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(54) **Title**: METHODS AND DEVICES FOR DELIVERING SUTURES IN TISSUE

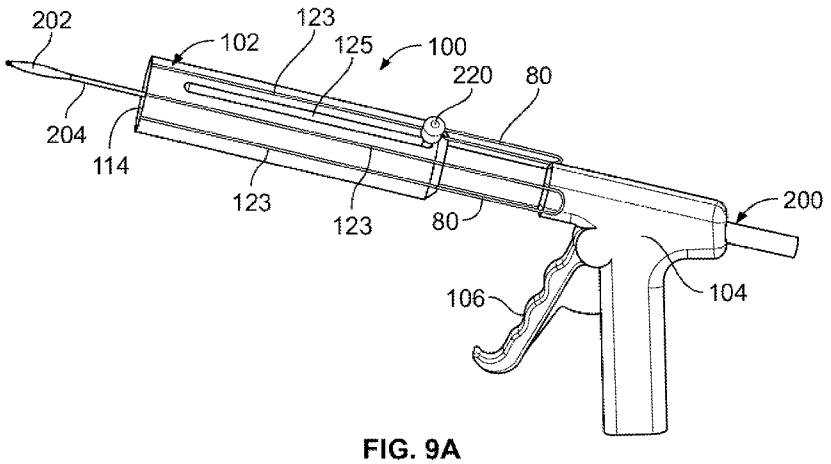

FIG. 9A

(57) **Abstract**: Methods and devices for driving a suture assembly employing elastically pre-shaped needles for piercing a tissue. The pre-shaped needles are held in a constrained state and can revert to a natural pre-shaped state prior to or during ejection from the device before entry into tissue allowing for the suture to follow a defined path similar to the pre-shaped needle such that removal of the needle allows for subsequent securing of the suture in or around tissue.

METHODS AND DEVICES FOR DELIVERING SUTURES IN TISSUE

CROSS-REFERENCE

[0001] This application is a non-provisional of U.S. Provisional Application No.: 61/135,479… filed 7/22/2008, and entitled "Automated Suturing Device for Apical Closure" the entirety of which is incorporated by reference herein.

BACKGROUND OF THE INVENTION

[0002] The present invention relates generally to systems and methods for the driving of a needle or suture through or into body tissue (typically, the needle will be affixed to a suture that remains in the tissue) using a catheter, introducer or other minimally invasive means. The methods and devices described herein can be used in any number of medical procedures, including but not limited to, approximating tissue (e.g., bring separated tissue together), ligating tissue (e.g., encircling or tying off), and fixating of tissue (attaching tissue to another structure or different tissue).

[0003] Commonly known suture systems mechanically drive needles thru the tissue wall to create passage for a suture. Such mechanisms are often complicated and require a skilled operator. In addition, the conventional mechanisms can involve many procedural steps to manipulate a needle to conform to a path to properly position the suture into tissue.

[0004] Conventional suture driving systems used for wound closure provides one example of existing suture driving systems. Such wound closure systems are used in transluminal medical procedures that are seeing a rise in popularity due to the reduction in surgical damage to healthy tissue, decreased recovery time, and ultimate cost savings to the patient associated with these procedures.

[0005] These transluminal procedures typically require a puncture into a body lumen and through the overlying tissue for the passing of catheters, guide wires, laparoscopes, endoscopes, vascular devices, etc. as required by the particular procedure. The punctures are created with instruments such as access needles, trocar, introducer sheaths, or other access devices and may measure from 1 to upwards of 15 mm in diameter. After completion of the procedure, the physician can utilize a closure system to close the puncture quickly to prevent further bleeding.

[0006] Manual compression of arterial or venous punctures is a common closure technique and an alternative to such closure systems. In this closure technique, medical personnel apply continuous pressure to the wound site allowing the blood to eventually clot sufficiently sealing the wound. However, this technique is typically very time consuming, requires the patient to bedridden for an extended time, and is not applicable for punctures over 4mm. The longer

recovery time increases overall cost and decreases patient satisfaction.

[0007] Sutures remain the preferred method of sealing such wounds, but the limited access and small size of the typical wound formed during a transluminal procedure complicates the task of sealing these wounds.

[0008] Generally, a physician must introduce a suture needle through the tissue tract and into the body lumen, position the needle, then passed the needle through tissue pulling the suture through as well. A number of devices are disclosed in U.S. Pat. No. 5,374,275 to Bradley et al., U.S. Pat. No. 5,364,408 to Gordon, U.S. Pat. No. 5,320,632 to Heidmueller, U.S. Pat. No. 5,403,329 to Hinchcliffe, U.S. Pat. No. 5,368,601 to Sauer et al., U.S. Pat. No. 5,431,666 to Auer et al. and international publications WO 94/13211 and WO 95/13021 each of the above references is incorporated by reference herein.

[0009] While these devices allow for sealing of the wound and driving the suture and needle through tissue, they are relatively complex and employ a significant number of moving parts. Accordingly, these devices are relatively costly to produce and are prone to mechanical failure.

[0010] U.S. Patent Nos. 5,527,322, 5,792,152, 6,206,893, and 6,517,553 all to Klein U.S. and Pat. No. 5,972,005 to Stalker (each of the above references is incorporated by reference herein) describes devices employing flexible or pre-shaped curved needles that are deformed from a natural shape during insertion or during advancement in tissue to close a puncture wound. U.S. Patent No. 7,377,926 to Topper et al. (incorporated by reference herein) teaches another system for inserting a needle. In this variation, the insertion device houses a bendable needle in one of the jaws and is adapted to carry a suture

[0011] However, systems, such as those described above often deform a needle to drive a suture. Deformation of the needle in this manner often results in device malfunction when placing the suture, or requires significant additional complex components to ensure proper movement of the needle and suture as desired. Accordingly, there remains a need for a simple mechanized device and method to accurately and precisely drive a suture through tissue in a constrained space such as is required in less invasive procedures.

[0012] Such systems can also perform closure of openings in organs, whether to repair a defect, to close a wound, or to close an incision made in the organ for the purpose of accessing the organ to perform a separate medical procedure. As one example, when performing valve repair or replacement within the heart, a surgeon can access an apex of the heart after performing a thoracotomy or a mini-thoracotomy. The thoracotomy allows the surgeon to manually close the opening in the heart tissue via a suture pattern. Such a pattern can include one or more concentric purse string suture patterns to ensure closure of the opening into the heart. Percutaneous access to the heart to perform such valve procedures results in many of the same benefits as other percutaneous procedures. Namely, reduced complications, cost and recovery

time on the part of the patient. However, percutaneous access leaves the surgeon with a small access path to close the opening in the heart.

[0013] The anatomical structure of the apical area permits the introduction of various surgical devices and tools into the heart without significant disruption of the natural mechanical and electrical heart function. Access to the heart through the femoral vessels in percutaneous methods is limited to the diameter of the vessel (approximately 8 mm). However, access to the heart through the apical area allows for a significantly larger access path (approximately 25 mm). Thus, apical access to the heart permits greater flexibility with respect to the types of devices and surgical methods that may be performed in the heart and great vessels. Such access is disclosed in Bergheim US Patent Application 20050240200, the entirety of which is incorporated by reference. Accordingly, there remains a need for a simple mechanized device that can accurately and precisely drive a suture through tissue allows the surgeon to close the heart tissue and complete the procedure in a percutaneous manner.

[0014] In addition, the methods and systems described herein have additional uses other than closure of tissue. In another example, U.S. Patent Application No. 20070203479 to Auth et al. (incorporated by reference herein) describes methods and devices, and systems for the partial or complete closure or occlusion of a patent foramen ovale ("PFO"). An improved suture driving device can be used for fixating tissue and eliminate the need for such implantable devices.

[0015] Accordingly, the need continues to exist for an improved suturing systems and methods that drive a suture for approximating tissue, ligating tissue, and/or fixating of tissue.

SUMMARY OF THE INVENTION

[0016] The following description includes an example of the methods and devices within the scope of this disclosure. It is also contemplated that combinations of aspects of various embodiments as well as the combination of the various embodiments themselves is within the scope of this disclosure.

[0017] In one variation, the invention includes a suture driving assembly for positioning a suture in a tissue section, the assembly comprising at least one needle assembly having a tissue piercing end distal to an elongate shaped section, the elongate shaped section having a curvilinear shape, the elongate shaped section being elastically deformable when restrained into a strained state and upon release assumes the curvilinear shape, the suture coupled to the needle assembly; a main body having a tissue engaging surface at a distal end, at least one constraining channel and at least one retrieving channel each of which having an opening at the tissue engaging surface; such that when the elongate shaped section of the needle assembly is in the restraining portion, the elongate shaped section is deformed into the strained state and when the elongate shaped section advances through the guide segment portion, the elongate shaped section assumes the curvilinear shape, upon continued advancement the elongated shaped section exits

through the opening of constraining channel in the curvilinear shape; a suture retriever assembly located in the needle retrieving channel.

[0018] The suture driving assemblies described herein can optionally include an expandable member axially moveable relative to the tissue engaging surface, the expandable member having a first reduced profile and an expanded profile, where in the reduced profile the expandable member can advance through an opening in the tissue section and where the expandable member can be withdrawn toward the tissue supporting face to secure the tissue section therebetween.

[0019] The needle assembly as well as the number of needle assemblies can vary depending upon the type of suture stitch required. For example, the device can include a single needle assembly having a single shaped section or multiple shaped sections. In alternate variations, the assembly comprises two or more needle assemblies. The needle assemblies as well as the shaped portions used in any particular suture driving mechanism need not have the same shape. Instead, a single suture driving assembly can use needle assemblies of differing shapes at the same time. However, the spacing and relation of the constraining channel and the retrieval channel shall be adjusted to accommodate a particular shape and configuration of a particular needle assembly.

[0020] In certain variations, the constraining channel can include a first cross-sectional shape and the guide segment has a second cross sectional shape, where the first and second cross-sectional shapes are different, where the second cross sectional shape permits at least a part of the shaped section of the needle assembly entering the guide segment to revert to the curvilinear shape prior to entry into the tissue.

[0021] The sutures used in the devices and methods described herein can include a needle assembly comprising a needle lumen extending through at least the tissue piercing end and where the suture is removably nested within the needle lumen. In additional variations, the suture can be located exterior to the needle assembly so that a first free end of the suture is inserted into the needle lumen at the tissue piercing end. In another variation, a single suture can be affixed at both ends to a needle assembly where the needle assembly comprises two shaped sections with each having a tissue piercing end.

[0022] Sutures used in the present devices and methods can be front loaded into a needle assembly. As a result, a suture retriever assembly can remove the suture from the needle assembly via a front portion of the needle assembly. In one example, the suture retriever assembly comprises at least one pawl member that reduces an opening of the retrieving channel to less than a size of the needle assembly and suture, where the pawl member is biased to allow movement of the needle assembly and suture in a first direction and resist movement of the needle assembly and suture in a second direction, where rearward movement of the needle

assembly from the retrieving channel causes the paw member to compress and retain the suture within the retrieving channel.

[0023] Alternate suture retriever assembly can include structures selected from the group consisting of a set of jaws, a recessed notch, pawl, funnel, catch cloth, magnetic coupling device, finger trap, or other gripping mechanism.

[0024] The devices of the present disclosure can include one or more vacuum lumens at the tissue engaging surface for securing tissue thereagainst. Alternately, or in combination, the tissue engaging surface can include a bonding agent for securing tissue thereagainst.

[0025] The devices described herein can be combined with various other medical implements to aid in the closure of tissue. For example, the devices can include one or more pledgets that removably positioned on the tissue engaging surface for placement at the opening in tissue.

[0026] In another variation, a suture driving assembly for closing an opening in a tissue section can include a first needle assembly having a tissue piercing end distal and being elastically deformable when restrained into a strained state and upon release assumes the curvilinear shape; a suture exterior to the needle assembly and having at least one end front-loaded into a needle lumen of a first tissue piercing portion of the first needle assembly; a main body having a tissue engaging surface at a distal end, at least one constraining channel and at least one retrieving channel each of which having an opening at the tissue engaging surface; where the constraining channel extends through the main body and comprises at least a restraining portion having a profile to maintain the needle assembly into the strained state and a guide segment portion adjacent to the constraining channel opening and having a profile to release needle assembly into the curvilinear shape when advanced therethrough and upon continued advancement the needle assembly exits the opening of the constraining channel in the curvilinear shape; a suture retriever assembly located in the needle retrieving channel and comprising a pawl mechanism, where the pawl mechanism interferes with the front loaded suture and needle assembly when advanced therein, where rearward movement of the front loaded suture and needle assembly causes the pawl to engage the suture to retain the suture within the needle retrieving channel; and an expandable member axially moveable relative to the tissue engaging surface, the expandable member having a first reduced profile and an expanded profile, where in the reduced profile the expandable member can advance through an opening in the tissue section and where the expandable member can be withdrawn toward the tissue supporting face to secure the tissue section therebetween when expanded.

[0027] The present disclosure also includes methods positioning a suture in a wall of an organ to close an opening in the wall. In one variation, the method includes placing a main body adjacent to a proximal side of the tissue, where the main body comprises at least one needle assembly coupleable to the suture and within a constraining channel located in the main body,

where the needle assembly comprises a tissue piercing end distal to an elongate shaped section, the elongate shape section having a curvilinear shape, the shaped section being elastically deformable into a strained state within the constraining channel, and a suture coupled to the needle assembly, the main body further including a tissue engaging surface; advancing an expandable member through the opening in the organ when the expandable member is in a reduced profile; expanding the expandable member to an expandable profile; positioning the wall of the organ between the main body and the expandable member; advancing the needle assembly from the constraining channel into a guide segment, where the guide segment permits the shaped section of the needle assembly located therein to revert to the curvilinear shape prior to leaving the guide segment and entering the wall of the organ; driving the needle assembly through a proximal side of the wall of the organ, such that the shaped section moves through the curvilinear shape so that the tissue piercing distal end and suture re-enter the main body at a retrieving channel; fully reducing the expandable member into a reduced profile; and withdrawing the main body.

[0028] In another variation, the method may further include advancing a plurality of needle assembly pairs, where each needle assembly pair is coupled to an end of a suture and where each needle assembly advances from a respective constraining channel into a respective guide segment, where the guide segment permits the shaped section of the respective needle assembly located therein to revert to the curvilinear shape prior to leaving the respective guide segment and enter the wall of the organ; and where the plurality of needle assemblies move through the curvilinear shape so that the tissue piercing distal end of each needle assembly pair re-enter the main body at a respective retrieving channel.

[0029] As described above, the method optionally includes the use of front-loaded sutures. Such sutures allow for securing the suture in the retrieving channel by advancing the needle assembly and suture against a pawl mechanism such that the pawl mechanism compresses the suture to retain the suture while allowing the needle assembly to be withdrawn back into the constraining channel.

[0030] The methods can include positioning the wall of the organ between the main body and the expandable member by axially moving the expandable member relative to the tissue engaging surface to capture the wall of the organ therebetween. To further stabilize the device, the method can include partially reducing the expandable member and positioning the partially reduced expandable member into the opening.

[0031] In another variation, the methods can include positioning a suture within a tissue of the heart for closing an opening in the heart. Such method can comprise placing a main body adjacent to an exterior surface of the heart, where the main body comprises at least one needle assembly coupled to the suture and within a constraining channel located in the main body,

where the needle assembly comprises a tissue piercing end distal to an elongate shaped section, the elongate shape section having a curvilinear shape, the shaped section being elastically deformable into a strained state within the constraining channel, and a suture coupled to the needle assembly, the main body further including a tissue engaging surface; advancing an expandable member through the opening and into the heart when the expandable member is in a reduced profile; expanding the expandable member to an expandable profile; positioning the a portion of the heart between the main body and the expandable member; advancing the needle assembly from the constraining channel into a guide segment, where the guide segment permits the shaped section of the needle assembly located therein to revert to the curvilinear shape prior to leaving the guide segment and entering the wall of the organ; driving the needle assembly through a proximal side of the wall of the organ, such that the shaped section moves through the curvilinear shape so that the tissue piercing distal end and suture re-enter the main body at a retrieving channel; reducing the expandable member into a reduced profile; and withdrawing the main body.

[0032] In certain variations, the suture driving assembly can be used to drive a needle without any suture. In such a case, the needle may be left within the tissue (to be removed later, to be absorbed by the native tissue, or for permanent placement.) Accordingly, needle driving assemblies having the same or similar structures disclosed herein are within the scope of this disclosure.

[0033] Additional suture driving assemblies are described in U.S. Patent application no. 12/188,430 entitled METHODS AND DEVICES FOR DELIVERING SUTURES IN TISSUE filed on August 8, 2008, the entirety of which is incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0034] Fig. 1 shows an example of a suture driving assembly.

[0035] Fig. 2A shows an isometric view of one variation of a needle or needle assembly with a back loaded suture.

[0036] Fig. 2B shows a side view of the needle assembly of Fig. 2A.

[0037] Figs. 2C to 2F show variations of front loaded sutures.

[0038] Fig. 2G shows a variation of a needle assembly having two curved sections affixed to a single suture.

[0039] Fig. 3A illustrates a partial cross sectional view of a distal portion of a suture driving assembly.

[0040] Fig. 3B shows the distal portion of a suture driving assembly with the needle assembly advanced through guide segments of constraining channels within the main body.

[0041] Figs. 4A to 4E illustrate a needle assembly advancing at a working surface of a main body

of a suture driving assembly.

[0042] Figs. 5A and 5B illustrate the needle assembly and suture respectively after actuation of the assembly.

[0043] Figs. 5C and 5D illustrate an example of a laced suture driven by a needle assembly after passing through tissue about an opening in the tissue.

