(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
4 September 2008 (04.09.2008)

PCT

(10) International Publication Number
WO 2008/106583 A1

(51) International Patent Classification:
A61B 10/02 (2006.01)

(21) International Application Number:
PCT/US2008/055248

(22) International Filing Date:
28 February 2008 (28.02.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/892,174 28 February 2007 (28.02.2007) US

(71) Applicant: **SUROS SURGICAL SYSTEMS, INC.** [US/US]; Northwest Technology Center, 6100 Technology Center Drive, Indianapolis, IN 46278 (US).

(71) Applicants and
(72) Inventors: **HARDIN, Terry, D.** [US/US]; 1487 Spectrum, Irvine, CA 92618 (US). **MARK, Joseph, L.** [US/US]; 5154 N. Capitol Avenue, Indianapolis, IN 46208 (US). **HODGE, William, O.** [US/US]; 3272 W. 600 N., Greenfield, IN 46140 (US). **NICOSON, Zachary, R.** [US/US]; 6149 Primrose Avenue, Indianapolis, IN 46220 (US). **MILLER, Michael, E.** [US/US]; 4560 West Woodpecker, Trafalgar, IN 46181 (US).

(74) Agent: **MURPHY, Kristin, L.**; Rader, Fishman & Grauer PLLC, 39533 Woodward Avenue, Suite 140, Bloomfield Hills, MI 48304 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

(54) Title: VACUUM ASSISTED BIOPSY DEVICE

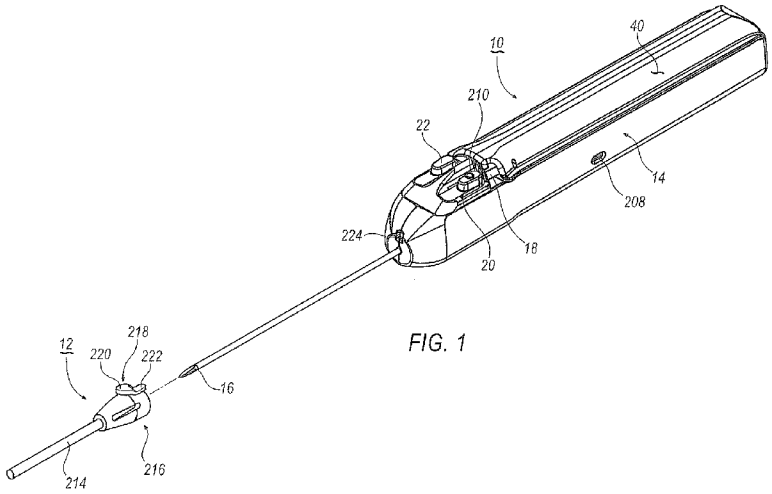

FIG. 1

(57) Abstract: A biopsy device is disclosed that comprises a cutting element mounted to a handpiece and a vacuum chamber. The cutting element comprises a stylet assembly and an outer cannula assembly. The stylet assembly includes a stylet that includes an open proximal end and a tissue opening at a distal end thereof. The tissue receiving opening is in communication with a lumen extending through the stylet. The outer cannula assembly includes an outer cannula that is slidably mounted over the stylet and has an open distal end with a cutting edge formed thereon. The vacuum chamber is in communication with the lumen of the stylet. The stylet is selectively advanced distally outwardly with respect to outer cannula to expose the tissue opening to targeted tissue. The outer cannula is selectively advanced over the tissue opening to sever tissue, while vacuum is generated in the vacuum chamber and delivered to the tissue opening through the lumen. The vacuum causes tissue to be drawn into and maintained in the tissue opening while the outer cannula severs tissue to obtain a biopsy core.

WO 2008/106583 A1

VACUUM ASSISTED BIOPSY DEVICE

Cross-Reference to Related Applications

[0001] This application is a Continuation-in-part of U.S. Serial No. 11/389,274, which is a Continuation-in-Part of U.S. Serial No. 10/964,959 filed October 14, 2004 which claims priority to U.S. provisional patent application Serial No. 60/510,866 filed on October 14, 2003, the disclosures of which are incorporated herein by reference in their entireties. This application also claims priority to U.S. provisional patent application Serial No. 60/892,174, the contents of which are also incorporated herein by reference in its entirety.

Technical Field

[0002] The present disclosure generally relates to the field of tissue sampling and harvesting. More specifically, the disclosure relates to biopsy needle sets and devices.

Background

[0003] In the practice of diagnostic medicine, it is often necessary or desirable to perform a biopsy, or to sample selected tissue from a patient for medical evaluation. Cytological and histological studies of the biopsy sample can then be performed as an aid to the diagnosis and treatment of disease. Biopsies can be useful in diagnosing and treating various forms of cancer, as well as other diseases in which a localized area of affected tissue can be identified.

[0004] Biopsies are routinely performed on tissue using a needle set, which typically includes a stylet with a pointed tip and a notch defined near its distal end. The stylet is slidably disposed within a cannula so that the notch can be alternately exposed or covered. Such needle sets are used with or incorporated in various forms of biopsy devices, such as single action or double action biopsy devices.

[0005] More specifically, one known exemplary single action biopsy device includes a hollow needle. A stylet is slidingly disposed within the hollow needle lumen and is moveable relative to needle. A distal end of the stylet is provided with a tissue cutting-point and a tissue opening is positioned adjacent to the distal end for receiving tissue samples. The stylet is slidable relative to needle between a first or retracted position and a second or extended position.

[0006] In the first position, the stylet is retracted within the needle such that the needle covers the tissue opening. In the second position, the distal end of the stylet is extended away from the needle to expose the tissue opening to tissues at the biopsy site.

[0007] During a biopsy procedure, the device will be positioned within a cavity at a targeted site for the biopsy. The stylet is momentarily driven into the tissue and tissue then prolapses into the tissue opening. The needle is then advanced along the stylet to cover the tissue opening. This forward movement of needle severs the prolapsed tissue to obtain a tissue sample, which becomes trapped in tissue opening of the stylet. With the needle 22 blocking the opening of tissue opening, the biopsy device is then withdrawn from the target site, carrying the sample within tissue opening. To collect the biopsy sample, the needle is once again retracted to expose tissue opening of the stylet. The procedure may be repeated several times until satisfactory samples have been obtained.

[0008] While single and double action biopsy devices are widely used, a basic problem remains in the field of biopsy, which is the need to obtain a sufficient amount of sample tissue. One potential cause of the problem is that as the needle passes over the tissue opening, the needle has a tendency to push the tissue away from the tissue opening. This results in samples that are inferior in quality or too small, which precludes the pathologist from conclusively determining whether disease is present, and if so, to what extent it has progressed. The pathologist must then issue an inconclusive diagnostic report. This causes the physician to recall the patient and attempt another needle biopsy, or in some situations, the patient is scheduled for a more invasive, traumatic and expensive procedure such as an open surgical biopsy.

[0009] The challenge has been to consistently obtain sufficient tissue volume and quality tissue cores, regardless of tissue type, to meet the needs of the pathologist so that a conclusive diagnosis can be achieved.

Summary

[0010] A biopsy device is disclosed that comprises a cutting element mounted to a handpiece and a vacuum chamber. The cutting element comprises a stylet assembly and an outer cannula assembly. The stylet assembly includes a stylet that includes an open proximal end and a tissue opening at a distal end thereof. The tissue receiving opening is in communication with a lumen extending through the stylet. The outer cannula assembly includes an outer cannula that is slidably mounted over the stylet and has an open distal end

with a cutting edge formed thereon. The vacuum chamber is in communication with the lumen of the stylet. The stylet is selectively advanced distally outwardly with respect to outer cannula to expose the tissue opening to targeted tissue. The outer cannula is selectively advanced over the tissue opening to sever tissue, while vacuum is generated in the vacuum chamber and delivered to the tissue opening through the lumen. The vacuum causes tissue to be drawn into and maintained in the tissue opening while the outer cannula severs tissue to obtain a biopsy core. A method of using the biopsy device is also disclosed.

Brief Description of the Drawings

[0011] Embodiments of the disclosure will now be described, by way of example, with reference to the accompanying drawings, wherein:

[0012] FIG. 1 is a perspective view of a biopsy device assembly, including a biopsy device and an introducer assembly.

[0013] FIG. 2 is an exploded view of the biopsy device of FIG. 1.

[0014] FIG. 3 is a perspective view of the underside of a pickup carriage assembly for use with the biopsy device.

[0015] FIG. 4 is an exploded view of the pickup carriage assembly, illustrating a moveable cam member and a spring member that attaches to a top surface of the pickup carriage.

[0016] FIG. 5 is a perspective view of the underside of the pickup carriage.

[0017] FIG. 6 is a perspective view of the moveable cam member.

[0018] FIG. 7 is a perspective view of a stylet and vacuum hub assembly.

[0019] FIG. 8 is a perspective view of the stylet and vacuum hub assembly of Fig. 7 with a vacuum chamber enclosure member attached and a cutting cannula assembly attached.

[0020] FIG. 9 is a perspective view of the cutting cannula assembly of Fig. 8.

[0021] FIG. 10 is a perspective view of one embodiment of a resilient bridge member.

[0022] FIG. 11 is a partial cut-away perspective view of the biopsy device with the introducer assembly attached to the front portion thereof.

[0023] FIG. 12 is a partial cut-away side elevational view of the biopsy device after a release latch has been activated and an actuating lever has been released (note that the bridge member of FIG. 10 has been omitted for clarity).

[0024] FIG. 13 is a side elevational view of the biopsy device after the actuating lever has been depressed a first time, thereby retracting a piston.

[0025] FIG. 14 is a side elevational view of the biopsy device after the actuating lever has been depressed a second time, thereby retracting the cutting cannula.

[0026] FIG. 15 is a side elevational view of the biopsy device after the actuating lever has been depressed a third time, thereby retracting the stylet into the cutting cannula.

[0027] FIG. 16 is a side elevational view of the biopsy device after the stylet has been fired away from a housing of the biopsy device.

[0028] FIG. 17 is a side elevational view of the biopsy device after the cutting cannula has been fired forward over the tissue receiving opening of the stylet.

[0029] FIG. 18 is a side elevational view of the biopsy device after the release latch has been released (note that the bridge member of FIG. 10 has been omitted for clarity).

[0030] FIG. 19 is a side elevational view of the biopsy device after the vacuum chamber has been retracted.

[0031] FIG. 20 is a side elevational view of the biopsy device after the cutting cannula has been retracted so as to expose the tissue receiving opening to permit tissue cores to be removed from the tissue receiving opening.

[0032] FIG. 21A-21D are various views of a valve member.

Detailed Description

[0033] Referring now to the drawings, preferred illustrative embodiments are shown in detail. Although the drawings represent some embodiments, the drawings are not necessarily to scale and certain features may be exaggerated, removed, or partially sectioned to better illustrate and explain the present disclosure. Further, the embodiments set forth herein are not intended to be exhaustive or otherwise limit or restrict the claims to the precise forms and configurations shown in the drawings and disclosed in the following detailed description.

[0034] Referring to FIG. 1, a perspective view of an exemplary biopsy device 10 in accordance with the present disclosure is illustrated. A separate and optional introducer assembly 12 is also illustrated.

[0035] As shown, biopsy device 10 is a handheld device and includes a housing 14 to which a stylet 16 is attached. Biopsy device 10 includes several release members 18, 20, and 22, to be explained in further detail below.

[0036] Referring to FIG. 2, an exploded view of biopsy device 10 is illustrated. As shown, in the exemplary embodiment housing 14 is a two piece member, including a first housing member 14a and a second housing member 14b. In one embodiment, first and second

housing members 14a and 14b are configured snap together to house actuation components of biopsy device 10. For example, first housing member 14a includes one or more slot members 24 positioned on top and bottom portions of first housing member 14a. Slot members 24 cooperate with and receive latch members 26 that are positioned on top and bottom portions of second housing member 14b. An interior of housing 14 is generally hollow to receive the actuation components.

