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(54) **Title:** CURVED NEEDLE SUTURING TOOL

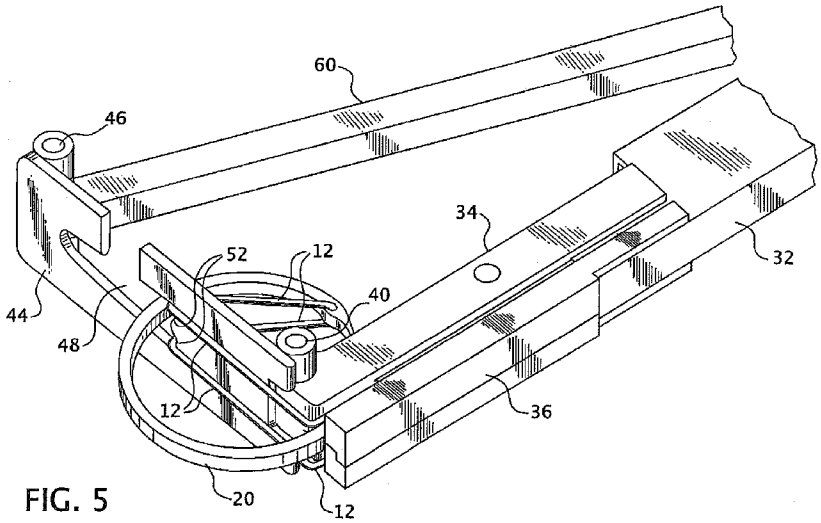

FIG. 5

(57) **Abstract:** A needle delivery device is described and includes generally, a needle made of a shape memory alloy pre-formed in an unconstrained configuration, such as, for example, an arc or a curved needle. The needle delivery device also includes a needle delivery guide, a suturing guide and a positioning member. The needle has an eye at its leading tip for holding suture material. The needle delivery guide has a needle channel for passage of the needle therethrough. The needle channel is configured to hold the needle in a constrained configuration, for example, in substantial alignment with the longitudinal axis of the needle channel. The suturing guide is pivotally connected to the delivery guide. The positioning member moves the suturing guide between an extended position and a collapsed position, wherein, in the extended position, the suturing guide is configured to stabilize the tissue and guide the needle in its unconstrained configuration and to enable access by, for example, a grasper or other tool, to the suture material.

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CURVED NEEDLE SUTURING TOOL

FIELD OF THE INVENTION:

[0001] The present invention relates to tools for surgical suturing, and more particularly, to a curved needle and tool for endoscopic surgical suturing, including, for example, natural orifice transenteric surgery.

BACKGROUND

[0002] Sutures are used to approximate, or bring together, tissue separated, for example, by some trauma, or wound or during a surgical procedure to close an incision or an organ perforation. Suturing instruments generally include a needle and a trailing length of suture material. In endoscopic procedures, the instruments placed through an instrument channel may include needles and sutures for stitching such a wound, incision or perforation within the patient's body cavity.

[0003] Physicians have often used endoscopes to examine, to biopsy, and to ablate the tissue of patients within lumens such as the esophagus and the bowel or other body cavity and internal patient sites. An endoscope generally includes either a rigid or flexible tube containing one or more optical fiber systems and, for operative uses (human or veterinary), one or more channels for passage of medical instruments. The optical system includes a light delivery system to illuminate the organ or site under inspection and a camera system to transmit the image of the site of interest to the viewer. The light source is normally outside the body and the light is typically directed via optical fiber bundles to the area of interest. The instrument channels and optical fiber bundles open into the body at the distal end of the endoscope and are generally parallel to the axis of the flexible endoscope.

[0004] A physician performing a therapeutic procedure with the use of an endoscope places flexible instruments through the instrument channels near the site within the body lumen or cavity where a procedure is to be performed while visualizing and illuminating an internal site using the optical fiber bundles.

[0005] More recently, a surgical technique known as natural orifice transenteric surgery (NOTES) is attracting interest. NOTES may be performed with an endoscope that is passed through a natural orifice, such as the patient's mouth, nose or anus, then through an internal incision in the stomach or colon, for example, thus avoiding any external incisions or scars. The NOTES technique has been used for diagnostic and therapeutic procedures in animal models, including transgastric (through the stomach) organ removal. Transcolonic approaches are also advocated for access to upper abdominal structures that may be more difficult to work with using a transgastric approach.

[0006] To minimize the trauma experienced by patients, both the number and diameter of the canula inserted into a patient should be minimized. When a procedure requires suturing tissue, a problem arises in the types of needles that can be delivered to the surgical site. Many surgeons prefer to use curved needles which are typically in the range of 1/4 to 5/8 of a circle (*i.e.* an arc whose interior angle is in the range of about 90 °- 225°). Needles of these dimensions would require canula, or endoscope working channels, large enough to accommodate the arc of the needle, which in many procedures, is not feasible. The preferred curved surgical needles cannot pass through the preferred, narrower, canula to the surgical site.

[0007] In an effort to resolve the problem, alloys that display a shape memory effect, such as those having approximately 50 atomic % nickel (Ni) and 50 atomic % titanium (Ti), are now widely used. The shape memory effect is arises due to a phase change that takes place in certain alloys as they are cooled or heated through their characteristic transformation temperature. The best known shape memory alloys are Ni-Ti (Nitinol) alloys in which the phase change is from an ordered cubic crystal form above the transformation temperature to a crystalline phase below the transformation temperature. The transformation is known as a martensitic transformation between a high temperature "austenitic" form and a low temperature "martensitic" form. An alloy becomes martensitic over a narrow temperature range as it is cooled through its transformation temperature and becomes austenitic over a narrow and slightly higher temperature range as it is heated through its transformation temperature. For a given alloy composition in a given annealed condition, the transformation takes place at a predictable,

repeatable temperature. The transformation takes place virtually instantaneously when the alloy in one phase reaches a temperature at which the other phase is thermodynamically more stable.

[0008] Shape memory alloys have been used for the manufacture of surgical needles wherein a surgical needle is fabricated from a shape memory alloy into the desired "arc" shape. The arc is maintained at a temperature well above the austenitic phase. The needle is then cooled, transforming the material to the martensitic phase. While in the martensitic phase, the needle is deformed (for example, straightened) to the extent necessary to be able to pass through a canula.

[0009] U.S. Patent No. 4,926,860 discloses arthroscopic instrumentation that takes advantage of the "superelasticity" inherent in shape memory alloys. Similar technology is disclosed in U.S. Patent No. 4,984,581. U.S. Patent No. 5,597,378 describes a method of making a shape memory alloy canula.

[0010] U.S. Patent No. 5,219,358 discloses a method for introducing a curved needle to a surgical site in a patient and comprises the steps of (a) inserting a canula into the patient to permit access form outside the patient to the surgical site, (b) providing a shape-metal-alloy needle that, having been formed into an arc shape and tempered at an elevated temperature, has been formed into an elongated shape while in a first, low-temperature state, (c) passing the elongated needle through the canula, and (d) heating the needle to a temperature at which the alloy is converted to a second, high-temperature state, thereby causing the needle to return to the arc shape. Heat can be provided, for example, by an illumination light, by a laser, or by a cautery instrument of any type used in endoscopic surgery. The needle is transformed to the austenitic phase and reverts to the curved shape. Thus, the alloy used for shape memory effect surgical needles preferably undergoes its phase transformation in a narrow range near normal body temperature. Since practical and medical reasons limit the temperature to which the needle can be heated at the surgical site, the alloy is preferably austenitic at a temperature slightly below body temperature, for example, at about 35 °C and above, or room temperature, about 25 °C.

[0011] Advances in shape memory effect materials and the manufacture of curved needles with such materials makes the use of curved needles in endoscopic surgery possible.

