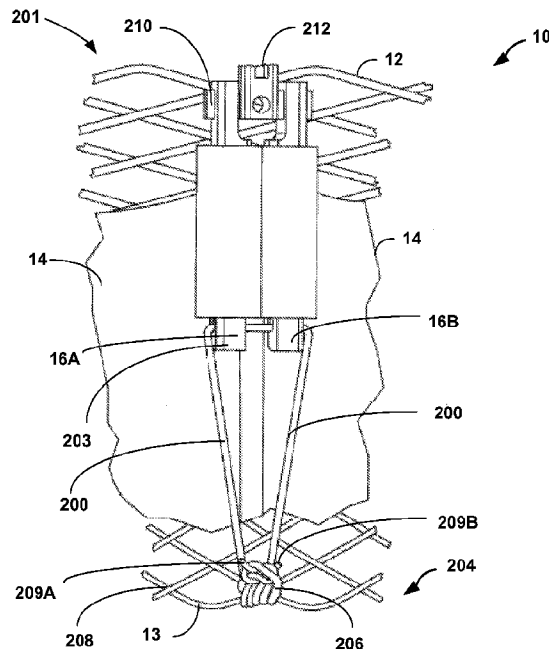




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(54) Title: COUPLING SYSTEM FOR MEDICAL DEVICES



(57) **Abrégé/Abstract:**

Techniques are described for delivering a replacement valve to a target location in a patient. In one example, a medical device system includes an implantable medical device comprising an expandable anchor, a locking member engaged to a first end of the anchor, two posts configured to engage the locking member, each of the posts being engaged to a portion of the anchor, each post defining a hole at a distal end of the post, and a fastening element extending through each hole of a respective post and being engaged to a second end of the anchor, where, in a locked configuration, the posts are secured to the locking member.

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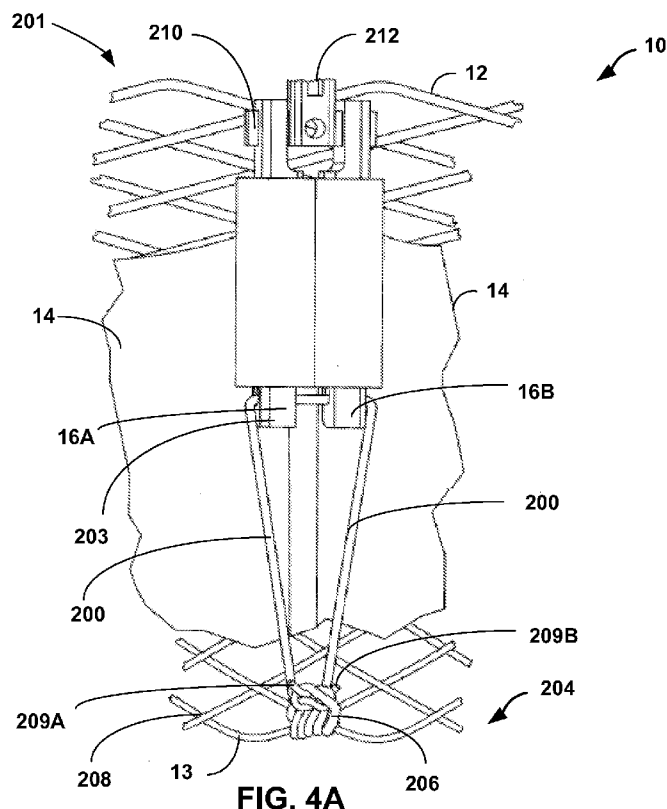
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(54) Title: COUPLING SYSTEM FOR MEDICAL DEVICES



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COUPLING SYSTEM FOR MEDICAL DEVICES

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority to US Provisional Application No. 61/506,845, filed July 12, 2011.

TECHNICAL FIELD

[0001] The disclosure relates to medical devices and, more particularly, to valve replacement devices.

BACKGROUND

[0002] Heart valve surgery is used to repair or replace diseased heart valves. Valve surgery is an open-heart procedure conducted under general anesthesia. An incision is made through the patient's sternum (sternotomy), and the patient's heart is stopped while blood flow is rerouted through a heart-lung bypass machine.

[0003] Valve replacement may be indicated when there is a narrowing of the native heart valve, commonly referred to as stenosis, or when the native valve leaks or regurgitates. When replacing the valve, the native valve is excised and replaced with either a biologic or a mechanical valve. Mechanical valves require lifelong anticoagulant medication to prevent blood clot formation, and clicking of the valve often may be heard through the chest.

[0004] Biologic tissue valves typically do not require such medication. Tissue valves may be obtained from cadavers or may be porcine or bovine, and are commonly attached to synthetic rings.

SUMMARY

[0005] In general, this disclosure describes techniques for delivering a replacement valve to a target location in a patient. The valve can be implantable or can be adapted to be temporarily positioned within the patient. In some examples, the disclosure is directed to techniques for

attaching posts of a post assembly to an expandable anchor of an implantable medical device, e.g., a replacement valve, and systems that utilize those techniques. Various techniques described in this disclosure can transfer the locking load from the post assembly to the anchor during delivery of the medical device. In addition, various techniques described in this disclosure can prevent asymmetric loading of the post assembly, thereby reducing stress on valve leaflets, for example.

[0006] In one example, this disclosure is directed to a medical device system comprising an implantable medical device comprising an expandable anchor, a locking member engaged to a first end of the anchor, two posts configured to engage the locking member, each post being engaged to a portion of the anchor, each post defining a hole at a distal end of the post, and a fastening element extending through each hole of a respective post and being engaged to a second end of the anchor, wherein, in a locked configuration, the posts are secured to the locking member.

[0007] In another example, this disclosure is directed to a coupling system between a delivery system and an expandable anchor of a medical device. The coupling system comprises a locking member engaged to a first end of the anchor, two posts configured to engage the locking member, each post being engaged to a portion of the anchor, each post defining a hole at a distal end of the post, and a fastening element extending through each hole of a respective post and being engaged to a second end of the anchor, wherein, in a locked configuration, the posts are secured to the locking member.

[0008] The details of one or more aspects of the disclosure are set forth in the accompanying drawings and the description below. Other features, objects, and advantages will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF DRAWINGS

[0009] FIG. 1A shows an example replacement heart valve in a deployed and locked configuration.

[0010] FIG. 1B shows an example replacement heart valve in a collapsed and delivery.

[0011] FIG. 2A illustrates an example medical device delivery system reversibly coupled to a medical device, wherein the medical device is in a collapsed configuration.

[0012] FIG. 2B shows an example medical device delivery system reversibly coupled to a medical device, wherein the medical device is in a deployed and locked configuration.

[0013] FIGS. 3A-3G illustrate an example medical device deployment and locking procedure.

[0014] FIG. 4A depicts a front view of a portion of one example configuration of a replacement heart valve, in accordance with various techniques of this disclosure.

[0015] FIG. 4B depicts a side view of the portion of a replacement heart valve shown in FIG. 4A, in accordance with various techniques of this disclosure.

[0016] FIG. 5 shows an example replacement heart valve in a deployed and locked configuration, in accordance with various techniques of this disclosure.

[0017] FIG. 6 depicts a front view of a portion of another example configuration of a replacement heart valve, in accordance with various techniques of this disclosure.

[0018] FIG. 7 depicts a front view of a portion of another example configuration of a replacement heart valve, in accordance with various techniques of this disclosure.

[0019] FIG. 8A depicts an example post having a rounded distal hole, in accordance with various techniques of this disclosure.

[0020] FIG. 8B is a close up view of a portion of FIG. 8A.

[0021] FIG. 9 depicts an example knot that may be used to engage the fastening element to the distal end of the anchor.

DETAILED DESCRIPTION

[0022] This disclosure describes techniques for delivering a replacement valve to a target location in a patient. The valve can be implantable or can be adapted to be temporarily positioned within the patient. In some examples, the disclosure is directed to techniques for attaching posts of a post assembly to an expandable anchor of an implantable medical device and systems that utilize those techniques. In one example implementation, the implantable medical device is a valve that can be locked and unlocked in order to reposition the valve. In particular, the valve includes an expandable anchor, and a post assembly and buckle that can be locked and unlocked as needed to position the valve.

[0023] Using the techniques described in this disclosure and as described in more detail below, a flexible fastening element engaged to the post assembly and anchor can transfer the

locking load (a static load) from the post assembly to the anchor during delivery of the medical device. In addition, the techniques described in this disclosure can prevent asymmetric loading of the post assembly, thereby reducing stress on valve leaflets, for example. Further, the techniques described below reduce sheathing strains in the anchor material, e.g., wire, at the braid attachment point. Sheathing strains are strains that are induced in the anchor material as a result of the valve collapsing into the outer sheath (e.g., sheath 110 of FIG. 2A). Any attachments to anchor material that constrain or prevent the wires from scissoring correctly at the intersections can result in bending of the wires. In accordance with various techniques described in this disclosure, the attachment between the posts and the anchor has been configured to minimize bending of the anchor wires during sheathing at the distal attachment point.

