterior leaflet PL attaches thereto. An anterior commissure AC and a posterior commissure PC at the junction of the two leaflets on each side are located just posterior to each fibrous trigone.
[0067] The peripheral mitral annulus MA is often described as kidney bean or D-shaped with a somewhat straighter side adjacent the anterior leaflet AL and a more rounded or convex side adjacent the posterior leaflet PL. The mitral annulus MA is typically viewed as having a major axis across its widest part, approximately between the commissures AC and PC, and a perpendicular minor axis that generally bisects both the anterior leaflet AL and posterior leaflet PL. A central axis Z flow direction is arbitrarily defined at the intersection of the major and minor axes.
[0068] FIG. **1**A-**1**E illustrate several steps of implanting and adjusting an annuloplasty ring **20** of

the present application. The procedure for gaining access to the mitral annulus involves making an incision through the patient's sternum (sternotomy) and then stopping the heart and rerouting blood flow through a heart-lung “cardiopulmonary” bypass machine. The mitral annulus is exposed through the left atrium. At this point a measurement is taken of the mitral annulus MA, typically by measuring the width across the major axis between the anterior and posterior commissures AC, PC as well as the leaflet area. Annuloplasty rings are conventionally provided in sizes between 24 and 40 mm, in 2 mm increments. The final size of the adjustable annuloplasty ring 20 as described herein is not constrained to these 2 mm increments, but is provided in a number of sizes per usual to best match the particular mitral annulus being repaired.

[0069] Once the mitral annulus MA is accessible, as seen in FIG. **1**A, a series of anchoring sutures **22** are pre-installed around the annulus. The anchoring sutures **22** are each looped through the atrial side to the ventricular side of the annulus, and then passed back up so that there are multiple pairs of sutures coming up out of the implantation site. In the illustrated embodiment, there are twelve pairs of sutures shown, though more or less may be utilized. Pledgets or small strips of fabric or other such backing (not shown) may be installed on the ventricular side of the suture loops to help prevent suture pull-through.

[0070] FIG. **1**B shows an annuloplasty ring **20** of the present application being advanced down to the mitral annulus MA along the pairs of sutures **22**. A distal end of a delivery or deployment system **24** attaches to a junction housing **26** at a midpoint of an anterior segment of the annuloplasty ring **22** and is used to parachute the ring down the array of sutures **22**. The deployment system **24** has a shaft **28** long enough to extend from outside the body to the surgical site, the shaft being connected to a proximal control handle as will be described below.

[0071] FIG. **1**C shows the implanted annuloplasty ring **20** after the pairs of sutures **20** have been tied off into knots **30** and severed close to the ring. The distal end of the deployment system **24** remains attached to the junction housing **26**. Following the process of anchoring the annuloplasty ring **20** to the mitral annulus MA, the left atrium is closed around the deployment system **24** with one or more purse string sutures. All other incisions are closed to prevent blood loss, with the deployment system **24** remaining such that it may be controlled by its proximal control handle outside the body. Subsequently, the patient is weaned off of cardiopulmonary bypass and heart restarted.

[0072] Adjustment of the annuloplasty ring **20** to optimize the repair is guided by a visualization technique such as transesophageal echocardiography (TEE) or in rare cases fluoroscopy, mainly focusing on residual mitral regurgitation, degree of leaflet coaptation and the presence of transmitral gradients. For example, FIG. **1**D illustrates the mitral valve MV during systole when the anterior leaflet AL and posterior leaflet PL come together or coapt. In this illustration, mitral regurgitation is indicated by the escaping blood flow which can be seen on TEE. This means that the leaflets AL, PL are not coapting, which may be corrected by reducing the size of the annuloplasty ring **20**. Even if there is no regurgitation seen, the surgeon may still decide to adjust the ring size in order to obtain a larger surface of coaptation.

[0073] FIG. **1**E shows the annuloplasty ring **20** being reduced in size using the proximal control handle **32**, which again is outside the body. Cinching the annuloplasty ring **20** in this regard brings the leaflets AL, PL closer together, and also the AL-PM diameter when desired, thus improving coaptation. In the illustration, the mitral valve MV is closed during systole with the leaflets coapting and no regurgitation detected. The annuloplasty ring **20** may be reduced in size by at least 2 mm across the major axis, equivalent to one standard ring size. Further reduction in major axis dimension may be provided up to 4 mm. Following ring size adjustments, the deployment system **24** is disengaged from the annuloplasty ring **20** and removed from the body. The purse string suture through the left atrial wall and any other openings are then closed to complete the procedure.

[0074] FIG. **2** is a perspective view of an exemplary deployment system **24** for the adjustable annuloplasty ring **20**, and FIG. **2**A is an enlarged view of the distal end of a deployment shaft **28**

coupled to the junction housing **26** of the annuloplasty ring. The proximal control handle **32** is shown in approximately the actual proportional size relative to the annuloplasty ring **20**, and generally comprises a cylindrical body having a plurality of controls thereon. The elongated shaft **28** is shown with a break, but may have a length of between 40-80 cm. The shaft is configured to have some lateral flexibility, but is stiff under compression and torque.

[0075] The distal end of the shaft **28** terminates in a tapered shroud or housing **34** with a pair of diametrically-opposed extensions **36** that straddle the junction housing **26** on radially inner and outer sides. Another way to see the housing **34** is that the extensions **36** define cutouts therebetween aligned around the periphery of the annuloplasty ring **20**. As will be explained below, the distal housing **34** encloses a number of operative elements which engage the junction housing **26** to adjust the size of the annuloplasty ring **20** and perform several other tasks.

[0076] FIG. **3** is a perspective view of the distal end of the deployment shaft **28** shown in phantom engaged with the junction housing **26**, while FIG. **4**A illustrates an inner coupling member **40** of the deployment system **24** engaged with the junction housing. One way to couple the deployment system **24** with the annuloplasty ring is by using an internally threaded coupling member **40** which engages external threads **42** on the junction housing **26**. The junction housing **26** has a main body **44** defining a three-way connection. Oppositely-directed side legs **46** extend along the periphery of the annuloplasty ring **20** and connect with an internal passage therein. A single upper port **48** having the external threads **42** thereon projects upward perpendicularly relative to the side legs **46**. The deployment shaft **28** connects to the annuloplasty ring **20** in line with the upper port **48**, and the coupling member **40** screws onto the external threads **42**. FIG. **4**B shows disengagement (unscrewing and retraction) of the coupling member **40** from the junction housing **26**, which is how the deployment system **24** is decoupled from the annuloplasty ring **20**.

