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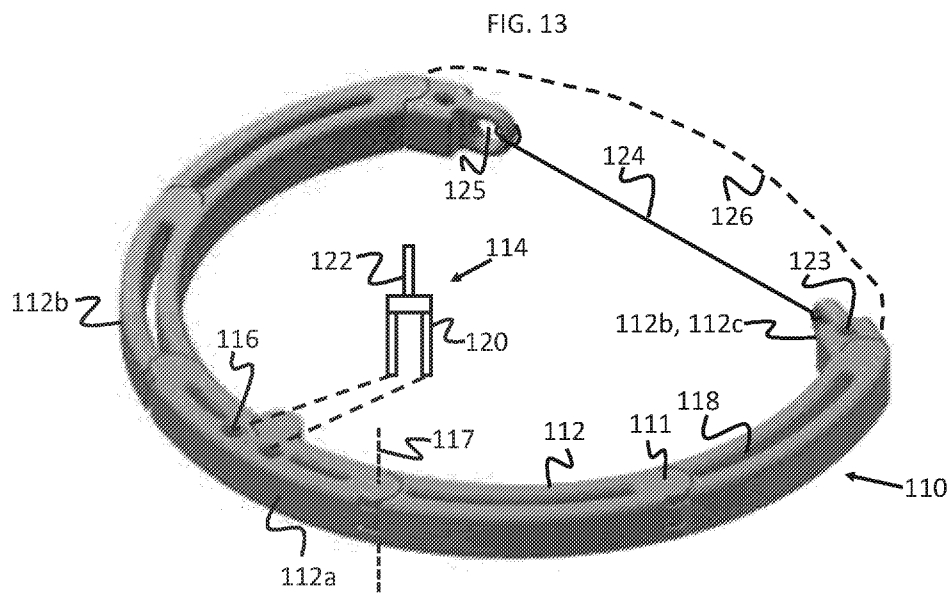
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(57) Abstract: An apparatus for implantation at an annulus (75) of an intracardiac valve includes an annuloplasty ring (110) comprising a plurality of rotatably adjoining segments (112). The ring is configured to pass over multiple threads (58), respective distal ends of which are distributed over the annulus, and, while passing over the threads, expand from a collapsed state to an expanded state by virtue of the segments rotating with respect to each other. The apparatus further comprises a lock (114), configured to lock the ring in the expanded state at the valve by inhibiting rotation of the segments with respect to each other. Other embodiments are also described.

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PERCUTANEOUS VALVE IMPLANTS

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application claims the benefit of US Provisional Application 62/791,912, entitled "Transcatheter ring and valve system," filed January 14, 2019, whose disclosure is
5 incorporated herein by reference.

FIELD OF THE INVENTION

Embodiments of the present invention relate generally to the field of medical devices, and particularly, to apparatus and methods for percutaneous valve repair and replacement.

BACKGROUND

10 In some subjects, an implant may be used to repair or replace an intracardiac valve.

US Patent 10,278,820 to Bar et al., whose disclosure is incorporated herein by reference, describes an apparatus that includes an assembly of tubes, each one of the tubes being shaped to define a tube lumen. The apparatus further includes a plurality of tissue anchors, each one of the tissue anchors being disposed within a respective one of the tube lumens, an expandable annular
15 structure, including a plurality of teeth, coupled to the assembly of tubes, and a plurality of control wires coupled to the annular structure, configured to position the tubes for deployment of the tissue anchors from the tube lumens, by manipulating the annular structure.

US Patent Application 10,463,486 to Bar et al., whose disclosure is incorporated herein by reference, describes an apparatus including a plurality of flexible tube guides, an annular assembly
20 of tubes, each of the tubes being slidably disposed within a respective one of the tube guides, a plurality of threads, each of which comprising a distal end that is carried by a respective one of the tubes, and an expandable annular structure coupled to the tube guides, configured to expand the assembly of tubes, from a collapsed configuration, over tissue of a subject, by moving the tube guides radially outward. The apparatus further includes a plurality of control wires coupled to the
25 tube guides, configured to position the tubes, subsequently to the expansion of the assembly, for deployment of the threads from the tubes and into the tissue, by flexing the tube guides.

US Patent Application Publication 2017/0258585 describes sensor-integrated prosthetic valves that can comprise a variety of features, including a plurality of valve leaflets, a frame assembly configured to support the plurality of valve leaflets and define a plurality of commissure

supports terminating at an outflow end of the prosthetic valve, a sensor device associated with the frame assembly and configured to generate a sensor signal, for example, a sensor signal indicating deflection of one or more of the plurality of commissure supports, and a transmitter assembly configured to receive the sensor signal from the sensor device and wirelessly transmit a
5 transmission signal that is based at least in part on the sensor signal.

SUMMARY OF THE INVENTION

There is provided, in accordance with some embodiments of the present invention, apparatus for implantation at an annulus of an intracardiac valve. The apparatus includes an annuloplasty ring including a plurality of rotatably adjoining segments, the ring being configured
10 to pass over multiple threads, respective distal ends of which are distributed over the annulus, and, while passing over the threads, expand from a collapsed state to an expanded state by virtue of the segments rotating with respect to each other. The apparatus further includes a lock, configured to lock the ring in the expanded state at the valve by inhibiting rotation of the segments with respect to each another.

15 In some embodiments, each pair of adjacent ones of the segments are hingedly connected to one another.

In some embodiments, the annuloplasty ring includes an element of shape-memory material divided into the segments by one or more folds.

In some embodiments, an adjacent two of the segments are configured to rotate radially
20 outward with respect to one another as the ring passes over the threads.

In some embodiments, the segments include multiple appended segments appended to the adjacent two of the segments, each of which is configured to rotate radially inward with respect to a neighboring one of the segments as the ring passes over the threads.

In some embodiments,
25 the adjacent two of the segments are shaped to define respective apertures, and the lock includes two bolts coupled to one another, such that the lock is configured to lock the ring by virtue of the bolts passing through the apertures.

In some embodiments, the ring further includes a longitudinal element joining a pair of the segments, the longitudinal element being configured to hold the ring in the expanded state by
30 pulling the pair of the segments toward one another.

In some embodiments, the longitudinal element is further configured to arc in response to

a radially-outward force applied to the longitudinal element subsequently to the locking of the ring.

In some embodiments, the ring further includes a cover configured to cover the segments, and the ring is configured to pass over the threads while the threads pass through the cover.

5 In some embodiments, the segments are shaped to define respective longitudinal slits running through respective interiors of the segments, and the ring is configured to pass over the threads while the threads run through the slits.

There is further provided, in accordance with some embodiments of the present invention, a method, including passing an annuloplasty ring, which includes a plurality of rotatably adjoining
10 segments, over multiple threads, respective distal ends of which are distributed over an annulus of an intracardiac valve, such that the ring expands from a collapsed state to an expanded state by virtue of the segments rotating with respect to each other. The method further includes locking the ring in the expanded state at the valve, by inhibiting rotation of the segments with respect to each another.

15 In some embodiments, the method further includes, subsequently to locking the ring in the expanded state, reshaping the ring by applying a radially-outward force to the ring.

In some embodiments, reshaping the ring includes reshaping the ring by implanting an expandable artificial valve over the ring such that, as the artificial valve expands, the artificial valve applies the radially-outward force to the ring.

20 There is further provided, in accordance with some embodiments of the present invention, an apparatus including an electronic sensor and an adapting piece of material shaped to define at least one passageway and coupled to the sensor. The sensor is configured to pass over a thread, which runs through the passageway, to an implantation site within a body of a subject.

In some embodiments, the sensor includes a pressure sensor.

25 In some embodiments, the apparatus further includes:
the thread;

a tube, configured to carry a distal end of the thread and to pass through tissue of the subject at the implantation site from a first side of the tissue to a second side of the tissue;

an expandable anchor disposed within the tube and coupled to the distal end of the thread;

30 and

an anchor-pushing element disposed within the tube proximally to the anchor, the anchor-

pushing element being configured to push the anchor from the tube subsequently to the tube passing through the tissue such that the anchor expands at the second side of the tissue and, subsequently to the sensor passing over the thread, anchors the sensor to the first side of the tissue at the implantation site.

5 In some embodiments, the adapting piece of material includes a block shaped to define a plurality of lumens, the block being configured to lock the sensor over the thread, subsequently to the sensor passing over the thread, by virtue of the thread looping through the lumens.

 In some embodiments,

 the implantation site includes an annulus of an intracardiac valve,

10 the apparatus further includes a valve implant configured to pass over the thread and over multiple other threads to the annulus, and

 the sensor is configured to pass over the thread onto the valve implant.

 In some embodiments,

 the implantation site includes an annulus of an intracardiac valve,

15 the apparatus further includes a valve implant configured to pass over the thread and over multiple other threads to the annulus, and

 the sensor is coupled to the valve implant such that the sensor is configured to pass over the thread together with the valve implant.

 There is further provided, in accordance with some embodiments of the present invention,
20 an apparatus including a valve implant, configured to pass over multiple threads to an annulus of an intracardiac valve, and an electronic sensor coupled to the valve implant.

 There is further provided, in accordance with some embodiments of the present invention, a method including passing an electronic sensor over at least one thread to an implantation site within a body of a subject, and locking the sensor over the thread at the implantation site.

25 In some embodiments, the implantation site includes an annulus of an intracardiac valve.

 In some embodiments, passing the sensor over the thread includes passing the sensor over the thread onto a valve implant.

 In some embodiments, the sensor is coupled to a valve implant, and passing the sensor over the thread includes passing the sensor over the thread together with the valve implant.

30 In some embodiments, passing the sensor over the thread includes passing the sensor over the thread by virtue of the thread passing through the valve implant.

In some embodiments, the implantation site includes an intracardiac wall.

In some embodiments, the implantation site includes a wall of a blood vessel.

There is further provided, in accordance with some embodiments of the present invention, apparatus for implantation at an annulus of an intracardiac valve. The apparatus includes an
5 expandable frame including a plurality of curved protrusions and configured to fit onto an annuloplasty ring implanted at the annulus by virtue of the protrusions curving over the ring. The apparatus further includes two or more valve leaflets coupled to the frame.

In some embodiments, the frame is shaped to define multiple apertures and is configured to pass over multiple threads, which pass through the apertures and through the ring, to the ring.

10 In some embodiments, the curved protrusions include:
respective concave portions, configured to curve over the ring; and
respective convex portions, which are disposed radially outward from the concave portions and are configured to press against tissue surrounding the annulus.

15 In some embodiments, the protrusions are arranged in a ring disposed at a bottom of the frame.

In some embodiments, the valve leaflets are coupled to the frame at a first height from the protrusions, and the apparatus further includes:

at least one other expandable frame including a plurality of other curved protrusions; and
two or more other valve leaflets coupled to the other frame at a second height from the
20 other curved protrusions, the second height being different from the first height.

There is further provided, in accordance with some embodiments of the present invention, a method including implanting an annuloplasty ring at an annulus of an intracardiac valve and, subsequently to implanting the annuloplasty ring, implanting an artificial valve, which includes a plurality of curved protrusions, over the ring, by fitting the protrusions over the ring.

25 There is further provided, in accordance with some embodiments of the present invention, an apparatus for implantation at an annulus of a mitral valve. The apparatus includes an expandable frame, an inverted arch extending from the frame, a flap coupled to the frame such that the flap extends into an interior of the frame, and a plurality of longitudinal elements that attach the flap to the arch.

30 In some embodiments, the frame is shaped to define multiple apertures and is configured to pass over multiple threads, which pass through the apertures, to the annulus.

In some embodiments, the flap hangs below the frame, and the longitudinal elements inhibit the flap from flapping upward.

In some embodiments,
the flap is configured to flap from a lower position, in which the flap hangs below the
5 frame, to a higher position, and
the longitudinal elements are maximally extended when the flap is in the higher position,
such that the longitudinal elements inhibit the flap from flapping upward from the higher position.

In some embodiments, an angle between a first plane defined by the arch and a second
plane defined by the frame is between 15 and 70 degrees.

10 There is further provided, in accordance with some embodiments of the present invention,
a method including delivering an artificial valve to an annulus of a mitral valve, the artificial valve
including an expandable frame, an inverted arch extending from the frame, a flap coupled to the
frame such that the flap extends into an interior of the frame, and a plurality of longitudinal
elements that attach the flap to the arch. The method further includes implanting the artificial
15 valve at the annulus such that the flap replaces a leaflet of the mitral valve.

In some embodiments,
the flap hangs below the frame,
the longitudinal elements inhibit the flap from flapping upward, and
the leaflet is a posterior leaflet.

20 In some embodiments,
the flap is configured to flap from a lower position, in which the flap hangs below the
frame, to a higher position,
the longitudinal elements are maximally extended when the flap is in the higher position,
such that the longitudinal elements inhibit the flap from flapping upward from the higher position,
25 and
the leaflet is an anterior leaflet.

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

BRIEF DESCRIPTION OF THE DRAWINGS

30 Fig. 1 is a schematic illustration of a thread-deployment apparatus deployed within a left
atrium of a heart of a subject, in accordance with some embodiments of the present invention;

Fig. 2 is a schematic illustration of a thread-deployment apparatus in its expanded state, in accordance with some embodiments of the present invention;

Fig. 3 is a schematic illustration of a longitudinal cross section through a tube and a tube guide, in accordance with some embodiments of the present invention;

5 Fig. 4 is a schematic illustration of an alternate thread-deployment apparatus, in accordance with some embodiments of the present invention;

Fig. 5 is a schematic illustration of a thread-deploying element, in accordance with some embodiments of the present invention;

10 Figs. 6A-D collectively show the deployment of a thread into tissue by a thread-deploying element, in accordance with some embodiments of the present invention;

Fig. 7 is a schematic illustration of an alternate thread-deploying element, in accordance with some embodiments of the present invention;

Figs. 8A-D collectively show the deployment of threads into tissue by a thread-deploying element, in accordance with some embodiments of the present invention;

15 Fig. 9 is a schematic illustration of a delivery of an implant to a mitral-valve annulus, in accordance with some embodiments of the present invention;

Fig. 10 is a schematic illustration of a locking apparatus for locking an implant over a valve annulus of a subject, in accordance with some embodiments of the present invention;

20 Figs. 11A-E collectively show the locking of an implant onto tissue, in accordance with some embodiments of the present invention;

Figs. 12A-B are schematic illustrations of an electronic sensor configured for implantation in a body of a subject, in accordance with some embodiments of the present invention;

Fig. 13 is a schematic illustration of an annuloplasty ring configured for implantation at an annulus of an intracardiac valve, in accordance with some embodiments of the present invention;

25 Fig. 14 is a schematic illustration of annuloplasty ring in a collapsed state, in accordance with some embodiments of the present invention;

Fig. 15 is a schematic illustration of an implantation of annuloplasty ring, in accordance with some embodiments of the present invention;

30 Fig. 16 is a schematic illustration of an artificial valve implanted over an annuloplasty ring, in accordance with some embodiments of the present invention;

Figs. 17A-C are schematic illustrations of expandable valve frames, in accordance with some embodiments of the present invention;

Fig. 18 is a schematic illustration of an artificial valve for implantation at an annulus of an intracardiac valve, in accordance with some embodiments of the present invention;

5 Fig. 19 is a schematic illustration of a valve in a collapsed state, in accordance with some embodiments of the present invention; and

Fig. 20 is a schematic illustration of a valve frame, in accordance with some embodiments of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS

10 OVERVIEW

In embodiments of the present invention, one or more threads are deployed at an implantation site within a heart of a subject, such as at the annulus of a valve within the heart. Following the deployment of the threads, at least one implant is passed over the threads to the implantation site. Subsequently, the implant is locked in place at the implantation site, using any
15 suitable lock that inhibits the thread from sliding through the implant.

In some embodiments, the implant comprises an electronic sensor, such as an electronic pressure sensor, coupled to an adapting piece of material, such as a ring or tube, shaped to define a passageway. The sensor is loaded onto a thread by passing the thread through the passageway, and the sensor is then delivered, over the thread, to the implantation site.

20 Alternatively or additionally, the implant may comprise an annuloplasty ring. One such ring described herein comprises a plurality of rotatably adjoining segments, such as a plurality of hingedly interconnected segments. The ring is passed over a plurality of threads while the ring is in a collapsed state. As the ring approaches the valve annulus at which the ring is to be implanted, the ring expands from the collapsed state to an expanded state, in which the ring covers the
25 annulus, by virtue of the segments rotating with respect to each other. Following the arrival of the ring at the annulus, the ring is locked in its expanded state. For example, two interconnected bolts may be passed through an adjacent pair of the segments, such that the segments cannot rotate with respect to one another.

Alternatively or additionally, the implant may comprise an artificial valve. In some
30 embodiments, the valve comprises multiple leaflets, such that the valve is configured to replace a native valve of the subject. In other embodiments, the valve comprises a flap, an inverted arch

beneath the flap, and a plurality of longitudinal elements connecting the arch to the flap. The flap may be configured to replace the posterior leaflet of the subject's mitral valve, in that the longitudinal elements may hold the flap in a position suitable for engagement with the native anterior leaflet of the mitral valve. Alternatively, the flap may replace the anterior leaflet, in that
5 the longitudinal elements may allow some flapping of the flap while inhibiting the flap from inverting.

Optionally, any of the artificial valves described herein may comprise a plurality of curved protrusions, which facilitate fitting the valve over an annuloplasty ring implanted at the annulus. The combination of an annuloplasty ring and an artificial valve may be advantageous for at least
10 two reasons. First, by virtue of the ring providing a docking site for the valve, the ring may reduce paravalvular leakage. Second, the ring may reduce the size of the annulus, thus facilitating use of a smaller artificial valve.

THREAD DEPLOYMENT

Reference is initially made to Fig. 1, which is a schematic illustration of a thread-
15 deployment apparatus 20 deployed within a left atrium 22 of a heart 24 of a subject, in accordance with some embodiments of the present invention.

To deliver thread-deployment apparatus 20 to left atrium 22, a sheath 26 is first inserted, percutaneously, into heart 24, e.g., via the femoral vein and inferior vena cava, or via the jugular vein and superior vena cava. Subsequently, techniques known in the art are used to pass sheath
20 26 through the interatrial septum and into the left atrium. Sheath 26 is typically advanced over a guidewire, under fluoroscopic guidance, and/or under the guidance of any other suitable imaging modality, such as ultrasound (e.g., transthoracic echocardiography (TTE) or transesophageal echocardiography (TEE)), magnetic resonance imaging (MRI), or computed tomography (CT).

Subsequently to delivery of the sheath to the left atrium, apparatus 20 is advanced distally
25 from sheath 26. In some embodiments, a catheter 28 is first advanced from the sheath, and apparatus 20 is then pushed through catheter 28, emerging from the distal end of the catheter.

In some embodiments, as shown in Fig. 1, sheath 26 is flexed within the left atrium, such that the distal opening of sheath 26 faces the mitral valve. Catheter 28 is similarly flexed. Subsequently, apparatus 20 is pushed, from the distal opening of catheter 28, toward the mitral
30 valve. Alternatively, for embodiments in which sheath 26 is flexed within the left atrium, catheter 28 may not be required, and apparatus 20 may be held by and pushed from sheath 26.

In other embodiments, sheath 26 is not flexed within the left atrium; rather, catheter 28 is

flexed subsequently to being advanced from the sheath, such that the opening of the catheter faces the mitral valve. Apparatus 20 is then advanced from the catheter.

