US008449559B2

(12) **United States Patent**
Keren et al.

(10) **Patent No.: US 8,449,559 B2**
(45) **Date of Patent: May 28, 2013**

(54) **METHOD FOR SUTURING**

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(73) Assignee: **Neatstitch Ltd.**, Orakiva (IL)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **13/204,684**

(22) Filed: **Aug. 7, 2011**

(65) **Prior Publication Data**

US 2012/0016385 A1 Jan. 19, 2012

Related U.S. Application Data

(62) Division of application No. 11/569,155, filed as application No. PCT/IL2005/000070 on Jan. 20, 2005, now Pat. No. 8,034,060.

(60) Provisional application No. 60/573,631, filed on May 21, 2004.

(51) **Int. Cl.**

A61B 17/04 (2006.01)
A61B 17/08 (2006.01)
A61B 17/00 (2006.01)

(52) **U.S. Cl.**

CPC ***A61B 17/0469*** (2013.01); *A61B 17/0482* (2013.01); *A61B 17/0057* (2013.01)
USPC **606/144**; 606/213

(58) **Field of Classification Search**

USPC 606/232, 153, 213, 151, 142, 144–150
See application file for complete search history.

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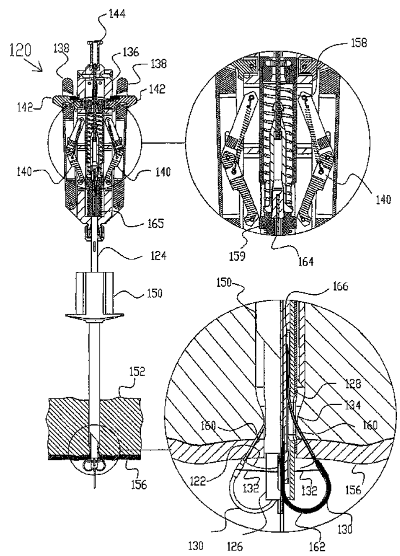
Primary Examiner — Tuan V Nguyen
(74) *Attorney, Agent, or Firm* — D. Kligler I.P. Services Ltd.

(57) **ABSTRACT**

A suture insertion device (**120**) includes a shaft (**124**), which is adapted to be inserted into a body cavity (**154**). First and second needles (**160**) hold respective first and second ends of a suture thread (**122**). First and second needle guides (**130**) are attached to the shaft and respectively hold the first and second needles. The needle guides have a first operative configuration in which the needle guides are held parallel to the axis of the shaft for insertion of the shaft into the body cavity and a second operative configuration in which the needle guides are deployed outward from the shaft within the body cavity so as to point the needles in a proximal direction. An ejector (**164**) is operative to eject the needles from the needle guides in the second operative configuration so as to cause the needles to penetrate tissue (**156**) adjoining the body cavity.

32 Claims, 28 Drawing Sheets



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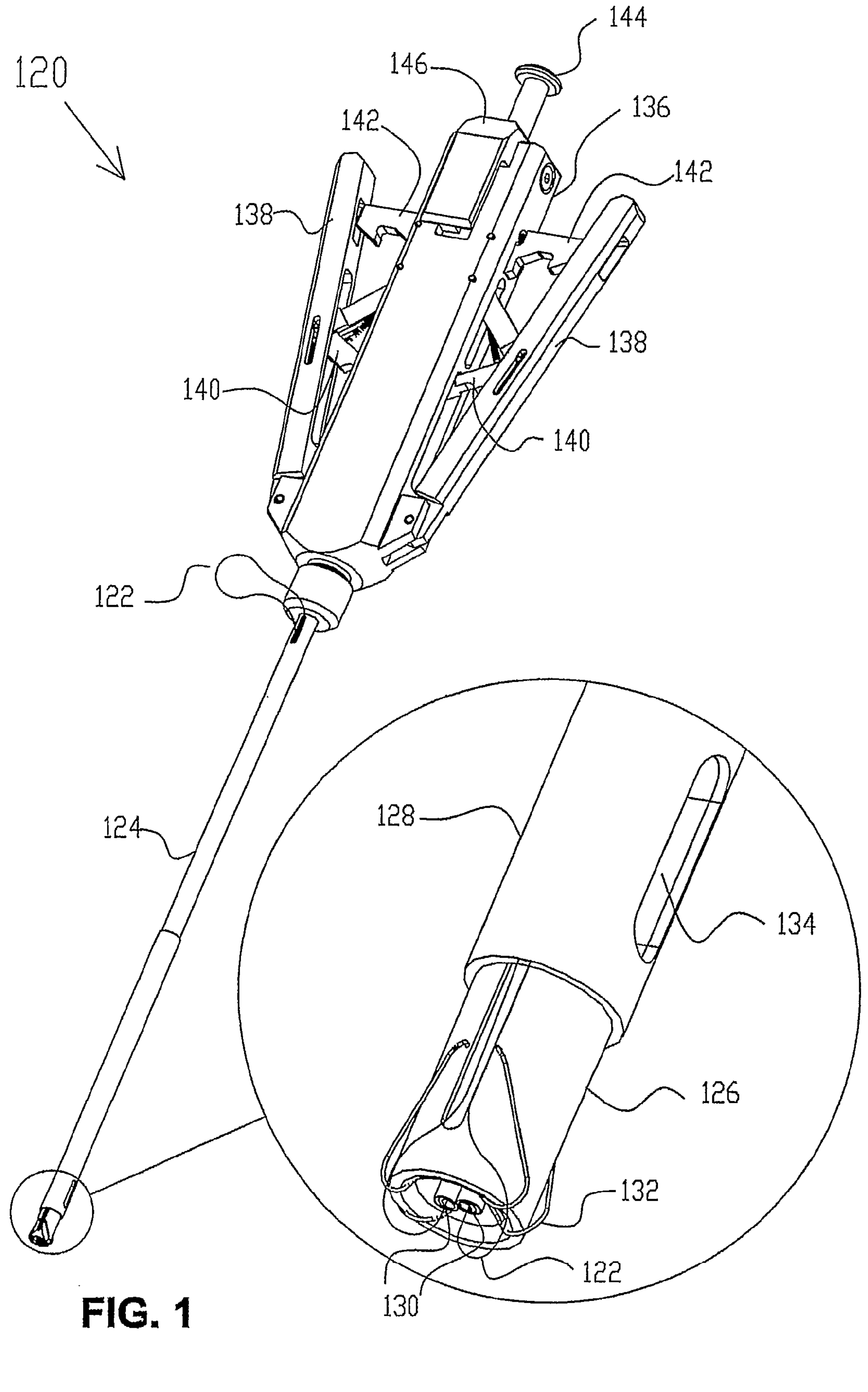
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FIG. 1

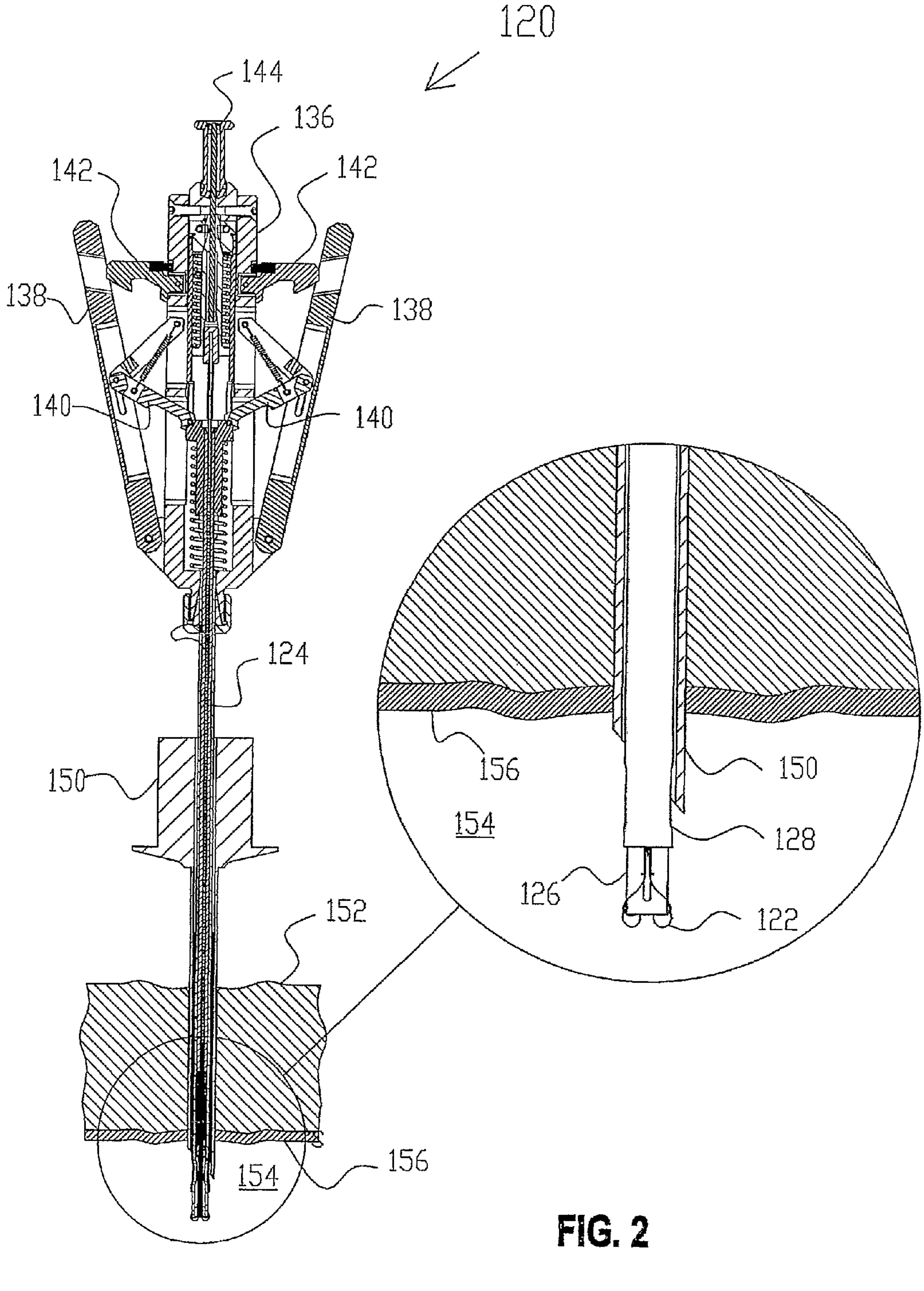
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FIG. 2

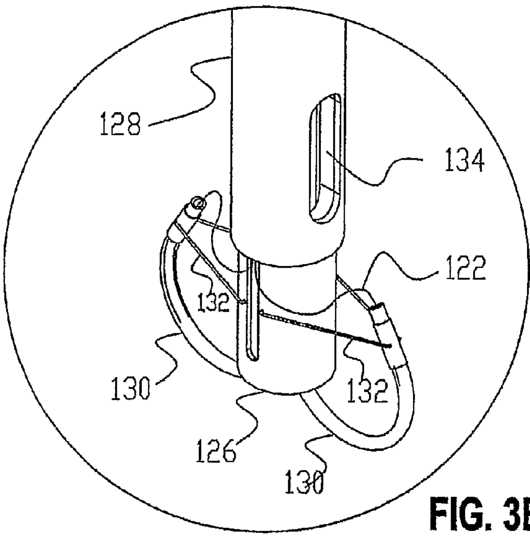

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FIG. 3B

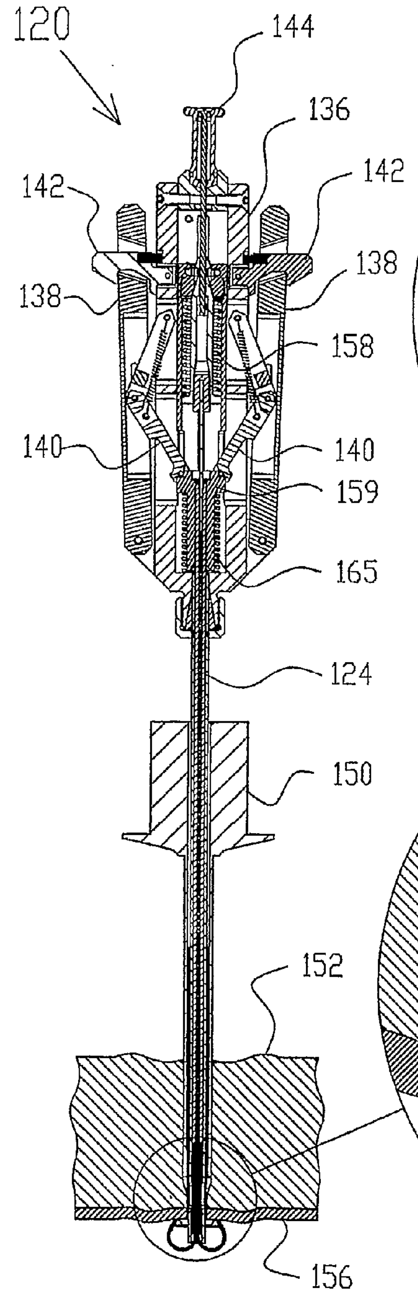
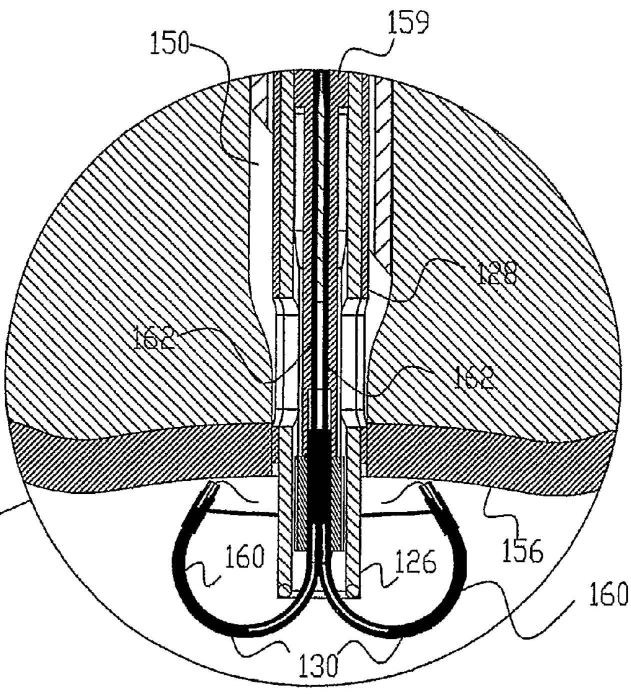

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FIG. 3A

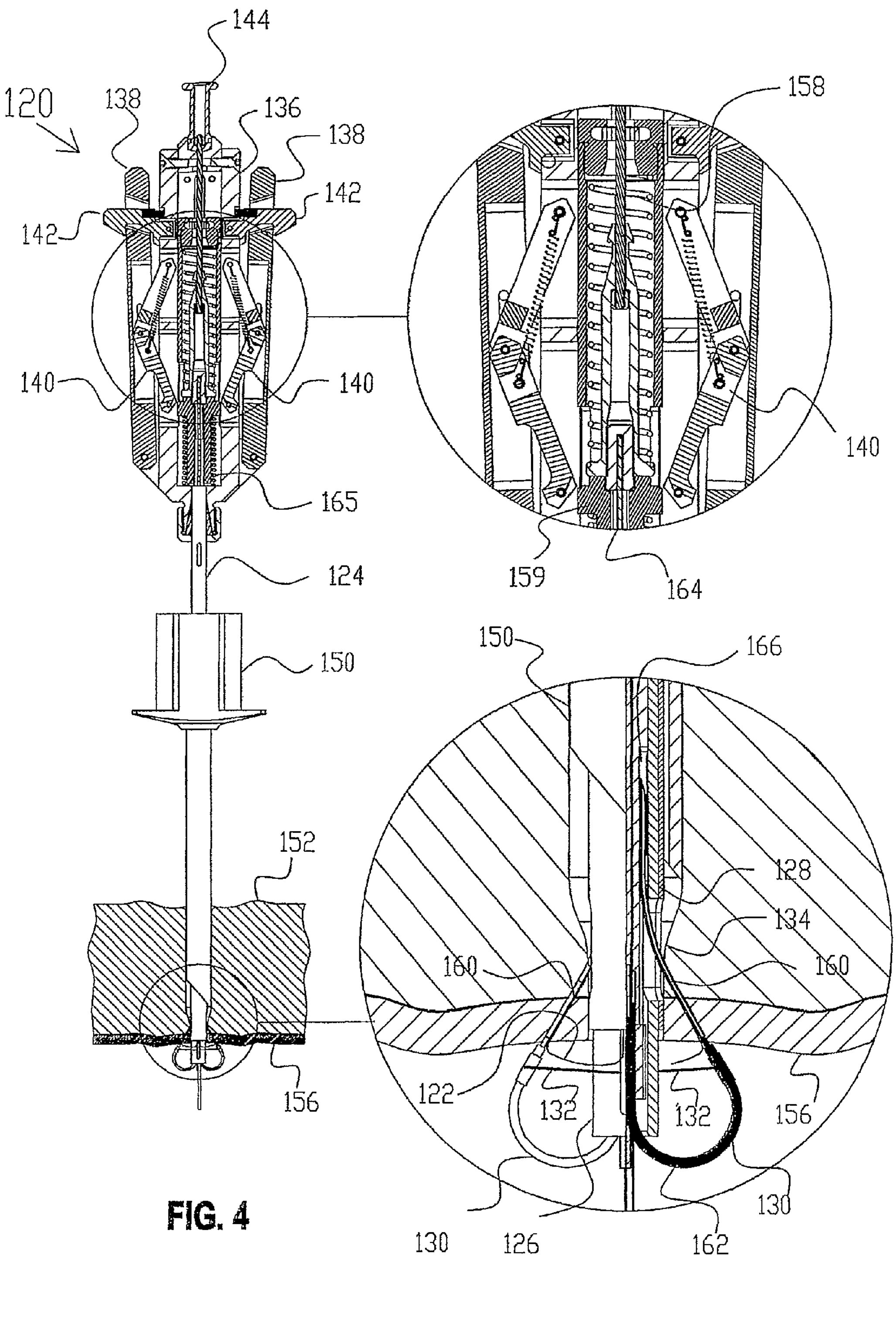

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FIG. 4

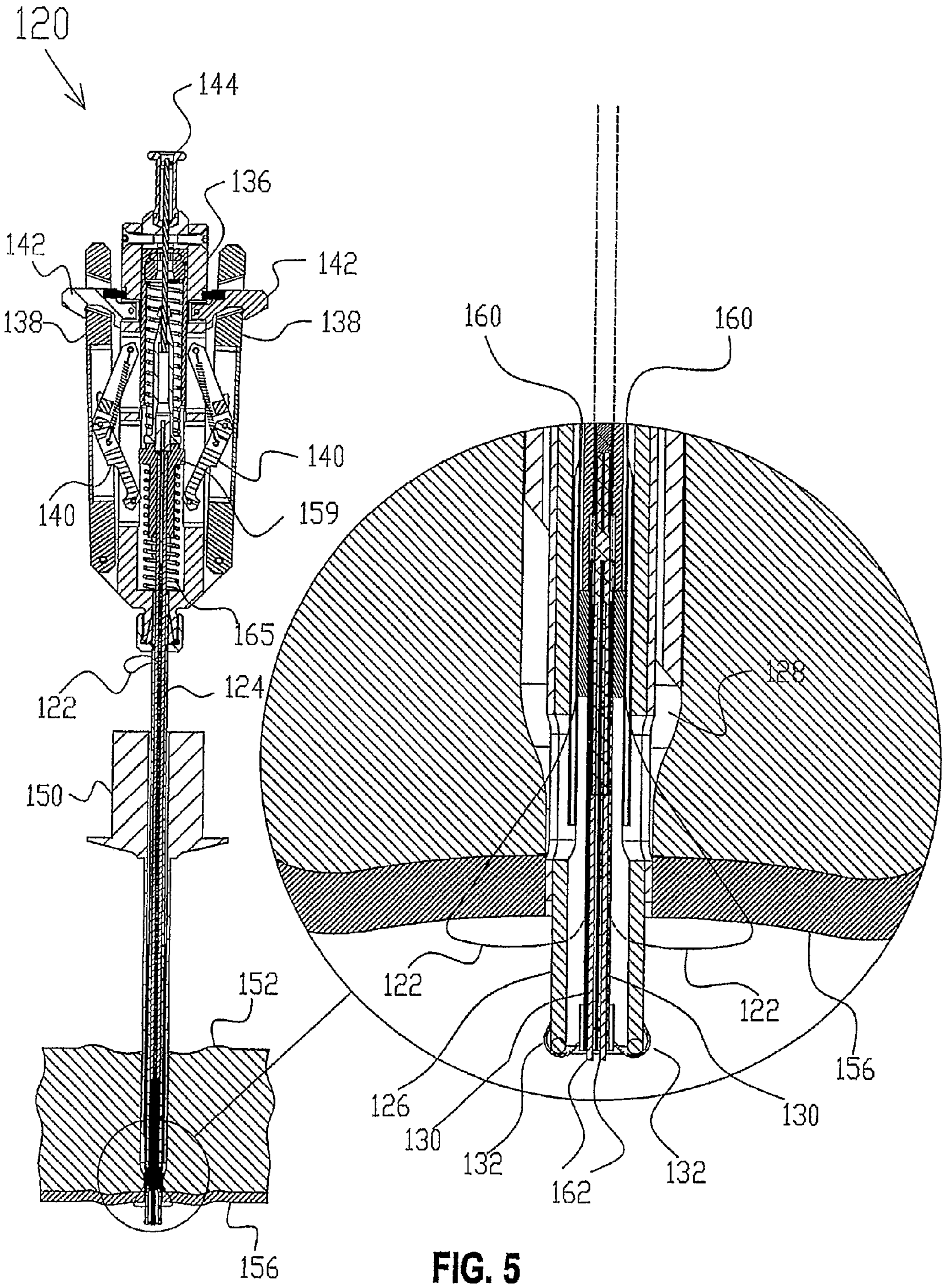
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FIG. 5