[0077] FIG. **5**A is a vertical sectional view of the interaction between the distal end of the deployment shaft **28** and the junction housing **26**, while FIG. **5**B is an exploded perspective view of the components thereof. The outer shroud or housing **34** has an upper recess **50** into which the distal end of the deployment shaft **28** is fixed, and a wider internal distal end which matches the cup-shape of the coupling member **40**. The coupling member **40**, in turn, is located at the distal end of an elongated tubular first shaft **52** which extends through a lumen of the deployment shaft **28** to the control handle **32**. A tubular second shaft **54** slides and rotates concentrically within the first shaft **52** and has a distal non-circular torque driver **56** thereon. As will be explained below, the torque driver **56** engages an element within the junction housing **26** to lock the shape of the adjustable annuloplasty ring **20**.

[0078] A final element of the deployment system **24** is an adjustment cable **58** that extends from the control handle **32** through the lumen of the tubular second shaft **54** to the junction housing **26**. FIG. **5**A shows the adjustment cable **58** in the form of a loop which extends through a subloop of the cinching element **60** that projects up through a central opening in the junction housing **26**. FIG. **5**C (sheet **12**) is a vertical sectional view showing tension being applied by the adjustment cable **58** through the deployment shaft **28** to the cinching element **60**. In one embodiment, the adjustment cable **58** comprises a filament, such as a polymeric suture or metal cable, while the cinching element **60** is formed by a flexible metallic wire. The cinching element **60** may be formed of Nitinol, stainless steel, or a cobalt chromium (CoCr) alloy, and will be described in greater detail below.

[0079] FIG. **6** is a perspective view of the exemplary adjustable annuloplasty ring **20**, and to better explain the construction thereof, FIG. **6**A is an enlarged cutaway view of one portion and FIG. **6**B is a radial sectional view thereof. As mentioned above, the annuloplasty ring defines a rounded D-shape with a straighter anterior segment **62** in which is centered the junction housing **26** opposite a rounded posterior segment **64**. Aside from the junction housing **26**, the exterior of the annuloplasty ring **20** is covered with a tubular fabric cover **66** with a sewing cuff **68** added to a peripheral outer edge. The fabric cover **66** closely surrounds a coiled body **70** through which a hollow filler member

72 extends. Finally, the cinching element **60** passes around the entire periphery of the annuloplasty ring **20** within a central lumen in the filler member **72**. The filler member **72** acts as a cushion between the cinching element **60** and coiled body **70**.

[0080] The radial sectional view of FIG. **6**B shows the extent that one embodiment of a sewing cuff **68** extends outward from the fabric cover **66**, which will be more fully discussed below. The sewing cuff **68** comprises a ring of fabric **74** formed by a single layer that is attached by a series of stitches **76** along the upper and lower edges to the fabric cover **66**. In one embodiment, the stitches **76** are colored differently than both the fabric cover **66** and ring of fabric **74** so that the upper and lower edges of the ring of fabric is accentuated. This serves to inform a surgeon where to pass the anchoring sutures—e.g., between the stitches **76** along the upper and lower edges of the ring of fabric **74**. The outer cover **66** further has a plurality of discrete marker bands **78** sewn thereto, at positions indicating the points on the ring corresponding to the fibrous trigones and midpoint of the posterior segment of the mitral annulus. The marker bands **78** help position the ring **20** around the annulus during implantation.

[0081] To further explain the structure of the annuloplasty ring **20**, FIG. **7** is a perspective view of the distal end of the deployment shaft **28** coupled to the ring having the outer cover removed, and FIG. **7**A is an exploded perspective view of the inner components of the annuloplasty ring, while FIG. **8**A is a perspective view of the ring with the outer cover **66** and inner filler member **72** removed, and FIG. **8**B is the same perspective view with the coiled body **70** removed illustrating the cinching element **60**. As can be seen from these images, each of the components of the cinching element **60**, coiled body **70** and filler member **72** approximately define the rounded D-shape of the annuloplasty ring **20**, and are preferably pre-formed into such a shape. For example, the coiled body **70** is desirably a highly elastic metal such as Nitinol and may be heat set into the illustrated shape.

[0082] As seen best in FIG. **7**A, both the coiled body **70** and filler member **72** define two free ends on their straighter anterior sides that are spaced apart to accommodate the junction housing **26** therebetween. In contrast, the cinching element **60** forms a continuous loop that passes into the interior of the junction housing **26** and projects upward in a vertical subloop **80** through the upper port **48** thereof (FIG. **8**A). As seen by the arrows in FIG. **8**B, pulling on the subloop **80** constricts the remainder of the cinching element **60** to reduce the circumference of the annuloplasty ring **20**. That is, both the coiled body **70** and filler member **72**, not to mention the outer fabric cover **66**, are flexible in terms of constriction, and thus the cinching element **60** determines their final size. As will be seen, the cinching element **60** is locked in its reduced diameter constricted state within the junction housing **26**. Due to the metallic nature of the cinching element **60** the ring size remains the same after constriction and is not subject to stretching from material creep.

[0083] The cinching element **60** provides an advantage over prior adjustable annuloplasty rings in that it remains in a continuous loop before and after ring adjustment. Prior annuloplasty rings having sutures that extend around the periphery of the annuloplasty ring required a tool to cut them, adding complexity to the deployment system. Furthermore, once cut, the free ends of the sutures sometimes presented sharp trimmed ends extending away from the annuloplasty ring potentially leading to tissue irritation or worse. Finally, sutures have been exclusively used in the past which are made of a polymer and subject to material creep, thus allowing the ring to expand over time. The cinching element **60**, on the other hand, is made of a metal such as a cobalt chromium alloy which resists creep.

[0084] FIGS. **8**A-**8**B also indicate how the junction housing **26** connects to the body of the annuloplasty ring **20**. The coiled body **70** in the illustrated embodiment has a series of regularly spaced apart coils around most of its periphery except at its free ends **82** which are more tightly coiled, forming something of a tube. The tubular free ends **82** abut outer flanges formed on the side legs **46** of the junction housing **26**. Although not shown, the outer cover **66** extends inward over the free ends **82** and is secured within a pair of grooves **84** defined between flanges on the side legs **46**.

The outer cover **66** may have smaller diameter ends formed by a cinched portion or constriction ring or the like to hold the ends within the grooves **84**. The filler body **72** may terminate co-extensively with the coiled body **70**, or may extend a short distance into the hollow side legs **46**.

[0085] FIG. **9**A is an enlarged perspective view of the junction housing **26** of the adjustable annuloplasty ring **20**, and FIG. **9**B is a cutaway view showing internal components thereof. As mentioned above, the junction housing **26** has a three-way connection with a main body **44** and oppositely-directed side legs **46**. The upper port **48** defines an upper opening of a vertical channel which leads down to a horizontal channel through the side legs **46**. As mentioned, the cinching element **60** extends around the ring and into the channels of the side legs **46**, and then upward in the subloop **80** so as to be accessible through the upper port **48**. The subloop **80** passes through the hollow center of a locking screw **86** positioned in the vertical channel. The locking screw **86** has external threads **88** which engage internal threads defined within the vertical channel of the junction housing **26**. For example, FIG. **9**B illustrates an inward projection **90** formed by the side legs **46** that may be shaped to mate with the external threads **88**. The locking screw **86** has a non-circular internal throughbore **92** to enable rotation by the torque driver **56** (See FIG. **5**B). In the embodiment illustrated in FIGS. **9**-**10**, the through bore **92** has a square configuration, though the torque driver **56** is shown with an alternative star-shaped configuration. Either can be utilized, and both are shown for just that purpose.

