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DESCRIPTION

[0001] In general, the devices, systems, and methods described here are for closing off a portion of tissue, e.g., the left atrial appendage, using a surgical, minimally invasive, or intravascular approach.

[0002] Atrial fibrillation is a common problem that afflicts millions of patients. Unfortunately, atrial fibrillation often results in the formation of a thrombus, or clot, in the appendage of the left atrium. This presents a problem, inasmuch as the thrombus can dislodge and embolize to distant organs, resulting in adverse events such as a stroke. For this reason, most patients with atrial fibrillation are treated with a blood thinner to help prevent the formation of a thrombus. Blood thinners, however, can present health risks (e.g., bleeding), particularly in the elderly, and often also require that the user make significant lifestyle changes.

[0003] Several methods have been developed to address the potential problem of thrombus formation in the left atrial appendage. One such method is suturing along the base, or ostial neck of the appendage, where it joins the atrial chamber. In this way, blood flow into the atrial appendage is cut-off, eliminating the risk of thrombus formation therein. This is typically done through open-heart surgery, making the availability of the procedure available to only those who are otherwise undergoing an open-heart procedure, or who are at particularly high risk. In addition, open-heart surgery requires general anesthesia and has a number of well-known risks, making it less desirable.

[0004] Other methods have also been investigated. For example, methods of stapling the base of the appendage and methods have been investigated, as have methods of filling the appendage with a space occupying, or occluding member. However, stapling is not a preferred method given the fragility of the appendage and the likelihood of its rupture. Occlusion devices may not effectively prevent all blood flow into the appendage, leaving areas of potential thrombus formation.

[0005] In EP-A-10010397 there is described an endoscope instrument, with a filament loop at the leading end which forms a closing knot when it is pulled at the trailing end. Fixing units for the filament are placed at the inner periphery of sprung forks to give a loose holding action on the filament. The filament loop is fed through a sleeve in one fork arm. Each fixing unit has clamping ridges to apply a clamping action on the filament loop at that point. The forks are of a plastics material which bends easily.

[0006] By contrast, in EP-A-1685802 there is described a medical procedure tool equipped with a flexible linear material for carrying out a specific procedure to a biological tissue and a linear material holding member for holding the linear material. A flexible first sheath is provided to come into contact with the base end side of the linear material holding member and a flexible second sheath is provided to be freely advancing and retracting with respect to the first sheath and the linear material holding member. An operator is provided for advancing and retracting manipulation of the second sheath together with a cutting means for cutting the linear material. The cutting means is provided with a first cutting part provided to the linear material holding member and a second cutting part that is provided to the front end of the second sheath and which, together with the first cutting part, grips the linear material therebetween. Furthermore, one of either the first cutting part or the second cutting part is a blade member.

[0007] Nevertheless additional devices and methods for closing the left atrial appendage would be desirable. In particular, devices and methods for closing the left atrial appendage using minimally invasive, intravascular, or a combination of these techniques, would be desirable in order to avoid the need for opening the chest. Of course, additional devices for use in open surgical procedures are desirable as well, especially when those devices offer additional advantages over standard devices.

BRIEF SUMMARY

[0008] According to the present invention there is provided a device for closing the left atrial appendage having the features set out in claim 1.

[0009] In addition there are described here devices, systems and methods for closing the left atrial appendage. Some of the methods described here utilize one or more guide members having alignment members to aid in positioning of a closure device. In general, these methods comprise advancing a first guide having a first alignment member into the left atrial appendage, advancing a second guide, having a second alignment member, into the pericardial space, aligning the first and second alignment members, advancing a left atrial appendage closure device into the pericardial space and adjacent to the left atrial appendage, and closing the left atrial appendage with the closure device.

[0010] The devices used in any of the methods described here may be advanced under any of a variety of visualization techniques, e.g., fluoroscopic visualization, ultrasound, etc. For example, the first guide, second guide, or both guides may be advanced under fluoroscopic visualization in some variations. Similarly, any of the devices used in any of the methods described here may be advanced over a guide element or guide wire. For example, the first guide, second guide, closure device, any additional guide, or any combination thereof, may be advanced over a guidewire. In some variations, the second guide is coupled to the closure device for at least a portion of the method.

[0011] The alignment members may be, or may comprise, any suitable alignment member. For example, they may be or may comprise magnets, radiopaque markers, echogenic markings, members configured to produce one or more audible signals, interconnecting or interlocking members, one or more vacuum members, or the like. In some variations, the alignment members are magnets.

[0012] The first guide may further comprise an expandable member, e.g., an expandable cage, an expandable struted structure, an expandable balloon, or the like. In some variations, the expandable member comprises an expandable balloon. The expandable member may be used for any suitable purpose, e.g., to atraumatically displace tissue, to help with identifying, sizing, protecting, isolating, stabilizing, or positioning tissue, or the like. In some variations, the expandable member is expanded within the left atrial appendage. In other variations of the methods described here, a third guide is advanced into the left atrial appendage, where the third guide has a proximal end and a distal end and comprises an expandable member. In some additional variations, the first and third guides are coupled together for at least a portion of the method. Again, the expandable member may comprise any suitable expandable member. In some variations, the expandable member is a balloon, which may or may not have one or more apertures therein. The apertures, for example, may be useful in enabling inflation and deflation of the balloon, may be useful for enabling passage of one or more guides or guidewires therethrough, or may be useful in enabling delivery of fluids, such as saline, contrast, drugs, etc., distal of the balloon.

[0013] The closure element alone may capture and release the left atrial appendage (i.e., it can open and close around the left atrial appendage), which may help facilitate optimal closure of the left atrial appendage, prior to permanent exclusion.

[0014] The methods described here may further comprise tensioning the suture. The methods may additionally comprise releasing the tension on the suture, e.g., to help facilitate repositioning of the device, and the like. The methods may further comprise releasing the suture from the closure element, tightening the suture, and severing the suture. When the methods include severing the suture, the suture may be severed in any suitable fashion. For example, the suture may be severed with a cutting element, or may be severed by the application of energy (e.g., light energy, thermal energy, RF energy, electrical energy, magnetic energy, electromagnetic energy, kinetic energy, chemical energy and combinations thereof). When a cutting element is used, it may be an element on the closure device itself, or it may be part of a separate device.

[0015] The methods described here may also include confirming satisfactory or optimal closure of the left atrial appendage prior to permanent exclusion, excluding or opening the left atrial appendage with the closure device, repositioning the closure device, reclosing the left atrial appendage, and permanently excluding the left atrial appendage.

[0016] Other methods for closing the left atrial appendage are also described. In these methods, a closure device is advanced into the pericardial space and adjacent to the left atrial appendage, the left atrial appendage is closed with the closure device, the left atrial appendage is secured with a suture, and then the suture is severed.

[0017] As with the methods described just above, the severing of the suture may be accomplished in any suitable fashion. For example, the suture may be severed with a cutting element, or by the application of energy (e.g., light energy, thermal energy, RF energy, electrical energy, magnetic energy, electromagnetic energy, kinetic energy, chemical energy and combinations thereof). When a cutting element is used, it may be an element on the closure device itself, or may be part of a separate device, or some combination of both may be used.

[0018] The closure device may comprise one or more expandable elements, and the closure device, the suture, or both may comprise a radiopaque material, echogenic material, or some combination thereof. In some variations, the closure device is made from a shape-memory material (e.g., a nickel titanium alloy, or the like), and in some variations, the suture is coupled to the closure device. In these methods, the closure device may be visualized while advanced, e.g., using fluoroscopy, ultrasound, a combination thereof, etc., and may or may not be advanced over a guide element or guidewire.

[0019] Additional methods for closing a left atrial appendage are also described here. These methods typically comprise advancing a first guide having a proximal end and a distal end into the left atrial appendage, through the left atrial appendage,

and out of the left atrial appendage, such that one of the proximal or distal ends is within the vasculature, and one of the proximal or distal ends is within a subthoracic space, and advancing a left atrial appendage closure device into the pericardial space and adjacent to the left atrial appendage, and closing the left atrial appendage with the closure device.

[0020] In these methods, the proximal end of the first guide may be within the vasculature, or within the subthoracic space. In some variations, the closure device is advanced into the pericardial space over the first guide. Again, as with all the methods described here, any of the devices may be advanced under any of a variety of visualization techniques. For example, the first guide, closure device, or both may be advanced under fluoroscopic or ultrasound visualization, or both. In some variations, the methods further comprise advancing a second guide into the left atrial appendage, where the second guide has a proximal end, a distal end, and comprises an expandable member. The expandable member may be any suitable expandable member (e.g., expandable struts, expandable cage, expandable balloon, or the like). In some variations, the first and second guides are coupled together for at least a portion of the method.

[0021] Devices for closing the left atrial appendage are also described here. The retention member may be configured to comprise first and second lumens, where the closure element is housed within the first lumen and the suture loop is housed within the second lumen. The second lumen may have a weakened region, a perforated region, or a slit or other opening configured to release and/or close the suture with the application of a force. In other variations, the retention member and the closure element are withdrawn or otherwise removed, leaving behind and/or closing the suture loop. In still other variations, the retention member comprises a first lumen and one or more releasable retention elements, where the closure element is housed within the first lumen and the suture loop is retained by the one or more releasable retention elements. The retention element may be any suitable element, for example, a releasable prong, a polymer tack, and the like.

[0022] The closure element may be made from any suitable material. In some variations, the closure element is made from a shape-memory material (e.g., a nickel titanium alloy). Similarly, the suture loop may be made from any suitable material (e.g., any suitable material useful for exclusion or closure). It may be bioabsorbable (e.g., biodegradable polymers, etc.), or non-bioabsorbable (e.g., non-biodegradable polymers, metals, etc.). The closure element, suture loop, or both may comprise a radiopaque or echogenic material.