[0037] While housing 14 has been described as snapping together, it is also understood that first and second housing members 14 may alternatively be secured together using fastening elements.

[0038] A top portion of each housing member 14a and 14b includes a holder 28 for securing a portion of a resilient bridge member 30. Each holder 28 extends upwardly from the top portion 32 and includes a groove 34 (best seen in FIG. 12) that receives mounting knobs 36 of a mounting member 38 positioned on a first end 35 of resilient bridge member 30.

[0039] An actuating lever 40 is pivotally attached to housing 14 by pivot arm 42 at a proximal end 44 of biopsy device 10. A forward end 46 of actuating lever 40 may rise upwardly from a top surface of housing 14 due to pivot arm 42. A lever release assembly 48 that carries a release mechanism 18 is attached to actuating lever 40. Lever release assembly 48 includes a downwardly extending latch arm 46 that selectively engages with a portion of a retaining member 50 disposed on a cam member 52 carried by a pickup carriage 54 (shown in FIGS. 3-5). A spring mechanism 53 serves to bias release mechanism 18 to an actuation position.

[0040] Pickup carriage 54 includes a pair of holders 56 that extend upwardly from a top surface thereof. Housing 14 includes an open channel 58 formed in the top surface thereof. When pickup carriage 54 is positioned within housing 14, holders 56 extend through channel 58 (seen in FIG 12). Each holder 56 includes a groove 60 that receives a mounting knob 36 from a mounting member 38 positioned on a second end 62 of resilient bridge member 30.

[0041] Referring to FIG. 10, resilient bridge member 30 includes a plurality of sections that are separated by hinge members 64a and 64b. Hinge members 64a and 64b are created by V-shaped notches that form thinned sections.

[0042] First end 35 of resilient bridge member 30 is secured to holders 28 and second end 62 is secured to holders 56 such that resilient bridge member 30 is positioned directly below actuation lever 40 when biopsy device 10 is assembled. Due to the configuration of resilient bridge member 30, when actuation lever 40 is depressed, actuation lever 40 pushes down on

resilient bridge member 30. The pushing action flattens out resilient bridge member 30, thereby sliding pickup carriage member 54 away from a distal end of biopsy device 10.

[0043] Secured to a top portion of housing 14 is an actuation button carrier 66 that carries release mechanisms 20 and 22. Release mechanism 20 includes a downwardly extending latch arm 68 that extends downwardly into first housing member 14a though an opening 70 formed therein. As will be explained in further detail below, release mechanism 20 is actuated to release stylet 16. More specifically, an end of latch arm 68 is configured to grip a retaining arm 72 of stylet 16. When release mechanism 20 is depressed, the end of latch arm 68 is biased upwardly, thereby releasing its grip on retaining arm 72 of stylet 16 and permitting stylet to advance forward.

[0044] Release mechanism 22 also includes a downwardly extending latch arm (not shown). As will be explained n further detail below, the latch arm of release mechanism 22 releases an outer cutting cannula 74. More specifically, when release mechanism 22 is depressed, the end of the latch arm of release mechanism 22 is biased upwardly, thereby releasing outer cutting cannula 74 and permitting outer cannula 74 to advance forward.

[0045] Other components of biopsy device 10 includes a stylet assembly 76, an outer cannula assembly 78, a cam member assembly 80, a support rib 82, and a piston member 84. Each element will be discussed in turn below.

[0046] Stylet assembly 76 is shown in FIG. 7. Stylet assembly 76 includes stylet 16, a first arm sub-assembly 86, and a second arm sub-assembly 88. Stylet 16 extends between a distal end 90 and an open proximal end 92. Adjacent distal end 90 is a tissue opening 94. Distal end 90 may further include a trocar piercing tip 95. Stylet 76 further defines an inner lumen 96 that extends between tissue opening 94 and proximal end 92. Positioned adjacent proximal end 92 are first and second seal members 98, 100, respectively. First seal member 98 is attached a first cap member 102 that is attached to second arm sub-assembly 88. Second seal member 100 positioned adjacent to a chamber wall member 103, which is positioned adjacent second end cap 104. Second end cap 104 is fixedly secured to stylet 16. Second seal member 100 (see FIG. 2) is disposed between first end cap 102 and chamber wall member 103. Thus, first end cap 102, chamber wall member 103, and first and second seal members 98, 100 cooperate with a cylinder 106 to define a vacuum chamber 108, to be explained in further detail below.

[0047] A notch 110 is cut into stylet 16, between first end cap 102 and chamber wall member 103. Notch 110 is in communication with inner lumen 96, which, in turn, is in

communication with tissue opening 94. A one-way valve member 109 (to be discussed in further detail below) is attached to open proximal end 92 (see, e.g., FIG. 2).

[0048] First arm sub-assembly 86 includes is generally L-shaped and includes a leg member 112 and a carrier member 114. Carrier member 114 is fixedly secured to stylet 16. Carrier member 114 includes a fitting member 116 that cooperative engages a side of complimentary member 118 that is disposed on a carrier member 120 that is part of second arm sub-assembly 88.

[0049] Second arm sub-assembly 88 includes a long leg member 122 and a short leg member 124 that are connected together by carrier member 120. When assembled (and as best seen in FIG. 7), short leg member 124 is disposed beneath leg member 112 of first arm sub-assembly 86, with carrier member 114 being positioned above carrier member 120. First cap member 102 is attached to carrier member 120. First cap member 120 is fixedly secured to cylinder 106. Thus, as vacuum chamber 108 moves, so does second arm sub-assembly 88.

[0050] Referring to FIG. 9, outer cannula assembly 74 includes an outer cutting cannula 126 that is fixedly attached to an outer cannula hub 128 at its proximal end. Outer cannula hub 128 includes a positioning member 130 on one side and a retaining member 132 on another. Retaining member 132 includes a retaining finger 134. A distal end 136 of outer cannula 126 is sharpened to sever tissue.

[0051] Referring to FIG. 2, outer cannula assembly 74 is assembled to stylet assembly 76 as follows. First, a bumper member 138 is positioned over stylet 16 and into contact with a mounting face 140. Support rib 82 is next slid onto stylet 16. Support rib 82 (best seen in FIG. 2) includes first and second mounting grooves 142, 144. First mounting groove 142 is configured to receive short leg member 124 of second arm sub-assembly 86 and leg member 112 of first arm sub-assembly 86. Second mounting groove 144 is configured to receive long leg member 122 of second arm sub-assembly 86. An outwardly extending spring mount 146 is formed on support rib 82. A biasing member 148, such as a spring is positioned on spring mount 146. Outer cannula hub 128 includes a spring mount 150 that receives and end of biasing member 148.

[0052] Referring now to FIGS. 3-6, pickup carriage 54 and cam member 52 will be described. Pickup carriage 54 includes a first elongated groove 152 and a second shortened groove 154. A mounting hole 156 is positioned opposite second groove 154. An access opening 158.

[0053] Cam member 52 includes a mounting member 160 that is received within mounting hole 156. A first pivot member 162 from cam member 52 is positioned within first groove 152 of pickup carriage 54. A second pivot member 164 from cam member 52 (seen in FIG. 2) is positioned within second groove 154. Retaining member 50 is positioned on an end of cam member 52 and is received within access opening 158.

[0054] A biasing member 166 received on a mounting portion 168 of pickup carriage 54. A distal end 170 of biasing member 166 contacts first pivot member 162 and biases first pivot member 162 toward a first end 172 of first groove 152. Pickup carriage 54 may further include a tang member 174 that partially retains a portion of biasing member 166.

[0055] A proximal end 176 of pickup carriage 54 includes a mounting post 178. A biasing member 180 is received on mounting post 178. An end of biasing member 180 engages an internal wall 182 formed by first and second housing members 14a and 14b when pickup carriage 54 is installed therewithin. When pickup carriage 54 is installed, holders 56 are oriented to extend upwardly through channel 58 formed through housing 14. Cam member 52 is installed on a bottom surface 184 of pickup carriage 54 as shown in FIG. 3.

[0056] Referring to FIGS. 12-20, operation of biopsy device 10 will now be described. Assuming biopsy device 10 is packaged in the fired position (see FIG. 12), biopsy device 10 must first be moved into the cocked position. To move biopsy device 10 into the cocked position, first release latch 18 is actuated to release actuation lever 40 from housing 14 (see FIG. 12). Actuation lever 40 is then depressed, pushing down on bridge member 30, which is attached to holders 56 of pickup carriage 54. Accordingly, when bridge member 30 is depressed, pickup carriage 54 is moved toward proximal end 44 of biopsy device 10.

[0057] As pickup carriage 54 moves toward proximal end 44 of biopsy device 10, a first pickup member 186 contacts a first tang member 188 that is carried on carrier member 120 that is part of second arm sub-assembly 88, and retracts vacuum chamber 108 proximally, as shown in FIG. 13. A first piston spring member 190 that is at least partially positioned over vacuum chamber 108, is compressed between a proximal face 192 of carrier member 120 and a first lower internal face 194 positioned within housing 14. A second spring member 196 is compressed between second end cap 104 and a second lower internal face 198 positioned within housing 14. This action also collapses the vacuum chamber 108, moving first end cap 102 towards chamber wall member 103. Air within vacuum chamber 108 is directed out through seal member 109 that is secured to proximal end 92 of stylet 16.

[0058] In one embodiment, seal member 109 is a configured as a duck-bill style valve member 109 (FIG. 2). Valve member 109 includes a body member 103 having an open distal end 105 that is connected to a tapered, duck bill, normally closed proximal end 107. Proximal end 107 includes a slit which is forced open when positive pressure is generated within stylet 16. Open distal end 105 is secured to proximal end 92 of stylet 16.

[0059] An alternative embodiment of seal member 109' is shown in FIGS. 21A-21D. Seal member 109' includes a body member 111 having an open distal end 119 and a normally closed proximal end. Adjacent to the proximal end of seal member 109' is a slit 113 that cooperates with a land member 115 to form a flap member 117. Slit 113 extends along a substantial portion of body member 111 such that land member 115 acts as a hinge for flap member 117. In operation, as positive pressure is generated within the system, flap member 117 will be forced open.

[0060] Spring member 180 biases pickup carriage 54 back toward a distal end of biopsy device 10. Actuation lever 40 is depressed again. The second depression of actuation lever 40 causes pickup carriage 54 to move in the proximal direction again. As pickup carriage 54 moves, a second pickup member 200 positioned on cam member 54 contacts a second tang member 202 that is carried on outer cannula hub 128. Such action retracts outer cannula assembly 74, moving distal end 136 thereof away from distal end 90 of stylet 16. Retaining member 132 is compressed inwardly until retaining finger 134 grips an internal ledge (not shown) formed in first housing member 14a. Retraction of outer cannula assembly 74 causes biasing member 148 to compress between a proximal face 204 of outer cannula hub 128 and a distal face 206 of support rib 82.

[0061] Spring member 180 biases pickup carriage 54 once again and actuation lever 40 is depressed a third time. The third depression of actuation lever 40 causes pickup carriage 54 to move proximally once again. As pick up carriage 54 moves proximally, first pickup member 186 engages with fitting member 116 that is carried on carrier member 114 of first arm sub-assembly 86 and pulls first arm sub-assembly 86 towards second arm sub-assembly 88. Once carrier 114 of first arm sub-assembly 86 reaches carrier 120 of second arm sub-assembly 88, stylet 16 is pulled into outer cannula 126 and stylet 16 is locked into the cocked position. On the third depression, actuation lever 40 locks down and latch release assembly 48 retains lever 40 against housing 14 (see FIG. 15), thereby providing a tactile indicator that biopsy device is in the cocked position.

Biopsy device may also include a visual indicator to indicate that biopsy device 10 is in the cocked position. In one embodiment, at least leg member 112 of first arm sub-assembly 86 may be constructed of a particular color that is different than the color of housing 14 and that will be visible through a window 208 only when biopsy device 10 is in the cocked position. For example, leg member 112 may be formed from a green material such that a portion of the green material is visible through window 208 when biopsy device 10 is in the cocked position so as to be in the "biopsy ready position." In contrast, when stylet 16 is in a non biopsy ready position, leg member 112 will be positioned away from indicator window 208.

