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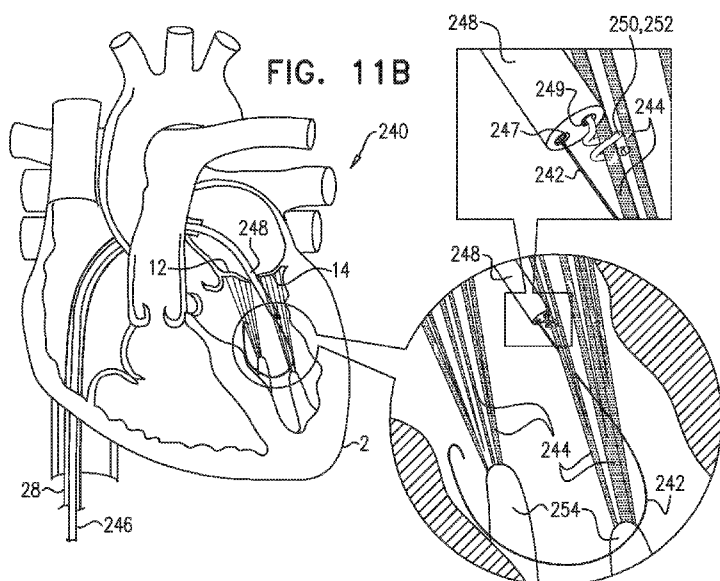
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(54) Title: TECHNIQUES FOR GUIDE-WIRE BASED ADVANCEMENT OF A TOOL



(57) Abstract: Apparatus comprises: (A) a housing (248), percutaneously deliverable to a heart of a subject, slidable along a guidewire (242), and shaped to define at least one opening (249); (B) a guide member (250), percutaneously deliverable to the heart, percutaneously removable from the subject, couplable to the housing, and having: (i) a distal portion, comprising a chord-engaging element (252), configured to be percutaneously slidably coupled to and decouplable from at least one chordae tendineae (244), and (ii) a proximal portion, comprising a longitudinal element (251); and (C) a deployment tool, configured (i) to be reversibly coupled to a tissue anchor (50,280), (ii) to be slidably coupled to the longitudinal element of the guide member, and (iii) to anchor the tissue anchor to a papillary muscle (254) of the subject. Other embodiments are also described.

TECHNIQUES FOR GUIDE-WIRE BASED ADVANCEMENT OF A TOOL**CROSS-REFERENCES TO RELATED APPLICATIONS**

The present application claims priority from US Provisional Patent application 61/733,979 to Reich et al., filed December 6, 2012, and entitled "Techniques for guide-wire based advancement of a tool"; and is related to:

(a) International Application PCT/IL20 11/000446 to Miller et al., entitled "Apparatus and method for guide-wire based advancement of a rotation assembly," filed on June 6, 2011 (which published as WO/2011/154942);

(b) US Patent Application 12/795,192 to Miller et al., entitled "A method for guide-wire based advancement of a rotation assembly," filed on June 7, 2010 (which published as US 2011/0301698);

(c) US Patent Application 12/795,026 to Miller et al., entitled "Apparatus for guide-wire based advancement of a rotation assembly," filed on June 7, 2010 (which published as US 2011/0106245), which is a continuation-in-part of US Patent Application 12/608,316 to Miller et al., entitled, "Tissue anchor for annuloplasty device," filed on October 29, 2009 (now US Patent 8,277,502); and

(d) US Patent Application 13/707,013 to Reich et al., entitled "Apparatus and method for guide-wire based advancement of a rotation assembly", filed on December 6, 2012 (which published as US 2013/0096672).

All of these applications are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates in general to valve and chordae tendineae repair. More specifically, the present invention relates to repair of an atrioventricular valve and associated chordae tendineae of a patient.

BACKGROUND

Ischemic heart disease causes mitral regurgitation by the combination of ischemic dysfunction of the papillary muscles, and the dilatation of the left ventricle that is present in ischemic heart disease, with the subsequent displacement of the papillary muscles and the dilatation of the mitral valve annulus.

Dilation of the annulus of the mitral valve prevents the valve leaflets from fully coapting when the valve is closed. Mitral regurgitation of blood from the left ventricle into the left atrium results in increased total stroke volume and decreased cardiac output, and ultimate weakening of the left ventricle secondary to a volume overload and a pressure overload of the left atrium.

Chronic or acute left ventricular dilatation can lead to papillary muscle displacement with increased leaflet tethering due to tension on chordae tendineae, as well as annular dilatation.

SUMMARY OF THE INVENTION

In some applications of the present invention, apparatus is provided comprising an implant comprising one or more primary adjustable repair chords and an adjustment mechanism that is configured to adjust a tension of the one or more adjustable repair chords and that is slidable along a guidewire toward an implantation site. Additionally, the apparatus comprises a first tissue-engaging element (e.g., a tissue anchor) that comprises one or more docking stations. Further additionally, in accordance with some applications of the present invention, a method is provided for implanting such apparatus. A respective guidewire is reversibly coupled to each one of the docking stations. The adjustment mechanism is slidable along the guidewire toward one of the one or more docking stations, and is coupled to the tissue-engaging element via the docking station. Thus, the docking station is a coupling element that provides coupling between two other elements (in this case, between adjustment mechanism and the tissue-engaging element.)

The repair chord comprises a flexible, longitudinal member (e.g., sutures or wires). The repair chord is coupled at a distal portion thereof to the adjustment mechanism. In some applications, the repair chord functions as artificial chordae tendineae. In other applications, the repair chord is used to adjust a distance between two portions of the ventricular wall. For some applications, the repair chord is coupled at a proximal portion thereof to a second tissue-engaging element (e.g., a tissue anchor which penetrates or clips a portion of tissue).

For other applications, the repair chord comprises a cord that is disposed within at least a portion of an annuloplasty ring structure (e.g., a full annuloplasty ring or a partial annuloplasty ring). For such applications, the annuloplasty ring structure comprises the adjustment mechanism that is coupled to the repair cord. The annuloplasty ring structure

is slidable along the guidewire toward one of the one or more docking stations, and is coupled to the tissue-engaging element via the docking station. It is to be noted that the annuloplasty ring structure may be provided independently of the adjustment mechanism and the repair chord. For such applications, the annuloplasty ring structure is slidable
5 along the guidewire toward one of the one or more docking stations, and is coupled to the tissue-engaging element via the docking station.

For yet other applications, a prosthetic heart valve and/or a support for the prosthetic heart valve is slidable along the guidewire toward one of the one or more docking stations, and is coupled to the tissue-engaging element via the docking station.

10 Thus, the tissue-engaging element and the docking station are used to facilitate implantation of an implant such as cardiac valve implants, namely annuloplasty ring structures, prosthetic valves, and/or apparatus for receiving a prosthetic valve (e.g., a docking station or a support for receiving the prosthetic valve).

Typically, during a transcatheter procedure, the first tissue-engaging element is
15 coupled to a first portion of tissue at a first implantation site in a heart of a patient. The adjustment mechanism is then slid along the guidewire and toward the first tissue-engaging element at the first implantation site. The proximal portion of the repair chord is then coupled via the second tissue-engaging element to a second portion of tissue at a second implantation site. Following the coupling of the second tissue-engaging element to
20 the second implantation site, the adjustment mechanism is further slid distally toward the first tissue-engaging element and is then coupled to the first tissue-engaging element via the one or more docking stations on the first tissue-engaging element. Following the coupling of the adjustment mechanism to the second tissue-engaging element, a length and tension of the repair chord is then adjusted in order to adjust a distance between the first
25 and second implantation sites. For applications in which the repair chord functions as an artificial chordae tendineae, the adjustment of the length and tension of the repair chord draws the leaflets together, and/or pulls the leaflet down toward the first implantation site to repair the valve.

In some applications of the present invention, the adjustment mechanism
30 comprises a spool assembly which adjusts a degree of tension of the repair chord. The spool assembly comprises a housing, which houses a spool to which a distal portion of the repair chord is coupled.

For applications in which the repair chord is coupled to two respective portions of the ventricular wall, the two portions are drawn together, thereby restoring the dimensions of the heart wall to physiological dimensions, and drawing the leaflets toward one another.

5 In some applications of the present invention, the adjustment mechanism comprises a reversible locking mechanism which facilitates bidirectional rotation of the spool in order to effect both tensioning and relaxing of the repair chord. That is, the spool is wound in one direction in order to tighten the repair chord, and in an opposite direction in order to slacken the repair chord. Thus, the spool adjustment mechanism facilitates bidirectional adjustment of the repair chord.

10 In some applications of the present invention, the adjustable repair chord is implanted during an open-heart or minimally-invasive procedure. In these applications, the delivery tool comprises a handle and a multilumen shaft that is coupled at a distal end thereof to the adjustment mechanism. The delivery tool functions to advance the adjustment mechanism to the first portion of tissue, implant the adjustment mechanism at
15 the first portion of tissue, and effect adjustment of the repair chord by effecting rotation of the spool. For applications in which the repair chord functions as an artificial chordae tendineae, prior to implantation of the adjustment mechanism, the distal portion of the delivery tool and the adjustment mechanism coupled thereto are advanced between the leaflets of the atrioventricular valve and into the ventricle toward the first portion of tissue.
20 The incision made in the heart is then closed around the delivery tool and the heart resumes its normal function during the adjustment of the length of the artificial chordae tendineae.

In some applications of the present invention, apparatus and method described herein may be used for providing artificial chordae tendineae in a left ventricle of the heart
25 and effecting adjustment thereof. In some applications, apparatus and method described herein may be used for providing artificial chordae tendineae in a right ventricle of the heart and effecting adjustment thereof. In some applications, apparatus and method described herein may be used for providing a system to adjust a length between two portions of the heart wall. For other applications apparatus and method described herein
30 may be used for providing a docking station for an annuloplasty ring or for a prosthetic valve.

In some applications of the present invention, a guide member, comprising a chord-engaging element that is slidably couplable to chordae tendineae of the patient is

used to guide a deployment tool to a papillary muscle of the patient, so as to facilitate anchoring of a tissue anchor (e.g., a tissue anchor of a docking assembly) to the papillary muscle.

There is therefore provided, in accordance with an application of the present invention, apparatus for facilitating anchoring of a tissue anchor to a papillary muscle of a heart of a subject, the papillary muscle being coupled to one or more chordae tendineae of the heart of the subject, the apparatus being configured to be used with a guidewire, and including:

a housing, percutaneously deliverable to the heart of the subject, slidable along the guidewire, and shaped to define at least one opening;

a guide member, percutaneously deliverable to the heart of the subject, percutaneously removable from the subject, couplable to the housing, and having:

a distal portion, including a chord-engaging element, configured to be percutaneously slidably coupled to at least one of the one or more chordae tendineae, and decouplable from the at least one of the one or more chordae, and

a proximal portion, including a longitudinal element; and

a deployment tool, configured (1) to be reversibly coupled to the anchor, (2) to be slidably coupled to the longitudinal element of the guide member, and (3) to anchor the tissue anchor to the papillary muscle of the subject.

In an application, the housing is configured to be decoupled from the guide member before the deployment tool is coupled to the guide member.

In an application, the tissue anchor includes a helical tissue anchor, and the deployment tool is configured to anchor the tissue anchor to the papillary muscle of the subject by rotating the tissue anchor.

In an application, the deployment tool includes a lance, configured to stabilize the deployment tool at the papillary muscle of the subject by penetrating tissue of the papillary muscle.

In an application, the lance is retractable into the deployment tool.

In an application, the apparatus further includes the anchor.

In an application, the guidewire includes a first guidewire, and the apparatus further includes a second guidewire, reversibly coupled to the anchor.

In an application, the apparatus further includes the guidewire, the guidewire being configured to be transluminally advanced to a vicinity of the one or more chordae tendineae of the subject.

5 In an application, the guidewire is configured to be transluminally advanced such that a distal portion of the guidewire is disposed between at least two chordae tendineae of the subject, the one or more chordae tendineae including at least one of the at least two chordae tendineae of the subject.

10 In an application, the housing is shaped to define a channel therethrough, the housing being slidable along the guidewire by the guidewire being slidable through the channel.

In an application, the chord-engaging element includes a helical element, configured to be housed by the housing, to be advanced out of the housing, and to form a helix outside of the housing.

15 In an application, the chord-engaging element is configured to be generally straight when housed by the housing, and to curl into the helix outside of the housing.

In an application, the chord-engaging element is configured to be helical when housed by the housing.

20 There is further provided, in accordance with an application of the present invention, a method for use with a papillary muscle of a heart of a subject, the papillary muscle being coupled to one or more chordae tendineae of the heart of the subject, the method including:

advancing a guide member to the chordae tendineae, the guide member having a proximal portion that includes a longitudinal element, and a distal portion that includes a chord-engaging element, configured to be slidably coupled to the chordae tendineae;
25 coupling the chord-engaging element to at least one of the one or more chordae tendineae;

sliding the chord-engaging element over the at least one of the chordae tendineae toward the papillary muscle; and

30 advancing a tool toward the papillary muscle of the subject by sliding the tool along the longitudinal element.

In an application, the chord-engaging element includes a helical chord-engaging element, and coupling the chord-engaging element to the at least one of the chordae

tendineae includes wrapping the helical chord-engaging element around the at least one of the chordae tendineae.

In an application, the method further includes, following the step of advancing, anchoring a tissue anchor to ventricular muscle tissue using the tool.

5 In an application, anchoring the tissue anchor includes anchoring the tissue anchor to ventricular muscle tissue in a vicinity of the papillary muscle.

In an application, anchoring the tissue anchor includes anchoring the tissue anchor to ventricular muscle tissue within 1 cm of the papillary muscle.

10 In an application, anchoring the tissue anchor includes anchoring the tissue anchor to the papillary muscle.

In an application, anchoring the tissue anchor includes anchoring a tissue anchor that is reversibly couplable to a guidewire.

15 In an application, the deployment tool includes a lance, and the method further includes, prior to anchoring the tissue anchor, stabilizing the tool with respect to the ventricular muscle tissue by penetrating the ventricular muscle tissue with the lance.

In an application, the method further includes retracting the lance into the deployment tool.

In an application, the step of advancing includes advancing, to the heart of the subject, a housing that is slidable along the guide member.

20 In an application, the method further includes, prior to the step of advancing, advancing a guidewire to a ventricle of the heart, and advancing the housing includes sliding the housing over the guidewire.

In an application, advancing the guidewire includes advancing a distal portion of the guidewire between at least two of the chordae tendineae of the subject.

25 In an application, the method further includes, subsequent to the step of advancing, sliding the chord-engaging element distally out of the housing.

In an application, the method further includes, subsequent to the step of coupling and prior to the step of advancing, proximally withdrawing the housing and decoupling the housing from the guide member while maintaining the coupling of the chord-engaging element to the at least one of the one or more chordae tendineae.

30

In an application, sliding the chord-engaging element distally out of the housing includes facilitating transitioning of the chord-engaging element from a generally straight state into a helical state.