[0023] In some variations, the elongate body has one or more curves along its length. The elongate body may or may not be steerable, and may or may not be configured as a catheter. In some variations, the closure element and the suture loop are separately actuatable. In other variations, the device further comprises a cutting element.

[0024] Systems for closing a left atrial appendage are also described here. Typically, the systems comprise a first guide having a size and length adapted for accessing the left atrial appendage through the vasculature, where the first guide comprises a first alignment member, a second guide having a size and length adapted for accessing the pericardial space from a subthoracic region, where the second guide comprises a second alignment member, and a closure device as hereinbefore described. The system may further comprise any suitable or useful device or component.

[0025] For example, in some variations the system further comprises an expandable member. The expandable member may be any suitable expandable member, and in some variations the expandable member is an expandable balloon with or without one or more apertures therein. The expandable member may be configured to be couplable to the first guide.

[0026] The systems described here may further comprise a device or element for severing the suture. In some variations, the closure device is couplable to the second guide.

[0027] The first and second alignment members may be any suitable alignment members. For example, they may be or may comprise magnets, radiopaque markers, echogenic markings, members configured to produce one or more audible signals, interconnecting or interlocking members, one or more vacuum members, or the like. In some variations, the alignment members are magnets, which may or may not be located at the distal ends of the first and second guides. The systems may further comprise instructions for using the first guide, second guide, closure device, or any combination thereof. In some variations, the elongate body of the closure device has one or more curves along its length, and the systems further comprise a straightening tube, configured to temporarily straighten the one or more curves.

BRIEF DESCRIPTION OF THE DRAWINGS

[0028]

FIG. 1 provides a cross-sectional representation of a heart showing various anatomical structures.

FIGS. 2A-2B are different views of an illustrative device that may be used with the systems and methods described herein.

FIG. 3A provides a close-up view of a distal end of an illustrative device having a retention member.

FIGS. 3B-3D depict illustrative retention members that may be used with the devices described herein.

FIG. 4 provides a close-up view of a distal end of an illustrative device, without a retention member.

FIG. 5 is a depiction of an illustrative device with the catheter body removed for purposes of description and clarity.

FIG. 6 provides another depiction of an illustrative device with the catheter body removed, here, showing more of the device.

FIG. 7 is a close-up view of an illustrative suture retention mechanism, here, shown as a suture hook.

FIG. 8 is a close-up view of a distal end of an illustrative device having a lumen therethrough.

FIG. 9 is a top side view of one variation of the proximal end of the devices described here.

FIG. 10 is a skewed end view of one variation of the proximal end of the devices described here.

FIG. 11 provides a cross-sectional view of one variation of the proximal end of the devices described here.

FIG. 12 is an illustrative suture cutter that may be used with the systems and methods described here.

FIGS. 13A and 13B are illustrative guides having alignment members.

FIGS. 14A-14D depict an illustrative method of closing the left atrial appendage.

FIGS. 15A-15D depict an alternative illustrative method of closing the left atrial appendage.

FIG. 15E depicts an illustrative device that may be used to perform the method depicted in FIGS. 15A-15D.

DETAILED DESCRIPTION

[0029] Described here are devices, systems, and methods for closing the left atrial appendage. In this regard, it may be helpful to start by briefly identifying and describing the relevant heart anatomy. Shown in FIG. 1 is a cross-sectional view of the heart (100). Shown there is left atrium (102) and left ventricle (104). In between the left atrium (102) and the left ventricle (104) is the mitral valve (also known as the bicuspid valve), which is defined by a pair of mitral valve leaflets (106). The leaflets are connected to chordae tendinae (108) that are in turn, connected to papillary muscles (110). The papillary muscles join ventricular wall (112). The left atrial appendage (114) is shown adjacent to, and is formed from, the wall of the left atrium (102).

[0030] As can be seen, the left atrial appendage (114) lies within the boundaries of the pericardium (116), and is in close proximity to the ventricular wall (112). The left atrial appendage typically has a tubular shape that approximates a cone, with a slight narrowing or neck in the plane of the orifice where it joins the left atrium (102). In patients with atrial fibrillation, the left atrial appendage (114) is the most common location for thrombosis formation, which, in time, may dislodge and cause a devastating stroke. Because stroke is the primary complication of atrial fibrillation, the left atrial appendage is frequently excluded from the left atrium in those patients undergoing procedures to treat atrial fibrillation, and is often removed or excluded at the time of other surgical procedures, such as mitral valve surgery, to reduce the risk of a future stroke. The devices and systems described here, help ensure proper closure of the left atrial appendage, at the neck or base of the left atrial appendage, along the anatomic ostial plane. In this way, exclusion of the entire left atrial appendage from systemic circulation may be facilitated.

I. Devices

[0031] The devices described here for closing the left atrial appendage generally comprise a closure element having one or more loops. The devices may be suitable for use with minimally invasive access to the left atrial appendage (e.g., through a small sub-xyphoid or other intercostal incision, through an incision in the costal cartilage, through a port, through the vasculature, etc.) or may be suitable for use with open surgical procedures. The lengths of the devices may be chosen as desirable.

[0032] FIGS. 2A and 2B provide different views of an exemplary device that may be used to close the left atrial appendage. Shown in FIG. 2A is device (200) comprising an elongate body (202) having a proximal end and a distal end, and a closure element (204). In this variation, the closure element comprises a loop that defines a continuous aperture therethrough suitable for encircle the left atrial appendage therein. The closure element is at least partially housed within the elongate body (202) and may be advanced therefrom, or retracted therein. Also shown in FIG. 2A is a lumen (214) for passage of a tools or fluids therethrough. For example, the lumen (214) may enable passage of a guide (with or without an alignment member), a guidewire, a suture cutter, fluids and/or drugs, and the like. Any number of lumens may be used for any suitable purpose. Suitable lumens will be described again with reference to FIG. 8. Also shown in FIGS. 2A and 2B is handle (206) having a linear actuation slide (208) and knob (210). Additional details of the handle will be discussed below.

[0033] In the variation shown in FIGS. 2A and 2B, the elongate body (202) comprises a curve (212) at a distal portion thereof. In instances where the elongate body (202) of the device comprises one or more curves, a straightening tube, or other straightening mandrel or mechanism may be used to temporarily straighten the elongate body during delivery (e.g., until the pericardial space is reached). After a particular location has been reached, the straightening tube or mandrel may then be withdrawn. The straightening tube may be made of any suitable material (e.g., a rigid plastic, stainless, combination thereof, etc.). Of course, it should be understood that the device need not comprise one or more curves as shown in FIGS. 2A and 2B. For example, the elongate body may be straight and flexible, and a pre-curved tube or mandrel may be employed during the methods to aid in delivery and use (e.g., while advanced to the left atrial appendage). Similarly, the elongate body may be straight and flexible, and have a pull wire attached thereto, so that when the pullwire is pulled proximally, the elongate body flexes and bends. In this variation, the elongate body may be maneuvered as appropriate. It should be understood that any of the devices described here may be configured for steerability, or may be configured for robotic use (e.g., configured for use with one or more robotic or other automated type device).

[0034] FIG. 3A provides additional detail of a suitable closure element. Shown there is a distal portion (300) of a suitable closure device having an elongate body (302) and a closure element assembly (304). In FIG. 3A, details of an elongate body extension, or tip (306) can be seen. This tip may be thermoformed or injection molded, or may be integral with the rest of the elongate body (302). In instances where a suture loop (308) is used, the tip (306) may serve to house a suture knot therein. It should be understood that when reference is made to the elongate body, it is meant to include any such tip (306) as shown in FIG. 3A. Also apparent in FIG. 3A is suture loop (308), which is shown passing through the tip (306) in a proximal direction and into a retention member (312) in a distal direction. Also shown passing through tip (306) in a proximal direction and into retention member (312) in a distal direction is closure element (310), which will form a loop to encircle the left atrial appendage. As can be seen by FIG. 3A, the retention member is configured to retain the closure element and the suture loop.

[0035] FIGS. 3B-3D depict illustrative retention members that may be used with the devices described herein. FIG. 3B shows an end view of a retention member (314) having first and second lumens (316, 318) for retaining a closure element and a suture loop therein. In this variation, the second lumen (318) has a slit or other opening (320) along its length, for allowing the suture to pass therethrough when it is ready to be deployed. Of course, it should be understood that the first and second lumens may be positioned or oriented in any suitable way with respect to each other, and similarly, the slit or other opening on the second lumen may be positioned or oriented in any suitable fashion with respect to the first lumen (e.g., it may be approximately 180°, approximately 150°, approximately 120°, approximately 90°, approximately 60°, approximately 30°, or the like, from the first lumen (316)). FIG. 3C provides an illustration of a retention member having a first lumen (322), a second lumen (324), and a slit (326). In this variation, the slit (326) is positioned closer to the first lumen (322) than the slit of FIG. 3B. The width or spacing of the slit opening may selected as desired or appropriate. Similarly, the slit need not extend or be continuous along the entire length of the retention member. In some variations, the slits may have prongs or arms along its length to help capture and retain the suture therein. In other variations, the slits may be covered at spaced apart locations therealong with a biodegradable polymer, temporarily used to tack or hold down the suture. Of course, in still other variations, the retention member does not comprise a slit, and instead comprises some other type of retention mechanism, such as the prongs or tacks described just above. In yet other variations, there are no slits or openings in the retention member and the suture loop is released upon removing or withdrawing the retention member and closing the device.