[0062] Once in the cocked position, or biopsy ready position, a biopsy may be performed. The operation will now be explained.

[0063] Typically, before a biopsy is performed, a targeted area must be identified. Any suitable method may be used to identify a targeted area for biopsy. Such methods include, but are not limited to, the methods and use of the devices described in co-pending application 10/649,068, the contents of which are incorporated herein by reference in its entirety.

[0064] Next, the entry site is prepared, as required (such as applying anesthesia, cleaning the biopsy area, etc.). During this step, an introducer assembly 12 (see FIG. 1) may be positioned over outer cannula 112 to provide a pathway to the target area. Introducer assembly 12 will be explained in further detail below.

[0065] Next, a tip of stylet 16 is placed at the targeted area. In one embodiment, stylet 16 may be fired prior to inserting biopsy device 10 into the patient. In another embodiment, stylet 16 is not fired until after biopsy device 10 is inserted into the patient. In one embodiment, the position and orientation of biopsy device 10 is maintained during the firing process.

[0066] A stylet release or firing member 20 is depressed, thereby releasing stylet assembly 76 from its cocked position into the fired position (FIG. 16). Such action exposes tissue opening 94 into which tissue may prolapse. Tissue receiving opening 94 is connected to inner lumen 96. Inner lumen 96 is connected to vacuum chamber 108.

[0067] To differentiate between stylet release member 20 and an outer cannula release member 22, stylet release member 20 may be a different color than housing 14 or outer cannula release member 22 (to be described below) to allow a user to visually differentiate between the two release members. In one embodiment, one of stylet and outer cannula release members 20, 22 may alternatively include a tactile indicator, such as a raised bump

210 on the release member, to allow a user to feel the differences between the two release members (see, e.g., FIGS. 1 and 11).

[0068] After stylet release member 20 is actuated, outer cannula release member 22 is then actuated. This action will release outer cannula assembly 78. Outer cannula assembly 78 is forced over stylet 16 by biasing members/springs 148, 190, and 196, such that outer cannula assembly 78 rapidly fires forward. As outer cannula assembly 78 is fired forward, vacuum chamber 108 is expanded so as to create a vacuum by drawing air through tissue opening 94 and lumen 96, and entering into vacuum chamber 108 through notch 110. A further explanation of the vacuum chamber may be found in commonly owned and co-pending U.S. application no. 11/389,274, the contents of which are incorporated herein by reference in its entirety.

[0069] In one embodiment (not shown), a vacuum valve having a slit that creates a flap may be provided that selectively covers the notch. When stylet 16 is fired forward, positive pressure generated inside vacuum chamber 108 closes the valve flap to prevent pressure from reaching the inside of lumen 96. When outer cannula 74 fires forward, the negative pressure inside vacuum chamber 108 opens the valve, allowing vacuum to be delivered to tissue opening 94 in stylet 16, through lumen 96.

[0070] As outer cannula assembly 78 is fired and vacuum is generated by the expansion of vacuum chamber 108, the vacuum biases tissue toward tissue opening 94 and holds tissue in place while outer cannula 74 slides over tissue opening 94. As outer cannula 74 slides, sharpened distal end 136 slices through the tissue, thereby severing the tissue so as to leave a biopsy core 212 within tissue opening 94.

[0071] Once biopsy core 212 is acquired, to retrieve biopsy core 212 from biopsy device 10, biopsy device 10 is removed from the patient. If an introducer assembly 12 is used, it is kept in position within the patient. Once removed from the patient, release member 18 is depressed once again to release latch member 26. Latch member 26 is depressed twice to pull back outer cannula 74 so as to expose tissue opening 94 (see FIGS. 18-20) and biopsy core 212. To obtain additional biopsy cores 212, the latch member 26 is depressed a third time (Fig. 20) to retract stylet 16 into the biopsy ready position.

[0072] Referring to FIGS. 1 and 11, introducer assembly 12 will now be explained. Introducer assembly 12 includes an introducer cannula 214 that is fixedly connected to an introducer hub 216. Introducer cannula 214 is hollow and is sized to slide over outer cannula 74 so as to be spaced proximally from distal end of outer cannula 74. Introducer hub 216

may include a normally closed valve (not shown) and includes an opening that is in communication with introducer cannula 214. Disposed on introducer hub 216 is a selectively releasable latch member 218 that includes a connecting member 220 and a releasing member 222. Releasing member 222 is received within an opening 224 to secure introducer assembly 12 to biopsy device 10.

[0073] In operation, introducer assembly 12 is positioned over outer cannula 74 and slid along outer cannula 74 until connecting member 220 of latch member 218 is received within opening 224, thereby connecting introducer assembly 12 to biopsy device 10. Introducer assembly 12 may be connected to biopsy device 10 either before or after biopsy device is placed in the biopsy ready position. Once connected, biopsy device 10 is inserted into the patient with introducer cannula 214. Introducer cannula 214 operates to maintain a pathway to the biopsy site.

[0074] Once biopsy cores 212 are taken, biopsy device 10 may be detached from introducer assembly 12 by depressing releasing member 222 such that connecting member 220 is released from opening 224. Once freed, introducer cannula 214 remains within the patient's body, to maintain the pathway to the biopsy site. Use of introducer assembly 12 minimizes trauma to the patient and eliminates the need for multiple reinsertions of biopsy device 10, as well as permits access to the biopsy site for treatment and other post biopsy activities. As such, after the biopsy cores 212 are removed from tissue opening 94, biopsy device 10 may be reinserted into introducer cannula 214 to take addition biopsy cores 212.

[0075] Alternatively, if desired, a biopsy marker (not shown) may be deployed into the biopsy cavity after biopsy cores 212 have been taken. In such a case, a site marker deployment device may be inserted within introducer assembly 12 after biopsy device 10 is removed therefrom. Once such example of a site marker deployment device is disclosed in commonly owned and co-pending application No. 11/238,295, the contents of which are incorporated herein by reference in its entirety.

[0076] While the embodiments of the present invention has been particularly shown and described with reference to the foregoing preferred embodiments, it should be understood by those skilled in the art that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention without departing from the spirit and scope of the invention as defined in the following claims. It is intended that the following claims define the scope of the invention embodiments within the scope of these claims and their equivalents be covered thereby. This description of the invention should be understood

to include all novel and non-obvious combinations of elements described herein, and claims may be presented in this or a later application to any novel and non-obvious combination of these elements. The foregoing embodiment is illustrative, and no single feature or element is essential to all possible combinations that may be claimed in this or a later application.

CLAIMS

What is claimed is:

1. A biopsy device, comprising:

a cutting element mounted to a handpiece, said cutting element comprising:

a stylet assembly having a stylet that includes an open proximal end and a tissue opening at a distal end thereof, wherein the tissue receiving opening is in communication with a lumen extending through the stylet; and

an outer cannula assembly including an outer cannula that is slidably mounted over the stylet and having an open distal end with a cutting edge formed thereon; and

a vacuum chamber in communication with the lumen;

wherein the stylet is selectively advanced distally outwardly with respect to outer cannula to open the tissue opening to targeted tissue;

wherein the outer cannula is selectively advanced over the tissue opening to sever tissue after a slight delay in which vacuum is generated in the vacuum chamber and delivered to the tissue opening through the lumen, the vacuum causing tissue to be drawn into and maintained in the tissue opening while the cutting cannula severs tissue to obtain a biopsy core.

2. The biopsy device of claim 1, further comprising a pickup carriage that operates to selectively move the stylet assembly and the outer cannula assembly between a biopsy ready and a fired position.

3. The biopsy device of claim 2, wherein the pickup carriage further includes a moveable cam member disposed on a bottom surface of the pickup carriage.

4. The biopsy device of claim 2, further comprising an actuation lever that is operatively connected to the pickup carriage by a resilient bridge member.

5. The biopsy device of claim 1, wherein the stylet assembly further comprises a first arm sub-assembly that is fixedly attached to the stylet and a second sub-assembly that is movably attached to the stylet.

6. The biopsy device of claim 5, wherein the first arm sub-assembly includes a leg member and a carrier member.

7. The biopsy device of claim 5, wherein the second arm sub-assembly includes a first leg member and a second leg member that are connected together by a carrier member.

8. The biopsy device of claim 1, wherein the vacuum chamber comprises first and second seal members and a cylinder disposed over the first and second seal members;

wherein the first seal member is operatively connected to a moveable portion of the stylet assembly and the second seal member is fixedly attached to a portion of the stylet proximal to the first seal member;

wherein the stylet further includes a notch that is in communication with the lumen; and

wherein the notch is positioned between the first and second seal members.

9. The biopsy device of claim 8, further comprising a vacuum valve that selective covers the notch.

10. The biopsy device of claim 1, further comprising a normally closed valve disposed on a proximal end of the stylet.

11. The biopsy device of claim 10, wherein the normally closed valve further comprises a body and a flap member that selective opens in response to positive pressure.

12. The biopsy device of claim 1, wherein the handpiece further comprises a stylet firing member and an outer cannula firing member, wherein the stylet firing member releases the stylet from a biopsy ready position to a fired position; and wherein the outer cannula firing member release the outer cannula from a biopsy ready position to a fired position.

13. The biopsy device of claim 12, wherein at least one of the stylet firing member and the outer cannula firing member includes an indicator that differentiates between the stylet firing member and the outer cannula firing member.

14. The biopsy device of claim 1, wherein the handpiece further comprises an indicator that informs a user when the biopsy device is in a biopsy ready position.

15. The biopsy device of claim 1, wherein the outer cannula assembly further comprises an outer cannula hub that is fixedly connected to the outer cannula; wherein the outer cannula hub includes a retaining member that serves to selectively retain the outer cannula assembly in a biopsy ready position within the handpiece.

16. The biopsy device of claim 15, further comprising a support rib, wherein the support rib is slidingly received on the stylet, proximal to the outer cannula hub.

17. The biopsy device of claim 16, wherein a biasing member is positioned between the support rib and the outer cannula hub.

18. The biopsy device of claim 1, further comprising an introducer assembly that is selectively engagable with the biopsy device, wherein the introducer assembly comprises an introducer cannula that is configured to be slidingly disposed over the outer cannula and sized such that a portion of the outer cannula is positioned distally of a distal end of the introducer cannula.

19. The biopsy device of claim 18, wherein the introducer assembly includes a latch member that cooperates with a portion of the handpiece of the biopsy device to selectively fix the introducer cannula to the biopsy device.

20. A method of using a biopsy device, comprising:

placing the biopsy device into a biopsy ready position by:

retracting a vacuum chamber;

retracting a cutting cannula;

retracting a stylet;

firing the stylet into a target site and exposing a tissue opening formed in a distal end of the stylet;

firing the cutting cannula, thereby generating vacuum which draws in and maintains tissue within the tissue opening of the stylet; wherein the cutting cannula slides over the tissue opening, thereby severing tissue so as to leave a biopsy core within the tissue opening.

21. The method of claim 20, wherein the step of placing the biopsy ready position further comprises:

actuating a latch member to release an actuating lever;

depressing the actuating lever a first time to retract the vacuum chamber;

depressing the actuating lever a second time to retract the cutting cannula; and

depressing the actuating lever a third time to retract the stylet.

22. The method of claim 21, wherein depressing the actuating lever moves a pickup carriage, wherein a moveable cam member disposed on the pickup carriage contacts an arm assembly that is slidably attached to the stylet assembly so as to retract the vacuum chamber when the actuating lever is depressed the first time;

wherein the moveable cam member contacts a portion of the cutting cannula so as to retract the cutting cannula when the actuating lever is depressed the second time; and

wherein the moveable cam member contacts a portion of the stylet so as to retract the stylet when the actuating lever is depressed the third time.

23. The method of claim 20, wherein after the cutting cannula is fired, the cutting cannula is retracted again so as to expose the biopsy core retained within the tissue opening.