[0086] Now with reference to FIGS. **10**A-**10**C and **5**C, the process for locking the cinching element **60** is explained. To recap, however, cinching the annuloplasty ring **20** and locking the cinching element **60** is done after anchoring the annuloplasty ring to the mitral annulus, as was described with reference to FIGS. **1**A-**1**E. That is, the annuloplasty ring **20** has been anchored to the annulus with sutures, and then in FIG. **1**E the ring is constricted via a mechanism within the control handle **32** to reduce the size of the annulus. Furthermore, this procedure is done under visualization after closing up the access incisions and restarting the patient's heart so as to observe any regurgitation through the mitral valve. The deployment shaft **28** extends from outside the patient's body into engagement with the annuloplasty ring **20** during this process. Prior to cinching the annuloplasty ring **20**, the surgeon observes the mitral valve function and if regurgitation is present, incrementally reduces the size of the ring **20** and then locks it when there is no more regurgitation.

[0087] FIG. **5**C illustrates the loop of the adjustment cable **58** being pulled in a proximal direction from the control handle **32**. The adjustment cable **58** passes through the subloop **80** of the cinching element **60**, and thus pulls the subloop up through the hollow locking screw **86** and reduces the circumference of the cinching element around the annuloplasty ring **20**, as was depicted in FIG. **8**C.

[0088] Once the proper size of the annuloplasty ring **20** is determined, the locking screw **86** is advanced by rotating and advancing the torque driver **56**, as seen in FIG. **10**B. Eventually, the lower end of the locking screw **86** pinches the diverging strands of the cinching element **60** against the interior lower wall of the junction housing **26**. The optimal extent to which the locking screw **86** advances and clamps against the cinching element **60** within the junction housing **26** may be determined empirically, and then implemented in a number of ways. For example, the locking screw **86** may be calibrated in terms of its thread pitch to advance a particular axial distance upon a predetermined angular rotation, monitored at the control handle **32**. Alternatively, the torque driver **56** may be actuated within the control handle **32** using a clutch mechanism which slips upon a predetermined reaction torque being sensed. Still further, the female threads within the junction housing **26** may be configured like a standard locking nut with a nylon insert or the like which provides a frictional resistance to further advancement of the locking screw **86** at a particular point. A nylon insert provides a further advantage in preventing reverse rotation of the locking screw **86**.

[0089] Finally, after advancing the locking screw **86** to firmly clamp against the cinching element **60**, as seen in FIG. **10**C, the deployment system **24** is disengaged from the junction housing **26**, such as was shown and described with respect to FIGS. **4**A-**4**B, and withdrawn from within the

body, while closing up any remaining incisions. This is done simply by severing or releasing one strand of the looped adjustment cable **58** from the control handle **32**, and then pulling the released strand from within the subloop **80**. No special cutter or other such instrument at the distal end of the deployment system **24** is required to sever the adjustment cable **58** or the cinching element **60**. What is left is the subloop **80** projecting somewhat from the upper port **48** of the junction housing **26**. Because of the rounded nature of the subloop **80**, it does not present any danger of lacerating or otherwise irritating tissue or leaflets within the mitral valve.

[0090] Exemplary aspects of the proximal control handle **32** will now be described with respect to FIGS. **11**, **12** and **12**A. The control handle **32** features a wand-like outer housing **100** which is generally cylindrical in exterior profile and sized to be easily manipulated with one hand by a surgeon or technician. The housing **100** may be formed by a pair of similar housing halves which are secured together with fasteners, adhesives, or the like. As seen in FIG. **12**, the housing **100** defines a series of internal chambers which receive rotatable actuator wheels and corresponding locking collars. More particularly, and with reference again to FIG. **11** and moving from a proximal end to a distal end, the control handle **32** has a first locking collar **102** and actuator wheel **104** for cinching the annuloplasty ring **20**, a second locking collar **106** and actuator wheel **108** for fixing the size of the annuloplasty ring, and a third locking collar **110** and actuator wheel **112** for disengaging the deployment system **24** from the annuloplasty ring. Each of the actuator wheels **104**, **108**, **112** rotates about a central axis of the control handle **32**, and each of the locking collars **102**, **106**, **110** slides axially between two positions on the control handle.

[0091] Each of the actuator wheels **104**, **108**, **112** has a tubular configuration with a central throughbore so that shafts, wires, etc. can pass axially therethrough. Each of the wheels **104**, **108**, **112** further has a scalloped or otherwise uneven outer surface to facilitate rotation, especially in the sometimes wet environment of the surgery suite. The uneven outer surface of each of the wheels **104**, **108**, **112** projects through a series of rectangular windows **101** formed in the outer housing **100** to enable the user to easily rotate the wheels. In the illustrated embodiment, the windows **101** are provided on opposite sides of the housing **100** so that a user can easily embrace the control handle **32** with the palm of one hand while applying torque to anyone of the wheels **104**, **108**, **112** with the thumb and finger.

[0092] FIG. **12** shows that each of the wheels **104**, **108**, **112** has a proximal extension **103** around which a ring-like body of the locking collars **102**, **106**, **110** is arranged to slide axially. Each of the locking collars **102**, **106**, **110** slide axially along the associated proximal extension **103** and permits rotation of the respective actuator wheel **104**, **108**, **112** when in the rightmost position. Each of the locking collars **102**, **106**, **110** has a pair of oppositely-directed tabs **105** that project outward through axial slots **107** in the housing **100**, the axial slots determining the extent of movement of each of the locking collars. The locking collars **102**, **106**, **110** each has a series of circumferentially-spaced internal splines **109** that mesh with a series of circumferentially-spaced axial ribs **111** on the respective actuator wheel **104**, **108**, **112**. When each locking collar **102**, **106**, **110** is in its left position, with the tabs **105** to the left within the slots **107**, the splines **109** engage with the ribs **111** to prevent the respective actuator wheel **104**, **108**, **112** from rotating.

[0093] With reference back to FIG. **11**, an enlargement of the components at the distal end of the deployment system **24** are shown. In particular, the outer deployment shaft **28** and the distal housing **34** are shown. The deployment shaft **28** enters the distal end of the control handle housing **100**, and is fixed rotationally therein by a non-circular end sleeve **114** held within a similarly-shaped recess in the handle. The coupling member **40** and first shaft **52** are shown extending distally from the housing **34**, and the tubular second shaft **54** and torque driver **56** from the first shaft. The first and second shafts **52**, **54** are rotatable within the outer shaft **28**, with the second shaft being linearly movable therein. Finally, the tension adjustment cable **58** is seen projecting from within the lumen of the second shaft **54**.