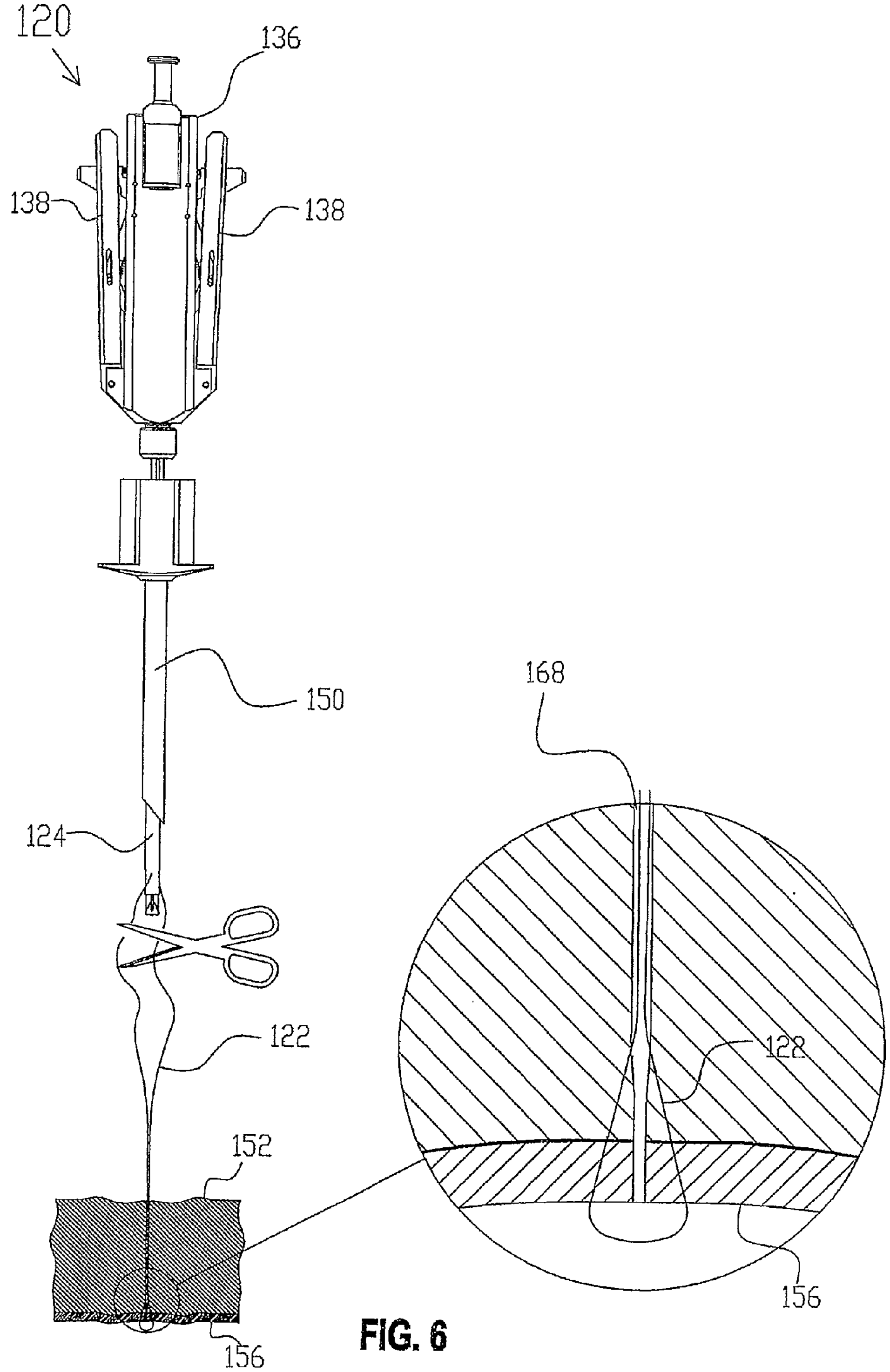


FIG. 6

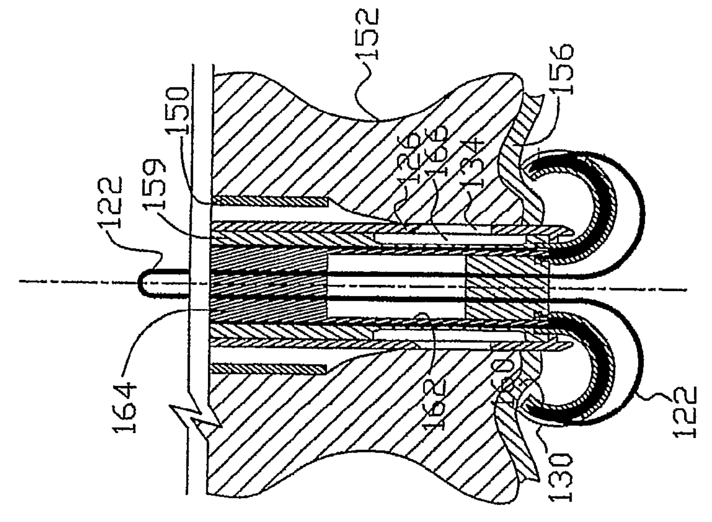


FIG. 9

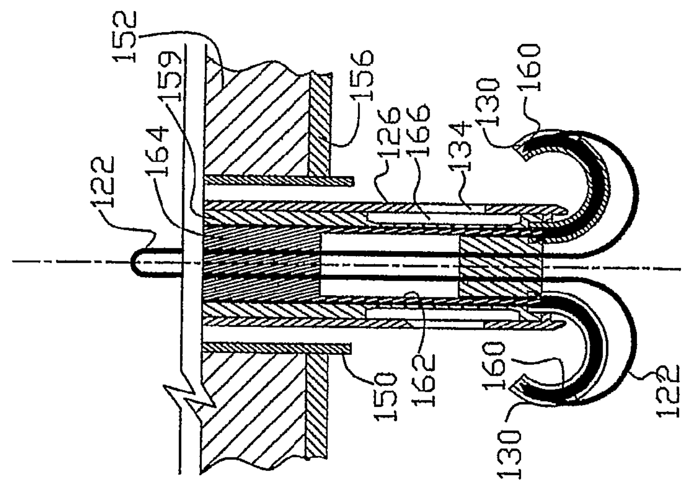


FIG. 8

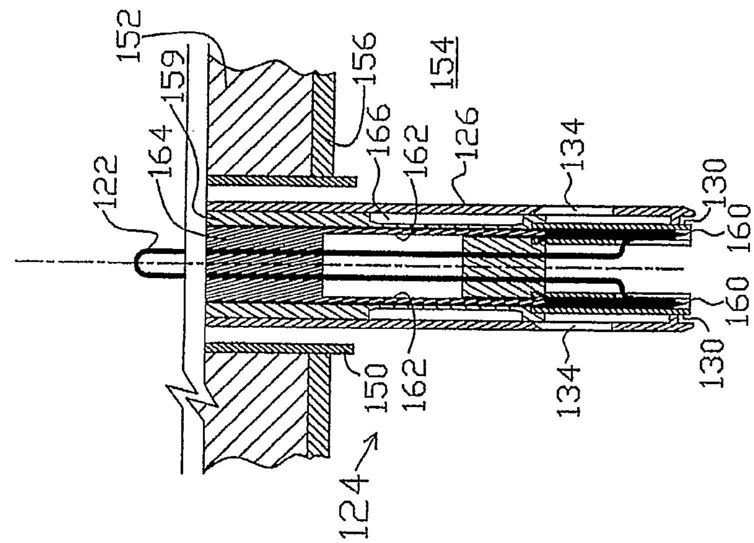


FIG. 7

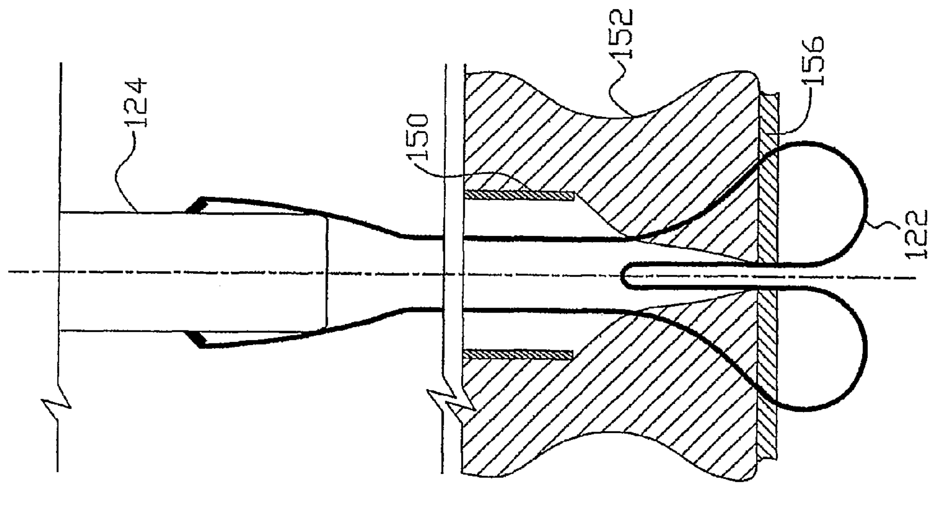


FIG. 12

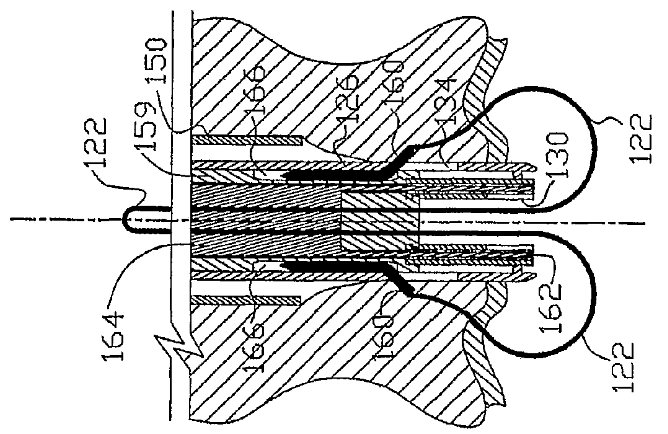


FIG. 11

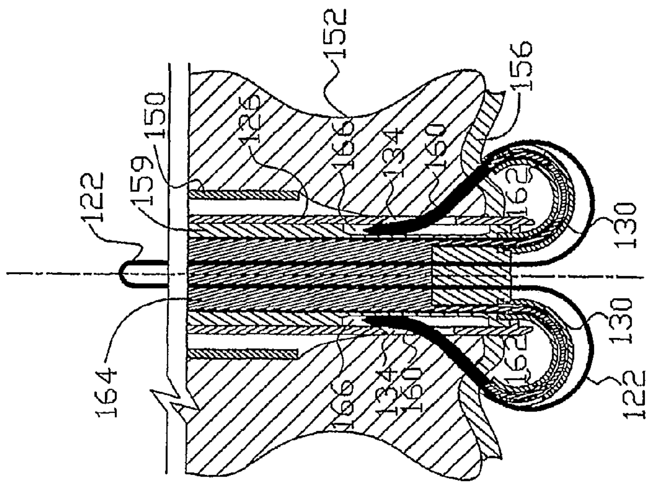


FIG. 10

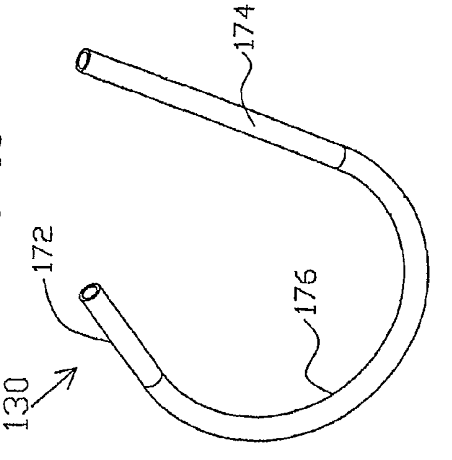


FIG. 15

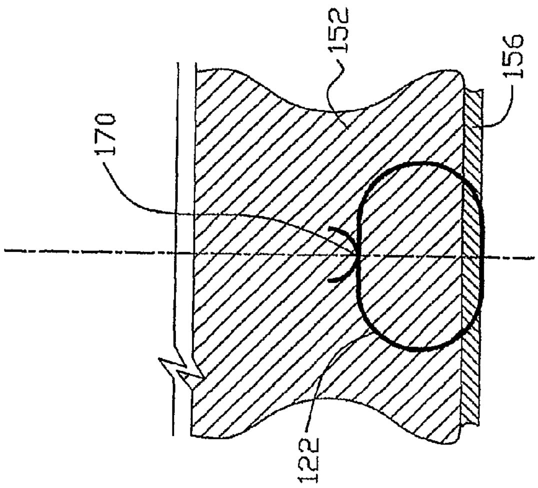
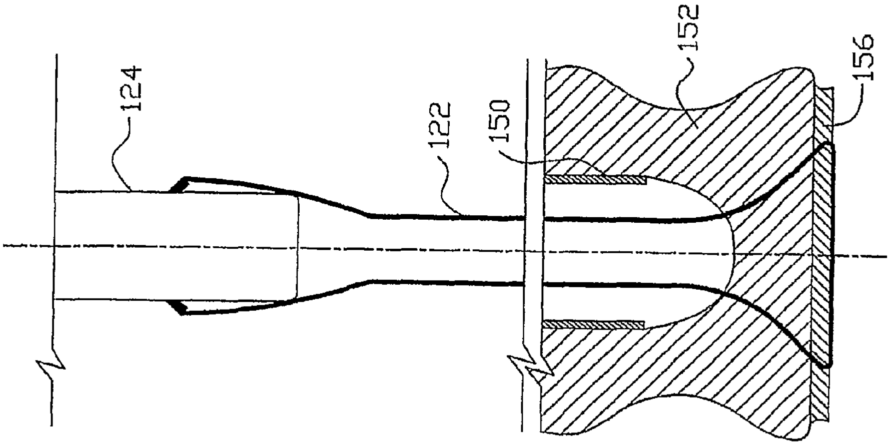


FIG. 14



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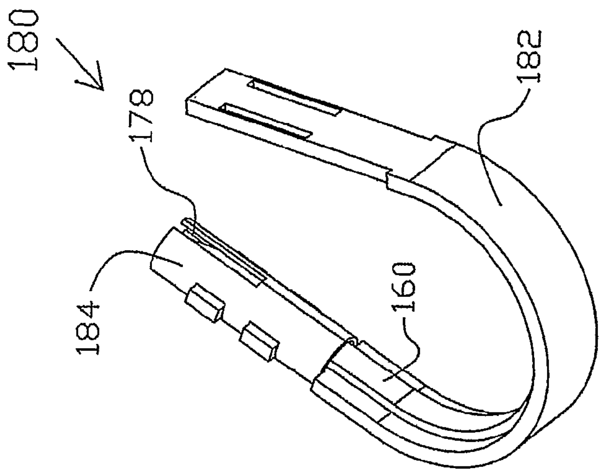


