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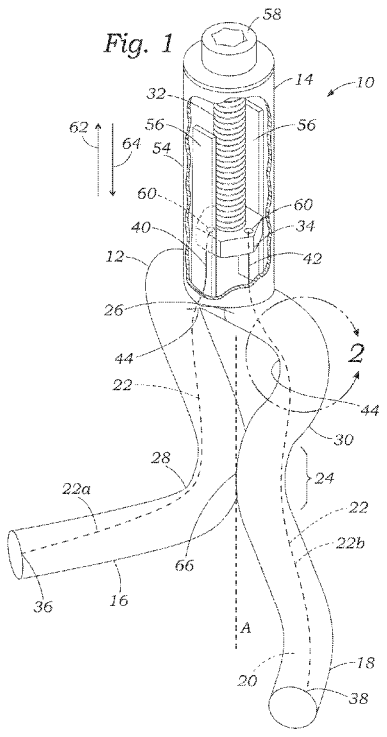
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(57) Abstract: Embodiments of a leaflet clip device and method of reducing regurgitation through a native heart valve are disclosed. A leaflet clip device can include an elongated clipping member having a first end portion and a second end portion and a tensioning mechanism coupled to the clipping member. The leaflet clip device can further include one or more tensioning members disposed within a lumen of the clipping member, wherein the one or more tensioning members are operatively connected to the tensioning mechanism to transform the clipping member from a delivery configuration to an implantation configuration.

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DEVICE AND METHOD FOR TREATING VASCULAR INSUFFICIENCY

FIELD

[001] This disclosure relates to devices and methods of treating heart valve insufficiency.

BACKGROUND

[002] Heart valve insufficiency typically involves regurgitation of blood through a heart valve that is unable to close completely or properly, resulting in impaired cardiovascular function. Valvular insufficiency can affect, for example, the mitral valve, the aortic valve, or the tricuspid valve, and can be associated with calcified or prolapsed leaflets, and/or expansion or deformation of the valve annulus. One method of treating heart valve insufficiency is to employ one or more leaflet clips to improve coaptation of the native valve leaflets. However, conventional leaflet clips can be difficult to implant, can interfere with the function of or damage associated valve structures such as chordae, and are frequently limited to use with a single type of heart valve. Accordingly, improvements to devices and methods of treating heart valve insufficiency are desirable.

SUMMARY

[003] An exemplary embodiment of a leaflet clip device can comprise an elongated clipping member having a first end portion and a second end portion and a tensioning mechanism coupled to the clipping member. The leaflet clip device can further comprise one or more tensioning members disposed within a lumen of the clipping member, wherein the one or more tensioning members are operatively connected to the tensioning mechanism to transform the clipping member from a delivery configuration to an implantation configuration. Some embodiments of the clip device may further comprise a retaining mechanism disposed within the lumen of the clipping member, wherein the retaining mechanism retains the shape of the clipping member in the implantation configuration.

[004] In some embodiments of the clip device, the clipping member can compromise a shape memory material. Additionally and/or alternatively, the tensioning mechanism can be centrally coupled to the clipping member with respect to the first end and the second end. In some embodiments, the one or more tensioning members can comprises a first tensioning member fixed at a distal end portion thereof to the first end portion of the clipping member and operatively connected to the tensioning mechanism at a proximal end portion of the first tensioning member, and a second tensioning member fixed at a distal end portion thereof to the second end portion of the clipping member and operatively connected to the tensioning mechanism at a proximal end portion of the second tensioning member. In some embodiments of the clip device, rotation of at least a portion of the tensioning mechanism can cause tensioning of the one or more tensioning members.

[005] In some embodiments of the clip device, the implantation configuration can comprise a primary clipping region defined between two leg portions of the clipping member. Additionally and/or alternatively, the tensioning mechanism can comprise a retaining mechanism configured to retain the clipping member in the implantation configuration. Additionally and/or alternatively, the one or more tensioning members can extend through a portion of the tensioning mechanism. Additionally and/or alternatively, the one or more tensioning members are fixed at one end to a portion of the tensioning mechanism.

[006] Additionally and/or alternatively, an exemplary leaflet clip device can comprise a clipping member comprising a tubular body having a lumen and two leg portions, wherein the clipping member can be transformed between a substantially linear delivery configuration and an implantation configuration in which the leg portions are drawn toward each other to capture a pair of leaflets between the leg portions and a tensioning mechanism configured to transform the clipping member from the delivery configuration to the implantation configuration. Additionally and/or alternatively, the clip device can further comprise one or more cords disposed within the lumen of the clipping member, wherein the one or more cords are operatively connected to the tensioning mechanism to

transform the clipping member from the delivery configuration to the implantation configuration. Additionally and/or alternatively, rotation of at least a portion of the tensioning mechanism can cause tensioning of the one or more cords, which causes the clipping member to transform from the delivery configuration to the implantation configuration.

[007] In some embodiments of the clip device, the tensioning mechanism can comprise a screw and a nut, the one or more cords being connected to the nut such that rotation of the screw causes the nut to move axially along the screw and apply tension to the one or more cords. In some embodiments the leaflet clip device can further comprise a retaining mechanism disposed within the lumen of the clipping member, wherein the retaining mechanism retains the clipping member in the implantation configuration.

[008] Additionally and/or alternatively, the tubular body can comprise a metal tube having circumferential slots axially spaced along the length of the tubular body. Additionally and/or alternatively, the clipping member in the implantation configuration can have the shape of the Greek letter omega. Additionally and/or alternatively, when the clipping member is in the implantation configuration, the leg portions can extend toward each other from respective ends of an intermediate portion of the tubular body to define a clipping region for capturing the pair of leaflets, with the leg portions extending away from each other moving a direction away from the clipping region.

[009] An exemplary method of reducing regurgitation through a native heart valve can comprise positioning a leaflet clip device adjacent the coaptation edges of two adjacent leaflets of the heart valve, wherein the leaflet clip device comprises a clipping member and first and second tensioning members disposed within a lumen of the clipping member, the first tensioning member fixed to a first end portion of the clipping member and the second tensioning member fixed to a second end portion of the clipping member, and applying tension to the tensioning members to transform the clipping member from a delivery configuration to an implantation configuration in which the coaptation edges of the leaflets are captured between two leg portions of the clipping member.

[010] Additionally and/or alternatively, applying tension can include rotating a tensioning mechanism operatively coupled to the first and second tensioning members. In some embodiments the method can comprise engaging a retaining mechanism to retain the clipping member in the implantation configuration. Additionally and/or alternatively, the clipping member can have a substantially linear shape in the delivery configuration.

[011] The foregoing and other objects, features, and advantages of the invention will become more apparent from the following detailed description, which proceeds with reference to the accompanying figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[012] FIG. 1 is a perspective view of a representative embodiment of a leaflet clip device with a portion of a tensioning mechanism broken away for purposes of illustration.

[013] FIG. 2 is enlarged portion of a clipping member of the clip device of FIG. 1, shown partially broken away for purposes of illustration.

[014] FIG. 3 is an enlarged portion of the leaflet clip device of FIG. 1, shown partially broken away for purposes of illustration.

[015] FIG. 4 is a perspective view of another representative embodiment of a leaflet clip device having a plurality of integral clipping members for engaging multiple pairs of leaflets.

[016] FIG. 5 is a front elevation view of another representative embodiment of a leaflet clip device.

[017] FIG. 6 is a perspective view of a representative embodiment of a leaflet clip device implanted in the native aortic valve.

[018] FIG. 7 is a side view of a delivery apparatus and leaflet clip device loaded in the delivery apparatus for delivery into a patient's body.

[019] FIG. 8 is a front elevation view of another representative embodiment of a leaflet clip device.

[020] FIG. 9 is a front elevation view of another representative embodiment of a leaflet clip device.

[021] FIG. 10 is a front elevation view of a screw of the leaflet clip device illustrated in FIG. 9.

[022] FIG. 11 is a front elevation view of another representative embodiment of a leaflet clip device.

[023] FIG. 12 is a front elevation view of another representative embodiment of a leaflet clip device.

[024] FIG. 13 is a front view of a clipping member formed from a laser cut metal tube, according to one embodiment.

[025] FIG. 14 illustrates a cut pattern for laser cutting a metal tube to form a clipping member, such as shown in FIG. 13.

[026] FIG. 15 is an enlarged view of a portion of the cut pattern shown in FIG. 14.

[027] FIG. 16 is a front view of a clipping member formed from a laser cut metal tube, according to another embodiment.

[028] FIG. 17 is an enlarged view of a portion of a cut pattern for laser cutting a metal tube to form a clipping member, such as shown in FIG. 16.

DETAILED DESCRIPTION

[029] For purposes of this description, certain aspects, advantages, and novel features of the embodiments of this disclosure are described herein. The disclosed methods, apparatuses, and systems should not be construed as limiting in any way. Instead, the present disclosure is directed toward all novel and nonobvious features and aspects of the various disclosed embodiments, alone and in various combinations and sub-combinations with one another. The methods, apparatus, and systems are not limited to

any specific aspect or feature or combination thereof, nor do the disclosed embodiments require that any one or more specific advantages be present or problems be solved.

[030] Features, integers, characteristics, compounds, chemical moieties or groups described in conjunction with a particular aspect, embodiment or example are to be understood to be applicable to any other aspect, embodiment or example described herein unless incompatible therewith. All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, can be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive. The invention is not restricted to the details of any disclosed embodiments. The invention extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

[031] Although the operations of some of the disclosed methods are described in a particular, sequential order for convenient presentation, it should be understood that this manner of description encompasses rearrangement, unless a particular ordering is required by specific language set forth below. For example, operations described sequentially can in some cases be rearranged or performed concurrently. Moreover, for the sake of simplicity, the attached figures cannot show the various ways in which the disclosed methods can be used in conjunction with other methods. Additionally, the description sometimes uses terms like "provide" or "achieve" to describe the disclosed methods. These terms are high-level abstractions of the actual operations that are performed. The actual operations that correspond to these terms can vary depending on the particular implementation and are readily discernible by one of ordinary skill in the art.

[032] As used in this application and in the claims, the singular forms "a," "an," and "the" include the plural forms unless the context clearly dictates otherwise. Additionally, the term "includes" means "comprises." Further, the terms "coupled" and

"associated" generally mean electrically, electromagnetically, and/or physically (*e.g.*, mechanically or chemically) coupled or linked and does not exclude the presence of intermediate elements between the coupled or associated items absent specific contrary language.