[0024] FIGS. 1A and 1B show replacement heart valve 10 including an expandable anchor 12, also referred to in this disclosure as anchoring element 12, shown comprising anchor material 13 (e.g., braided wire), and replacement valve leaflets 14 (not shown in FIG. 1B for clarity). Leaflets 14 may comprise, for example, treated animal pericardium tissue, e.g., bovine or porcine, or a synthetic material. Anchor 12 may be fabricated by using self-expanding patterns (laser cut or chemically milled), wire braids and materials, such as a stainless steel, nickel-titanium (“Nitinol”) or cobalt chromium but alternatively may be fabricated using balloon-expandable patterns where the anchor is designed to plastically deform to its final shape by means of balloon expansion. Replacement heart valve 10 also includes first locking members 16, also referred to herein as posts, and second locking members 18, also referred to in this disclosure as buckles.

[0025] As shown and described in more detail below, in accordance with this disclosure, each post assembly includes two posts associated with each buckle, and each buckle is engaged to a first end of anchor 12, e.g., a proximal end. Each post defines a hole at the post’s distal end and a flexible fastening element, e.g., a suture, extends through each hole of a respective post and is engaged to a second end of the anchor, e.g., a distal end. The tissue of valve leaflets 14 is squeezed between the two post legs of each post assembly. By utilizing the post assembly and fastening elements described in this disclosure, the forces applied to the anchor during compression from an unlocked state to a locked state, e.g., as the anchor is opened in a calcified annulus (also referred to as the “locking load”) can be

transferred from the post assembly to the second end of the anchor, e.g., anchor 12. In this manner, the fastening element also relieves the valve leaflets of the locking loads.

Transferring the locking load from the post assembly and valve leaflets to the anchor and fastening element may reduce the stress on the valve leaflets, for example, thereby increasing the longevity of the valve.

[0026] FIG. 1A shows anchor 12, in a fully deployed configuration in which anchor 12 is locked and maintained in the deployed configuration by the locking interaction between first locking members 16, e.g., posts, and second locking members 18, e.g., buckles. FIG. 1B shows replacement heart valve 10 in a collapsed delivery configuration in which the replacement heart valve is delivered within a delivery system to a target location within the patient (delivery system not shown).

[0027] In this embodiment, valve leaflets 14 are attached to posts 16 at the valve's three commissures, e.g., commissures 19A-19C. Posts 16 therefore support the valve within the anchoring element. The posts and buckles (or other suitable first and second locking members) are both coupled to the anchor. When the anchoring element 12 is in the collapsed configuration as shown in FIG. 1B, each locking element of posts 16 which is configured to lock with a corresponding locking element of buckles 18 is located distally relative to the locking element of the buckle to which it is adapted to be locked. Stated alternatively, the locking elements of the buckles which are configured to lock to the locking elements of the posts are located proximally to the locking elements of the posts in the delivery configuration.

[0028] FIGS. 2A and 2B illustrate an exemplary embodiment of a delivery system 100 and components thereof which can be used to deliver and deploy a medical device at a target location in a patient. Delivery system 100 includes handle 120, sheath 110, catheter 108 disposed with sheath 110, and actuation elements 106A and 106B which are reversibly coupled to replacement heart valve 10. In FIG. 2A, heart valve 10 is in a collapsed delivery configuration (also shown in FIG. 1B) within sheath 110. Delivery system 100 also includes guidewire G and nosecone 102. In some embodiments catheter 108 has central lumen 109 and a plurality of circumferentially disposed lumens Lu.

[0029] In FIGS. 2A and 2B, the plurality of actuation elements 106A are shown reversibly coupled to a proximal region of anchoring element 12. Specifically, actuation elements

106A are reversibly coupled to the proximal end of the anchoring element 12 via a reversible coupling mechanism. Actuation elements 106B are reversibly coupled to a region of the replacement heart valve distal to the proximal end of the anchoring element. Specifically, actuation elements 106B are shown reversibly coupled to posts 16 via a reversible coupling mechanism. Details of this and similar embodiments can be found in U.S. Patent Publication Nos. 2005/0137686 and U.S. Patent No. 7,959,666.

[0030] In the embodiments shown in FIG. 1A-2B, anchoring element 12 comprises a braided material, such as Nitinol, and is formed of one or more strands of material. In one embodiment, the anchoring element 12 is formed of a shape memory material and is heat set in a self-expanded configuration, such that when the anchoring element is deployed from the sheath of the delivery system, the braid will begin to naturally begin to shorten and expand from the collapsed delivery configuration to the memory self-expanded configuration. The self-expanded configuration can be thought of as an at-rest or partially deployed configuration, and is described in more detail in U.S. Patent Publication No. 2005/0137686 and U.S. Patent No. 7,959,666. Once the anchoring element has expanded to the partially deployed configuration, at least one of the actuators 106A and 106B is actuated via an actuator on a handle disposed external to the patient. As is described in more detail in U.S. Patent Publication No. 2005/0137686 and U.S. Patent No. 7,959,666, actuators 106B can be actuated in the proximal direction relative to the actuation elements 106A, which applies a proximally directed force to the posts, which applies a proximally directed force to a distal region of the anchoring element. Actuators 106A can, alternatively or in addition to the proximally directed force, be actuated in a distal direction to apply a distally directed force on a proximal region of the anchoring element. The axially directed forces actively foreshorten the anchoring element, moving the posts closer to the buckles until the posts and buckles lock together to lock the anchoring element in a fully deployed and locked configuration. The locked configuration is therefore shorter than the partially-deployed configuration.

[0031] FIGS. 3A-3G illustrate an exemplary method of delivering a replacement aortic heart valve in a delivery configuration and deploying it from a delivery sheath to a fully deployed and locked configuration. In this embodiment actuation elements 106B are reversibly

coupled to the posts of the replacement valve, but actuation elements 106A, which may also be referred to herein as “fingers,” are reversibly coupled to the buckles. There are three actuation elements 106A reversibly coupled to the three buckles, and there are three actuation elements 106B reversibly coupled to each set of posts. As seen in FIG. 3A, replacement valve 10 is delivered in a collapsed delivery configuration within sheath 110 in a retrograde fashion through aorta A over guidewire G and placed across a patient’s aortic valve using known percutaneous techniques.

[0032] Once sheath 110 is positioned across the native valve as shown in FIG. 3A, sheath 110 is retracted proximally relative to the replacement valve using an actuator on the delivery system handle which is disposed external to the patient (examples of which are described in detail below). As the sheath is withdrawn, as seen in FIG. 3B, the distal portion of anchoring element 12 begins to self-expand due to the material properties of the anchoring element. The anchoring element can have a memory self-expanded configuration such that as the sheath is withdrawn the anchor begins to self-expand, or return to its memory configuration. As the sheath continues to be retracted proximally, the anchoring element continues to self-expand, as shown in FIGS. 3C and 3D. In FIG. 3E the sheath has been retracted proximally such that the distal end of the sheath is disposed proximal to the distal end of fingers 106A. In FIG. 3E the sheath is not retracted far enough proximally to allow the fingers to self-expand. As such, although the anchoring element is completely out of the sheath, the proximal end of the anchor does not expand towards its memory configuration. Only after the sheath has been retracted past the distal end of catheter 108 can the fingers fully self-expand, as is shown in FIG. 3F. This allows the proximal end of the anchoring element to expand.

[0033] The anchoring element is then actively foreshortened (and potentially further expanded) to the fully deployed and locked configuration shown in FIG. 3G by the application of axially directed forces (proximally and distally directed). To actively foreshorten the anchoring element, a proximally directed force is applied to posts via actuation elements 106B (not shown in FIGS. 3A-3G but which are coupled to the posts), and/or a distally directed force is applied to buckles via actuation elements 106A. In one embodiment a proximally directed force is applied to posts through actuation elements 106B, and fingers 106A are held in position to apply a distally directed force to the buckles. This

active foreshortening causes the posts and buckles to move axially closer to one another until they lock together, which maintains the anchoring element in a fully deployed and locked configuration in FIG. 3G. The actuation elements 106A and 106B are then uncoupled released from the buckles and posts, respectively, and the delivery system is then removed from the patient. The details of exemplary locking processes and release processes are described in detail below. Additional details of delivery, deployment, locking, and release processes that may be incorporated into this and other embodiments can be found in U.S. Patent Publication No. 2005/0137699, filed Nov. 5, 2004, U.S. Patent Publication No. 2007/0203503, filed Feb. 14, 2007, and U.S. Patent Publication No. 2005/0137697, filed Nov. 21, 2004.