FIG. 17B

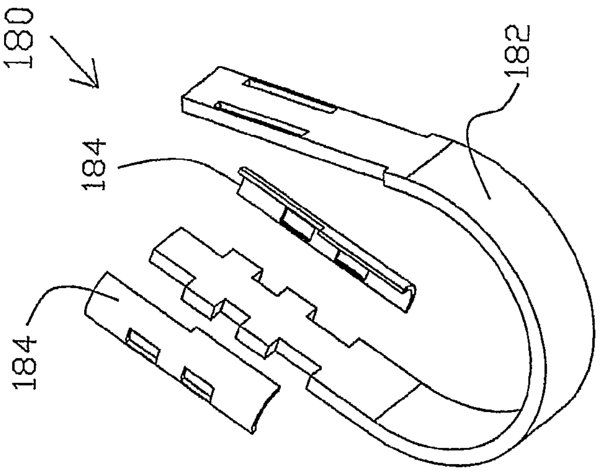


FIG. 17A

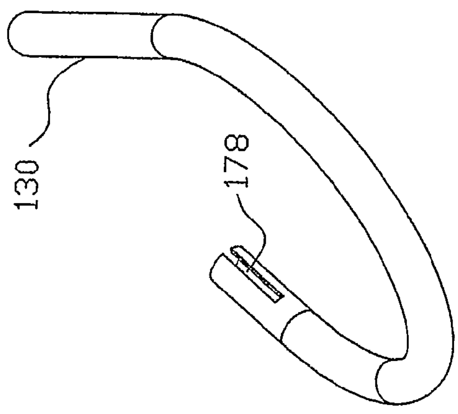


FIG. 16

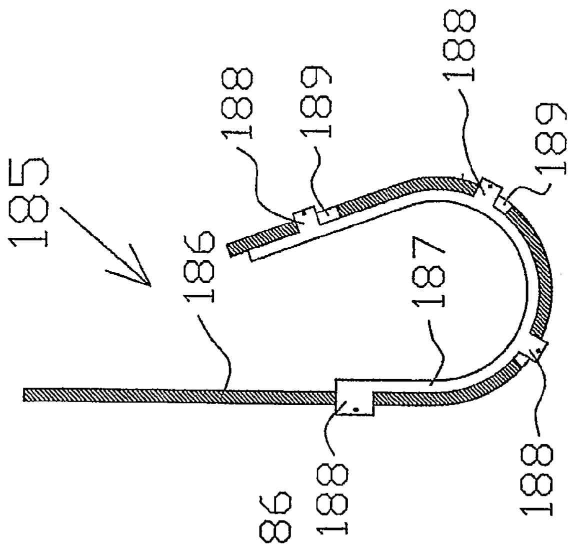


FIG. 18C

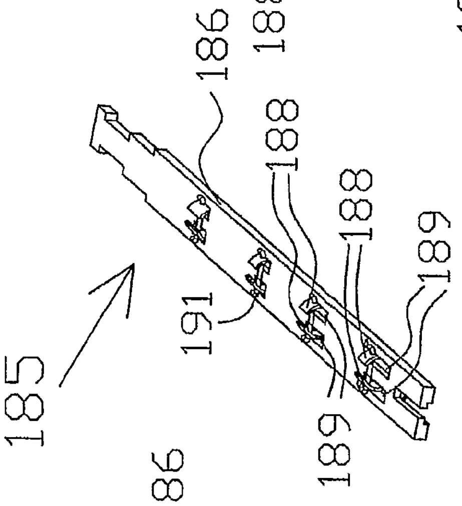


FIG. 18B

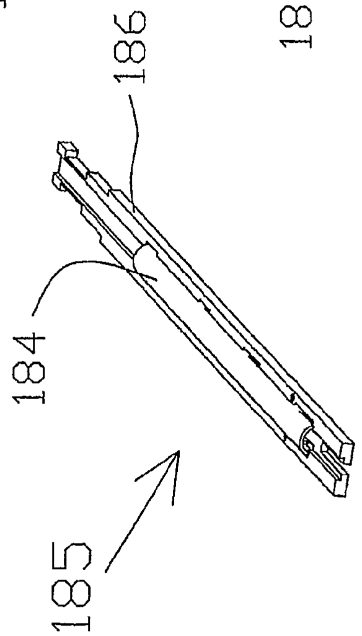


FIG. 18A

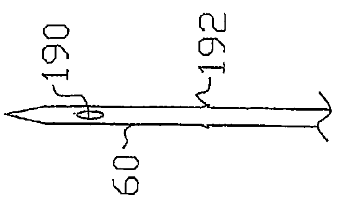


FIG. 19A

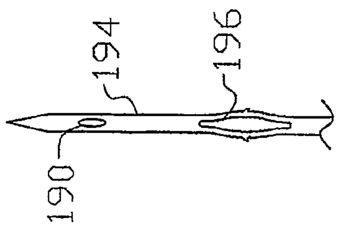


FIG. 19B

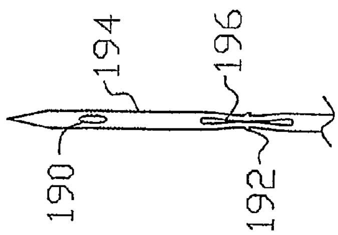


FIG. 19C

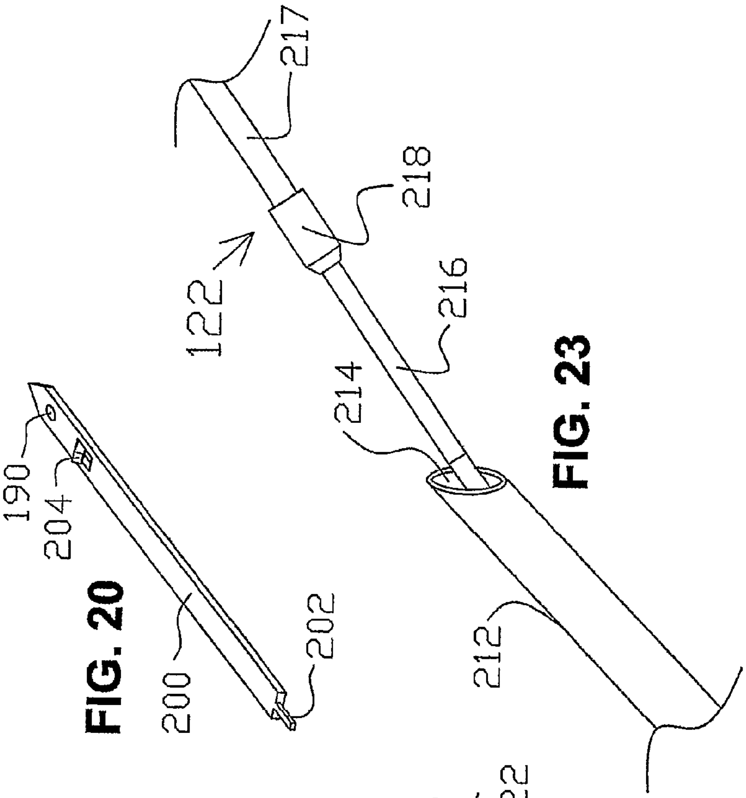


FIG. 20

FIG. 23

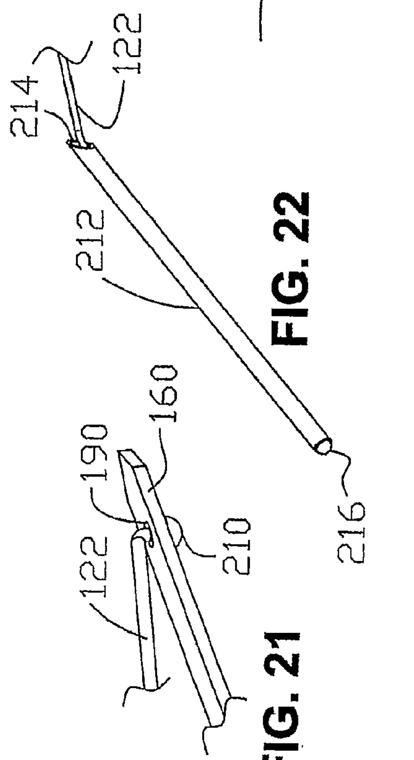


FIG. 21

FIG. 22

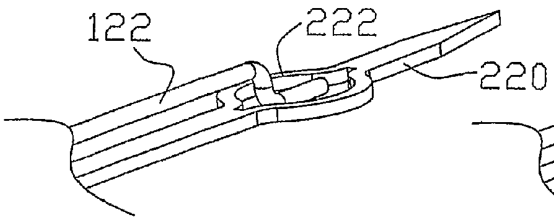


FIG. 24A

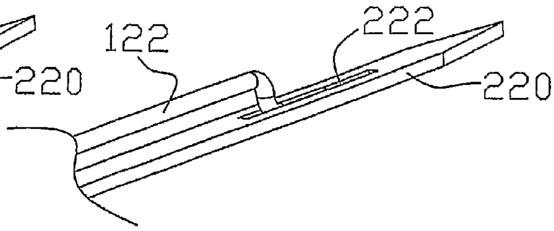


FIG. 24B

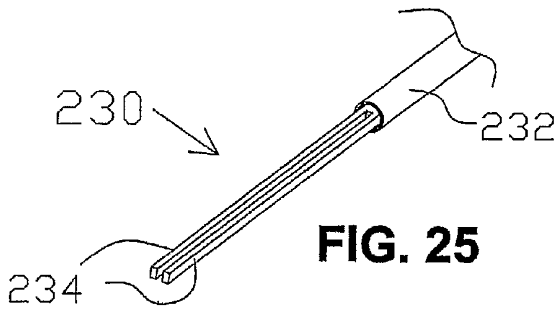


FIG. 25

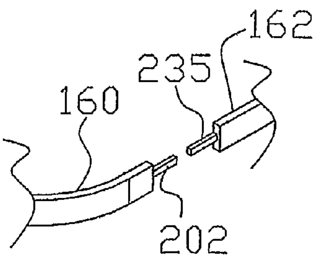


FIG. 26A

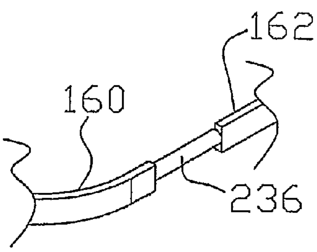


FIG. 26B

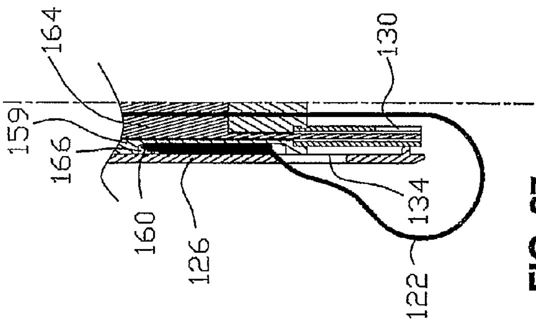


FIG. 27

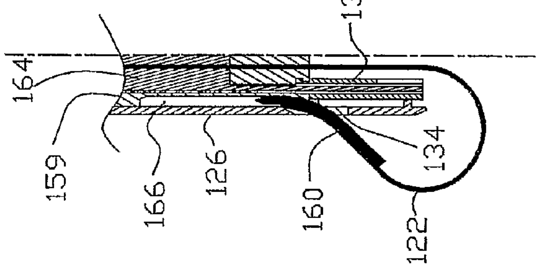
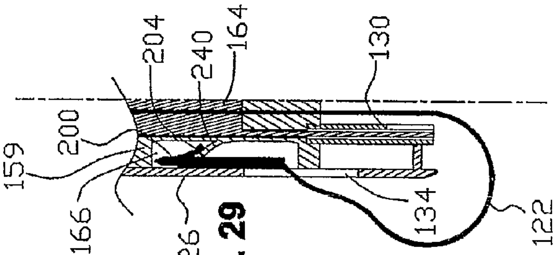


FIG. 28



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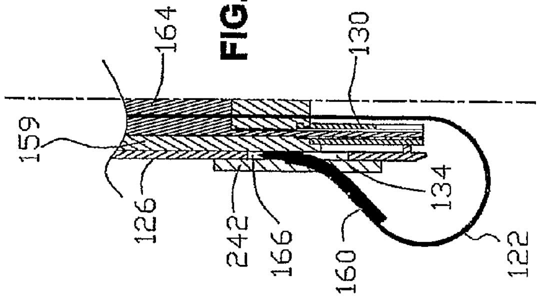


FIG. 30

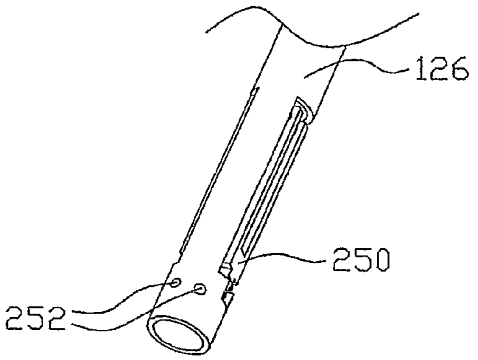


FIG. 31A

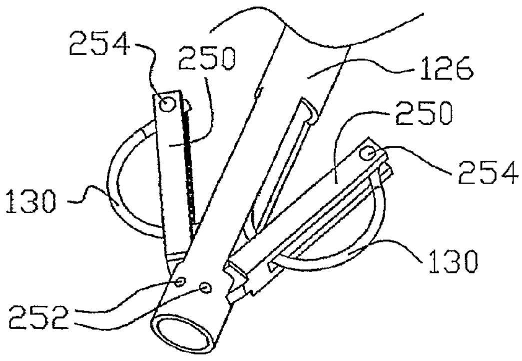


FIG. 31B

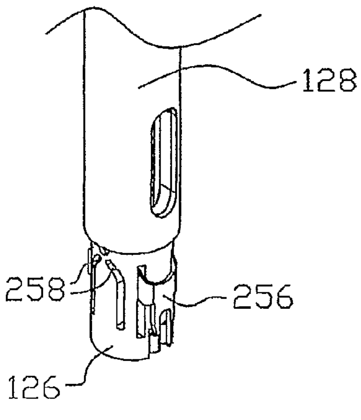
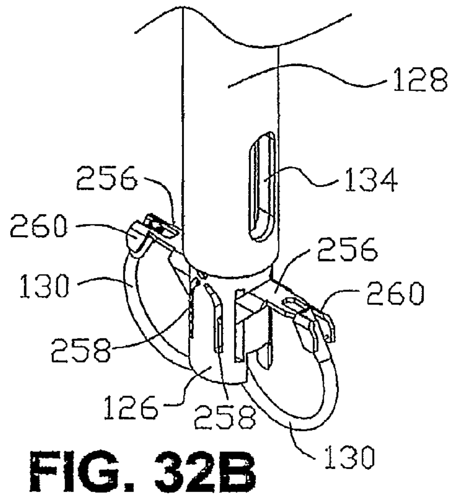


FIG. 32A



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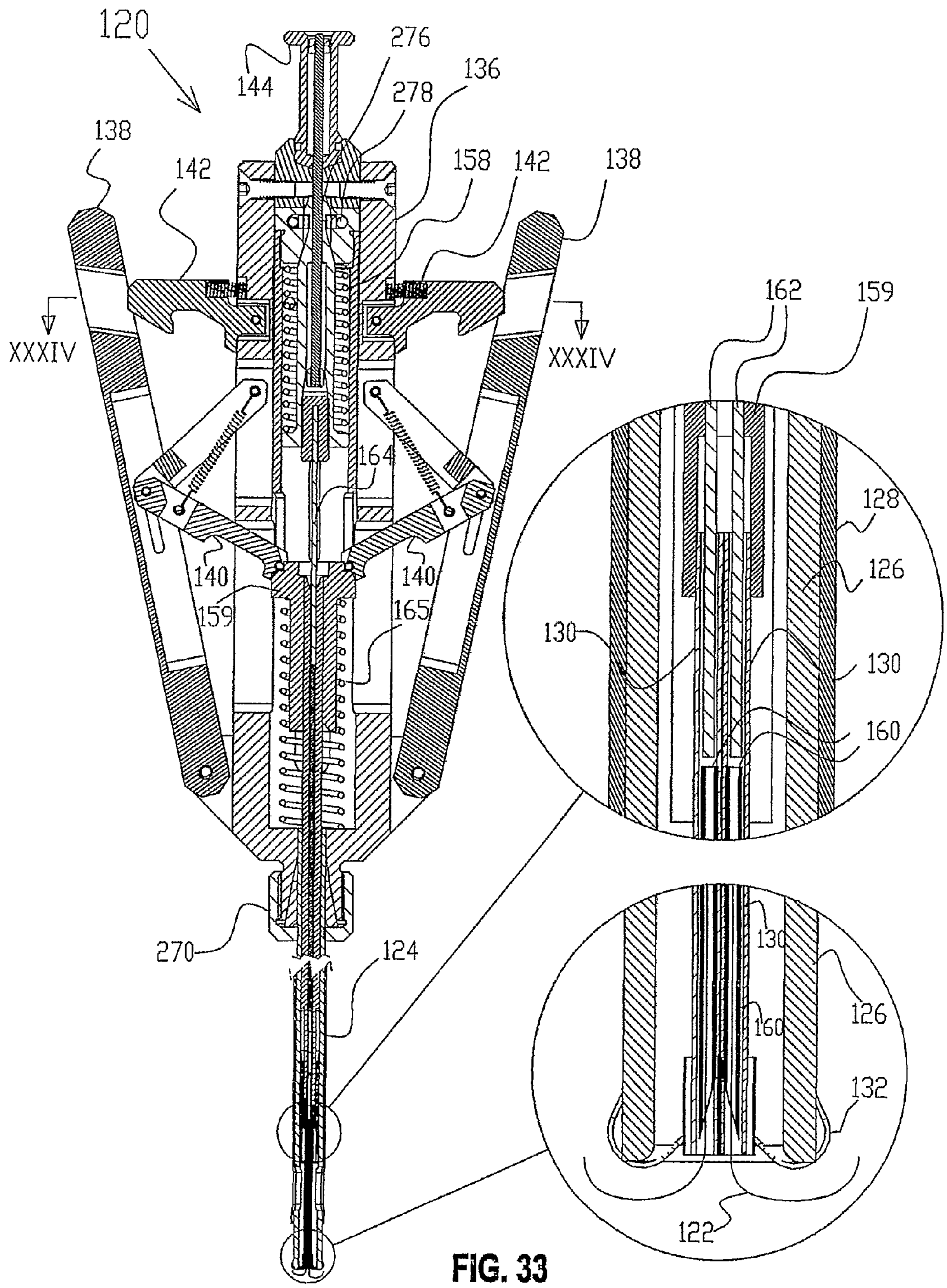
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FIG. 33

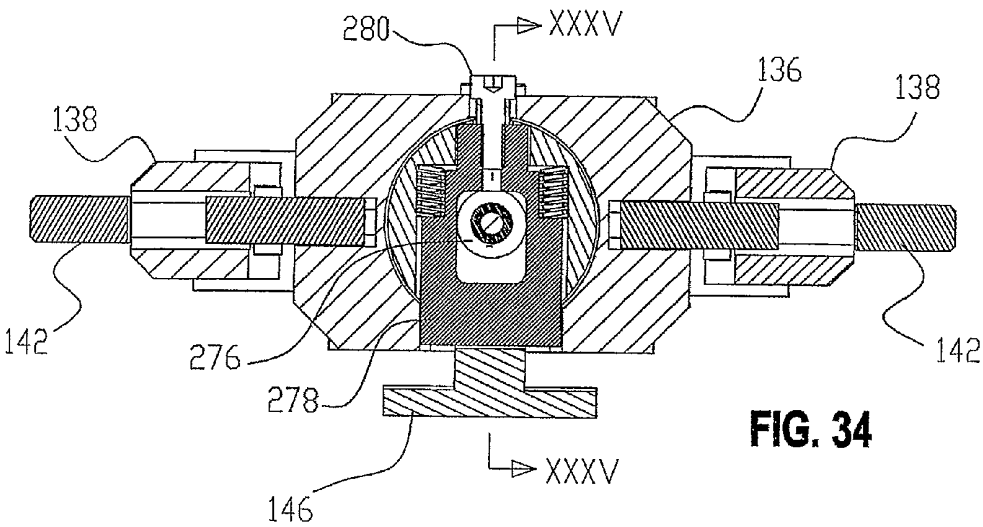
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FIG. 34

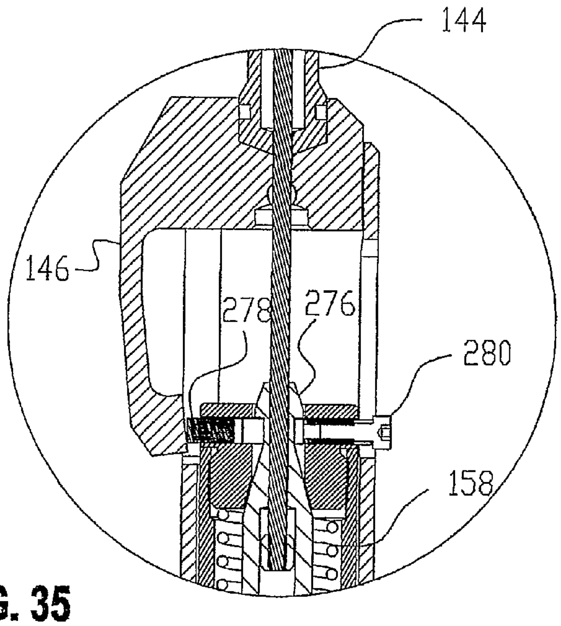
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FIG. 35