24. The method of claim 20, further comprising attaching an introducer assembly over the cutting cannula prior to firing the stylet assembly.

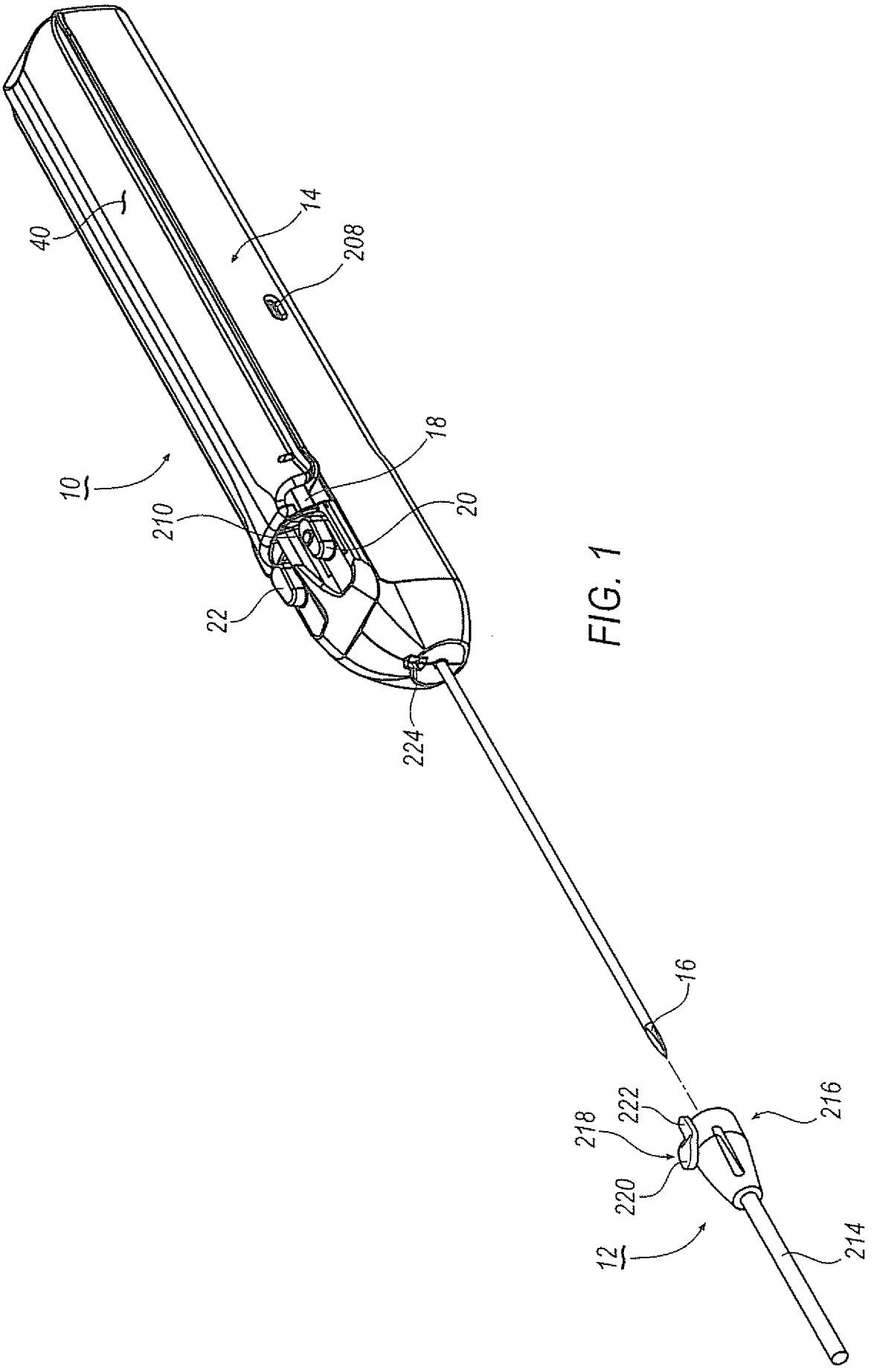

FIG. 1

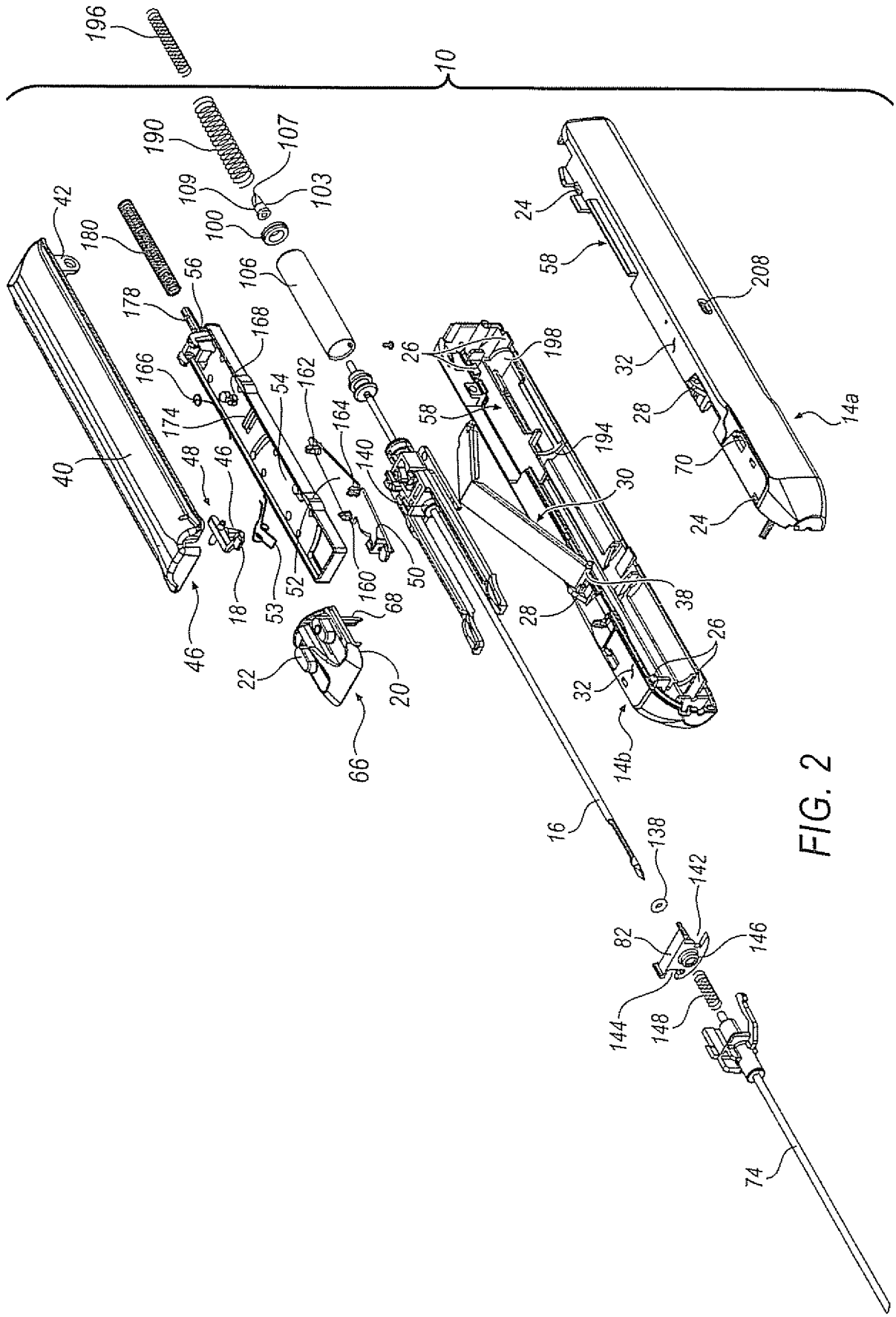
196
10
190
107
109
103
100
42
180
106
56
178
168
166
54
162
164
174
48
46
140
40
58
26
198
24
58
208
32
28
14a
194
30
70
24
18
53
52
160
68
50
38
28
26
46
22
20
32
66
14b
16
138
142
82
146
144
148
74