[0044] Figs. 6A to 6C provide another example of a configuration of a main body having two pairs of constraining and retrieval channels to produce a desired stitch

[0045] Figs. 7A and 7B illustrate examples of needle or suture retrieval devices.

[0046] Figs. 8A to 8D illustrate an example of a suture retrieval device used to retrieve a front-loaded suture.

[0047] Figs. 8E to 8G illustrate another example of a suture retrieval device used to retrieve a front-loaded suture.

[0048] Fig. 9A shows another example of a suture driving assembly having a device that extends within a main body of the assembly along with a dilation device.

[0049] Fig. 9B illustrates the suture driving assembly of Fig. 9A

[0050] Fig. 9C shows an example of a dilation device.

[0051] Fig. 9D illustrates a front view of the suture driving assembly of Fig. 9B.

[0052] Fig. 9E is a perspective view of a tissue engaging surface of s suture driving assembly where the needle assemblies and sutures are extended from the constraining channels in the main body.

[0053] Fig. 9F illustrates an introducer and dilation device that can be advanced through the suture driving assembly of Fig. 9A.

[0054] Figs. 10A to 10F illustrate an example of a suture driving assembly when used to place a suture in an organ. In the present example the suture is used to temporarily secure an access sheath for performing an additional procedure within the heart.

DESCRIPTION OF THE PREFERRED EMBODIMENT

[0055] The above variations are intended to demonstrate the various examples of embodiments of the methods and devices of the invention. It is understood that the embodiments described above may be combined or the aspects of the embodiments may be combined in the claims.

[0056] The present invention relates generally to systems and methods for the driving of a needle or suture through or into body tissue (typically, the needle will be affixed to a suture that remains in the tissue) using a catheter, introducer or other minimally invasive means. The methods and devices described herein can be used in any number of medical procedures, including but not limited to, approximating tissue (e.g., bring separated tissue together), ligating tissue (e.g., encircling or tying off), and fixating of tissue (attaching tissue to another structure

or different tissue).

[0057] As noted herein, the suture driving methods and assemblies described are discussed in relation to vascular wound closure allowing a physician to quickly, easily, and accurately insert a suture immediately following the procedure to prevent excessive blood loss by the patient. In addition the suture driving methods and devices can be used in various other areas (such as cardiology, urology, gynecology, or other vascular surgery applications) to approximate, ligate, or fixate tissue.

[0058] Fig. 1A shows an example of a suture driving assembly **100**. In this variation, the suture driving assembly **100** includes a main body **102** coupled to a handle portion **104**. The handle portion **104** can include any number of actuating triggers or levers **106**, **108** where each lever functions to drive and/or retract the needle assembly to or from tissue. In the illustrated example, the needles are driven through the tissue or "thrown" via a trigger assembly **106**. Once the needles are thrown through the tissue and the = sutures are in place, the needle and suture withdraw into the device using a retrieval mechanism **108**. Alternatively, variations of the device include passive retrieval assemblies that decouple the suture from the needle assembly once the suture is properly placed through tissue. The needle assembly can then be retracted back into the main body leaving only the suture affixed within one or more retrieval channels **112**. Other variations of the device include passive retrieval assemblies where the thrown needle picks up the stored suture and retrieves the suture to properly place it through tissue. In addition, the handle portion **104** can also include ports or couplings for fluid, suction/vacuum, drug delivery, or similar items that require coupling to the device **102**.

[0059] As discussed below, the main body **102** of the suturing driving assembly **100** includes any number of constraining channels **110** and retrieval channels **112** that open at a tissue engaging surface **114**.

[0060] The suture driving assembly **100** drives one or more pre-shaped needles (not shown in Fig. 1) through tissue in a manner that allows the pre-shaped needle to revert to its natural state or shape prior to entering tissue. This aspect allows the needle to be first maintained in a pre-deployment shape within a constraining channel **110** and yet deployed from the assembly **100** in the natural state. Such deployment permits the needle (and any attached suture) to pass through tissue in a predetermined path as defined by the natural shape without requiring deformation of the needle.

[0061] The suture driving assembly **100** of the present variation can also include an expandable device **200**. In the illustrated example, the expandable device **200**comprises an expandable member (in this variation the expandable member is a balloon but the expandable member can be an expandable spline basket, an expandable funnel, a stent-like structure, etc.) **202** affixed to a shaft **204**. Additional variations include an expandable member **202** comprising a mechanical

basket, a fan shaped element, or any number of expandable structures commonly used in medical applications to secure tissue to a particular surface.

[0062] The shaft **204** can be axially moveable relative to the main body **102** so that tissue can be captured between the expandable member (or balloon) **202** of the expandable device **200** and the tissue engaging surface **114**. Such movement can occur via a surgeon withdrawing the proximal end of the expandable device **200**. Moreover, the variations of the assembly **100** can include various mechanism to lock the position of the expandable portion **202** with respect to the tissue engaging surface **114** so that a surgeon does not need to maintain constant tensile force on the expandable device **200**. In addition, the expandable device **200** can include a guide wire lumen to assist in placing the expandable member **202**.

[0063] As noted above, the tissue engaging surface **114** can also include any number of means to assist with securing tissue **2** against the tissue engaging surface **114** of the main body **102**. For example, the tissue engaging surface **114** can include a number of vacuum or suction ports to affix tissue to the surface **144**. Moreover, the tissue engaging surface **114** can be rough, channeled, or have other relief contours to move fluid or other substances away from the surface.

[0064] Figs. 2A and 2B show isometric and side views of one variation of a needle or needle assembly **90**. As will be discussed below, the suture driving assembly **100** can include any number of needles or needle pairs depending upon the desired application.

[0065] The needle assembly **90** typically comprises a tissue piercing end **92** distal to an elongate shaped section **94**. The guide or shaped segment located within the main body allows the elongate shaped section **94** to revert to its natural shape prior to entering tissue as the piercing end **92** and shaped section **94** exits from the main body. The needle assembly **90** also includes a suture **80** coupled thereto. The shaped section **94** of the needles of the present devices includes a curvilinear shape. This shape can be planar (such as a curved needle), or can be three dimensional (as shown by the helix curvilinear shape that wraps about axis **A**). As noted above, the shaped section **94** of the needle assembly **90** comprises a center line **C**. In certain variations of the device, the angular bend of the shaped section **94** matches a centerline of the guide or shaped segment located to permit the shaped section **94** to revert to the natural curvilinear shape from a constrained state.

[0066] In addition, the shaped section **94** of the needle assembly **90** is elastically deformable into a pre-deployment shape when in the constrained state. Upon release, the shaped section **94** assumes its pre-set curvilinear shape. The needle assembly **90** can also include various features to aid in removal of the needle or suture from the body. For in certain variations of the device, the needle assembly **90** can include a notch, groove, or shoulder adjacent to the tissue piercing tip **92** where the notch **95** increases the ability of a retrieval assembly to withdraw the needle

and/or suture. As illustrated, a suture **80** can be "back-fed" into the shaped portion **94**. The suture **80** can be glued, crimped, or otherwise affixed to the shaped portion **94**.

[0067] In some variations, it is desirable to have a needle assembly that does not contain any notch or openings that create areas of increases stress and create a risk of fracture areas. Accordingly, Figs. 2C to 2E illustrate side views of needle assemblies having a "front-loaded" suture **80**. As used herein, a front-loaded suture is one that can be removed from a front or tissue piercing end of the needle assembly. This configuration does not require the needle to be withdrawn through the retrieval channels in main body. Instead, once the needle assembly delivers the suture into the retrieval channel, because the suture is front loaded, it can be decoupled from the needle body at a front or tissue piercing portion. Such front-loaded sutures can be used with variations of the present suture loading device. Fig. 2C illustrates a suture **80** that is front-loaded into a lumen **93** of the needle assembly **90**. The bend **86** of the suture **80** as it exits the lumen **93** holds the suture **80** against the shaped needle portion **94** causing the suture to reside within the lumen **93** adjacent to the tissue piercing end **92**. Once the suture is advanced into a retrieving channel in the main body, retraction of the shaped section **94** causes the suture **80** to lift or decouple out of the lumen **93**. Fig. 2D illustrates a suture **80** as having an opening or aperture **82** that can be hooked onto the tissue piercing end **92**. Fig. 2E illustrates a cape **84** that is removably seated on the tissue piercing end **92**. Clearly, any means of affixing the suture in a front loaded manner is within the scope of this disclosure. In such front-loaded configurations, rearward movement of the shaped portion **94** when the suture is held such as in the retrieval channel causes the suture **80** to detach from the tissue piercing end **92**. The sutures of the front-loaded needle assembly variations extend along an exterior surface of the shaped portion of the needle. As a result, the shaped portion **94** can be retracted or withdrawn while the suture **80** can be advanced into the device and ultimately secured or otherwise tied to accomplish closure of the opening in tissue.

[0068] Fig. 2F illustrates another front-loaded suture design where the suture extends through the shaped section **94** of the needle assembly **90**. The suture **80** can have an optional bend **86** to secure the suture **80** against the needle assembly **90** during advancement. Alternatively, the needle assembly can have an increased frictional surface in the needle lumen to maintain the suture within the needle lumen when advancing the needle assembly through tissue. The remainder of the suture **80** extends through the shaped section **94** and out of a proximal end of the shaped section **94**. Once the tissue piercing end **92** enters a retrieval channel, a suture retrieval device can secure the suture so that the needle assembly **90** can be retracted into a constraining channel.

[0069] Although the needles are shown having a helical shape, any number of curvilinear shapes are within the scope of the disclosure. For example, the shapes may be in a single plane or

extend to form a 3-dimensional shape. In addition, the curvilinear shapes may have a plurality of curves, a single curve, and/or can be a partial circular shape.

[0070] The tissue piercing end and/or curved shaped section **94** can be comprised of a spring steel or other alloy that is set into shape. Alternatively, memory alloys can be employed. Such alloys include superelastic nickel-titanium (NiTi), copper-aluminum-nickel (CuAlNi), copper-zinc-aluminum (CuZnAl), or other shape memory alloys that are well known in the art.

[0071] Fig. 2G shows a variation of a needle assembly having two shaped sections **94**affixed to a single suture **80**. This particular configuration is useful to produce a "mattress" stitch pattern. Accordingly, the associated suture driving assembly **100** will include multiple constraining channels as well as guide segments.

[0072] Fig. 3A illustrates a partial cross sectional view of a distal portion of a suture driving assembly **100**. As shown, in this variation, the main body **102** includes a main lumen **118** through which the expanding member **202** and shaft **204** can advance. The main body **102** also includes any number of constraining channels **110** that terminate at a tissue engaging surface **114** of the main body **102**. The constraining channel **110** can extend fully or partially through the main body **102**. A needle assembly, and in certain variations a suture, can be loaded within the constraining channel **110** (though for the sake of illustration the suture and needle assembly are omitted from this figure). The constraining channel **110** comprises at least a restraining portion **111** having a profile to maintain the elongate shaped section into the strained state. In the illustrated variation, the guide portion is linear. However, variations of the device include restraining portions **111** having a variety of shapes.

[0073] The restraining portion **111** of the constraining channel **110** transitions into a guide segment **113** that is adjacent to the tissue engaging surface **114**. The guide segment comprises a shape or a profile that matches the curvilinear shape of the shaped section of a needle. As a result, as the needle exits the main body, the needle passes through a guide segment having a curvilinear shape that allows the shaped section of the needle assembly to revert to its unconstrained curvilinear shape. Therefore, the needle assembly passes through tissue in its unconstrained state to the retrieval channels as illustrated below. Fig. 3B illustrates the shaped section **94** of a needle assembly as it passes through the guide segment **113** of a constraining channel **110**. Once the needle assembly **90** is advanced a sufficient distance, the tissue piercing end **92** enters the retrieval channel **112**. As discussed below, the needle assembly **90** can be advanced through the retrieval channel to a retrieval device (not shown) that pulls the needle assembly and suture through the main body. Alternatively, the needle assembly **90** can be retracted back into the constraining channel **110** leaving the suture secured within the retrieval channel **112**. Doing so prevents the need of having to retrieve the entire through the main body. Instead, the needle assembly **90** can be withdrawn or retracted into the main body so that

only the suture(s) must be retrieved through the main body.

[0074] Fig. 4A illustrates a perspective view of a working end of a main body **102** of a suture driving assembly **100**. As shown, the main body **102** can include a tissue engaging surface **114** having a number of constraining channels **110** and retrieval channels **112** with respective openings in the tissue engaging surface **114**. The number and spacing of the constraining and retrieval channels **110** and **112** will vary depending upon the type of stitch or suture pattern sought. In addition, the sizing of the openings of the constraining and retrieval channels **110** and **112** can also vary.

[0075] As discussed above, the tissue engaging surface **114** can be flat, funneled, concave (as shown), or otherwise shaped to ensure proper tissue contact for insertion of a suture. Moreover, the tissue engaging surface **114** can include protrusions **116**, channels, or other features to allow fluid to move away from the tissue engaging surface or to better compress the area of tissue in which a needle assembly is to be placed. The main body **102** can also include features such as channels **122** to direct the needle assembly through tissue. Furthermore, the main body **102** can include a main lumen **118** for delivery of an expanding device (not shown) as well as other medical tools/devices. Such a lumen **118** is required in those variations of the device configured for performing procedures within an organ or providing an access path within the organ. Fig. 4A also shows a relief opening **123** between the openings of adjacent constraining channels **110**. A relief is typically used in variations of the device having a single suture joined to two needle assemblies **90**. The relief opening **123** allows a suture that is joined by two needles to exit the main body when the suture is held within the main body **102**. As shown below, variations of the main body **102** can include one or more suture relief openings on a side as well.

[0076] Fig. 4B illustrates the main body of Fig. 4A after a needle assembly **90** having two shaped sections **94**, is advanced from constraining channels **110** of the main body **102**. As discussed herein, the constraining channels **110** can contain a segment adjacent to the opening in the tissue engaging surface **114** that allows the shaped section **94** of the needle assembly **90** to revert to its unconstrained state. This allows the needle assembly to pass through tissue in a manner that is pre-determined by the curvilinear shape of the needle assembly **90**. In the illustrated example, the needle assembly **90** is similar to that shown in Fig. 2G. As a result, in the illustrated example, as the shaped sections **94** revert to their unconstrained shape or profile, they orient in a helical curvilinear shape. In order to further direct the needle assembly **90** towards a respective retrieval channel **112**, the tissue piercing end **92** of the shaped section **94** enters a guide path or guide channel **122**. As shown in Fig. 4C, the guide path **122** deflects the shaped section **94** towards the retrieval channel **114** such that continued advancement of the needle assembly **90**. Fig. 4D illustrates the device of Fig. 4C where the tissue piercing ends of

the needle assembly **90** are advanced into the retrieval channels **112** in the main body **102**.

[0077] Figs. 4A to 4D illustrate one example of a suture advancing device where the suture follows the shaped section **94** of the needle assembly **90**. However, as discussed above, variations of the device can include sutures that are front loaded within the needle assembly. Fig. 4E illustrates such an example after the needle assembly **90** is received within the retrieval channel **114** a suture **80** extending along an exterior of the shaped section **94** of the needle assembly **90**.

[0078] Figs. 5A and 5B illustrate partially cross-sectional perspective view of a main body **102** having a needle assembly **90** with two shaped sections that is advanced between guide segments **113** of a constraining channels **110** and retrieval channels **112**. As shown, the shaped portions of the needle assembly **90** are coupled by a single suture **80**. As a result, as the needle assembly **90** leaves the constraining channels **110**, the mid section of the suture exits the main body **102** via a suture relief opening **123**. The ends of the suture **80** are located within the retrieval channels **112** where any number of mechanisms can be used to withdraw the suture ends.

[0079] Figs. 5C and 5D illustrate respectively, the path of a variation of a needle assembly **90** and suture **80** when advanced in the manner shown in Figs. 5A and 5B for closing an opening **6** in tissue **2**. To clarify the path of the suture and needle assembly, the suture driving assembly is not shown in Figs. 5C and 5D. As illustrated, the shaped sections **94** of the needle assembly **90** passes through tissue **2** in its unconstrained shape. In the variation shown in Fig. 5C, the needle assembly **90** is coupled to a single suture **80** and pulls the suture **80** through the tissue. Fig. 5D illustrates the state of the tissue **2** after the needle assembly **90** passes from the tissue **2** leaving only the suture **80** remaining in tissue. The resulting laced suture **80** passes through tissue about an opening **6** in the tissue but prior to tightening of the suture **80**. Once the suture is "thrown" about the opening **6**, the physician can secure the suture to close the opening **6**. This particular suture pattern, when tightened, results in a purse string stitch. Clearly, devices within the scope of this disclosure can include any number of tissue receiving openings.

[0080] As discussed herein, the configuration of constraining and retrieval channels can be configured in any number of different variations to produce suture patterns as desired. For example, Figs. 6A to 6C illustrate another such example. Clearly, any number of variations is within the scope of this invention with the illustrated variations depicting some possible variations.

[0081] Figs. 6A and 6B provide another variation such of a main body **102** according to the present disclosure. In this variation, the main body **102** includes two adjacent pairs of constraining channels **110** and two adjacent pairs of retrieval channels **112** having openings in the tissue engaging surface **114**. Though each of the openings of the individual pair of

constraining channels **110** are joined by a suture relief passage **123**, additional variations might not have these passages **123**. As noted herein, such passages **123** are required when using a single suture between adjacent shaped sections of a needle assembly. Fig. 6A illustrates a first needle assembly **90** passing between a pair of constraining channels **112** and a pair of retrieval channels **112**. Fig. 6B illustrates a second needle assembly **90** passing between the adjacent pair of constraining channels **112** and retrieval channels **112**. Although the figures depict the needle assemblies being thrown sequentially, certain variations of the device allow for throwing the first and second needle assemblies at the same time.