[0034] FIGS. 4A and 4B depict a front view and a side view, respectively, of a portion of one example configuration of a replacement heart valve, in accordance with various techniques of this disclosure. FIGS. 4A and 4B will be described together for purposes of conciseness. FIG. 4A depicts two first locking members, namely posts 16A and 16B of a post assembly, engaged to a portion of anchor 12 and a second locking member, namely buckle 18, engaged to a first end of anchor 12. FIG. 4A further depicts flexible fastening element 200 extending through a hole (hole 202 of FIG. 4B) in each respective post 16A, 16B (collectively referred to as “posts 16”) and being engaged to a distal end of anchor 12, shown generally at 204. In one example, fastening element 200 is looped through a hole (shown at 202 in FIG. 4B) at distal end 203 of each post 16A, 16B and engaged via knot 206 to a braid intersection at a distal end of anchor 12 (near the inflow of valve 10 at the commissure). An example braid intersection of anchor 12 is depicted at 208. The braid intersection at which knot 206 is attached may be referred to as a braid attachment point. In the example configuration shown in FIG. 4A, fastening element 200 comprises first end 209A and second end 209B, where the first end and the second end are secured together, e.g., tied together in a knot, about one of the braid intersections at the distal end of the anchor.

[0035] As seen in FIG. 4A, posts 16A and 16B are independent parts and slide on rail 210 of post top 212. Post top 212 is configured to engage buckle 18, thereby securing posts 16 to buckle 18 in a locked configuration of valve 10, as depicted in FIG. 4B. Posts 16A, 16B, buckle 18, and fastening element form a coupling system between a delivery system for valve 10 (shown generally at 218 in FIG. 5) and expandable anchor 12.

[0036] The two posts 16A, 16B squeeze leaflets 14 together at the commissure. A two-post configuration, as in FIG. 4A, distributes the leaflet closure load (a dynamic load) created during opening and closing of valve 10 along the length of each post 16A, 16B, in accordance with certain techniques of this disclosure.

[0037] As mentioned above, engaging fastening element 200 to the post assembly and distal end 204 of anchor 12 can transfer the locking load from the post assembly to anchor 12 during delivery of the medical device, e.g., valve 10. In addition, the techniques described in this disclosure can equalize tension on both sides of the post assembly, e.g., tension self-equalizes on either side of the post assembly, which prevents asymmetric loading of the post assembly. Equalizing tension can reduce stress on valve leaflets, for example, thereby improving valve leaflet longevity. Further, when valve is opening and closing in vivo, fastening element 200 shares a component of the load, which also reduces the stress on the valve leaflets and increases device longevity.

[0038] FIG. 5 shows an example replacement heart valve in a deployed and locked configuration, in accordance with various techniques of this disclosure. As shown in the example configuration of FIG. 5, posts 16A and 16B are engaged to a portion of anchor 12 and a second locking member, namely buckle 18, is engaged to a first end of anchor 12. Posts 16A, 16B extend only partially along longitudinal length L of anchor 12, and fastening element 200 extends from a hole in the distal end of a respective post and attaches to an inflow end of valve 10, shown generally at 216. That is, rather than extend each post the entire length L of anchor 12 to inflow end 216 of valve 10, posts 16 in the example configuration of FIG. 5 extend part way, with flexible fastening element 200 extending between posts 16 and inflow end 216 of valve 10 and tied via knot 206 to the distal end of anchor 12. Such a configuration provides for more flexibility of the post assembly by allowing the post assembly and, in particular, fastening element 200, to move as the valve changes shape during positioning. In addition, use of flexible fastening element 200 allows the braid length to be set by tuning the length of the fastening element.

[0039] In some examples, fastening element 200 is comprised of a suture material. In one example, fastening element 200 may comprise a monofilament suture. In another example, fastening element 200 may comprise a braided suture. In some examples, fastening element 200 may comprise a polyethylene material, e.g., a high molecular weight polyethylene

material. One example fastening element 200 that may be used to implement certain techniques of this disclosure is Force Fiber[®] suture, available from Teleflex Medical OEM, which is a braided, ultra-high molecular weight polyethylene suture. Such a fastening element is strong and abrasion resistant and may provide a minimum tensile strength of about 15 pounds-force (lbf). Of course, fastening elements that comprise other materials may be used, e.g., polymers such as polyester, or other synthetic material.

[0040] FIG. 5 further depicts a delivery system in combination with replacement valve 10. The delivery system, shown generally at 218, includes catheter 220, actuator retaining elements 222, actuation elements 224, and collar 226. In some examples, this disclosure is directed to a coupling system for coupling delivery system 218 to anchor 12. In one configuration, posts 16A, 16B, buckle 18, and fastening element form the coupling system between delivery system 218 and anchor 12.

[0041] For purposes of conciseness, only some of the features of delivery system 218 of FIG. 5 have not been described. Additional features with respect to delivery system 218 of FIG. 5 are shown and described in more detail with respect to FIG. 4 in U.S. Patent Application Publication No. 2010/0280495. In addition, other example features of valve 10 are shown and described in WO 2005/062980.

[0042] In accordance with this disclosure, fastening element 200 may be engaged to the second end of anchor 12 in various ways. In the example configuration shown in FIG. 5, fastening element 200 comprises a first end and a second end, where the first end and the second end are secured together, e.g., tied together in a knot, about one of the braid intersections at the distal end of the anchor. Other configurations are possible, however, and are described below with respect to FIGS. 6 and 7.

[0043] FIG. 6 depicts a front view of a portion of another example configuration of a replacement heart valve, in accordance with various techniques of this disclosure. In FIG. 6, fastening element 200 comprises first end 209A and second end 209B, where first end 209A and second end 209B are secured together, e.g., tied together in knot 206, between posts 16A and 16B. Fastening element 200 is looped around a braid intersection at distal end 204 of anchor 12.

[0044] FIG. 7 depicts a front view of a portion of another example configuration of a replacement heart valve, in accordance with various techniques of this disclosure. In FIG. 7, fastening element 200 comprises first end 209A and second end 209B, where first end 209A is secured to distal end 204 of anchor 12 about a first intersection, e.g., tied in knot 206A, and where second end 209B is secured to distal end 204 of anchor 12 about a second intersection e.g., tied together in knot 206B, at distal end 204 of anchor 12. To minimize wear, fastening element 200 may be secured to distal end 204 of anchor 12 and not to an intermediate portion of anchor 12, e.g., an intersection located between the distal end of anchor 12 and the distal end of a post.

[0045] In some example configurations, rather than use a fastening element that extends from a hole in the distal end of each post of a post assembly to the distal end of anchor 12 (as shown in FIG. 5), one or more fastening elements, e.g., a Nitinol wire, may be woven through the hole in the distal end of each post of a post assembly and into anchor 12. In one example, the fastening element(s) are separate elements from anchor 12. In other words, the fastening elements are added to secure posts 16 to anchor 12 after anchor 12 has been formed. In another example, the fastening element(s) are not separate elements from anchor 12. The fastening elements are, for example, the braided wire used to form anchor 12 and posts 16 are secured to anchor 12 during the process of forming anchor 12 rather than after anchor 12 has been formed.

[0046] In another example configuration, rather than using a suture as fastening element 200, a wire, e.g., Nitinol wire, may be used as fastening element 200. For example, fastening element 200 of FIG. 4A may be a wire instead of a suture. In one example, ends 209A, 209B of wire fastening element 200 may be threaded through distal holes of each respective post 16A, 16B twice to form loops about distal ends 203 in order to secure fastening element 200 to posts 16.

[0047] In one example configuration, fastening element 200, e.g., a suture, may be covered by fabric cloth, e.g., polyester. The fabric cloth may reduce wearing of the suture on the wires of anchor 12.

[0048] In another example configuration, fastening element 200 may comprise a spring. The spring may extend part of the way between the distal end of a post and the distal end of anchor 12. The fastening element and spring may be designed, e.g., length and spring

constant, in order to provide an appropriate length for anchor 12 and an appropriate locking force in a locked configuration.

[0049] FIG. 8A depicts an example post defining a rounded distal hole, in accordance with various techniques of this disclosure. In particular, FIG. 8A depicts post 16 defining distal hole 202, where distal hole 202 is partially defined by a curved portion.

[0050] FIG. 8B depicts a close up view of a portion of the post depicted in FIG. 8A. As seen in FIG. 8B (an enlarged portion of post 16 in FIG. 8A), a portion of outer surface 218 of post 16 defines curved portion 221 around distal hole 202, where curved portion 221 and distal hole 202 are collectively referred to as a rounded distal hole. The curvature of curved portion 221 may be defined by a radius of curvature. By providing curved portion 221 to distal hole 202 (as compared to hole 222 of FIG. 8B which does not have a curved portion), frictional wear between fastening element 200 (as shown, for example, in FIGS. 4A and 4B) and post 16 may be reduced, thereby increasing longevity of valve 10.