However, it has been found that in the process of puncturing a patient's tissue at an internal site through a canula or the working channel of an endoscope, there is a tendency for the tissue to shift. This is particularly true for tissues of the gastrointestinal tract. The pressure of the curved needle puncturing the tissue, first in one direction and then in a second opposite direction as the curve of the needle circles around back through the tissue, pulls at the tissue and causes it to shift, ripple or buckle, such that one or both of the first and second punctures of the curved needle are not in the desired location. A means of stabilizing the tissue while suturing with a curved needle is needed.

SUMMARY OF THE INVENTION

[0012] A solution to the problems of delivery of a curved needle through a channel and stabilization of the tissue to be sutured is provided by the needle delivery device of the present invention. The needle delivery device includes generally a needle made of a shape memory alloy pre-formed in an unconstrained configuration, such as, for example, an arc or a curved needle. The shape memory alloy may be, for example, a Ni - Ti alloy, such as Nitinol. The needle delivery device also includes a needle delivery guide, a suturing guide and a positioning member. The needle has an eye therein for holding suture material.

[0013] The needle delivery guide has a distal end and a proximal end and defines a needle channel for passage of the needle therethrough. The needle channel defines a longitudinal axis and is configured to hold the needle in a constrained configuration, for example, in substantial alignment with the longitudinal axis of the needle channel.

[0014] The suturing guide is connected, and preferably pivotally connected, to the delivery guide. The positioning member moves the suturing guide between an extended position and a collapsed position. In various embodiments, when the suturing guide is in the extended position, it may be configured to stabilize the tissue and to guide the needle in its unconstrained configuration. The extended position may also enable access to the suture material by auxiliary instruments.

[0015] In one embodiment, the delivery guide may comprise an elongate member and a pair of constraining members that extend axially from the elongate member at its distal end, and together the elongate member and the constraining members define the needle channel. The elongate member is preferably flexible. The constraining members may be rigid for at least a portion of their length. The suturing guide in this embodiment may form a plate that is pivotally attached at a first end to one member of the pair of constraining members, and pivotally attached at an opposing second end to the positioning member. The plate may define an opening for receiving the needle in the unconstrained configuration thereof and further, an access opening for access to the suture material.

[0016] In an embodiment of the positioning member, a rod having a distal end and a proximal end is pivotally connected at the distal end to the second end of the plate and slidably connected at the proximal end to the elongate member. The positioning member may further include an elongate rail positioned along a portion of the length of the elongate channel member and a bracket pivotally connected to the proximal end of the rod for sliding engagement with the rail to move the plate between the collapsed position in which the bracket slides proximally along the rail to pivot the plate toward the elongate member and the extended position in which the bracket slides distally along the rail to move the plate away from the elongate member. The extended position of the plate is preferably transverse to the longitudinal axis of the constraining members.

[0017] In one embodiment of the present invention, the needle delivery device is intended for use with an endoscope. The elongate member of the needle delivery guide is therefore configured for passage through a first working channel of an endoscope. A grasper is provided for passage through a second working channel of the endoscope for grasping the suture material.

[0018] The needle delivery device may also include a means positioned at the proximal end of the needle delivery guide and operatively connected to the positioning member, for effecting the movement of the suturing guide. Alternatively, the positioning member may be

pulled proximally and pushed distally by manipulation, by the surgeon, of an instrument, such as a probe or another grasper, inserted into the first working channel with the delivery device.

[0019] A method of suturing using the needle delivery device and a method of preparing the needle delivery device are also described.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] The novel features of the invention are set forth with particularity in the appended claims. The invention itself, however, both as to organization and methods of operation, together with further objects and advantages thereof, may best be understood by reference to the following description, taken in conjunction with the accompanying drawings in which:

FIG. 1 is a perspective view of an embodiment of the needle delivery device of the present invention with the needle in a compressed state;

FIG. 2 is a view of the deployment of the suturing guide of the needle delivery device prior to penetration of the tissue;

FIG. 3 is a side view illustrating the curved needle having exited the delivery guide and punctured the tissue in a distal direction and beginning the reverse puncture in a proximal direction;

FIG. 4 is a side view illustrating the curved needle after completion of the reverse puncture of the tissue in the proximal direction;

FIG. 5 is an alternative view of the curved needle of FIG. 4 showing the position of the suture after a single stitch;

FIG. 6 is a side view of the curved needle being drawn back into the needle delivery device; and

FIGS. 7a - 7g schematically illustrate the curved needle assembly and a grasper forming a chain stitch.

DETAILED DESCRIPTION

[0021] Before the present embodiments of an instrument and method for its use are described, it is to be understood that this invention is not limited to the particular process steps and materials disclosed herein as such process steps and materials may vary somewhat. It is also to be understood that the terminology used herein is used for the purpose of describing particular embodiments only and is not intended to be limiting since the scope of the present invention will be limited only by the appended claims.

[0022] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood to one of ordinary skill in the art to which this invention belongs. Although any method, instrument and materials similar or equivalent to those described herein may be used in the practice or testing of the invention, particular embodiments of a method, instrument and materials are now described.

[0023] It must be noted that, as used in this specification and the appended claims, the singular forms "a," "an," and "the" include plural referents unless the content clearly dictates otherwise.

[0024] In describing and claiming the present invention, the following terminology will be used in accordance with the definitions set out below.

[0025] As used herein, the term "patient," used herein, refers to any human or animal on which a procedure requiring suturing may be performed.

[0026] As used herein, the term "biocompatible" includes any material that is compatible with the living tissues and system(s) of a patient by not being substantially toxic or injurious and not causing immunological rejection.

[0027] As used herein, the term "bioabsorbable" includes the ability of a material to be dissolved and/or degraded, and absorbed, by the body.

[0028] As used herein, the term "shape memory" includes the tendency of a material, such as but not limited to a suitably prepared nickel-titanium alloy ("Nitinol"), to return to a preformed shape, following deformation from such preformed shape.

[0029] As used herein, the term "arc" is meant to refer generally to a curved shape. Although an arc of a circle is the shape most commonly used for a surgical needle, “arc” as used herein is not limited to the curve or arc of a circle.

[0030] As used herein, the term "integral" means that two or more parts so described are affixed, fastened or joined together so as to move or function together as a substantially unitary part. "Integral" includes, but is not limited to, parts that are continuous in the sense that they are formed from the same continuous material, but also includes discontinuous parts that are joined, fastened or affixed together by any means so as to become substantially immovably affixed to, and substantially unitary with, each other.

[0031] As used herein, the term "proximal" (or any form thereof), with respect to a component of an instrument, means that portion of the component that is generally nearest the practitioner, physician, or surgeon, or nearest to the end of the instrument handled by the practitioner, physician, or surgeon, when in use; and with respect to a direction of travel of a component of an instrument, means toward the end of the instrument generally nearest the practitioner, physician, or surgeon, or handled by the practitioner, physician, or surgeon, when in use.

[0032] As used herein, the term "distal" (or any form thereof), with respect to a component of an instrument, means that portion of the component that is generally farthest from the practitioner, physician, or surgeon, or farthest from the end of the instrument handled by the practitioner, physician, or surgeon, when in use; and with respect to a direction of travel of a component of an instrument, means away from the end of the instrument generally nearest the practitioner, physician, or surgeon, or handled by the practitioner, physician, or surgeon, when in use.

[0033] As used herein, the term "transverse" (or any form thereof), with respect to an axis, means extending in a line, plane or direction that is across such axis, i.e., not co-linear or parallel therewith. "Transverse" as used herein is not to be limited to "perpendicular".

[0034] As used herein, the term "longitudinal axis", with respect to an instrument, means the exact or approximate central axis defined by said instrument along its greater dimension, i.e., along its length, from its distal end to its proximal end, and vice versa, and is not intended to be limited to imply a straight line, wherein, for example, an instrument is flexible and includes or may include a bend angle it is intended that "longitudinal axis" as used herein follows such bend angle.