Initially, apparatus 20 is in a collapsed, or "crimped," state. In some embodiments, a retaining tip 30, which initially covers the distal end of apparatus 20, holds the apparatus in this collapsed state. Subsequently to the distal advancement of apparatus 20 from sheath 26, retaining tip 30 is pushed off of the distal end of the apparatus, using a pushing wire that passes, from the retaining tip, through the length of sheath 26 to the exterior of the subject. Apparatus 20 may then expand (or "open") within the atrium. Additionally to the removal of retaining tip 30, a slider 32 may be used to open the apparatus, as further described below with reference to Fig. 2. Alternatively to using slider 32, a covering sheath may be retracted from over the apparatus.

Apparatus 20 comprises an annular assembly (or "collection") of tubes 34, along with a plurality of flexible tube guides 35. Each of tubes 34 is slidably disposed within a respective tube guide 35, such that the tube guide guides the movement of the tube. Typically, each of the tube guides is cylindrical in shape.

Apparatus 20 further comprises an expandable annular structure 36, which is coupled to the tube guides. In some embodiments, annular structure 36 is manufactured from a suitable shape-memory material, e.g., Nitinol. The pushing-off of retaining tip 30, and/or the appropriate movement of slider 32, allows annular structure 36 to expand, such that annular structure 36 expands radially-outward towards its predetermined, "remembered" shape. In other embodiments, annular structure 36 is manufactured from a non-shape-memory material, such as stainless steel, polymeric tubing, and/or any other suitable metals, polymers, or combinations thereof. In such embodiments, the pushing-off of retaining tip 30, and/or the appropriate movement of slider 32, allows annular structure 36 to spring from its crimped state. In any case, as the annular structure expands, the annular structure expands the assembly of tubes over the tissue 42 of the subject, by moving tube guides 35 radially outward.

A plurality of threads (not shown) pass from tubes 34 to the exterior of the subject. Following the expansion of the annular structure (and, hence, of the annular assembly of tubes) within the subject, the tubes are positioned and/or oriented over tissue 42, for the subsequent deployment of the threads from the tubes into tissue 42. For example, the tubes may be positioned over the mitral-valve annulus (i.e., at the top face of the annulus, inside the left atrium), for the subsequent deployment of the threads into the annulus.

In general, apparatus 20 may comprise any suitable number of tubes, such as 4-20 tubes. Tubes 34 may be manufactured from any suitable metal or plastic material. Typically, the tubes

pass through the entire length of sheath 26, such that, throughout the delivery, deployment, and subsequent use of apparatus 20, the proximal ends of tubes 34 are positioned outside of the subject. Typically, apparatus 20 is rotatable around a central longitudinal axis 44 of the apparatus.

Typically, apparatus 20 comprises a plurality of longitudinal wires 38, which are coupled
5 to the annular structure, typically at the proximal end (or "top") of the annular structure. As further described below with reference to Fig. 2, longitudinal wires 38 may facilitate adjusting the radius of apparatus 20, thus facilitating the positioning of tubes 34 for the deployment of the threads from the tubes, and/or facilitating the crimping of the apparatus following the deployment of the threads. In some embodiments, longitudinal wires 38 may be further used to manipulate annular structure
10 36, thus facilitating the positioning of the tubes. For example, by applying a pushing force to the annular structure, longitudinal wires 38 may move annular structure 36 (and hence also the tubes) in the axial direction, i.e., in a direction that is parallel to central longitudinal axis 44, such that each tube is brought into contact with the valve annulus.

Typically, apparatus 20 further comprises a plurality of control wires 40, which are coupled
15 to the respective distal portions of tube guides 35. Control wires 40 are configured to flex the tube guides, thus positioning and/or orienting the tubes for the subsequent deployment of the threads. For example, as described with reference to Figs. 12A-D of US Patent 10,463,486 to Bar et. al, to move a thread-deployment position radially inward (i.e., toward axis 44), the relevant tube may be flexed radially inward; conversely, to move the thread-deployment position radially outward,
20 the relevant tube may be flexed radially outward.

Following any necessary positioning and/or orienting of any particular tube 34, the tube is pushed through the tube guide within which the tube is contained, such that the tube penetrates tissue 42. Subsequently, the thread is deployed from the tube, i.e., the thread is passed from within
25 the tube or from the outer surface of the tube and through the tissue, as further described below with reference to Fig. 3. (The thread may be passed from the outer surface of the tube by retracting the tube, and/or by pushing an anchor, to which the thread is coupled, from the outer surface of the tube.)

Although Fig. 1 shows the deployment of apparatus 20 specifically within a left atrium, it is noted that apparatus 20 may be similarly deployed at other suitable location within the body of
30 the subject. For example, apparatus 20 may be deployed within the right atrium of the subject, to facilitate the delivery of threads to the tricuspid-valve annulus.

Reference is now made to Fig. 2, which is a schematic illustration of thread-deployment apparatus 20 in its expanded state, in accordance with some embodiments of the present invention.

Reference is first made to the inset portion of Fig. 2, which shows a tube 34 passing partly through a tube guide 35, along with a thread 58 passing from the distal end of the tube guide.

As described above with reference to Fig. 1, tube guide 35 is flexible. For example, tube guide 35 may be shaped to define a plurality of circumferential grooves 54. For example, each groove 54 may extend for at least 50%, such as at least 65%, of the circumference of tube guide 35, such that tube guide 35 is divided, by the grooves, into a plurality of semi-connected segments 56. In such embodiments, tube guide 35 is flexible by virtue of grooves 54, in that segments 56 may swivel relative to each other. Alternatively, tube guide 35 may be flexible by virtue of the material from which the tube guide is made, and/or by virtue of any suitable manufacturing process. In general, tube guide 35 may be manufactured from any suitable plastic or metal material, such as Nitinol.

As described above with reference to Fig. 1, tube guides 35 guide the passage of the tubes, thus facilitating the deployment of threads 58 from the tubes. In some embodiments, prior to threads 58 being deployed, the distal ends of threads 58 are carried inside tubes 34, as further described below with reference to Fig. 3. In such embodiments, threads 58 may pass through the distal ends of tube guides 35, and then run along the outside of tube guides 35 and tubes 34 to the exterior of the subject. Alternatively, instead of passing through the distal ends of the tube guides, threads 58 may pass through apertures in the walls of the tubes, and/or apertures in the walls of the tube guide. As yet another alternative, threads 58 may run inside tubes 34 to the exterior of the subject.

In other embodiments, prior to threads 58 being deployed, the distal ends of threads 58 are carried on the outside surface of tubes 34. For ease of description, however, the remainder of the present description generally assumes that the distal ends of the threads are carried inside tubes 34, as shown in Fig. 2.

Typically, each one of the tube guides is coupled to at least one control wire 40. In some embodiments, as shown in Fig. 2, each of control wires 40 comprises a looped distal end 46, which is coupled to a respective one of the tube guides. Typically, looped distal end 46 is radially-oriented, such that an outer arm 48 of the looped distal end, which is closer to the tube and tube guide, is disposed at a first radius, and an inner arm 50 of the looped distal end, which is further from the tube and tube guide, is disposed at a second radius that is smaller than the first radius. (In this context, the "radius" refers to the distance from axis 44.)

(It is noted that outer arm 48 and inner arm 50 may also be said to belong to the entire control wire, rather than only to looped distal end 46. Thus, for example, it may be said that outer

arm 48 and inner arm 50 extend from looped distal end 46 to the exterior of the subject.)

In some embodiments, control wires 40 are directly coupled to the tube guides. In other embodiments, the control wires are indirectly coupled to the tube guides, in that, for example, the control wires are coupled to annular structure 36, which is in turn coupled to the tube guides. It is
5 noted that, in the context of the present application, including the claims, the term "coupled" may include, within its scope, either a direct coupling or an indirect coupling.

Typically, for embodiments in which the control wires are looped, each tube guide is flexed by moving one proximal end of the attached control wire with respect to the other proximal end of the control wire. For example, the proximal end 50p of inner arm 50 may be pulled or pushed
10 while the proximal end 48p of outer arm 48 is held in place or allowed to freely slide; alternatively, proximal end 48p may be pulled or pushed while proximal end 50p is held in place or allowed to freely slide. The flexing of the tube guides facilitates positioning the tubes, as described with reference to Figs. 12A-D of US Patent 10,463,486 to Bar et al.

In other embodiments, the control wires are not looped, but rather, are longitudinal,
15 similarly to longitudinal wires 38. Typically, in such embodiments, each tube is coupled to two control wires, with one of the two control wires disposed at a greater radius than the other control wire. (In such embodiments, the outer control wire is analogous to outer arm 48, and hence may be referred to as the "outer control arm," while the inner control wire is analogous to inner arm 50, and hence may be referred to as the "inner control arm.") The two control wires may be coupled
20 to a common point on the tube guide. Alternatively, the outer control wire may be coupled at a slightly more proximal position than the inner control wire. For example, the two control wires may be coupled, respectively, to two different segments 56 belonging to the tube, at a distance of 0.5-10 mm from one another.

In yet other embodiments, a single longitudinal control wire is coupled to each one of the
25 tube guides. In such embodiments, each tube guide may be flexed by moving the attached control wire relative to the tube that passes through the tube guide.

As described above with reference to Fig. 1, slider 32 may be used to expand (i.e., open) and crimp (i.e., close) both the assembly of tubes 34 and annular structure 36. Typically, slider 32 slides along a "track" that is formed by control wires 40; for example, slider 32 may slide along
30 both inner arms 50 and outer arms 48 of the control wires. When the slider is at (or near) its most distal position on this track, the assembly of tubes, and the annular structure, are held in a crimped position. Hence, to crimp the apparatus, slider 32 may be slid distally along the control wires, such that the slider exerts a crimping force on the tube assembly and the annular structure.

Subsequently to the distal sliding of the slider, catheter 28 and/or sheath 26 may be slid distally along longitudinal wires 38, thus further crimping the apparatus. Finally, catheter 28 and/or sheath 26 may be passed over the apparatus. Conversely, to expand the apparatus, slider 32 may be slid proximally along the control wires, such as to allow the annular structure, and hence also the assembly of tubes, to expand.

Typically, each inner arm passes through the slider at a radius that is smaller than the radius at which the corresponding outer arm passes through the slider. For example, slider 32 may comprise a first cylinder 67a, through which the respective outer arms of the control wires pass, and a second cylinder 67b, disposed distally from, and being narrower than (i.e., having a smaller radius than), first cylinder 67a, through which the respective inner arms of the control wires pass. This configuration facilitates the crimping of the apparatus, in that slider 32 may slide to a more distal position than might otherwise be possible.

Typically, annular structure 36 comprises a triangular-wave-shaped ring having alternating top and bottom vertices, each of the bottom vertices being coupled to a respective one of the tube guides. In such embodiments, longitudinal wires 38 are typically coupled to the top vertices of the annular structure. As described above, longitudinal wires 38 facilitate adjusting the radius of apparatus 20, in that the radius may be adjusted by sliding catheter 28 (and/or sheath 26) along the longitudinal wires. This adjustment may facilitate the positioning of tubes 34 for the deployment of the threads from the tubes, and/or the crimping of the apparatus following the deployment of the threads.

Reference is now made to Fig. 3, which is a schematic illustration of a longitudinal cross section through a tube 34 and a tube guide 35, in accordance with some embodiments of the present invention.

In some embodiments, as shown in Fig. 3, each tube 34 comprises a pointed distal end 64. In such embodiments, the distal end of thread 58 is typically disposed near distal end 64, within tube 34. As further shown in Fig. 3, thread 58 may pass through the distal end of the tube and tube guide, and run alongside tube guide 35 and tube 34 to the exterior of the subject. Typically, a plurality of expandable anchors 60 are disposed, respectively, within the tubes, and the distal ends of threads 58 are coupled to the expandable anchors. In such embodiments, a plurality of anchor-pushing elements 62 may be disposed within the tubes, proximally to the anchors.

(For embodiments in which tubes 34 comprise pointed distal ends 64, as in Fig. 3, tubes 34 may alternatively be referred to as "needles," and tube guides 35 as "needle guides." In some embodiments, tube 34 is distally coupled to a needle, comprising distal end 64. In the context of

the present application, including the claims, such a needle may be considered an extension of the tube.)

To deploy a particular thread, the tube that contains the distal end of the thread is passed through the tissue, such that the thread is also passed through the tissue. (Tubes 34 may extend to the exterior of the subject, in which case the tubes may be pushed directly; alternatively, separate tube-pushing elements, which are disposed proximally to the tubes and extend to the exterior of the subject, may be used to push the tubes.) Subsequently, anchor 60 is pushed from the tube, using anchor-pushing element 62. Upon exiting from the tube, anchor 60 expands at the far side of the tissue, e.g., as shown in Fig. 9. Subsequently, the tube and anchor-pushing element are retracted into tube guide 35.

Subsequently to the deployment of anchor 60, a pulling force may be continuously applied to thread 58, to hold anchor 60 in place until the implant is locked in place, e.g., as described below with reference to Figs. 10 and 11A-E. Alternatively or additionally, a retainer (not shown), coupled to thread 58, may facilitate holding the anchor in place by engaging with the near side of the tissue, as described in US Patent 10,278,820, whose disclosure is incorporated herein by reference. Such a retainer may, for example, comprise a plurality of prongs, which project radially outward from thread 58.

As described above with reference to Fig. 1, tubes 34 may be positioned at the top face of the mitral-valve annulus, within the left atrium. In some embodiments, to deploy anchors 60, tubes 34 are passed through the annulus and into the left ventricle, such that anchors 60 expand within the left ventricle, beneath the leaflets of the valve. In other embodiments, the tubes emerge from the tissue above the leaflets of the valve, within the left atrium. In some embodiments, pointed distal end 64 is curved radially inward, such that the tube exits the valve annulus through the radially-inward-facing face of the valve annulus. In such embodiments, the anchors may be deployed along the radially-inward-facing face of the valve annulus, as shown in Fig. 9.

In some embodiments, the tubes penetrate the tissue only after all of the tubes have been appropriately positioned and/or oriented. In other embodiments, at least one of the tubes may penetrate the tissue before all of the tubes have been appropriately positioned and/or oriented, such that the subsequent positioning of the other tubes does not cause the first tube to move from its intended penetration site. For example, the sequence of (i) positioning and/or orienting the tube, (ii) passing the tube through the mitral valve annulus, (iii) passing the tissue anchor from the tube, and (iv) retracting the tube and anchor-pushing element, may be performed one tube at a time, for each of the tubes. Alternatively, for example, after positioning and/or orienting each tube, the tube

may penetrate the tissue of the annulus, but the tissue anchors may not be passed from the tube until at least some of the other tubes have also penetrated the tissue.

It is noted that each tube, along with the corresponding tube guide and/or any of the other components described above that facilitate deployment of the thread, may be referred to as a
5 "thread-deploying element," such that apparatus 20 may be referred to as an annular assembly of thread-deploying elements.

Reference is now made to Fig. 4, which is a schematic illustration of an alternate thread-deployment apparatus 20a, in accordance with some embodiments of the present invention.

In general, apparatus 20a is similar to apparatus 20, e.g., with respect to the manner in
10 which expandable annular structure 36 expands the assembly of tubes 34 over the tissue prior to the deployment of the threads, and the manner in which the tubes are positioned and/or oriented. Apparatus 20a differs from apparatus 20, however, with respect to the configuration of tubes 34, and the manner in which the threads are deployed.

In particular, in apparatus 20a, each tube 34 comprises an arced distal portion 66, disposed
15 proximally to tube guide 35. For example, distal portion 66 may be shaped to define a distally-facing crescent, comprising a first tube-end 68a and a second tube-end 68b. In general, arced distal portion 66 is less flexible than more proximal portions of tube 34; for example, arced distal portion 66 may be rigid. (In some embodiments, a portion of tube 34 that is immediately proximal to the arced distal portion may also be rigid.)

As further described below with reference to Figs. 5 and 7, at least one arced needle is
20 disposed within arced distal portion 66. Each of the arced needles is coupled to the distal end of a respective thread 58 (not shown in Fig. 4), which, as in apparatus 20, may run alongside tube 34, or within tube 34, to the exterior of the subject. As further described below, the arced needles are configured to loop the threads through the tissue of the valve annulus, by arcedly passing, from
25 arced distal portion 66, through the tissue. By virtue of the threads looping through the tissue, it may not be necessary to deploy any anchors.

Typically, first tube-end 68a and second tube-end 68b are pointed. (Thus, as in apparatus
20, tube 34 may be referred to as a "needle," and tube guide 35 may be referred to as a "needle guide.") In such embodiments, to facilitate the deployment of the threads, first tube-end 68a and
30 second tube-end 68b may penetrate the tissue of the annulus, prior to the passing of the arced needle(s) from arced distal portion 66 and through the tissue.

Each tube, along with the arced needle(s) contained therein and/or any of the other components described below that facilitate deployment of the thread(s), may be referred to as a "thread-deploying element," such that apparatus 20a may be referred to as an annular assembly of thread-deploying elements. In this regard, reference is now made to Fig. 5, which is a schematic illustration of a thread-deploying element 65, in accordance with some embodiments of the present invention. (Fig. 5 does not show the portion of tube 34 that is proximal to distal portion 66, or tube guide 35.)

In the particular embodiment shown in Fig. 5, a single arced needle 70, having a pointed distal end 70d, is disposed within arced distal portion 66. Thread 58 is coupled to the proximal end 70p of needle 70. Thread-deploying element 65 comprises one or more (e.g., exactly two) distal shafts 72, which are coupled to the tube in contact with needle 70. As further described below with reference to Figs. 6A-D, shafts 72 are configured to pass needle 70 through tissue 42, by rotating. Typically, shafts 72 are rotated by rotating one or more proximal shafts 74. For example, one or more belts 76 may, collectively, mechanically couple shafts 72 to each other and to proximal shafts 74, such that distal shafts 72 rotate in response to rotation of the proximal shafts. (It is noted that any shaft that is not in contact with needle 70 is referred to herein as a "proximal shaft," even if the shaft is relatively close to distal portion 66 of the tube.)

Reference is now made to Figs. 6A-D, which collectively show the deployment of thread 58 into tissue 42 by thread-deploying element 65, in accordance with some embodiments of the present invention.

Fig. 6A shows the penetration of tissue 42 by arced distal portion 66 of tube 34. Following the penetration of the tissue, as shown in Fig. 6B, distal shafts 72 are rotated (via rotation of proximal shafts 74), such that needle 70 arcedly passes, from arced distal portion 66, through tissue 42. (The motion of the needle may also be described as a "rotation.") As the needle passes through the tissue, thread 58, which is coupled to the proximal end of the needle, also passes through the tissue. Typically, the needle is rotated such that the entire needle passes (i) through one of the tube-ends and into the tissue, (ii) through the tissue, and (iii) through the other one of the tube-ends. For example, the needle may undergo a full rotation of 360 degrees.

Fig. 6C shows the configuration of thread-deploying element 65 following the rotation of needle 70. In this configuration, thread 58 arcedly passes through the tissue from one tube-end through the other tube-end, and then, from an aperture in arced distal portion 66, to the exterior of the subject. (For clarity, in Fig. 6C, the path of thread 58 is emphasized.)