[0036] FIG. 3D provides another variation of a retention member. In this variation, the retention member has a first lumen (328), second lumen (330), and a separation region (332). The separation region may be constructed in any suitable fashion. For example, the separation region may comprise a perforated region adapted to perforate and release the suture with the application of force. Alternatively, the separation region may be a thin-walled or other type of weakened region that may be configured to break and release the suture. It should be understood that the retention member may have any suitable geometry or shape, and may be made from any suitable material. Similarly, the lumens need not be full circles or have a circular cross-

sectional geometry. When these or other types of retention members are used, the suture loop may be torn out, pulled through, or otherwise released from the retention member after it has been properly positioned and tightened as desirable.

[0037] The above described components may be made of any suitable material. For example, the closure element may be made from a shape-memory material, such as a shape-memory alloy (e.g., nickel titanium alloy, etc.), may be made from stainless steel, polyester, nylon, polyethylene, polypropylene, some combination thereof, etc. Similarly, the suture loop may be made of any suitable material useful in exclusion or closure, and the term "suture loop" should be understood accordingly. For example, it may be made of a biodegradable material (e.g., polylactic acid, polyglycolic acid, polylactic-co-glycolic acid, etc.), or may be made of a non-biodegradable material (e.g., metal, steel, polyester, nylon, propylene, silk, and combinations thereof). In some variations, as will be described in more detail below with reference to the methods, the suture loop is made from a biodegradable material such that the suture loop degrades after a period of time has elapsed (e.g., for sufficient scarring to be achieved). It should be understood, that any part of the device may comprise, include, or be made from a radiopaque or echogenic material to help facilitate visualization. For example, the closure element, the suture loop, the elongate body, or any combination of these components may comprise a radiopaque or echogenic material.

[0038] The suture loop and the closure element may be configured to have any appropriate perimeter. For example, they may have a perimeter of 114.3mm (4.5 inches) in a fully expanded state, a perimeter of about 109.2mm (about 4.3 inches), about 83.8mm (about 3.3 inches), about 101.6mm (about 4.0 inches), about 88.9mm (about 3.5 inches), 76.2mm (3.0 inches), about 68.6mm (about 2.7 inches), about 63.5mm (about 2.5 inches), about 38.1mm (about 1.5 inches), about 31.8mm (about 1.25 inches) or the like. Of course, these perimeters will vary as the closure element and suture loop are actuated and retracted.

[0039] For additional clarity, FIG. 4 provides a view of distal portion (300) of FIG. 3A, without retention member (312), thus showing the looped nature of closure element (310) and suture (308). FIG. 5 is a view of distal portion (300), without retention member (312), tip (306), and elongate body (302), thus providing additional details of this variation of the device. Shown there is of course, closure element (310) and suture (308). Suture (308) further comprises a surgical knot (e.g., a one way slipknot or other suitable knot) (500). Also shown is an anchoring feature (502), here shown as a tube, for anchoring one side of the closure element (310). The opposite side of the closure element is the active or actuation side (i.e., one side remains anchored while the other side has additional active length). Of course, when anchoring is used, it may be done in any suitable way. In other variations (not shown here), both sides of the closure element are active and actuatable (i.e., neither side is anchored). The device may also comprise a suture tube (504) for facilitating suture passage.

[0040] FIG. 6 shows additional proximal detail of a suitable closure device. In this view, the elongate body and tip have been removed, but the retention member remains. Of particular interest here is suture hook (600). Suture hook (600) captures suture loop (308) so that the closure element (310) may be advanced and retracted separately from suture loop (308) when the two are coupled together. That is, the suture hook (600) prevents the suture from tightening as the closure element is actuated, so that the device may be positioned as desirable before the suture is actuated. The suture hook (600) may also help prevent excess suture from opening and closing, and thus help prevent excess suture from getting caught on anatomical structures, instruments, etc. Also shown in FIG. 6 is a proximal length of the closure element (602). In some variations, it may be useful to have at least a portion of the proximal length of the closure element (602) coated with a lubricious coating, in order to help facilitate slidable actuation. Any suitable lubricious coating may be used (e.g., PTFE, etc.). The suture hook (600) is shown in greater detail in FIG. 7. While the suture hook shown in FIG. 7 has a rounded atraumatic tip, it need not be so. Indeed, any suitable tip may be used. The suture hook may be made of any suitable material.

[0041] FIG. 8 provides details of the distal portion of an illustrative closure device (800), here comprising at least one lumen (802) in the elongate body (804). The lumen may be used for any suitable purpose. For example, it may be used to enable passage of one or more guides or guidewires therethrough, one or more tools therethrough, or the like. The lumen may also be used as a flush lumen, a vacuum lumen, a drug delivery lumen, or the like. The elongate body may comprise any number of lumens, and it should be understood that the lumens need not traverse the entire length of the elongate body, nor form a completely bounded aperture (i.e., the use of lumens herein is intended to capture instances where a slit or groove may be used with one or more guides, guidewires, or additional tools).

[0042] FIG. 9 is one variation of a suitable handle (900) for the devices described herein. In this variation, the handle comprises a linear actuation slide (902) for actuating the closure element, and a suture knob (904) for actuating the suture. While not shown, the suture hook, described above, or similar such feature, helps enable the separate actuation capability described here. Thus when the slide (902) is pushed distally, the closure element, which has been at least partially retained within the elongate body, will be advanced distally, and the loop size of the closure element will get bigger. Conversely, when the slide is retracted proximally, the closure element will be retracted and the loop size will get smaller. The suture loop is not affected in this process. Instead, the suture loop in this variation is controlled by the suture knob. Of course, the suture loop need not be actuated by a

knob. That is, the suture may be separately actuated by an additional slide, lever, button, or the like. Similarly, the closure element need not be actuated by a slide. It may be actuated by a button, knob, lever, or the like.

[0043] Also shown in FIG. 9 is suture cutting slot (906). While not easily shown in this view, the suture runs through the handle and into the knob. The suture cutting slot enables the suture to be cut easily, as the suture traverse the slot and the slot provides a viewing window and access point for suture severing. Of course, the suture need not be severed in such a fashion. In some variations, the closure device itself comprises a cutting element for severing the suture (e.g., a blade actuated by a button or some other mechanism). FIG. 10 provides a skewed end view of the handle shown in FIG. 9 so that additional details may be seen. Specifically, shown here are suture knob lock (1000) and luer fitting (1002) at the proximal end of the handle lumen.

[0044] FIG. 11 provides a cross-sectional view of a portion of handle (1100), here showing a length of the handle including the suture knob (1102) and the slide actuator (1104) in its most retracted position. Suture knob (1102) comprises an outer knob (1106), and outer knob bearing (1108), inner knob (1110) and inner knob bearing (1112), thrust bearing (1114) and slip clutch plates (1116) that when actuated (when the knob (1102) is turned or rotated) apply a tension upon the suture loop causing it to release from the retention member. In one variation, the slip clutch plates (1116) have particular force settings and are configured to provide tactile feedback to the operator indicating closure. In other variations, the clutch plates (1116) may have a particular force limitation in order to protect against shearing or cutting of tissue by the suture during release or tightening of the suture loop. For example, in these variations, once the suture loop reaches a pre-determined force, the outer knob (1106) and outer knob bearing (1108) may disengage from inner knob (1110) and inner knob bearing (1112) by slipping or the like (e.g., similar to a gas cap when overtightened).

[0045] Also shown is a suture reel area (1118) and a suture severing slot (1120), which, as described briefly above, is used to help terminate the suture by placement of blade, scalpel, or other sharp instrument therein. As described above, in some variations, the closure device itself comprises a suture cutting device or mechanism, and this may be located at the same place as the suture severing slot (1120) or some other place. For example, the device may include a blade or other cutting mechanism that may be actuated by a blade, lever, knob, etc., whether or not located in the suture severing slot location. Lumen (1122) may be used for placement of a guide (with or without an alignment member), guidewire, one or more tools (e.g., a suture cutter, visualization devices, etc.), one or more fluids (e.g., saline, drugs, etc.), as described above.

II. Methods

[0046] Methods for closing the left atrial appendage are also described here. The left atrial appendage may be accessed in any suitable fashion, and any of the devices described here may be used. For example, the left atrial appendage may be accessed from the inside of the heart, or may be accessed from the outside of the heart. In some variations, the left atrial appendage is accessed from both the inside of the heart, and the outside of the heart. Typically, the appendage is closed off from the outside of the heart, even when accessed from the inside of the heart.

[0047] In variations when the left atrial appendage is accessed from both the inside and the outside of the heart, it may be useful to employ the use of guides having alignment members. In this way, accessing the left atrial appendage may be more easily facilitated. It may also be useful to employ the use of a positioner or stabilizer, to help position devices relative to the left atrial appendage and to stabilize the appendage while it is being closed off. The positioner or stabilizer may be any suitable stabilizer or positioner, e.g., an expandable member or the like. More details of this will be described below.

[0048] In some variations, the methods of closing the left atrial appendage comprise advancing a closure device into the pericardial space and adjacent to the left atrial appendage, closing the left atrial appendage with the closure device, securing the closed left atrial appendage with a suture, and then severing the suture. The closure device may be any suitable closure device, such as a device having an elongate body with a closure element comprising a loop defining a continuous aperture therethrough, as described above. The suture may be severed in any suitable fashion, and at any suitable location along its length (i.e., from immediately adjacent to the knot at the left atrial appendage to just proximal to, or just distal to, the skin surface). In some instances it may be desirable to sever the suture at the knot itself (e.g., in instances where it is desirable to release tension on the suture entirely).