[0035] As used herein, the term "internal site" of a patient means a lumen, body cavity or other location in a patient's body including, without limitation, sites accessible through natural orifices or through incisions.

[0036] The present invention has application in conventional endoscopic and open surgical instrumentation, as well as application in robotic-assisted surgery. The embodiments shown illustrate the use of the invention in connection with an endoscope within an internal site of a patient. The invention is useful in a variety of minimally invasive medical procedures, including without limitation medical procedures performed through laparoscopic incisions for access to body cavities and internal organs of the body or through natural orifices. The invention also encompasses apparatus and methods employing endoscopic devices in general, including various forms and variations of endoscopes, including without limitation: laparoscopes, gastroscopes, peritoneoscopes, sigmoidoscopes, fiberoptic endoscopes, arthroscopes, amnioscopes, and the like.

[0037] One embodiment of the needle delivery device 10 of the present invention is shown in FIGS. 1-6. The device 10 includes generally a needle 20 having a tip 24 for piercing, or puncturing tissue, and an eye 22 for holding a length of suture material 12. Any suitable known suture material may be used and will be determined in most instances by the nature of the procedure and type of tissue to be sutured, as well as the preferences of the surgeon or practitioner performing the procedure.

[0038] The preferred material for the needle 20 is a superelastic, shape memory alloy such as Nitinol (Ni - Ti); however, other non Ni - Ti alloys may be used. Any Nitinol alloy selected will have properties whereby the temperature at which the martensitic to austenitic phase change occurs is lower than the working temperature of the device (*i.e.*, room or body temperature). A permanent bend may be heat set in a superelastic Nitinol needle by maintaining the needle in the desired final shape while subjecting it to a prescribed high temperature for a specific time period. The needle can be elastically manipulated far beyond the point at which stainless steel or other metals would experience plastic deformation. Nitinol and other superelastic materials, when sufficiently deformed, undergo a local phase change at the point of stress to what is called "stress-induced martensite". When the stress is released, the material resiliently returns to the austenitic state.

[0039] A second method of imparting a permanent bend to the material is by a process commonly known as cold working. Cold working involves mechanically overstressing or over bending the superelastic instrument. The material within the bending region undergoes a localized phase shift from austenite to martensite and does not fully return to its original shape. In the case of the cold-worked instrument, the result is a permanent curve about the bending zone which has been locked in to at least a partial martensitic crystalline state. In contrast, the entire heat-annealed instrument is in an austenitic condition, even in the curved region, and only is temporarily transformed to martensite under sufficient bending stresses. Therefore, the flexural properties of the annealed instrument vary little across its length. Conversely, the bend of a cold-worked instrument, which contains martensite, has increased resistance to deformation and therefore, holds its shape better than the more flexible bend of the pure austenitic instrument. This increased rigidity can be an advantage for certain clinical applications.

[0040] Cold working permanently locks a portion of crystalline structure of the bending zone into at least a partial martensitic condition while the unstressed portions of the canula remains in the austenitic state. Cold worked Ni - Ti alloys are discussed in "Linear Superelasticity in Cold-Worked Ni--Ti", (Zadno and Duerig) pp. 414 to 419, in Engineering Aspects of Shape Memory Alloys, Butterworth-Heineman, Boston, Mass. (Duerig et al, editors) which is incorporated herein by reference. In addition to Nitinol, superelastic biocompatible

polymeric materials with sufficient rigidity for both deployment and shape memory to assume a desired curve may also be used in certain applications, either alone or in combination with reinforcing metal components.

[0041] The primary purpose of using a Nitinol or other superelastic alloys for the needle is that it can be constrained into one shape during its passage to the treatment site, and then deployed into its preformed unconstrained configuration without experiencing any plastic deformation. In the embodiment of the needle 20 shown in the Figures, the preformed configuration is an arc or curve. When not constrained by some deforming pressure, and when heated to its austenitic temperature, the needle 20 assumes its unconstrained, preformed configuration, for example, the arc shape shown. For convenience in this specification and the appended claims, we refer to the curved needle as being in the shape of an arc, although clearly the needle could have any "remembered" shape desired.

[0042] In the embodiment shown, the needle 20 is constrained when it travels through the needle delivery channel 38 in the delivery guide 32. As shown in FIGS. 1 and 2, the constrained configuration would be linear, or in general alignment with the longitudinal axis of the needle channel 38 in which the needle 20 resides as it is inserted into an endoscope or canula (not shown) for transport to an internal patient site.

[0043] In one embodiment, the needle delivery device 10 generally includes, in addition to the needle 20, a delivery guide 32, a suturing guide, which is shown in the form of a plate 44, a positioning member, which is shown as a bar 60 pivotally attached to plate 44 and to the distal end of the delivery guide 32.

[0044] Referring to FIGS. 2 and 3, the delivery guide 32 includes an elongate member 30 and a pair of constraining members 34, 36 defining a needle channel 38 between the front 34 and back 36 constraining members and through the elongate member 30.

[0045] The suturing guide includes plate 44 having an opening 48 for passage of the needle 20, as described in more detail hereinafter. Opening 48 has a pair of indentations 52 to define a guide path for each strand of a double stranded suture 12 as the needle 20, in its

unconstrained, arced configuration, passes through the tissue from the distal side 102 to the proximal side 100, through opening 48. Plate 44 also includes a cut away section through the side of plate 44 to opening 48 to define an access path 54 through which graspers 80, as illustrated schematically in FIG. 7, can access and grasp a section of suture 12.

[0046] Plate 44 is pivotally connected to the front constraining member 34 by pivot pin 40. At the opposite side of plate 44, pivot pins 46 pivotally connect plate 44 to the distal end of a positioning bar 60. Positioning bar 60 includes an area 66 having a reduced width at its proximal end. The proximal end of positioning bar 60 may be pivotally connected to the delivery guide 32 by pivot pins 64 in bracket 62. Positioning bar 60 may have an elongate slot (not shown) for sliding engagement with the pin 64 to allow the proximal end of bar 60 to slide proximally along the side of delivery guide 32 to collapse plate 44 against the delivery guide 32 for travel through the channel of an endoscope or canula and to slide distally and outwardly from delivery guide 32 to extend plate 44 onto the tissue 100.

[0047] In an alternative embodiment, as shown in FIG. 2, delivery guide 32 may have a rail 42. The proximal end of positioning bar 60 includes a pin, clevis member or the like for sliding engagement with the rail 42 to allow positioning bar 60 to travel distally to extend plate 44 and proximally to collapse plate 44 against delivery guide 32. In the extended position, the longitudinal axis of plate 44 is transverse, and generally perpendicular to the longitudinal axis of the delivery guide 32.

[0048] In use, the needle delivery device 10 would be inserted through the proximal end of a canula or the working channel of an endoscope and directed distally through the canula or channel to the internal patient site in need of suturing. When inserted into such a channel, the positioning bar 60 and plate 44 would be collapsed against the side of the delivery guide 32. Needle 20 would be constrained in the needle channel 38 between constraining members 32 and 34, as shown in FIG. 1.

[0049] When the needle delivery device 10 reaches the area within the patient site in need of suturing, as determined by the surgeon or practitioner, the distal tip 24 of the needle 20 is placed against the proximal side 100 of the tissue at the site 84 desired for the first puncture of

the needle 20 through the tissue. The positioning bar 60 slides down the rail 42 along the side of the elongate member 32 and pivots at each end about pivot pins 64 and 46 to lower plate 44 from the collapsed position into its extended position, as shown in FIG. 3. Plate 44 pivots about pivot pin 40 away from constraining member 34 to lie across a section of tissue 100 in the intended path of the curved needle 20. When plate 44 is in the extended position, it presses gently against the tissue and holds, or stabilizes, the tissue in position. The needle 20 is deployed from needle channel 38, whereupon, it assumes its unconstrained, preformed configuration, such as the arced shape shown.