There is further provided, in accordance with an application of the present invention, a method for use with a tissue anchor and a papillary muscle of a heart of a subject, the papillary muscle being coupled to one or more chordae tendineae of the heart of the subject, the method including:

percutaneously advancing to the chordae tendineae, along a guidewire that has been advanced to the chordae tendineae of the subject, a housing, shaped to define at least one opening;

advancing a distal portion of a guide member out of the opening of the housing, the distal portion of the guide member including a chord-engaging element;

coupling the chord-engaging element to at least one of the one or more chordae tendineae;

exposing a proximal portion of the guide member out of the opening of the housing by withdrawing the housing proximally with respect to the guide member, the proximal portion of the guide member including a longitudinal element; and

anchoring the tissue anchor to ventricular muscle tissue of the subject by advancing a deployment tool, reversibly couplable to the tissue anchor, along the longitudinal element.

In an application, the method further includes, subsequently to the step of coupling and prior to the step of anchoring, sliding the chord-engaging element along the at least one chordae tendineae toward the papillary muscle.

In an application, the method further includes decoupling the housing from the guide member before advancing the deployment tool along the longitudinal member.

In an application, the tissue anchor includes a helical tissue anchor, and anchoring the tissue anchor includes rotating the tissue anchor.

In an application, the guidewire includes a first guidewire, and anchoring the tissue anchor includes anchoring a tissue anchor that is reversibly couplable to a second guidewire.

In an application, anchoring the tissue anchor includes anchoring the tissue anchor to ventricular muscle tissue in a vicinity of the papillary muscle.

In an application, anchoring the tissue anchor includes anchoring the tissue anchor to ventricular muscle tissue within 1 cm of the papillary muscle.

In an application, anchoring the tissue anchor includes anchoring the tissue anchor to the papillary muscle.

- 5 In an application, the deployment tool includes a lance, and the method further includes, before anchoring the tissue anchor, stabilizing the deployment tool with respect to the ventricular muscle tissue by penetrating the ventricular muscle tissue with the lance.

In an application, the method further includes retracting the lance into the deployment tool.

- 10 In an application, the step of advancing includes advancing the chord-engaging element out of the opening of the housing such that the chord-engaging element forms a helix outside of the housing.

- In an application, advancing the chord-engaging element out of the opening of the housing includes facilitating a transition of the chord-engaging member from a generally
15 straight state into a helical state.

The present invention will be more fully understood from the following detailed description of applications thereof, taken together with the drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

- Figs. 1-2 are schematic illustrations of apparatus comprising a tissue-engaging
20 element comprising a docking station coupled to a guidewire, in accordance with some applications of the present invention;

Fig. 3 is a schematic illustration of advancement of an adjustment mechanism along the guidewire toward the docking station of Figs. 1 and 2, in accordance with some applications of the present invention;

- 25 Figs. 4-5 are schematic illustrations of engaging a leaflet with a leaflet engaging element, in accordance with some applications of the present invention;

Fig. 6 is a schematic illustration of coupling of the adjustment mechanism of Fig. 3 to the docking station, in accordance with some applications of the present invention;

Figs. 7-9 are schematic illustrations of adjusting by the adjustment mechanism a length of a repair chord coupled to the adjustment mechanism, in accordance with some applications of the present invention;

Fig. 10 is a schematic illustration of the adjustment mechanism and the repair
5 chord, in accordance with some other applications of the present invention; and

Figs. 11A-F are schematic illustrations of a system and techniques for use thereof, for delivering a tissue anchor to a papillary muscle of a subject, in accordance with some applications of the invention.

DETAILED DESCRIPTION OF EMBODIMENTS

10 Reference is now made to Figs. 1-2, which are schematic illustrations of a system
20 comprising a docking assembly 150 for implantation at a first implantation site 5 of a patient, in accordance with some applications of the present invention. As shown in Fig. 2, docking assembly 150 comprises a tissue-engaging element having (1) a distal portion comprising a tissue anchor 50 (e.g., a helical tissue anchor as shown by way of illustration
15 and not limitation), and (2) a proximal portion comprising a docking platform 54, and at least one docking station 56. Thus, docking assembly 150 comprises (a) the distal portion which engages the tissue of the patient (i.e., the tissue-engaging element), and (b) the proximal portion which is coupled to docking station 56. At least one guide member, (e.g., a guidewire 40, shown in Fig. 2) is reversibly coupled to docking assembly 150 (e.g.,
20 by being looped around, or otherwise coupled to, a portion of assembly 150) so as to define first and second portions 40a and 40a' that extend away from assembly 150.

Tissue anchor 50 is typically implanted within cardiac tissue in a manner in which a distal portion of anchor 50 does not extend beyond an epicardium of heart 2 of the patient. Thus, anchor 50 is implanted at an intracardiac site such that the implant, (e.g.,
25 the adjustment mechanism or an implant comprising the adjustment mechanism) that is eventually coupled thereto (as described hereinbelow) is implanted at the intracardiac site such that no portions of the adjustment mechanism extend beyond the epicardium of the heart.

Docking assembly 150 and guidewire 40 are advanced toward implantation site
30 typically during a transcatheter procedure, as shown. However, it is to be noted that the scope of the present invention includes the advancement of assembly 150 and guidewire 40 during a minimally-invasive or open-heart procedure. The procedure is typically

performed with the aid of imaging, such as fluoroscopy, transesophageal echo, and/or echocardiography.

The transcatheter procedure typically begins with the advancing of a semi-rigid guidewire into a right atrium of the patient. The semi-rigid guidewire provides a guide for the subsequent advancement of a sheath 28 therealong and into the right atrium. For some applications, once sheath 28 has entered the right atrium, the semi-rigid guidewire is retracted from the patient's body. Sheath 28 typically comprises a 13-20 F sheath, although the size may be selected as appropriate for a given patient. Sheath 28 is advanced through vasculature into the right atrium using a suitable point of origin typically determined for a given patient. For example:

- sheath 28 may be introduced into the femoral vein of the patient, through an inferior vena cava, into the right atrium, and into the left atrium transseptally, typically through the fossa ovalis;
- sheath 28 may be introduced into the basilic vein, through the subclavian vein to the superior vena cava, into the right atrium, and into the left atrium transseptally, typically through the fossa ovalis; or
- sheath 28 may be introduced into the external jugular vein, through the subclavian vein to the superior vena cava, into the right atrium, and into the left atrium transseptally, typically through the fossa ovalis.

In some applications of the present invention, sheath 28 is advanced through the inferior vena cava of the patient (as shown) and into the right atrium using a suitable point of origin typically determined for a given patient.

Sheath 28 is advanced distally until the sheath reaches the interatrial septum. For some applications, a resilient needle and a dilator (not shown) are advanced through sheath 28 and into the heart. In order to advance sheath 28 transseptally into the left atrium, the dilator is advanced to the septum, and the needle is pushed from within the dilator and is allowed to puncture the septum to create an opening that facilitates passage of the dilator and subsequently sheath 28 therethrough and into the left atrium. The dilator is passed through the hole in the septum created by the needle. Typically, the dilator is shaped to define a hollow shaft for passage along the needle, and the hollow shaft is shaped to define a tapered distal end. This tapered distal end is first advanced through the

hole created by the needle. The hole is enlarged when the gradually increasing diameter of the distal end of the dilator is pushed through the hole in the septum.

The advancement of sheath 28 through the septum and into the left atrium is followed by the extraction of the dilator and the needle from within sheath 28. Subsequently, a docking-assembly delivery tool 30 is advanced through sheath 28. Tool 30 is typically advanced within a lumen of an advancement sheath 22 having a distal end 24. Advancement sheath 22 is advanced within sheath 28. Delivery tool 30 is coupled at a distal end thereof to a manipulator 32 which is reversibly coupled to docking station 56 and docking platform 54 of docking assembly 150. Manipulator 32 has (1) lateral arms which cup platform 54, and (2) a docking-station-coupler 34, as shown in Fig. 1. Coupler 34 is biased to move radially-inward, as shown in Fig. 1. Docking station 56 is ribbed, such that coupler 34, when moved radially inward, engages at least one rib of docking station 56, thereby coupling assembly 150 to delivery tool 30.

Delivery tool 30 and manipulator 32 are shaped so as to define a lumen for passage therethrough of guidewire 40.

Docking assembly 150 is implanted in implantation site 5 by rotating tool 30 in order to rotate anchor 50 and corkscrew anchor 50 into tissue of site 5. Site 5 typically comprises a portion of tissue at an intraventricular site in heart 2 of the patient. As shown, site 5 includes a papillary muscle 4, by way of illustration and not limitation. It is to be noted that site 5 includes any portion of cardiac tissue, e.g., a portion of a free wall of the ventricle, a portion of the septum facing the ventricle, a portion of tissue at a base of the papillary muscle, or a portion of the wall at the apex of the ventricle. (For the purposes of the claims, "a portion of tissue of a ventricle" includes any portion of cardiac tissue, e.g., a portion of a free wall of the ventricle, a portion of the septum facing the ventricle, a portion of tissue at a base of the papillary muscle, or a portion of the wall at the apex of the ventricle.)

Following the implantation of assembly 150 at site 5, tool 30 is disengaged from assembly 150 when the physician pulls on tool 30. This pulling pulls on manipulator 32 such that coupler 34 is actively moved radially outward against the ribs of docking station 56, and is thereby decoupled from station 56. At the time of pulling, tissue at implantation site 5 pulls on assembly 150 (in the direction opposite the direction of pulling by the physician) so as to help disengage tool 30 from assembly 150.

As shown in Fig. 2, following the decoupling of tool 30 from assembly 150, tool 30 is pulled proximally along guidewire 40 and is extracted from the body of the patient together with advancement sheath 22, leaving behind assembly 150 and guidewire 40.

Fig. 3 shows advancement of an implant (e.g., a spool assembly 36 comprising an adjustment mechanism 43) along guidewire 40 by an adjustment-mechanism delivery tool 64, in accordance with some applications of the present invention. Tool 64 is surrounded by and slidable within an advancement sheath 60 having a distal end 62.

Spool assembly 36 is surrounded by a braided fabric mesh, e.g., a polyester mesh, which promotes fibrosis around assembly 36 and facilitates coupling of assembly 36 to tissue of heart 2. Assembly 36 houses a rotatable structure (e.g., a spool as shown hereinbelow) that is surrounded by a housing 49. Housing 49 is coupled to a distal cap 44 which facilitates coupling of assembly 36 to docking station 56 of docking assembly 150. As shown, cap 44 is shaped so as to define a plurality of baffles 47 that are disposed angularly with respect to a distal end of cap 44. Baffles 47 are coupled to the distal end of cap 44 along respective coupling joints which facilitate movement of each baffle 47. During the coupling of spool assembly 36 to docking station 56, the ribbed portion of docking station 56 pushes inwardly baffles 47 of cap 44, as is described hereinbelow. Baffles 47 then expand and engage an area of docking station 56 between the ribs of the ribbed portion so as to dock and lock assembly 36 to docking station 56.

Additionally, cap 44 is shaped so as to define a central opening therethrough which facilitates passage therethrough of guidewire 40. Additionally, spool assembly 36 and the components thereof are shaped so as to define a central opening (i.e., an opening having the same axis as guidewire 40). That is, spool 46 has a central opening, and housing 49 has a central opening which facilitates passage of spool 46 and housing 49 along guidewire 40.

As shown, adjustment mechanism 43 is coupled to a distal portion of a repair chord 74 (e.g., repair chord 74 is looped through or otherwise coupled to a portion of adjustment mechanism 43). Chord 74 comprises a flexible longitudinal member. For some applications, and as is described hereinbelow, chord 74 functions as an artificial chordae tendineae. A proximal portion of chord 74 is coupled to a leaflet-engaging element 72 (e.g., a clip, as shown). Leaflet-engaging element 72 is disposed within a holder 70 that is coupled to delivery tool 64. Chord 74 a superelastic, biocompatible

material (e.g., nitinol, ePTFE, PTFE, polyester, stainless steel, or cobalt chrome). Typically, chord 74 comprises an artificial chordae tendineae.

5 Figs. 4-5 are schematic illustrations of the engaging of leaflet-engaging element 72 to at least one leaflet 14 of a mitral valve of the patient, in accordance with some applications of the present invention. As shown in Fig. 4, the clip is opened from a remote location outside the body of the patient.

For some applications, the clip typically is shaped so as to define at least one coupling protrusion 73. The clip has a tendency to close, and is initially held open by a cord (not shown) that is coupled to a surface of the clip, extends through delivery tool 64,
10 and is held taught outside of the heart. Once the clip has been advanced to the desired location on the leaflet, the cord is relaxed, allowing the clip to close. The cord is removed, typically by releasing one end thereof and pulling the other end. The positioning of holder 70 between the leaflets (Fig. 5) helps ensure that the clip engages exactly one of the leaflets. It is noted that in Fig. 5 the clip is shown engaging only a single leaflet (leaflet
15 14). The clip typically engages the leaflet by clamping the leaflet such that the clip engages atrial and ventricular surfaces of the leaflet. The clip may puncture the leaflet, or may merely press firmly against the leaflet.

It is to be noted that the scope of the present invention include the clipping together of both leaflets 12 and 14. For applications in which system 20 is used to repair a
20 tricuspid valve of the patient, the clip may clip any one, two, or all three leaflets together.

Holder 70 is shaped to define a groove which houses the clip during the advancement of tool 64 toward the ventricle. The groove functions as a track to facilitate slidable detachment of the clip from holder 70 following the engaging of the clip to leaflet 14.

25 Alternatively, the clip has a tendency to open. In order to close the clip, a cord is provided. A distal-most portion of the cord is looped around the clip. Once the clip has been advanced to the desired location on the leaflet, as shown in Fig. 5, the surgeon pulls on both ends of the cord, thereby causing the clip to become locked closed. The cord is removed, typically by releasing one end thereof and pulling the other end.

30 It is to be noted that the scope of the present invention includes any leaflet-engaging element known in the art.

As shown in Fig. 5, portions 74a and 74b extend from leaflet-engaging element 72 toward adjustment mechanism 43. Portions 74a and 74b define portions of a single chord 74 that is looped through a portion of mechanism 43. Alternatively, portions 74a and 74b represent two distinct chords which are coupled at their distal ends to adjustment
5 mechanism 43 and at their proximal ends to leaflet-engaging element 72.

As shown, leaflet-engaging element 72 engages leaflet 14 prior to coupling spool assembly 36 to docking station 56.

Fig. 6 shows spool assembly 36 being coupled to docking station 56, in accordance with some applications of the present invention. Following the coupling of leaflet-engaging element 72 to leaflet 14, spool assembly 36 is pushed distally toward docking
10 station 56. Spool assembly 36 is coupled to an advancement shaft 80 which pushes assembly 36. Shaft 80 slides within a lumen of delivery tool 64 and within a lumen of holder 70 so as to advance spool assembly 36, while leaflet-engaging element 72 remains engaged with leaflet 14. Advancement shaft 80 functions to advance distally spool
15 assembly 36 and functions to facilitate engagement between spool assembly 36 and docking station 56.