FIG. 2

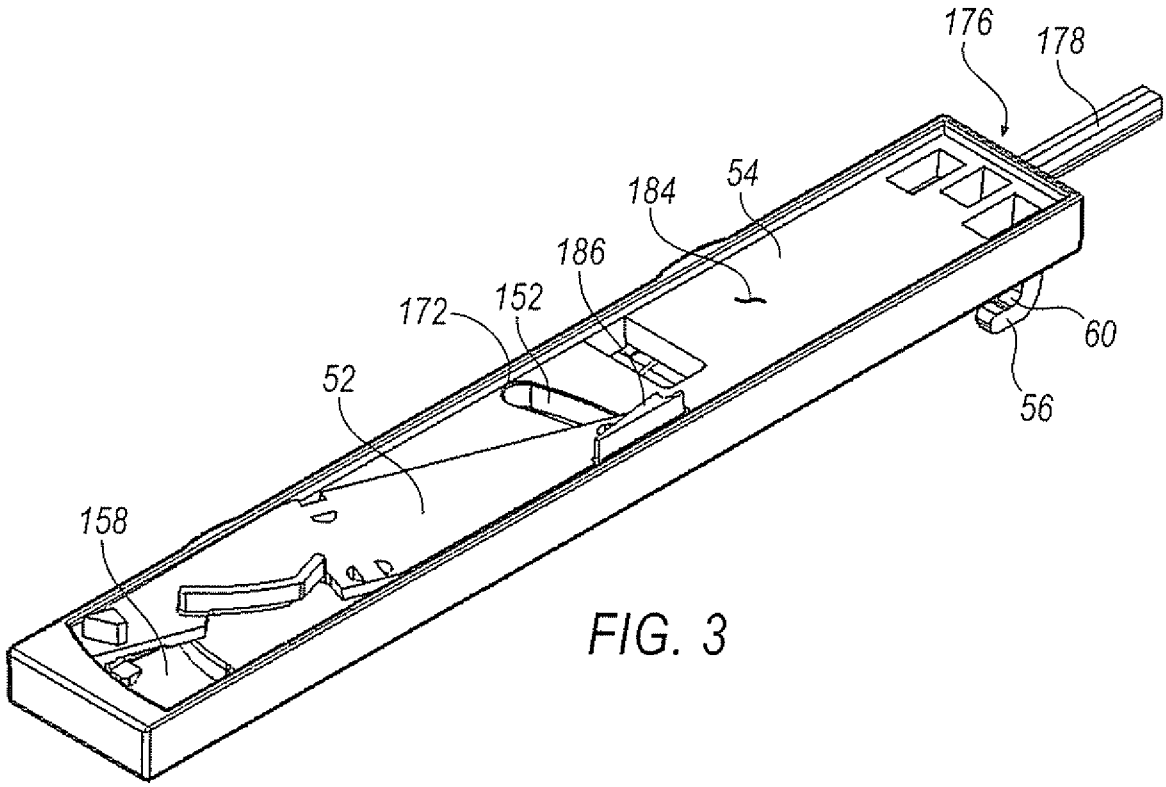
176
178
184
54
186
172
152
60
52
56
158

FIG. 3

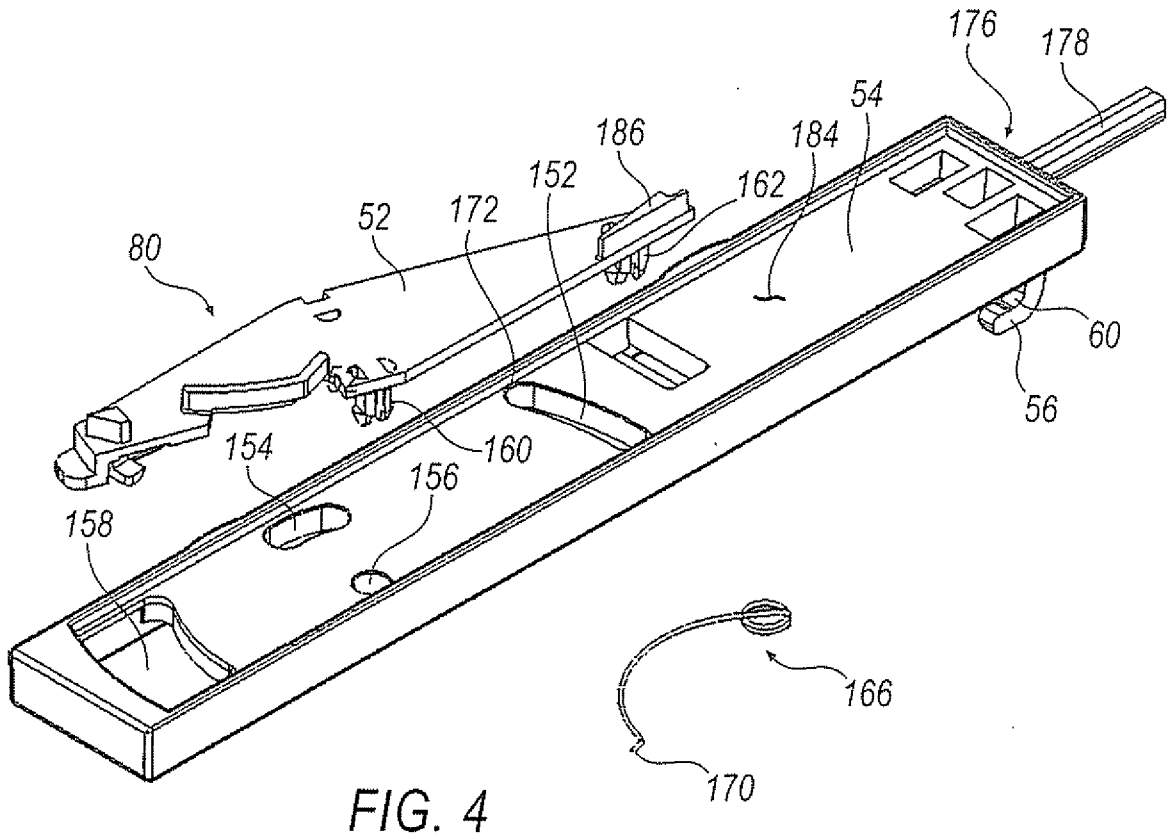
176
178
54
186
184
152
162
172
52
80
60
56
154
160
156
158
166
170

FIG. 4

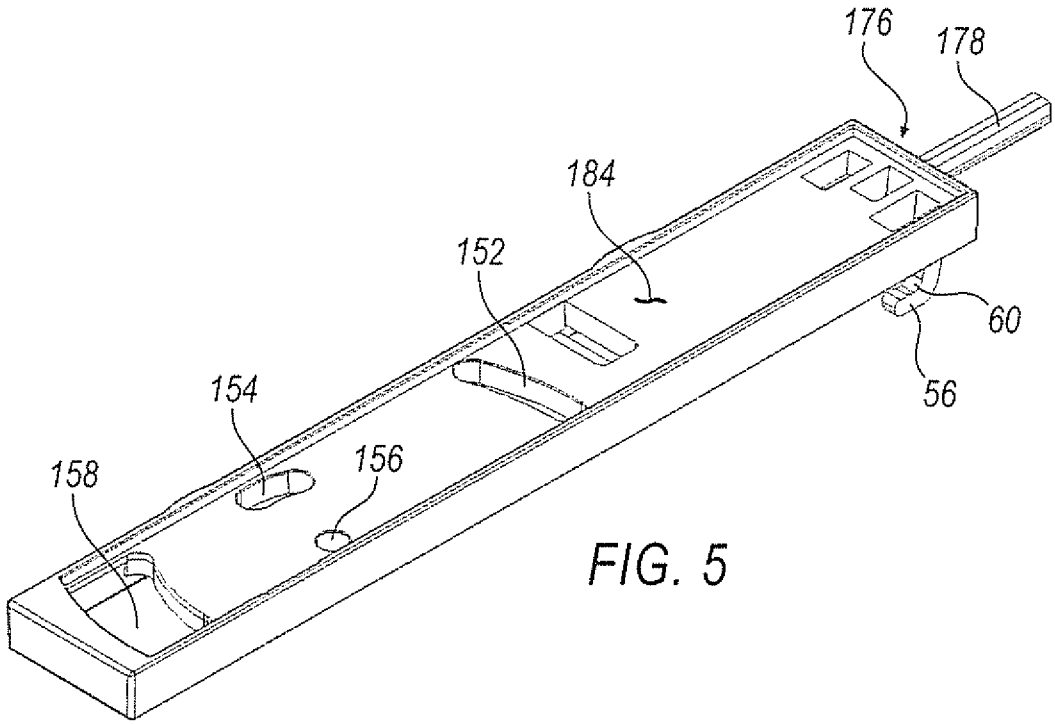

FIG. 5

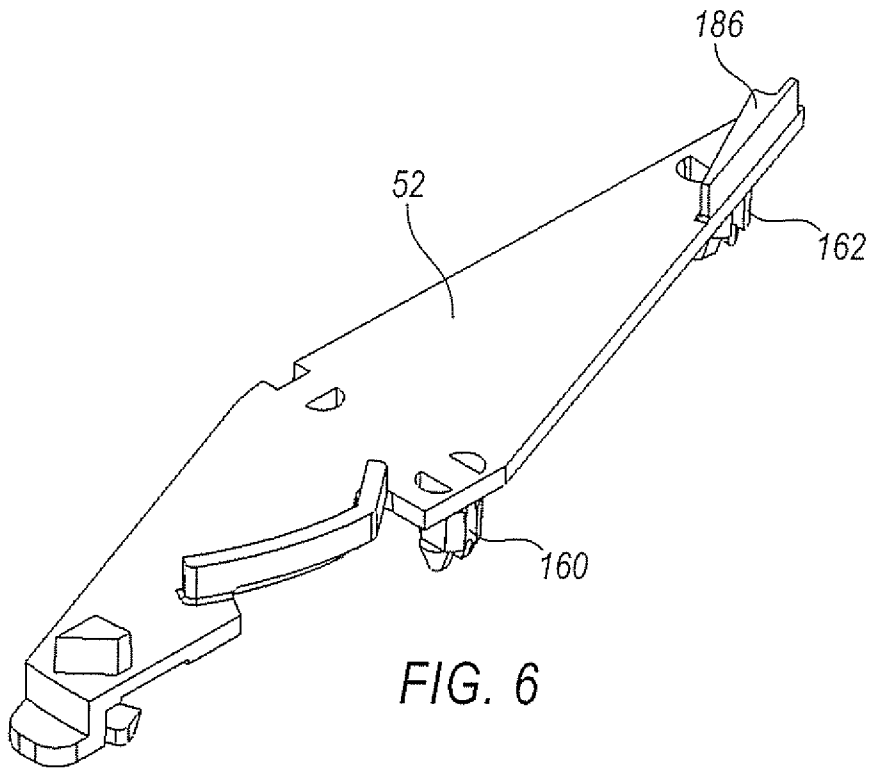

FIG. 6

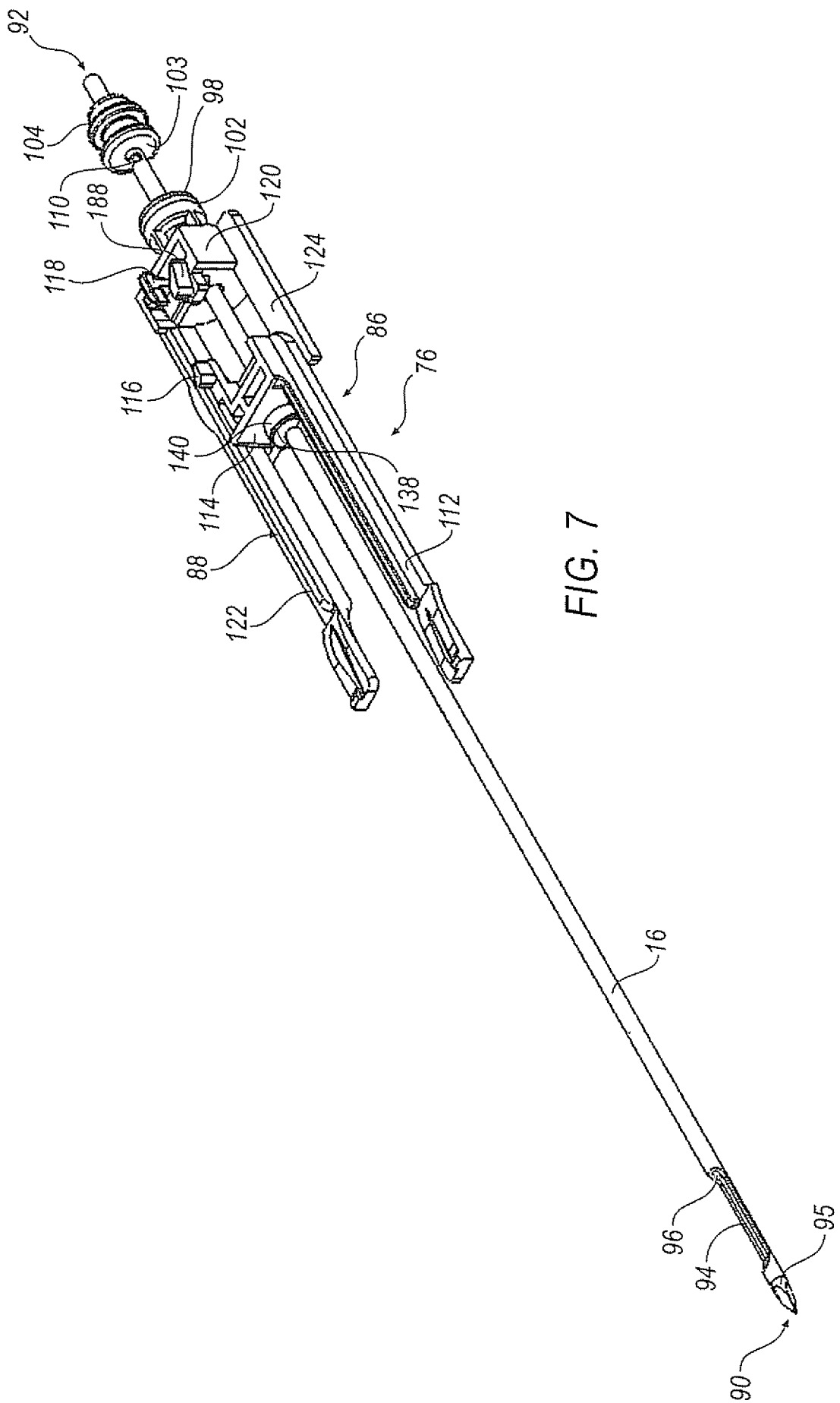
92
103
98
104
102
110
188
120
118
124
86
76
116
140
138
114
112
88
122
16
96
95
94
90