[0051] FIG. 9 depicts an example knot that may be used to engage the fastening element to the distal end of the anchor. Using knot 206 shown in FIG. 9, as fastening element 200 is routed from the distal end of anchor 12 to posts 16, knot 206 pushes fastening element 200 away from anchor 12 so that fastening element 200 does not run along the braid intersections of anchor 12. In other words, the design of knot 206 provides some clearance between the material of anchor 12, e.g., moving braid intersections, and fastening element 200, which reduces wear on fastening element 200 and improves device longevity. In addition, in some example configurations, the configuration of knot 206 reduces the sheathing profile. For example, knot 206 may include square knot 230 that rests in a gap, e.g., gap 232, between wires 13 of anchor 12, rather than on top of an intersection 208. Such a configuration may allow the valve to consistently collapse into a smaller outer sheath.

[0052] As described above, the techniques of this disclosure can transfer the locking load from the post assembly to the anchor during delivery of the medical device. In addition, the techniques described in this disclosure equalize tension on either side of the post legs. Equalizing tension prevents asymmetric loading of the post assembly, thereby reducing stress on valve leaflets and improving device longevity. Further, the techniques described above reduce the sheathing strains in the wire of the anchor at the braid intersection point.

[0053] The above disclosure is intended to be illustrative and not exhaustive. The description will suggest many variations and alternatives to those of ordinary skill in the art. All of these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached hereto.

CLAIMS:

1. A medical device system comprising:
an implantable medical device comprising an expandable anchor;
a locking member engaged to a first end of the anchor;
two posts, each post being engaged to a portion of the anchor, each post defining a hole at a distal end of the post; and
a fastening element extending through each hole of a respective post and being engaged to a second end of the anchor,
wherein, in a locked configuration, the posts are secured to the locking member.
2. The system of claim 1, wherein the implantable medical device is a replacement valve, the system further comprising:
at least two valve leaflets, each of the at least two valve leaflets engaged to a respective one of the two posts.
3. The system of claim 1, wherein each hole is further defined by a radius of curvature.
4. The system of claim 1, wherein the fastening element comprises a braided suture.
5. The system of claim 4, wherein the braided suture comprises polyethylene.
6. The system of claim 1, wherein the fastening element comprises a spring.
7. The system of claim 1, wherein the expandable anchor comprises a braided wire, the braided wire comprising a plurality of intersections.
8. The system of claim 7, wherein the fastening element comprises a first end and a second end, and wherein the first end and the second end are secured together about one of the plurality of intersections at the distal end of the anchor.

9. The system of claim 8, wherein the first end and the second end are secured together about one of the plurality of intersections at the distal end of the anchor by a knot.
10. The system of claim 7, wherein the fastening element comprises a first end and a second end, wherein the first end is secured to the distal end of the anchor about a first one of the plurality of intersections, and wherein the second end is secured to the distal end of the anchor about a second one of the plurality of intersections at the distal end of the anchor.
11. The system of claim 1, wherein the expandable anchor has an unexpanded state and an expanded state, wherein in the expanded state the expandable anchor has a length, wherein in the expanded state the two posts engage the locking member, and wherein in the expanded state the combination of the locking member and the two posts extends along only a portion of the length of the expandable anchor.
12. A coupling system between a delivery system and an expandable anchor of a medical device, the coupling system comprising:
- a locking member engaged to a first end of the anchor;
 - two posts configured to engage the locking member, each of the posts being engaged to a portion of the anchor, each post defining a hole at a distal end of the post; and
 - a fastening element extending through each hole of a respective post and being engaged to a second end of the anchor,
- wherein, in a locked configuration, the posts are secured to the locking member.
13. The system of claim 12, wherein the expandable anchor comprises a braided wire, the braided wire comprising a plurality of intersections, wherein the fastening element comprises a first end and a second end, and wherein the first end and the second end are secured together about one of the plurality of intersections at the distal end of the anchor.
14. The system of claim 12, wherein each hole is further defined by a radius of curvature.

15. The system of claim 12, wherein the fastening element comprises a braided suture, and wherein the braided suture comprises polyethylene.

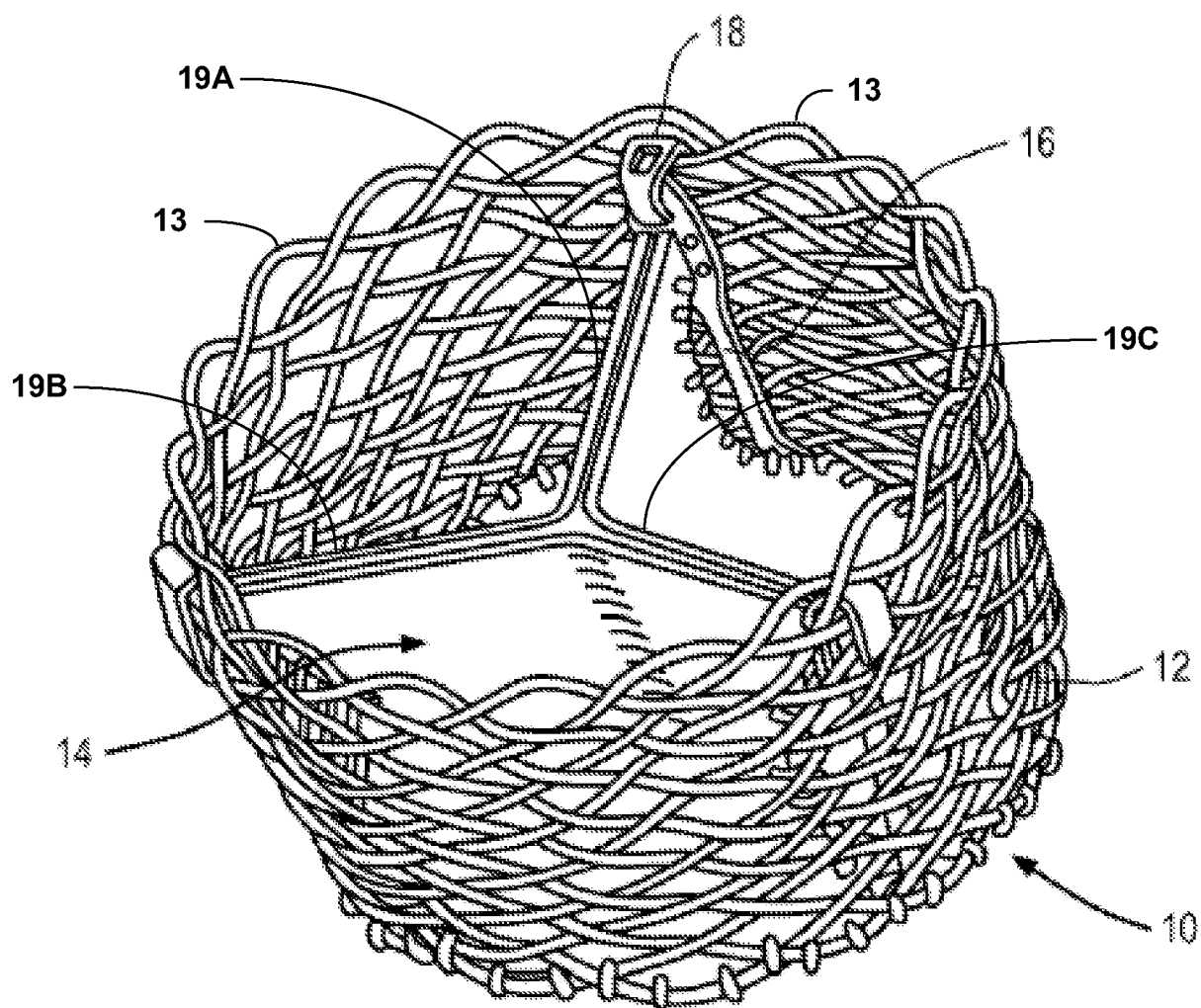
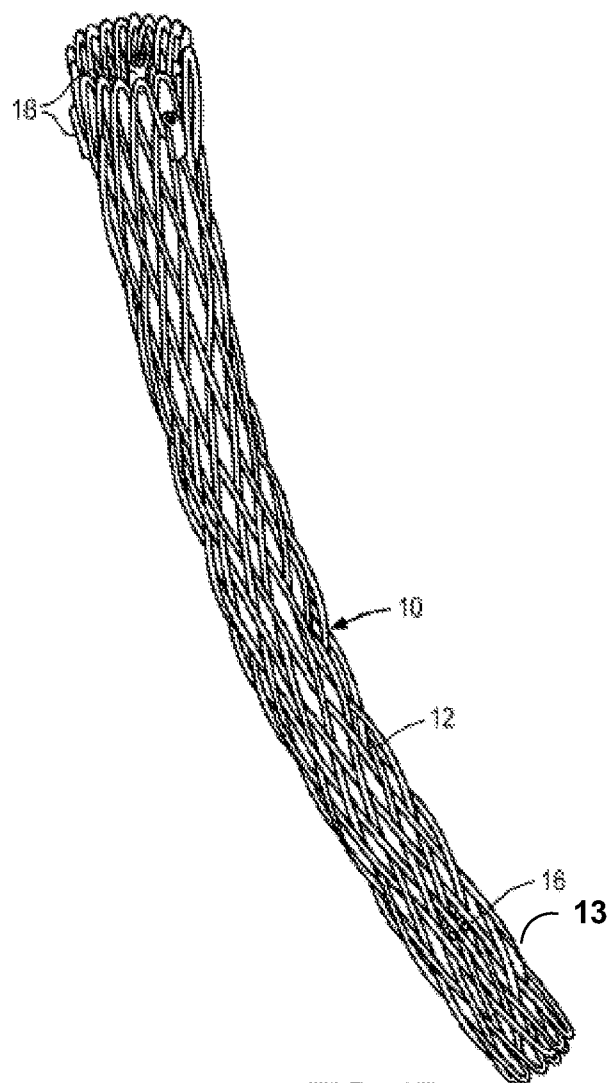
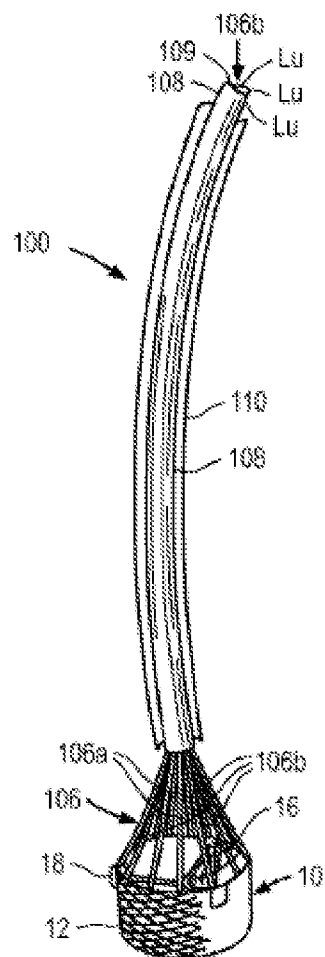