[0049] An illustrative device (1200) for severing a suture is shown in FIG. 12. The device depicted there may be threaded over the suture and then actuated to cut the suture with a blade or similar cutting feature housed within distal portion (1202). While a device having a blade housed therein is depicted in FIG. 12, any suitable cutting device may be used, and the device may be made from or comprise any suitable materials (e.g., a radiopaque or echogenic material). In some variations, the closure device

has a cutting element thereon, for cutting the suture. Of course, the suture need not be severed with a blade or other such cutting feature. The suture can be severed by the application of energy. For example, the suture may be severed with the application of light energy, thermal energy, RF energy, electrical energy, magnetic energy, electromagnetic energy, kinetic energy, chemical energy, and combinations of any of the above. Additional methods will now be described.

A. Transseptal and Pericardial Access

[0050] In some variations, the methods for closing the left atrial appendage include accessing the left atrial appendage from both the inside of the heart and the outside of the heart. In these variations, one or more guides having alignment members are often used to align the inside and outside access devices together. To access the inside of the heart, the vasculature is typically used. For example, access may be obtained via one or several of the various veins or arteries (jugular, femoral, carotid, etc.). In some variations, the heart is accessed on the inside via the common femoral vein (e.g., the left common femoral vein) using a standard Seldinger technique with a needle. An introducer wire may then be advanced through the needle, followed by an introducer sheath. The introducer wire may then be removed. In some variations, a guiding catheter sheath may be placed as an alternative to an introducer sheath or the initial sheath may be replaced with a guiding catheter sheath.

[0051] Using fluoroscopy, an angiogram performed through the sheath, a catheter placed through the sheath, a guiding catheter sheath, or any combination thereof, may be performed to observe anatomical characteristics and considerations of the access route for the purpose of transseptal access into the left atrium (e.g., tortuosity, clots, devices, such as vena cava filters, etc.). Fluoroscopy, ultrasound, intracardiac echocardiography, extracardiac echocardiography, transesophageal echocardiography, or combinations thereof, may be used to help visualize transseptal access to the left atrium, and access to the left atrium may be obtained using standard transseptal access techniques.

[0052] For access to the heart from the outside, a subthoracic access point may be used. The access point is typically identified based on patient anatomic characteristics. In some variations, the access point is right of the xyphoid process and pointed towards the patient's left shoulder, but may be at any suitable location (e.g., intercostal access via a sternotomy, thoracostomy, or thoracotomy, or in the costal cartilage itself). Once the access point has been determined, a needle (e.g., a 17G Tuohy needle) may be advanced using standard pericardiocentesis techniques under fluoroscopic guidance. After access to the pericardium has been obtained, a guidewire may be advanced through the needle under fluoroscopic visualization within the pericardiac sac. The needle may then be removed. Access to the pericardial space has thus been obtained.

[0053] Turning now to the figures, after access from the inside and outside of the heart has been obtained using the above described devices and techniques, the devices are ready for use. For example, first (1300) and second (1302) guides having alignment members as shown in FIGS. 13A and 13B respectively may be used to guide the procedure. The alignment member may be any suitable alignment member (e.g., interconnecting elements, one or more vacuum members, radiopaque or echogenic markers, members that are configured to produce an audible response, magnets, etc.). Here, the alignment members are magnets (1304, 1306) located at the distal ends of the guides. The magnets may be made from or comprise any suitable magnetic material, e.g., a rare earth magnet, such as neodymium-iron-boron, cobalt-samarium, or other powerful fixed magnet elements. These guides may be used for guiding additional tools and/or devices to the left atrial appendage.

[0054] The guides may have any suitable lengths and/or dimensions. For example, the guides may have a diameter of about 0.254mm to about 1.270mm (about 0.010 inches to about 0.050 inches), about 0.508mm to about 0.762mm (about 0.020 inches to about 0.030 inches) or the like. In some variations the first guide has a diameter of about 0.635mm (about 0.025 inches) and the second guide has a diameter of about 0.889mm (about 0.035 inches). Similarly, the length may be any suitable length. For example, from about 50 cm to about 300 cm or more, from about 100 cm to about 200 cm, from about 200 cm to about 250 cm, and the like. In some variations, the first guide has a length of about 250 cm and the second guide has a length of about 90 cm. The outer diameter of the alignment element may also be selected as desirable. For example, it may be from about 1.27mm to about 5.08mm (about 0.05 inches to about 0.2 inches) or more. In some variations, the outer diameter of the alignment member of the first guide is about 2.692mm (about 0.106 inches) and the outer diameter of the alignment member of the second guide is about 4.318mm (about 0.170 inches). It should be understood that these dimensions are suitable for any guide, not only guides having alignment members comprising one or more magnets.

[0055] For example, turning to FIG. 14A, the first guide (1400) may be advanced into the left atrial appendage (1404), while the second guide (1402) may be advanced into the pericardial space adjacent to the left atrial appendage. Either of these guides may be advanced under any of a variety of visualization techniques, e.g., fluoroscopic visualization, ultrasound visualization, some combination thereof, etc. A balloon catheter (1406) or other expandable member may be advanced over the first guide, or in

conjunction with the first guide (e.g., it may be coupled to or be part of the first guide) and into the left atrial appendage as shown in FIG. 14B. Similarly, a closure device (1408) may be advanced over the second guide, or in conjunction with the second guide (e.g., it may be coupled to or be part of the second guide), as shown in FIG. 14B.

[0056] In instances where a balloon is used as an expandable member, it may be made of any suitable material. For example, it may be made of polyisoprene, or other suitable materials. Similarly, the balloon may have any suitable dimensions. For example, it may have an outer diameter of approximately 10-40 mm, approximately 20-30 mm, or the like. Similarly, it may have any suitable length. For example, it may have a length of about 5 mm to about 50 mm, about 10 mm to about 20 mm, or the like. In some variations, the balloon has an outer diameter of approximately 20-30 mm, and a length of about 20 mm.

[0057] The expandable member (in this variation, shown as an expandable balloon) is inflated to position and stabilize the left atrial appendage, as shown in FIG. 14C. In its expanded state, the expandable member helps locate the ostial plane of the left atrial appendage. Specifically, when the expandable member is expanded, the left atrial appendage is distended and its shape is changed from roughly conical to roughly spherical, thus better defining the junction between the left atrial appendage and left atrium. In addition, the expandable member in its expanded state may be at a pressure much greater than that of the left atrium proper, resulting in a significant differential in tension between the left atrial appendage and the left atrium. The expandable member may have one or more apertures therethrough for passage of contrast to facilitate visualization.

[0058] While the expandable member is still in its expanded state, a closure element (1410) of a closure device (1408) may be placed around the left atrial appendage and closed as shown in FIG. 14D. However, in some variations, the closure element is placed around the left atrial appendage while the balloon is in its deflated or unexpanded state, and then the balloon is expanded. A suture may then be deployed from the device, tightened around the closed appendage, released from the device, and severed, leaving the closed appendage in place. Of course, in some instances it may be desirable to confirm proper closure of the appendage prior to tightening of the suture, and then again after the suture has been tightened using fluoroscopic or other visualization techniques. If closure is not adequate or otherwise not desirable, the loop may be opened, repositioned, closed, and then confirmed once again.

[0059] Specifically, it is desirable that the left atrial appendage be closed off as close to the anatomical ostial plane as possible (i.e., the opening that separates the left atrium from the left atrial appendage). If the left atrial appendage is closed off above the plane of the orifice (toward the left atrial appendage tip or away from the anatomical ostial plane), this may result in a persistent diverticulum of the left atrial appendage, which in turn may result in an additional site or nidus for thrombus formation despite complete exclusion of the left atrial appendage from the left atrium. In some individuals, the geometry of the left atrium and left atrial appendage may be such that the neck or narrowing between them is poorly defined from the epicardial, or outer aspect. In addition, the external geometry of the left atrial appendage-left atrial junction is difficult to differentiate from an epicardial perspective. This may be compounded by the fact that the anatomy is moving vigorously when the procedures are employed while the heart is beating and the lungs remain inflated (i.e., closed chest procedures). From an inside aspect, or endocardial view, fluoroscopy and ultrasound methods provide limited information or ability to landmark the true three-dimensional characteristics of the anatomic ostial plane. Thus the use of the devices described here help facilitate proper positioning and closure of the left atrium, and may be used during beating heart procedures, thus resulting in significant advantages over known left atrial appendage closure devices.

[0060] Of course, many variations on this method are possible. For example, the guides may be used as guidewires or rails for additional devices to slide over, or the guides may be coupled to the devices described just above. Additional guides or guidewires may also be used, and confirmation steps may be used throughout as appropriate. The guides having the alignment members thereon may be used or removed during the methods as appropriate or desirable. In some variations, the closure device has one or more bends or curves along its length, and a tip straightener or straightening tube is used to temporarily straighten the bend during advancement of the device into the pericardial space. In other variations, where the device includes a straight elongate body, a pre-curved device may be used to aid in delivery after proper access has been obtained. In some variations, the suture loop is made from a biodegradable material and is configured to biodegrade after sufficient time has passed to ensure scarring or formation of new tissue that effectively seals of the appendage.

B. Transseptal or Pericardial Access

[0061] In the methods described just above, access to the left atrial appendage was obtained both from inside and outside the heart. Of course, the left atrial appendage may be closed off using the systems and devices described here without performing both access procedures as described above. For example, in some variations the methods comprise advancing a first guide

having a proximal end and a distal end into the left atrial appendage, through the left atrial appendage, and out of the left atrial appendage, such that one of the proximal or distal ends is within the vasculature, and one of the proximal or distal ends is within the subthoracic space.