As described hereinabove, docking station 56 has one or more locking mechanisms (e.g., one or more ribs 57, shown in the enlarged cross-sectional image of Fig. 6) which project laterally such that rib 57 defines a shelf and an depressed area underneath the shelf
20 (i.e., the cross-sectional diameter at rib 57 is larger than the cross-sectional diameter at the area underneath the shelf). As described hereinabove, cap 44 of assembly 36 is shaped so as to define a plurality of baffles 47. As cap 44 engages docking station 56, baffles 47 are pushed inward and upward angularly as each baffle slides against rib 57. After each baffle 47 passes the shelf of rib 57, the baffle engages the depressed area underneath the shelf of
25 rib 57, as shown in the enlarged cross-sectional image of Fig. 6. The shelf of rib 57 prevents upward movement of baffles 47 and thereby locks in place baffles 47 and cap 44 with respect to docking station 56. Rib 57, therefore, comprises a locking mechanism so as to lock implant 42 (e.g., adjustment mechanism 43) to tissue anchor 50.

Following the coupling of assembly 36 to docking station 56, spool 46 is rotated in
30 a first rotational direction in order to advance with respect to spool 46 and contact with spool 46 successive portions of chord 74. For example, when the successive portions of chord 74 are advanced with respect to spool 46, the successive portions of chord 74 are looped around spool 46. The rotating of spool 46 in the first rotational direction pulls tight

and adjusts a length of chord 74 between leaflet 14 and spool 46, in order to adjust a distance between leaflet 14 and implantation site 5 and to facilitate coaptation between leaflets 12 and 14, as is described hereinbelow.

5 Housing 49 is shaped so as to provide openings 41a and 41b for passage therethrough of portions 74a and 74b, respectively, of chord 74 into housing 49. For some applications of the present invention, portions 74a and 74b define portions of a single chord 74 that is looped through spool 46. For other applications, portions 74a and 74b define discrete chords which are each coupled at respective distal ends thereof to spool 46.

10 The enlarged, cross-sectional image of Fig. 6 shows spool 46 within housing 49. Spool 46 defines an upper surface 150, a lower surface 152, and a cylindrical body portion disposed vertically between surfaces 150 and 152. Spool 46 is shaped to provide a driving interface, e.g., a channel, which extends from an opening provided by upper surface 150 to an opening provided by lower surface 152. A proximal portion of the driving interface is shaped to define a threaded portion 146 which may or may not be tapered. Threaded
15 portion 146 of spool 46 is engageable by a threaded portion of a screwdriver head 92 of a screwdriver 90. Screwdriver 90 is coupled to a distal end of shaft 80. For some applications, shaft 80 rotates screwdriver 90. For other applications, shaft 80 is shaped so as to define a lumen for advancement therethrough of a screwdriver-rotation tool that facilitates rotation of screwdriver 90. Rotation of screwdriver 90 and screwdriver head 92
20 rotates spool 46, as the respective threaded portions of spool 46 and screwdriver head 92 engage. The cylindrical body portion of spool 46 is shaped to define one or more holes which function as respective coupling sites for coupling (e.g., looping through the one or more holes, or welding to spool 46 in the vicinity of the one or more holes) of any number of chords 74 to spool 46.

25 Lower surface 152 of spool 46 is shaped to define one or more (e.g., a plurality, as shown) recesses 154 which define structural barrier portions 155 of lower surface 152. It is to be noted that any suitable number of recesses 154 may be provided, e.g., between 1 and 10 recesses, circumferentially or otherwise, with respect to lower surface 152 of spool 46.

30 As shown, a locking mechanism 45 is disposed in communication with lower surface 152 of spool 46 and disposed in communication with at least in part to a lower surface of housing 49. Typically, a cap 44 maintains locking mechanism 45 in place with respect to lower surface 152 of spool 46 and lower surface of housing 49. For some

applications, locking mechanism 45 is coupled, e.g., welded, to the lower surface of housing 49. Typically, locking mechanism 45 defines a mechanical element having a planar surface that defines slits. It is to be noted that the surface of locking mechanism 45 may also be curved, and not planar. Locking mechanism 45 is shaped to provide a protrusion 156 which projects out of a plane defined by the planar surface of the mechanical element. The slits of mechanism 45 define a depressible portion 128 that is disposed in communication with and extends toward protrusion 156. Depressible portion 128 is moveable in response to a force applied thereto typically by an elongate locking mechanism release rod 94 which slides through a lumen of screwdriver 90 and a torque-delivering tool that is coupled thereto.

It is to be noted that the planar, mechanical element of locking mechanism 45 is shown by way of illustration and not limitation and that any suitable mechanical element having or lacking a planar surface but shaped to define at least one protrusion may be used together with locking mechanism 45.

Cap 44 is provided that is shaped to define a planar surface and an annular wall having an upper surface thereof. The upper surface of the annular wall is coupled to, e.g., welded to, a lower surface provided by housing 49. The annular wall of cap 44 is shaped to define a recessed portion 144 of cap 44 that is in alignment with a recessed portion 142 of spool housing 49.

As shown, a distal end 96 of locking mechanism release rod 94 pushes distally on depressible portion 128 in order to unlock locking mechanism 45 from spool 46. Pushing depressible portion 128 by locking mechanism release rod 94 pushes distally protrusion 156 within recessed portion 142 of housing 49 and within recessed portion 144 of cap 44, which frees protrusion 156 from recesses 154 of spool 46. Once protrusion 156 is released from recesses 154 of spool 46, the physician is able to rotate spool 46 bidirectionally in order to adjust a tension of chord 74.

When the physician rotates spool 46 in the first rotational direction, chord 74 is pulled tight, and leaflet 14 is drawn toward adjustment mechanism 40 and toward anterior leaflet 12 of mitral valve 8.

In the resting state (i.e., prior to the rotation of spool 46 in order to adjust chord 74, following coupling of leaflet-engaging element 72 to leaflet 14) chord 74 is wrapped around spool 46 a few times (e.g., three times, by way of illustration and not limitation). This winding provides excess slack to chord 74 (in case portions 74a and 74b are coupled

too tightly to leaflet 14). If the physician wishes to provide slack to member 74 or to any one of portion 74a or 74b, the physician unwinds a bit of the wrapped portion of member 74 from around spool 46 (e.g., by unwinding chord 74 a few times from around spool 46, or by unwinding chord 74 entirely from around spool 46 so that chord 74 slides freely through spool 46 within a channel provided therein). In order to accomplish such unwinding, the physician rotates spool 46 in a rotational direction in which it unwinds the wrapped portion of chord 74. Since chord 74 is looped through spool 46 in the channel provided therein, when chord 74 is unwound from spool 46, the physician can pull on one or both portions 74a and 74b so as to adjust, make even, or further slacken any one of or both portions 74a and 74b that extend from spool 46.

When the physician desires to pull tight chord 74, he or she effects rotation of spool 46 in a first rotational direction, i.e., the direction opposite the second rotational direction in which spool 46 is rotated during the unwinding of chord 74 from spool 46. Rotation of spool 46 in the first rotational direction winds chord 74 around spool 46, while rotation of spool 46 in a second rotational direction that is opposite the first rotational direction, unwinds the portion of longitudinal chord 74 from around spool 46.

Fig. 7 shows spool assembly 36 following the adjustment of chord 74 by rotating screwdriver 90 in the direction as indicated by the arrow, and the partial removal of screwdriver 90, in accordance with some applications of the present invention. As shown in the enlarged cross-sectional image of Fig. 7, successive portions of chord 74 are wrapped around spool 46. That is, chord 74 is wrapped more times around spool 46 following adjustment (e.g., an additional 4 times, as shown in Fig. 7), than prior to adjustment (Fig. 6). This pulls chord 74 from a slackened state (Fig. 6) to a taut state (Fig. 7) in order to adjust a length of chord 74 between adjustment mechanism 43 and the proximal end of chord 74 that is coupled to leaflet-engaging element 72. Additionally, this applying of tension to chord 74 adjusts a length between first and second implantation sites 5 and 7. Typically, chord 74 is adjusted while heart 2 is beating.

As shown, rod 94 is shaped so as to define a central lumen and a distal opening for passage therethrough of guidewire 40. Additionally, depressible portion 128 is shaped so as to provide an opening for passage of guidewire 40 therethrough. Guidewire 40 is looped around a distal looping element 55 of docking platform 54 of docking assembly 150. Following the adjusting of the tension and length of chord 74, screwdriver 90 is decoupled from spool 46 (e.g., by being unscrewed from threaded portion 146 of spool 46)

and is advanced proximally together with rod 94 away from spool assembly 36, as shown in the enlarged, cross-sectional image of Fig. 7.

Following the decoupling of screwdriver 90 from spool 46 and the removal of screwdriver 90, guidewire 40 remains coupled to docking platform 54 and docking assembly 150. Guidewire 40 then facilitates subsequent advancement of screwdriver 90 or any other tool to access spool assembly 36 and/or to facilitate further adjustment of chord 74 beyond the initial adjustment. Guidewire 40 may remain chronically coupled to docking assembly 150 and may be accessible at a subcutaneous location of the patient, e.g., a port. For other applications, guidewire 40 is removed from docking assembly 150 when the physician determines that further adjustment of chord 74 is not needed. The physician removes guidewire 40 by pulling, from outside the body of the patient, one end of guidewire 40 so that guidewire 40 slides around element 55 and is unlooped therefrom. The physician continues to pull on the end of guidewire 40 until the second end of wire 40 is exposed and removed from the patient.

Following the removal of locking-mechanism release rod 94, depressible portion 128 is no longer depressed by distal end 96 of rod 94, and protrusion 156 returns within a recess 154 of spool 46 so as to lock spool 46 in place and restriction rotation thereof in either direction (Fig. 7).

Reference is now made to Figs. 3-7. It is to be noted that spool assembly 36 is only coupled to docking assembly 150 following the coupling of leaflet-engaging element 72 to leaflet 14. This is done in order to reduce the strain on implantation site 5. Should spool assembly 36 be implanted at implantation site 5 prior to engaging leaflet 14 with leaflet-engaging element 72, more strain would be applied to implantation site 5 than if spool assembly 36 had been implanted following the coupling of leaflet-engaging element 72 to leaflet 14, as described herein. That is, the pulling force is applied in a downward direction from leaflet 14 toward implantation site 5 instead of from implantation site 5 upward toward leaflet 14.

Fig. 8 shows system 20 following the removal of the tool used to rotate spool 46 of spool assembly 36, in accordance with some applications of the present invention. As shown, chord 74 is pulled tight such that its length and tension are adjusted, and leaflet 14 is pulled and adjusted commensurate with the adjustment of chord 74. Guidewire 40 remains coupled to spool assembly 36 and to docking assembly 150, as shown, such that

portions 40a and 40a' extend from spool assembly 36. Guidewire 40 facilitates the reintroduction of the tool used to rotate spool 46, or of any other tool.

Fig. 9 shows system 20 following the removal of guidewire 40 from heart 2, in accordance with some applications of the present invention. As shown, the adjustment of chord 74 draws leaflets 12 and 14 together. It is to be noted that although leaflet-engaging element 72 is shown as engaging only leaflet 14, the scope of the present invention includes the engaging of both leaflets 12 and 14 by leaflet-engaging element 72.

Fig. 10 shows a system 220, as described hereinabove with reference to system 20, with the exception that implantation site 5 includes tissue of the wall of the ventricle at the base of papillary muscle 4 in a vicinity of the apex of the heart, in accordance with some applications of the present invention. Implantation site 5 is shown by way of illustration and not limitation, and as described hereinabove, site 5 may include any portion of tissue of heart 2. It is to be noted that although leaflet-engaging element 72 is shown as engaging only leaflet 14, the scope of the present invention includes the engaging of both leaflets 12 and 14 by leaflet-engaging element 72.

Reference is now made to Figs. 11A-F, which are schematic illustrations of a system 240 and techniques for use thereof, for delivering a tissue anchor 280 to a papillary muscle of a subject, in accordance with some applications of the invention. For some applications of the invention, tissue anchor 280 comprises tissue anchor 50 of docking assembly 150, described hereinabove. Alternatively, tissue anchor 280 may comprise a different tissue anchor. Similarly, tissue anchor 280 may comprise a helical tissue anchor, as shown in Figs. 11A-F by way of illustration and not limitation, or may comprise a different tissue anchor.

As described hereinabove (e.g., with reference to Figs. 1-2), transcatheter access to heart 2 typically begins with the advancing of a semi-rigid guidewire into the left atrium of the patient, and sheath 28 is subsequently advanced along (e.g., over) the guidewire, to the left atrium. Typically, but not necessarily, this is performed using a standard transseptal puncture procedure, and further typically, the guidewire is advanced to the heart transfemorally, as shown. Alternatively, the guidewire may be advanced using a retrograde approach, via the aorta of the subject. Similarly, any suitable approach may be used such as, but not limited to, those described with reference to Figs. 1-2. For some applications, such that those described with reference to Figs. 11A-F, the guidewire is not immediately retracted from the body of the patient. The guidewire is shown in Figs. 11A-

F as a guidewire 242. Typically, guidewire 242 is advanced such that it passes leaflets 12 and 14, and reaches and/or passes one or more chordae tendineae 244 (Fig. 11A). For some applications, guidewire 242 passes between two or more chordae tendineae 244. For some applications guidewire 242 is configured (e.g., shape-set) to facilitate such positioning. Fig. 11A also shows a chord-engaging tool 246 being subsequently advanced distally along guidewire 242, toward chordae tendineae 244.

A distal portion of chord-engaging tool 246 comprises or defines a housing 248, and the chord-engaging tool is advanced such that housing 248 is disposed in a vicinity of (e.g., close to and/or touching) one or more of the chordae tendineae (Fig. 11B). Typically, tool 246 (e.g., housing 248 thereof) is shaped to define a channel 247 therethrough, through which guidewire 242 is slidable. Disposed within housing 248 is at least part of a guide member 250, which has a distal portion and a proximal portion. The distal portion of guide member 250 comprises a chord-engaging element, such as, but not limited to, a helical chord-engaging element 252, which is configured to be slidably coupled to at least one of the chordae tendineae.

Fig. 11B shows element 252 having been advanced out of an opening 249 defined by housing 248, and forming a helix outside of the housing. For some applications, when disposed within housing 248, element 252 is generally straight (e.g., is held generally straight within a lumen of the housing), and curls into the helix as it emerges from the housing. Alternatively, element 252 is also helical when disposed within housing 248. Element 252 wraps around one or more of the chordae tendineae as the element forms the helix outside of the housing. For some applications, element 252 is rotated to facilitate this wrapping. Similarly, housing 248, element 252, and guidewire 242 may be manipulated (e.g., moved back and forth) to facilitate engagement of the chordae tendineae by element 252.