As shown in Fig. 6D, following the rotation of the needle, tube 34 is retracted through the tube guide, such that arced distal portion 66 is withdrawn from the tissue. Following the withdrawal of the thread-deploying element, thread 58 loops through tissue 42, such that, following the withdrawal of apparatus 20a from the body of the subject, two different segments of the thread - a first segment 63a and a second segment 63b - pass from the tissue to the exterior of the subject.

Reference is now made to Fig. 7, which is a schematic illustration of an alternate thread-deploying element 51, in accordance with some embodiments of the present invention. (Similarly to Fig. 5, Fig. 7 does not show the entirety of tube 34, or tube guide 35.)

Thread-deploying element 51 may be used with thread-deployment apparatus 20a (Fig. 4), alternatively or additionally to thread-deploying element 65. Thread-deploying element 51 is similar to thread-deploying element 65 in at least some ways. For example, in thread-deploying element 51, tube 34 comprises arced distal portion 66, comprising tube-ends 68a and 68b. Thread-deploying element 51 also differs from thread-deploying element 65 in at least some ways. For example, instead of a single arced needle, thread-deploying element 51 comprises a pair of arced needles, comprising a first arced needle 70a and a second arced needle 70b. Typically, first arced needle 70a comprises a first pointed distal end 59a and a first needle body 61a, which are reversibly coupled to one another. Similarly, second arced needle 70b comprises a second pointed distal end 59b and a second needle body 61b, which are reversibly coupled to one another. A first thread 58a is coupled to first pointed distal end 59a, while a second thread 58b is coupled to second pointed distal end 59b.

As further described below with reference to Figs. 8A-D, first arced needle 70a and second arced needle 70b deploy first thread 58a and second thread 58b by arcedly passing through tissue 42, toward one another, from, respectively, first tube-end 68a and second tube-end 68b. Upon the two arced needles colliding with one another within the tissue, first pointed distal end 59a and second pointed distal end 59b couple to one another, such that first thread 58a is coupled to second thread 58b. Thus, the two threads effectively become a single thread that loops through the tissue, similarly to the looping of thread 58 shown in Fig. 6D.

Typically, the respective proximal ends of the arced needles are coupled to a hinge 55, which may be controlled by a hinge-control rod 53. Typically, as shown in Fig. 7, hinge 55 is v-shaped, the respective proximal ends of the arced needles being coupled to the respective ends of the hinge, and the distal end of hinge-control rod 53 being disposed inside of the hinge. A spring (or "clamp") 57 applies a closing force to the hinge, such that, when the distal end of hinge-control

rod 53 is at a relatively proximal position (as in Fig. 7), the hinge is almost closed, and the arced needles are inside of arced distal portion 66. Conversely, when hinge-control rod 53 is pushed, against the hinge, to a more distal position, the hinge is opened, causing the arced needles to pass from arced distal portion 66 and through the subject's tissue.

5 First pointed distal end 59a and second pointed distal end 59b may be configured to couple to one another in any suitable way. For example, as shown in Fig. 7, first pointed distal end 59a may be shaped to define a male connecting tip, and second pointed distal end 59b may be shaped to define a female connecting tip configured to fittingly receive first pointed distal end 59a. Upon a sufficient force being applied to hinge 55 by hinge-control rod 53, first pointed distal end 59a is
10 forced into second pointed distal end 59b.

Reference is now made to Figs. 8A-D, which collectively show the deployment of threads 58a and 58b into tissue 42 by thread-deploying element 51, in accordance with some embodiments of the present invention.

First, as shown in Fig. 8A, first tube-end 68a and second tube-end 68b penetrate tissue 42.
15 Next, as indicated by the downward-pointing arrow in Fig. 8B, the hinge-control rod is pushed against the hinge, thus causing the hinge to open and passing the arced needles through the tissue. Upon the hinge being sufficiently opened, first pointed distal end 59a couples to second pointed distal end 59b. Subsequently, as indicated by the upward-pointing arrow in Fig. 8C, the hinge-control rod is withdrawn (i.e., moved proximally), such that hinge 55 is closed by spring 57. As
20 the hinge closes, the hinge applies a force to first needle body 61a and second needle body 61b that exceeds the connective force between the needle bodies and the respective distal ends of the needles. Consequently, the needle bodies are detached from the respective distal ends of the needles. Finally, as shown in Fig. 8D, thread-deploying element 51 is withdrawn.

IMPLANT DELIVERY AND LOCKING

25 Reference is now made to Fig. 9, which is a schematic illustration of a delivery of an implant 71 to a mitral-valve annulus 75, in accordance with some embodiments of the present invention.

Following the deployment of threads 58, the thread-deployment apparatus is crimped, inserted into catheter 28 and/or sheath 26 (Fig. 1), and then withdrawn from the subject.
30 Subsequently, an implant 71 may be delivered to mitral-valve annulus 75 over the threads. As shown in Fig. 9, implant 71 may comprise an annuloplasty ring. Alternatively or additionally, as

further described below with reference to Figs. 12A-B and Figs. 16A-C, the implant may comprise a sensor and/or an artificial valve.

First, implant 71 is loaded onto the threads, by passing the proximal ends of the threads through respective apertures in the implant. (It is noted the implant may be loaded onto the threads
5 even before the threads are deployed.) A single thread that loops through the tissue, as described above for apparatus 20a (Fig. 4), may function as two separate threads, in that each segment (or "arm") of the loop may pass through a different respective aperture in the implant.

Next, a plurality of hollow pushing rods 73, comprising respective distal heads 79, may be loaded onto the threads proximally to the implant. Pushing rods 73 may then push the implant
10 through sheath 26, along the threads, to the valve annulus. It is noted that pushing rods 73, along with any other rods described herein, are typically flexible, such that the rods may follow any number of turns within the body of the subject.

In some embodiments, one or more retraction-threads 69 are looped through or around implant 71. If the physician ascertains that the implant was improperly positioned (i.e., that the
15 threads were improperly placed), decides to replace implant 71 with another implant (e.g., due to implant 71 being improperly sized or shaped), or decides not to perform any implantation at all, retraction-threads 69 may be used to retract implant 71. Subsequently, even if no implantation is to be performed, there may be no need to operate invasively on the subject; rather, provided that anchors 60 are secure (e.g., by virtue of being held in place by the aforementioned retainers), it
20 may be sufficient to simply cut threads 58.

Reference is now made to Fig. 10, which is a schematic illustration of a locking apparatus 77 for locking implant 71 (Fig. 9) over the valve annulus of the subject, in accordance with some embodiments of the present invention.

Subsequently to the delivery of the implant to the valve annulus as shown in Fig. 9, pushing
25 rods 73 are withdrawn, and a plurality of locking apparatuses 77 are then loaded onto the threads. (Typically, one locking apparatus is loaded onto each of the threads.) Locking apparatus 77 comprises an inner tube 78 and a lock 80, comprising one or more blocks of material (e.g., any biocompatible, rigid plastic or metal material). Lock 80 comprises a proximal face 100p and a distal face 100d, and is shaped to define a plurality of lumens that run between proximal face 100p
30 and distal face 100d. Each locking apparatus is loaded onto its corresponding thread by looping the thread through the lumens of the lock. As further described below with reference to Figs. 11A-E, inner tube 78 is configured to hold lock 80 within the inner tube, and to deliver the lock to the implant over thread 58 while the implant is in contact with the tissue of the subject. Subsequently

to the delivery of lock 80, thread 58 is cut proximally to the lock, and inner tube 78 is withdrawn.

By virtue of thread 58 looping through the lumens of the lock, a frictional force is generated as the lock slides along the thread. This frictional force inhibits the lock from sliding proximally along the thread following the delivery of the lock to the implant. Hence, the lock, when in contact
5 with the implant at the implantation site, locks the implant over the thread, thus inhibiting the implant from migrating from the implantation site.

In general, the lock may be shaped to define any suitable number of lumens. Fig. 10 shows one possible embodiment, in which lock 80 is shaped to define three lumens: a central lumen 86c, and two side lumens 86s. Thread 58 may loop through the lock (i.e., through the lumens of the
10 lock) in any suitable manner. Typically, the thread is looped through the lock such that the thread circles through the lock between 1 and 10 times, e.g., between 2 and 10 times. For example, given the three lumens shown in Fig. 10, thread 58 may be looped through the lock such that thread 58 circles twice through the lock before passing to the proximal end of the lock. In particular, the thread may pass, from the distal end of lock 80, proximally through central lumen 86c, distally
15 through one of side lumens 86s, proximally through the central lumen, distally through the other one of the side lumens, and then proximally through the central lumen.

In some embodiments, lock 80 comprises a proximal block 80p of material, which comprises proximal face 100p, and a distal block 80d of material, which comprises distal face 100d. In such embodiments, each of the lumens runs through both proximal block 80p and distal
20 block 80d. (Equivalently, it may be said that each of the proximal block and distal block is shaped to define a plurality of lumens, the lumens of the proximal block being aligned with those of the distal block.) When delivering the lock to the implant, proximal block 80p is held by inner tube 78 proximally to, and at a distance from, distal block 80d, with a gap 81 separating between the distal and proximal blocks. Gap 81 facilitates the delivery of the lock to the implant, by reducing
25 the friction that is generated as the lock passes over the thread. As further described below with reference to Fig. 11B, subsequently to the delivery of the lock to the implant, a rod 84, disposed within inner tube 78, pushes the proximal block onto the distal block. The pushing of the proximal block onto the distal block increases the frictional force between the lock and the thread such that, subsequently, the lock is unlikely to move proximally along the thread.

30 In other embodiments, lock 80 comprises a single block of material that, alone, generates sufficient friction to inhibit movement of the lock along the thread in the absence of a sufficient applied force. In such embodiments, the lock may be delivered to the implant by pulling the thread taut while applying a pushing force to inner tube 78 that is sufficient to overcome the friction

generated between the thread and the lock.

In general, lock 80 may have any suitable shape. For example, each of proximal block 80p and distal block 80d may be disk-shaped, or the lock may comprise a single, disk-shaped block of material. Typically, the thickness of the lock - i.e., the distance between proximal face 100p and
5 distal face 100d - is between 2 and 6 mm. For example, in embodiments in which the lock comprises two blocks of material, the thickness of each block - i.e., the distance between the proximal face and the distal face of each block - may be between 1 and 3 mm.

Typically, inner tube 78 is shaped to define a lateral aperture 87 in the wall of the tube. Thread 58 is passed through aperture 87, such that the thread exits from the inner tube, proximally
10 to lock 80, through aperture 87. As further described below with reference to Fig. 11C, subsequently to the delivery of lock 80 to the implant, as the thread is pulled taut, an outer tube 82, which is slidably disposed over inner tube 78, is slid distally over the inner tube. As outer tube 82 passes over aperture 87, a sharp distal edge 88 of the outer tube cuts thread 58. (Equivalently, to cut the thread, the inner tube may be withdrawn while the outer tube is held in place. In the
15 context of the present application, including the claims, such a maneuver is also said to comprise a sliding of the outer tube over the inner tube.)

In some embodiments, locking apparatuses 77 are also used to deliver the implant, in place of pushing rods 73. That is, locks 80 are loaded onto the threads proximally to the implant, and locking apparatuses 77 then push the implant, together with the locks, to the valve annulus.

20 Reference is now made to Figs. 11A-E, which collectively show the locking of implant 71 onto tissue 42, in accordance with some embodiments of the present invention.

Each of Figs. 11A-E shows a transverse cross-section through implant 71, with thread 58 passing from anchor 60, through tissue 42, and through the implant. By virtue of showing anchor 60, Figs. 11A-E assume that thread-deployment apparatus 20 (Fig. 1) was used to deploy thread
25 58. It is noted, however, that the techniques described herein with reference to Fig. 11A-E may also be practiced in a scenario in which the thread loops through the tissue, following the deployment of the thread by alternate thread-deployment apparatus 20a (Fig. 4).

Fig. 11A shows the configuration of locking apparatus 77 following the delivery of lock 80, over thread 58, to implant 71. In particular, in this configuration, inner tube 78 holds the lock
30 (e.g., by squeezing, i.e., exerting a radially-inward force on, the lock), with distal block 80d in contact with the implant, and with proximal block 80p being at a small distance from distal block 80d.

As indicated by the downward-pointing arrow in Fig. 11B, subsequently to the delivery of the lock, rod 84 pushes the proximal block onto the distal block. Next, as indicated by the downward-pointing arrow in Fig. 11C, outer tube 82 is pushed, such that the outer tube slides over the inner tube and over at least part of aperture 87. As outer tube 82 passes over aperture 87, outer tube 82 cuts the thread, i.e., the outer tube severs the distal portion of the thread, which loops through the lock and passes through the implant, from the more proximal portion of the thread. In some embodiments, outer tube 82 continues to be pushed after the thread is cut, until the outer tube reaches the distal end of the inner tube. Following the cutting of the thread, the more proximal portion of the thread may be removed from the subject.

Subsequently to the cutting of the thread, as indicated by the upward-pointing arrow in Fig. 11D, the inner tube is withdrawn, i.e., pulled proximally, while rod 84 pushes the lock against the implant, such that the inner tube slides from over the lock. The inner tube, outer tube, and rod are then withdrawn from the subject. Subsequently, as shown in Fig. 11E, the lock continues to hold implant 71 in place, by virtue of the looping of thread 58 through the lock.

As noted above with reference to Fig. 10, in some embodiments, lock 80 comprises a single block, rather than separate proximal and distal blocks. Even in such embodiments, however, locking apparatus 77 typically comprises rod 84, since, as described immediately above, rod 84 facilitates releasing the lock from the inner tube, by pushing the lock against the implant such that the lock is not pulled away from the implant as the inner tube is withdrawn.

It is noted that each thread may comprise a polymer, a metal (e.g., Nitinol), and/or any other suitable material. For embodiments in which the threads are metallic, the threads may be alternatively referred to as “wires.”

SENSOR IMPLANTS

Reference is now made to Figs. 12A-B, which are schematic illustrations of an electronic sensor 102 configured for implantation in a body of a subject, in accordance with some embodiments of the present invention.

In some embodiments, implant 71 (Fig. 9) comprises sensor 102. Sensor 102 may comprise a pressure sensor, such as a microelectromechanical systems (MEMS) pressure sensor, configured to measure the pressure within the heart of the subject. Alternatively or additionally, sensor 102 may comprise any other type of sensor, such as a temperature sensor, a flow-rate sensor, or an oxygen-saturation sensor. For example, sensor 102 may comprise the Titan Wireless Implantable Hemodynamic Monitor (WIHM) of Integrated Sensing Systems Inc. (MI, USA), or

any other suitable off-the-shelf product configured to sense one or more intracardiac parameters.

Implant 71 further comprises an adapting piece 104 of material, such as plastic or metal, coupled (e.g., glued and/or screwed) to sensor 102. Adapting piece 104 is shaped to define at least one passageway 106 (e.g., an aperture and/or a lumen) through which thread 58 may pass. For example, adapting piece 104 may comprise a tube or ring. Passageway 106 may have any suitable length and width.

Sensor 102 is configured to pass over thread 58, while the thread runs through passageway 106, to an implantation site within the body of the subject. Subsequently to passing over the thread to the implantation site, the sensor is locked over the thread (i.e., is inhibited from moving relative to the thread) using lock 80 or any other suitable lock that grips the thread proximally to the sensor. For example, as shown in Figs. 12A-B, the sensor may be locked by proximal block 80p and distal block 80d. (For simplicity, the looping of the thread through the blocks is not shown explicitly in Figs. 12A-B.) Alternatively, distal block 80d, without proximal block 80p, may lock the sensor in place.

In some embodiments, the lock is delivered to the sensor following the delivery of the sensor to the implantation site, e.g., as described above with reference to Figs. 11A-E.

In other embodiments, at least part of the lock is delivered to the implantation site together with the sensor. For example, distal block 80d may be coupled (e.g., glued and/or screwed) to the sensor, such that distal block 80d passes over the thread together with the sensor. Subsequently to the delivery of the sensor, proximal block 80p may be passed, over the thread, onto distal block 80d. In such embodiments, distal block 80d may also adapt the sensor for passage over the thread, in that the sensor may be passed over the thread by virtue of the thread passing through the lumens of block 80d. In other words, adapting piece 104 may comprise block 80d, such that the adapting piece need not necessarily be shaped to define any passageway for the thread aside from the lumens of block 80d.

In some embodiments, sensor 102 is implanted at the annulus of an intracardiac valve, such as a mitral valve, a tricuspid valve, a pulmonary valve, or an aortic valve. In such embodiments, as shown in Fig. 12B, sensor 102 may be implanted over another valve implant 71', such as another sensor, an artificial valve, and/or an annuloplasty ring, such as the one described immediately below with reference to Figs. 13-15. For example, valve implant 71' may first be passed over multiple threads to the annulus, and the sensor may then be passed over one or more of the threads onto valve implant 71'. Alternatively, the sensor may be initially coupled to (or constitute an integral part of) the valve implant, such that the sensor passes over one or more of the threads

together with the valve implant. In such embodiments, the sensor need not necessarily comprise adapting piece 104, given that the sensor may be passed over the threads by virtue of the threads passing through the implant.

Alternatively, the sensor may be implanted at an intracardiac wall, such as the wall of an atrium or ventricle of the heart. As yet another alternative, the sensor may be implanted at the wall of a blood vessel, such as the aorta, pulmonary artery, or pulmonary vein.

In some embodiments, as shown in Figs. 12A-B, the sensor is anchored at the implantation site by anchor 60, which is expanded at the far side of tissue 42. For example, to implant the sensor at the septal wall of the left atrium, the anchor may be expanded at the opposite side of the septal wall, in the right atrium. As another example, to implant the sensor at the outer wall of the left atrium, the anchor may be expanded along the epicardial wall.

In some embodiments, to deliver the anchor and thread for the implantation of the sensor, a smaller thread-delivery apparatus, comprising a subset of the elements of thread-delivery apparatus 20 (Fig. 1) that does not include a full assembly of tubes or expandable annular structure 36, is used. Such an apparatus may comprise, for example, a single tube 34, which carries the distal end of the thread, and anchor-pushing element 62 (Fig. 3). As described above with reference to Fig. 3, tube 34 may be passed through tissue 42 from the near (or “proximal”) side of the tissue to the far (or “distal”) side of the tissue. Subsequently, the anchor-pushing element may push the anchor from the tube such that the anchor expands at the far side of the tissue and, subsequently to delivery of the sensor, anchors the sensor to the near side of the tissue.

In other embodiments, as described above with reference to Fig. 4 and the subsequent related figures, the thread loops through the tissue, such that anchor 60 is not needed. In such embodiments, adapting piece 104 may be shaped to define two passageways, one for each arm of the loop. Alternatively, two adapting pieces, each shaped to define a different respective passageway, may be coupled to the sensor, and a different respective arm of the loop may pass through each adapting piece. Typically, in such embodiments, two locks are used, one for each arm of the loop.

Optionally, a smaller thread-delivery apparatus, comprising a subset of the elements of thread-delivery apparatus 20a (Fig. 4) that does not include a full assembly of tubes or expandable annular structure 36, may be used to loop the thread through the tissue at the implantation site.

In some embodiments, the thread passes through the sensor itself, such that adapting piece 104 may not be required. For example, a first hole and a second hole may be drilled through the casing of an off-the-shelf sensor. Subsequently, to load the sensor onto a thread, the thread may

be passed into the sensor through the first hole, through the sensor, and out from the sensor through the second hole. Alternatively, a proprietary sensor, which is shaped to define a passageway for the thread, may be manufactured.