[0094] Now referring to FIG. **12**, the first shaft **52** is seen extending as far as to within the distal

most actuator wheel **112**. Although not shown, the first shaft **52** is fixed with respect to an internal bore of the actuator wheel **112** which is thus capable of rotating the first shaft. The second shaft **54** continues in a proximal direction and terminates at a non-circular head **113** that meshes with and is rotated by a similarly shaped inner bore of a clutch member **115**. The clutch member **115** has a cylindrical exterior which fits within an inner chamber of the middle actuator wheel **108**. Rotation of the middle actuator wheel **108** rotates the clutch member **115** until a predetermined reaction torque is met. The non-circular head **113** of the second shaft **54** is biased in a distal direction by a spring **117** fitted over the distal end of a threaded rod **119**. The threaded rod **119** in turn engages internal threads within the middle actuator wheel **108**. The distal bias of spring **117** maintains a distal force on the second shaft **54** so that the torque driver **56** at its distal end stays within the throughbore **92** of the locking screw **86** (see FIG. **10**B).

[0095] The tension adjustment cable **58** extends proximally through the second shaft **54** and, as seen in FIG. **12**, through the clutch member **115**, middle actuator wheel **108**, through the proximal actuator wheel **104**, and is secured at both free ends to a tension adjuster **116**. FIG. **12**A is an enlarged view of the connection between the tension adjustment cable **58** and control handle **32**. The tension adjuster **116** has a distal stub **117** with a lateral hole to which one free end of the tension adjustment cable **58** attaches, such as with a loop and crimp as shown. The other free end of the tension adjustment cable **58** passes all the way through the tension adjuster **116** and is secured to a cleat and cutting guide assembly **118** in the form of small tabs with holes therethrough. The tension adjuster **116** further includes a ring reduction indicator **120** on a distal end. External threading **121** on the distal end of the tension adjuster **116** mesh with internal threads **122** on the first actuator wheel **104**. Rotation of the first actuator wheel **104** causes axial displacement of the tension adjuster **116**. Rotation in one direction displaces the tension adjuster **116** proximally so as to pull the tension adjustment cable **58** and constricted the annuloplasty ring. As the tension adjuster **116** moves proximally (to the right), the ring reduction indicator **120** gradually projects farther out of the proximal end of the control handle housing **100**. The indicator **120** has a series of millimeter markings thereon which are calibrated to correspond to reduction in the major diameter of the annuloplasty ring.

[0096] FIG. **13**A-**13**C are perspective views of the proximal control handle **32** during operation thereof, and FIG. **13**D is an enlarged view of an operation to sever the adjustment cable **58** within the deployment system. First, FIG. **13**A illustrates rightward displacement of the first locking collar **102** which releases the first actuator wheel **104** for rotation. As suggested by a first graphic indicator **123**, rotation of the first actuator wheel **104** adjusts the size of the annuloplasty ring **20**. More particularly, rotating the first actuator wheel **104** displaces the tension adjuster **116** (to the right) to reduce the size of the annuloplasty ring **20**. The indicator **120** projects out of the housing **100** and tracks the incremental decrease in ring size in mm of major axis reduction. As mentioned above, the surgeon monitors blood flow through the mitral valve looking for excessive regurgitation. At some magnitude of ring constriction, regurgitation will be minimized.

[0097] FIG. **13**B shows movement of the middle locking collar **106** to the right which frees up the middle actuator wheel **108** to rotate. As suggested by a second graphic indicator **124**, rotation of the middle actuator wheel **108** locks the desired size of the annuloplasty ring **20**. As the actuator wheel **108** rotates, the clutch member **115** also rotates to, in turn, rotate the non-circular head **113** of the second shaft **54**. The second shaft **54** rotates the torque driver **56** at its distal end to tighten the locking screw **86** and clamp against the cinching element **60** (see FIG. **10**B). At a predetermined reaction torque, the clutch member **115** slips to stop rotation of the torque driver **56**. The slippage will ideally be felt or heard as audible clicking to notify the user. The predetermined torque applied to the locking screw **86** is calibrated to reliably clamp the cinching element **60** in a cinched position with a desired annulus reduction of the ring **20**.

[0098] Subsequently, the adjustment cable **58** is decoupled from the subloop **80** of the cinching element **60**. FIG. **13**D shows a schematic cutter or scissors being used to sever the portion of one of

the lengths of the adjustment cable **58** between tabs of the cleat and cutting guide assembly **118**. This frees up the adjustment cable **58** to be pulled free of the subloop **80** when the deployment system **24** is removed from the body.

[0099] Finally, FIG. **13**C shows rightward displacement of the third locking collar **110** which releases the distal actuator wheel **112** for rotation. As suggested by a third graphic indicator **125**, rotation of the distal actuator wheel **112** decouples the deployment system **24** from the annuloplasty ring **20**. Namely, the actuator wheel **112** rotates the first shaft **52** and distal coupling member **40** of the deployment system **24** (see FIG. **4**B). Once the coupling member **40** detaches from the threading on the junction housing **26**, the deployment system **24** is ready to be removed from the body.

[0100] As mentioned above, the sewing cuff **68** is added to increase the radial extent of the material used to anchor the ring. FIG. **14** is a schematic view of an anterior segment of an adjustable annuloplasty ring **130** without the sewing cuff **68** and having a deployment shaft **132** attached thereto. An outer cover **134** is partially removed to illustrate the tightly coiled sections of the internal coiled body **136**. A suture needle leading an anchoring suture **140** is shown being threaded through an outer periphery of the anterior ring segment.

[0101] FIG. **14**A is a sectional view through the annuloplasty ring **130** indicating one possible path of the suture **140** through the ring. Namely, without the radially extended cuff **68**, the surgeon must attempt to snag the suture needle **138** through the outer fabric cover **134**, which is relatively thin. Inevitably, the needle **138** passes inward to some extent between coils of the coiled body **136** and potentially through a filler member **141**. If the surgeon catches a number of suture needle **138** passes through the tightly coiled body **136**, there results a high drag force on the array of sutures **140** as the annuloplasty ring **130** is parachuted down to the mitral annulus. Moreover, sutures **140** passed through the tightly wound portion of the coiled body **136** sometimes interferes with an even constriction of the annuloplasty ring, deforming the reduced diameter shape. This highlights a need to add a suture cuff to the outer periphery of the outer cover **134**. More particularly, adding a suturing cuff permits passage of anchoring sutures therethrough instead of through the adjustable structural elements of the ring, helps maintain a generally annular shape of the ring during size adjustment, and minimizes dragging forces of sutures through the implant during delivery to the annulus.