Fig. 11C shows chord-engaging tool 246 (including housing 248) being subsequently moved distally such that chord-engaging element 252 slides distally along the one or more chordae tendineae that have been engaged, such that element 252 reaches (e.g., touches) a papillary muscle 254 (e.g., the papillary muscle to which the chordae tendineae engaged by element 252 is coupled).

Subsequently, tool 246 (including housing 248) is withdrawn proximally, while guide member 250 is held in place (e.g., by a counter force), such that tissue-engaging element 252 remains coupled to the chordae tendineae in close proximity to (e.g., in

contact with) papillary muscle 254, and exposing the proximal portion of guide member 250, comprising a longitudinal element 251. Typically, tool 246 (including housing 248) is subsequently withdrawn into sheath 28, and further typically, is decoupled from the guide member and/or removed from the body of the patient.

5 Fig. HE shows a deployment tool 260 being transcatheterally advanced into heart 2 of the subject, and being slid along guide member 250 (e.g., along longitudinal element 251 thereof). For some applications, tool 260 comprises one or more eyelets 262, slidable over longitudinal element 251. For some applications, tool 260 is advanced via an overtube 258, which may itself be advanced through sheath 28. For some applications,
10 tool 260 is advanced via tool 246 (e.g., via a lumen therethrough), and overtube 258 in Figs. 11E-F represents tool 246 functioning as an overtube.

 Guide member 250 (e.g., longitudinal element 251 thereof) guides deployment tool 260 toward papillary muscle 254. For some applications, deployment tool 260 comprises a distal lance 264, configured to penetrate tissue of papillary muscle 254, and to stabilize
15 tool 260 at the papillary muscle. For some such applications, lance 264 is retractable into the body of tool 260. For applications in which deployment tool comprises lance 264, the lance is typically slidable through a hole in anchor 280. Alternatively, anchor 280 may comprise lance 264, and the lance is configured to stabilize the anchor at the papillary muscle during anchoring, e.g., during rotation of the anchor.

20 Deployment tool 260 is configured to anchor tissue anchor 280 to papillary muscle 254. For some applications, and as shown in Fig. HE, tissue anchor 280 is reversibly coupled to the distal end of tool 260. For some applications, the tissue anchor is housed within tool 260 and is advanced out of the tool prior to or during anchoring. For applications in which anchor 280 comprises a helical anchor, the anchor is typically
25 anchored to the papillary muscle by being rotated by tool 260, or by a component thereof.

 For some applications, system 240 is configured to facilitate anchoring of tissue anchor 280 to other ventricular muscle tissue in the vicinity of papillary muscle 254 (e.g., within 1 cm of the papillary muscle). For example, a sufficient distance between (1) a distal-most part of tool 260 at which the tool is slidably coupled to longitudinal element
30 251 (e.g., the distal-most eyelet 262), and (2) a distal end of anchor 280 may be provided to allow the tissue anchor to be anchored slightly away from chord-engaging element 252 (e.g., within 1 cm of the papillary muscle). Flexibility of longitudinal element 251 may alternatively or additionally facilitate such anchoring of anchor 280. Alternatively or

additionally, the operating physician may stop advancing tool 260 such that a length of guide member 250 (e.g., of longitudinal element 251 thereof) between the distal-most eyelet 262 and chord-engaging element 252 is sufficient to facilitate such anchoring of anchor 280.

5 Fig. 11F shows guide member 250 and deployment tool 260 having been retracted proximally (e.g., into overtube 258 and/or out of the body of the patient), exposing a guidewire 282, reversibly coupled to anchor 280, and extending proximally (e.g., into overtube 258 and/or out of the body of the subject).

Chord-engaging element 252 is typically decoupled from chordae tendineae 244 by
10 withdrawing guide member 250 slightly proximally with respect to tool 260, thereby straightening out the helix formed by element 252. For example, the helix may be progressively drawn into tool 260, or past an eyelet 262 thereof, and responsively straighten. Alternatively, chord-engaging element 252 may be decoupled from the chordae tendineae using tool 246 (e.g., housing 248 thereof), such as by re-advancing the
15 tool distally, and withdrawing member 250, including element 252 thereof, into the tool.

For some applications, chord-engaging element 252 is decoupled from chordae tendineae 244 after anchoring of tissue anchor 280 (e.g., after tissue anchor 280 has been partially or fully advanced into papillary muscle 254). For some such applications, this is facilitated by flexibility of element 252 (e.g., that which facilitates curling and
20 straightening thereof), e.g., by facilitating movement of element 252 through and/or around portions of anchor 280.

For some applications, chord-engaging element 252 is decoupled from chordae tendineae 244 prior to anchoring of tissue anchor 280. For example, chord-engaging element 252 may be decoupled from the chordae tendineae subsequently to lance 264
25 penetrating tissue and thereby stabilizing tool 260 and anchor 280 with respect to the tissue.

It is to be noted that guidewire 282 is a different guidewire to guidewire 242, described with reference to Figs. 11A-B. As described hereinabove, for some applications, tissue anchor 280 comprises tissue anchor 50 of docking assembly 150.
30 Similarly, guidewire 282 may comprise guidewire 40, described hereinabove, and may be reversibly coupled to anchor 280 via a docking station 56 of the docking assembly.

It is to be noted that, although guidewire 242 is shown in Figs. 11A-E as being present in heart 2, and is shown in Fig. 11F as having been withdrawn from the heart, guidewire 242 may be withdrawn at any point in the procedure following the coupling of chord-engaging element 252 to chordae tendineae 244 (Fig. 11B).

5 For some applications, the step shown in Fig. 11F is generally similar to the step shown in Fig. 2. The apparatus and techniques described with reference to Figs. 11A-F may be used in combination with the apparatus and techniques described with reference to Figs. 1-10, e.g., to facilitate anchoring of docking assembly 150 to a papillary muscle. For some such applications, the step described with reference to Fig. 11F may precede the step
10 shown in Fig. 3, mutatis mutandis.

For some applications of the present invention, systems 20, 220, and 240 are used to treat an atrioventricular valve other than the mitral valve, i.e., the tricuspid valve. For these applications, systems 20, 220, and 240 placed in the right ventricle instead of the left ventricle.

15 It is to be noted that the scope of the present invention includes the use of systems 20, 220, and 240 on other cardiac valves, such as the pulmonary valve or the aortic valve.

It is to be further noted that the scope of the present invention includes the use of systems 20, 220, and 240 on other tissue other than cardiac tissue, e.g., gastric tissue or any other suitable tissue or organ.

20 For some applications, system 240 and/or the techniques described with reference to Figs. 11A-F may be used to deliver a plurality of tissue anchors 280 to the papillary muscle, and/or to deliver a plurality of tissue anchors to a plurality of papillary muscles.

Additionally, the scope of the present invention includes applications described in the following applications, which are incorporated herein by reference. In an application,
25 techniques and apparatus described in one or more of the following applications are combined with techniques and apparatus described herein:

- PCT Publication WO 06/097931 to Gross et al., entitled, "Mitral Valve treatment techniques," filed March 15, 2006;
- US Provisional Patent Application 60/873,075 to Gross et al., entitled,
30 "Mitral valve closure techniques," filed December 5, 2006;

- US Provisional Patent Application 60/902,146 to Gross et al., entitled, "Mitral valve closure techniques," filed on February 16, 2007;
- US Provisional Patent Application 61/001,013 to Gross et al., entitled, "Segmented ring placement," filed October 29, 2007;
- 5 • PCT Patent Application PCT/IL07/001503 to Gross et al., entitled, "Segmented ring placement," filed on December 5, 2007;
- US Patent Application 11/950,930 to Gross et al., entitled, "Segmented ring placement," filed on December 5, 2007, which published as US Patent Application Publication 2008/0262609;
- 10 • US Provisional Patent Application 61/132,295 to Gross et al., entitled, "Annuloplasty devices and methods of delivery therefor," filed on June 16, 2008;
- US Patent Application 12/341,960 to Cabiri, entitled, "Adjustable partial annuloplasty ring and mechanism therefor," filed on December 22, 2008, which published as 2010/0161047;
- 15 • US Provisional Patent Application 61/207,908 to Miller et al., entitled, "Actively-engageable movement-restriction mechanism for use with an annuloplasty structure," filed on February 17, 2009;
- US Patent Application 12/435,291 to Maisano et al., entitled, "Adjustable repair chords and spool mechanism therefor," filed on May 4, 2009, which published as 2010/0161041;
- 20 • US Patent Application 12/437,103 to Zipory et al., entitled, "Annuloplasty ring with intra-ring anchoring," filed on May 7, 2009, which published as 2010/0286767;
- PCT Patent Application PCT/IL2009/000593 to Gross et al., entitled, "Annuloplasty devices and methods of delivery therefor," filed on June 15, 2009, which published as WO 10/004546;
- 25 • US Patent Application 12/548,991 to Maisano et al., entitled, "Implantation of repair chords in the heart," filed on August 27, 2009, which published as 2010/0161042;
- 30

- US Patent Application 12/608,316 to Miller et al., entitled, "Tissue anchor for annuloplasty ring," filed on October 29, 2009, which published as 2011/0106247;
 - 5 • PCT Patent Application PCT/IL2009/001209 to Cabiri et al., entitled, "Adjustable annuloplasty devices and mechanisms therefor," filed on December 22, 2009, which published as WO 10/073246;
 - US Patent Application 12/689,635 to Zipory et al., entitled, "Over-wire rotation tool," filed on January 19, 2010, which published as 2010/0280604;
 - 10 • US Patent Application 12/689,693 to Hammer et al., entitled, "Application Deployment techniques for annuloplasty ring," filed on January 19, 2010, which published as 2010/0280605;
 - US Patent Application 12/706,868 to Miller et al., entitled, "Actively-engageable movement-restriction mechanism for use with an annuloplasty structure," filed on February 17, 2010, which published as 2010/0211166; and/or
 - 15 • US Patent Application 12/795,026 to Miller et al., entitled, "Apparatus for guide-wire based advancement of a rotation assembly," filed on June 7, 2010, which published as 2011/0106245.
- 20 It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof that are not in the prior art, which would occur to persons skilled in the art upon reading the foregoing
- 25 description.

CLAIMS

1. Apparatus for facilitating anchoring of a tissue anchor to a papillary muscle of a heart of a subject, the papillary muscle being coupled to one or more chordae tendineae of the heart of the subject, the apparatus being configured to be used with a guidewire, and
5 comprising:
 - a housing, percutaneously deliverable to the heart of the subject, slidable along the guidewire, and shaped to define at least one opening;
 - a guide member, percutaneously deliverable to the heart of the subject, percutaneously removable from the subject, couplable to the housing, and having:
10 a distal portion, comprising a chord-engaging element, configured to be percutaneously slidably coupled to at least one of the one or more chordae tendineae, and decouplable from the at least one of the one or more chordae, and
 - a proximal portion, comprising a longitudinal element; and
 - a deployment tool, configured (1) to be reversibly coupled to the anchor, (2) to be
15 slidably coupled to the longitudinal element of the guide member, and (3) to anchor the tissue anchor to the papillary muscle of the subject.
2. The apparatus according to claim 1, wherein the housing is configured to be decoupled from the guide member before the deployment tool is coupled to the guide member.
- 20 3. The apparatus according to claim 1, wherein the tissue anchor comprises a helical tissue anchor, and wherein the deployment tool is configured to anchor the tissue anchor to the papillary muscle of the subject by rotating the tissue anchor.
4. The apparatus according to any one of claims 1-3, wherein the deployment tool comprises a lance, configured to stabilize the deployment tool at the papillary muscle of
25 the subject by penetrating tissue of the papillary muscle.
5. The apparatus according to claim 4, wherein the lance is retractable into the deployment tool.
6. The apparatus according to any one of claims 1-3, further comprising the anchor.
7. The apparatus according to claim 6, wherein the guidewire comprises a first
30 guidewire, and wherein the apparatus further comprises a second guidewire, reversibly coupled to the anchor.

8. The apparatus according to any one of claims 1-3, further comprising the guidewire, the guidewire being configured to be transluminally advanced to a vicinity of the one or more chordae tendineae of the subject.
9. The apparatus according to claim 8, wherein the guidewire is configured to be
5 transluminally advanced such that a distal portion of the guidewire is disposed between at least two chordae tendineae of the subject, the one or more chordae tendineae including at least one of the at least two chordae tendineae of the subject.
10. The apparatus according to claim 8, wherein the housing is shaped to define a channel therethrough, the housing being slidable along the guidewire by the guidewire
10 being slidable through the channel.
11. The apparatus according to any one of claims 1-3, wherein the chord-engaging element comprises a helical element, configured to be housed by the housing, to be advanced out of the housing, and to form a helix outside of the housing.
12. The apparatus according to claim 11, wherein the chord-engaging element is
15 configured to be generally straight when housed by the housing, and to curl into the helix outside of the housing.
13. The apparatus according to claim 11, wherein the chord-engaging element is configured to be helical when housed by the housing.
14. A method for use with a papillary muscle of a heart of a subject, the papillary
20 muscle being coupled to one or more chordae tendineae of the heart of the subject, the method comprising:
- advancing a guide member to the chordae tendineae, the guide member having a proximal portion that includes a longitudinal element, and a distal portion that includes a chord-engaging element, configured to be slidably coupled to the chordae tendineae;
- 25 coupling the chord-engaging element to at least one of the one or more chordae tendineae;
- sliding the chord-engaging element over the at least one of the chordae tendineae toward the papillary muscle; and
- advancing a tool toward the papillary muscle of the subject by sliding the tool
30 along the longitudinal element.
15. The method according to claim 14, wherein the chord-engaging element includes a helical chord-engaging element, and wherein coupling the chord-engaging element to the

at least one of the chordae tendineae comprises wrapping the helical chord-engaging element around the at least one of the chordae tendineae.

16. The method according to any one of claims 14-15, further comprising, following the step of advancing, anchoring a tissue anchor to ventricular muscle tissue using the
5 tool.

17. The method according to claim 16, wherein anchoring the tissue anchor comprises anchoring the tissue anchor to ventricular muscle tissue in a vicinity of the papillary muscle.

18. The method according to claim 17, wherein anchoring the tissue anchor comprises
10 anchoring the tissue anchor to ventricular muscle tissue within 1 cm of the papillary muscle.

19. The method according to claim 17, wherein anchoring the tissue anchor comprises anchoring the tissue anchor to the papillary muscle.

20. The method according to claim 16, wherein anchoring the tissue anchor comprises
15 anchoring a tissue anchor that is reversibly couplable to a guidewire.

21. The method according to claim 16, wherein the deployment tool includes a lance, and the method further comprises, prior to anchoring the tissue anchor, stabilizing the tool with respect to the ventricular muscle tissue by penetrating the ventricular muscle tissue with the lance.

22. The method according to claim 21, further comprising retracting the lance into the
20 deployment tool.

23. The method according to any one of claims 14-15, wherein the step of advancing comprises advancing, to the heart of the subject, a housing that is slidable along the guide member.