[033] As used herein, the term "proximal" refers to a position, direction, or portion of a device that is closer to the user and further away from the implantation site. As used herein, the term "distal" refers to a position, direction, or portion of a device that is further away from the user and closer to the implantation site. Thus, for example, proximal motion of a device is motion of the device toward the user, while distal motion of the device is motion of the device away from the user. The terms "longitudinal" and "axial" refer to an axis extending in the proximal and distal directions, unless otherwise expressly defined.

[034] As used herein, the terms "integrally formed" and "unitary construction" refer to a construction that does not include any welds, fasteners, or other means for securing separately formed pieces of material to each other.

[035] FIG. 1 illustrates a representative embodiment of a leaflet clip device 10. The clip device 10 in the illustrated embodiments comprises an elongate clipping member 12 and a tensioning mechanism 14. The clipping member 12 can comprise an elongate generally tubular or cylindrical body having a first end portion 16, a second end portion 18, a lumen 20 extending from the first end portion 16 to the second end portion 18. The tensioning mechanism 14 can comprise one or more cords or tensioning members 22 disposed within the lumen 20 of the clipping member 12. As used herein, the term "tensioning member" or "cord" refers to a slender length of material that can be formed from a single wire, strand, fiber, or filament, or can comprise multiple wires, strands, fibers, or filaments.

[036] The clipping member 12 can be transformed from a delivery configuration to an implantation configuration, and vice versa. In the delivery configuration, the clipping member 12 can be in a substantially longitudinally extended or straightened configuration (see FIG. 7). In the implantation configuration (see FIG. 1), two portions

of the clipping member 12 are drawn toward each other forming a primary clipping region 24, such that a portion of one or more native valve leaflets can be captured, or pinched, between the two portions of the clipping member within the primary clipping region (see FIG. 6).

[037] The clipping member 12 in the illustrated embodiment has a shape similar to the Greek letter "omega" in the implanted configuration. In particular, the clipping member 12 can have an intermediate portion 26 (which can extend linearly as shown or can be curved) and first and second leg portions 28, 30, respectively, which extend toward each other moving in a direction extending away from respective ends of the intermediate portion 26 to form the clipping region 24. The leg portions 28, 30 then extend away from each other moving in a direction extending away from the clipping region 24. Other delivery configurations for the clipping member 12 are also possible. For example, the clipping member 12 can be folded in half such that the first and second leg portions 28, 30 are straightened and extend parallel and side-to-side with respect to each other in the delivery configuration.

[038] The leaflet clip device 10, and any of the other leaflet clip embodiments described herein, can be used to treat valvular insufficiency or regurgitation by remodeling the annulus and/or the leaflets of a heart valve. For example, FIG. 6 illustrates a leaflet clip device 10 situated in a native aortic valve 200. The native aortic valve 200 can include three valve leaflets 210, 212, 214 attached to a valve annulus 216. The valve leaflets 210 and 212 can form a first commissure 218, the leaflets 212 and 214 can form a second commissure 220, and the leaflets 210 and 214 can form a third commissure 222.

[039] The leaflet clip device 10 is shown situated adjacent the first commissure 218, such that the leaflet clip device 10 engages the leaflets 210 and 212. The leaflet clip device 10 is also shown situated near the wall of the valve annulus 216. In this manner, the leaflet clip 10 can improve coaptation of the leaflets 210, 212 at the commissure 218, thereby reducing regurgitation through the valve 200 due to valvular insufficiency. Additionally, although the leaflet clip 10 is shown clipped to the respective valve leaflets

adjacent the annulus 216, the leaflet clip 10 can be clipped to the valve leaflets at any suitable location along the leaflets, including at the center of the native valve, as desired.

[040] Although one clip device 10 is shown implanted in the native aortic valve, a plurality of leaflet clips 10 can be implanted to reduce dilatation of the annulus 216 and/or to address abnormalities in the shape of the annulus 216. For example, a leaflet clip 10 can be implanted on each pair of leaflets, for example, at each commissure 218, 220, 222. Alternatively or additionally, multiple clip devices 10 can be implanted along the coaptation edges of a pair of adjacent leaflets. For example, multiple clip devices 10 can be implanted along the coaptation edges of leaflets 210, 212.

[041] Referring again to FIG. 1, the tensioning mechanism 14 can be operatively coupled to the clipping member 12 via the tensioning members 22, which apply tension to the clipping member 12 to transform the clipping member 12 from the delivery configuration to the implantation configuration and/or to bring the leg portions 28, 30 closer together to the final implantation configuration after partial deployment from the delivery configuration, as further described below.

[042] In particular embodiments of the leaflet clip device 10, the clipping member 12 can be formed (e.g., laser cut) from a metal tube, such as shown in FIGS. 13 and 16. The tube can be formed with a plurality of slots or cuts along the length of the tube to promote bending of the tube from the delivery configuration to the implantation configuration.

[043] In some embodiments, the clipping member 12 can be formed from a nonlinearly elastic, super-elastic, and/or shape-memory material, such as Nitinol, and is shape set in the implantation configuration. The clipping member 12 can be retained in the delivery configuration during delivery of the device within a patient's body, such as with a sheath of a delivery apparatus, and when released from the delivery configuration, the clipping member 12 automatically reverts back toward the implantation configuration. In some embodiments, the clipping member 12 can self-deploy under its own resiliency from the delivery configuration to a partially deployed configuration such that the leg portions 28, 30 are spaced apart from each other at the clipping region 24. The tensioning mechanism

14 can then be used to draw the leg portions 28, 30 closer together to the implantation configuration shown in FIG. 1 with sufficient force to engage and anchor itself onto a pair of native valve leaflets. In other embodiments, the clipping member can be shape set in a substantially straight or linear deliver configuration and the tensioning mechanism 14 is used to deform or bend the clipping member from the delivery configuration to the implantation configuration.

[044] In alternative embodiments, the clip device 10 does not have a tensioning mechanism 14 and the shape-memory material of the clipping member 12 causes the clipping member 12 to transform from the delivery configuration to the implantation configuration under its own resiliency and provide sufficient force against the native leaflets to anchor the clipping member 12 onto a pair of the native leaflets without a separate tensioning mechanism.

[045] In other embodiments, the clipping member 12 can be formed from a linearly elastic material, such as stainless steel or cobalt chromium alloy. In such embodiments, the tensioning mechanism 14 can be used to transform or deform the clipping member 12 from the delivery configuration to the implantation configuration. Linearly elastic metals, such as stainless steel or cobalt chromium alloy, also deform plastically after an applied force exceeds a predetermined threshold. In some embodiments, the tensioning mechanism 14 can be used to plastically deform the clipping member 12 as it is deformed from the delivery configuration to the implantation configuration.

[046] FIG. 13 illustrates an example of a clipping member 12 formed from a laser cut metal tube. FIG. 14 shows an exemplary cut pattern for the metal tube used to form the clipping member 12 shown in FIG. 13. FIG. 15 is an enlarged view of a portion of the cut pattern shown in FIG. 14. Although not shown, the clipping member can include a covering extending over and covering the outer surface of the metal tube. The covering can comprise a suitable fabric (e.g., a polyethylene terephthalate (PET) fabric), non-fabric polymeric materials (e.g., polyurethane or silicone), or natural tissue (e.g., pericardium tissue)

[047] As shown in FIGS. 14 and 15, a series of axially-spaced, circumferential cuts can be formed in the clipping member 12 at selected locations. Along the leg portions 28, 30, the cuts form a series of circumferential gaps 80 with tabs 82 and notches 84 on opposite sides of central portions of the gaps 80. In the illustrated embodiment, the clipping member 12 has no or substantially no shape memory toward the implantation configuration and is shown in FIG. 13 in its natural resting state prior to being transformed into the implantation configuration. The clipping member in this example can comprise, for example, a stainless steel or cobalt chromium alloy metal tube. By application of forces to the clipping member 12, as further described below, it can be transformed from a substantially straight or linear configuration to the implantation configuration shown in FIG. 1. The gaps 80 promote bending of the clipping member as it is bent into the implantation configuration. The tabs 82 can reside in corresponding notches 84 to resist undesirable torqueing of the clipping member as it is transformed into the implantation configuration.

[048] FIG. 16 shows another example of a clipping member 12 formed from a laser cut metal tube. The clipping member 12 of FIG. 16 can be substantially the same as the clipping member of FIG. 13 except that the circumferential cuts form mating features that help maintain the shape of the clipping member when being transformed into the implantation configuration. In particular, as shown in FIG. 17, the cuts form a series of circumferential gaps 86 with tabs 88 and notches 90 on opposite sides of central portions of the gaps 86. The tabs 88 have non-linear opposing edges 92 that can engage similarly shaped non-linear edges 94 of the notches 90 when the clipping member is bent toward the implantation configuration. The edges 92 of the tabs 88 can frictionally engage the edges 94 of the notches 90 to resist straightening of the clipping member back toward the delivery configuration. FIG. 16 shows the clipping member retained in a partially deployed state by the retaining features of the cuts without application of other forces on the clipping member. In some embodiments, the retaining features of the cuts can be configured to retain the shape of the clipping member in the implantation configuration shown in FIG. 1.

[049] When the clipping member 12 is in the implanted configuration, the clipping strength of the leaflet clip device can be determined. As used herein, the terms "clip retention force" and "clipping strength" refer to a force in the proximal direction that can be withstood by a leaflet clip device without disengaging from the leaflets of a heart valve when the clipping member is in the implantation configuration. In some embodiments, the clip device and/or a delivery apparatus for the clip device can include a strain gauge or equivalent device that is operable to measure the retention force of the leaflet clip device 10.

[050] The tensioning mechanism 14 can be configured to permit fine closure movement of the leaflet clip device to the implantation configuration. In particular embodiments, the clip retention force can be completely controllable via the tensioning mechanism 14. For example, in the embodiment illustrated in FIGS. 1 and 3, the tensioning mechanism 14 can comprise a screw 32 and a moveable element such as a nut 34, which is threadably engaged with and moveable along the length of the screw 32. The tensioning mechanism 14 can further include a housing 54 containing the screw 32 and the nut 34, and two plates or bars 56 on opposite sides of the nut 34. The plates 56 contact adjacent surfaces of the nut 34 and prevent rotation of the nut 34 upon rotation of the screw 32. Hence, rotation of the screw 32 produces axial movement of the nut 34 along the length of the screw within the housing 54.

[051] The screw 32 can have a proximal end portion 58 that can be releasably connected to a delivery apparatus or another tool that can be manipulated to rotate the screw 32. For example, a rotatable shaft of a delivery apparatus or another tool can have a distal end portion releasable connected to the proximal end portion 58 of the screw 32. The proximal end portion of the shaft can be rotated by a user (either manually or by activating a motor that rotates the shaft), which in turn rotates the screw 32.

