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(54) **Title**: MEDICAL TOOL FOR REDUCED PENETRATION FORCE WITH FEEDBACK MEANS

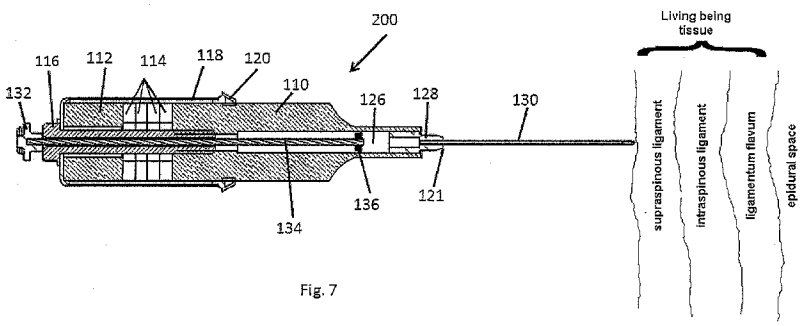


Fig. 7

(57) **Abstract**: A medical device for reducing the force necessary to penetrate living being tissue using a variety of reciprocating motion actuators, including piezoelectric, voice coil, solenoids, pneumatics or fluidics. The reciprocating actuator drives a penetrating member, such as a needle, through the tissue at a reduced force while the device detects the passage of the penetrating member through the tissue. Upon passage of the penetrating member through the tissue, electrical power to the reciprocating actuator is automatically terminated. One exemplary method for detecting this passage is via a fluid-containing syringe that is coupled to a channel within the penetrating member. Once the penetrating member tip has passed through the living tissue, the fluid within the syringe no longer experiences any pressure and a plunger within the syringe displaces indicating passage of the penetrating member tip. This motion can provide direct tactile feedback to an operator of the medical device or can automatically open a switch providing electrical power to the medical device. Alternatively, a pressure transducer can also monitor the pressure within the penetrating member channel and automatically activate the switch to cut off the electrical power.

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MEDICAL TOOL FOR REDUCED PENETRATION FORCE WITH FEEDBACK MEANS

BACKGROUND OF THE INVENTION

CROSS-REFERENCE TO RELATED APPLICATIONS

This PCT Application claims the benefit under 35 U.S.C. §119(e) of Provisional Application Serial No. 61/089,756 filed on September 15, 2008 entitled MEDICAL TOOL FOR REDUCED PENETRATION FORCE WITH FEEDBACK MEANS and whose entire disclosure is incorporated by reference herein.

Field of the Invention

[0001] The present invention generally pertains to handheld medical devices, and more specifically to electrically driven lancets; epidural catheter inserters; biopsy medical instruments, such as bone biopsy medical devices; vascular entry penetrating members, spinal access needles and other catheterization needles. The invention is applicable to the delivery and removal of blood, tissues, medicine, bone marrow, nutrients or other materials within the body.

Description of Related Art

[0002] Epidural anesthesia is a form of regional anesthesia involving injection of drugs directly into the epidural space. To begin the procedure, a needle is inserted from the outer layer of skin, through several layers of tissue and finally placed within the epidural space, through which a catheter is optionally passed. Local anesthetics are injected into the epidural space causing temporary loss of sensation and pain by blocking the transmission of pain signals through nerves in or near the spinal cord. The procedure can be unpleasant to the patient because of the high force levels required for the relatively dull epidural needle to penetrate the supraspinous ligament, interspinous ligament and ligamentum flavum. One complication is that a clinician will accidently overshoot and puncture the dura because of this high force of penetration and an almost-instantaneous change in resistance upon passing the needle into the epidural space (i.e., high forward momentum followed by instantaneous minimization of force). Upon puncturing the dura, the cerebrospinal fluid can leak into the epidural space causing the patient to experience severe post dural puncture headache, lasting from days to possibly years. Significant leakage can cause enough intracranial hypotension as to tear veins, cause subdural hematoma, and traction injuries to the cranial nerves resulting in tinnitus, hearing loss, dizziness, facial droop, or double vision.

[0003] A bone marrow biopsy is used for diagnosing tumors and a variety of bone diseases. The most commonly used site for the bone biopsy is the anterior iliac crest. A major disadvantage is the force required to penetrate the bone tissue, and the twisting motion often used to force the needle inward, which results in patient discomfort as well as possible healing complications from damaged tissues. The penetration force can also be tiring for clinicians and lead to multiple sampling attempts. Complications are rare but can include bleeding, pain, and infection. Pain is minimized with proper local anesthesia, though the patient still experiences a pressure sensation during insertion and retraction during some procedures. Another problem is crushing the sample or being unable to retrieve part of all of it, limiting the ability to diagnose. As shown in **FIG. 1**, a biopsy tool **PA1** typically comprises a handle (not shown) and hollow cannula **1** with cannula distal end **1'** surrounding a stylet **2** attached to the handle. To penetrate through cortical bone, a clinician pushes the cannula and stylet through the bone to the marrow. The distal tip **3** of the inner stylet or trocar is sharpened and has an angled chisel-like face **4** which reduces the surface area to reduce the exertion force.

[0004] Currently, to minimize the possibility of a dura puncture, the epidural catheter insertion process is typically performed very slowly and with a 16-18 gauge, specially designed, relatively dull needle **PA2**, such as the one shown in **FIG. 2** called a Tuohy needle **5**. An epidural needle, such as the Tuohy needle **5** or Hustead needle, has a directional curved tip **6**, which decreases the "sharpness" at the needle and, therefore, makes accidental dura puncture more difficult. The curved tip also facilitates directing an indwelling catheter into the epidural space and a tip opening **7** facilitates catheter or fluid introduction or removal. Unfortunately, this dull curved-tip design actually increases the force a clinician must use and makes it more difficult for a clinician to stop the forward momentum upon penetration of the dural space. Additionally, the Tuohy design increases the likelihood that a clinician relies on tactile feedback during penetration. In other words, during the insertion procedure a clinician will rely on feeling a "popping" sensation - indicative of passing the needle past the ligamentum flavum - to locate the tip of the needle within the epidural space and quickly stop the forward momentum being applied. Still, because penetration into other tissues, such as muscle, calcified ligament, or regular ligament may produce a similar popping, a clinician may not fully perceive the correct location of the needle tip where the tip of the needle is occluded until passing through these tissues.

[0005] Several alternate technologies have been developed that attempt to minimize the dura puncture risk, while also giving the clinician indication of successful epidural

placement. For example, the detection method and apparatus disclosed in U.S. Patent Application Publication No. 2007/0142766 (Sundar, et al.), the contents of which are incorporated by reference, relies on a spring-loaded plunger pushing a fluid into the epidural space upon successful entry. Accordingly, the clinician is given a visual indicator (i.e., the movement of the plunger as the fluid experiences a loss of resistance at the needle opening), and would cease applying forward force. Similarly, U.S. Patent No. 5,681,283 (Brownfield) also relies on a visual indicator to communicate successful entry of a needle into a cavity to the clinician. Unfortunately, while a visual indicator is a positive advancement, the actual cause of the accidental dural wall puncture—that is, the high force applied by the clinician against the needle to pass through the various tissue layers and then stop—is not taught or suggested.

[0006] Therefore, there exists a need for a tool that reduces the puncture force of a needle, such as a Tuohy needle, and enables a clinician to perform a more controlled entry into the epidural space, thereby reducing the possibility of an accidental dura puncture.

[0007] While accidental dura puncture is a concern, simply locating the epidural space may pose a challenge even to the most skilled physicians. Therefore, when a needle such as a Tuohy needle is passed through the ligamentum flavum and into the epidural space, it is helpful for a clinician to receive immediate feedback indicating successful penetration and the location of the tip of the needle. A basic conventional feedback device such as the one in **FIG. 2a** comprises a needle (not shown) attached to a syringe **PA3** at a front portion **9**, and wherein the syringe **PA3** is formed of a tubular body **10** and houses a biasing element **11** comprising a stem acting as a biasing element. To provide feedback indicating successful epidural penetration the device relies on a biasing force acting against the biasing element **11** which then acts upon a fluid, such as saline or air within the syringe. Essentially, in this hydraulic feedback method, as the biasing force acts upon the fluid, the fluid translates this pressure to an opening of the needle tip. An opposing force, acting on the needle tip as it is held against a tissue such as the ligamentum flavum, acts to prevent the fluid from being released from the syringe. Typically, a clinician's thumbs act as the biasing force source which in turn acts upon the plunger stem. The clinician's thumbs serve to "feel" the hydraulic resistance exerted on the fluid by the opposing tissue force. Upon entering the epidural space, however, the opposing pressure of tissue acting against the tip is removed, and a pressure drop allows the biasing force to move solution out of the syringe through the needle tip. The clinician becomes aware of successful penetration of the epidural space due to his/her thumbs "feeling" the sudden pressure drop or loss of resistance at the plunger

stem. Also, the clinician may receive visual indication of successful penetration by witnessing the plunger advancing through the syringe externally as the fluid is released into the epidural space in the patient. One problem with this conventional device and method is that it is difficult for a clinician to both apply a biasing force on the plunger while also applying an advancing force against the syringe body in order to advance the needle through the ligamentum flavum. Moreover, to prevent accidental dura puncture, clinicians tend to hold the conventional syringe in such a way as to hold the patient steady, while applying a forward momentum against the syringe, and while applying a biasing force against the plunger stem. This is both awkward and uncomfortable to the clinician and patient.

[0008] Some advancements have also attempted to provide an automatic biasing element to act against the plunger of an epidural syringe while also providing visual indication or feedback, rather than tactile response, of successful puncture of various internal target areas in the human body. For example, in U.S. Patent Publication No. 2007/0142766 (Sundar et al.), a spring is utilized to act with a biasing force against the syringe plunger. When the epidural needle attached to the syringe passes through into the dural space, the pressure drop allows the spring to bias the plunger. As the plunger moves, the stem provides at least some visual indication as it moves with the plunger. Similarly, U.S. Patent No. 5,024,662 (Menes et al.), which is hereby incorporated by reference, provides visual indication by utilizing an elastomer band to provide the biasing force against the plunger stem. In U.S. Patent No. 4,623,335 (Jackson) which is hereby incorporated by reference, an alternative device assists in visually indicating a pressure to identify the location of the needle tip. In addition, U.S. Patent No. 7,297,131 (Call) which is hereby incorporated by reference, uses a pressure transducer to translate a pressure change into an electronic signal. The electronic signal is then converted to a visual display indicator, for example by activating a light emitting diode to emit.

[0009] Therefore, a need exists to overcome the challenges not addressed by conventionally available technologies that reduces the force necessary for penetration of a sharp medical element of a medical device through tissue and also has the ability to deliver (e.g., deliver saline solution, or drugs, etc.) or retrieve materials subcutaneously (e.g., bone biopsy, etc.).

[0010] A need also exists to provide visual, tactile, electrical or additional indication to a clinician that the penetrating member has successfully penetrated the specific body space such as the epidural space, especially when the force to enter such a space has been

substantially reduced. And this same force reduction must be either controlled or shut off immediately upon entry into the epidural space to avoid (easier) penetration of the dura.

[0011] Specifically, a need exists in the medical device art for an improved medical device having a penetrating element that is vibrated at a frequency that thereby reduces the force required to penetrate tissue, reduces the amount of resulting tissue damage and scarring, improving body space or vessel access success rate, minimizes introduction wound site trauma and, most importantly, improves patient comfort while minimizing potential complications.

[0012] A need exists for a clinician to be able to use less force to penetrate hard tissue such as the cortical bone during bone biopsy, which would reduce clinician fatigue, patient discomfort, and tissue damage while improving the sampling success rate and quality. There is a need to sense proper location, stop forward motion and collect the sample. There is a further need to turn device on after collection and to reduce force and patient discomfort as the penetrating member is being retracted from the body.

[0013] There is also a need for spinal access procedures where a clinician would want a reduction of force as well as to know the location of the needle tip but applied to a relatively-sharp penetrating member, such as a pencil point tip, as the clinician does not want to core tissue.

[0014] There is also a need for performing nerve block procedures where a clinician would want a reduction of force as well as to know the location of the needle tip. And this same force reduction must be either controlled or shut off immediately upon entry into the desired location.

All references cited herein are incorporated herein by reference in their entireties.

SUMMARY OF THE INVENTION

[0015] The basis of the invention is a handheld medical device, (e.g., epidural needle, bone biopsy device, spinal needle, regional block needle, catheter introducer needle, etc.) having a penetrating member (e.g., an introducer needle, Tuohy needle, pencil point tipped needle, trocar needle (e.g., JAMSHIDI® biopsy needle), etc.), at a distal end, for use in procedures, (e.g., vascular entry and catheterization, single shot or continuous epidurals, spinal access, regional blocks, or bone biopsy, etc.), wherein the medical device comprises at least one driving actuator, (e.g., a piezoelectric, voice coil, solenoid, pneumatic, fluidic or any oscillatory or translational actuator etc.) attached to the penetrating member (e.g., at a proximal end of the penetrating member), and wherein the driving actuator translates the

penetrating member, causing it to reciprocate at small displacements, thereby reducing the force required to penetrate through tissues.

[0016] Additionally, the invention comprises a means for providing feedback, either visually, audibly, or by tactile response, using a variety of detection mechanisms (such as, but not limited to, electrical, magnetic, pressure, capacitive, inductive, etc. means), to indicate successful penetration of various tissues, or of voids within the body such as the epidural space so that the clinician knows when to stop as well as to limit power to the driving mechanism.

[0017] Actuator technologies that rely on conventional, single or stacked piezoelectric material assemblies for actuation are hindered by the maximum strain limit of the piezoelectric materials themselves. Because the maximum strain limit of conventional piezoelectric materials is about 0.1% for polycrystalline piezoelectric materials, such as lead zirconate titanate (PZT) polycrystalline (also referred to as ceramic) materials and 0.5% for single crystal piezoelectric materials, it would require a large stack of cells to approach useful displacement or actuation of, for example, a handheld medical device usable for processes penetrating through tissues. However, using a large stack of cells to actuate components of a handpiece would also require that the tool size be increased beyond usable biometric design for handheld instruments.

[0018] Flextensional actuator assembly designs have been developed which provide amplification in piezoelectric material stack strain displacement. The flextensional designs comprise a piezoelectric material driving cell disposed within a frame, platen, endcaps or housing. The geometry of the frame, platten, endcaps or housing provides amplification of the axial or longitudinal motions of the driver cell to obtain a larger displacement of the flextensional assembly in a particular direction. Essentially, the flextensional actuator assembly more efficiently converts strain in one direction into movement (or force) in a second direction. Flextensional piezoelectric actuators may be considered mid-frequency actuators, e.g., 25-35kHz. Flextensional actuators may take on several embodiments. For example, in one embodiment, flextensional actuators are of the Cymbal type, as described in United States Patent No. 5,729,077 (Newnham), which is hereby incorporated by reference. In another embodiment, flextensional actuators are of the amplified piezoelectric actuator ("APA") type as described in U.S. Patent No. 6,465,936 (Knowles), which is hereby incorporated by reference. In yet another embodiment, the actuator is a Langevin or bolted dumbbell-type actuator, similar to, but not limited to that which is disclosed in U.S. Patent

Application Publication No. 2007/0063618 A1 (Bromfield), which is hereby incorporated by reference.

[0019] In a preferred embodiment, the present invention comprises a handheld device including a body, a flextensional actuator disposed within said body and a penetrating or "sharps" member attached to one face of the flextensional actuator. In the broadest scope of the invention, the penetrating member may be hollow or solid. The actuator may have an internal bore running from a distal end to a proximal end or may have a side port located on the penetrating member attachment fitting. Therefore for single use penetrating members there is no need to sterilize the penetrating member after use. Where the penetrating member is hollow, it forms a hollow tubular structure having a sharpened distal end. The hollow central portion of the penetrating member is concentric to the internal bore of the actuator, together forming a continuous hollow cavity from a distal end of the actuator body to a proximal end of the penetrating member. For example, the flextensional actuator assembly may utilize flextensional Cymbal actuator technology or amplified piezoelectric actuator (APA) technology. The flextensional actuator assembly provides for improved amplification and improved performance, which are above that of a conventional handheld device. For example, the amplification may be improved by up to about 50-fold. Additionally, the flextensional actuator assembly enables handpiece configurations to have a more simplified design and a smaller format.

[0020] One embodiment of the present invention is a resonance driven vascular entry needle to reduce insertion force of the penetrating member and to reduce rolling or collapsing of vasculature.

[0021] An alternative embodiment of the present invention is a reduction of force epidural needle that provides the clinician a more controlled entry into the epidural space, minimizing the accidental puncturing of the dural sheath. In this embodiment, an actuator, for example, a Langevin actuator (more commonly referred to as a Langevin transducer), has a hollow penetrating member, for example a hollow needle, attached to a distal portion of the actuator. The Langevin actuator in this embodiment may be open at opposite ends. The openings include a hollow portion extending continuously from the distal end of the actuator to a proximal end of the actuator. The distal opening coincides with the hollow penetrating member. A plunger, having a handle, a shaft and a seal is also attached to the actuator at an opposite end of the sharps member. The plunger's shaft is slidably disposed within the continuous, hollowed inner portion of the actuator. The seal is attached to a distal portion of the plunger's shaft and separates a distal volume of the hollowed inner portion of the

actuator from a proximal volume of the hollowed inner portion. Because the plunger's shaft is slidably disposed, the plunger is also slidably disposed and, in response to a motion of the shaft in a distal direction, reduces the distal volume of the hollowed inner portion and increases the proximal volume. Conversely, in response to a motion of the shaft in a proximal direction, the seal also moves in a proximal direction, thereby reducing the proximal volume of the hollowed portion and increasing the distal volume. The motion of the plunger's shaft, and, effectively, the plunger's seal, is actuated by an external force acting on the plunger's handle. When electrically activated, the actuator transfers compression and expansion of the piezoelectric material portion to a hollow and penetrating tip of the hollow needle. Langevin actuators may be considered high frequency actuators, e.g., > 50 kHz.

[0022] Another embodiment of the invention provides a bone marrow biopsy device having an outer casing, an actuator, for example, a Langevin actuator (e.g., see, for example, U.S. Patent No. 6,491,708 (Madan, et al.), whose entire disclosure is incorporated by reference herein), including a first body portion and a second body portion of the actuator, with piezoelectric material formed between the first and second body portions, wherein the actuator is disposed at least partially within the casing. The invention further includes a handle, an outer cannula, such as a needle, having an open distal end and an open proximal end with the cannula positioned at a distal portion of the actuator. In one aspect of the present embodiment, the invention further comprises a stylet having a penetrating distal tip attached to the handle at a portion opposite the distal tip, wherein the stylet is slidably disposed through a center cavity of the body and cannula. The actuator is formed with a distal opening formed at a distal end of the actuator, and a proximal opening formed at a proximal end of the actuator with a centralized hollow bore extending from the distal opening to the proximal opening, thereby defining a hollow channel.

[0023] More precisely, the outer cannula is a hollow tube fixedly attached at the distal end of the actuator such that the open proximal end of the cannula coincides with the distal opening of the actuator distal end. The stylet is slidably and centrally disposed within the actuator from the proximal end through the hollow channel and through the distal end. The stylet is also of predetermined length such that it is slidably and centrally located through the outer cannula, with the distal tip of the stylet protruding past the open distal end of the cannula.

[0024] The various actuators of the present invention must be connected electrically to an external electrical signal source. Upon excitation by the electrical signal, the actuators

convert the signal into mechanical energy that results in vibratory motion of an end-effector, such as an attached needle or stylette. In the case of a Langevin actuator, the vibratory motion produced by the piezoelectric materials generates a standing wave through the whole assembly such as that in graph in **FIG. 17**. Because at a given frequency, a standing wave is comprised of locations of zero-displacement (node, or zero node) and maximum displacement (anti-node –not shown) in a continuous manner, the displacement that results at any point along the actuator depends on the location where the displacement is to be measured. Therefore, the horn is typically designed with such a length so as to provide the distal end of the horn at an anti-node when the device is operated. In this way, the distal end of the horn experiences a large vibratory displacement in a longitudinal direction with respect to the long axis of the actuator. Conversely, the zero node points are locations best suited for adding port openings or slots so as to make it possible to attach external devices to the actuator. As indicated by line **ZN**, the port opening **SP** coincides with the zero node location and the smaller displacement at zero node points are less abrasive to an attached device.

[0025] Accordingly, an alternative embodiment, the actuator may be formed with a distal opening formed at the distal end of the actuator, a port opening on at least a portion of the actuator, and a hollow bore extending from the distal opening to and in communication with the port opening. Preferably, the port opening may be a side port on a horn side of the actuator. More preferably, the port opening is generally located (preferably centered) at a zero node location of the actuator, and most preferably centered at a zero node location on a horn side of the actuator. Additionally, a means for providing feedback, for example any of those conventional feedback devices disclosed above used for indication of successful body location such as the epidural space penetration is in communication with the present embodiment by attachment at the port opening location, or preferably at the side port. Alternatively, any means capable of delivering fluid, such as a catheter tube or conventional syringe can be attached at the port opening location, or preferably at the side port.

[0026] The present invention relates generally to oscillatory or translational actuated handheld device for penetration through various tissues within a body for the delivery or removal of bodily fluids, tissues, nutrients, medicines, therapies, placement or removal of catheters, etc.. For example for piezoelectric devices, the present invention is a handpiece including a body, at least one piezoelectric element disposed within the body, and a sharps member for tissue penetration, such as a syringe, epidural needle or biopsy needle located at a distal portion of the handheld device, having a feedback means capable of indicating

successful penetration of the body space, such as epidural space by providing visual, audible or tactile indications using any well-known detection mechanisms such as but not limited to electrical, magnetic, pressure, capacitive, inductive, etc. means.

[0027] Additionally, with the use of proper circuitry the handheld medical device comprising an actuator is provided with a means for shutting off external power to the driving actuator (e.g., one or more of piezoelectric elements, voice coil, solenoid, other oscillatory or translational actuator, etc.) upon penetration of a particular tissue or internal portion of a body such as the epidural space. The means for shutting off external power to the driving actuator may be implemented as part of the aforementioned means for providing visual, audible or tactile indications or may be a separate means altogether. Preferably the means for shutting off external power to the driving actuator upon penetration of a particular tissue or internal portion of for example, the epidural space, may be accomplished by incorporating proper circuit configurations to aforementioned electrical means to trigger a switching means in order to cut off power to the driving actuator. Such a means is described in U.S. Patent No. 5,575,789 (Bell et al.) whose entire disclosure is incorporated by reference herein. By providing such electrical cut-off means, upon successfully penetrating the epidural space for example, a clinician receives one or more of a visual, audible, and tactile indications as well as a loss of power to the device as a secondary indication that a particular internal portion of a body has been penetrated. Furthermore, with a loss of power to the device by cutting off electrical power to the driving actuator, the force or forward momentum necessary for further penetration of tissue will cease and in turn, will decrease the potential for unwanted body area puncture such as accidental dural puncture.

[0028] Additionally the invention with specific control electronics will provide reduction of force as the penetrating member is retracted from the body.

[0029] In one embodiment, the penetrating or sharp tubular member is a part of a vascular entry needle.

[0030] In another embodiment, the penetrating sharp tubular member is a Tuohy needle.

[0031] In yet another embodiment, the penetrating or sharp tubular member is a trocar and stylet assembly, such as a JAMSHIDI® biopsy needle.

[0032] In yet another embodiment, the penetrating or sharp tubular member is a pencil point tipped needle.

[0033] In yet another embodiment, the penetrating or sharp tubular member is part of a trocar access port.

[0034] These and other features of this invention are described in, or are apparent from, the following detailed description of various exemplary embodiments of this invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0035] Exemplary embodiments of this invention will be described with reference to the accompanying figures.

[0036] **FIG. 1** is a partial isometric view of a distal end of a prior art biopsy needle;

[0037] **FIG. 2** is a partial side view of a distal end of a prior art epidural needle;

[0038] **FIG. 2a** is a plan view of a conventional prior art loss of resistance syringe;

[0039] **FIG. 3** is a graph illustrating the penetration force of a penetrating member;

[0040] **FIG. 4** is a cross section of a Langevin actuator, more commonly referred to as a Langevin transducer, for use as an actuator in a first embodiment of the present invention;

[0041] **FIG. 4a** is needle design with the side port located in the penetrating member hub providing external access such as for pressure sensor connection or catheter entry location.

[0042] **FIG. 5** is a cross section of a vascular entry needle used in a first embodiment of the invention;

[0043] **FIG. 6** is a cross section of a plunger used in a first embodiment of the invention;

[0044] **Fig. 6a** depicts the present invention including a sterilization sleeve for wires and housing;

[0045] **Fig. 6b** depicts the present invention including a battery and inverter compartment attached at the end of the actuator;

[0046] **FIG. 7** is a cross section of a first embodiment of the invention;

[0047] **FIG. 7a** is a cross-section of an alternate design of the first embodiment of the invention that incorporates the side port on the penetrating member hub.