[0050] The tip 24 of needle 20 punctures the proximal side 100 of the patient's tissue at a first puncture site 84 and passes through the tissue to the distal side 102, and curves around to puncture the distal side 102 of the tissue at a second puncture site 86, going back through the tissue in a proximal direction to the proximal side 100, as shown in FIG. 4. Having plate 44 in the extended position on the proximal side 100 of the tissue holds the tissue in position so that the tissue doesn't buckle or ripple and the second puncture 86 occurs at the intended site. The curved needle 20 passes through opening 48 in plate 44, as shown in FIG. 5, pulling the suture material 12, which is attached through the eye 22 of needle 20, through the first and second puncture sites 84, 86. The suture material 12 is guided and separated by the indented sections 52 of opening 48.

[0051] The needle 20 is withdrawn back into needle channel 38, back through the second and then the first puncture sites 84, 86. As the needle 20 is pulled into channel 38, it is deformed into the constrained configuration.

[0052] Referring to FIG. 7, a suturing procedure is shown schematically that makes advantageous use of the needle delivery device 10 of the present invention. As described above, the needle 20 is directed through a first working channel of an endoscope (not shown) in the distal direction to an internal patient site having tissue in need of suturing and positioned on and passes through the tissue at the desired first puncture site 84. Continued advancement of the portion of needle 20 that remains in the needle channel 38 in the distal direction, causes the tip and trailing arc of the unconstrained curve of the needle 20 to move back through the tissue in

the proximal direction, through second puncture site 86, as shown in FIG. 7a. The suture is shown passing through the first and second puncture sites 84, 86. Although not shown in detail in the schematic of FIG. 7, the plate 44 will be in its extended position, on tissue 100 to stabilize the tissue against buckling or rippling or movement away from the path of the needle 20.

[0053] As shown in FIG. 7b, a grasper 80 or similar tool that can grasp and hold the suture 12, without damaging it, would be passed through a second working channel of an endoscope (not shown) or through another canula to the internal patient site. The jaws 82 of grasper 80 grasp the suture 12 at a location proximal to the second puncture site 86, preferably between the second puncture site 86 and the eye 22 of needle 20. Referring to FIG. 7c, the grasper 80 pulls the suture 12 proximally, away from the needle 20 to begin the creation of a loop 14 of suture 12. The needle 20 and a retained section of suture 16 are drawn proximally back into the needle channel 38 while the grasper 80 holds the now completely formed suture loop 14. As the needle 20 is drawn back, as shown in FIG. 7d, the curved needle 20 withdraws distally through the second puncture site 86 and through the first puncture site 84 to the needle channel 38. The grasped loop 14 remains on the proximal side 100 of the tissue.

[0054] At this stage, the surgeon or practitioner, at his or her option, can either (i) complete a single suture stitch 88 by tying the suture material of loop 14 held by the grasper 80, then cutting the tied suture material 12, and moving the plate 44 into the collapsed position, as shown in FIG. 6 for a second single stitch (and any number of additional stitches deemed necessary or desirable by the surgeon or practitioner), or, as shown in FIGS. 7e and 7 f, (ii) continue the first stitch by moving the plate 44 of the needle delivery device 10 laterally and passing the tip 24 of needle 20 and the retained suture material 16 through the loop 14 of the suture material 12 held by the grasper 80 and on to the proximal side 100 of the tissue at a third puncture site 94.

[0055] The needle 20 is advanced distally out of the needle channel 20 to make the third puncture at the third puncture site 94 and form the second stitch 98. As the needle 20 advances, it assumes the unconstrained, arc configuration and the tip 24 and trailing arc of needle 20 curve back in the proximal direction, pulling the retained suture 16 with it to puncture the distal side

102 of the tissue at the fourth puncture site 96, as shown in FIG. 7g, forming a third stitch 92. By passing the retained suture section 16 through the loop 14 held by grasper 80, the second stitch 98 is linked by the continuous length of suture 12 to the first stitch 88, tying it into place. To continue the chain stitch further, the jaws 82 of grasper 80 pull the suture 12 as shown in FIGS. 7b –d and the needle delivery guide 10 is moved laterally to create another puncture and another stitch as shown in FIGS 7e-g, linking and tying the third and subsequent stitches.

[0056] The steps are repeated until a desired area of the tissue at the internal patient site is sutured, either in a series of single stitches or in a continuous stitch, such as the chain stitch just described. When the stitching is complete, the needle 20 is withdrawn into needle channel 38 into its constrained configuration. Positioning bar 60 is pulled proximally, so that plate 44 is moved into its collapsed position against the side of delivery guide 32. The needle delivery device 10 is withdrawn from the patient site, for example proximally through the working channel of the endoscope or canula.

[0057] The devices disclosed herein can be designed to be disposed of after a single use, or they can be designed to be used multiple times. In either case, however, the device can be reconditioned for reuse after at least one use. Reconditioning can include any combination of the steps of disassembly of the device, followed by cleaning or replacement of particular pieces, and subsequent reassembly. In particular, the device can be disassembled, and any number of the particular pieces or parts of the device can be selectively replaced or removed in any combination. Upon cleaning and/or replacement of particular parts, the device can be reassembled for subsequent use either at a reconditioning facility, or by a surgical team immediately prior to a surgical procedure. Those skilled in the art will appreciate that reconditioning of a device can utilize a variety of techniques for disassembly, cleaning/replacement, and reassembly. Use of such techniques, and the resulting reconditioned device, are all within the scope of the present invention.

[0058] Preferably, the various embodiments of the invention described herein will be processed before patient use. First, a new or used instrument, in this case, a needle delivery device is obtained and if necessary, cleaned. The needle delivery device can then be sterilized by

any suitable known sterilization technique. This can be done by any number of ways known to those skilled in the art including beta or gamma radiation, ethylene oxide, or steam. In one sterilization technique, the needle delivery device is placed in a closed and sealed container, such as a plastic or TYVEK bag. The container and instruments are then placed in a field of radiation that can penetrate the container, such as gamma radiation, x-rays, or high-energy electrons. The radiation kills bacteria on the instruments and in the container. The sterilized instruments can then be stored in the sterile container. The sealed container keeps the deployment device and anchors sterile until it is opened in the medical facility.

[0059] In summary, numerous benefits are apparent which result from employing the concepts of the invention. The foregoing description of one or more embodiments of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise form disclosed. Obvious modifications or variations are possible in light of the above teachings. The embodiments were chosen and described in order to best illustrate the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to best utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. It is intended that the scope of the invention be limited only by the claims appended hereto.

Claims:

1. A needle delivery device comprising:

a needle for holding suture material and being made of a shape memory alloy preformed in an unconstrained configuration;

a needle delivery guide having a needle channel for passage of the needle therethrough, a distal end and a proximal end, said needle channel defining a longitudinal axis and being configured to hold the needle in a constrained configuration;

a suturing guide connected to the delivery guide; and,

a positioning member for moving the suturing guide between an extended position and a collapsed position, wherein, in said extended position the suturing guide is configured to guide the needle in the unconstrained configuration thereof.

2. The needle delivery device recited in claim 1 wherein the needle channel of the needle delivery guide is defined by an elongate member and a pair of constraining members extending axially from the elongate member at the distal end of the delivery guide.

3. The needle delivery device recited in claim 2 wherein at least a portion of the pair of constraining members is rigid.

4. The needle delivery device recited in claim 2 wherein the elongate member is flexible.

5. The needle delivery device recited in claim 2 wherein the suturing guide is a plate pivotally attached at a first end to one member of said pair of constraining members, and pivotally attached at an opposing second end to the positioning member, said plate defining an opening for receiving the needle in the unconstrained configuration thereof.

6. The needle delivery device recited in claim 5 wherein the plate further defines an access opening for access to the suture material.

7. The needle delivery device recited in claim 5 wherein the positioning member comprises a rod having a distal end pivotally connected to the second end of the plate and a proximal end slidably connected to the elongate member.