[052] A first cord 22a can have a distal end portion 36 attached to the first end portion 16 of the clipping member 12 and a second cord 22b can have a distal end portion 38 attached to the second end portion 18 of the clipping member 12. The distal end portions 36, 38 of the cords 22a, 22b can be fixedly secured to portions of the clipping member

12, such as by welding the distal end portions 36, 38 to the luminal surface of the clipping member 12. Proximal end portions 40, 42 of the first and second cords 22a, 22b can be fixedly secured to the nut 34, for example, by placing the proximal end portions 40, 42 into respective bores 60 in the nut 34 and welding them into place. Tension can be applied to the first and second cords 22a, 22b by movement of the nut 34 away from the clipping member 12 along the length of the screw 32 in the proximal direction, as indicated by arrow 62. Tension on the first and second cords 22a, 22b can be released or eased by movement of the nut 34 towards the clipping member 12 in the distal direction, as indicated by arrow 64.

[053] Tensioning of the cords 22a, 22b is effective to apply a compressive or buckling force to the leg portions 28, 30, which causes the leg portions to buckle at the clipping region 24 and/or cause the leg portions to be drawn closer together at the clipping region and apply sufficient retention force against the native leaflets along the coaptation edges of the leaflets. Further tensioning of the cords 22a, 22b can permit manipulation of the intermediate portion 26 of the clipping member to perform reshaping of the cusp region of the native valve. As noted above, the clipping member 12 can be comprised of flex cuts and/or thinning of tube material at predetermined locations along the clipping member 12 where bending of the clipping member 12 is desired, for example thinning and/or flex cuts at bends 44, 66. The length, positioning, frequency, and amount of material removal of the flex cuts can allow for a multitude of options to produce flexion in specific areas in a defined sequence, location, resolution, and with a defined curvature.

[054] Fine closure movement of the leaflet clip device 10 can depend on the pitch of threading of the screw 32. For example, a relatively smaller pitch will increase the amount of control over the spacing between the leg portions 28, 30 at the clipping region 24 and the retention force applied to a pair of native leaflets.

[055] In lieu of or in addition to locking flex cuts (as shown in FIG. 17), some embodiments of the leaflet clip device 10 can include one or more retaining features to help retain the clipping member 12 in its implantation configuration. For example, the clipping member 12 can comprise a retaining mechanism 46 at each bend 44, which

retains that portion of the clipping member in its deformed state once a predetermined angle of curvature in the clipping member 12 is reached. As shown in FIG. 2, each locking mechanism 46 can be disposed within the lumen of the clipping member 12 at bends 44. Each locking mechanism 46 can include at least a first locking member 48 and a second locking member 50 configured to move relative to each other as the clipping member is transformed from the delivery configuration to the implantation configuration. The locking members 48, 50 can have opposing edges having complimentary shapes that nest against each other in the implantation configuration. For example, the first locking member 48 can have a notch 68 that receives a projection 70 of the second locking member 50.

[056] When the clipping member 12 is substantially straightened in the delivery configuration, the locking members 48, 50 are placed in an overlapping position relative to each and can slide against one another as the clipping member 12 moves toward the implantation configuration. When the bend 44 reaches a predetermined curvature, for example when the implantation configuration is reached, and the projection 70 moves into engagement within the notch 68, as shown in FIG. 2. The locking members 48, 50 can be biased laterally against each other to force the projection 70 to engage the notch 68. Engagement of the locking members 48, 50 resists further bending of the clipping member at bend 44 beyond the implantation configuration and bending of the clipping member back toward the delivery configuration at bend 44. The retaining members 46 can decrease the load placed on the cords 22a, 22b and can increase the ability of the clip device to maintain a consistent retention force on the leaflets for a longer period of time.

[057] Additionally and/or alternative, the tensioning mechanism 14 can also include a retaining or locking mechanism for retaining the clipping member 12 in the implantation configuration. For example, the tensioning mechanism 14 can retain the clipping member in the implantation configuration due to the balance of tension forces in the one or more cords 22 with the frictional forces between the screw 32 and the nut 34. In this manner, the screw 32 and the nut 34 serve as a retaining mechanism. Additionally and/or alternatively, a variable pitch screw can provide a retaining mechanism whereby a

nut 34 can travel along a first portion of the screw having a first pitch and then locks onto or creates a mechanical interference with a second portion of the screw having a second pitch different than the first pitch, as further described below in connection with FIGS. 9-10.

[058] FIG. 7 shows the distal end portion of a delivery apparatus 400 for delivering and implanting a clip device 10 percutaneously within a patient's body, according to one embodiment. The delivery apparatus can comprise an outer sheath 402, a first shaft 404 extending through the sheath 402, and a second shaft 406 extending through the first shaft 404. The sheath 402 has a lumen sized to receive and retain the clip device 10 in the delivery configuration for delivery through the patient's body. The inner shaft 404 can be releasably connected to a convenient location on the clip device, as the tensioning mechanism 14 as shown. The shaft 404 can be used to manipulate or adjust the position of the clip device 10 relative to the sheath 402 and the implantation location. For example, the shaft 404 can be used to deploy the clip device 10 from the sheath 402, move the clip device distally and proximally relative to the implantation location, and/or rotate the clip device relative to the implantation location. The second shaft 406 can be releasably coupled to the proximal end portion 58 of the screw 32 of the tensioning mechanism 14. The second shaft 406 can be rotated relative to the first shaft 404 by a user to rotate the screw 32 and adjust the tension on the cords 22a, 22b. The proximal end portions of the sheath 402, the first shaft 404, and the second shaft 406 can be coupled to a handle of the delivery apparatus, which can include appropriate controls (e.g., knobs) that allow a user to control movement the sheath 402, the first shaft 404, and the second shaft 406.

[059] The delivery apparatus 400 and a clip device 10 contained within the sheath 402 can be introduced into a patient's vasculature (e.g., via the femoral artery or other suitable access point) and percutaneously advanced to the patient's heart with a leaflet clip device 402 using any of various delivery techniques. In a transfemoral procedure, the delivery apparatus 400 can be inserted through a femoral artery and the aorta to the heart in a retrograde direction (typically, but not exclusively used for deploying a clip on

the leaflets of the aortic or mitral valves). Similarly, the delivery apparatus 400 can be inserted through a femoral vein and the vena cava to the right side of the heart in an antegrade direction (typically, but not exclusively used for deploying a clip on the leaflets of the pulmonary or tricuspid valves). In a transventricular procedure, the delivery apparatus 400 can be inserted through a surgical incision made in the chest and on the bare spot on the lower anterior ventricle wall (typically, but not exclusively used for deploying a clip on the leaflets of the aortic or mitral valves). Similarly, the delivery apparatus 400 can be inserted through a surgical incision on the wall of the right ventricle to access the pulmonary or tricuspid valves. In a transatrial procedure, the delivery apparatus 400 can be inserted through a surgical incision made in the wall of the left or right atrium to access the native valves on the left or right sides, respectively, of the heart. In a transaortic procedure, the delivery apparatus 400 can be inserted through a surgical incision made in the ascending aorta and advanced toward the heart (typically, but not exclusively used deploying a clip on the leaflets of the aortic or mitral valves). In a transeptal procedure, the delivery apparatus 400 can be advanced to the right atrium, such as via a femoral vein, and through the septum separating the right and left ventricles (typically, but not exclusively used for deploying a clip on the leaflets of the aortic or mitral valves). Further details of delivery techniques for accessing the native valves of the heart are disclosed in U.S. Patent Publication No. 2014/0067052.

[060] Once located proximate the desired heart valve, the leaflet clip device 10 can then be deployed from the sheath 402, such as by pushing the clip device 10 distally from the sheath 402 using the shaft 404 and/or retracting the sheath 402 relative to the clip device. Once the clip device is deployed from the sheath, the clip device can be advanced distally, retracted proximally, and/or rotated as needed to position the leaflet clip device 10 such that a pair of first and second leaflets are positioned generally within the primary clipping region 24 with the first leg portion 28 adjacent one of the leaflets and the second leg portion 30 adjacent the other leaflet.

[061] The delivery apparatus can be used to adjust the tensioning mechanism 14 until the desired predetermined implantation configuration is achieved with the leaflets

engaged and pinched between the leg portions 28, 30. For example, the user can rotate the shaft 406, which rotates the screw 32, thereby increasing tension on the cords 22a, 22b until the implantation configuration is achieved.

[062] In alternative embodiments, a clip device can comprise multiple clipping members that are configured to engage multiple pairs of native leaflets. As shown in FIG. 4, for example, a leaflet clip device 300 comprises an annular ring having three clipping members 302, 304, 306 spaced approximately 120 degrees from each other, each configured to be implanted on a pair of native leaflets, such as at a commissure of the native valve. The clip device 300 can comprise a tubular structure and be formed from, for example, a shape-memory material (e.g., Nitinol) or a plastically-deformable material (e.g., stainless steel or cobalt chromium alloy). In other embodiments, the clip device can comprises an annular ring having two clipping members spaced approximately 180 degrees from each other, such as for implantation on the leaflets of the native mitral valve.

[063] In still alternative embodiments, the clip device can comprise an open ring (i.e., a ring that extends less than 360 degrees) having a number of clipping members that is less than the number of native leaflets of the valve in which the device is to be implanted. For example, the clip device can comprise an open ring having two clipping members spaced approximately 120 degrees from each other and is configured to engage two pairs of native leaflets but not the third pair of native leaflets.

[064] A leaflet clip device can include any one of a number of different tensioning mechanisms configured to apply tension to one or more cords disposed within a clipping member and/or transform the clipping member from a delivery configuration to an implantation configuration. For example, FIGS. 5 and 8-12 illustrate various embodiments of a leaflet clip device having different tensioning mechanisms.

[065] FIG. 5 illustrates a leaflet clip device 500, according to another embodiment. The leaflet clip 500 comprises a tensioning mechanism 502 and a clipping member 504 defining a lumen 506. The tensioning mechanism 502 can comprise one or more fasteners 508. One or more cords 510 can be disposed within the lumen 506 and can be

attached at their distal end portions 512 to respective locations on the clipping member 504, as described above in connection with the embodiment of FIG. 1. The one or more cords 510 can pass through the fastener 508 and can have proximal end portions connected to a delivery apparatus and/or extending outside of the patient's body. The fastener 508 (such as a suture clip) can be advanced over the cords 510 in the direction indicated by arrow 516 and pushed against an intermediate portion 514 of the clipping member 504 so as to retain tension on the cords. The portions of the cords proximal to the clipping member 504 can be severed with the delivery apparatus or another tool.