[0048] **FIG. 8** is a cross section of another alternate design of the first embodiment of the invention of **Fig. 7;**

[0049] **FIG. 9** is an isometric view of a second embodiment of the present invention;

[0050] **FIG. 9a** is an isometric view of an alternate design of the second embodiment using a side port on the actuator for attachment location of the pressure sensor or entry of a catheter;

[0051] **FIG. 9b** is an isometric view of more preferred alternate design of the second embodiment using a side port on the penetrating member hub for attachment location of the pressure sensor or entry of a catheter;

[0052] **FIG. 10a** is a cross section of an inner stylet for use in a third embodiment of the present invention;

[0053] **FIG. 10b** is a cross section of an outer penetrating member, such as a trocar, for use in a third embodiment of the present invention;

[0054] **FIG. 10c** is a cross section showing the relative positioning of the inner stylet of **Fig. 10a** within the outer penetrating member of **Fig. 10b** for use in a third embodiment of the present invention;

[0055] **FIG. 11** is a cross section of a third embodiment of the present invention;

[0056] **FIG. 12** is a cross section of a fourth embodiment of the present invention;

[0057] **FIG. 13** is a cross section of a penetrating member attached to an amplified piezoelectric actuator for use in a fifth embodiment of the present invention;

[0058] **FIG. 13a** is cross section of an alternate APA design of a penetrating member with side port for use the present invention;

[0059] **FIG. 14** is a cross section of a fifth embodiment of the present invention;

[0060] **FIG. 14a** is a cross section of the fifth embodiment of the present invention using a penetrating member with side port of **Fig. 13a**;

[0061] **FIG. 15** is a cross section of a sixth embodiment of the present invention comprising a Cymbal actuator;

[0062] **FIG. 16** is a cross section of the sixth embodiment of the present invention using the penetrating member with side port of **Fig. 13a**;

[0063] **FIG. 17** shows the correlation between zero node points of a standing wave and the location of a side port on a Langevin actuator without the actuator handle shown;

[0064] **FIG. 17a** shows the correlation between zero node points of a standing wave and the location of a side port on the penetrating member connected to the Langevin actuator;

[0065] **FIG. 18a** is a functional diagram of a seventh embodiment of the present invention depicting a side port at a zero node location on a Langevin actuator without the handle shown;

[0066] **FIG. 18b** is a functional diagram of a seventh embodiment of the present invention comprising the side port of **FIG. 18a** in communication with a central channel extending the length of a Langevin actuator and without the handle shown;

[0067] **FIG. 18c** is a sketch of a eighth embodiment of the present invention comprising two side ports in communication with needle attachment one connected to the front portion of the Langevin actuator and the other connected to the penetrating member without the actuator handle shown;

[0068] **FIG. 18d** is a sketch of a eighth embodiment of the present invention comprising the side port connected to the short bore and communication with needle attachment that is

also connected to the front portion of the Langevin actuator and without the handle shown of the actuator of **FIG. 18a**;

[0069] **FIG. 19** is a drawing of a ninth embodiment of the present invention comprising a conventional syringe of **FIG. 2a** attached at the side port location of the actuator shown in **Fig. 18** and without the actuator handle shown;

[0070] **FIG. 19a** is a drawing of a ninth embodiment of the present invention comprising a conventional syringe of **FIG. 2a** attached at the side port location of the penetrating member hub shown in **FIG. 18c** with the actuator also connected into the hub and without the actuator handle shown;

[0071] **FIG. 19b** is a drawing of a pressure sensing pump system for connection to a penetrating member.

[0072] **FIG. 20a** is a cross-sectional view of a tenth embodiment of the present invention using a voice coil for the driving actuator;

[0073] **FIG. 20b** is a cross-sectional view of the tenth embodiment of the present invention using a voice coil for the driving actuator wherein the position of the magnetic member and the coil are reversed from that of **FIG. 20a**;

[0074] **FIG. 20c** is an isometric cross-sectional view of the tenth embodiment of the present invention using two coils;

[0075] **FIG. 20d** is a side cross-sectional view of the tenth embodiment of the present invention using a solenoid with springs; and

[0076] **FIG. 21** is an exemplary schematic of an electrical power cut off for use in the various embodiments of the present invention.

BRIEF DESCRIPTION OF THE INVENTION

[0077] The preferred embodiments of the present invention are illustrated in **Figs. 3-21** with the numerals referring to like and corresponding parts. For purposes of describing relative configuration of various elements of the invention, the terms "distal", "distally", "proximal" or "proximally" are not defined so narrowly as to mean a particular rigid direction, but, rather, are used as placeholders to define relative locations which shall be defined in context with the attached drawings and reference numerals. A listing of the various reference labels are provided at the end of this Specification. In addition, U.S. A.S.N. 12/163,071 entitled "Medical Tool for Reduced Tool Penetration Force," filed on June 27, 2008 is incorporated by reference in its entirety.

[0078] The effectiveness of the invention as described, for example, in the aforementioned preferred embodiments, utilizes reduction of force to optimize penetrating

through tissue or materials found within the body. Essentially, when tissue is penetrated by the high speed operation of a penetrating member portion of the device, such as a needle, the force required for entry is reduced. In other words, a reduction of force effect is observed when a penetrating member (also referred to as a "tubular member"), for example a needle, is vibrated axially (e.g., reciprocated) during the insertion process and enough mechanical energy is present to break adhesive bonds between tissue and the penetrating member. The threshold limits of energy can be reached in the sonic to ultrasonic frequency ranges if the necessary amount of needle displacement is present.

[0079] To exploit the reduction of force effect, the medical device of the present invention is designed such that the penetrating distal tip portion attains a short travel distance or displacement, and vibrates sinusoidally with a high penetrating frequency. Utilizing the various device configurations as described in the aforementioned embodiments, it has been determined that the sinusoidal motion of the sharp distal tip must include a displacement for piezoelectric tools of between 35-100μm, more preferably between 50-100μm, at a frequency of between 20-50kHz, but most preferably at 20-25 kHz. This motion is caused by the penetrating member **20** being attached to an actuating piezoelectric actuator operated at 50-150 Vpp/mm, but most preferably at 90 Vpp/mm where Vpp is known as the peak-to-peak voltage.

[0080] For example, **FIG. 3** shows a graphical representation of the resisting force versus depth of a bone biopsy needle penetrating into hard tissue. In **FIG. 3**, the curve labeled **A** represents data for a needle in an "off" or non-vibrating condition and the curve labeled **B** represents data for a medical device having a needle that is vibrated by a piezoelectric actuator at 38 kHz and a displacement of 100μm. As apparent from **FIG. 3,** curve **A** shows that without being vibrated, the force necessary to penetrate into a material is much higher than that for a needle being oscillated, such as that represented by curve **B**.

[0081] By way of example only, referring to **FIG. 4**, a Langevin actuator, generally indicated as **100**, comprises a piezoelectric actuator which includes a body having a central hollow channel and includes a displaceable member (also referred to as a "horn") **110,** an anchor (also referred to as a "rear mass") **112** and at least one piezoelectric element **114**, but preferably comprises more than one. In particular, each piezoelectric element **114** may be formed into a piezoelectric ring that forms a hollow portion and wherein the piezoelectric elements **114** are secured within the body and attached between horn **110** and rear mass **112**. A hollow or solid threaded bolt **116** is disposed within a center portion of rear mass **112**,

extending through a center portion of the at least one of piezoelectric elements **114** and ending within a central portion of horn **110.** The bolt compresses the rear mass **112,** the at least one of piezoelectric elements **114** and horn **110.** The horn **110** and rear mass **112** are made of a metal such as titanium, stainless steel, ceramic (which include polycrystalline and single crystal inorganic materials), plastic, composite or, preferably, aluminum. The bolt **116** is of the same material as the horn **110** and rear mass **112.** To protect patient and clinician from electric shock, at least a portion of the Langevin actuator **100,** preferably at least the whole of the rear body **112,** all of the at least one piezoelectric elements **114,** and at least a portion of the horn **110,** are disposed within a handle **118.** Electrical connection is made at metallic tabs (not shown) formed between opposing faces of the at least one of piezoelectric elements **114.** These tabs can be coupled via electrical conductors **114b** connected to an AC power source or battery (e.g., positioned within a battery compartment of the present invention). The handle **118** comprises a shell portion which may be a plastic or a metal and a seal **120** which may be an elastomer. Seal **120** prevents moisture from entering or exiting from the central portions of the rear mass **112,** piezoelectric elements **114** and horn **110.** The central portion of the rear mass **112,** piezoelectric elements **114** and horn **110** coincide with the hollow portion of the bolt **116** forming a continuous bore **126** within the Langevin actuator **100,** the bore **126** having a distal opening **122** at a distal face **121** and a proximal opening **124** at a face opposite to the distal face **121.** A Luer taper nose **123** is added to the actuator for clarity of connection.

[0082] It should be understood that the number of piezoelectric elements **114** does not form a limitation on the present invention and that it is within the broadest scope of the present invention to include one or more piezoelectric elements **114.**

[0083] According to an alternative embodiment, a side port (not shown) may be formed at the horn **110** side of the actuator and the continuous bore **126** extends from a distal opening **122** at distal face **121** and in communication with this side port.

The functional performance of the medical device is driven by the piezoelectric elements section. Piezoelectric elements **114,** such as each of one or more piezoelectric material rings are capable of precise, controlled displacement and can generate energy at a specific frequency. The piezoelectric materials expand when exposed to an electrical input, due to the asymmetry of the crystal structure, in a process known as the converse piezoelectric effect. Contraction is also possible with negative voltage. Piezoelectric strain is quantified through the piezoelectric coefficients d_{33}, d_{31}, and d_{15}, multiplied by the electric field, E, to determine the strain, x, induced in the material. Ferroelectric polycrystalline materials, such

as barium titanate (BT) and lead zirconate titanate (PZT), exhibit piezoelectricity when electrically poled. Simple devices composed of a disk or a multilayer type directly use the strain induced in a material by the applied electric field. Acoustic and ultrasonic vibrations can be generated by an alternating field tuned at the mechanical resonance frequency of a piezoelectric device. Piezoelectric components can be fabricated in a wide range of shapes and sizes. In one embodiment, piezoelectric component may be 2-5mm in diameter and 3-5mm long, possibly composed of several stacked rings, disks or plates. The exact dimensions of the piezoelectric component are performance dependent. The piezoelectric single or polycrystalline materials may be comprised of at least one of lead zirconate titanate (PZT), multilayer PZT, lead magnesium niobate-lead titanate (PMN-PT), multilayer PMN-PT, lead zinc niobate-lead titanate (PZN-PT), polyvinylidene difluoride (PVDF), multilayer PVDF, and other ferroelectric polymers. These materials also can be doped which changes properties and enhances the performance of the medical device. This list is not intended to be all inclusive of all possible piezoelectric materials. For example there is significant research into non-lead (Pb) containing materials that once developed will operate in this invention.

[0084] In the embodiment shown in **FIG. 4a** the side port **SP** is located on the penetrating member hub **525** of the hollow needle **130**. In this alternate embodiment the hollow needle **130** penetrating member hub **525** is preferably metal or a combination of metal insert molded in a plastic. The side port **SP** would contain a female Luer taper opening to attach a loss of resistance conventional syringe **PA3**.

[0085] Referring now to **FIG. 5**, a penetrating member, generally indicated as **20**, for use in a first embodiment of the present invention comprises an attachment fitting **128** connected to proximal end **130b** and the distal end **130a** of a hollow needle **130** penetrates tissue. By way of example only, the attachment fitting **128** may comprise a Luer taper, plastic or metal fitting.

[0086] Referring now to **FIG. 6,** a plunger **12** for use in a first embodiment of the present invention comprises a plunger handle **132** attached to a proximal end **134a** of a plunger shaft **134**, and a plunger seal **136** attached to a distal end **134b** of the plunger shaft **134**. The plunger seal is used to seal the handle **118** so that contaminates such as water or bodily fluids do not reach the actuator elements or electrical connections. In another embodiment, the plunge will create a vacuum in the hollow penetrating member to aspirate bodily fluids and/or tissue for sampling such as in a soft tissue biopsy procedure.

[0087] In the most preferred embodiment, the side port is located on the penetrating member hub **525** at the end attachment point

[0088] Referring now to **FIG. 7**, a first embodiment of the present invention, for example a penetrating introducer, generally indicated as **200,** comprises an actuator, such as the Langevin actuator **100** described in **FIG. 4**, with the penetrating member **20** of **FIG. 5** being attached at a distal face **121** of the actuator. The needle attachment fitting **128** is a threaded fitting, Luer taper, compression fitting or the like, and couples hollow needle **130** to a portion of distal face **121** such that it communicates with a distal volume of continuous bore **126**. Plunger handle **132** may be a threaded, clamped, compressed or the like to bolt **116** so as to immobilize plunger **12** of **FIG. 6**. The present invention is sterilizable using such methods as steam sterilization, a sleeve, gamma, ethylene oxide (ETO). For example, **FIG. 6a** depicts a sterilization sleeve **115** for wires and housing used with the present invention. The preferred material for the needle attachment **128** is a metal or a metal insert in a molded plastic. **FIG. 6b** shows the Langevin actuator **100** with a possible configuration of the battery & inverter compartment **117** attached to the end of the actuator.

[0089] Returning to **Figs. 4 and 7**, upon application of an external AC current at a predetermined frequency to the at least one of piezoelectric elements **114**, the Langevin actuator **100** reactively changes shape in a sinusoidal fashion such that the relative position of distal face **121** with respect to say, a fixed position of plunger handle **132** attached to and held in place by bolt **116,** changes by a predetermined displacement. Because the AC current is a sinusoidal signal, the result of activating the piezoelectric elements **114** is a sinusoidal, back and forth motion of the distal face **121** of horn **110**, and, subsequently, a back and forth motion of needle **130,** thereby reducing the force necessary for penetration through tissue. As mentioned previously, the AC energization can be provided directly from an AC source or from a DC source (e.g., onboard batteries) coupled to an inverter (e.g., oscillator/amplifier, etc.) which in turn is coupled to the piezoelectric elements **114**. The DC source is the more preferred embodiment as wires and connections will need additional sterilization features.

[0090] **FIG. 7a** depicts a similar invention as shown in **FIG. 7** but includes a penetrating member hub **525** with a side port **SP** connected to the hollow needle **130**. This configuration enables pressure sensor to be mounted in the side port **SP** which once removed provides for a catheter to be inserted or fluids removed. This is likely the preferred embodiment when compared to **FIG. 7** as the entire active device will not be at risk for contamination since the

catheter or fluids do not traverse the actuator only the hollow needle **130** which could be manufactured for single use.

[0091] Referring to **FIG. 8**, a supported introducer, generally indicated as **201,** is similar to the penetrating introducer **200** of **FIG. 7** additionally comprising support wings **111,** existing for example as a flat portion onto which a user can grasp, and extending radially from an outer surface forming a mechanical zero node of the horn **110,** as described later with regard to **FIG. 17**. A side port **SP** (not shown) could be 90 degrees clockwise or counterclockwise from the support wings that may be a location for providing access for aspirated sample retrieval, catheter insertion etc..

[0092] In an alternate embodiment of the present invention, the penetrating introducer **201** of **FIG. 8** exists as a catheterization introducer, generally indicated as **202**, as shown in **FIG. 9**. In this embodiment, rather than a plunger being introduced from a proximal end of the device, a catheter **129** is introduced from the proximal end of the device and is received through bore **126** as shown in **FIG. 4**, and may be passed through hollow needle **130**. Upon having been inserted into a patient, hollow needle **130** forms a subcutaneous tunnel through which catheter **129** is introduced into the body. Upon successful introduction, the actuator may be detached from hollow needle **130** by decoupling attachment fitting **128** from the horn **110**.

[0093] A more preferred embodiment **202b** is shown in **FIG. 9a** where a side port **SP** permits the introduction of the catheter **129** into the present invention, rather than through the proximal end, as shown in **FIG. 9**. This configuration enables pressure sensor to be mounted in the side port **SP** which once removed enables a catheter to be inserted or fluids removed near the distal face **121** of the device. This is likely the preferred embodiment when compared to **FIG. 9** as the entire active device will not be at risk for contamination since the catheter or fluids do not traverse the entire actuator.

[0094] In the most preferred embodiment **202c** is shown in **FIG. 9b** where the side port **SP** located on the penetrating member hub **525** permits a pressure sensor to be mounted in the side port **SP** which once removed provides entry of an instrument such as a catheter **129** to be inserted or fluids aspirated. This is likely the preferred embodiment when compared to **FIG. 9** as the entire active device will not be at risk for contamination since the catheter or fluids do not traverse the actuator only the hollow needle **130**.

[0095] Now referring to **FIG. 10a**, an inner stylet, generally indicated as **14**, comprises an inner stylet handle **142** attached to a proximal end of an inner stylet shaft **144**. At a distal end of the inner stylet shaft **144,** opposite to the handle **142** is a sharpened inner stylet tip

146. To support the inner stylet shaft **144,** an outer trocar tube, generally indicated as **15**, shown in **FIG. 10b** comprises a trocar attachment fitting **148** attached at a proximal end of an outer trocar body **150**, which is a tubular structure open at opposite ends. The trocar attachment fitting **148** is hollow such that outer trocar body **150** is disposed within it. Additionally, one of the openings formed at opposite ends of the trocar body **150** is a distal trocar opening **152**, the outer walls of which form distal trocar tip **154**. As shown in **FIG. 10c**, inner stylet shaft **144** may be slidably disposed within outer trocar body **150** with inner stylet tip **146** extending beyond distal trocar tip **154**. Together, the inner stylet **14** of **FIG. 10a** and outer trocar tube **15** of **FIG. 10b** form a structure similar to a trocar needle (e.g., a JAMSHIDI® biopsy tool).

[0096] Referring now to **FIG. 11,** inner stylet **14** is slidably disposed within bore **126** of Langevin actuator **100** of **FIG. 4** and outer trocar tube **15** of **FIG. 10b**, with outer trocar tube **15** attached to horn **110** to form a bone biopsy device, generally designated as **300**. Inner stylet **14** extends in a manner such that handle **142** contacts bolt **116** when fully seated, with inner stylet shaft extending from handle **142** through proximal opening **124**, through bore **126** and hollow portion of outer trocar body **150** finally terminating as inner stylet tip **146** at a location beyond distal trocar tip **154**. In this embodiment, when the at least one of piezoelectric elements **114** of Langevin actuator **100** of **FIG. 4** is electrically actuated via electrical conductors **114b** at a predetermined frequency, motion in the form of compression and expansion of the rings is transferred to an anti-node location at the distal face **121** of horn **110**. The motion is then transferred as actuation of outer trocar tube **15** of **FIG. 10b**.

[0097] In an alternate embodiment, an advanced bone biopsy device, generally indicated as **400**, shown in **FIG. 12**, comprises all of the elements of bone biopsy device **300** of **FIG. 11**, except that upon electrical activation of Langevin actuator **100** of **FIG. 4** at a predetermined frequency, the motion is transferred as actuation of inner stylet **14**. To perform this function, the positioning of the inner stylet shaft **14** of **FIG. 10a** and outer trocar tube **15** of **FIG. 10b** are inverted with respect to the configuration of **FIG. 11**. For example, in the advanced bone biopsy device **400**, outer trocar tube **15** is attached to bolt **116**. Additionally, inner stylet **14** extends in a manner such that handle **142** contacts distal face **121** of horn **110** when fully seated, with inner stylet shaft **144** extending from handle **142** through distal opening **122,** through bore **126** and hollow portion of outer trocar body **150**, finally terminating as inner stylet tip **146** at a location beyond distal trocar tip **154**.

[0098] While the previous embodiments have been described with respect to a Langevin actuator **100** as the actuating mechanism, the invention is not so limited. For example, as

shown in **FIG. 13**, a hollow tubular structure having a sharpened distal tip **513b** of the penetrating member **513** is attached at its proximal end **513a** to an Amplified piezoelectric actuator (APA) **510** forming an APA needle, generally designated as **16**. The amplified piezoelectric actuator (APA) **510** comprises a frame **512**, normally formed of a metal such as brass or stainless steel, and a piezoelectric material **514** compressed within frame **512**. An APA bore **526** may extend from a distal face through piezoelectric material **514** and through a proximal face **512a** of frame **512**. Hollow penetrating member **513**, for example a hypodermic needle, is attached to the distal face **512b** of frame **512**, such that the hollow portion is concentrically aligned with the APA bore **526**. As shown in **FIG. 14**, APA needle **16** may be disposed within a handle **518** forming an APA syringe, generally designated as **500**. Important to this embodiment is that a proximal face **512a** of frame **512** of amplified piezoelectric actuator (APA) **510** must be fixed as shown at **516** attachment point to an inner portion of handle **518** such that the APA bore **526**, hollow penetrating member **513**, a handle proximal opening **524** and handle distal opening **521** form a continuous channel through which fluids may pass into a patient. **Figs. 13a** and **14a** show alternate embodiments **16b** and **500b**, respectively, with a detachable penetrating member hub **525** enabling the single use penetrating member with re-usable active motion handle where the penetrating member hub **525** is described previously.

[0099] In operation, the piezoelectric material **514** expands during the AC voltage cycle, which causes the frame's proximal and distal faces **512a, 512b** formed opposite of one another to move inward toward each other. Conversely, when piezoelectric material **514** compresses during the opposite AC cycle, an outward displacement of the frame's proximal and distal faces **512a, 512b** away from one another occurs. However, in the present embodiment, the proximal face **512a** of the frame is fixedly attached to body's **518** attachment point **516** so that any movement in the piezoelectric material stack will result in only a relative motion of distal face **512b** and, thereby, a motion of the penetrating member **513**.

[00100] Two examples of applicable amplified piezoelectric actuators (APAs) are the non-hinged type, and the grooved or hinged type. Details of the mechanics, operation and design of an example hinged or grooved APA are described in United States Patent No. 6,465,936 (Knowles et al.), which is hereby incorporated by reference in its entirety. An example of a non-hinged APA is the Cedrat APA50XS, sold by Cedrat Technologies, and described in the Cedrat Piezo Products Catalogue "Piezo Actuators & Electronics" (Copyright© Cedrat Technologies June 2005).

[00101] Preferably, the APAs of the present invention are operated at frequencies in the range of 100Hz to 20kHz, more preferably 100Hz to 1kHz.

[00102] Alternatively, the actuator of the present invention may be a Cymbal actuator. For example, in **FIG. 15**, a Cymbal syringe, generally indicated as **600**, including a Cymbal actuator **610** which comprises two endcaps **612** with the distal endcap **612b** and proximal endcap **612a** with at least a piezoelectric element **514** formed between the endcaps. The Cymbal syringe is centered on the Cymbal bore **626**. The endcaps **612** enhance the mechanical response to an electrical input, or conversely, the electrical output generated by a mechanical load. Details of the flextensional Cymbal actuator technology is described by Meyer Jr., R.J., et al., "Displacement amplification of electroactive materials using the Cymbal flextensional transducer", Sensors and Actuators A 87 (2001), 157-162. By way of example, a Class V flextensional Cymbal actuator has a thickness of less than about 2mm, weighs less than about 3 grams and resonates between about 1 and 100kHz depending on geometry. With the low profile of the Cymbal design, high frequency radial motions of the piezoelectric material are transformed into low frequency (about 20-50kHz) displacement motions through the cap-covered cavity. An example of a Cymbal actuator is described in United States Patent No. 5,729,077 (Newnham et al.) and is hereby incorporated by reference. While the endcaps shown in the figures are round, they are not intended to be limited to only one shape or design. For example, a rectangular Cymbal endcap design is disclosed in Smith N.B., et al., "Rectangular Cymbal arrays for improved ultrasonic transdermal insulin delivery", J. Acoust. Soc. Am. Vol. 122, issue 4, October 2007. Cymbal actuators take advantage of the combined expansion in the piezoelectric charge coefficient d_{33} (induced strain in direction 3 per unit field applied in direction 3) and contraction in the d_{31} (induced strain in direction 1 per unit field applied in direction 3) of a piezoelectric material, along with the flextensional displacement of the endcaps **612**, which is illustrated in **FIG. 15**. The design of the endcaps **612** allows both the longitudinal and transverse responses to contribute to the strain in the desired direction, creating an effective piezoelectric charge constant (d_{eff}) according to the formula, $d_{eff} = d_{33} + (-A*d_{31})$. Since d_{31} is negative, and the amplification factor (A) can be as high as 100 as the endcaps **612** bend, the increase in displacement generated by the Cymbal compared to the piezoelectric material alone is significant. The endcaps **612** can be made of a variety of materials, such as brass, steel, titanium or KOVAR™, a nickel-cobalt ferrous alloy compatible with the thermal expansion of borosilicate glass which allows direct mechanical connections over a range of

temperatures, optimized for performance and application conditions. The endcaps **612** also provide additional mechanical stability, ensuring long lifetimes for the Cymbal actuators.

[00103] The Cymbal actuator **610** drives the penetrating member **513**. When activated by an AC current, the Cymbal actuator **610** vibrates sinusoidally with respect to the current's frequency. Because endcap **612a is** fixed to an inner sidewall of body **518**, when Cymbal actuator **610** is activated, endcap **612b** moves with respect to the body in a direction parallel to the hypothetical long axis of the medical device. Further, the displacement of penetrating member **513** is amplified relative to the displacement originating at piezoelectric material **514** when it compresses and expands during activation due in part to the amplification caused by the design of endcaps **612**. For example, the piezoelectric material **514** alone may only displace by about 1–2 microns, but attached to the endcaps **612**, the Cymbal actuator **610** as a whole may generate up to about 1kN (225 lb-f) of force and about 80 to 100 microns of displacement. This motion is further transferred through the penetrating member **513** as an amplified longitudinal displacement of 100-300 microns. For cases requiring higher displacement, a plurality of Cymbal actuators **610** can be stacked endcap-to-endcap to increase the total longitudinal displacement of the penetrating member **513**. **FIG. 16** shows an alternate embodiment **600b** with a detachable penetrating member hub **525** enabling the single use penetrating member with reusable active motion handle.

[00104] In alternate embodiments of the present invention, an additional port opening is formed in communication with a channel formed within the body of the actuator, for example a Langevin actuator. In particular, **Figs. 17-19** are directed to these alternate embodiments and it should be noted that for clarity reasons, the handle **118** of the Langevin actuator is not shown in these figures.