[0062] Once access has been obtained in this fashion, a closure device may then be advanced into the pericardial space and adjacent to the left atrial appendage, and the left atrial appendage closed off. Of course, the proximal end of the first guide may be within the vasculature, or may be within the subthoracic space. In some variations the closure element is advanced into the pericardial space over the first guide. In other variations, these methods further comprise advancing a second guide into the left atrial appendage, where the second guide comprises an expandable member. The second guide may be advanced to the left atrial appendage over the first guide, though need not be advanced in such a fashion.

[0063] Other methods of closing the left atrial appendage without performing both access procedures (i.e., transseptal and epicardial) are also described here. In general, these methods comprise accessing the inside of the left atrial appendage from the epicardial space, using a device that is configured to puncture the appendage wall. An expandable member, such as a balloon, is then advanced through the puncture and into the left atrial appendage and inflated to help position the left atrial appendage while it is being closed off.

[0064] Making reference now to the figures, FIG. 15A shows a left atrial appendage closure device (1500) being advanced adjacent to the left atrial appendage (1502) from the outside of the heart. The closure device may be advanced in any suitable fashion. For example, it may be advanced via a subthoracic approach, or via intercostal or intracostal access, via open surgical access, or the like, as described above. The closure device comprises a closure element (1504) (e.g., a loop as shown in FIG. 15A) that is advanced over the left atrial appendage (1502) and tightened to close off the appendage. The device may comprise a blade or other cutting mechanism (1506), and such mechanism may be used to puncture the left atrial appendage after it has been closed, so that access may be obtained to the inside of the appendage as shown in FIG. 15B. Once access to the inside of the appendage has been obtained, an expandable member (which may be part of the closure device or be a different device meant to cooperate with the closure device) may be expanded within the left atrial appendage for positioning and such as described above. The left atrial appendage may then be closed off again (and confirmed with the visualization techniques described above), and a suture deployed to permanently fix the left atrial appendage in its closed position. The device (1500) may then be withdrawn proximally, and the suture (1510) severed using any of the techniques described above. An illustrative device (1512) for accomplishing this method is shown in FIG. 15E. Shown there is device having a proximal end (1513) and a distal end (1515), balloon (1514), retractable blade (1520), blade actuator (1516), and inflation lumen (1518) for inflating the balloon. Of course other suitable devices may also be used to accomplish this method.

III. Systems

[0065] Also described here are systems for closing a left atrial appendage. In general, the systems may comprise a closure device useful for performing a left atrial appendage closure procedure as described above, together with one or more additional components. For example, the system may comprise a first guide having a size and length adapted for accessing the left atrial appendage through the vasculature and comprising an alignment member, a second guide having a size and a length adapted for accessing the pericardial space from a subthoracic region and comprising an alignment member, and a closure device. The alignment member may be any suitable alignment member. For example, the alignment member may comprise radiopaque or echogenic markers, members configured to produce an audible response, one or more interconnecting members, one or more vacuum members, or magnets. In some variations, the alignment members of the first and second guides comprise magnets as shown in FIGS. 13A and 13B respectively.

[0066] The closure device may be any of the closure devices described above. For example, the closure device may be one having a closure element that comprises a loop defining a continuous aperture therethrough. The system may further comprise an expandable member or a device comprising an expandable member. The expandable member may be any suitable expandable member, such as, e.g., the balloon catheters described above. The expandable member may have one or more apertures therein for allowing contrast or other fluids to pass therethrough. The system may further comprise a suture loop, and the suture loop may or may not be coupled or couplable to the closure device.

[0067] The systems may also comprise one or more devices for severing the suture. Similarly, the systems may also comprise one or more devices for temporarily straightening one or more curves along the elongate body of the closure device. Of course, the device may comprise instructions for using any, all, or a portion of, the system components (e.g., first guide, second guide, closure device, straightening tube, suture cutter, or some combination thereof).

[0068] Although the foregoing device has, for the purposes of clarity and understanding been described in some detail by way of illustration and example, it will be apparent that certain changes and modifications may be practiced while still falling within the scope of the appended claims.

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

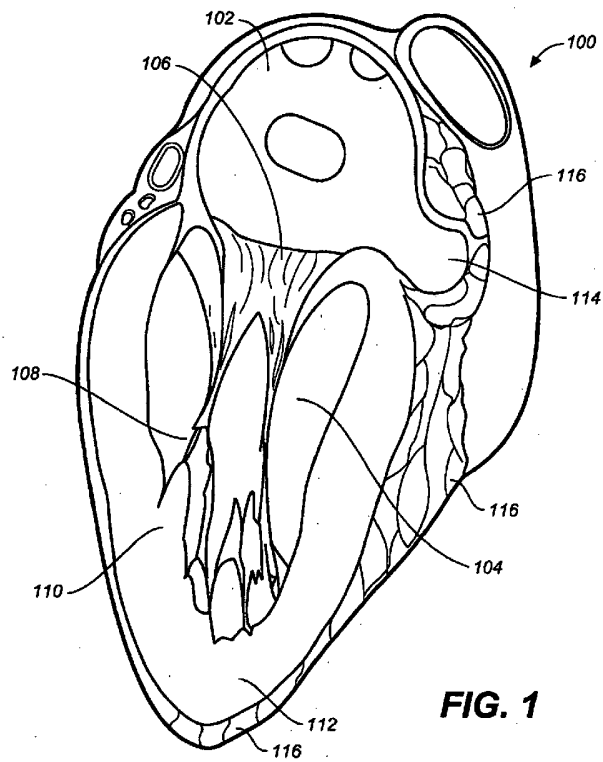
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- [EP1685802A \[0006\]](#)

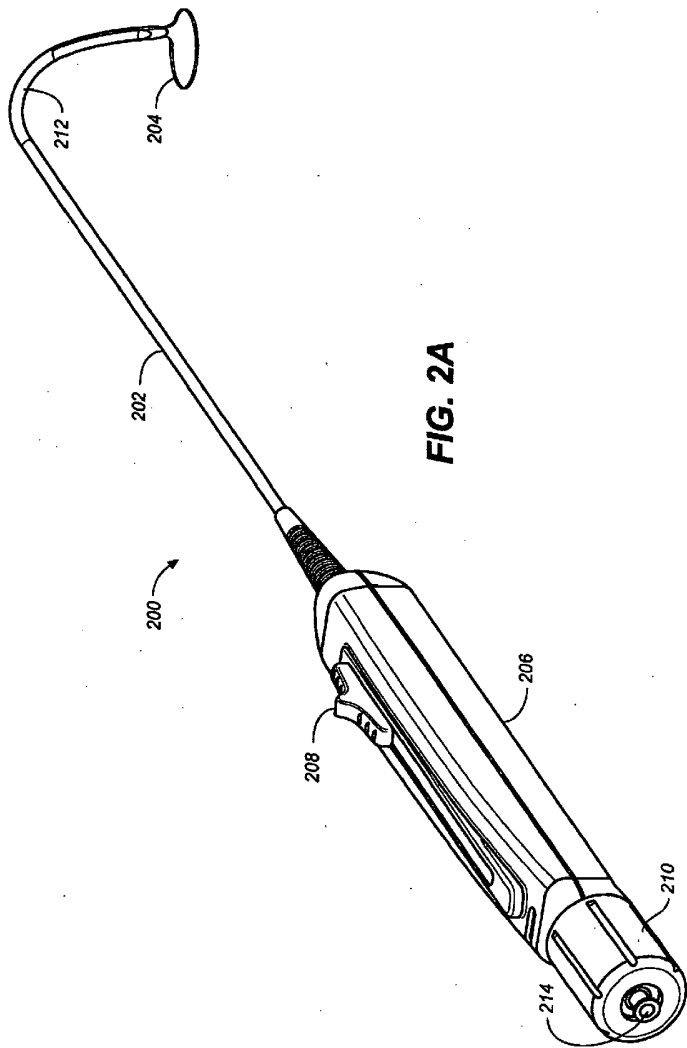
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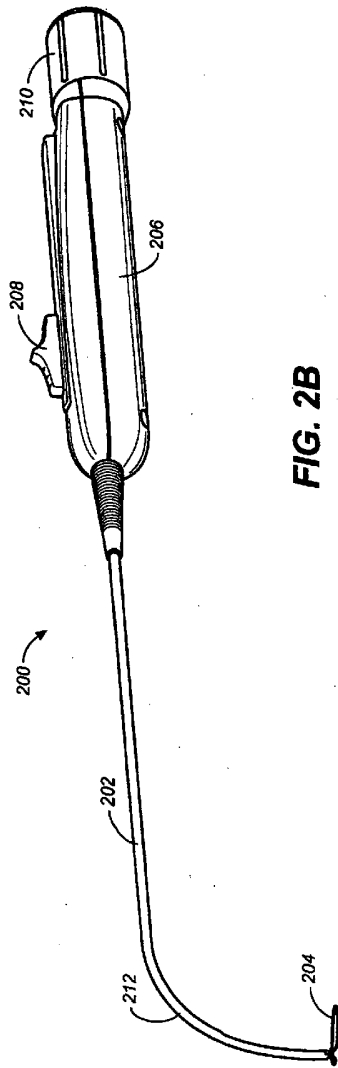
1. Indretning til lukning af et venstre forkammervedhæng, omfattende:
et langstrakt legeme (302) med en proksimal ende og en distal ende;
et lukkeelement (310) omfattende en løkke definerende en åbning egnet til deri at
5 omkranse venstre forkammervedhæng, lukkeelementet (310) er i det mindste
delvist indesluttet i det langstrakte legeme (302);
en sutur omfattende en suturknude (500) og suturløkke (308);
et holdelement (312) konfigureret til at fastholde lukkeelementet (310) og
suturløkken (308),
10 og **kendetegnet** ved, at den yderligere omfatter
en suturkrog (600) anbragt i det langstrakte legeme (302), hvori suturkrogen (600)
indfanger og holder en del af suturløkken (308) inden i det langstrakte legeme
(302).
- 15 2. Indretning ifølge krav 1, hvori lukkeelementet (310) er fremstillet af et
formhukommelsesmateriale.
3. Indretning ifølge krav 2, hvori lukkeelementet (310) er fremstillet af en nikkel-titan-
legering.
- 20 4. Indretning ifølge krav 1, hvori suturløkken er bioabsorberbar.
5. Indretning ifølge krav 1, hvori suturløkken er ikke-bioabsorberbar.
- 25 6. Indretning ifølge krav 1, hvori det langstrakte legeme (302) har en eller flere kurver
langs dets længde.
7. Indretning ifølge krav 1, hvori det langstrakte legeme (302) er styrbart.
- 30 8. Indretning ifølge krav 1, hvori det langstrakte legeme (302) er et kateter.
9. Indretning ifølge krav 1, hvori lukkeelementet (310), suturen, eller begge omfatter et
stråleuigennemtrængeligt eller ekkogent materiale.
- 35 10. Indretning ifølge krav 1, hvori lukkeelementet (310) kan aktiveres til at reducere en
omkreds deraf.
11. Indretning ifølge krav 1, hvori lukkeelementet (310) og suturløkken er separat