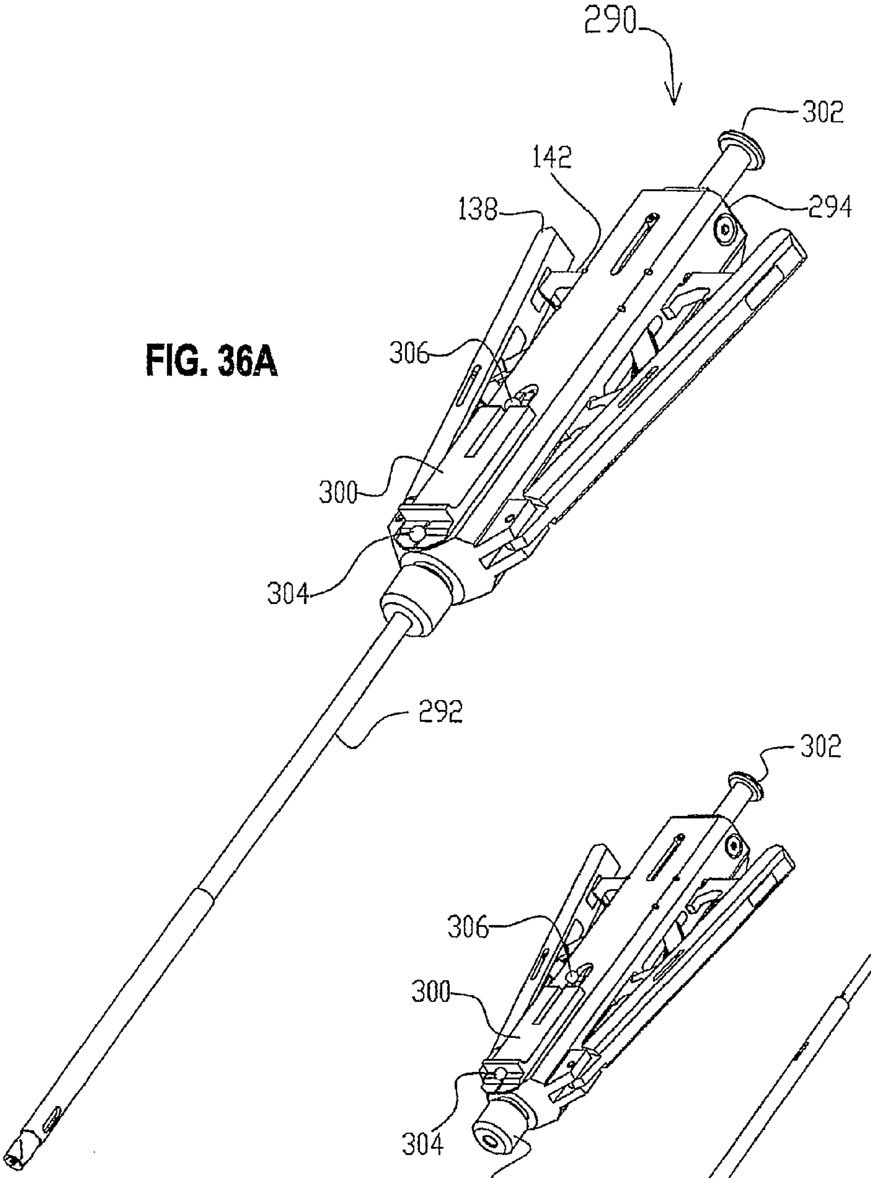


FIG. 36A

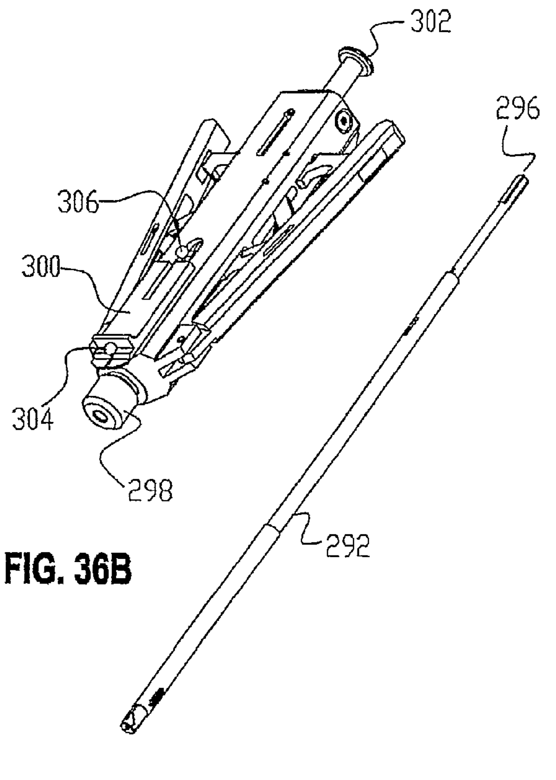


FIG. 36B

FIG. 37A

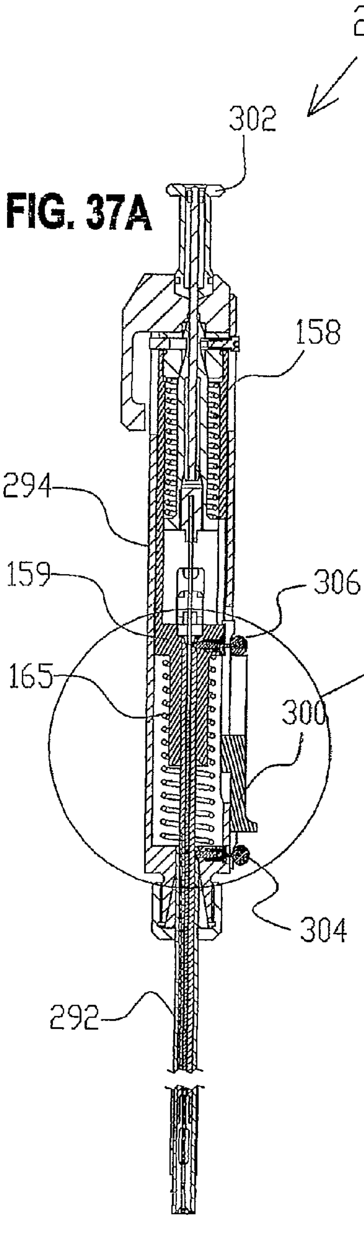


FIG. 37B

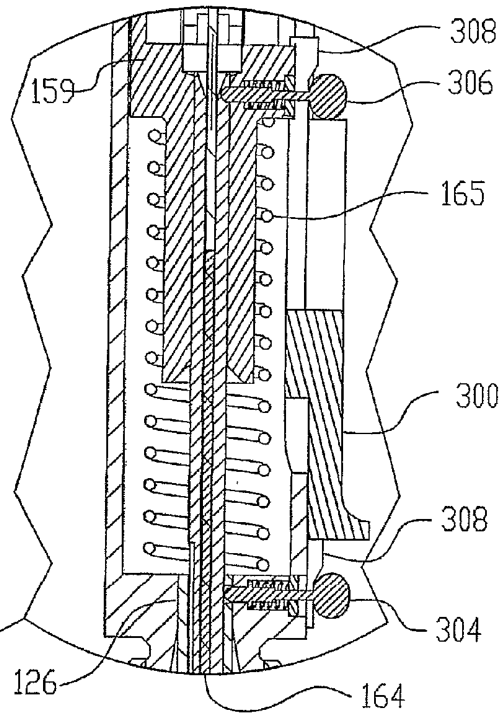


FIG. 37C

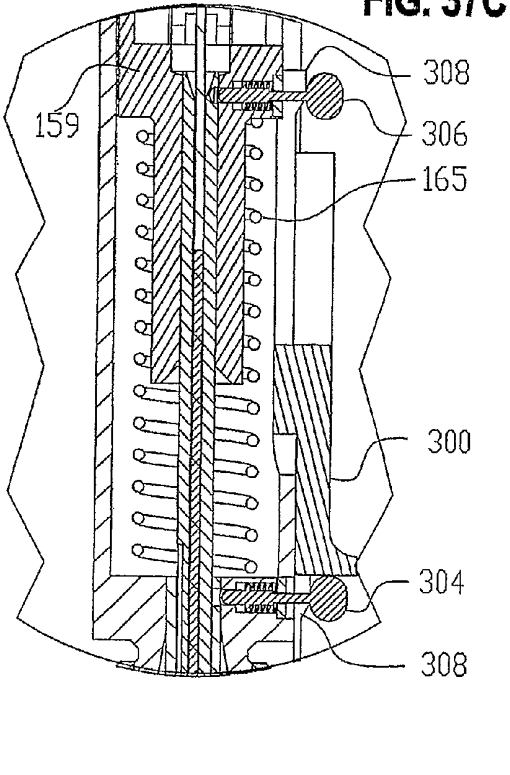


FIG. 38B

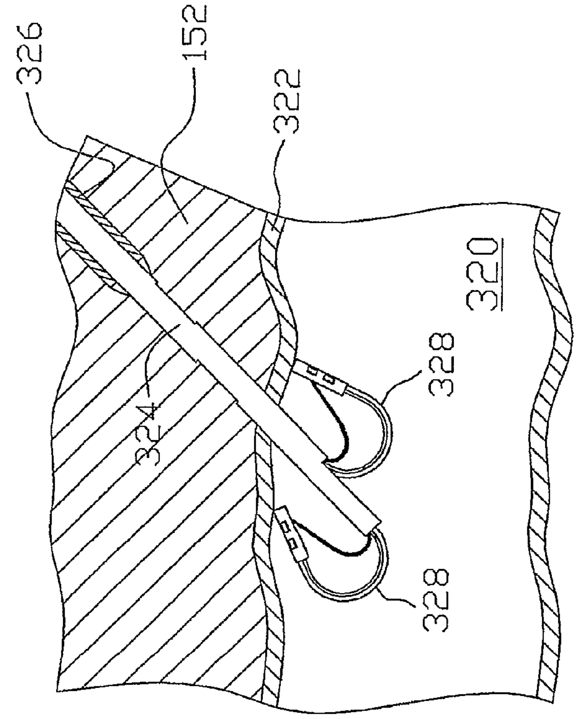
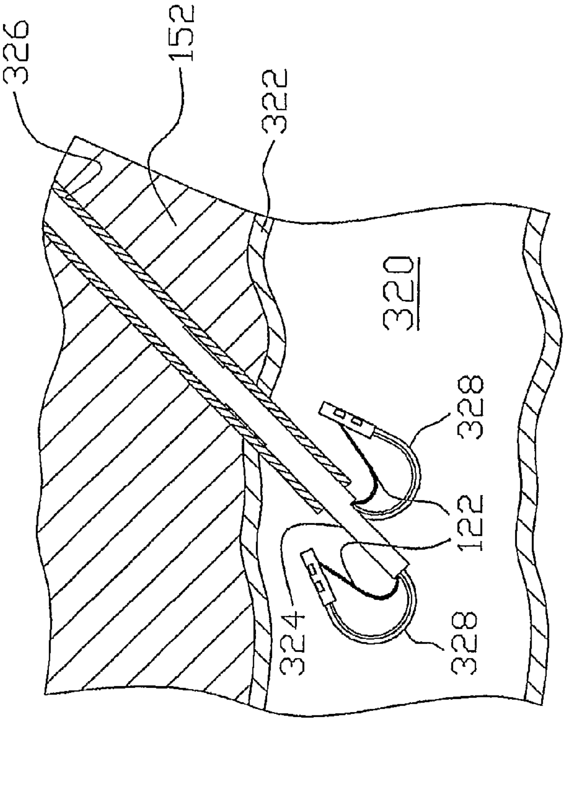


FIG. 38A



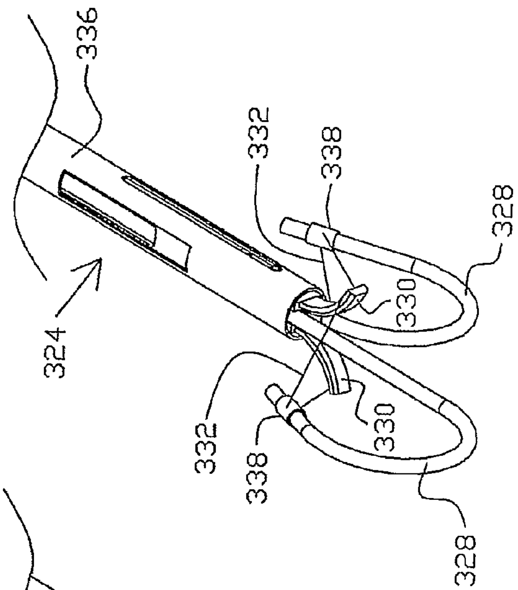


FIG. 41

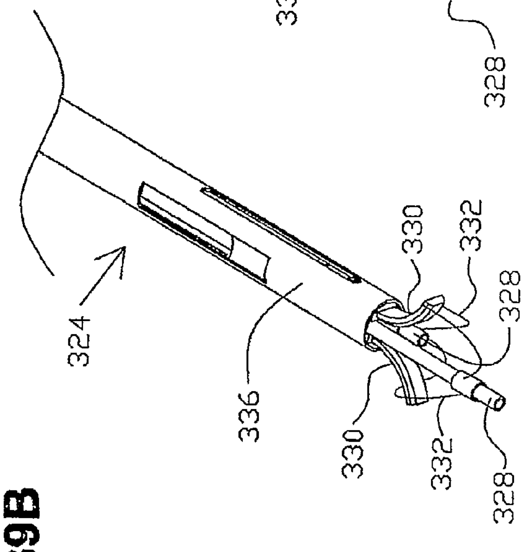


FIG. 40

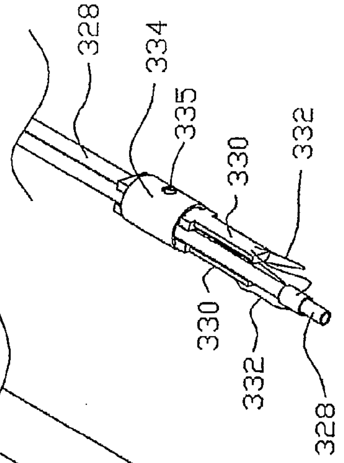


FIG. 39B

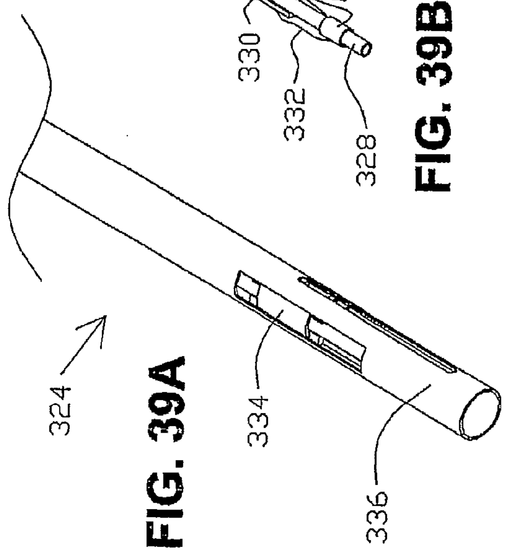


FIG. 39A

FIG. 42

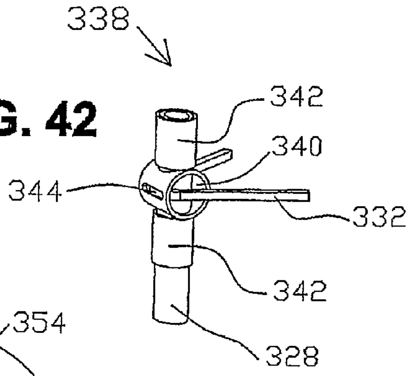


FIG. 43

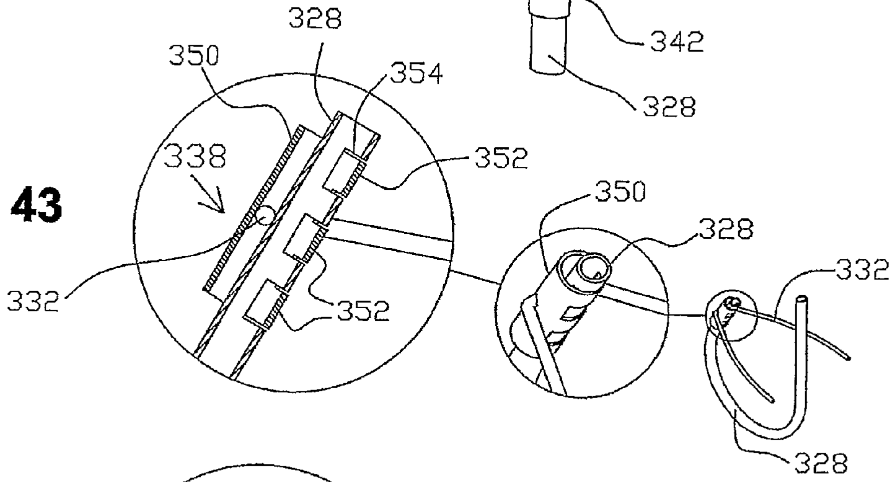


FIG. 44

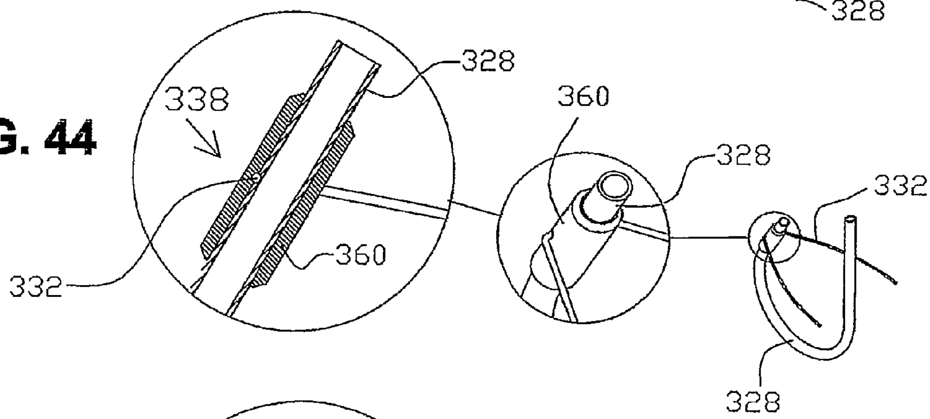


FIG. 45

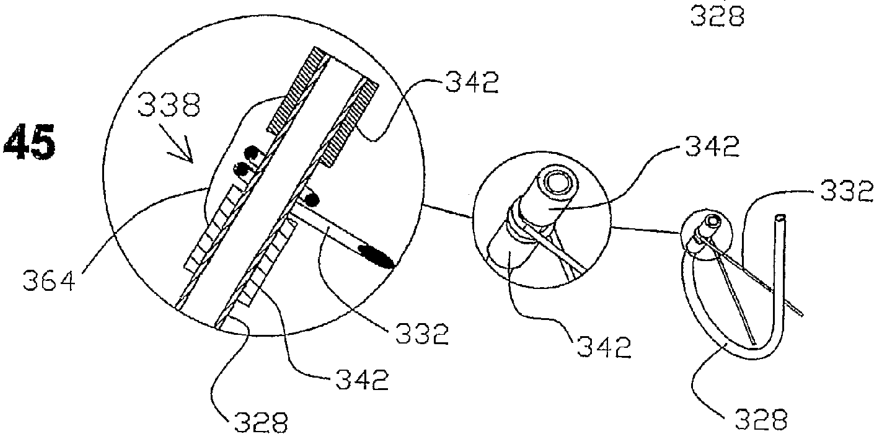


FIG. 46

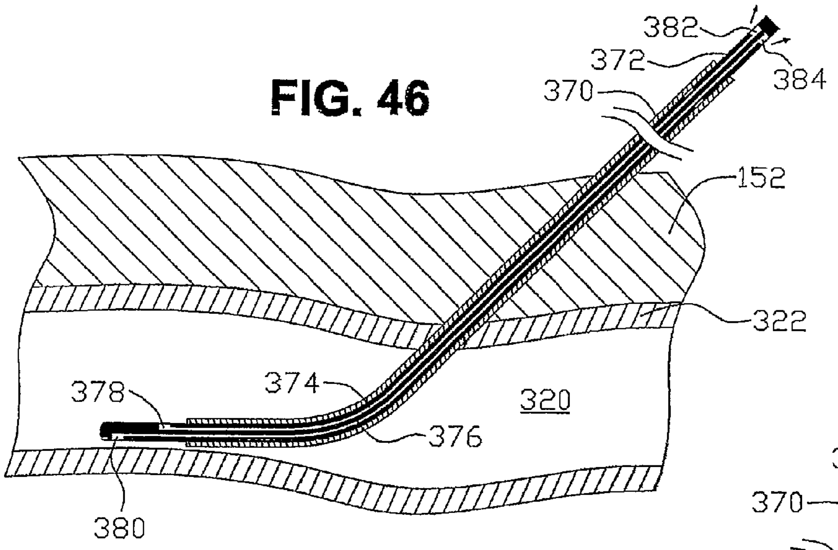


FIG. 47

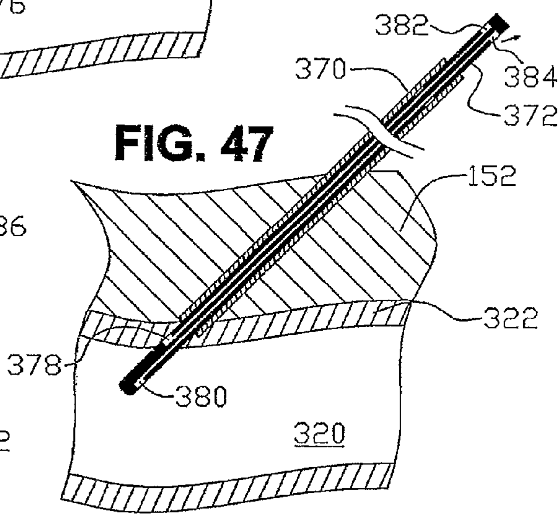


FIG. 48

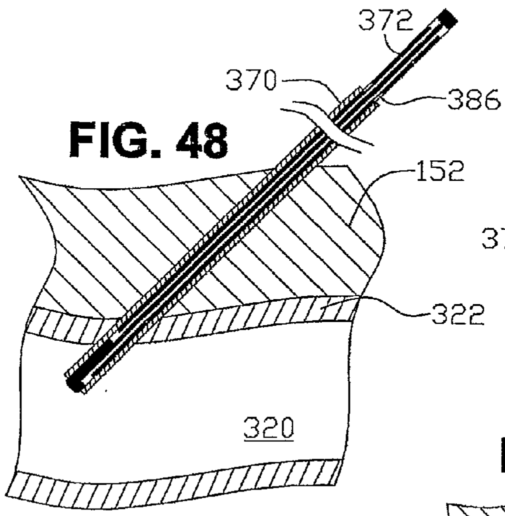
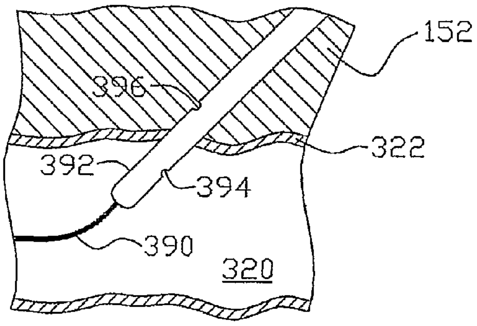


FIG. 49



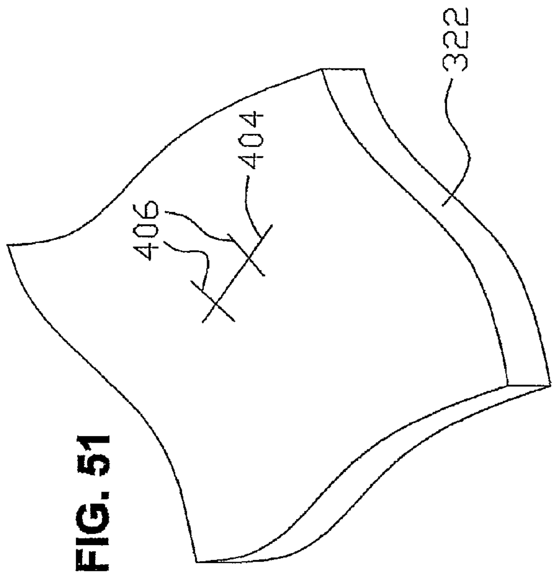


FIG. 51

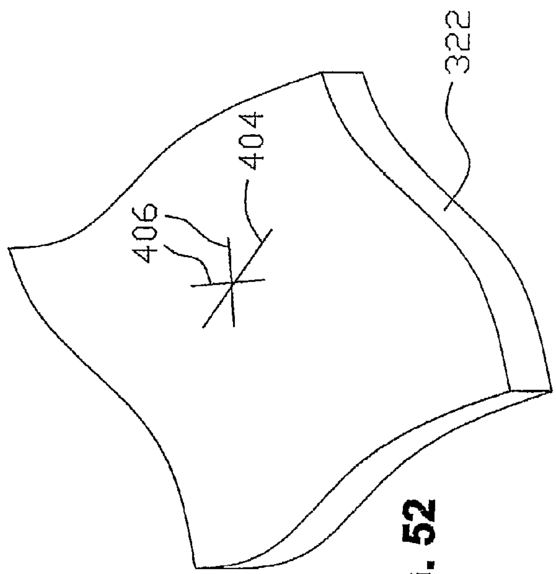


FIG. 52

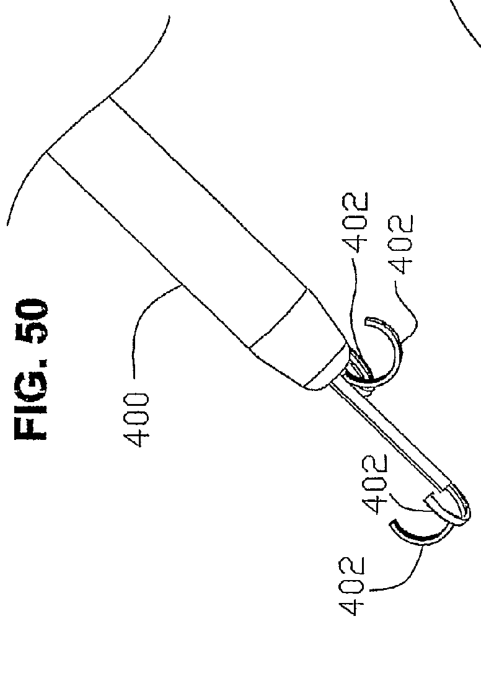


FIG. 50

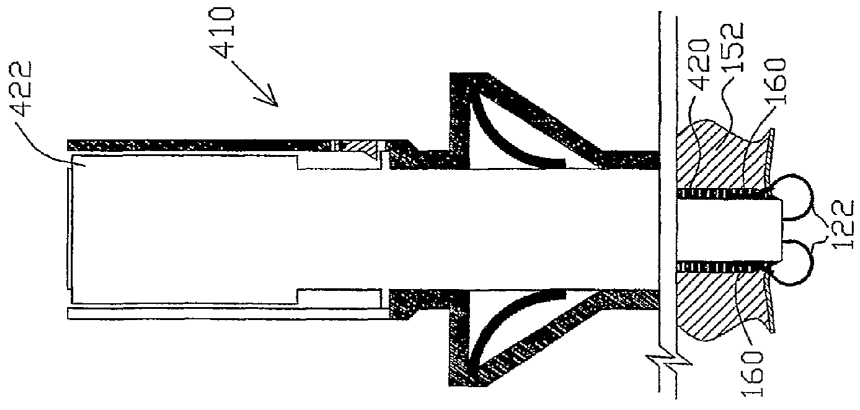


FIG. 55

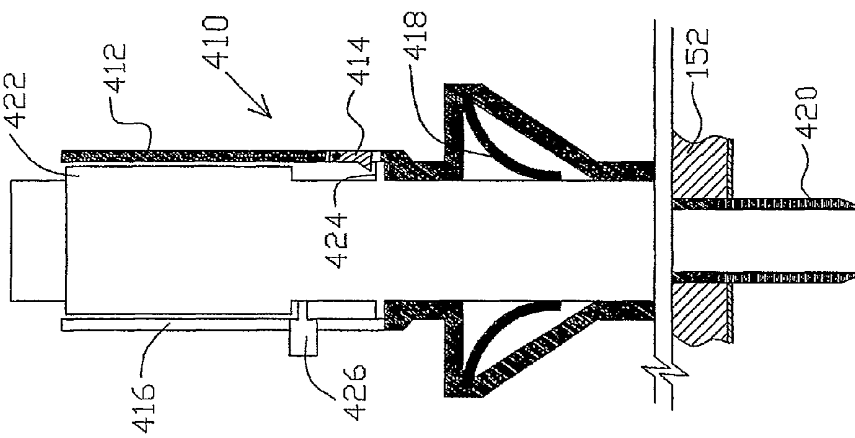


FIG. 54

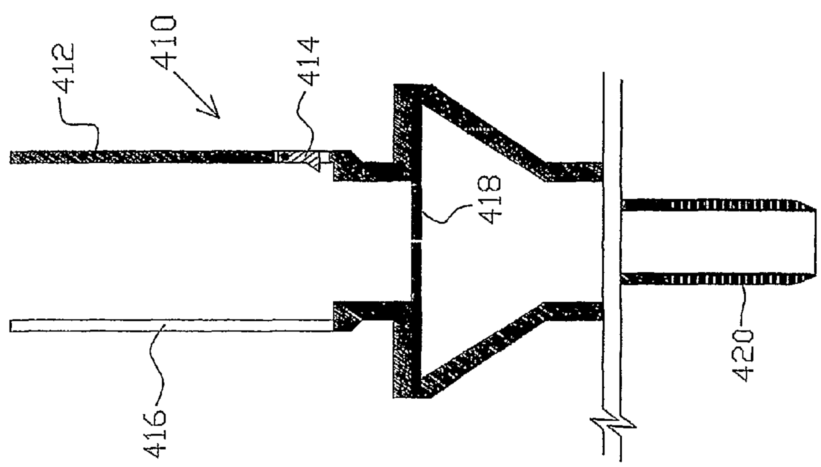


FIG. 53

FIG. 57

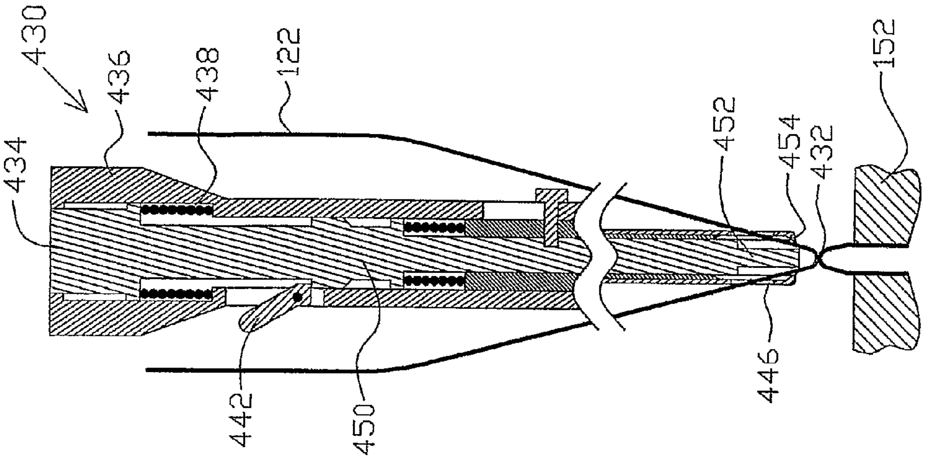

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FIG. 56

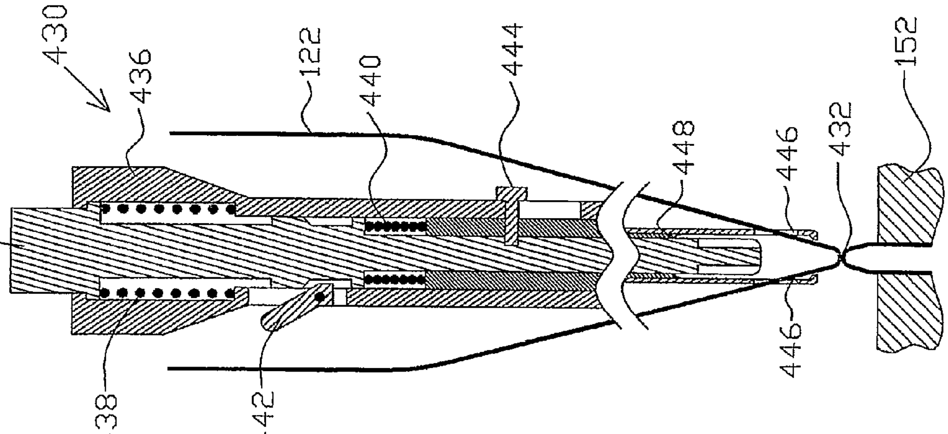
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FIG. 59