[0082] Fig. 6C illustrates the sutures **80** depicted in Figs. 6A and 6B once thrown and when the suture driving apparatus is removed from the tissue **2**. As shown, the configuration of Figs. 6A and 6B produce two perpendicular placed horizontal mattress stitches (one the sutures are properly secured). The illustrated variation also depicts the use of supports or surgical pledgets **160** that can be delivered on the tissue engaging surface of the main body and secured when the needle assembly passes through. Any variation depicted herein can include such pledgets (whether such pledgets are individually spaced about the opening or fully encircle the tissue opening).

[0083] Surgical pledgets can comprise biocompatible material (including polyamide, polyethylene, polypropylene, polyethylene terephthalate, polyurethane, polytetrafluoroethylene, various bioresorbable polymers and/or small pieces of autologous tissue. These pledgets are typically used in with the surgical suture to distribute the force of the suture applied on the tissue over a larger area or to aid in steaming the leakage of bodily fluids such as blood that results from penetration of bodily tissue by a suture needle and suture.

[0084] Figs. 7A to 7B illustrate variations of suture retrieval device **126** that resides within the retrieval channel **112**. As shown, as the tissue piercing end **92** of the needle assembly **90** enters the retrieval channel **112** variations of the assembly include a retrieval device **126**. In Fig. 7A, the retrieval device **126** shows an example of a clamp or jaw type structure. Fig. 7B shows a retrieval device **126** including a window or slot **128** to capture the tissue piercing tip **92** (or a slot formed in the needle). However, the devices described herein are can include any retrieval device. For example, the retrieval device can comprise a cloth that is penetrated by the needle. The retrieval device **126** can be a finger-trap tubular type of device where tension applied to the device causes compression of the tube allowing for a pulling motion to secure the suture or needle for removal. The retrieval device can be a magnetic coupling device to also aid in removal of the needle or tissue piercing end. In addition, the retrieval devices disclosed in the references discussed in the background section can also be combined with the devices described herein.

[0085] Fig. 8A illustrates another variation of a suture retrieving assembly **126** that comprises a

pawl-type mechanism located in the retrieval channel **112**. In the illustrated variation, the pawl-type mechanism comprises a slotted funnel **128** where the slots form sections **132** of the funnel that function as pawl-members. As shown by Fig. 8B, from the view taken along line 8B-8B from Fig. 8, the funnel sections **132** form an opening **134** that restricts a diameter of the retrieval channel **112**. As shown in Fig. 8C, when a front-loaded suture **80** is loaded into or on a needle assembly **90**, the arms **132** of the funnel **130** expand to allow passage of the suture **80** and needle assembly **90** through the funnel **130**. However, the funnel members **132** function as a pawl mechanism as they are biased to return to the natural state shown in Fig. 8A. Accordingly, as the needle **90** and suture **80** are retrieved, the arm member (or members) **132** frictionally engage the suture **132** and can compress or bite into the suture. The relatively rigid nature of the needle assembly prevents the funnel members **132** from preventing rearward movement. Accordingly, withdrawing the suture **80** and needle assembly **90** dislodges the front-loaded suture **80** and traps the suture within the funnel **130** as shown in Fig. 8D as the needle assembly **90** is withdrawn. In some variations, the funnel **130** is moveable within the retrieval channel so that the suture **80** can be withdrawn without moving the suture driving assembly. However, in cases where the funnel **130** is stationary, the entire suture driving assembly or the main body alone can be withdrawn to ready the suture for tying about a tissue opening.

[0086] Various additional pawl mechanisms are intended to be within the scope of this disclosure, for example, the paw mechanism can comprise a traditional pawl comprising of a hook or tooth located on an arm, where the pawl is biased to engage a suture as it enters the retrieval channel. For example, Figs. 8E to 8G illustrate a pawl-type mechanism **136** that is biased within a retrieving channel **112** of a device to reduce a size of the channel **112**. As illustrated in Fig. 8E, as the front-loaded suture **80** and needle assembly **80** enter the retrieval chamber, the pawl mechanism **136** interferes with the suture **80** and needle assembly **90**. Because the pawl-mechanism **136** is spring biased, the suture **80** and needle assembly **90** deflect the pawl-mechamis **136**. At this point, as shown in Fig. 8F one or more teeth or protrusions **138** on the pawl-mechanism **136** bite into the deformable suture **80**. Once the pawl-mechanism **136** engages the suture **80**, the needle assembly **90** can be withdrawn leaving the suture **80** secured within the retrieval channel **112**. The pawl-mechanism **136** can then be withdrawn in thee channel **112** or the entire device can be withdrawn to pull the secured suture. In addition, the surface of the retrieval channel **112** can have any number of protrusions, hooks, or other features to capture the suture or increase friction against a captured suture.

[0087] Fig. 9A shows another variation of a suture driving assembly **100** having a expandable device **200** extending through a main lumen. Again, the expandable device **202** can include a balloon **202** or other expandable member affixed to a shaft **204**. The expandable device **202** can optionally be stationary within the main lumen or can be moveable relative to the main

body **102**. The present variation also optionally includes a pin or lever **220** that is moveable within the main body **102**. As discussed below, the pin **220** allows advancement of an introducer or other device through the main body. Once the pin **220** is advanced to a desired location, the pin **220** can be removed from the main body **102** to de-couple the main body from the introducer/device located within the main body.

[0088] Fig. 9B illustrates the main body **102** of Fig. 9A. As shown, the main body **102** of the present illustration can include a number of suture channels **123** that extend along an exterior surface of the main body **102**. As discussed above, such a feature allows a suture to ext the main body when both ends of the suture are joined to one or more needle assemblies that are advanced through tissue. In the illustrated variation and as shown in Fig. 9A, the main sutures **80** can optionally extend through a rear portion of the main body **80**. Though not shown, the sutures could be wrapped about spools (not shown) or placed in protective tubing (not shown) rather than remain exposed. Alternatively, the suture channels **123** can extend only through a portion of the main body **102** where the section of suture leaving the suture channel **123** can then be affixed or seated in any portion of the suture driving assembly **100**.

[0089] Fig. 9B also shows the suture driving assembly as only having a trigger **106**. In such variations, the handle portion **104** and trigger **106** rely on a spring based mechanism so that once the trigger **106** is fully actuated, the spring based mechanism releases the trigger **106** and withdraws the needle assembly within the tissue engaging surface **114**. As a result, manual retrieval of the needle assembly is not required.

[0090] Fig. 9B also illustrates the main body **102** as having a slot **125** to accommodate the pin **220** shown in Fig. 9A. The slot **125** can optionally extend through the proximal and/or distal ends of the main body to allow decoupling.

[0091] In those cases where the suture driving assembly **100** relies on a vacuum source **170** to assist in securing tissue against the tissue engaging surface **114**, the handle portion **104** or main body **102** can be fluidly coupled to the vacuum source **170** by any conventional means. In addition, the suture driving assembly **100** can also be coupled to any additional fluid supplies to deliver medication, irrigation, or other fluids to the site of the tissue repair.

[0092] Fig. 9C shows the expandable device **200** of Fig. 9A. In the present variation, the expandable device **200** can include a shaft **204** having a guide wire lumen **205** extending therethrough. The shaft **204** can have sufficient column strength to allow a surgeon to manipulate a handle **206** at the end of the device **200** to advance the balloon **202** or other expandable member into the tissue being closed. Moreover, in those cases where the expandable device requires a fluid source **208**, the handle **206** can include any number of fluid lumens and connectors to fluidly couple the fluid source **208** to the expandable device/balloon **202**.

[0093] Fig. 9D illustrates the tissue engaging surface **114** as viewed along lines 9D-9D in Fig. 9B. For purposes of illustration, the handle portion and trigger are not shown. Fig. 9D shows the tissue engaging surface **114** of the main body **102** as being tapered or concave with a number of vacuum **119** ports located in the surface **114** and adjacent to both the main lumen **118** and the constraining and retrieval channels **110** and **112**. As discussed above, some or all of the ports **119** can be coupled to other fluid delivery sources for irrigation or delivery of other substances.

[0094] Fig. 9D also shows two pairs of constraining channels **110** opening onto the tissue engaging surface **114**. Each of the constraining channels **110** joins a suture channel **123** as shown in Figs 9A and 9B. Accordingly, as the suture advances through the main body, the mid section of the suture can travel outside of the main body **102** along the suture channels **123**. The illustration also shows a number of retrieval channels **112** equal to the number of constraining channels **110**. In this variation, the retrieval channels **112** have a tapered opening in the tissue engaging surface **114**. The suture retrieval devices **126** discussed above can be located within the tapered opening or more distally in the channel **112**.

[0095] Fig. 9E illustrates the tissue engaging surface **114** of the main body **102** where two pair of needle assemblies **90** are partially deployed from the main body **102**. In this variation, the needle assembly pairs **90** are located 90 degrees relative to one another. As shown, the curved section of the needle assemblies **94** comprises a curvilinear shape having a single curve. This variation of the needle assemblies **90** also includes a suture **80** that is front loaded into the needle assembly adjacent to a tissue piercing end **92**. Fig. 9E illustrates the needle assemblies **90** just as the tissue piercing ends **92** and front loaded suture **80** are entering the retrieval channels **112**. As discussed above, once the needle assemblies **90** enter the retrieval channels **112**, a retrieval mechanism (not shown) secures the sutures **80** so that upon retraction of the needle assemblies **90**, the sutures **80** remain within the tissue.

[0096] Fig. 8F illustrates one example of a device that can be advanced through a main body of a suture driving assembly. In this variation, the device comprises an introducer **230** located on a dilation device **232** having a dilation tip **234** extending from the introducer **230**. Advancement of the dilation device **232** and/or introducer **230** can occur via manipulation of the dilation device **232** through a rear end of the suture driving assembly. However, the illustrated variation shows a pin/lever **220** that is irremovably coupled to the dilation device **232** so that the introducer **230** and dilation device **232** can be advanced via movement of the pin **220** as it extends from a slot in the main body as shown in Fig. 9A.

[0097] Figs. 10A to 10F illustrate an example of a procedure for closing an opening in an organ. In this example, the organ comprises an apical portion **14** of a heart **12**. However, it is within the scope of this disclosure that the suture driving assembly described above can be used in a variety of situations where closing of a puncture, tear, or opening in tissue is required and in

any number of organs.. When used in the illustrated apical approach, the suture driving assembly is useful for closing a puncture **16** in the heart's apex **14** after performing a trans-apical valve replacement or repair, when placing a ventricular assist device, or other procedure that would benefit from closing an opening in the heart. As illustrated below, the suture driving device can also be used to deliver additional devices to the tissue site.

[0098] Fig. 10A illustrates the heart **12** after a physician tracks a guidewire **8** into an apical portion **14** of the heart where an apical opening **16** allows access to the interior of the heart. Next, the surgeon tracks an expanding device **200** over the guidewire and into the opening at the apical portion **14**. In this example the expanding device is a balloon catheter but as noted above, any type of expanding device can be used. Moreover, any traditional technique for tracking a guidewire and catheter can be employed to position the guidewire and expandable device into the heart **12**.

[0099] Once the physician expands the balloon **202** within the heart **12**, the physician can then advance a main body **102** of the suture driving assembly **100** a shaft **204** of the expanding device **200**. At this time the surgeon can expand the balloon **202** to minimize dislodging of the assembly from the heart. As shown in Fig. 10B, once the main body **102** of the device **100** engages the apex **14** of the heart **12**, the surgeon compresses the apex **14** between the balloon **202** and the tissue engaging surface **114** of the main body. As noted above, the main body can include any number of features to ensure good contact with the tissue. For example, the surgeon can draw suction through ports in the main body to ensure that the apical wall **14** secures to the main body **102**.

[0100] The physician can optionally fully or partially deflate the balloon **202** (or reduce a diameter of other expandable structures if used). Once reduced, the expandable portion **202** or balloon can be retracted into the apical opening **202** as shown in Fig. 10C. This partial retraction of the balloon into the opening can further stabilize the device to the organ or tissue.

[0101] As illustrated in Fig. 10D, once the physician is satisfied with the placement of the device **100**, the physician can actuate the device **100** to advance the needle assemblies**100** and throw the sutures **80** through the apical tissue. As noted herein, the needle assemblies can be fired simultaneously or sequentially. In some variations the balloon or expandable member remains inflated during advancement of the needles. In such cases, the balloon/expandable member can be fabricated so that the needle assembly will deflect away from the surface of the expandable member to prevent rupture or trapping of the needles. Moreover, the needle assemblies can fully penetrate the wall of tissue or can remain within the wall. The depth of the throw is typically a function of the type of tissue, the tissue engaging surface, and the design of the needle assembly. In cases such as an apical procedure, the needles may not need to fully penetrate the walls of the organ. For example, the needles in the present example do not reach

the balloon but remain within the hearts apical tissue until they return to the retrieval channels.

[0102] After placement of the suture the main body **102** can be retracted to expose the suture ends outside the body cavity so that the surgeon can secure the sutures. The balloon can then be deflated and removed. The physician can then place an appropriate port/cannula through the apical puncture **16** and hold the port in place during the procedure by tightening of the stitch. After the procedure is complete, the port/cannula is removed and the purse string suture is drawn tight and secured with a knot or cinch to provide closure of the apical puncture.

[0103] Fig. 10E shows an alternative approach, in this variation the surgeon retracts the main body **102** and disengages any vacuum or suction being applied. Next, the surgeon advances a port or introducer sheath **230** the main lumen **118** of the main body **102** and ultimately advanced into the apical opening **16**. As noted above, the introducer sheath **230** can be advanced using a pin **220** that slides through an opening in the main body **102**. Alternatively, the introducer **230** can be advanced by manipulation of a proximal end of the dilator device **232**. The dilator device **232** eases the transition through the apical opening **16** and ensures a seal between the apical opening **16** and introducer sheath **230**. The expandable member/balloon can be removed prior to, or during insertion of the introducer sheath **230** within the heart. Alternatively, though not illustrated the balloon can remain in place until the introducer is secured.

[0104] As shown in Fig. 10F, once the physician places the introducer sheath **230**, the surgeon withdraws the main body **102** to expose the sutures that were previously thrown in the tissue. Removal of the main body allows access to the sutures **80** so that the sutures can be tighted around the dilator **16** and/or introducer sheath **230**. As a result, the sutures **230** are temporarily tensioned about the introducer sheath **230** to form a tissue seal around the introducer sheath **230.** This temporary fixation allows the physician to create an access path into the heart for performing any appropriate procedures. Once the procedure is completed, the surgeon removes the introducer, and any other remaining devices as necessary while leaving the sutures **80** in place.. Once all devices are removed from the opening, the physician secures the sutures **80** to close the apical opening. Fig. 6C provides an example of the suture pattern that will be left in the apical portion of the wall upon removal of the remaining devices.

CLAIMS

What is claimed is:

1. A suture driving assembly for positioning a suture in a tissue section, the assembly comprising:

at least one needle assembly having a tissue piercing end distal to an elongate shaped section, the elongate shaped section having a curvilinear shape, the elongate shaped section being elastically deformable when restrained into a strained state and upon release assumes the curvilinear shape, the suture coupled to the needle assembly;

a main body having a tissue engaging surface at a distal end, at least one constraining channel and at least one retrieving channel each of which having an opening at the tissue engaging surface;

such that when the elongate shaped section of the needle assembly is in the restraining portion, the elongate shaped section is deformed into the strained state and when the elongate shaped section advances through the guide segment portion, the elongate shaped section assumes the curvilinear shape, upon continued advancement the elongated shaped section exits through the opening of constraining channel in the curvilinear shape;

a suture retriever assembly located in the needle retrieving channel;

an expandable member axially moveable relative to the tissue engaging surface, the expandable member having a first reduced profile and an expanded profile, where in the reduced profile the expandable member can advance through an opening in the tissue section and where the expandable member can be withdrawn toward the tissue supporting face to secure the tissue section therebetween.

2. The suture driving assembly of claim 1, where the at least one needle assembly comprises at least two needle assemblies.

3. The suture driving assembly of claim 1, where the constraining channel comprises a first cross-sectional shape and the guide segment has a second cross sectional shape, where the first and second cross-sectional shapes are different, where the second cross sectional shape permits at least a part of the shaped section of the needle assembly entering the guide segment to revert to the curvilinear shape prior to entry into the tissue.

4. The suture driving assembly of claim 3, where the guide segment comprises an oval cross-sectional shape.

5. The suture driving assembly of claim 1, where the expandable member is located on a distal end of a shaft, where the shaft extends through at least a portion of the body.

6. The tissue closure assembly of claim 5, where the shaft comprises a guidewire lumen such that the suture driving assembly can be advanced over a guidewire.

7. The suture driving assembly of claim 1, where the expandable member comprises a balloon.

8. The suture driving assembly of claim 7, where the balloon comprises a material selected from PET, nylon, TPE, silicone, and latex.

9. The suture driving assembly of claim 1, where the needle assembly comprises a needle lumen extending through at least the tissue piercing end and where the suture is removably nested within the needle lumen.

10. The suture driving assembly of claim 9, where the suture is exterior to the needle assembly and a first free end of the suture is inserted into the needle lumen at the tissue piercing end.

11. The suture driving assembly of claim 10, where a second free end of the suture is coupled to a second needle assembly having a second tissue piercing end distal to a second elongate shaped section, where the second free end of the suture is inserted into a second needle lumen at the second tissue piercing end.