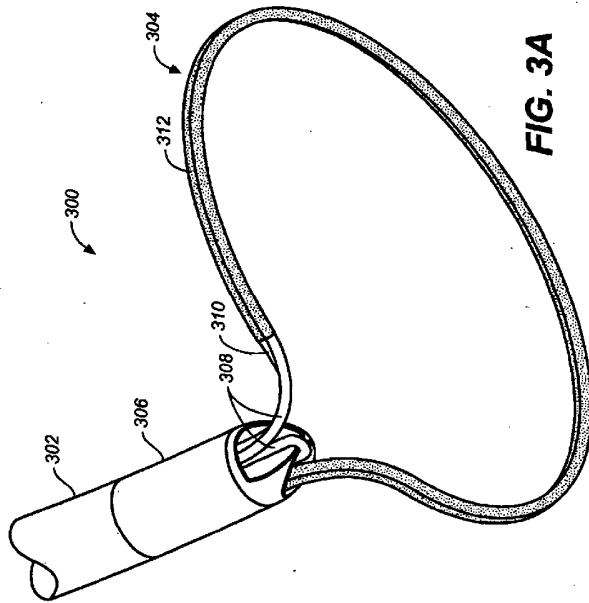
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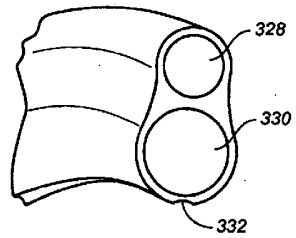
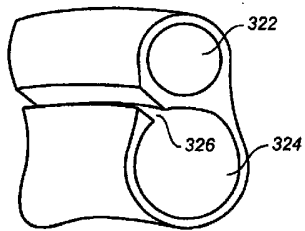
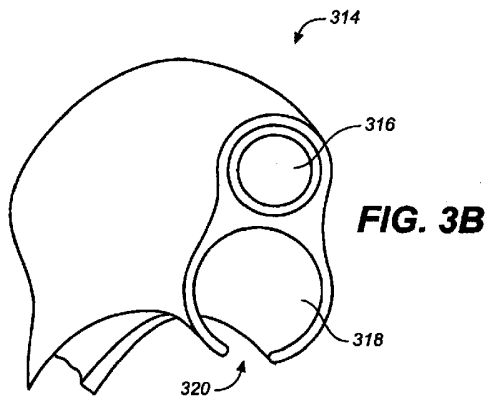
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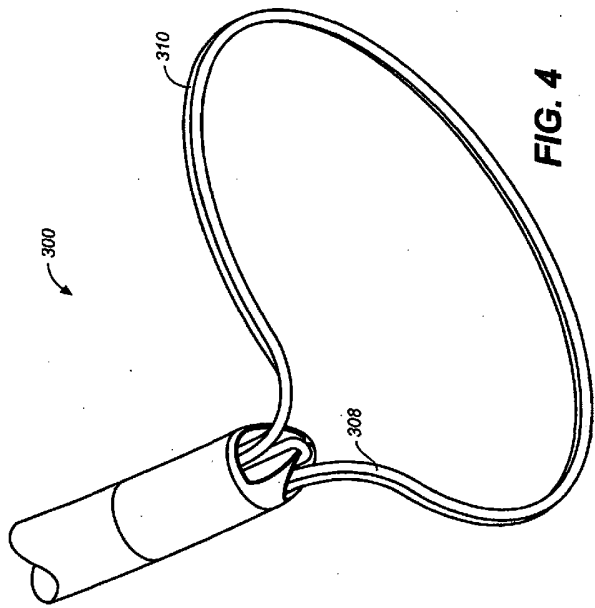