FIG. 7

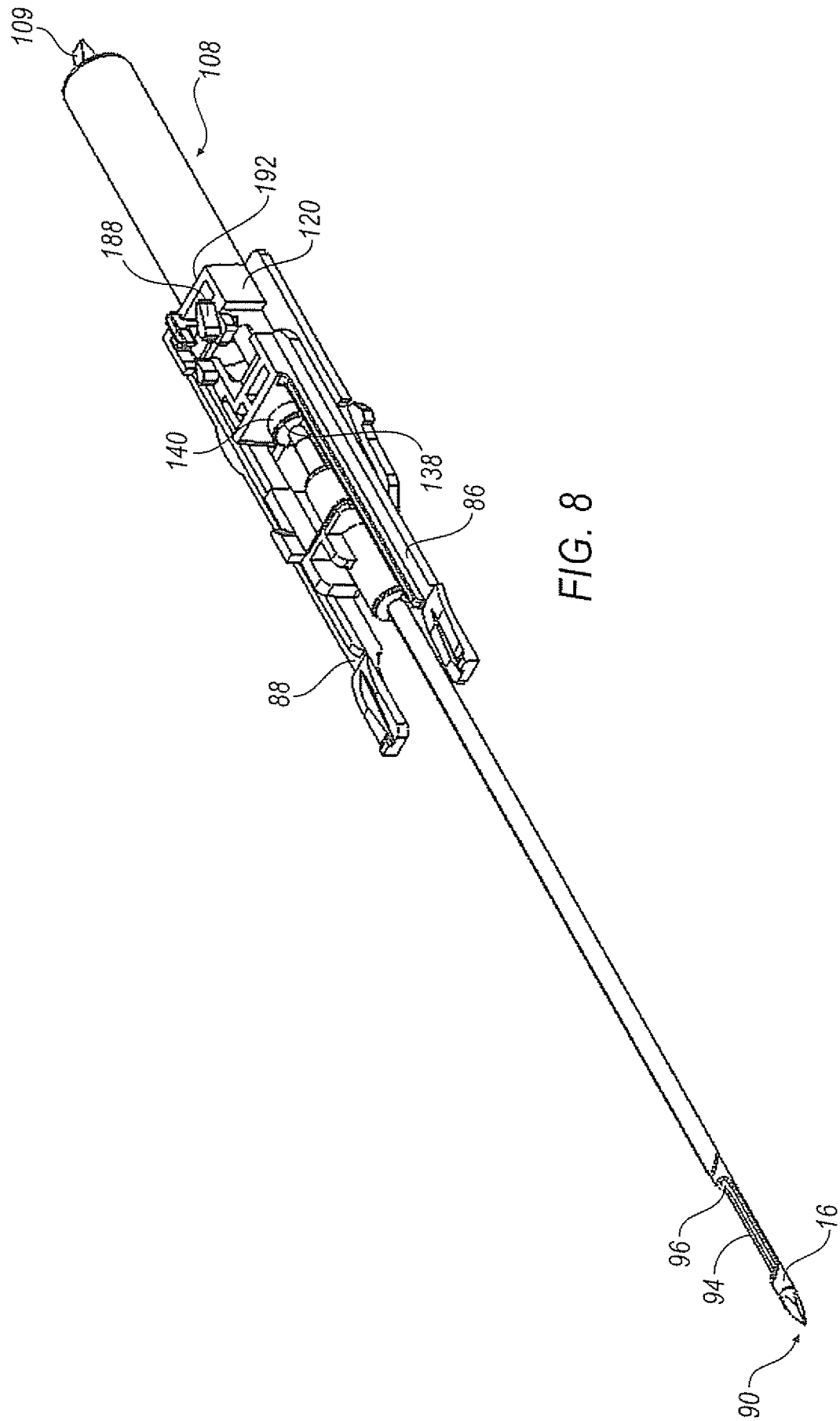

FIG. 8

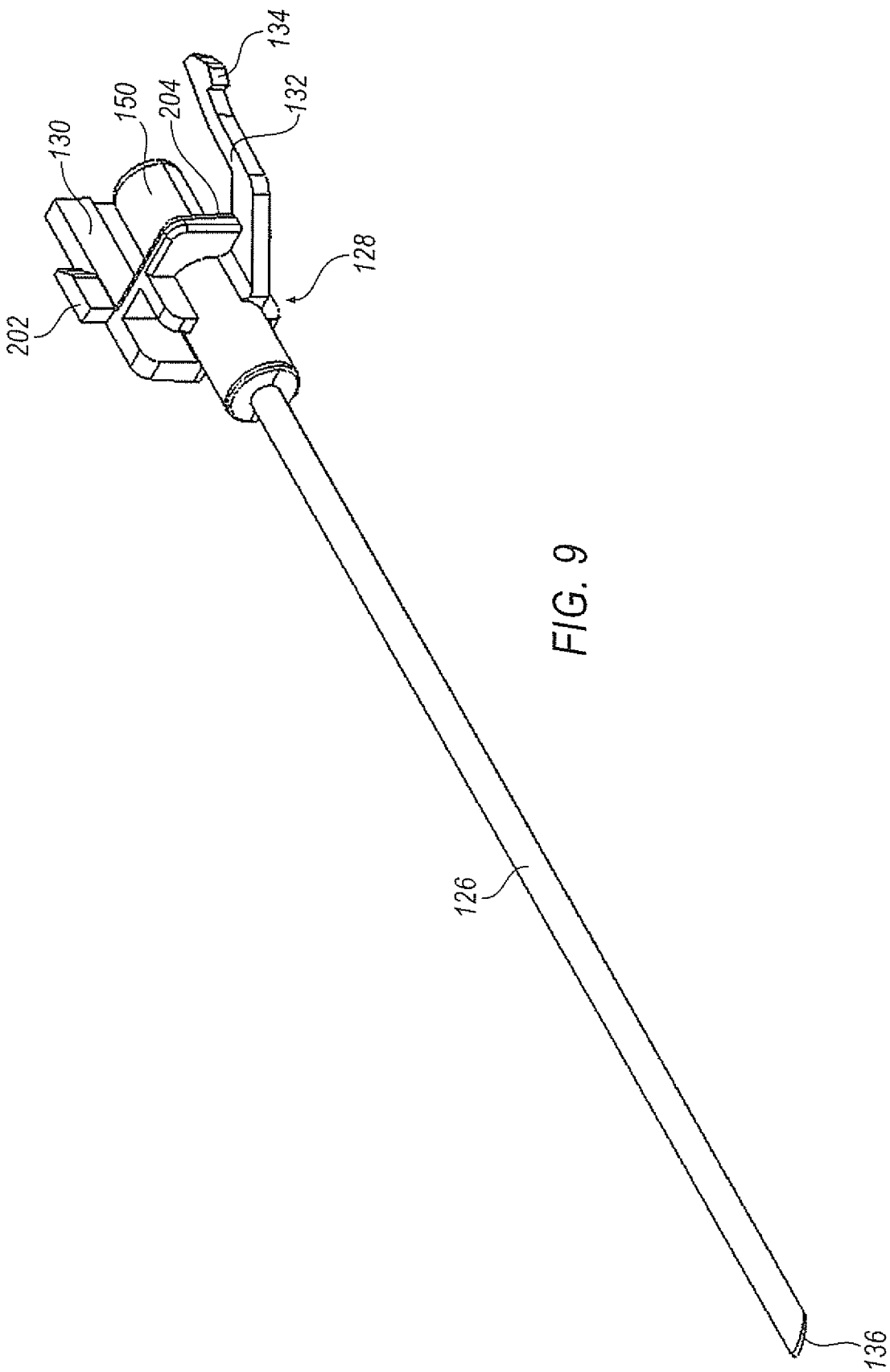

FIG. 9

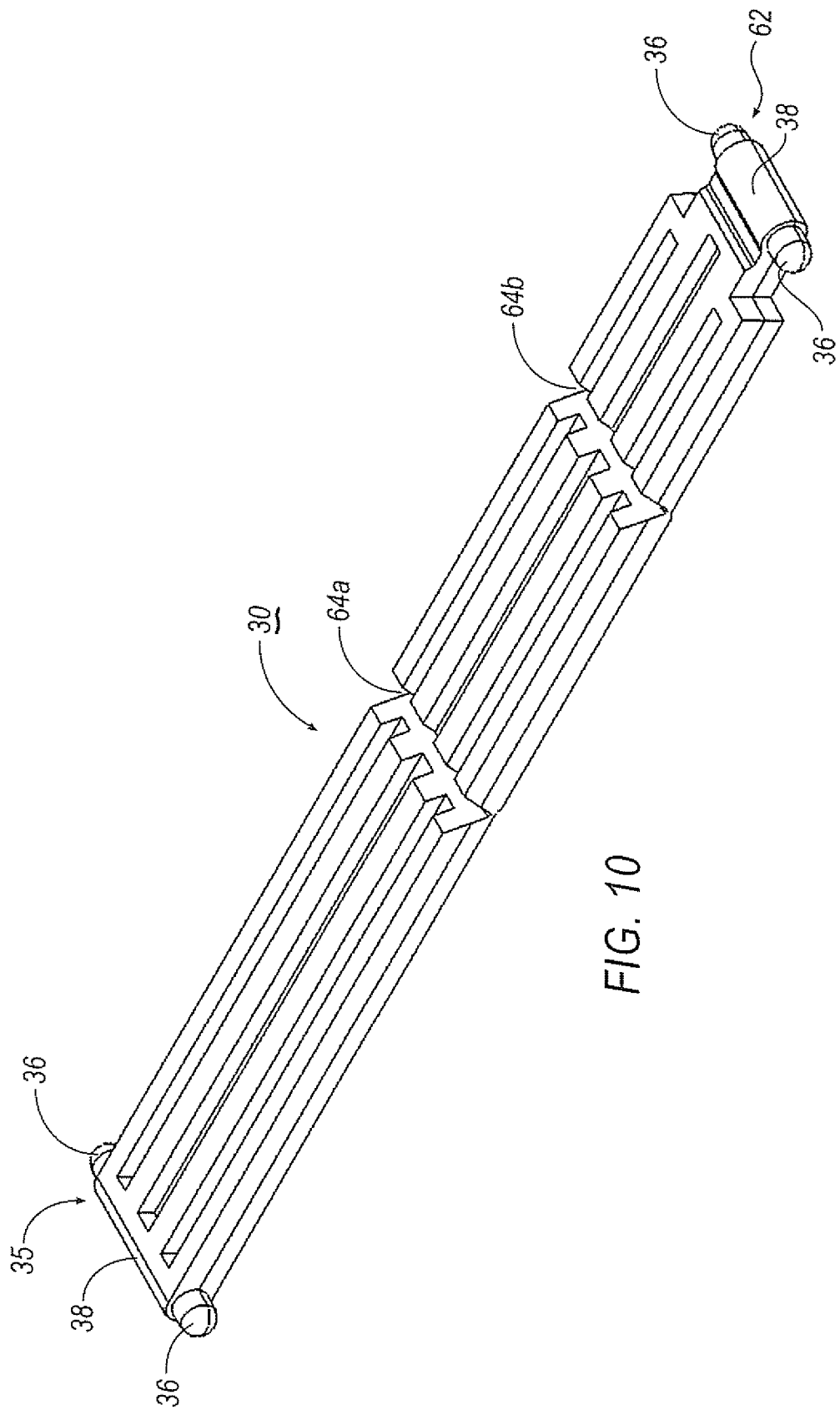

FIG. 10

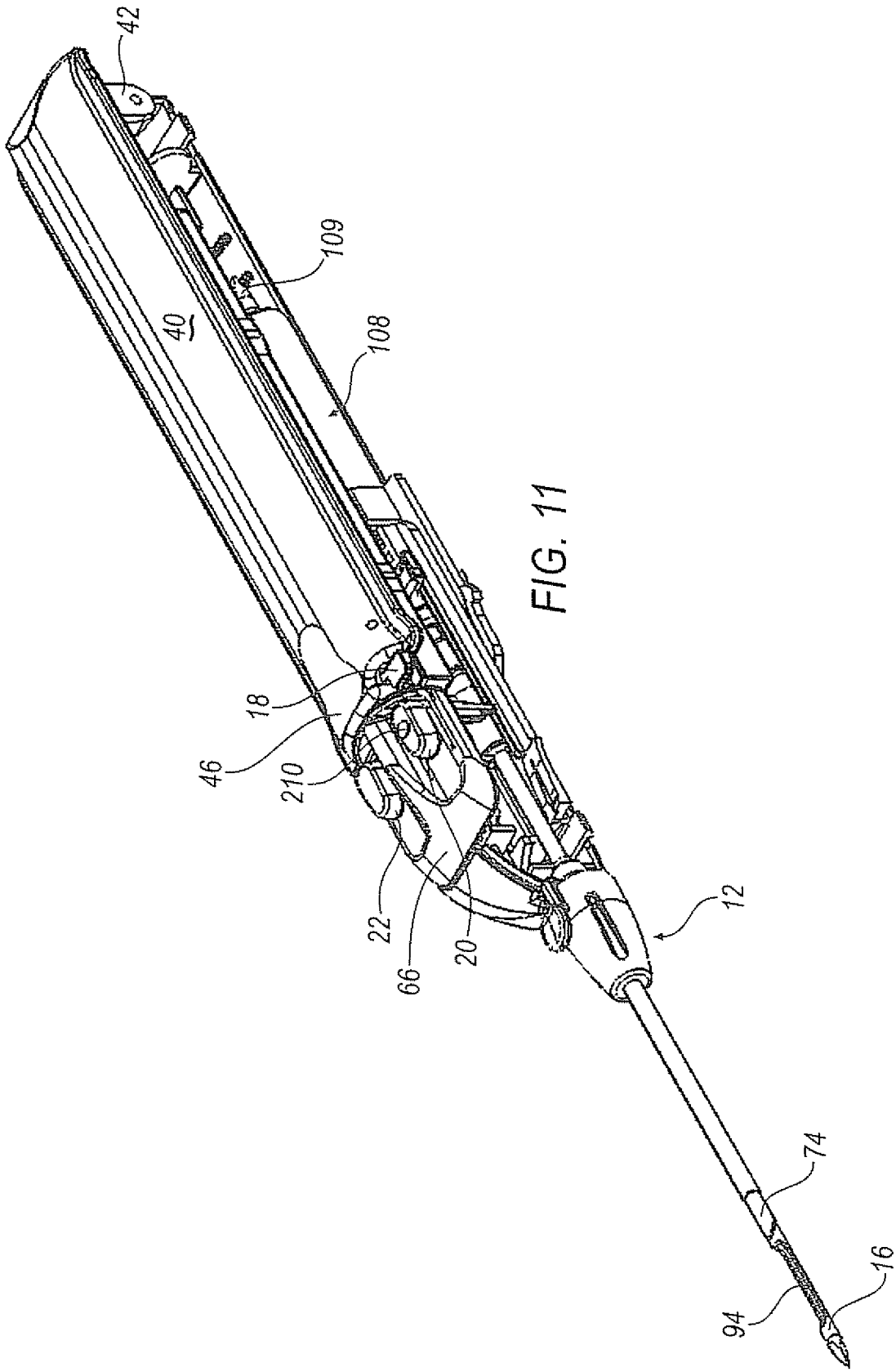

FIG. 11

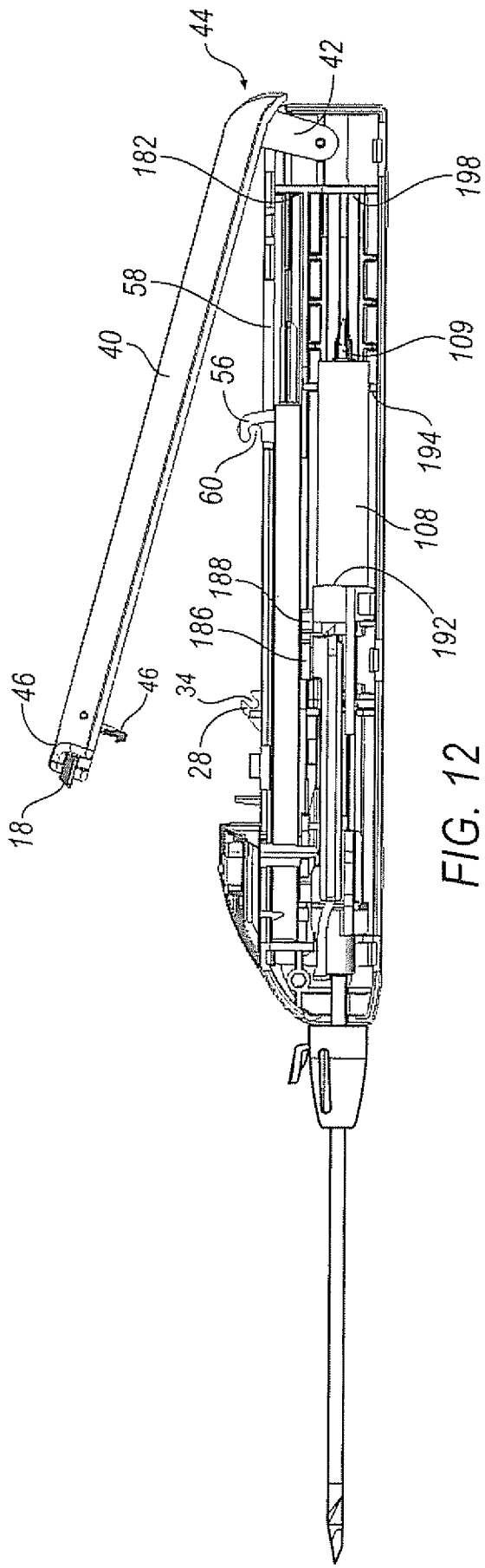

FIG. 12

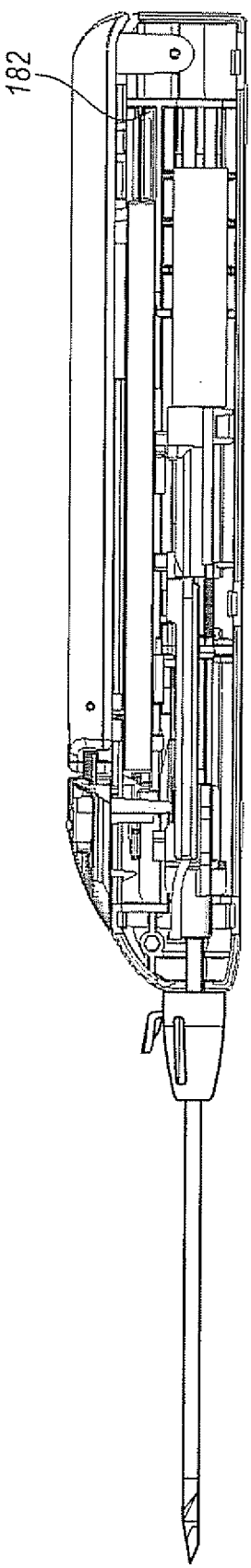

FIG. 13

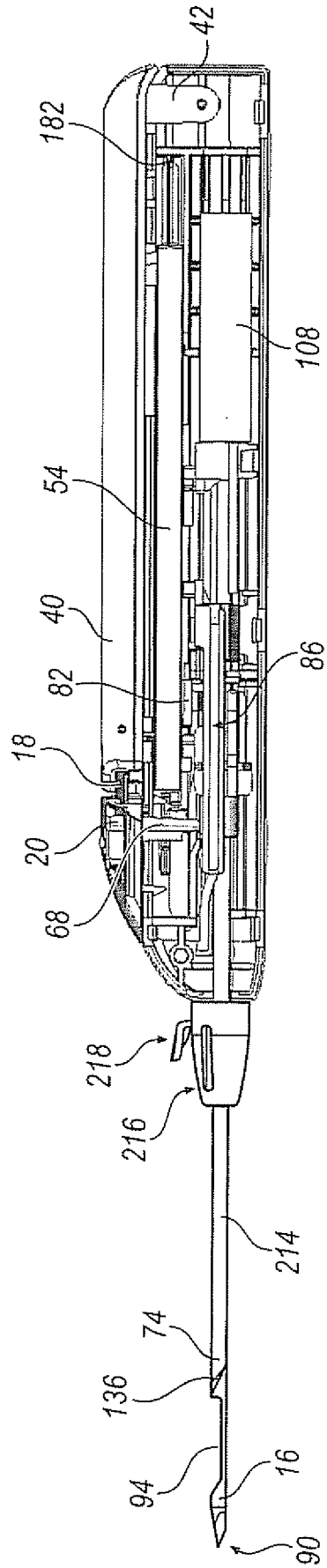