[0102] FIG. **15** is a sectional view through an annuloplasty ring of the present application having an outer sewing cuff **68** as described above. One possible path of an anchoring suture through the ring is shown passing mostly through the sewing cuff **68**, and at most through the outer cover **66**. As mentioned, this sewing cuff configuration includes a ring of fabric **74** formed by a single layer that is attached by a series of stitches **76** along the upper and lower edges to the fabric cover **66**. The fabric **74** is desirably a woven polyester velour cloth.

[0103] FIGS. **16**A-**16**F are radial sectional views through alternative annuloplasty rings showing a variety of supplemental sewing cuffs that can be used. Each of the sewing cuffs are shown attached to a radially exterior periphery of an outer cover **66**, and attached with two lines of stitching **142**, as described above. First, FIG. **16**A shows a cuff formed by a ring of folded cloth **144** which has a reduced axial dimension relative to the sewing cuff **68**. The cloth **44** is rolled and tucked under at both of the bottom edges, and may be formed of a polymer fabric such as polyethylene terephthalate.

[0104] FIG. **16**B shows another sewing cuff defined by a tubular ring of fabric **146**, again attached by two rows of stitches **142**. FIG. **16**C shows a still further suture cuff **148** having a multiply folded strip of polyethylene terephthalate. More critically, the suture cuff **148** is folded upon itself so as to have four sequential radial layers. In FIG. **16**D the sewing cuff **150** is also a strip of polyethylene terephthalate that is folded several times upon itself to result in six sequential radial layers. FIG. **16**E shows a more loosely folded strip **152** forming the sewing cuff, the strip also desirably be formed of polyethylene terephthalate. FIG. **16**F shows a sewing cuff **154** that is an extension of two

peripheral edges of the outer cloth **66**. More specifically, the two edges extend radially outward and are folded inward upon themselves and sutured together to form a flat sewing lip of sorts.

[0105] It should be understood that the various adjustable annuloplasty rings disclosed herein may be formed in a planar shape, as shown up to now, or in a three-dimensional saddle shape as are a number of prior art fixed-size annuloplasty rings. A saddle shape helps with restoring shape and dynamic motion of the annulus, and also helps provide in-plane stiffness with an out-of-plane flexibility to achieve and maintain the size reduction in the anterior-posterior dimension. Any of the annuloplasty rings described previously may be formed with a saddle shape, such as described below.

[0106] One particularly successful fixed-size ring of the prior art is available as the Physio II annuloplasty ring from Edwards Lifesciences Corp. of Irvine, CA. FIG. **17** is a front elevational view of a saddle-shaped coiled body **160** in the shape of a Physio II ring that may be used with the adjustable annuloplasty rings of the present application. In particular, the coiled body **160** as an upward bow in the posterior segment **162**, a higher upward bow in the anterior segment **164**, and low points at the lateral side segments **166**. The resulting shape is a lopsided saddle, somewhat resembling a lopsided Pringles brand potato chip. The coiled body **160** can be substituted for the coiled body **70** in the earlier-described adjustable annuloplasty ring **20**, with the rest of the ring being unchanged. The coiled body **160** can again be formed of Nitinol, which provides the stiffness and remodeling characteristics needed for mitral valve repair. The Nitinol body **160** can be heat set into the desired saddle shape.

[0107] FIG. **18** is a front elevational view of an alternative saddle-shaped coiled body **170** having coiled regions of different spring rate. For example, a series of radially-extending junctions **172** may be provided to separate first segments **174**, a second segment **176**, and third segments **178**. The first segments **174** are located adjacent to the tightly coiled anterior bow, the second segment **176** is centered on the posterior bow, and the two third segments **178** are located in between the first and second segments, roughly at the commissures of the mitral valve leaflets. The two pairs of first segments **174** and third segments **178** are desirably symmetric across a minor axis of the ring **170**. Each of these helically coiled segments **172**, **174**, **178** may be configured with different spring rates, with the symmetric pairs of the first and third segments **174**, **178** preferably being identical in spring rate to each other. This allows more control in regions around the annuloplasty ring **170** to address different pathologies. For example, the common condition of ischemic mitral regurgitation, or IMR, leads to varying stiffness around the mitral annulus. Providing relatively more flexible or stiffer segments around the ring periphery allows the surgeon to customize the ring for the particular pathology. For instance, one proposed coiled body **170** has more flexible third segments **178** adjacent the commissure regions of the mitral valve which are more susceptible to suture dehiscence. Additionally, one or more regions of the anterior or posterior side of the coiled body **170**, such as the P.sub.3 segment (posterior side, closer to the posterior commissure PC), may be made stiffer to reinforce areas which are prone to prolapse.

[0108] Another idea for the coiled body is to provide segments that are much more flexible to enable transient expansion during the systolic/diastolic cycle. FIG. **19**A is a front elevational view of a saddle-shaped annuloplasty ring **180** with a coiled body **182**, and FIG. **19**B schematically illustrates expansion of the body during expansion of the annulus during the normal cardiac cycle. As before, the adjustable annuloplasty ring **180** has a cinching element **184** extending within the coiled body **182** and having a circumference that is controlled via a deployment system (not shown). The coiled body **182** features a series of expandable segments **186***a*, **186***b*, **186***c* distributed around its periphery which each include tightly wound coiled segments abutting one another. During the normal systolic/diastolic cycling, the tightly wound portions of the expandable segments **186***a*, **186***b*, **186***c* are allowed to spread apart, as seen in FIG. **19**B.

[0109] Another option is to have an adjustable ring that integrates design and performance characteristics of the Physio II, mentioned above, with another annuloplasty ring from Edwards

Lifesciences available under the tradename Physio Flex. FIG. **20** is a front elevational view of another saddle-shaped annuloplasty ring **190** having a coiled body **192** and a size-adjustable remodeling core **194** positioned therethrough, and FIG. **21** is a front elevational view of the remodeling core. The ring **190** is shown without an outer suture-permeable cover for clarity. The remodeling core **194** has tapered free ends **196**, **198** that overlap on a posterior side thereof and permit size adjustment of the ring **190**.

[0110] FIG. **22** is a view of the inner components of the saddle-shaped annuloplasty ring **190** with the addition of a cinching element **200**, and FIG. **23** is a sectional view through a junction housing **202** thereof. The ring **190** is size-adjustable via the cinching element **200** in the same way as described above for the annuloplasty ring **20** and cinching element **60**. That is, a deployment system (not shown) may be coupled to the junction housing **202** for advancing the ring **190** to the mitral annulus, and the deployment system may have an internal mechanism as described above for pulling the cinching element **200** up through the junction housing **202** to constrict the ring, and thus the annulus to which it is anchored.