[00105] Because the port opening is provided so as to attach a means for providing visual, audible or tactile feedback response (e.g., using any well-known detection mechanisms such as but not limited to electrical, magnetic, pressure, capacitive, inductive, etc. means) to indicate the successful penetration of the specific tissue such as the epidural space, it must be formed at a location which will be least detrimental to such means. In other words, because the actuator vibrates at high frequencies, each point along the actuator experiences a different displacement defined by a standing wave. In **FIG. 17**, a displacement graph **G1** represents a standing wave having longitudinal displacements at points along the length of a Langevin actuator operated at 38 kHz. As can be seen in a displacement graph **G1**, two nodes having near zero displacement exist at particular locations in the standing wave. The two node ("zero node" **ZN**) locations on the Langevin

actuator **LT** are therefore defined at a particular lengths along the Langevin actuator. In the specific design shown in **FIG. 17** the nodes on the standing wave correspond to zero node, or locations having minimum displacements on the Langevin actuator **LT**. The locations of the zero nodes on the Langevin actuator **LT** are then located at a proximal face (not shown) of the rear mass opposite to the distal face **121.** Line **ZN** defines the physical location of the other zero node at which a side port **SP** should be located, preferably centered, when formed in a Langevin actuator **LT** relative to second zero node of the standing wave in displacement graph **G1**. In the case shown in **FIG. 17,** the side port **SP** is formed at the horn **110** of the Langevin actuator **LT,** however a port opening is not necessarily so limited. A port opening can be placed anywhere along an actuator but a zero node location is preferred.

[00106] In a more preferred embodiment, **FIG. 17a** describes the side port **SP** location on the zero node **ZN** of the penetrating member hub **525.** In this embodiment, the design length includes both the needle length and actuator length to achieve the zero node **ZN** on the hollow needle **130** which includes length of penetrating member hub **525.** A side port **SP** can be placed anywhere along hollow needle **130** but a zero node location on the penetrating member hub **525** is preferred.

[00107] In **FIG. 18a**, a general side port configuration **700** of the present invention is shown with a side port **SP** as the port opening centered at a zero node location along the horn **110.** Support wings **111** are also formed at a zero node to assist the clinician is holding and stabilizing the device.

[00108] In a seventh embodiment of the present invention shown in **FIG. 18b,** a first side port configuration **700a** has a channel for passing liquid, air or other materials comprises a continuous path from the proximal opening **124** through bore **126** passing through a distal opening (not shown) and extending through hollow needle **130** ending at a distal end **130a** of the hollow needle which is open. In this seventh embodiment, the channel is in communication with the side port **SP** at a location along bore **126.** Preferably, the side port **SP** is located at such a location along the actuator forming the first side port configuration **700a** that acts as a zero node upon activating the device to vibrate.

[00109] Alternatively, as shown in an eighth embodiment of the invention in **FIG. 18c,** a second side port configuration **700b** has a channel for passing liquid, air or other materials comprises a continuous path located on the hollow needle **130** penetrating member hub **525.** In this eighth embodiment, the channel is in communication with the side port **SP** at a location along penetrating member hub **525.** Preferably, the side port **SP** is located at such a location along the entire length (actuator and penetrating member) forming the second side

port configuration **700b** that acts as a zero node upon activating the device to vibrate. In a secondary side port SP located on the actuator an indicator such as an light emitting diode **1026** can be attached and connected to the electronics to indicate a visual loss of resistance.

[00110] Alternatively, as shown in an eighth embodiment of the invention in **FIG. 18d,** a second side port **SP** configuration **700c** has a small bore **126a** for passing liquid, air or other materials located at zero node ZN to and from the hollow needle **130**.

[00111] In a ninth embodiment of the present invention shown in **FIG. 19,** a feedback capable reduction of force tool **800** is provided. By way of example only, tool **800** comprises a means for providing tactile feedback response via a conventional loss of resistance syringe **PA3** having a biasing element **11** with a plunger or balloon (e.g., elastomer device) or any other device that creates pressure then detects or measures pressure change. This device is coupled at a port location, preferably a side port **SP** located, via, by way of example only, a Luer Taper, male/female connector, screw-type connector, and preferably centered, at a zero node location. The tool **800** also includes an indicator in communication with the actuator **700** such as, but not limited to, an audible indicator, tactile indicator, or visual (e.g., deflation, optical, etc.).

[00112] In a most preferred embodiment of the present invention shown in **FIG. 19a,** a feedback capable reduction of force tool **800** is located on the hollow needle 130 at a zero node ZN on the penetrating member hub **525**.

[00113] Another embodiment described in **FIG. 19b**, a possible pressure sensor feedback system **1020** containing a small pumping mechanism equipped with a pressure or flow sensor to meter the amount of fluid being moved, a reservoir **1021** mounted on a base **1024**. The pump fills with saline and connect via flexible tubing **1022** via an attachment fitting **1023** to the side port **SP** of the penetrating member. When loss of resistance (LOR) is detected, the electronic control system will close a switch and an indicator such as a light emitting diode (LED) (not shown) located on the side port **SP** of the actuator will turn-on indicating loss of resistance. The electronics control system at this point will turn the actuator off so that forward motion ceases. In additional embodiment, besides the visual signal, an audible signal a 'beep' could be incorporated into the pump system.

[00114] By way of example only, the following is an exemplary method of using the present invention, whereby a clinician uses the present invention for an epidural procedure. When performing an epidural procedure, the clinician first fills syringe **PA3** with a fluid, such as a saline solution or air. The clinician then inserts the front portion **9** of the syringe into the side port **SP** of the actuator **700b**. Upon electrically activating the actuator, the

clinician holds actuator **700b** with a first hand while pressing the distal end **130a** of the hollow needle against a patient's back. The clinician continues to provide forward momentum, while also providing a biasing force against biasing element **11,** advancing hollow needle **130**. With continued forward momentum, the hollow needle punctures the supraspinous ligament, the instraspinous ligament, and the ligamentum flavum (see **FIG. 7**, for example). Upon puncturing the ligamentum flavum, the distal end **130a** of the needle enters the epidural space at which point there is a pressure drop from the biasing element **11** to the opening at the distal end **130a.** The pressure drop allows for the solution to be ejected from the opening at the distal end **130a**, and the continued biasing of the biasing element **11** combined with the loss of volume of saline results in a loss of resistance (LOR) against the clinician's thumb and a visibly identifiable motion of the biasing element **11**. When the biasing element moves due to this lack of resistance, the clinician quickly identifies that the epidural space has been successfully reached and quickly stops forward momentum of the actuator. Additionally, because the activation of the actuator results in a vibration of the needle **130,** the clinician does not need to provide such a high penetration force and can quickly react to stop himself/herself before advancing the needle beyond the epidural space.

[00115] It should be further noted that it is within the broadest scope of the present invention to include syringes or other mechanisms which provide automatic biasing, such that the clinician does not have to apply a biasing force against the biasing element **11** prior to entry into, for example, the epidural space. In particular, the automatic biasing force (implemented, for example, via a spring, an elastomer, or any other well-known biasing mechanism such as, but not limited to, those described in U.S. Patent Publication No. 2007/0142766 (Sundar, et al.)) maintains an equal resistance as the needle is moved through the supraspinous ligament, the instraspinous ligament, and the ligamentum flavum. Upon entry into the epidural space, the biasing force is no longer resisted and this can be manifested in a variety of ways to the clinician, but not limited to, movement of the biasing element, or any other visual, audible or tactile indication using any well-known detection mechanisms such as but not limited to electrical, magnetic, pressure, capacitive, inductive, etc. means. For example, a pressure signal indicative of a loss of solution resistance automatically cuts off power to the driver actuator (e.g., piezoelectric elements, voice coil, solenoid, etc.).

[00116] While feedback means have been coupled to the side port **SP,** the invention is not so limited to feedback means. Any device may be coupled to a port location of the actuator,

or ideally at the side port **SP** location even those devices simply being a means for providing or removing liquid, gas or other material such as a conventional syringe.

[00117] While the above-described embodiments of the present invention are made with respect to a handheld medical tool having a vibrating penetrating member and utilizing a Langevin actuator, Cymbal actuator, or APA for actuation, as mentioned earlier, the present invention is not limited to these actuator assemblies. Generally, any type of motor comprising an actuator assembly, further comprising a mass coupled to a piezoelectric material, or a voice coil motor, or solenoid, or any other translational motion device, would also fall within the spirit and scope of the invention. Furthermore, where the actuator assembly comprises a mass coupled to a piezoelectric material, the actuator assembly having a geometry which, upon actuation, amplifies the motion in a direction beyond the maximum strain of the piezoelectric material, would also fall within the spirit and scope of the present invention.

[00118] **FIG. 20a** depicts an alternative embodiment **900** of the present invention using a voice coil for the driving actuator rather than piezoelectric elements. Voice coil actuator (also referred to as a "voice coil motor") creates low frequency reciprocating motion. The voice coil has a bandwidth of approximately 10 – 60 Hz and a displacement of up to 10mm that is dependent upon applied AC voltage. In particular, when an alternating electric current is applied through the conducting coil **902**, the result is a Lorentz Force in a direction defined by a function of the cross-product between the direction of current through the conductive coil **902** and magnetic field vectors of the magnetic member **904**. The force results in a reciprocating motion of the magnetic member **904** relative to the coil support tube **906** which is held in place by the body **910**. With the magnetic member **904** fixed to a driving tube **912**, the driving tube **912** communicates this motion to an extension member **914** which in turn communicates motion to the penetrating member **20**.

[00119] A first attachment point **916a** fixes the distal end of the coil support tube **906** to the body **910**. A second attachment point **916b** fixes the proximal end of the coil support tube **906** to the body **910**. The conducting coil may be made of different configurations including but not limited to several layers formed by a single wire, several layers formed of different wires either round or other geometric shapes. In a first embodiment of the conducting coil shown in **FIG. 20a**, a first layer of conductive wire is formed by wrapping the wire in a turn-like and spiral fashion and in a radial direction around the coil-support tube with each complete revolution forming a turn next to the previous one and down a first longitudinal direction of the coil support tube. After a predetermined number of turns, an

additional layer is formed over the first layer by overlapping a first turn of a second layer of the wire over the last turn of the first layer and, while continuing to wrap the wire in the same radial direction as the first layer, forming a second spiral of wiring with at least the same number of turns as the first layer, each turn formed next to the previous one and in a longitudinal direction opposite to that of the direction in which the first layer was formed. In this embodiment, additional layers may be added by overlapping a first turn of each additional layer of the wire over the last turn of a previous layer and, while continuing to wrap the wire in the same radial direction as the previous layer, forming an additional spiral of wiring with at least the same number of turns as the previous layer, each turn formed next to the previous one and in a longitudinal direction opposite to that of the direction in which the previous layer is formed.

[00120] An alternative voice coil embodiment **900b** is shown in **FIG. 20b**. In particular, in this alternative, the locations of the magnetic member **904** and conductive coil **902** are switched. In other words, the conductive coil is wrapped around and attached to the driving tube **912** and the magnetic member **904** is located along an outside radius of the coil support tube **906**.

[00121] An electrical signal is applied at the conductive attachment sites **918** and **920** and causes the formation of the Lorentz force to form in an alternating direction that moves the conductive coil **902** and extension member **914** reciprocally along the longitudinal axis of the device. The conductive coils are physically in contact with the driving tube in this embodiment.

[00122] **FIG. 20c** depicts another embodiment of the present invention using a voice coil type actuating mechanism and is of a different configuration than that used in Figs. **20a** and **20b**. For example, in this alternative embodiment, a voice-coil actuating mechanism is substituted with a dual-coil actuating mechanism and as a result of this substitution, the magnetic member **904** of the voice-coil is replaced with second conductive coil **922**. In other words, the second conductive coil **922** is wrapped around and attached to the driving tube **912** and the first conductive coil **902** is located, as in the first preferred embodiment, along an outside radius of the coil support tube **906**. In a first embodiment of the configuration of **FIG. 20c**, the inner coil **922** is conducting direct current **DC** and the outer coil is conducting alternating current **AC**. In an alternative embodiment, the inner coil is conducting alternating current **AC** and the outer coil is conducting direct current **DC**. In an additional embodiment, both the inner coil and the outer coil are conducting alternating current **AC.**

[00123] In all of the voice coil actuator configurations described, springs may be used to limit and control certain dynamic aspects of the penetrating member **20**. **FIG. 20d** depicts another variation of the voice coil actuator mechanism of the tenth embodiment using springs, Medical Tool using solenoid actuator **1000**. As with the other voice coil embodiments using coils, the basic principle of actuation is caused by a time varying magnetic field created inside a solenoid coil **1002** which acts on a set of very strong permanent magnets. The magnets **1004** and the entire penetrating member **20** assembly oscillate back and forth through the solenoid coil **1002**. The springs **1014** (such as those shown in **FIG. 20d**) absorb and release energy at each cycle, amplifying the vibration seen at the penetrating member **20.** The resonant properties of the device can be optimized by magnet selection, number of coil turns in the solenoid, mass of the shaft, and the stiffness of the springs.

[00124] From the above description, it may be appreciated that the present invention provides significant benefits over conventional medical devices. The configuration of the actuating means described above, such as embodiments comprising a Langevin actuator, Cymbal actuator, or an APA, accommodates the use of piezoelectric actuating members in a medical instrument by enabling the displacement of the penetrating sharps member or needle to such frequencies that cause a reduction of force needed for penetrating through tissue during procedures such as bone biopsy, epidural catheterization or vascular entry. Electrical signal control facilitated by an electrically coupled feedback system could provide the capability of high oscillation rate actuation, control over penetration depth, electrical cut off (faster response than human) and low traction force for these procedures. **FIG. 21** depicts, by way of example only, an electrical cut off configuration. A pressure transducer **PT** monitors the pressure from the penetrating member **20** or of a fluid in communication with the tissue through the present invention. While the penetrating member **20** is penetrating tissue, the pressure detected by the pressure transducer PT is high and the switch **S** is normally closed. As soon as there is a drop in pressure (indicating passage through the final layer of tissue), the pressure transducer **PT** signal opens the switch **S**, thereby cutting off power to the medical tool. In addition, or a visual, audible or tactile indicator immediately activates warning the operator of sufficient passage by the penetrating member **20** and power cut off. It is within the broadest scope of the present invention to encompass a variety of power cut off configurations, including solid state switching and/or digital controls.

[00125] Another electrical power cut off implementation detects a forward motion of the biasing element **11** discussed previously. In particular, once the penetrating member 20

passes through the last tissue layer, pressure on the biasing element **11** is relieved and the incremental movement of the biasing element **11** into the body **10** is detected by a sensor which instantly opens the switch S and thereby cuts off electrical power to the present invention.

[00126] Additionally, the feedback control of the electronics enables the device to be vibrated in such a way that the force is also reduced as the penetrating member is retracted from the living being as would be necessary in bone biopsy after the tissue is extracted.

[00127] Now that exemplary embodiments of the present invention have been shown and described in detail, various modifications and improvements thereon will become readily apparent to those skilled in the art. While the foregoing embodiments may have dealt with the penetration through skin, bone, veins and ligaments as exemplary biological tissues, the present invention can undoubtedly ensure similar effects with other tissues which are commonly penetrated within the body. For example there are multiplicities of other tools like central venous catheter introducers, laparoscopic instruments with associated sharps, cavity drainage catheter kits, and neonatal lancets, as well as procedures like insulin administration and percutaneous glucose testing, to name a few, where embodiments disclosed herein comprising sonically or ultrasonically driven sharps members may be used to precisely pierce or puncture tissues with minimal tinting. Accordingly, the spirit and scope of the present invention is to be construed broadly and limited only by the appended claims, and not by the foregoing specification.

REFERENCE LABELS

A	Static needle force curve
B	Vibrating needle force curve
G1	Displacement Graph
LT	Langevin actuator (also known as Langevin transducer)
PA1	Conventional biopsy needle
PA2	Conventional epidural needle
PA3	Conventional Syringe
PT	Pressure transducer
S	Switch
SP	Side Port
ZN	Zero node
1	Cannula
1'	Cannula distal end

2	Stylet
3	Distal tip
4	Stylet tip angled face
5	Tuohy needle
6	Tuohy curved tip
7	Tip opening
9	Front portion
10	Tubular body
11	Biasing element
12	Plunger
14	Inner Stylet
15	Outer trocar tube
16	APA needle
16b	Alternate embodiment
20	Penetrating member
100	Langevin actuator
110	Horn
111	Support wings
112	Rear mass
114	Piezoelectric elements
114b	Electrical conductors
115	Sterilization sleeve
116	Bolt
117	Battery & inverter compartment
118	Handle
120	Seal
121	Distal face
122	Distal opening
123	Luer taper nose
124	Proximal opening
126	Bore
126a	Short bore
128	Attachment fitting
129	Catheter

130 Hollow needle
130a Distal end of hollow needle
130b Proximal end of hollow needle
132 Plunger handle
134 Plunger shaft
134a Proximal end of plunger shaft
134b Distal end of plunger shaft
136 Plunger seal
142 Inner stylet handle
144 Inner stylet shaft
146 Inner stylet tip
148 Trocar attachment fitting
150 Outer trocar body
152 Distal trocar opening
154 Distal trocar tip
200 Penetrating introducer
202b More preferred embodiment
202c Most preferred embodiment
201 Supported introducer
202 Catheterization introducer
300 Bone biopsy device
400 Advanced bone biopsy device
500 APA syringe
500b Alternate embodiment
510 Amplified piezoelectric actuator (APA)
512 Frame
512a Proximal end of frame
512b Distal end of frame
513 Penetrating member
513a Proximal end of penetrating member
513b Distal tip of penetrating member
514 Piezoelectric material
516 APA attachment point
518 Handle

521 Handle distal opening
524 Handle proximal opening
525 Penetrating member hub
526 APA bore
600 Cymbal syringe
600b Alternate embodiment
610 Cymbal actuator
612 Endcap
612a Proximal endcap
612b Distal endcap
626 Cymbal bore
616 Cymbal attachment point
700 General side port configuration
700a First side port configuration
700b Second side port configuration
800 Feedback capable reduction of force tool
900 Medical tool using voice coil actuator
900b Alternate voice coil embodiment
902 Conducting coil
904 Magnetic member
906 Coil support tube
910 Body
912 Driving tube
914 Extension member
916a First attachment point
916b Second attachment point
918 First conductive attachment site
920 Second conductive attachment site
922 Second conductive coil
1000 Medical tool using solenoid actuator
1002 Solenoid coil
1004 Magnets
1014 Spring
1020 Pressure feedback system

1021 Reservoir with integrated pump

1022 Flexible tubing

1023 Attachment fitting

1024 Base

1025 On/off switch

1026 Light emitting diode

CLAIMS

WHAT IS CLAIMED IS:

1. A medical device for penetrating living being tissue, said device comprising:

a penetrating member which is reciprocated away from and into said medical device for reducing the force needed to penetrate living being tissue;

a driving actuator coupled to said penetrating member for converting electrical energy into reciprocating motion when energized; and

an electrical power cut off for automatically de-energizing said medical device when said penetrating member has passed through the living being tissue.

2. The medical device of Claim 1 wherein said driving actuator comprises:

an actuator having a distal end and said penetrating member coupled thereto, said actuator including a first channel extending to said distal end, said actuator further including at least one piezoelectric element for converting electrical energy into oscillatory motion when energized;

said actuator further comprising a second channel having a first end in communication with said first channel and a second end positioned at an exterior surface of said actuator; and

said actuator displacing said distal end and said penetrating member in oscillatory motion when said at least one piezoelectric element is energized.

3. The medical device of Claim 2 wherein said at least one piezoelectric element is adapted for vibrating at a frequency to produce sinusoidal displacement of said penetrating member.

4. The medical device of Claim 2 wherein said first channel extends through said penetrating member and a third channel extends through said at least one piezoelectric element, said first and third channels being aligned, and wherein said actuator further comprises an anchor having a fourth channel extending therethrough along a longitudinal axis of said anchor, said fourth channel being aligned with said first and third channels to form a continuous channel through said actuator.

5. The medical device of Claim 2 wherein said first channel extends through a portion of said penetrating member.

6. The medical device of Claim 1 wherein said penetrating member is one of a hypodermic needle, catheterization needle, Tuohy needle, bone biopsy trocar, spinal needle,

nerve block needle, trocar access ports and interventional radiology needle.

7. The medical device of Claim 2 wherein said actuator is a Langevin actuator.

8. The medical device of Claim 7 wherein said distal end of said Langevin actuator defines an anti-node.

9. The medical device of Claim 1 wherein an exterior surface of said actuator comprises a side port for providing fluid communication with, or passage of a catheter within, said penetrating member.

10. The medical device of Claim 2 wherein said second channel in communication with first channel extends radially from a longitudinal axis of said actuator and is centered at a location defining a zero-node.

11. The medical device of Claim 1 further comprising a fluid-containing syringe coupled to a port within said actuator, said fluid-containing syringe comprising a moveable biasing element disposed therein and wherein said biasing element is in fluid communication with a channel within said penetrating member, said biasing element providing an indicator when said penetrating member has passed through the living being tissue.

12. The medical device of Claim 1 further comprising a fluid-containing syringe coupled to a port within a needle attachment fitting of said medical device, said fluid-containing syringe comprising a moveable plunger disposed therein and wherein said plunger is in fluid communication with a channel within said penetrating member, said plunger providing an indication when said penetrating member has passed through the living being tissue.

13. The medical device of Claim 1 further comprising a loss of resistance pump system interfaced with said actuator, said loss of resistance pump comprising a visual indicator that automatically indicates entry of said penetrating member within a desired bodily area.

14. The medical device of Claim 13 wherein said visual indicator comprises an LED.

15. The medical device of Claim 12 wherein said plunger provides one of a visual, audible or tactile indication that said penetrating member has passed through the living being tissue.

16. The medical device of Claim 12 wherein said plunger activates said electrical power cut off.

17. The medical device of Claim 1 wherein a pressure transducer detects pressure within said channel of said penetrating member and activates said electrical power cut off.

18. The medical device of Claim 1 wherein said driving actuator comprises a voice coil coupled to said penetrating member, said voice coil converting electrical energy into oscillatory motion when energized.

19. The medical device of Claim 18 wherein said voice coil comprises a coil surrounding permanent magnets and said penetrating member.

20. The medical device of Claim 19 further comprising springs positioned on opposite sides of said coil and permanent magnets.

21. The medical device of Claim 18 wherein said voice coil comprises permanent magnets surrounding a coil and said penetrating member.

22. The medical device of Claim 18 wherein said voice coil comprises a pair of concentric coils surrounding said penetrating member.

23. The medical device of Claim 1 wherein said reciprocating actuator is one of a pneumatic or fluidic actuator.

24. The medical device of Claim 12 wherein said plunger is used to aspirate matter from said living being via said medical device.

25. A method for reducing the force needed to penetrate living being tissue, said method comprising:

reciprocating a penetrating member against the living being tissue using a reciprocating actuator that converts electrical energy to reciprocating motion;

detecting the passage of said penetrating member through said living being tissue; and

automatically cutting off the electrical energy to said reciprocating actuator when said penetrating member has passed through said living being tissue.

26. The method of Claim 25 wherein said step of detecting the passage of said penetrating member through said living being tissue comprises the movement of a plunger within a fluid-containing syringe that is in fluid communication with a channel within said penetrating member.

27. The method of Claim 26 wherein said plunger is coupled to a switch that provides electrical energy to said reciprocating actuator.

28. The method of Claim 25 wherein said step of detecting the passage of said penetrating member comprises a pressure actuator that monitors pressure within a channel of

said penetrating member and wherein said pressure actuator provides an output that controls the operation of a switch that provides electrical energy to said reciprocating actuator.

29. The method of Claim 25 wherein said reciprocating actuator is at least one piezoelectric element.

30. The method of Claim 29 wherein said reciprocating actuator is a Langevin actuator.

31.The method of Claim 30 wherein said reciprocating actuator is a voice coil.

32. The method of Claim 30 wherein said reciprocating actuator is one of a pneumatic and fluidic actuator.

33. The method of Claim 37 further comprising the step of using said plunger to aspirate matter from the living being using said medical device.