Following the implantation of the sensor, the sensor may wirelessly transmit data, such as
5 pressure measurements, using Bluetooth or any other suitable communication protocol.

ANNULOPLASTY RINGS

Reference is now made to Fig. 13, which is a schematic illustration of an annuloplasty ring 110 configured for implantation at an annulus of an intracardiac valve, in accordance with some
10 embodiments of the present invention. Reference is additionally made to made to Fig. 14, which is a schematic illustration of annuloplasty ring 110 in a collapsed state, in accordance with some embodiments of the present invention, and to Fig. 15, which is a schematic illustration of an implantation of annuloplasty ring 110, in accordance with some embodiments of the present invention.

In some embodiments, implant 71 (Fig. 9) comprises annuloplasty ring 110. Ring 110
15 comprises a plurality of rotatably adjoining segments 112, which may be made from any suitable biocompatible metal or plastic and/or a biological material, such as bone. Typically, at least some of segments 112 are arced, e.g., with a radius of curvature between 8 and 30 mm.

Typically, each pair of adjacent segments 112 are hingedly connected to one another, i.e., the pair are connected to one another at a hinge 111, such that the pair may rotate (or “swivel”)
20 with respect to one another about an axis of rotation 117 defined by hinge 111. In particular, the pair may rotate radially inward or outward until the respective ends 121 of the pair contact one another.

Alternatively, ring 110 may comprise an element of shape-memory material divided into segments 112 by one or more folds. The folds function analogously to hinges 111, in that each
25 pair of adjacent segments may rotate with respect to one another about an axis of rotation defined by the fold that separates the pair from one another.

Typically, ring 110 further comprises a cover 128 - comprising, for example, a sleeve and/or a mesh - configured to at least partly cover the segments. Advantageously, cover 128,
30 which is typically made from a flexible biocompatible fabric such as polyester or polytetrafluoroethylene (PTFE), may facilitate the growth of tissue over the ring following the implantation of the ring.

Segments 112 are shaped to define respective apertures 118 through which threads 58 may pass. The cover is also shaped to define multiple apertures 130 aligned with apertures 118. Thus, ring 110 may pass over the threads while the threads run through the apertures.

5 In some embodiments, apertures 118 comprise longitudinal slits, which run (typically lengthwise) through respective interiors of the segments. (Similarly, although not shown in Fig. 15, cover 128 may be shaped to define multiple slits aligned with the slits in the segments). An advantage of longitudinal slits, relative to smaller circular apertures, is that the ring may be more easily fitted to the valve annulus.

10 To implant ring 110, the ring is passed over threads 58, the respective distal ends of which are distributed over the annulus, while the ring is in the collapsed state shown in Fig. 14 and at the left side of Fig. 15. (Typically, while collapsed, the ring is elliptically-shaped.) Given that the threads are farther apart from each other closer to the valve annulus, the ring expands from its collapsed state to the expanded state shown in Fig. 13 and at the right side of Fig. 15 as the ring passes over the threads and approaches the annulus, by virtue of the segments rotating with respect
15 to each other. Typically, while expanded, the segments are maximally rotated, in that the respective ends 121 of each adjacent pair of segments contact one another.

Typically, segments 112 comprise two adjacent segments 112a configured to rotate radially outward with respect to one another as the ring approaches the valve annulus, as indicated by first rotation-indicating arrows 113 in Fig. 14. Segments 112 may further comprise multiple
20 appended segments 112b, each of which is configured to rotate radially inward with respect to an adjacent segment, as indicated by second rotation-indicating arrows 115. Typically, an equal number of segments 112b are appended to each segment 112a. For example, the ring may comprise a sequence of one, two, or three segments 112b appended to each segment 112a.

As shown in Fig. 13 and Fig. 15, the implant further comprises a lock 114, configured to
25 lock the ring in its expanded state at the valve annulus by inhibiting rotation of the segments with respect to each another. For example, segments 112a may be shaped to define respective apertures 116, and lock 114 may comprise two bolts 120 coupled to one another, such that the lock is configured to lock the ring by virtue of bolts 120 passing through apertures 116. Following the entry of the lock into the apertures, friction between the bolts and the segments inhibits the lock
30 from sliding out of the apertures. Alternatively or additionally, the bolts may mechanically lock to the segments; for example, one or more latches within the segments may grip the bolts.

Typically, bolts 120 are hollow, such that, following the delivery of the ring to the annulus, the lock may be delivered to the ring over respective threads, or over a single looped thread,

passing through apertures 116 and bolts 120. For example, as shown in Fig. 15, a retraction-thread 69 (described above with reference to Fig. 9) may be looped through apertures 132 in cover 128, which are aligned with apertures 116, and through apertures 116. Following the delivery of the ring to the annulus, the lock may be delivered to the ring by passing each bolt over a different
5 respective arm of the retraction-thread.

Typically, lock 114 comprises a handle 122. Handle 122 facilitates delivering the lock to the ring and pushing the lock into the ring, in that a pushing rod 73 (Fig. 9) may push the handle. In some embodiments, distal head 79 of pushing rod 73 is coupled to the handle; for example, the handle and the distal head may each be at least partly threaded, such that the distal head may be
10 screwed onto or into the handle. In such embodiments, following the pushing of the lock into the ring, the pushing rod may be uncoupled from the handle, e.g., by unscrewing the pushing rod from the handle. Alternatively, in the event that the ring needs to be moved, the lock may be removed from the ring by pulling the pushing rod. (In the event that the pushing rod was not coupled to the handle or was already withdrawn from the handle, the handle may be pulled using another tool
15 delivered percutaneously to the implantation site.)

In some embodiments, each segment is rotatably adjoined at each of its ends to another one of the segments, such that the segments define a closed loop. Typically, however, two opposing segments 112c – such as the two appended segments farthest from segments 112a (or segments 112a, for embodiments in which the ring does not comprise any other segments) – are
20 joined to another segment only at one end. A longitudinal element 124, such as a wire (e.g., a Nitinol wire) or a thread, joins segments 112c to one another. Longitudinal element 124 is configured to hold the ring in the expanded state, by pulling segments 112c toward one another by virtue of the tension in longitudinal element 124. The longitudinal element may be tied to segments 112c (e.g., via apertures 125 in the segments through which the longitudinal element is
25 passed), welded to segments 112c, or fastened to segments 112c using any other suitable technique.

In some embodiments, ring 110 is implanted at a mitral-valve annulus. In such embodiments, typically, segments 112 define an arc, e.g., a U-shaped arc, and the longitudinal element joins the two ends of the arc. Hence, typically, ring 110, when in its expanded state,
30 conforms to the natural “closed-arc” shape of the mitral valve annulus, as shown at the right side of Fig. 15. (The closed-arc shape may alternatively be referred to as a D-shape, given the similarity of the closed-arc shape to a “D.”)

In some embodiments, segments 112c are aligned with the trigones of the mitral-valve

annulus. For example, segments 112c may be shaped to define apertures 123, and the ring may be implanted such that respective threads deployed at the trigones pass through apertures 123.

Subsequently to the implantation of the ring (including the locking of the ring in its expanded configuration), the ring may be locked over threads 58 using locks 80 (Fig. 10) or any other locks configured to grip the threads proximally to the ring. Subsequently, another implant may be implanted over the locks. Alternatively, the other implant may be implanted over the ring, and the ring and the other implant may then be locked together, using a single set of locks. For example, an artificial valve (or “replacement valve”) may be delivered percutaneously via the threads and implanted over the ring, e.g., as further described below with reference to Fig. 16.

In some embodiments, subsequently to locking the ring, the ring is reshaped by the application of a radially-outward force to the ring. For example, the radially-outward force may cause the ring (and hence, the valve annulus) to adopt a rounder shape, as indicated by an alternate-shape-indicator 126 in Fig. 13. To facilitate this change of shape, longitudinal element 124 may be configured to arc in response to the radially-outward force being applied to the longitudinal element. In addition to the arcing of the longitudinal element, segments 112c may rotate radially outward.

For example, an expandable (e.g., an inflatable or a self-expanding) artificial valve may be delivered to the ring, e.g., via percutaneous catheter delivery. Subsequently, the artificial valve may be implanted over the ring such that, as the artificial valve expands, the artificial valve applies a radially-outward force to the ring.

Typically, the portion of cover 128 containing longitudinal element 124 is stuffed with a stuffing material. Advantageously, this stuffing material increases the rigidity of the ring, such as to facilitate reshaping the ring as described above and/or to facilitate fitting a valve over the ring.

In some embodiments, as shown in Fig. 15, the ring is anchored at the implantation site by anchors 60 at the far side of the tissue. In other embodiments, threads 58 loop through the tissue, as described above with reference to Fig. 4 and the subsequent related figures. The ring may be implanted over any suitable number of threads or thread-loops, such as between 4 and 12, e.g., 6-10, such as eight, threads or thread-loops.

ARTIFICIAL VALVES

Reference is now made to Fig. 16, which is a schematic illustration of an artificial valve 134 implanted over an annuloplasty ring 146, in accordance with some embodiments of the present invention.

In some embodiments, implant 71 (Fig. 9) comprises artificial valve 134 and ring 146. Valve 134 comprises an expandable frame 136 comprising a body 138, which may comprise a plurality of adjoining struts, and a plurality of curved structural elements, referred to herein as protrusions 140, that protrude from body 138. Frame 136 is configured to fit onto ring 146 by virtue of protrusions 140 curving over the ring.

Valve 134 further comprises a valve skirt 142, comprising any suitable polymer or metal, which at least partly covers the frame. Valve 134 further comprises two or more (e.g., exactly three) valve leaflets 144, comprising any suitable polymer or biological material, which are coupled to the frame. (The presence of multiple leaflets inhibits inversion of the leaflets.)

Prior to implantation of the valve, ring 146 is implanted at the annulus, e.g., via threads 58, as described above with reference to Fig. 9. (The threads may be anchored or looped through the tissue.) Subsequently, valve 134 is implanted over the ring.

In some embodiments, the valve is implanted over threads 58, which may comprise, for example, between 6 and 40, such as 6-14, threads or thread-loops. First, the valve is passed over the threads in a collapsed state. As the valve approaches the annulus, the valve expands to the expanded state shown in Fig. 16, by virtue of the threads being farther apart from each other closer to the valve annulus. Subsequently to the valve reaching the ring, continued pushing of the valve by pushing rods 73 (Fig. 9) causes the valve to fit onto the ring, by virtue of protrusions 140 curving over the ring. (In some embodiments, the protrusions expand slightly to conform to the thickness of the ring.) Following the fitting of the valve onto the ring, the valve and the ring may be locked into place using locks 80 (Fig. 10) or any other suitable locks configured to grip the threads proximally to the valve.

In other embodiments, the valve is implanted via a separate percutaneous catheter delivery, without using the threads. As yet another alternative, the valve may be surgically implanted; in such embodiments, frame 136 need not necessarily be expandable.

To facilitate the fitting of the valve over the ring, the valve and the ring typically have the same general shape. For example, both the valve and the ring may be circular, as illustrated in Fig. 16. Alternatively, both the valve and the ring may have the closed-arc shape illustrated in Fig. 13 and Fig. 15; in such embodiments, ring 146 may comprise ring 110, described above with reference to Figs. 13-15. By virtue of the expandability of frame 136, the valve may conform to a range of sizes of ring 146.

Further details regarding frame 136 are hereby described with reference to Fig. 17A, which is a schematic illustration of the frame in accordance with some embodiments of the present invention.

Typically, protrusions 140 are distributed around the circumference of frame 136. For example, the frame may comprise a ring 141 of protrusions disposed beneath and/or level with body 138.

Typically, protrusions 140 comprise respective concave portions 148, which are configured to curve over the annuloplasty ring and thus facilitate the fitting of the valve onto the ring. In some embodiments, each concave portion 148 comprises a first curved arm 148a and a second curved arm 148b that protrude separately from body 138 and meet at a junction 158.

Additionally, the protrusions may comprise respective convex portions 150, which are disposed radially outward from (i.e., farther from body 138 than) the concave portions. Convex portions 150 help to stabilize the valve and to reduce leaking into the atrium, by virtue of the curved lower portion 143 of each convex portion pressing against the tissue of the annulus and/or the upper portion 145 of each convex portion pressing against the atrial wall.

Typically, the length L_0 of upper portion 145, which is typically straight, is between 5 and 40 mm, such as between 15 and 25 mm. The angle α of upper portion 145 with respect to the plane of the annulus is typically between 10 and 90 degrees, such as between 30 and 60 degrees.

In some embodiments, frame 136 is shaped to define multiple apertures 152 configured to facilitate passage of the threads therethrough. For example, the struts of body 138 may be shaped to define apertures 152, e.g., by virtue of the apertures being drilled through the struts. Alternatively or additionally, as shown in Fig. 17A, apertures 152 may be disposed between protrusions 140 and body 138, e.g., between first arm 148a, second arm 148b, and body 138. (In such embodiments, skirt 142 is shaped to define multiple apertures aligned with apertures 152.)

Typically, frame 136 further comprises two or more vertical support rods 154, which are coupled to body 138 and are configured to support leaflets 144 (Fig. 16). In particular, the two edges of each leaflet may be coupled to a respective two of the support rods, such that the leaflet is disposed between the two support rods. For example, for embodiments in which the valve comprises exactly three leaflets, the frame may comprise exactly three support rods 154, each leaflet being coupled to a different respective pair of the support rods. Typically, each support rod is shaped to define a series of apertures 156, via which the leaflet edge and skirt 142 (Fig. 16) may be sewn onto the support rod.

In other embodiments, the skirt is shaped to define the leaflets, such that the leaflets are coupled to the frame by virtue of the skirt covering frame. In such embodiments, support rods 154 may not be required.

Typically, body 138 and protrusions 140 are formed from a single piece of Nitinol or
5 another shape-memory material, e.g., using laser cutting.

Reference is now additionally made to Figs. 17B-C, which are schematic illustrations of frame 136 in accordance with some embodiments of the present invention.

In general, the most suitable position of leaflets 144 (Fig. 16) with respect to the annulus may vary between different subjects and different clinical conditions. To address this challenge,
10 some embodiments of the present invention provide a kit of valves 134, which vary from each other with respect to the height of the leaflets relative to the portion of the valve that rests on the annulus; for example, the valves may vary from each other with respect to the height of the leaflets from protrusions 140. Thus, advantageously, the leaflets may be suitably positioned by selecting the most appropriate valve from the kit for implantation.

For example, in Fig. 17A, the support rods are positioned with the bottom ends of the support rods being approximately aligned with the bottom of the protrusions (which rest on the annulus), such that upon implantation of the valve, the leaflets, which are coupled to the support rods, are situated entirely above the annulus. In Figs. 17B-C, on the other hand, the bottom ends of the support rods are lower than the protrusions, such that the leaflets are positioned at least
20 partly below the annulus. A kit may thus comprise any of the valves of Figs. 17A-C, alternatively or additionally to any number of other valves in which the support rods have respective other, intermediate vertical positions. (It is noted that the scope of the present invention includes providing a kit of valves having different respect leaflet heights regardless of whether the valves comprise protrusions 140.)

(Typically, as the support rods are moved lower, the height of body 138 decreases. Thus, for example, in the embodiment of Fig. 17C, body 138 may comprise an annular strut, or an annulus of multiple adjoining struts, that is level with protrusions 140.)

Reference is now made to Fig. 18, which is a schematic illustration of an artificial valve 162 for implantation at an annulus of a mitral valve, in accordance with some embodiments of the
30 present invention. Reference is additionally made to Fig. 19, which is a schematic illustration of valve 162 in a collapsed state, in accordance with some embodiments of the present invention.

Valve 162 is similar to valve 134 (Fig. 16) in several ways. For example, valve 162

comprises an expandable frame 164 and a valve skirt 166 that covers frame 164. Moreover, in some embodiments, frame 164 comprises protrusions 140, such that the frame may fit over an annuloplasty ring.

Valve 162 also differs from valve 134 in several ways. In particular, valve 162 comprises
5 an inverted arch 168 that extends from the frame. (Arch 168 is referred to as “inverted” with reference to the upright position of the valve shown in Fig. 18.) Valve 162 also comprises, instead of a plurality of leaflets, a flap 170 coupled to frame 164 such that flap 170 extends into the interior of the frame. Valve 162 further comprises a plurality of (e.g., between two and ten) longitudinal elements 172, such as threads, cords, or wires, which attach the flap to arch 168. For example,
10 one end of each longitudinal element 172 may be welded or tied to arch 168, and the other end may be welded or tied to the edge of the flap.

Valve 162 is configured to partly replace a native mitral valve of the subject, in that flap 170 may replace one of the leaflets of the mitral valve, and the longitudinal elements may function with respect to the flap as do the chordae tendineae with respect to the leaflet.

For example, Fig. 18 shows an embodiment in which the flap hangs below the frame and the longitudinal elements are maximally, or nearly maximally, extended, such that the longitudinal elements inhibit the flap from flapping upward. In such embodiments, the flap may replace the posterior leaflet of the mitral valve, in that the flap may engage with the native anterior leaflet without (or with minimal) movement.
15

Alternatively, the longitudinal elements may be longer than is depicted in Fig. 18, such that the longitudinal elements allow more movement of the flap. In such embodiments, the flap may flap from a lower position, in which the flap hangs below the frame as shown in Fig. 18, to a higher position, in which the edge of the flap is approximately level with (e.g., within 5 mm of) the frame. The longitudinal elements may be maximally extended when the flap is in the higher position, such that the longitudinal elements inhibit the flap from inverting, i.e., from flapping
20 upward from the higher position. In such embodiments, the flap may replace the anterior leaflet of the mitral valve.

In some embodiments, flap 170 belongs to skirt 166, i.e., the skirt is shaped to define the flap, such that the flap is coupled to the frame by virtue of the skirt covering the frame. In other
30 embodiments, the flap is coupled to the frame separately from the skirt, e.g., via support rods similar to those shown in Figs. 17A-C.

As shown in Fig. 19 (which, for ease of illustration, omits longitudinal elements 172), arch 168 does not inhibit the collapsing of the valve, such that the valve may be percutaneously

delivered to the implantation site.

Reference is now made to Fig. 20, which is a schematic illustration of frame 164 (including both a side view and an overhead view), in accordance with some embodiments of the present invention.

5 In some embodiments, frame 164 comprises a ring 174 of inward-pointing structural elements, referred to herein as protrusions 176. Each protrusion 176 may be v-shaped, terminating at a bottom tip 178. In some embodiments, ring 174 adjoins ring 141 such that each protrusion 176 is opposite a different respective protrusion 140.

10 In such embodiments, arch 168 may extend from two of protrusions 176, identified in Fig. 19 as a first protrusion 176a and a second protrusion 176b. For example, for embodiments in which protrusions 176 are v-shaped, one end of the arch may extend from bottom tip 178 of first protrusion 176a, and the other end may extend from the bottom tip of second protrusion 176b. For embodiments in which the frame is circular, the circumferential angle between first protrusion 176a and second protrusion 176b may be between 20 and 70 degrees.

15 Typically, the arch is not perpendicular to the frame, but rather, is angled towards the flap. Thus, for example, the angle θ between the plane defined by the arch and the plane defined by the frame may be between 15 and 70 degrees.