[0111] As seen in FIG. **23**, the solid anterior segment of the remodeling core **194** passes straight through a bore in a clamp member **204** held within the junction housing **202**. The cinching element **200** extends through apertures on both lateral sides of the clamp member **204** and extends upward in a subloop through a central bore of a locking screw **206**. The locking screw **206** is positioned below an upper port of the junction housing **202** and has external threads that engage internal threads therein. As with the locking screw **86** described above, the locking screw **206** may be advanced using a torque driver of a deployment system to clamp the cinching element **200** within the clamp member **204** once the proper size of the annuloplasty ring **190** is attained. The tapered free ends **196**, **198** on the posterior side of the remodeling core **194** (see FIG. **21**) slide relative to each other to permit cinching of the ring **190**.

[0112] The remodeling core **194** may be formed of Nitinol and heat set to the particular shape shown, though other materials such as stainless steel or a Co—Cr alloy may also be used. The remodeling core **194** is formed with the anterior and posterior bows, as shown, resulting in a saddle shape. The coiled body **192** need not be shape set to the saddle shape, and simply follows the contours of the core **194**, which reduces manufacturing costs and may be stiffer and thus more effective in remodeling the annulus to a desired saddle shape.

[0113] Another technique for shaping the otherwise flexible and adjustable annuloplasty rings is to add rigid shaped sleeves in strategic locations. For example, FIG. **24** is a front elevational view of inner components of a still further saddle-shaped annuloplasty ring **210** having a coiled body **212** and a shaped sleeve **214** surrounding a posterior segment to form an upward bow. FIG. **24**A is a sectional view through the posterior segment thereof showing that the shaped sleeve **214** has an open slot **216** along an upper generatrix and closely surrounds a tubular friction-reducing member **218** surrounding the coiled body **212**. The shaped sleeve **214** may be formed of a metal, such as titanium, Co—Cr or stainless steel, and defines the upward bow on the posterior side of the ring **210**. The friction-reducing member **218** may be heat shrink polymer, silicone or cloth to limit metal-metal friction between the coiled body **212** and sleeve **214**.

[0114] FIG. **25** is a front elevational view of inner components of another saddle-shaped annuloplasty ring **220** having a coiled body **222** surrounded by a shaped sleeve **224** on an anterior segment to form an upward bow. Again, the sleeve **224** may be formed of a metal, such as titanium, Co—Cr or stainless steel, and provides a rigid upward bow to the ring **220**. In this embodiment, a central hole on the top of the sleeve **224** accommodates the junction housing which projects therethrough to receive a deployment shaft. Although not shown, a friction-reducing tube as described above may be introduced between the coiled body **222** and sleeve **224**. Another alternative is to position the shaped sleeve **224** within the coiled body **222**, in which case the friction-reducing member would be to the outside of the sleeve. Of course, the present application contemplates a ring with both a posterior sleeve **214** (FIG. **24**) and an anterior sleeve **224** to

provide two upward bows.
[0115] FIG. **26** is a front elevational view of an annuloplasty ring **230** having a saddle-shaped support body **232** formed by laser cutting a Nitinol tube. A series of elliptical-shaped gaps **234** are cut into a tubular Nitinol body, preferably before heat setting the body into the appropriate saddle-shape. The elliptical shape of the shape permits the design to be optimized to minimize high stress concentration areas. This construction enhances the ability to control the stiffness of the annuloplasty ring **230**, while still enabling post-implant circumferential constriction as described herein. The width of the elliptical shaped gaps **234** around a circumference of the support body **232** may be varied to vary the post-implant flexibility around the ring. Again, it may be desirable to increase the flexibility at the lateral commissure regions while maintaining a relatively stiffer upward anterior and posterior curves to better support a diseased mitral valve prone to regurgitation. Furthermore, the wall thickness of the tubular blank used to form the support body may be modified to increase the overall stiffness if needed.
[0116] The cinching elements disclosed herein are continuous loops, and thus the portion that sticks out the junction housing is relatively smooth and thus unobtrusive. However, sometimes the portion extending out of the junction housing is relatively long due to a large size reduction in the ring, which could cause problems and should be managed.
[0117] FIG. **27** is a perspective view of the junction housing **26** from which the subloop **80** has been retracted upward to cinch the annuloplasty ring **20**. The portion of the subloop **80** extending above the upper port **48** can sometimes be relatively long. Consequently, FIGS. **28**A and **28**B illustrate a solution. FIG. **28**A shows the junction housing **26** with a coupling member **40** of the deployment shaft attached. An exemplary spring-biased finger **240** is shown in contact with the exterior of the coupling member **40**. In one embodiment, the finger **240** attaches around one of the side legs of the junction housing **26** so as to be spring biased toward the coupling member **40**. A short perpendicular extension **244** of the finger **240** extends radially. The finger **240** may be covered with fabric, as shown.
[0118] FIG. **28**B shows the inner coupling member **40** removed and deployment of the spring-biased finger **240** to fold the subloop **80** of the elongated cinching element against the junction housing **26**. That is, the metallic subloop **80** is bent over so that it lies on top of the upper port **48**. In the same manner, FIG. **29** is a side elevational view of an alternative configuration for folding the elongated cinching element **80** through the use of two spring-biased fingers **240**, **246**. The spring-biased fingers **240**, **246** again may be covered with fabric, as shown.
[0119] The present application is mainly concerned with mechanisms for constricting the annuloplasty ring post-implant. However, sometimes the mitral valve that has been repaired fails completely, for instance due to excessive calcification, and must be replaced. Recent advances in heart valve replacements provide opportunities for implanting an expandable valve delivered percutaneously or transapically without stopping the heart and removing the native valve leaflets. Additionally, such expandable valves may be implanted within a previously implanted prosthetic heart valve, or within an annuloplasty ring. These are known as valve-in-valve and valve-in-ring procedures respectively. Often, such procedures are not available for smaller diameter and uses because of the presence of a relatively rigid previously implanted prosthetic valve or ring which reduces the total available orifice to an insufficient amount. However, some prior heart valves and annuloplasty rings are configured for expansion, and the present application contemplates adding such a feature to the rings disclosed herein.
[0120] FIG. **30**A is a schematic view of an adjustable annuloplasty ring **250** of the present application having a cinching element **252** and junction housing **254** that permit but limit expansion of the ring. The cinching element **252** extends around the periphery of the ring to and projects up through the junction housing **254**, as has been described. Although the junction housing **254** contains a mechanism clamping the cinching element **252** and fixing a reduced size of the ring **250**, the mechanism may be calibrated to resist expansion from natural cardiac cyclic forces but

allow slippage and permit expansion from larger outward forces, such as from an expansion balloon.

[0121] Consequently, FIG. **30**A shows outward forces being exerted on the ring **250**, such as from an expansion balloon, which are large enough to pull the cinching element **252** through the clamping mechanism within the junction housing **254**. The clamping mechanism within the junction housing **254** may be configured to have a spring element applying the locking force, therefore limiting the force by design. Ultimately, FIG. **30**B is a view of the annuloplasty ring **250** after expansion showing the cinching element **252** stretched taut to its full circumference and limiting further expansion. That is, the subloop that previously extended up from the junction housing **254** has been pulled downward and now extends around the circumference of the ring **250**. The material of the cinching element **252** is sufficient to withstand any further expansion from the balloon, and subsequently a valve-in-ring procedure may be performed to install a prosthetic valve within the ring **250**.