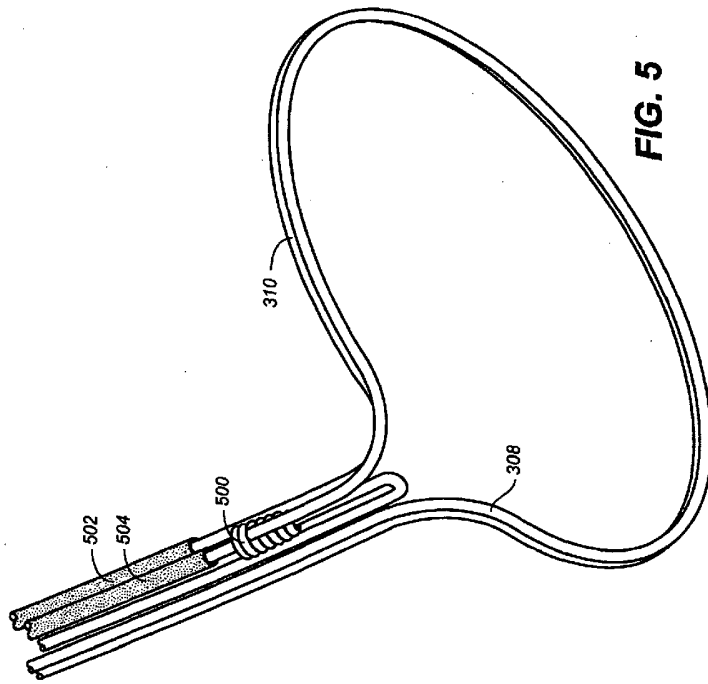


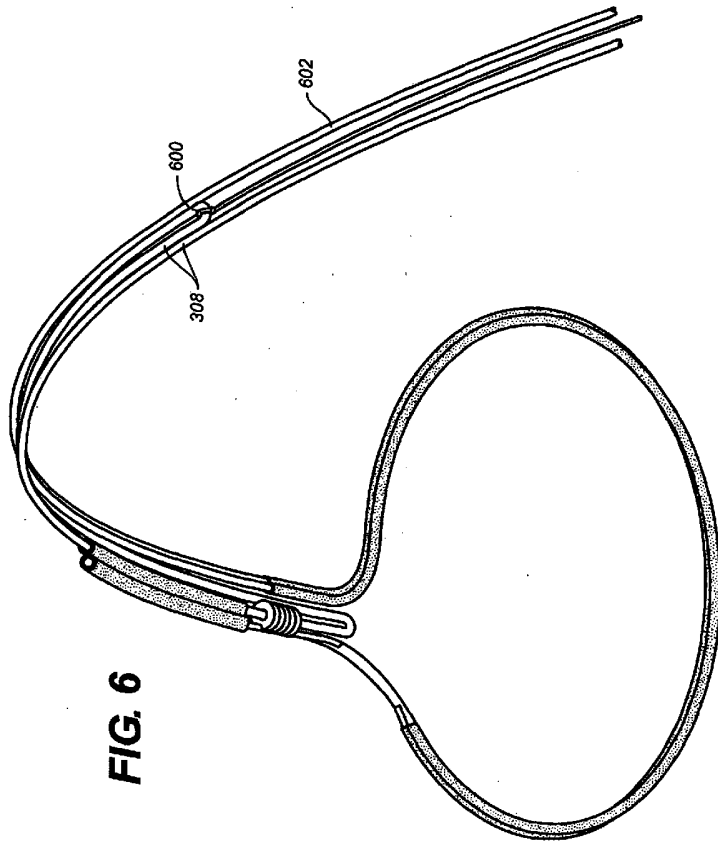


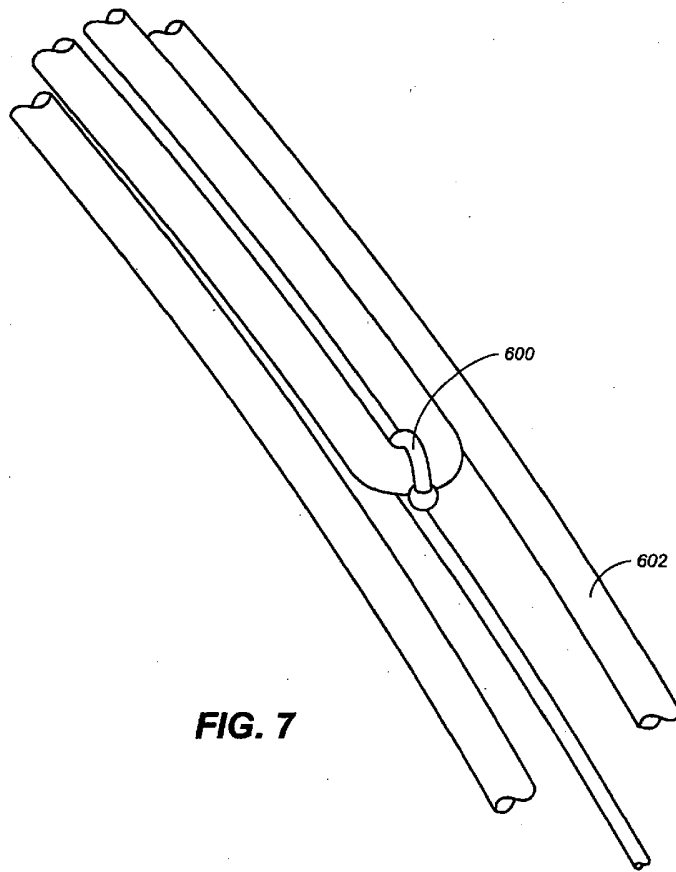












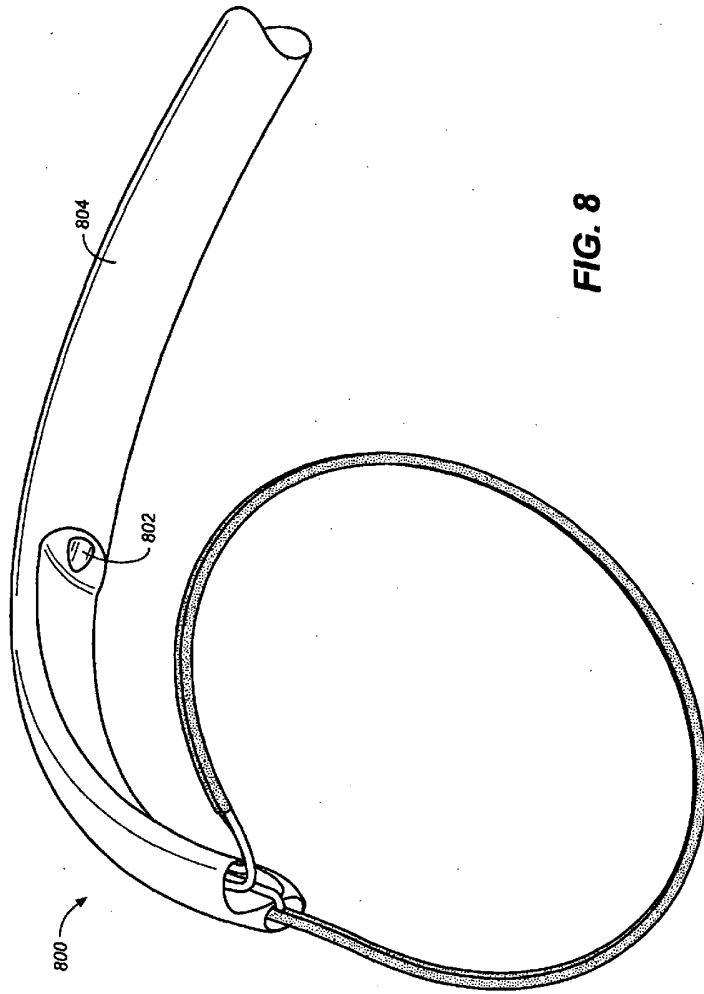
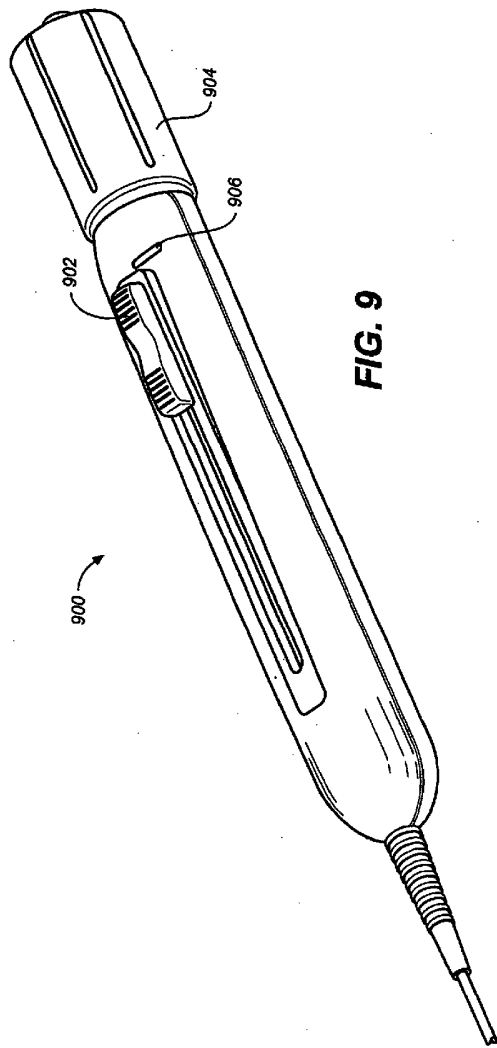
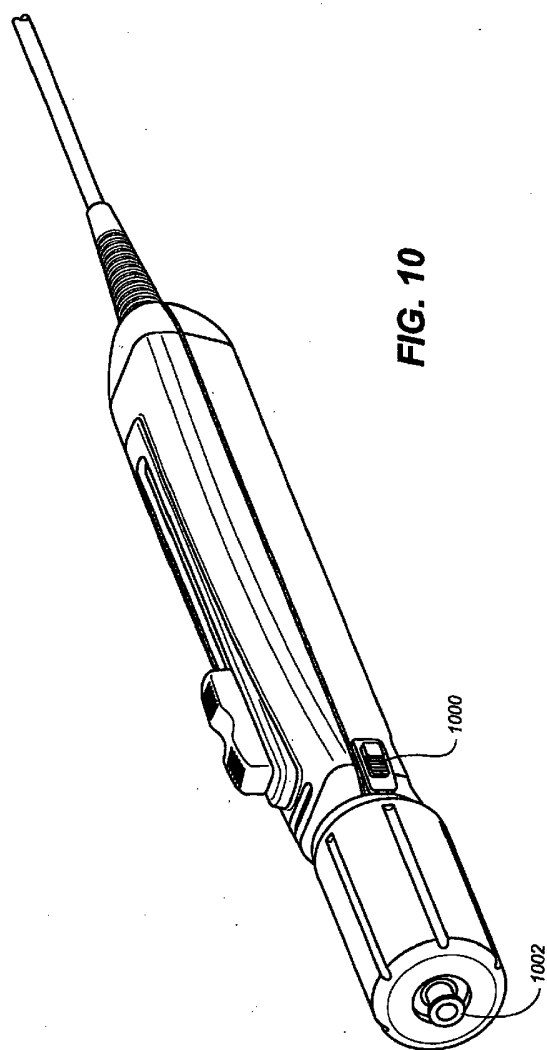
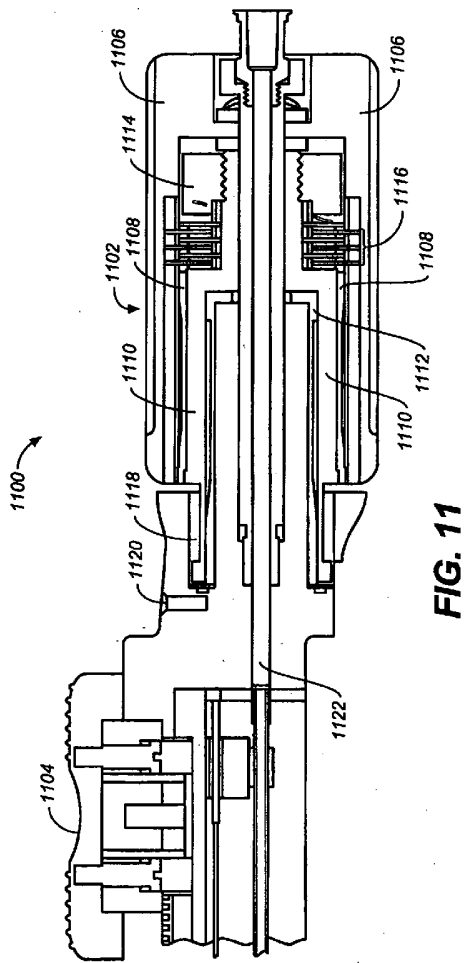
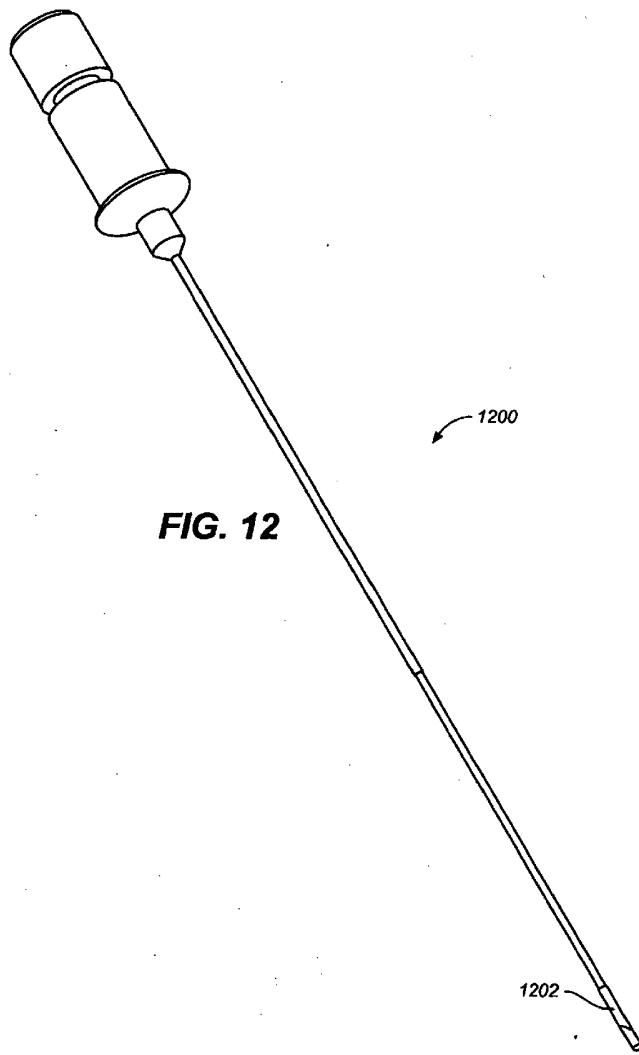