[066] The fastener 508 can be a suture clip, or another type of fastener that can be deployed from a catheter and secured to a suture within the patient's body. Various suture clips and deployment techniques for suture clips that can be used in the methods disclosed in the present application are disclosed in U.S. Publication Nos. 2014/0031864 and 2008/0281356 and U.S. Patent No. 7,628,797. In the case of a slideable fastener, the fastener 508 can be movable along the cords 510 in a distal direction toward the clipping member, and configured to resist movement in a proximal direction along the cords in the opposite direction. Thus, once placed against the clipping member, the fastener 508 can resist the cords 510 pulling through the fastener under the tension of the cords. In this manner, the fastener 508 serves as a retaining member to assist in maintaining the shape of the clipping member in the implantation configuration.

[067] The delivery apparatus can include a mechanism configured to adjust the tension applied to the cords 510 until the desired predetermined implantation configuration is achieved. For example, the cords 510 can be releasably coupled to respective shafts or other components that can be controlled by a user. The delivery apparatus can also include a mechanism for deploying the fastener 508 onto the cords and/or advancing the fastener 508 over the cord until it abuts the clipping member.

[068] FIG. 8 illustrates a leaflet clip device 600, according to another embodiment. The clip device 600 comprises a tensioning mechanism 602 and a clipping member 604 defining a lumen 606. The tensioning mechanism 602 can comprise one or more fasteners 608 (e.g., suture clips) and a pulley system 610 comprising one or more pulley

wheels or sheaves 612 disposed within the lumen 606. One or more cords 614 can be disposed within the lumen 606 and attached at their distal end portions 616 to respective locations on the clipping member 604, as described above in connection with the embodiment of FIG. 1. The one or more cords 614 can pass through the fastener 608 that allows for one directional movement of the cords 614 through the fastener. As shown, the cords 614 can be weaved around the wheels 612 as they extend through the lumen.

[069] The delivery apparatus can include a mechanism that allows tension to be applied to the cords 614 within the clipping member 604 until the desired predetermined implantation configuration is achieved and a mechanism to deploy and advance the fastener 608 over the cords 614, as discussed above in connection with the embodiment of FIG. 5. The use of pulley wheels 612 to support the cords 614 in advantageous in that it significantly reduces the force required to deform the clipping member to the implantation configuration by application of tensile forces on the cords. The pulley wheels 612 are also positioned at strategic locations within the lumen to promote flexing of the clipping member at the desired locations upon application of tension on the cords. Other uses of a pulley system could further distribute the tension force/load on the cords depending upon the needs of the procedure.

[070] FIG. 9 illustrates a leaflet clip device 700, according to another embodiment. The clip device 700 comprises a tensioning mechanism 702 and a clipping member 704 defining a lumen 706. The tensioning mechanism 702 can comprise a screw 708 and a nut 710 disposed on the screw, similar to the tensioning mechanism 14 of FIG. 1. Instead of a separate housing for the tensioning mechanism, the screw 708 can be at least partially disposed within the lumen 706 of the clipping member. Two walls or projections 718 can be located on opposite sides of the nut 710 within the lumen 706 to contact and prevent rotation of the nut 710 upon rotation of the screw 708.

[071] One or more cords 712 can be disposed within the lumen 706 and can be attached at their distal end portions 714 to respective locations on the clipping member 704, as described above. The cords 712 can be attached at their proximal end portions to

the nut 710. As such, rotation of the screw 708 is effective to move the nut 710 axially along the screw to adjust the tension on the cords, as described in detail above in connection with the embodiment of FIG. 1.

[072] The tensioning mechanism 702 can include a retaining or locking mechanism in the form of a variable-pitch screw. As best shown in FIG. 10, for example, the screw 708 can include a first threaded portion 720 having threads defining a first pitch and a second threaded portion 722 having threads defining a second pitch, smaller than the first pitch. The nut 710 has internal threads that correspond to the threads of the first threaded portion 720 and can move axially along the screw upon rotation of the screw. The internal threads of the nut 710 are substantially different from the threads of the second threaded portion 722 (e.g., the threads are larger and/or have a smaller pitch than the threads of the second threaded portion) such that when the nut 710 reaches the second threaded portion 722, a mechanical interference occurs that resists further movement of the nut to assist in retaining the clipping member in its deformed state.

[073] FIG. 11 illustrates a leaflet clip device 800, according to another embodiment. The clip device 800 comprises a tensioning mechanism 802 and a clipping member 804 defining a lumen 806. The tensioning mechanism 802 can comprise a worm screw 808 and a worm wheel or gear 810 engaged with the screw 808. The screw 808 and the wheel 810 can be mounted within the lumen 806 with the proximal end portion of the screw 808 exposed outside of the clipping member for connection to a delivery apparatus or tool used for rotating the screw. Rotation or torque on the worm screw 808 is converted to rotation or torque on the worm wheel 810.

[074] One or more cords 812 can be disposed within the lumen 806 and can be attached at their distal ends 814 to respective locations on the clipping member 804, as previously described. The one or more cords 812 can be attached at their proximal end portions to a central shaft 816 of the worm wheel 810. A mechanism in the delivery system (e.g., a torque shaft) can rotate the screw 808, causing the worm wheel 810 and the shaft 816 to rotate. As the worm wheel 810 is rotated, tension is applied to the one or more cords 812 as the slack in the cords become wrapped around the shaft 816. A single

worm wheel 810 can be used to apply tension to multiple cords 812, as shown. In alternative embodiments, first and second worm wheels 810 can be mounted on respective shafts on opposite sides of the screw 808 with each wheel 810 connected to a respective cord 810 that extends through that side of the clipping member. Tension can be applied to the one or more cords 812 within the clipping member 804 until the desired predetermined implantation configuration is reached.

[075] FIG. 12 illustrates a leaflet clip device 900, according to another embodiment. The clip device 900 can comprise a tensioning mechanism 902 and a clipping member 904 defining a lumen 906. The tensioning mechanism 902 can comprise a central bevel gear 908 and one or more side bevel gears 910, for example disposed on either side of the central bevel gear 908. Each side gear 910 can be mounted on a respective shaft 916 or a common shaft that extends through both side gears 910. The gears 908, 910 can be mounted in the lumen 906 except that a shaft portion 909 of the central gear 908 can be exposed outside of the clipping member for connection to a delivery apparatus or tool used for rotating the screw. Rotation or torque of the central gear 908 (by rotating the shaft portion 909) is converted to rotation or torque on the two side gears 910.

[076] One or more cords 912 can be disposed within the lumen 906 and can be attached at their distal end portions 914 to respective locations on the clipping member 904 as previously described. Each of the one or more cords 912 can be attached at its proximal end portion to a shaft 916 of a respective side gear 910. A mechanism in the delivery system (e.g., a torque shaft) can rotate the central gear 908, causing the side gears 910 to rotate. As the side gears 910 rotate, tension is applied to the one or more cords 912 as slack in each cord is wrapped around a respective shaft 916. Tension can be applied to the one or more cords 912 within the clipping member 904 until the desired predetermined implantation configuration is reached.

[077] In view of the many possible embodiments to which the principles of the disclosed technology can be applied, it should be recognized that the illustrated embodiments are only preferred examples and should not be taken as limiting the scope of the disclosure. Rather, the scope of the disclosure is defined by the following claims.

We claim:

1. A leaflet clip device, comprising:

an elongated clipping member having a first end portion and a second end portion;

a tensioning mechanism coupled to the clipping member; and

one or more tensioning members disposed within a lumen of the clipping member, wherein the one or more tensioning members are operatively connected to the tensioning mechanism to transform the clipping member from a delivery configuration to an implantation configuration.

2. The leaflet clip device of claim 1, further comprising a retaining mechanism disposed within the lumen of the clipping member, wherein the retaining mechanism retains the shape of the clipping member in the implantation configuration.

3. The leaflet clip device of any one of claims 1-2, wherein the clipping member comprises a shape memory material.

4. The leaflet clip device of any one of claims 1-3, wherein the tensioning mechanism is centrally coupled to the clipping member with respect to the first end portion and the second end portion.

5. The leaflet clip device of any one of claims 1-4, wherein the one or more tensioning members comprises:

a first tensioning member fixed at a distal end portion thereof to the first end portion of the clipping member and operatively connected to the tensioning mechanism at a proximal end portion of the first tensioning member; and

a second tensioning member fixed at a distal end portion thereof to the second end portion of the clipping member and operatively connected to the tensioning mechanism at proximal end portion of the second tensioning member.

6. The leaflet clip deice of any one of claims 1-5, wherein rotation of at least a portion of the tensioning mechanism causes tensioning of the one or more tensioning members.

7. The leaflet clip device of any one of claims 1-6, wherein the implantation configuration comprises a primary clipping region defined between two leg portions of the clipping member.

8. The leaflet clip device of any one of claims 1-7, wherein the tensioning mechanism comprises a retaining mechanism configured to retain the clipping member in the implantation configuration.

9. The leaflet clip device of any one of claims 1-8, wherein the one or more tensioning members extend through a portion of the tensioning mechanism.

10. The leaflet clip device of any one of claims 1-9, wherein the one or more tensioning members are fixed at one end to a portion of the tensioning mechanism.

11. A leaflet clip device, comprising:

a clipping member comprising a tubular body having a lumen and two leg portions, wherein the clipping member can be transformed between a substantially linear delivery configuration and an implantation configuration in which the leg portions are drawn toward each other to capture a pair of leaflets between the leg portions; and

a tensioning mechanism configured to transform the clipping member from the delivery configuration to the implantation configuration.

12. The leaflet clip device of claim 11, further comprising one or more cords disposed within the lumen of the clipping member, wherein the one or more cords are operatively connected to the tensioning mechanism to transform the clipping member from the delivery configuration to the implantation configuration.

13. The leaflet clip device of claim 12, wherein rotation of at least a portion of the tensioning mechanism causes tensioning of the one or more cords, which causes the clipping member to transform from the delivery configuration to the implantation configuration.

14. The leaflet clip device of any one of claims 12-13, wherein the tensioning mechanism comprises a screw and nut, the one or more cords being connected to the nut such that rotation of the screw causes the nut to move axially along the screw and apply tension to the one or more cords.

15. The leaflet clip device of any one of claims 11-14, further comprising a retaining mechanism disposed within the lumen of the clipping member, wherein the retaining mechanism retains the clipping member in the implantation configuration.

16. The leaflet clip device of any one of claims 11-15, wherein the tubular body comprises a metal tube having circumferential slots axially spaced along the length of the tubular body.

17. The leaflet clip device of any one of claims 11-16, wherein the clipping member in the implantation configuration has the shape of the Greek letter omega.