42
182
108
54
40
82
86
18
20
68
218
216
214
74
136
94
16
90

FIG. 14

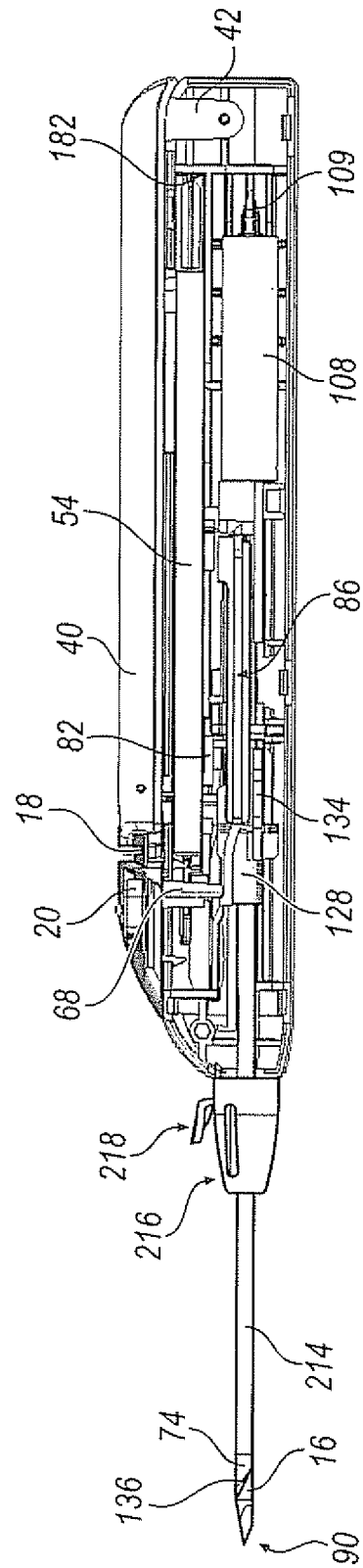
42
182
109
108
54
86
40
82
134
18
20
128
68
218
216
214
74
16
136
90

FIG. 15

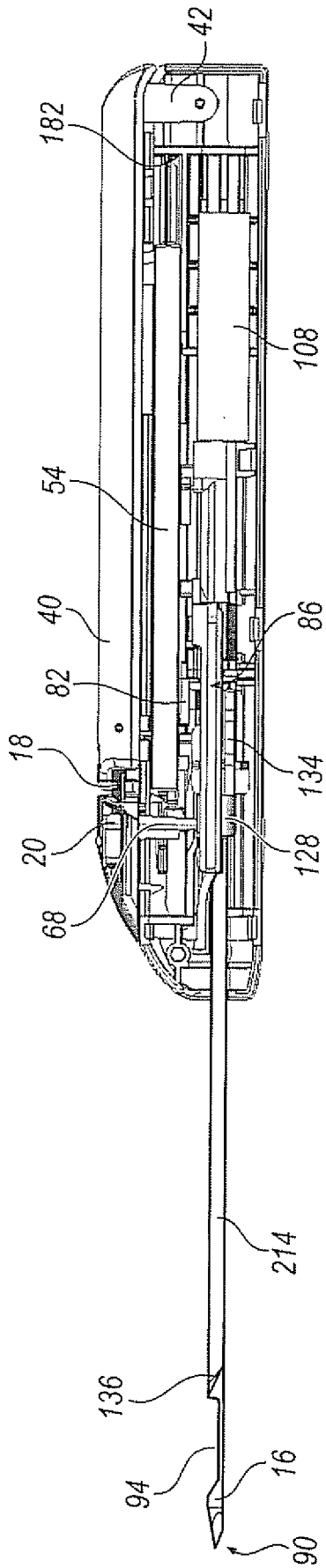

FIG. 16

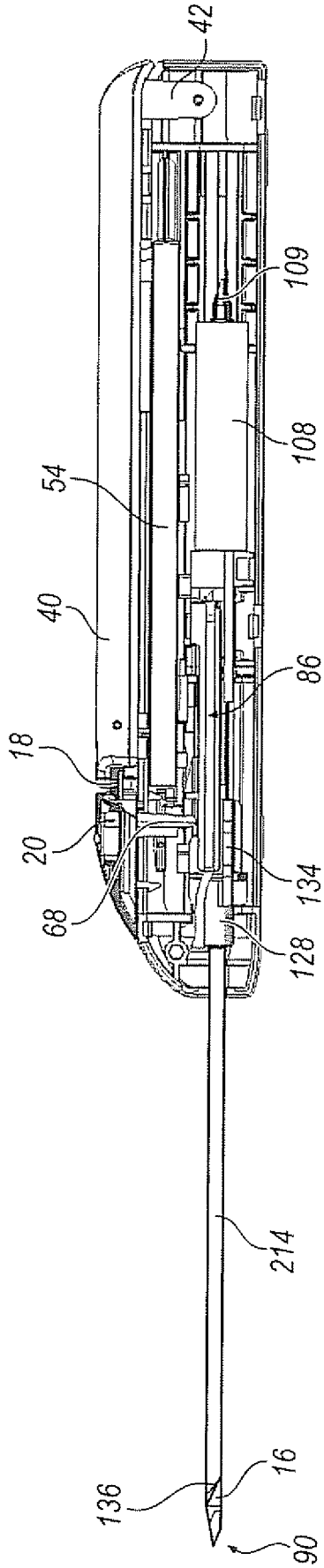
42
109
108
54
40
86
18
20
68
134
128
214
136
16
90