8. The needle delivery device recited in claim 7 wherein the positioning member further comprises an elongate rail positioned along a portion of the length of the elongate member and a bracket pivotally connected to the proximal end of the rod for sliding engagement with the rail to move the plate between the collapsed position in which the bracket slides proximally along the rail to pivot the plate toward the elongate member and the extended position in which the bracket slides distally along the rail to move the plate away from the elongate member.

9. The needle delivery device recited in claim 8 wherein the constraining members have a longitudinal axis and the extended position of the plate is transverse to the longitudinal axis of the constraining members.

10. The needle delivery device recited in claim 2 wherein the elongate member is configured for passage through a first working channel of an endoscope.

11. The needle delivery device recited in claim 10 further comprising means positioned at the proximal end of the needle delivery guide operatively connected to the positioning member for effecting the movement of the suturing guide.

12. The needle delivery device recited in claim 1 wherein, in the extended position, the suturing guide is positioned to lie on tissue, in use, to stabilize the tissue during suturing thereof.

13. The needle delivery device recited in claim 1 wherein, in the collapsed position, the suturing guide is positioned adjacent the needle delivery guide.

14. The needle delivery device recited in claim 1 wherein the preformed unconstrained configuration of the needle is an arc.

15. The needle delivery device recited in claim 1 wherein, in the preformed unconstrained configuration, the needle is a curved needle.

16. The needle delivery device recited in claim 15 wherein the needle has an eye for holding suture material positioned at the leading tip of the curved needle.

17. The needle delivery device recited in claim 1 wherein the constrained configuration of the needle is substantially axial relative to the longitudinal axis of the needle channel.

18. The needle delivery device recited in claim 1 wherein the shape memory alloy is a Ni--Ti alloy.

19. An endoscopic suturing method comprising:

a.) directing a needle delivery device through a first working channel of an endoscope in the distal direction to an internal patient site having tissue in need of suturing, said needle delivery device comprising:

a needle having an eye therein through which a length of suture material is attached, the needle being made of a shape memory alloy preformed in a curved configuration;

a needle delivery guide having a needle channel for passage of the needle therethrough, a distal end and a proximal end, the needle channel having a longitudinal axis and being configured to hold the needle in a constrained, substantially axial configuration relative to the axis of the needle channel;

a suturing plate pivotally connected to the delivery guide and defining an opening therethrough and a lateral access path; and,

a positioning member for moving the suturing plate between an extended position and a collapsed position;

b.) positioning the distal end of the needle delivery guide on tissue at a first puncture site at the internal patient site;

c.) moving the suturing plate into the extended position;

d.) advancing the needle distally out of the needle channel whereupon the needle punctures the tissue at the first puncture site drawing the suture material through the first puncture site, and assumes the curved configuration as the needle leaves the needle channel;

e.) continuing to advance the needle distally out of the needle channel whereupon the curve of the curved needle directs the needle proximally to puncture the tissue at a second puncture site spaced from the first puncture site, drawing the suture material through the second puncture site and through the opening in the suture plate;

f.) directing a grasper distally through a second working channel of the endoscope to the internal patient site;

g.) grasping the suture material at a location proximal to the second puncture site;

h.) pulling the needle proximally into the needle channel while the grasper holds the suture material, whereupon the curved needle withdraws distally through the second puncture site and through the first puncture site to the needle channel and the grasped suture material forms a loop on the proximal side of the tissue;

i.) optionally (i) completing a single suture stitch, comprising tying the suture material held by the grasper and cutting the tied suture material, or (ii) continuing the stitch, comprising moving the needle delivery device laterally and directing the eye of the needle through the loop of the suture material held by the grasper and positioning the needle on tissue at a third puncture site at the internal patient site;

repeating steps d) through i) until a desired area of the tissue at the internal patient site is sutured; and,

moving the needle proximally into the needle channel and moving the suturing plate into the collapsed position.

20. A method comprising:

obtaining a surgical instrument, wherein the surgical instrument comprises a needle delivery device comprising:

a needle for holding suture material and being made of a shape memory alloy preformed in an unconstrained configuration;

a needle delivery guide having a needle channel for passage of the needle therethrough, a distal end and a proximal end, said needle channel having a longitudinal axis and being configured to hold the needle in a constrained configuration;

a suturing guide pivotally connected to the delivery guide; and,

a positioning member for moving the suturing guide between an extended position and a collapsed position, wherein, in said extended position the suturing guide is configured to guide the needle in the unconstrained configuration thereof and to enable access to the suture material;

sterilizing the surgical instrument; and

storing the surgical instrument in a sterile container.