18. The leaflet clip device of any one of claims 11-17, wherein when the clipping member in the implantation configuration, the leg portions extend toward each other from respective ends of an intermediate portion of the tubular body to define a clipping region for capturing the pair of leaflets, the leg portions extending away from each other moving a direction away from the clipping region.

Fig. 1

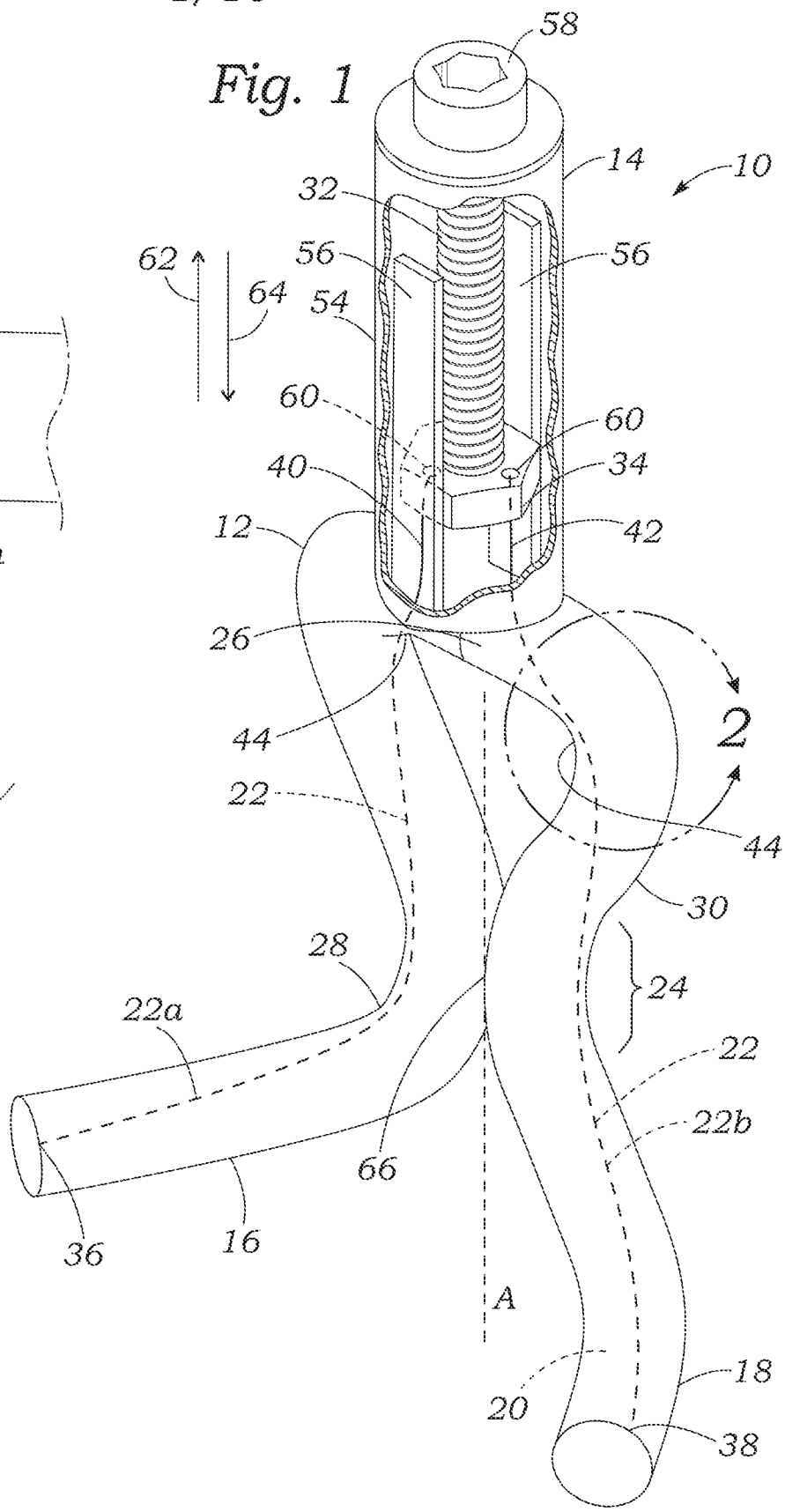
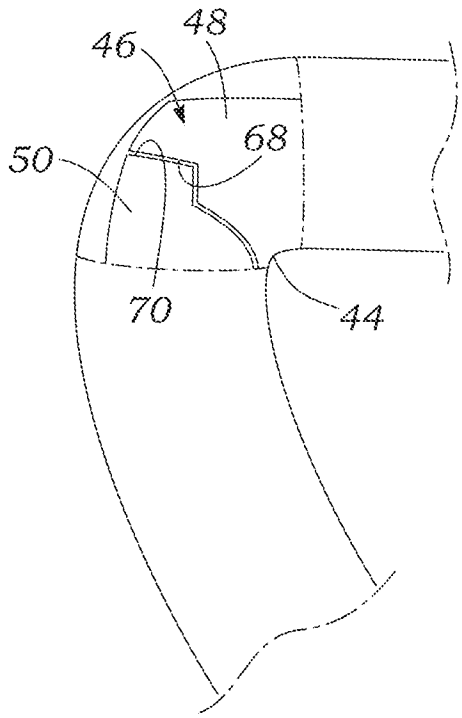

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Fig. 2


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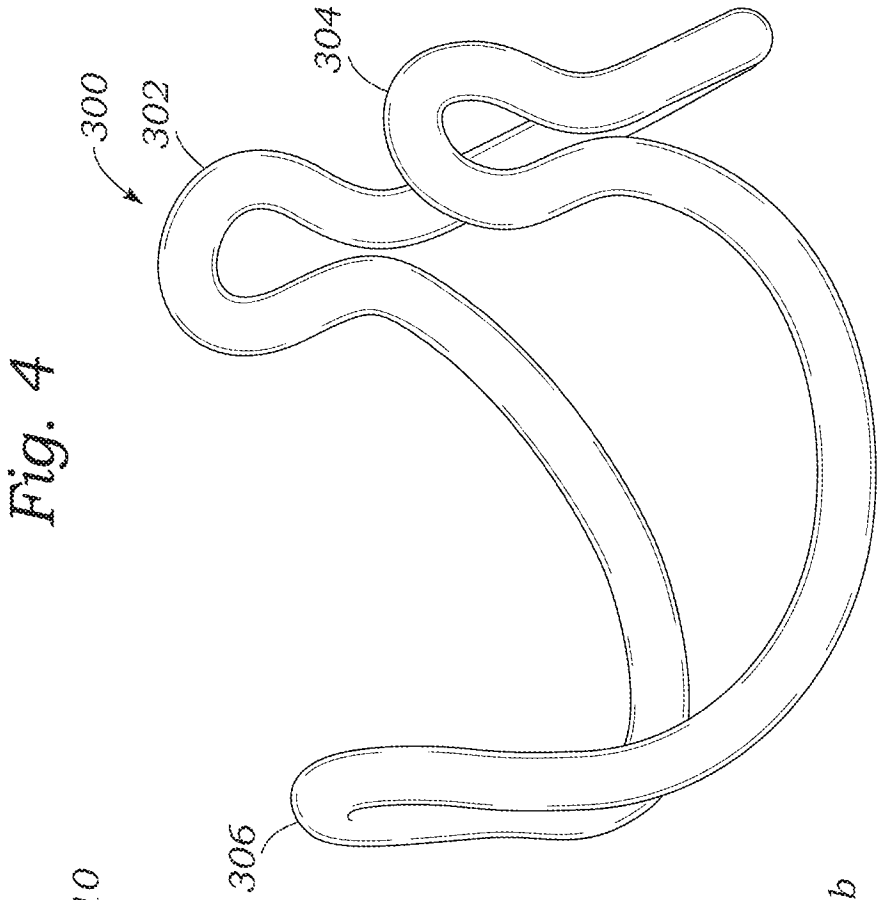