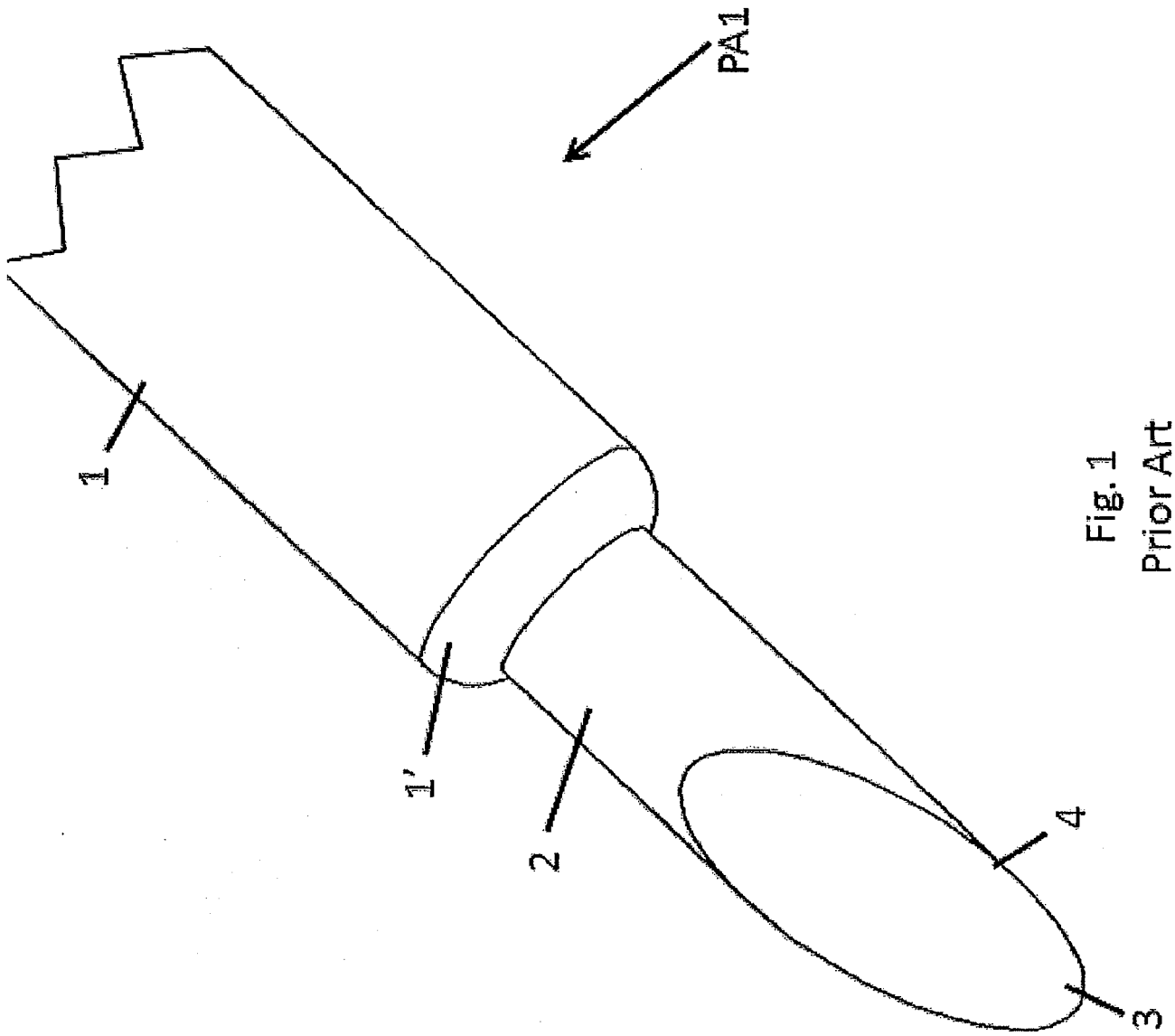


Fig. 1
Prior Art

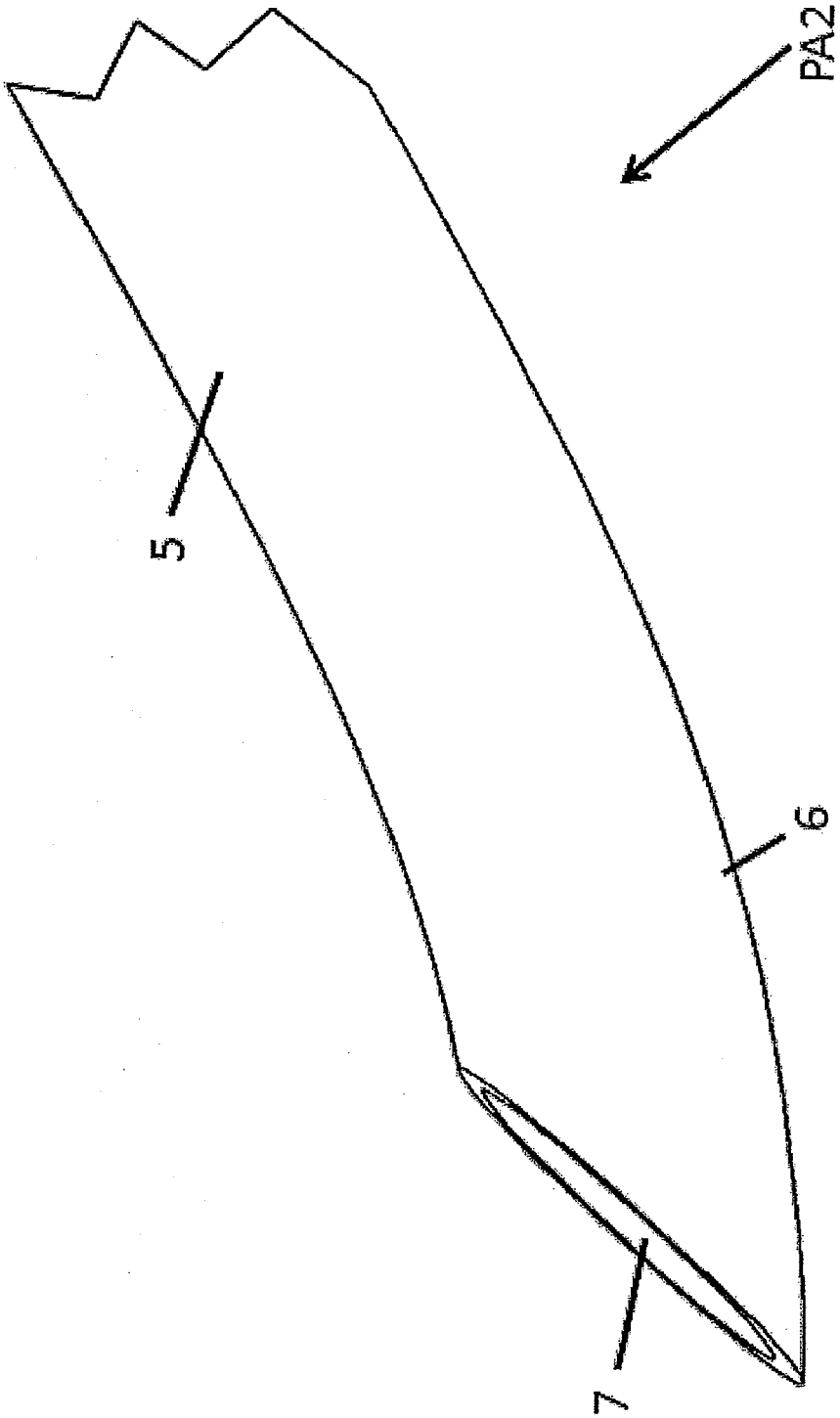


Fig. 2
Prior Art

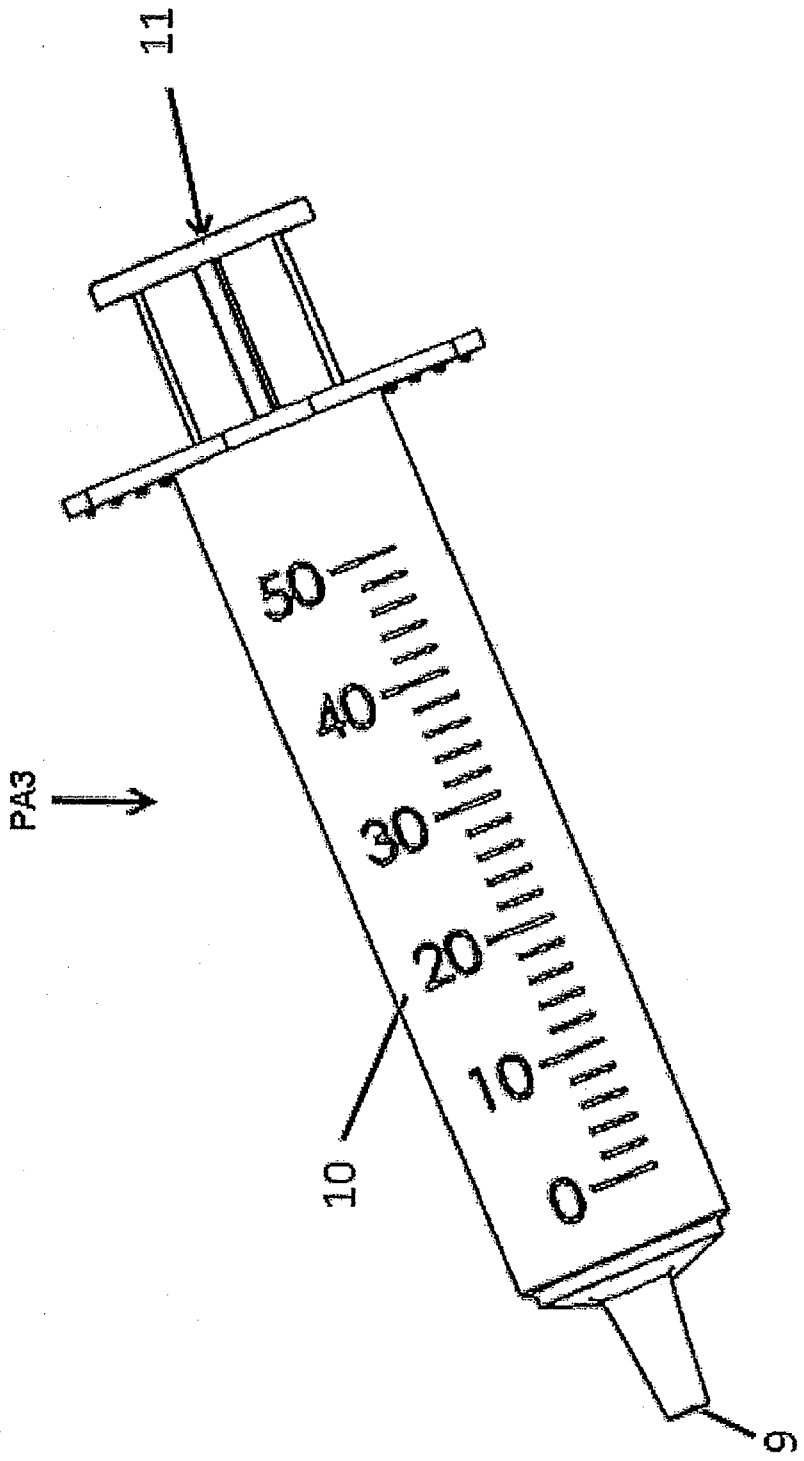
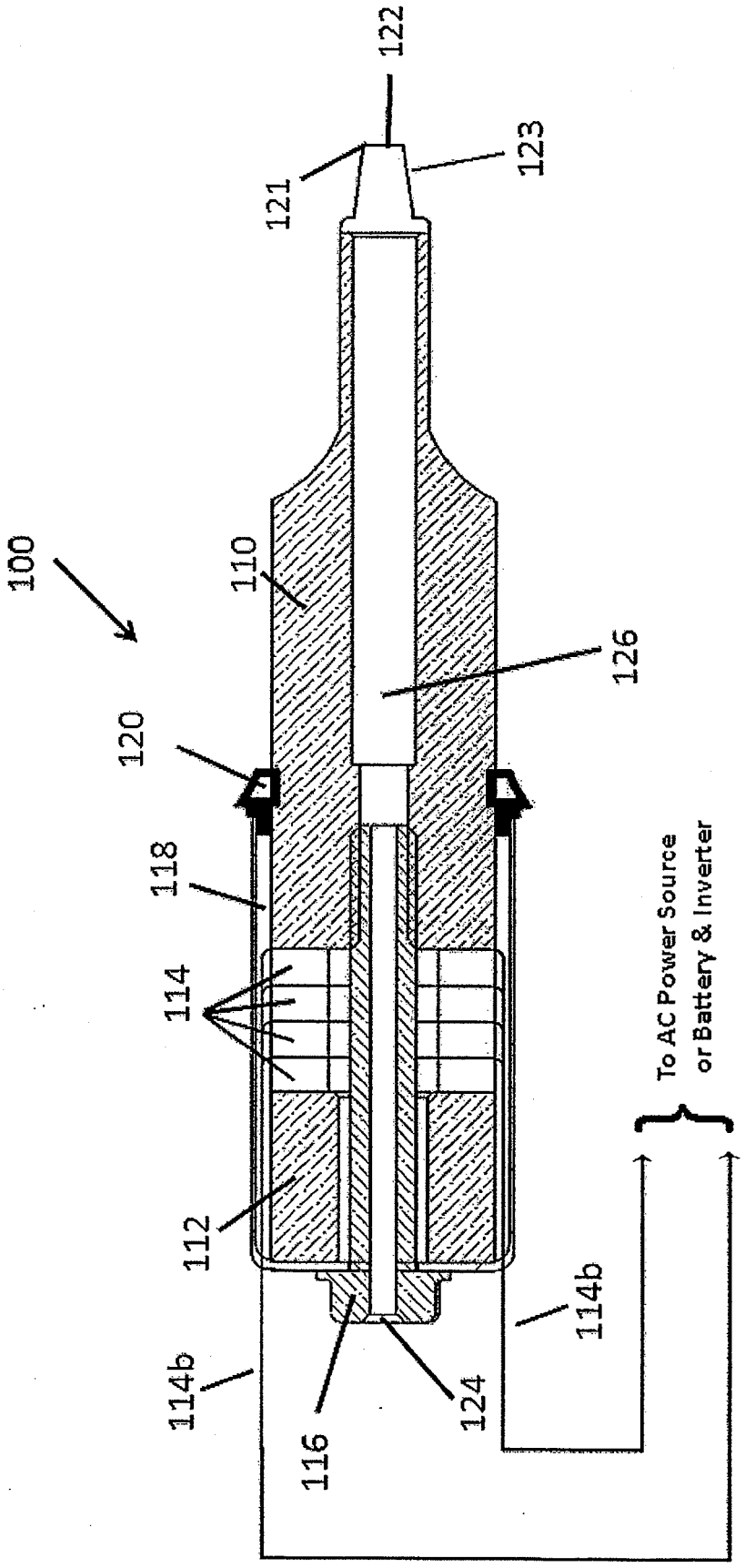


Fig. 2a
Prior Art


A
B
300
250
200
150
100
50
0
Force [Newtons]
0
2
4
6
8
10
12
Depth [millimeters]

Fig. 3

Fig. 4


100
110
120
118
114
112
114b
116
124
114b
126
121
122
123
To AC Power Source
or Battery & Inverter

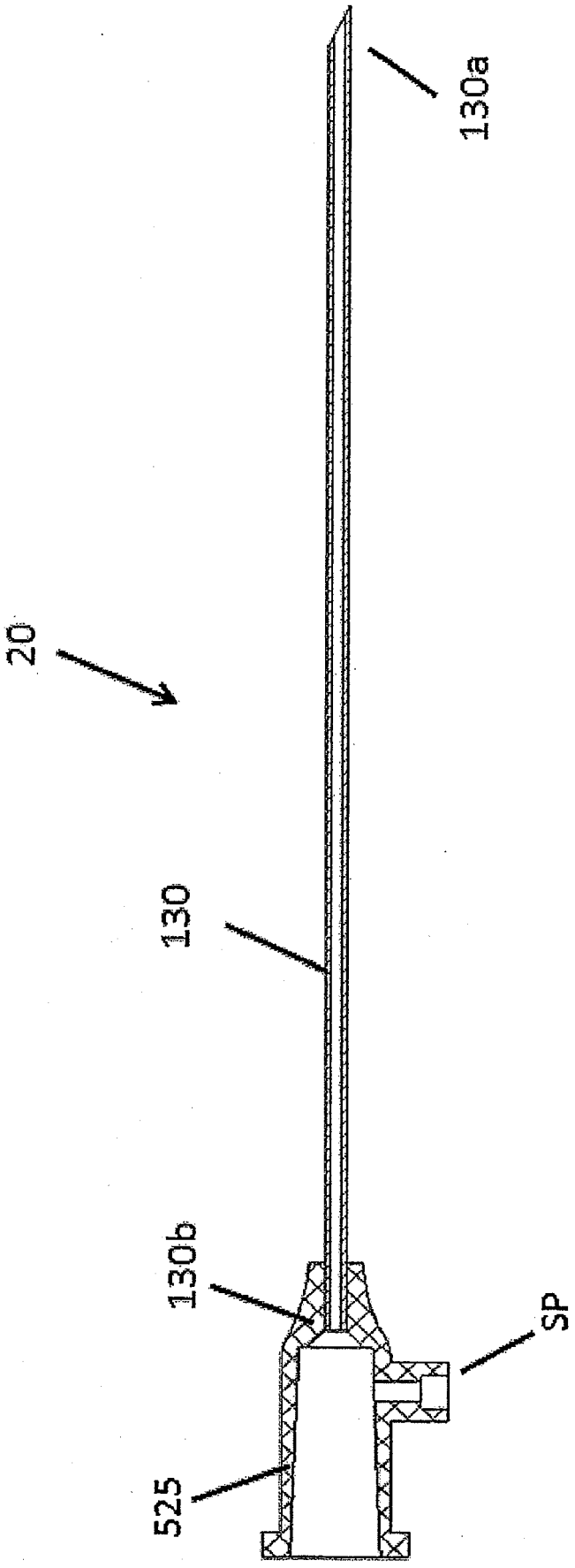


Fig. 4a

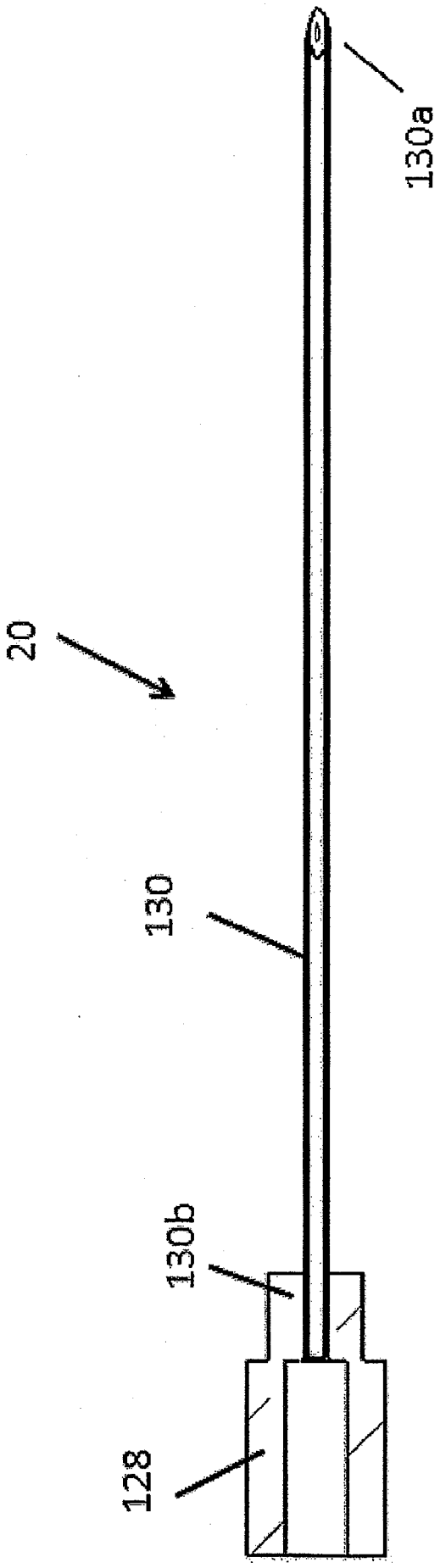


Fig. 5

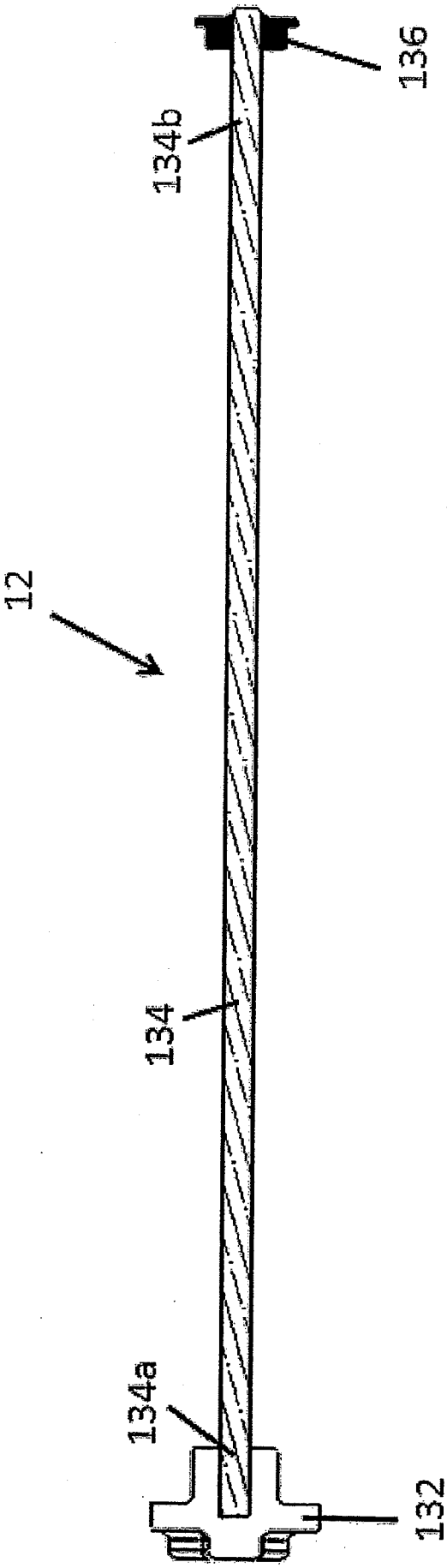
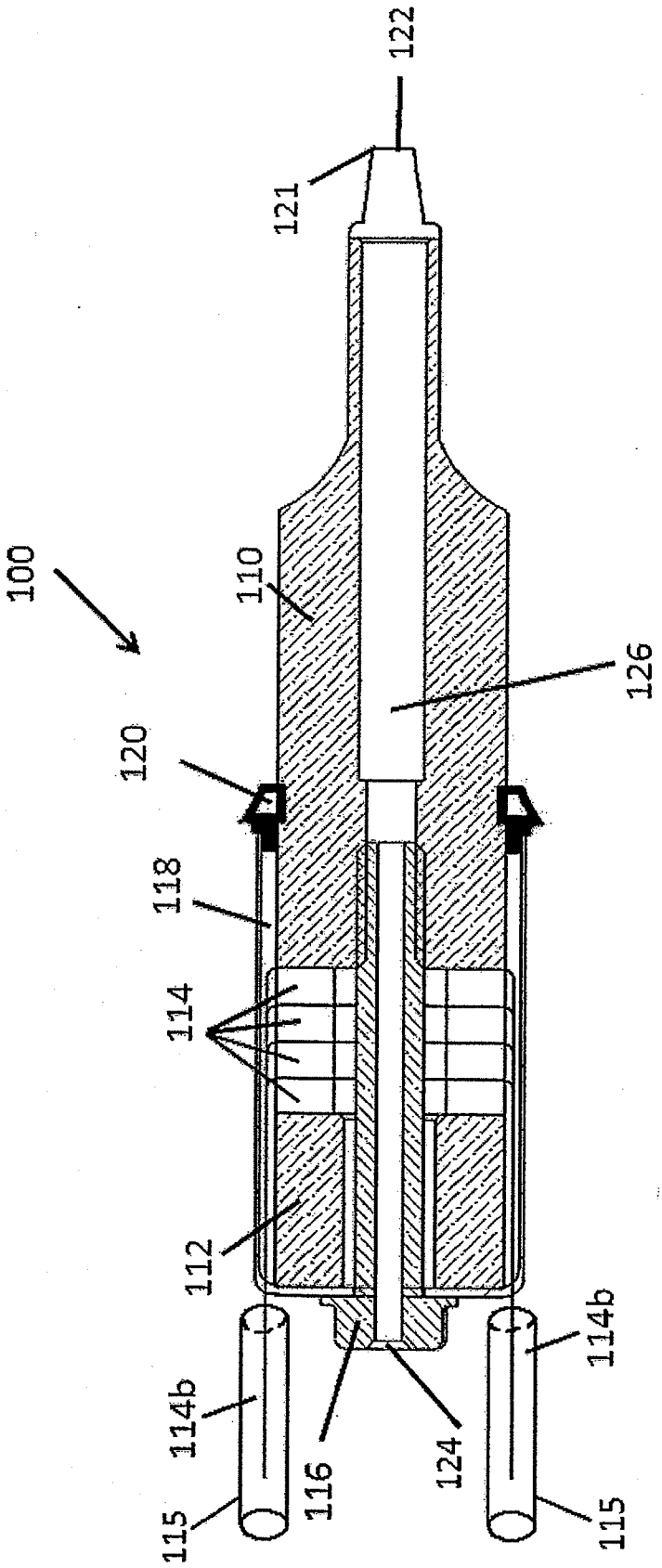