FIG. 1A



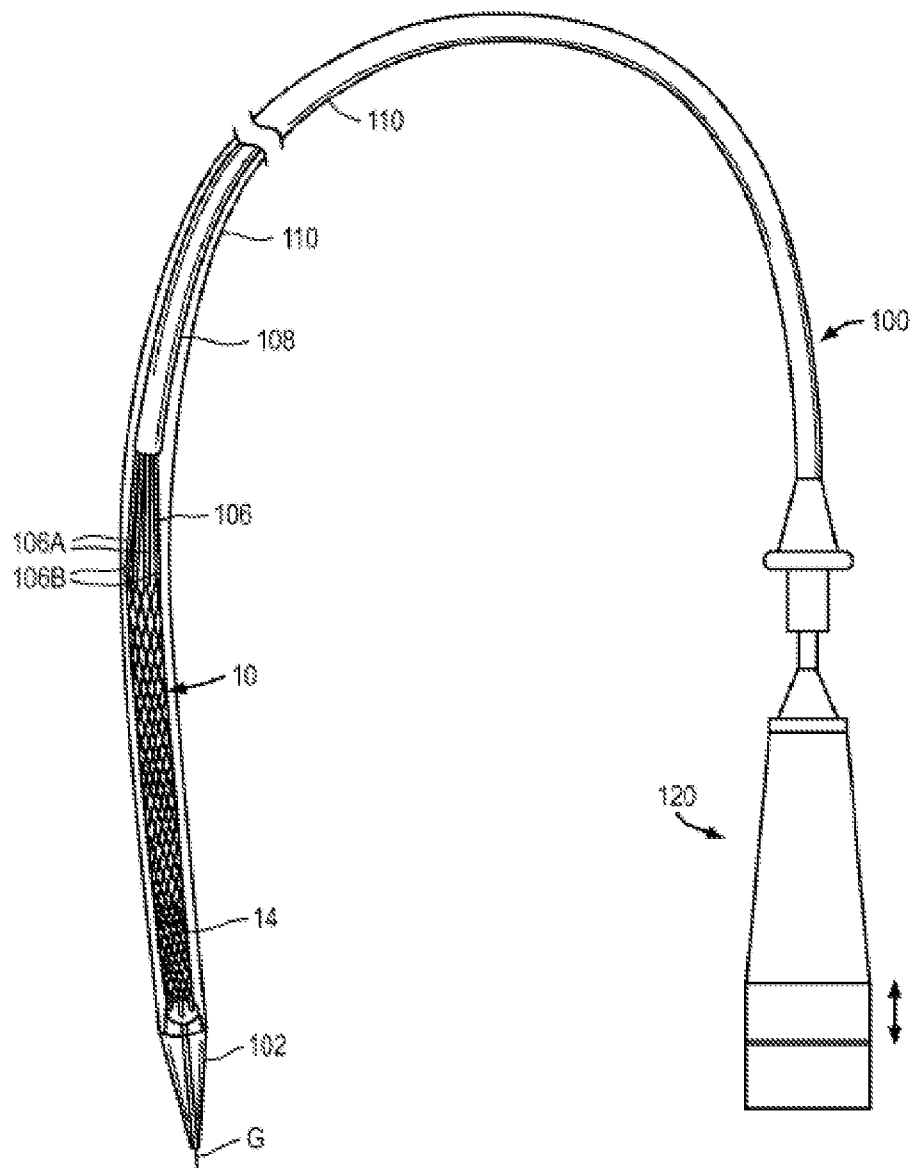


FIG. 2A

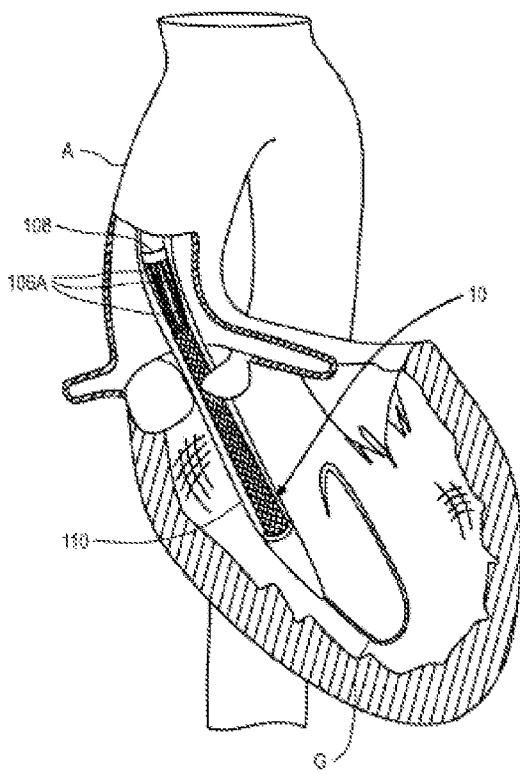


FIG. 3A

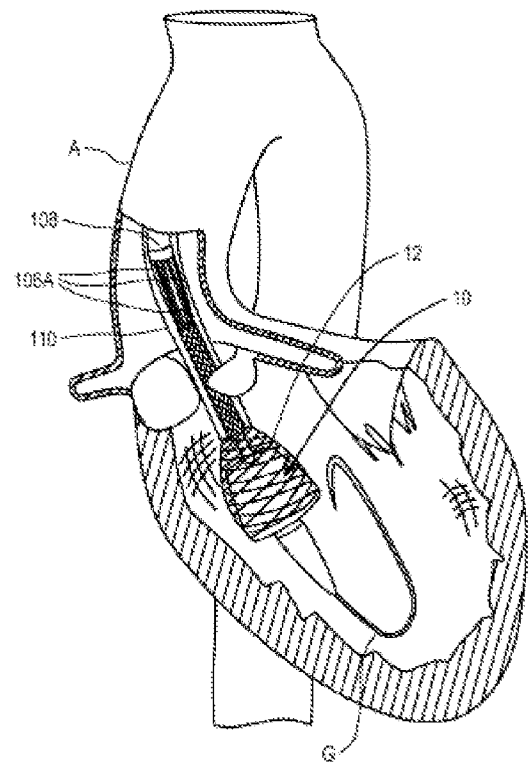


FIG. 3B

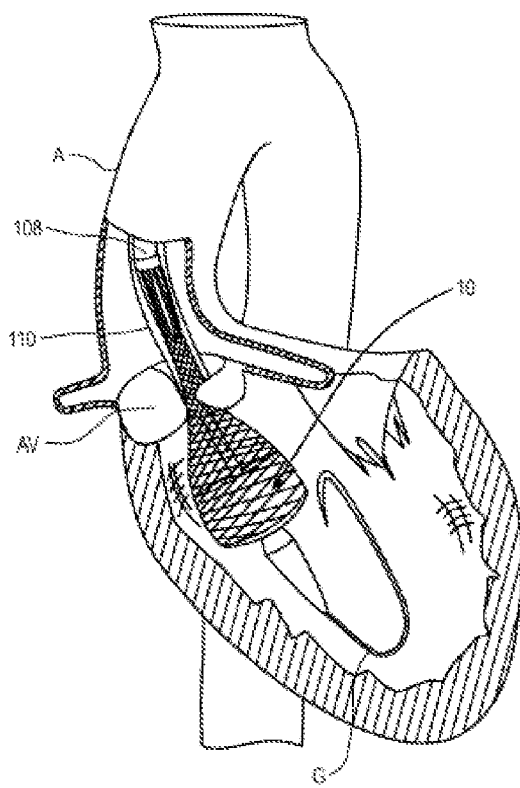


FIG. 3C