12. The suture driving assembly of claim 1, where the suture is removably front-loaded into the tissue piercing end.

13. The suture driving assembly of claim 12, where the suture retriever assembly comprises at least one pawl member that reduces an opening of the retrieving channel to less than a size of the needle assembly and suture, where the pawl member is biased to allow movement of the needle assembly and suture in a first direction and resist movement of the needle assembly and suture in a second direction, where rearward movement of the needle assembly from the retrieving channel causes the paw member to compress and retain the suture within the retrieving channel.

14. The suture driving assembly of claim 1, where the retrieving channel extends only partially through the main body.

15. The suture driving assembly of claim 1, where the curvilinear shape of the shaped section comprises a three-dimensional curvilinear shape.

16. The suture driving assembly of claim 1, where the shaped section comprises a plurality of curved segments such that advancement of the needle assembly causes the tissue piercing end to penetrate tissue at a plurality of locations.

17. The suture driving assembly of claim 16, where the shaped section comprises a helically shaped section.

18. The suture driving assembly of claim 1, where the restraining portion maintains the strained state of the shaped section in a substantially linear shape.

19. The suture driving assembly of claim 1, where the constraining channel is tapered towards the guide segment such that a diameter of the guide segment closely matches a diameter of the shaped section.

20. The suture driving assembly of claim 1, where the constraining channel comprises an inner diameter larger than a diameter of the guide segment.

21. The suture driving assembly of claim 1, further comprising at least a second needle assembly comprising a second tissue piercing end distal to a second shaped section having a second curvilinear shape, the second shaped section being elastically deformable into a second strained state and upon release assumes the second curvilinear shape.

22. The suture driving assembly of claim 21, where a second end of the suture is coupled to the second needle assembly.

23. The suture driving assembly of claim 1, where at least the shaped section comprises a material selected from the group consisting of a spring metal and a shape memory alloy.

24. The suture driving assembly of claim 1, where the suture retriever assembly comprises a structure selected from the group consisting of a set of jaws, a recessed notch, pawl, funnel, catch cloth, magnetic coupling device, finger trap, or other gripping mechanism.

25. The suture driving assembly of claim 1, where the distal end comprises one or more vacuum lumens for securing tissue thereagainst.

26. The suture driving assembly of claim 1, where the distal end comprises a bonding agent for securing tissue thereagainst.

27. The suture driving assembly of claim 1, where the distal end comprises a pledget removably positioned on the tissue engaging surface.

28. A suture driving assembly for closing an opening in a tissue section, the assembly comprising:

a first needle assembly having a tissue piercing end distal and being elastically deformable when restrained into a strained state and upon release assumes the curvilinear shape;

a suture exterior to the needle assembly and having at least one end front-loaded into a needle lumen of a first tissue piercing portion of the first needle assembly;

a main body having a tissue engaging surface at a distal end, at least one constraining channel and at least one retrieving channel each of which having an opening at the tissue engaging surface;

where the constraining channel extends through the main body and comprises at least a restraining portion having a profile to maintain the needle assembly into the strained state and a guide segment portion adjacent to the constraining channel opening and having a profile to release needle assembly into the curvilinear shape when advanced therethrough and upon continued advancement the needle assembly exits the opening of the constraining channel in the curvilinear shape;

a suture retriever assembly located in the needle retrieving channel and comprising a pawl mechanism, where the pawl mechanism interferes with the front loaded suture and needle assembly when advanced therein, where rearward movement of the front loaded suture and needle assembly causes the pawl to engage the suture to retain the suture within the needle retrieving channel; and

an expandable member axially moveable relative to the tissue engaging surface, the expandable member having a first reduced profile and an expanded profile, where in the reduced profile the expandable member can advance through an opening in the tissue section and where the expandable member can be withdrawn toward the tissue supporting face to secure the tissue section therebetween when expanded.

29. The suture driving assembly of claim 28, where the needle assembly further comprises an elongate shaped section having a curvilinear shape.

30. The suture driving assembly of claim 28, further comprising a second needle assembly where a second end of the suture is front loaded into a second tissue piercing portion of the second needle assembly, where a second intermediate section of the suture extends along an exterior of the needle assembly

31. The suture driving assembly of claim 28, where the expandable member is located on a on a distal end of a shaft, where the shaft extends through at least through a portion of the body.

32. The tissue closure assembly of claim 31, where the shaft comprises a guidewire lumen such that the suture driving assembly can be advanced over a guidewire.

33. The suture driving assembly of claim 28, where the expandable member comprises a balloon.

34. The suture driving assembly of claim 33, where the balloon comprises a material selected from PET, nylon, TPE, silicone, and latex.

35. The suture driving assembly of claim 28, where the pawl mechanism reduces a diameter of the retrieving channel to less than a size of the needle assembly and suture, where the pawl mechanism is biased to allow movement of the needle assembly and suture in a first direction and resist movement of the needle assembly and suture in a second direction, where rearward movement of the needle assembly from the retrieving channel causes the paw mechanism to compress and retain the suture within the retrieving channel.

36. The suture driving assembly of claim 28, where the retrieving channel extends only partially through the main body.

37. The suture driving assembly of claim 28, where the curvilinear shape of the shaped section comprises a three-dimensional curvilinear shape.

38. The suture driving assembly of claim 28, where the shaped section comprises a plurality of curved segments such that advancement of the needle assembly causes the tissue piercing end to penetrate tissue at a plurality of locations.

39. The suture driving assembly of claim 38, where the shaped section comprises a helically shaped section.

40. The suture driving assembly of claim 28, where the restraining portion maintains the strained state of the shaped section in a substantially linear shape.

41. The suture driving assembly of claim 28, where the needle assembly comprises a material selected from the group consisting of a spring metal and a shape memory alloy.

42. The suture driving assembly of claim 28, where the distal end comprises one or more vacuum lumens for securing tissue thereagainst.

43. The suture driving assembly of claim 1, where the distal end comprises a bonding agent for securing tissue thereagainst.

44. The suture driving assembly of claim 28, where the distal end comprises a pledget removably positioned on the tissue engaging surface.

45. A method for positioning a suture in a wall of an organ to close an opening in the wall, the method comprising:

placing a main body adjacent to a proximal side of the tissue, where the main body comprises at least one needle assembly coupleable to the suture and within a constraining channel located in the main body, where the needle assembly comprises a tissue piercing end distal to an elongate shaped section, the elongate shape section having a curvilinear shape, the shaped section being elastically deformable into a strained state within the constraining channel, and a suture coupled to the needle assembly, the main body further including a tissue engaging surface;

advancing an expandable member through the opening in the organ when the expandable member is in a reduced profile;

expanding the expandable member to an expandable profile;

positioning the wall of the organ between the main body and the expandable member;

advancing the needle assembly from the constraining channel into a guide segment, where the guide segment permits the shaped section of the needle assembly located therein to revert to the curvilinear shape prior to leaving the guide segment and entering the wall of the organ;

driving the needle assembly through a proximal side of the wall of the organ, such that the shaped section moves through the curvilinear shape so that the tissue piercing distal end and suture re-enter the main body at a retrieving channel;

fully reducing the expandable member into a reduced profile; and

withdrawing the main body.

46. The method of claim 45, where advancing the needle assembly comprises advancing a plurality of needle assembly pairs, where each needle assembly pair is coupled to an end of a suture and where each needle assembly advances from a respective constraining channel into a respective guide segment, where the guide segment permits the shaped section of the respective needle assembly located therein to revert to the curvilinear shape prior to leaving the respective guide segment and enter the wall of the organ; and where the plurality of needle assemblies move through the curvilinear shape so that the tissue piercing distal end of each needle assembly pair re-enter the main body at a respective retrieving channel.

47. The method of claim 46, where each guide segment and each retrieving channel is positioned to feed at least one suture across the opening.

48. The method of claim 46, where the plurality of needle assembly pairs comprises two pairs coupled respectively to a first and second suture.

49. The method of claim 48, where each guide segment and each retrieving channel is positioned to feed the first suture approximately 90 degrees from the second suture relative to the opening in tissue.

50. The method of claim 45, further comprising securing the suture in the retrieving channel while withdrawing the needle assembly back into the constraining channel.

51. The method of claim 50, where the suture is front loaded into the needle assembly such that securing the suture in the retrieving channel comprises advancing the needle assembly and suture against a pawl mechanism such that the pawl mechanism compresses the suture to retain the suture while allowing the needle assembly to be withdrawn back into the constraining channel.

52. The method of claim 45, where the expandable member comprises a structure selected from the group consisting of a balloon, a spline basket, a spline basket, an expandable funnel, and a stent-like structure.

53. The method of claim 45, where positioning the wall of the organ between the main body and the expandable member comprises axially moving the expandable member relative to the tissue engaging surface to capture the wall of the organ therebetween.

54. The method of claim 53, further comprising partially reducing the expandable member and positioning the partially reduced expandable member into the opening.

55. The method of claim 45, where the main body further comprising at least a second needle assembly, coupled to a second end of the suture, where the second needle assembly comprises a second tissue piercing end distal to a second shaped section having a second curvilinear shape, the second shaped section being elastically deformable into a second strained state and upon release assumes the second curvilinear shape.

56. The method of claim 45, where driving the needle assembly comprises driving the needle assemblies on either side of the opening, the method further comprising securing the suture within the tissue after removing the main body to close the opening.

57. The method of claim 45, further comprising applying suction through a port on the main body to secure the wall of the organ against the tissue engaging surface.

58. The method of 57, where applying suction comprises applying suction after or during expanding the expandable member to the expanded profile.

59. The method of claim 45, further comprising inserting an introducer sheath through the main body and into the opening.

60. The method of claim 59, where inserting the dilator device through the main body and into the opening occurs after withdrawing the main body to expose the suture.

61. The method of claim 59, further comprising dilating the opening by inserting a dilator device through the main body and into the opening.

62. The method of claim 59, further withdrawing the main body from the organ while leaving the access introducer sheath and suture in the organ to create a temporary access path to the organ.

63. The method of claim 62, further comprising performing a procedure on the organ through the access device, removing the access device, and subsequently closing the opening using the suture.

64. A method positioning a suture within a tissue of the heart for closing an opening in the heart, the method comprising:

placing a main body adjacent to an exterior surface of the heart, where the main body comprises at least one needle assembly coupled to the suture and within a constraining channel located in the main body, where the needle assembly comprises a tissue piercing end distal to an elongate shaped section, the elongate shape section having a curvilinear shape, the shaped section being elastically deformable into a strained state within the constraining channel, and a suture coupled to the needle assembly, the main body further including a tissue engaging surface;

advancing an expandable member through the opening and into the heart when the expandable member is in a reduced profile;

expanding the expandable member to an expandable profile;

positioning the a portion of the heart between the main body and the expandable member;

advancing the needle assembly from the constraining channel into a guide segment, where the guide segment permits the shaped section of the needle assembly located therein to

revert to the curvilinear shape prior to leaving the guide segment and entering the wall of the organ;

driving the needle assembly through a proximal side of the wall of the organ, such that the shaped section moves through the curvilinear shape so that the tissue piercing distal end and suture re-enter the main body at a retrieving channel ;

reducing the expandable member into a reduced profile; and

withdrawing the main body.

65. The method of claim 64, where advancing the needle assembly comprises advancing a plurality of needle assembly pairs, where each needle assembly pair is coupled to an end of a suture and where each needle assembly advances from a respective constraining channel into a respective guide segment, where the guide segment permits the shaped section of the respective needle assembly located therein to revert to the curvilinear shape prior to leaving the respective guide segment and enter the wall of the organ; and where the plurality of needle assemblies move through the curvilinear shape so that the tissue piercing distal end of each needle assembly pair re-enter the main body at a respective retrieving channel.

66. The method of claim 64, where each guide segment and each retrieving channel is positioned to feed at least one suture across the opening.

67. The method of claim 64, where the plurality of needle assembly pairs comprises two pairs coupled respectively to a first and second suture.

68. The method of claim 67, where each guide segment and each retrieving channel is positioned to feed the first suture approximately 90 degrees from the second suture relative to the opening in tissue.

69. The method of claim 64, further comprising securing the suture in the retrieving channel while withdrawing the needle assembly back into the constraining channel.

70. The method of claim 69, where the suture is front loaded into the needle assembly such that securing the suture in the retrieving channel comprises advancing the needle assembly and suture against a pawl mechanism such that the pawl mechanism compresses the suture to retain the suture while allowing the needle assembly to be withdrawn back into the constraining channel.

71. The method of claim 64, where the expandable member comprises a structure selected from the group consisting of a balloon, a spline basket, a spline basket, an expandable funnel, and a stent-like structure.

72. The method of claim 64, where positioning the wall of the heart between the main body and the expandable member comprises axially moving the expandable member relative to the tissue engaging surface to capture the wall of the heart therebetween.

73. The method of claim 53, further comprising partially reducing the expandable member and positioning the partially reduced expandable member into the opening.

74. The method of claim 64, where the main body further comprising at least a second needle assembly, coupled to a second end of the suture, where the second needle assembly comprises a second tissue piercing end distal to a second shaped section having a second curvilinear shape, the second shaped section being elastically deformable into a second strained state and upon release assumes the second curvilinear shape.

75. The method of claim 64, where driving the needle assembly comprises driving the needle assemblies on either side of the opening, the method further comprising securing the suture within the tissue after removing the main body to close the opening.

76. The method of claim 64, further comprising applying suction through a port on the main body to secure the wall of the heart against the tissue engaging surface.

77. The method of 76, where applying suction comprises applying suction after or during expanding the expandable member to the expanded profile.

78. The method of claim 64, further comprising inserting an introducer sheath through the main body and into the opening.

79. The method of claim 78, where inserting the dilator device through the main body and into the opening occurs after withdrawing the main body to expose the suture.

80. The method of claim 78, further comprising dilating the opening by inserting a dilator device through the main body and into the opening.

81. The method of claim 78, further withdrawing the main body from the heart while leaving the access introducer sheath and suture in the heart to create a temporary access path to the heart.

82. The method of claim 82, further comprising performing a procedure on the heart through the access device, removing the access device, and subsequently closing the opening using the suture.