24. The method according to claim 23, further comprising, prior to the step of
25 advancing, advancing a guidewire to a ventricle of the heart, wherein advancing the housing comprises sliding the housing over the guidewire.

25. The method according to claim 24, wherein advancing the guidewire comprises
30 advancing a distal portion of the guidewire between at least two of the chordae tendineae of the subject.

26. The method according to claim 23, further comprising, subsequent to the step of advancing, sliding the chord-engaging element distally out of the housing.

27. The method according to claim 26, further comprising, subsequent to the step of coupling and prior to the step of advancing, proximally withdrawing the housing and
5 decoupling the housing from the guide member while maintaining the coupling of the chord-engaging element to the at least one of the one or more chordae tendineae.

28. The method according to claim 26, wherein sliding the chord-engaging element distally out of the housing comprises facilitating transitioning of the chord-engaging element from a generally straight state into a helical state.

10 29. A method for use with a tissue anchor and a papillary muscle of a heart of a subject, the papillary muscle being coupled to one or more chordae tendineae of the heart of the subject, the method comprising:

percutaneously advancing to the chordae tendineae, along a guidewire that has been advanced to the chordae tendineae of the subject, a housing, shaped to define at least
15 one opening;

advancing a distal portion of a guide member out of the opening of the housing, the distal portion of the guide member including a chord-engaging element;

coupling the chord-engaging element to at least one of the one or more chordae tendineae;

20 exposing a proximal portion of the guide member out of the opening of the housing by withdrawing the housing proximally with respect to the guide member, the proximal portion of the guide member including a longitudinal element; and

anchoring the tissue anchor to ventricular muscle tissue of the subject by advancing a deployment tool, reversibly couplable to the tissue anchor, along the
25 longitudinal element.

30. The method according to claim 29, further comprising, subsequently to the step of coupling and prior to the step of anchoring, sliding the chord-engaging element along the at least one chordae tendineae toward the papillary muscle.

31. The method according to claim 29, further comprising decoupling the housing
30 from the guide member before advancing the deployment tool along the longitudinal member.

32. The method according to claim 29, wherein the tissue anchor includes a helical tissue anchor, and wherein anchoring the tissue anchor comprises rotating the tissue anchor.

33. The method according to claim 29, wherein the guidewire includes a first
5 guidewire, and anchoring the tissue anchor comprises anchoring a tissue anchor that is reversibly couplable to a second guidewire.

34. The method according to any one of claims 29-33, wherein anchoring the tissue anchor comprises anchoring the tissue anchor to ventricular muscle tissue in a vicinity of the papillary muscle.

10 35. The method according to claim 34, wherein anchoring the tissue anchor comprises anchoring the tissue anchor to ventricular muscle tissue within 1 cm of the papillary muscle.

36. The method according to claim 34, wherein anchoring the tissue anchor comprises anchoring the tissue anchor to the papillary muscle.

15 37. The method according to any one of claims 29-33, wherein the deployment tool includes a lance, and wherein the method further comprises, before anchoring the tissue anchor, stabilizing the deployment tool with respect to the ventricular muscle tissue by penetrating the ventricular muscle tissue with the lance.

38. The method according to claim 37, further comprising retracting the lance into the
20 deployment tool.

39. The method according to any one of claims 29-33, wherein the step of advancing comprises advancing the chord-engaging element out of the opening of the housing such that the chord-engaging element forms a helix outside of the housing.

40. The method according to claim 39, wherein advancing the chord-engaging element
25 out of the opening of the housing comprises facilitating a transition of the chord-engaging member from a generally straight state into a helical state.

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FIG. 1

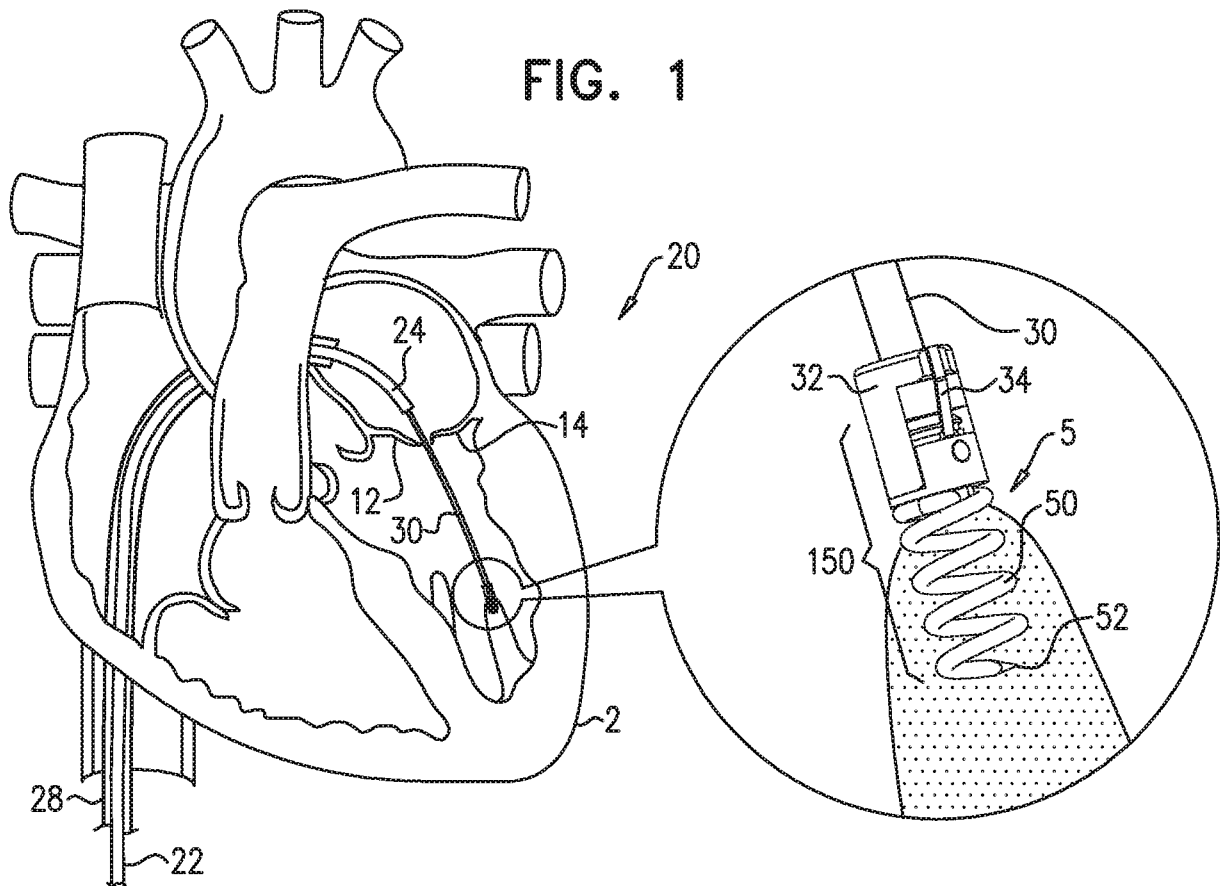
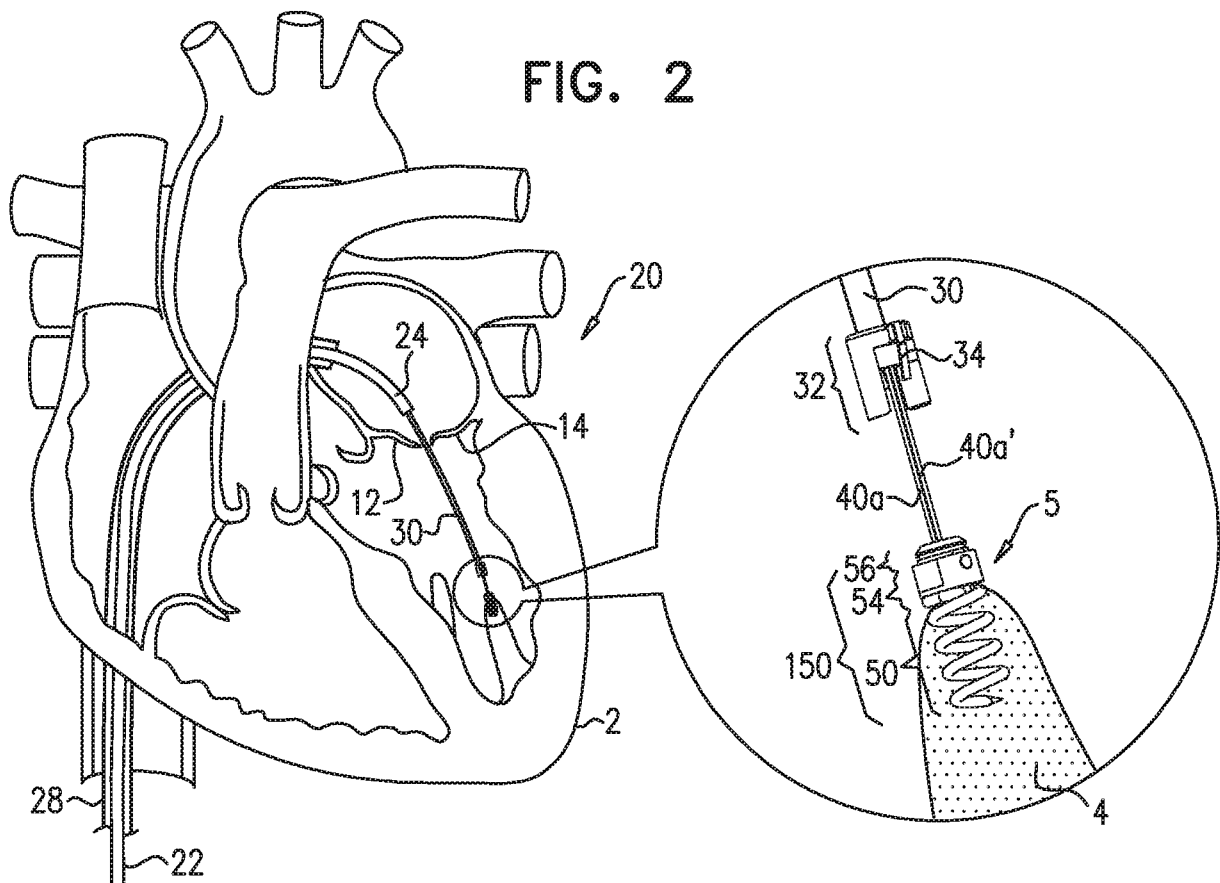