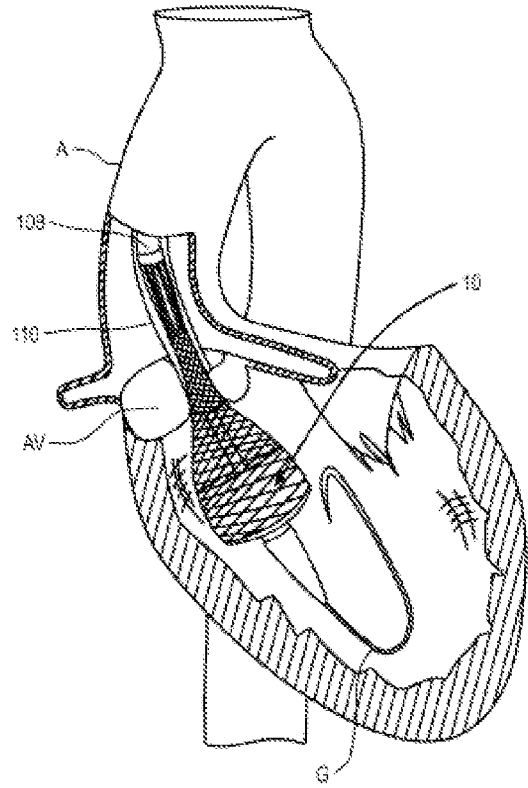


FIG. 3D

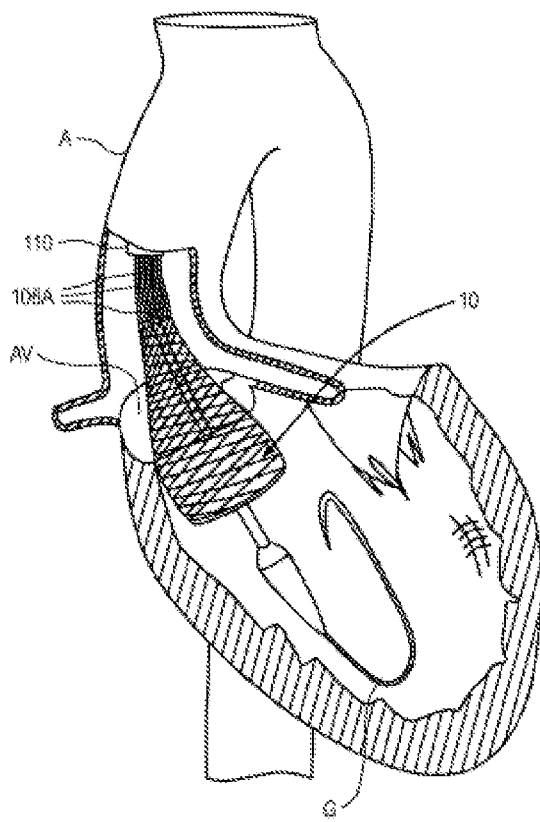


FIG. 3E

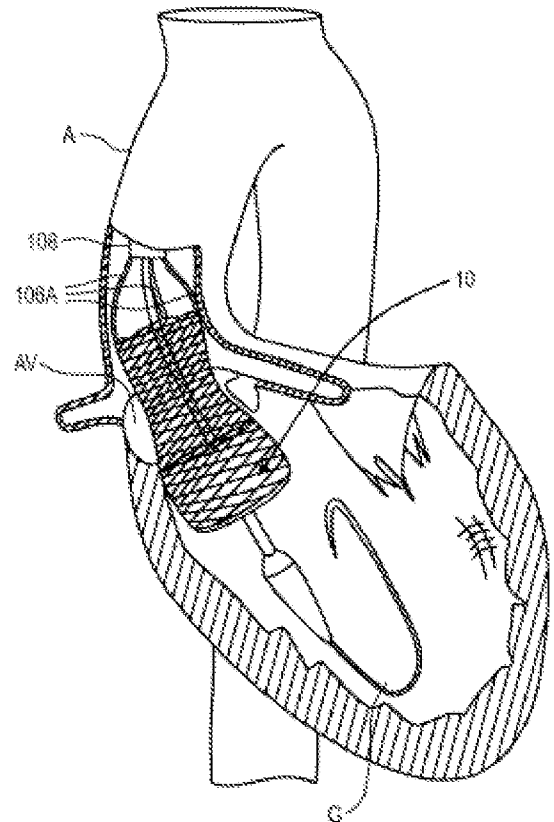


FIG. 3F

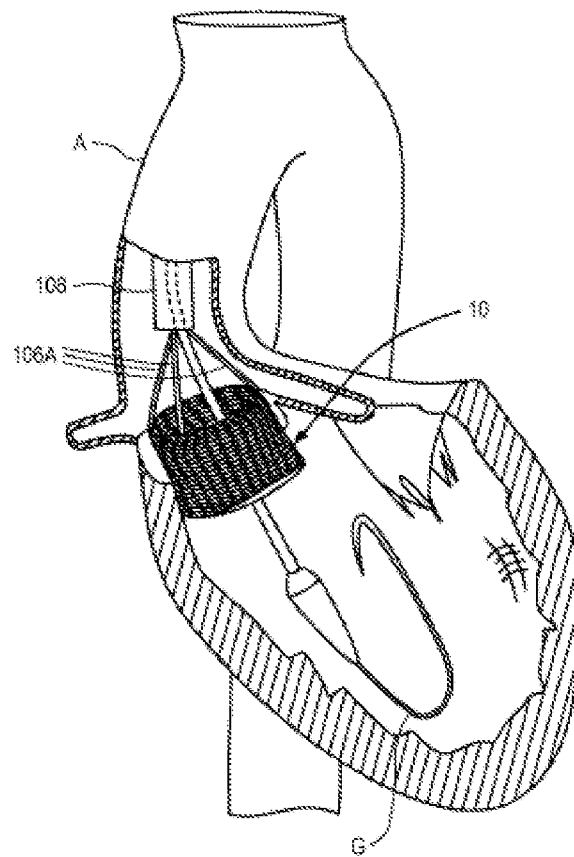
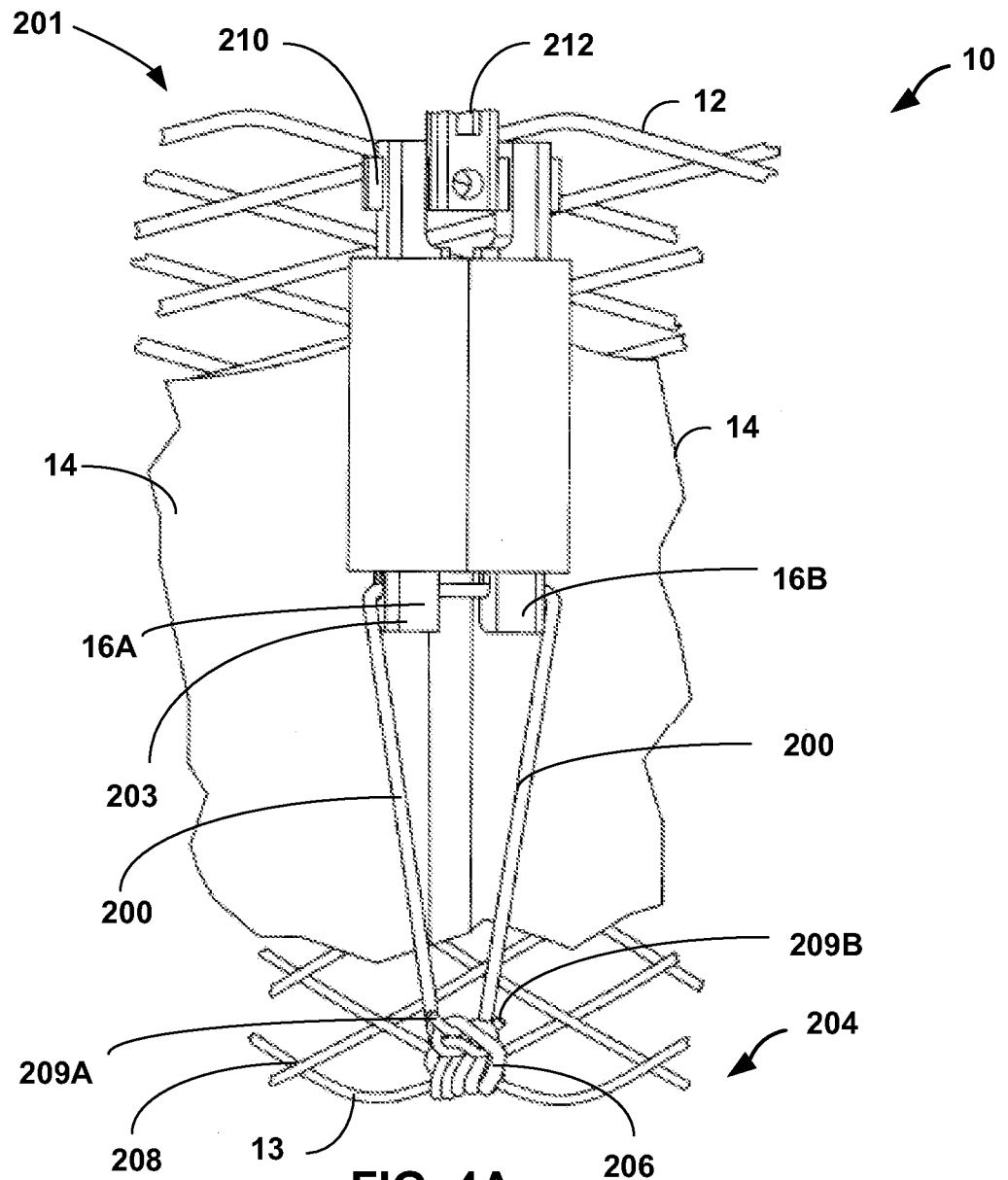