Fig. 6

Fig. 6a



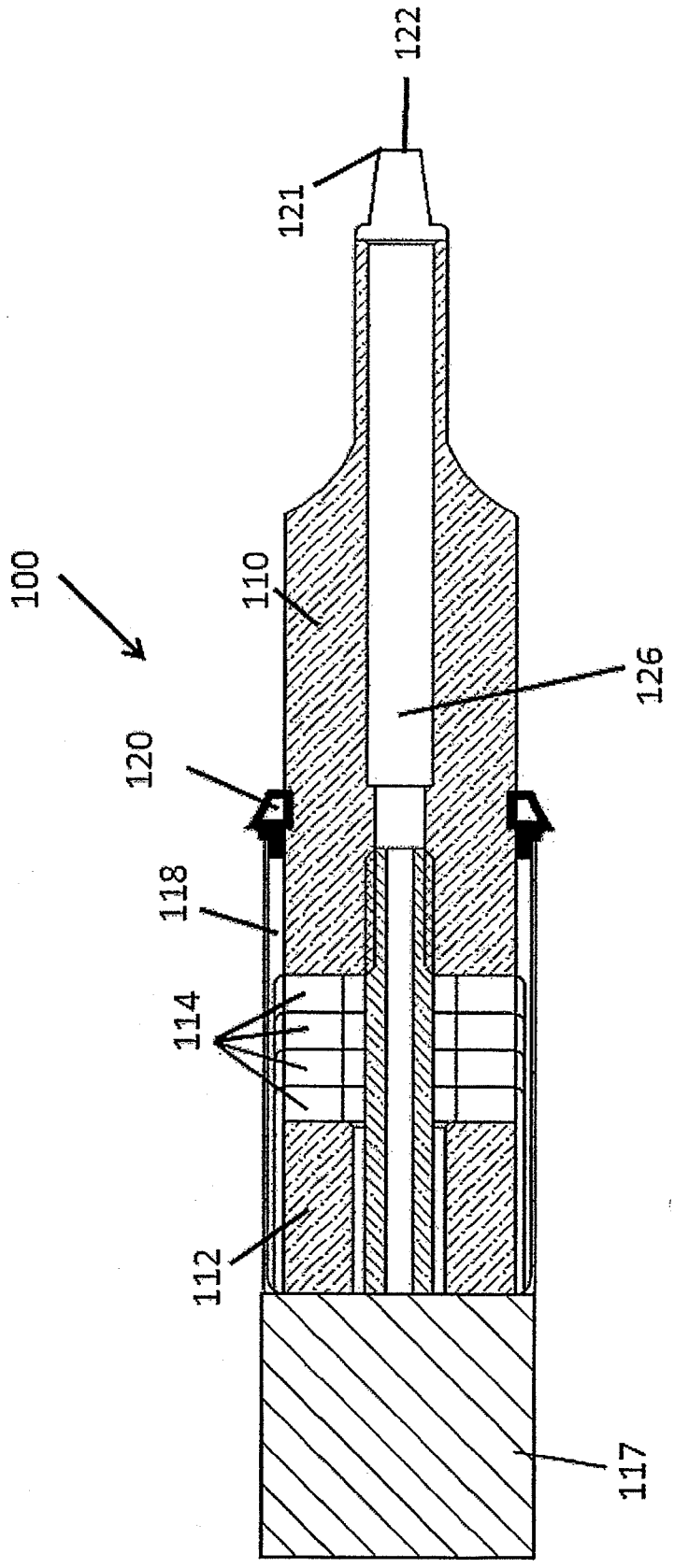


Fig. 6b

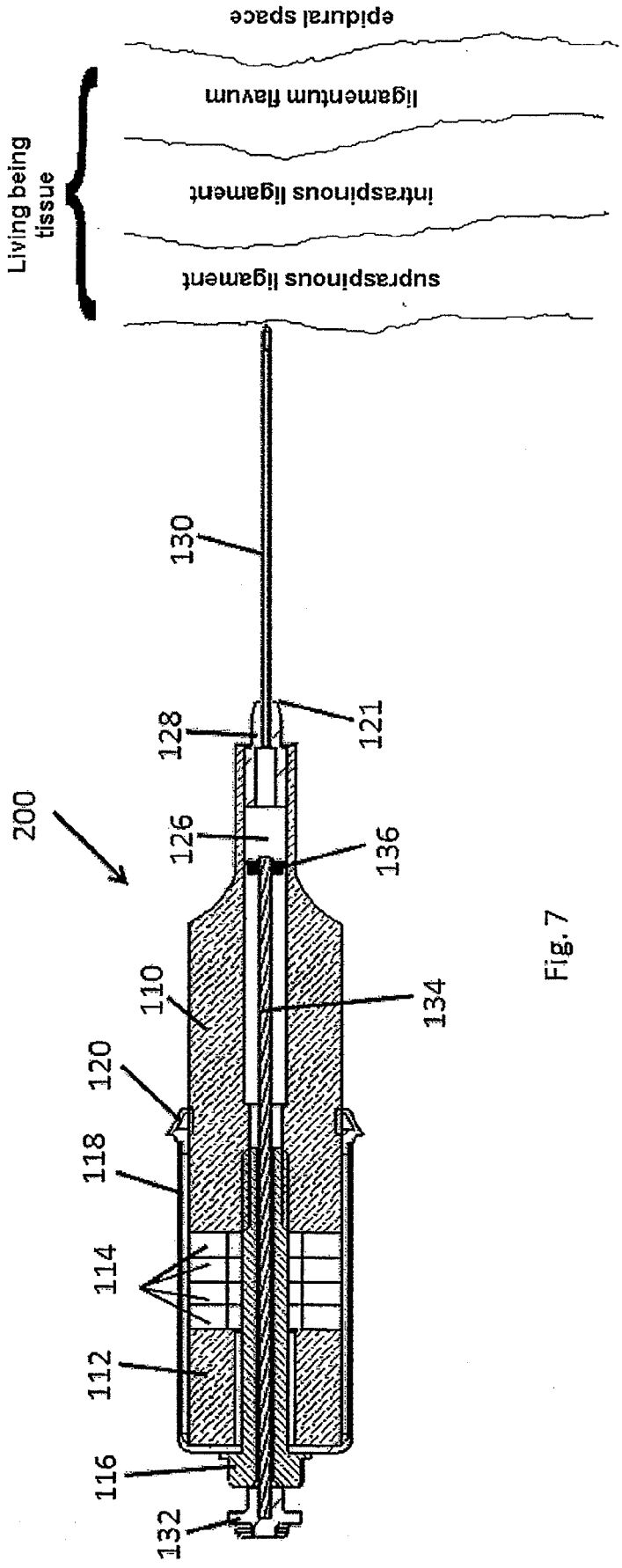

epidural space
ligamentum flavum
intraspinous ligament
supraspinous ligament
Living being tissue
130
128
121
200
126
136
110
134
120
118
114
112
116
132

Fig. 7

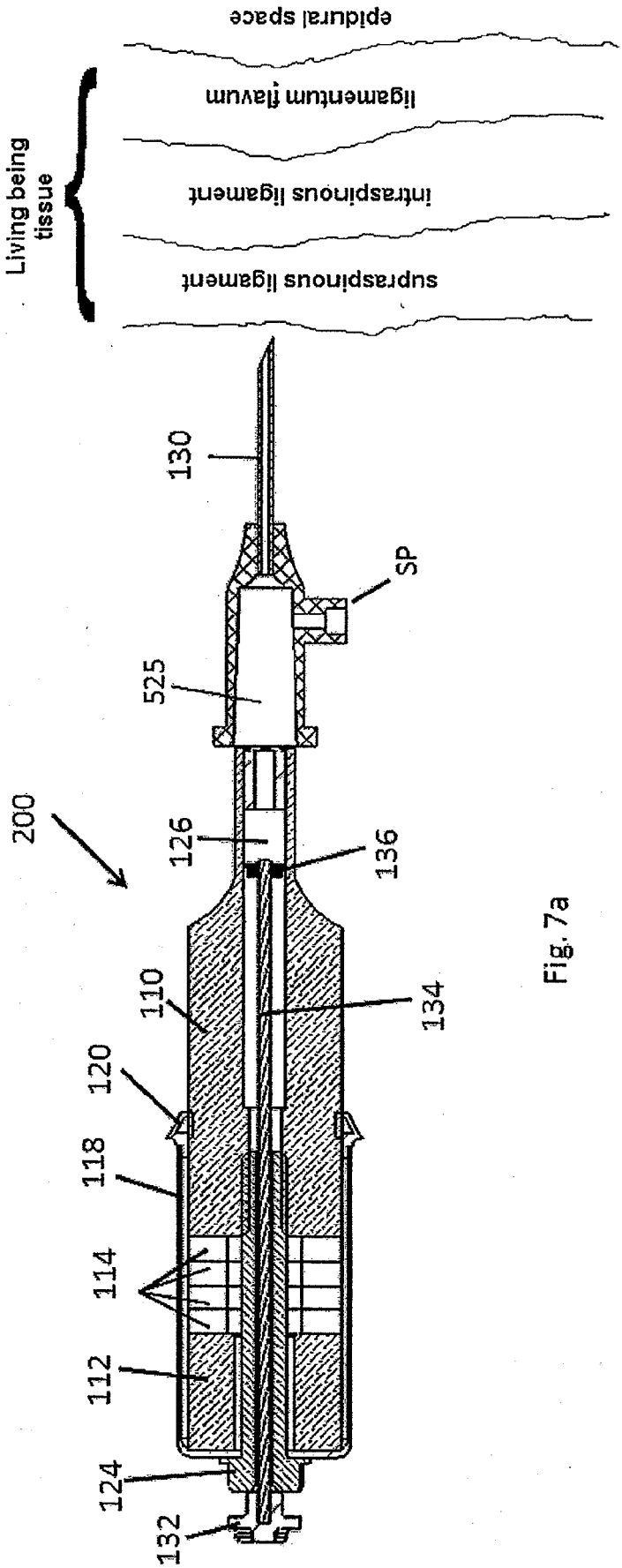

epidural space
ligamentum flavum
interspinous ligament
supraspinous ligament
Living being tissue
130
SP
525
200
126
136
110
134
120
118
114
112
124
132

Fig. 7a

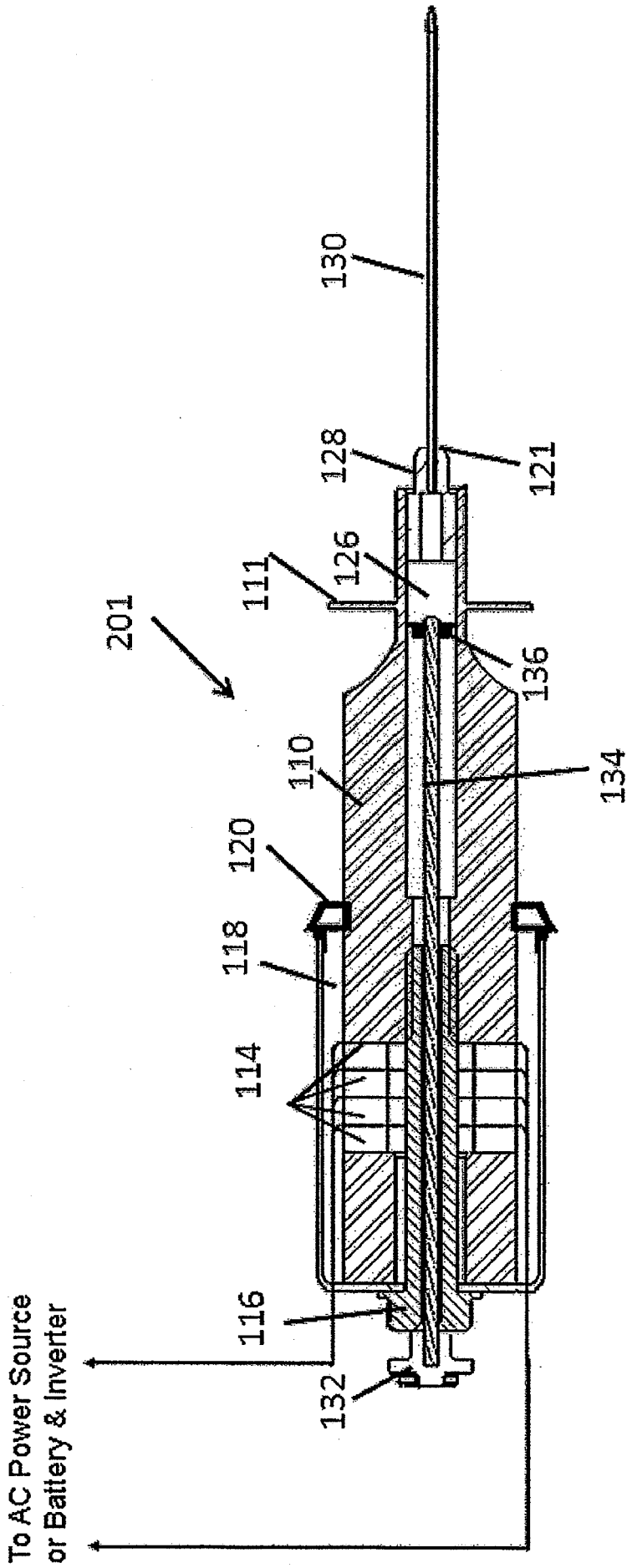

130
128
121
126
111
201
136
110
134
120
118
114
116
132
To AC Power Source
or Battery & Inverter