FIG. 2



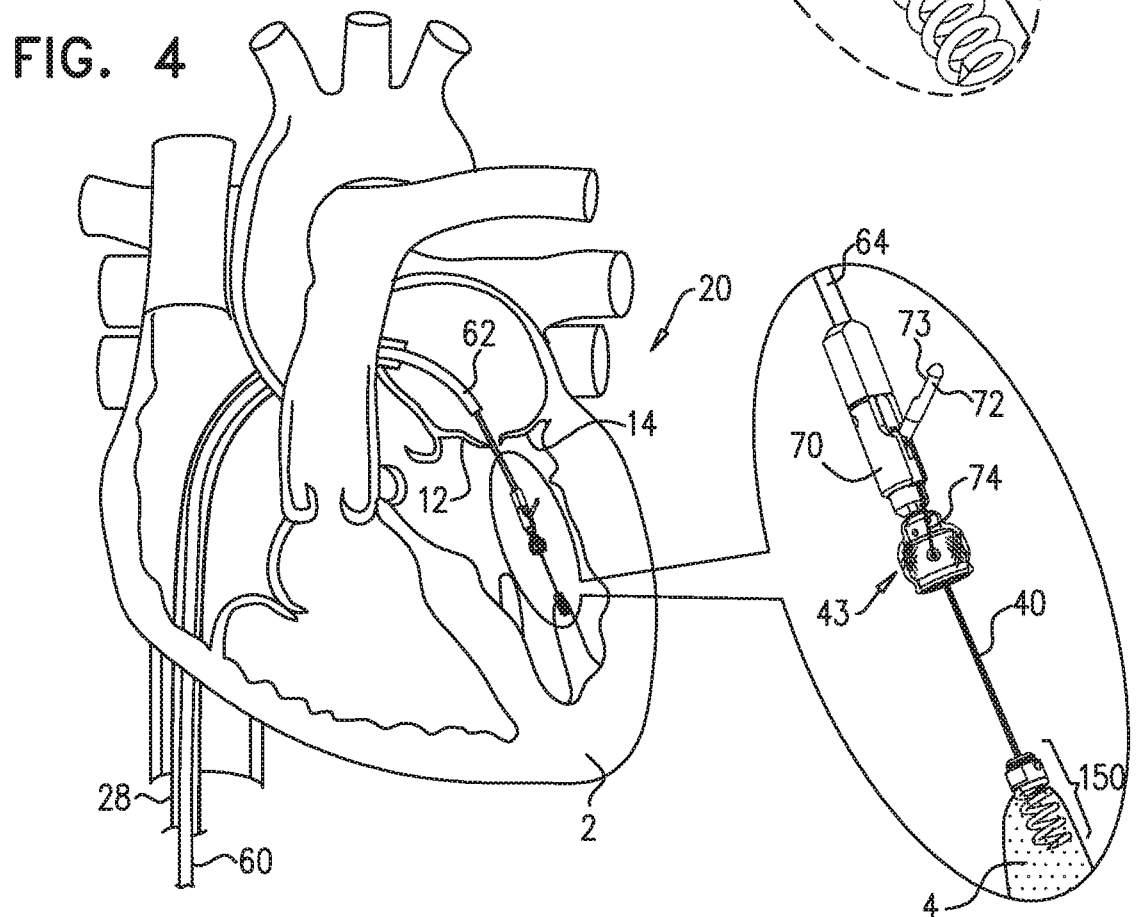
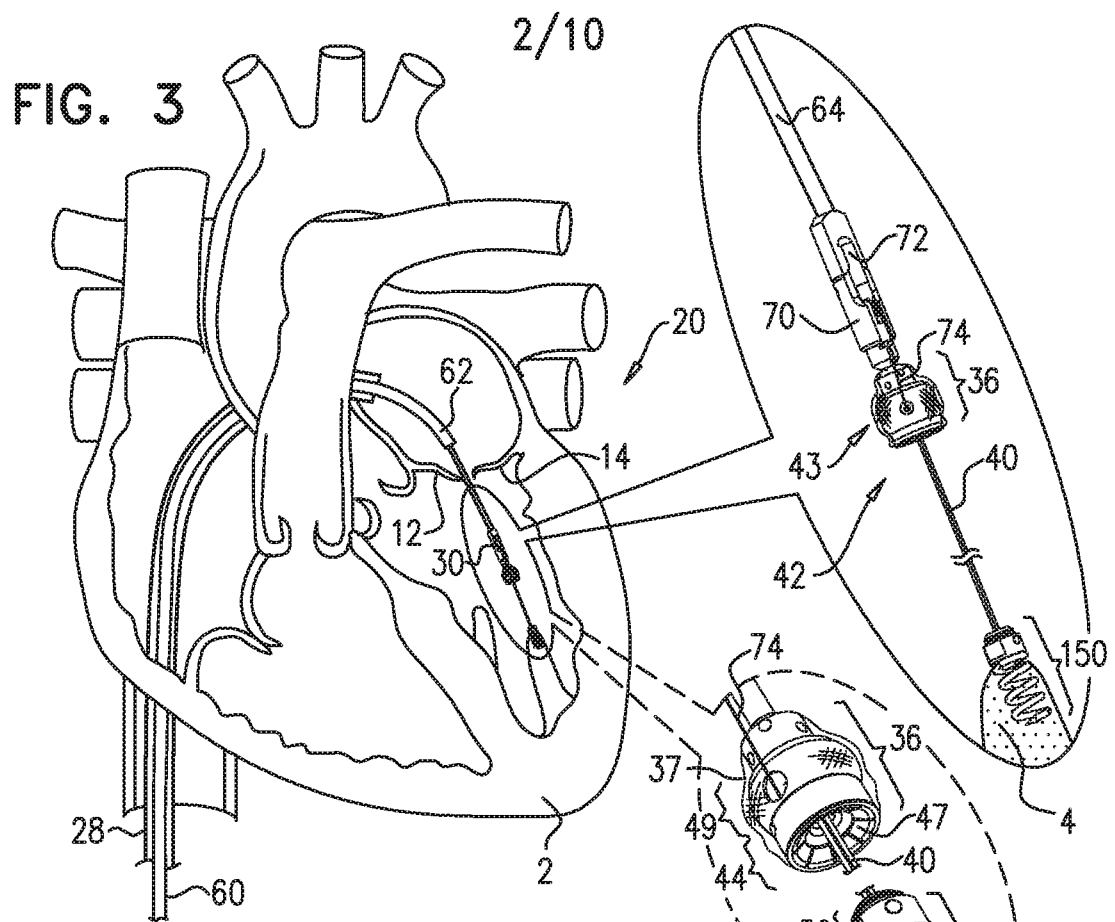
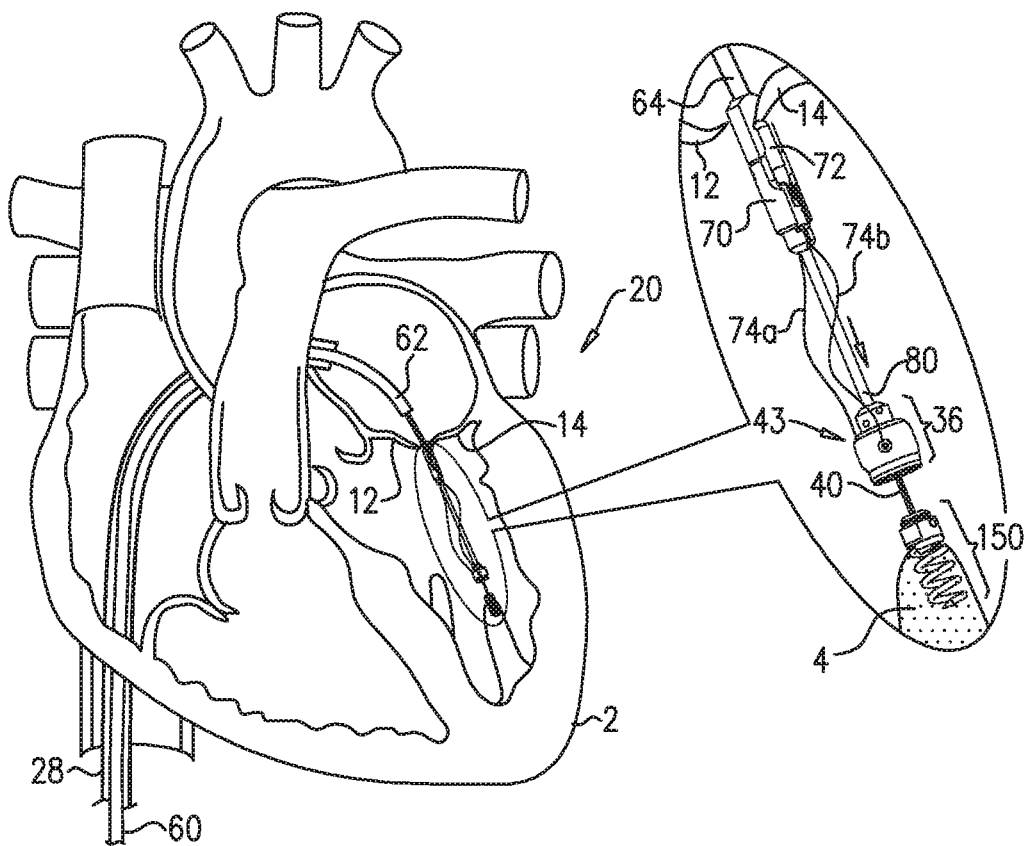


FIG. 5



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FIG. 6

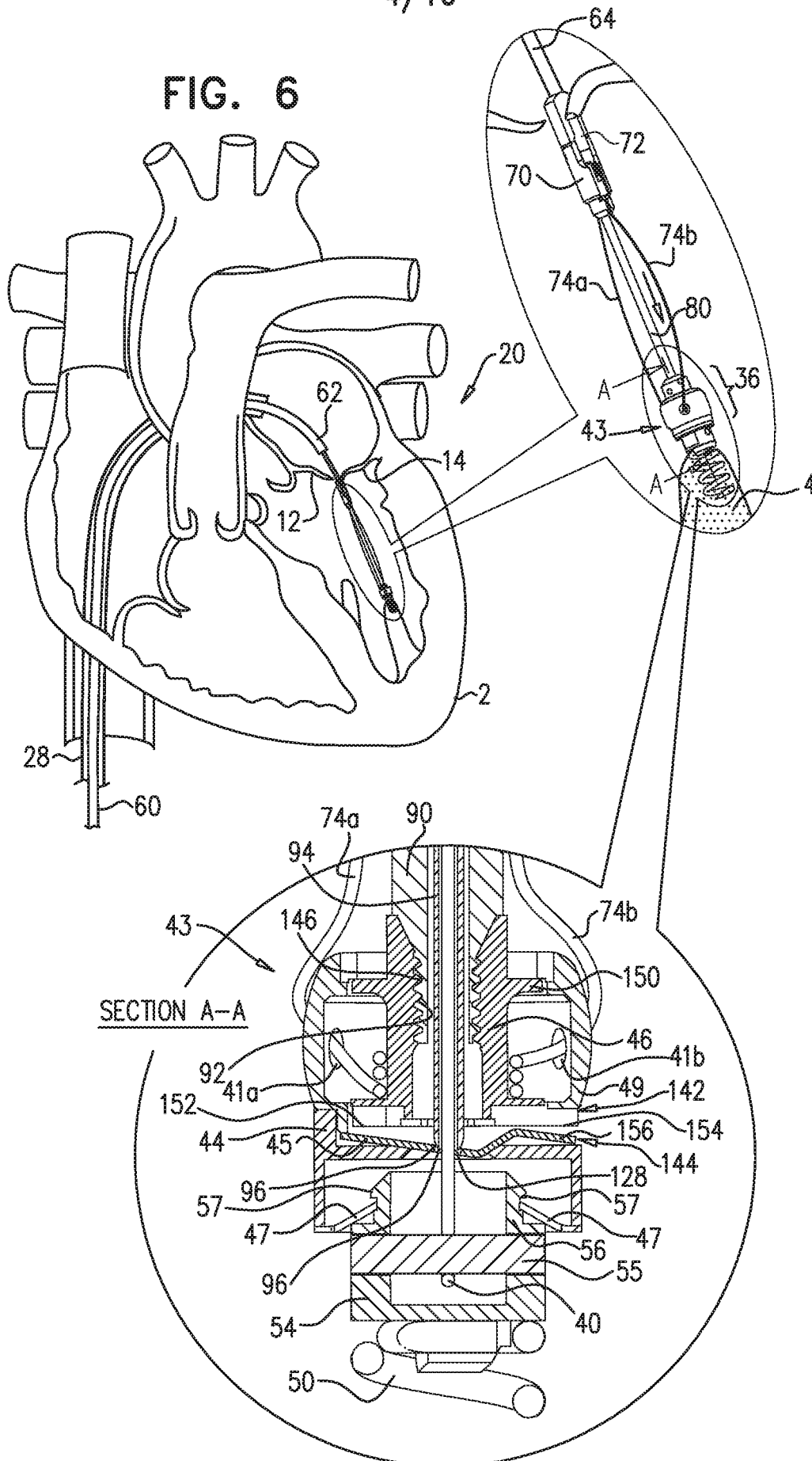


FIG. 7

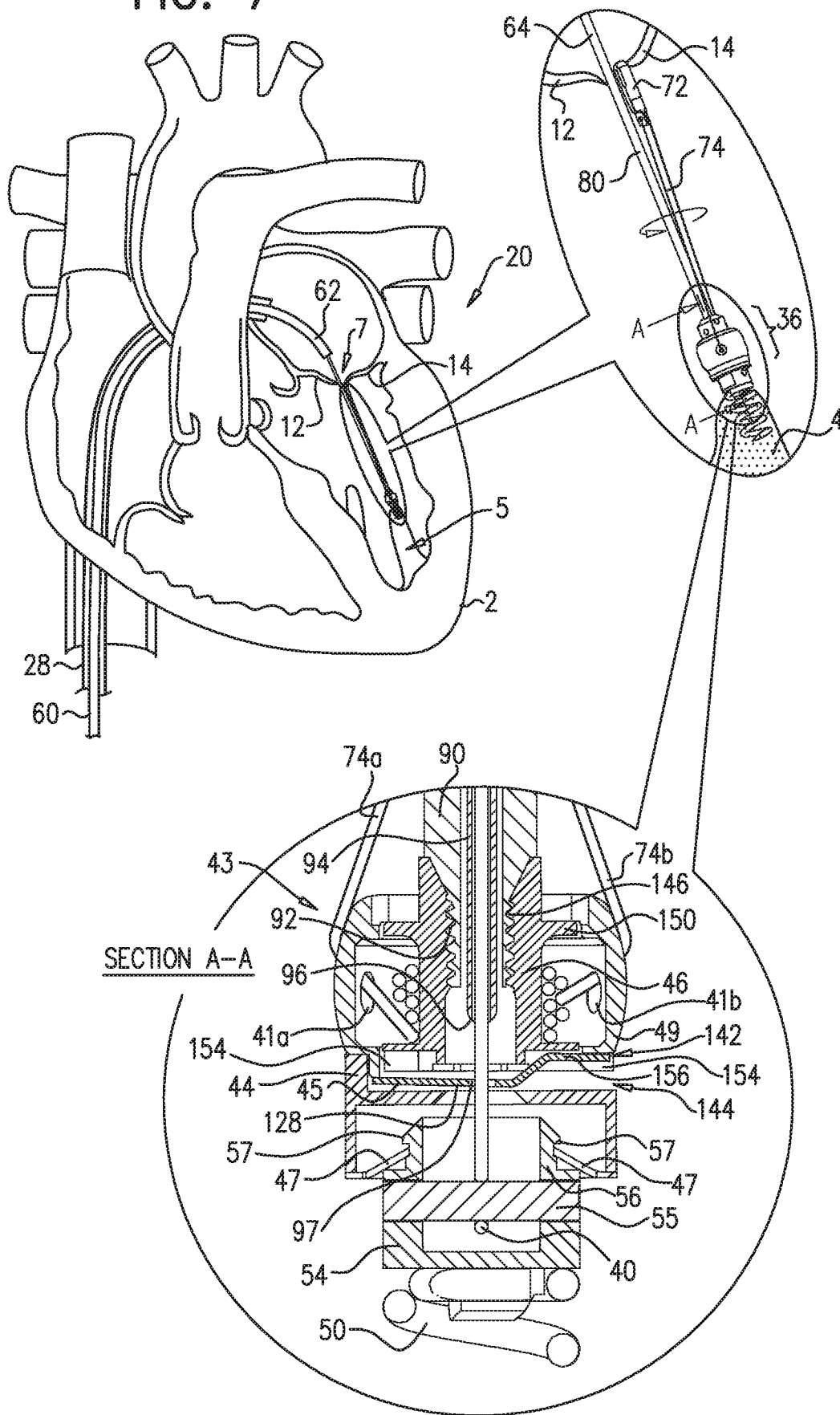
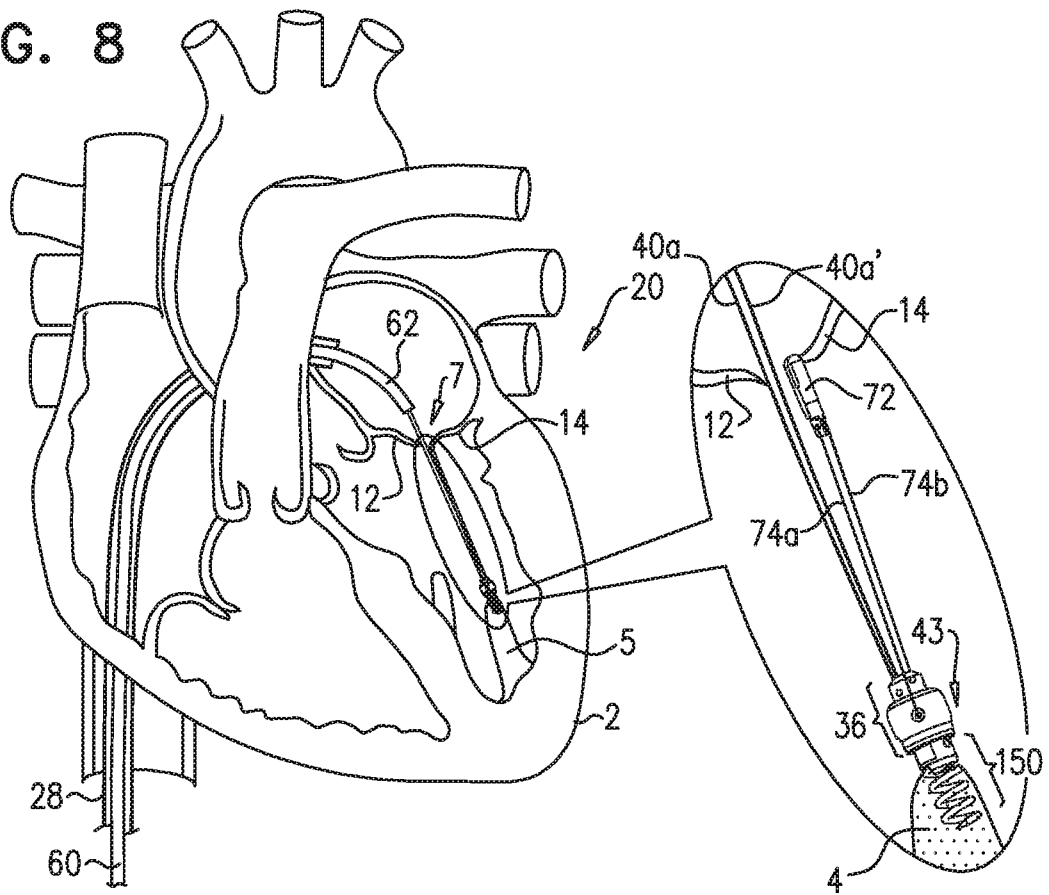