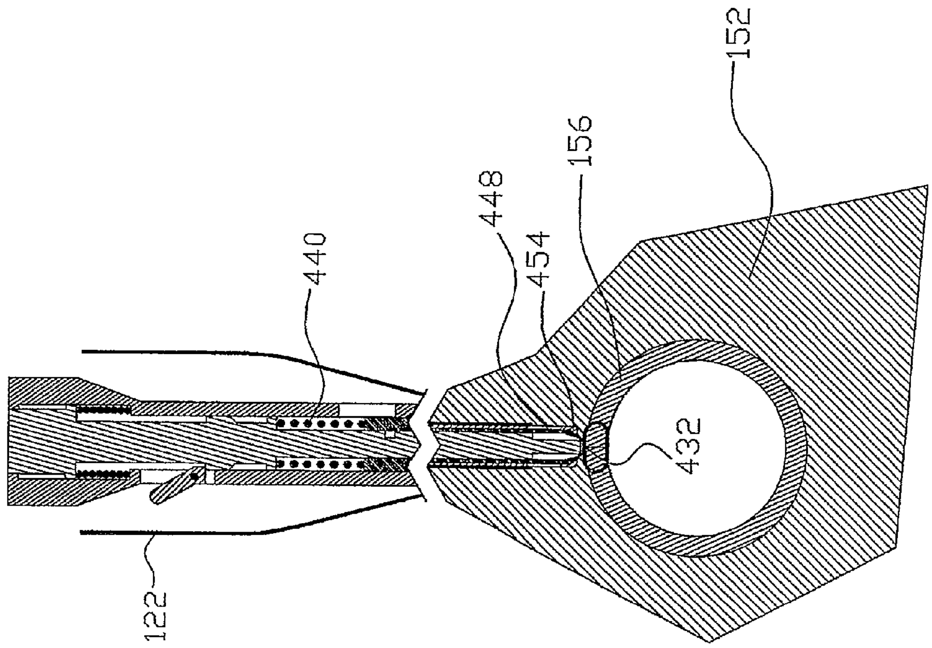


FIG. 58

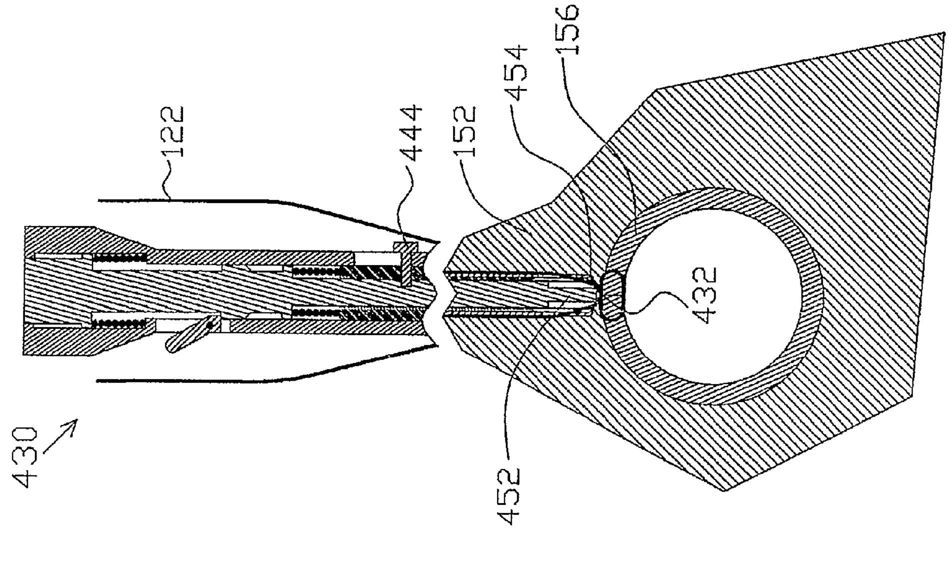
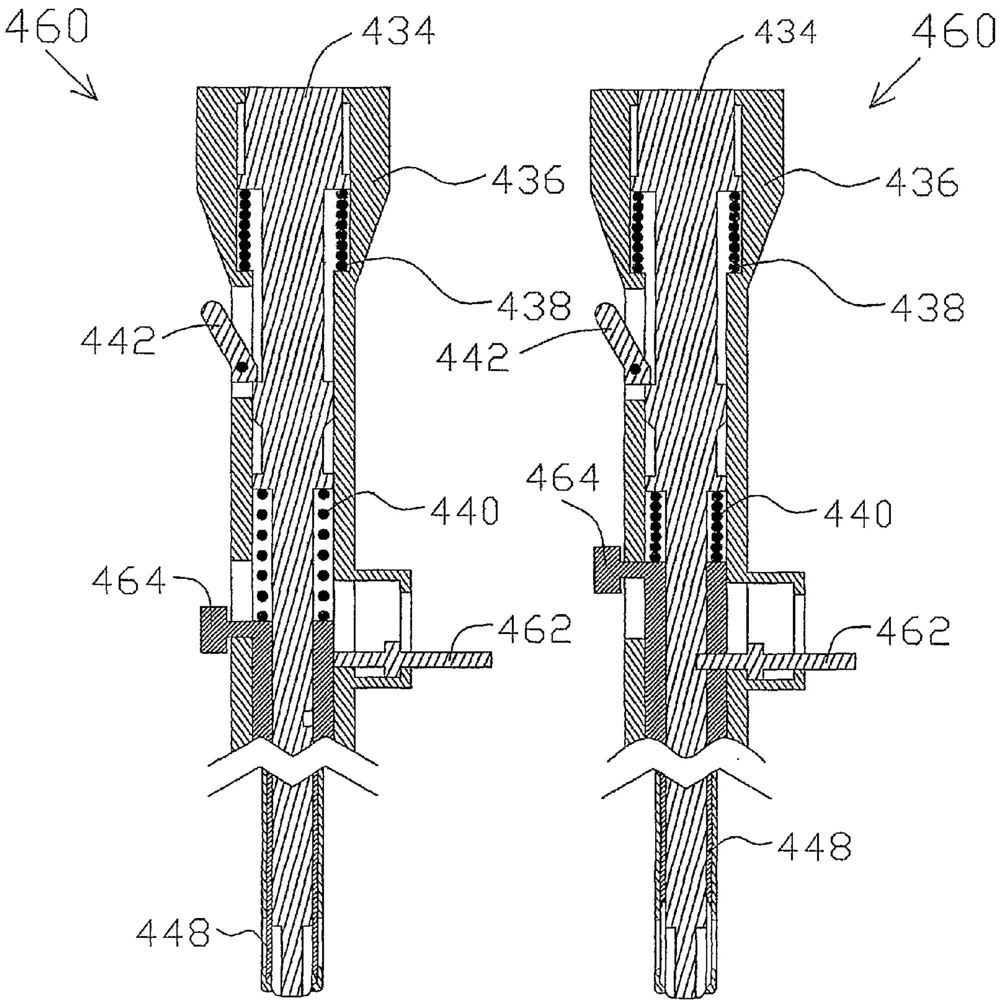


FIG. 60A

FIG. 60B



METHOD FOR SUTURING

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a division of U.S. patent application Ser. No. 11/569,155, filed in the national phase of PCT Patent Application PCT/IL2005/000070, which claims the benefit of U.S. Provisional Patent Application 60/573,631, filed May 21, 2004, which is incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates generally to medical devices, and specifically to minimally-invasive suturing devices and techniques.

BACKGROUND OF THE INVENTION

Minimally-invasive surgical procedures frequently involve insertion of instruments into a body cavity through a tissue puncture site. Examples of such procedures include insertion of vascular catheters through a puncture site in a blood vessel and insertion of laparoscopic instruments through a puncture site in the abdominal wall. (In the context of the present patent application and in the claims, the term "cavity" is used broadly to refer to any and all sorts of volumes inside the body, including lumens, such as blood vessels.) It is desirable, in order to facilitate healing and reduce complications, to suture the puncture site shut at the end of the procedure. Although the skin at the outer end of the puncture can easily be sutured, it is difficult to access and suture the internal tissues (such as the intima of the blood vessel or the abdominal fascia) through the puncture. Therefore, at the end of a vascular catheterization procedure, for example, many cardiologists and invasive radiologists simply press on the puncture site mechanically to achieve homeostasis. This mechanical technique requires the patient to remain immobilized for a long time (typically 2-8 hours), and increases the risk of subsequent bleeding.

A number of specialized instruments have been developed for percutaneous suturing of vascular puncture sites. For example, U.S. Pat. No. 5,417,600, whose disclosure is incorporated herein by reference, describes a suture applying device that comprises a shaft with a pair of needles near its distal end. The needles are joined by a length of suture. The shaft is used to introduce the needles into a lumen of a body structure and then to push the needles back through tissue on either side of the puncture site. After the needles have passed through the tissue, they are drawn outward, leaving a loop of suture behind to close the puncture site.

As another example, U.S. Pat. No. 5,868,762, whose disclosure is incorporated herein by reference, describes a device for suturing a vascular puncture site. The device includes a shaft having a distal end terminating in a pair of resilient prongs. Each of the prongs carries a suture anchor, attached to one end of a suture. The shaft is introduced into the puncture site, whereupon the prongs expand to an open position, thus positioning the suture anchors for penetration of the vascular wall by manipulation of the shaft. The prongs are then retracted, leaving the suture anchors to secure the sutures to the vascular wall tissue.

U.S. Pat. No. 6,245,079, whose disclosure is incorporated herein by reference, describes a suturing device having a distal portion that is inserted percutaneously through an incision into a blood vessel. The distal portion has two retractable arms, which extend and hold a suture within the blood vessel.

Retractable needles are deployed from the device to pierce the vessel wall, release the suture ends from the retractable arms, and then pull the suture through the vessel wall.

Other exemplary devices and methods for suturing internal puncture sites are described in U.S. Pat. Nos. 6,517,553, 6,451,031 and 5,411,481, whose disclosures are incorporated herein by reference.

SUMMARY OF THE INVENTION

Embodiments of the present invention that are disclosed hereinbelow provide devices and methods for suturing a puncture site in the body of a patient with enhanced safety and convenience.

In these embodiments, a suture insertion device comprises a shaft, which is inserted by an operator through the puncture so that the distal end of the shaft protrudes into an underlying body cavity. The shaft carries, at its distal end, a pair of flexible needles, which are held by respective needle guides. Each needle holds one end of a suture. Typically, during insertion of the shaft through the puncture, the needle guides are held straight and parallel to the axis of the shaft, so that the device maintains a narrow profile. In some embodiments, the needle guides comprise a resilient material, such as a superelastic material. The resilient needle guides are produced in a curved form, but are forced to remain generally straight and parallel within the shaft during insertion of the shaft through the puncture.

Once the distal end of the shaft is inside the cavity, the needle guides are deployed outward from the shaft. In this configuration, the needle guides point the needles in the proximal direction, i.e., back toward the cavity wall that is to be sutured. In some embodiments, superelastic needle guides are deployed in the distal direction, out of the distal end of the shaft, and are configured to assume a "U" shape upon release from the shaft so as to point the needles in the desired proximal direction. The ends of the needle guides are then brought into contact with the cavity wall. Typically, the needles are contained within the needle guides, so that the points of the needles do not contact the cavity wall or other tissues within the cavity during the stage of the procedure.

When the needle guides are properly positioned, the operator actuates an ejector in the shaft to eject the needles rapidly from the needle guides in the proximal direction. Typically, the needles comprise an elastic material, which straightens as the needles exit the needle guides. The needles penetrate the cavity wall, thus drawing the suture through the wall at respective points on either side of the puncture. In some embodiments, the needles are aimed to engage the sides of the shaft after penetrating the cavity wall and are then captured alongside or in the shaft. The needle guides (now empty) are pulled back into the shaft, and the device is withdrawn from the body, pulling the suture ends with it. The suture is then tied to close the internal puncture.

The use of needles and needle guides in the manner described herein gives embodiments of the present invention substantial advantages over suturing devices known in the art. For example, ejection of the needles in the proximal direction eliminates the risk of accidentally puncturing other surfaces or organs deeper inside the body. Furthermore, because the needles remain inside the needle guides until the needle guides actually contact the cavity wall that is to be sutured, the risk that the needles will accidentally catch and suture other tissues to the cavity wall is also reduced. The needle guides may be made stiff enough to provide precise control of the locations at which the needles penetrate the cavity wall, while the needles themselves may be very thin and flexible in order to reduce trauma and bleeding when they do penetrate the tissue.

Although the embodiments described herein relate particularly to closure of punctures in body cavities, such as blood vessels or the abdominal cavity, the principles of the present invention may also be applied in closing holes of other types in body tissue, as well as performing other functions in minimally-invasive surgery.

There is therefore provided, in accordance with an embodiment of the present invention, a suture insertion device, including:

a shaft, having a longitudinal axis and a distal end, which is adapted to be inserted into a body cavity;

first and second needles, which are configured to hold respective first and second ends of a suture thread;

first and second needle guides, which are attached to the shaft and respectively hold the first and second needles, the needle guides having a first operative configuration in which the needle guides are held parallel to the axis for insertion of the shaft into the body cavity and a second operative configuration in which the needle guides are deployed outward from the shaft within the body cavity so as to point the needles in a proximal direction; and

an ejector, which is operative to eject the needles from the needle guides in the second operative configuration so as to cause the needles to penetrate tissue adjoining the body cavity.

Typically, the needles have respective points, and the needle guides contain the needles so that the points do not contact the tissue while the needles are held by the needle guides. The needle guides have respective outer ends, and are typically deployed outward from the shaft in the second operative configuration so as to permit an operator of the device to bring the outer ends of the needle guides into engagement with the tissue before ejecting the needles.

In disclosed embodiments, in the second operative configuration, the needle guides curve out of the shaft so as to point in the proximal direction. In some embodiments, the needle guides are deployed from the distal end of the shaft and curve back in the proximal direction.

Typically, the needle guides include a superelastic material, which is formed prior to assembly of the device so as to have a curved shape. In some embodiments, the needle guides include superelastic tubes having lumens that contain the needles. In other embodiments, the needle guides include plates of the superelastic material, and the needles are held against the plates until the needles are ejected. In one such embodiment, the needle guides include covers for holding the needles against the plates, and the covers are attached to the plates so as to shift longitudinally along the plates when the needle guides are deployed from the first operative configuration to the second operative configuration.

Typically, the needles include an elastic material, which is formed so that the needles assume a straight shape upon being ejected from the needle guides.

In some embodiments, the device includes one or more stabilizers, which are contained within the shaft while the needle guides are in the first operative configuration, and which are coupled to be deployed together with the needle guides so as to stabilize the needle guides in the second operative configuration. In one embodiment, the needle guides have outer ends from which the needles are ejected, and the stabilizers include cords, which couple the outer ends of the needle guides to the shaft. The stabilizers may include wings, which extend outward from the distal end of the shaft in a direction transverse to a plane defined by the needle guides, and wherein the cords couple the needle guides to the wings. Additionally or alternatively, the stabilizers may include couplers, which are attached to the outer ends of the needle guides so as to fix the cords to the needle guides. In another embodiment, the stabilizers include struts, which open outward from the shaft in order to hold the needle guides.

In a disclosed embodiment, the first and second needle guides are non-symmetrical in the second operative configuration. Typically, the needle guides have respective outer ends, and are formed so that in the second operative configuration, the outer ends of the first and second needle guides may be brought into simultaneous engagement with the tissue while the shaft is angled obliquely relative to the tissue.

In one embodiment, the suture thread held by the first and second needles is a first thread, and the device includes third and fourth needle guides and third and fourth needles, which are respectively held by the third and fourth needle guides and are configured to hold a second suture thread, wherein the ejector is operative to eject the first, second, third and fourth needles, thereby passing the ends of both the first and second suture threads through the tissue. The first, second, third and fourth needles and the first and second suture threads may be configured so as to produce two parallel stitches through the tissue. Alternatively, the first, second, third and fourth needles and the first and second suture threads may be configured so as to produce two crossed stitches through the tissue.

In some embodiments, the needles are formed from a plate of a flat material. Typically, each of the needles includes an eye, and each of the first and second ends of the suture thread is respectively inserted through and fastened within the eye of one of the first and second needles.

In other embodiments, each of the needles includes a tube. Typically, each of the first and second ends of the suture thread is respectively inserted into and fastened within the tube of one of the first and second needles. In one embodiment, the needles have an outer dimension that is less than or equal to a diameter of the suture thread, and the ends of the suture thread are narrowed for insertion into the tube.

In disclosed embodiments, in the second operative configuration, the needle guides are configured to point the needles toward the shaft, so that the needles strike the shaft after passing through the tissue. Typically, the shaft includes a needle trap, for capturing and holding the needles when the needles strike the shaft. In one embodiment, the needle trap includes a cavity in an outer surface of the shaft. The needles may include a protrusion, which engages the needle trap so as to prevent release of the needles from the needle trap. Additionally or alternatively, the needle trap includes an elastomeric material, which is penetrated by the needles when the needles strike the shaft.

In some embodiments, the ejector includes first and second ejector ends and is configured to drive the first and second ejector ends into the first and second needle guides, respectively, in order to eject the needles. In one embodiment, each of the needles has a tail, and each of the ejector ends has a nose, which is coupled to the tail of one of the needles so as to push the needles out of the needle guides.

In disclosed embodiments, the device includes a needle guide holder, which is coupled to advance the needle guides from the first operative configuration to the second operative configuration and is adapted to return the needle guides to the first operative configuration after ejection of the needles. Typically, the ejector includes an actuator, which is coupled to the needle guide holder so as to be operable to eject the needles only when the needle guides are in the second operative configuration.

Additionally or alternatively the ejector is coupled to the needle guide holder so that actuation of the ejector by an operator of the device causes the needle guide holder to return the needle guides to the first operative configuration automatically, without further action by the operator. In one embodiment, the device includes first and second springs, wherein the needle guide holder is coupled to cock the first spring when the needle guides are advanced to the first operative configuration, and wherein the second spring is coupled to actuate the ejector, such that actuation of the second spring causes the first spring to be released, thereby causing the needle guide holder to return the needle guides to the first operative configuration.

In one embodiment, the device includes a handle coupled to the shaft, wherein the needle guide holder is contained in the handle, and the device includes a release actuator, which is operable to release the shaft from the handle, so as to permit replacement of the shaft.

In disclosed embodiments, the needle guides are contained inside the shaft in the first operative configuration, and the needle guides are adapted to withdraw automatically into the shaft after ejection of the needles.

Typically, ejection of the needles causes the ends of the suture thread to pass through the tissue, so that upon withdrawal of the device from the body cavity following the ejection of the needles, the suture thread tightens through the tissue while the ends of the suture thread are accessible outside the body cavity.

In some embodiments, the device includes a cannula, which is adapted to pass from a body surface through a puncture into the body cavity, the cannula having a lumen, wherein the shaft is adapted to pass through the lumen so as to access the body cavity. In one embodiment, the cannula has a distal end and includes a pliable material at the distal end, and wherein after penetrating the tissue, the needles penetrate and are captured in the pliable material.

In another embodiment, the shaft contains a lumen, which is shaped to receive a guide wire so as to permit the device to be inserted into the body cavity over the guide wire.