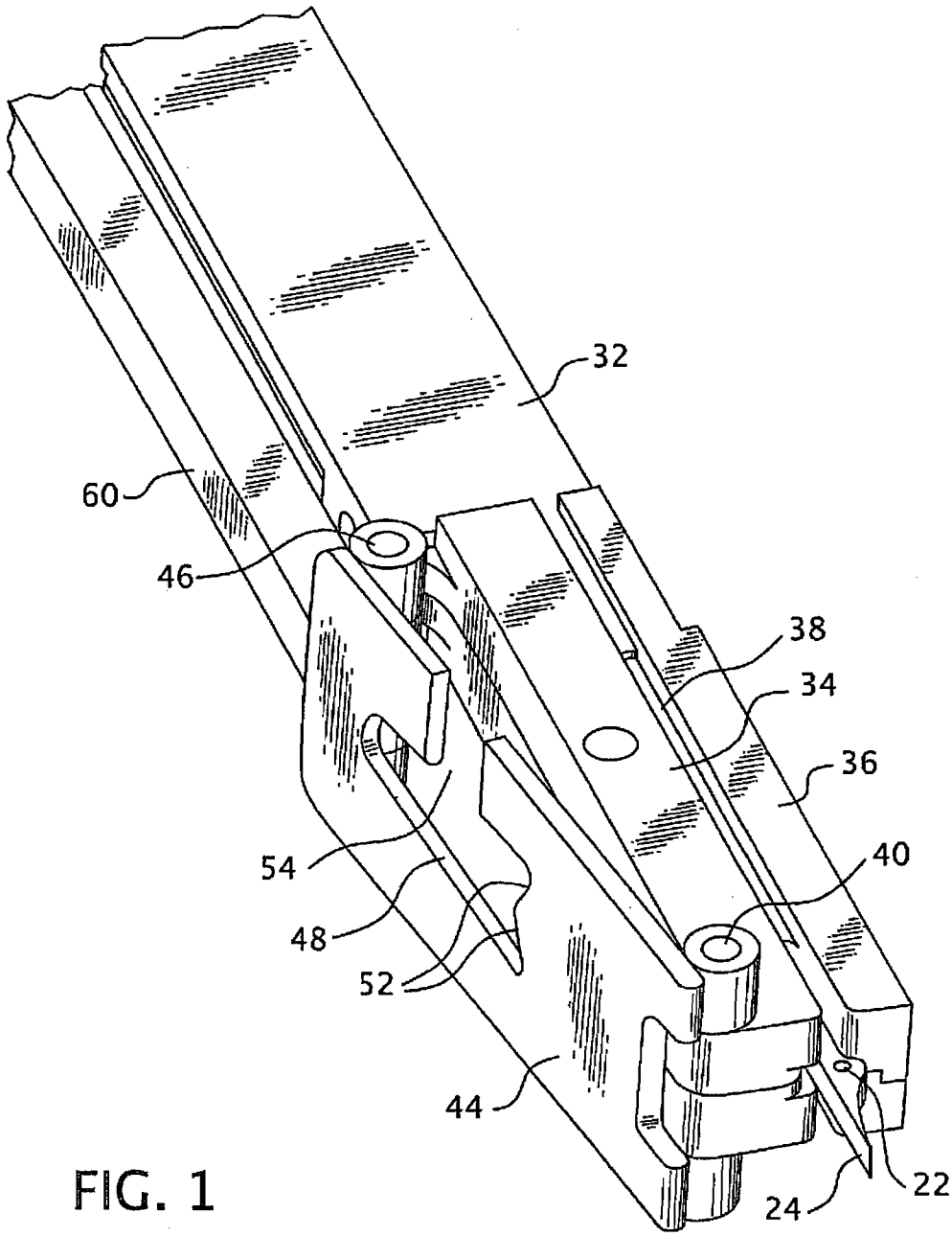

FIG. 1

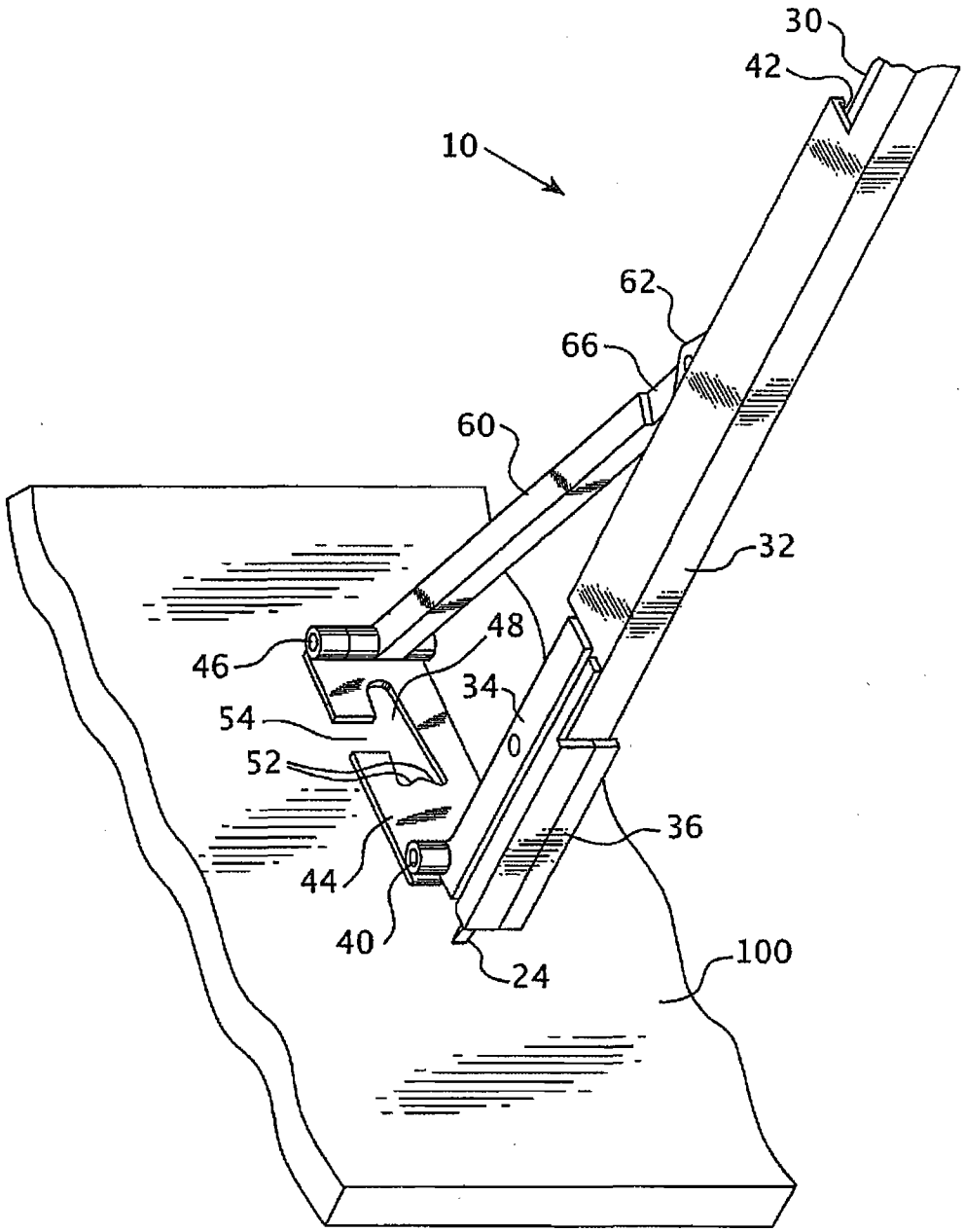

FIG. 2

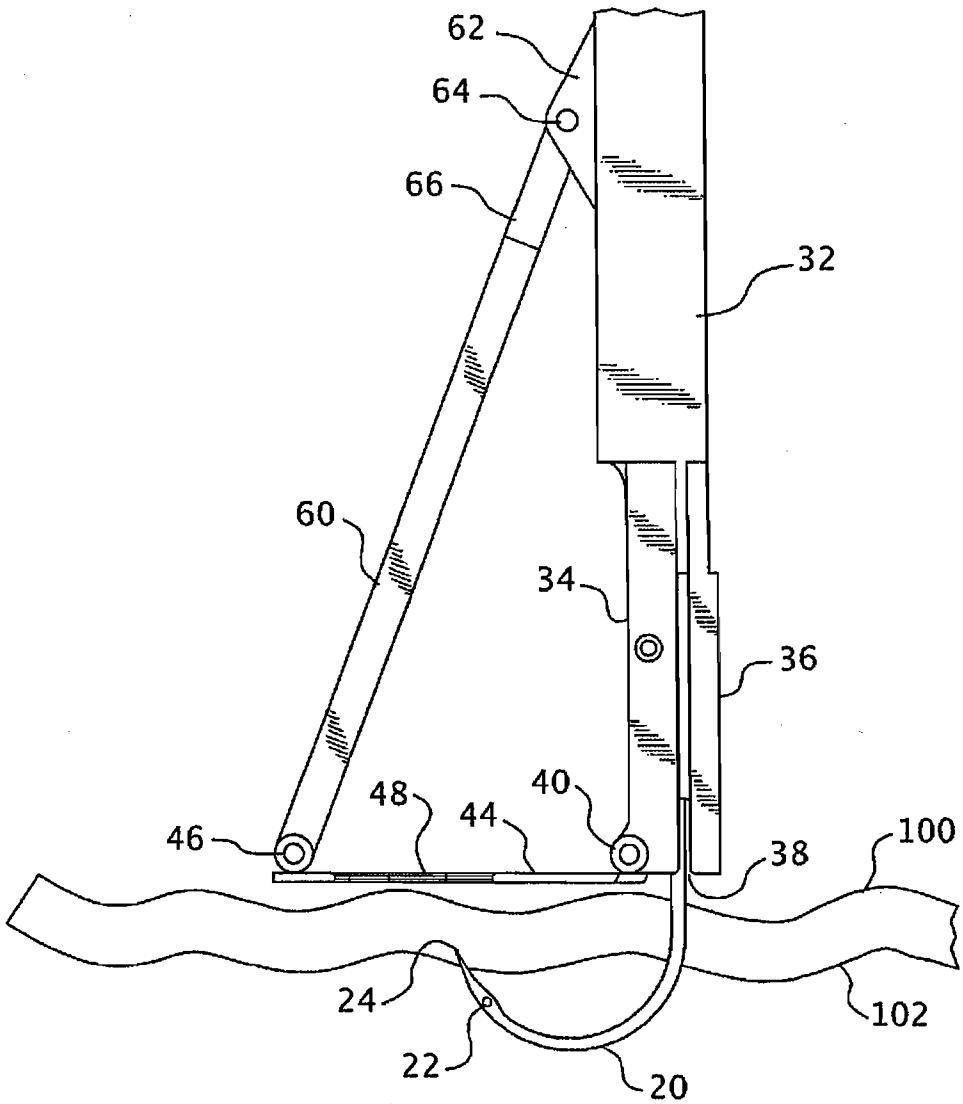

FIG. 3

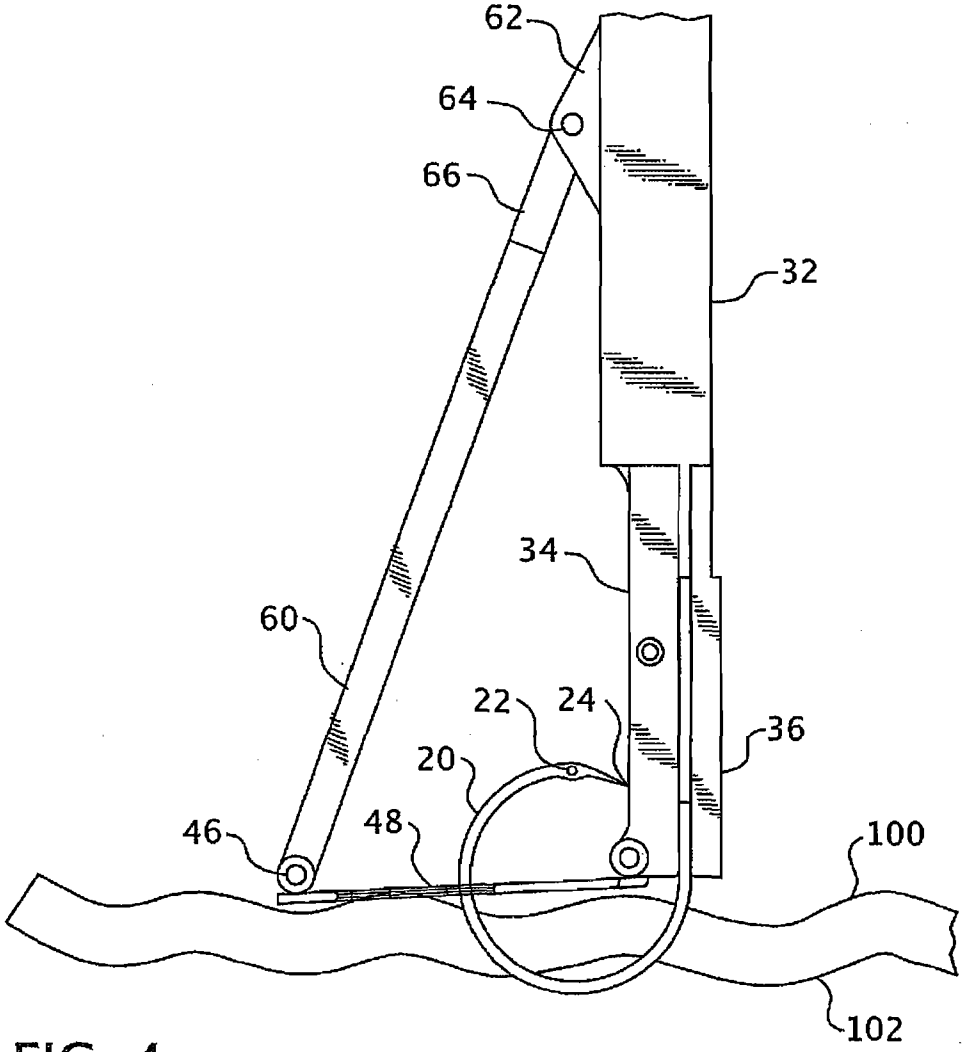

FIG. 4

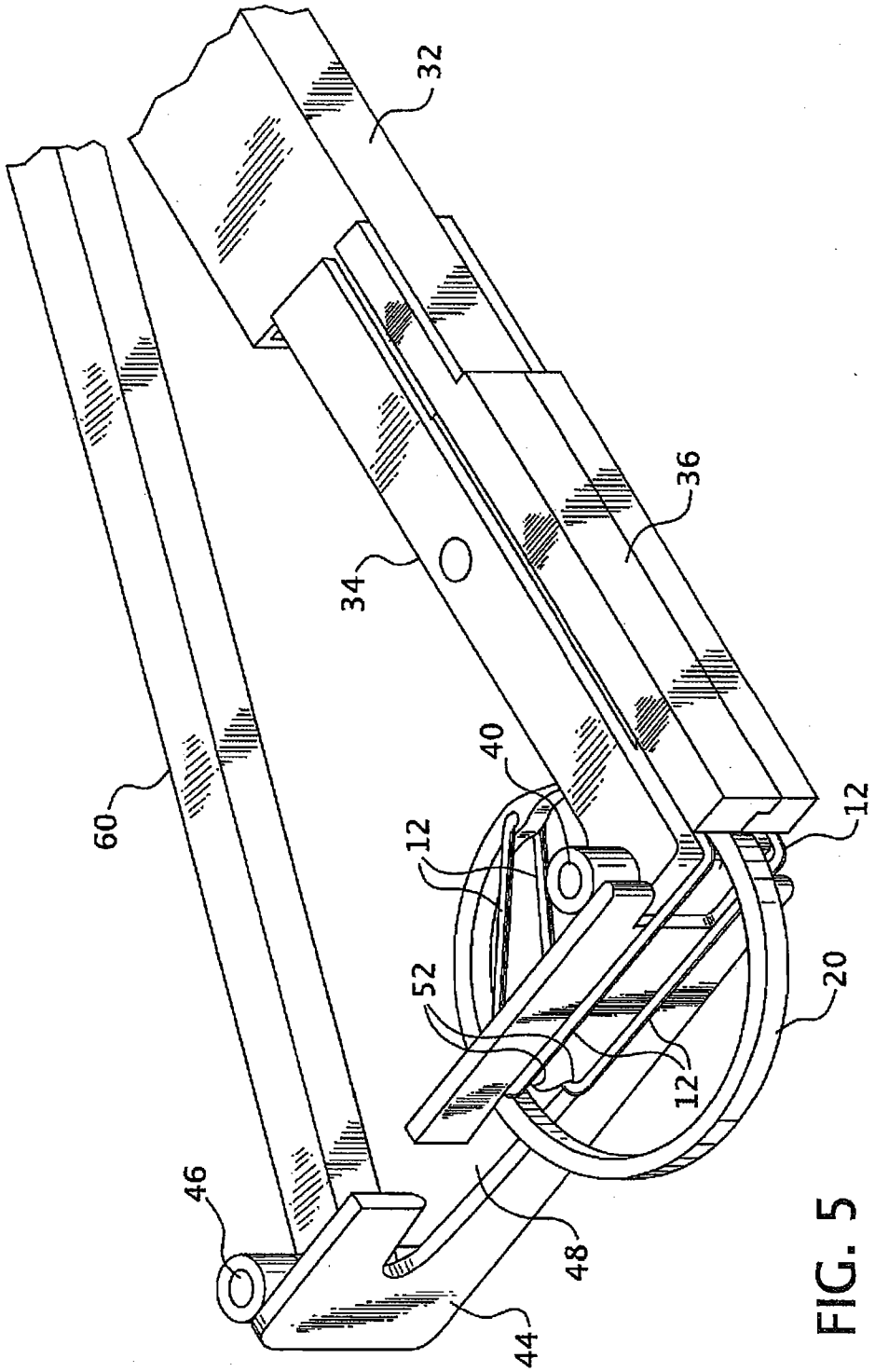

FIG. 5

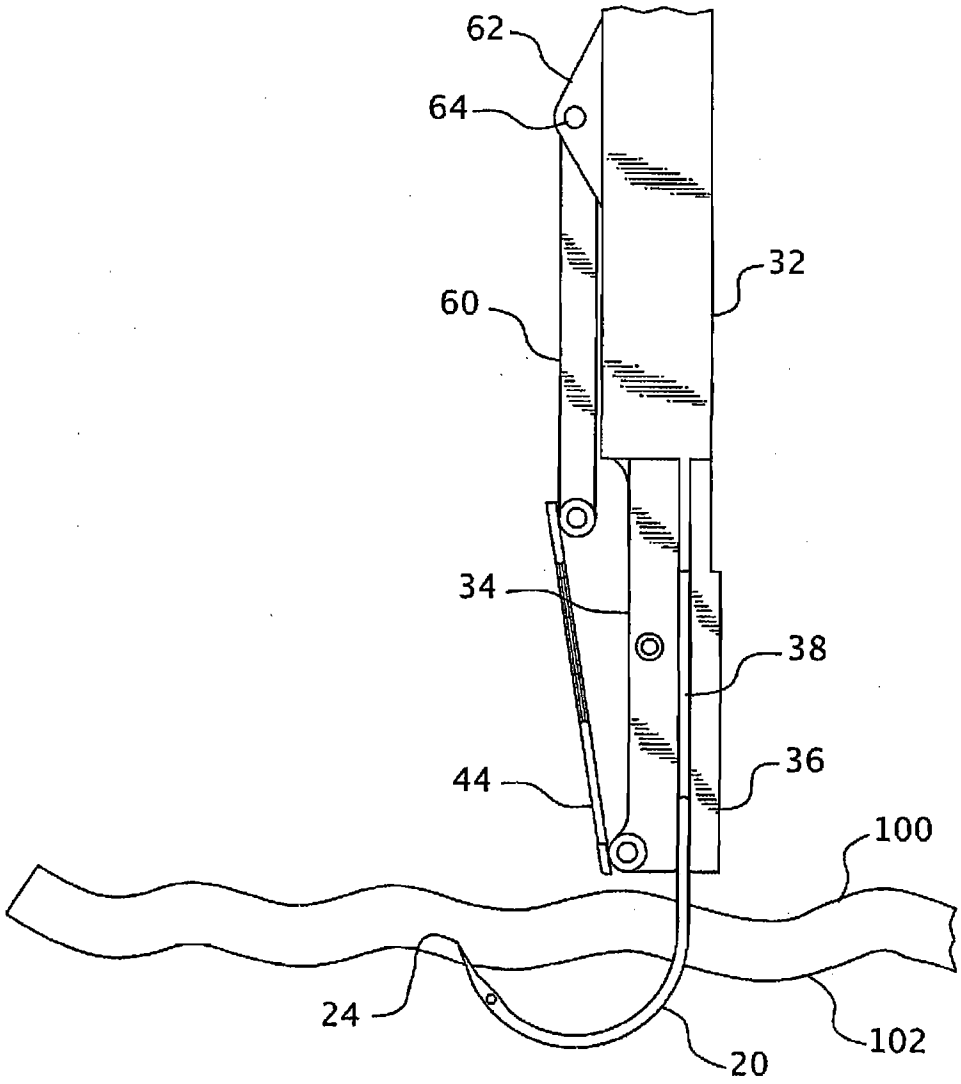

FIG. 6

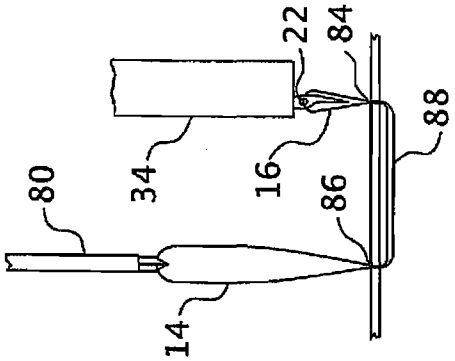

FIG. 7d

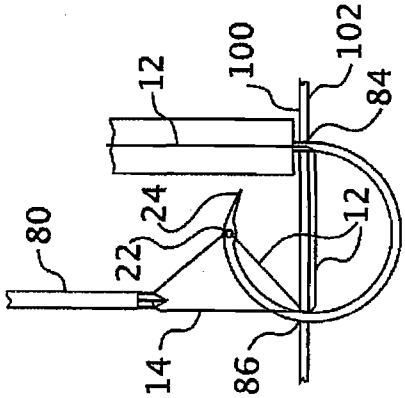

FIG. 7c

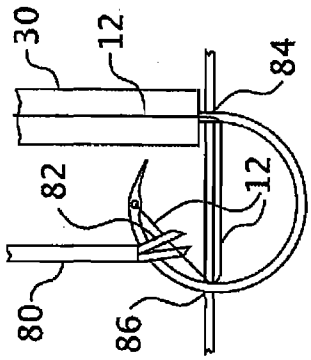

FIG. 7b

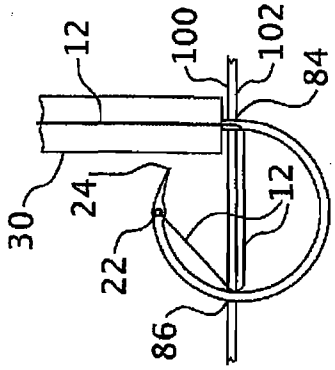

FIG. 7a

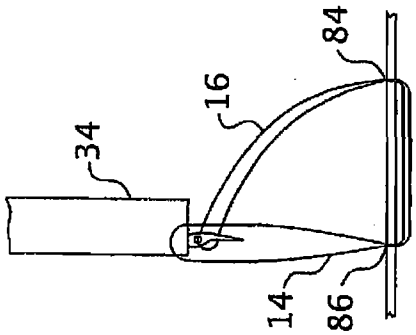

FIG. 7f

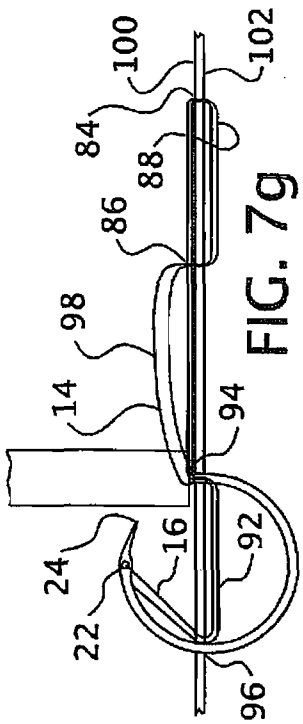

FIG. 7g

FIG. 7e

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/061269

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/04 A61B17/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/147456 A1 (DIDUCH ET AL.) 10 October 2002 (2002-10-10) abstract; figures 2a,2b,9a paragraphs [0038], [0054] - [0056], [0071]	1-4, 10-18,20