Typically, the frame (including, for example, the two rings of protrusions) and the arch are formed from a single piece of Nitinol or another shape-memory material, e.g., using laser cutting.

20 In some embodiments, frame 164 is shaped to define multiple apertures, as described above for frame 136 (Fig. 16). In such embodiments, valve 162 may pass over multiple threads, which pass through the apertures, to the annulus. Alternatively, valve 162 may be implanted percutaneously or surgically, without using the threads.

25 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 description.

CLAIMS

1. Apparatus for implantation at an annulus of an intracardiac valve, the apparatus comprising:

an annuloplasty ring comprising a plurality of rotatably adjoining segments, the ring being
5 configured to:

pass over multiple threads, respective distal ends of which are distributed over the annulus, and

while passing over the threads, expand from a collapsed state to an expanded state by virtue of the segments rotating with respect to each other; and

10 a lock, configured to lock the ring in the expanded state at the valve by inhibiting rotation of the segments with respect to each another.

2. The apparatus according to claim 1, wherein each pair of adjacent ones of the segments are hingedly connected to one another.

3. The apparatus according to claim 1, wherein the annuloplasty ring comprises an element
15 of shape-memory material divided into the segments by one or more folds.

4. The apparatus according to any one of claims 1-3, wherein an adjacent two of the segments are configured to rotate radially outward with respect to one another as the ring passes over the threads.

5. The apparatus according to claim 4, wherein the segments comprise multiple appended
20 segments appended to the adjacent two of the segments, each of which is configured to rotate radially inward with respect to a neighboring one of the segments as the ring passes over the threads.

6. The apparatus according to claim 4,
wherein the adjacent two of the segments are shaped to define respective apertures, and
25 wherein the lock comprises two bolts coupled to one another, such that the lock is configured to lock the ring by virtue of the bolts passing through the apertures.

7. The apparatus according to any one of claims 1-3, wherein the ring further comprises a longitudinal element joining a pair of the segments, the longitudinal element being configured to hold the ring in the expanded state by pulling the pair of the segments toward one another.

30 8. The apparatus according to claim 7, wherein the longitudinal element is further configured to arc in response to a radially-outward force applied to the longitudinal element subsequently to the locking of the ring.

9. The apparatus according to any one of claims 1-3, wherein the ring further comprises a cover configured to cover the segments, and wherein the ring is configured to pass over the threads while the threads pass through the cover.

10. The apparatus according to any one of claims 1-3, wherein the segments are shaped to
5 define respective longitudinal slits running through respective interiors of the segments, and wherein the ring is configured to pass over the threads while the threads run through the slits.

11. A method, comprising:

passing an annuloplasty ring, which includes a plurality of rotatably adjoining segments, over multiple threads, respective distal ends of which are distributed over an annulus of an
10 intracardiac valve, such that the ring expands from a collapsed state to an expanded state by virtue of the segments rotating with respect to each other; and

locking the ring in the expanded state at the valve, by inhibiting rotation of the segments with respect to each another.

12. The method according to claim 11,

15 wherein an adjacent two of the segments are shaped to define respective apertures, and wherein locking the ring comprises locking the ring by passing two bolts, which are coupled to one another, through the apertures.

13. The method according to any one of claims 11-12, further comprising, subsequently to locking the ring in the expanded state, reshaping the ring by applying a radially-outward force to
20 the ring.

14. The method according to claim 13,

wherein the ring further includes a longitudinal element joining a pair of the segments, and wherein applying the radially-outward force to the ring comprises applying the radially-outward force to the longitudinal element such that the longitudinal element arcs in response to
25 the force.

15. The method according to claim 13, wherein reshaping the ring comprises reshaping the ring by implanting an expandable artificial valve over the ring such that, as the artificial valve expands, the artificial valve applies the radially-outward force to the ring.

16. Apparatus, comprising:

30 an electronic sensor; and

an adapting piece of material shaped to define at least one passageway and coupled to the sensor,

the sensor being configured to pass over a thread, which runs through the passageway, to an implantation site within a body of a subject.

17. The apparatus according to claim 16, wherein the sensor comprises a pressure sensor.

18. The apparatus according to claim 16, further comprising:

5 the thread;

a tube, configured to carry a distal end of the thread and to pass through tissue of the subject at the implantation site from a first side of the tissue to a second side of the tissue;

an expandable anchor disposed within the tube and coupled to the distal end of the thread;

and

10 an anchor-pushing element disposed within the tube proximally to the anchor, the anchor-pushing element being configured to push the anchor from the tube subsequently to the tube passing through the tissue such that the anchor expands at the second side of the tissue and, subsequently to the sensor passing over the thread, anchors the sensor to the first side of the tissue at the implantation site.

15 19. The apparatus according to claim 16, wherein the adapting piece of material comprises a block shaped to define a plurality of lumens, the block being configured to lock the sensor over the thread, subsequently to the sensor passing over the thread, by virtue of the thread looping through the lumens.

20. The apparatus according to any one of claims 16-19,

20 wherein the implantation site includes an annulus of an intracardiac valve,

wherein the apparatus further comprises a valve implant configured to pass over the thread and over multiple other threads to the annulus, and

wherein the sensor is configured to pass over the thread onto the valve implant.

21. The apparatus according to any one of claims 16-19,

25 wherein the implantation site includes an annulus of an intracardiac valve,

wherein the apparatus further comprises a valve implant configured to pass over the thread and over multiple other threads to the annulus, and

wherein the sensor is coupled to the valve implant such that the sensor is configured to pass over the thread together with the valve implant.

30 22. Apparatus, comprising:

a valve implant, configured to pass over multiple threads to an annulus of an intracardiac valve; and

an electronic sensor coupled to the valve implant.

23. A method, comprising:

passing an electronic sensor over at least one thread to an implantation site within a body of a subject; and

5 locking the sensor over the thread at the implantation site.

24. The method according to claim 23, wherein the sensor comprises a pressure sensor.

25. The method according to claim 23, wherein the implantation site includes an annulus of an intracardiac valve.

26. The method according to claim 25, wherein passing the sensor over the thread comprises
10 passing the sensor over the thread onto a valve implant.

27. The method according to claim 25, wherein the sensor is coupled to a valve implant, and wherein passing the sensor over the thread comprises passing the sensor over the thread together with the valve implant.

28. The method according to claim 27, wherein passing the sensor over the thread comprises
15 passing the sensor over the thread by virtue of the thread passing through the valve implant.

29. The method according to any one of claims 23-28, wherein the implantation site includes an intracardiac wall.

30. The method according to any one of claims 23-28, wherein the implantation site includes a wall of a blood vessel.

20 31. The method according to any one of claims 23-28, further comprising, prior to passing the sensor over the thread:

passing a tube, which carries a distal end of the thread, through tissue of the subject at the implantation site from a first side of the tissue to a second side of the tissue; and

25 subsequently to passing the tube through the tissue, pushing an expandable anchor, which is coupled to the distal end of the thread, from the tube such that the anchor expands at the second side of the tissue and, subsequently to the sensor passing over the thread, anchors the sensor to the first side of the tissue at the implantation site.

32. Apparatus for implantation at an annulus of an intracardiac valve, the apparatus comprising:

30 an expandable frame comprising a plurality of curved protrusions and configured to fit onto an annuloplasty ring implanted at the annulus by virtue of the protrusions curving over the

ring; and

two or more valve leaflets coupled to the frame.

33. The apparatus according to claim 32, wherein the frame is shaped to define multiple apertures and is configured to pass over multiple threads, which pass through the apertures and
5 through the ring, to the ring.

34. The apparatus according to any one of claims 32-33, wherein the curved protrusions comprise:

respective concave portions, configured to curve over the ring; and

10 respective convex portions, which are disposed radially outward from the concave portions and are configured to press against tissue surrounding the annulus.

35. The apparatus according to any one of claims 32-33, wherein the protrusions are arranged in a ring disposed at a bottom of the frame.

36. The apparatus according to any one of claims 32-33, wherein the valve leaflets are coupled to the frame at a first height from the protrusions, and wherein the apparatus further comprises:
15 at least one other expandable frame comprising a plurality of other curved protrusions; and
two or more other valve leaflets coupled to the other frame at a second height from the other curved protrusions, the second height being different from the first height.

37. A method, comprising:

20 implanting an annuloplasty ring at an annulus of an intracardiac valve; and
subsequently to implanting the annuloplasty ring, implanting an artificial valve, which includes a plurality of curved protrusions, over the ring, by fitting the protrusions over the ring.

38. The method according to claim 37, further comprising, prior to implanting the artificial valve over the ring, passing the artificial valve over multiple threads, which pass through the artificial valve and through the ring, to the ring.

25 39. The method according to any one of claims 37-38,
wherein the curved protrusions include respective concave portions and respective convex portions, which are disposed radially outward from the concave portions, and
wherein fitting the protrusions over the ring comprises fitting the protrusions over the ring by fitting the concave portions over the ring, and
30 wherein implanting the artificial valve comprises implanting the artificial valve such that the convex portions press against tissue surrounding the annulus.

40. Apparatus for implantation at an annulus of a mitral valve, the apparatus comprising:
an expandable frame;
an inverted arch extending from the frame;
a flap coupled to the frame such that the flap extends into an interior of the frame; and
5 a plurality of longitudinal elements that attach the flap to the arch.
41. The apparatus according to claim 40, wherein the frame is shaped to define multiple apertures and is configured to pass over multiple threads, which pass through the apertures, to the annulus.
42. The apparatus according to any one of claims 40-41, wherein the flap hangs below the
10 frame, and wherein the longitudinal elements inhibit the flap from flapping upward.
43. The apparatus according to any one of claims 40-41,
wherein the flap is configured to flap from a lower position, in which the flap hangs below the frame, to a higher position, and
wherein the longitudinal elements are maximally extended when the flap is in the higher
15 position, such that the longitudinal elements inhibit the flap from flapping upward from the higher position.
44. The apparatus according to any one of claims 40-41, wherein an angle between a first plane defined by the arch and a second plane defined by the frame is between 15 and 70 degrees.
45. A method, comprising:
20 delivering an artificial valve to an annulus of a mitral valve, the artificial valve including:
an expandable frame,
an inverted arch extending from the frame,
a flap coupled to the frame such that the flap extends into an interior of the frame,
and
25 a plurality of longitudinal elements that attach the flap to the arch; and
implanting the artificial valve at the annulus such that the flap replaces a leaflet of the mitral valve.
46. The method according to claim 45, wherein delivering the artificial valve comprises delivering the artificial valve by passing the artificial valve over multiple threads, which pass
30 through the artificial valve, to the annulus.
47. The method according to any one of claims 45-46,
wherein the flap hangs below the frame,

wherein the longitudinal elements inhibit the flap from flapping upward, and
wherein the leaflet is a posterior leaflet.

48. The method according to any one of claims 45-46,

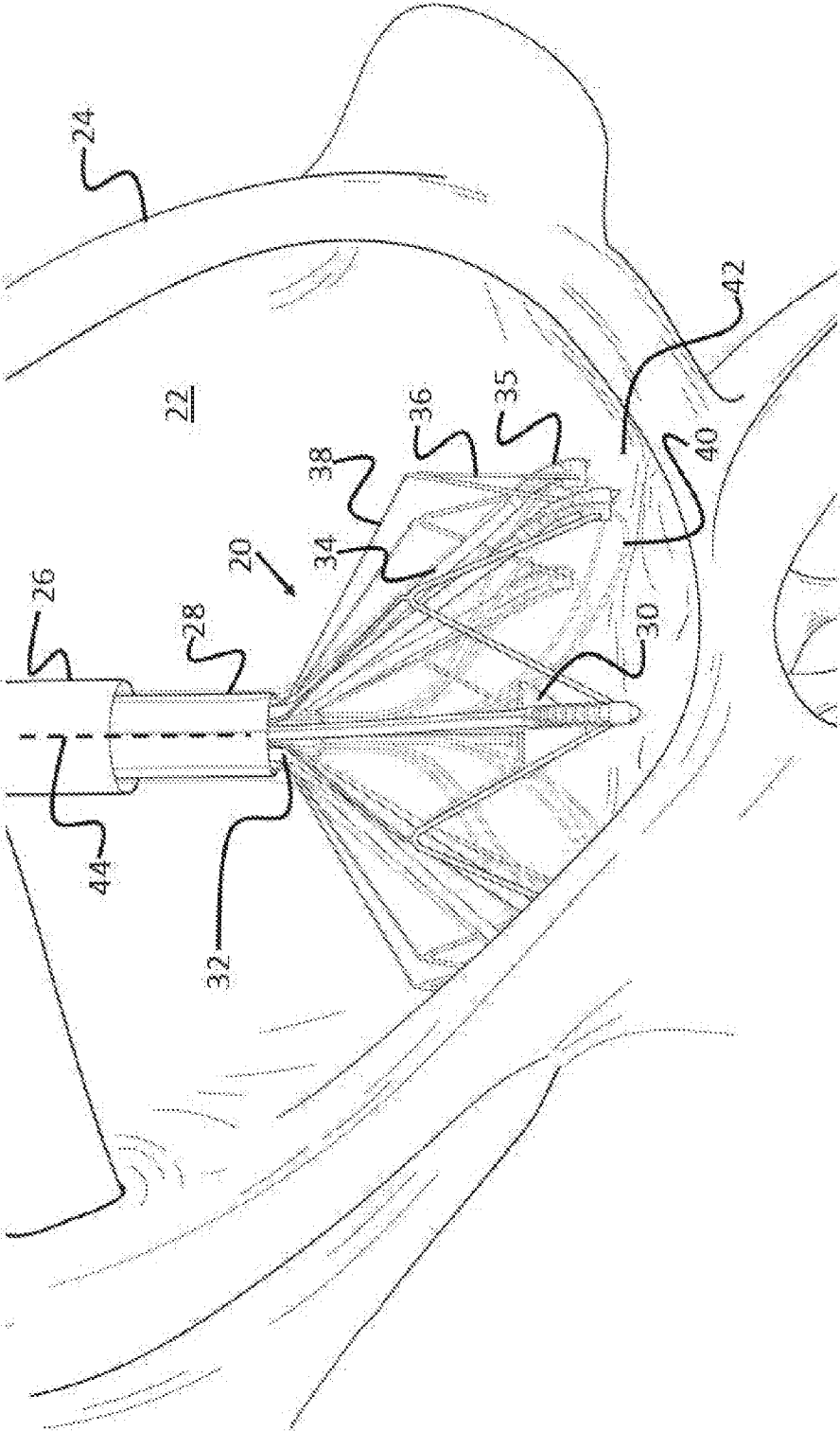
5 wherein the flap is configured to flap from a lower position, in which the flap hangs below
the frame, to a higher position,

wherein the longitudinal elements are maximally extended when the flap is in the higher
position, such that the longitudinal elements inhibit the flap from flapping upward from the higher
position, and

wherein the leaflet is an anterior leaflet.