FIG. 3G

**FIG. 4A**

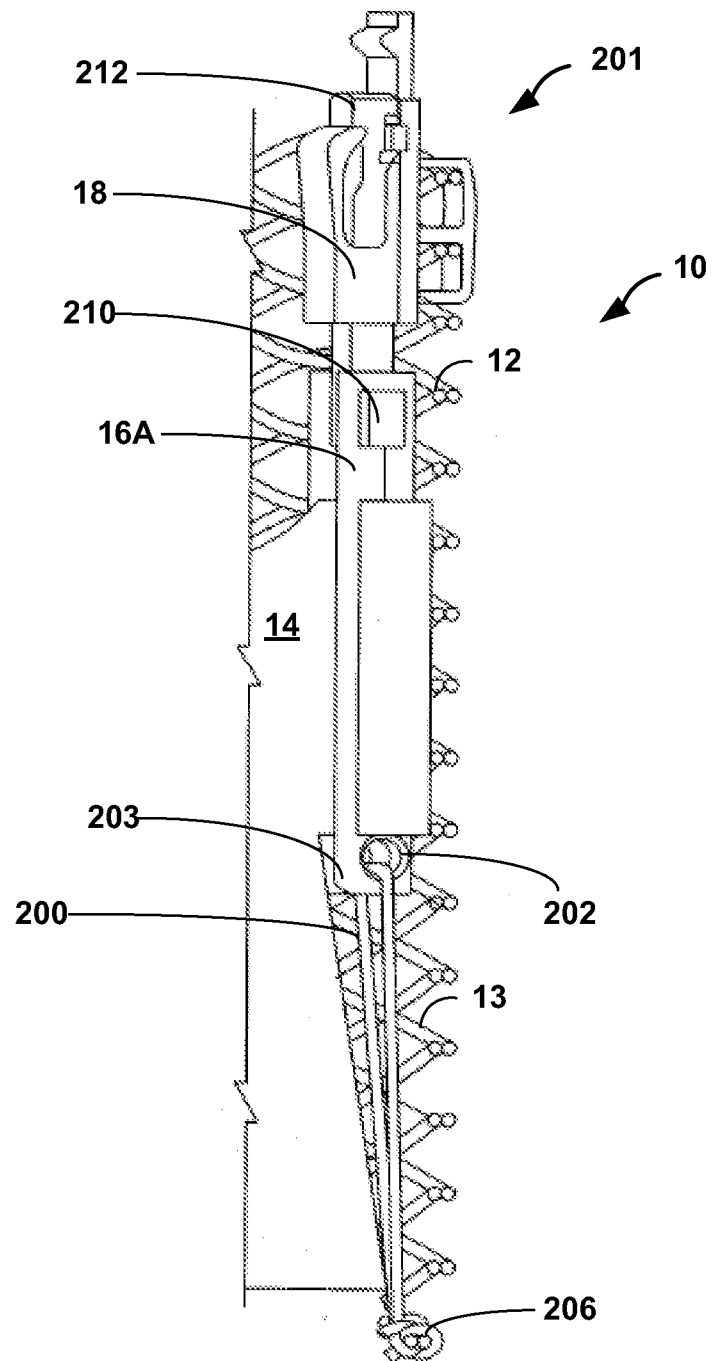


FIG. 4B

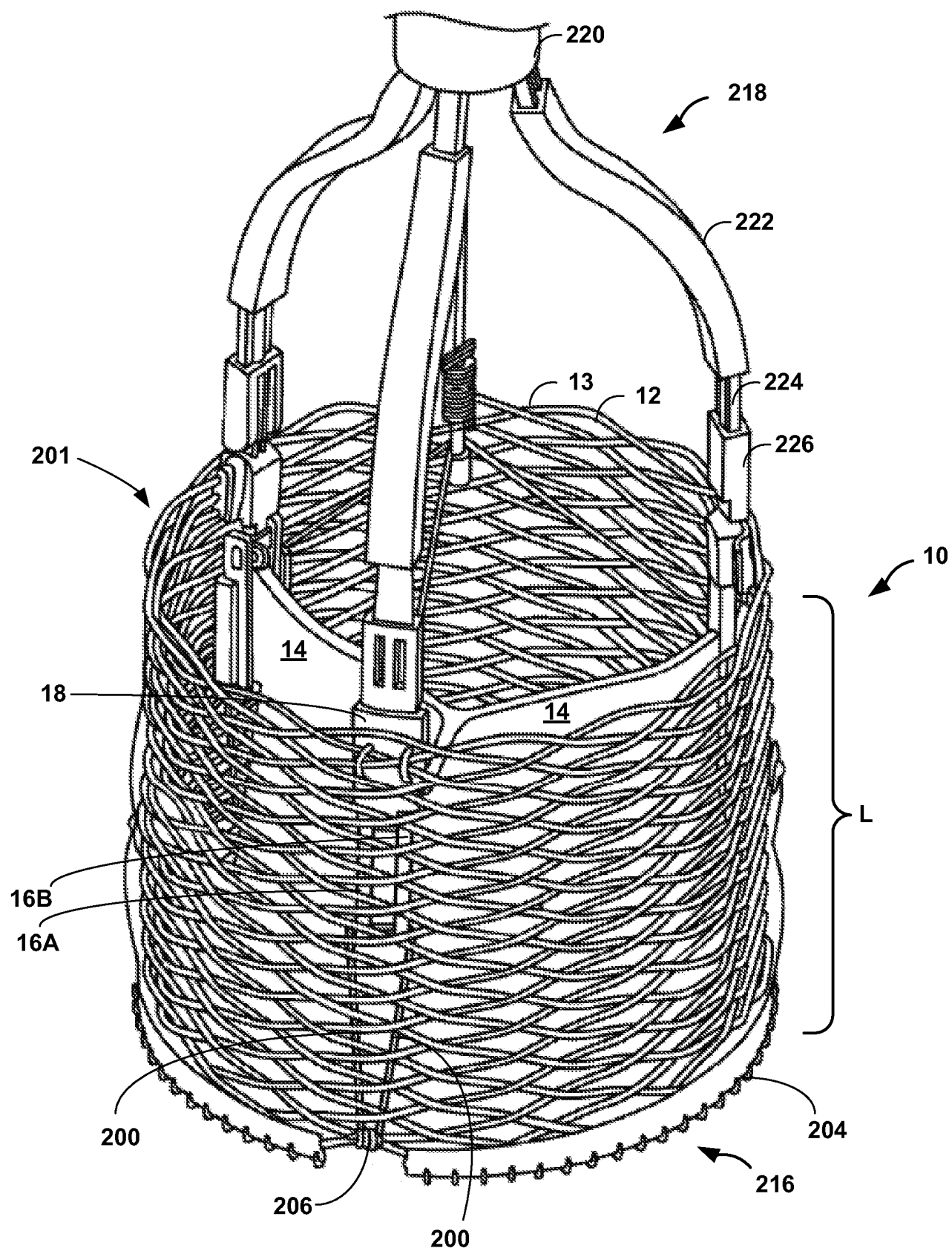


FIG. 5

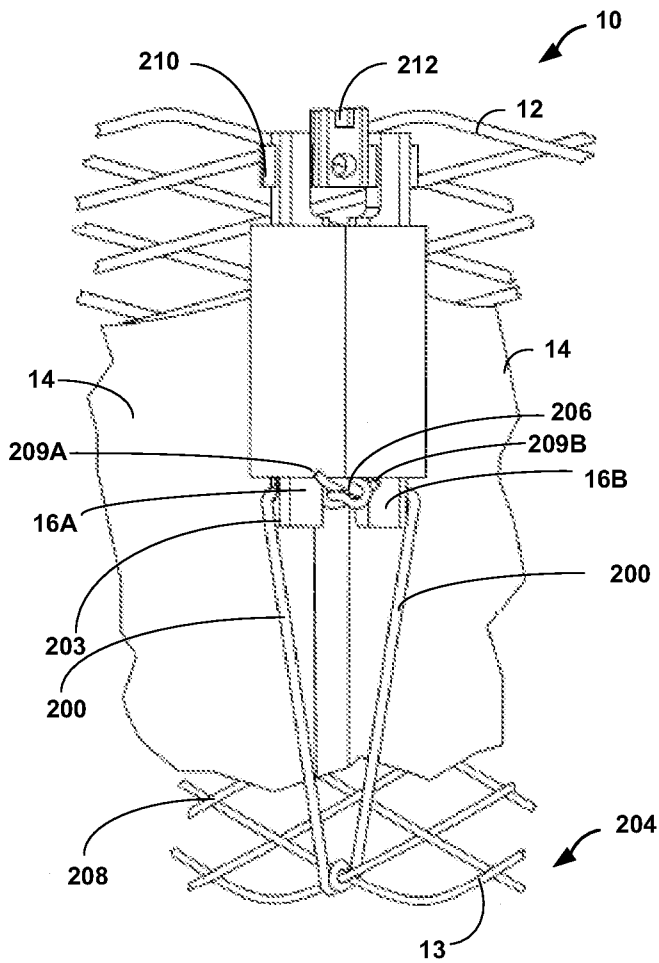


FIG. 6