A	US 5 037 433 A (WILK ET AL.) 6 August 1991 (1991-08-06) abstract; figures column 1, line 53 - column 2, line 11 column 5, line 16 - column 6, line 17	1,2,10, 11,14-18
A	US 5 741 278 A (STEVENS) 21 April 1998 (1998-04-21) abstract; figures column 2, lines 1-63	1,14-18

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 September 2008	10/09/2008

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Giménez Burgos, R

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/061269

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2006/007399 A (SMITH & NEPHEW, INC.) 19 January 2006 (2006-01-19) abstract; figures	1,2,12, 13,18
A	US 2004/249394 A1 (MORRIS ET AL.) 9 December 2004 (2004-12-09) abstract; claims 1,7,8; figures	1,2, 12-18

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/061269

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

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

1. [X] Claims Nos.: 19
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

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

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2008/061269

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2002147456 A1	10-10-2002	US 2004010273 A1	15-01-2004
US 5037433 A	06-08-1991	AU 7901891 A	10-12-1991
		WO 9117712 A1	28-11-1991
US 5741278 A	21-04-1998	AU 3330395 A	07-03-1996
		WO 9604853 A1	22-02-1996
		US 5573542 A	12-11-1996
WO 2006007399 A	19-01-2006	AU 2005262460 A1	19-01-2006
		EP 1755461 A1	28-02-2007
		JP 2008503263 T	07-02-2008
US 2004249394 A1	09-12-2004	NONE	