Fig. 4

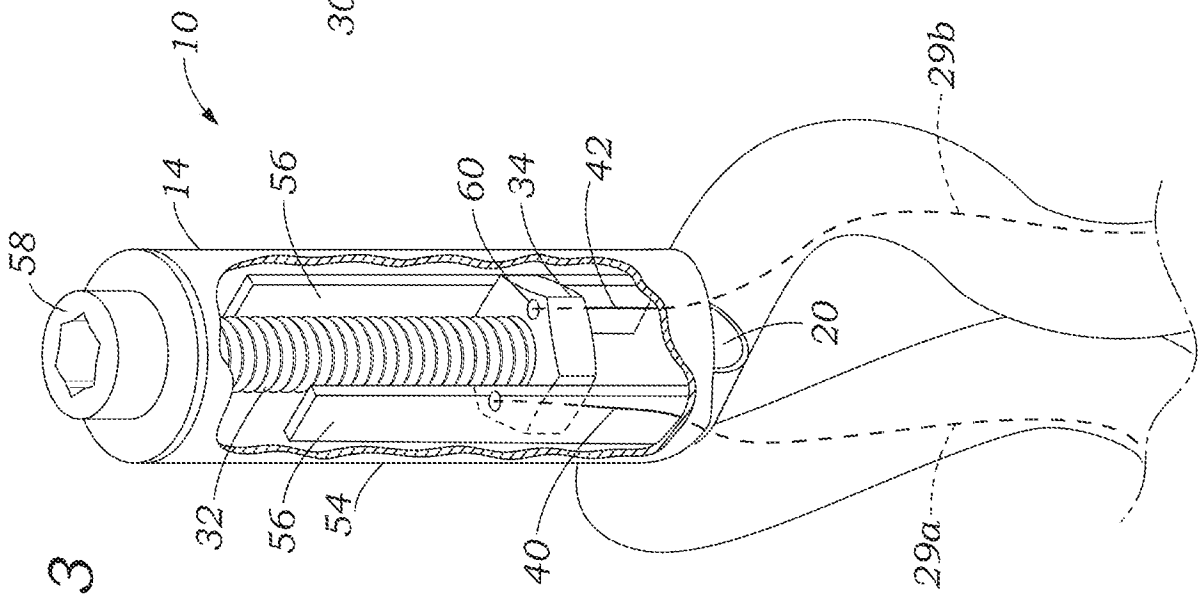


Fig. 3

Fig. 6

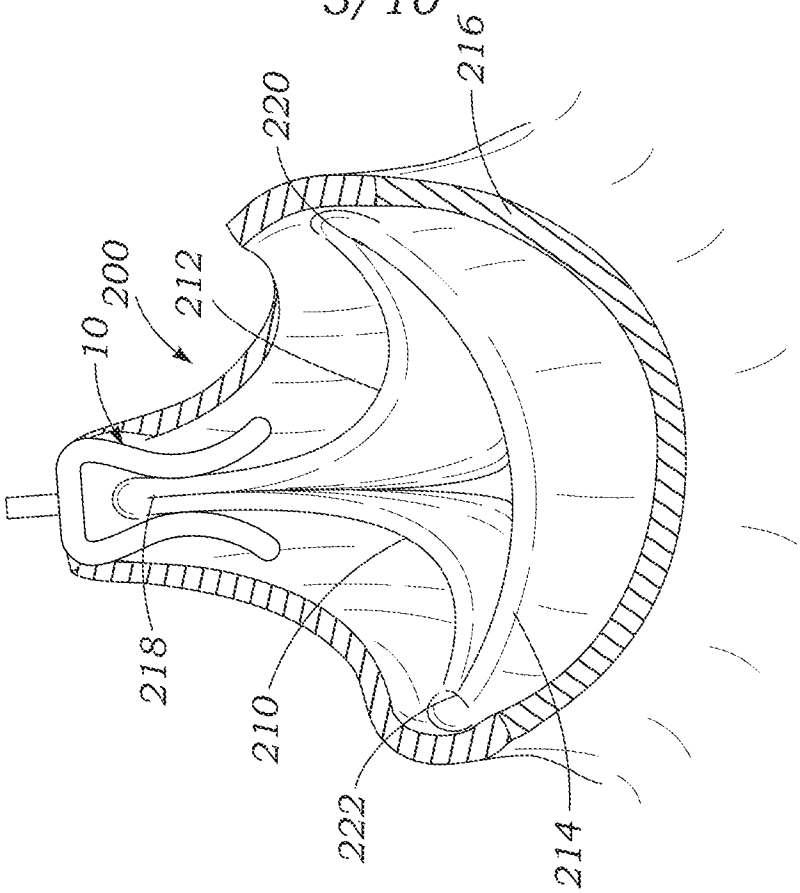
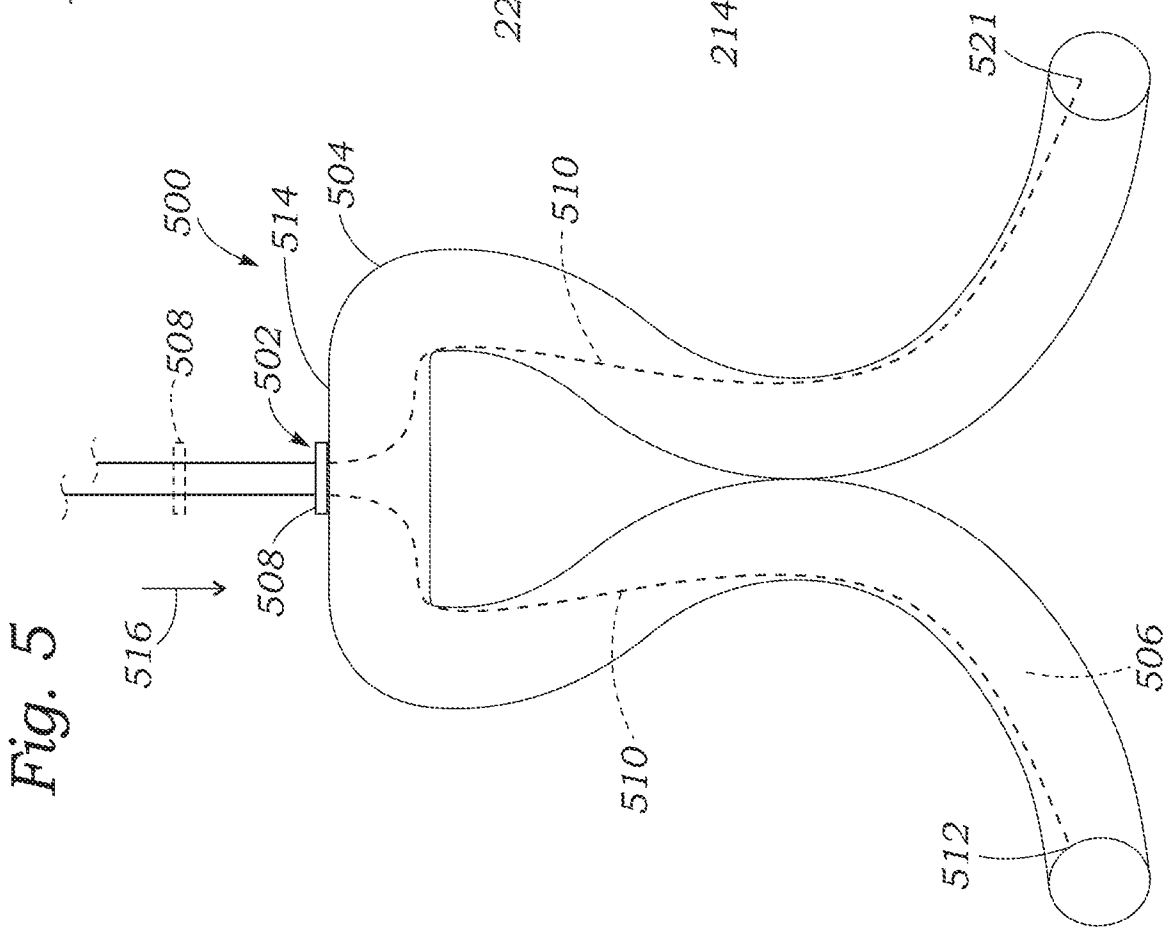

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Fig. 5


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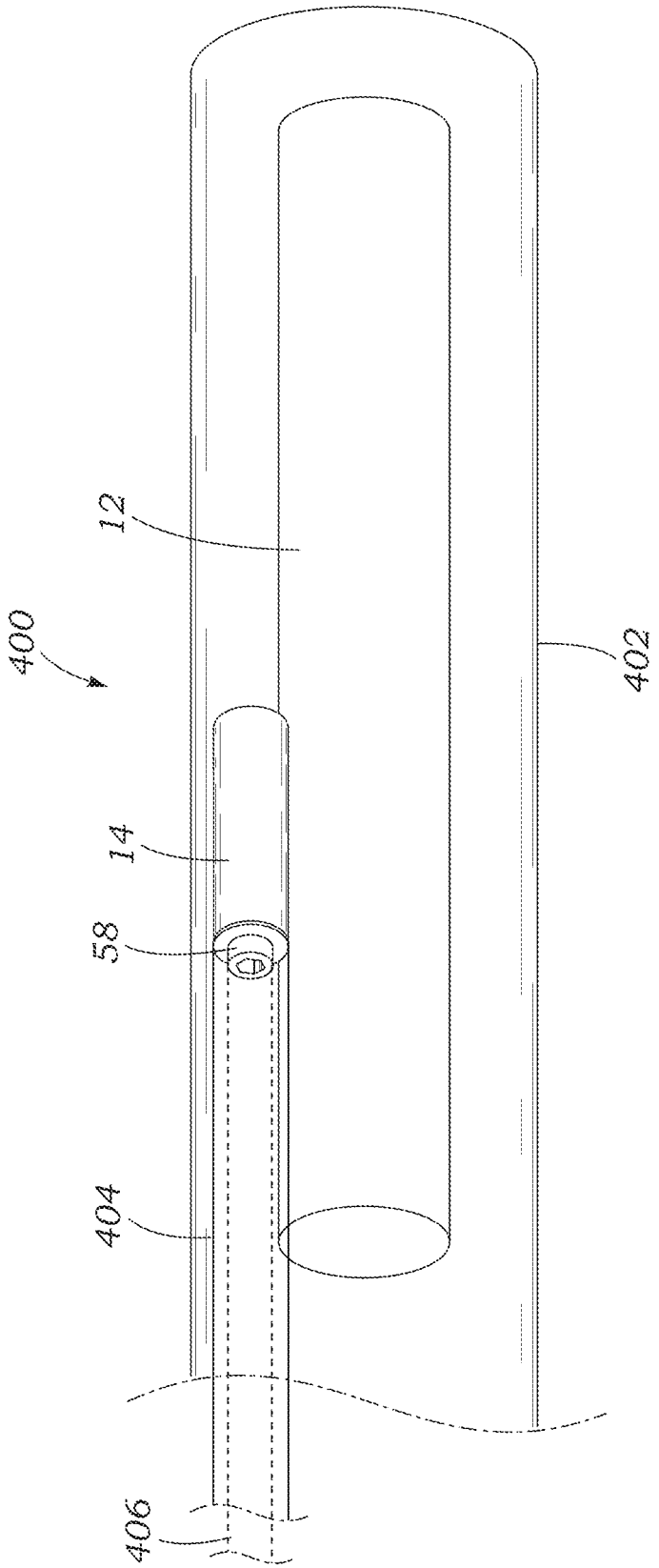