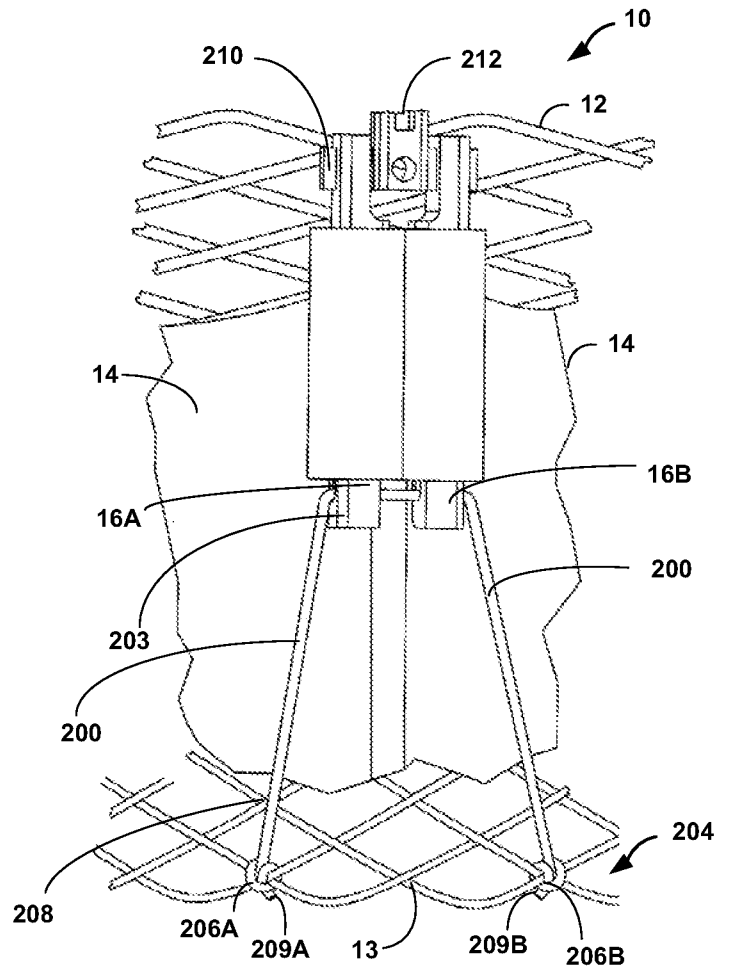


FIG. 7

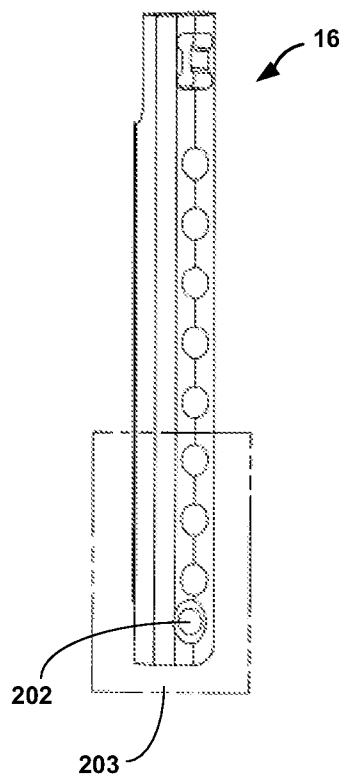


FIG. 8A

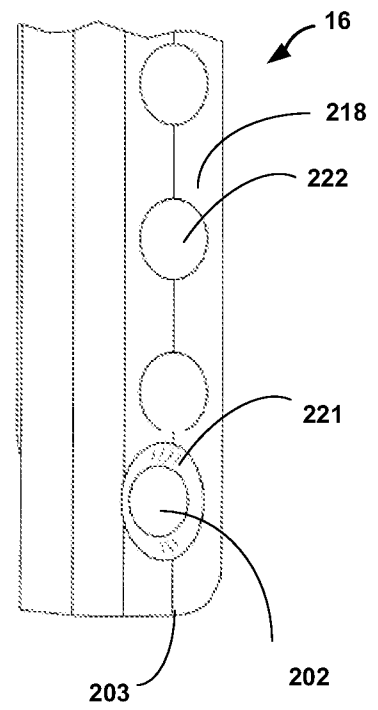
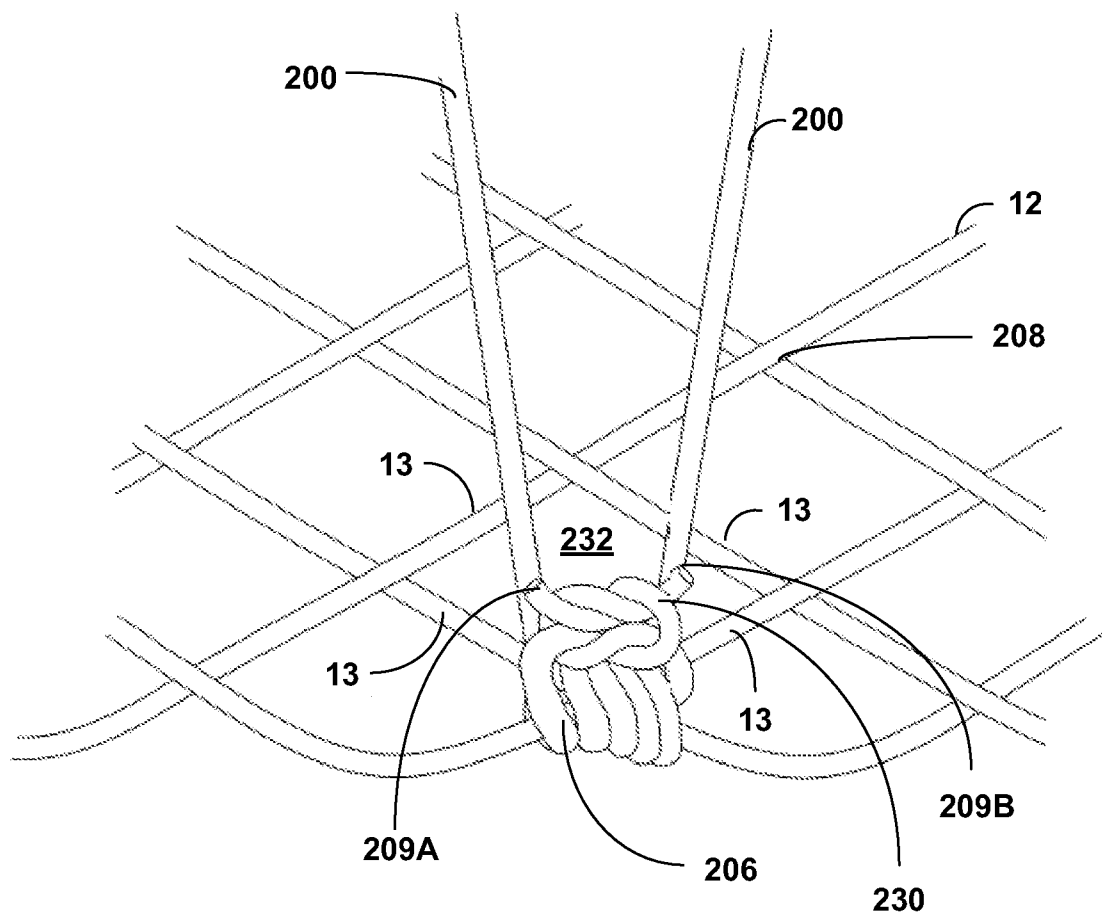


FIG. 8B

**FIG. 9**