[0122] FIG. **31**A is a schematic view of another adjustable annuloplasty ring **260** having a cinching element **262** extending around the ring and up through a junction housing **264**, and a secondary cord **266** within the ring to limit expansion thereof. The secondary cord **266** is shown in an undulating pattern around the periphery of the inside of the ring **260** so as to have excess length that serves no function during normal implantation, adjustment, and physiological function. During a valve-in-ring procedure, and in contrast with the version described above, the cinching element **262** is held firmly within the junction housing **264** but is configured to break upon application of expansion forces during a valve-in-ring procedure. FIG. **31**B shows the annuloplasty ring **260** after expansion with the cinching element **262** broken and the secondary cord **266** expanded taut. The cinching element **262** may have a particular tensile strength which withstands normal physiological expansion forces, but breaks upon application of a larger force. Alternatively, the cinching element **262** could be provided with a weakened point which breaks upon application of the balloon expansion. The total length of the secondary cord **266** may be designed to allow installation of the largest prosthetic heart valve practical to be implanted within the particularly sized ring, and to have a sufficient tensile strength to avoid over-expansion. For example, the annuloplasty ring **260** may be sized for a relatively small annulus, such as 25 mm, with the total length of the secondary cord **266** being calibrated to be 27 mm. This accommodates installation of a prosthetic heart valve one size greater than the annulus.

[0123] FIGS. **32-35** are various views of an annuloplasty ring **270** comprising an alternative junction housing **272** with certain modifications from junction housings described above. The modified junction housing **272** has a main body **274** constructed so as to be a molded part, and the annuloplasty ring **270** again has a peripheral rounded D-shaped body **276** that is fabric-covered for anchoring purposes. The annuloplasty ring body **276** may be constructed in any manner described herein. The new junction housing **272** enables a deployment system, represented by the distal end of the deployment shaft **280**, to be secured to the housing via a quick-release harness **278**.

[0124] FIG. **33** shows the new junction housing **272** exploded. The housing **272** comprises the main body **274** having a radial channel **282** in a bottom surface that receives and retains the quick-release harness **278**, which is in the form of an elongated strap or filament sized to loop under the main body. As seen in FIG. **32**, the harness **278** extends proximally up through the deployment shaft **280** and eventually terminates in a control handle (not shown). The harness **278** thus retains the deployment shaft **280** in contact with the junction housing **272**. Much like the earlier looped adjustment cable **58** described with respect to the first deployment system **24**, the free ends of the harness **278** may be routed through a cleat and cutting guide assembly in the handle so that one strand may be severed and the entire harness then removed by pulling it out from under the junction housing **272**. The quick-release harness **278** thus substitutes for the threaded connection in the first embodiment.

[0125] With reference to FIGS. **33-35**, the junction housing **272** further has a locking screw **284**

that mates with internal threads **286** within the main body **274**, as before. A retention cap **288** having oppositely-extending wings **290** seats within slots **291** at the upper port of the main body **274** and may be ultrasonically-welded thereto to prevent the locking screw **284** from coming loose within the body. The wings **290** preferably have holes through which the strands of the harness **278** pass to help keep them aligned.

[0126] FIG. **35** shows the cross-section of the ring **270** with a cinching element **292** extending peripherally through an inner channel and emerging in a subloop through the junction housing **272**. The deployment shaft **280** contains a tension mechanism such as described above which can pull the subloop **292** upward and thus cinch the ring **270** smaller. Likewise, the deployment shaft **280** also may incorporate a torque driver to advance the locking screw **284** and clamp the cinching element **292** in a final position within the junction housing **272**. In all respects, the various mechanisms for cinching the ring may be as described above.

[0127] FIG. **36** is a schematic view of a size-adjustable annuloplasty ring **300** having an alternative cinching element **302** that extends internally around a periphery and through an anterior junction housing **304** in two directions. More particularly, the cinching element **302** may be a metallic wire (such as described above) with two terminal ends **306***a*, **306***b* which pass in opposite directions through a clamping mechanism (also such as described above) within the junction housing **304**. Each of the terminal ends **306***a*, **306***b* connects to a pull suture **308***a*, **308***b*, preferably just outside of the junction housing **304**. The pull sutures **308***a*, **308***b* extend internally in opposite directions alongside the cinching element **302** around the ring circumference and pass into the junction housing **304** from opposite directions. The pull sutures **308***a*, **308***b* are then directed upward in strands **310***a*, **310***b* through the upper port of the junction housing **304**, through a deployment system **312**, and eventually to a tensioning mechanism within a proximal control handle (not shown). Pulling on the strands **310***a*, **310***b* as indicated in FIG. **36** cinches the ring **300** smaller, as previously explained, and the cinching element **302** is clamped within the junction housing **304**.

[0128] FIG. **37**A shows a portion of the modified deployment system **312**, and FIG. **37**B is the junction housing **304** after cinching and severing the pull sutures **308***a*, **308***b* to leave just the cut off strands **310***a*, **310***b*. Instead of a looped cinching element as described elsewhere herein, the pull sutures **308***a*, **308***b* are severed by a modified deployment system **312** that incorporates a cutting tool, shown schematically as tube **314**. Various ways to sever sutures are known in the art, and any could be implemented within the tube **314**. Because the strands **310***a*, **310***b* are sutures, they do not present a significant risk of irritation to the mitral valve if the cut off ends are left hanging from the junction housing **304**, as opposed to metallic ends. Moreover, the cinching element **302** that extends around the inside of the ring **300** and is clamped within the junction housing **304** is a metallic cable that is durable and resists creep.

[0129] FIG. **38** is a schematic view of a further size-adjustable annuloplasty ring **320** having a cinching element **322**, and FIG. **39** is a perspective view of a junction housing **324** therefor after cinching and removal of a pair of tension suture loops. The cinching element **322** once again extends internally around the ring circumference and through the anterior junction housing **324** in two directions, and may be a metallic wire as described above to prevent long-term creep. Terminal ends of the cinching element **322** have small rings **326***a*, **326***b* connected thereto. Two strands each of two tension suture loops **328***a*, **328***b* couple to the separate rings **326***a*, **326***b*. The suture loops **328***a*, **328***b* then extend in opposite directions alongside the cinching element **322** around the ring periphery and pass into the junction housing **324** from opposite directions. The tension suture loops **328***a*, **328***b* extend through the upper port **330** of the junction housing **324**, through a deployment system (not shown) and eventually to a tensioning mechanism within a proximal control handle (not shown). Pulling on the suture loops **328***a*, **328***b* as indicated in FIG. **38** cinches the ring **320** smaller, as explained.