In yet another embodiment, the shaft contains first and second lumens having respective first and second ports disposed along the shaft at different, respective longitudinal positions, such that flow of a body fluid from the cavity through the first and second lumens is indicative of a depth of insertion of the shaft inside the body cavity.

There is also provided, in accordance with an embodiment of the present invention, a device for adjusting a depth of a cannula in a blood vessel relative to a vessel wall, the device including an elongate body, which is adapted for insertion through the cannula, the body containing first and second lumens having respective first and second distal ports and first and second proximal ports, the first and second distal ports being disposed along the body at different, respective longitudinal positions.

Typically, the depth of the device within the blood vessel is ascertainable responsively to flow of blood via the first distal port through the first lumen, while the second distal port is blocked by the vessel wall, whereby the depth of the cannula is adjusted with respect to the device.

There is additionally provided, in accordance with an embodiment of the present invention, a device for knotting a suture thread having first and second ends that have been passed through a body tissue, the device including:

a device body, having a distal end with one or more openings for receiving the ends of the suture thread after a knot has been tied in the thread;

a capture mechanism, which is contained within the body and is operative to capture the knot between the openings so as to hold the knot as the knot is tightened against the body tissue; and

a blade, which is operative to cut off the ends of the suture thread while the knot is held by the capture mechanism.

In a disclosed embodiment, the device body is tubular, and the capture mechanism is mounted to slide within the tube in order to capture the knot. The device may include a spring within the device body, which is coupled to drive the blade to cut off the ends of the suture thread.

There is further provided, in accordance with an embodiment of the present invention, a method for suturing tissue adjoining a body cavity in a body of a patient, the method including:

providing a shaft having a longitudinal axis and a distal end and having first and second needle guides attached thereto in a first operative configuration in which the needle guides are parallel to the axis, the needle guides holding first and second needles, to which respective first and second ends of a suture thread are attached;

inserting the distal end of the shaft into the body cavity while the needle guides are in the first operative configuration;

deploying the needle guides outward from the distal end of the shaft into the body cavity so that the needle guides assume a second operative configuration in which the needles held by the needle guides point in a proximal direction; and

ejecting the needles from the needle guides in the second operative configuration so as to cause the needles to penetrate the tissue adjoining the body cavity.

In a disclosed embodiment, the needles have respective points, and the needle guides contain the needles so that the points do not contact the tissue while the needles are held by the needle guides. The needle guides have respective outer ends, and the method includes bringing the outer ends of the needle guides in the second operative configuration into engagement with the tissue before ejecting the needles. Typically, bringing the outer ends of the needle guides into engagement with the tissue includes pulling the shaft in the proximal direction so as to create tension in the tissue by pressure of the outer ends of the needle guides against the tissue before ejecting the needles.

In disclosed embodiments, the method includes, after ejecting the needles through the tissue, pulling the shaft together with the needles and the needle guides in the proximal direction so as to remove the shaft, the needles, the needle guides and the ends of the suture thread from the body while the suture thread tightens through the tissue. Typically, inserting the distal end of the shaft includes introducing the distal end of the shaft through a puncture in the tissue, and the method includes tying the suture thread after pulling the shaft together with the needles and the needle guides in the proximal direction so as to close the puncture.

In one embodiment, introducing the distal end includes inserting the distal end of the shaft through a laparoscopic puncture port, and tying the suture thread includes closing the laparoscopic puncture port.

In another embodiment, introducing the distal end includes inserting the distal end of the shaft into a blood vessel, and tying the suture thread includes closing the puncture in a blood vessel wall. Typically, inserting the distal end of the shaft into the blood vessel includes passing the distal end of the shaft through the puncture at an oblique angle relative to the blood vessel wall, and ejecting the needles includes passing the first and second needles through the blood vessel wall at respective first and second locations that are longitudinally spaced along a length of the blood vessel, so that the suture thread, when tied, is parallel to a longitudinal axis of the blood vessel.

There is moreover provided, in accordance with an embodiment of the present invention, a method for manipulating a cannula in a blood vessel, the method including:

passing a cannula from a body surface through a puncture in the vessel wall into the blood vessel;

inserting an elongate body through the cannula, the elongate body containing first and second lumens having respective first and second distal ports disposed along the body at different, respective longitudinal positions; and

adjusting a depth of insertion of the cannula in the blood vessel while observing a flow of a body fluid from the blood vessel through the first and second lumens.

In a disclosed embodiment, adjusting the depth includes positioning the elongate body so that blood flows via the first distal port through the first lumen, while the second distal port is blocked by the vessel wall, and aligning the cannula relative to the elongate body. The cannula is then positioned so that both the first and second distal ports are blocked by the cannula.

There is moreover provided, in accordance with an embodiment of the present invention, a method for suturing a body tissue, the method including:

passing first and second ends of a suture thread through the body tissue from a distal side of the tissue to a proximal side of the tissue;

pulling the first and second ends so as to tighten the suture thread against the tissue;

tying a knot between the first and second ends;

inserting the ends of the suture thread through respective openings in a capture mechanism of a knot pushing device after tying the knot, so that the knot is held between the openings;

pressing the knot pushing device toward the body tissue so as to tighten the knot against the body tissue; and

releasing a blade within the knot pushing device after tightening the knot so as to cut off the ends of the suture thread while the knot is held by the capture mechanism.

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

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic, pictorial illustration showing a suture insertion device, in accordance with an embodiment of the present invention;

FIG. **2** is a schematic, sectional illustration showing insertion of the distal end of a suture insertion device into a body cavity, in accordance with an embodiment of the present invention;

FIG. **3**A is a schematic, sectional illustration showing deployment of needle guides at the distal end of a suture insertion device, in accordance with an embodiment of the present invention;

FIG. **3**B is a schematic, pictorial illustration showing a detail of the distal end of the suture insertion device shown in FIG. **3**A;

FIG. **4** is a schematic, sectional illustration showing ejection of needles from the distal end of a suture device, in accordance with an embodiment of the present invention;

FIG. **5** is a schematic, sectional illustration showing retraction of needle guides into a suture insertion device after insertion of a suture through the wall of a body cavity, in accordance with an embodiment of the present invention;

FIG. **6** is a schematic, pictorial illustration showing completion of a suture insertion operation using a suture insertion device, in accordance with an embodiment of the present invention;

FIGS. **7-14** are schematic, sectional illustrations showing details of successive stages in suturing a puncture in a body cavity using a suture insertion device, in accordance with an embodiment of the present invention;

FIG. **15** is a schematic, pictorial illustration of a needle guide, in accordance with an embodiment of the present invention;

FIG. **16** is a schematic, pictorial illustration of a needle guide, in accordance with another embodiment of the present invention;

FIG. **17**A is a schematic, exploded view of a needle guide, in accordance with yet another embodiment of the present invention;

FIG. **17**B is a schematic, pictorial illustration showing the needle guide of FIG. **17**B in its assembled configuration;

FIGS. **18**A and **18**B are schematic, pictorial illustrations showing elements of a needle guide in top and bottom views, respectively, in accordance with an embodiment of the present invention;

FIG. **18**C is a schematic, sectional illustration showing the needle guide of FIGS. **18**A and **18**B in a curved configuration, in accordance with an embodiment of the present invention;

FIG. **19**A is a schematic, frontal view of a suture needle, in accordance with an embodiment of the present invention;

FIGS. **19**B and **19**C are schematic, frontal views of a suture needle in compressed and open configurations, respectively, in accordance with an embodiment of the present invention;

FIG. **20** is a schematic, pictorial illustration of a suture needle, in accordance with another embodiment of the present invention;

FIG. **21** is a schematic, pictorial illustration showing fixation of a suture to a needle, in accordance with an embodiment of the present invention;

FIG. **22** is a schematic, pictorial illustration showing fixation of a suture to a needle, in accordance with another embodiment of the present invention;

FIG. **23** is a schematic, pictorial illustration showing details of a suture fixed to a needle, in accordance with an embodiment of the present invention;

FIGS. **24**A and **24**B are schematic, pictorial illustrations showing successive stages in fixation of a suture to a needle, in accordance with still another embodiment of the present invention;

FIG. **25** is a schematic, pictorial illustration of a needle ejector, in accordance with an embodiment of the present invention;

FIGS. **26**A and **26**B are schematic, pictorial illustrations showing details of a technique for coupling an ejector to a needle, in accordance with an embodiment of the present invention;

FIGS. **27-30** are schematic, sectional illustrations showing needle traps for capture of a suture needle in the shaft of a suture insertion device, in accordance with embodiments of the present invention;

FIGS. **31**A and **31**B are schematic, pictorial illustrations showing details of needle guides and stabilizing struts for the needle guides at the distal end of a suture insertion device, before and during deployment of the needle guides, in accordance with an embodiment of the present invention;

FIGS. **32**A and **32**B are schematic, pictorial illustrations showing details of needle guides and stabilizing struts for the needle guides at the distal end of a suture insertion device, before and after deployment of the needle guides, in accordance with another embodiment of the present invention;

FIG. **33** is a schematic, sectional illustration showing details of mechanisms in a suture insertion device, in accordance with an embodiment of the present invention;

FIG. **34** is a schematic, cross-sectional illustration of the suture insertion device of FIG. **33**, taken along a line XXXIV-XXXIV in FIG. **33**;

FIG. **35** is a schematic, cross-sectional detail illustration of the suture insertion device of FIG. **33**, taken along a line XXXV-XXXV in FIG. **34**;

FIG. **36**A is a schematic, pictorial illustration of a suture insertion device with a removable shaft, in accordance with an embodiment of the present invention;

FIG. **36**B is a schematic, pictorial illustration showing the separate shaft and handle, respectively, of the suture insertion device of FIG. **36**A;

FIG. **37**A is a schematic, sectional illustration of a suture insertion device with a removable shaft, in accordance with an embodiment of the present invention;

FIGS. **37**B and **37**C are schematic, sectional illustrations showing details of a mechanism for connecting the shaft to the handle of the device of FIG. **37**A, prior to and during removal of the shaft from the handle;

FIGS. **38**A and **38**B are schematic, pictorial illustrations showing the distal end of an angled suture insertion device in operation within a blood vessel, in accordance with an embodiment of the present invention;

FIG. **39**A is a schematic, pictorial illustration showing the distal end of an angled suture insertion device before deployment of needle guides therefrom, in accordance with an embodiment of the present invention;

FIG. **39**B is a schematic, pictorial, internal view of the suture insertion device of FIG. **39**A;

FIGS. **40** and **41** are schematic, pictorial illustrations showing the angled suture insertion device of FIG. **39**A in successive stages of deployment of the needle guides;

FIGS. **42-45** are schematic, detail illustrations showing couplers for attaching stabilizers to a needle guide, in accordance with embodiments of the present invention;

FIGS. **46-48** are schematic, sectional illustrations showing successive stages in the operation of a device for positioning a cannula in a blood vessel prior to suturing, in accordance with an embodiment of the present invention;

FIG. **49** is a schematic, pictorial illustration showing positioning of a suture insertion device in a blood vessel using a guide wire, in accordance with an embodiment of the present invention;

FIG. **50** is a schematic, pictorial illustration showing the distal end of a suture insertion device with four needle guides, in accordance with an embodiment of the present invention;

FIGS. **51** and **52** are schematic top views of suture patterns created by a suture insertion device, in accordance with embodiments of the present invention;

FIG. **53** is a schematic, sectional illustration of a trocar for use with a suture insertion device, in accordance with an embodiment of the present invention;

FIGS. **54** and **55** are schematic, sectional illustrations showing stages in the operation of a suture insertion device in conjunction with the trocar of FIG. **53**, in accordance with an embodiment of the present invention;

FIG. **56** is a schematic, sectional illustration of a knot pushing and cutting device, in accordance with an embodiment of the present invention;

FIGS. **57-59** are schematic, sectional illustrations showing successive stages in the operation of the device of FIG. **56**, in accordance with an embodiment of the present invention; and

FIGS. **60**A and **60**B are schematic, sectional illustrations showing actuation and re-cocking, respectively, of a knot pushing and cutting device, in accordance with another embodiment of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS

FIG. **1** is a schematic, pictorial illustration showing a device **120** for insertion of a suture **122** in body tissue, in accordance with an embodiment of the present invention. Device **120** is adapted particularly for closure of laparoscopic port puncture sites in the peritoneum, following laparoscopic surgery. Devices of this sort may also be adapted, however, for closure of punctures in blood vessels following vascular catheterization, as well as other surgical operations. Some of these alternative applications and embodiments are described further hereinbelow.

Device **120** comprises a shaft **124**, whose distal end is shown enlarged in the inset in FIG. **1**. The device is shown in FIG. **1** in its initial, closed configuration. In this configuration, shaft **124** is inserted through the puncture, as described hereinbelow. The shaft comprises a distal tube **126**, which holds needle guides **130**. The needle guides comprise a resilient material, typically a superelastic material, such as Nitinol, which is formed so that when deployed (as shown below), the needle guides curve back in the proximal direction. In the initial configuration shown in FIG. **1**, however, the needle guides are held straight and parallel to the axis of shaft **124** by the constraint of tube **126**. Stabilizers **132** are connected to guides **130** to help maintain the guides in the desired position when the guides are deployed, as described hereinbelow.

The two ends of suture **122** are respectively connected to needles (not seen in this figure) inside guides **130**. An optional outer tube **128** covers and protects the suture. The central portion of suture **122**, between the ends that are connected to the needles, feeds up along shaft **124**. If the suture is long enough, the middle of the suture may protrude from the proximal end of the shaft, as shown in FIG. **1**. Tube **128** has side ports **134** for capturing the needles after they are ejected from guides **130**.

A medical practitioner manipulates and operates device **120** using a handle **136**. In order to deploy needle guides **130** once the distal end of shaft **124** is properly positioned, the practitioner squeezes hand grips **138** together. Squeezing the grips causes levers **140** to move downward (in the distal direction), thus pushing the needle guides out of tube **126**. Locking hooks **142** then hold grips **138** in place against handle **136** for the duration of the operation. Once the needle guides are deployed, the practitioner presses a release button **146** to eject the needles from guides **130**. Details of the guide deployment and needle ejection mechanisms are described hereinbelow.

Device **120** may be designed to be either disposable after a single use or reusable. In reusable product versions, a cocking knob **144** is used to reset the needle release mechanism after use, as described further hereinbelow. The cocking knob is not required in single-use versions.

FIG. **2** is a schematic, sectional illustration showing insertion of the distal end of suture insertion device **120** into a body cavity **154**, in accordance with an embodiment of the present invention. In this example, a trocar **150** has been passed through outer tissue **152** and penetrates a wall **156** of the cavity. In the case of laparoscopic surgery, wall **156** comprises the abdominal fascia. Shaft **124** is then inserted through the working channel of trocar **150** so that the distal end of the shaft protrudes into cavity **154**. Similar techniques may be used to insert the shaft of the suture insertion device into body cavities of other sorts, such as blood vessels, with different sorts of cannulae and working channels as appropriate. (The term "cannula" is used in the present patent application and in the claims to denote any and all tubes for insertion into body cavities, including—but not limited to—laparoscopic trocars and vascular sheaths.) Alternatively, in some cases, the practitioner may insert shaft **124** directly through the puncture into the body cavity, without using a cannula.

FIGS. **3**A and **3**B schematically illustrate deployment of needle guides **130** from the distal end of shaft **124**, in accordance with an embodiment of the present invention. FIG. **3**A is a schematic, sectional illustration of device **120**, while FIG. **3**B is a schematic, pictorial illustration showing a detail of the distal end of the device. At this stage of the procedure, the practitioner has pulled trocar **150** in the proximal direction, out of the body, so that the end of the trocar is above the area of cavity wall **156**. The practitioner then squeezes grips **138** together, so that the grips are locked by hooks **142**. Inward pressure of grips **138** forces levers **140** to move downward, thus pressing on a guide holder **159**, which forces needle guides **130** out of the distal end of tube **126**. Once deployed in this manner out of tube **126**, guides **130** relax to assume their pre-formed, curved configuration.

In this configuration of guides **130**, needles **160** are aimed back in the proximal direction, toward cavity wall **156**. Stabilizers **132** help to maintain the relative rigidity of guides **130**, so as to ensure that the needles are aimed in the proper direction. These stabilizers typically comprise metal wires or threads made from a suitable polymer or silk. The stabilizers are also useful in keeping body tissue and other objects out of the space between guides **130** and tube **126**, so that needles **160** do not accidentally catch such tissues or objects when the needles are ejected. Needles **160** typically comprise a thin, elastic material, such as Nitinol. Unlike guides **130**, which are produced so as to have a curved form in their relaxed state, needles **160** are straight when not geometrically constrained. Alternatively, the needles may comprise a plastic material, such as stainless steel. Although guides **130** are flexible enough to be held straight within tube **126** before they are deployed, the guides are still substantially stiffer than the needles. Therefore, the needles bend freely to assume the curvature of the guides. Ejector end pieces **162** in shaft **124** engage the rear ends of needles **160** within guides **130** in order to eject the needles from the guides, as shown in the next figure.

During insertion of shaft **124** into cavity **154** and deployment of guides **130** from the shaft, needles **160** remain completely contained within the guides. The practitioner releases the needles from the guides only after the outer ends of the guides have been brought into contact with cavity wall **156**. The practitioner is typically able to verify that the ends of the guides are in contact with the wall by pulling gently outward on handle **136** and feeling the resistance as the ends of the guides press against the wall. Because the needles remain within the guides throughout this stage of the procedure, the chances that one of the needles will snag (and accidentally suture) other tissue within cavity **154** is very slight. Furthermore, because the needles are aimed to pass through wall **156** in the proximal direction, i.e., from inside cavity **154** outward, there is no danger of injury to other structures and surfaces inside the cavity. As noted above, stabilizers **132** help to prevent the needles from catching any other tissues before passing through wall **156**.

FIG. **4** is a schematic, sectional illustration showing ejection of needles **160** from guides **130**, in accordance with an embodiment of the present invention. Actuation of button **146** (FIG. **1**) releases an ejection spring **158**, which then exerts rapid downward pressure on an ejector **164**. The resulting downward motion of the ejector forces end pieces **162** into guides **130**, thus pushing needles **160** forward out of guides **130** and through the tissue of wall **156**. The needles pull the ends of suture **122** along with them through the tissue. Typically, as shown in the figure, the end sections of guides **130** are straight, causing needles **160** to straighten immediately as they exit the guides. The end sections of the guides are aimed toward side ports **134**, so that after passing through wall **156**, the needles enter the side ports and are captured in a needle trap **166** within tube **126**.

When grips **138** are squeezed together, levers **140** not only force guide holder **159** downward, but also compress a retraction spring **165**. When ejection spring **158** is released by button **146**, however, the tension holding levers **140** against guide holder **159** is also relaxed, so that the guide holder is free to move back up. Therefore, immediately after ejector **164** has ejected needles **160** from guides **130**, spring **165** is released and forces guide holder **159** back upward. This reaction takes place automatically, typically within less than 0.1 sec of the actuation of button **146**, and thus pulls guides **130** back into shaft **124**. Further details of the mechanisms in handle **136** are described hereinbelow with reference to FIG. **33**.

FIG. **5** is a schematic, sectional illustration showing retraction of needle guides **130** into tube **126** after insertion of suture **122** through cavity wall **156**, in accordance with an embodiment of the present invention. Retraction spring **165** has expanded, causing holder **159** to pull guides **130** back into their original, straightened configuration within tube **126**. Ejector end pieces **162** remain within guides **130**, while needles **160** are pulled upward within needle traps **166**. The needles pull the ends of suture **122** up along with them. The practitioner pulls device **120** out through tissue **152** (typically together with trocar **150**). As a result, the middle part of suture **122** feeds down along shaft **124** through the puncture in cavity wall **156**, and then up through the cavity wall behind the needles.

FIG. **6** is a schematic, pictorial illustration showing completion of a suture insertion procedure using device **120**, in accordance with an embodiment of the present invention. The entire suture **122** has fed through the holes in cavity wall **156** that were made by needles **160**, and then back up through an opening **168** in the body surface at the upper end of the puncture. The suture is now snipped off from shaft **124**, and is then tied to close the puncture in wall **156**. The suture may be tied manually or, alternatively, using a knot pushing device, such as the devices shown in FIGS. **56**-**59** and in FIGS. **60**A and **60**B.

Reference is now made to FIGS. **7**-**14**, which are schematic, sectional illustrations showing details of the suturing procedure described above, in accordance with an embodiment of the present invention. FIGS. **7**-**11** show the distal end of shaft **124**, including needle guides **130** and needles **160**, at successive stages in the procedure. Outer tube **128** is omitted from this embodiment. FIGS. **12**-**14** show the final stages of closure of the suture.

As shown in FIG. **7**, during insertion of shaft **124** through trocar **150** into body cavity **154**, needle guides **130** are held straight, parallel to the axis of tube **126**. In the context of the disclosed embodiments of the present invention and in the claims, the terms "straight" and "parallel" do not necessarily mean that the guides are strictly straight or parallel to the axis in the geometrical sense, but rather indicate that the general orientation of the guides in this configuration runs along the axis of shaft **124**. Downward movement of guide holder **159** (or equivalently, upward movement of tube **126**) pushes guides **130** distally out of the end of tube **126**, so that the guides are deployed in their curved configuration, as shown in FIG. **8**. In this configuration, side ports **134** open into needle traps **166**, in preparation for ejection of the needles. Although in FIG. **8** the distal end of device **120** is relatively far from cavity wall **156**, it will be observed that guides **130** may be deployed in this manner even when the distal end of the device is nearly flush with the inner surface of the cavity wall. Device **120** is thus suitable for use even in very narrow cavities, such as blood vessels (including vessels that are partially occluded by atherosclerotic plaques).