Fig. 8

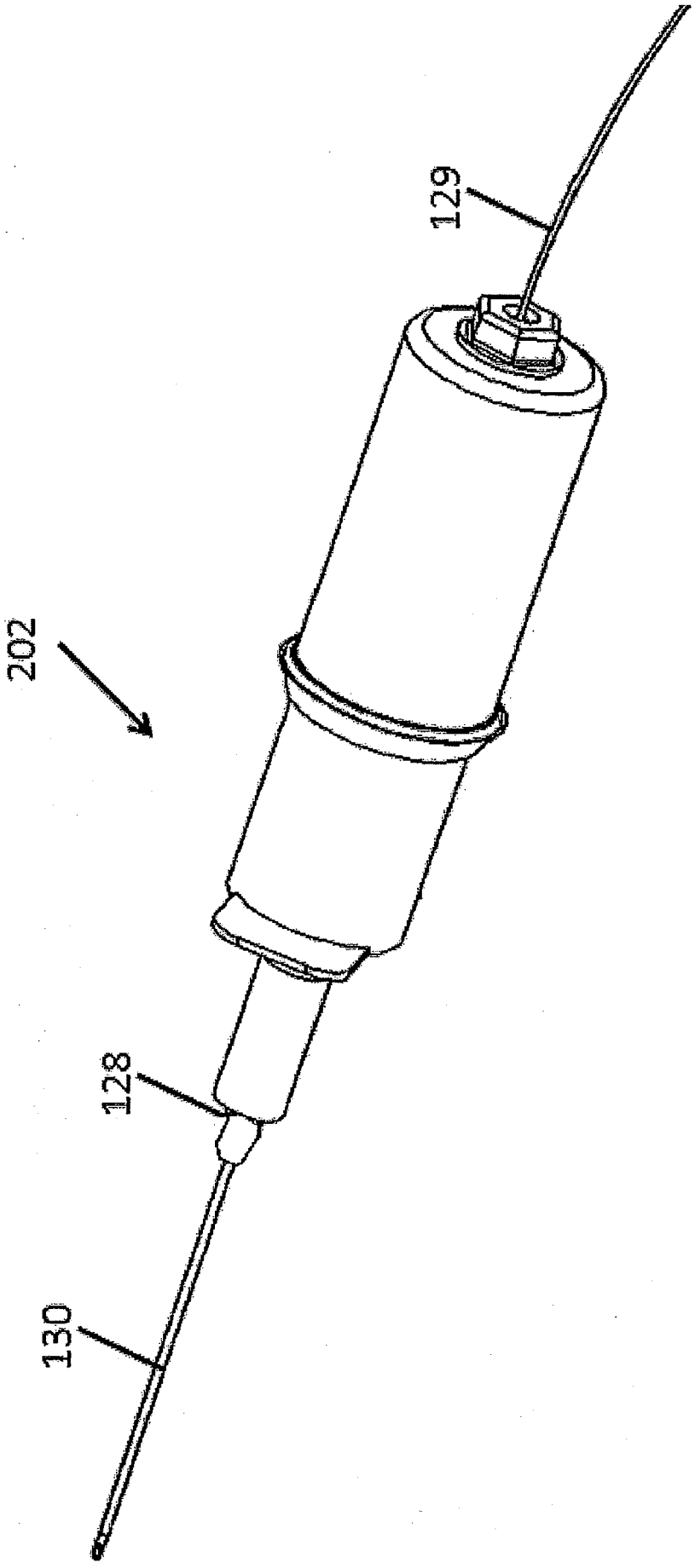


Fig. 9

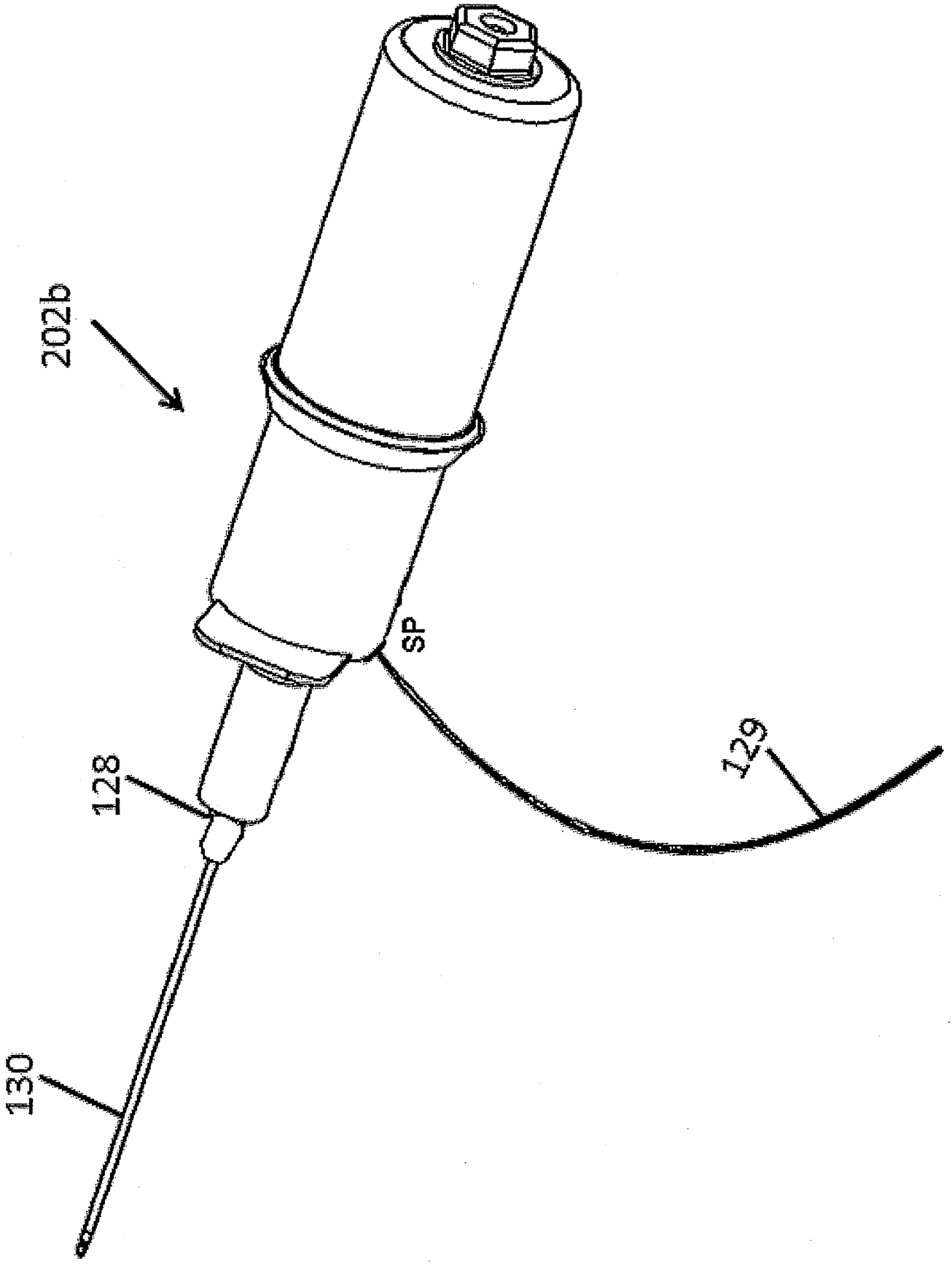


Fig. 9a

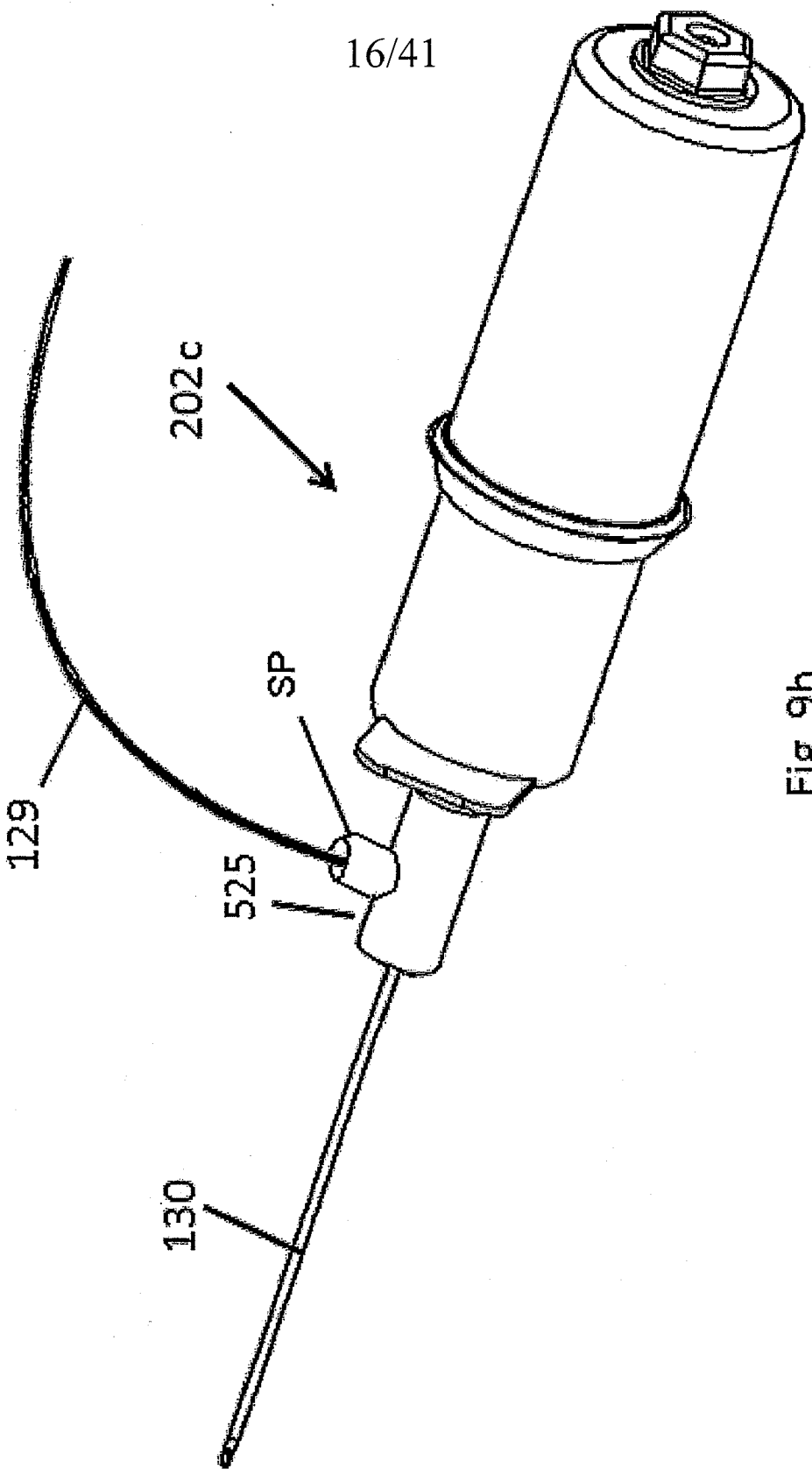


Fig. 9b

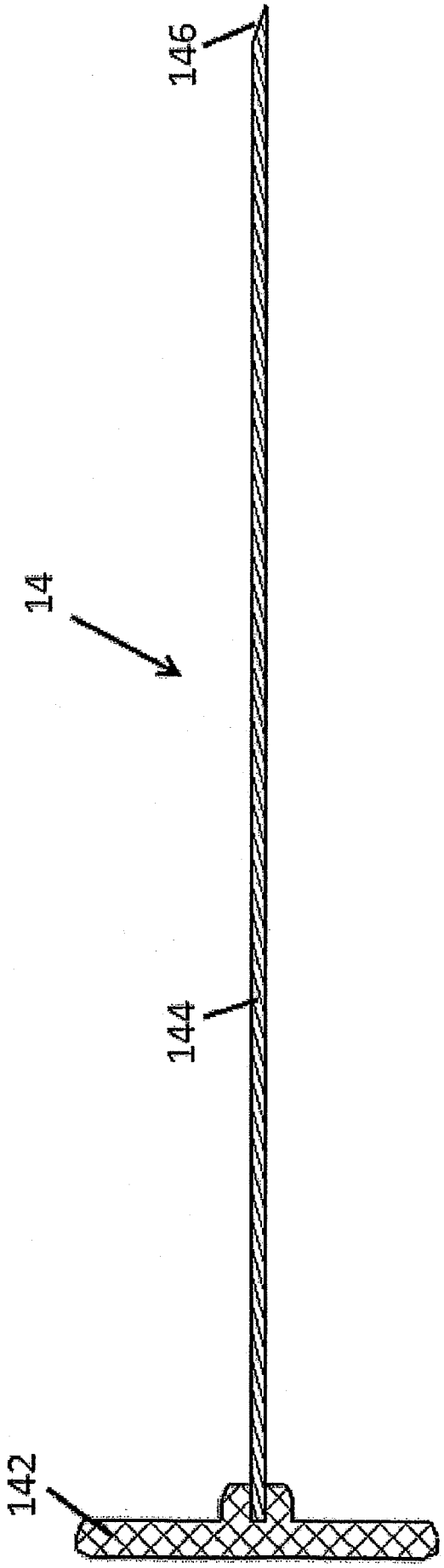


Fig. 10a

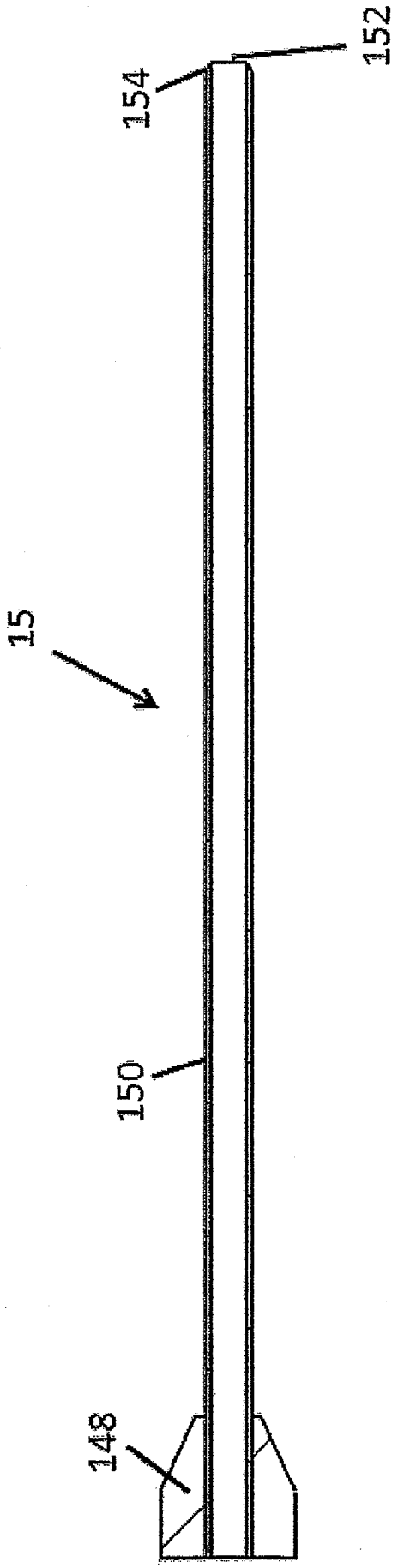


Fig. 10b

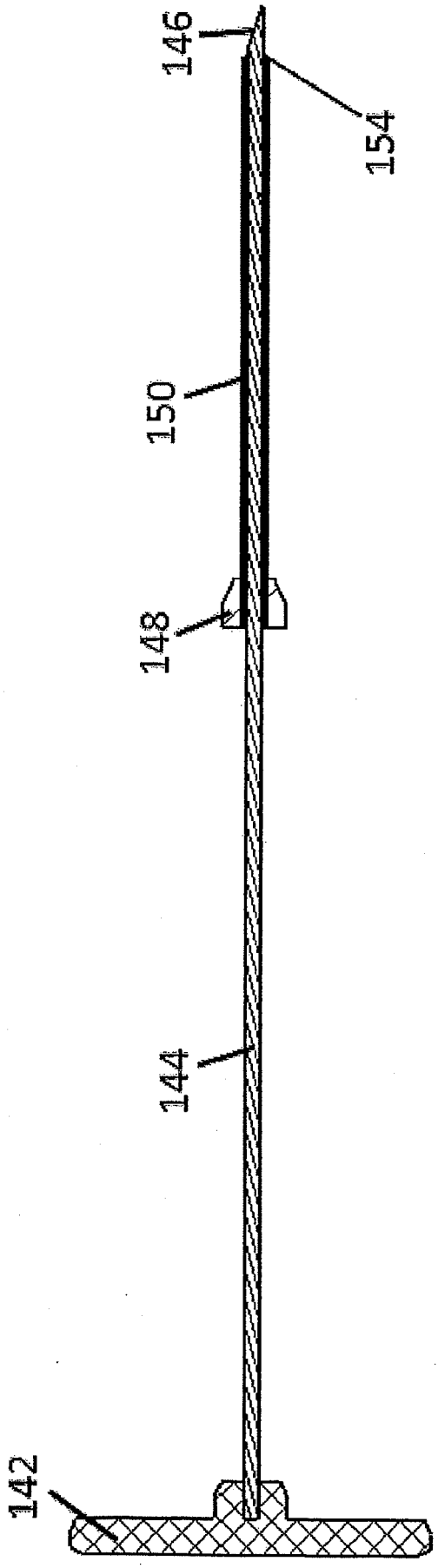


Fig. 10c

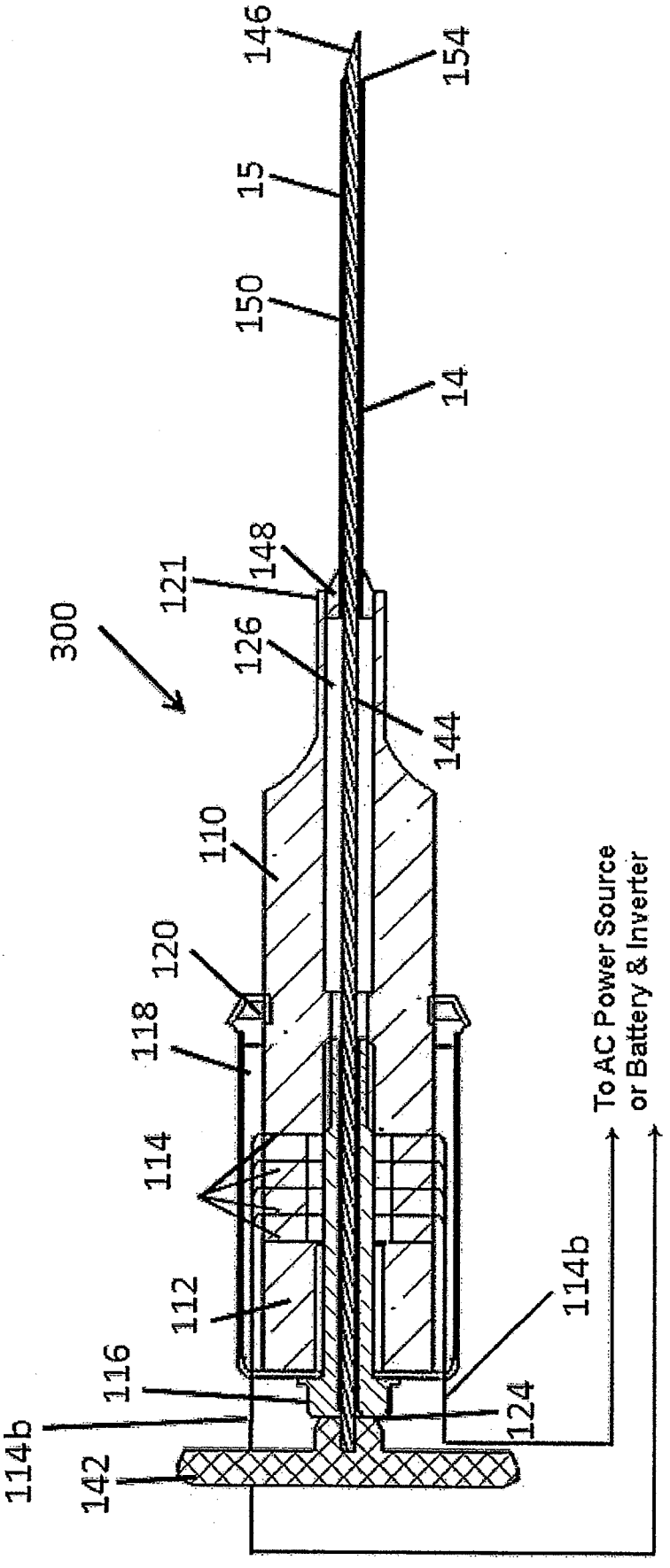

146
154
15
150
14
148
121
300
126
144
110
120
118
114
112
116
114b
142
124
114b
To AC Power Source
or Battery & Inverter