[0130] Once the ring **320** has been cinched to a desired size, the lengths of the cinching element **322** that extend through the junction housing **324** are clamped to prevent release. Subsequently, one

strand of each of the two tension suture loops **328***a*, **328***b* is then released or cut at the control handle, allowing the entire loop to be pulled free from within the ring **320**, through the junction housing **324** and also the deployment system. This leaves nothing projecting beyond the upper port **330** of the junction housing **324**, as seen in FIG. **39**.

[0131] It should be apparent that the individual features of the various size-adjustable annuloplasty rings described herein may be combined, if not explicitly stated. For instance, the cinching element **322** and tension suture loops **328***a*, **328***b* described with respect to FIGS. **38-39** may easily be incorporated into the annuloplasty ring **20** of the first embodiment, while the various suture cuffs shown in FIGS. **15-16** could be used on any of the rings. It is therefore an axiom that any combination of features is contemplated short of them being redundant, mutually exclusive and/or physically impossible, and the claims presented below should not be viewed otherwise.

[0132] While the foregoing is a complete description of the preferred examples, various alternatives, modifications, and equivalents may be used. Moreover, it will be obvious that certain other modifications may be practiced within the scope of the appended claims.

Claims

1. An annuloplasty ring and shape adjustment system, comprising: an annuloplasty ring defining a continuous peripheral shape around a central aperture and a central axis, the annuloplasty ring having a contractible inner body defining a lumen extending therethrough, wherein the inner body extends around the peripheral shape and has two ends connected to each other by a junction housing, the annuloplasty ring further including a flexible non-extensible cinching element formed in a complete loop, the cinching element passing through the inner body lumen and into the junction housing, wherein the junction housing has an inner cavity with three openings-first and second aligned openings in communication with the inner body lumen at the two ends of the inner body, and a third opening at an upper port facing axially up from the housing—wherein the cinching element has a main portion generally in a plane of the inner body and a subloop that projects perpendicular to the main portion through the upper port, and wherein the inner body has a relaxed implant shape when the cinching element is under no tension and a smaller, contracted shape when the cinching element is placed under tension.

2. The system of claim 1, wherein the junction housing has external threads for attachment of a delivery shaft thereto.

3. The system of claim 1, wherein the annuloplasty ring further includes a locking member within the junction housing configured to clamp onto the cinching element and maintain the cinching element under tension around the inner body.

4. The system of claim 3, wherein the locking member comprises a locking screw positioned in a vertical channel of the junction housing aligned with the upper port, the locking screw having external threads which engage internal threads defined within the vertical channel, and the locking screw having a non-circular internal throughbore that receives the subloop of the cinching element, wherein rotational advancement of the locking screw down into the vertical channel eventually clamps divergent portions of the cinching element against the inner cavity of the junction housing.

5. The system of claim 1, wherein the cinching element is metallic.

6. The system of claim 5, wherein the cinching element is a cobalt chromium alloy.

7. The system of claim 1, wherein the inner body is formed of a metallic tube having V-shaped gaps formed therein to permit contraction.

8. The system of claim 7, wherein the inner body is heat set into a saddle shape.

9. The system claim 1, further including a hollow compressible filler member extending within the inner body lumen and through which the cinching element extends.

10. The system claim 1, further including a tubular fabric cover surrounding the inner body and having a sewing cuff of a ring of fabric attached to an outer periphery of the fabric cover.

11. An annuloplasty ring and shape adjustment system, comprising: an annuloplasty ring defining a continuous peripheral shape around a central aperture and a central axis, the annuloplasty ring having a contractible inner body defining a lumen extending therethrough, wherein the inner body extends around the peripheral shape and has two ends connected to each other by a junction housing, the annuloplasty ring further including a flexible cinching element formed in a continuous loop, the cinching element passing through the inner body lumen and into the junction housing, wherein the cinching element forms a subloop through a port formed in the junction housing, and wherein the inner body has a relaxed implant shape when the cinching element is under no tension and a smaller, contracted shape when the cinching element is placed under tension; a deployment system including an elongated deployment shaft having a distal end configured to attach to the port of the junction housing, and a proximal control handle, the control handle having an adjustment cable connected to a tension actuator configured to pull the adjustment cable in a proximal direction, wherein the adjustment cable has a length sufficient to extend through a lumen in the elongated shaft and loop through the subloop, wherein actuation of the tension actuator pulls the adjustment cable and in turn places the cinching element under tension to convert the inner body from the relaxed implant shape toward the smaller, contracted shape.

12. The system of claim 11, wherein the annuloplasty ring further includes a locking member within the junction housing configured to clamp onto the cinching element and maintain the cinching element under tension around the inner body, and the control handle has a locking actuator connected to an elongated torque shaft configured to slide axially and rotate concentrically within the deployment shaft, the torque shaft having a distal non-circular torque driver shaped to mate with a similarly-sized and shaped opening in the locking member, wherein rotation of the torque shaft causes the locking member to clamp onto the cinching element.

13. The system of claim 12, wherein the locking member comprises a locking screw positioned in a vertical channel of the junction housing aligned with the port, the locking screw having external threads which engage internal threads defined within the vertical channel, and the locking screw having a throughbore that receives the subloop of the cinching element, the torque shaft and torque driver being hollow to receive the subloop and the adjustment cable passes through the torque shaft to loop through the subloop, wherein rotational advancement of the locking screw down into the vertical channel eventually clamps divergent portions of the cinching element against the inner cavity of the junction housing.

14. The system of claim 12, wherein the tension actuator and locking actuator are wheels positioned within a housing of the control handle and mounted to rotate about a longitudinal axis of the housing, the wheels being exposed through windows formed in the housing and each having a locking collar associated therewith with a tab extending to the exterior of the housing, the tabs being arranged to toggle between permitting and preventing rotation of a respective wheel.

15. The system of claim 14, wherein the wheels each have a scalloped or uneven outer surface to facilitate rotation.

16. The system of claim 11, wherein the junction housing has external threads for attachment of the delivery system thereto, and the control handle has an attachment actuator connected to an elongated attachment shaft configured to slide axially and rotate concentrically within the deployment shaft, the attachment shaft having a distal end with internal threads for mating with the external threads on the junction housing, wherein rotation of the attachment shaft enables attachment and detachment of the delivery system from the annuloplasty ring.

17. The system of claim 11, wherein the delivery system has a quick-release harness in the form of a loop of flexible material that extends from the control handle and around the junction housing, wherein one end of the loop of flexible material is severable within the control handle to enable the detachment of the delivery system from the annuloplasty ring.

18. The system of claim 11, wherein the cinching element is metallic.

19. The system of claim 11, wherein the inner body is formed of a metallic tube having V-shaped

gaps formed therein to permit contraction.

20. The system of claim 19, wherein the inner body is heat set into a saddle shape.