Fig. 7

Fig. 8

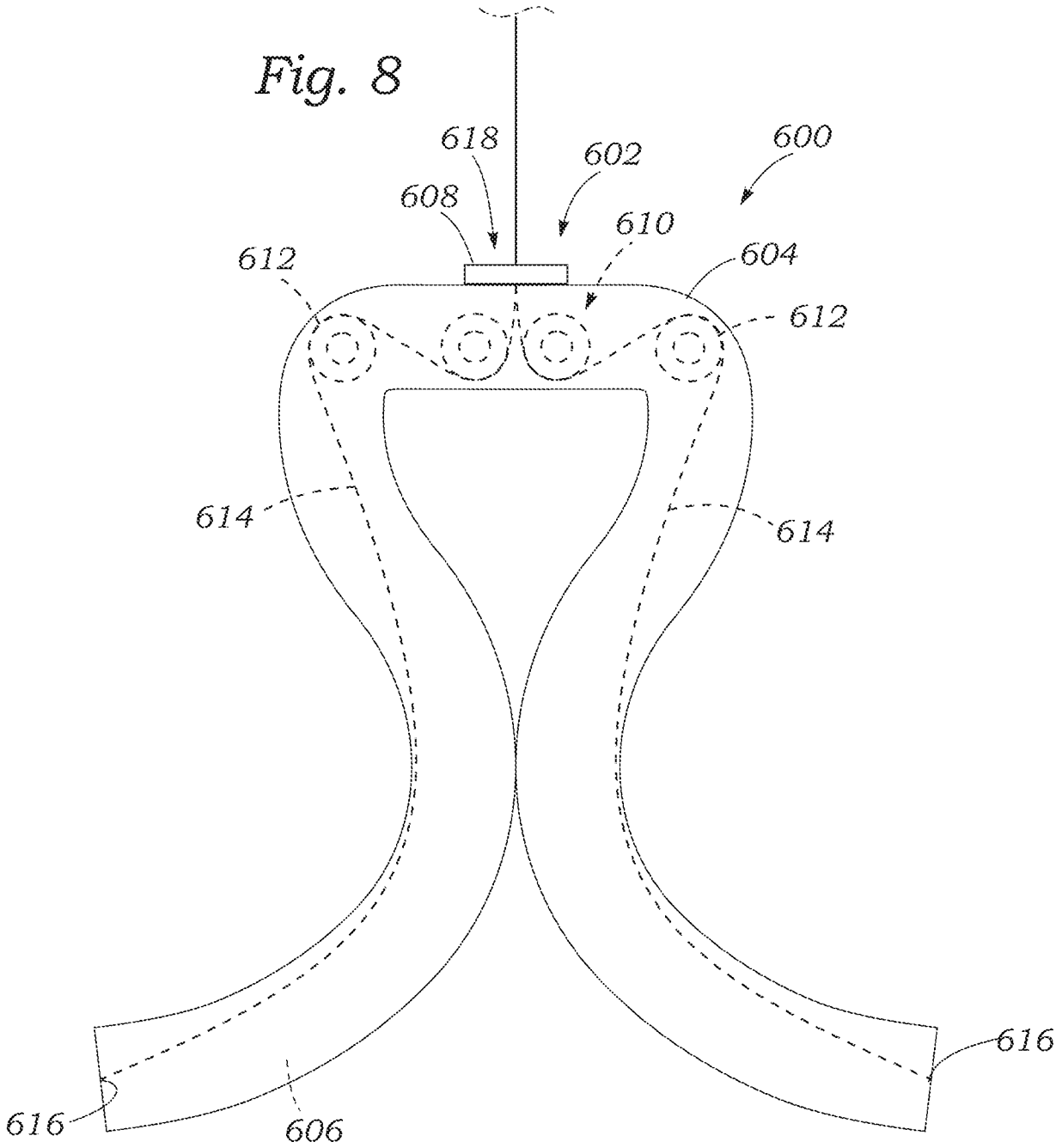


Fig. 10

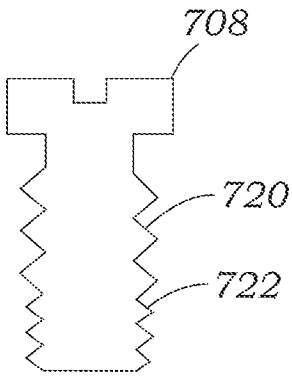


Fig. 9

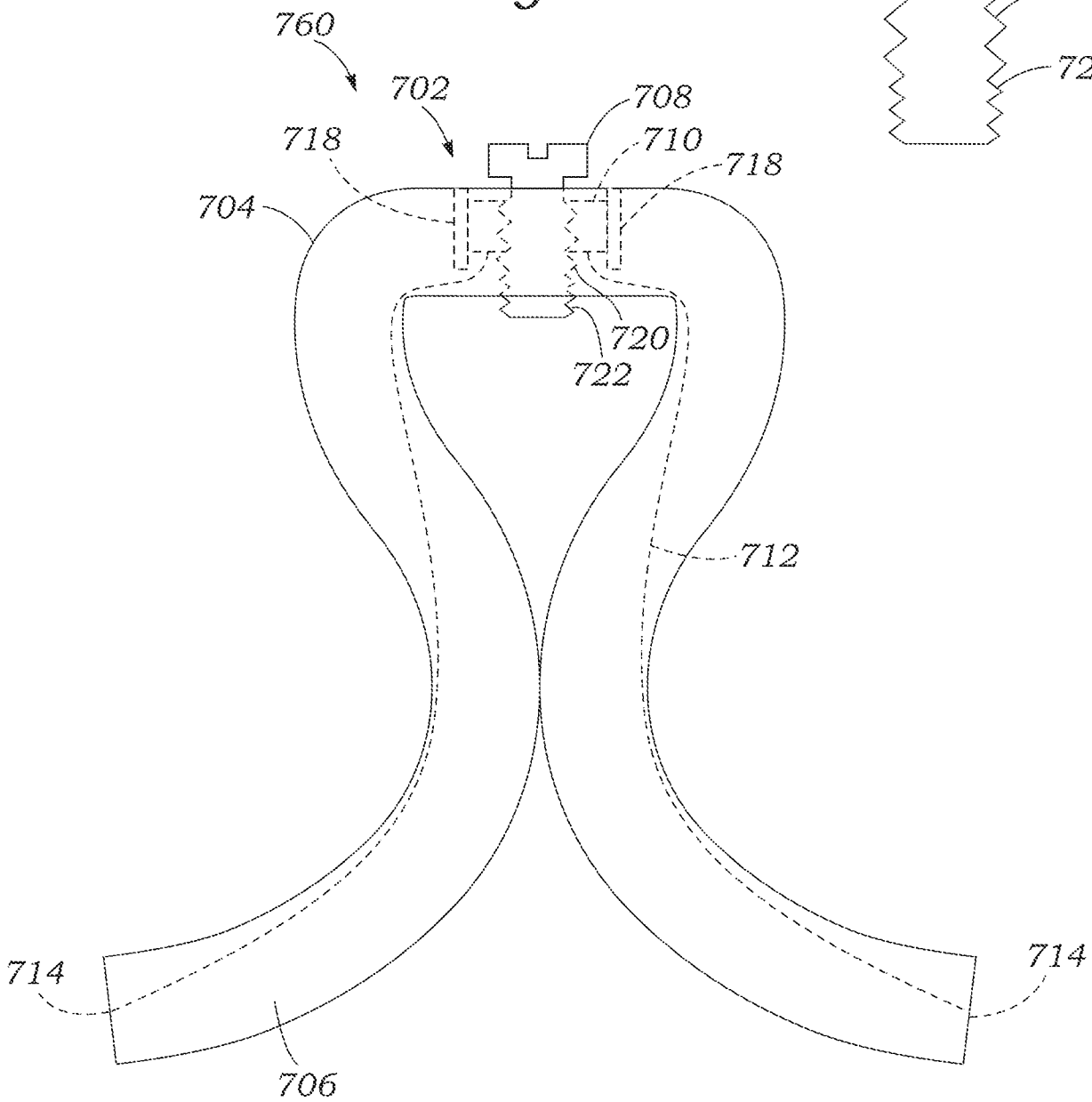


Fig. 11

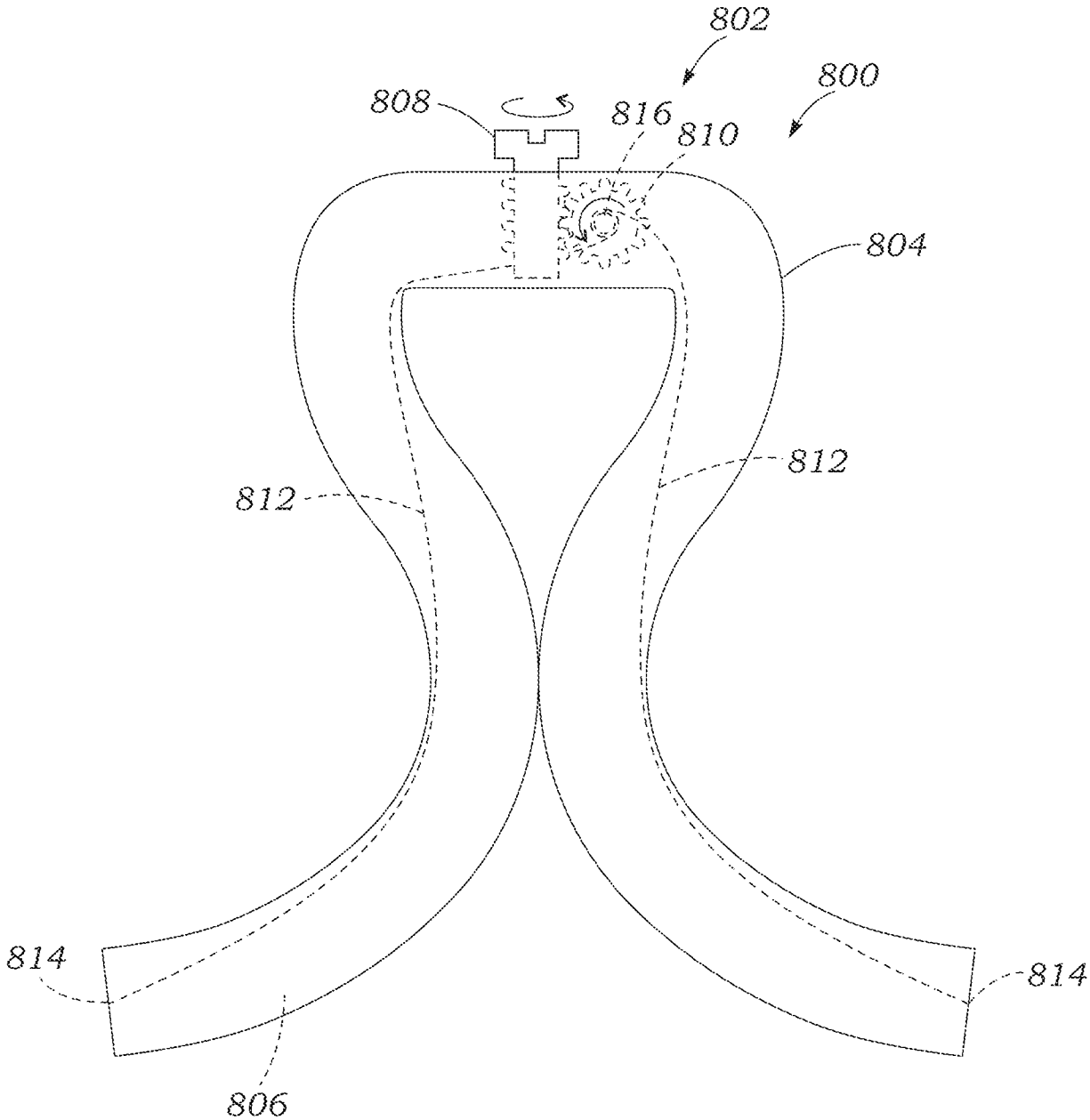


Fig. 12

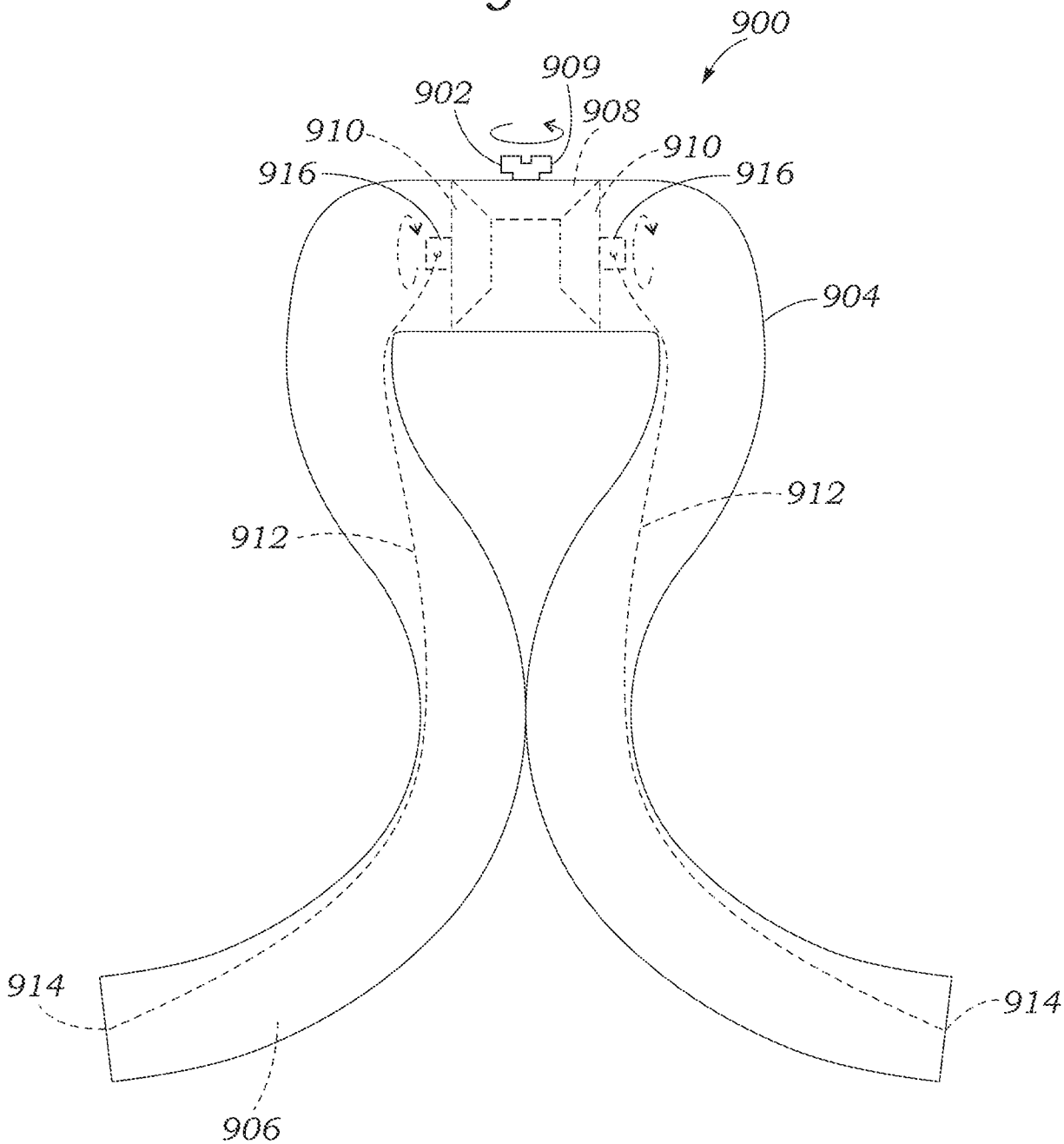


Fig. 13

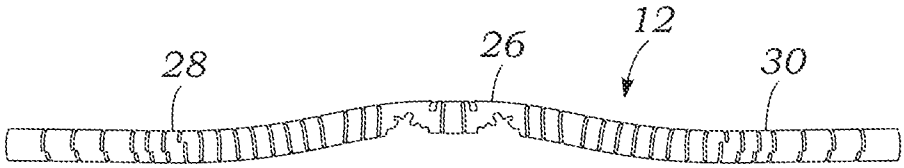


Fig. 14

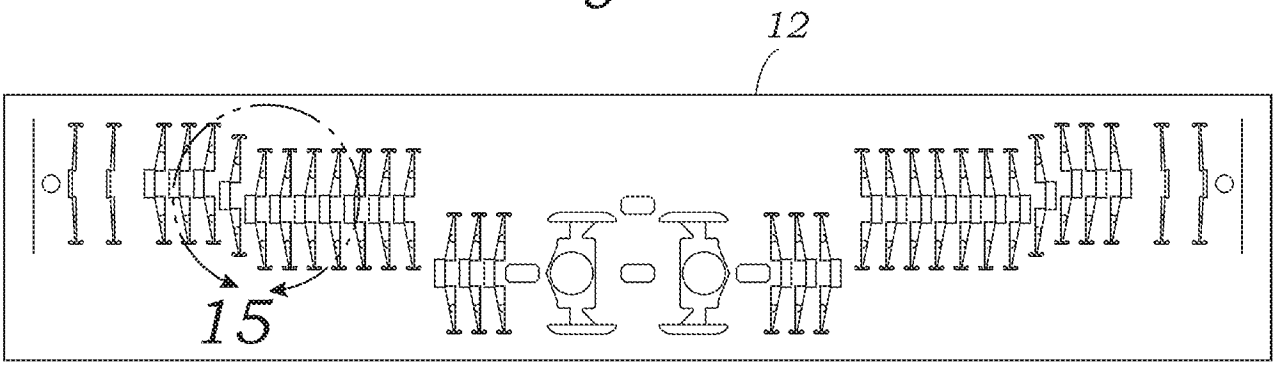


Fig. 15

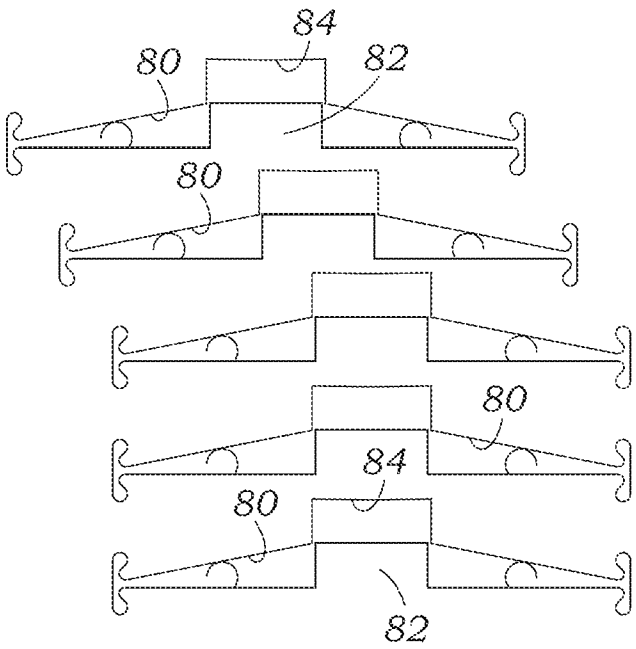


Fig. 16

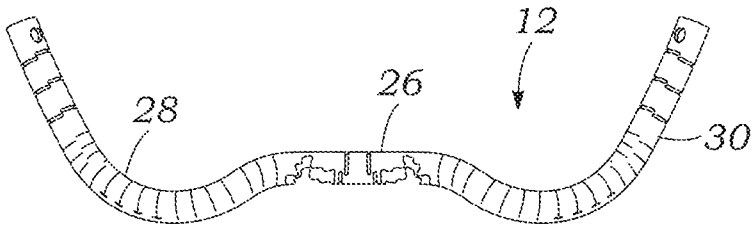
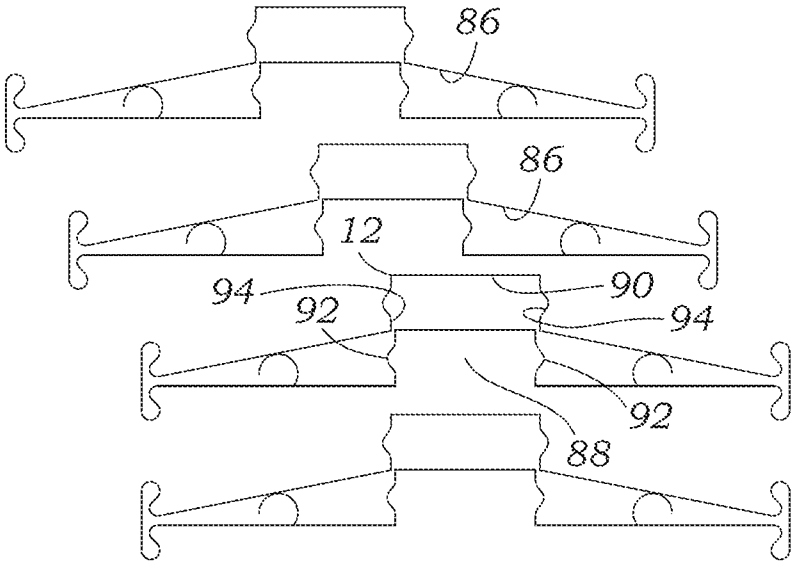


Fig. 17



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/037461

A. CLASSIFICATION OF SUBJECT MATTER

A61F 2/24(2006.01)i, A61L 27/50(2006.01)i

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)
A61F 2/24; A61B 17/10; A61B 17/29; A61B 17/062; A61B 17/08; A61L 27/50

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: heart leaflet, clip, capture, tensioning, lumen

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2016-0157862 A1 (HERNANDEZ, C. R. et al.) 09 June 2016 See claims 1-10; figures 33-34.	1-3,11-14
A	US 2004-0220593 A1 (GREENHALGH, E. S.) 04 November 2004 See the whole document.	1-3,11-14
A	US 2011-0077668 A1 (GORDON, L. et al.) 31 March 2011 See the whole document.	1-3,11-14
A	US 2013-0138121 A1 (EDWARDS LIFESCIENCES CORPORATION) 30 May 2013 See the whole document.	1-3,11-14
A	US 2014-0066693 A1 (GOLDFARB, E. A. et al.) 06 March 2014 See the whole document.	1-3,11-14

☐ 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
"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	Date of mailing of the international search report
14 September 2017 (14.09.2017)	**14 September 2017 (14.09.2017)**

Name and mailing address of the ISA/KR
International Application Division
Korean Intellectual Property Office
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Facsimile No. +82-42-481-8578

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Telephone No. +82-42-481-3362

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/037461

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 4-10,15-18
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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:

1. ☐ As all required addtional 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 an additional fees, this Authority did not invite payment of any 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.:

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.

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