Fig. 11

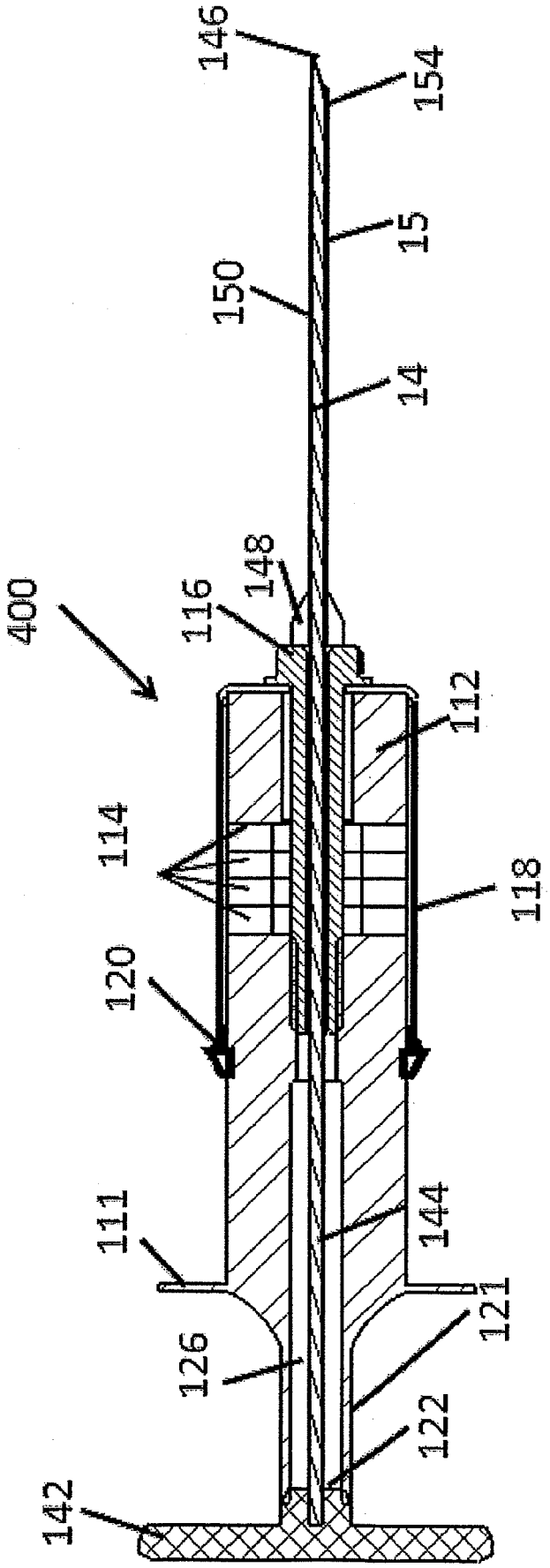

146
154
15
150
14
148
400
116
112
114
118
120
111
144
121
126
122
142

Fig. 12

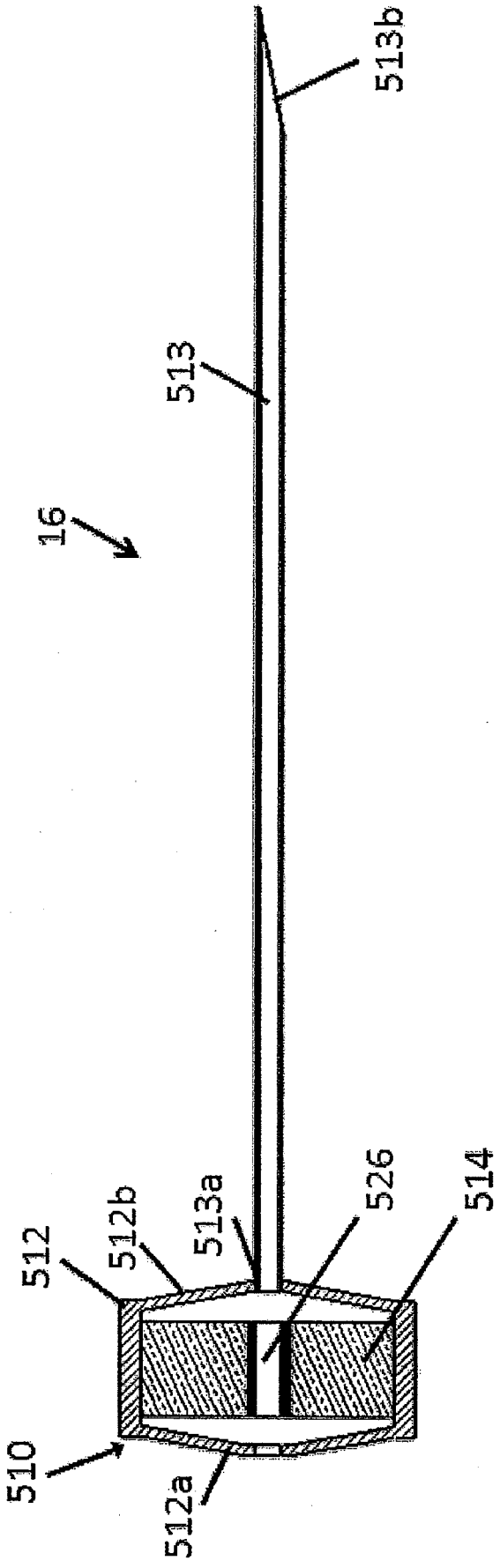


Fig. 13

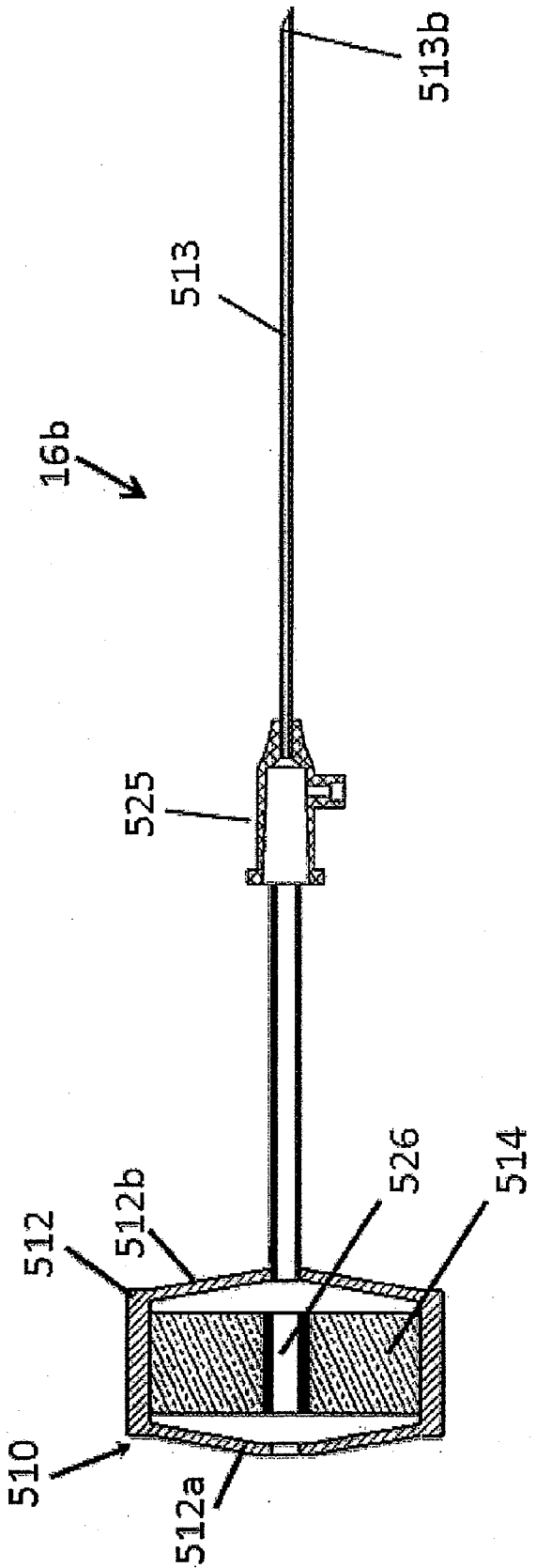


Fig. 13a

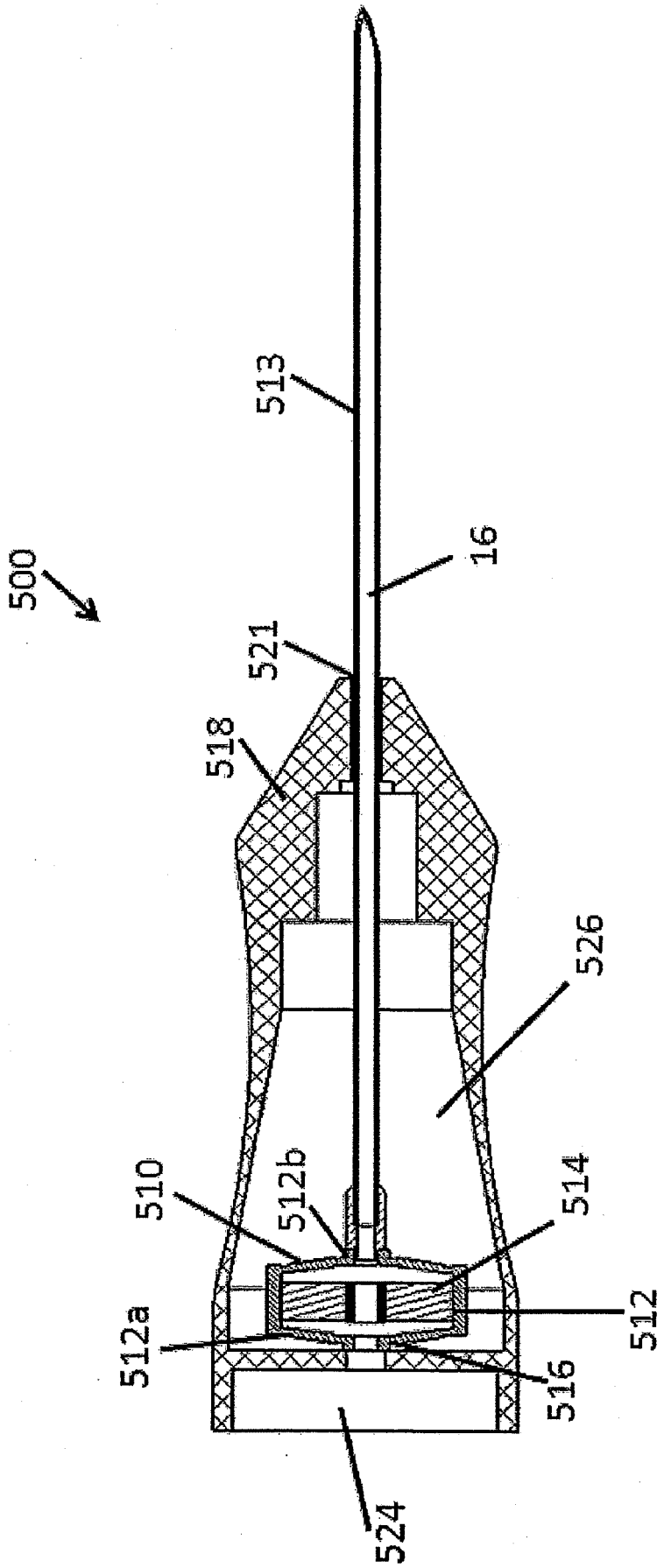


Fig. 14

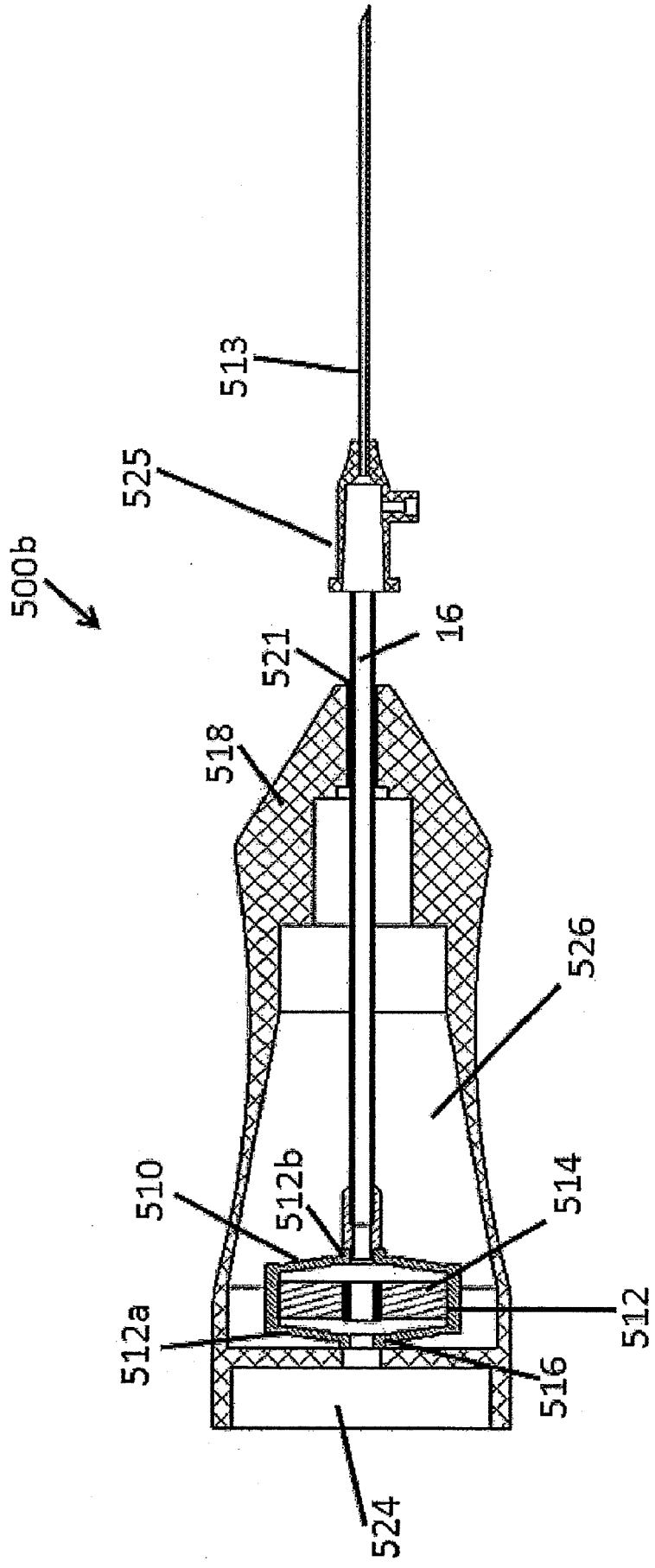


Fig. 14a

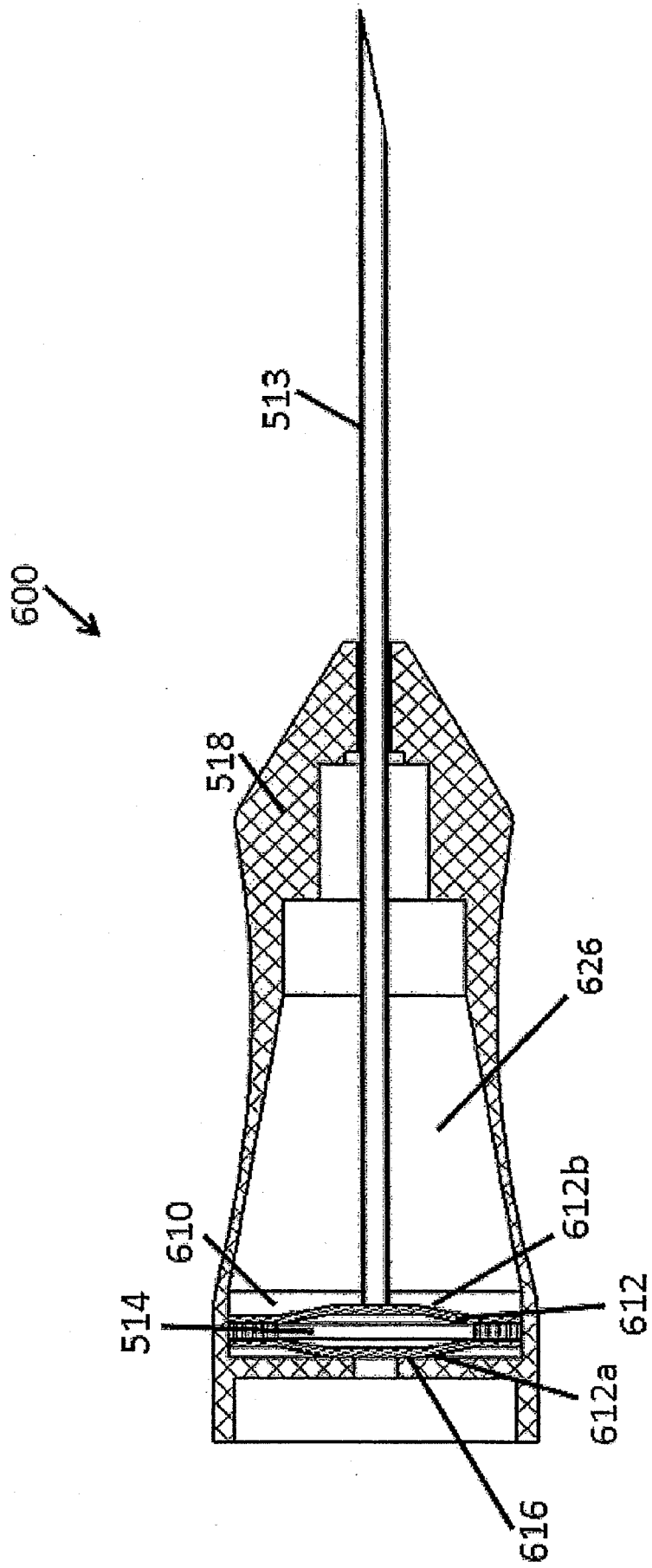


Fig. 15

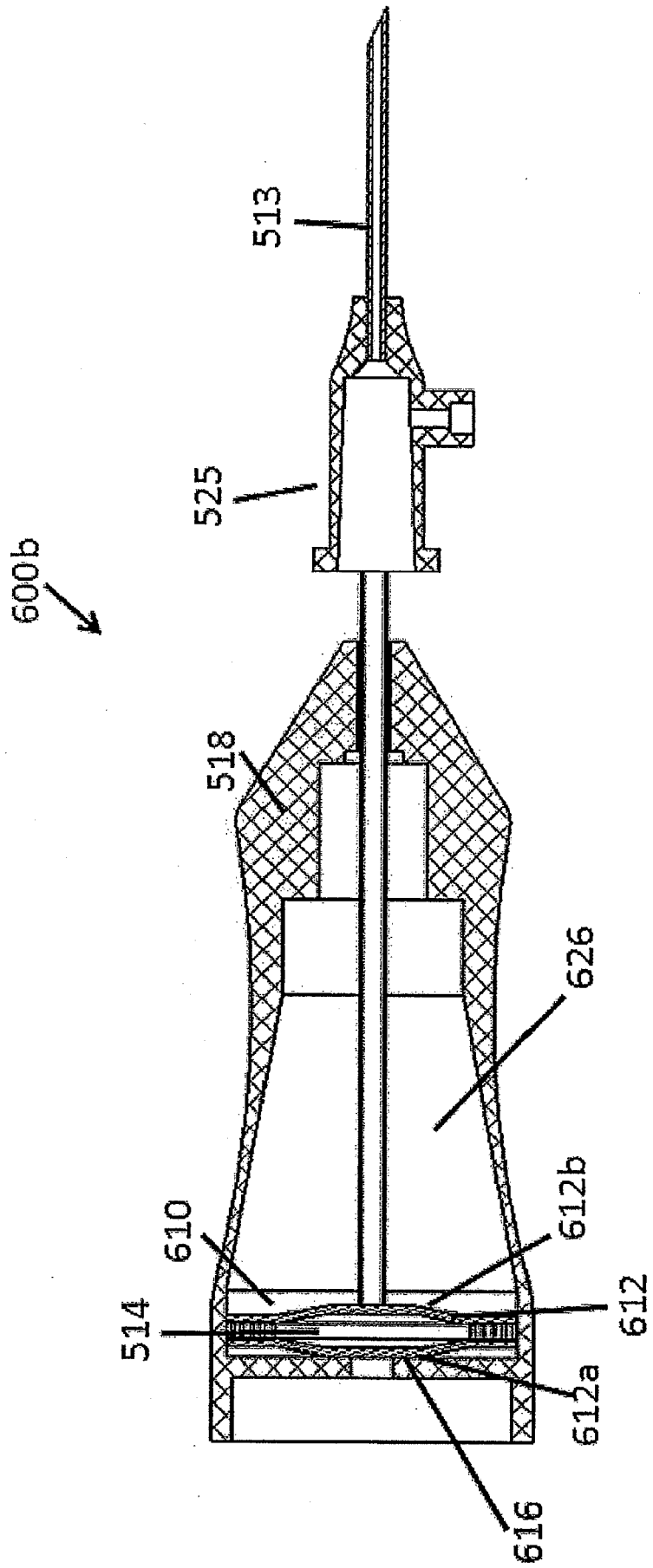


Fig. 16

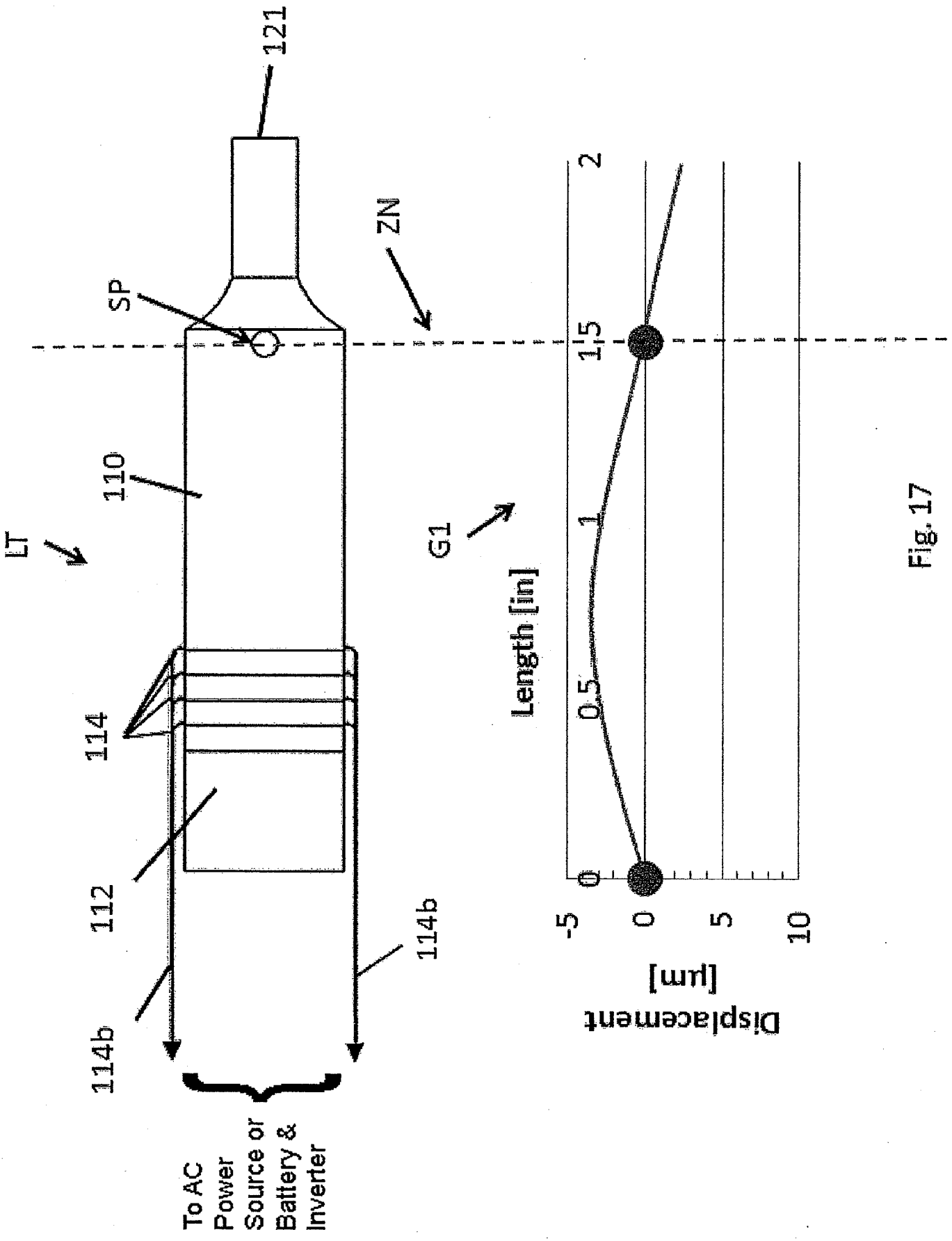

121
ZN
SP
110
LT
114
112
114b
114b
To AC Power Source or Battery & Inverter
G1
Length [in]
2
1.5
1
0.5
0
-5
0
5
10
Displacement [µm]

Fig. 17

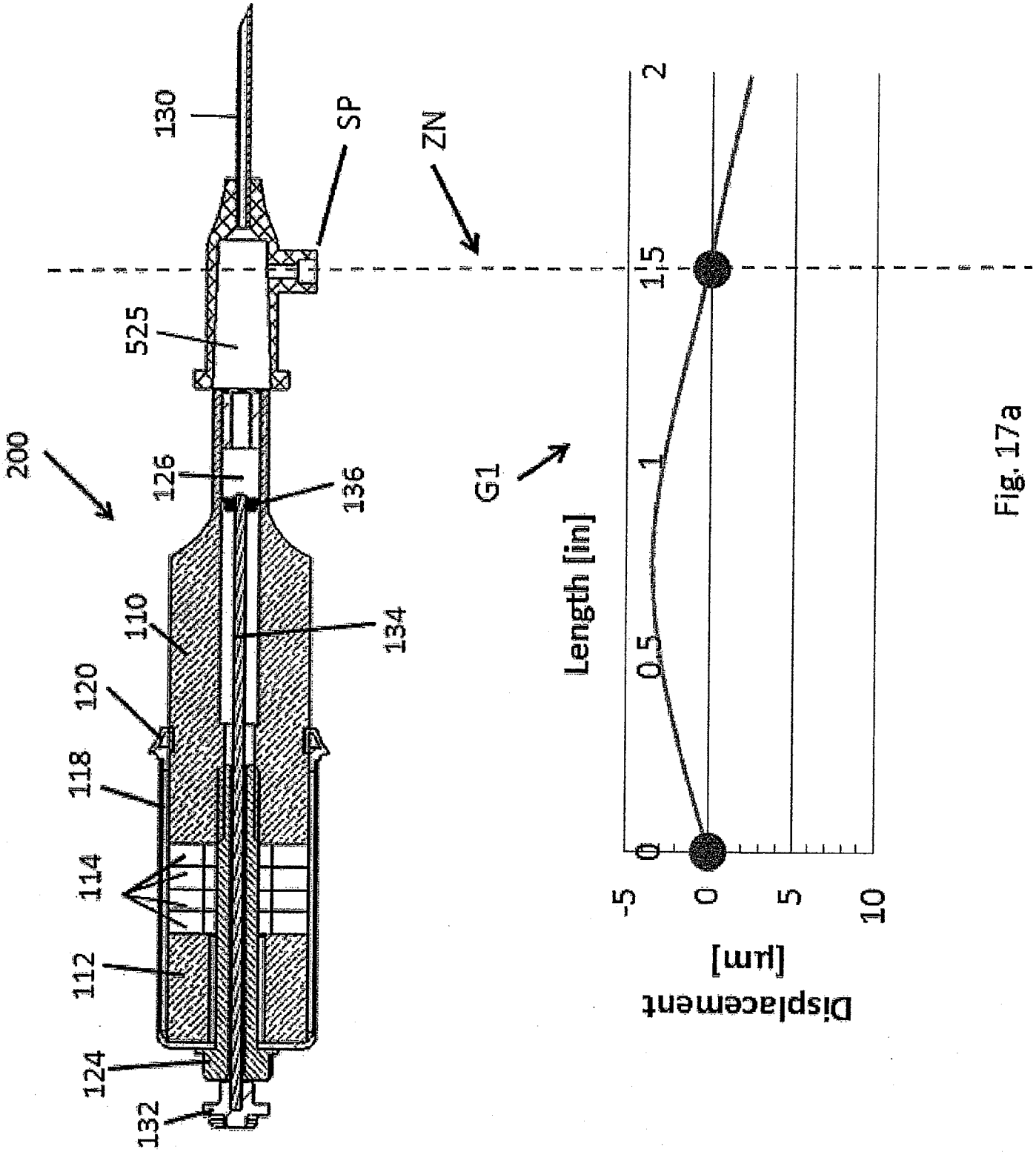

200
130
SP
ZN
525
126
136
110
134
120
118
114
112
124
132
G1
Length [in]
0
0.5
1
1.5
2
-5
0
5
10
Displacement
[µm]

Fig. 17a

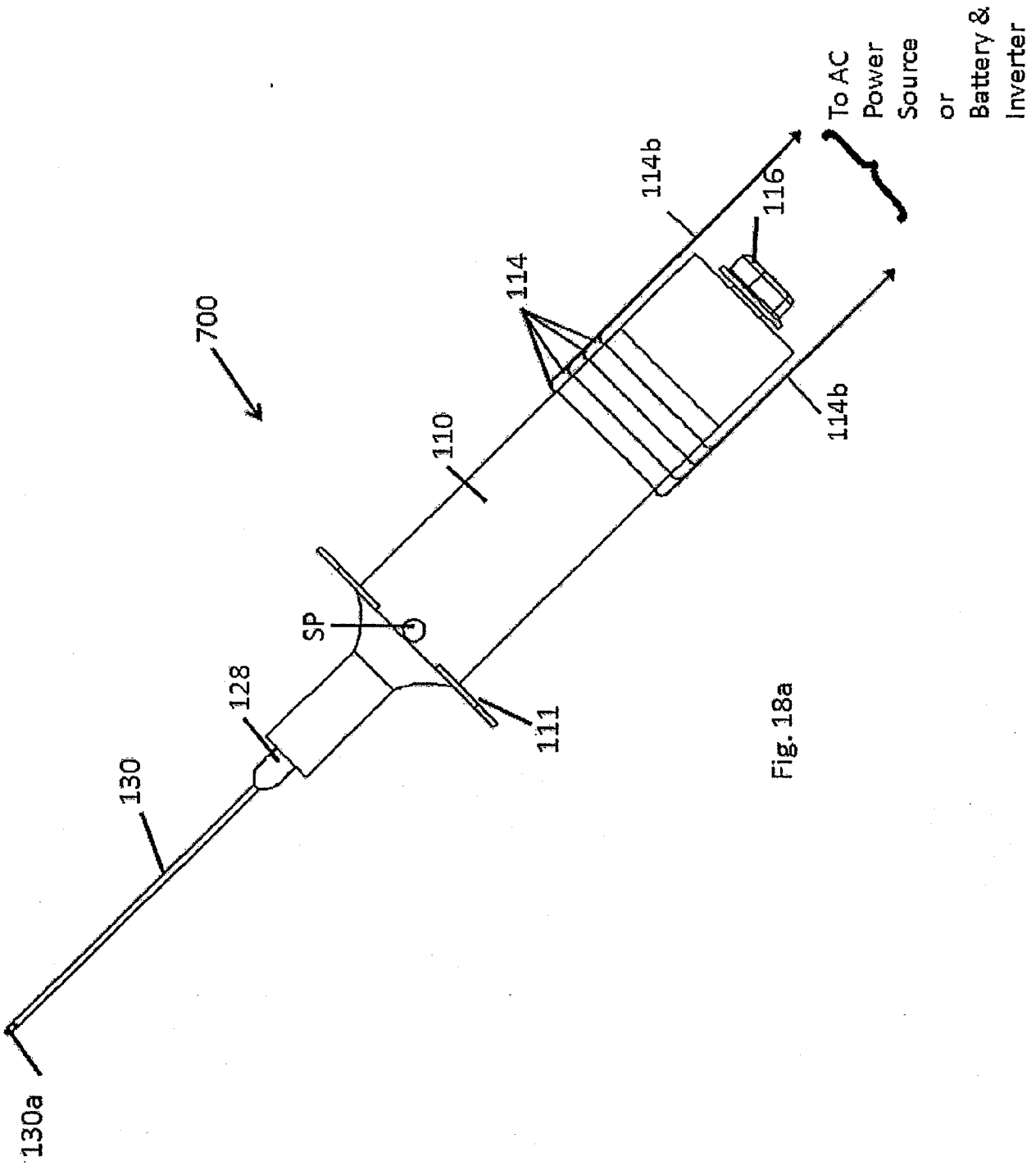

700
130a
130
128
SP
111
110
114
114b
116
114b
To AC
Power
Source
or
Battery &
Inverter

Fig. 18a

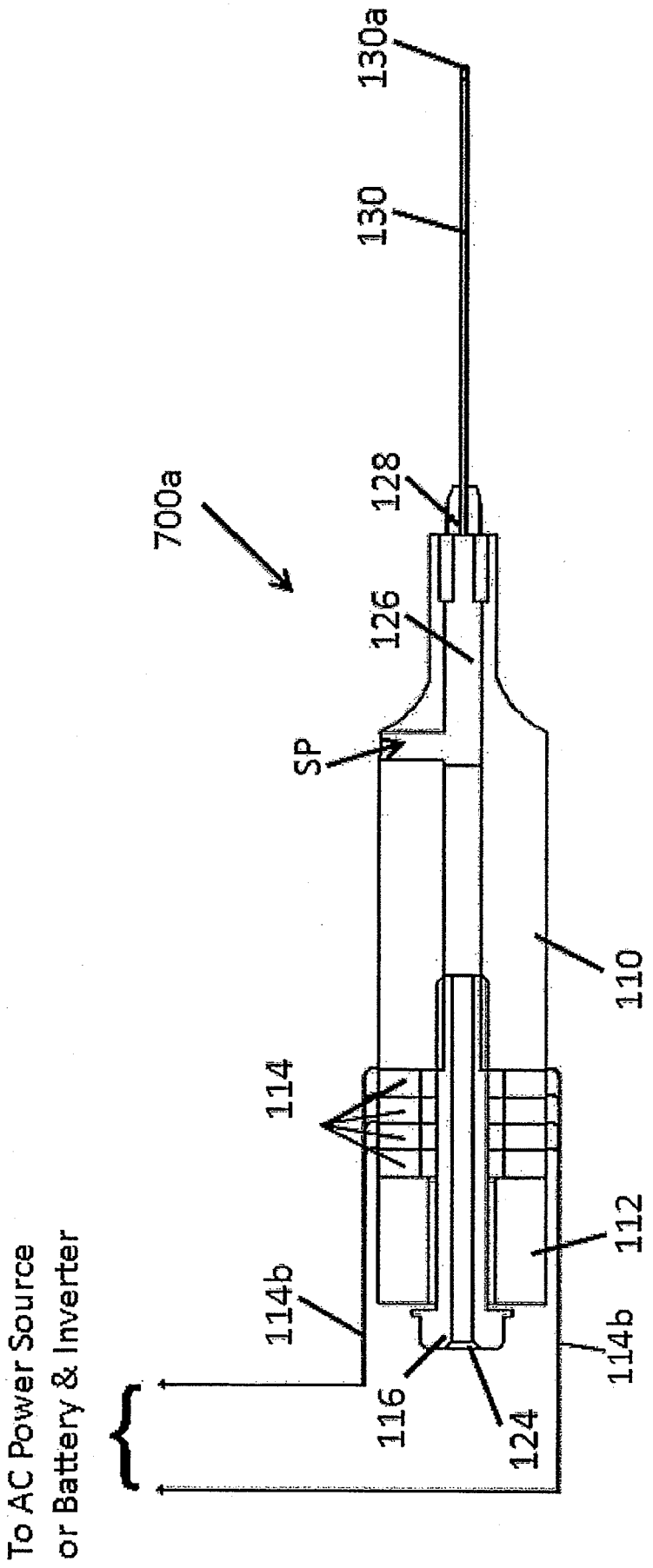

130a
130
128
700a
126
SP
110
114
112
114b
116
124
114b
To AC Power Source
or Battery & Inverter

Fig. 18b

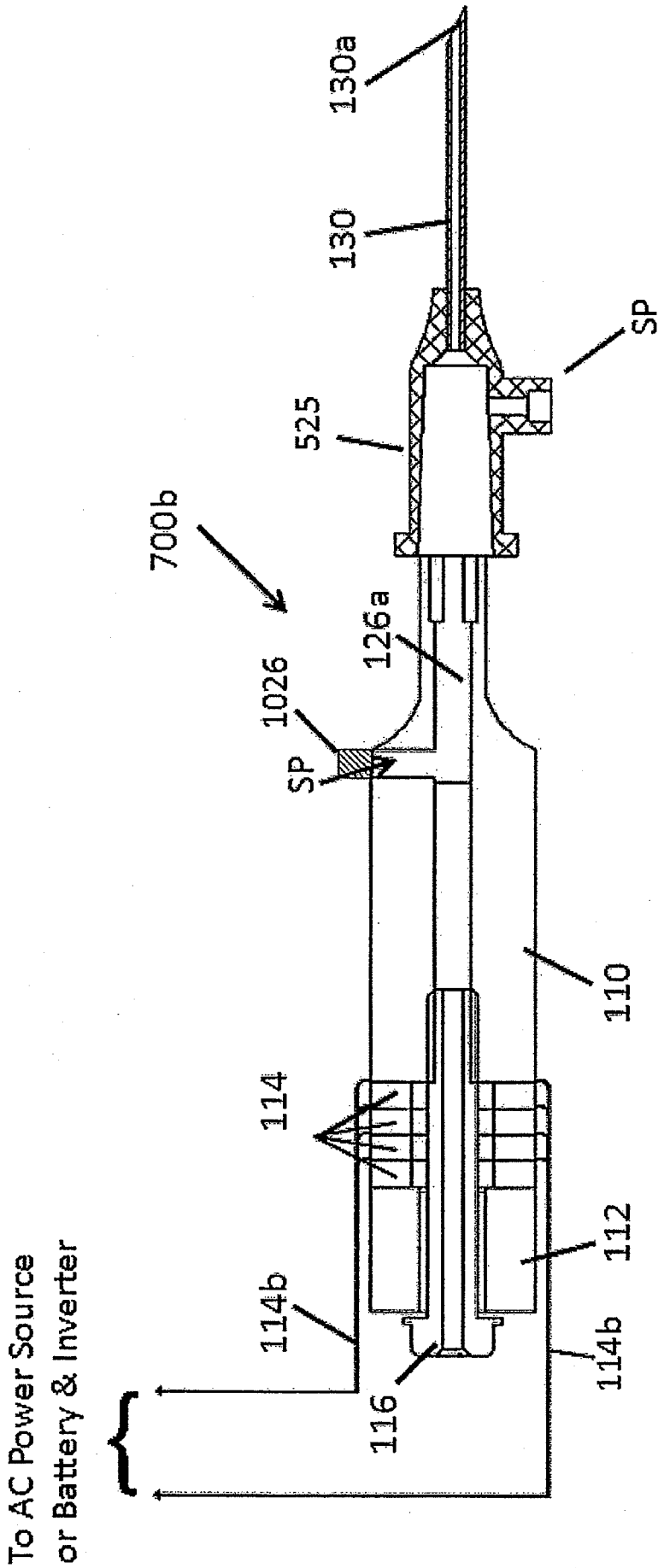

130a
130
SP
525
700b
126a
1026
SP
110
114
112
114b
116
114b
To AC Power Source
or Battery & Inverter

Fig. 18c

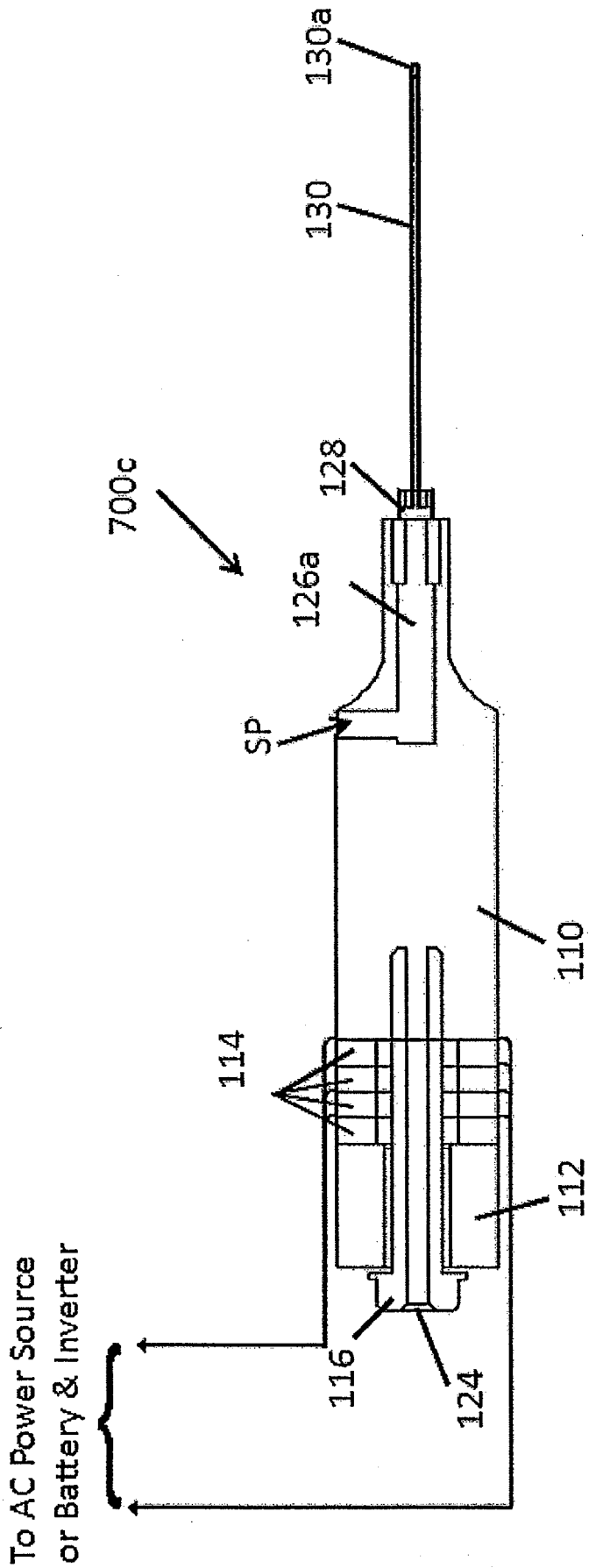

130a
130
128
700c
126a
SP
110
114
112
116
124
To AC Power Source
or Battery & Inverter