FIG. 8



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FIG. 9

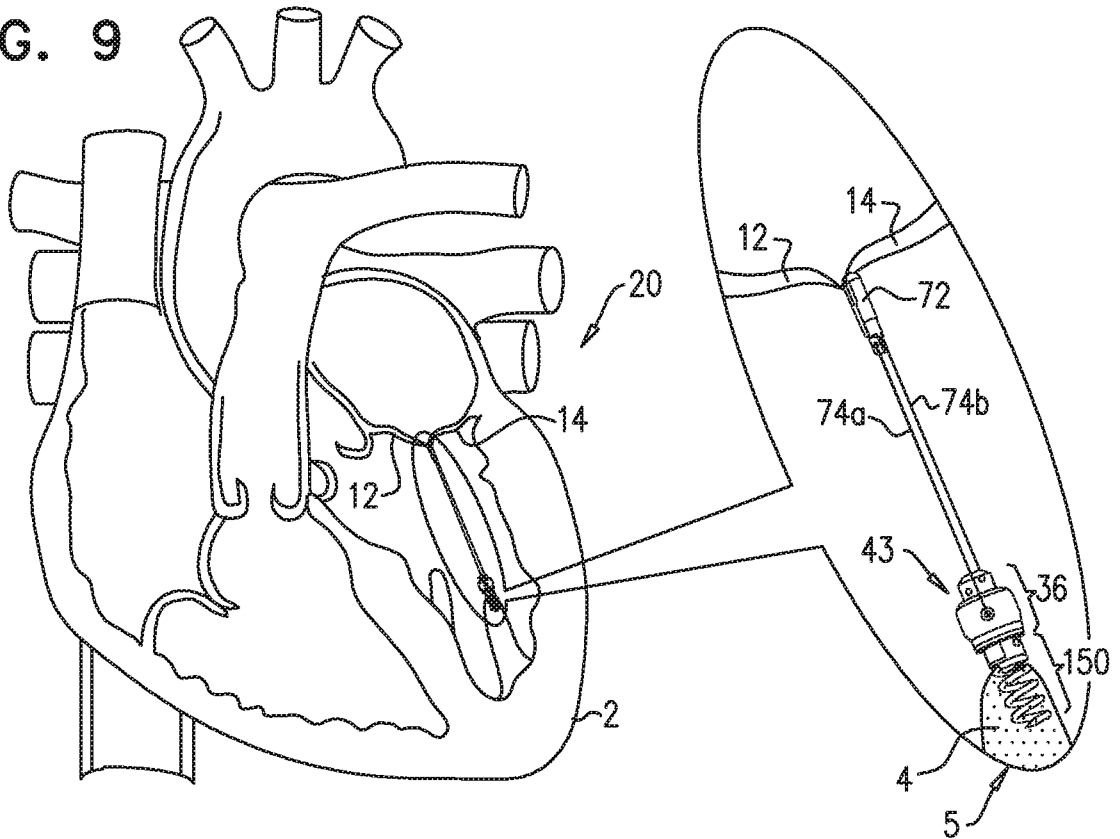


FIG. 10

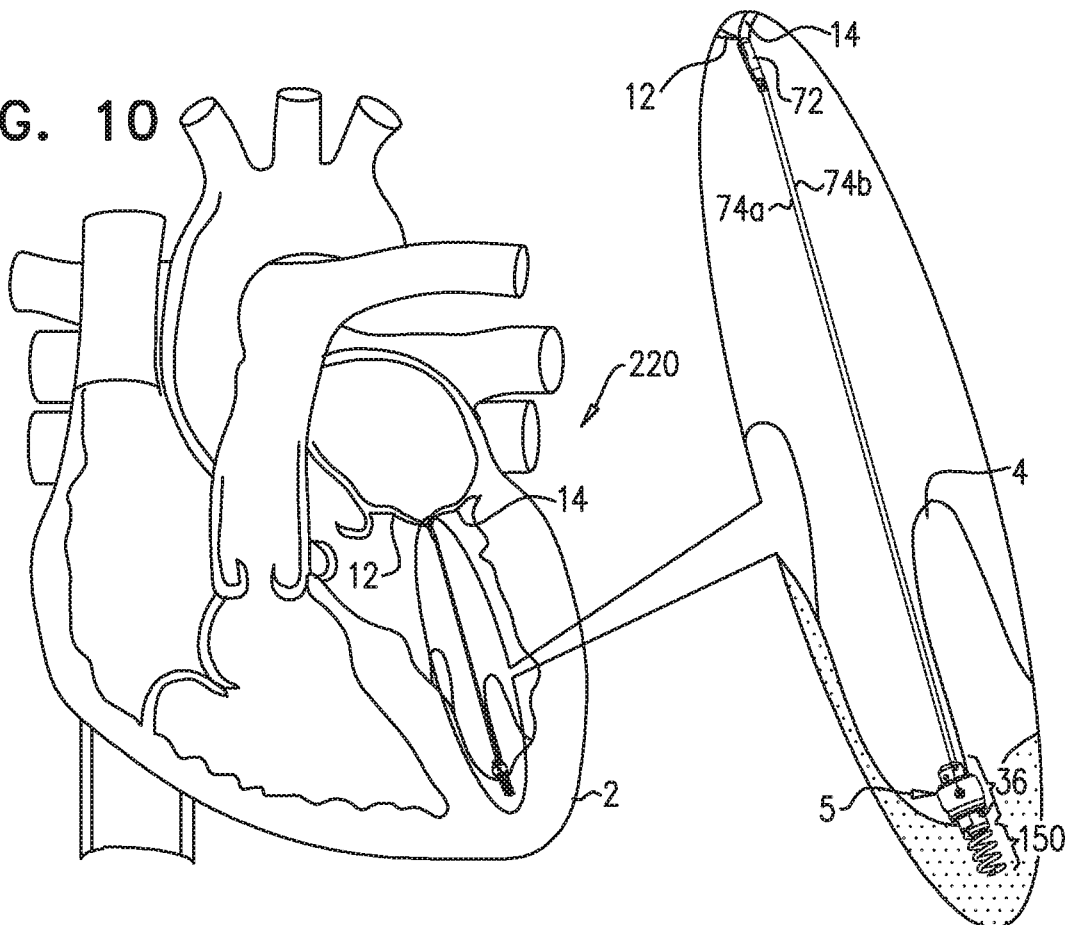


FIG. 11A

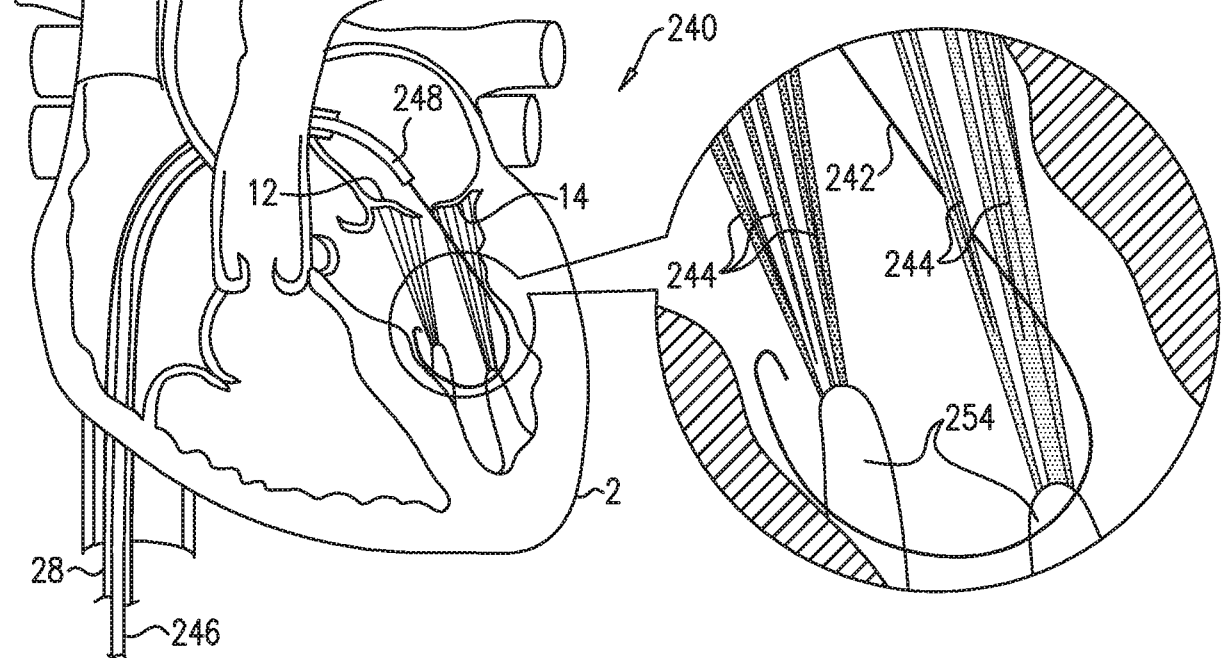
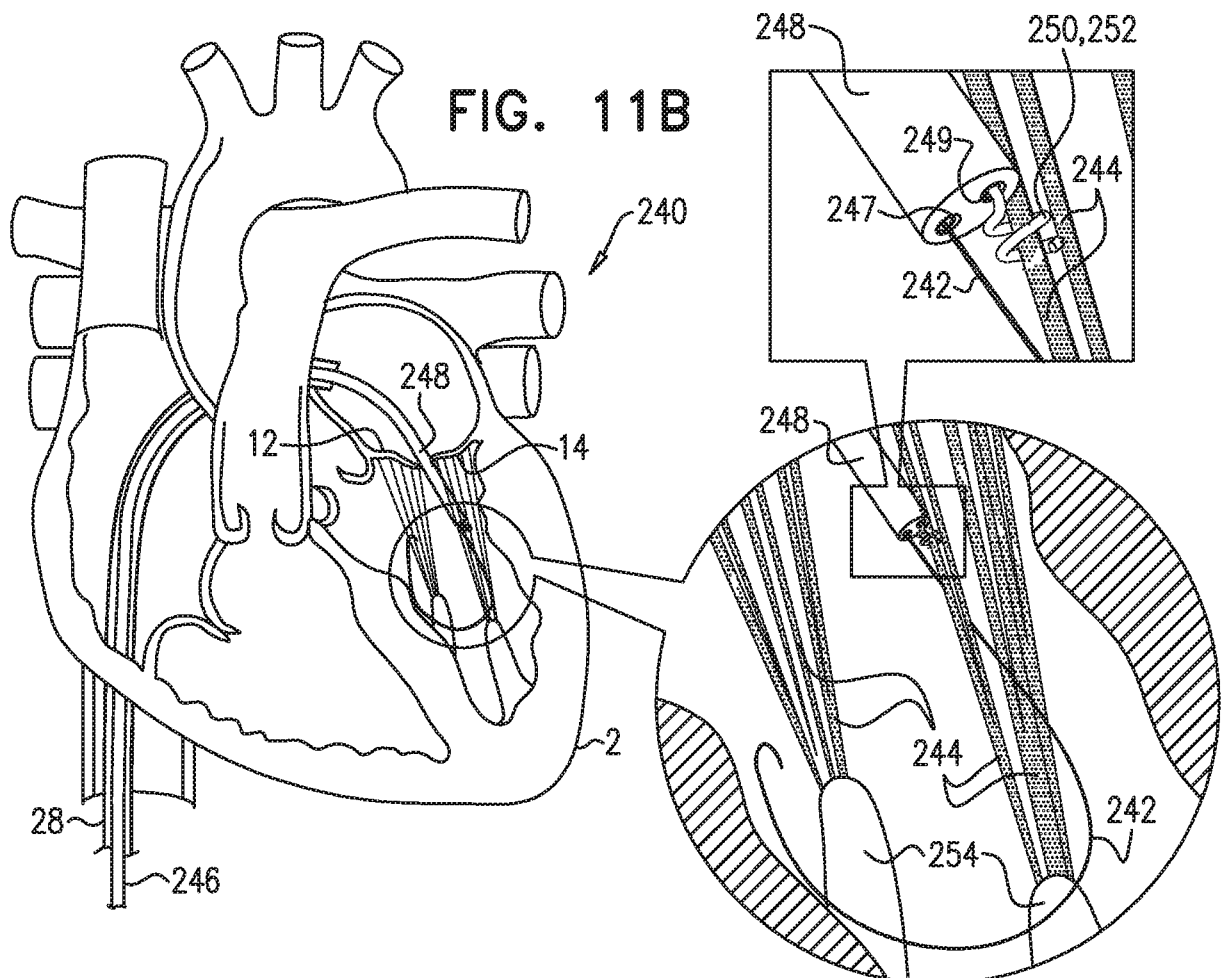
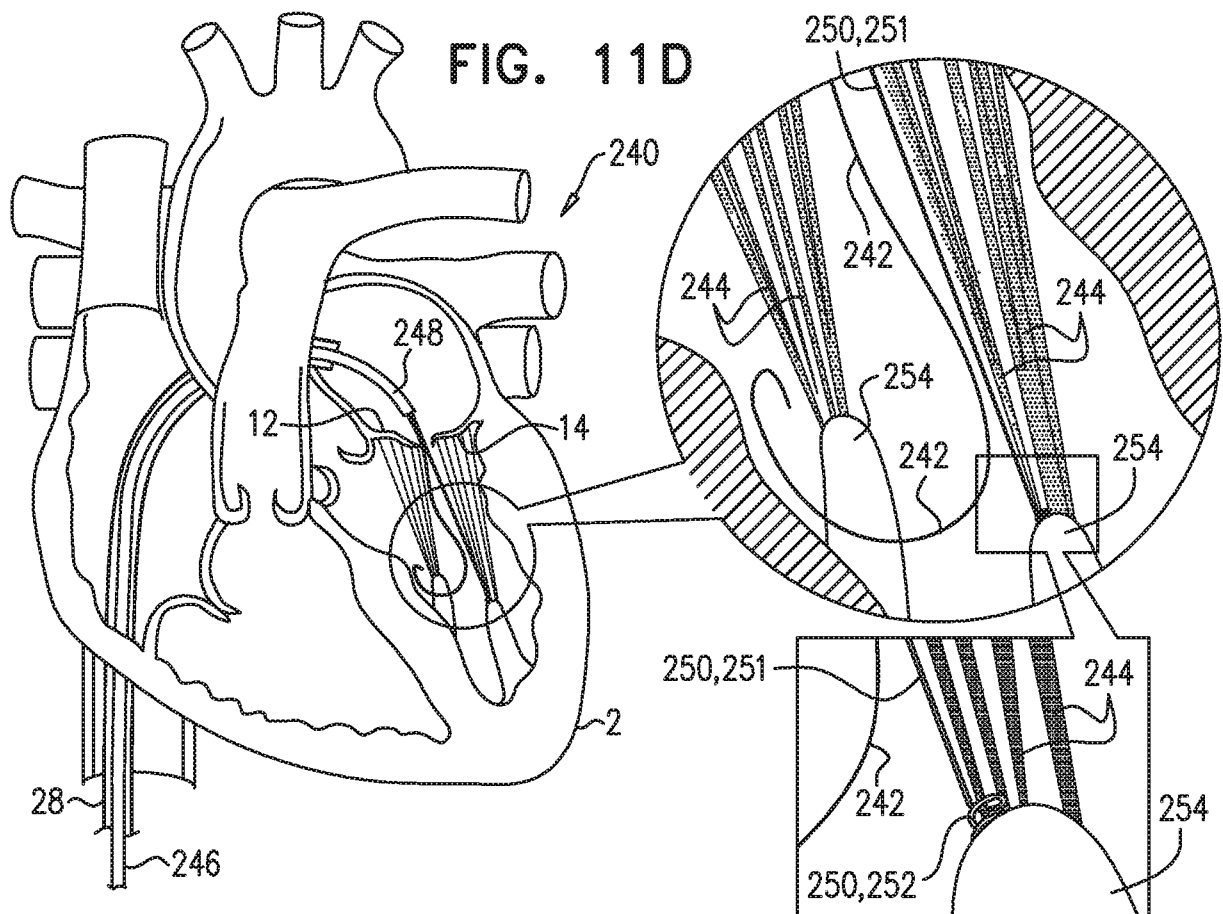
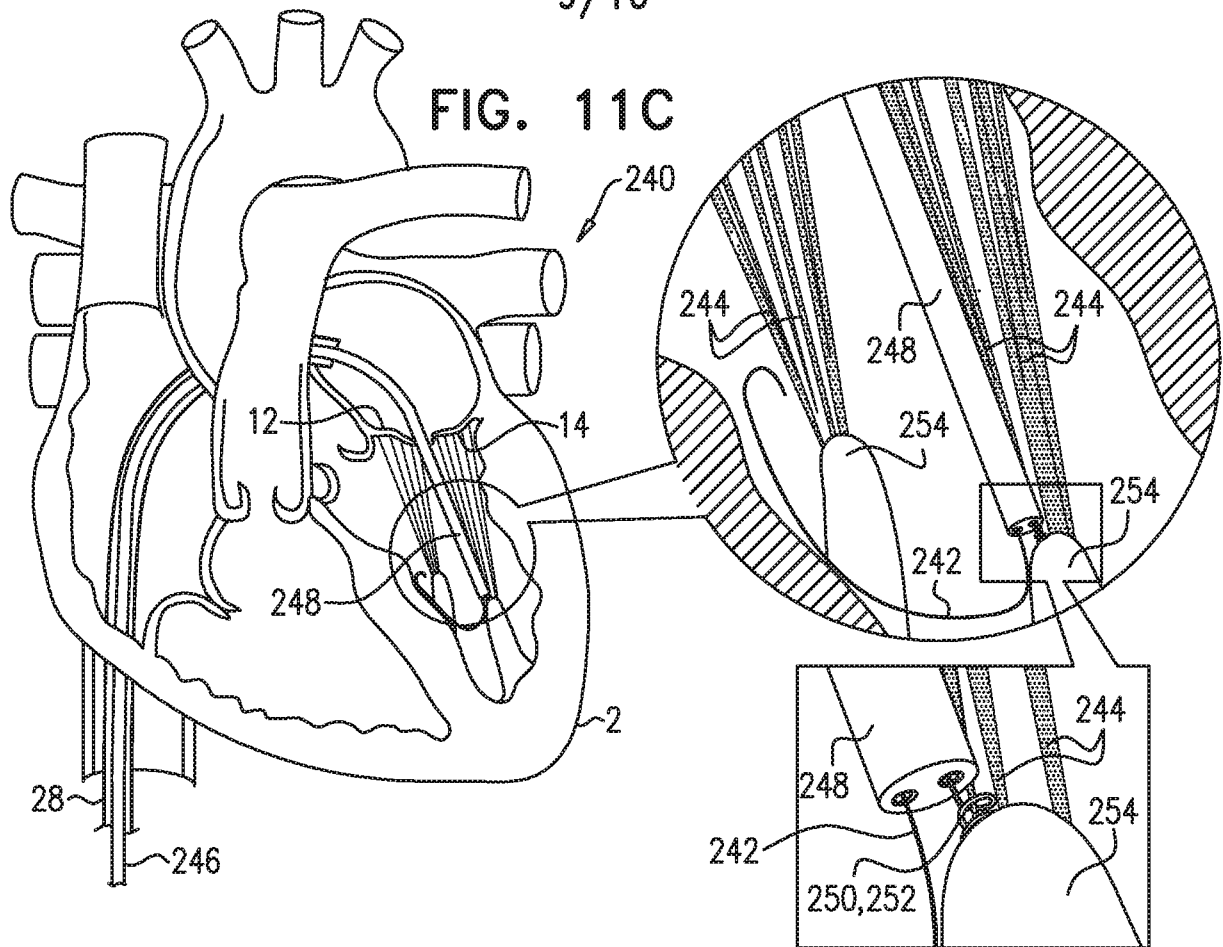