10

FIG. 1



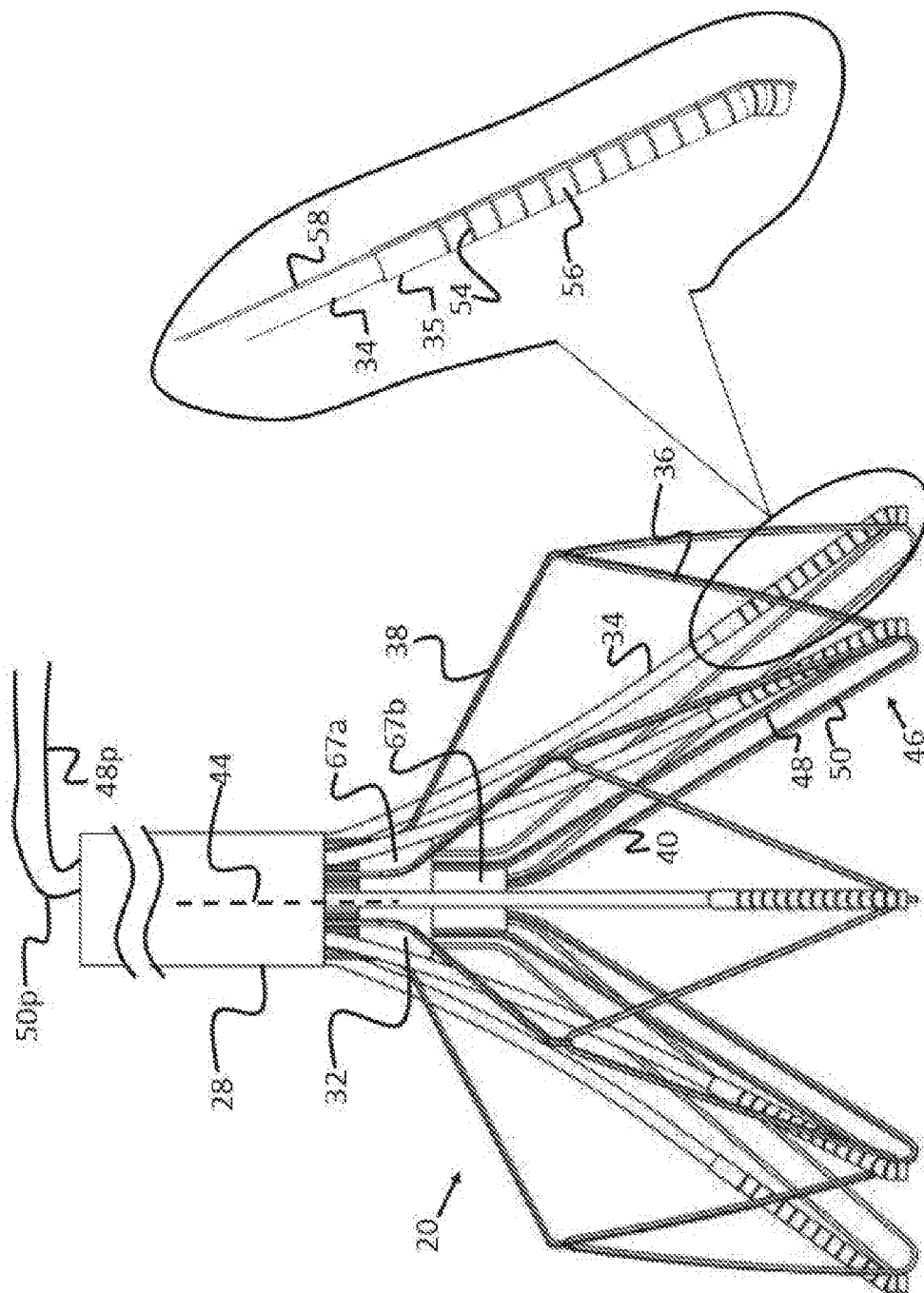
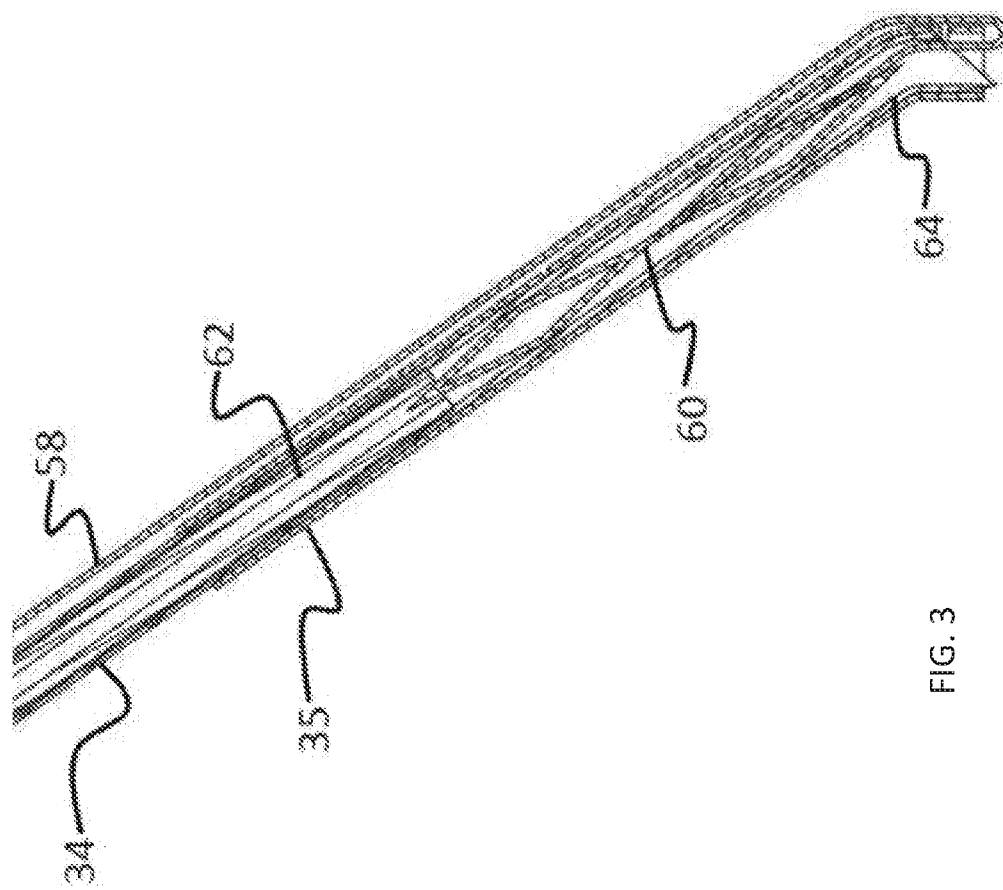
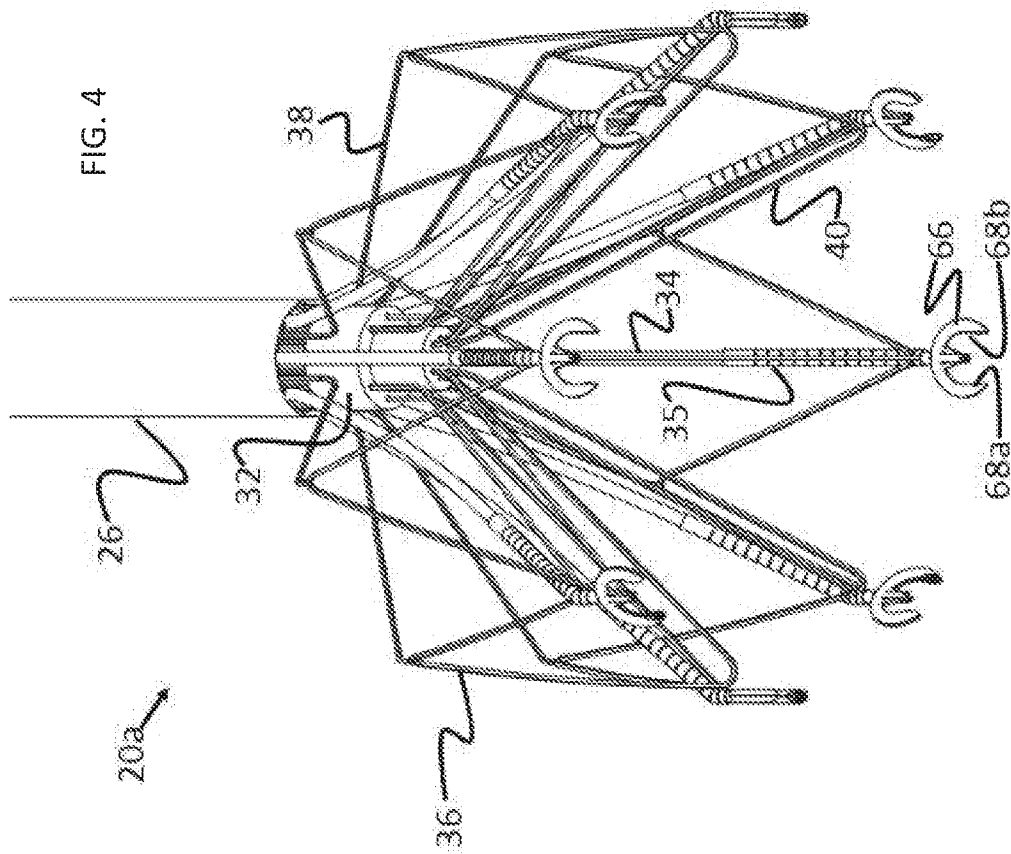
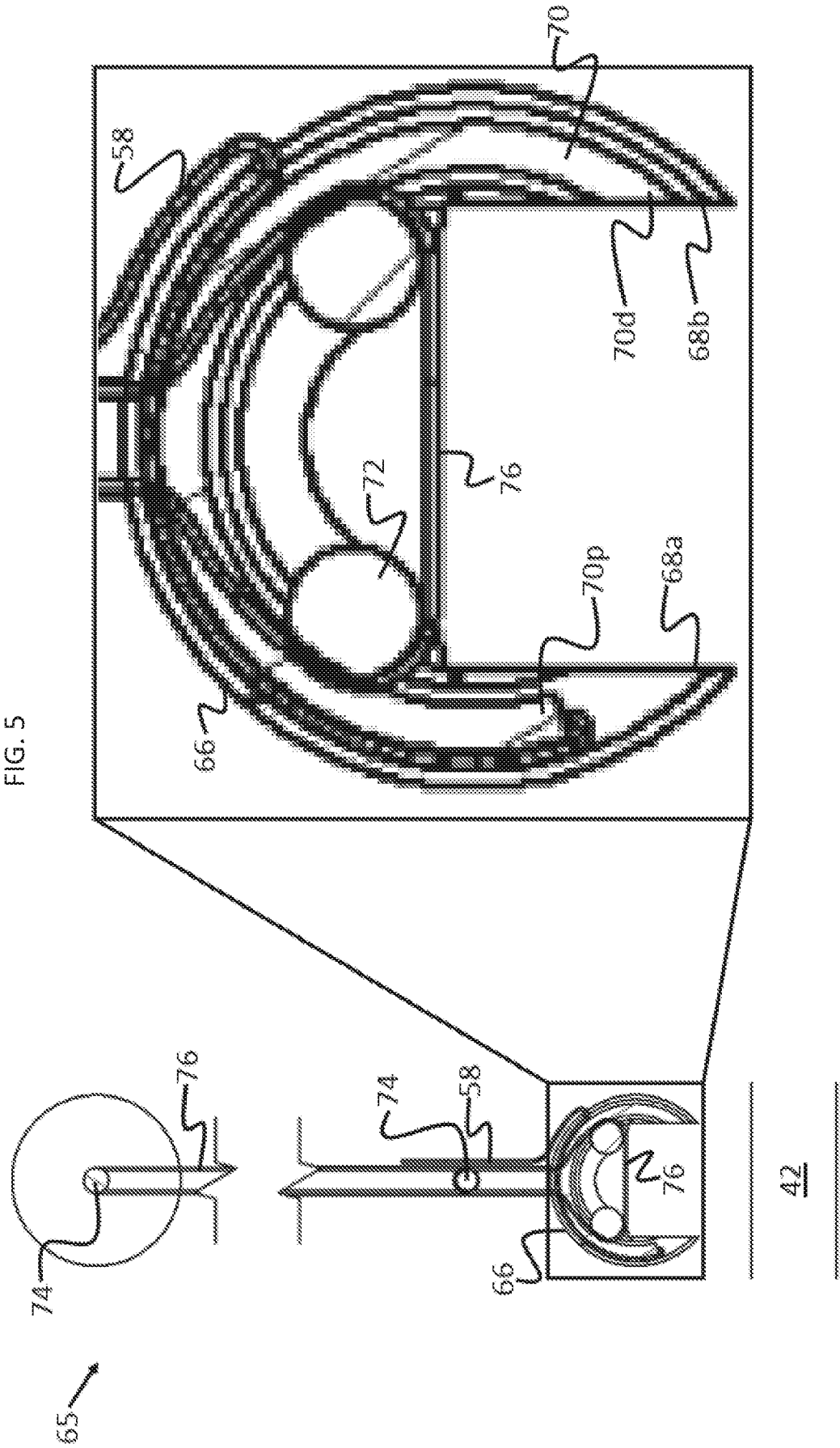
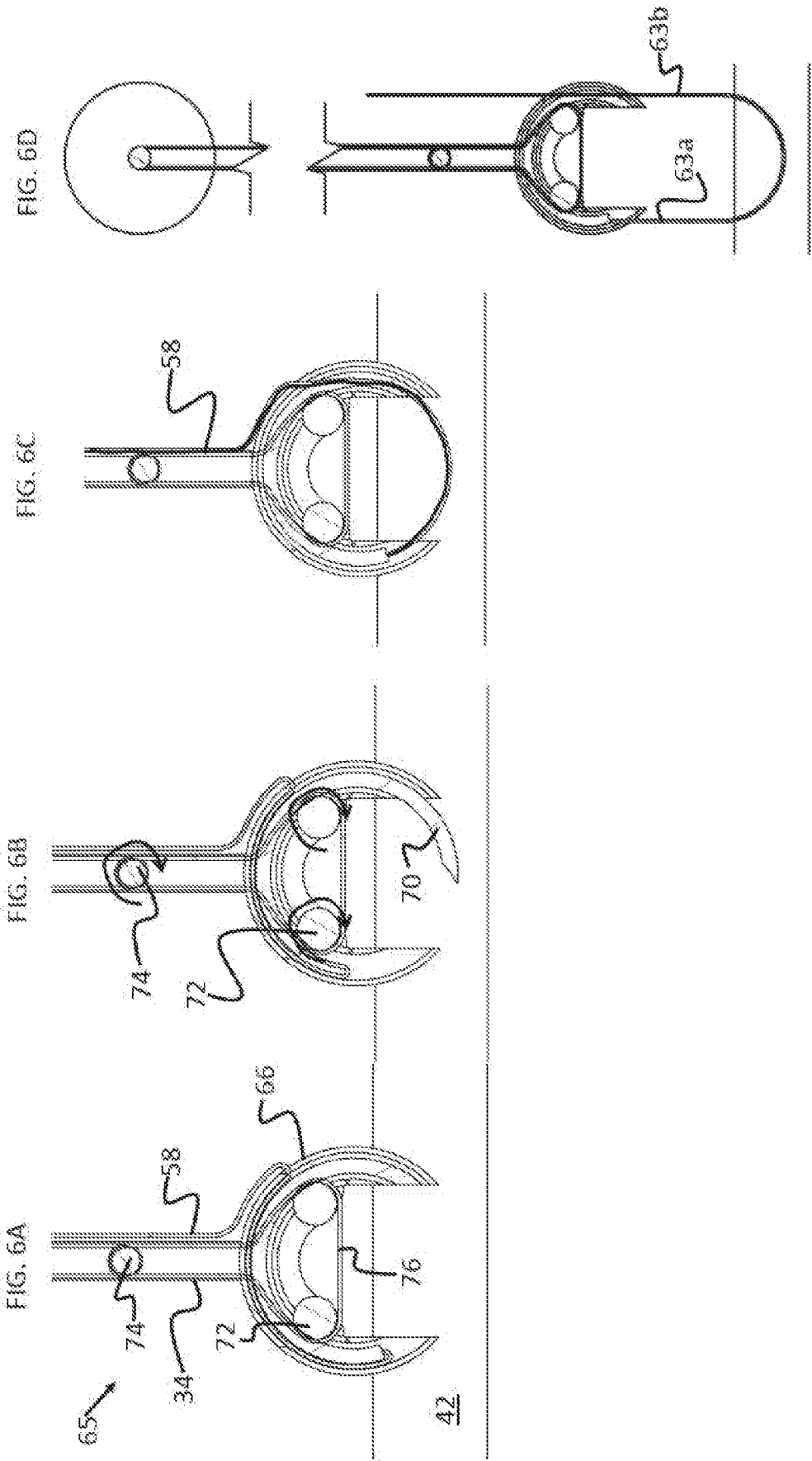


FIG. 2







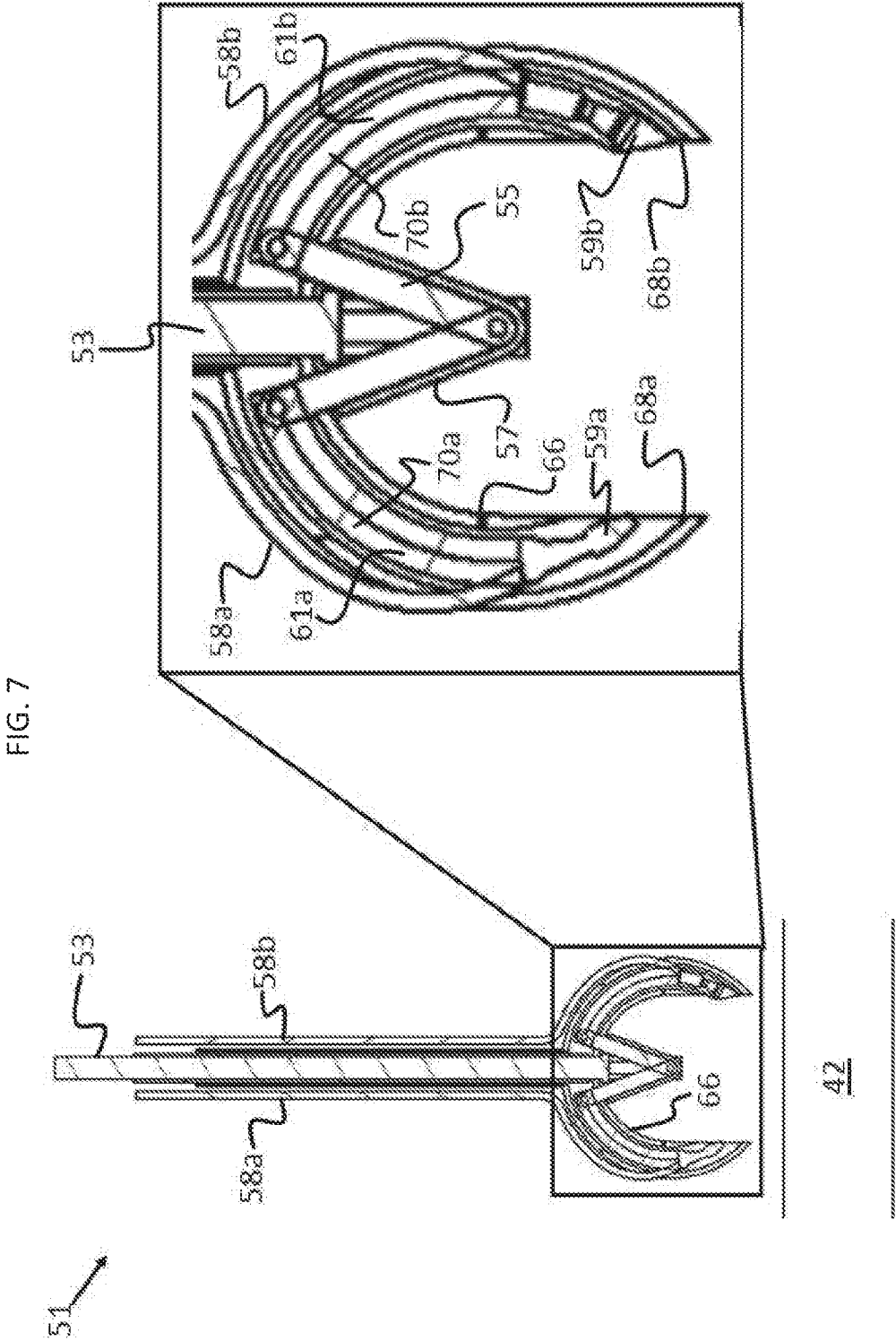


FIG. 8A

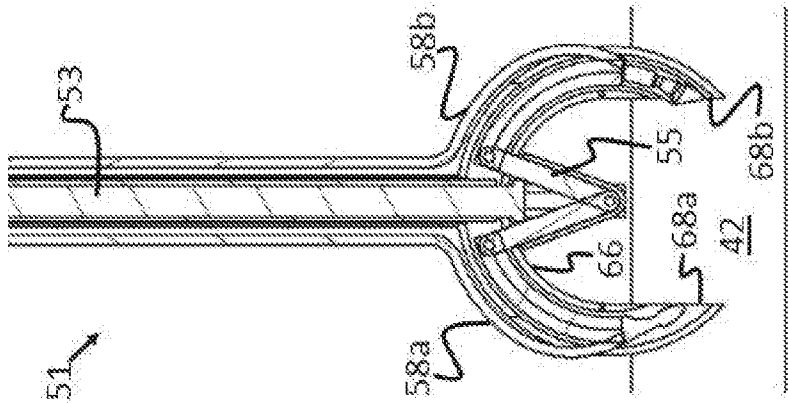


FIG. 8B

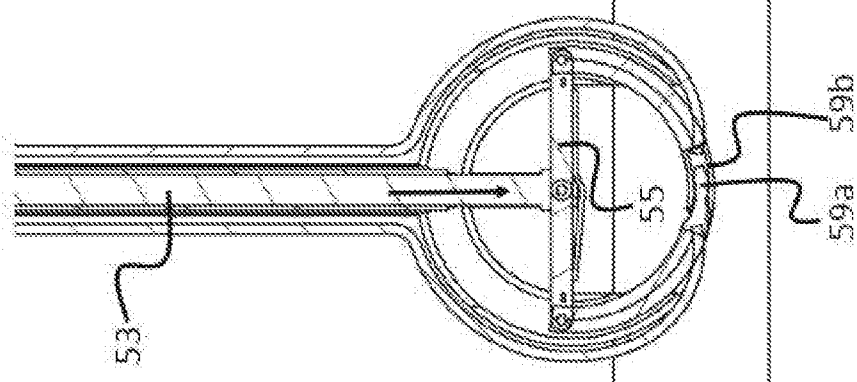


FIG. 8C

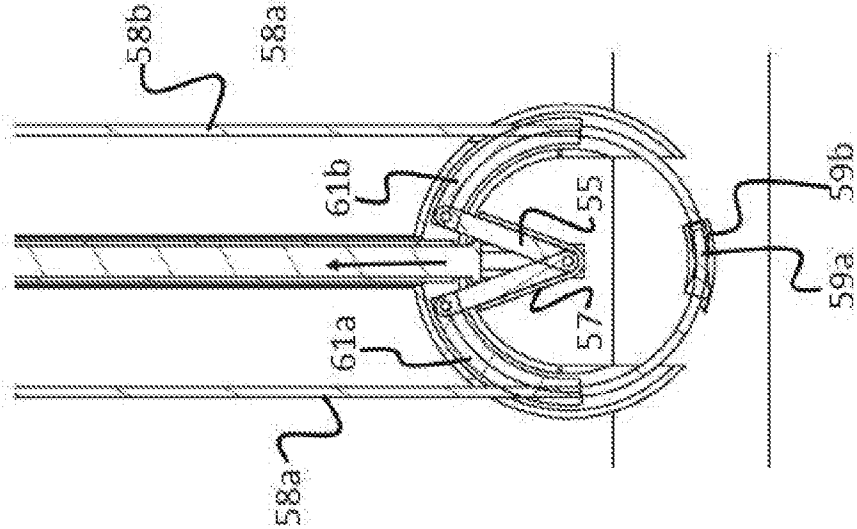
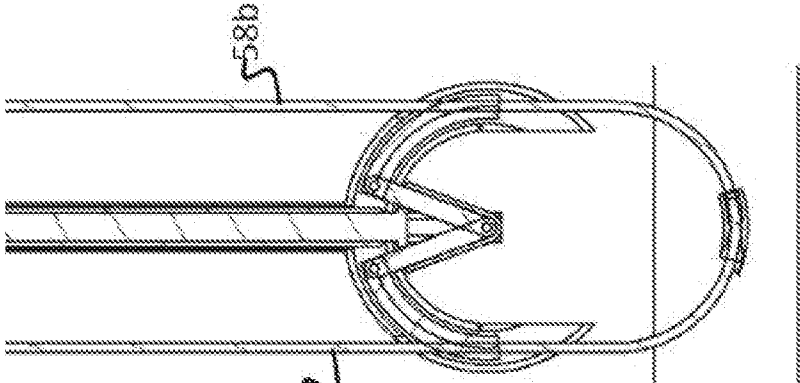