After guides **130** are deployed, but before ejecting needles **160**, the practitioner pulls device **120** in the proximal direction so that the ends of guides **130** engage cavity wall **156**, as shown in FIG. **9**. Gently pulling the device outward in this manner deforms and creates tension in the tissue. This tension enhances the penetration of the needles through the cavity wall when the needles are subsequently ejected and also helps to ensure that a sufficient length of tissue will be captured between the tips of the two needles. The practitioner triggers the ejection mechanism (as shown in FIG. **4**), causing ejector **164** to move rapidly downward, and thus pushing ejector ends **162** into guides **130**, as shown in FIG. **10**. As a result, needles **160** are rapidly ejected from guides **130**. The needles pass straight through wall **156** into ports **134** and are captured in needle traps **166**. Subsequent upward movement of guide holder **159**, as shown in FIG. **11**, pulls guides **130** back up into the lower end of tube **126** and may simultaneously pull needles **160** up into the needle traps, as well. The needles are pulled into the traps by friction between the needles and guide holder **159** and possibly by catching on hooks or other protrusions within traps **166**, as described further hereinbelow.

Shaft **124** is then withdrawn from trocar **150** and moved up, away from the body, as shown in FIG. **12**. The ends of the suture are pulled up along with the shaft, thus pulling the central part of the suture downward through the puncture in wall **156**. When the entire suture has passed down through the puncture, the practitioner may pull the suture tight in order to close the puncture, as shown in FIG. **13**. Immediate tensioning of the suture in this manner is useful, for example, when closing a puncture in a blood vessel following catheterization in order to reduce bleeding. The practitioner may simultaneously twist shaft **124** in order to close the puncture more tightly. The practitioner then ties a knot **170**, as shown in FIG. **14**, removes trocar **150**, and closes the puncture at the external body surface, as well.

FIG. **15** is a schematic, pictorial illustration showing details of guide **130**, in accordance with an embodiment of the present invention. The guide is typically fabricated from a tube of superelastic material, such as Nitinol, as noted above. The tube may have substantially any suitable profile, such as a circular profile, an elliptical profile, or a rectangular or oblong profile. Tubes of this sort are available, for example, from Johnson Matthey Inc. (San Jose, Calif.). Non-circular profiles are advantageous in that they may force needle **160** to maintain a desired orientation (assuming the needle profile to be non-circular), and they may also provide greater stability against sideways bending of the guides.

A central portion **176** of the tube is then set (or "trained") to assume a curved shape in its austenitic state, as shown in FIG. **15**, while end sections **172** and **174** are held straight. Methods for "training" Nitinol in this manner are known in the art. Typically, the tube is placed in a mandrel of the desired shape and is then heated to a high temperature (typically 500° C. for at least 5 min) and cooled thereafter. Guides **130** may be formed in this way with a bend angle slightly smaller than the actual, desired bend angle that the guides are to assume when deployed. This technique can be used to create a certain preload tension in stabilizers **132** when the guides are deployed (FIG. 3B), thus enhancing the stability of the deployed guides.

FIG. **16** is a schematic, pictorial illustration of needle guide **130**, in accordance with another embodiment of the present invention. This embodiment is similar to that shown in FIG. **15**, with the addition of a slot **178** at the outer end of the guide. Slot **178** can be used to accommodate the end of suture **122**, in order to reduce the likelihood that the suture sill snag on other parts of device **120** or on body structures in cavity **154**.

FIGS. **17**A and **17**B are schematic, pictorial illustrations of a needle guide **180**, in accordance with yet another embodiment of the present invention. FIG. **17**A is an exploded view showing the parts of the needle guide, while FIG. **17**B shows the needle guide in its assembled configuration. Needle guide **180** in this embodiment is made from a plate **182** of Nitinol, which is trained to shape in the manner described above. Needle **160** is held in place against plate **182** by a collar, which may be formed, for example, from two sections **184** that are fastened together over the end of the plate. Typically, sections **184** comprise a suitable metal, such as stainless steel or titanium, and are welded together over plate **182**, using laser welding or another suitable technique. One or more additional sleeves (not shown) may be fastened over plate **182** at other locations in order to prevent sideward movement of the needle.

Reference is now made to FIGS. **18**A, **18**B and **18**C, which schematically illustrates a needle guide **185**, in accordance with still another embodiment of the present invention. FIGS. **18**A and **18**B are top and bottom views, respectively, of needle guide **185** in the straight configuration in which the needle guide is held within shaft **124**, while FIG. **18**C is a sectional view through the needle guide in its curved configuration. (The terms "top" and "bottom" here refer to the perspective of FIG. **18**C.) Needle guide **185** comprises a plate **186** and a cover **187**, both of which are typically made of Nitinol. A slot is cut in plate **186** to accommodate needle **160**. This configuration permits the use of a relatively thick, strong needle while still bending to a small radius of curvature, as shown in FIG. **18**C. Plate **186** and cover **187** are trained to this shape in the manner described above.

As shown in FIG. **18**B, cover **187** is secured to plate **186** by protrusions **188**, which fit into slots **189** in the plate. The protrusions are fixed in place by pins **191**. As can be seen in the figure, the more distal slots are longer than the corresponding protrusions, thus permitting cover **187** to shift longitudinally relative to plate **186** when guide **185** bends. The relative movement is helpful in relieving strains that might otherwise lead to material failure.

FIG. **19**A is a schematic, frontal view of needle **160**, in accordance with an embodiment of the present invention. In this embodiment, needle **160** is cut from a flat sheet of metal, typically a superelastic metal such as Nitinol. (Alternatively, in other embodiments, as shown below, needle **160** may be produced from a tube or rod, which may have a circular or elliptical profile.) Needle **160** may be cut using a laser or a suitable die, as is known in the art. As noted earlier, the needle is produced so that in its relaxed, austenitic state, the needle is straight, but because the needle is made from thinner, more flexible material than guide **130**, the needle bends with the guide when the guide is deployed. An eye **190** is also cut in the needle to accommodate suture **122**. Optionally, protrusions **192** are formed on the shank of needle **160** in order to catch on the inner sides of needle trap **166**, thereby holding the needle more securely in the trap as shaft **24** is withdrawn from the body. The pointed tip of needle **160** may also be ground down to a sharper point, in order to facilitate passage of the needle through cavity wall **156**.

It is possible and desirable to make needles **160** very thin and flexible. The shape and aim direction of the needles is determined by guides **130**, which are relatively stiff and stable, rather than by the needles themselves. Thin needles are able to pass through cavity wall **156** more easily, with less tissue trauma and ancillary bleeding, than are the thicker, stiffer needles that are used in suturing devices known in the art.

FIGS. **19**B and **19**C are schematic, frontal views of a suture needle **194** in compressed and open configurations, respectively, in accordance with another embodiment of the present invention. Needle **194** is similar to needle **160**, as shown in FIG. **19**A, with the addition of a resilient expanding section **196**. The needle is cut from a sheet of elastic material in the shape shown in FIG. **19**B. Inside guide **130**, however, section **196** is compressed into the shape shown in FIG. **19**C. When the needle is ejected from the guide, section **196** opens outward, so that protrusions **192** on section **196** help to secure the needle within needle trap **166**.

FIG. **20** is a schematic, pictorial illustration of a suture needle **200**, in accordance with yet another embodiment of the present invention. Needle **200** has an elastic protrusion **204**, which is typically formed by cutting and then applying appropriate heat treatment to the needle material. Protrusion **204** is used to secure needle **200** in a needle trap by catching on a suitable hook in the needle trap (as shown below in FIG. **29**). Needle **200** may also have a narrow tail **202**, to facilitate coupling of the needle to ejector end piece **162** (as shown below in FIGS. **26**A and **26**B). Although the needles shown in this figure and in the preceding figures each have a certain combination of features, these combinations have been chosen solely for the sake of illustration. Other combinations of these features, or similar features, will be apparent to those skilled in the art.

FIG. **21** is a schematic, pictorial illustration showing fixation of suture **122** to needle **160**, in accordance with an embodiment of the present invention. Suture **122** is fed through eye **190**, and is then heated to form a bulb **210**, which holds the suture in place. This technique is suitable particularly for polypropylene sutures, but it may also be used with polymer sutures of other types. A similar sort of bulb may be formed from a suitable biocompatible adhesive, such as Loctite Hysol® M-31CL epoxy, and this fixation technique may thus also be used with other types of sutures, such as silk.

FIG. **22** is a schematic, pictorial illustration showing fixation of suture **122** to a needle **212**, in accordance with another embodiment of the present invention. Needle **212** in this case is tubular and may be made, for example, from a tube of superelastic material, such as Nitinol. Suture **122** is fed in through the pointed front end **214** of the needle. The suture may then be glued in place using a suitable biocompatible adhesive, such as the above-mentioned Hysol epoxy. Alternatively or additionally, the end of the suture may be fed through to the rear end of the needle and then heat treated to form a bulb **216**.

FIG. **23** is a schematic, pictorial illustration showing details of suture **122** fixed to needle **212**, in accordance with an embodiment of the present invention. This embodiment addresses the problem that the suture itself may be too thick to fit inside the lumen of the tubular needle. Therefore, suture **122** in this embodiment is made up of a short, thin end section **216**, which is coupled to a thicker main section **217** by a coupler **218**. Section **216** may comprise a metal wire, such as a braided stainless steel wire, which may be glued or otherwise fixed inside needle **212**, as described above. Section **217** typically comprises a polymer, such as a polymer that gradually dissolves inside the body (for example, Ethicon Monocryl® or Vicryl®), as is known in the art. Sections **216** and **217** may be joined to connector **218** by pressure crimping, glue, welding, or any other suitable means known in the art.

Other methods for producing suture **122** with narrow end sections will be apparent to those skilled in the art. For example, the ends of a polymer suture may be heated and drawn to a smaller diameter. As another example, if the suture comprises a core with a braided exterior over the core, the exterior braiding may be removed from the ends of the suture to narrow their diameter. One advantage of using a thick suture, of comparable diameter to that of needle **212**, is that the suture then completely fills the trace that the needle makes through cavity wall **156**, thus sealing and reducing leakage through the trace.

FIGS. **24**A and **24**B are schematic, pictorial illustrations showing successive stages in fixation of suture **122** to a flat needle **220**, in accordance with still another embodiment of the present invention. Needle **220** is cut from a sheet of elastic material, and an eye having the form of a slot **222** is cut through the needle near the pointed tip. To insert suture **122**, slot **222** is pulled open, as shown in FIG. **24**A, and the end of the suture is fed into the open slot. The slot is then released, so that it clamps shut, holding the suture in place, as shown in FIG. **24**B.

In the embodiments shown above, ejector **164** and ejector end pieces **162** are formed from a single piece of material, which may be a metal, such as stainless steel or Nitinol, or a suitable plastic. Typically, ejector **164** comprises a rod or tube, whose distal end is cut to form the end pieces, typically by laser cutting or fine machining. Alternatively, the ejector may be formed by injection molding. As noted earlier, end pieces **162** are made sufficiently thin and flexible so that they can advance freely into guides **130** while the guides are deployed in their curved configuration.

FIG. **25** is a schematic, pictorial illustration of an ejector **230**, in accordance with an alternative embodiment of the present invention. In this embodiment, ejector comprises an ejector body **232** and separate end pieces **234**, which are fixed to body **232**. The end pieces may be fixed to the body by any suitable means, such as crimping, glue, laser welding or a coupling pin (not shown). End pieces **234** may comprise, for example, two parallel strips fixed together, or a single strip, wire or tube that is bent in the middle. Alternatively, the end pieces may be cut out in an elongated U-shape from a metal plate, by laser cutting, for example. In this case, the two end pieces may be made to bow slightly outward for greater mechanical strength during ejection of needles **160** from guides **130**. Other arrangements of end pieces **234** will be apparent to those skilled in the art.

FIGS. **26**A and **26**B are schematic, pictorial illustrations showing details of a technique for coupling ejector end piece **162** to needle **160**, in accordance with an embodiment of the present invention. Needle **160** ends in tail **202**, as described above with reference to FIG. **20**. End piece **162** has a matching tip **235**. A connector **236** fits over and holds tail **202** and tip **235** together. This arrangement ensures secure, positive engagement between the ejector end piece and the needle during ejection. Typically, connector **236** is securely fastened to tip **235** but not to tail **202**, so that needle **160** is freed from the connection after the needle is ejected, while connector **236** remains attached to the ejector end piece inside guide **130**.

FIGS. **27-30** are schematic, sectional illustrations showing different arrangements of needle trap **166**, in accordance with embodiments of the present invention. The figures show needle **160** and trap **166** in the situation illustrated in FIG. **11**, in which guide holder **159** and guides **1.30** have been withdrawn upward inside tube **126**, and the needle is captured in the trap. In the embodiment shown in FIG. **27**, needle **160** has been drawn completely inside trap **166**, along with the end of suture **122** that is attached to the needle. As noted earlier, friction between the needle and the guide holder tends to draw the needle upward into the trap. Alternatively, as shown in FIG. **28**, the entry to trap **166** may be sufficiently narrow and geometrically bent so that needle **160** lodges in the entry when the needle is ejected from guide **130**. The needle may also include a bend point introduced at the time of manufacture, so that the needle bends and lodges in the desired position. The needle may remain stuck in this position when guide holder **159** moves upward, or alternatively, the needle may be drawn part way into trap **166** by the movement of the guide holder. In any of these embodiments, protrusions **192** on the shank of the needle (as illustrated in FIGS. **18** and **19**A) may assist in holding the needle securely inside the trap.

FIG. **29** shows a needle trap with a hook **240**, for use with needles of the type of needle **200** (FIG. **20**). When the needle enters trap **166**, protrusion **204** catches on hook **240**, and thus prevents the needle from sliding back out of the trap.

In FIG. **30**, tube **126** is surrounded by a collar **242** made of a pliable material, typically a suitable elastomer, such as silicone. Trap **166** is defined by port **134** in the outer surface of tube **126**, which is covered by collar **242**, Needle **160** passes through the collar and is held in place by pressure of the collar against the tube. Protrusions **192** on the shank of the needle may help to hold the needle more securely in the trap. In this case, the needle is captured securely irrespective of the upward movement of guide holder **159**. Alternatively, a pliable collar may be placed over port **134** for use in conjunction with other types of traps, such as that shown in FIG. **28**.

FIGS. **31**A and **31**B are schematic, pictorial illustrations showing details of stabilizer struts **250** for needle guides **130**, in accordance with an alternative embodiment of the present invention. Although stabilizers **132** (FIG. **3**B) provide good control of the positions of guides **130** in the radial direction, they still permit some transverse movement. Struts **250**, on the other hand, are stiff enough to give complete control over the movement of guides in all directions. The struts are connected at one end to tube **126** by hinges **252**, and at the other end by hinges **254** to guides **130**. During insertion and removal of the suture insertion device from the body, struts **250** and guides **130** are closed inside tube **126**, as shown in FIG. **31**A. The struts and guides are deployed outward, as shown in FIG. **31**B, prior to ejection of the needles.

FIGS. **32**A and **32**B are schematic, pictorial illustrations showing details of stabilizer struts **256** for needle guides **130**, in accordance with another embodiment of the present invention. In this embodiment, unlike the embodiment of FIGS. **31**A and **31**B, guides **130** are deployed out of the distal end of tube **126**. To accommodate this arrangement, struts **256** are attached by a sliding hinge **238** to tube **126**. The struts are attached at their outer ends to guides **130** by fixed hinges **260**.

FIG. **33** is a schematic, sectional illustration showing details of the mechanisms in handle **136** and shaft **124** of device **120**, in accordance with an embodiment of the present invention. Device **120** is shown here in its initial state (as in FIG. **2**), wherein ejection spring **158** is cocked and retraction spring **165** is relaxed. Levers **140** engage guide holder **159**, but both guide holder **159** and ejector **164** remain in their initial, elevated positions, such that guides **130** are held inside tube **126** and needles **160** are contained within guides **130**. The elements within handle **136** are held in place by a locking nut **270** with a conical fitting.

Prior to ejection of needles **160**, an ejector head **276**, at the upper end of ejector **164**, is held in place by a clip **278**. Since head **276** is firmly fixed to ejector **164**, the ejector cannot eject needles **160** from guides **130** until clip **278** is released by actuation of release button **146** (FIG. **1**). The release button, however, is not aligned with clip **278** until grips **138** have been closed. Closing the grips causes levers **140** to lower guide holder **159**, and with it to lower ejector **164** and head **276**. This is the situation shown in FIGS. **3**A and **3**B, in which guides **130** have been deployed from tube **126**. Lowering holder **159** in this manner aligns release button **146** with clip **278**, as well as compressing retractor spring **165**, as noted above.

FIGS. **34** and **35** are schematic, cross-sectional illustrations of device **120**, showing details of the operation of release button **146**, in accordance with an embodiment of the present invention. The cross-section in FIG. **34** is taken along a line XXXIV-XXXIV in FIG. **33** (except that FIG. **34** shows device **120** in the configuration of FIG. **3**A, in which grips **138** have already been closed and locked by hooks **142**). The cross-section shown in FIG. **35** is taken along a line XXXV-XXXV in FIG. **34**.

As shown in FIG. **34**, clip **278** is spring-loaded against a pin **280**, which slides up and down with head **276**. As long as ejector head **276** is in the upper position shown in FIG. **33**, button **146** does not contact clip **278**, and therefore, the ejector head cannot be released from the clip. Ejector spring **158** therefore remains cocked, and needles **160** remain within guides **130**. Thus, there is no danger that the needles will be ejected from the guides (in the distal direction) before the guides are fully deployed.

When grips **138** are squeezed together, ejector head **276** and clip **278** are lowered to the position shown in FIG. **35**. Now, when the practitioner presses button **146**, clip **278** is pushed inward along pin **280**, so that head **276** is released from the clip. As a result, spring **158** is fee to expand, driving ejector **164** downward (FIG. **4**) so as to eject needles **160**. The subsequent automatic release of retraction spring **165** (FIG. **5**), by disengagement of the ends of levers **140** from guide holder **159**, causes the guide holder to retract guides **130** into tube **126**, thus completing the process.

FIGS. **36**A-**36**B are schematic, pictorial illustrations of a suture insertion device **290** with a removable shaft **292**, in accordance with an alternative embodiment of the present invention. FIG. **36**A shows the device in its operational configuration, with shaft **292** and a handle **294** fitted together. FIG. **36**B shows the separate shaft **292** and handle **294**, respectively. Operation of device **290** is identical to that of device **20**, except for the added facilities in device **290** for replacing the shaft and reusing the handle. Typically, the shaft is suitable for only a single use, and is then disposed of, because the operation of loading needles **160** into guides **130** is most conveniently performed in the manufacturing plant. Therefore, device **120**, with integral shaft **124**, can be used only once. On the other hand, handle **294** can be reused multiple times, by performing suitable sterilization and replacing shaft **292** after each use.

As shown in FIG. **36**B, shaft **292** comprises a proximal fitting **296**, for mating with the mechanisms of guide holder **159** and ejector **164** inside handle **294**. Fitting **296** fits into a receptacle **298** in the handle and is held in place by locking pins **304** and **306**. A release actuator **300** is used to release these pins when the shaft is to be replaced. (The release mechanism is shown in greater detail below in FIGS. **37**A, **37**B and **37**C.) In preparation for reuse, the practitioner or other operator releases hooks **142** to open grips **138** and pulls up on a knob **302** to re-cock ejection spring **158**. A new shaft **292** is then fitted into receptacle **298**; and device **290** is ready for reuse.

FIGS. **37**A-**37**C are schematic, sectional illustrations of suture insertion device **290**, in accordance with an embodiment of the present invention. FIG. **37**A provides an overview of the device, while FIGS. **37**B and **37**C show details of the mechanism used for connecting shaft **292** to handle **294**. In FIG. **37**B, shaft **292** is connected to handle **294** and ready for operation. Pin **304** engages tube **126** of shaft **292**, while pin **306** engages guide holder **159** to enable deployment of the needle guides. To release pins **304** and **306**, as shown in FIG. **37**C, release actuator **300** is pushed downward, causing diagonal sections **308** to slide under the heads of the pins. This action pulls the pins outward, away from shaft **292**, and thus releases the shaft from the handle.

In an alternative embodiment, not shown in the figures, device **120** (FIG. **1**) may be reused in its entirety multiple times. For this purpose, after each use, the operator releases hooks **142** to open grips **138** and pulls up on a knob **144** to re-cock ejection spring **158**. The operator then inserts a new pair of suture needles, with a suture connected between them, into guides **130**. After sterilization, the device is ready for reuse.

FIGS. **38**A and **38**B are schematic, pictorial illustrations showing the distal end of an angled suture insertion device **324** in operation within a blood vessel **320**, in accordance with an embodiment of the present invention. Although in the preceding embodiments, device **120** was inserted straight through tissue through wall **156** of cavity **154** (as is typical, for example, in laparoscopic surgery), the principles of that device may be adapted, with certain modifications, for closing diagonal punctures as are commonly used in vascular catheterization procedures. This sort of adaptation is shown in FIGS. **38**A and **38**B and the figures that follow.

In the scenario shown in FIG. **38**A, a cannula **326** (also referred to as a sheath) has been inserted through a wall **322** of blood vessel **320**. Vessel **320** may be the femoral artery, for example, or substantially any other blood vessel large enough to accommodate cannula **326** and device **324**. After completion of a catheterization procedure, the catheter (not shown) is withdrawn from cannula **326**, and device **324** is inserted in its stead. Guides **328** are then deployed from the shaft of device **324**, in the manner described above. After deploying the guides, the practitioner withdraws cannula **326**, as shown in FIG. **38**B, and pulls device **324** outward until the ends of guides **328** engage wall **322**. The needles are then ejected from the guides through wall **322**, and suture **122** is tied in place. The course of the procedure follows the steps described above with reference to FIGS. **7**-**14**.

It can be seen in FIGS. **38**A and **38**B that guides **328** are non-symmetrical, i.e., the guides have different lengths and curvatures to accord with the angled entry of cannula **326** into vessel **320**. This arrangement permits suture **122** to be inserted through vessel wall **322** along the longitudinal axis of the vessel. This feature of the present embodiment is important because the puncture in the blood vessel wall typically cuts the wall in a peripheral direction. A longitudinal suture is generally most effective against subsequent peripheral tearing of the vessel wall along the puncture line. The configuration of guides **328** also permits the needles to penetrate wall **322** at points that are relatively far apart, so that the suture captures a substantial length of the wall tissue.