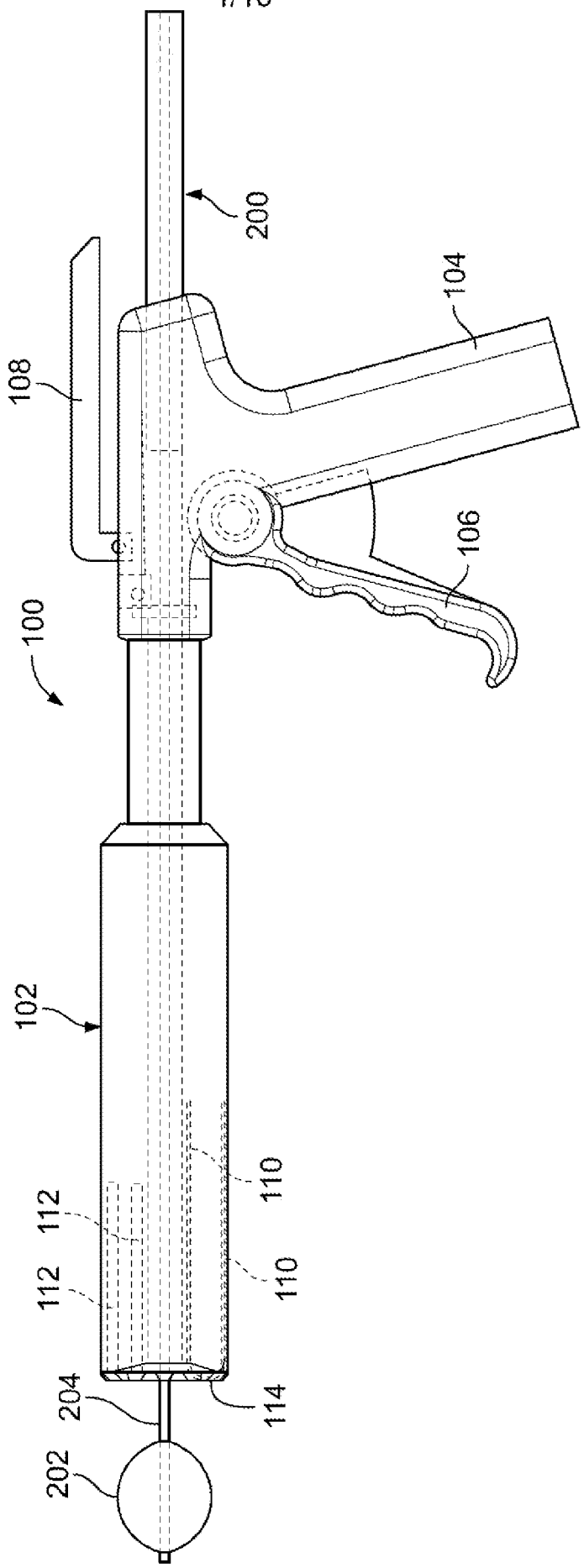

FIG. 1

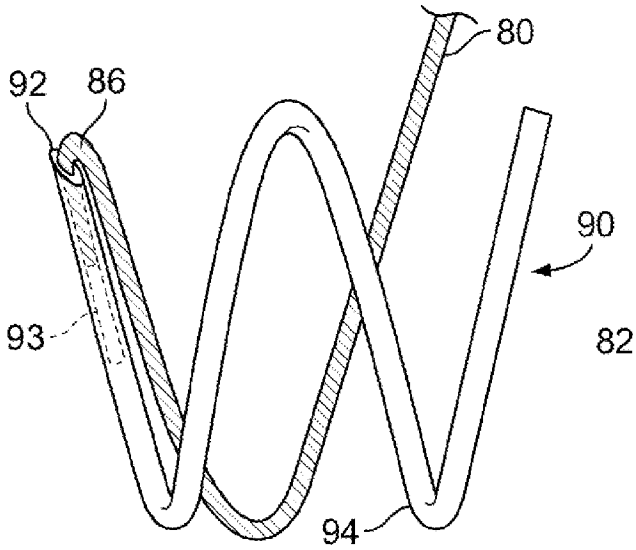

FIG. 2C

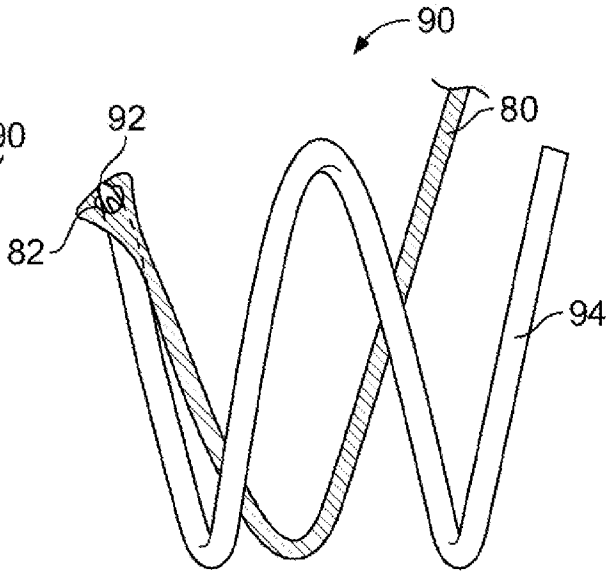

FIG. 2D

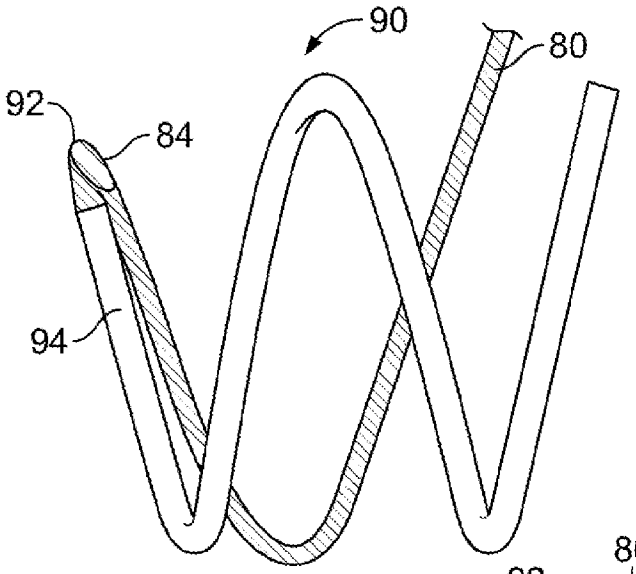

FIG. 2E

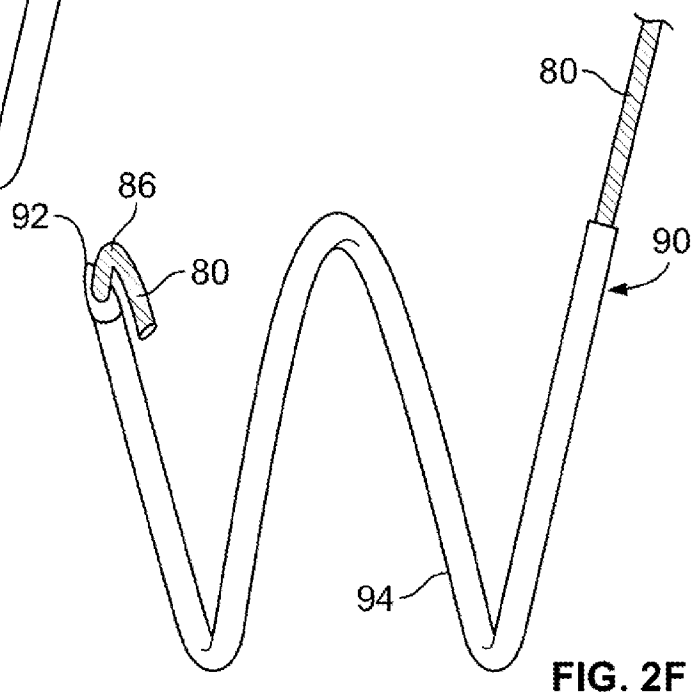

FIG. 2F

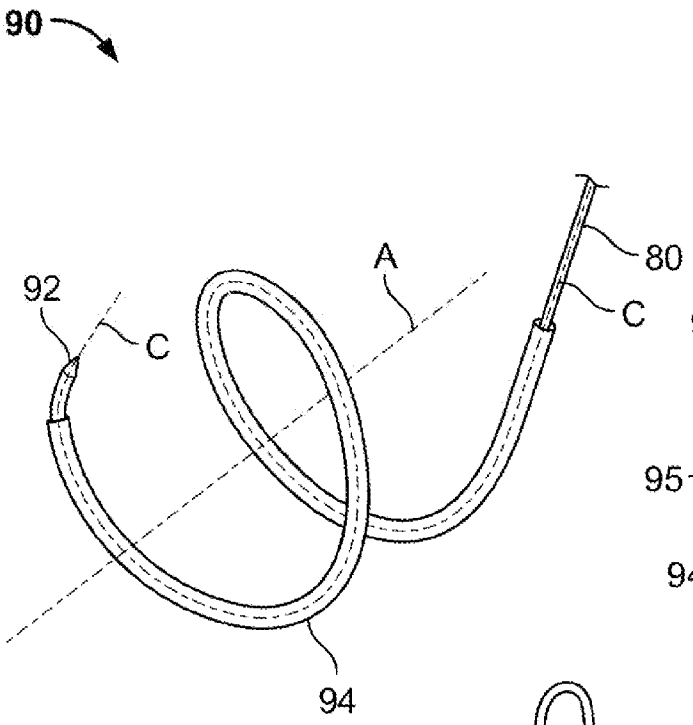

FIG. 2A

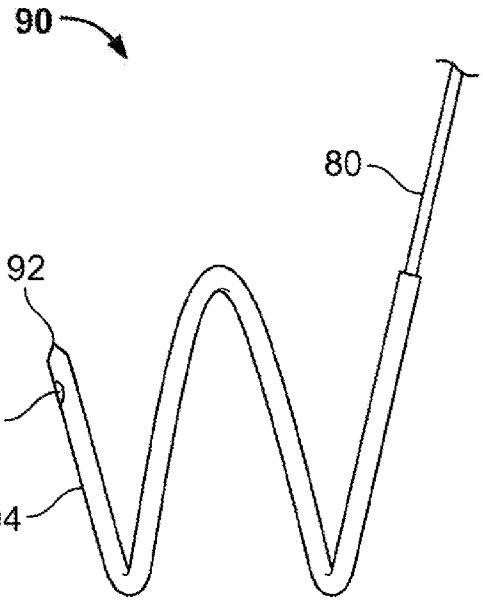

FIG. 2B

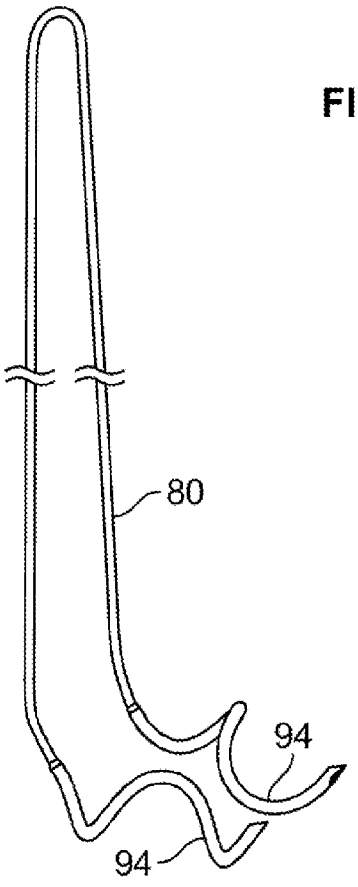

FIG. 2G

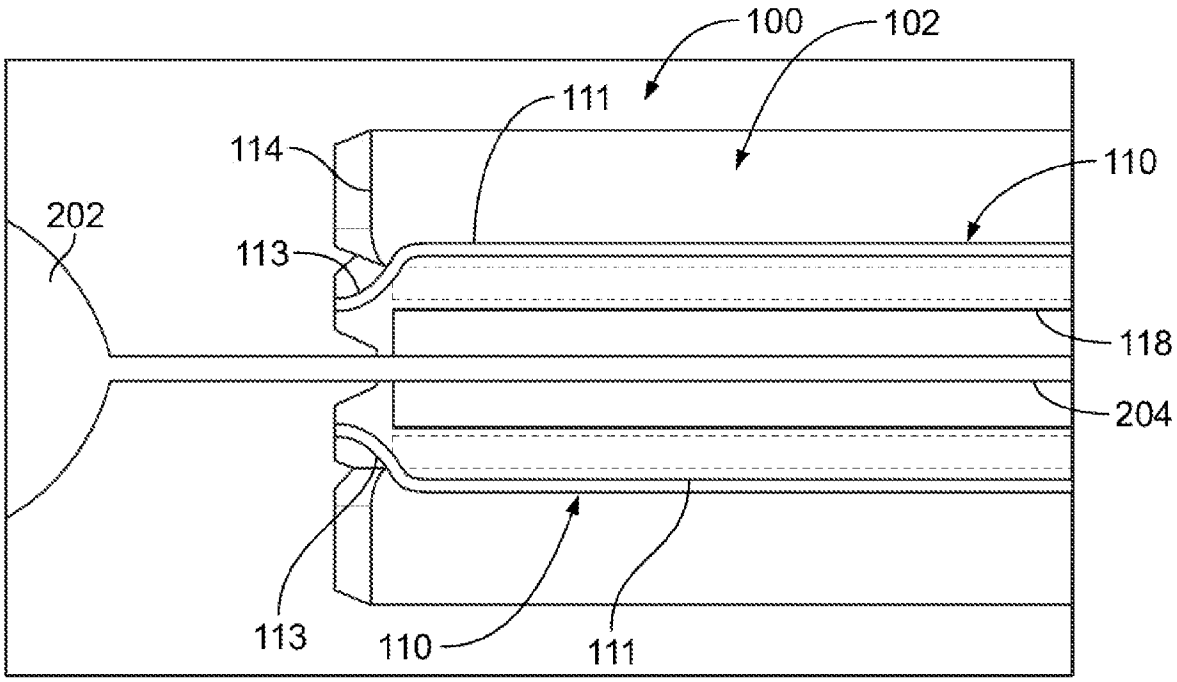
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FIG. 3A

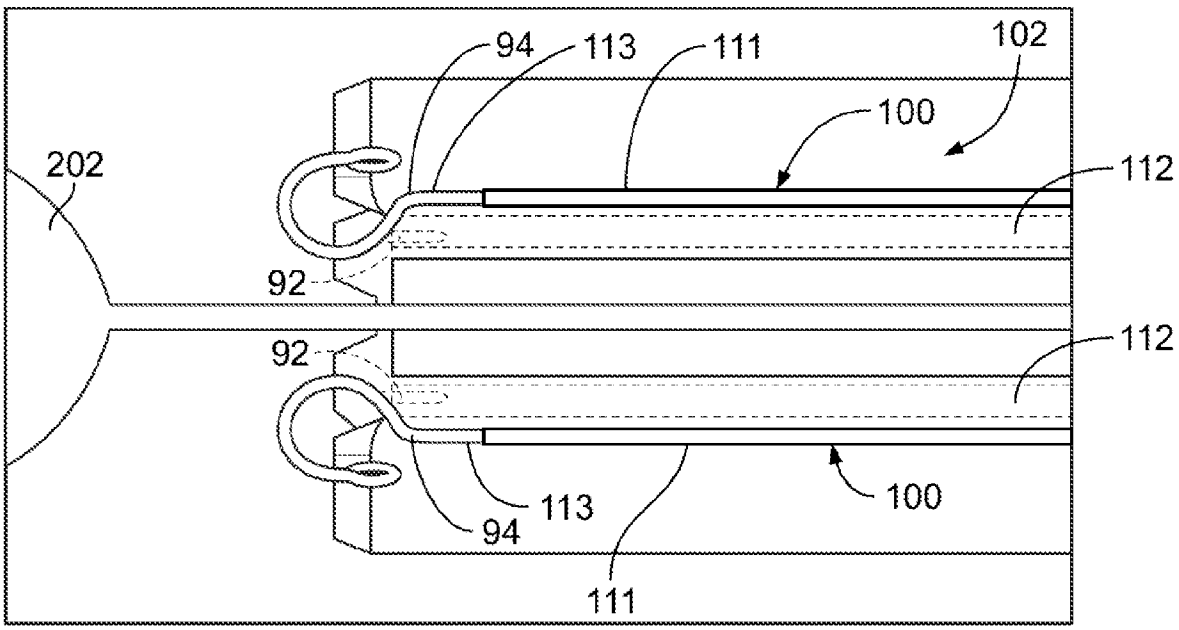
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FIG. 3B