FIG. 8D



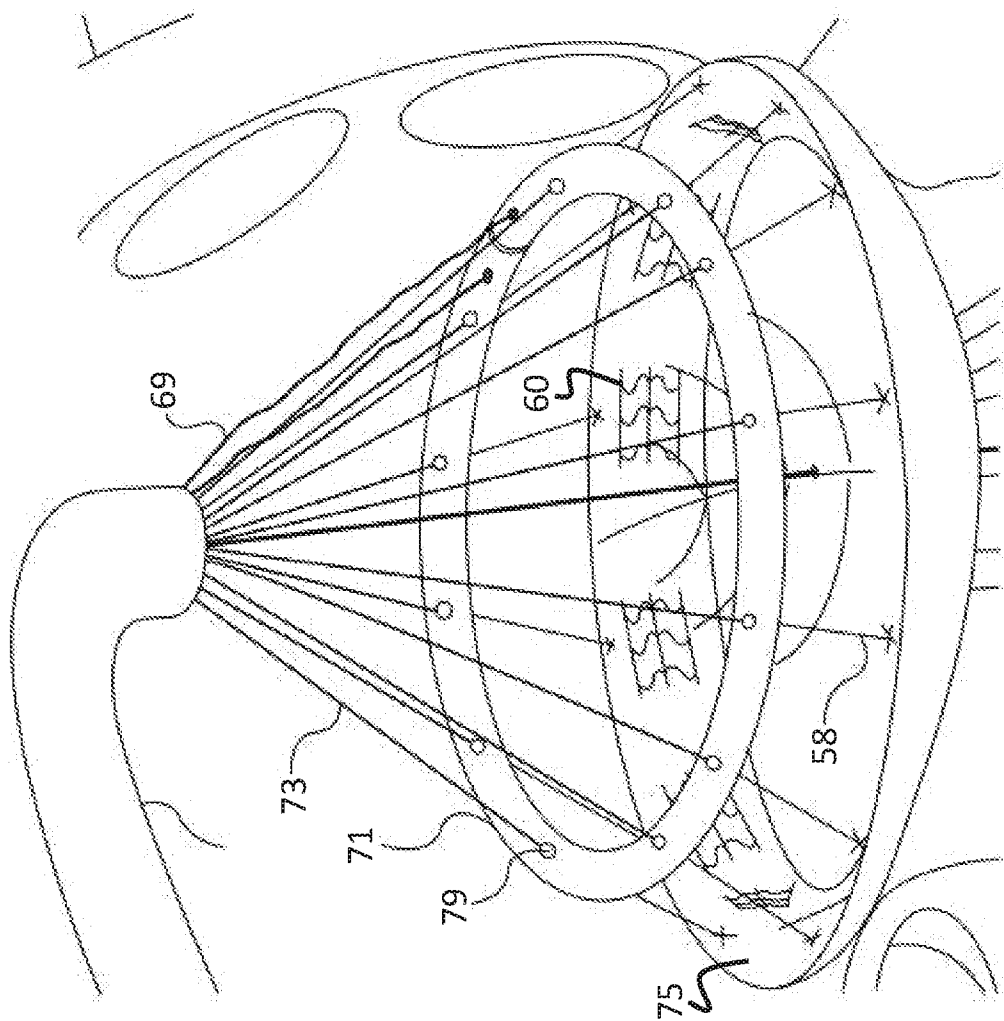
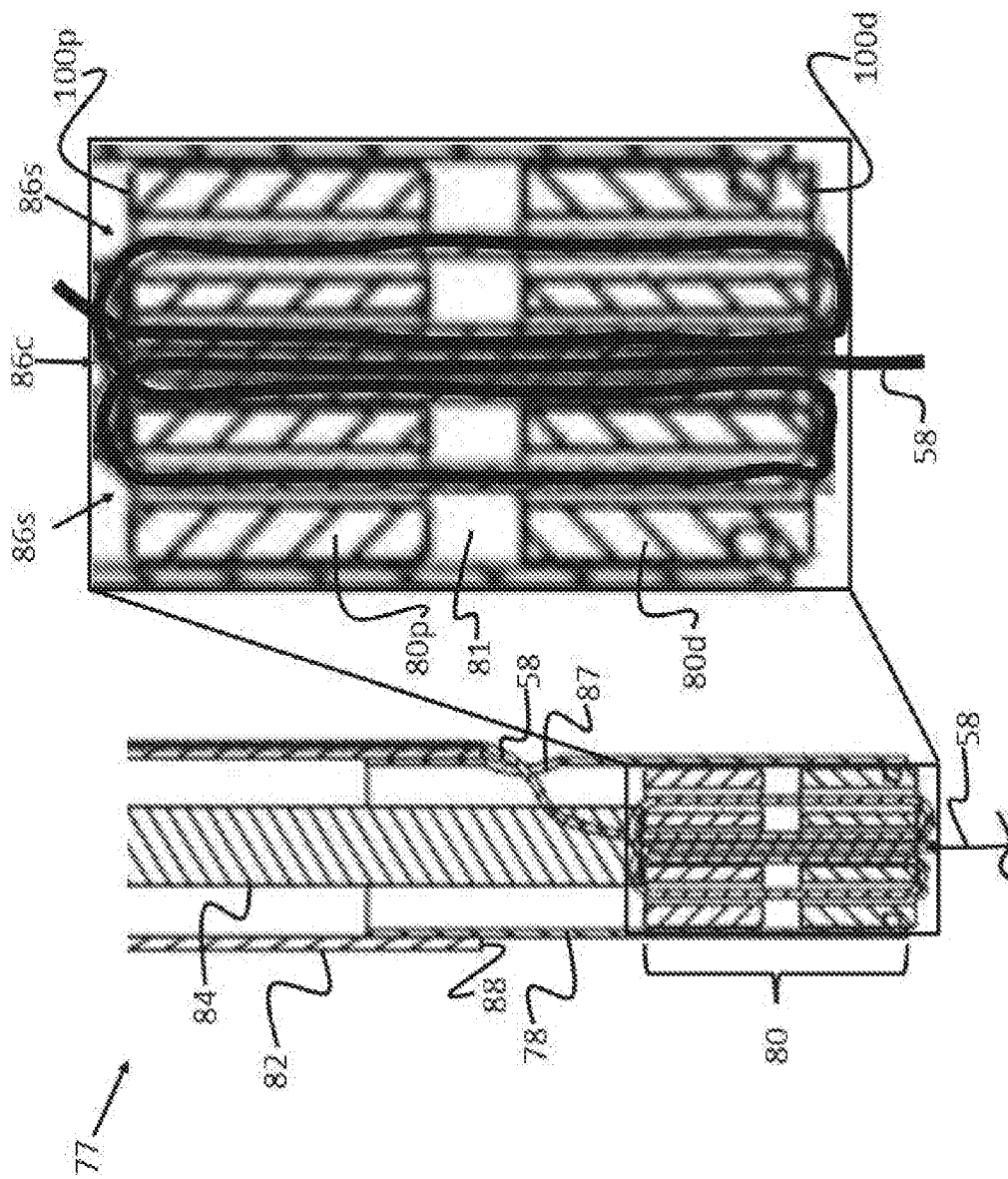


FIG. 9

FIG. 10



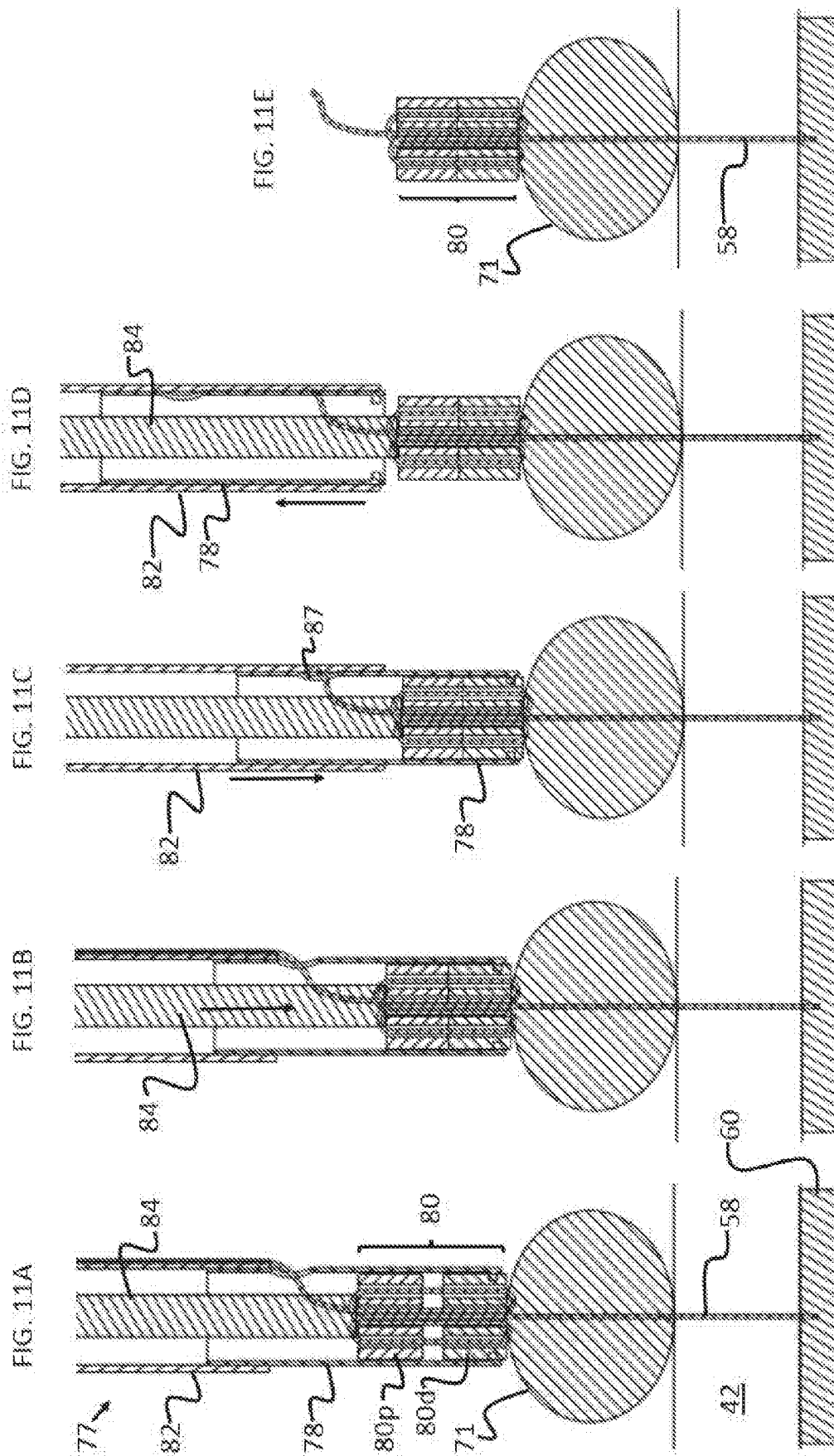


FIG. 12A

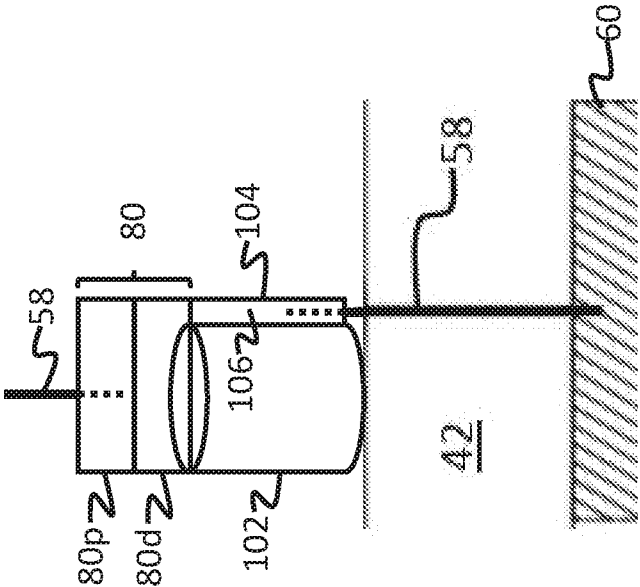
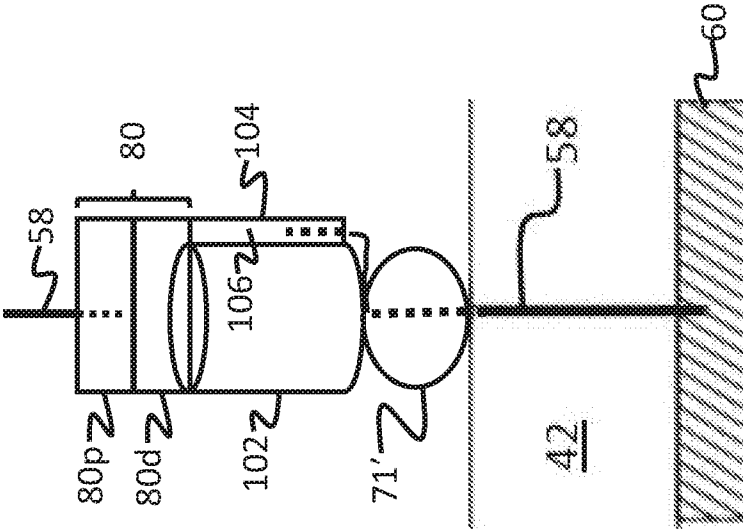