FIG. 17

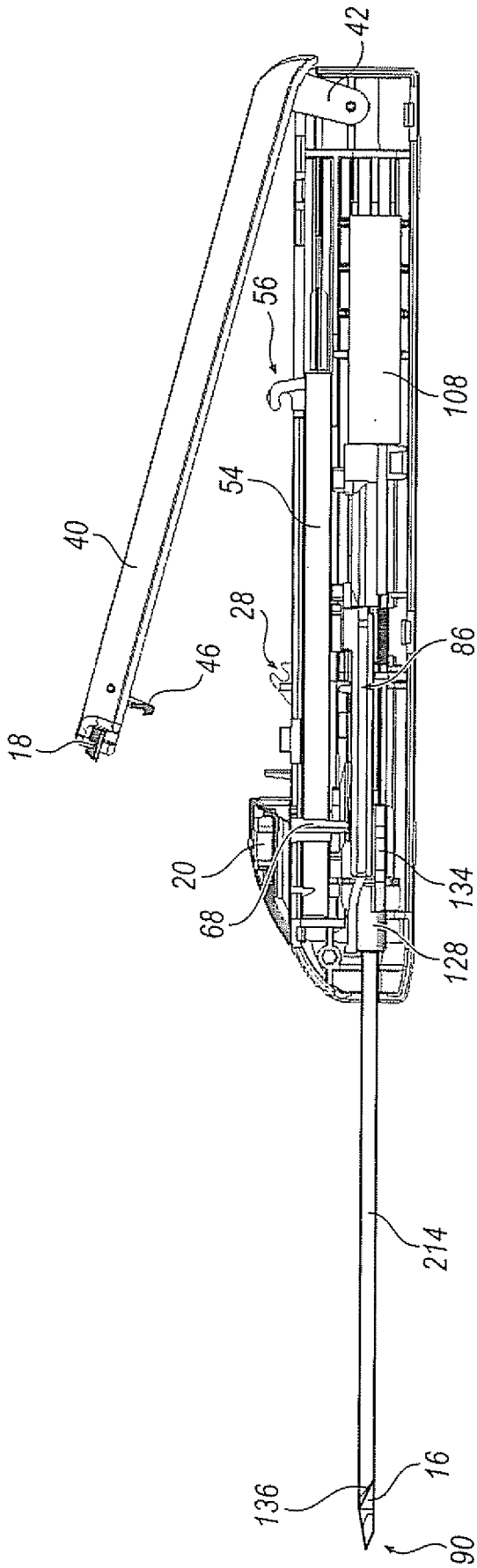
42
56
108
54
40
28
46
86
18
20
68
134
128
214
136
16
90

FIG. 18

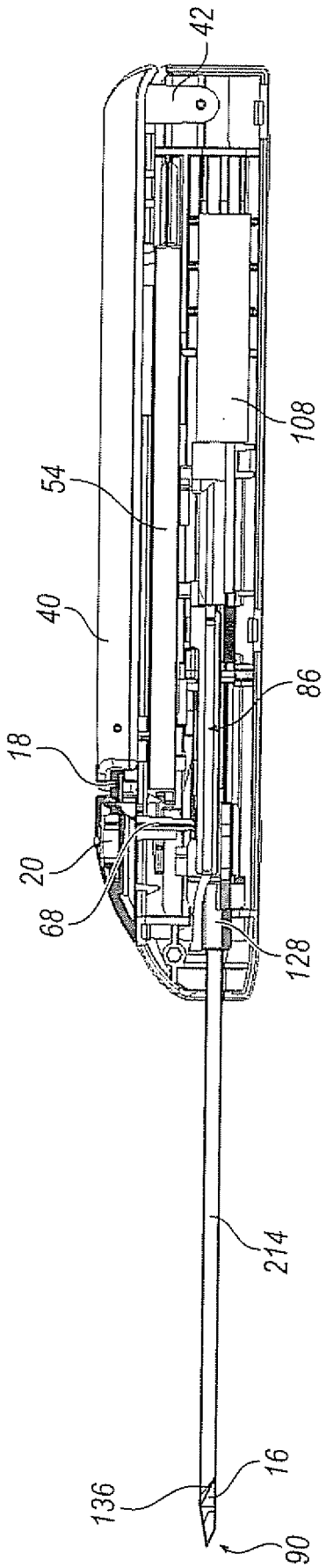
42
108
54
40
86
18
20
68
128
214
136
16
90

FIG. 19

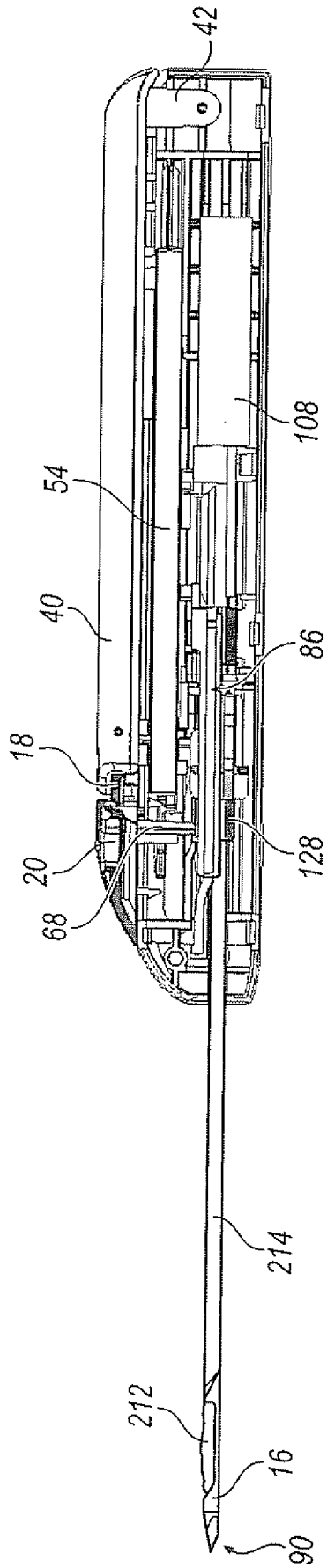
42
108
54
40
86
18
20
68
128
214
212
16
90

FIG. 20

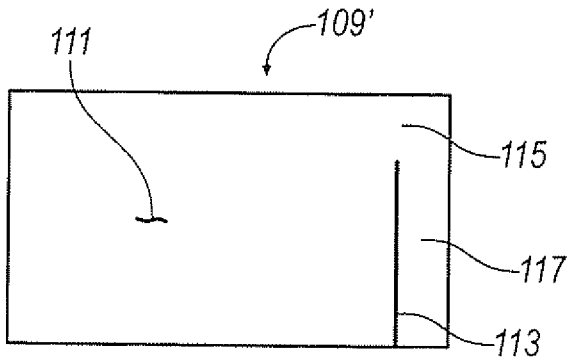

FIG. 21A

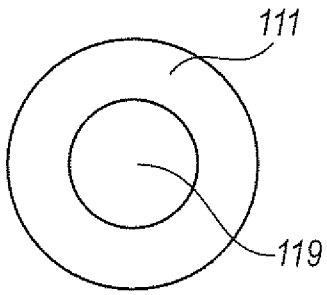

FIG. 21C

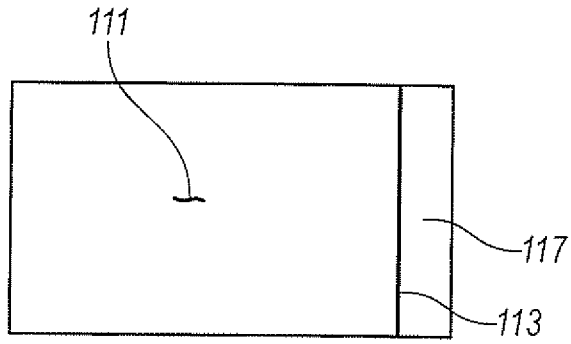

FIG. 21B

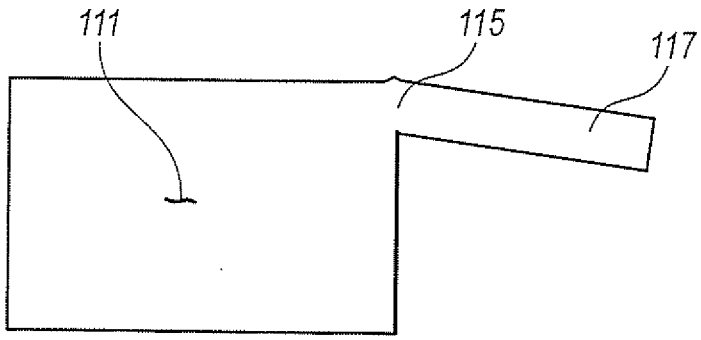

FIG. 21D

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/055248

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B10/02

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 A	US 2005/080355 A1 (MARK JOSEPH L [US]) 14 April 2005 (2005-04-14) abstract; figures 5-10 paragraphs [0002], [0012], [0032] - [0037] -----	1,8-10, 15 2-7, 11-14, 16-19
A	WO 2005/063126 A (SENORX INC [US]) 14 July 2005 (2005-07-14) abstract; figures paragraphs [0001], [0014], [0049] -----	1-19

-/--

[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
4 June 2008	17/06/2008

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	Lager, Johan

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/055248

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 202 04 363 U1 (HESKE NORBERT F [DE]; HESKE THOMAS [DE]) 29 May 2002 (2002-05-29) abstract; figures page 1, lines 3-8 page 2, lines 46-66 page 9, line 270 - page 10, line 298 page 12, lines 371-404 page 25, line 804 - page 27, line 863 page 28, line 904 - page 29, line 929	1-19
A	WO 97/20504 A (BIOPSYS MEDICAL INC [US]) 12 June 1997 (1997-06-12) abstract; figures page 3, line 21 - page 6, line 4 page 8, lines 12-22 page 13, line 14 - page 14, line 9	1-19

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/055248

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.: 20-24
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/US2008/055248

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2005080355 A1	14-04-2005	US 2007106176 A1	10-05-2007
WO 2005063126 A	14-07-2005	AU 2004308386 A1	14-07-2005
		CA 2550137 A1	14-07-2005
		EP 1696800 A2	06-09-2006
		JP 2007516048 T	21-06-2007
DE 20204363 U1	29-05-2002	NONE	
WO 9720504 A	12-06-1997	CA 2239614 A1	12-06-1997
		DE 69633640 D1	18-11-2004
		DE 69633640 T2	03-11-2005
		EP 0939604 A1	08-09-1999
		JP 2001515372 T	18-09-2001
		US 5769086 A	23-06-1998