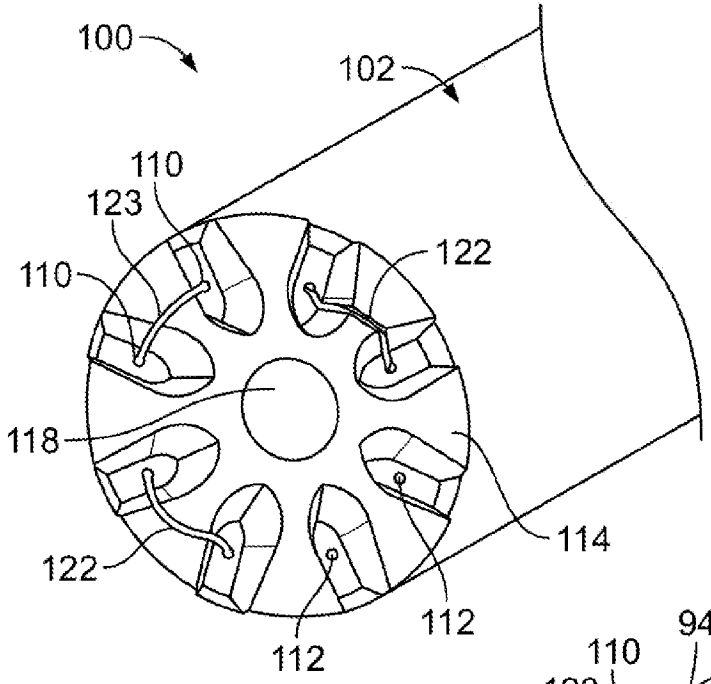

FIG. 4A

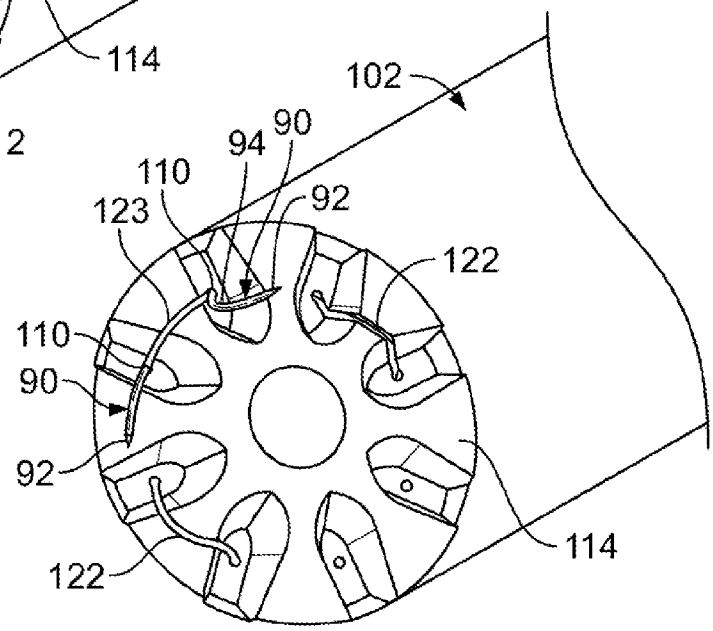

FIG. 4B

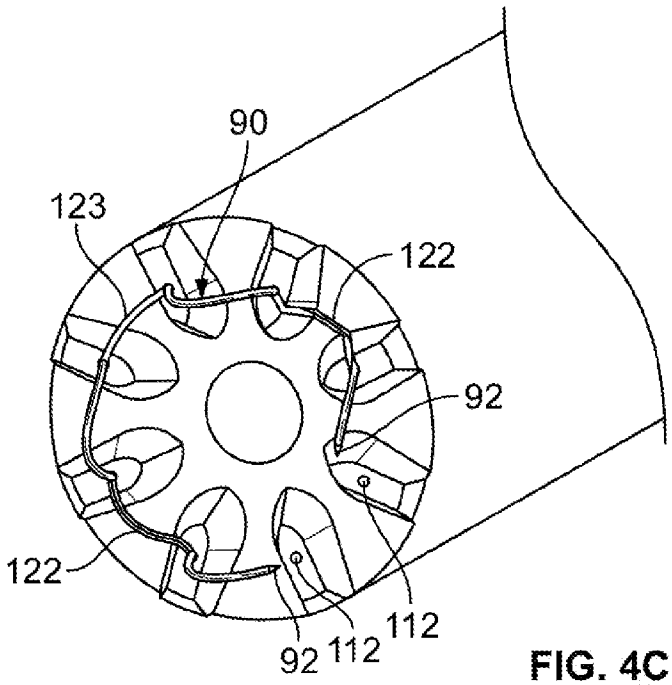

FIG. 4C

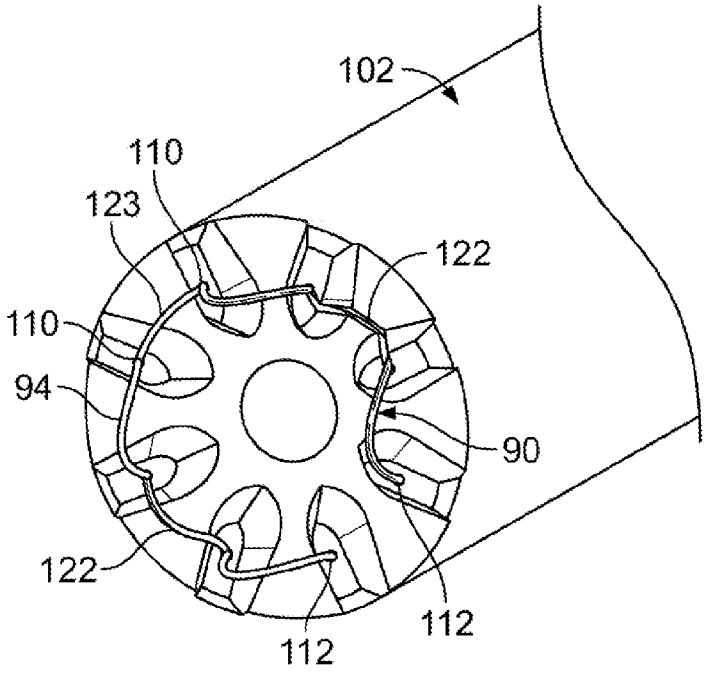

FIG. 4D

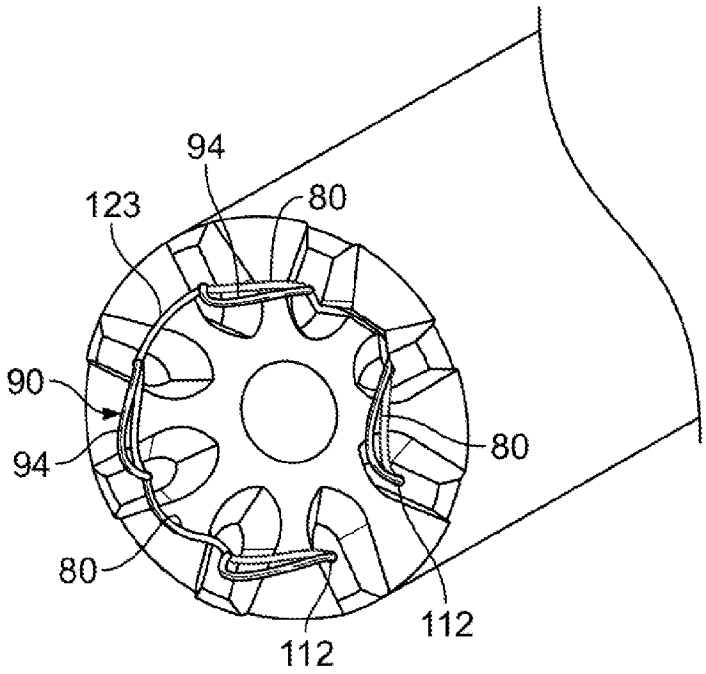

FIG. 4E

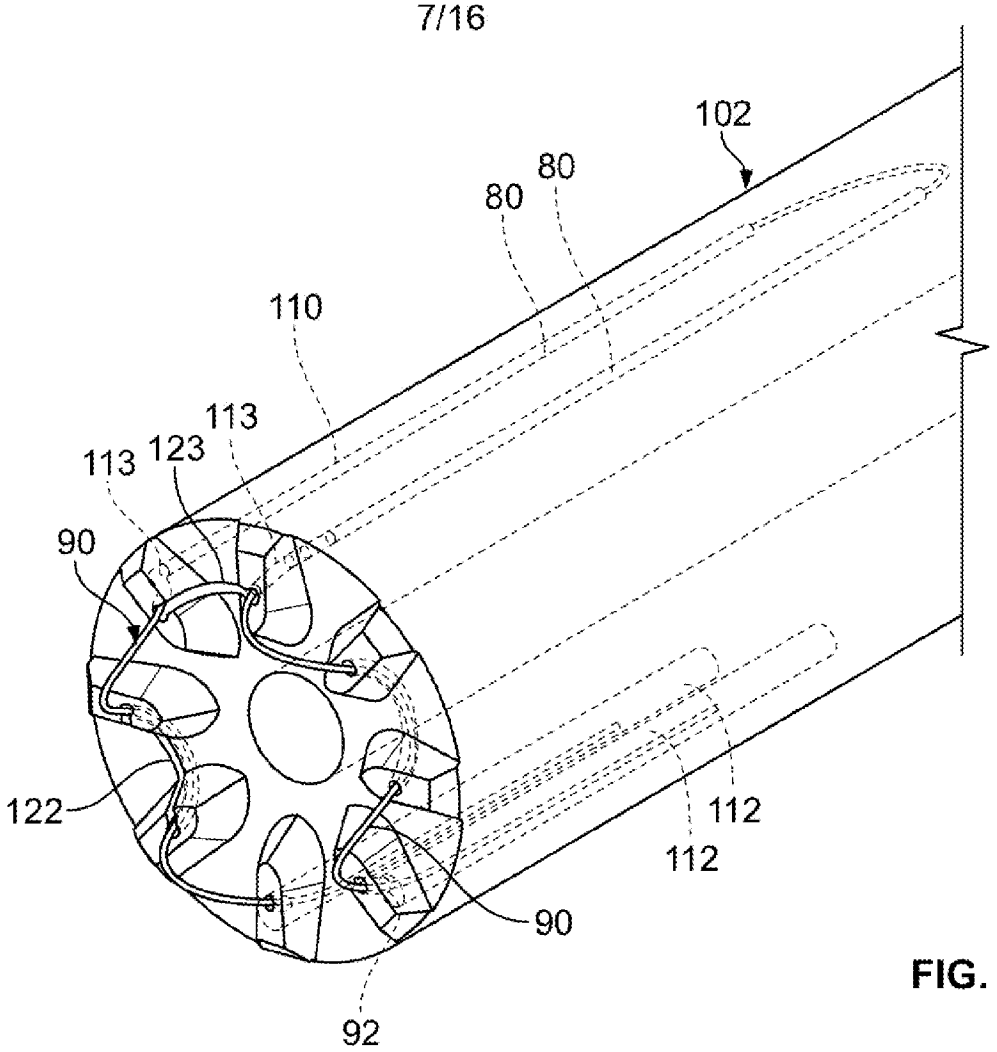

FIG. 5A

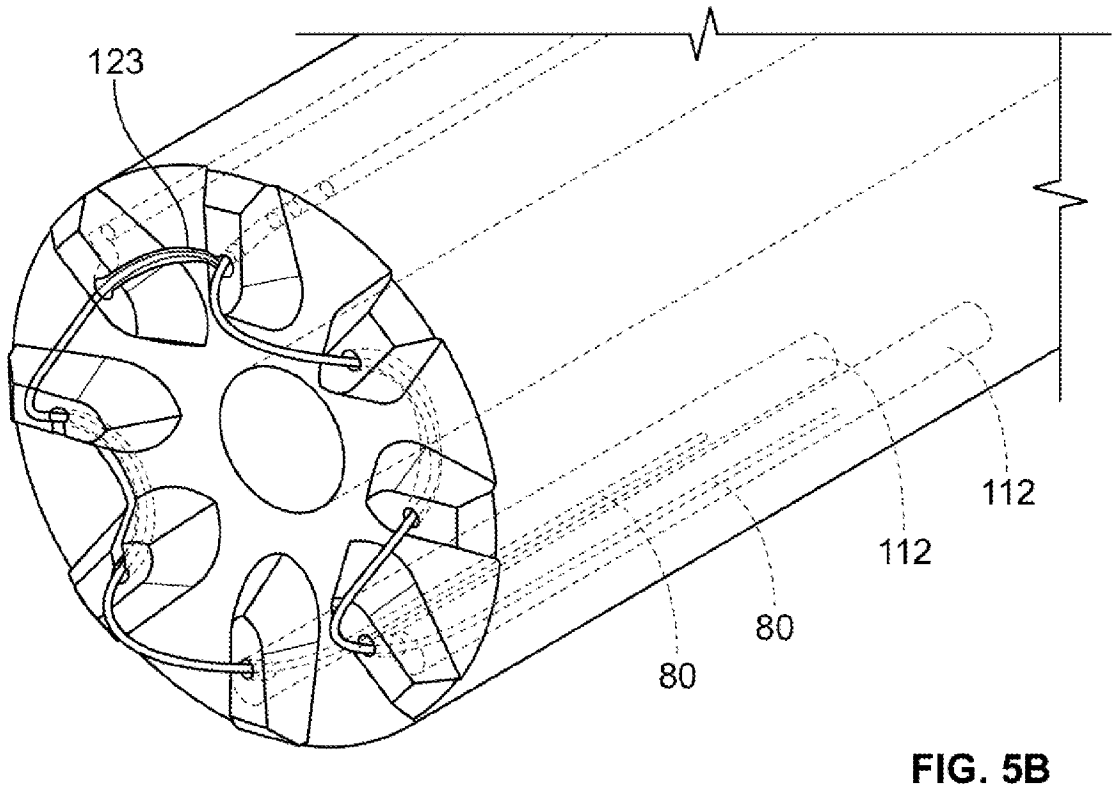

FIG. 5B

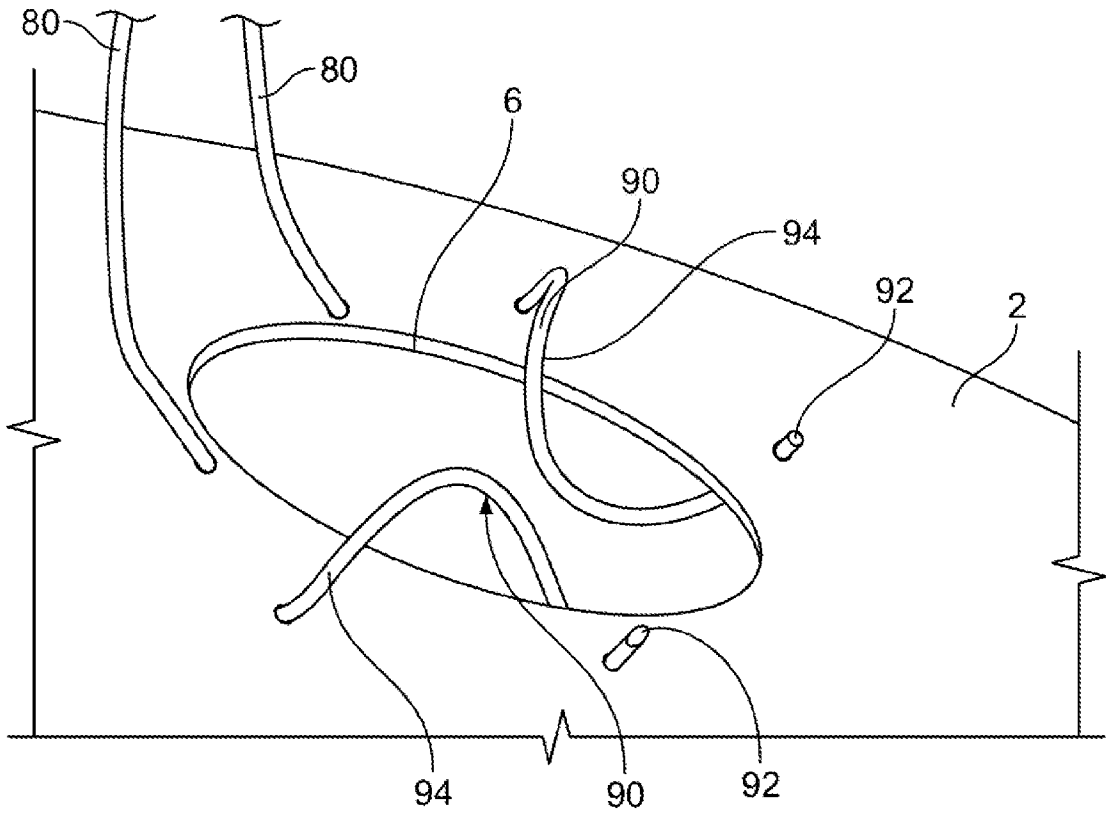

FIG. 5C

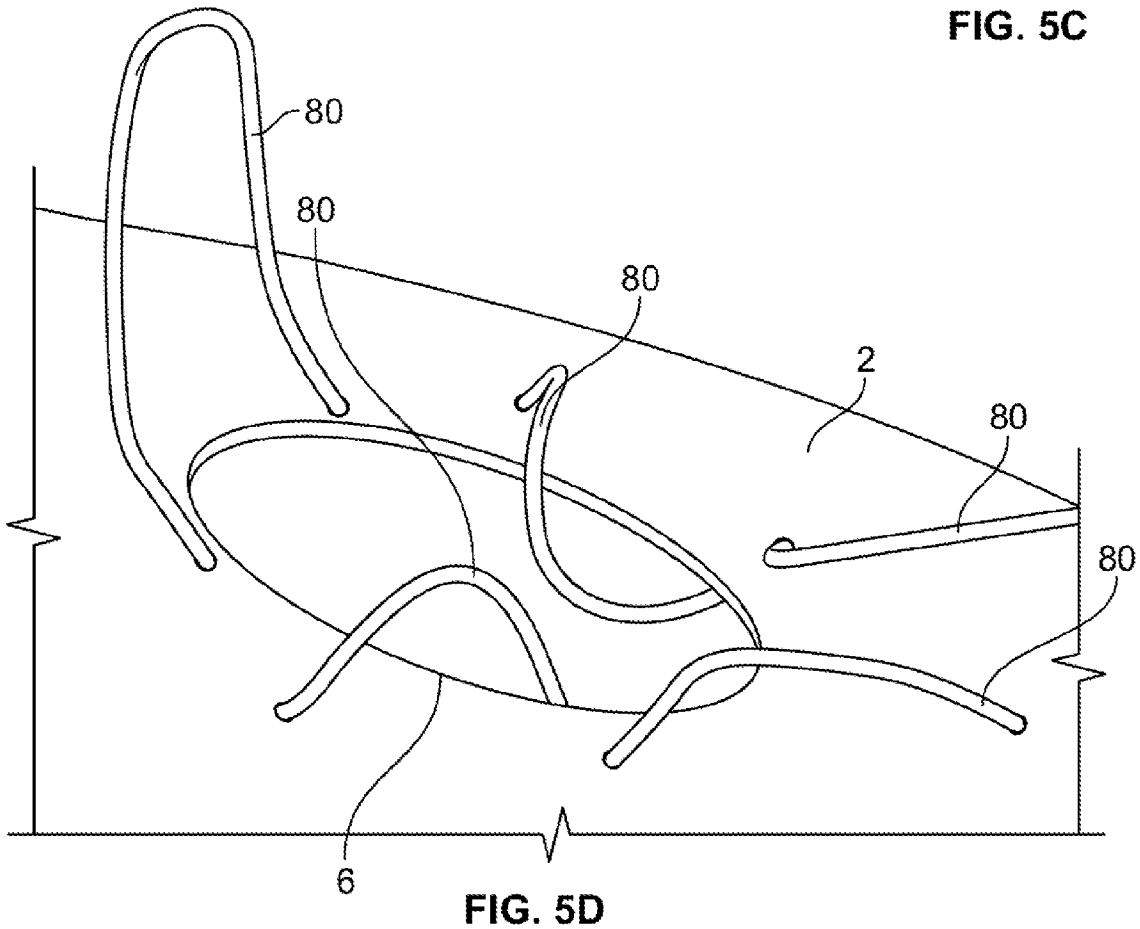

FIG. 5D

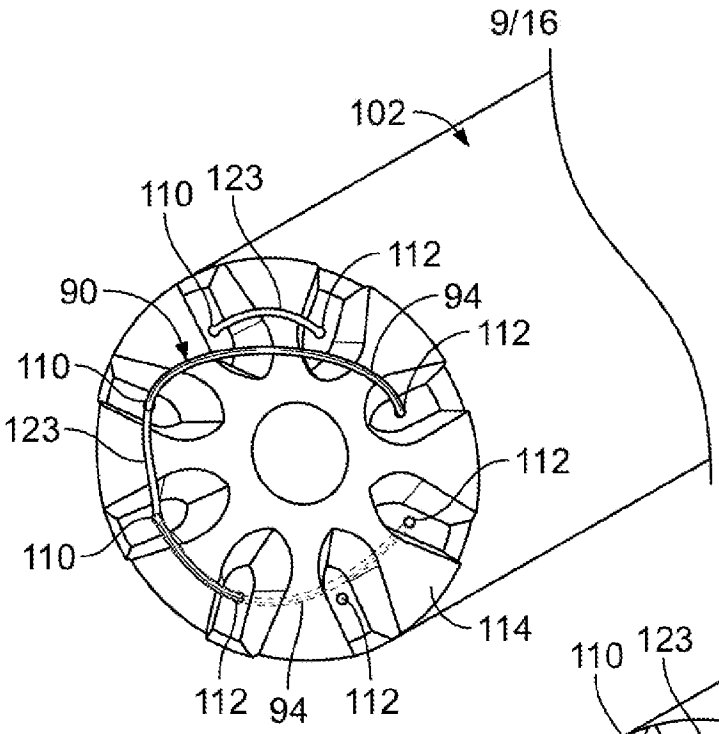

FIG. 6A

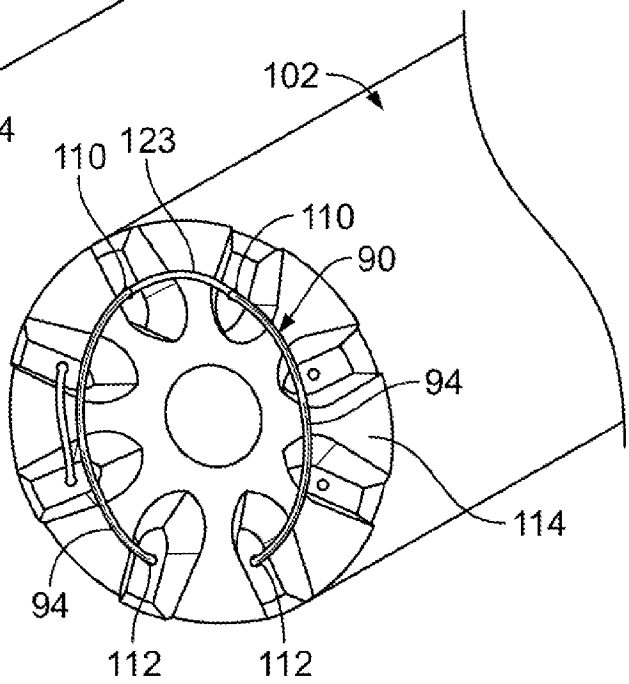

FIG. 6B

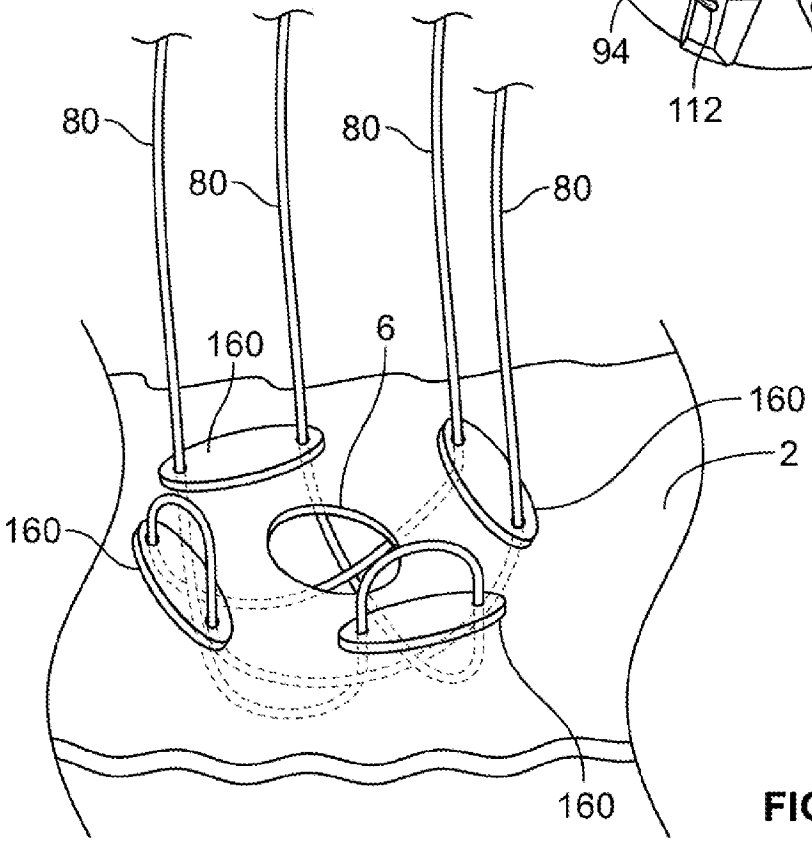

FIG. 6C

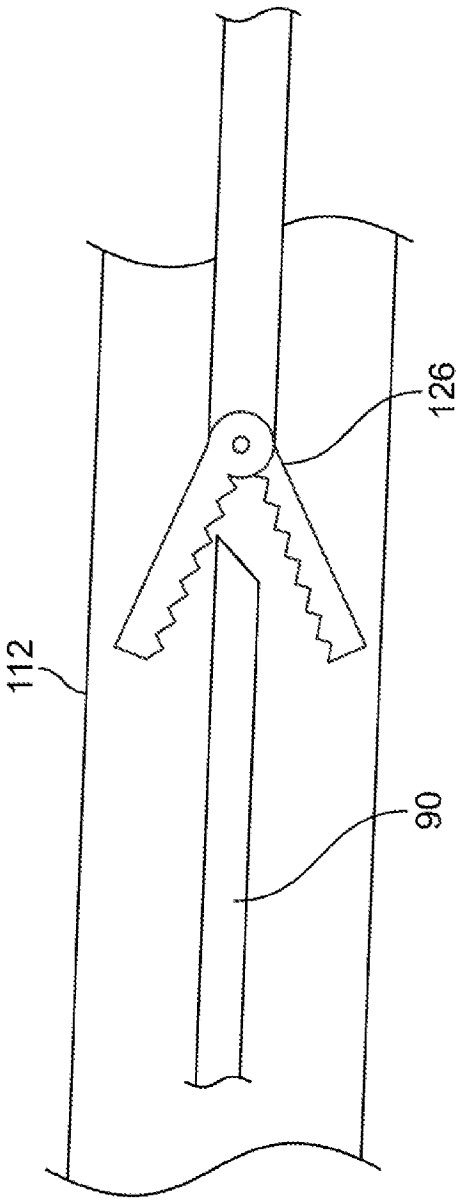

FIG. 7A

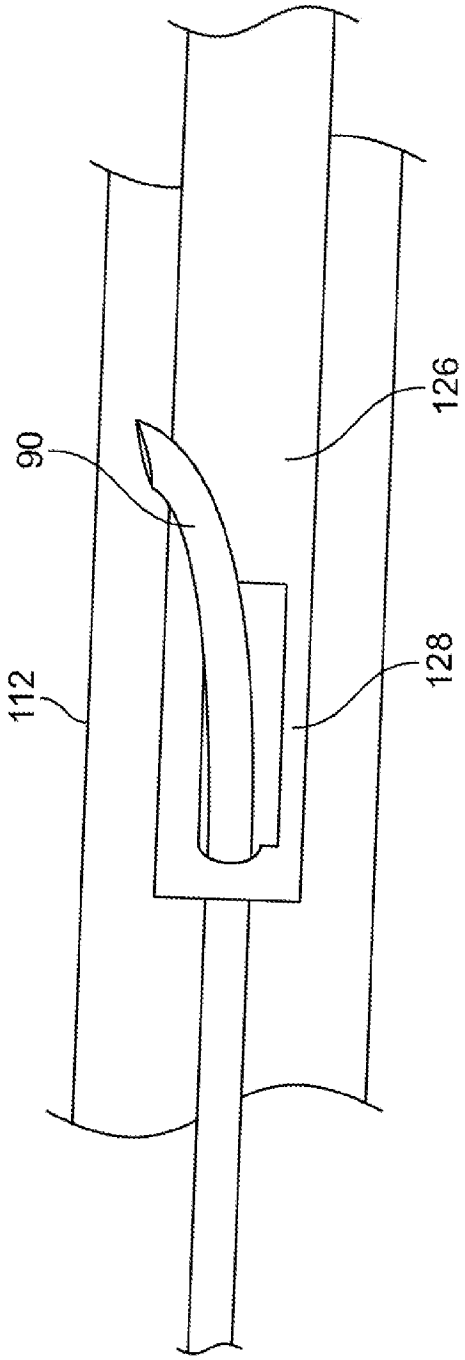

FIG. 7B

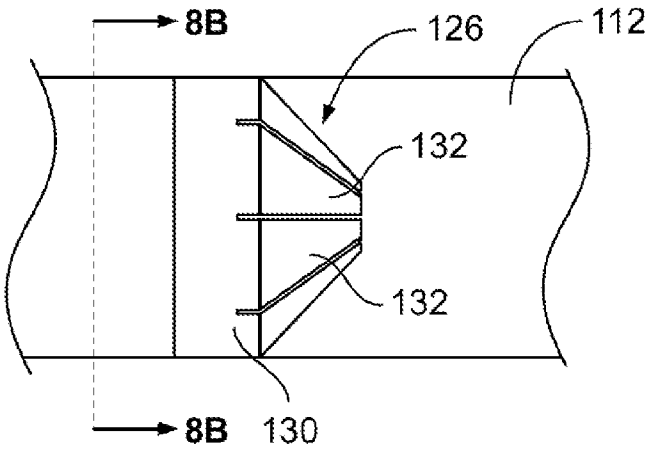

FIG. 8A

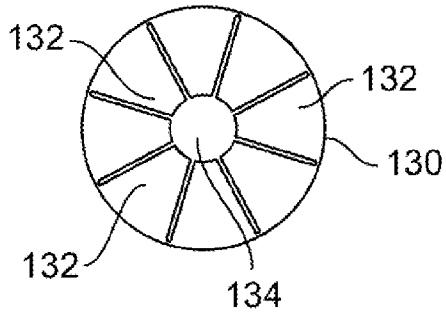

FIG. 8B

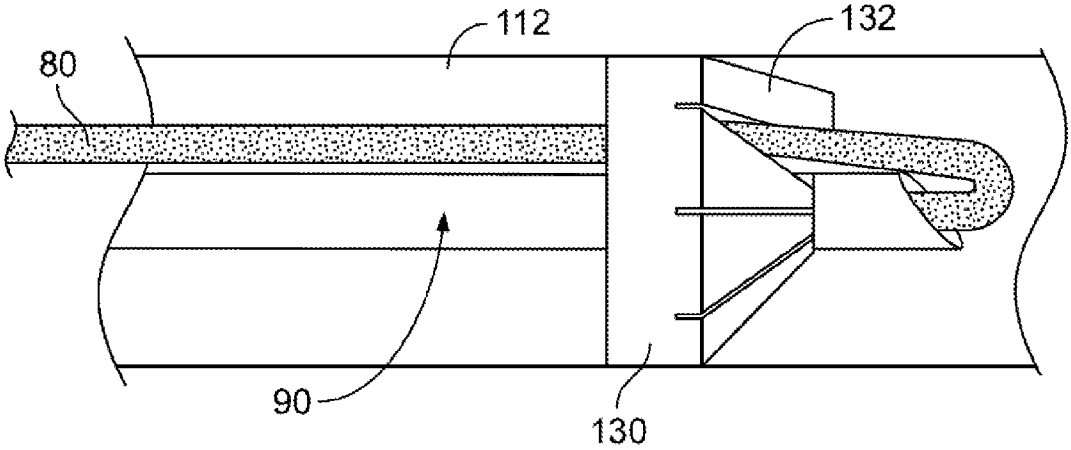

FIG. 8C

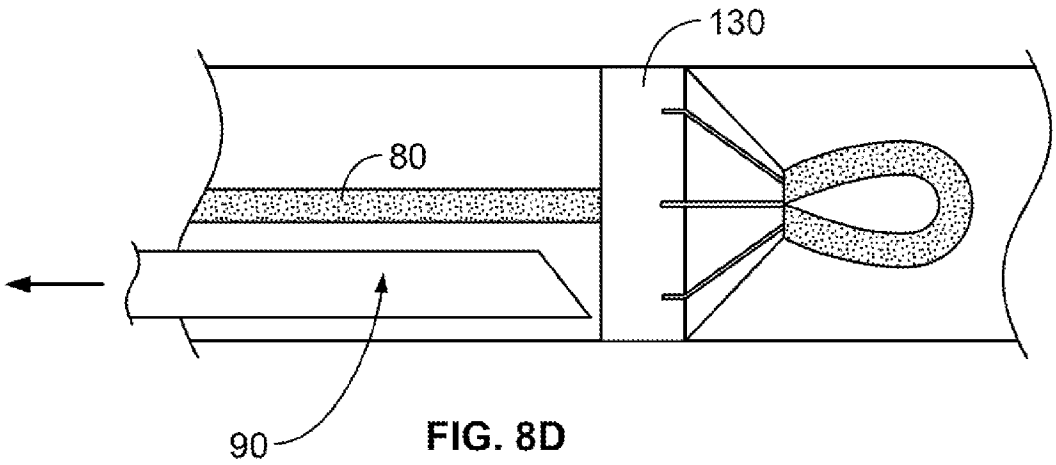

FIG. 8D

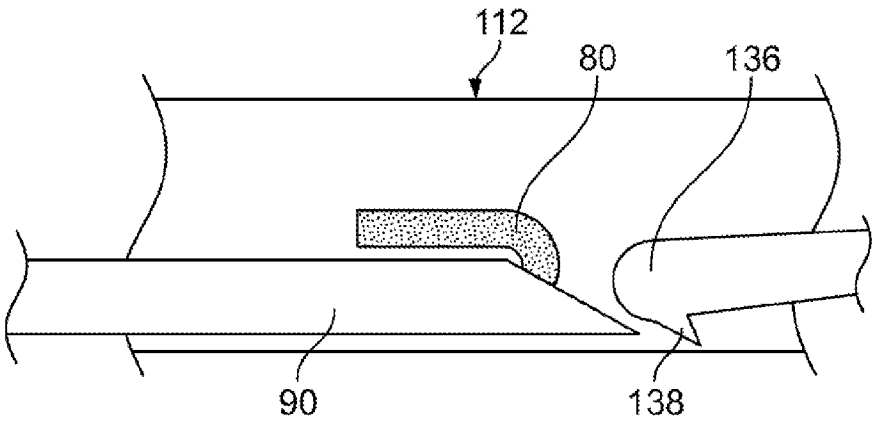

FIG. 8E

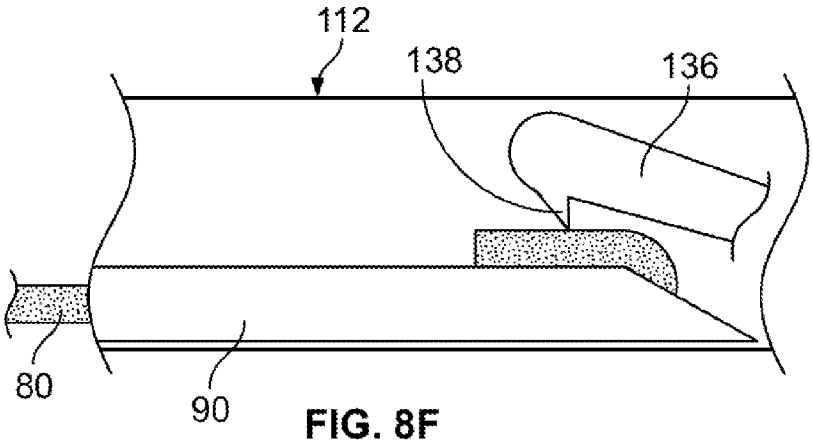