FIGS. **39**A and **39**B are schematic, pictorial illustrations showing the distal end of suture insertion device **324** before deployment of needle guides **328**, in accordance with an embodiment of the present invention. FIG. **39**A is an external view of device **324**, wherein the needle guides are covered by an outer tube **336**, while FIG. **39**B show an internal view of device **324**, with tube **336** removed. Suture **122** is omitted from these figures and the subsequent figures for the sake of simplicity.

Because of the non-symmetrical construction of guides **328**, along with the fact that the components of device **324** must fit within a narrower diameter than those of comparable devices for laparoscopic use (such as device **120**), device **324** comprises an arrangement of stabilizing wings **330** and support cords **332** that stabilizes the guides upon deployment. This arrangement helps to reduce both radial bending and transverse twisting of the guides, thus ensuring that the needles are ejected through the vessel wall in the proper locations. Wings **330** are fastened together by a collar **334**, with a pin **335** that prevents longitudinal movement of the wings along the axis of device **324**. The wings typically comprise a superelastic material, such as Nitinol, which is set to assume a curved shape in the austenitic state (as shown in the figures that follow). During insertion and removal of device **324** through tissue **152**, however, wings **330** are constrained by tube **336** to remain straight against guides **328**, as shown in FIG. **39**B, and cords **332** hang loosely between the wings and the guides. Cords **332** typically comprise braided metal wire, such as stainless steel wire, but they may alternatively comprise polymer or silk threads.

FIGS. **40** and **41** are schematic, pictorial illustrations showing suture insertion device **324** in successive stages of the deployment of needle guides **328**, in accordance with an embodiment of the present invention. After the distal end of device **324** has been inserted into vessel **320**, as shown in FIG. **40**, tube **336** is pulled back in the proximal direction, thus releasing wings **330** to curve outward, away from the axis of the tube. Then, as shown in FIG. **41**, the guide holder (not shown in this figure) is advanced, pushing guides **328** distally out of the end of tube **336**. The superelastic guides likewise assume their curved shapes when released from the tube. Wings **330** extend outward in a direction that is transverse to the plane of guides **328**. The guides are typically formed with slightly less curvature than the guides will actually have in their deployed configuration, so as to mechanically preload cords **332** upon deployment. The cords are fastened to guides **328** by couplers **338**. The tension of the cords in this configuration prevents radial and transverse movement of the guides.

FIGS. **42**-**45** are schematic, detail illustrations showing couplers **338** for attaching support cords to needle guide **328**, in accordance with embodiments of the present invention. In the embodiment of FIG. **42**, coupler **338** comprises a short tubular section **340**, with holes cut in its sides to fit over guide **328**. Section **340** may be produced by any suitable method known in the art, such as molding or machining by laser or mechanical means. A slot **344** in section **340** captures cord **332** so as to prevent movement of the cord within the coupler. Section **340** is held in place on guide **328** by collars **342**, which may be welded, crimped or glued in place or may be formed from superelastic shape memory material, which is heat treated to fit tightly against the guide.

In the embodiment of FIG. **43**, coupler **338** comprises a tubular section **350**, which fits longitudinally over guide **328**. Tubular section **350** has slots **352**, which mate with corresponding grooves **354** on guide **328**. The slots and grooves are locked together by the pressure of cord **332** between the tubular section and the guide on the opposite side of the guide. Alternatively, cord **332** may be pressed in place against guide **328** by an elastic tubular coupler **360**, as shown in FIG. **44**. Further alternatively, as shown in FIG. **45**, cord **332** may be looped around guide **328** and (if metal cord is used) welded in place. Collars **342** may be used to hold the looped cord in place, and the entire assembly may optionally be coated by a layer of glue **364**. Other coupling arrangements will be apparent to those skilled in the art.

FIGS. **46**-**48** are schematic, sectional illustrations showing successive stages in the operation of a positioning device **372** for adjusting the position of a cannula **370** in blood vessel **320** prior to suturing, in accordance with an embodiment of the present invention. As noted above, such a cannula is generally used initially for insertion of a catheter into the blood vessel. The sequence of actions shown in FIGS. **46**-**48** takes place after the catheter has been removed from the patient's body, in preparation for suturing the blood vessel. The purpose of these actions is to position cannula **370** at a proper depth so that when suture insertion device **324** (FIG. **38**A) is inserted through the cannula, the distal end of the suture insertion device will be properly located for deployment of needle guides **328**.

Positioning device **372** comprises two lumens **374** and **376**, having respective distal ports **378**, **380** and proximal ports **382**, **384**. Distal ports **378** and **380** are longitudinally offset, so that port **380** is closer to the distal end of device **372** than port **378**. Initially, as shown in FIG. **46**, device **372** is inserted through cannula **370** until both of distal ports **378** and **380** protrude through the distal end of the cannula. The practitioner will recognize that device **372** has reached this insertion depth by the outflow of blood through both of proximal ports **382** and **384** (as indicated by the small arrows in FIG. **46**).

Now the practitioner withdraws cannula **370**, and device **372** along with it, in the proximal direction. When the distal tip of device **372** approaches vessel wall **322**, distal port **378** of lumen **374** will be occluded by the vessel wall. Because of the longitudinal offset between the distal ports, however, port **380** still remains in the bloodstream at this point, as shown in FIG. **47**. The practitioner will recognize this position by the cessation (or at least reduction) of blood outflow through proximal port **382**, while blood continues to flow from port **384**. The exact depth of device **372** relative to vessel wall **322** is now known.

Finally, the practitioner advances cannula **370** in the proximal direction, while holding device **372** in place relative to the patient's body, until blood outflow through both of proximal ports **382** and **384** ceases, as shown in FIG. **48**. In this position, the distal end of the cannula is precisely aligned with the distal end of device **372**, at the proper depth within vessel **320** for subsequent insertion of suture insertion device **324**. A mark **386** may also be provided on the shaft of device **372** in order to indicate the proper position of the cannula at this stage. Positioning device **372** is now removed from cannula **370**, and suture insertion device **324** is inserted.

FIG. **49** is a schematic, pictorial illustration showing positioning of a suture insertion device **392** in blood vessel **320** using a guide wire **390**, in accordance with an alternative embodiment of the present invention. Such guide wires are commonly used in catheterization procedures, and device **392** has a lumen (not shown) that permits the device to ride over the guide wire after the catheter has been withdrawn from the body. Although no cannula is shown in this figure, it is also possible to insert the suture insertion device over a guide wire within such a cannula.

Alternatively or additionally, suture insertion device **392** itself may comprise distal ports **394**, **396** and lumens (not shown) as in positioning device **372**, as an aid to the practitioner in positioning the suture insertion device at the proper depth. In this case, as shown in FIG. **49**, the practitioner will know that the suture insertion device is located at the appropriate depth when blood flows out through port **394** but not port **396**.

FIG. **50** is a schematic, pictorial illustration showing the distal end of a suture insertion device **400** with four needle guides **402**, in accordance with an embodiment of the present invention. Device **400** permits two pairs of needles to be ejected into the target tissue, each pair having a suture connected between them. (The needles and sutures are not shown in the figure for simplicity of illustration.) Thus, device **400** may be used to insert two sutures simultaneously or in immediate succession without removing the device from the body to reload. This arrangement is not only convenient for the practitioner, but also ensures that the sutures will be correctly positioned relative to one another.

FIGS. **51** and **52** are schematic top views of stitch patterns that may be created in vessel wall **322** by suture insertion device **400**, in accordance with embodiments of the present invention. Each stitch pattern comprises two sutures **406**, which are used to close a puncture **404**. In FIG. **51**, sutures **406** are side by side. The two sutures may be aligned along the longitudinal axis of the blood vessel and spaced peripherally around the axis. This pattern is achieved by stringing each suture between one of the long guides and one of the short guides to either side of device **400**. Alternatively, the sutures may be aligned peripherally and spaced longitudinally along the blood vessel by stringing one of the sutures between the pair of longer guides and the other suture between the pair of shorter guides. Further alternatively, the sutures may be strung crosswise between opposing long/short pairs of guides **402** in order to give crossed stitches in the "X" pattern shown in FIG. **52**.

Although FIGS. **50**-**52** show a certain specific configuration of needle guides **402** and resultant suture patterns, the relative positions and shapes of the needle guides may be modified to provide other suture spacings and patterns as required by other procedures and puncture sizes.

FIGS. **53**-**55** are schematic, sectional illustrations of a trocar **410** for use with an integrated suture insertion device **422**, in accordance with an embodiment of the present invention. The principles of this embodiment may also be applied to cannulae of other types, such as sheaths used in vascular catheterization. FIG. **53** shows trocar **410** by itself, while FIG. **54** shows the trocar after insertion of device **422**. (Device **422**, which is shown in outline in order to simplify the illustration, is assumed to be similar in operation to device **120**, shown in FIG. **1**, aside from the differences that are described hereinbelow.) FIG. **55** shows trocar **410** and device **422** after deployment of needle guides **130** and ejection of needles **160**.

Trocar **410** comprises an outer tube **412**, which is sized to accept the handle of device **422**. A locking clip **414** mates with a ridge **424** on device **422** to hold the device in place inside tube **412**. A slot **416** may be provided in outer tube **412** to accommodate controls on the handle of device **422**, as well as to ensure proper rotational alignment of the device. The outer tube of the trocar is sealed off from the inner (distal) part by a leaf valve **418**, which prevents outflow of gas (from the abdominal cavity during laparoscopy, for example) or fluid (such as blood during vascular catheterization) upon insertion of the trocar into the body. The leaf valve opens inward when the suture insertion device is inserted into the trocar.

The outer surface of the distal end of the trocar may comprise a pliable material **420**, such as rubber, which is soft enough to be penetrated by needles **160**. Upon ejection of needles **160** from guides **130**, as shown in FIG. **55**, the needles penetrate and are trapped within material **420**. This feature of trocar **410** obviates the need for needle traps **166** (FIG. **10**) in the shaft of suture insertion device **422** and thus simplifies the design of device **422**. After ejection of the needles, trocar **410** is withdrawn from the patient's body together with device **422**, leaving the suture to be tied off by the practitioner. The practitioner may tie and cut the suture manually, as is known in the art, or may alternatively use a dedicated knot pushing device, as described hereinbelow.

FIGS. **56-59** are schematic, sectional illustrations showing the structure and operation of a knot pushing and cutting device **430**, in accordance with an embodiment of the present invention. Device **430** comprises a suture capture mechanism **452** and a suture cutting blade **448**. To use device **430**, the practitioner makes a sliding knot **432** in suture **122** and then passes the ends of the suture through slits **446** in the sides of the distal end of device **430**, as shown in FIG. **56**. The practitioner next grasps device **430** by a handle **436** and presses down on a suture capture button **434**, as shown in FIG. **57**. Pressing this button pushes the rounded lower end of capture mechanism **452** to engage a lower shoulder **454** of device **430**. As a result, suture **122** is trapped in slits **446**, and knot **432** is prevented from sliding sideways as device **430** presses the knot down through tissue **152**. Pressing down on button **434** also compresses a capture spring **438** and locks the capture mechanism in its lowered position by engagement between a ridge **450** on the mechanism and a mating clip **442** on handle **436**.

After performing the steps shown in FIGS. **56** and **57**, the practitioner pushes device **430** downward through tissue **152** in order to tighten knot **432** against cavity wall **156**, as shown in FIG. **58**. While pushing the knot downward with one hand, the practitioner holds the ends of suture **122** with the other. In this manner, the suture itself guides the distal end of device **430** down through the tissue to the puncture site. The distal tip of capture mechanism **452** may include a flexible element in order to prevent over-tightening of knot **432**.

After tightening down one knot in this manner, the practitioner may choose to make an additional knot in suture **122** before cutting it. To make the additional knot, the practitioner presses clip **442**, which releases ridge **450** and thus permits spring **438** to pull mechanism **452** up and away from shoulder **454**. The practitioner then withdraws device **430** from tissue **152**, ties another knot, and repeats the steps illustrated in FIGS. **56-58** in order to push the second knot down against the first one. These operations may be repeated as many times as desired. Alternatively, if only a single knot is to be made in suture **122**, capture spring **438** and clip **442** may be omitted from device **430**.

While the practitioner ties and pushes the knots into position, blade **448** is held in place by a pin **444**. After tying and tightening the knot (or knots), the physician pulls out pin **444**, thus releasing a cutting spring **440**. This spring drives blade **448** rapidly downward, so that the blade cuts suture **122** at shoulder **454**, as shown in FIG. **59**. Optionally, blade **448** may be mounted in a helical groove (not shown) inside the shaft of device **430**, so that the blade cuts the suture with a downward rotational motion. Device **430** and the remaining suture are then withdrawn from the body, leaving the suture tied in place, as illustrated in FIG. **14**.

FIGS. **60**A and **60**B are schematic, sectional illustrations showing actuation and re-cocking, respectively, of a knot pushing and cutting device **460**, in accordance with another embodiment of the present invention. Device **460** is similar in operation to device **430**, as described above, except that device **460** may be used for pushing and cutting multiple sutures. For this purpose, blade **448** in device **460** has a reset handle **464** and a reusable release pin **462**. After tightening the knot made in the suture, in the manner described above, the practitioner pulls out pin **462** in order to actuate blade **448**, as shown in FIG. **60**A. Subsequently, to prepare device **460** for reuse, the practitioner pulls handle **464** upward to re-cock cutting spring **440** and then pushes pin **462** inward in order to lock blade **448** in place. The practitioner presses clip **442** to release capture spring **438**, and the device is now ready for reuse.

As another alternative, the features of devices **430** and **460** may be implemented in a two-part knot pusher and cutter, including a single-use shaft and a reusable handle, along the lines of the principles of suture insertion device **290** (FIG. **36**A).

Although the embodiments described above relate mainly to suturing of punctures intentionally made by medical practitioners in the course of various minimally-invasive procedures, the principles of the present invention may also be applied in other sorts of surgical procedures and devices. For example, devices similar to those described above may be used in laparoscopic suturing of punctures and other holes in body organs, including both iatrogenic and pathological holes. Applications of this sort may include closure of an iatrogenic rupture of a bile duct, suturing of a perforated ulcer (gastric, duodenal, etc.), suturing of holes left after instrumental colon anastomoses, and sealing of a perforated uterus. Most of these applications at present can be performed only using open surgical techniques. Devices in accordance with embodiments of the present invention may be used to insert any type and number of sutures at once, depending on the diameter and tissue type of the hole.

In other embodiments, devices in accordance with the principles of the present invention may be used in laparoscopic urological procedures, such as uterine suspension for treatment of uterine prolapse. Minimally-invasive sutures can be applied in this manner to secure the uterus in its elevated position. Other possible applications include arthroscopic procedures, such as suturing torn menisci in the knee and rotator cuff tears in the shoulder, as well as minimally-invasive suturing of small lesions in the spine and in the brain, via burr holes in the skull (using suitably miniaturized versions of the devices described hereinabove).

It will thus be appreciated that the embodiments described above are cited by way of example, and that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof which would occur to persons skilled in the art upon reading the foregoing description and which are not disclosed in the prior art.

The invention claimed is:

1. A method for suturing tissue adjoining a body cavity in a body of a patient, the method comprising:

providing a shaft having a longitudinal axis and a distal end and having first and second needle guides attached thereto in a first operative configuration in which the needle guides are parallel to the axis, the needle guides holding first and second needles, to which respective first and second ends of a suture thread are attached;

inserting the distal end of the shaft into the body cavity while the needle guides are in the first operative configuration, wherein in the first operative configuration, the needles pointing in a distal direction;

deploying the needle guides outward from the distal end of the shaft into the body cavity so that the needle guides assume a second operative configuration in which the needles held by the needle guides point in a proximal direction, wherein the needle guides curved out of the shaft so as to point in the proximal direction toward the shaft;

ejecting the needles from the needle guides in the second operative configuration so as to cause the needles to penetrate the tissue adjoining the body cavity; and capturing and holding the first and second ends of the suture thread with the shaft after the needles have passed through the tissue.

2. The method according to claim **1**, wherein the needles have respective points, and wherein the needle guides contain the needles so that the points do not contact the tissue while the needles are held by the needle guides.

3. The method according to claim **2**, wherein the needle guides have respective outer ends, and comprising bringing the outer ends of the needle guides in the second operative configuration into engagement with the tissue before ejecting the needles.

4. The method according to claim **3**, wherein bringing the outer ends of the needle guides into engagement with the tissue comprises pulling the shaft in the proximal direction so as to create tension in the tissue by pressure of the outer ends of the needle guides against the tissue before ejecting the needles.

5. The method according to claim **1**, and comprising, after ejecting the needles through the tissue, pulling the shaft together with the needles and the needle guides in the proximal direction so as to remove the shaft, the needles, the needle guides and the ends of the suture thread from the body while the suture thread tightens through the tissue.

6. The method according to claim **5**, wherein inserting the distal end of the shaft comprises introducing the distal end of the shaft through a puncture in the tissue, and comprising tying the suture thread after pulling the shaft together with the needles and the needle guides in the proximal direction so as to close the puncture.

7. The method according to claim **6**, wherein introducing the distal end comprises inserting the distal end of the shaft through a laparoscopic puncture port, and wherein tying the suture thread comprises closing the laparoscopic puncture port.

8. The method according to claim **6**, wherein introducing the distal end comprises inserting the distal end of the shaft into a blood vessel, and wherein tying the suture thread comprises closing the puncture in a blood vessel wall.

9. The method according to claim **8**, wherein inserting the distal end of the shaft into the blood vessel comprises passing the distal end of the shaft through the puncture at an oblique angle relative to the blood vessel wall, and wherein ejecting the needles comprises passing the first and second needles through the blood vessel wall at respective first and second locations that are longitudinally spaced along a length of the blood vessel, so that the suture thread, when tied, is parallel to a longitudinal axis of the blood vessel.

10. The method according to claim **1**, wherein deploying the needle guides comprises pushing the needle guides out through the distal end of the shaft, whereupon the needle guides curve back in the proximal direction.

11. The method according to claim **1**, wherein the needle guides comprise a superelastic material, which is formed so as to have a curved shape when deployed from the shaft.

12. The method according to claim **1** wherein the needles comprise an elastic material, which is formed so that the needles assume a straight shape upon being ejected from the needle guides.

13. The method according to claim **1**, wherein deploying the needle guides comprises deploying one or more stabilizers, which are contained within the shaft while the needle guides are in the first operative configuration, so as to stabilize the needle guides in the second operative configuration.

14. The method according to claim **1**, wherein the first and second needle guides are non-symmetrical in the second operative configuration.

15. The method according to claim **14**, wherein the needle guides have respective outer ends, and comprising, after deploying the needle guides, bringing the outer ends of the first and second needle guides into simultaneous engagement with the tissue while the shaft is angled obliquely relative to the tissue, wherein ejecting the needles comprises ejecting the needles while the first and second needle guides are in the simultaneous engagement with the tissue and the shaft is angled obliquely.

16. The method according to claim **1**, wherein the suture thread held by the first and second needles is a first thread, and wherein providing the shaft comprises providing third and fourth needle guides attached to the shaft and providing third and fourth needles, which are respectively held by the third and fourth needle guides and hold a second suture thread, and wherein the ejecting the needles comprises ejecting the first, second, third and fourth needles, thereby passing the ends of both the first and second suture threads through the tissue.

17. The method according to claim **16**, wherein ejecting the first, second, third and fourth needles comprises making two parallel stitches through the tissue.

18. The method according to claim **16**, wherein ejecting the first, second, third and fourth needles comprises making two crossed stitches through the tissue.

19. The method according to claim **1**, wherein the needles are formed from a plate of a flat material.

20. The method according to claim **1**, wherein each of the needles comprises a tube.

21. The method according to claim **1**, wherein ejecting the needles comprises aiming the needles toward the shaft, and comprising capturing and holding the needles against the shaft after the needles have penetrated the tissue.

22. The method according to claim **21**, wherein deploying the needle guides comprises configuring the needle guides to point the needles toward the shaft, so that the needles strike the shaft after passing through the tissue.

23. The method according to claim **1**, wherein ejecting the needles comprises actuating an ejector so as to drive first and second ejector ends into the first and second needle guides, respectively, in order to eject the needles.

24. The method according to claim **23**, wherein actuating the ejector comprises coupling the ejector to the needle guides so that the ejector cannot be actuated when the needle guides are in the second operative configuration.

25. The method according to claim **1**, and comprising returning the needle guides to the first operative configuration after ejection of the needles, and withdrawing the shaft from the body while the needle guides are in the first operative configuration.

26. The method according to claim **25**, wherein ejecting the needles comprises actuating an ejector, and wherein returning the needle guides comprises coupling the ejector to the needle guides so that actuation of the ejector causes the needle guides to return to the first operative configuration automatically.

27. The method according to claim **1**, wherein providing the shaft comprises coupling a handle to the shaft, the handle comprising controls for use by an operator, and comprising, after ejecting the needles and removing the shaft from the body, releasing the shaft from the handle and replacing the shaft.

28. The method according to claim **1**, wherein providing the shaft comprises holding the needle guides inside the shaft in the first operative configuration.

29. The method according to claim **28**, wherein ejecting the needles comprises withdrawing the needle guides automatically into the shaft after ejection of the needles.

30. The method according to claim **1**, wherein inserting the distal end comprises passing a cannula from a body surface through a puncture into the body cavity, and inserting the shaft through a lumen of the cannula.

31. The method according to claim **1**, wherein the shaft contains a lumen, and wherein inserting the distal end comprises passing the shaft into the body cavity over the guide wire.

32. The method according to claim **1**, wherein the shaft contains first and second lumens having respective first and second ports disposed along the shaft at different, respective longitudinal positions, and wherein inserting the shaft comprises observing a flow of a body fluid from the cavity through the first and second lumens in order to adjust a depth of insertion of the shaft inside the body cavity.

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patsnap

专利名称(译)	缝合方法		
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摘要(译)

缝合线插入装置（120）包括轴（124），其适于插入体腔（154）中。第一和第二针（160）分别保持缝合线（122）的第一和第二端。第一和第二针引导件（130）附接到轴并分别保持第一和第二针。针引导件具有第一操作构造，其中针引导件保持平行于轴的轴线以将轴插入体腔中，以及第二操作构造，其中针引导件从身体内的轴向外展开空腔，以便将针指向近端方向。推出器（164）用于在第二操作构造中从针导向器中弹出针，以使针穿透邻接体腔的组织（156）。