Fig. 18d

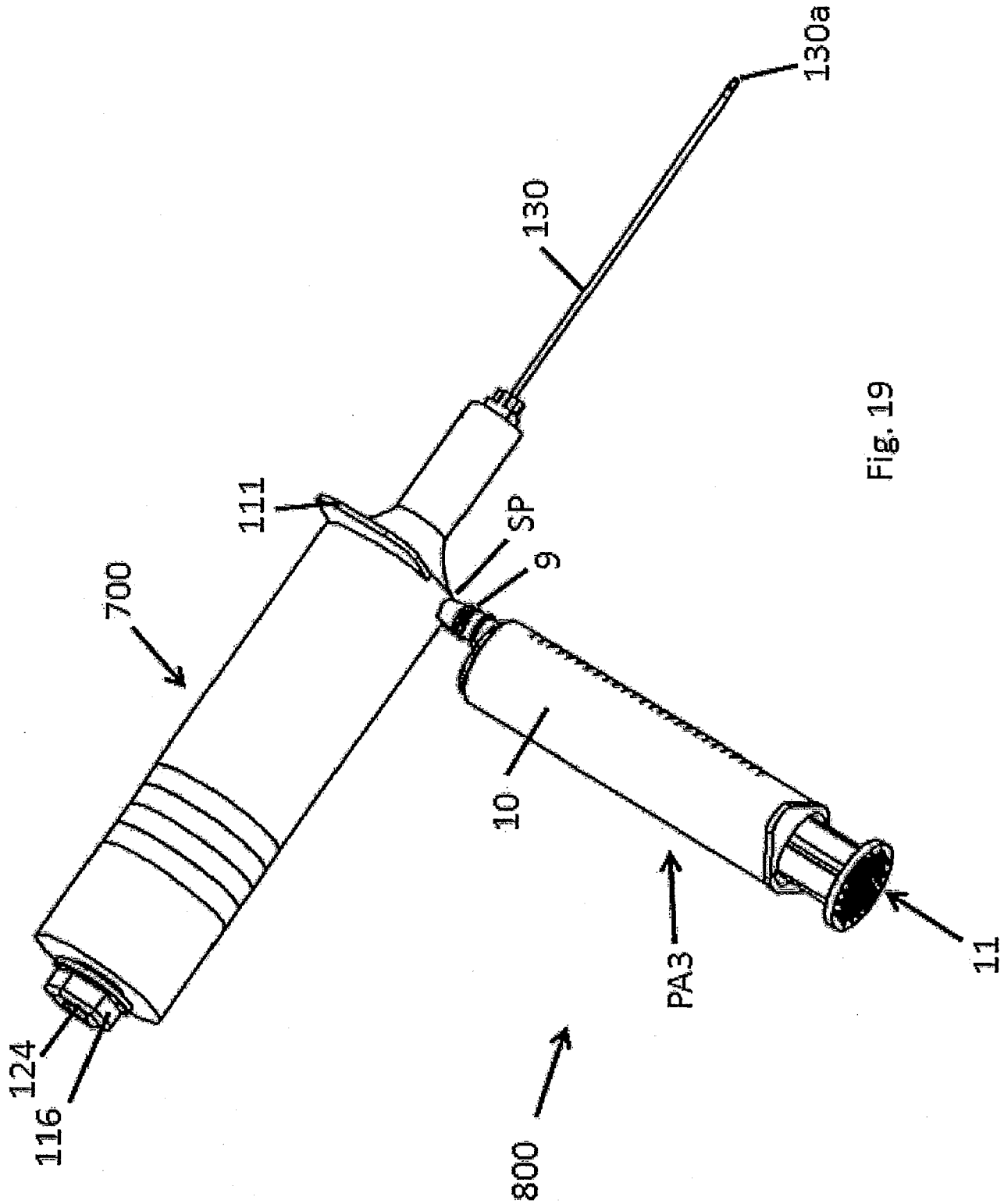


Fig. 19

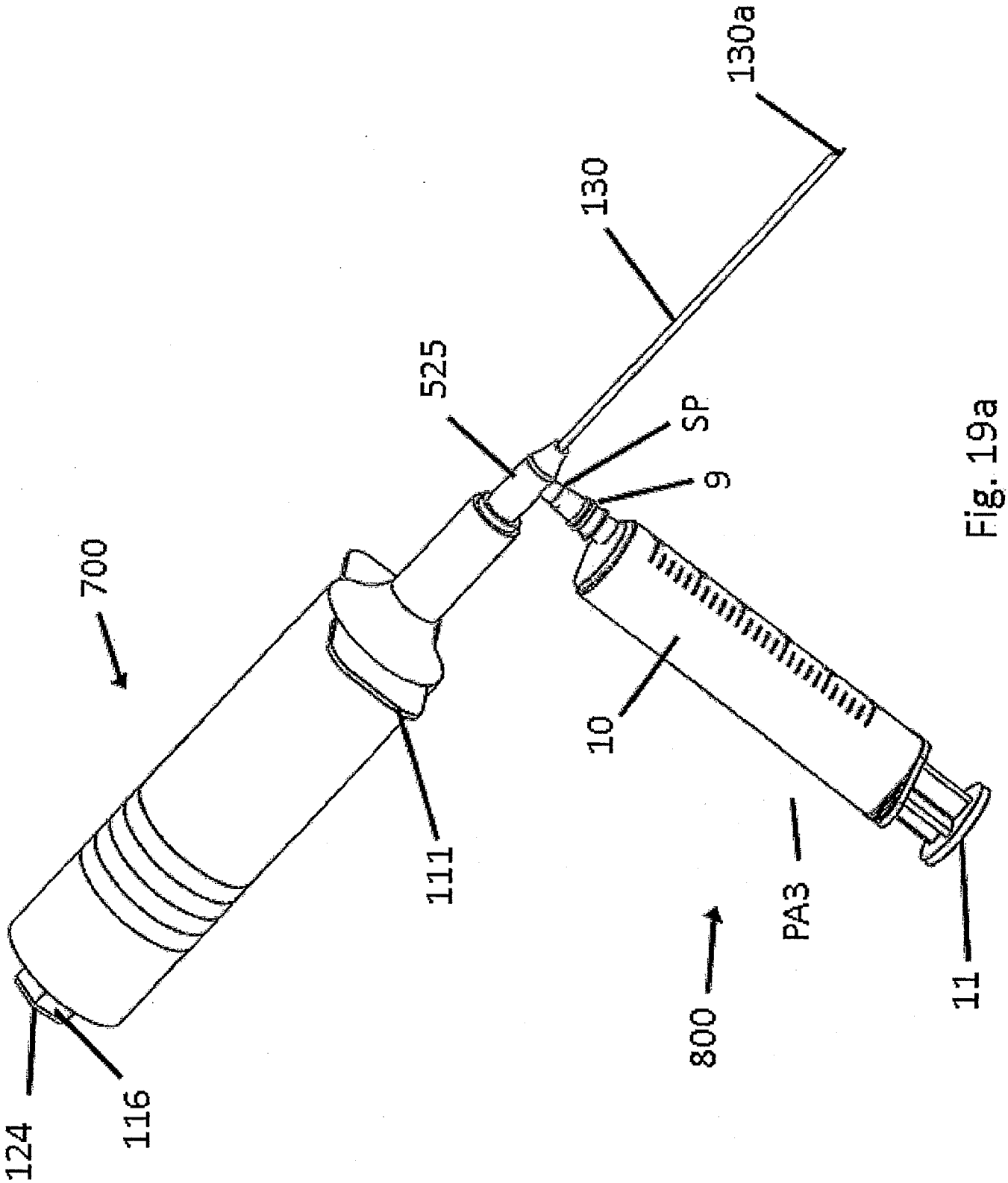


Fig. 19a

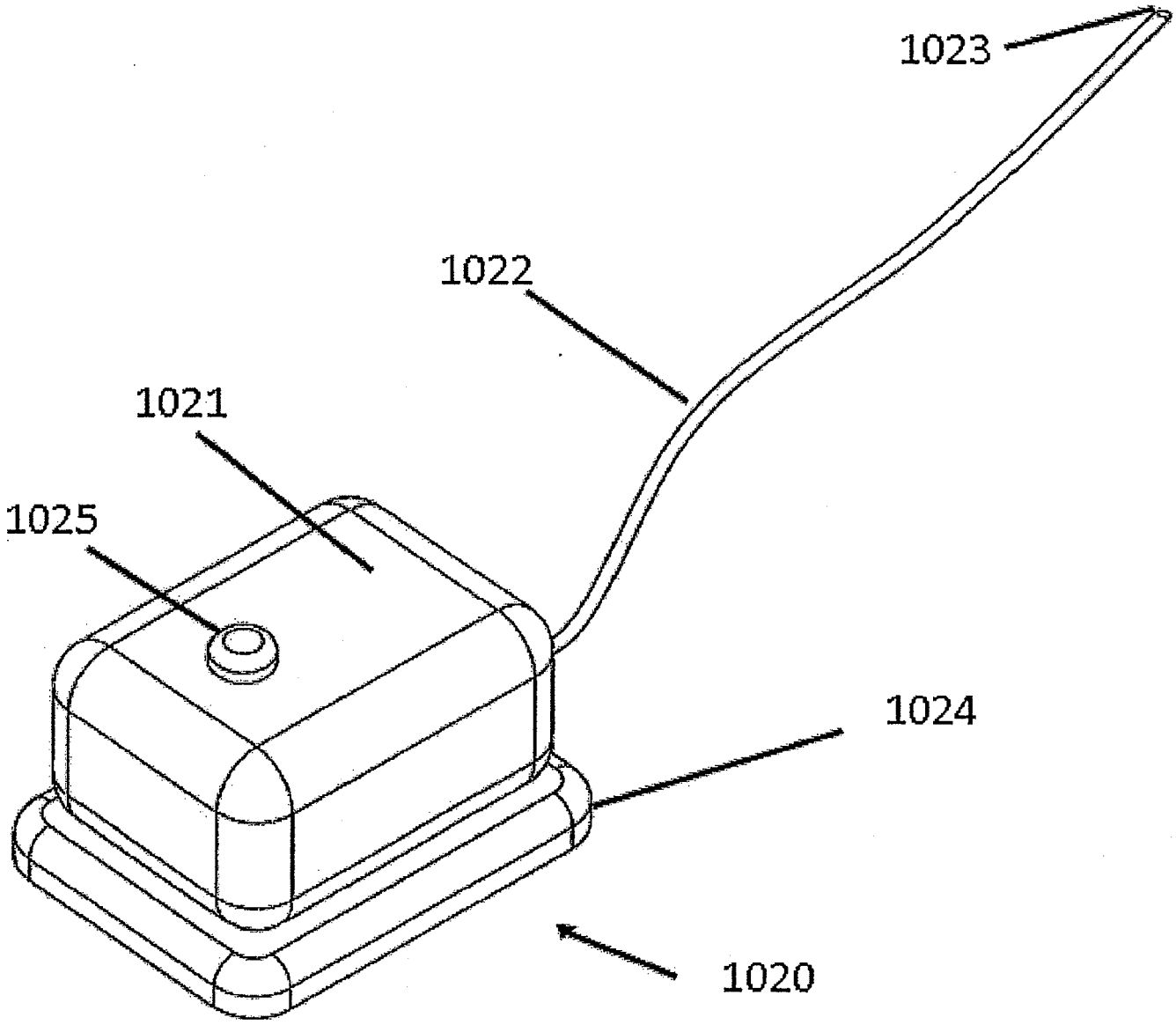


Fig. 19b

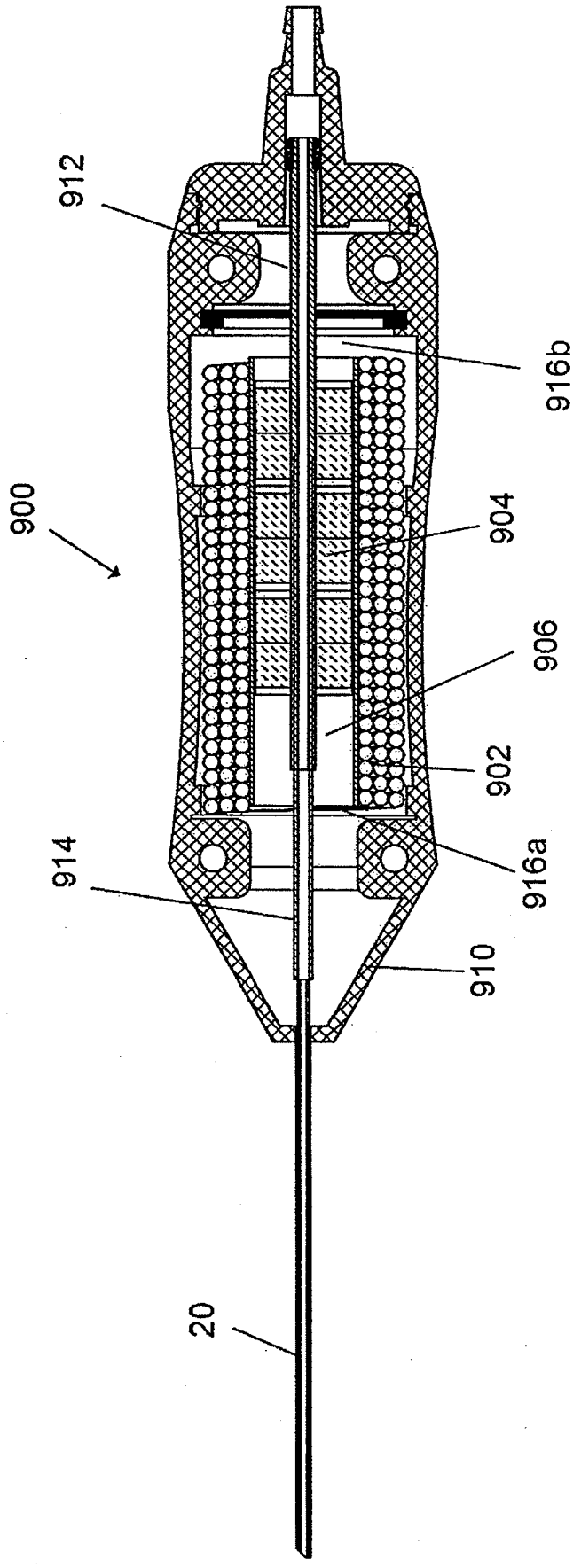


Fig. 20a

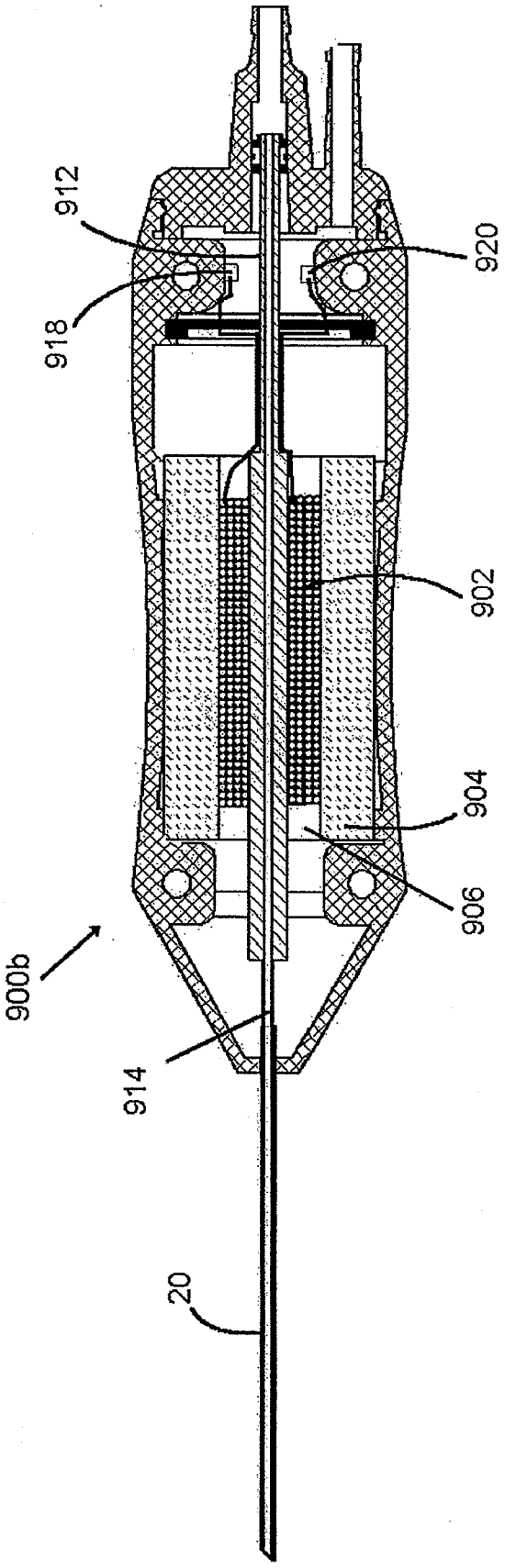


Fig. 20b

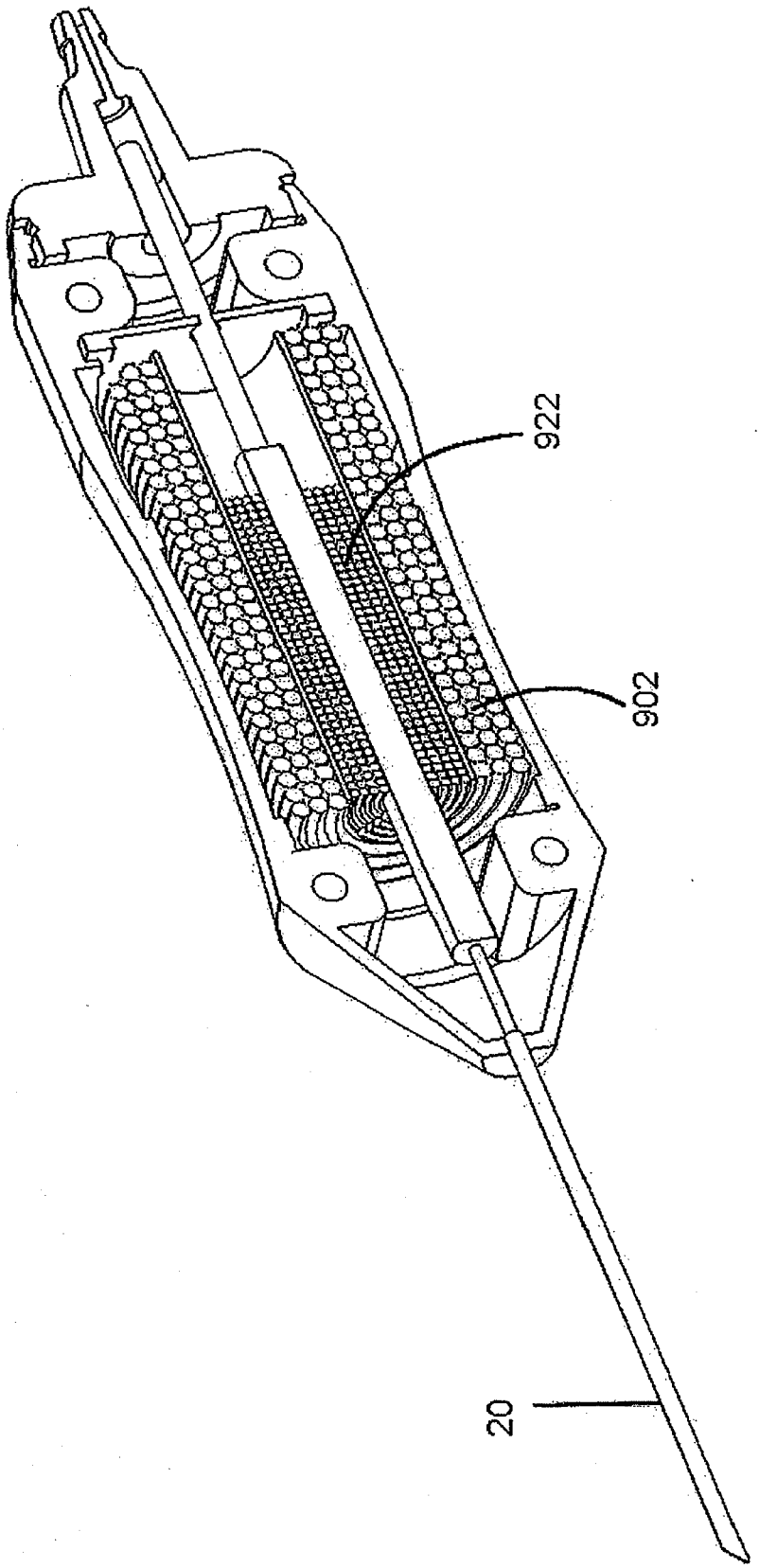


Fig. 20c

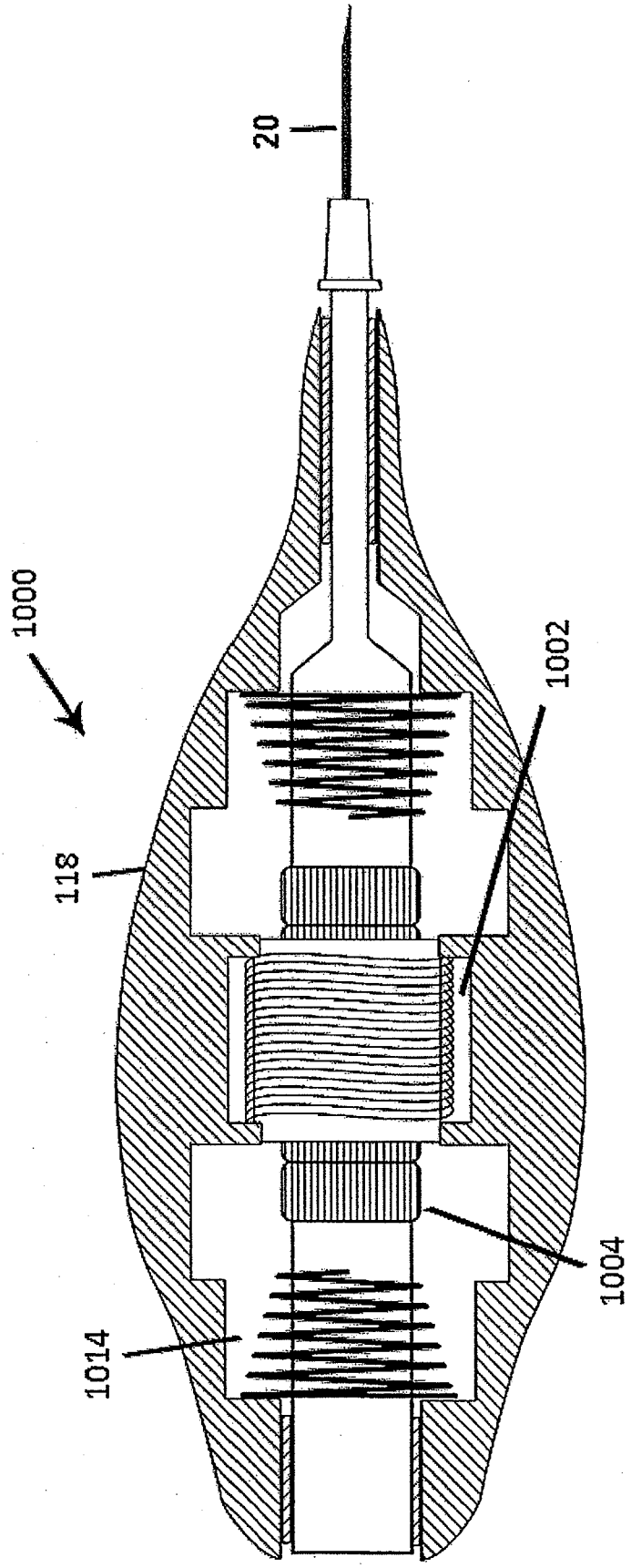


Fig. 20d

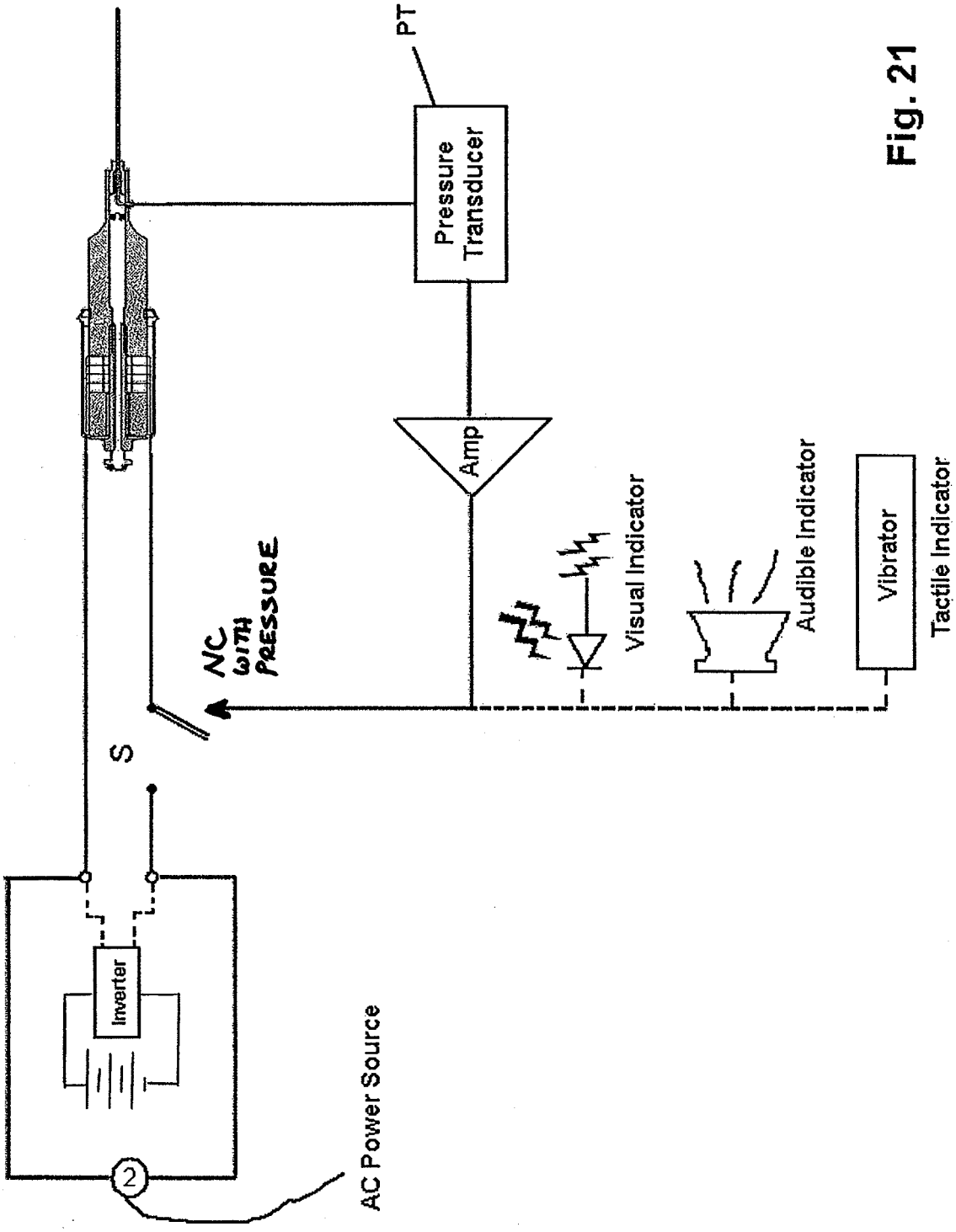

PT
Pressure Transducer
Amp
NC WITH PRESSURE
S
Visual Indicator
Audible Indicator
Vibrator
Tactile Indicator
Inverter
2
AC Power Source

Fig. 21