FIG. 8F

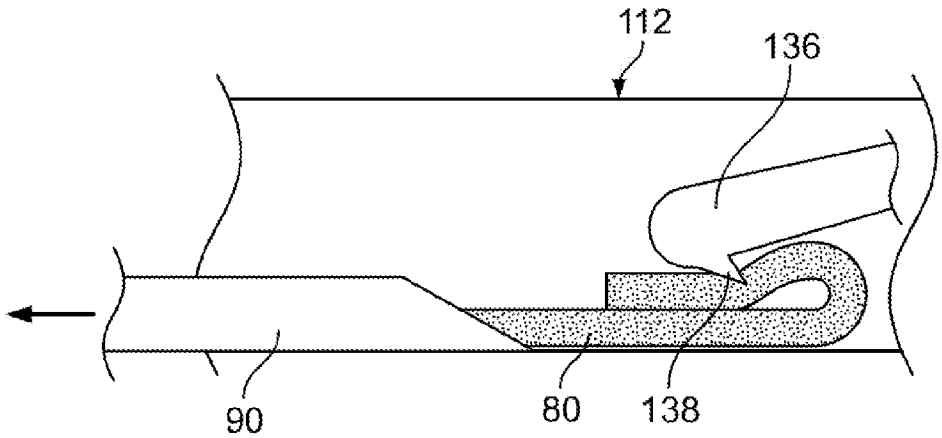

FIG. 8G

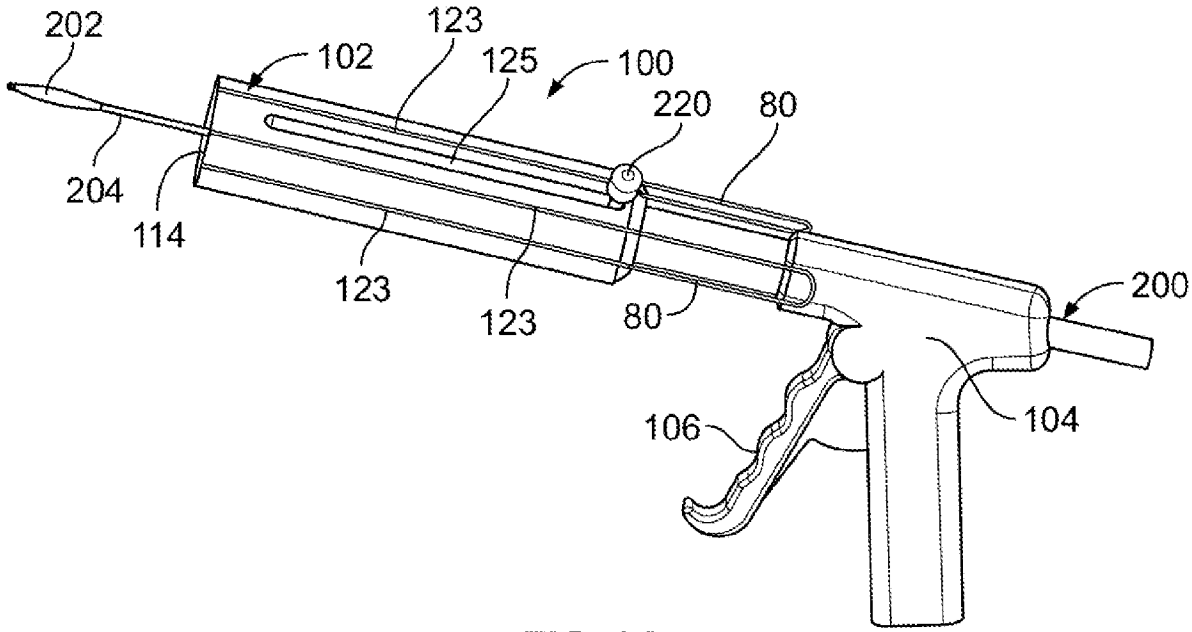

FIG. 9A

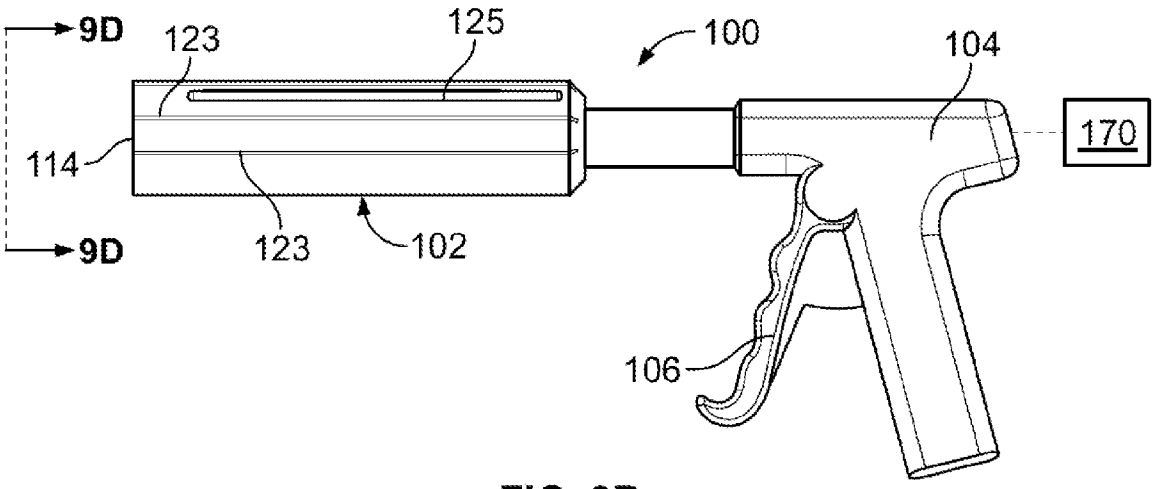

FIG. 9B

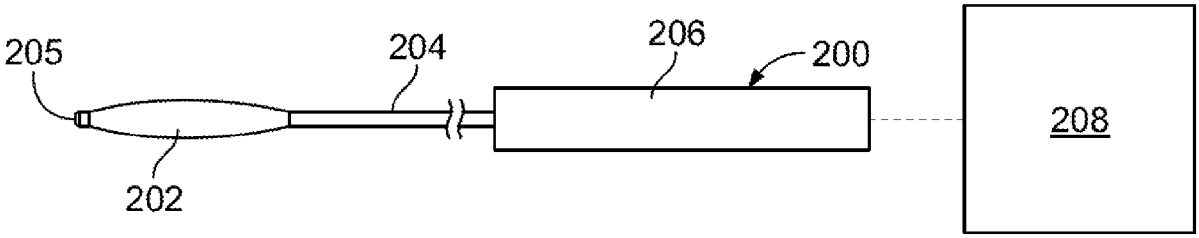

FIG. 9C

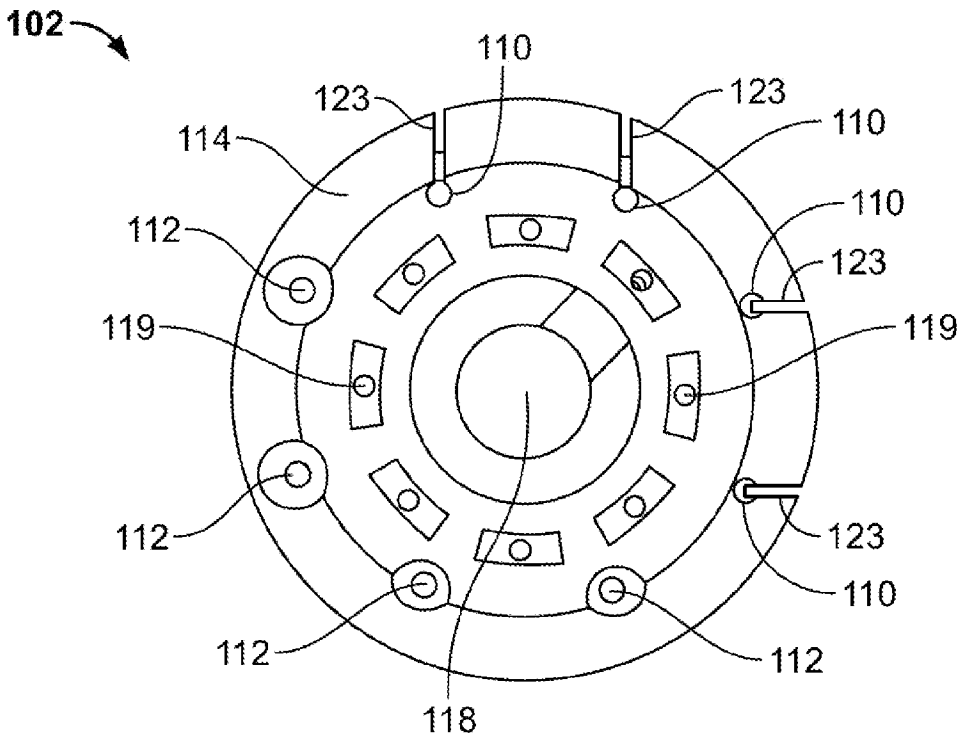

FIG. 9D

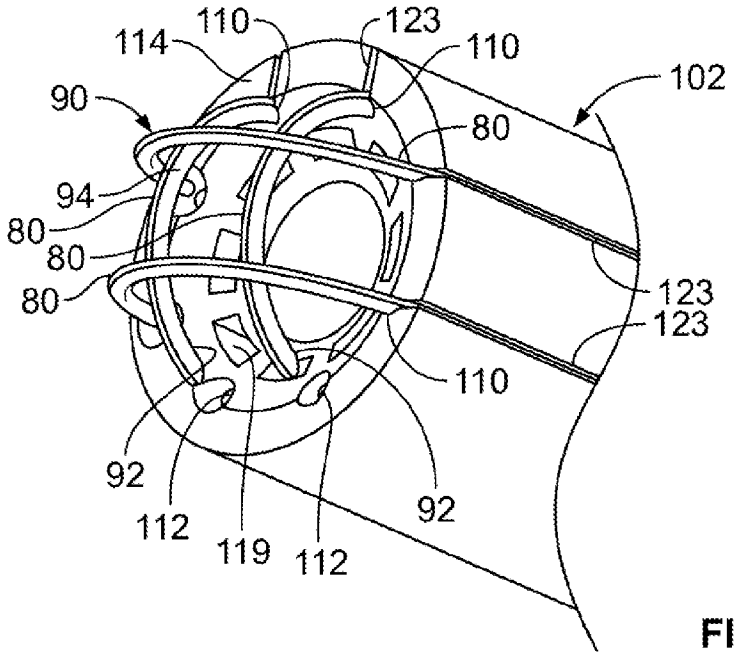

FIG. 9E

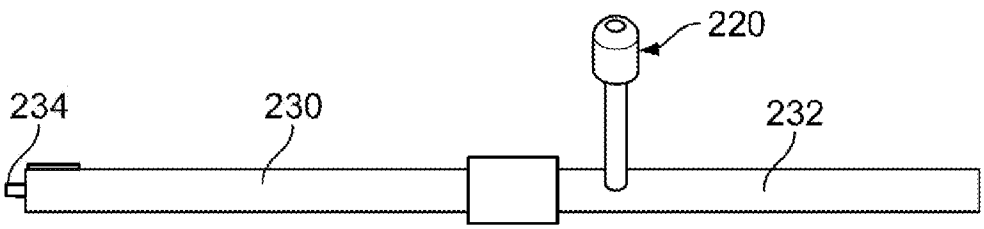

FIG. 9F

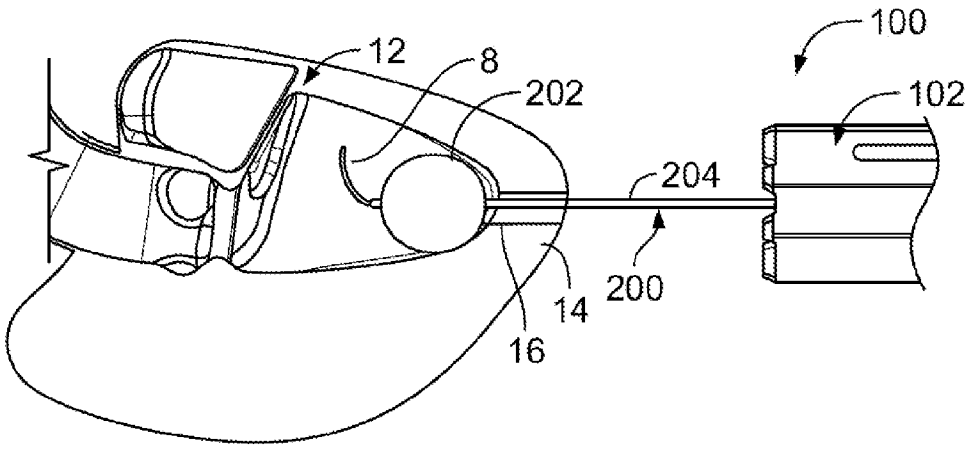

FIG. 10A

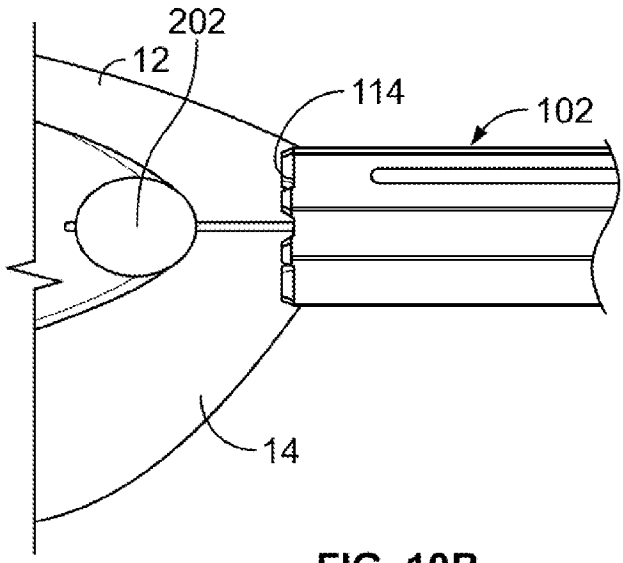

FIG. 10B

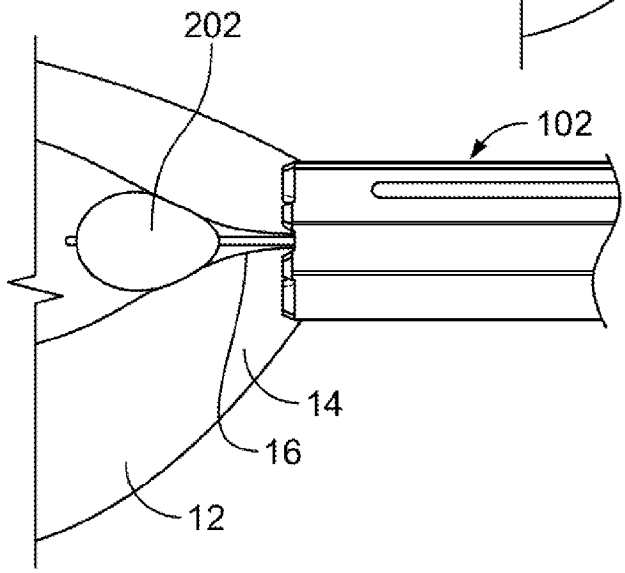

FIG. 10C

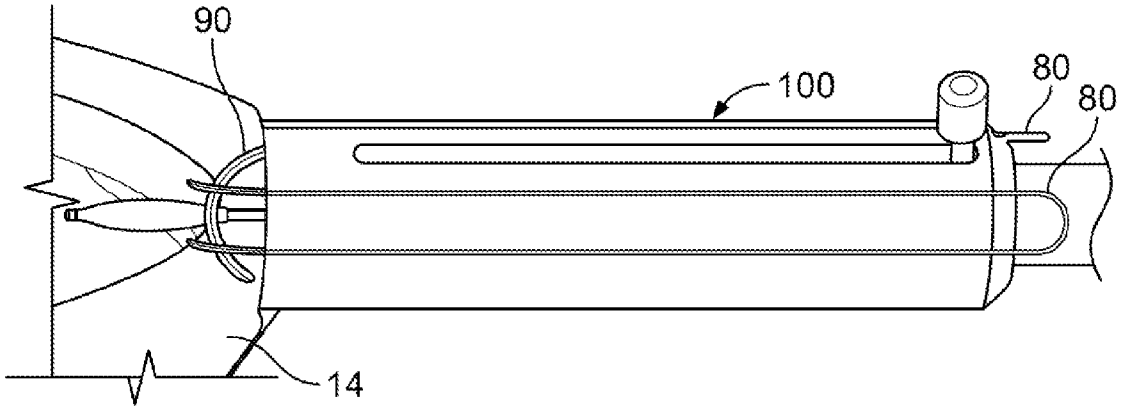

FIG. 10D

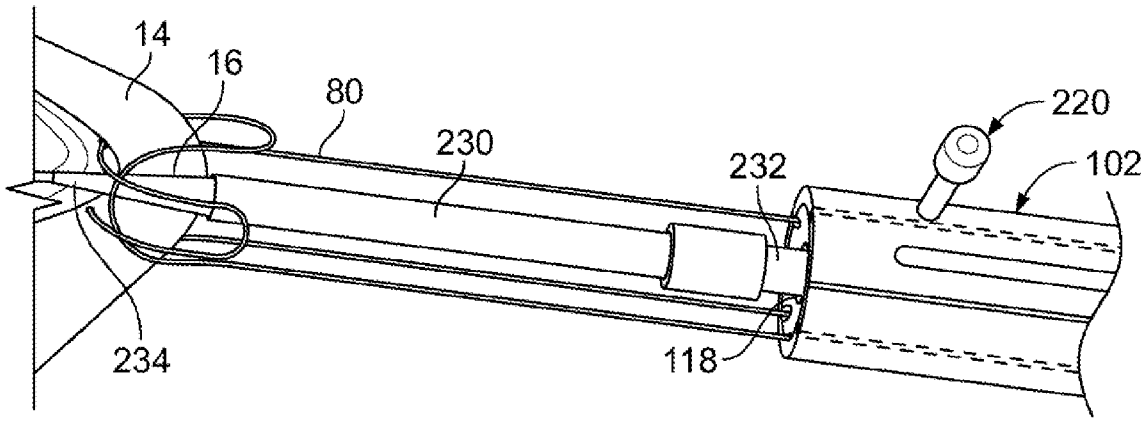

FIG. 10E

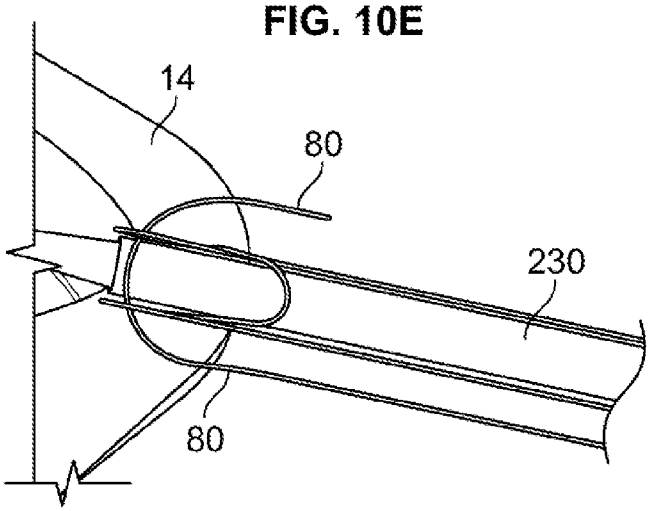

FIG. 10F

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/051442

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/04 (2009.01)
USPC - 606/139
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 17/03, 17/04, 19/00 (2009.01)
USPC - 606/139, 144, 148

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,074,404 A (STALKER et al) 13 June 2000 (13.06.2000) entire document	1-82
Y	US 2007/0203507 A1 (MCLAUGHLIN et al) 30 August 2007 (30.08.2007) entire document	1-82
Y	US 2006/0253126 A1 (BJERKEN et al) 09 November 2006 (09.11.2006) entire document	6, 32
Y	US 6,626,917 B1 (CRAIG) 30 September 2003 (30.09.2003) entire document	9-13, 15-17, 28-42, 44
Y	US 2006/0178560 A1 (SAADAT et al) 10 August 2006 (10.08.2006) entire document	25, 27, 42, 44, 57, 58, 76, 77
Y	US 2003/0176878 A1 (BOLDUC et al) 18 September 2003 (18.09.2003) entire document	26, 43
Y	US 5,222,508 A (CONTARINI) 29 June 1993 (29.06.1993) entire document	50, 51, 69, 70
Y	US 5,613,974 A (ANDREAS et al) 25 March 1997 (25.03.1997) entire document	59-63, 78-82

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

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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"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
30 August 2009	08 SEP 2009
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2005)