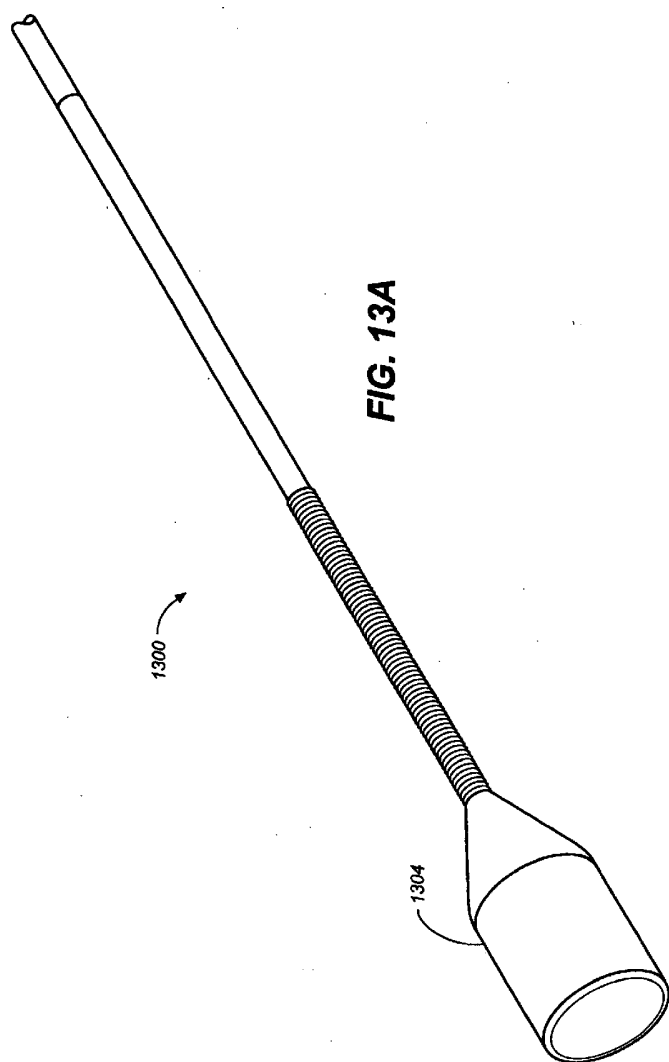
FIG. 8

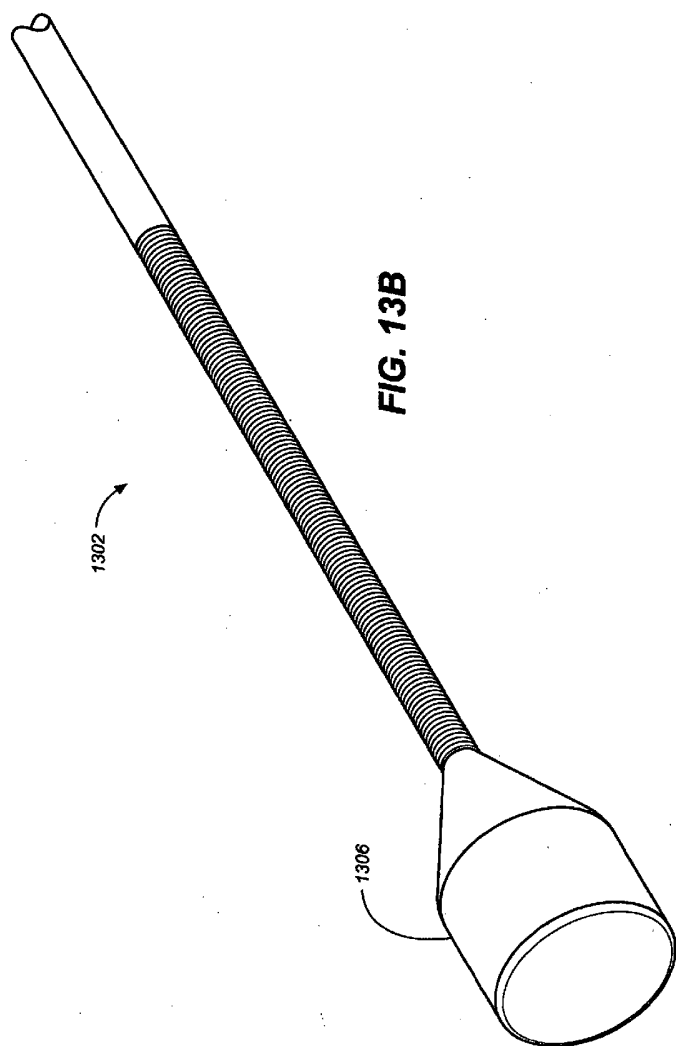












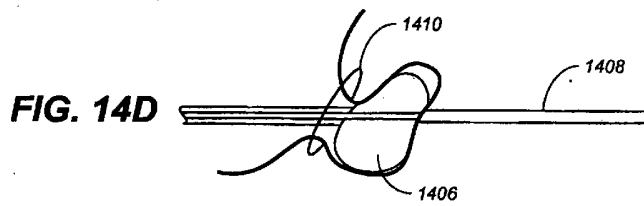
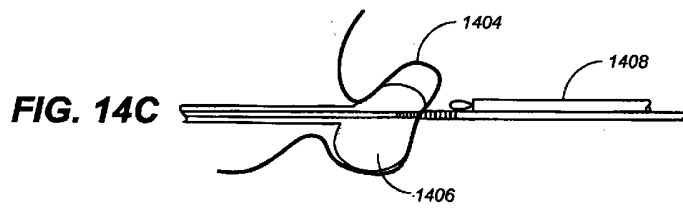
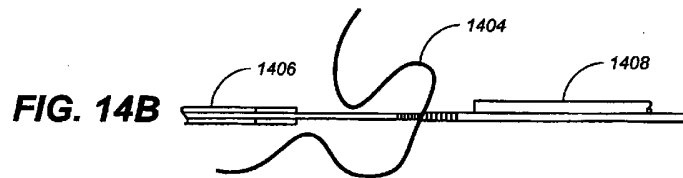
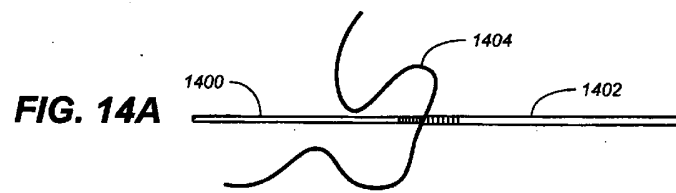


FIG. 15A

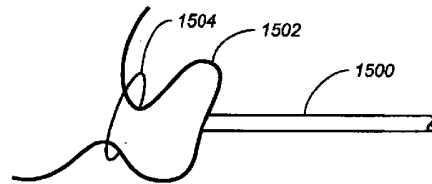


FIG. 15B

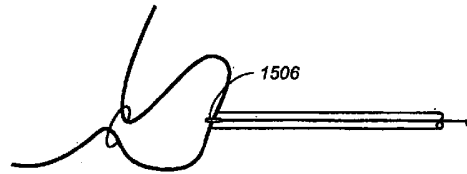


FIG. 15C

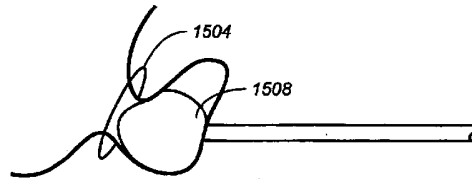
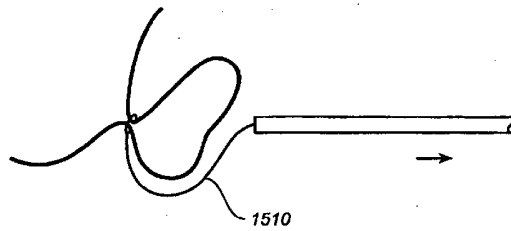


FIG. 15D



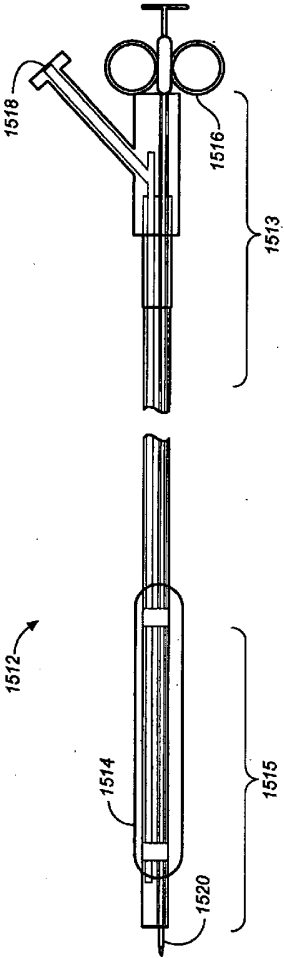


FIG. 15E