FIG. 12B



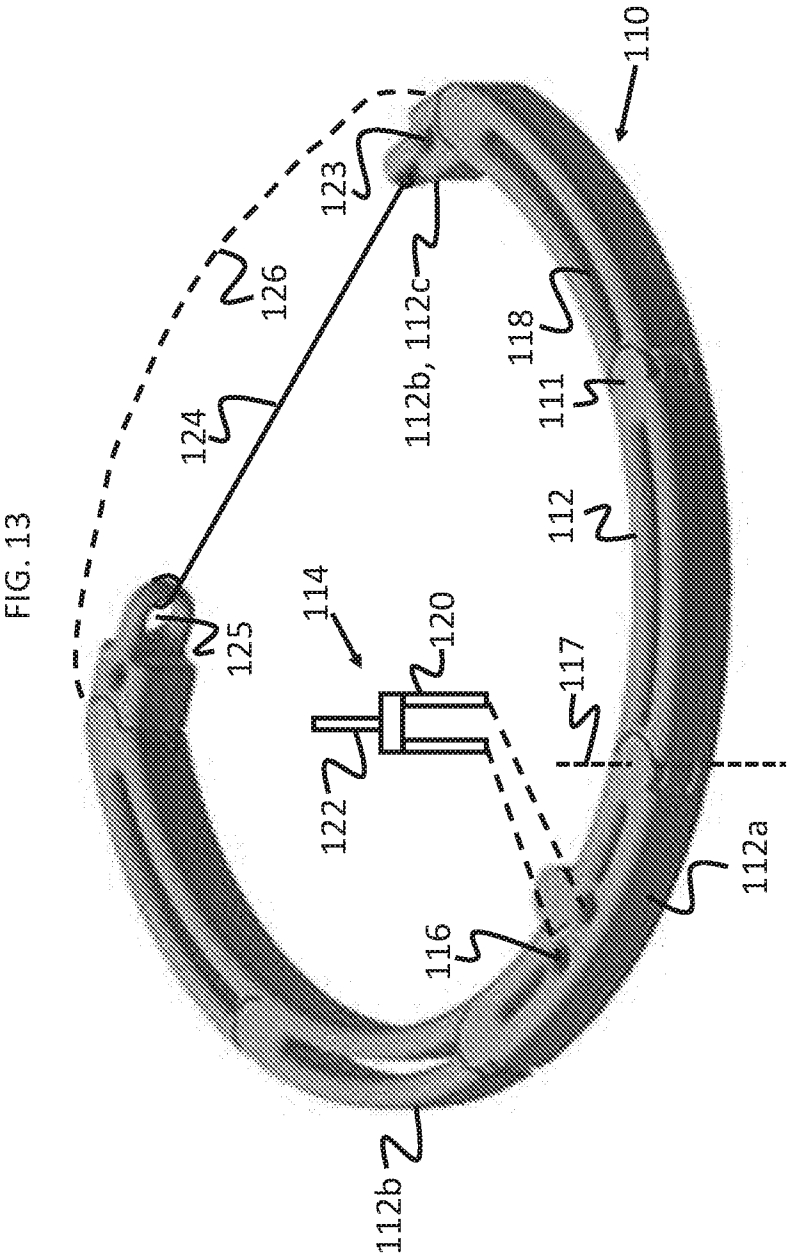


FIG. 14

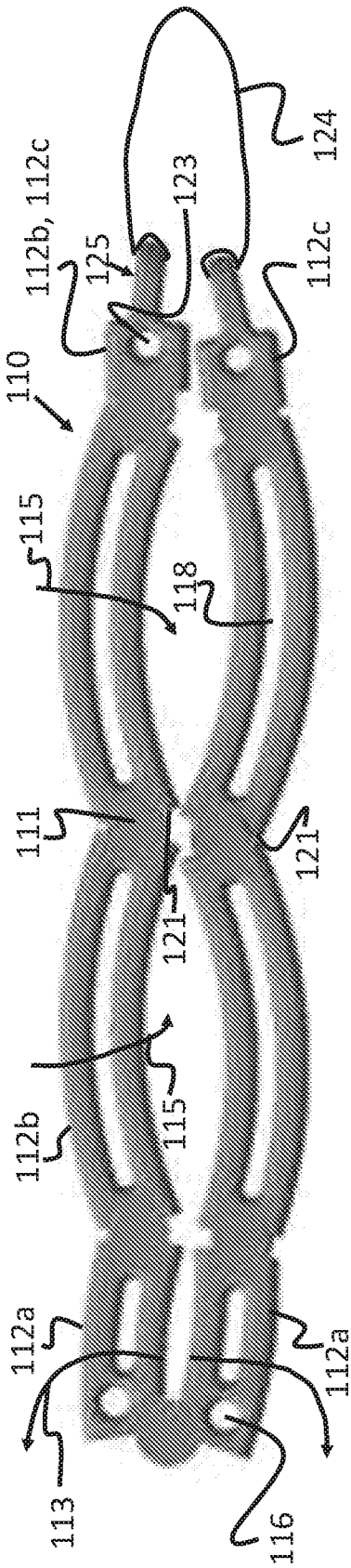
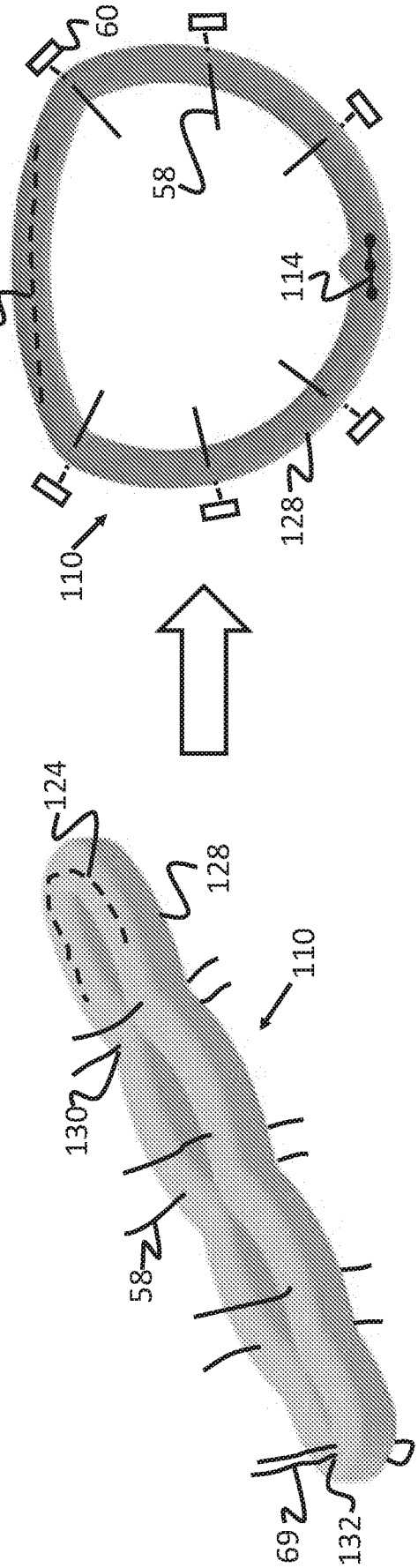
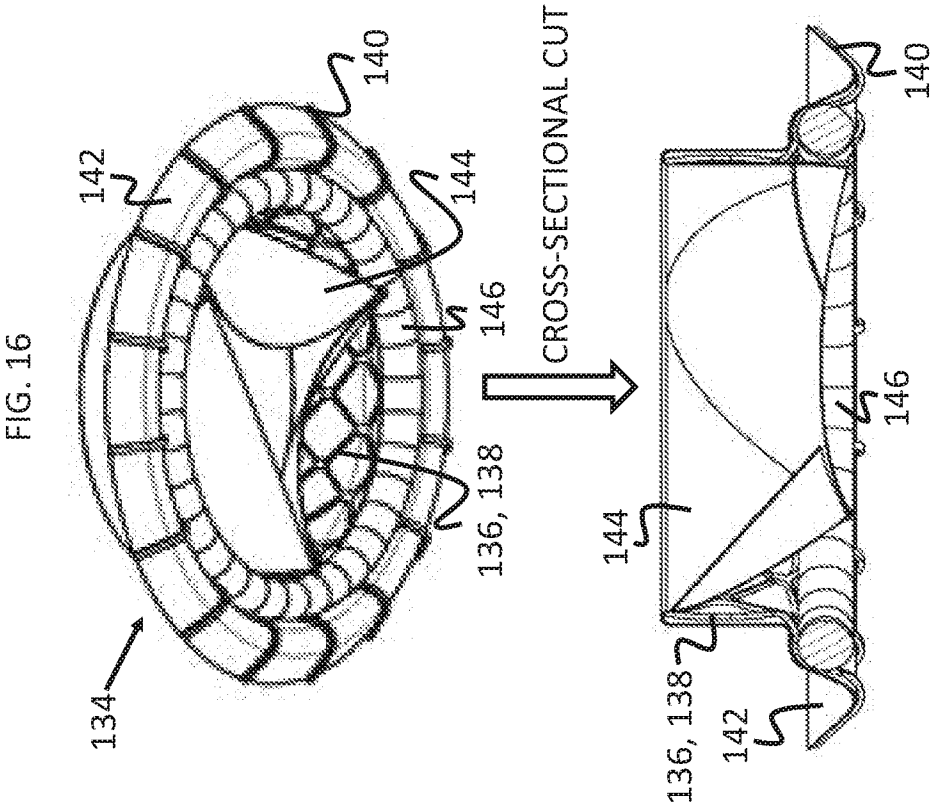


FIG. 15





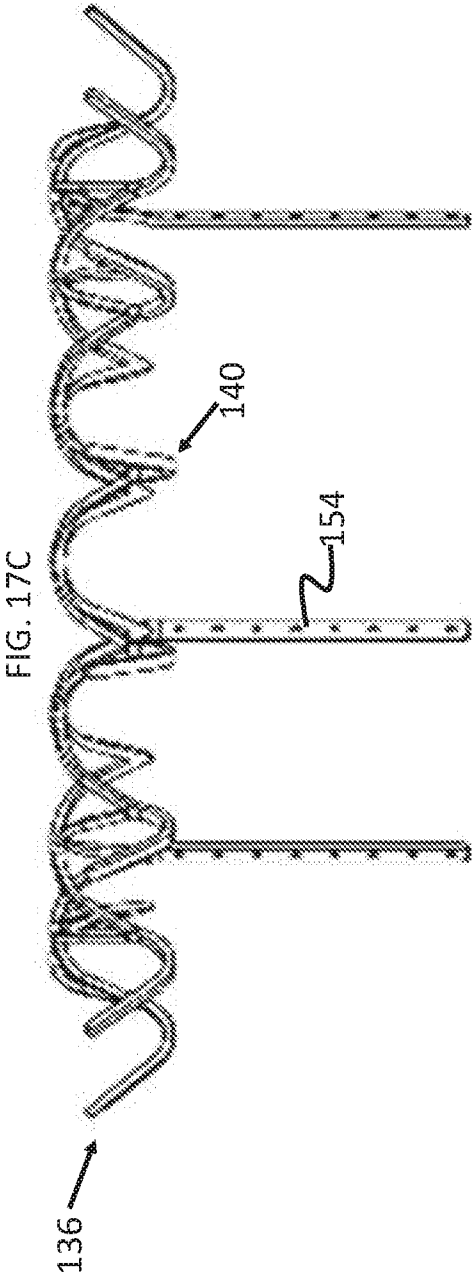
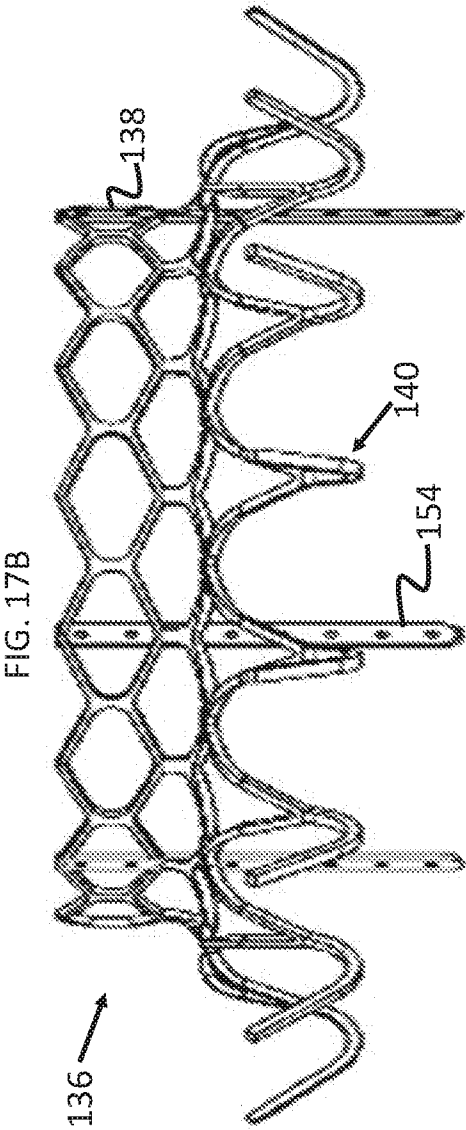


FIG. 18

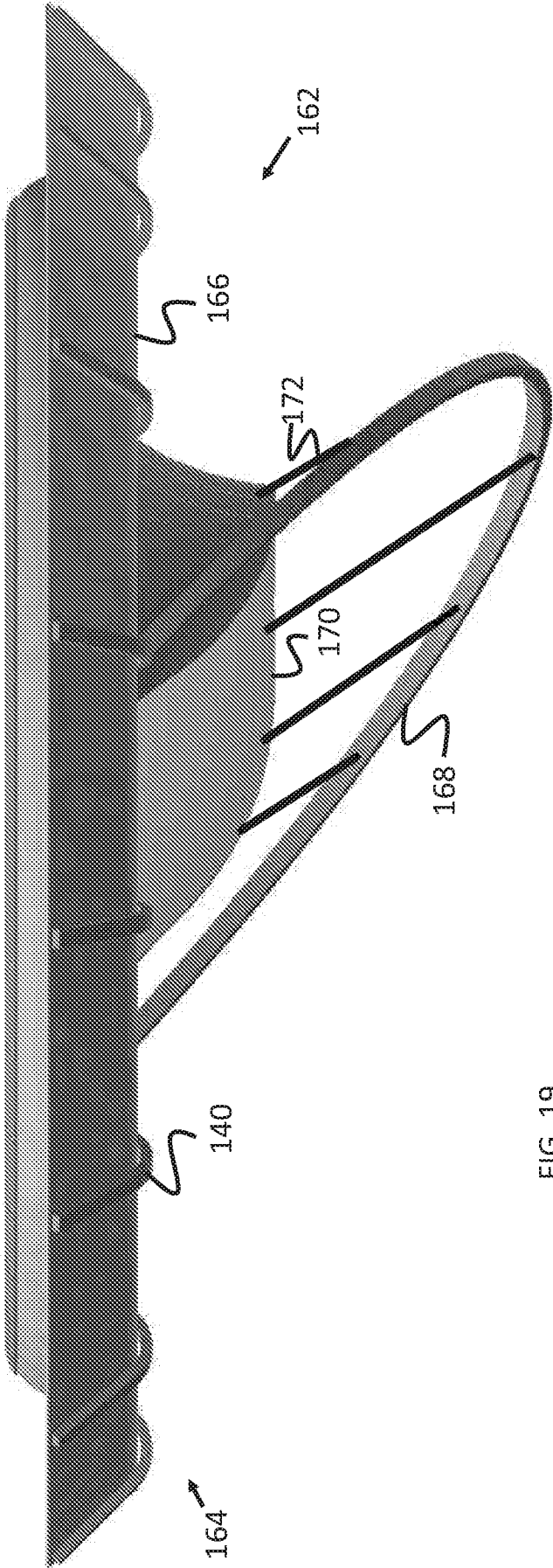


FIG. 19

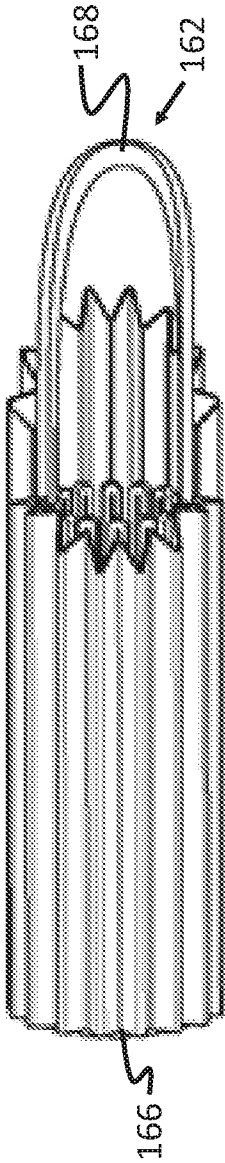
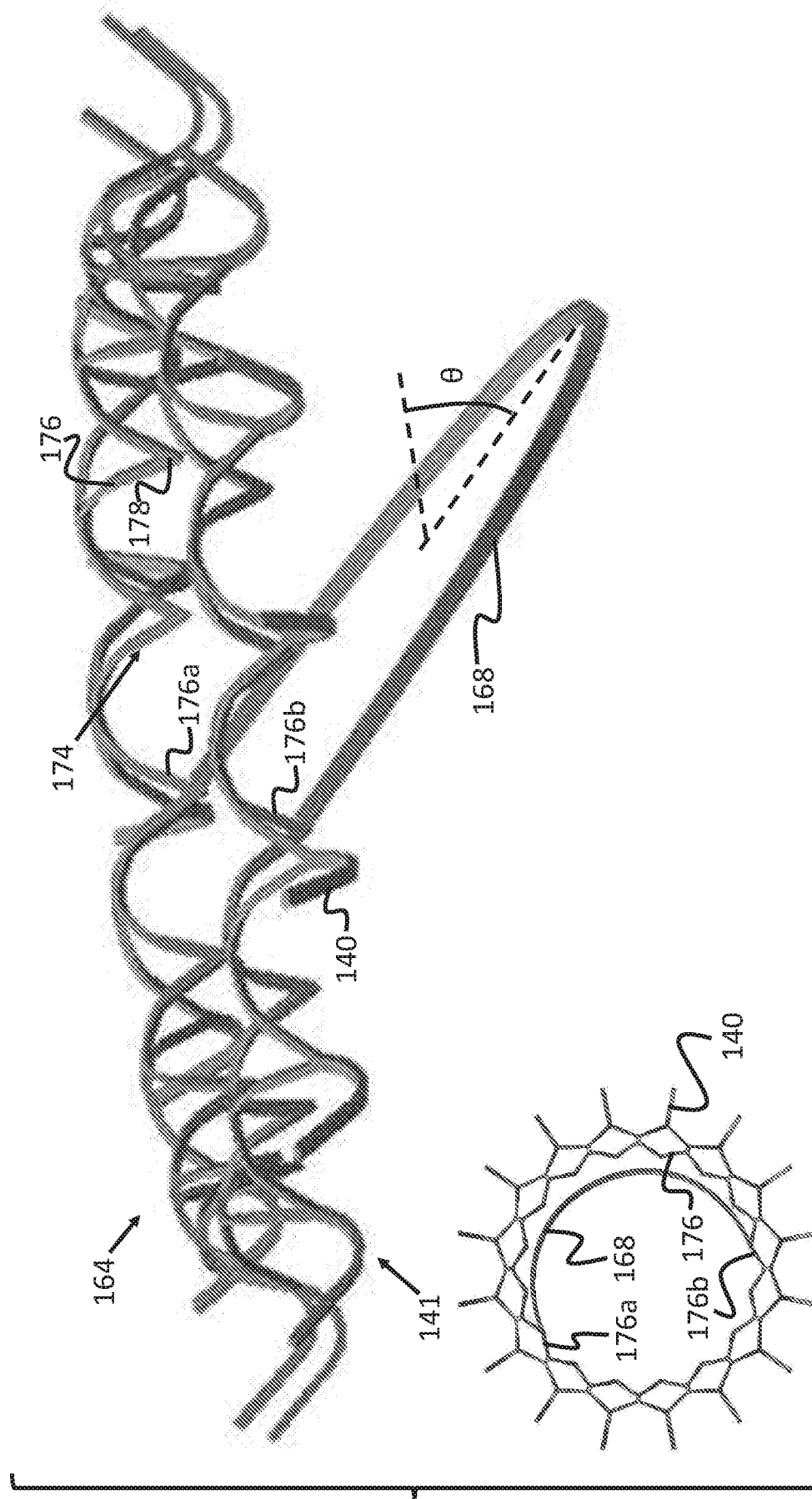


FIG. 20



INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2020/050226

A. CLASSIFICATION OF SUBJECT MATTER IPC (20200101) A61F 2/24 CPC (20130101) A61F 2/2442, A61F 2/2448, A61F 2/2466 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 (20200101) A61F 2/24 CPC (20130101) A61F 2/2442, A61F 2/2448, A61F 2/2466 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) Databases consulted: Google Patents, Orbit Search terms used: ANNULOPLASTY RING SEGMENT ROTATION INHIBITING		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2013226289 A1 VALCARE INC [US] 29 Aug 2013 (2013/08/29) fig. 1, 11, 15, 16, para. 53, 59, 62, 112-113, 130, 136,	1-8, 11-15
X	US 2012123531 A1 MICARDIA CORP [US] et al 17 May 2012 (2012/05/17) fig. 1, 15, para. 58, 60, 62, 72	1-3, 7-11, 14, 15
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A	US 2014031930 A1 EDWARDS LIFESCIENCES CORP [US] 30 Jan 2014 (2014/01/30) whole doc.	1-15
A	US 2015245910 A1 RIGHINI GIOVANNI [CH] et al. 03 Sep 2015 (2015/09/03) whole doc	1-15
☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "D" document cited by the applicant in the international application "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "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 "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "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 27 May 2020		Date of mailing of the international search report 27 May 2020
Name and mailing address of the ISA: Israel Patent Office Technology Park, Bldg. 5, Malcha, Jerusalem, 9695101, Israel Email address: pctoffice@justice.gov.il		Authorized officer SHUSHAN Hadas Telephone No. 972-73-3927218

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2020/050226

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See extra sheet.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-15

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet):

* This International Searching Authority found multiple inventions in this international application, as follows:

Invention/s 1	which refer to an apparatus and a method for using an apparatus for implantation at an annulus of an intracardiac valve comprising an annuloplasty ring comprising plurality of rotatably adjoining segments, configured to pass over multiple threads distributed over the annulus and a lock configured to lock the ring.	Claim/s 1-15
Invention/s 2	-which refer to an apparatus and a method for using an apparatus comprising an electronic sensor configured to pass over threads, and an adapting piece of material shaped to define a passageway, coupled to the sensor. Wherein the apparatus further comprising a valve implant configured to pass over multiple threads to an annulus of an intracardiac valve. And an electronic sensor coupled to the implant.	Claim/s 16-31
Invention/s 3	which refer to an apparatus and a method for using an apparatus for implantation at an annulus of an intracardiac valve comprising an expandable frame comprising a plurality of curved protrusions and further comprising two or more leaflets coupled to the frame where in the expandable frame configured to fit onto an annuloplasty ring implant by virtue of protrusions curving over the ring.	Claim/s 32-39
Invention/s 4	which refer to an apparatus and a method using an apparatus for implantation at an annulus of a mitral valve comprising an expandable frame, an inverted arch expanding from the frame and a flap coupled to the frame and a plurality of longitudinal elements that attach to the flap.	Claim/s 40-48