FIG. 11B



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FIG. 11E

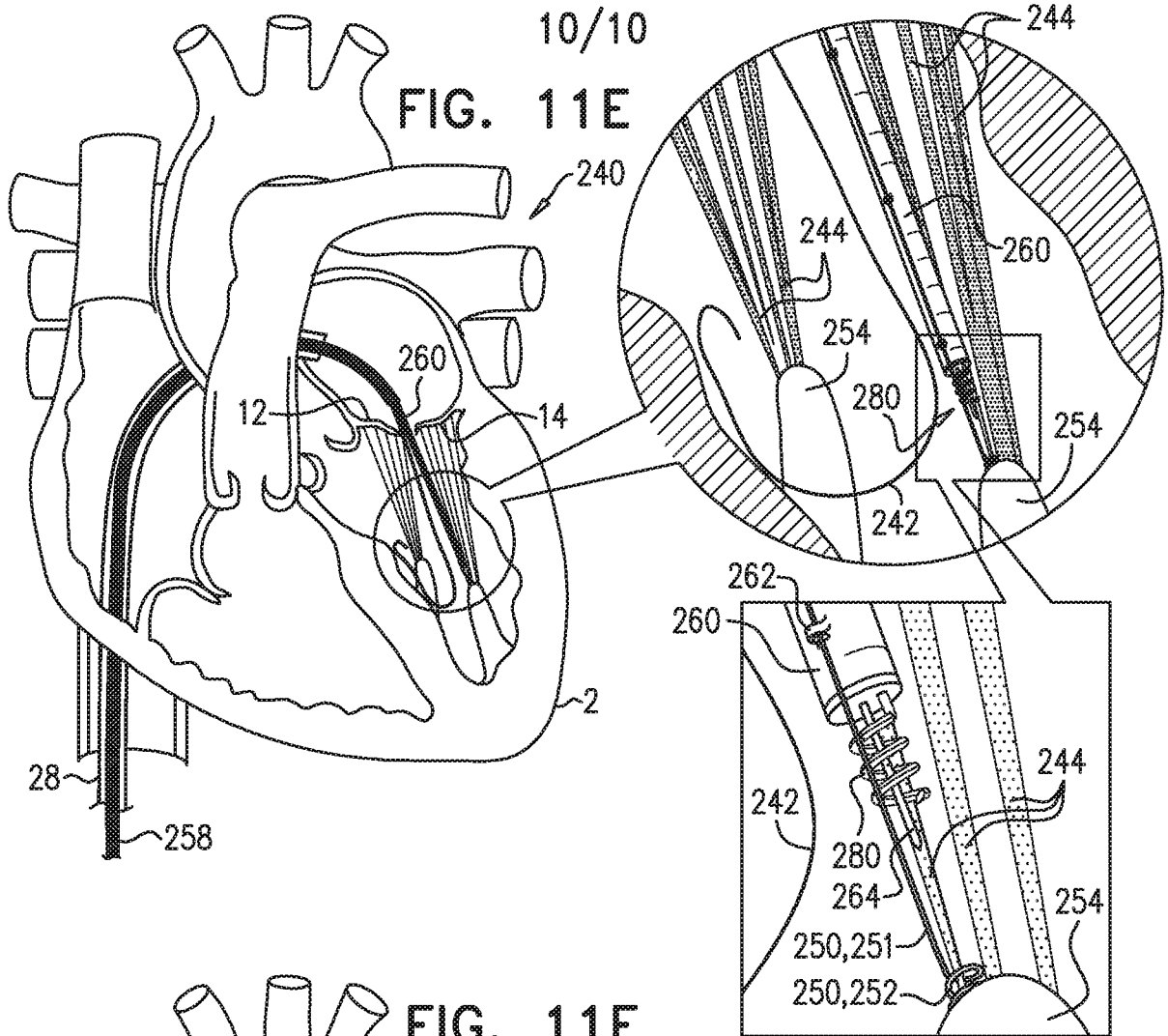
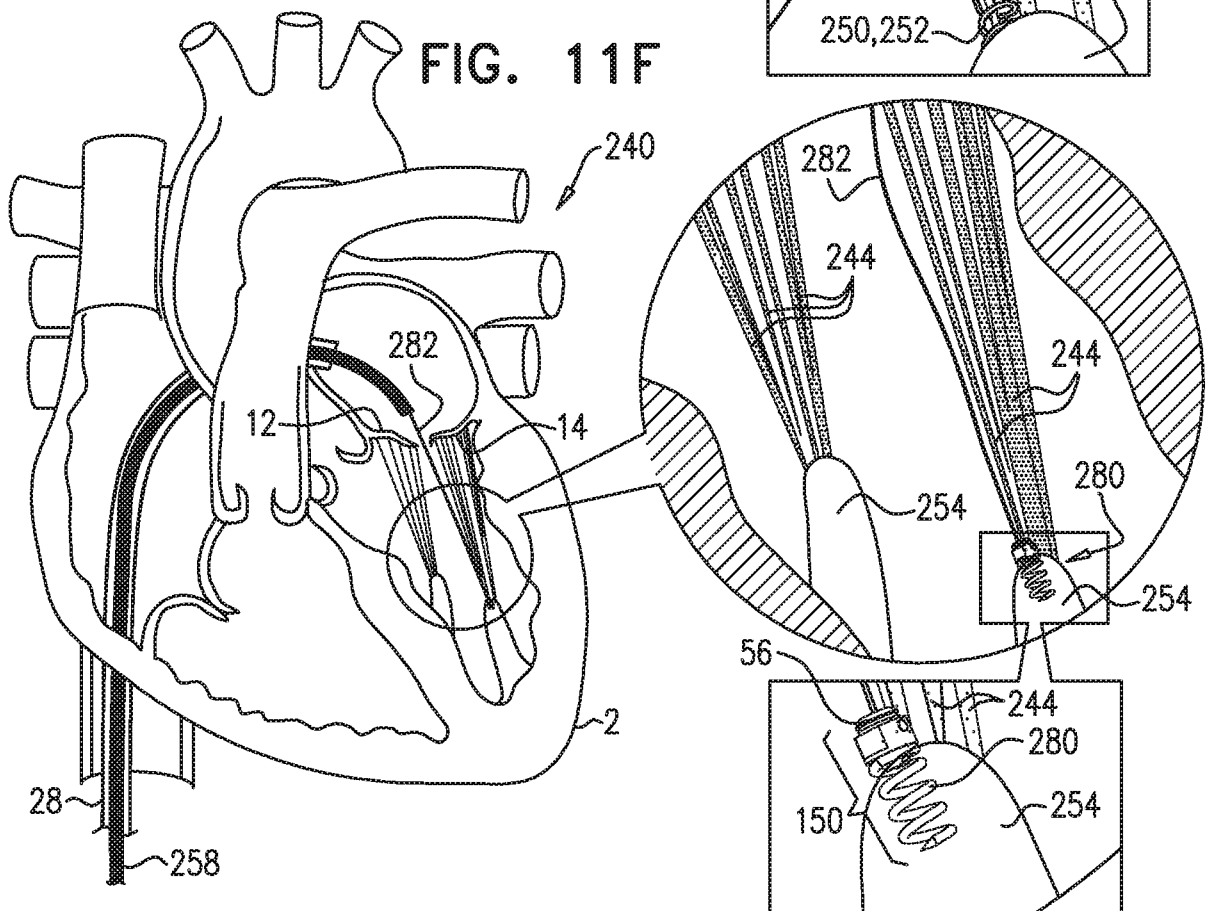


FIG. 11F



INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL1 3/50992

A. CLASSIFICATION OF SUBJECT MATTER

IPC (8) - A61M 5/00, 25/00, 25/09 (2014.01)

USPC - 606/139, 148; 623/2.11

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8): A61M 5/00, 25/00, 25/09 (2014.01)

USPC: 606/139, 148; 623/2.1 1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

MicroPatent (US-G, US-A, EP-A, EP-B, WO, JP-bib, DE-CB, DE-A, DE-T, DE-U, GB-A, FR-A); IP.com; Google/Google Scholar; PubMed/MEDLINE: anchor, helix, lance retract, heart, atrioventricular, valve, papillary, chordae, repair

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 201 1/0106245 A1 (MILLER, E et al.) May 5, 2011; abstract; paragraphs [0039]-[0040], [0127]-[0128], [0141], [0153], [0165]	1-3, 6-11, 13-20, 23-27, 29-36, 39
Y		4-5, 12, 21-22, 28, 37-38, 40
Y	US 2004/01 76788 A1 (OPOLSKI, SW) September 9, 2004; abstract, paragraphs [0009], [0011], [0014]	4-5, 21-22, 37-38
Y	US 2004/0193191 A1 (STARKSEN, NF et al.) September 30, 2004; abstract; paragraph [0022]	12, 28, 40
A	US 201 1/0282361 A1 (MILLER, E et al.) November 17, 2011; entire document	1-40
A	US 2010/0161041 A1 (MAISANO, F et al.) June 24, 2010; entire document	1-40
A	US 2007/01 18151 A1 (DAVIDSON, MJ) May 24, 2007; entire document	1-40
A	US 2011/0288635 A1 (MILLER, E et al.) November 24, 2011; entire document	1-40
A	US 2010/0280603 A1 (MAISANO, F et al.) November 4, 2010; entire document	1-40

☒ Further documents are listed in the continuation of Box C.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

04 March 2014 (04.03.2014)

Date of mailing of the international search report

21 MAR 2014

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
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